Optimisation of Gestational Age Estimates in Low-Income Settings

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Declaration

I declare that this Thesis has been written by myself and that none of this work has been submitted for any other degree or professional qualification. I confirm that the work is my own, apart from the publications contained within this Thesis which were jointly written. In this instance, my personal contribution and the contributions of others have been explicitly outlined within the introductory paragraphs of each chapter. I confirm that appropriate credit has been conferred within this Thesis when referencing the work of others.

Alexandra Catherine Viner

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Abstract and Lay Summary

Abstract

Accurate estimates of gestational age are fundamental to the provision of obstetric care, helping to facilitate appropriate antenatal care schedules and the identification and management of high-risk pregnancies. At a population level, accurate estimates of gestational age are required for the global reporting of obstetric and neonatal outcomes, for example, the rates of pre-term birth, and are a key component of strategies to reduce neonatal morbidity and mortality.

Early pregnancy ultrasound is considered the most accurate way to determine gestational age and is undertaken as part of routine care in high-income settings. However, despite the recommendation from the World Health Organisation that all women receive at least one ultrasound prior to 24 weeks' gestation, this remains unavailable to the majority of women in low-income settings. Instead, gestational age is derived from the last menstrual period or by measurement of the symphysis fundal height, methods known to be considerably less accurate.

There are a number of barriers to the widespread provision of ultrasound as part of routine care in low- and middle- income settings, not least the lack of

trained practitioners. Although effective, the length and complexity of many previous training programmes has been prohibitive, with practitioners struggling to secure cover for their clinical duties in order to provide or attend training. Furthermore, few initiatives have explored the widespread implementation of these programmes and how they may be sustained within pre-existing healthcare structures.

Ultrasound determination of gestational age relies on the assumption that the size of the fetus is consistent with its age and is therefore best performed prior to 14 weeks' gestation, when natural variation in fetal size is least apparent. Unfortunately, the majority of women in low- and middle- income countries do not seek antenatal care until later and would therefore require dating by different biometric parameters. In high-income settings the gold standard would be a combination of measurements, however there are concerns about the time investment required to develop such skills. The work in this Thesis explores the development of a novel strategy to optimise estimates of gestational age in Malawi, through the development and implementation of a bespoke education package to teach midwives how to date pregnancies using ultrasound measurement of the fetal femur length.

A systematic review investigated the previous initiatives that had been undertaken to train practitioners in low- and middle- income countries to determine gestational age using ultrasound, finding major inconsistences in the current provision of ultrasound training and highlighting the need for a more consistent and robust approach. Less than half of the programmes met international recommendations for the delivery of safe and sustainable training, and many had not considered how ultrasound may be integrated into clinical practice thereafter. The evidence synthesised went on to inform the development of a new programme, where it was hypothesised that ultrasound-naive midwives could be taught to date pregnancies using fetal femur length.

Pilot work helped to shape and refine the programme, which was delivered by local teams across six sites in Malawi in 2021. All but one midwife completed the course, with all demonstrating significant increases in their knowledge, confidence, and practical skills, achieving the criteria specified for competency within the specified two weeks. Skills were sustained at a 3-month follow up, and of the images submitted for remote image review, over 87% were deemed acceptable. These results suggest that femur length is a sufficiently simple measurement to be taught effectively over a short timescale, making it a potentially viable option for the upscale of ultrasound to date pregnancies in this setting.

A mixed methods study, run by the wider collaborative group, evaluated the implementation of ultrasound into routine services, however the work in this Thesis focused more specifically on the provision of the programme itself. Outcomes were reported in the context of an implementation framework, providing valuable insight into factors influencing the longterm sustainability of such endeavours. It is clear this is an important area for ongoing research.

In conclusion, this Thesis proposes that measurement of fetal femur length should be considered a potential option for the determination of gestational age in low- and middle- income settings. Not only is it considerably more accurate than the current standard of care, but midwives with no prior experience of ultrasound can be trained to perform these measurements, confidently and competently, after just two weeks of training, a substantially shorter training duration than many previous initiatives. Although many implementation challenges persist, this programme provides a potentially more sustainable means by which to provide a greater number of women more accurate estimates of gestational age.

Lay Summary

Knowing how far along pregnancies are (pregnancy dating) and when a baby is due to be born is important for pregnancy care. It helps doctors and midwives to review women at the right time during pregnancy and assists in treating women at higher risk of complications. Knowing the age of the unborn baby is also important for developing new treatments to care for babies. Without it, women may miss out on treatments to help their babies, especially if they are considered likely to deliver early. Knowing how far along pregnancies are is also important when reporting how pregnancy outcomes vary according to different countries.

An ultrasound scan in early pregnancy is considered the most accurate way to find out how far along a pregnancy is. This is undertaken as part of routine care in the UK where all women are offered a 'booking' scan before the baby is 14 weeks' old. During this scan the length of the baby is measured and used to calculate it's age and when it is due to be born. Although this is recommended for all women by the World Health Organisation, most women in low-income settings do not get one. Instead, the age of the baby is worked out from the mother's last menstrual period or by measurement of the 'bump', methods known to be much less accurate.

There are a number of reasons why ultrasound is not available in low- and middle- income settings, especially the lack of trained staff. Although some training has been provided in this setting, it has often been too difficult and

long to set up longterm. Indeed, little research has been done to look at how to fit training into current healthcare systems.
Using ultrasound to work out the age of unborn babies, assumes the size of the baby is in keeping with its age. This is most likely to be the case before it is 14 weeks' old. As the baby gets older and bigger however, factors other than age affect how big the baby grows. This means that measuring it's size to work out its age becomes less accurate and we can no longer measure it's length. Instead we have to take measurements of different body parts.

Unfortunately, most women in low-income countries do not see the midwife until after the baby is 14 week's old. This means that measuring the length of the baby would not be right for them. Instead we must use different measurements. In the UK we would take a combination of measurements, including around the baby's head, around its abdomen and the length of it's thigh bone. However, these can be difficult and can take beginner scanners a long time to learn. This Thesis therefore, explores a new way to improve pregnancy dating in Malawi. We aimed to teach midwives to work out how far along pregnancies are by taking an ultrasound measurement of the fetal thigh bone.

A review of previous attempts to teach healthcare workers in low-income countries to date pregnancies using ultrasound was performed. This revealed major differences in current ultrasound training and the need for a more consistent approach. It also showed that less than half of the programmes met international standards for the delivery of safe training. It also showed that not many had thought about how ultrasound may be set up after the end of training. This information was used to develop a new programme, where we hoped that midwives who had not used ultrasound before could be taught to date pregnancies using a measurement of the babies' thigh bone.

We tested the programme before it was delivered by local teams across six sites in Malawi in 2021. All but one midwife finished the course. All showed improvement in their knowledge, confidence, and practical skills and they passed the tests to be signed off within two weeks. Re-testing 3 months later showed they had kept up their skills.

These results suggest that ultrasound measurement of the baby's thigh bone is simple enough to be taught quickly. This may make it a good option to improve pregnancy dating in low-income countries. This Thesis also looked at what things affected the delivery of the training, considering what might be needed to roll it out on a larger scale. It is clear this is an important area for ongoing research.

In conclusion, this Thesis suggests that ultrasound measurement of baby's thigh bones may be a good option to work out how old unborn babies are in low-income countries. It is more accurate than measuring the bump or working it out from the mothers' last menstrual period and midwives will no experience of using ultrasound can be taught to do it in less than 2 weeks. Although there will still be difficulties in rolling it out, this may be a better way to give mothers in low-income countries a better idea of how old their unborn baby is and when it will be born.

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Presentations and Publications Relating to this Thesis

Poster Presentations

- **Training in Ultrasound to Determine gestational Age (TUDA): Efficacy of a novel education package for to teach ultrasound-naive healthcare professionals basic obstetric ultrasound in Malawi.**

  Alexandra Viner, Gladys Membe-Gadama, Doris Kayambo, Sonia Whyte, Martha Masamba, Caroline J Hollins Martin, Brian Magowan, Rebecca M Reynolds, Sarah J Stock, Bridget Freyne, Jane Norman, Luis Gadama.

  RCOG Annual Academic Meeting, 2022

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- **Training in Ultrasound to Determine Gestational Age (TUDA): Lessons Learned from a Pilot Study to Implement Ultrasound Training for Midwives in Malawi.**

  Alexandra Viner, Brian Magowan, Doris Kayambo, Gladys Membe-Gadama, Luis Gadama.

  Global Women's Research Society Virtual Conference, 2020, Virtual, UK.

Oral Presentations

- **Training in Ultrasound to Determine Gestational Age: Evaluation of a novel education package in Malawi.**

  Alexandra Viner, Gladys Membe-Gadama, Doris Kayambo, Sonia Whyte, Martha Masamba, Caroline J Hollins Martin, Brian Magowan, Rebecca Reynolds, Sarah J Stock, Bridget Freyne, Jane Norman, Luis Gadama.

  The Gynaecological Club of Great Britain and Ireland, Spring Meeting, April 2022, Edinburgh, UK

- **Training in Ultrasound to Determine Gestational Age: Efficacy of a novel education package in Malawi.**

  Alexandra Viner, Gladys Membe-Gadama, Doris Kayambo, Sonia Whyte, Martha Masamba, Caroline J Hollins Martin, Brian Magowan, Rebecca Reynolds, Sarah J Stock, Bridget Freyne, Jane Norman, Luis Gadama.

  Edinburgh Obstetrical Society Junior Members' Meeting , 2021, Edinburgh, UK.

- **Training in Ultrasound to Determine Gestational Age in Low- and Middle- Income Countries: A Systematic Review.**

  Alexandra Viner, Isioma Okolo, Jane Norman, Sarah Stock, Rebecca Reynolds.

  Oxford-Edinburgh Women's Health Virtual Networking Event, 2021, Virtual

- **Novel Low-Cost Phantoms for Basic Obstetric Ultrasound Training in Low-Income Countries.**

  Alexandra Viner, Brian Magowan.

  Edinburgh Obstetrical Society Junior Members' Meeting , 2020, Edinburgh, UK.

- **Optimising Gestational Age Estimates in Malawi: A DIPLOMATIC Project.**

  Alexandra Viner, The DIPLOMATIC Collaborative.

  Royal College of General Practitioners Primary Care Conference, 2019, Liverpool, UK.

  Runner up in 'Best Global Health Project'

Publications

- Viner AC, Membe-Gadama G, Whyte S, Kayambo D, Masamba M, Makwakwa E, Lissauer D, Stock SJ, Norman JE, Reynolds RM, Magowan B, Freyne B and Gadama L (2022) Training in Ultrasound to Determine Gestational Age (TUDA): Evaluation of a Novel Education Package to Teach Ultrasound-Naive Midwives Basic Obstetric Ultrasound in Malawi. Front. Glob. Womens Health 3:880615. doi: 10.3389/fgwh.2022.880615

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Abbreviations

Abbreviation	Full Definition
AC	Abdominal circumference
ACOG	American College of Obstetricians and Gynaecologists
AI	Artificial Intelligence
AMANHI	Alliance for Maternal and Newborn Health Improvement
ANC	Antenatal Care
BMUS	British Medical Ultrasound Society
BPD	Biparietal Diameter
CHAM	Christian Health Association of Malawi
CHW	Community Health Worker
COMREC	College of Medicine Research and Ethics Committee
CPD	Continuing Professional Development
CRL	Crown Rump Length
DHO	District Health Officer
DHSS	Directors of Health and Social Services
DIPLOMATIC	using eviDence, Implementation science and a clinical Platform to Optimise MATernal and newborn health in low Income Countries
DNO	District Nursing Officer
EBP	Evidence Based Practice
ECUREI	Ernest Cook Ultrasound Research and Education Institute
EDD	Estimated Date of Delivery
FANC	Focussed Antenatal Care
FL	Femur length
GDP	Gross Domestic Product
GHP	Global Health Partnership
GHR	Global Health Research
HC	Head circumference
HRCSI	Health Research Capacity Strengthening Initiative
HSA	Health Surveillance Assistants
ICC	Intraclass Correlation Coefficients
IS	Implementation Science

ISUOG	International Society for Ultrasound in Obstetrics and Gynaecology
ITW	Imaging the World
LOA	Limits of Agreement
LMIC	Low- and middle- income country
LMP	Last menstrual period
MDHS	Malawi Demographic and Health Surveys
MEIRU	Malawi Epidemiology and Intervention Research Unit
MLW	Malawi-Liverpool-Wellcome Trust Clinical Research Programme
MMAT	Mixed Methods Assessment Tool
MOH	Ministry of Health
NCST	National Commission for Science and Technology
NGOs	Non-Governmental Organisations
NHSRC	National Health Sciences Research Committee
NICE	National Institute for Health Care Excellence
NIHR	National Institute for Health Research
OSATs	Observed Structured Assessment Tools
OSCE	Observed Structured Clinical Examination
OSP	Obstetric Sweep Protocol
PICO	Population Intervention Comparison Outcome
PFT	Private for Profit
PNFP	Private not for Profit
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
QI	Quality Improvement
RCOG	Royal College of Obstetricians and Gynaecologists
RCR	Royal College of Radiologists
RE-AIM	Reach Effectiveness Adoption Implementation Maintenance
SBA	Skilled Birth Attendant
SDG	Sustainable Development Goals
SFH	Symphysis-fundal height
SCOG	Society of Canadian Obstetricians and Gynaecologists
SWiM	Synthesis Without Metanalysis
TBA	Traditional Birth Attendant
TCD	Transcerebellar Diameter

TUDA	Training in Ultrasound to Determine gestational Age
UN	United Nations
UNICEF	United Nations International Children's Emergency Fund
WHO	World Health Organisation

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Chapter 1

General Introduction

Part 1: Gestational Age

The first part of the introduction to this Thesis focuses on the concept of gestational age, its implications for clinical and academic practice and the different ways it may be determined.

1.1 Gestational Age

Gestational age refers to the age of the fetus, from the first day of the last menstrual period (LMP) to the current date, given in completed weeks and days.

1.1.1 Importance of Accurate Estimates

Accurate estimates of gestational age are fundamental to the provision of effective obstetric care. They facilitate appropriate antenatal schedules, the timely identification of pregnancies requiring referral to high-risk clinics; and at booking, allow the calculation of the estimated date of delivery (EDD). They also facilitate the appropriate assessment of fetal growth and permit the identification of preterm birth, enabling the optimal timing of referral and intervention and ensuring they are delivered in the most suitable setting (Butt et al., 2014, Papageorghiou et al., 2014, Fung et al., 2020). They also assist in the appropriate scheduling of repeat caesarean sections and post-dates induction of labour, helping to minimise the risk of iatrogenic preterm birth or post-dates stillbirth (Whitworth et al., 2015).

From a woman's perspective, accurate estimates of gestational age allow families to prepare for birth, be this by arranging childcare for existing children, or in many countries around the world, help women to decide at what point they should travel to be close to a birth facility (Fulcher et al., 2015). Once the baby is born, an accurate gestational age helps neonatal practitioners to interpret the baby's size in the correct context. For babies born small, a knowledge of whether this is because they are preterm or growth restricted is crucial, as the mechanisms and management differ (Sifianou., 2006, Malhotra et al., 2019). Without an accurate estimate of gestational age, women risk missing out on essential interventions which may improve outcomes for their babies, for example magnesium sulphate or antenatal corticosteroids (Doyle et al., 2009, Roberts et al., 2017) or indeed risk being exposed to unnecessary ones, a factor especially pertinent in low- and middle- income countries (LMICs) where resources are scarce.

Accurate estimates of gestational age are also important from a public health perspective, where they are not only an essential component of the global reporting of obstetric and neonatal outcomes, but also a key factor in the strategies which aim to improve them (Lynch et al., 2007). Preterm birth refers to babies born before 37 completed weeks of pregnancy and affects over 15 million babies worldwide (Lee et al., 2019). It is the leading cause of mortality in children under 5, and of those who survive, many are affected by lifelong disability. Global inequalities in survival are striking, with less than 50% of babies born under 32 weeks in low-income countries surviving, compared with nearly all babies born at that gestation in high-income settings (WHO., 2018). While some interventions, such as antenatal corticosteroids (Roberts et al., 2017), have been proven to be of value in high income settings, the majority require further evaluation in low-income populations (Althabe et al., 2015, Vogel et al., 2017). Without reliable information pertaining to gestational age however, ongoing research into meaningful strategies to improve outcomes for babies in born to mothers in low-income settings is near impossible, impeding efforts 'to reduce under 5 mortality', the United Nations (UN) Sustainable Development Goal (SDG) 3.2, (United Nations., 2015).

1.2 The Determination of Gestational Age

Despite being so widely encountered, the concept of gestational age is complicated, namely on account of the ambiguity surrounding the start of pregnancy. With no way of knowing the exact point at which fertilisation or implantation took place, we are unable to know the exact time at which the pregnancy began and are thus unable to establish the 'true gestational age' of any pregnancy. Instead, we use a variety of methods to make estimates of gestational age, with the accuracy of each method expressed as the 95% confidence intervals within which the 'true gestational age' is thought to lie. For example, if a method is said to be accurate to +/- 5 days, this means that in 95% of cases the 'true gestational age' is presumed to lie within the 10-day range extending from 5 days before to 5 days after the assigned age.

1.2.1 Clinical Determination of Gestational age

1.2.1.1 Last Menstrual Period

It is widely accepted that the duration of human pregnancy is 280 days or 40 weeks (Baskett et al., 2000), which, in the absence of information pertaining to fertilisation or implantation, is counted from the first day of the last menstrual period (LMP). Current gestational age is described as the time that has elapsed from this date, usually expressed in completed weeks and days (Treloar et al., 1967, Anderson et al., 1981, Baskett et al., 2000), with the EDD established as 280 days later. While low cost and readily available, the use of LMP for the determination of gestational age is imperfect. In the first instance, it relies on the accurate recall of the LMP, which in itself is problematic, with previous work suggesting that up to 45% of women are unable to recall their LMP (Campbell et al., 1998, Wegienka et al., 2005). Secondly, in order to be precise, it also relies on the assumption that women's menstrual cycles are regular and uniform in length, with ovulation occurring mid-cycle (Treloar et al., 1967, Anderson et al., 1981, Baskett et al., 2000). While this is undoubtedly the case for many women, short interpregnancy intervals, prior use of hormonal contraceptives and natural variation in the timing of ovulation all influence individual cycles (Treloar et al., 1967, Geirsson et al., 1991), resulting in a proportion of women for whom this method will be less appropriate. Overall, estimates of gestational age derived from the LMP are considered accurate to +/- 4.65 weeks (Lee et al., 2020).

1.2.1.2 Clinical Examination

Physical examination, either pelvic or abdominal, can also be used to determine gestational age, with the size of the uterus used as a proxy for gestational age. While again, low cost and readily available, it too is vulnerable to potential inaccuracy (Self et al., 2022). Firstly, the size of the uterus may be influenced by a variety of factors distinct from fetal size, for example fibroids or multiple pregnancy, which may result in an overestimation of fetal gestation (Lee et al., 2020). Secondly, the measurement obtained may be affected by maternal obesity, impacting not only the ability of the operator to palpate the fundus, but also on the measurement itself, again risking an overestimation of gestational age. Estimates of gestational age derived from symphysis-fundal height (SFH) are considered accurate to +/- 7.4 weeks (Lee et al., 2020).

1.2.1.3 Neonatal Assessment

Although too late to influence the management of pregnancy, gestational age may be determined by neonatal examination. First described in 1966, (Farr et al., 1966) this method has undergone multiple iterations (Dubowitz et al., 1970, Capurro et al., 1978, Ballard et al., 1979), with the most commonly utilised assessments now the Dubowitz Examination or the New Ballard Score (Dubowitz et al., 1970, Ballard et al., 1991). Each evaluates the newborn according to a combination of physical and neuromuscular attributes, providing them with an overall score which is then used to estimate their gestational age at birth. Compared with the New Ballard Score, the Dubowitz Examination boasts superior accuracy, +/- 27 days vs +/- 18 days respectively (AMANHI Study Group., 2021). Although rarely used in high-income settings, this form of pregnancy dating remains commonplace in many LMICs (Lee et al., 2017).

1.2.2 Ultrasound Determination of Gestational Age

The use of ultrasound in obstetrics was pioneered by the Scottish Obstetrician Ian Donald, whose work laid the foundation for many of our modern practices (Donald et al., 1958). Since then, ultrasound has maintained an excellent safety profile (Torloni et al., 2009) and is now considered an essential component of routine antenatal care in high-income settings, not only for the purpose of dating pregnancies, but also to screen for fetal structural anomalies and as a means by which to assess fetal growth. (Public Health England. 2015) The determination of gestational age using ultrasound is achieved by taking standardised measurements of the fetus and is again reliant on the notion that the size of the fetus is consistent with its age. During the first 14 weeks of pregnancy, the first trimester, natural variation in fetal size is least apparent and the primary determinant of the size of the fetus is its age (Geirsson, 1991). However, as the pregnancy progresses, factors other than age begin to influence fetal dimensions (Wisser et al., 1994, Caughey et al., 2008) and the accuracy of using fetal size to determine gestation decreases. Consequently, where possible, it is preferable that the determination of gestational age is undertaken prior to 14 weeks gestation, as this will be more precise than measurements obtained thereafter (Caughey et al., 2008).

Since the advent of fetal biometry, numerous studies have sought to develop of standards of fetal size. However many of these have produced significantly different results, raising concerns about the legitimacy of their findings. A systematic review exploring the methodology used in studies to create charts of fetal size identified substantial heterogeneity in how these studies were designed, including a wide variation in sample size and selection and the choice of statistical modelling (Ioannou et al., 2012). Although some consensus as to the optimum approach has been agreed, namely that relating to the statistical analysis, other aspects remain controversial and continue to be debated (Altman et al., 1993, Royston et al., 1998, Silverwood et al., 2007).

Charts of fetal biometry serve two main purposes; to use fetal size to estimate gestational age, or, if the gestational age is known, to use fetal size to assess growth, which may be done on a single occasion or by evaluating the growth trajectory between multiple timepoints (Ioannou et al., 2012). Although these charts are frequently viewed as a single entity, it is important to maintain this distinction, as the intended purpose of the chart dictates the methodology and analysis that should have been employed in its development (Chitty et al., 1994, Ioannou et al., 2012,).

Another consideration when developing charts from which to establish gestational age, is the method used to determine gestational age in the original studies. With no alternative, much of the data underpinning early charts was derived from clinical estimates of gestational age based on the LMP, which we know is problematic (Campbell et al., 1998, Wegienka et al., 2005, Lee et al., 2020). More recent studies to derive charts for fetal dating in later pregnancy however, have used a combination of early pregnancy ultrasound and 'certain' LMP, using the gold standard measurement of crown rump length (CRL) to corroborate the gestational age assigned by the LMP (Altman et al., 1997, Leung et al., 2008, Papageorghiou et al., 2016, AMANHI, 2020, Rodriguez-Sibaja et al., 2021). Although still reliant on the concept of LMP, and a growth parameter that may already be adversely affected (Mukri et al., 2008), this is considered the best available method against which to compare methods of determining gestational age in the second and third trimesters (Papageorghiou et al., 2014).

1.2.2.1 Determination of Gestational Age <14 weeks'

Crown Rump Length

The recommended gold standard for the determination of gestational age prior to 14 weeks is by measurement of the fetal crown rump length (CRL) (Loughna et al., 2009, Salomon et al., 2013, Butt et al., 2014, Papageorghiou et al., 2014, Pettker et al,. 2017). This is a straight measurement taken along the length of the fetus, from the tip of its head to its rump. For the image to be appropriate for measurement, a horizontal midline sagittal view of the fetus needs to be captured. It should be in a 'neutral' position, i.e. not too flexed nor too extended, and the legs should not be included within the measurement (Loughna et al., 2009, Butt et al., 2014). Pregnancy dating by measurement of the CRL is considered accurate to +/- 5-7 days (Robinson et al., 1975, Hadlock et al., 1992, Verberg et al., 2008, Papageorghiou et al., 2014, Napolitano et al., 2014).

However, when the measurement of CRL exceeds 84mm, corresponding to a gestational age of 14+0, increased fetal flexion limits the accuracy of the measurement and therefore renders it ineffectual for the purpose of dating (Hadlock et al., 1992, Salomon et al., 2013, Butt et al., 2014). Instead, the determination of gestational age is then based on the measurement of alternative parameters, namely the biparietal diameter (BPD), head circumference (HC), abdominal circumference (AC), femur length (FL), or their combination (NICE, 2008, Loughna et al., 2009, Salomon et al., 2010, Salomon et al., 2013, Butt et al., 2014, Papageorghiou et al., 2016, Pettker et al., 2017, Salomon et al., 2019). More recent work has also explored measurement of the transcerebellar diameter (TCD) as a possibility (Chavez et al., 2007). In contrast to consistent support for the first trimester measurement of CRL, there is no such consensus on the ideal parameters by which to establish gestational age after 14 weeks.

1.2.2.2 Determination of Gestational Age >14 Weeks'

1.2.2.2.1 Single Parameters

Head Circumference

When considering a single parameter by which to determine gestational age after 14 weeks' gestation, it is generally accepted that measurement of the HC is the most precise (Law et al., 1982, Hadlock et al., 1982, Ott et al., 19824, Chervenak et al., 1998). This should be obtained from a cross-sectional image of the fetal skull encompassing several specific anatomical landmarks. As depicted in Figure 1-1, the image should be in the axial plane at the level of the thalami and cavum septum pellucidem, displaying a continuous midline echo and symmetrical appearances of the cerebral hemispheres. The cerebellum should not be visible. Callipers should then be placed so that the ellipse lies circumferentially on the outer border of the fetal skull, but not inclusive of the skin (Butt et al., 2014, Salomon et al., 2010). When taken from an appropriate image, the HC is considered accurate to +/- 7-12 days in the second trimester and +/-14-25 days in the third (Altman and Chitty., 1997, Butt et al., 2014, AMANHI, 2020).

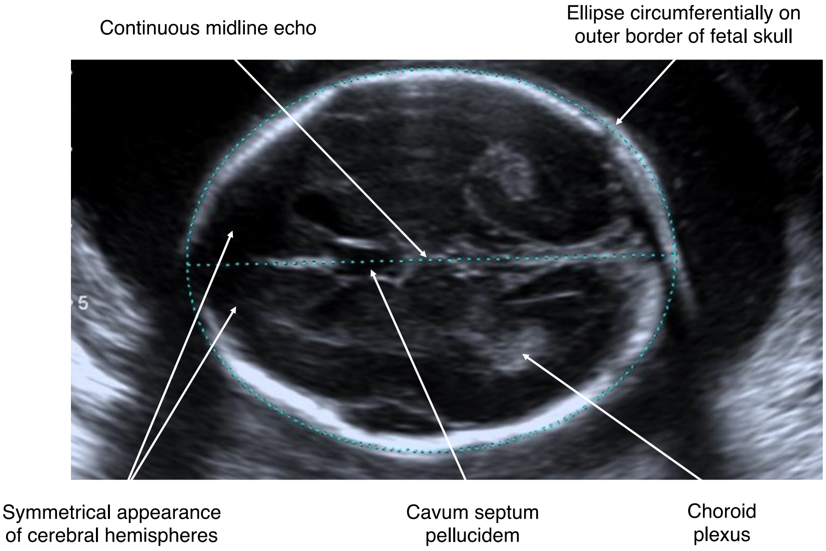

Figure 1-1 Ultrasound view required for the measurement of head circumference (HC) > 14 weeks' gestation.

Cross-sectional image of the fetal skull in the axial plane. Section captured at the level of the thalami and cavum septum pellucidem, displaying a continuous midline echo and symmetrical appearances of the cerebral hemispheres.
Image captured by Alexandra Viner on GE Voluson P8 Ultrasound Machine. Included with patient permission.

Biparietal Diameter

Measurement of the BPD requires practitioners to obtain the same cross-sectional image of the fetal skull as the HC, before taking a straight measurement across its widest part. Considered less accurate than HC, the BPD is thought to be accurate to +/- 8-23 days in the second trimester and +/- 23-27 in the third (Hadlock et al., 1981, Altman and Chitty., 1997). In contrast to the HC, which is less influenced by the shape of the head, measurements of BPD also rely on the assumption that the fetal skull is of a normal shape and are therefore more vulnerable to inaccuracy in circumstances where the shape or proportion of the fetal skull is abnormal (Hadlock et al., 1981, Salomon et al., 2010, Salomon et al., 2019). It is for this reason that some groups, for example the British Medical Ultrasound Society (BMUS), advise against its application in clinical practice (Loughna et al., 2009), although it still remains a component of some guidance (Butt et al., 2014, Pettker et al., 2017).

Abdominal Circumference

Measurement of the AC is achieved by taking a circumferential measurement around a transverse section of the fetal abdomen. As shown in Figure 1-2, the image should be in the axial plane, incorporating the stomach bubble and the umbilical vein at the level of the portal sinus. It should be as circular as possible, displaying a full rib. The kidneys should not be visible. Callipers should be placed on the outermost edges of the skin, so that the ellipse lies circumferentially and includes the soft tissues and adipose layer (Loughna et al., 2009, Salomon et al., 2010). The AC is considered accurate to +/- 7-16 days in the second trimester and +/- 18-32 in the third (Hadlock et al., 1982, Chervenak et al., 1998).

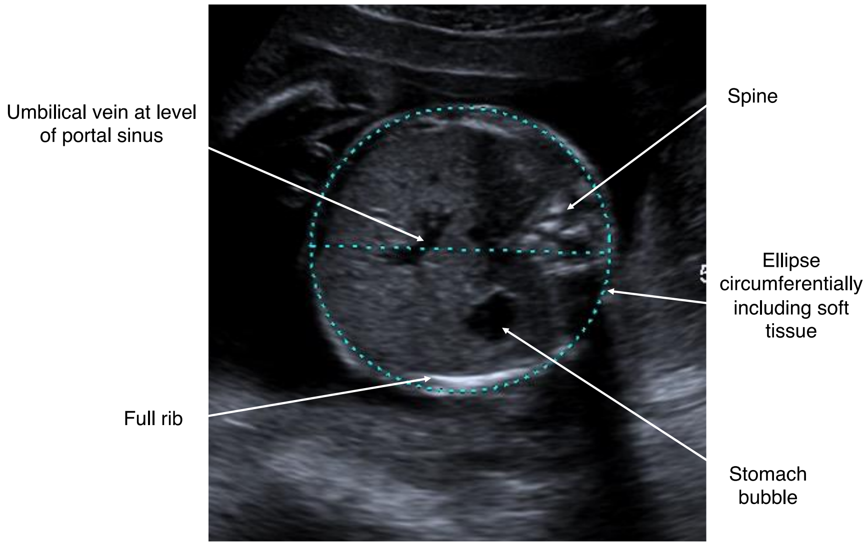

Figure 1-2 Ultrasound view required for the measurement of abdominal circumference (AC) >14 weeks gestation.

Transverse image of the fetal abdomen in the axial plane. Section captured in the axial plane incorporating the stomach bubble and the umbilical vein at the level of the portal sinus. Image captured by Alexandra Viner on GE Voluson P8 Ultrasound Machine. Included with patient permission.

Unfortunately, in contrast to the bony structures of HC, BPD and FL, the AC is more vulnerable to factors influencing fetal growth (Hadlock et al., 1982, Benson. 1991, Chervenak et al., 1998) and is therefore subject to much greater variability than the other parameters. It is for this reason its use as a single parameter is not recommended (Loughna et al., 2009, Butt et al., 2014, Pettker et al., 2017).

Femur Length

With practitioners only required to obtain a horizontal image with both ends of the bone clearly visible, measurement of the fetal femur is arguably the most simple to obtain. As shown in Figure 1-3, only the ossified diaphysis should be measured, excluding the distal femoral epiphysis and any bony spur artifacts (Loughna et al., 2009, Salomon et al., 2010). While early work suggested accuracy was comparable with HC (Hadlock et al. 1991, Altman and Chitty. 1997), more recent work, undertaken across 3 LMIC sites, has suggested that FL may even be superior as a single parameter. In this work, FL was reported as being accurate to +/- 13 days between 24-30 weeks and +/- 20 between 30-37 weeks, as opposed to the +/- 15 days and +/- 25 days attributed to HC (AMANHI. 2020).

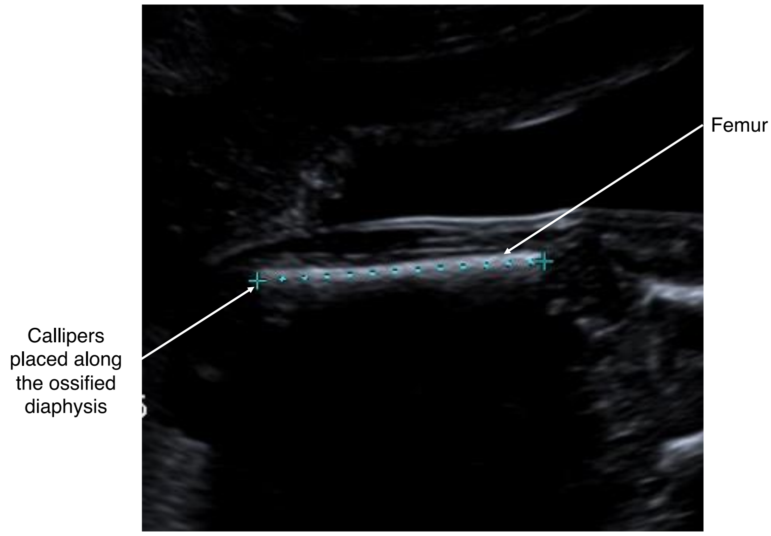

Figure 1-3 Ultrasound view required for the measurement of femur length (FL) >14 weeks gestation.

Femur shown horizontally with both ends visible.
Image captured by Alexandra Viner on GE Voluson P8 Ultrasound Machine. Included with patient permission.

Transcerebellar Diameter

Although measurement of the transcerebellar diameter (TCD) is not routinely practised in high-income settings, it has been explored as a potential method by which to determine gestational age in LMICs, largely on account of its relative imperviousness to growth restriction (Reece et al., 1987). The cerebellum is a dumbbell shaped structure located in the posterior cranial fossa, with the TCD its maximum transverse diameter. Measurement of the TCD is achieved by first obtaining the view previously described for measurement of the HC/BPD and then tilting the ultrasound probe posteriorly to obtain the transcerebellar plane. Along with the cerebellum, both the cavum septum pellucidem and the thalami should be visible (Bethune et al., 2013), as depicted in Figure 1-4. The straight distance between the cerebellar hemispheres is then measured, with the callipers placed on the outermost edges. Measurement of TCD is thought to be accurate to +/- 13 days between 24-30 weeks and +/- 17 between 30-37 weeks (AMANHI. 2020).

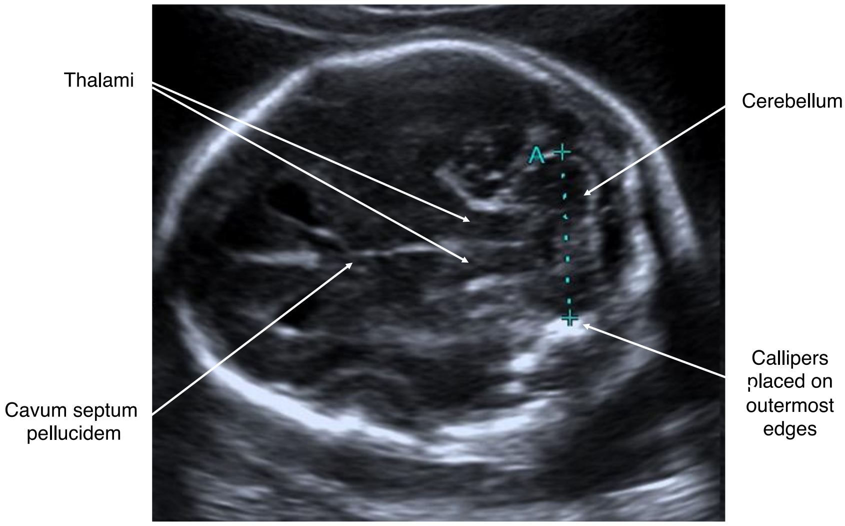

Figure 1-4 Ultrasound view required for the measurement of transcerebellar diameter (TCD) >14 weeks gestation.

Transcerebellar plane incorporating the cerebellum, cavum septum pellucidem and the thalami.
Image captured by Alexandra Viner on GE Voluson P8 Ultrasound Machine. Included with patient permission.

1.2.2.2.2 Limitations of Single Parameters

When considering any of the aforementioned parameters, it is important to acknowledge there are some additional limitations which may result from certain circumstances. Congenital infections and structural/chromosomal anomalies may limit, accelerate or alter the growth of certain structures, for example the head or femurs (Pathak and Lees., 2009, Silasi et al., 2015, Racicot and Mor., 2017) and the AC is especially vulnerable to the influence of factors affecting fetal growth (Hadlock et al., 1982, Benson. 1991, Chervenak et al., 1998). In addition, obtaining accurate measurements of the HC, BPD and TCD is frequently more technical at advancing gestations, when the fetal head is often deeper within the maternal pelvis.

There is also evidence that fetal parameters are influenced by parental ethnicity, (Alexander et al., 1999, Kierans et al., 2008, Hanley et al., 2013, Buck et al., 2015) with babies from different ethnic groups displaying different growth potential. Such is the concern, that some advocate the use of customised growth charts, designed to take account of a number of maternal characteristics including age and ethnicity (Kierans et al., 2008, Roex et al., Hanley et al., 2013, Buck et al., 2015, Gardosi et al., 2018) when assessing fetal growth, believing this will avoid the misclassification of some normal babies as growth restricted and vice versa. Conversely other groups, most notably the multi-national INTERGROWTH-21st collaboration, disagree with this approach, instead encouraging the use of charts derived from international populations (Bhutta, 2013, Uauy et al., 2013, Papageorghiou et al., 2014).

Although opinion remains divided regarding growth surveillance (Gardosi et al., 2013, Papageorghiou et al., 2014, Buck et al., 2015, Gardosi et al., 2018), there is no suggestion that the use of these biometric parameters for the determination of gestational age is inappropriate, especially when undertaken as early in the pregnancy as possible.

1.2.2.2.3 Composite Measurements

The accuracy of determining gestational age after 14 weeks can be improved by the combination of multiple parameters (Hadlock et al., 1984, Hadlock et al., 1987, Benson., 1991, Hill et al., 1992, Geirsson et al., 1993), although there is no universal consensus as to which is preferable. The use of all 4 parameters, HC/BPD/AC/FL, is reported as accurate to +/- 7-10 days between 14-22 weeks', +/- 10-14 days between 22-28 weeks' and +/- 21-30 days in the third trimester (Benson. 1991, Pettker et al., 2017), with the combination of HC, AC and FL considered accurate to +/- 10-13 days in the second trimester and +/- 13-18 days in the third (Hadlock et al., 1984). Recent work undertaken by the INTERGROWTH-21st Project reported the combination of HC and FL as +/- 6-7 days at 14 weeks', +/- 12-14 days at 26 weeks' and +/-14-17 days between 30-34 weeks' (Papageorghiou et al., 2014) suggesting this to be the optimum combination.

A summary of the accuracy of each of these methods, using equations derived from methodologically robust studies is presented in Table 1-1.

Table 1-1. Summary of the accuracy of ultrasound derived estimates of gestational age (days).

	Accuracy of estimates of gestational age using ultrasound			
	<13+6 weeks	14-23+6 weeks	24-29+6 weeks	30-36+6 weeks
CRL (Sladkevicius et al., 2004)	+/- 5	-	-	-
Single Parameters				
- **HC** (Papageorghiou et al., 2008)	-	+/- 9	+/- 16	+/- 23
- **BPD** (Leung et al., 2008)	-	+/- 13	+/- 19	+/- 22
- **AC** (Hadlock et al., 1984)	-	+/- 14	+/- 16	+/- 24
- **FL** (Leung et al., 2008)	-	+/- 10	+/-14	+/- 17
- **TCD** (Rodriguez-Sibaja et al., 2020)	-	+/- 9	+/- 12	+/- 13
Multiple Parameters				
- **BPD/HC/AC/FL** (Sun et al., 2020)	-	+/- 12	+/- 17	+/- 12
- **HC/AC/FL** (Hadlock et al., 1984)	-	+/- 10	+/- 11	+/- 18
- **HC/FL** (Papageorghiou et al., 2016)	-	+/- 9	+/- 13	+/- 16
- **TCD/FL** (AMANHI, 2020)	-	-	+/- 11	+/- 15

1.2.2.3 Current practice

Although generally accepted that the combination of multiple parameters is superior to the measurement of a single parameter, guidance varies in relation to the preferred combination. Both the American College of Obstetricians and Gynaecologists (ACOG) and the Society of Obstetricians and Gynaecologists of Canada (SOGC) endorse the use of all four of the parameters (Butt et al., 2014, Pettker et al., 2017), whereas the International Society for Ultrasound in Obstetrics and Gynaecology (ISUOG) recommends only the combination of HC and FL (Salomon et al., 2013). In contrast, guidance from the BMUS states that gestational age after 14 weeks should be determined using a single measurement of HC, or, if this is not possible, from a measurement of FL (Loughna et al., 2009). As such, practice varies depending on local policy, although it will not affect the majority of women attending for antenatal care in high-income settings, most of whom will have presented prior to 14 weeks' gestation and therefore had their pregnancy dated via measurement of the CRL.

1.3 Determination of Gestational Age in Low- and Middle-Income Settings

Despite recommendation by the World Health Organisation (WHO) that all women should receive an ultrasound scan prior to 24 weeks' to 'estimate gestational age, improve detection of fetal anomalies and multiple pregnancies, reduce induction of labour for post term pregnancy and improve a woman's pregnancy experience,' (WHO., 2016) ultrasound remains unavailable to many women living in LMICs, where instead, gestational age is derived either from the LMP, abdominal palpation or neonatal assessment (Harrison et al., 2016, Unger et al., 2019), methods known to be considerably less accurate.

1.3.1 Barriers to Ultrasound in Low- and Middle- Income Settings

There are a number of barriers to the widespread provision of ultrasound as part of routine antenatal care in LMICs, ranging from economical and geographical, to human factors and the ability of healthcare services to accommodate such a programme. (Smith and Nakimuli., 2020) Not only is considerable investment required to procure the relevant technology, but also to develop the necessary infrastructure, both within the workforce itself and the systems within which they operate.

Despite a significant number of programmes demonstrating efficacy in training healthcare workers to perform obstetric ultrasound (Rijken et al., 2009, Kimberly et al., 2010, Lagrone et al., 2012, Wylie et al., 2013, McClure et al., 2014, Bentley et al., 2015, Wanyonki et al., 2017, Swanson et al., 2019), one of the most frequently cited barriers is the lack of trained practitioners (Shah et al., 2015, Kim et al., 2018, Maw et al., 2019). Much of the training described in the literature has been provided in collaboration with foreign organisations, with little documented about how these are sustained after the funding has been expended (Kim et al., 2018). Although effective, the length and complexity of many programmes, some of which last months, is prohibitive, with practitioners struggling to secure cover for their clinical duties in order to provide or attend training (Shah et al., 2015, Kim et al., 2018, Maw et al., 2019). Likewise, an increasingly mobile workforce appears to have disrupted attempts to upscale the provision of ultrasound in many LMICs, with those who provide scans or supervision frequently changing posts or moving away (Greenwold et al., 2014). **Part 2** of the introduction to this Thesis explores these previous initiatives in more depth.

Concern regarding how ultrasound services may fit within pre-existing services is also a frequently cited barrier (Shah et al., 2015, Maw et al., 2019). Some worry that it may lead to staff becoming complacent, using ultrasound to reassure women without performing other essential aspects of antenatal care (Kim et al., 2018). Others worry about the burden it may place on already overstretched healthcare workers (Shah et al., 2015, Maw et al., 2019).

Although predominantly positive, there is evidence of cultural resistance to ultrasound in some LMICs. Some believe that ultrasound is harmful to the fetus (Firth et al., 2011, Ranji et al., 2012, Oluoch et al., 2015), and for many, there is reticence to receiving investigations or imaging in pregnancy, as these are primarily associated with illness (Oluoch et al., 2015, Roberts et al., 2016). The explanation women receive from providers appears to be highly influential as to how the ultrasound is perceived, with this linked to both acceptance and satisfaction (Tautz et al., 2000, Ugwu et al., 2011, Kim et al., 2018). Conversely, there are lots of reports of favourable attitudes towards ultrasound (Kim et al., 2018). Many felt it was an important tool for reassurance (Rijken et al., 2012, Ross et al., 2018), reporting that they were relieved to see their baby was healthy (Tautz et al., 2000, Oluoch et al., 2015) and had been excited to see it on the screen (Oluoch et al., 2015). There is also evidence to suggest that ultrasound services may have a 'magnetic' effect, encouraging women, and their husbands, to attend ANC services (Kimberly et al., 2010, Ross et al., 2018). Healthcare providers also tended to view ultrasound favourably, with most believing it helped them to provide better care (Oluoch et al., 2015).

Challenges with energy supply, connectivity, security and space are also described as common barriers (LaGrone et al., 2012, Kim et al., 2018, Maw et al., 2019), as are issues securing regular supplies of consumables such as ultrasound gel (Seffah et al., 2009, Shah et al., 2015, Puchalski et al., 2016). Procuring durable machines with provision for local maintenance and repair has also been a barrier, although this has diminished somewhat with the advent of smaller, cheaper and more durable machines (Becker et al., 2016). Unfortunately, overcoming some of the other barriers is less straightforward, especially with regards to the provision of effective and sustainable ultrasound training programmes.

1.3.2 Automated Determination of Gestational Age in Low- and Middle-Income Settings

Although traditionally, trained practitioners have been required to perform and interpret ultrasound examinations, advances in teleradiology and mobile computing technology have provided the opportunity for the exploration of alternative strategies which may eliminate the need for a comprehensively trained practitioner. Established in 2008, Imaging the World (ITW) is a non-profit organisation whose primary aim is to improve access to imaging in under-resourced and rural areas. Using a novel technique termed the 'obstetric sweep protocol' (OSP), minimally trained practitioners are able to capture and transmit ultrasound images for remote interpretation and feedback, provided by volunteer radiology professionals. The OSP refers to a series of 'sweeps' performed with the ultrasound probe across the maternal abdomen, in relation to anatomical landmarks, providing information on fetal number, fetal presentation, placental site, liquor volume and gestational age (DeStigter et al., 2011). Indeed, one study showed over 94% of gestational ages obtained via this method were within +/- 7 days of the gold standard (Dougherty et al., 2020). Despite practitioners being able to perform these scans successfully in a matter of hours (DeStigter et al., 2011, Toscano et al., 2021, DeStigter et al., 2021), this system is still heavily reliant on trained personnel to interpret the images and provide feedback.

To try to address this limitation, there has been increasing interest in the use of artificial intelligence (AI) and machine learning to complement these processes, with the development of systems able to undertake automated interpretation of images submitted from similar sweep protocols. Until recently, this was primarily focused on the determination of gestational age from HC images obtained using 3D ultrasound, encompassing the standard plane (Ryou et al., 2016, Namburete et al., 2018), as previously described in Section 1.2.2.2.1. However, not only is 3D ultrasound prohibitively expensive for most LMIC settings (Roy-Lacroix et al., 2017), but the prerequisite standard plane for the measurement of HC is unlikely to be consistently captured using the OSP (Kwitt et al., 2013, Maraci et al., 2017). Consequently, an automated system was developed that would permit the determination of gestational age from the HC without capturing the standard plane and using 2D ultrasound images. In order to overcome the challenge of a suboptimal view, this approach estimated gestational age from the combination of several HC measurements obtained from a number different frames. Although feasibility studies found this approach able to determine gestational age to within +/- 8.1 days of an experienced operator (Van de Heuvel et al., 2019), there are reservations about the accuracy of HC to determine gestational age, especially at later gestations and in populations with a high prevalence of growth restriction (Maraci et al., 2020).

More recent work, therefore, has explored the potential for the automated determination of gestational age via measurement of the TCD, (Maraci et al., 2020) a parameter shown to retain good accuracy for the determination of gestational age, even in the context of growth restriction or advancing gestation, situations commonly encountered in the LMIC population. Unlike previous initiatives, this approach is reliant on practitioners being able to identify and acquire short video clips of the fetal head, which are then analysed by the automated system which recognises the correct plane and takes the appropriate measurement. Validated on a large data set, this approach has already demonstrated effective technology and very good accuracy in relation to manual measurements (Maraci et al., 2020). Although work is ongoing to integrate this technology into a low-cost handheld device and to further evaluate its usability (Von Dadelszen et al., 2020) therefore it is not yet available out with research settings.

Part 2: Training

The second part of the introduction to this Thesis focuses on training healthcare professionals in LMICs, both in a general sense and specifically to perform obstetric ultrasound. As training healthcare workers in LMICs to determine gestational age using ultrasound was to be a fundamental part of this work, a systematic review of the literature was undertaken and is presented within this part of the Introduction.

1.4 Training Healthcare Workers in Low- and Middle- Income Settings

While providing healthcare workers with effective training may be relatively straightforward in high-income settings, there are a number of additional complexities influencing the training of healthcare workers in LMICs. The healthcare systems of many LMICs are both overstretched and overburdened, with too few workers struggling to meet demand (Chen et al., 2004, Cancedda et al., 2015). Many move away, seeking better conditions, further compounding the problem and placing those who remain under additional pressure (Mormina and Pinder. 2018). Not only does this attrition of skilled workers affect service provision, but also impacts on the provision of training and continuing professional development (CPD) opportunities (Willis-Shattuck et al., 2008). Rural communities are often worse affected, with opportunities for professional development further hindered by poor transport links and limited telecommunication services (Kawooya. 2012). Inadequate funding, equipment, space, and training materials are also frequently cited barriers to diverse and effective training programmes (Cancedda et al., 2015, Lassi et al., 2016).

While efforts to recruit and train new healthcare workers are ongoing, workforce strategies have also sought to retain those already in service by addressing a variety of motivational factors. Adequate remuneration, access to training and mentoring and opportunities for career progression have all been found to be important motivating factors, and as such, the provision of effective training programmes is seen as crucial for the retention of a skilled, motivated and fulfilled workforce (Chen et al., 2004, Willis-Shattuck et al., 2008).

Although there are a diverse array of native programmes (Frenk et al., 2010), many training initiatives in LMICs continue to be delivered as part of collaborations with foreign institutions (Mormina et al., 2018). While these Global Health Partnerships (GHP) are known to be strong facilitators of healthcare capacity strengthening (Crisp and Chen. 2014), they are not without challenges. Unfortunately, driven by the priorities of the collaborating partners, many programmes have been misaligned with the needs of the local workforce, providing training that is at odds with requirements (Chen et al., 2004, Celletti et al., 2011). Likewise, many initiatives have failed to integrate themselves within national policy, limiting the opportunity for ongoing support and investment from local governments (Celletti et al., 2011, Cancedda et al., 2015,).

By focusing preferentially on clinicians, many programmes have failed to address the educational needs of other cadres of healthcare worker (Celletti et al., 2011), limiting their opportunities for career development and exacerbating pre-existing disparities in skill mix. Financing is also problematic, with the intermittent availability and spending restrictions applicable to donor funds often hindering the ability of programmes to invest in the necessary supporting infrastructures (Vujicic et al., 2012, Cancedda et al., 2015, WHO. 2015), therefore limiting sustainability.

In order to address these issues, a number of best practices have been suggested for the development and implementation of training programmes in LMICs, especially those which are conceived as part of GHP (Cancedda et al., 2015). Programmes should be embedded within pre-existing systems and aligned with local priorities, with coordination and oversight provided by the local teams. As well as clinical training, efforts should also be made to develop practitioners' management and leadership skills, with those exhibiting key attributes identified and supported to become mentors (Mormina et al., 2018). Training should be underpinned by appropriate policy and resource provision, with named individuals taking responsibility for managing, planning and coordinating programmes. These should be supported by adequate ongoing supervision and overseen by the relevant governing bodies (Dawson et al., 2013). Finally, training initiatives should be accompanied by robust sustainability strategies, taking into account how they will continue to be implemented over time (Collins et al., 2010, Kerry et al., 2014).

Although optimising training initiatives is vital, another important strategy for the strengthening and expansion of the healthcare workforce is the concept of 'task shifting,' described as '*the rational redistribution of tasks among health workforce teams'* (WHO. 2008). This involves delegating some tasks from more qualified workers, to those who have undergone less training, in an effort to make the overall workforce more efficient. Safe, acceptable and effective, this approach has been shown to improve both the quality and coverage of healthcare services in LMICs (WHO. 2018) and is already widely practiced.

1.5 Training in Ultrasound

Despite technological advances, the accuracy of ultrasound examinations remains primarily dependent on the skill of the operator and their ability to capture and interpret the appropriate images (Tolsgaard et al., 2013, Tolsgaard., 2018). Sonographers or radiologists have traditionally provided this service, but the increase of access to ultrasound and the subsequent growth of its application within a broad range of medical and surgical specialities has led to a new generation of clinicians seeking to perform and interpret their own ultrasound examinations. Although not requiring the same experience or breadth of skill demanded by radiology training, these practitioners are still expected to have undergone appropriate training and achieved a certain level of proficiency (ISUOG Education Committee. 2013, Royal College of Radiologists. 2017).

Learning to perform ultrasound requires the acquisition and integration of a number of different skills and while there is no universally agreed or standardised approach to training, it is generally acknowledged that it requires a combination of both didactic and 'hands on' tuition (Tolsgaard., 2018). Preliminary theoretical training should include; the basic physics of ultrasound, how to safely operate the equipment and appropriately optimise the image, how to perform indication specific examinations, how to capture and store images and how to interpret and report findings. (Royal College of Radiologists., 2017). This should then be followed by a period of practical training, undertaken under the direct supervision of an experienced practitioner and structured according to the specific objectives of the training (ISUOG Education Committee. 2013, Royal College of Radiologists. 2017). Practitioners must demonstrate adequate proficiency prior to independent practice and training should be complemented by ongoing CPD activities and the regular review and audit of practice. (IUSOG Education Committee. 2013, Royal College of Radiologists. 2017). While there are no specific stipulations about where this should take place, for most it is 'in-service' training, undertaken in the context of providing clinical care.

Although these principles serve as a guide, there is no consensus agreement regarding the optimum approach. There is no specific definition as to what constitutes competency to perform ultrasound examinations and these decisions are generally delegated to the relevant governing body of each country (ISUOG Education Committee. 2013, Royal College of Radiologists. 2017).

In the UK, training in obstetric ultrasound is provided, either for doctors as part of general training in obstetrics and gynaecology, or for other healthcare professionals, as a formal postgraduate qualification, with the depth of tuition aligned with the practitioners interests. All Obstetric and Gynaecology trainees receive basic training, including how to confirm viability, locate the placenta, determine presentation, establish gestational age and evaluate the amniotic fluid volume, with those who seek to specialise in fetal medicine receiving additional training in more complex examinations. This training is undertaken alongside clinical commitments and is most commonly supervised by either sonographers or experienced obstetricians. Trainees are expected to collect evidence of their skills by keeping a logbook and undertaking ultrasound specific Objective Structured Assessments of Technical Skills (OSATS). They are deemed capable of undertaking an independent ultrasound examination for a specific indication once they have achieved three OSATS where an assessor has deemed them competent for that task. Although delivered by local teams, this training programme is overseen by the Royal College of Obstetricians (RCOG) (RCOG. 2021).

For other UK healthcare professionals, including midwives, training is delivered more formally via University accreditation and depending on individual requirements, this is typically a Postgraduate Certificate (PGCert), Diploma or Master's Degree (MSc). Courses are usually part-time for a minimum of 12 months, requiring an upfront clinical practice placement agreement to ensure access to 'hands on' sessions. Assessments are usually undertaken by a designated clinical mentor, with final clinical examinations performed by an external assessor. Interestingly, midwives are usually expected to have had some previous exposure to ultrasound prior to applying, and unless sponsored to attend, need to self-fund their tuition (British Medical Ultrasound Society).

In contrast to this relatively structured approach, evidence suggests that a significant proportion of practitioners performing ultrasound examinations in LMICs have received little or no formal training. Indeed, there is a general paucity of collated evidence pertaining to specific initiatives to train practitioners in this setting to perform obstetric ultrasound. **Section 1.6** presents a systematic review undertaken to establish the current evidence relating specifically to training in ultrasound to determine gestational age in LMICs.

1.6 Training in ultrasound to determine gestational age in Low-and Middle- income countries: A systematic review

The following materials have been published in Frontiers in Global Women's Health under the same title by Alexandra C Viner (AV), Isioma Okolo (IO), Professor Jane E Norman (JN), Dr Sarah J Stock (SS) and Professor Rebecca M Reynolds (RR).

AV conceptualised and designed the protocol for this study, under the guidance of JN, SS and RR. AV developed and piloted the search strategy, with assistance from Ruth Jenkins, librarian at the University of Edinburgh. Searches were run by AV, with all eligible studies screened for inclusion by both AV and IO. AV performed the primary data extraction, with verification from IO. Both AV and IO graded the methodological quality of the studies selected for inclusion. Data was synthesised by AV, who also prepared the first draft of the manuscript, under the guidance of SS and RR. All authors provided critical insight for the manuscript. Of note, the work here is presented as it appears in Frontiers in Global Women's Health. This includes numbered referencing, maintained for the ease of the reader and American spelling. References and details of the search strategy are provided as a chapter appendix.

In summary, this work demonstrated a lack of consensus or standardised approach to the current training of practitioners in LMICs to date pregnancies using ultrasound, reflecting the wider challenges of developing and delivering effectual training in this setting. Over half of the programmes did not conform to the ISUOG recommendation that training incorporate didactic and ‘hands on’ components, followed by practical assessment (ISUOG Education Committee. 2013) and only one met the WHO recommendation that practitioners should perform 200 supervised ultrasound examinations prior to independent practice (WHO. 2011). Having highlighted the paucity of high quality data in this field and the need for a more consistent approach, this work makes key recommendations for the development, delivery and reporting of contextually appropriate, safe and sustainable training in basic obstetric ultrasound.

1.7 Abstract

1.7.1 Introduction

Establishing an accurate gestational age is essential for the optimum management of pregnancy, delivery and neonatal care, with improved estimates of gestational age considered a public health priority by the World Health Organisation (WHO). Although ultrasound is considered the most precise method to achieve this, it is unavailable to many women in low- and middle- income countries (LMICs), where the lack of trained practitioners is considered a major barrier. This systematic review explores what initiatives have previously been undertaken to train staff to date pregnancies using ultrasound, which were successful and what barriers and facilitators influenced training.

1.7.2 Methods

The systematic review was conducted according to PRISMA guidelines and the protocol registered (PROSPERO CRD42019154619). Searches were last performed in July 2021. Studies were screened independently by two assessors, with data extracted by one and verified by the other. Both reviewers graded the methodological quality using the Mixed Methods Assessment Tool. Results were collated within prespecified domains, generating a narrative synthesis.

1.7.3 Results

25/1262 studies were eligible for inclusion, all of which were programme evaluations. 18 were undertaken in Africa, 3 in South-East Asia, 1 in South America and 3 across multiple sites, including those in Africa, Asia and South America. 5 programmes specified criteria to pass, and within these 96% of trainees did so. Trainee follow up was undertaken in 18 studies. 10 met recommendations for training outlined by the International Society of Ultrasound in Obstetrics and Gynaecology (ISUOG) but only 1 met the current standards set by the WHO.

1.7.4 Discussion

This systematic review is the first to evaluate this topic and has uncovered major inconsistencies in the delivery and reporting of basic obstetric ultrasound training in LMICs, with the majority of programmes not meeting minimum recommendations. By identifying these issues, we have highlighted key areas for improvement and made recommendations for reporting according to the RE-AIM framework. With an increasing focus on the importance of improving estimates of gestational age in LMICs, we believe these findings will be of significance to those seeking to develop and expand the provision of sustainable obstetric ultrasound in LMICs.

1.8 Introduction

Gestational age is the age of the fetus, from the first day of the last menstrual period to the current date, as given in weeks and days. Establishing an accurate gestational age is fundamental to the optimum management of pregnancy, delivery and neonatal care, as well as an essential component of strategies to improve neonatal outcome. Not only are precise estimates of gestational age required to facilitate a more accurate global reporting of preterm birth and intrauterine growth restriction, but also to permit vital ongoing research into how to improve outcomes for these babies. Indeed the World Health Organisation (WHO) has regularly cited the need for improved estimates of gestational age as a public health priority.(1–3) While accurate estimates of gestational age are important in any setting, they are even more so in low- and middle- income countries (LMICs), where the burden of perinatal complications is high, but the availability of resources and a contextualised evidence base low.

Although there are a number of different ways to determine gestational age, they vary in their accuracy, with early estimation using ultrasound considered the most accurate.(4–7) However, despite recommendation from the WHO that all women receive an ultrasound scan prior to 24 weeks to 'estimate gestational age, improve detection of fetal anomalies and multiple pregnancies and reduce induction of labour for post term pregnancy'(8) this remains unavailable to many women living in LMICs. Here, gestational age is derived from the last menstrual period or by abdominal palpation, both of which are less accurate than ultrasound. Scaled provision of ultrasound is challenging for multiple reasons,(9–14) with the lack of trained practitioners considered a major barrier.(12,15)

While there is no universally agreed or standardised approach to training in ultrasound, the International Society of Ultrasound in Obstetrics and Gynaecology (ISUOG) and WHO do both provide guidance. ISUOG recommends that training should involve the combination of both didactic and 'hands on' tuition, as well as practical assessment, with practitioners able to demonstrate adequate proficiency prior to independent practice.(16) WHO recommends that trainees undertake a minimum number of supervised scans, (n=50 1st trimester and n=200 2nd/3rd trimester), although makes no specific reference as to what should constitute competency itself.(17)

With an increasing focus on the importance of improving estimates of gestational age in LMICs, we believe it is important to establish the current evidence pertaining to previous initiatives to train staff in this context to date pregnancies using ultrasound. Therefore, the aim of this systematic review was to establish; what proportion of training was delivered in line with recommended standards, what proportion of initiatives were successful and what factors influenced the delivery of training.

1.9 Methods

1.9.1 Search strategy

Our search strategy aimed to identify all available literature relating to any previous initiatives undertaken to train practitioners in the use of ultrasound to determine gestational age in LMICs. Following testing, searches were initially performed in November 2019 and updated in July 2021. Databases searched included EMBASE, AMED, MEDLINE, CINAHL, AIM, Global Health, Global Index Medicus, Cochrane and Web of Science, and we performed additional checks of the grey literature and reference lists of included papers to ensure additional relevant studies were not missed. The review was registered with the International prospective register of systematic reviews (PROSPERO Record CRD42019154619) and was conducted in accordance to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA). The search strategy is available in the supplementary materials.

Population

Healthcare workers in LMICs

Intervention

Training in ultrasound to determine gestational age

Comparison

None

Outcomes

The proportion of training was delivered in line with recommended standards (ISUOG/WHO)

The proportion of training was successful (trainees passed assessment)

The factors which influenced delivery of training

1.9.2 Inclusion criteria

All reports or studies of any design where participants either provided or underwent training in ultrasound to determine gestational age in LMICs, as defined by the World Bank list of Economies (June 2020),(18) were included. There was no restriction placed on date, however abstracts must have been available in English to be considered for initial screening.

1.9.3 Exclusion criteria

Studies which were not undertaken in LMICs were excluded, as were studies relating to training in obstetric ultrasound that did not include the determination of gestational age. Where there was uncertainty as to whether the assessment of gestational age was included in the training programmes, further information was sought online and the authors contacted directly for clarification (n=14)(19,20,29–32,21–28) If the inclusion of gestational age assessment in the training could not be verified, the studies were excluded (n=9.) See *Fig. 1* for further details.

1.9.4 Study selection and data extraction

Eligible abstracts were uploaded and managed in Covidence systematic review software (Veritas Health Innovation) and duplicates removed. All abstracts were screened independently by two assessors (AV and IO) according to the criteria outlined above. Data was extracted directly into a customised form created within Covidence by one reviewer (AV) and verified by the other (IO). Any disagreements were resolved by discussion, without the need for a third reviewer. Where multiple papers were identified pertaining to the same study or training programme, they were amalgamated into a single study. All were reviewed for data extraction, with the manuscript containing the majority of the information cited as the primary source.

1.9.5 Study quality assessment

The methodological quality of the studies was assessed independently by two reviewers (AV and IO) using the Mixed Methods Assessment Toot (MMAT). The MMAT was selected to permit the simultaneous assessment of a range of different study types.(33) In situations where the training had been undertaken as part of a larger study, only the evidence pertaining to the quality of the educational intervention itself was assessed, as opposed to the methodologies used for the ‘parent’ study. Scores were not used to dictate inclusion or exclusion, rather to illustrate the quality of the evidence.

1.9.6 Data analysis

In the absence of data suitable for meta-analysis, results were collated according to the Cochrane Synthesis Without Meta-analysis (SWiM) guidelines.(34) Data was extracted into pre-defined groups generated according to the PICO format. These included who participated in and delivered training, the setting and duration, what was taught within the curricula and how were trainees assessed and followed up. The overall quality of training was evaluated based on its adherence to ISUOG and WHO recommendations and where possible, success was defined as the proportion of trainees who passed. If formally reported in the context of implementation outcomes, data was also collected on factors identified as having facilitated or acted as a barrier for training.

1.10 Results

In total, 25/1262 studies were included (Figure 1-5 PRISMA Diagram), (28,29,41–50,30,51–53,31,35–40) all of which were programme evaluations. The majority were undertaken in Africa (n=18, 72%), (26,27,42,43,46–49,51,28,29,31,34,36,37,39,41) with 3 in South East Asia (12%), (32,41,46) 1 in South America (4%)(52) and several across multiple sites in Africa, Asia and South America (n=3, 12%).(36,45,55) Most were descriptive studies (n=23, 92%)(28,30,42,44–52,31,53,55,56,35–41) of which 3 (12%)(41,44,47) employed mixed methods. The remaining 2 (8%)(29,43) were case reports. All studies were published from 2008 onwards.

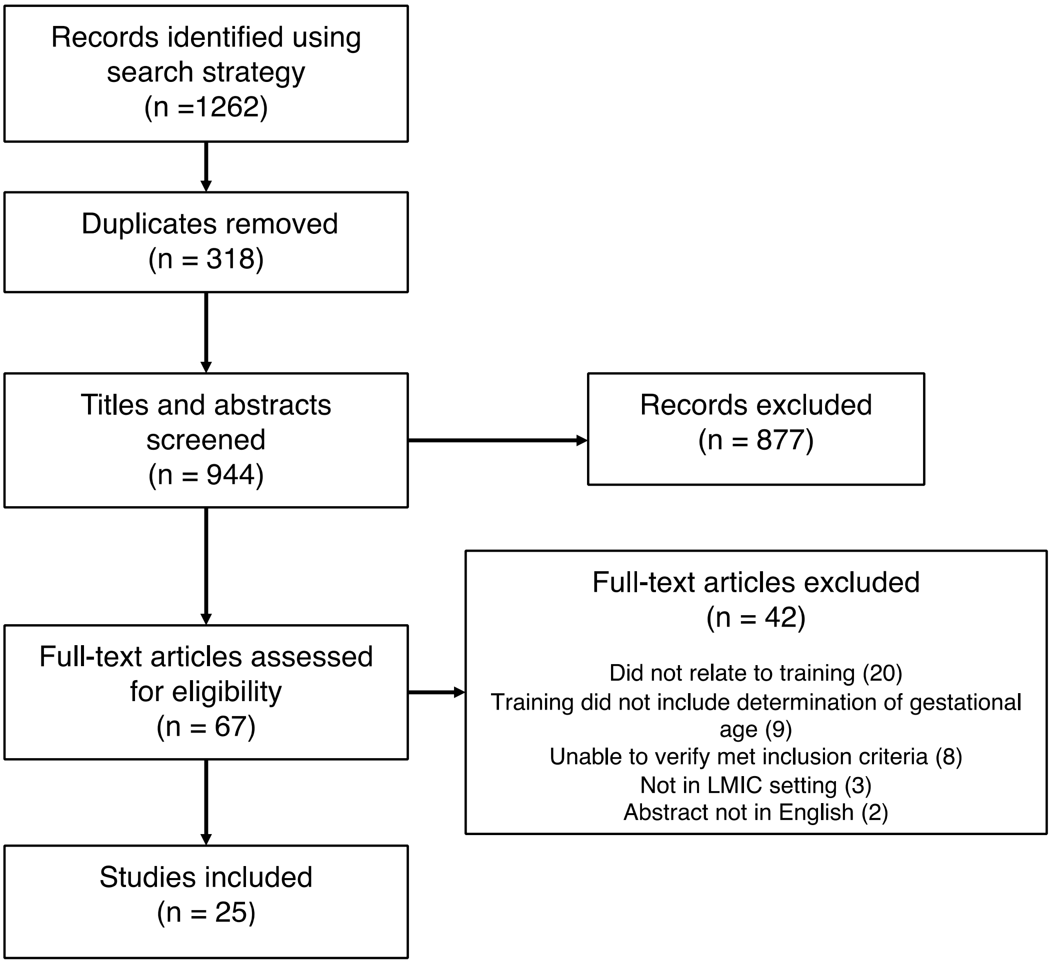

Figure 1-5 PRISMA Diagram

Just over half of the included studies (n=15, 60%) (28,30,43,48,49,51,53,31,32,35,37–39,41,42) focused on evaluating the training programmes themselves, whereas the remainder (n=10, 40%)(29,36,40,44–47,50,52,55) described training which had been undertaken as part of a larger study to facilitate a different research question. Of these, 2 provided training with the aim of developing new standards for fetal dating and growth,(36,55) 3 sought to assess the impact of introducing antenatal ultrasound on maternal and fetal outcomes,(40,45,47) 1 evaluated the implementation of the INTERGROWTH-21st standards(44) and 1 evaluated a new tele-ultrasound system.(52) In the remaining 3 studies, training was provided to ensure access to an accurately dated study cohort.(29,46,50)

Four (16%) studies presented data on the barriers and facilitators to the provision of ultrasound training, having formally reported this in the context of implementation outcomes.(41,44,47,55) Table 1-2. Characteristics of included studies (presented alphabetically by first author) provides an overview of the main characteristics of each study.

Table 1-2. Characteristics of included studies (presented alphabetically by first author)

Authors	Study Design	Journal and year	Location	Number and cadre of Trainees	Previous experience of ultrasound	Recruitment of Trainees	Funding	Strengths	Limitations	MMAT Score
Adler(35)	Observational study *Non randomised*	Int J Emerg Med 2008	Lugufu Refugee Camp Tanzania	10 trainees Physicians and clinical officers	Unspecified	Recruitment method unspecified	None	Detailed description of overall programme. Trainees must achieve a certain number of supervised scans. Attempt made to undertake follow up.	No practical or written assessment of skill. No mentoring. Follow up only concerned the use of the machine not the quality of the scans performed.	2
Ahmadzia (28)	Prospective cohort study *Non randomised*	African Health Sciences 2018	Mulago National Referral Hospital, Kampala Urban Uganda	40 trainees Medical students and junior/senior house officers	Some had previous training or experience of using ultrasound	Voluntary No criteria specified for participation	None	Matched pre and post intervention testing with responses from 95% of trainees.	Time between tests not standardised – No differentiation made for those who had previous experience of using ultrasound. No opportunity for trainees to perform ultrasound themselves. No practical assessment of skill. No mentoring or follow up.	2
AMANHI (36)	Prospective cohort study *Non randomised*	The Lancet 2020	Sylhet, Bangladesh. Karachi, Pakistan. Pemba, Tanzania. Rural/Peri Urban	10 trainees Sonographers	All had previous training or experience of using ultrasound	Recruitment method unspecified	Bill and Melinda Gates Foundation	Written and practical trainee assessment. Matched pre and post testing. Trainees mentored with ongoing quality assessment and feedback relating to their images.	Limited description of programme.	4

Baj(37)	Survey *Quantitative descriptive*	Ultrasound 2015	Ernest Cook Ultrasound Research and Education Centre(ECUREI) Kampala Urban Uganda	Number of trainees unspecified High school graduates	None had previous training or experience of using ultrasound	Voluntary Must be USS naïve	None	Undertaken in established ultrasound training centre. Detailed description of design of programme with careful consideration given to the rural low resource context.	Training not provided to the intended participant group. No opportunity for trainees to perform ultrasound themselves. No practical or written assessment of skill. No mentoring or follow up. No reporting or analysis of results of training.	-
Bentley (38)	Prospective cohort study *Non randomised*	J Ultrasound Med 2015	Teaching Hospital Monrovia Urban Liberia	31 trainees Midwives	Unspecified	Voluntary Participation extended to all midwives at the site	Health Education and Relief Through Teaching	Matched pre and post intervention testing Practical trainee assessment. Attempt made to undertake follow up.	Limited description of programme. Unclear if trainees had prior experience in ultrasound. Incomplete data capture for all trainees – Only 55% underwent practical assessment. Only 45% followed up. No mentoring.	2
Boamah (29)	Case report *Quantitative descriptive*	JMIR Res Protoc 2014	Kintampo North Municipal and South District Hospitals, Brong Ahafo Region Rural Ghana	15 trainees Midwives	None had previous training or experience of using ultrasound	Voluntary Participation extended to all midwives at the sites	National Institute of Environmental Health Sciences. Global Alliance for Clean Cookstoves Thrasher Research Fund	Clear description of training programme. Trainees provided with extensive practical experience. Trainees mentored with ongoing quality assessment and feedback relating to their images.	Training took place in phases over 2 years – May not be generalisable to other low resource settings. Images reviewed but no formal practical assessment. No reporting or analysis of results of training.	-

Enabudoso (30)	Survey *Quantitative descriptive*	Tropical Journal of Obstetrics and Gynaecology 2017	Conference Hall, University of Benin Teaching Hospital Urban Nigeria	67 trainees Obstetricians, radiologists, sonographers and private practitioners	Some had previous training or experience of using ultrasound	Voluntary Participants had to pay to attend (Approx. £225)	None	Detailed description of content of programme.	No practical or written assessment of skill. No mentoring or follow up. No reporting or analysis of results of training.	1
Greenwold (39)	Prospective cohort study *Non randomised*	International Journal of Obstetrics and Gynaecology 2014	Mandimba Health Clinic, Mandimba District Rural Mozambique	9 trainees Nurses and clinical officers	None had previous training or experience of using ultrasound	Recruitment method unspecified	Medical Aid Films. MaMA Mozambique. Sonosite.	Refresher sessions provided 4 months after initial training. Discussed barriers and facilitators to implementing ultrasound.	No practical or written assessment of skill. Reported detection rates for specific findings were unverified by experienced sonographers.	3
Kawooya (40)	Before and after study *Non randomised*	Ultrasound Quarterly 2015	Six health centres in Mpigi District Rural Uganda Training at Ernest Cook Ultrasound Research and Education Centre (ECUREI) Kampala	14 trainees Midwives	Unspecified	Recruitment method unspecified	General Electric. Midwives Antenatal Ultrasound Project. STRIDES for family health/US AID-Uganda	Undertaken in established ultrasound training centre. Some but not all scan images were reviewed for quality.	Limited description of programme. No practical or written assessment of skill.	2
Kim(41)	Mixed Methods study	BMC Medical Education	Urban Nepal	228 trainees Radiologists, physicians, nurses,	Unspecified	Voluntary	JW LEE Centre for Global Medicine	Matched pre and post intervention testing. Formal review of implementation reporting	Limited description of training programme.	2

		2021		midwives and paramedics		No criteria specified for participation	of Seoul National University College of Medicine	on implementation outcomes.	Extent of previous ultrasound experience unclear. No opportunity for trainees to perform ultrasound themselves. No practical assessment of skill. Only presents scores for approx. 50% of participants.	
Kimberly (42)	Before and after study *Non randomised*	Ultrasound in Med and Biol 2010	Kapiri District Hospital, Mukonchi Rural Health Centre, Nkole Rural health Centre Rural Zambia	21 trainees Midwives	None had previous training or experience of using ultrasound	Recruitment method unspecified	None Sonosite donated the machines	Practical assessment of skill. Attempt made to undertake follow up. Some but not all scan images were reviewed for quality. Discussed barriers and facilitators to implementing ultrasound.	Uneven range of ultrasound exposure during training. No specification of the requirements to pass the assessments. Incomplete data capture for all trainees – Only 52% followed up. No mentoring.	2
Kinnevey (31)	Survey *Quantitative descriptive*	International Journal of MCH and AIDS 2016	Health centres in 11 districts Rural Uganda Training at Ernest Cook Ultrasound Research and Education Centre (ECUREI) Kampala	12 trainees Midwives	None had previous training or experience of using ultrasound	Voluntary No criteria specified for participation	Uganda Protestant Medical Bureau	Undertaken in established ultrasound training centre.	Limited description of training programme. No practical or written assessment of skill. No mentoring or follow up. No reporting or analysis of results of training.	2

Lee(43)	Case report *Quantitative descriptive*	Global Humanitarian Technology Conference 2015	Nursing School Bwindi Rural Uganda	Number of trainees unspecified Nurses	None had previous training or experience of using ultrasound	Compulsory All nursing students	Imaging the World	Detailed description of overall programme. Practical and written assessment of trainee assessment with specific requirements to pass.	Limited reporting of results of training.	-
Mashamba (53)	Before and after study *Non randomised*	Poster presentation 2018	Gauteng Province South Africa	10 trainees Advanced midwives	Unspecified	Trainees selected No criteria specified for participation	Unspecified	Trainees mentored.	No description of training programme or assessment process. Unclear if trainees had prior experience in ultrasound.	-
Millar(44)	Mixed methods study	JMIR Res Protoc 2018	Jacaranda Health Maternity hospital, Nairobi Peri-urban Kenya	7 trainees Sonographers and nurse midwives	All had previous training or experience of using ultrasound	Trainees selected Must have previous experience of using ultrasound	Bill and Melinda Gates Foundation	Clear description of training programme. Pre implementation site assessments. Practical assessment of skill with specific requirements to pass. Trainees mentored with ongoing quality assessment and feedback relating to their images. Refresher sessions provided 6 months after initial training. Formal review of implementation reporting on implementation outcomes.	Limited reporting of results of training.	5

Nathan (45)	Prospective cohort study *Non randomised*	Curr Probl Diagn Radiol 2017	Chimaltenango, Guatemala Lusaka, Zambia Western Province, Kenya Thatta, Pakistan Equateur, DRC Rural sites	41 trainees Physicians, nurse midwives and trained birth attendants	None had previous training or experience of using ultrasound	Trainees selected No criteria specified for participation	Bill and Melinda Gates Foundatio n	Detailed description of overall programme. Pre implementation site assessments. Written and practical trainee assessment with specific requirements to pass. Trainees mentored with ongoing quality assessment of their images. Strong collaboration with local teams.	Limited information about how the ultrasound training was delivered at each of the sites. Many of the scans were performed out with the intended gestational age range.	4
Neufeld (46)	Before and after study *Non randomised*	Ultrasound Obstet Gynecol 2009	Rural Bangladesh Training at the Atomic Energy Commission Obstetric Hospital, Dhaka	9 trainees Paramedics	None had previous training or experience of using ultrasound	Recruitment method unspecified	United Nations Children's Fund. UK MRC. Swedish Internation al Developm ent Cooperati on Agency	Trainees mentored. Robust analysis of trainee vs trainer measurements.	Limited description of training programme or assessment. If trainee measurements were poor they were excluded from review	3
Rijken(32)	Before and after study *Non randomised*	Ultrasound Obstet Gynecol 2009	Shoklo Malaria Unit, Thai-Burmese Border Rural	4 trainees Nurses and high school graduates	None had previous training or experience of using ultrasound	Trainees selected By interview based on motivation	None University Medical Centre Utrecht donated the Machines	Undertaken in established ultrasound training centre. Practical assessment of skill. Robust analysis of trainee vs trainer measurements.	Limited description of training programme and assessment.	3

Sarris(55)	Prospective cohort study *Non randomised*	BJOG 2013	Pelotas, Brazil. Nagpur India, Parklands Suburb, Nairobi Kenya Multiple Urban Sites	9 lead sonographers. At least 1 from each participating site Unspecified number of additional sonographers from participating sites. Trained by lead sonographer from their site	All had previous training or experience of using ultrasound	Voluntary Must be motivated and experienced	Bill and Melinda Gates Foundatio n	Detailed description of programme and assessment. Practical assessment of trainee assessment with specific requirements to pass. Trainees mentored with ongoing quality assessment of their images. Formal review of implementation reporting on implementation outcomes. Strong collaboration with local teams.		5
Shah(51)	Before and after study *Non randomised*	BMC Internation al Health and Human Rights 2009	Kirehe and Rwinkwavu District Hospitals, Eastern Province Rural Rwanda	15 trainees Physicians	Unspecified	Voluntary Participation extended to all physicians at the site	Sonosite donated the machines	Clear description of training programme. Ongoing quality assessment review of proportion of images.	No practical or written assessment of skill. Not all images were reviewed and no feedback provided to trainees.	1
Shah(47)	Mixed methods study	PLOS One 2020	Public District Hospital and Health Centres, Busoga Region Urban and rural Uganda	25 trainees Nurse midwives and physicians	None had previous training or experience of using ultrasound	Voluntary Must provide antenatal care at the site	Bill and Melinda Gates Foundatio n	Clear description of training programme and rationale for iterative changes. Written and practical trainee assessment with specific requirements to pass. Trainees mentored with ongoing quality	Survey data only available for 68% of trainees.	4

								assessment and feedback relating to their images.		
Toscano (52)	Observational study *Non randomised*	BMC Pregnancy and Childbirth 2021	Health Centre, Lima Urban Peru	2 trainees Nurse and care technician	None had previous training or experience of using ultrasound	Recruitment method unspecified	Innovate Peru	Detailed description of programme. All images reviewed. Thorough reporting of results of image review.	No practical or written assessment of skill. No feedback provided to trainees.	3
Vinayak (48)	Prospective cohort study *Non randomised*	Ultrasound in Med and Biol 2017	Health Centres Rural Kenya Training in Aga Khan University Hospital	3 trainees Midwives	None had previous training or experience of using ultrasound	Voluntary Must have passed e-module	Philips Medical Systems	Detailed description of programme and rationale for iterative changes. Practical and written assessment of trainee assessment. Trainees mentored with ongoing quality assessment of their images.	No specification of the requirements to pass the assessments.	3
Wanjiku (49)	Prospective cohort study *Non randomised*	BMC Health Services Research 2018	Health Centres Rural Kenya	33 trainees Clinical officers, nurses and community workers	None had previous training or experience of using ultrasound	Voluntary No criteria specified for participation	DAK foundation. Rotary Club of Greater Sydney	Practical and written assessment of trainee assessment with specific requirements to pass.	Limited information about how the ultrasound training was delivered at each of the sites. The length of time between the end of training and assessment was inconsistent between trainees.	3
Wylie(50)	Prospective cohort study *Non randomised*	Malaria Journal 2013	Ndirande Antenatal Care Clinic, Blantyre Urban Malawi	4 trainees Clinicians and nurses	None had previous training or experience	Recruitment method unspecified	Sonosite donated the Machines	Trainees mentored with ongoing quality assessment of their images	Limited description of training programme. No practical or written assessment of skill.	2

					of using ultrasound				Limited reporting of results of training.	

1.10.1 Quality appraisal of the included papers

Two (8%)(44,55) studies achieved the maximum MMAT score, indicating high quality, with 9 (36%)(32,36,39,45–49,52) rated as of moderate quality. Ten (40%)(28,30,31,35,38,40–42,50,51) studies were considered low quality. The remaining 4 (16%)(29,37,43,53) did not provide sufficient information to permit a full assessment.

1.10.2 Participants and Faculty

Training was provided to local practitioners in all studies, with few (n=5, 20%) designed for those with previous experience of using ultrasound.(28,30,36,44,55) Over half (n=14, 56%) focused on training those who had not used ultrasound before.(29,31,49,50,52,54,32,37, 42,43,45–48) and 6 (24%) of the studies did not comment on trainees' prior experience.(35,38,40,41,51,53) Of the 10 (40%) studies where training had been developed by local teams,(30–32,37,40,41,43,45,53,55) the majority (8, 80%) were in collaboration with overseas institutions.(31,32,37,40,41,43, 45,55) Local practitioners delivered the training in 14 (56%) of the programmes.(30,31,47,48,53,55,32,37,40,41,43–46)

1.10.3 Setting and duration of training

Just over half of the studies (n=15, 56%)(28,29,49–52,54,32,35 ,38,42,44,45,47,48) reported training that had been delivered in a clinical setting, with the remainder undertaken across a variety of other sites. These included The Ernest Cook Ultrasound Research and Education Institute (ECUREI) in Kampala, Uganda (a specialist ultrasound training centre,; n=3, 12%)(31,37,40) a refugee camp (n=1, 4%)(32) a nursing school (n=1, 4%)(43) and a conference centre (n=1, 4%).(30) The majority took place in rural settings (n=16, 64%),(29,31,47–49,51,53,54,32,35,36,40,42,43,45,46) although the specific site was unspecified in 4 (16%).(36,41,53,55) The duration of training was highly variable, ranging from one day to several years. Ten (40%) programmes lasted a week or less,(28,30,35,36,38,41,49 ,50,52,55) with nearly all completed within 3 months (n=22, 88%).(28,30,44–53,31,54,55,32,35–38,40,41) Only 3 (12%) programmes lasted longer than 6 months,(29,42,43) with 2 (8%) of these lasting over a year.(29,43)

1.10.4 Content of training curricula

All of the studies described initiatives that included training in ultrasound to determine gestational age, with the majority of programmes (n=18, 72%) focused solely on obstetric ultrasound.(28,29,44,46–48,50,52,53,55,31,32, 36,37,40–43) Others (n=7, 28%) were more diverse,(30,35,38,45,49,51,54) including scanning for cervical length (n=3, 12%)(38,51,57) and gynaecological conditions such as fibroids (n=2, 8%).(30,54) A small number of studies (n=3, 12%) reported multi-system training, including ultrasound to detect abnormalities in the renal and hepatobiliary systems.(35,49,51) Even within the 18 studies focused exclusively on obstetric indications, there was still relative heterogeneity in the range of topics covered. A third taught fetal biometry alone (n=6, 33%),(32,36,44,46,50,55) with 1 teaching practitioners to perform ‘sweeps’ of the maternal abdomen to permit measurements to be performed by trained staff working remotely.(52) The remainder (n=11, 61%) covered a wider range of obstetric topics including placental site and amniotic fluid index.(28,29,53,31,37,40–43,47,48) Detailed information pertaining to the content of the different curricula is provided in

Table 1-3. Specific topics covered within each training programmes (presented alphabetically by first author).

1.10.5 Components of training programmes

Table 1-4. Specific components of training programmes (presented alphabetically by first author) illustrates the individual components encompassing each of the training packages, highlighting a number of consistencies between the programmes, especially with regard to training methodologies. 23 programmes made some reference to didactic teaching (28,29,42,43, 45,47,48,50–54,30,55,31,32,35,36,38,40,41), be this in person or online and nearly all (n=22, 88%) described the inclusion of supervised ‘hands on’ training. (28,29,44–53,30,54,55,32,35,36,38,40,42,43)

Table 1-3. Specific topics covered within each training programmes (presented alphabetically by first author)

				Content of Curricula										
Author	**Year**	**Duration of training**	**Previous experience of USS**	**Machine safety and set up**	**Early pregnancy complications**	**Identification of multiple pregnancy**	**Fetal presentation**	**Amniotic fluid index**	**Placental site**	**Fetal biometry**	**Fetal anomaly**	**Cervical length**	**Gynae**	**Other systems**
Adler(35)	2008	4 days					✓			✓				✓
Ahmadzia (28)	2018	1 day	✓	✓			✓	✓	✓	✓				
AMANHI (36)	2020	4 days	✓							✓				
Baj(37)	2015	8 weeks		✓	✓	✓	✓	✓	✓	✓	✓			
Bentley(38)	2015	1 week		✓	✓	✓	✓		✓	✓		✓		
Boamah(29)	2014	2 years				✓			✓	✓				
Enabudoso (30)	2017	5 days	✓	✓						✓	✓		✓	
Greenwold (54)	2014	8 weeks		✓	✓	✓	✓		✓	✓			✓	
Kawooya (40)	2015	3 months		✓		✓	✓	✓	✓	✓	✓			
Kinnevey (31)	2016	6 weeks		✓						✓	✓			
Kim(41)	2021	2 days				✓		✓		✓	✓			
Kimberly (42)	2010	6 months		✓		✓	✓		✓	✓				
Lee(43)	2015	3 years		✓		✓	✓	✓	✓	✓				
Mashamba (53)	2018	12 weeks								✓	✓			
Millar(44)	2018	2 weeks	✓							✓				
Nathan(45)	2017	2 weeks		✓		✓	✓	✓	✓	✓	✓	✓		
Neufeld(46)	2009	6 weeks		✓						✓				
Rijken(32)	2009	3 months								✓				
Sarris(55)	2013	3 days	✓							✓				
Shah(51)	2009	9 weeks		✓	✓		✓		✓	✓		✓		✓

Shah(47)	2020	2 weeks		✓		✓	✓	✓	✓	✓				
Toscano (52)	2021	1 day		✓										
Vinayak(48)	2017	4 weeks		✓		✓	✓	✓	✓	✓				
Wanjiku(49)	2018	1 day					✓		✓	✓				✓
Wylie(50)	2013	1 week								✓				

Table 1-4. Specific components of training programmes (presented alphabetically by first author)

		Components of training programme													
		Logistics		Teaching Methodology				Assessment					Follow up		
Author	**Year**	**Training delivered in clinical setting**	**Training delivered by local teams**	**Pre course learning**	**e-learning**	**Didactic training**	**Supervised hands on training**	**Knowledge test**	**Practical test**	**Test of trainee confidence**	**Matched pre post course testing**	**Evaluation of training**	**Supervision or mentorship**	**Remote image review**	**Subsequent retesting**
Adler(35)	2008	✓				✓	✓								
Ahmadzia (28)	2018	✓				✓	✓	✓		✓	✓	✓			
AMANHI (36)	2020					✓	✓	✓	✓		✓		✓	✓	
Baj(37)	2015	ECUREI	✓		✓							✓			
Bentley (38)	2015	✓				✓	✓	✓	✓	✓	✓				✓
Boamah (29)	2014	✓				✓	✓						✓	✓	
Enabudoso (30)	2017		✓	✓		✓	✓			✓		✓			
Greenwold (54)	2014	✓				✓	✓						✓	✓	
Kawooya (40)	2015	ECUREI	✓			✓	✓						✓		
Kinnevey (31)	2016	ECUREI	✓			✓				✓					
Kim(41)	2021		✓			✓		✓		✓	✓	✓			
Kimberly (42)	2010	✓				✓	✓		✓				✓		
Lee(43)	2015		✓		✓	✓	✓	✓	✓				✓	✓	
Mashamba (53)	2018		✓			✓	✓						✓		
Millar(44)	2018	✓	✓				✓		✓				✓	✓	
Nathan(45)	2017	✓	✓			✓	✓	✓	✓				✓	✓	✓
Neufeld(46)	2009		✓				✓		✓				✓		
Rijken(32)	2009	✓	✓			✓	✓	✓	✓				✓	✓	
Sarris(55)	2013		✓			✓	✓		✓				✓	✓	

Shah(51)	2009	✓				✓	✓						✓	✓	
Shah(47)	2020	✓	✓			✓	✓		✓	✓	✓		✓	✓	
Toscano (52)	2021	✓				✓	✓							✓	
Vinayak(48)	2017	✓	✓	✓	✓	✓	✓	✓	✓				✓	✓	
Wanjiku(49)	2018	✓		✓	✓		✓	✓	✓				✓		✓
Wylie(50)	2013	✓				✓	✓						✓	✓	

1.10.6 Assessments

Despite the majority of studies describing improvements in trainees' knowledge and skill after training, not all provided data to support this, with 11 (44%) studies failing to carry out any trainee evaluation.(29,30,53,31, 35,37,39,40,50–52) The remainder (n=14, 56%)(28,32,47–49,55,36,38,41–46) undertook some form of assessment ranging from written tests (n=9, 64%),(28,32,36,38,41,43,45,48,49) to supervised practical exams (n=12, 86%)(32,36,49,55,38,42–48) or a combination of both (n=7, 50%).(32, 36,38,43,45,48,49) Of the programmes which undertook practical assessments, 5 (36%) did so in the format of Observed Structured Clinical Examinations (OSCEs).(38,42,43,47,49)

1.10.7 Training delivered in line with recommended standards

10 (40%) of the studies reported training that incorporated both didactic and 'hands on' components, as well as some form of practical assessment,(32,36,38,42,43,47–49,55,57) however in only 1(29) did trainees undertake the minimum number of supervised scans recommended by the WHO.

1.10.8 Success of training

Despite making efforts to assess the trainees, only 5 studies (36%) specified a pass mark.(43–45,47,55) Of the 103 trainees assessed within these 5 studies, 99 (96%) passed. Despite 18 studies providing follow up, (29,32,49–

55,58,36,42–48) only 3 (12%) arranged for repeat assessments to explore the retention of knowledge and skills. (38,49,57) Of these only 1 specified a pass mark.(45) Of the 40 trainees who were reassessed within this programme, all retained their competency. Further detail pertaining to programme assessment and follow up is shown in Table 1-5. Studies which undertook formal trainee assessment or follow up (presented alphabetically by first author).

Table 1-5. Studies which undertook formal trainee assessment or follow up (presented alphabetically by first author)

Author	Year	Total number of participating trainees and number who sat assessment	Methods of assessment and definition of competency	Proportion of trainees who passed assessment/achieved competency	Subsequent supervision or follow up	Proportion of trainees who maintained competency on any subsequent retesting
Ahmadzia (28)	2018	40 trainees All 40 underwent written assessment	Written assessment only Matched pre/post survey assessing self-assessment of ultrasound proficiency and knowledge No definition of competency and no specific requirements in order to 'pass'	No specific requirements to 'pass' Mean improvement of 5.8 points for post training scores	No follow up described	No subsequent retesting described
AMANHI (36)	2020	10 trainees All 10 underwent practical assessment Unspecified number underwent written assessment	Written and practical assessment Matched pre/post knowledge test Fetal biometric measurements obtained by trainees compared with those of trainers No definition of competency and no specific requirements in order to 'pass'	No specific requirements to 'pass' 28% increase in post training knowledge scores	All study images were saved and transferred to the study supervisor for quality assessment undertaken against predefined criteria Feedback was provided to the sonographers every quarter	No subsequent retesting described
Bentley (38)	2015	31 trainees All 31 underwent written assessment	Written and practical assessment	No specific requirements to 'pass'	All three components of assessment repeated 1 year later (Survey, knowledge test and OSCE)	Written and practical assessment repeated 1 year later

		17 trainees underwent practical assessment	Matched pre/post knowledge test OCSE assessment No definition of competency and no specific requirements in order to 'pass'	Knowledge test mean score 90% OSCE mean score 78%	Unclear if any subsequent communication between training team and trainees from the end of the course to the repeat testing	14/31 underwent knowledge test Mean score 66% 8/31 underwent OSCE Mean score 55%
Boamah (29)	2014	15 trainees Midwives	No formal assessment described	No specific requirements to 'pass' 4 out of 15 midwives selected	All images transferred to the study supervisor for informal review every 2 weeks with feedback provided. 5% of all images were reviewed formally against predefined quality criteria	3/4 1 sonographer was required to leave the programme due to a consistent inability to meet quality standards
Greenwold (54)	2014	9 trainees Nurses and clinical officers	No formal assessment described	No specific requirements to 'pass'	10 month follow Information on ultrasound findings collected and transferred to study team every week. Images also sent but unclear how these were assessed for quality	No subsequent retesting described
Kimberly (42)	2010	21 trainees 17 trainees underwent practical assessment	Practical assessment only OSCE assessment No definition of competency and no specific requirements in order to 'pass'	No specific requirements to 'pass'	All images were saved during the independent scanning. 49% were reviewed 70% of BPD measurements were felt to be inaccurate and FL was not performed consistently enough to accurately determine gestational age A follow up visit was undertaken 1 year after the training and	No subsequent retesting described

					midwives surveyed regarding their use of ultrasound following the training. 13/21 trainees responded	
Kim(41)		228 trainees 85 trainees underwent written assessment	Written assessment only Matched pre/post knowledge test No definition of competency and no specific requirements in order to 'pass'	No specific requirements to 'pass'	No follow up described	No subsequent retesting described
Lee(43)	2015	22 nurses All 22 underwent both written and practical assessment	Written and practical assessment Trainees were required to achieve a score of 80% or above in both components to pass	100% passed both components (22/22)	Longterm quality assurance programme Trainees required to submit all images form first 100 independent scans for quality assessment and feedback. No indication as to how these were assessed for quality. Trainees are required to submit 2 images of each parameter per week thereafter for longterm quality assessment	No subsequent retesting described
Mashamba (53)	2018	10 trainees Advanced midwives	No formal assessment described	No specific requirements to 'pass'	12 weeks of mentoring and assessment following initial training No further information provided	No subsequent retesting described
Millar(44)	2018	6 trainees	Practical assessment only	50% of trainees passed (3/6 trainees)	12 months of follow up after initial training	No subsequent retesting described

		All 6 underwent practical assessment	Fetal biometric measurements obtained by trainees compared with those of trainers Competency defined as the ability to perform three consecutive scans with 'precise measurements and an accurate EDD' No specific definition of what constituted 'precise'		Unspecified proportion of images transferred to study team for quality assessment undertaken against predefined criteria and feedback provided Reinforcement training was provided by the study team 6 months after the initial training	
Nathan (45)	2017	41 trainees All 41 underwent both written and practical assessment	Written and practical assessment Trainees were required to achieve a score of 75% or above in both components to pass	100% passed both components (41/41) Written 95% on their 1st attempt (39/41) 4% on their 2nd attempt (2/41) Practical 88% on their 1st attempt (36/41) 12% on their 2nd attempt (5/41)	12 week post training follow up – Parent study pilot phase *(First Look Study)* All images and their interpretations were transferred weekly to the study team for quality assessment against predefined criteria with feedback provided Local trainers met with the trainees twice a week at the participating sites to troubleshoot and provide advice or 'hands on' assistance Based on their submitted images some trainees were provided with targeted remedial assistance	Practical assessment was repeated 3 months later (40/41 trainees – one withdrew from study) 100% passed Following this period 10% of all images recorded during the parent study were transferred for ongoing quality assessment and feedback
Neufeld	2009	9 trainees	Practical assessment only	No specific requirements to 'pass'	No follow up described	No subsequent retesting described

(46)		All 9 underwent practical assessment	Fetal biometric measurements obtained by trainees compared with those of trainers No definition of competency and no specific requirements in order to 'pass'	However 33% (3/9 trainees) were noted to have 'larger errors' and required additional training		
Rijken (32)	2009	4 trainees All 4 underwent both written and practical assessment	Written and practical assessment Post course knowledge test Fetal biometric measurements obtained by trainees compared with those of trainers A difference in measurements corresponding to a difference in gestational age +/- 7 days was considered acceptable, however there was no stipulation on how many times this must be achieved to pass	No specific requirements to 'pass'	Longterm quality assurance programme All trainees required to submit 5 images of each parameter for review every 6 months and individual feedback is provided No indication as to how these images are assessed for quality	No subsequent retesting described
Sarris (55)	2011	9 trainees All 9 underwent practical assessment	Practical assessment only Fetal biometric measurements obtained by trainees compared with those of trainers and all images reviewed for quality against a set of criteria	100% passed both components (9/9)	Follow up throughout the duration of the parent study – *INTERGROWTH-21st* Regular site visits by the study team to provide support, ensure ongoing functionality of ultrasound	No subsequent retesting described

			Competency defined as - The ability to perform three consecutive scans with measurements to within 1 standard deviation of the trainers - A score of 67% or more for each of their images		machines and to verify adherence to protocols 10% of all images recorded during the parent study were transferred for ongoing quality assessment and feedback against predefined criteria If >10% of a sonographers images were scored poorly they would be recalled for re-training. If scores remained low their certification was withdrawn	
Shah(51)	2009	15 trainees Physicians	No formal assessment described	No specific requirements to 'pass'	10 week post training follow up Unspecified proportion of images and a record of their interpretation transferred to the study team for review No indication of how these were assessed for quality or if feedback was provided	No subsequent retesting described
Shah(47)	2020	25 trainees All 25 underwent practical assessment	Practical assessment only (must have undertaken 25 supervised scans prior to sitting assessment) OSCE assessment Trainees were required to achieve a score of 80% or above to pass	96% trainees passed (24/25 trainees) 88% on their 1st attempt (22/25) 8% on their 2nd attempt (2/25)	3 month post training follow up For 8 weeks all images transferred to the study team for quality assessment undertaken by two trainers against predefined criteria During this period the local lead sonographer also visited each site weekly to check the machines	No subsequent retesting described

					and to provide 'hands on' supervision for those who had been identified as requiring assistance based on the remote quality assessment of images For 3 months after the training trainers communicated twice weekly with the trainees via WhatsApp to troubleshoot and offer advice on scans and to try to mitigate any issues	
Vinayak (48)	2017	3 trainees All 3 underwent both written and practical assessment	Written and practical assessment Pre course knowledge test Post course knowledge test OSCE assessment Trainees were required to achieve a score of 100% to commence training No definition of competency and otherwise no specific requirements in order to 'pass'	100% passed the pre course knowledge test (3/3) All 3 (100%) were reported to have passed the post course knowledge test and OSCE although no pass marks were specified.	Follow up throughout the duration of the study – Duration unspecified All images and their interpretations transferred to the study team immediately after completion of the ultrasound scan. These were assessed immediately by two reviewers against predefined criteria who provided feedback in real time	No subsequent retesting described
Wanjiku (49)	2018	33 trainees All 33 underwent written assessment 20 trainees underwent practical assessment	Written and practical assessment Matched pre/post knowledge test OSCE assessment	100% passed the pre course knowledge test (33/33) 27%% passed the post course knowledge test (9/33)	All assessments repeated 3-4 months later (Knowledge test and OSCE) If they fail trainees are offered refresher teaching before further assessment 3-4 months later.	Written and practical assessment repeated 3-4 months later If trainees failed this assessment they were

			Trainees were required to achieve a score of 90% or above No definition of competency and no specific requirements in order to pass OSCE		There does not appear to be a limit on the number of refresher courses trainees may attend	offered refresher teaching 9/33 passed the knowledge test
Wylie(50)	2013	4 trainees Clinicians and nurses	No formal assessment described	No specific requirements to 'pass'	4 month post training follow up All images recorded transferred to study supervisor for ongoing quality assessment and feedback. No indication as to how these were assessed for quality.	No subsequent retesting described

1.10.9 Barriers and Facilitators

Alongside the evaluation of the training itself, 4 studies (16%) also explored what factors influenced the delivery of the training, providing detailed descriptions of implementation and reporting outcomes in the context of recognised frameworks. (41,44,47,55)

Time for faculty to deliver and practitioners to attend training was cited as a significant barrier, with staff reporting concerns about competing priorities both in terms of attempting to incorporate ultrasound into routine services and in the provision of ongoing supervision and support. (41,44,47)

The attitude and perception of individuals undergoing training was identified as a key factor, with those who were enthusiastic and open-minded about the provision of ultrasound acting as strong facilitators of the programmes.(40,53) Conversely, staff who were resistant to change or resentful of being asked to undertake extra work led to barriers for implementation.(40,43,46) Empowering trainees to take ownership of the programmes, especially with regards to the organisation and scheduling of the service, was reported as an important approach in mitigating some of these issues,(43,46,53) as did the provision of regular feedback.(43,53) Ensuring training was delivered in partnership with, and supported by local teams was also cited as important in ensuring longevity of programmes,(43,53) helping to facilitate regular access to consumables and adequate referral systems for when concerns were raised.

Finally, the cost of training was reported as an important barrier to the sustainable delivery of training and wider implementation of ultrasound.(43)

1.11 Discussion

1.11.1 Key findings

Despite similarities in pedagogical approach, we identified substantial heterogeneity in the content and duration of the programmes and the way in which they assessed participants. Less than half of the initiatives adhered to the ISUOG recommendation that training incorporate both didactic and 'hands on' components, as well as practical assessment, and in only 1 programme (29) did trainees perform the number of supervised scans recommended by the WHO.(17) Within the programmes that referenced specific requirements to pass (n=5, 20%) (43–45,47,55), 96% did so, however the remaining 80% (n=20) of programmes did not report such outcomes, making it near impossible to evaluate 'success'. Similarly, little consideration was given to the scalability of training initiatives, with only 4 studies (16%) formally evaluating the implementation of their programme into routine services. With the upscale of training programmes considered a major challenge, future endeavours should seek to explore how training can be incorporated into pre-existing systems. Overall, this review highlights an inconsistent approach to the delivery and reporting of training in ultrasound to determine gestational age, at odds with international recommendations.

1.11.2 Ensuring quality

1.11.2.1 Training methodology – 'Hands on' teaching and assessment

Given that ultrasound examinations are an important component of obstetric decision making, it is of paramount importance that they are of sufficient quality. As the accuracy of ultrasound is primarily dependent on the skill of the operator,(59) adequate training is essential. While there is no universally agreed or standardised approach to training, nor a specific definition as to what constitutes competency to perform independent ultrasound examinations, there are some recommendations which seek to ensure that practitioners are appropriately trained and have demonstrated adequate proficiency prior to performing scans independently.(16,17,59)

While only 10 programmes (40%) incorporated all three of the components recommended by the ISUOG,(32,36,38,42,43,47–49,55,57) the combination of didactic and 'hands on' training was adopted by 22 (88%),(28,29,44–53,30,54,55,32,35,36,38,40,42,43) meaning it was predominantly the lack of trainee assessment that resulted in programmes to failing to meet the required standards. Indeed, even amongst those who did perform assessments, the absence of criteria to "pass" makes it impossible to know whether training had been successful and if trainees were truly competent to perform scans independently. As such, it appears that the majority of practitioners trained by these initiatives have not met either ISUOG or WHO standards, a finding in keeping with previous work undertaken in 2012 by LaGrone et al.(60) Although undertaking 200 supervised ultrasound scans may not necessarily be achievable in many LMIC healthcare systems, delivering training that involves didactic and 'hands on' components, as well as robust assessments should be. We believe this should be an important focus to improve the quality of future initiatives.

1.11.2.2 Ongoing mentorship and quality assurance

Another key factor in ensuring both the quality and longevity of programmes is the support provided to trainees at the end of the training period, helping to build confidence and ensure examinations continue to be of an appropriate standard.(44,47) Recent advances in tele-radiology have played a huge part in enabling this, presenting a meaningful solution to the ways in which programmes can overcome the challenge of providing ongoing supervision in remote geographical locations or when faculty are scarce. 13 of the programmes included in this review describe the transfer of ultrasound images(29,32,51,55,36,39,43–45,47,48,50) for remote review, with feedback provided via the same platform. This approach appears to help reinforce positive practice and address areas for improvement where necessary. Although dependent on adequate internet coverage, the majority of programmes employing these techniques reported successful implementation. Indeed, with access to smartphones ever expanding, this relatively simple approach may provide a cost effective solution to improving support and mentorship for all manner of training programmes.

1.11.3 Sustainability/Embedding in pre-existing services

1.11.3.1 Collaborative partnerships

The literature surrounding the delivery of successful and sustainable programmes, suggests that a thorough consideration of how training can be supported, delivered and integrated within the resource constraints of pre-existing healthcare systems is essential.(14,61) The involvement of local practitioners and key stakeholders from the outset is important in ensuring programmes are able to correctly prioritise context-specific training needs and focus only on what is necessary for the local population,(62,63) a concept supported by the qualitative findings of Shah et al.(47) Likewise by empowering and assisting local teams to develop training, programmes are also able to ensure the design and delivery of materials are socially and culturally relevant and communities are adequately engaged in the expansion of new services.(14,15,64) Although local teams were involved in the design of 10 (30–32,37,40,41,43,45,53,55) and the delivery of 14 of the studies,(30,31,47,48,53,55,32,37,40,41,43–46) the majority were partnered with overseas institutions,(31,32,40,43–48,55) highlighting the complexity of establishing truly native initiatives. Central to this is the ability of groups to access adequate financial support, often granted preferentially to teams partnered with institutions from high income settings(65) Access to sufficient and sustainable financing programmes is essential, not only to establish training at an individual level, but to upscale, embed and maintain the provision of ultrasound services thereafter.(66,67) Although there are numerous benefits to collaboration, these alliances are not without challenges and care must be taken to ensure they are balanced and that oversight and ownership remains with the LMIC partner.(63,68–70)

1.11.4 Strengths and limitations

The substantial discrepancy in the depth and quality of information provided by individual studies may have risked the misinterpretation of some findings, and the inability to contact authors for verification led to the exclusion of 9 programmes which may have been relevant. Furthermore, there were great disparities in the way studies reported findings, again limiting direct comparisons. In only representing programmes which have been reported, this review is subject to a degree of publication bias, exacerbated by the fact most papers were written in English by authors from British or American institutions. The fact that most studies describe collaborations with overseas institutions further alludes to the potential omission of indigenous programmes, which appear underrepresented in the literature. It is also likely that much training is delivered ad hoc in an apprenticeship-type model, which was not captured in this review. By predominantly summarising training delivered within the context of research projects, it is also possible that results have been confounded by the additional allocation of resources afforded by study activities and may not be truly representative of the ‘real world’ context.

That said, our review aimed to be as inclusive as possible and as such, incorporated descriptions of training from a wide variety of sources and settings. Whilst the heterogeneity of our results made direct comparisons challenging, this is the first systematic review to focus specifically on the provision of training in ultrasound to determine gestational age. Our findings therefore, have enabled us to provide valuable insight into what should constitute best practice in the development and reporting of training programmes and indeed what may be required to upscale them.

1.11.5 Recommendations

Having collated our results and found significant disparity in the quality of data, we have generated key recommendations for the reporting of training in basic obstetric ultrasound, presented in the context of the RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) framework, as presented in Table 1-6. Recommendations for the reporting of ultrasound training programmes presented within the RE-AIM framework. RE-AIM is an implementation tool which has been used extensively in both high- and low-income settings for the evaluation of skills training,(41,71–75) helping to facilitate the translation of research into practice.

Table 1-6. Recommendations for the reporting of ultrasound training programmes presented within the RE-AIM framework.

Recommendation	Description of Recommendation
Reach	*Providers* • Who developed the training? • What are the qualifications/experience of those providing the training? • Which local stakeholders were involved in its organisation and delivery? *Participants* • Who participated in the training (demographic characteristics)? • How were they recruited? • Which individuals were included or excluded in the training? Why? • What proportion of eligible participants received the training? • What prior experience did they have? • What are their qualifications? • Were they given any incentive to participate?
Effectiveness **or Efficacy**	• How were participants assessed and by whom? • What was the pass mark? How was this determined? • Describe what follow up was undertaken • Were trainees reassessed? • If reassessed what was the retention rate of skills/knowledge? • Were there any quality assurance processes? • Did the participants receive any formal certification or accreditation? If so, who bestowed this?
Adoption	*Setting level* • Where was the training delivered?

	- Which sites were included or excluded in the intervention? Why? - Describe the characteristics of the participating sites - What site preparation was undertaken prior to the training? *Individual level* - What proportion of those invited to participate completed the training? - Describe individuals' feedback on their experience of participating in the training
Implementation	*Content & Setting* - Provide a brief description of the purpose of the training - Describe the learning objectives and how the training priorities were established - Describe the specific training materials provided to both the faculty and the participants and how these were developed *Education Methodology* - How was the training delivered? (lectures, small group sessions, 'hands on' practice, level of direct supervision etc.) - What was the ratio of trainers to trainees? - Indicate how many ultrasound examinations were performed by each trainee and what proportion of these were directly supervised *Fidelity* - What percent of training delivery adhered to the original protocol? - Did the training require any adaptation or modification? If so, describe and explain the rationale for changes

	Costs • Who funded the training? • What was the final cost of the training?
Maintenance	• What consideration was given to factors affecting the delivery of the training? • What consideration was given to the ongoing provision of ultrasound and its integration into pre-existing services? • Were these studied formally? *Individual level* • What is the percentage of skills/knowledge retention amongst participants at or beyond 6months from original ultrasound training? • *Setting level* • Is the program ongoing 6 months post formal study funding? • Has ultrasound training/provision been adapted into the local setting over time?

1.12 Conclusion

There is substantial heterogeneity in the current approach to training practitioners to determine gestational age using ultrasound in LMICs, with many programmes failing to meet international recommendations for the delivery of safe and sustainable training programmes. Our review highlights the need for a more consistent approach and has identified key areas we believe should be the focus of future initiatives to deliver high quality training in basic obstetric ultrasound. With an increasing focus on the importance of improving estimates of gestational age in LMICs, we believe this review will be of interest to those seeking to develop and expand the provision of basic obstetric ultrasound in LMICs.

1.12.1 Funding

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1.12.2 Acknowledgements

We would like to thank Ruth Jenkins at the University of Edinburgh for her assistance in the development and piloting of our search strategy.

Part 3: Specific context

The final part of the introduction to this Thesis provides an overview of the wider context for this work.

1.13 The DIPLOMATIC Collaboration

The DIPLOMATIC collaboration (using eviDence, Implementation science and a clinical trial PLatform to Optimise MATernal and newborn health in low-Income Countries) is a National Institute for Health Research (NIHR) Global Health Research Group based in Malawi, Zambia and the UK. The multidisciplinary group, including obstetricians, paediatricians, midwives, social scientists and policy makers, was formed with a strategic vision aligned with SDG 3.2, 'to reduce under 5 mortality' (United Nations, 2015), aiming to do so by reducing preterm birth and stillbirth in LMICs and to optimise the outcomes for those babies born preterm.

1.13.1 Work packages

Following a systematic review to identify research gaps (Wastnedge et al., 2022), the group employed modified Delphi methodology to identify and agree the top evidence-based priorities for the project (de Meyrick, 2003). The process was led by key local stakeholders and policy makers and identified; the need for improved and more robust routine data collection, the need to implement practices already known to be of benefit in this setting and the need to optimise estimates of gestational age to facilitate the suitably robust evaluation of future endeavours. The overall project was subdivided into eight separate, but linked, work packages, as depicted in Figure 1-6. Overview of the DIPLOMATIC Work Packages. The work in this Thesis focuses primarily on *Work Package 5,* 'to build capacity in early pregnancy scanning', with **Chapters 3, 4** and **5** referencing work undertaken in Malawi.

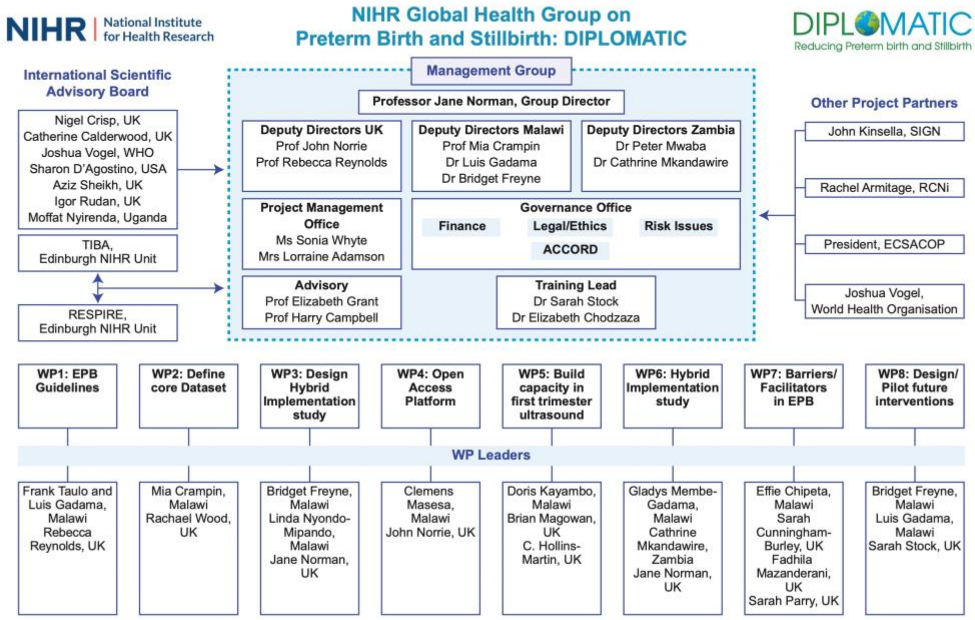

Figure 1-6. Overview of the DIPLOMATIC Work Packages.

1.13.2 Zambia

Although collaborators from the University of Lusaka, Zambia were involved in the identification and ranking of the evidence-based priorities which would shape the individual work packages, the majority of these were led by researchers from Malawi and the UK. As a result, the development and piloting of the education package, as described in **Chapter 3**, was undertaken solely in Malawi. Likewise, although the completed education package described in **Chapter 4** was implemented across 10 sites in Zambia, this was co-ordinated exclusively by the local team, with little feedback to the wider group. It is for this reason that the work in this Thesis focusses specifically on the work undertaken in Malawi. Further information pertaining to this is provided in **Chapter 6**.

1.14 Malawi

Malawi, 'the warm heart of Africa', is a landlocked country in South-East Africa, with an estimated population of over 19 million people (The World Bank, 2022). With an economy primarily based on agriculture, forestry and fishing, and a Gross Domestic Product (GDP) of $11.9 billion, Malawi is considered one of the world's poorest countries (The World Bank, 2022). Having gained independence from Britain in 1964, Malawi is a generally peaceful country with a democratic government (Kalinga., 1998).

1.14.1 Healthcare System in Malawi

Healthcare services in Malawi are provided by a combination of public, private for profit (PFP) and private not for profit (PNFP) sectors. Public services, provided free of charge, account for just over half (52%) of healthcare amenities (Mchenga et al., 2022), with PNFP the next largest provider of care (25%). The PNFP sector comprises of religious institutions, non-governmental organisations (NGOs) and company clinics, with the majority of care organised by the Christian Health Association of Malawi (CHAM). Although most of these facilities charge user fees, there is organisational overlap with the Ministry of Health (MOH) and this sector often provides essential services, such as maternal and child health care to harder to reach rural communities (Makwero, 2018, Mchenga et al. 2022). The PFP sector provides the remaining 23% of care, predominately via private hospitals and clinics run by small groups or individual practitioners, usually general practitioners or clinical officers. Traditional healers and birth attendants are another important component of health services in Malawi and would also be considered part of the PFP sector (Makwero, 2018).

Public healthcare services are organised into 4 levels; community, primary, secondary and tertiary, with all but the latter falling under the jurisdiction of the District Council and overseen by the Directors of Health and Social Services (DHSS), formally known as District Health Officers (DHOs) (Makwero, 2018).

Community services are delivered by Health Surveillance Assistants (HSA), Community Health Workers (CHW) and traditional healers, whose primary focus is that of health promotion and preventative medicine, usually delivered door to door or via mobile clinics. HSAs usually receive about 6 weeks of basic health training, whereas CHW are volunteers with no formal training but who work as a liaison between healthcare services and the communities they serve (Makwero, 2018).

Primary level care is delivered through health centres and community hospitals, which provide maternity care, together with outpatient and some inpatient services. These facilities are largely run largely by nursing and midwife assistants, along with some clinicians. District hospitals provide secondary level care, acting as referral centres for the primary level care facilities, while also providing outpatient and inpatient care. They are also equipped to provide surgical procedures, for example caesarean sections. There are 23 such hospitals, with care provided by nurses, midwives, medical assistants, clinical officers and a few general practitioners. Medical assistants and clinical officers receive 2 and 3 years clinical training respectively and provide the majority of care in these facilities, including performing the surgical procedures (Makwero, 2018).

Tertiary level care is provided by 4 central hospitals, which although designed to provide specialist care, also provide treatment that could be offered at primary and secondary level care. 50% of Malawi's doctors work in these 4 hospitals (Government of the Republic of Malawi, 2017), highlighting the maldistribution of the health workforce commonly encountered in LMICs (Chen et al., 2004).

Despite signing the Abuja Declaration to commit a minimum of 15% of the national budget to heath (Organisation of African Unity, 2001), the healthcare system in Malawi remains underfunded and is highly dependent on donor aid (Masefield et al., 2020). Having once contributed nearly 70% of the total health expenditure, donor financing fell significantly in 2013 following the exposure of a financial scandal dubbed 'Cashgate', which saw millions of pounds stolen from the government via fraudulent payments to businessmen (Adhikari et al., 2019).

1.14.2 Antenatal Care in Malawi

Antenatal care (ANC) is defined as 'the care provided by skilled health care professionals to pregnant women and adolescent girls, in order to ensure the best health conditions for both mother and baby during pregnancy' (WHO, 2016). It has been shown to reduce maternal and perinatal morbidity and provides an important opportunity to identify and manage concurrent illness. In order to try to address poor ANC coverage in LMICs (Moller et al., 2013), the WHO introduced the new Focused Antenatal Care (FANC) model in 2002, recommending women attend for at least 4 ANC visits during pregnancy (WHO, 2002). This was adopted by Malawi the following year (Mchenga et al., 2019). In 2016 the WHO updated their guidance, doubling the number of recommended visits, now termed ‘contacts’, to 8, advising that these should be provided at 12, 20, 26, 30, 34, 36, 38 and 40 weeks’ gestation. Although Malawi is currently preparing to move to the new 8-visit model, this is not yet national standard (Chirwa et al., 2020). Current standards dictate that during ANC visits pregnant women should be screened for complications such as anaemia, bacteriuria, pre-eclampsia and STIs, provided with malaria prophylaxis and tetanus vaccinations and given advice about birth preparedness (Ng’ambi et al., 2022). In line with WHO recommendations (WHO, 2016), pregnant women in Malawi carry their own handheld pregnancy record known as the ‘health passport’.

The majority of ANC in Malawi (80%) is provided by midwives or nurses in primary level facilities, with the remaining women receiving care from doctors, clinical officers or maternal-child aides (Mchenga et al., 2019). Traditional Birth Attendants (TBA) also played a prominent role, undertaking 14% of deliveries, until their practice was ‘banned’ in 2007, when the Safe Motherhood Initiative set targets for Skilled Birth Attendants (SBA) and TBA were not felt to fulfil the description of ‘skilled’ practitioners (Uny et al., 2019).

Despite progress in improving maternal and neonatal outcomes since 2000 (Colbourn et al., 2013), data from the Malawi Demographic and Health Surveys (MDHS) suggests that only 49% of women in Malawi achieved the 4 visits recommended by FANC between 2003 and 2010 (Kuuire et al., 2017). A variety of factors have been associated with this, including attitudes towards pregnancy, marital, education and socio-economic status, parity, hospital inefficiencies, lack of spousal support, conflicting ANC promotion messages and cultural factors all contributing to delays in seeking ANC (Pell et al., 2013, Roberts et al., 2016, Manda-Taylor et al., 2017, Mchenga et al., 2019). Indeed, in many cases women still seek care from TBAs, often as a result of previous poor experiences with healthcare workers, or a belief that they should only attend clinics if ill (Roberts et al., 2016).

1.14.3 Antenatal Ultrasound in Malawi

Guidelines from the Association of Obstetricians and Gynaecologists of Malawi (AOGM), developed in association with the University of Malawi College of Medicine, recommend ultrasound in a variety of different antenatal and intrapartum scenarios, including, amongst others; to confirm presentation, to assess fetal growth and wellbeing and to determine gestational age if dates are uncertain (AOGM, 2015). Despite purposing to ‘emphasize those practices that are evidence based and available in Malawi’, ultrasound is not available to a significant proportion of the pregnant population. Although there is no published data describing the coverage of antenatal ultrasound in Malawi, anecdotal evidence suggests this is only provided consistently at the central hospitals, reflecting a mis-match between the recommended standards of care and what can actually be provided. As with so many other aspects of healthcare provision, those living rurally are left at a significant disadvantage.

The barriers to ultrasound in LMICS have been described in detail in **Section 1.3.1** and are likely to be representative of those encountered by service providers in Malawi, including, broadly, a lack of investment, a lack of resources (ultrasound machines, electricity, consumables) and a lack of trained practitioners. Although a number of organisations including Imaging the World, RAD-AID, Worldwide Radiology are currently working to improve access to ultrasound technology in Malawi, the lack of trained practitioners remains a significant problem. Unfortunately, in contrast to many high-income settings, where a considerable amount of training in ultrasound is provided in-service (**Section 1.5**), this option is extremely limited in Malawi on account of the lack of skilled practitioners able to provide this training. With that in mind, efforts to train healthcare workers to perform ultrasound examinations may need to rely on a ‘training of the trainers’ model, with the initial training provided by international groups, or pre-service training, whereby staff are taught as part of their undergraduate programme. Indeed, should there be sufficient buy-in at an institutional and governmental level, the latter approach may be preferable, so as to avoid staff needing to take time away from their clinical duties to attend training. Either way, there would need to be substantial effort at an organisational and facility level in order to equip individual health centres to provide on ongoing ultrasound service, from the procurement of ultrasound machines and consumables, to the creation of protocols, referral pathways and quality assurance processes.

1.14.4 Health research in Malawi

Compared with many LMICs, Malawi has a fairly strong research sector, however it remains constrained by limited access to human resources, infrastructure and funding (Gooding et al., 2018). In 2008, the internationally funded Health Research Capacity Strengthening Initiative (HRCSI) was launched and has since helped to enhance both institutional and individual health research capacity through the provision of fellowships, grants and support (Cole et al., 2016). In 2011, the Malawi Ministry of Health released a 5-year strategic plan to improve the coordination and regulation of research activity in Malawi. Seeking to improve the development of local evidence-based practices and policy implementation, this plan outlined four key objectives; to build research capacity, to improve access to resources for health research, to strengthen research governance and to promote the implementation of research findings into policy and practice (Government of Malawi., 2011). Health research in Malawi is overseen by the National Commission on Science and Technology (NCST), with powers delegated to the National Health Sciences Research Committee (NHSRC) and the College of Medicine Research and Ethics Committee (COMREC). Owing to the frequency of international collaborations, it also has national guidelines for collaborative agreements involving external institutions.

1.14.5 Impact of COVID in Malawi

The WHO was first informed about the emergence of the novel SARS-CoV-2 virus on 31 December 2019, declaring a pandemic just 10 weeks later on 11 March 2020 (WHO. 2020). With an already vulnerable healthcare system, the COVID-19 pandemic exacerbated pre-existing problems in Malawi pertaining to insufficient human and material resources. A pandemic preparedness evaluation undertaken in February 2020, revealed substantial gaps in the resources needed to treat patients with COVID-19, in particular oxygen, and as such highlighted the crucial importance of early containment (Sonenthal et al., 2020).

Like many countries, Malawi enacted a series of policies to try to reduce the spread of COVID-19 and mitigate the resultant socio-economic impact, including the dissemination of public health information, the implementation of disease surveillance, the preparation of health facilities and the enacting of restrictions on public gatherings, all of which began before the first documented case of COVID-19 in Malawi on 2 April 2020. While some of these efforts proved successful, for example a significant increase in testing capacity, others were met with resistance, for example the Government's attempt to enforce a national lockdown, which was overturned in court (Mzumara et al., 2021).

In addition to the direct consequences of the pandemic, there have also been a variety of additional unintended consequences, predominantly affecting women. Increased rates of gender-based violence, child marriages and teenage pregnancies were all reported (Mzumara et al., 2021), and are likely to have long-lasting effects.

At the time of writing, the number confirmed cases of COVID-19 in Malawi was 85,929, with 2638 reported deaths (WHO. 2022). Although as with most countries, studies of seroprevalence have suggested that infection rates are likely to have been higher than those officially reported (Marah and Chibwana, 2020).

1.15 Implementation Science

Implementation science (IS) is ‘the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice in order to improve the quality and effectiveness of health services’ (Eccles and Mittman, 2013). With increasing recognition of the need for translatable and generalisable research, IS emerged as a response to concerns regarding the excessive time taken to translate evidence-based practices (EBPs) into routine care, which, according to some studies, was up to 17 years (Bauer et al., 2015).

A relatively new field, some elements of IS overlap with quality improvement (QI), although the former is more focused on the development of generalisable knowledge, suitable for application across a broader context than that specifically studied (Bauer et al., 2015). Typically involving rigorous methodology, a multidisciplinary approach and a variety of theories and frameworks, IS is especially useful for the evaluation of complex interventions, where change is facilitated by not one, but multiple variables (Churruca et al., 2018). As such, implementation research studies a broader range of factors including not only the patient, but the provider, organisation and underlying policy (Bauer et al., 2015).

Designing, delivering and sustaining any intervention is a complicated process, not only because this often relies on multifaceted behavioural and institutional factors, but also because of the need to be adopted within local contexts. Therefore, by enhancing our understanding of how and why interventions work in certain circumstances, the aim is to better apply them to generalisable ‘real world’ scenarios.

Most implementation research involves both quantitative and qualitative methodology. Quantitative measures may include surveys or tools to assess context, patient and provider perception or behaviour, utilisation of services and fidelity to protocols. Qualitative methods include focus groups, semi-structured interviews and observations of behaviour. Frameworks, illustrative or narrative tools which provide structure to the representation of variables, are other fundamental components of IS and are particularly helpful for describing, analysing and evaluating outcomes (Peters et al., 2013). The framework chosen to guide the design, delivery and interpretation of this work is further outlined below.

1.15.1 RE-AIM Framework

The RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) framework is an implementation tool, first described by Glasgow et al. in 1999 (Glasgow et al., 1999). Initially designed to enhance the generalisability of research findings and improve the translation of evidence into practice, the RE-AIM framework has adapted and evolved and is now used in both the planning and evaluation of complex interventions (Glasgow et al., 2019). The framework operates across both individual and organisational levels and consists of 5 dimensions; Reach, Effectiveness, Adoption, Implementation and Maintenance (Holtrop et al., 2021).

Reach refers to the target population of the intervention, presented as the number who were willing to participate and their demographic characteristics. Effectiveness assesses the overall impact of the intervention, both in terms of its efficacy and any concurrent positive or negative effects. Adoption considers the proportion of individuals or organisations willing to initiate or accept the intervention. Implementation considers how the intervention was delivered and includes fidelity to protocols and what, if any, adaptations are required, encouraging groups to explore factors which influenced outcomes. Maintenance evaluates the extent to which the intervention was embedded in current policies and sustained (Glasgow et al., 2019, Kwan et al., 2019.)

In encouraging researchers to consider these outcomes, the RE-AIM framework is well placed to help groups reflect on what interventions are effective, in what context and why, rendering it a vital tool for the sustainable implementation of pragmatic and contextually appropriate interventions (Sweet et al., 2014). As one of the most commonly used frameworks in implementation science, the RE-AIM framework has been used extensively, in both high- and low- income settings, to evaluate the provision of skills training (Holtrop et al., 2021).

1.16 Hypotheses, Aims and Outline of Thesis

Despite growing appreciation for the importance of accurate estimates of gestational age in LMICs and recommendation by the WHO that all women receive at least one ultrasound in pregnancy, this option remains unavailable to the majority of women living in LMICs, where previous attempts to upscale ultrasound programmes have been mixed. The current body of evidence, presented in **Part 1 of this Introduction,** suggests that a lack of trained healthcare workers is a significant barrier to the realisation of universal access to ultrasound, (Shah et al., 2015, Kim et al., 2018) therefore this work has focused on the development of a novel strategy to increase the number of trained practitioners in Malawi and Zambia and thereby optimise estimates of gestational age.

Findings of a systematic review, presented in **Part 2 of this Introduction,** suggested significant disparities among the previously documented programmes to teach healthcare workers in LMICs to date pregnancies using ultrasound, which were further compounded by inconsistent reporting. The majority of programmes failed to meet recognised international standards and only a fifth undertook assessments where trainees were required to meet a certain standard to pass. In addition, very few of the previous initiatives had considered the subsequent implementation of ultrasound into routine services, or, in the case of overseas partnerships, how these could be sustained at the end of funding.

The overarching aim of this Thesis therefore, was to explore a novel strategy for the optimisation of gestational age estimates in Malawi and Zambia and to evaluate its implementation into routine services.

I hypothesised that femur length could be used to determine gestational age in LMICs and that ultrasound-naive practitioners could be trained to competency in basic obstetric ultrasound in less than 2 weeks. This Thesis contains an overall methods chapter (**Chapter 2**) and 3 results chapters (**Chapters 3-5**).

The evidence synthesised in **Part 2 of this Introduction** informed the development of a novel approach (described in **Chapter 3**), providing guidance on pedagogic approach and methods of assessment, as well as ensuring comprehensive and relevant reporting of results. The exploration of the barriers and facilitators encountered by previous groups also provided useful insight into how to avoid common pitfalls and enhance known enablers, important information for maximising both the immediate chance of success and the subsequent widespread implementation of ultrasound.

Chapter 3 describes the design, development and initial piloting of a novel education package to teach ultrasound-naive practitioners to date pregnancies using femur length. This not only involved the development of a training programme, but also a context specific guideline to inform the integration of ultrasound services into routine antenatal care. It was hypothesized that femur length would be a suitable means by which to teach practitioners to determine gestational age. Findings helped to improve and refine the training programme, the next iteration of which is described in **Chapters 4 and 5.**

In **Chapter 4,** the efficacy of the refined training programme was tested following its delivery across 6 sites in Malawi. It was hypothesized that ultrasound-naive practitioners could be trained to competency in basic obstetric ultrasound in less than 2 weeks.

In **Chapter 5,** the factors influencing the both the implementation of the education package and ultrasound services into routine care were explored, with findings presented in the context of a recognised implementation framework. It was hypothesized that it would be feasible to deliver this programme across multiple sites in Malawi.

Chapter 6 provides an overview of my findings and how they contribute to the current body of evidence. By reflecting on both the successes and unique challenges encountered as part of this work, I discuss how it will inform future work, guiding ongoing efforts for the expansion and widespread provision of sustainable obstetric ultrasound in LMICs.

1.17 Appendices

1.17.1 References

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Health. 1999;89(9):1322–7.

1.17.2 Search Strategy

Database	Search terms used and limits applied	Date of last search	Number of records returned
EMBASE	low income country*.mp. OR income*.mp. or Income/ OR family income*.mp. OR household income*.mp. OR income group*.mp. OR middle income group*.mp. OR middle income country*.mp. OR developing country*.mp. or developing countries/ OR rural*.mp. OR rural area*.mp. OR rural health*.mp. or rural health/ OR rural health services*.mp. or rural health services/ OR rural population*.mp. or rural population/ OR refugee*.mp. or refugees/ OR migrant*.mp. or "transients and migrants"/ OR low resource*.mp. OR deprived*.mp. OR poverty*.mp. or poverty/ OR under resourced*.mp. OR Afghanistan*.mp. or afghanistan/ OR Albania*.mp. or albania/ OR Algeria*.mp. or algeria/ OR American samoa*.mp. or american samoa/ OR Angola*.mp. or angola/ OR Argentina*.mp. or argentina/ OR Armenia*.mp. or armenia/ OR Azerbaijan*.mp. or azerbaijan/ OR Bangladesh*.mp. or bangladesh OR Belarus*.mp. or belarus OR Belize*.mp. or belize/ OR Benin*.mp. or benin/ OR Bhutan*.mp. or bhutan/ OR Bolivia*.mp. or bolivia/ OR "Bosnia and Herzegovina"/ or bosnia*.mp. OR Botswana*.mp. or botswana/ OR Brazil*.mp. or brazil/ OR Bulgaria*.mp. or bulgaria/ OR Bukina Faso*.mp. OR Burundi*.mp. or burundi/ OR Cabo verde*.mp. OR Cambodia*.mp. or cambodia/ OR Cameroon*.mp. or cameroon/ OR Central african republic*.mp. or central african republic/ OR Chad*.mp. or chad/ OR China*.mp. or china/ OR Colombia*.mp. or colombia/ OR Comoros*.mp. or comoros/ OR Congo*.mp. or congo/ OR Democratic republic congo*.mp. or democratic republic congo/ OR costa rica*.mp. or costa rica/ OR cote d'ivoire*.mp. or cote d'ivoire/ OR cuba*.mp. or cuba/ OR africa*.mp. or africa/ OR (africa adj3 sahara).mp. OR north africa*.mp. or northern africa/ OR south africa*.mp. or south africa/ OR Central africa*.mp. OR Djibouti*.mp. or djibouti/ OR Dominica*.mp. or dominica/ OR Dominican republic*.mp. or dominican republic/ OR ecuador*.mp. or ecuador/ OR egypt*.mp. or egypt/ OR El salvador*.mp. or el salvador/ OR Equatorial Guinea*.mp. or equatorial guinea/ OREritrea*.mp. or eritrea/ OR Eswatini*.mp. OR Ethiopia*.mp. or ethiopia/ OR swaziland*.mp. or swaziland/ OR fiji*.mp or fiji/ OR gabon*.mp. or gabon/ OR gambia*.mp. or gambia/ OR georgia*.mp. or georgia/ OR ghana*.mp. or ghana/ OR grenada*.mp. or grenada/ OR guatemala*.mp. or guatemala/ OR new guinea*.mp. or new guinea/ OR Guinea-Bissau*.mp. or guinea-bissau/ OR guyana*.mp. or guyana/ OR Haiti*.mp. or haiti/ OR Honduras*.mp. or honduras/ OR India*.mp. or	12/7/21	562

	india/ OR Indonesia*.mp. or indonesia/ OR Iran*.mp. or iran/ OR Islamic Republic*.mp. OR iraq*.mp. or Iraq/ OR jamaica*.mp. or jamaica/ OR jordan*.mp. or jordan/ OR Kazakhstan*.mp. or kazakhstan/ OR kenya*.mp. or kenya/ OR kiribati*.mp. or kiribati/ OR korea*.mp. or korea/ OR Kosovo*.mp. or kosovo/ OR Kyrgyz republic*.mp. or kyrgyz republic/ OR (republic adj2 lao).mp. OR Lebanon*.mp. or lebanon/ OR libya*.mp. or libya/ OR Madagascar*.mp. or madagascar/ OR malawi*.mp. or malawi/ OR malaysia*.mp. or malaysia/ OR maldives*.mp. or maldives/ OR Mali/ OR marshall islands*.mp. or marshall islands/ OR mauritania*.mp or mauritania/ OR mauritius*.mp. or mauritius/ OR carribean islands*.mp. or carribean islands/ OR indian ocean*.mp. or indian ocean/ OR (federated adj3 micronesia).mp. OR Mexico*.mp. or mexico/ OR new mexico*.mp. or new mexico/ OR (state adj2 mexico).mp. OR (gulf adj2 mexico).mp. OR Mexico city*.mp. or mexico city/ OR Moldova*.mp. or moldova/ OR Mongolia*.mp. or mongolia/ OR inner mongolia*.mp. or inner mongolia/ OR Montenegro*.mp. or montenegro/ OR Morocco*.mp. or morocco/ OR Mozambique*.mp. or mozambique/ OR myanmar*.mp. or myanmar/ OR Namibia*.mp. or namibia/ OR Nauru*.mp. or nauru/ OR Nepal*.mp. or nepal/ OR Nicaragua*.mp. or nicaragua/ OR Niger*.mp. or niger/ OR Nigeria*.mp. or nigeria/ OR North Macedonia*.mp. or macedonia republic/ OR Pakistan*.mp. or pakistan/ OR Papua New Guinea*.mp. or papua new guinea/ OR Paraguay*.mp. or paraguay/ OR (Peru* or peru).mp. OR Philippines*.mp. or phillipines/ OR Romania*.mp. or romania/ OR Rwanda*.mp. or rwanda/ OR Russian Federation*.mp. or russian federation/ OR USSR*.mp. or USSR/ OR Samoa*.mp. or samoa/ OR São Tomé*.mp. OR Senegal*.mp. or senegal/ OR Serbia*.mp or serbia/ OR Sierra Leone*.mp. or sierra leona/ OR Solomon Islands*.mp. or solomon islands/ OR Somalia*.mp or somalia/ OR South Sudan*.mp. or south sudan OR Sri Lanka*.mp or sri lanka OR St. Lucia*.mp. OR (vincent adj2 grenadines).mp. OR sudan*.mp. or sudan/ OR Suriname*.mp. or suriname/ OR syrian Arab Republic*.mp. or syrian arab republic/ OR Tajikistan*.mp. or tajikistan/ OR Tanzania*.mp. or tanzania/ OR Thailand*.mp. or thailand/ OR Timor-Leste*.mp. or timor leste/ OR Togo*.mp. or togo/ OR Tonga*.mp. Or tonga/ OR Tunisia*.mp. or tunisia/ OR Turkey*.mp. or turkey/ OR Turkmenistan*.mp. or turkmenistan/ OR tuvalu*.mp. or tuvalu/ OR Uganda*.mp. or uganda/ OR Ukraine*.mp. or ukraine/ OR Uzbekistan*.mp. or uzbekistan/ OR Vanuatu*.mp. or vanuatu/ OR Venezuela*.mp. or venezuela/ OR Vietnam*.mp. or vietnam/ OR (west bank and gaza*).mp. OR yemen*.mp. or yemen/ OR Zambia*.mp. or zambia/ OR Zimbabwe*.mp. or zimbabwe/ OR lesotho*.mp. Or lesotho/ OR (Liberia* or Liberia).mp. AND gestation*.mp. OR gestation period*.mp. OR gestational age*.mp or gestational age/ OR pregnancy*.mp. OR pregnancy/ OR (estimated adj3 delivery).mp. OR estimated due date*.mp. OR due date* OR confinement*.mp. OR conceptional age*.mp. OR prenatal*.mp.		

	AND fetal*.mp. OR obstetric*.mp. AND ultrasound*.mp OR scan*.mp OR scanning*.mp. OR sonogram*.mp. OR ultrasonogrphy*.mp or ultrasonography/ or ultrasonography, prenatal.mp. OR sonography*.mp OR portable ultrasound scanner*.mp OR ultrasound scanner*.mp. OR ultrasonographic*.mp. AND training*.mp. OR curriculum*.mp. or curriculum/ OR education*.mp. or education/ OR teaching*.mp. or teaching/ OR (learning* or learning).mp. OR course*.mp. OR qualification*.mp. OR programme development*.mp. or program development/ OR supervision*.mp. OR mentoring*.mp. OR simulation*.mp. or simulation training/		
AMED	Search terms as per EMBASE	12/7/21	0
MEDLINE	Search terms as per EMBASE	12/7/21	288
CINAHL	low and middle income countries/ or low income country OR income/ or income OR rural health or rural health centers/ or rural areas/ or rural health services/ or hospitals, rural/ or rural health personnel/ or rural population/ OR low resource settings OR deprived OR under resourced OR developing countries/ or developing countries OR refugee or refugees/ OR poverty/ or poverty or poverty areas/ OR Afghanistan or afghanistan/ OR Albania or albania/ OR American samoa or american samoa/ OR Algeria or algeria/ OR Angola or angola/ OR Argentina or argentina/ OR Armenia or armenia/ OR Azerbaijan or azerbaijan/ OR Bangladesh or bangladesh/ OR Belarus or byelarus/ OR Belize OR Benin OR Bhutan or bhutan/ OR Bolivia OR Bosnia OR Botswana OR Brazil or brazil/ OR Bulgaria OR Bukina Faso/ or bukina faso OR Burundi/ or Burundi OR Cabo verde or cape verde/ OR Cambodia OR Cameroon or cameroon/ OR Central african republic or central african republic/ OR Chad OR China or china/ OR Colombia/ OR Comoros OR Congo or congo/ or demographic republic of congo/ OR costa rica or costa rica/ OR cote d'ivoire or cote d'ivoire/ OR cuba OR africa or africa/ or africa south of the sahara/ OR north Africa OR south africa or south africa/ or africa, southern OR africa, western/ OR Central africa or africa, central/ OR Djibouti or djibouti/ OR Dominica or dominica/ OR Dominican republic or dominican republic/ OR Ecuador/ OR Egypt/ or eygpt OR El Salvador OR	12/7/21	60

	Equatorial Guinea or equatorial guinea/ OR Eritrea or ertrea/ OR Eswatini OR Ethiopia OR swaziland OR menalasia/ OR gabon OR gambia/ or gambia OR georgia or georgia/ or georgia, republic/ OR ghana or ghana/ OR grenada OR Guatemala OR new guinea or new guinea/ OR Guinea-Bissau or guinea bissau/ OR Guyana OR Haiti OR Honduras OR India or india/ OR Indonesia or indonesia/ OR Iran OR Islamic Republic OR iraq OR Jamaica OR jordan or jordan/ OR Kazakhstan OR kenya/ OR Kiribati OR Korea OR Kosovo or yugoslavia/ OR Kyrgyz republic OR republic adj2 lao or laos/ OR Lebanon OR Libya OR Madagascar/ OR malawi/ OR malaysia or malaysia/ OR Maldives OR marshall islands OR Mauritania/ OR mauritius or indian ocean islands/ OR carribean islands OR federated adj3 micronesia or micronesia/ OR Mexico or mexico/ or new mexico/ OR Moldova OR Mongolia OR inner Mongolia OR Montenegro OR Morocco/ OR Mozambique/ OR myanmar/ OR Namibia/ OR Nauru OR Nepal/ OR Nicaragua/ OR Niger/ OR Nigeria/ OR North Macedonia OR Pakistan/ OR Papua New Guinea or papua new guinea/ OR Peru OR Philippines OR Romania OR Rwanda/ OR Russian Federation OR USSR/ or USSR OR Samoa OR Sao Tome OR Senegal OR Serbia OR Sierra Leone OR Solomon Islands OR Somalia/ OR South Sudan OR Sri Lanka/ OR St Lucia OR vincent adj2 grenadines OR Suriname/ OR syrian Arab Republic OR Tajikistan OR Tanzania/ OR Thailand/ OR Timor-Leste or east timor/ OR Togo/ OR polynesia/ OR Tunisia OR Turkey/ OR Turkmenistan/ OR Tuvalu OR Uganda/ OR Ukraine OR Uzbekistan/ OR Vanuatu OR Venezuela/ OR Vietnam OR west bank and gaza OR yemen OR Zambia/ OR Zimbabwe OR lesotho/ OR Liberia/ AND Gestation OR estimated adj3 delivery OR estimated due date OR due date OR confinement OR conceptional age OR prenatal OR pregnancy/ AND Fetal OR obstetric or obstetric care/ AND ultrasound OR scan OR scanning OR sonogram OR ultrasonography OR sonography OR portable ultrasound scanner OR ultrasound scanner OR ultrasonographic AND Training OR curriculum or curriculum/ or course content/ OR education OR teaching OR learning/ OR course OR qualification OR programme development OR supervision or supervisors and supervision/ OR mentoring or mentorship/ OR simulation		

AIM	gestation OR gestation period OR gestational age OR pregnancy OR estimated due date OR due date OR confinement OR conceptional age OR prenatal AND fetal or obstetric AND ultrasound OR scan OR scanning OR sonogram OR ultrasonography OR sonography OR portable ultrasound scanner OR ultrasound scanner OR ultrasonographic AND training OR curriculum OR education OR teaching OR learning OR course OR qualification OR programme development OR supervision OR mentoring OR simulation	12/7/21	0
Global Index Medicus	Search terms as per AIM	12/7/21	90
Cochrane	low income country OR lowest income group IR income OR family income OR gross national income OR household income OR income group OR middle income group OR middle income country OR developing country OR rural OR rural area OR rural health OR rural healthcare OR rural population OR refugee OR migrant OR low resource OR deprived OR poverty OR under resourced AND gestation OR gestation period OR gestational age OR pregnancy OR estimated due date OR due date OR confinement OR conceptional age OR prenatal AND fetal or obstetric AND ultrasound OR scan OR scanning OR sonogram OR ultrasonography OR sonography OR portable ultrasound scanner OR ultrasound scanner OR ultrasonographic AND training OR curriculum OR education OR teaching OR learning OR course OR qualification OR programme development OR supervision OR mentoring OR simulation	12/7/21	48

Web of Science	All=(low income country OR lowest income group OR income OR family income OR gross national income OR household income OR income group OR middle income group OR middle income country OR developing country OR rural OR rural area OR rural health OR rural healthcare OR rural population OR refugee OR migrant OR low resource OR deprived OR poverty OR under resourced) AND All=(gestation OR gestation period OR gestational age OR pregnancy OR estimated due date OR due date OR confinement OR conceptional age OR prenatal) AND All=(fetal or obstetric) AND All=(ultrasound OR scan OR scanning OR sonogram OR ultrasonography OR sonography OR portable ultrasound scanner OR ultrasound scanner OR ultrasonographic) AND All=(training OR curriculum OR education OR teaching OR learning OR course OR qualification OR programme development OR supervision OR mentoring OR simulation)	12/7/21	214

Chapter 2

Methods

Methods specific to each study are described in **Chapters 3 to 5**. This chapter provides supplementary information pertaining to recruitment, data collection and analysis, in addition to an overview of the context and setting.

2.1 Setting

2.1.1 Malawi-Liverpool-Wellcome Trust Clinical Research Programme

The Malawi-Liverpool-Wellcome Trust Clinical Research Programme (MLW), is a leading research institution based in Blantyre, Malawi, dedicated to improving population health in Sub-Saharan Africa. Led by International and Malawian Scientists, it is a partnership between the University of Malawi College of Medicine, The Liverpool School of Tropical Medicine, The University of Liverpool and the Wellcome Trust.

2.1.2 Malawi Epidemiology and Intervention Research Unit

The Malawi Epidemiology and Intervention Research Unit (MEIRU), is a prominent research organisation, split between sites in Karonga, Northern Malawi and Lilongwe, the country's capital. Led by International and Malawian Scientists, this institute is a partnership between the College of Medicine at the University of Malawi, The London School of Hygiene and Tropical Medicine, The University of Glasgow and the Wellcome Trust. The work in **Chapters 3**, **4** and **5** was based in, and supported by MLW and MEIRU.

2.1.3 Zambia

Although the completed education package, developed as a result of the work outlined in **Chapter 3**, was also implemented by collaborators from The University of Lusaka, Zambia, the analyses and results presented within this Thesis relate only to work undertaken in Malawi. A detailed explanation of the rationale behind that decision is provided in **Chapter 6**.

2.2 Individual Studies

The work presented in this Thesis relates to the following studies and approvals:

1. Training in Ultrasound to Determine Gestational Age (TUDA, ethical approval P06/19/2714). Chief Investigator Professor David Lissauer.
2. Evaluating the Implementation of Routine Antenatal Ultrasound for Estimating Date of Delivery in Malawi (ethical approval P08/19/2768). Chief Investigator Professor David Lissauer.

In both cases sponsorship was provided by the University of Edinburgh, on the proviso that local ethical approval was obtained. It was not deemed necessary to obtain additional UK ethical approval.

2.3 Training in Ultrasound to Determine Gestational Age (TUDA)

This study involved the development and piloting of an education package to teach midwives in Malawi to date pregnancies using ultrasound. The programme, described in detail in **Chapter 3**, was developed as a collaboration between Obstetricians in the UK and Malawi, all of whom were investigators in the DIPLOMATIC study. It was piloted twice, before being implemented across 6 sites as part of the DIPLOMATIC 'parent' study; 'Evaluating the Implementation of Routine Antenatal Ultrasound for Estimating Date of Delivery in Malawi'. Details of this are outlined in **Section 2.4**.

2.3.1 Development of Training Programme and Course Materials

The curriculum was developed by a team of Obstetricians from Malawi and the UK, with input from the wider DIPLOMATIC group. The core group met via Zoom (Zoom Video Communications, Inc. Version 5.6.1) to co-create a context specific and culturally appropriate programme and to generate supporting training materials and data collection tools. It was agreed that in line with ISUOG guidance, the programme would involve both didactic and 'hands on' training, as well as practical assessment. All resources were reviewed and agreed by the wider team prior to being finalised. We also developed novel low-cost phantoms for use as scan simulators. Further details of this are presented in **Chapter 3**.

2.3.2 Development of Context Specific Guideline

A detailed and context specific guideline on the use of ultrasound to determine gestational age, 'Establishing estimated due date (EDD) by ultrasound biometry and its use in antenatal care', was also developed to form part of the overall education package, as outlined in **Section 2.3.2**. This was generated to support the midwives to integrate ultrasound into their routine practice and was based on study specific best practice. It was developed by the Obstetricians and Midwives within the DIPLOMATIC group and was approved by all members of the collaboration prior to finalisation. Further details are outlined in **Chapter 3**.

2.3.3 Pilot of Training Programme

The training programme was piloted across 2 different sites in Malawi in January and February 2020. The first iteration was held in Blantyre, with the theoretical component delivered at MLW and the 'hands on' sessions run in the Queen Elizabeth Central Hospital and Ndirande Health Centre. The second pilot was delivered in Mzuzu, where the theoretical component was delivered in a conference room at Mzuzu Central Hospital and the 'hands on' component at the neighbouring 'Ebola Camp', a large building adjacent to the hospital, purpose built in 2019 to care for patients with Ebola. The geographical distribution of the pilot sites is shown in Figure 2-1. Locations of pilot sites for TUDA study, with the 'Ebola Camp' shown in Figure 2-2. External façade of the 'Ebola Camp' in Mzuzu and Figure 2-3. Inside the 'Ebola Camp' in Mzuzu.

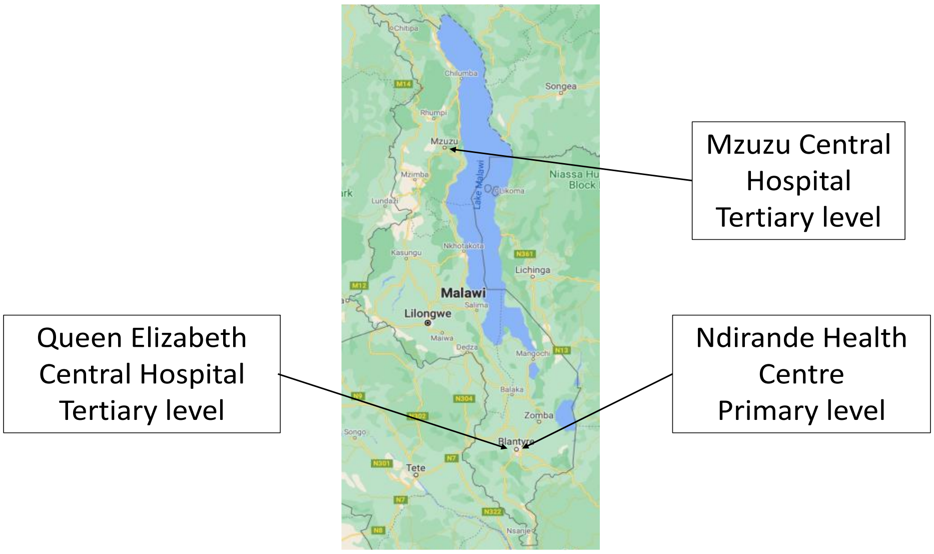

Figure 2-1. Locations of pilot sites for TUDA study

Figure 2-2. External façade of the ‘Ebola Camp’ in Mzuzu
Photo taken by Alexandra Viner.

Figure 2-3. Inside the ‘Ebola Camp’ in Mzuzu
Photo taken by Alexandra Viner.

2.3.4 Recruitment Methods

2.3.4.1 Midwives

Midwives were approached to participate having been identified by their local District Nursing Officer (DNO), based on their engagement in service improvement and their role as a key provider of antenatal care to women at the participating facilities. They gave informed written consent and were provided with daily reimbursement for their participation. Henceforth, these participants will either be referred to as ‘midwives’ or ‘trainees’.

2.3.4.2 Pregnant Women

Following discussion with and approval from community leaders and the local Directors of Health and Social Services (DHSS), pregnant women were recruited from the routine antenatal clinics of the participating sites and were eligible to participate if they were over 18 years old, thought to be less than 24+6 week’s gestation and able to provide informed written consent. Patient information leaflets and consent forms were provided in Chichewa and Tumbuka, as well as English and consent was only taken by Chichewa or Tumbuka speaking members of the team, thus ensuring that all questions could be appropriately answered and that consent was fully informed. All pregnant women received a drink and a snack, as well as financial reimbursement to cover their travel. As is custom in Malawi, these participants will henceforth be referred to as ‘pregnant women’ or ‘clients.’

For the first iteration of the programme, pregnant women were recruited to assist in the 'hands on' sessions from that morning's antenatal clinic. However, for the second iteration, they were recruited over the preceding 2 weeks and scheduled to attend on specific days.

2.3.5 Data Collection

Trainees completed a pre-course questionnaire collecting demographic information including qualifications, years of clinical experience, current role and if they had any prior training or experience in performing ultrasound examinations. They were also surveyed regarding their attitude towards and confidence using ultrasound, with their responses captured using a 5-point Likert scale (1=Strongly Disagree, 5=Strongly Agree). This questionnaire was repeated at the end of the 5-day pilot, with trainees also required to provide their feedback on the programme via an evaluation form.

During the 'hands on' sessions, each client volunteer underwent an ultrasound scan by a trainer and up to 3 trainees. For each scan performed, data was collected on the number of fetuses seen, fetal viability and the gestational age and EDD, determined by the machine from the average of 3 femur length measurements obtained from 3 different images. Until a report was generated at the end of the examination, both the trainers and trainees were blinded to the measurements of femur length and the corresponding gestational age. This was achieved by altering the display settings on the individual ultrasound machines. To ensure there were no obvious fetal anomalies or pregnancy complications, the trainers performed their examinations first. However, trainees were not made aware of the trainers' results until all examinations were complete.

Data was also collected pertaining to the client's LMP, specifically whether this was known exactly, to the nearest month or not at all. If the client had an unknown LMP, or it was deemed inaccurate following the trainer's ultrasound examination, the gestational age and EDD were updated in the health passport, the clients' personal hand-held health record.

All data collection forms were completed on Samsung Galaxy Tab A 10.1 tablets provided by MLW, with trainees and trainers each allocated a unique access code. Information was uploaded to the secure server at MLW at the end of each day and accessed via a secure website.

2.3.6 Completion of Education Package

As a result of the pilot work, the training programme was updated and improved, as described in **Chapter 3**. It was then incorporated into the completed education package which consisted of; facility preparation, the context specific guideline, the training programme and materials, remote image review and reassessment.

2.4 Evaluating the Implementation of Routine Antenatal Ultrasound for Estimating Date of Delivery in Malawi

This mixed methods study, run by the wider DIPLOMATIC group, was a quasi-experimental trial, seeking to explore what factors may influence the upscale of basic antenatal ultrasound in LMIC settings. It was undertaken across 6 sites in Malawi, from 7 October 2020 to 30 June 2021. All participating sites were primary level Health Centres; South Lunzo, Zingwangwa and Mpemba, all of which are in Blantyre, Southern Malawi. Area 25, in Lilongwe and Karonga and Chirumba, both of which are in Northern Malawi. The distribution of the participating sites is shown in Figure 2-4. Location of sites for study 'Evaluating the Implementation of Routine Antenatal Ultrasound for Estimating Date of Delivery in Malawi'.

The education package described in **Section 2.3.6** formed the intervention for this study, with the facility preparation, community sensitisation programme and baseline data collection started in October 2020. The training programme itself was delivered across these sites in January and February 2021, with post implementation data collection continued until 30 June 2021. Although a variety of different outcomes were explored as part of the overall study, the work contained within this Thesis is primarily focused on the efficacy (**Chapter 4**) and implementation (**Chapter 5**) of the education package itself.

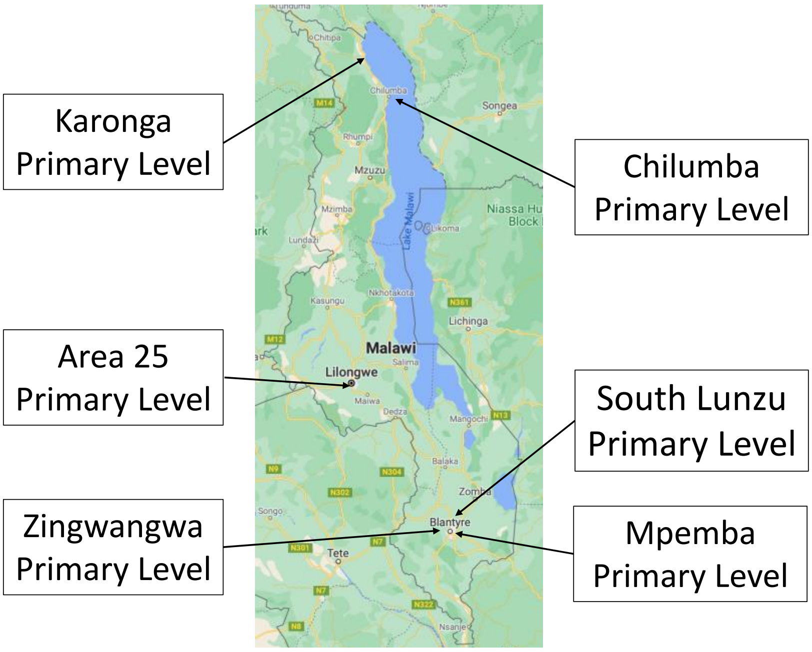

Figure 2-4. Location of sites for study 'Evaluating the Implementation of Routine Antenatal Ultrasound for Estimating Date of Delivery in Malawi'

2.4.1 Recruitment Methods

2.4.1.1 Midwives

Recruitment of the midwives (trainees) involved in this study was as previously described for the pilot work in **Section 2.3.4.1.**

2.4.1.2 Pregnant Women

Recruitment of the pregnant women involved in this study differed slightly from that described for the pilot work. Firstly, any pregnant woman over the age of 18 was eligible to participate, regardless of her presumed gestational age, although efforts were made to recruit clients at their first presentation to antenatal services, as early in pregnancy as possible. Secondly, as ultrasound is a WHO recommended component of routine antenatal care, and the study sought to explore the factors influencing its incorporation into routine practice, it was deemed appropriate by the local ethics committee to recruit participants via institutional consent.

During the pre-implementation phase, information regarding the study was provided via community sensitisation activities. Key stakeholders including health service providers, clients and community leaders were engaged to discuss the importance of the proposed intervention and early attendance at ANC, with posters and written information provided in Chichewa, Tumbuka and English at the participating facilities.

Once recruiting, information was also provided to all pregnant women attending the participating sites as part of the health talk. Delivered each day by the midwife in charge, health talks are the main way in which pregnant women are provided with key information about their antenatal care. Depending on which clinic they precede, the health talks may relate to important interventions in pregnancy, such as malaria prophylaxis, or may explain how to recognise signs of labour or provide advice about breastfeeding.

Having been provided with information about the study, informed verbal consent was sought for inclusion. Any woman who did not wish to take part was excluded, with their ongoing antenatal care provided as per standard care.

2.4.1.3 Trainers

Unlike the TUDA pilot study, where the training programme was delivered by the team of DIPLOMATIC obstetricians who had developed it, this education package was delivered exclusively by local faculty, who were recruited based on the criteria below.

- They must be an obstetrician (trainee or consultant), radiologist, sonographer, midwife or clinical officer, who had received training in basic obstetric ultrasound (via a formal or apprenticeship model) and who had performed independent obstetric ultrasound for a minimum of 1 year.
- They must be capable and confident to troubleshoot any problems the trainees may encounter when performing scans.

All trainers attended a virtual ‘training of the trainers’ session in January 2021 and were provided with a detailed training manual and course materials. All complied with the same standard operating procedures. Henceforth, these participants will either be referred to as ‘trainers’ or ‘faculty’.

2.4.2 Data collection

Prior to the training, each midwife undertook a 24-question multiple choice knowledge test to assess their theoretical understanding of ultrasound, scanning technique and basic fetal anatomy. They also completed a questionnaire using a 5-point Likert scale (1=Strongly Disagree, 5=Strongly Agree) to assess their attitude towards and confidence using ultrasound. Both assessments were repeated immediately after completion of the training and again 3 months later.

'Hands on' sessions were largely conducted as for the pilot, described in **Section 2.3.5**, with the exception that they now also involved a formal Observed Structure Clinical Examination (OSCE). As well as collecting data on the number of fetuses seen, fetal viability and the gestational age and EDD, determined by the machine from the average of 3 femur length measurements, this examination also assessed 17 additional components mapped to the TUDA curricula. Further details of this are provided in **Chapter 4**. As before, all information was collected on study tablets prior to being uploaded onto the secure server at MLW.

2.4.3 Qualitative Data

Qualitative data assessing the acceptability, feasibility and adoption of ultrasound was collected in the form of stakeholder meetings, semi-structured and in-depth interviews, focus group discussions and structured observations. Although undertaken by other members of the DIPLOMATIC group, some results are presented within the manuscript in **Chapter 5**. Participants included Health Officials, Community Leaders, Midwives, Obstetricians, TBAs and Clients. Interviews and discussions were conducted in either Chichewa or English, according to the interviewee's preference and were recorded and transcribed verbatim. Where included, this data has been appropriately acknowledged.

2.5 Disruptions

The planning and delivery of the work contained within this Thesis was affected by 2 major external factors. The first was a short period of political unrest in late 2019, following the Presidential Election in Malawi in May 2019, and the second was the COVID-19 pandemic from March 2020 onwards.

2.5.1 Demonstrations in Malawi

On 21 May 2019, Peter Mutharika of the Democratic Progressive Party was elected President for a second term. However, this was challenged shortly after, with two of his opponents claiming ballot papers had been doctored with Tipp-Ex and totals deliberately miscalculated. They claimed that the Electoral Commission had been involved and went to court to seek to nullify the results and demand a re-run of the election (Rakner, 2021). These allegations prompted widespread demonstrations throughout the three biggest cities in Malawi; Lilongwe, Blantyre and Mzuzu, which involved thousands of people and became increasingly violent. Roads were blocked, shops ransacked and police officers attacked. Protesters also gathered on the runways of Blantyre and Lilongwe airports, causing significant disruption to travel. These demonstrations cumulated in July and August of 2019, at the same time the initial pilot of the TUDA study was planned. The UK foreign office advised against travel to Malawi (Foreign Office, 2019) and MLW and MEIRU advised their staff to stay at home from the 21 August to the 2 September 2019, forcing the pilot to be postponed until January 2020 due to the challenges of rescheduling.

2.5.2 COVID-19

The WHO was first informed about the emergence of the novel SARS-CoV-2 virus on 31 December 2019, declaring a pandemic just 10 weeks later on 11 March 2020 (WHO. 2020). In the UK on 16 March 2020, all who could were advised to work from home, with a national lockdown imposed on 23 March 2020 (UK Government. 2020). To permit the prioritisation of clinical care, research activity relating to this project was halted by the sponsor, the University of Edinburgh on 17 March 2020 and by the College of Medicine Research Ethics Committee (COMREC) in Malawi on 30 March 2020. I was redeployed back to clinical work, with an interruption to my research studies from 1 April to 1 August 2020.

Although research activities in Malawi were recommenced on 7 October 2020, following approval from both COMREC and the University of Edinburgh, the COVID-19 pandemic continued to have ongoing implications throughout the duration of these projects. Firstly, although considered reasonable to restart research activities, there were still additional demands on the healthcare system in Malawi, which affected both the availability of healthcare professionals and the way in which routine care was being delivered. Secondly, due to the time lost while projects were suspended, it was not possible to adequately pilot a bespoke app developed by the data managers at MLW to facilitate remote image review. Thirdly, again as a result of time delays, it was necessary to alter the study design for ‘Evaluating the Implementation of Routine Antenatal Ultrasound for Estimating Date of Delivery in Malawi’ and truncate the period of post-implementation data collection. The specific impact of these factors on the work within this Thesis is discussed in more detail in **Chapters 4, 5** and **6**.

2.6 Materials

2.6.1 Equipment

Equipment	Manufacturer
DP-10 Ultrasound Machines	Mindray
35C50EB Convex Ultrasound Probe	Mindray
Samsung Galaxy Tab A 10.1	Samsung
Voluson P8 Ultrasound Machine	GE Healthcare
4C-RS Convex Ultrasound Probe	GE Healthcare

2.6.2 Software

Item	Supplier
Covidence Systematic Review Software	Veritas Health Innovation
NVivo	QSR International Pty Ltd
Prism Version 9	GraphPad
SPSS Version 24.0	IBM
WhatsApp	Facebook
Zoom Video Communications Version 5.6.1	Open Source

2.7 Statistical Analysis

Quantitative analyses were performed using SPSS Version 24.0 (IBM, Armonk, NY: IBM Corp), with figures produced using GraphPad Prism Version 9 (GraphPad Software Inc, California, USA). Normality of data was assessed visually using histograms, with no requirement for transformation.

In **Chapter 4**, matched pre and post course knowledge tests were analysed using paired t tests, with results presented as mean +/- SD. Within the pre and post course questionnaires, questions evaluating similar concepts, for example confidence, were allocated into 4 groups for analysis, with the reliability of these groupings tested using Cronbach's alpha. >0.9 was considered excellent reliability, >0.8 good, >0.7 acceptable, >0.6 questionable, >0.5 poor and <0.5 unacceptable. If a group did not demonstrate sufficient reliability (>0.8), the statements within the group were broken down and analysed as single items. Although the optimum approach for the analysis of Likert scale data remains under debate (Norman, 2010, Sullivan et al., 2013), this data was considered ordinal and therefore analysed non-parametrically using the Wilcoxon Signed Rank Test.

Bland Altman plots were used to assess the 95% level of agreement (LOA) between the gestational ages assigned by the trainees versus those obtained by the trainers and Intraclass Correlation Coefficients (ICC) were used to assess the inter-rater reliability of the reviewers assessing the follow up scans. P-values < 0.05 were considered statistically significant.

The qualitative data presented in **Chapter 5** was analysed by other members of the DIPLOMATIC group using Nvivo Version 12 (Nvivo QSR International Pty Ltd. 2018). Transcripts were coded iteratively, with codes grouped into categories and then themes. These were then reviewed to identify patterns and make comparisons across the groups.

Chapter 3

Development of a novel education package to teach midwives in Malawi to date pregnancies using ultrasound.

This chapter describes the design, development and piloting of a novel education package to teach midwives in Malawi to date pregnancies using fetal femur length. The first half details the process of establishing a curriculum and producing and piloting training materials, with the second half describing the generation of a study specific guideline, 'Evaluating the Implementation of Routine Antenatal Ultrasound for Estimating Date of Delivery in Malawi', to support the midwives to integrate ultrasound into their routine practice.

The work in this Chapter provides a detailed overview of the evolution of this education package, which, although developed to be contextually appropriate for implementation in Malawi, also conforms to ISUOG recommendations (ISUOG Education Committee. 2013). By describing the challenges encountered and how these were overcome, it demonstrates the importance of a flexible and pragmatic approach, alongside rigorous evaluation prior to implementation and upscale. By incorporating small group sessions to encourage the midwives to envisage how they would run an ultrasound service, the programme also encouraged the midwives to take ownership of the project, with the context specific guideline supporting and empowering them to implement ultrasound into their routine practice.

3.1 Development of a novel training programme - Using midwife led ultrasound scanning to date pregnancy in Malawi.

The following materials have been submitted for publication in the Journal of Midwifery and Women's Health under a similar title by Alexandra C Viner (AV), Dr Gladys Membe-Gadama (GMG), Sonia Whyte (SW), Dr Doris Kayambo (DK), Dr Martha Masamba (MM), Professor Caroline Hollins-Martin (CHM), Dr Brian Magowan (BM), Professor Rebecca M Reynolds (RR), Dr Sarah J Stock (SS), Dr Bridget Freyne (BF) and Dr Luis Gadama (LG).

AV prepared the protocol for this study, with input and guidance from all authors. The education package was developed by AV, GMG, DK, MM, BM, CHM and LG, with AV, GMG, DK, BM and LG co-ordinating the pilot training in Malawi. Data was analysed by AV, who also prepared the first draft of the manuscript, under the guidance of SW, SS, BM, BF and LG. All authors provided critical insight for the manuscript.

3.2 Abstract

The use of ultrasound to determine gestational age is fundamental to the optimum management of pregnancy and is recommended for all women by the WHO, yet remains unavailable to many women in low-income countries where trained practitioners are scarce. Although previous initiatives have demonstrated efficacy in training midwives and technicians to perform antenatal ultrasound, these programs have often been too long and too complex to be realistic within the specific constraints of this context, highlighting the need for a novel and pragmatic approach. We describe the development and piloting of a bespoke course to teach midwives three fundamental components of early antenatal ultrasound scanning; to identify the number of fetuses, confirm fetal viability and to determine gestational age. Having established that five days is insufficient, we propose that the minimum duration required to train ultrasound-naive midwives to competency is ten days. Our completed program therefore consists of one and a half days of didactic teaching, followed by eight and a half days of supervised 'hands on' practical training, where trainees are assessed on their skills. This package has been subsequently been successfully implemented across six sites in Malawi, where 28 midwives have achieved competency. By describing the processes involved in our cross-continental collaboration, we explain how unexpected challenges helped shape and improve our program,

demonstrating the value of pre-implementation piloting and a pragmatic and adaptive approach.

3.3 Introduction

DIPLOMATIC (using eviDence, Implementation science and a clinical trial PLatform to Optimize MATernal and newborn health in low Income Countries) is a multidisciplinary collaboration between researchers in Malawi, Zambia and the UK, whose aim is to reduce under five mortality through the reduction of preterm birth and stillbirth. As a fundamental component of obstetric and neonatal care, the WHO has regularly cited the need for improved estimates of gestational age as a public health priority (UNICEF, 2015, Vogel et al., 2015, Lee et al., 2019) not only to enhance clinical care but also to strengthen the evaluation of interventions in pregnancy and the recognition and reporting of perinatal complications.

There are a number of different ways to determine gestational age which vary in their accuracy. Early estimation using ultrasound is considered the most accurate (Loughna et al., 2009, Butt et al., 2014, Pettker et al., 2017, NICE. 2021). Despite WHO recommendation that all women receive an ultrasound scan prior to 24 weeks to ‘estimate gestational age, improve detection of fetal anomalies and multiple pregnancies and reduce induction of labour for post term pregnancy’ (WHO. 2016) this remains unavailable to many women living in LMICs. Here, gestational age is derived from the LMP or by abdominal palpation, both of which are less accurate than ultrasound. Scaled provision of ultrasound is challenging for multiple reasons (Seffah et al., 2009, Shah et al., 2015, Puchalski et al., 2016, Wanyonyi et al., 2017, Kim et al., 2018), with the lack of trained practitioners a recurrent barrier (Shah et al., 2015, Kim et al., 2018).

Here we report the development of a training package which aimed to 'build capacity' in early pregnancy ultrasound. Several programs have demonstrated efficacy in training midwives and technicians in LMIC settings to perform obstetric ultrasound (Rijken et al., 2009, Kimberly et al., 2010, LaGrone et al., 2012, Wylie et al., 2013, Bentley et al., 2015, Wanyonyi et al., 2017), however they have often been difficult to sustain within existing health systems. To overcome these issues, we aimed to develop a bespoke training package which taught the fundamentals of obstetric ultrasound in the minimum time possible.

3.4 Programme Development

3.4.1 General content of curriculum

The curriculum was developed by a team of Obstetricians from Malawi and the UK, with input from the wider DIPLOMATIC group, including Midwives, Paediatricians and Social Scientists. In contrast to prior initiatives (Rijken et al., 2009, Kimberly et al., 2010, Boamah et al., 2014, Greenwold et al., 2014, Bentley et al., 2015, Nathan et al., 2017, Vinayak et al., 2017, Shah et al., 2020) focused on delivering comprehensive training, we aimed to train ultrasound-naive midwives to perform simple examinations, competently and independently, within the proposed training timeframe of one to two weeks.

As such, we required a basic curriculum containing the fundamental components of ultrasound prior to 24 weeks' gestation: (i) number of fetuses, (ii) confirmation of fetal viability and (iii) determination of gestational age by measurement of crown rump length (CRL) prior to 14 weeks' gestation or fetal femur length (FL) thereafter.

Determination of gestational age after 14 weeks' gestation may involve a combination of measurements of abdominal circumference (AC), biparietal diameter (BPD), head circumference (HC) and femur length (Loughna et al., 2009, Butt et al., 2014, Pettker et al., 2017), although there is no universal agreement as to which combination of these performs best (Butt et al., 2014, Papageorghiou et al., 2017, Pettker et al., 2017, Salomon et al., 2019) as the variation in the gestational ages assigned by these different approaches is minimal. This is shown in Table 1-1. Summary of the accuracy of ultrasound derived estimates of gestational age.

The accuracy of any ultrasound based parameter is dependent on the practitioner being able to obtain the measurement from a suitable ultrasound image. Unlike AC, BPD and HC which require the operator to obtain a circumferential measurement from a cross sectional image encompassing several specific anatomical landmarks, the FL requires only a horizontal image of the bone with both ends clearly visible, making this the easiest measurement for beginners (Loughna et al., 2009 Salomon et al., 2019). In previous programs where healthcare workers in LMICs have been taught fetal biometry, FL has been the parameter performed most accurately and consistently (Neufeld et al., 2009, Ohaqwu et al., 2015, Nathan et al., 2017, Shah et al., 2020). Having considered these factors, the group agreed it was both pragmatic and clinically viable to teach trainees to determine gestational age using FL from 14 weeks gestation.

3.4.2 Specific content of curriculum

Topics included an introduction to the DIPLOMATIC project, patient safety, communication and security/maintenance of the machines. Ultrasound specific themes included basic ultrasound physics and how to operate the machines, along with scanning to establish the number of fetuses, confirmation of fetal viability and determination of gestational age using either CRL or FL. It was also deemed important to encourage the midwives to envisage the ongoing implementation of ultrasound, therefore themes surrounding the role of the midwife in performing obstetric ultrasound and the incorporation of scanning into routine antenatal clinics were also included.

3.4.3 Development of program and training materials

Having established the 'core concepts', the multinational team met 8 times via online video conferencing to co-create a culturally appropriate and context specific program with supporting training materials. To maximize trainees' practical experience, we agreed didactic teaching would form the basis of the morning sessions, with practical 'hands-on' scanning in the afternoons. Although classroom based, we sought to deliver the theoretical components interactively via a combination of presentations, small group sessions and simulation tasks.

Every session was framed with specific learning objectives, with speaker notes and prompts provided to encourage interaction with and amongst the trainees. One member of the team drafted the presentation slides, before the group met online to edit and annotate them together. A comprehensive training manual, a detailed handbook for trainees and laminated 'cheat sheets' were also generated using the same approach. A detailed contextualized guideline on the use of ultrasound to determine gestational age was also included.

Small group sessions focused on the role of the midwife in obstetric scanning, the incorporation of ultrasound into routine practice and how to care for the machines. These activities were intended to encourage discussion and team problem solving, as well as to encourage trainees to take ownership of the service and to anticipate and troubleshoot what they envisaged may be barriers to its implementation in their facilities.

To help the trainees acclimatize to the machines and build confidence prior to scanning clients, we developed novel low-cost phantoms as simulators. These were made from cheap, readily available materials that had proved robust and able to withstand the warm climate. Having trialled a variety of materials, we found that rubber erasers and chicken bones had the best echogenicity, with water the best medium. Our phantoms therefore consisted of water filled latex gloves containing different shaped rubber erasers, as shown in Figure 3-1 and chicken bones in hot water bottles as femur length simulators, as shown in Figure 3-2.

Figure 3-1. Ultrasound appearance of rabbit shaped rubber eraser contained within a water filled rubber glove.
Ultrasound image captured by Alexandra Viner using Fujifilm SonoSite M-Turbo ultrasound machine. Photo by Alexandra Viner.

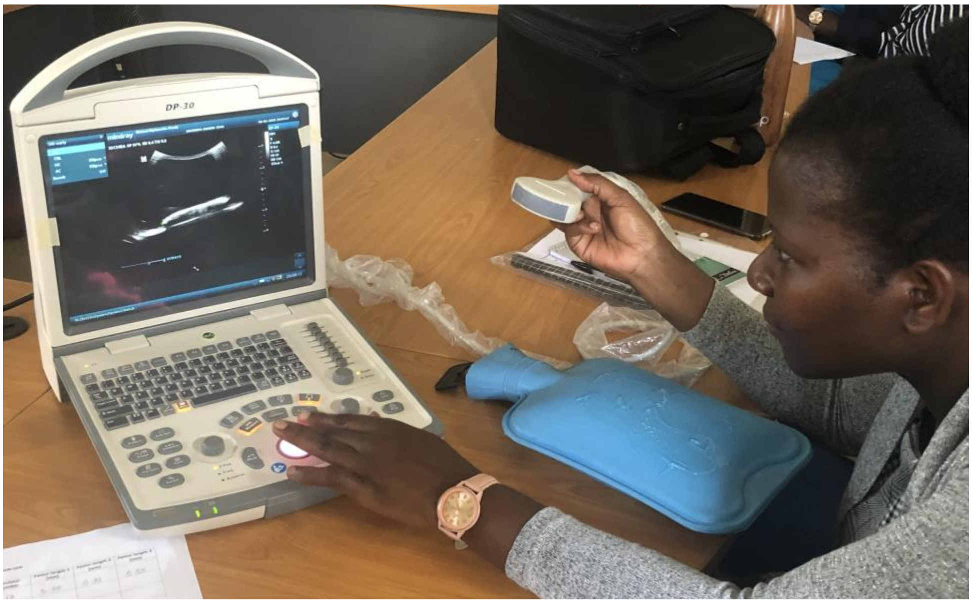

Figure 3-2. Simulation practice using home-made ultrasound phantom – Water filled hot water bottle containing a chicken thigh bone.
Photo taken by Alexandra Viner and used with permission of those pictured.

3.4.4 'Hands on' practical sessions

In the afternoons, trainees were scheduled to undertake supervised ultrasound examinations on pregnant volunteers, recruited during the morning from the antenatal clinics. Women provided informed written consent and to ensure safeguarding, were scanned by a trainer first to confirm fetal viability and the absence of any anomalies. Trainees then undertook structured ultrasound examinations supported by the trainers. As well as performing the scan itself, trainees were expected to set up the machines, provide an explanation of the objectives and limitations of ultrasound and to communicate and document the results.

3.4.5 Assessment

To assess trainees' progress, their measurements of client's fetal femur length were compared with those obtained by the trainer. Using the average of three measurements from three separate images, trainees were considered competent if they demonstrated adequate global skill and their measurements fell within +/- 10% of that of the trainer on five consecutive occasions. Once achieved, remote supervision would be provided via review of their images.

3.5 Ethical Approval

Ethical approval was obtained from the University of Malawi – College of Medicine Research and Ethics Committee (COMREC) P06/19/2714. Written informed consent was acquired from both the midwives and the pregnant women, and it was made clear that it was the training program that was under evaluation, not the individual midwives.

3.6 Piloting

The materials were piloted during two rounds of training in Malawi in early 2020, where a total of 24 ultrasound-naive midwives participated in two five-day training courses. The first was held in Blantyre at the Queen Elizabeth Central Hospital and Ndirande Health Centre, with the second in Mzuzu at Mzuzu Central Hospital. Midwives were invited to participate by the Malawian Obstetricians, based on their role as a key provider of antenatal care at the participating sites and in order to represent a broad range of ages and experience. The courses were conducted by the curriculum's authors in conjunction with local practitioners, with the training team meeting at the end of each day to review which aspects of the day had been successful and what could be improved. In addition to this, a post-course evaluation form surveyed the midwives' satisfaction with the program and sought their opinion as to how the training could be enhanced, with this information helping to refine and improve the program. Figure 3-3 shows a trainer supervising an ultrasound examination during one of the 'hands on' sessions.

Figure 3-3. Supervised 'hands on' practice during the Mzuzu pilot.
Photo taken by Alexandra Viner and used with permission of those pictured.

3.7 Lessons learned from pilot

3.7.1 Content of the program

Despite actively seeking clients in the first trimester, we were only able to identify two women who were of an appropriate gestational age to facilitate a measurement of CRL. With the majority of women in LMIC settings not attending their first antenatal visit until later in the second trimester (Finlayson et al., 2013, Benova et al., 2018) and concerns regarding inadequate exposure to scanning clients at this gestation, we made the pragmatic decision to remove measurement of CRL from the curriculum. While this approach was necessary to facilitate this training programme, the group appreciates that it is at odds with the principles of trying to encourage women to attend for ANC in the first trimester.

Despite the simulation tasks, trainees found some aspects of the practical sessions particularly challenging, highlighting the need for some concepts to be covered in more detail prior to scanning clients. This was especially relevant to the identification of fetal parts and the manipulation of the probe to achieve the desired planes. Prior to the second iteration, we developed additional interactive sessions using plastic dolls to help trainees visualize fetal orientation and to further illustrate how manipulation of the probe would yield certain images, as shown in Figure 3-4, supplementing our pre-existing materials with more examples of how fetal parts appear on ultrasound.

Figure 3-4. Interactive session with trainer demonstrating how to orientate the probe over the fetus to obtain specific images.
Photo taken by Doris Kayambo and used with permission of those pictured.

3.7.2 Organization of the programme

Having adapted the content of the programme we also amended the schedule, moving all didactic sessions to the first two days, enabling the rest of the time to be spent on intensive ‘hands on’ training. These changes proved more effective, helping trainees be better prepared for scanning clients and able to achieve far more with each interaction than previously.

3.7.3 Client recruitment

Having anticipated that it would be easy to recruit client volunteers from antenatal clinics, we were surprised to find this challenging. By lunchtime most women had left and of those who remained, many were unable to wait for a scan. As a result, another member of the faculty was required to recruit volunteers from different clinical areas, reducing the ratio of trainers to trainees. These issues resulted in insufficient numbers of client volunteers, detracting from the trainees’ ‘hands on’ experience and ultimately diminishing the success of the training. Prior to the second iteration, efforts were made to approach and recruit clients in advance, requesting they attend on designated days. Although not everyone attended, this did improve consistency in the availability of clients.

3.7.4 Availability of trainers

Apart from two UK volunteers, all trainers participated alongside their clinical commitments, resulting in fluctuating availability depending on emergency activity. Although this had little effect on the didactic sessions, it did impact on the practical ones where trainees derive maximal benefit from close supervision and support.

3.7.5 Inequality of scanning opportunities

Throughout both iterations of the course, we noted inconsistencies in the overall number of scans performed by individual trainees. While problems with client recruitment certainly contributed, this also highlighted the varying degrees of confidence, engagement and skill amongst the cohort. The trainees who displayed greater natural aptitude and confidence towards scanning were able to perform their examinations more quickly, with those who found it more challenging taking longer. Unfortunately, this meant that trainees progressing well had more opportunity to scan clients, often to the detriment of those who needed the additional exposure. To address these inequalities, we made daily recommendations as to the number of scans expected of individual trainees, with volunteers allocated to specific groups to balance opportunity.

3.7.6 Site used for training

An unexpected influence on the efficacy of the training was the environment in which the 'hands on' sessions were conducted. During the first iteration these were conducted in the local health facility where the midwives were based. In contrast, for the second iteration the practical sessions took place in a building adjacent to the hospital which had been purpose built for the Ebola outbreak.

Although the latter seemed superior, boasting a large communal area and multiple adjoining consultation rooms and now primarily used for training, it quickly became apparent that the midwives who underwent their training here were less engaged and less proactive than those training in their own facility, perhaps due to a relative detachment to the setting. Not only were the midwives more relaxed in their own facility, but they took greater ownership of the sessions, requiring no prompting to set up or tidy away. When complimented on their enthusiasm and commitment, they described pride in their workplace having been chosen to host the training and desire to ensure that it was efficient and successful.

3.7.7 Methods of assessment

Although similar initiatives have been undertaken, there is no universally agreed definition of competency in performing basic obstetric ultrasound, therefore we agreed to assess trainees based on both their global skill and the accuracy of their measurements. Without having established any specific criteria for the judgement of global skill however, we found considerable inconsistency in how individual trainers approached this assessment and to what degree they assisted the trainees in obtaining measurements.

To standardize assessment and improve transparency we developed a formal assessment tool to facilitate OSCEs. Trainees are assessed on their ability to perform specific tasks such as the optimization of their images, their communication and documentation of results, as well as five ‘critical’ tasks aligned with the key objectives of the training.

For the scan to constitute a ‘pass’, trainees must perform it independently and achieve all five of the critical tasks and at least six of the remaining 12. They must also establish gestational age to within +/- seven days of the trainer. Once these criteria were met for five consecutive scans, trainees were deemed competent to perform basic obstetric scans independently, although undoubtedly they will require, and should be provided with, ongoing support.

3.7.8 Duration of the course

Having hypothesized that it may be possible to deliver this package over the course of a single week, it became apparent that this was unattainable and trainees required more practical experience. Although most trainees developed their skills rapidly, none achieved the requirements outlined for certification within this time frame. Given the rapid progress however, we believed that 10 days would be sufficient for the majority to train to competency. Table 3-1 summarises the recommendations made for the delivery of the ultrasound training programme.

Table 3-1. Recommendations for the delivery of the training programme.

Organization	- Allow ten days for the delivery of the training - Complete all didactic teaching prior to commencing 'hands on' sessions - Where possible host 'hands on' sessions in the trainee's own health facility - During the practical sessions try to maintain one trainer for every three trainees
Recruitment	- Recruit client volunteers prior to the start of the training and request they attend on specific days - Recruit sufficient volunteers to facilitate four scans per trainee per day
Assessment	- Standardise assessment using the OSCE checklist

3.8 Completed training package

Following significant delays because of COVID-19, we were able to implement this training program across six sites in Malawi in early 2021. The completed program is shown in Table 3-2.

Table 3-2. Components of completed training programme.

Lectures	- Introduction to ultrasound - Scanning tips and orientation - Introduction to the ultrasound machine - How to scan for number of fetuses, fetal viability and fetal presentation - How to scan for gestational age using fetal femur length
Small group sessions	- Incorporating ultrasound into your routine antenatal clinics - Safety and storage of the ultrasound machines
Simulation sessions	- What's in the bag? (Ice breaker) - Femur length simulators - Femur length – Good or bad?
'Hands on' practical sessions	Scan practice on client volunteers directly supervised by trainers
Formal Trainee Assessments	Observed scans formally assessed by trainers

28 of the 29 participating midwives achieved competency and have been supported to incorporate basic ultrasound into their routine practice as part of an implementation study, the results of which are pending. All were well motivated to participate and acceptability was excellent.

3.9 Strengths

The strengths of this work include its pragmatic and adaptive approach, which facilitated evolution of the program via real time feedback provided by participants during each iteration. By undertaking two rounds of piloting we have been able to identify and overcome a number of challenges and develop an effective and context specific program which is both culturally appropriate and which has been refined to meet the needs of those participating.

3.10 Limitations

Although detailing the challenges of developing the program, this does not address its feasibility or the challenges of its implementation, both of which are currently being evaluated.

3.11 Conclusion

We have demonstrated that it is possible to teach the basics of obstetric ultrasound in a relatively short time, creating the opportunity to upscale ultrasound skills and services in low resource settings. Although challenges were encountered, it is clear these can be overcome with adaptive processes, maximizing both the chances of immediate success and the likelihood of widespread adoption and implementation.

3.12 Acknowledgements

On behalf of the DIPLOMATIC collaborators we would like to thank Frank Taulo, Nelson Ngosi, Kelvin Mwale and Chimwemwe Nanguwo for their help in delivering the training, Patricia Munthali Khomani, Mtondera Munthali, Shakira Namisengo and Lorraine Adamson for their administrative assistance and Thokozani Ganiza and Lumbani Makhaza for their help with data collection. We would also like to thank the Ministry of Health in Malawi who supported this work and the practitioners who gave up their time to participate. We are also extremely grateful to all the participants who volunteered during our pilot training courses.

3.13 Context Specific Guideline

This guideline was developed as part of the education package, to support and empower the midwives to incorporate ultrasound into their routine practice during the supervisory period of the training programme. Based on a pre-existing maternity guideline, developed by the Association of Obstetricians and Gynaecologists of Malawi (Association of Obstetricians and Gynaecologists of Malawi, 2015), it aimed to provide an overview of how ultrasound could be integrated into pre-existing services, while also ensuring that it was used appropriately within the confines of the study. Most importantly, it aimed to promote safe and effective care, which was feasible within the constraints of the Malawian healthcare system and established infrastructures.

It was generated by the same group as the training programme, Alexandra C Viner (AV), Dr Gladys Membe-Gadama (GMG), Sonia Whyte (SW), Dr Doris Kayambo (DK), Dr Martha Masamba (MM), Professor Caroline Hollins-Martin (CHM), Dr Brian Magowan (BM), Professor Rebecca M Reynolds (RR), Dr Sarah J Stock (SS), Dr Bridget Freyne (BF) and Dr Luis Gadama (LG), and received approval from the wider DIPLOMATIC collaboration. AV performed the literature search and prepared the first draft, with input, guidance and approval of all authors. Subsequent versions were edited by AV, again with the input, guidance and approval of all authors, alongside the wider DIPLOMATIC collaboration.

One of the challenges associated with the antecedent guideline, was the difficulty in enacting all recommendations consistently and equitably, especially those relating to ultrasound. The guideline stated that all women with an uncertain gestational age, be this due to an unknown LMP, or on account of discrepancy between presumed dates and clinical examination, be referred for a confirmatory ultrasound. However, on account of limited availability and inconsistent provision of ultrasound services, this was largely untenable, resulting in the majority of women in this situation not receiving recommended care.

Having reached the consensus agreement that fetal FL would be used to determine gestational age within our programme, we sought to generate new guidance to support the midwives to use ultrasound to optimise estimates of gestational age. This built on the pre-existing guideline and included an overview of the evidence to support the use of FL to determine gestational age. Ultrasound was highlighted as an adjunct and not a replacement for current standards of care, with emphasis placed on the importance of thorough history taking and the use of SFH measurements to monitor fetal growth. Most importantly, this document also provided guidance on the action required should the midwives encounter problems such as non-viability, or if they were unsure of their findings.

It was initially reviewed and updated following the pilot work and again after the implementation of the education package within the mixed methods study, with the main changes relating to the means by which the midwives should seek assistance. Initial plans had been to utilise a bespoke application (app) to facilitate remote image review and feedback, however as discussed in **Chapters 4** and **5** this proved to be problematic. As such we reverted to pre-existing pathways, including seeking advice over the phone or referring clients for a second opinion.

3.14 Establishing estimated due date (EDD) by ultrasound biometry and its use in antenatal care.

3.15 Introduction

Gestational age is the age of the fetus, from the first day of the last menstrual period (LMP) to the current date, as given in weeks and days. Establishing an accurate gestational age is fundamental to the management of pregnancy, birth and neonatal care, permitting the optimal timing of antenatal interventions and the avoidance of unnecessary ones. It is also used to calculate the estimated due date (EDD) and facilitate the accurate assessment of fetal growth (Butt et al., 2014, Papageorghiou et al., 2014). While there are a number of different ways to determine gestational age, they vary in their accuracy, with early estimation using ultrasound measurements of the fetus considered the most precise (Loughna et al., 2009, Butt et al., 2014, Pettker et al., NICE, 2021). We recommend this as a standardised approach to determining the gestational age and estimated date of delivery for women receiving antenatal care in Malawi.

3.16 Background

Clinical estimates of gestational age derive from recall of the first day of the LMP, supplemented by clinical examination, with the EDD assigned as 280 days after the LMP (Pettker et al., 2017. While this is low cost and readily available, it is not infallible. To be precise, dating from the LMP relies not only on accurate recall, but also on the assumption that women's cycles are regular and uniform in length and that ovulation occurs mid-cycle (Butt et al., 2014). When all of these criteria are met and women are 'certain' of their LMP, the accuracy of the derived gestational age is thought to be +/- 14 days (Dewhurst et al., 1972, Campbell et al., 1998). However, even then, between 11-42% of gestational ages derived in this way are reported as less accurate (Whitworth et al., 2014), and indeed up to 45% of women are unable to recall their LMP (Wegienka et al., 2005). Therefore overall, estimates of gestational age derived from the LMP are considered accurate to +/- 4.65 weeks (Lee et al., 2020).

Physical examination, either pelvic or abdominal, can provide additional information regarding pregnancy dates, with the size of the uterus considered an approximate measure of gestational age. However, uterine size may affected by additional factors such as fibroids or multiple pregnancy, which will impact on the verity of the assigned gestational estimate. Furthermore, maternal habitus may also hinder examination and cause further discrepancy.

The determination of gestational age using ultrasound is achieved by taking standardised measurements of the fetus, relying on the notion that the size of the fetus is consistent with its age. Variation in fetal size is least apparent in the first trimester, increasing steadily throughout the pregnancy as other factors which influence fetal growth start to contribute to the overall fetal proportions (Wisser et al., 1994). As such, estimation of gestational age using ultrasound, or indeed any other method, is most accurate when undertaken in the first trimester and least accurate in the third (Caughey et al., 2008). First trimester estimates of gestational age using ultrasound are described as being accurate to +/- 5-7 days (Sladkevicius et al., 2004), compared with +/- 12-18 days in the third trimester (Hadlock et al., 1984, Butt et al., 2014, Papageorghiou et al., 2016, Pettker et al., 2017, Sun et al., 2020). When ultrasound is used to establish the gestational age, the machine will not only give the current gestational age as determined by the specific measurement, it will also give the corresponding EDD. Therefore, an EDD assigned by an ultrasound scan in early pregnancy is considered the most reliable. Depending on the gestation determined by the scan however, the EDD should either be accepted regardless of that suggested by the LMP, or reviewed and potentially altered, as is the case after 24 weeks (Miller at al., 2017, Pettker et al., 2017). This will be discussed in more detail later in the guidance.

Evidence suggests that a scan in early pregnancy to optimise assessment of gestational age reduces postdates inductions and improves detection of multiple pregnancy (Whitworth et al., 2014). Additionally, the scan may also permit earlier identification of non-viable pregnancies and help facilitate more timely management (WHO. 2016).

3.17 General Considerations

All women attending for their first antenatal visit should be asked about their LMP, including the date of the first day of that period, whether they considered it to be normal (or unusually heavy or light) and whether they had been using hormonal contraceptives in the last 3 months. This date should be documented in the health passport but not yet used to officially determine the gestational age or calculate the estimated date of delivery (EDD). If the client does not know the dates of her LMP then this should be documented as ‘unknown’.

Good Practice Point

Taking a thorough history is a vital component of all booking visits and should not be omitted on account of the presence of ultrasound. Gaining an understanding of the LMP is important for all clients attending for their first visit, as it will provide information with which to correlate the scan. For example, if the scan shows the woman is over 24 weeks gestation and the EDD suggested by the ‘certain’ LMP falls within certain parameters, then the EDD derived from the LMP may actually be more accurate than that assigned by the scan and should be used instead. This is discussed in more detail later in this guidance (Caughey et al., 2008, Verberg et al., 2008, Butt et al., 2014, Miller at al., 2017).

The benefits and limitations of ultrasound should be explained to the client and she must give her consent. If she declines to have a scan then the gestational age and EDD should be calculated according to previous routine care, using the LMP and clinical examination.

Good Practice Point

It should be explained to clients that the purpose of the ultrasound is to look for the number of babies, confirm viability by seeing a heartbeat and to establish the gestational age and EDD. She should be aware that while ultrasound is safe for both her and the baby, it cannot be used to guarantee a straightforward pregnancy even if the findings are normal. The operator will not be able to report on fetal anomalies, placental site or look for fetal sex.

Practitioners performing ultrasound should have undergone training to do so and achieved the required standard to be considered ready to perform ultrasound independently. Where provided, they should engage with ongoing medical education activities and quality assurance procedures.

Good Practice Point

If the ultrasound practitioner is unsure about the accuracy of the measurements obtained or is concerned about unusual findings they should seek a second opinion. If possible, this could initially be from a colleague in the Health Centre, however if no-one is available or there remains uncertainty, they should contact the referral centre to arrange repeat imaging using the pre-existing referral pathway.

Good Practice Point

Every pregnant woman should be offered an ultrasound at the earliest opportunity in their pregnancy to identify the number of fetuses, confirm viability and determine gestational age. Ideally this should be performed in the first, or second trimester. Ultrasound should still be performed if the first visit is at a later gestation than this, but with the understanding that the gestational age and corresponding EDD will be less precise.

Grade C Evidence

All pregnant women should have at least one ultrasound scan during pregnancy, to document the number of fetuses, confirm viability and establish gestational age. Fetal viability is described as seeing the presence of cardiac activity at the time of the scan. As there is least natural variation in fetal size in the first trimester, the most accurate EDD is one calculated from an ultrasound scan in early pregnancy, therefore where possible the scan should be undertaken at the earliest opportunity in the pregnancy. If this is not possible, the scan should still be offered at later gestations, although the EDD which is suggested by this may need to be revised in accordance to the LMP if known. This is explained later in the guidance (Miller at al., 2017, Pettker et al., 2017) .

Once the scan has been completed and the gestational age and EDD determined, this information should be discussed with the client and documented in the health passport. The EDD assigned at this stage should be used for the duration of the pregnancy and not changed. When the client attends for subsequent visits or at delivery, the gestational age on that day should be determined from the documented EDD and not from measurement of the symphysis fundal height (SFH), which should instead be used to assess fetal growth.

Grade C Evidence

Once the EDD has been established by ultrasound in early pregnancy, it should not be altered. It should be used throughout the remaining pregnancy to calculate the gestational age at any given point, be it at subsequent antenatal visits or at delivery. This can be done using a pregnancy wheel, specific smartphone app or a simple calendar. Measurements of the SFH should still be undertaken but these should be used to assess growth and not to estimate the gestation. If the SFH is ≤3cm or ≥3cm than expected for the gestation, the client should be referred to the obstetricians as per pervious protocols (Salomon et al., 2010, Association of Obstetricians and Gynaecologists of Malawi, 2015).

Gestational age should be determined from the average of three femur length measurements, taken from three separate images. *Grade C Evidence*

While a first trimester measurement of crown rump length is considered the most accurate method to determine gestational age (Sladkevicius et al., 2004, Loughna et al., 2009, ISUOG, 2013, Butt et al., 2014, Papageorghiou et al., 2014), it is only considered valid up until 13+6 week's gestation and is therefore unsuitable for the majority of women in Malawi who present to antenatal services later than this. Instead, we recommend measurement of the fetal femur length performed after 14 weeks. The femur is the largest of the fetal bones and the easiest to image. It is measured along its long axis and so should be visualised in the horizontal plane, filling the screen. Care must be taken to ensure areas are not obscured by shadowing and that the measurement only contains the osseous portion of the bone and not the epiphyseal cartilage (Loughna et al., 2009, Salomon et al., 2010). While less affected by growth patterns than other measurements such as the abdominal circumference, the femur length is still vulnerable to the natural variation in fetal size seen with increasing gestation. It is also influenced by ethnicity and some skeletal abnormalities (Pathak and Lees, 2009, Silasi et al., 2015, Racicot and Mor, 2017). If taken in the second trimester, the femur length is considered accurate to +/- 7-17 days, if done in the third trimester, +/- 17-21 days (Leung et al., 2008, AMHANI, 2020.

Determining the Estimated Due Date from the Ultrasound Scan

> If the gestational age determined by the ultrasound scan shows the fetus to be <24 weeks then the EDD established by the scan should be accepted regardless of that suggested by the LMP, even if the woman is sure of her dates.
>
> *Grade C Evidence*

Due to the aforementioned limitations of using the LMP to establish gestational age, the EDD determined from an ultrasound scan <24 weeks is considered more accurate, even if the woman is sure of her dates, and therefore should be used to calculate the EDD (Verberg et al., 2008, WHO, 2016, Miller at al., 2017).

If the gestational age determined by the ultrasound scan shows the fetus is between 24-28 weeks' gestation then the EDD established by the scan should be considered in the context of the EDD suggested by the LMP (if known) as shown in Table 3-3. Quick guide to the determination of gestational age using ultrasound. If the two dates are within 14 days of each other, then the EDD suggested by the LMP should be used. If there is >14 days difference or the LMP is unknown, then the EDD determined be the scan should be accepted.

Grade C Evidence

Due to the decreasing accuracy of ultrasound measurements taken to determine gestational age in later pregnancy, it can, in the context of a 'certain' LMP be more accurate to accept the dates assigned by the LMP. However, if this is unknown or there is uncertainty surrounding the validity of the LMP, for example, if it was unusually heavy or light, the periods have been very irregular or the client has taken any hormonal contraceptives in the preceding 3 months, then the EDD from the scan should be used (Miller et al., 2017, Pettker et al., 2017).

If the gestational age determined by the ultrasound scan shows the fetus is >28 weeks' gestation then the EDD established by the scan should be considered in the context of the EDD suggested by the LMP (if known) as shown in the table below. If the two dates are within 21 days of each other, then the EDD suggested by the LMP should be used. If there is >21 days difference or the LMP is unknown, then the EDD determined be the scan should be accepted.

Grade C Evidence

If the client books later than 28 weeks it should be accepted that any estimate of gestational age is likely to be vulnerable to significant inaccuracy and thus interpreted with caution.

Table 3-3. Quick guide to the determination of gestational age using ultrasound

Gestational age as determined by USS	Use EDD assigned by LMP (if known)	Use EDD assigned by ultrasound
<24 weeks	NEVER	ALWAYS
24-28 weeks	If there is <14 days difference between EDD assigned by LMP and USS	If there is >14 days difference between EDD assigned by LMP and USS *or* If LMP not known
>28 weeks	If there is <21 days difference between EDD assigned by LMP and USS	If there is >21 days difference between EDD assigned by LMP and USS *or* If LMP not known

3.18 Chapter Conclusion

The work presented in **Chapter 3** describes the development of a novel education package to teach midwives in Malawi to date pregnancies using ultrasound, including the generation of a context specific guideline to support and empower the midwives to incorporate ultrasound into their routine practice. While many aspects of this were successful, there were some unexpected challenges which impacted on the ability of the group to deliver the training as initially intended. That said, these provided important opportunities to improve and refine the package, which was to the overall benefit of the programme.

Unfortunately, despite plans to provide additional training for this cohort of midwives, together with repeat assessments according to the newly developed OSCE format, we were unable to formally facilitate this training as a result of the COVID-19 pandemic. Instead, the midwives underwent additional training sessions at the Queen Elizabeth and Mzuzu Central Hospitals, which was provided by the local obstetricians. Regrettably, due to the constraints of the ethical approval, we were unable to collect formal data on these sessions and their outcomes, although anecdotal evidence suggests the majority were able to maintain and develop skills sufficient to be considered competent for independent practice. Although it should be recognised that this group did not undergo the formal assessment recommended by this programme.

Chapter 4 describes the evaluation of the completed education package, when delivered as part of the DIPLOMATIC mixed methods study, ‘Evaluating the Implementation of Routine Antenatal Ultrasound for Estimating Date of Delivery in Malawi’.

Chapter 4

Training in Ultrasound to determine gestational age (TUDA): Evaluation of a novel package for ultrasound-naive healthcare professionals in Malawi.

The following materials have been published in Frontiers in Global Women's Health under the same title by Alexandra C Viner (AV), Dr Gladys Membe-Gadama (GMG), Sonia Whyte (SW), Dr Doris Kayambo (DK), Dr Martha Masamba (MM), Enita Makwakwa (EM), Professor David Lissauer (DL), Dr Sarah J Stock (SS), Professor Jane E Norman (JN), Professor Rebecca M Reynolds (RR), Dr Brian Magowan (BM), Dr Bridget Freyne (BF), Dr Luis Gadama (LG) on behalf of the DIPLOMATIC Collaboration.

AV prepared the protocol for this study, with input and guidance from all authors. The education package was developed by AV, GMG, DK, MM, BM and LG, with GMG, MM, EM and LG co-ordinating the delivery of the training in Malawi. Data was analysed by AV, who also prepared the first draft of the manuscript, under the guidance of SW, SS, JN, DL, BM, BF and LG. All authors provided critical insight for the manuscript. Of note, the work here is presented as it appears in Frontiers in Global Women's Health using American spelling.

In summary, this work demonstrates that ultrasound-naive practitioners can be taught to perform basic obstetric ultrasound dating scans using measurement of the fetal femur length, confidently and competently, after just 10 days of training. All trainees displayed significant increases in their knowledge, confidence, and practical skills, which were sustained at 3 month follow up. In contrast to many other programmes developed in collaboration with groups from high income countries (Kimberley et al., 2010, Wylie et al., 2013, Boamah et al., 2014, Greenwold et al., 2014, Nathan et al., 2017,) our training was delivered exclusively by local faculty who were orientated to the programme virtually.

4.1 Abstract

4.1.1 Introduction

Although ultrasound to determine gestational age is fundamental to the optimum management of pregnancy and is recommended for all women by the World Health Organization, it remains unavailable to many women in low-income countries where trained practitioners are scarce. This study aimed to evaluate a novel, context-specific education package to teach midwives basic obstetric ultrasound, including the determination of gestational age by measurement of fetal femur length.

4.1.2 Methods

The study was conducted across six sites in Malawi in January 2021. Following a virtual ‘training of the trainers’, local teams delivered a 10-day programme encompassing both didactic and ‘hands on’ components. Matched pre and post course tests assessed participants’ knowledge of key concepts, with Objective Structured Clinical Examinations used to evaluate practical skills. To achieve a pass, trainees were required to establish the gestational age to within +/- 7 days of an experienced practitioner and achieve an overall score of >65% on 5 consecutive occasions. A matched pre and post course survey explored participants’ attitudes and confidence in performing ultrasound examinations.

4.1.3 Results

Of the 29 midwives who participated, 28 finished the programme and met the criteria specified to pass. 22 midwives completed the matched knowledge tests, with the mean (SD) score increasing from 10.2(3.3) to 18(2.5) after training (P<0.0001). Mean difference 7.9, 95% CI 6.5-9.2. Midwives passed 87% of the Observed Structured Clinical Examinations, establishing the gestational age to within +/- 7 days of an experienced practitioner in 89% of assessments. Beliefs regarding the importance of antenatal ultrasound increased post course (p=0.02), as did confidence in performing ultrasound examinations (p <0.0001).

4.1.4 Conclusion

This study demonstrates not only that ultrasound-naive practitioners can be taught to perform basic obstetric ultrasound dating scans, confidently and competently, after 10 days of training, but also that local teams can be orientated to successful deliver the programme virtually. Previous ultrasound training initiatives, while often more comprehensive in their syllabus, have been of considerably longer duration and this is likely to be a barrier to upscaling opportunities. We propose that this focussed training increases the potential for widescale and sustainable implementation.

4.2 Background

As a fundamental component of obstetric and neonatal care, the World Health Organisation (WHO) has regularly cited the need for improved estimates of gestational age in low- and middle- income countries (LMICs) as a public health priority (World Health Organisation, 2015, Vogel et al., 2015, Lee et al., 2019) not only to enhance clinical care but also to strengthen the global reporting of pregnancy complications and to facilitate the evaluation of context-specific interventions to improve outcomes.

There are a number of different ways to determine gestational age but early pregnancy ultrasound is considered the most precise (National Institute of Clinical Excellence, 2008, Loughna et al., 2009, Butt et al., 2014, Pettker et al., 2017). Despite WHO guidance recommending that all women receive an ultrasound scan prior to 24 weeks to ‘estimate gestational age, improve detection of fetal anomalies and multiple pregnancies and reduce induction of labour for post term pregnancy’ (World Health Organisation, 2016), this remains unavailable to many women living in LMICs. In these settings, gestational age is derived from either the last menstrual period (LMP) or by abdominal palpation, both of which are substantially less accurate than ultrasound (Treloar et al., 1967, Baskett et al., 2000, Lee et al., 2020). Scaled provision of ultrasound is challenging for a number of reasons (Seffah et al., 2009, Shah et al., 2015, Puchalski et al., 2016, Wanyonyi et al., 2017, Kim et al., 2018) ranging from economical and geographical, to human factors and healthcare infrastructures (Smith et al., 2020). Indeed, one of the most frequently cited barriers is the lack of trained practitioners (Shah et al., 2015, Kim et al., 2018). Despite a number of previous programmes demonstrating success in training healthcare workers to perform obstetric ultrasound, the length and complexity of many programmes has been prohibitive, with practitioners struggling to secure cover for their clinical duties in order to provide or attend training (Shah et al., 2015, Kim et al., 2018, Maw et al., 2019).

This study evaluated a novel training programme designed to teach ultrasound-naive healthcare practitioners' basic obstetric ultrasound, using fetal femur length to determine gestational age. We explored the ability of midwives to perform and interpret ultrasound examinations. We assessed the accuracy of their fetal measurements compared to experienced practitioners and evaluated post course changes in their knowledge and confidence. Our hypothesis was that midwives could be trained to competency within 2 weeks. We also reviewed the quality of images obtained over the following 3 months and evaluated skill retention by repeating written and practical assessments at the end of this period.

4.3 Pedagogical Framework

Our programme was designed to teach ultrasound naive midwives in LMIC settings to perform the basics of obstetric ultrasound, including:

- The safe and appropriate use of an ultrasound machine
- The identification of number of fetuses
- The confirmation of fetal viability
- The confirmation of fetal presentation
- The determination of gestational age and estimated date of delivery by measurement of fetal FL
- The upkeep and secure storage of the ultrasound machines

The training programme was based on pilot work undertaken in Malawi in early 2020 and included both didactic and practical components. The first day and a half comprised of intense 'classroom based' sessions, followed by eight and a half days of practical 'hands on' experience. Details of these sessions are shown in Table 4-1. Components of ultrasound course. Simulation sessions using bespoke low-cost phantoms were incorporated into the 'classroom' component, not only to help familiarise trainees with the machines, but also to help them develop confidence with probe manipulation prior to scanning volunteers. Small group sessions were intended to encourage discussion and team problem solving, as well as to encourage trainees to take ownership of the service and to anticipate and troubleshoot what they envisaged may be barriers to the implementation of ultrasound in their facilities.

The ‘hands on’ sessions were conducted at the individual facilities, during which trainees had the opportunity to perform directly supervised ultrasound examinations on client volunteers. Feedback was provided in real-time and, as their skills evolved, trainees were supported to perform their scans with increasing independence. To complement the training, trainees were provided with a comprehensive printed handbook containing all of the information relayed in the lectures. Laminated sheets encompassing key concepts were also made available with each of the ultrasound machines as aide memoires.

Table 4-1. Components of ultrasound course

Lectures	- Introduction to ultrasound - Scanning tips and orientation - Introduction to the ultrasound machine - How to scan for number of fetuses, fetal viability, and fetal presentation - How to scan for gestational age using fetal femur length
Small group sessions	- Incorporating ultrasound into your routine antenatal clinics - Safety and storage of the ultrasound machines
Simulation sessions	- What's in the bag? (Ice breaker) - Femur length simulators - Femur length – Good or bad?
'Hands on' practical sessions	Scan practice on client volunteers directly supervised by trainers
Formal Trainee Assessments	Observed scans formally assessed by trainers

4.4 Competencies and Standards

In the absence of a universally accepted definition of what constitutes competency in obstetric ultrasound, our group reached a consensus agreement based on previous initiatives (Neufeld et al., 2009, Sarris et al., 2013, Nathan et al., 2014, Millar et al., 2018, Shah et al., 2020). Trainees were evaluated by way of Observed Structured Clinical Examinations (OSCEs) and their ability to determine the gestational age of clients to within +/- 7 days of the trainers. The OSCE comprised of 17 components mapped to the curricula, with 5 tasks considered ‘essential’. To pass, the trainee was required to achieve an overall score of 11 (65%) or greater, correctly perform all 5 of the ‘essential’ tasks and determine gestational age to within +/-7 days of the gestational age assessed by their trainer. Both trainers and trainees were blinded to the measurements and gestational age until the end of the examination. Once trainees performed 5 consecutive examinations fulfilling these criteria, they were deemed competent to perform these basic ultrasound scans independently. Details of the OSCE components are shown in Table 4-2. Components of Observed Structured Clinical Examination (OSCE) with ‘essential’ tasks depicted in bold. A flowchart illustrating the protocol for assessment of competency is shown in Figure 4-1. Flowchart depicting methodology of trainee assessment.

Table 4-2. Components of Observed Structured Clinical Examination (OSCE) with 'essential' tasks depicted in bold.

Is the trainee able to set up and switch on the scanner?
Is the trainee able to prepare and position the client appropriately?
Does the trainee ensure that they start a new examination by pressing either 'end exam' or 'new patient'?
Does the trainee orientate the probe correctly?
Does the trainee assess the uterus sufficiently to establish number of fetuses?
Does the trainee determine number of fetuses correctly?
Is the trainee able to identify and display the fetal heart?
Based on this does the trainee correctly interpret fetal viability?
Does the trainee correctly determine fetal presentation?
Does the trainee optimize their images where appropriate?
Does the trainee obtain a suitable image from which to take their first measurement?
Does the trainee obtain a suitable image from which to take their second measurement?
Does the trainee obtain a suitable image from which to take their third measurement?
Is the trainee able to generate a report for their ultrasound scan?
Does the trainee consider the LMP when interpreting the scan results and correctly determine the EDD?
Does the trainee document their results adequately?
Does the trainee explain their results to the client?

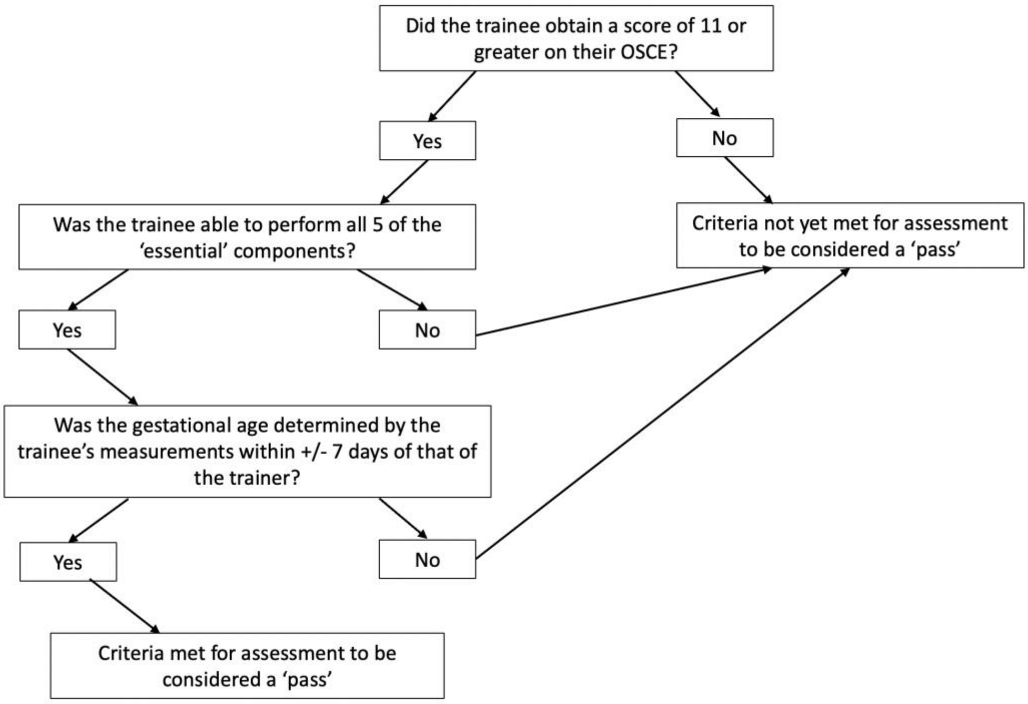

Figure 4-1. Flowchart depicting methodology of trainee assessment.

4.5 Learning Environment

4.5.1 Setting

The training was conducted in January-February 2021 as part of a 'parent' study exploring what factors may influence the upscale of basic antenatal ultrasound in LMIC settings (PACTR202010788566263). The project ran across 6 health facilities in Malawi, selected to encompass both urban and rural facilities. These included 3 sites in Blantyre, 1 in Lilongwe and 2 in the northern district of Karonga.

4.5.2 Faculty

15 local trainers were recruited to facilitate the course based on the following predefined criteria, kept intentionally broad to reflect the general paucity of trained practitioners in many LMIC settings. They should be an obstetrician (trainee or consultant), radiologist, sonographer, midwife or clinical officer, who has received training in basic obstetric ultrasound (via a formal or apprenticeship model) and who has performed independent obstetric ultrasound for a minimum of 1 year. They must also be capable and confident to troubleshoot any problems the trainees may encounter performing scans.

9 of the trainers were doctors in obstetrics and gynaecology, 4 were clinical officers, 1 a radiographer and 1 a clinical associate. 11 had received formal training in obstetric ultrasound, with the remaining 3 taught ‘on the job’. They had an average of 5.9 years’ experience in performing obstetric ultrasound, ranging from 1.5-16 years. All trainers attended a training of the trainers’ session, held virtually as a result of COVID-19 restrictions. All were provided with a detailed training manual and complied with the same standard operating procedures. A ratio of 1:4 trainers to trainees was maintained for all ‘hands on’ sessions.

4.5.3 Trainees

29 midwives were selected to participate by their local District Nursing Officer (DNO), based on their role as a key provider of antenatal care to women at the

participating facilities and their engagement in service improvement. In order to preserve the continuity of subsequent scanning services, we sought to train a minimum of 4 midwives per site. Unfortunately, in order to ensure the ongoing provision of routine clinical care at the facilities during the training period, not all midwives at each site were able to participate. All held either a Degree or Diploma in Nursing and Midwifery and none had any previous experience of using ultrasound. They had an average of 10.5 years of experience, ranging from 1 to 30 years, representative of the skill mix working within the participating facilities.

4.5.4 Volunteers

‘Hands on’ sessions were made possible thanks to client volunteers, eligible to participate if they were over 18 years old, thought to be over 14 weeks gestation and able to provide informed written consent. They were provided with a small allowance to cover their travel expenses, and each was allocated a unique identification number to maintain their confidentiality.

4.5.5 Follow up and image review

All training was complete by the end of February 2021, with remote supervision and image review provided for the following 3 months. To assess the ongoing quality of the ultrasound examinations, trainees were required to submit images for regular review. Images were assessed by two independent reviewers who were experienced in obstetric ultrasound and blinded to the midwife submitting the image. If the reviewer was confident that the image was that of a femur, they went on to assess the quality of the image using the following criteria;

- The femur should be displayed horizontally at an angle <45 degrees
- Both ends of the femur should be clearly visible
- The femur should fill >50% of the ultrasound images
- If depicted, the callipers should be correctly placed

If the reviewer did not consider the image to be clearly that of a femur, the image was deemed unacceptable, and no further assessment of that image was performed. Of those that were rated, a score of 2 out 3 was deemed acceptable for those without callipers and 3 out of 4 if callipers were shown. Scores and comments were fed back to the trainees weekly.

4.6 Data collection

Prior to the training, each trainee undertook a 24-question multiple choice knowledge test to assess their theoretical understanding of ultrasound, scanning technique and basic fetal anatomy. They also completed a questionnaire using a 5-point Likert scale (1=Strongly Disagree, 5=Strongly Agree) to assess their attitude towards and confidence using ultrasound. Both assessments were repeated immediately after completion of the training and again 3 months later.

4.6.1 Statistical methods

Data was analysed using SPSS (IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp). Matched pre and post course knowledge tests were analysed using paired t tests, with a Bland Altman plot used to assess the level of agreement between the gestational ages assigned by the trainees versus those obtained by the trainers. Within the pre and post course questionnaires, questions evaluating similar concepts, for example confidence, were allocated into 4 groups for analysis, with the reliability of these groupings tested using Cronbach's alpha. If scoring >0.8, these were then analysed as a group using a Wilcoxon signed rank test. If a group did not demonstrate adequate reliability, scoring <0.8, the statements were analysed as single items. Intraclass correlation coefficients (ICC) were used to assess the inter-rater reliability of the reviewers assessing the follow up scans. A p-value < 0.05 was considered statistically significant.

4.7 Ethical considerations

All participants (trainees and client volunteers) provided informed written consent, with participant information leaflets and consent forms available in both Chichewa and Tumbuka, as well as in English. As key stakeholders, the Ministry of Health in Malawi and the District Health Officers of the participating sites were involved in the conception of the project and supportive of its implementation. This study was approved by the University of Edinburgh and the University of Malawi – College of Medicine Research and Ethics Committee (COMREC) P08/19/2768.

4.8 Results

At the end of the 10-day programme, 28 trainees had completed the training and all were certified as competent. The remaining trainee was unable to finish the course due to illness. 395 clients participated across the six sites, all of whom had a viable intrauterine pregnancy. No woman required referral for any suspected complication or anomaly, however 1 client was referred for high risk care following the identification of multiple pregnancy (twins). 2 clients were found to be less than 14 weeks gestation and therefore ineligible to participate. 212 clients were unable to recall their LMP (54%) and 153 (39%) presented prior to 24 weeks gestation.

4.8.1 Knowledge test

22 of the 28 trainees completed matched pre and post course knowledge tests. All improved on their original score, with the mean (SD) score rising from 10.2(3.3) to 18(2.5) following training ($P<0.0001$). The mean difference was 7.9, 95% CI 6.5-9.2.

4.8.2 Changes in confidence and perception

Cronbach's alpha confirmed 'good' reliability within groups 1-3, as depicted in Table 4-3, Table 4-4 and Table 4-5, therefore the responses to these questions were analysed as a group. The questions allocated into group 4 however, were found to demonstrate ‘poor’ reliability and therefore were analysed as single statements as shown in Table 4-6. 23 of the 28 trainees completed matched pre and post course questionnaires, the results of which are summarised in Table 4-3, Table 4-4, Table 4-5 and Table 4-6. Prior to training, most disagreed with the suggestion that ultrasound posed risks for the mother and baby, however the overall strength of this conviction increased following the programme ($p=0.027$). Trainees’ confidence in performing ultrasound examinations also increased after training ($p < 0.0001$), as did their perceived ability to incorporate ultrasound into their routine work (p 0.016). Their belief regarding the importance of ultrasound in antenatal care and their interest in performing scans also increased, however these results did not reach significance.

Table 4-3. Pre and post course questionnaire results. Group 1 – Trainee's perceived risk of using ultrasound in pregnancy.

Group 1 Trainees' perceived risk of using ultrasound in pregnancy	Cronbach's alpha	Median scores (n=23)		Total scores (n=23)		Wilcoxon Signed Rank Test
		Pre	**Post**	**Pre**	**Post**	
1. I believe that ultrasound has risks for the mother	0.812	2	1	40	31	p = 0.027
2. I believe that ultrasound has risks for the baby		2	1	41	32	

Table 4-4. Pre and post course questionnaire results. Group 2 – Trainees' beliefs about the role of ultrasound in antenatal care.

Group 2 Trainees' beliefs about the role of ultrasound in antenatal care	**Cronbach's alpha**	**Median scores (n=23)**		**Total scores (n=23)**		**Wilcoxon Signed Rank Test**
		Pre	**Post**	**Pre**	**Post**	
1. I believe that every pregnant woman should have an ultrasound scan	0.885	5	5	102	99	p = 0.092
2. I believe that providing an ultrasound scan will improve maternity care		5	5	101	110	
3. I believe that it is important to perform ultrasound scans to determine number of fetuses		5	5	99	113	
4. I believe that it is important to perform ultrasound scans to determine fetal viability		5	5	100	110	

5. I believe that it is important to perform ultrasound scans to determine gestational age		5	5	99	110	
6. I believe that midwives should perform ultrasound scans		5	5	100	111	

Table 4-5. Pre and post course questionnaire results. Group 3 – Trainee confidence in performing ultrasound examinations.

Group 3 Trainee confidence in performing ultrasound examinations	Cronbach's alpha	Median scores (n=23)		Total scores (n=23)		Wilcoxon Signed Rank Test
		Pre	**Post**	**Pre**	**Post**	
1. I am confident in discussing the reasons for doing an ultrasound scan in pregnancy with clients	0.863	4	5	94	112	p = <0.0001
2. I am confident in discussing the process of doing an ultrasound scan with clients		4	5	85	111	
3. I am confident in setting up and using an ultrasound machine		3	5	73	108	
4. I am confident in cleaning and storing an ultrasound machine		3	5	73	105	

5. I am confident to perform an unsupervised obstetric ultrasound scan to determine number of fetuses		2	5	58	102	
6. I am confident to perform an unsupervised obstetric ultrasound scan to determine fetal viability		2	5	63	104	
7. I am confident to perform an unsupervised obstetric ultrasound scan to determine gestational age		2	5	59	99	
8. I am confident in asking for help		5	5	96	107	

Table 4-6. Pre and post course questionnaire results. Group 4 – Trainees' attitudes towards incorporating ultrasound into their own practice.

<u>Group 4</u> **Trainees' attitudes towards incorporating ultrasound into their own practice**	**Cronbach's alpha**	**Median scores (n=23)**		**Total scores (n=23)**		**Wilcoxon Signed Rank Test**
		Pre	**Post**	**Pre**	**Post**	
1. I am interested in performing basic obstetric ultrasound scans	0.554	5	5	106	112	p = 0.248
2. I have time to incorporate ultrasound scans into my antenatal clinics		4	5	89	106	p = 0.016

4.8.3 Practical Skills

Of the 405 OSCE assessments that were undertaken, 351 (86.7%) were considered a pass. Every assessment scored the required 11 or more, with 277 (56%) achieving the top mark of 17. Of the 54 assessments marked as a fail, 8 were due to an inability to complete one of the 'essential' tasks, 41 due to insufficient accuracy in the determination of gestational age and 5 on account of both. Aside from the accurate determination of gestational age, the most common problem encountered within the OSCE was the inability to correctly determine fetal presentation. Trainees were able to determine gestational age to within +/- 7 days in 359 (89%) of cases, with Bland Altman analysis approximating the overall level of agreement for three ranges of gestational age shown in Figure 4-2 Bland Altman plots of comparison between the gestational ages assigned by the trainees vs the trainers for three ranges of gestational age.

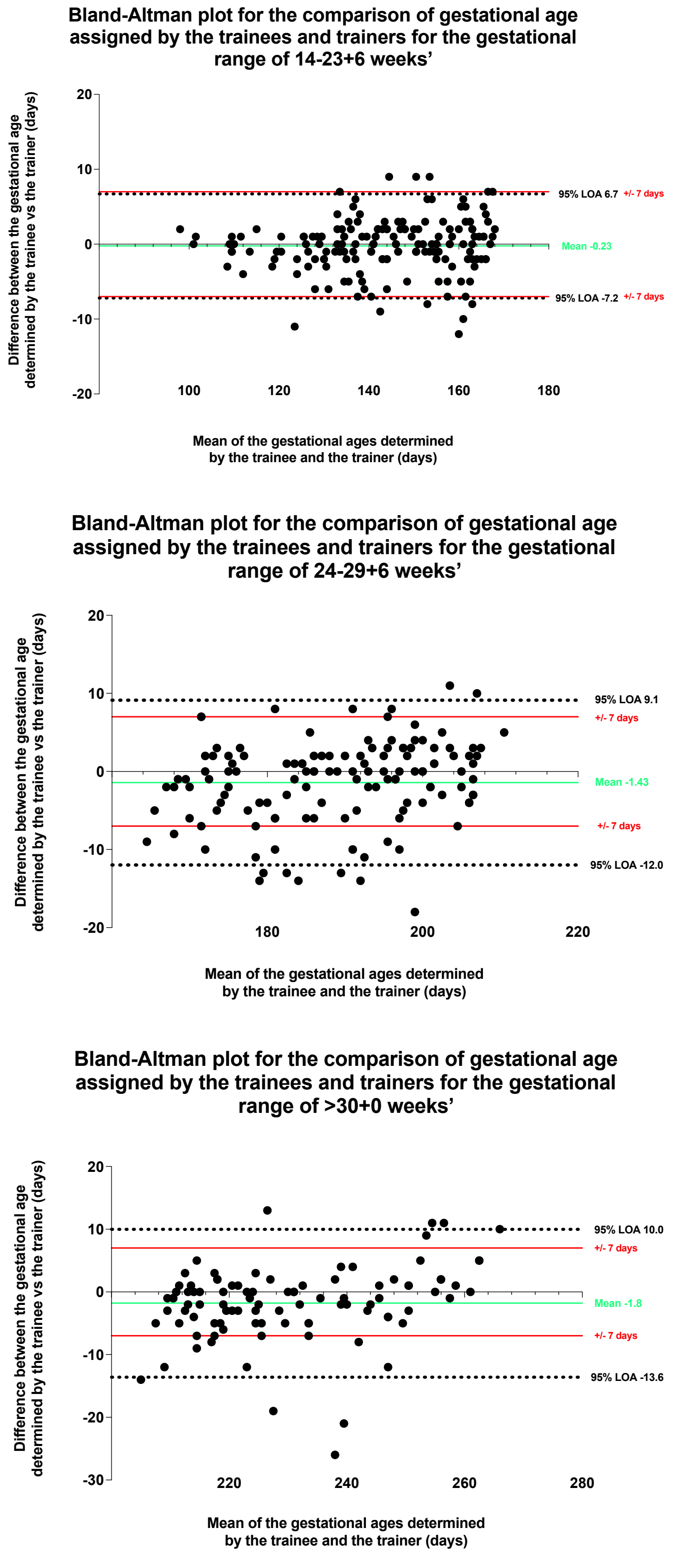

Figure 4-2 Bland Altman plots of comparison between the gestational ages assigned by the trainees vs the trainers for three ranges of gestational age.

4.8.4 Maintenance of skills

Due to illness and competing clinical duties, repeat assessments after 3 months were only obtained for 9 trainees. Within this group, the mean score of 19 obtained at the end of the training was maintained (P=0.772). Trainees maintained their beliefs regarding the importance of ultrasound within antenatal care and continued to report high levels of confidence in performing independent ultrasound examinations (P=0.916 and P=0.670, respectively).

27 repeat OSCE examinations were undertaken by 9 trainees. 23 of the assessments met the criteria to pass with all 9 trainees demonstrating retention of their practical skills. The mean (SD) OSCE score was 16.8(0.5), with all 5 ‘essential’ tasks completed successfully for every assessment. Trainees were able to determine the gestational age to within +/-7 days of the trainers on 24 (86%) occasions.

4.8.5 Image review

A total of 130 images were submitted for review in the 3 months following the training. Of these, one reviewer marked 17 (13%) as unacceptable and the other 13 (10%). In 9 (6%) cases this was because the reviewers did not consider the image to be that of a femur. One reviewer awarded 67 (52%) of the images the top score, the other 57 (44%). The most common source of error was that the femur did not fill >50% of the image. Levels of agreement between the reviewers were high, as demonstrated by an ICC of 0.962 ($p<0.0001$).

4.8.6 Cost

The total cost of delivering this programme across 6 sites was £55,182, including the provision of 6 Mindray DP-10 ultrasound machines.

4.9 Discussion

We have demonstrated that it is possible to train ultrasound-naive practitioners to perform basic obstetric ultrasound scans, confidently and competently, after just 10 days of training, with skills retained after 3 months of independent practice. Despite having no prior experience in using ultrasound, all trainees displayed significant increases in their knowledge, confidence, and practical skills. These were sustained in the group available for follow up, however as this was only a third of participants this result should be interpreted with caution. Furthermore, in contrast to many other programmes that have been developed in collaboration with groups from high income countries (Shah et al., 2009, Kimberly et al., 2010, Wylie et al., 2013, Boamah et al., 2014, Greenwold et al., 2014, Bentley et al., 2015, Wanjiku et al., 2018), our training was delivered exclusively by local faculty who were orientated to the programme virtually. This not only improved the immediate success of the programme, as the local team were much better placed to navigate the intricacies of the setting and troubleshoot any unexpected issues, but also makes this a more sustainable model.

This package was differentiated from previous programmes described in the literature by applying a simplified approach to a similar baseline pedagogical framework (Kimberly et al., 2010, Sarris et al., 2013, Wylie et al., 2013, Boamah et al., 2014, Nathan et al., 2014, Shah et al., 2020). Firstly, we chose to date pregnancies using FL as a single parameter. Compared with the conventional, more complex circumferential measurements of abdominal circumference (AC) and head circumference (HC), measurement of the FL requires only an image of a straight bone, making it a much easier measurement to obtain (Butt et al., 2014, Salomon et al., 2019). The reported difference in the gestational age assigned by FL alone is only +/-2.4 days at <24+0 weeks, +/-1.7 days at 24-29+6 days and +/-1.8 days at >30+0 weeks (The WHO Alliance for Maternal and Newborn Health Improvement Late Pregnancy Dating Study Group, 2020). We believe that utilising this approach has the potential to maximise the sustainability and implementation of this US training programmes without compromising clinical care. Secondly, in contrast to other programmes (Nathan et al., 2014, Baj et al., 2015, Bentley et al., 2015, Kinnevey et al., 2016, Enabudoso et al., 2017, Kim et al., 2021), we purposefully excluded items such as the identification of fetal anomaly or measurement of cervical length and covered only the fundamentals of basic obstetric ultrasound. This approach was agreed with local stakeholders as an appropriate approach, which minimised training time and thus time from work, while maximising the possibility for accurate gestational age assessment in the community in line with WHO guidance.

Our programme was further strengthened by the robust approach to assessment. There is a lack of consensus on the assessment of competency in obstetric ultrasound and a number of previous programmes have omitted practical assessment completely (Adler et al., 2008, Shah et al., 2009, Boamah et al., 2014, Enabudoso et al., 2017, Ahmadzia et al., 2018, Toscano et al., 2021). The OSCE approach to 'hands-on' assessment is well established (Kimberly et al., 2010, Bentley et al., 2015, Vinayak et al., 2017, Wanjiku et al., 2018, Shah et al., 2020), as is the concept of comparing trainee measurements with those obtained by the faculty (Neufeld et al., 2009, Rijken et al., 2009, Sarris et al., 2013, Millar et al., 2018, The WHO Alliance for Maternal and Newborn Health Improvement Late Pregnancy Dating Study Group, 2020). By combining these, we sought to ensure that all aspects of our curriculum were assessed, with trainees demonstrating their ability to explain and document their findings as well as obtain accurate results. The need to achieve this on five consecutive occasions is more demanding than any previous programme, but we felt that it was important to ensure trainees were able to perform consistently and well prior to independent practice.

Local faculty, training midwives in their own health facilities was also an important strength, not only because it supported unbroken scanning experience, but also because the faculty were familiar and trusted colleagues, from whom the midwives were comfortable seeking help. This helped to foster a supportive learning environment, exemplified by the midwives continuing to seek clarification regarding their scans when unsure, predominantly via a designated WhatsApp group (WhatsApp. Facebook Inc. 2020). The local training team were also able to visit the sites intermittently to provide in person support.

Despite delivering successful training, there were some unanticipated challenges, namely power outages, transport strikes and a pandemic. Problems arising as a result of strike action were easily mitigated by adopting a pragmatic approach and moving ‘hands on’ sessions to alternative days, although this did result in some of the post-course responses being overlooked, thus limiting our matched pairs. Although a little disruptive, this ensured adequate numbers of pregnant volunteers were available to undergo ultrasound scans. Delayed timelines as a result of COVID-19 impacted our ability to obtain follow up data for all participants and restrictions not only prevented the UK faculty from travelling to participate, but also necessitated a virtual orientation of the local team members who had not been present for the pilot training. Initially perceived as a set-back, this subsequently emerged as an important strength. Not only was virtual orientation both straightforward and effective, but the training enhanced by the exclusively local faculty, able to build on their pre-existing rapport with the midwives. Crucially, this also demonstrates that the programme can be delivered successfully by local teams out with those who developed it, a strong predictor of success in other settings.

Collating the trainees' images for remote review was also found to be an unexpected challenge. Having initially developed a bespoke mobile application to facilitate this, we found that users with non-android devices were unable to download it and were therefore unable to submit or review images. As a result, trainees were required to print a subset of their anonymised images, which were then collected in person with feedback provided a few days later. Although ultimately effective, this approach resulted in delays to feedback and entailed the ongoing provision of various consumables. Had it been possible under our ethics approvals, a pragmatic approach to overcome this issue might have been to facilitate follow up via WhatsApp. Cheap and readily available, the use of WhatsApp in healthcare projects is well established (Mars et al., 2016, Eke et al., 2021) and this approach would be well aligned with the concept of embedding initiatives into pre-existing systems.

Following the success of this training program, it is being evaluated as part of a mixed methods quasi-experimental trial with the primary outcome of proportion of women with accurate gestational age assessment at 6 health centres in Malawi. The results of this program and progress of the trial have been endorsed by the Reproductive Health Directorate of the Ministry of Health of Malawi, the Association of Malawian Midwives and the Society of Obstetricians and Gynaecologists of Malawi. In addition, we have identified one trainee per site (n=6) with an aptitude for scanning who will be mentored to become the next generation of trainers. Finally, in collaboration with regulatory bodies in Malawi, we are discussing a how to incorporate basic obstetric ultrasound into the nursing and midwifery curriculum in Malawi, demonstrating the ongoing local commitment to upscale this service. Although ours was an experienced group, with an average of 10.5 years clinical experience, we believe that by integrating this programme into midwifery training ultrasound skills could be made accessible to midwives at all professional levels.

4.10 Conclusion

The TUDA training program is an effective method of training midwives in basic obstetric ultrasound in a two week period, thus overcoming a major barrier cited by previous initiatives (Shah et al., 2015, Wanyonyi et al., 2017, Kim et al., 2018, Lamprecht et al., 2018, Maw et al., 2019). This program has the potential to contribute to efforts to achieve coverage of current WHO recommended guidance for basic obstetric ultrasound in LMICS. By empowering local faculty to provide supportive supervision in the trainees primary place of work, local acceptability was increased and basic implementation hurdles overcome during the training phase facilitating progression to independence and retention of skills.

4.11 Acknowledgements

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4.12 Funding

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4.13 Chapter Conclusion

In support of the hypotheses of this Thesis, the work presented in **Chapter 4** supports the hypothesis that fetal femur length could be used to determine gestational age in LMICs and that ultrasound-naive practitioners could be trained to competency in basic obstetric ultrasound in less than 2 weeks. Furthermore, the finding that over half (54%) of participating pregnant women were unable to recall their LMP, provides additional justification for the need to improve estimates of gestational age within this population.

The ease and speed at which trainees were able to develop skills in dating pregnancies using FL, and the consequent impact on training time, suggests that this approach may indeed provide a pragmatic solution to the barriers in training adequate numbers of healthcare workers, previously encountered as a result of long training programmes. Likewise, the efficacy of this approach may be enough to justify the acceptance of the small decrease in accuracy seen as a result of using FL for the determination of gestational age using FL alone, as compared with the more complex ‘gold standard’ composite measurements of AC/HC/FL.

While **Chapter 4** evaluated the efficacy of this novel training programme, it did not consider its implementation, a vital component in the appraisal of initiatives and their potential sustainability and longevity. In **Chapter 5** this was explored by the evaluation of the programme in the context of the RE-AIM framework.

Chapter 5

Implementation of a novel ultrasound training programme for midwives in Malawi: A mixed methods evaluation using the RE-AIM framework.

The following materials have been submitted for publication in Frontiers in Health Services under the same title by Alexandra C Viner (AV), Monica P. Malata (MPM), Medrina Mtende (MM), Dr Gladys Membe-Gadama (GMG), Dr Martha Masamba (MMa), Catherine Bamuya (CB), Enita Makwakwa (EM), Professor David Lissauer (DL), Dr Sarah J. Stock (SS), Professor Jane E. Norman (JN), Professor Rebecca M. Reynolds (RR), Dr Brian Magowan (BM), Dr Bridget Freyne, Dr Luis Gadama and Professor Effie Chipeta (EC) and the DIPLOMATIC Collaboration.

AV prepared the protocol for this study, with input and guidance from all authors. MPM, MM, CB and EC established the qualitative framework, with AV, GMG, DK, MM, BM and LG developing the education package. GMG, MM, EM and LG co-ordinated the delivery of the training in Malawi, with MPM, MM, CB and EC overseeing the qualitative data collection and analysis. Quantitative data was analysed by AV, who also prepared the first draft of the manuscript, under the guidance of SW, SS, JN, DL, BM, BF, LG and EC. All authors provided critical insight for the manuscript.

In summary, this work demonstrates that although effective in improving the knowledge, confidence and practical skills of the participating midwives, there were a variety of challenges complicating the implementation and maintenance of this education package. While our adaptive approach mitigated many issues, some problems persisted, especially with regard to subsequent supervision and the maintenance of services. Although very motivated to participate in the training, the midwives reported varying levels of satisfaction towards the education package, largely on account of the varied provision of supervision and mentorship across sites and voiced concerns about staffing and workload. These findings were reflective of previous literature (Dawson et al., 2014, Shah et al., 2015, Ahman et al., 2018, Maw et al., 2019, Vesel et al., 2019).

5.1 Abstract

5.1.1 Introduction

Despite recommendation that all women receive an ultrasound in pregnancy prior to 24 weeks', this remains unavailable to many women in low-income countries where trained practitioners are scarce. Although many programmes have demonstrated efficacy, few have achieved longterm sustainability, with a lack of information about how best to implement such programmes. This mixed-methods study aimed to evaluate the implementation of a novel education package to teach ultrasound-naive midwives in Malawi basic obstetric ultrasound, assessing its impact in the context of the Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework.

5.1.2 Methods

The study ran across six sites in Malawi between October 2020 and June 2021, encompassing three phases; pre-implementation, implementation and post-implementation. 29 midwives underwent a bespoke education package with matched pre and post course surveys assessed their knowledge, attitudes and confidence and 'hands on' assessments evaluating practical skills. Training evaluation forms and in-depth interviews explored their satisfaction with the package, with repeat assessment and remote image review evaluating maintenance of skills.

5.1.3 Results

28/29 midwives completed the training, with significant increases in knowledge, confidence and practical skills. Adherence to the education package varied, however many changes to the proposed methodology were adaptive and appeared to facilitate the efficacy of the programme. Unfortunately, despite reporting approval regarding the training itself, satisfaction regarding supervision and follow up was mixed, reflecting the difficulties encountered with providing ongoing in-person and remote support.

5.1.4 Conclusion

This programme was successful in improving trainees' knowledge, confidence and skill in performing basic obstetric ultrasound, largely on account of an adaptive approach to implementation. The maintenance of ongoing support was challenging, reflected by trainee dissatisfaction. By evaluating the success of this education package based on its implementation and not just its efficacy, we have generated new insights into the barriers to sustainable upscale, specifically those surrounding maintenance.

5.2 Background

The WHO has regularly cited the need for improved estimates of gestational age, a fundamental component of obstetric and neonatal care, as a public health priority (Vogel et al., 2015, WHO. 2015, Lee et al., 2019), not only to enhance clinical care, but to strengthen global reporting of pregnancy complications and to facilitate evaluation of context-specific interventions to improve outcomes. Although considered the most precise way to date pregnancies (NICE, 2008, Butt et al., 2014, WHO. 2016, Pettker et al., 2017), and recommended by the WHO (WHO. 2016), ultrasound remains unavailable to the majority of women living in LMIC, where gestational age is determined from either the LMP or abdominal palpation, both of which are substantially less accurate than ultrasound (Treloar et al., 1967, Baskett et al., 2000, Lee et al., 2020).

Scaled provision of ultrasound is challenging for a number of reasons (Seffah et al., 2009, Shah et al., 2015, Puchalski et al., 2016, Wanyonyi et al., 2017, Kim et al., 2018, Maraci et al., 2020), not least because of the lack of trained practitioners (Shah et al., 2015, Kim et al., 2018). Although many programmes have demonstrated efficacy in training healthcare works to perform ultrasound examinations (Shah et al., 2009, Kimberley et al., 2010, Sarris et al., 2013, Boamah et al., 2014, Greenwold et al., 2014, Swanson et al., 2014, Enabudoso et al., 2017, Millar et al., 2018), few have become embedded within pre-existing systems and achieved longterm sustainability, perhaps in part due to a relative lack of information about how best to implement such programmes (Viner et al., 2022).

This mixed-methods study aimed to evaluate the implementation of a novel education package to teach ultrasound-naive midwives in Malawi basic obstetric ultrasound, assessing its impact in the context of the RE-AIM framework (Glasgow et al., 1999).

5.3 Methods

This study was undertaken as part of a ‘parent’ study exploring what factors may influence the upscale of basic antenatal ultrasound in LMIC settings (PACTR202010788566263). It was carried out across 6 sites in Malawi, selected to encompass both urban and rural facilities. The pre-implementation phase began in October 2020 and lasted 14 weeks. Implementation took place for 4 weeks in January-February 2021 and the post-implementation phase extended for 18 weeks until the end of June 2021.

5.3.1 Pre-Implementation Phase (14 weeks)

5.3.1.1 Development of Education Package

The education package was developed by a team of Obstetricians from Malawi and the UK and aimed to teach the midwives basic obstetric ultrasound, namely to identify the number of fetuses, confirm fetal viability and presentation and to determine gestational age by measurement of the fetal femur length. Specific consideration was given to implementation, for example, how to facilitate ongoing supervision and mentorship, and the programme also included a number of small group sessions encouraging the midwives to think about how they would incorporate scans into their routine practice. It was piloted twice in early 2020 and these iterations were instrumental in shaping the final programme (Viner et al., 2022). In order to facilitate remote image review, we also developed a bespoke app to permit image transfer and messaging between the trainees and faculty.

5.3.1.2 Facility Preparation and Participant Recruitment

The participating sites were all primary level facilities, serving populations of between 20,300 to 596,230. 3 were in Blantyre, 1 in Lilongwe and 2 in the northern district of Karonga. The number of staff providing antenatal care at these sites ranged from 6 to 23 and in order to preserve the continuity of subsequent scanning services while accounting for staff absence or relocation, we sought to train a minimum of 4 midwives per site. Midwives were invited to participate having been identified by their local District Nursing Officer (DNO) as a key provider of antenatal care to women at the participating facilities and engaged in service improvement.

Trainers were recruited based on pre-specified criteria. All must have received training in basic obstetric ultrasound, have at least 12 months experience of performing ultrasound independently, and be confident to troubleshoot any problems the trainees may encounter. Having been provided with a comprehensive training manual, the faculty were orientated to the programme virtually as a result of the ongoing COVID-19 pandemic. This brief was delivered by the team responsible for the course development and included the content and delivery of the curriculum, how to facilitate the ‘hands on’ sessions and how to assess the trainees according to standardised criteria.

Each site was provided with a new, locally sourced, DP-10 ultrasound machine (Mindray, Shenzhen, China) and consumables including ultrasound gel and tissues. Training materials, including comprehensive printed handbooks for both trainees and trainers were also distributed to participating sites, along with copies of the context specific guideline.

To ensure adequate numbers of client volunteers were available to participate in the ‘hands on’ sessions of the training programme, participating sites were encouraged to recruit women in advance and request they attend on specific days. Pregnant women were eligible to participate as client volunteers if they were over 18 years old, thought to be over 14 weeks gestation and able to provide informed written consent. All were provided with a small allowance to cover their travel expenses.

5.3.2 Implementation Phase (4 weeks)

5.3.2.1 Delivery of Education Package

The education package was delivered across the 6 sites in January-February 2021 with the ultrasound training programme consisting of 2 days didactic teaching, followed by 8 days of supervised ‘hands on’ practice, as shown in Figure 5-1. Overview of the ultrasound training programme.

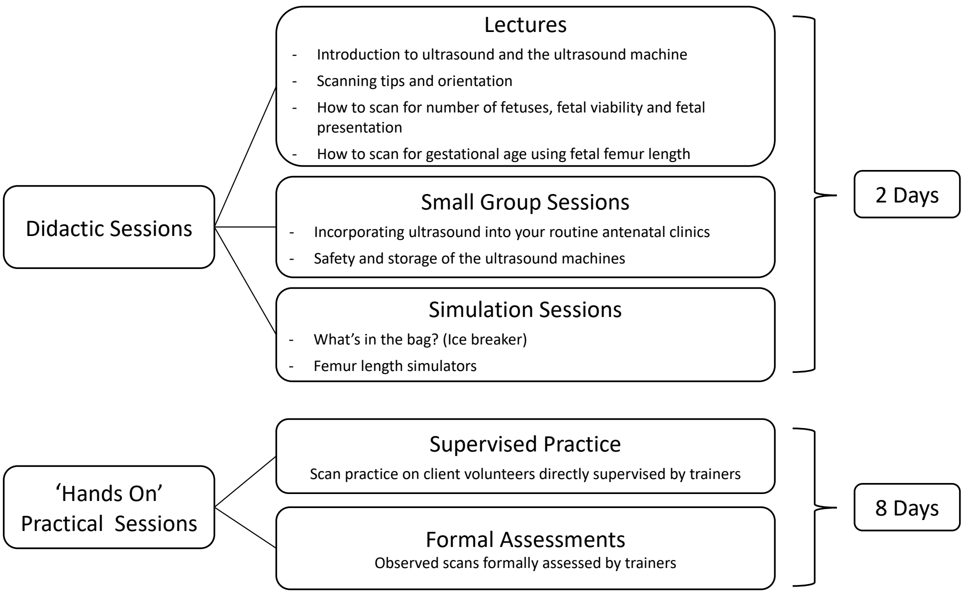

Figure 5-1. Overview of the ultrasound training programme.

5.3.3 Post Implementation Phase (18 weeks)

Remote supervision and image review was provided for 3 months following training. Trainees and faculty were requested to download our bespoke app to their personal devices and each was given an individual pin. Trainees were required to submit images which were assessed against pre-specified criteria by two independent reviewers experienced in obstetric ultrasound. Anonymised feedback was provided to all trainees every 1-2 weeks. Figure 5-2. provides an overview of the implementation process.

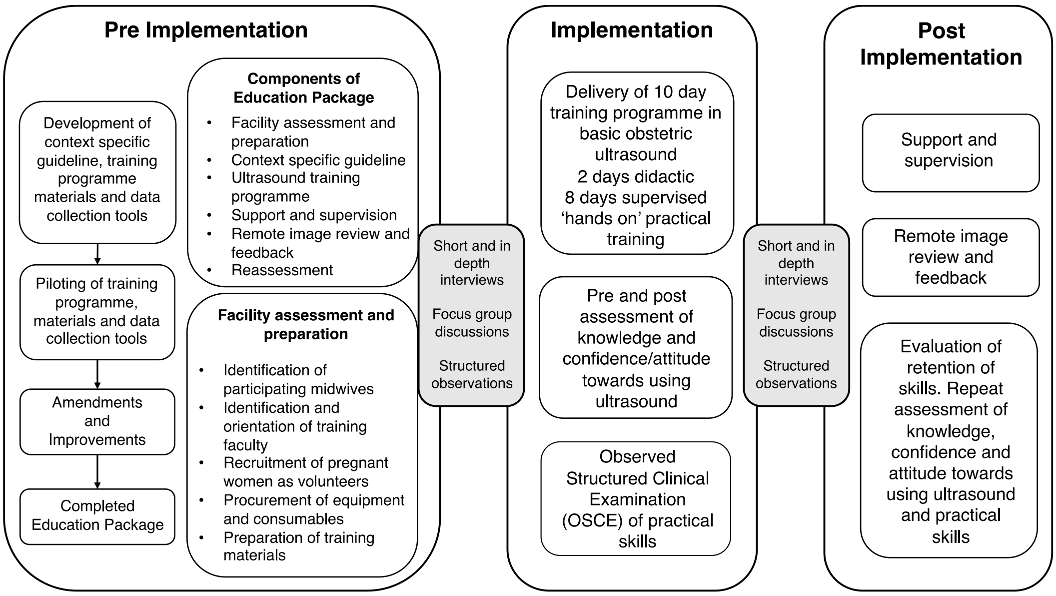

Figure 5-2. Overview of the implementation process.

5.3.4 Data Collection and Outcomes

As part of the training programme, each trainee undertook a 24-question multiple choice knowledge test to assess their theoretical understanding of ultrasound and completed a questionnaire using a 5 point Likert scale (1=Strongly Disagree, 5=Strongly Agree) to assess their attitude towards, and confidence using, ultrasound. Both of these assessments were repeated immediately after completion of the training and again 3 months later. Trainees also undertook Observed Structured Clinical Examinations (OSCEs) to assess their practical skills and completed a post course evaluation form at the end of the programme. All data were collected on encrypted, password protected tablets and transferred to the secure study server daily. A proportion of purposively sampled midwives (n=14, 48%) also underwent an in-depth interview at the end of the programme.

In-depth interviews were undertaken by trained research assistants under the direct supervision of the authors MPM and CB. Sampling was purposive, targeting only the midwives who had undergone the ultrasound training and the interviews took place at the study sites until data was saturated. The broad topic guide sought to explore the midwives response to training and the subsequent support they received, as well as their overall attitude towards using ultrasound. Interviews were conducted in either Chichewa or English, according to the interviewee's preference, and were recorded and transcribed verbatim. All transcripts were translated into English by trained transcribers, with verification undertaken by either MPM or CB. To ensure confidentiality, participants were dissuaded from using names and all recordings were stored using unique identifiers. Interviews were undertaken April-May 2021, approximately 10 weeks after the ultrasound training.

5.3.5 Data Analysis

Outcomes were evaluated in the context of the RE-AIM framework, with Table 5-1 providing details of this process, along with outcome indicators and the relevant data sources.

Quantitative data were analysed using SPSS (IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp). Pre and post course questions evaluating similar concepts were allocated into 4 groups for analysis; perceived risk, beliefs regarding the role of ultrasound, confidence and attitudes towards using ultrasound, with reliability of the groupings tested using Cronbach's alpha. If scoring >0.8, good reliability, they were then analysed as a group using a Wilcoxon signed rank test. If a group did not demonstrate adequate reliability, scoring <0.8, the statements were analysed as single items. Matched pre and post course knowledge tests were analysed using paired t tests. A p-value < 0.05 was considered statistically significant.

For the qualitative data, a thematic framework was generated based on the topic guides, with revisions undertaken as new themes emerged. Transcripts were iteratively coded using NVivo software (QSR International Pty Ltd), with codes grouped into categories and then themes. These were reviewed to identify patterns and make comparisons across the groups.

Table 5-1. Implementation process outcomes and corresponding data sources

RE-AIM component	Indicators	Data Sources
Reach	Number of midwives participating and their demographic/professional characteristics Number of clients recruited	Enrolment records
Effectiveness	Proportion of midwives certified as competent at the end of training	Assessment scores
	Change in perception and confidence	Pre and post course questionnaires
Adoption	Motivation to attend training	Post course evaluation form
	Acceptability of training	In-depth interviews
Implementation	Context and setting	Facility assessments
	Education methodology	Education package
	Fidelity to education package and adaptions	Anecdotal reports of training In-depth interviews
	Cost	Administrative records
Maintenance	Strategy to ensure integration into pre-existing services and long-term provision of ultrasound	Protocol In-depth interviews
	Quality assurance/retention of skills	Remote image review and repeat assessment scores

5.4 Ethical Considerations

As key stakeholders, the Ministry of Health in Malawi and the Directors of Health and Social Services (DHSS) of the participating sites were involved in the planning and implementation of this project. All participants (trainees and client volunteers) provided informed written consent, with participant information leaflets and consent forms available in both Chichewa and Tumbuka, as well as in English. This study was approved by the University of Edinburgh and the University of Malawi – College of Medicine Research and Ethics Committee (COMREC) P08/19/2768.

5.5 Results

5.5.1 Reach

All midwives who were invited to participate did so. 29 midwives participated in the training, all of whom held either a Diploma or Degree in Nursing/Midwifery and none had any previous experience of using ultrasound in pregnancy. They had an average of 11 years of clinical experience, ranging from 1-30 years. All undertook practical assessments, with 22 completing matched pre and post course knowledge tests and 23 completing both pre and post course questionnaires. Post course evaluation data was available for 19 participants and 14 underwent an in-depth interview.

Training was provided by 15 trainers, all of whom held either a Medical Degree or a Diploma in Clinical Medicine or Radiology. 12 had undergone formal training in ultrasound, with 3 receiving 'on the job' training from experienced practitioners. They had an average of 6 years' experience in performing obstetric ultrasound, ranging from 1-16 years. Trainers were paid to contribute and all who were invited to participate did so.

395 pregnant women participated in the 'hands on' element of the training, and of these 212(54%) were unable to recall their LMP. Within the group who did know their LMP, a further 85 were assigned a new gestational age based on the measurements obtained by the trainer, suggesting that their LMP had been inaccurate. In total therefore, ultrasound improved the accuracy of pregnancy dating for 297(75%) of the women who participated.

5.5.2 Effectiveness

28 midwives achieved the criteria specified to 'pass'; 5 consecutive scans where they achieved both a score of >65% on the OSCE and determined the gestational age to within +/- 7 days of the trainer, with one midwife unable to complete the programme due to illness. Knowledge improved after the training, as did the midwives' confidence in performing ultrasound scans, as presented in Table 5-2. This quantitative increase in confidence was mirrored in the midwives' reflections on their progress.

> "Though by and by, the more you practice the more you develop some experience and we tend to laugh '*ah ah the same patients we could spend so much time with but now we just go and follow the steps, nothing*

complicated.' We have indeed gained some momentum." *Midwife from rural site K*

Table 5-2. Summary of quantitative results

Knowledge Test (24 questions) N=22	**Mean scores (SD)**		**Paired t test**
	Pre	Post	p= <0.0001
	10.2(3.3)	18(2.5)	
Pre and Post Course Questionnaire N=23	**Median Scores**		**Wilcoxon Signed Rank Test**
	Pre	Post	
- Beliefs around importance of ultrasound	5	5	p= 0.092
- Confidence performing ultrasound	2	5	p= <0.0001
- Interest in performing ultrasound	5	5	p= 0.248
Practical Assessments N= 405	Pass		Fail
	351		54

5.5.3 Adoption

5.5.3.1 Motivation to attend training

The most common reason the midwives chose to participate in the training, was that they believed skills in ultrasound would help them provide better care and also enhance their own skills. They further expressed their frustration at the limitations of trying to determine gestational age clinically.

> "Most of the women do not know their last date of menstrual period so with the scanning introduced; in most cases we do find the EDD which most of the women did not know." *Midwife from urban site Z*

The post course questionnaire data (Table 5-2. Summary of quantitative results) supported an overall increase in the midwives' beliefs regarding the importance of ultrasound in antenatal care after training, although this result did not reach significance. The midwives were also motivated on a personal level, believing that gaining skills in ultrasound would be important for their professional development, although one expressed disappointment at not being paid extra to perform scans.

> "This training is useful because it's like we are increasing our knowledge and our CV (Curriculum Vitae) is also updated... this study is very beneficial in all levels, whether for the facility or individually." *Midwife from rural site K*

> "The investigators need to motivate healthcare staff by giving them something.. this is the only study that we are involved with without being paid anything… healthcare staffs are not motivated to help". *Midwife from urban site Z*

5.5.3.2 Acceptability of training

The midwives welcomed the concept of training in ultrasound, with 95% (n =18/19) agreeing or strongly agreeing that the course was relevant to them. 100% (n= 19) reported that they had enjoyed the course.

> "To us it is a welcomed idea… because now we have added another knowledge that we were not able to do… like a next step of caring for our patients." *Midwife from urban site Z*

Post course questionnaires revealed no difference in the midwives interest in performing scans (Table 5-2. Summary of quantitative results). A third of respondents to the post course evaluation (n=6/19) requested the incorporation of additional components, for example liquor volume.

> "The gap is there as we cannot scan pregnancy in the first trimester, of course I can just see a gestation sac but I cannot determine gestation age because we were given the limits… We should be taught all areas of scanning." *Midwife from urban site Z*

5.5.4 Implementation

5.5.4.1 Cost of Implementation

The total cost of delivering this programme across 6 sites was £55,182. This included facility preparation, trainee and trainer allowances, client travel reimbursement, refreshments, all training materials and 6 new ultrasound machines.

5.5.4.2 Adaptations to implementation

As a result of COVID-19 restrictions, the theoretical component of the course was delivered virtually, with all trainees attending simultaneously. To enable trainers to rotate to the different sites, delivery of the ‘hands on’ sessions were staggered. All trainees attended both the online theoretical and the practical ‘hands on’ sessions, which, with the exception of the simulation sessions, were delivered according to the training manual. Importantly, a ratio of 1:4 trainers to trainees was maintained for all ‘hands on’ sessions.

> “From day one we were learning step by step until practicals. We were taught to follow an order of things.” *Midwife from Urban Site A*

Although all trainees completed practical assessments, the overall number of clients recruited per site varied greatly, affecting trainees’ scanning exposure. The total number of scans performed by individual trainees ranged from 7-38, with an average of 18. Likewise, there were some issues with data collection, with not all trainees completing all forms. On one occasion this was due to an uploading error, however at other times it appears to have been oversight.

The greatest deviation from proposed methodology occurred in the provision of mentorship and follow up, which was purposed to occur as a hybrid of site visits and remote image review. Unfortunately, competing clinical duties, especially in the context of COVID-19, limited opportunities for the faculty to visit the sites and users with non-android devices were unable to download the bespoke app developed for remote review. Consequently, trainees were required to print a subset of their anonymised images, which were then collected in person with general and targeted feedback provided a week later.

5.5.4.3 Fidelity to training package

Despite reporting satisfaction with the training course itself, attitudes towards the subsequent supervision was mixed, varying between sites. Some midwives viewed this favourably, whereas others felt the supervision had been lacking.

> "Training was enough because we had supervisors who were helping us do the scanning properly and right now I would say we have support..." *Midwife from urban site A*

> "We feel that the support being provided is very good from the people who taught us this intervention…" *Midwife from urban site S*

> "…But we are somehow lacking supervision." *Midwife from rural site C*

> "Say maybe it is thirty percent. Cause I haven't been mentored but during the rotation for the other team, they were mentored once." *Midwife from urban site Z*

5.5.5 Maintenance

Aside from seeking refresher training and more robust mentorship, the midwives expressed strong sentiment that in order for ultrasound services to be sustained, efforts should be made to train more staff. Not only were they concerned about workload, but interruption to services when staff moved posts. They felt that the government should be involved in trying to facilitate this.

"For effective implementation of ultrasound scanning intervention, every health worker must be trained..." *Midwife from rural site C*

"It must involve every midwife because staff who are currently working at antenatal department won't be working there forever." *Midwife from urban site A*

"The main problem is workload because there are a lot of clients here but the nurses who provide scanning are few..." *Midwife from urban site A*

"The NGO has specific time to support us so after those have left the government should take over so that the project is sustainable" *Midwife from urban site S*

They reported improved interpersonal relationships within the health facilities as a result of the introduction of ultrasound, feeling this to be a protective factor for longterm sustainability.

"The support being provided by our colleagues is good as well..." *Midwife from urban site M*

"When I fail on something I call a colleague for help." *Midwife from urban site Z*

5.6 Discussion

We have demonstrated that this bespoke education package was effective in improving the knowledge, confidence and practical skills of ultrasound-naive midwives in Malawi and that the recruited midwives were very motivated to participate in the training. Indeed, as 75% of the pregnant women who participated had either an unknown, or inaccurate gestational age, the potential benefit of initiatives such as this to enable midwives to improve pregnancy dating is clear. The midwives were largely satisfied with the programme, although there was some concern about the varied provision of mentorship and follow up. Implementation was challenging for a number of reasons, not least the COVID-19 pandemic, however many issues were overcome by the adoption of a flexible and pragmatic approach. A detailed description of the content and evaluation of training programme is provided elsewhere (Viner et al., 2022).

The 'Reach' dimensions of the programme were largely satisfactory. Despite the midwives being a relatively senior cohort, this appeared to be a fair representation of the skill mix at the participating sites. While this may have influenced the time taken to develop practical skills, the fact this was variable within the group is very typical of training in ultrasound (ISUOG, 2013, Royal College of Radiologists, 2017). All midwives invited to participate did so, reflecting the interest in performing ultrasound scans which was also expressed during the qualitative interviews. Unfortunately, in order to preserve normal service provision at the health centres, not all midwives who worked there were able to attend. The diversity of the trainers, both in their background and experience, reflects the limited number of trained practitioners in LMICs who may available to facilitate such a programme (Shah et al., 2015, Kim et al., 2018, Viner et al., 2022), further demonstrated by the need for some to rotate around the sites to provide training. Although all trainers invited to participate did so, they were paid for their involvement which may have influenced their decision to contribute. Unfortunately, we do not have any information on the number of pregnant women who declined to participate and are therefore unable to comment on the proportion who were willing to undergo ultrasound, although this is being explored as part of the ‘parent’ study.

Our education package was effective in improving the midwives’ knowledge, confidence and practical skill in performing basic obstetric ultrasound, although satisfaction with the training was mixed. Differences in opinion were largely grouped by site, suggesting disparity in each site’s approach to training and follow up. Unfortunately, while being complicated by multiple connection issues, the virtual sessions also meant that the midwives missed out on the simulation sessions; a vital component of the training package which would have enabled them to familiarise themselves with both the machine and basic scanning techniques prior to scanning pregnant women (Nitsche et al., 2013, Pereira et al., 2015, Orr et al., 2018). Some of the health centres suffered power outages during training, limiting practical experience, with others affected by local transport strikes, preventing the trainers from reaching the sites and therefore forcing sessions to be moved to different days. Despite recommending that pregnant women were approached in advance, recruitment of client volunteers to assist with the ‘hands on’ sessions was very varied between sites, heavily impacting on trainees’ individual exposure to practical experience.

The ‘Maintenance’ dimension of this programme had mixed results. Plans for remote image review were complicated by users with non-android devices being unable to download the bespoke app and therefore being unable to submit or review images. Consequently, trainees were required to print a subset of their anonymised images, which were then collected in person, with feedback provided a few days later. Although sufficient, this caused delays in providing feedback and required the additional provision of consumables such as printer paper. Had our ethical approval permitted, an alternative option would have been to facilitate follow up via WhatsApp (Facebook Inc, 2020). Cheap and readily available, the use of WhatsApp in healthcare projects is well established (Mars et al., 2016, Eke et al., 2021) and as this is the current way in which midwives seek advice, it would be well aligned with the concept of embedding initiatives into pre-existing systems (Pantoja et al., 2014, Imamura et al., 2016).

Our qualitative findings are largely in keeping with the published literature regarding similar endeavours, with concerns about staffing, workload and the migratory workforce reflective of previous sentiments (Dawson et al., 2014, Shah et al., 2015, Ahman et al., 2018, Maw et al., 2019, Vesel et al., 2019). Likewise, despite being motivated to perform ultrasound examinations, there is often resistance to being asked to do so without additional renumeration (Shah et al., 2015, Kim et al., 2018). Interestingly, this is the first study to suggest that the introduction of ultrasound may have a specific role in improving team dynamics.

Our study does have some limitations. Unfortunately, having to move some sessions to alternative days meant that post course tests/questionnaires were overlooked, limiting our matched pairs. Likewise, delayed timelines as a result of COVID-19, resulted in a lack of follow up data for all participants, therefore data pertaining to the retention of skills should be interpreted with caution. The strength of the qualitative data could have been improved by including formal structured observation of training sessions and in-depth interviews with the training faculty, however this was not possible within human resource constraints. Finally, the implementation of this education package was undertaken within the context of a research study and therefore it should be acknowledged that it will have benefitted from additional funds and support which may not have been available without substantial buy-in from the Malawian Government. That said, the progress of this programme has been endorsed by the Reproductive Health Directorate of the Ministry of Health of Malawi, the Society of Obstetricians and Gynaecologists of Malawi and the Association of Malawian Midwives, with discussions ongoing about how to incorporate this into the nursing and midwifery curriculum in Malawi.

This package was strengthened by being delivered exclusively by local trainers, a contrast to many similar programmes and an important feature for sustainability. Not only were the local team better placed to understand the complexities of the setting, but also better equipped to troubleshoot any unexpected issues. A huge effort was made to adapt the training programme to try to mitigate the effects of COVID-19 and the scope for reactive and iterative changes within the protocol meant the approach to implementing the package was both pragmatic and representative of a ‘real world’ scenario. By evaluating the implementation of this education package using the RE-AIM framework, we have been able to highlight the specific domains which require further input, in this case ‘maintenance’. In doing so we believe this will help focus efforts to optimise uptake and sustainability.

5.7 Conclusion

By evaluating the success of this education package based on its implementation and not just its efficacy, we have generated new insights into the barriers to sustainable upscale, largely those of maintenance. While aspects of implementation were challenging, an adaptive approach meant that this education package was successful in improving the knowledge, confidence and practical skills of a representative cohort of ultrasound-naive midwives in Malawi. However, the subsequent maintenance of support and supervision was problematic, highlighting the need for more work to determine the optimum approach to facilitate this.

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5.9 DIPLOMATIC Collaboration

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5.11 Chapter Conclusion

The work presented in **Chapter 5** supports the hypothesis that it would be feasible to deliver this education programme across multiple sites in Malawi, however highlighted some areas for improvement. It explored the factors influencing the both the implementation of the training programme and its subsequent maintenance, reporting results in the context of a recognised implementation framework. By highlighting the specific aspects of implementation that were particularly challenging, new insights have been generated regarding the barriers to sustainable upscale, providing opportunities to tailor future efforts and resources to address these concerns

Chapter 6 provides an overview of the findings of this Thesis and how they contribute to the current body of evidence. By reflecting on both the successes and unique challenges encountered as part of this work, I consider how it will inform future endeavours and guide ongoing efforts for the expansion and widespread provision of sustainable obstetric ultrasound in LMICs.

Chapter 6

Discussion

6.1 Summary of Results

The work presented in this Thesis was based on the hypotheses that fetal femur length could be used to determine gestational age in LMICs, that practitioners with no prior experience of ultrasound could be trained to competency in basic obstetric ultrasound in less than 2 weeks, and that it would be feasible to deliver a bespoke ultrasound training programme across multiple sites in Malawi.

Despite growing appreciation for the importance of accurate estimates of gestational age in LMICs, and recommendation from the WHO that all women receive at least one ultrasound prior to 24 weeks', (WHO, 2016) this remains unavailable to the majority of women in LMICs. The lack of trained practitioners is considered a significant barrier to the realisation of universal access to ultrasound, (Shah et al., 2015, Kim et al., 2018, Maw et al., 2019) with previous attempts to upscale ultrasound yielding mixed results (Kim et al., 2018, Smith and Nakimuli., 2020). Although effective, the length and complexity of many previous training programmes have been prohibitive, with practitioners struggling to secure cover for their clinical duties in order to provide or attend training (Shah et al., 2015, Kim et al., 2018, Maw et al., 2019).

Findings of a systematic review presented in **Part 2 of Chapter 1**, suggested that there are major inconsistencies in the current provision of training in ultrasound, further compounded by significant variation in how initiatives are reported. The majority of programmes failed to meet international standards recommended by the ISUOG and WHO, and only a fifth undertook assessments where trainees were required to achieve a certain standard to pass. Furthermore, very few of the previous initiatives had explored the subsequent implementation of ultrasound within pre-existing healthcare structures, or in the case of overseas partnerships, how these could be sustained after the cessation of external funding.

The work presented in **Chapter 3** drew on the findings of this review and described the development and piloting of a novel education package to teach midwives in Malawi to date pregnancies using fetal femur length. This included the development of a range of training materials and the generation of a context specific guideline to support and empower the midwives to incorporate ultrasound into their routine practice. While many aspects were successful, there were unanticipated challenges including client volunteer recruitment, inequality of scanning opportunities and difficulties with the proposed methods of assessment. However, in troubleshooting these issues, the programme was improved and refined, demonstrating the benefits of thorough piloting prior to widespread implementation.

The work presented in **Chapter 4** supports the hypotheses that fetal FL could be used to determine gestational age in LMICs and that practitioners with no prior experience of using ultrasound can be trained to perform basic obstetric ultrasound scans competently within 2 weeks. All trainees displayed significant increases in their knowledge, confidence and practical skills, which were sustained at 3-month follow up. The ease and speed at which trainees developed skills in dating pregnancies using FL, suggests that this is a sufficiently simple measurement that can be taught effectively over a short timeframe, making it a pragmatic and potentially viable option for the upscale of ultrasound to date pregnancies in this setting. The fact that over half (54%) of the participating pregnant women in our cohort of volunteers were unable to recall their LMP, further justifies the need for improved estimates of gestational age within this population.

In **Chapter 5** the implementation of the training was evaluated in the context of the RE-AIM framework (Glasgow et el., 2019), with results supporting the hypothesis that it would be feasible to deliver this programme across multiple sites in Malawi. 'Reach' was satisfactory, with the trainees and trainers largely representative of the skill mix within the Malawian healthcare system, and as described in **Chapter 4, '**efficacy' was excellent. 'Adoption' was satisfactory with the trainees well motivated to attend and pleased with the provision of the training course itself. A pragmatic and iterative approach allowed 'implementation' to be flexible and adaptive, reflecting the modifications that may be required in 'real world' scenarios. Difficulties with the provision of ongoing supervision and mentorship, however, resulted in the ‘maintenance’ aspect of the package not being delivered as intended, thus impacting on the success of the overall implementation. These challenges were reflected in the trainees’ feedback.

In conclusion, this Thesis presents evidence to support a novel strategy to optimise the determination of gestational age estimates in LMIC, taking into consideration the challenges of implementing this into pre-existing healthcare systems and how these may be addressed.

6.2 Clinical and Wider Implications

6.2.1 Recommendations for a standardised approach

As the first to evaluate the evidence pertaining to previous initiatives to train practitioners in LMICs to date pregnancies using ultrasound, the work in this Thesis highlighted important deficiencies in the provision of ultrasound training in this setting. This not only related to inconsistencies regarding the reporting of such initiatives, but crucially relating to programmes’ non-compliance with international recommendations (ISUOG Education Committee, 2013, Royal College of Radiologists, 2017). Unfortunately, aside from emphasising this shortcoming and appealing for greater scrutiny when it comes to delivering ultrasound training in LMICs, there is little that can be done to address the latter. However, we were able to draw on the evidence synthesised by this review to generate new recommendations for the reporting of future initiatives.

Our recommendations may not only help to standardise the description of these training programmes, helping to better facilitate meaningful comparisons and evaluations, but also, we hope, expedite the translation of evidence into practice. We anticipate that if initiatives are reported with the depth of information demanded by our recommendations, then future groups may be better able to replicate and draw on those programmes deemed a success. Furthermore, if reviewed and adopted during the development process, these recommendations may also have the potential to enhance the quality of future training, by prompting teams to consider certain aspects they may previously have overlooked, for example, ongoing quality assurance or how the training will be incorporated and upscaled within the specific constraints of the setting.

6.2.2 Simple and effective training programme

The findings in this Thesis support the novel approach of using fetal FL as a means by which to date pregnancies in LMICs, and the work done has provided an effective, acceptable and context-specific training programme to teach midwives with no experience of ultrasound to be able do so. Although a number of different approaches are currently under evaluation to improve the ultrasound determination of gestational age in LMICs, (Maraci et al., 2017, Van de Heuvel et al., 2019, Maraci et al., 2020, Von Dadelszen et al., 2020), this programme offers a short, simple and immediate option by which to achieve this objective in line with international standards (WHO, 2011, ISUOG Education Committee, 2013). The fact that local teams with no prior experience of the programme were able to deliver it, successfully, with only a brief virtual orientation is a testament to its simplicity and suggests that it may be translatable to other, similar settings, without significant external input. Furthermore, not only has the programme been endorsed by the Reproductive Health Directorate of the Ministry of Health in Malawi, the Association of Malawian Midwives and the Society of Obstetricians and Gynaecologists of Malawi, but since the cessation of study specific support, a further 18 midwives in Malawi have already been successfully trained using these materials, suggestive of early indication of ongoing commitment and sustainability.

6.2.3 Provision of accurately dated birth cohort

Although the cohort of client volunteers involved in this work benefitted from improved estimates of their gestational age, formal evaluation of the clinical implication of this was out with the scope of this work and was instead explored as part of the wider DIPLOMATIC study 'Evaluating the Implementation of Routine Antenatal Ultrasound for Estimating Date of Delivery in Malawi', the results of which are awaited. While the current evidence for the impact of ultrasound in LMICs on pregnancy outcomes remains mixed (Harris and Marks, 2009, Hofmeyr, 2009, Ross et al., 2013, Goldenberg et al., 2019), it is anticipated that the work in this Thesis will serve to strengthen ongoing research activity in Malawi through the provision of accurately dated birth cohorts. 'Generation Malawi' is an upcoming UK Medical Research Council and Wellcome funded longitudinal study of mental and physical health which aims to establish a multi-generational family/birth cohort across MEIRU sites (MEIRU, 2022). Ultrasound pregnancy dating forms part of this protocol and will be facilitated as a result of this programme, highlighting the importance of accurate estimates of gestational age, not only for individuals' clinical care, but also from a public health and research perspective.

6.3 Reflections

6.3.1 Global Research Partnerships

Although huge emphasis was placed on establishing and developing the DIPLOMATIC collaborative according to recognised best practice principles for North-South research collaboratives (Netherlands Development Assistance Research Council, 2001, Costello and Zumla, 2000, Afsana et al., 2009, Swiss Commission for Research Partnership with Developing Countries, 2012, Nuffield Council on Bioethics, 2014, Larkan et al., 2016), there were nonetheless challenges when it came to the day-to-day conduct of this research, with the work in this Thesis representing a complex interplay of scientific, social and ethical influences. The research agenda was agreed following a modified Delphi process (de Meyrick, 2003), led by the interdisciplinary Malawian and Zambian stakeholders, and individual roles and responsibilities were clarified. Not only did this ensure that this work was in line with local policies and priorities, but also that there was no duplication with other groups. Although there is no anecdotal evidence of cultural resistance to ultrasound in Malawi, we sought to involve and obtain the support of community leaders prior to the introduction of these services in local health centres, to ensure this work did not result in any discord between the research team and the local communities. All potential outputs were considered from the outset, with authorship determined according to guidance issued by the International Committee of Medical Journal Editors (ICMJE) (International Committee of Medical Journal Editors, 2021).

Although regular meetings were established between the different work packages, and less frequently between the whole group, communication was sometimes difficult. Meetings were, at times, limited by poor internet connection and the absence of key players. In particular, the dialogue with the group in Zambia was somewhat fragmented. As *Work Package 5,* 'build capacity in early pregnancy scanning' was led by a Malawian Obstetrician, the absence of the Zambian team during planning meetings resulted in the education package being predominantly developed and piloted by the Malawian and UK Obstetricians. Likewise, once the completed package was agreed, the team in Zambia implemented this autonomously, with minimal communication or interaction with the wider group. While this was hugely positive in many ways, it did somewhat limit the opportunities for shared learning and insights, making it difficult to draw and reflect on shared experiences. The lack of personal involvement with the work being undertaken in Zambia, is reflected in the Malawi focus of this Thesis. Despite these complexities, communication was always open, honest and transparent, and, for the most part effective, and the work in this Thesis and that of the wider DIPLOMATIC group, serves as a testament to what can be achieved, almost exclusively, by virtual means.

Following the collective success of the DIPLOMATIC collaboration, further funding has been secured for a number of additional *Work Packages*, most notably for an ongoing ‘South to South’ partnership between researchers in Malawi and Zambia. Not only is this significant for the ongoing development of the GHP, but most importantly, represents a strong ongoing commitment to sustainable and long-lasting strengthening of local research capacity.

6.3.2 Research in Covid-19 Pandemic

Although in many ways, a time of extraordinary global collaboration and scientific progress, the COVID-19 pandemic had a huge impact on many research activities (Department for Business, Energy and Industrial Strategy. 2020, Wyatt et al., 2021, Gao et al., 2021), including ours. Indeed, on a global level, the consequences were intensified, with weakened healthcare systems and economic vulnerability widening the already substantial pre-existing disparities in research capacity and clinical care (Glover et al., 2020).

Despite many devastating effects, the COVID-19 pandemic did facilitate some positive change, namely in the emergence and acceleration of new, more flexible ways of working. The move to ‘virtual’ events has widened access, with more people able to attend conferences and meetings without the logistical and financial constraints of travel, a factor especially pertinent to researchers in LMICs. The recording of these events, with the flexibility to watch at any time, has also been a welcome change (Carr et al., 2021). Likewise, advances in the quality and utilisation of telecommunications systems have permitted groups from all over the world to meet easily and more regularly, without financial constraints, to collaborate (Wyatt et al., 2020, Keesara et al., 2020, Kniffin et al., 2021), strengthening global networks and partnerships.

Unsurprisingly, the COVID-19 pandemic had a huge impact on this work, affecting not only the timescales, but also the logistics of our programme delivery. Having revised and improved the education package as a result of the pilot work, it then required further adaptation to facilitate virtual delivery of the theoretical components, which unfortunately resulted in the trainees foregoing valuable simulation activities, a key component of the preparation for the 'hands on' sessions. Likewise, my being unable to travel to assist in facilitating the training was not only a personal disappointment, but also required additional preparatory activity to enable the local teams to deliver the programme. This involved additional detail being incorporated into the training manual and the provision of a virtual 'training of the trainers' session. Unfortunately, there was no opportunity to pilot this new approach or for the local trainers to practice running the sessions.

Naturally, there were some resulting issues, predominately relating to omissions in post-course data collection, which led to fewer matched pairs of assessments than desired. Likewise, staff shortages and conflicting clinical responsibilities, already problematic but undoubtedly exacerbated by COVID-19, affected the trainers' ability to visit the sites as intended to provide periodic ‘in-person’ supervision. As described in **Chapter 5**, this impacted heavily on the midwives’ satisfaction with the programme and may have, to some extent, hindered the ongoing development of their confidence and skills, although this was not evident in the subset available for follow up. Although not directly impacting the work described in this Thesis, the delays to the DIPLOMATIC study ‘Evaluating the Implementation of Routine Antenatal Ultrasound for Estimating Date of Delivery in Malawi’ encountered as a result of the pandemic, significantly shortened the time available for post implementation data collection. Despite these challenges, there were also unanticipated benefits which proved advantageous for the implementation of the education package. These are described below.

6.4 Strengths and Limitations

The systematic review, presented in **Chapter 1 Part 2**, was, to our knowledge, the first to explore the evidence pertaining to training in ultrasound to determine gestational age, providing invaluable insight into the strengths and limitations of previous initiatives. By drawing on the experience of others, we were able to develop a novel, context specific programme and maximise on pedagogical and logistical approaches that had previously proven effective. We believed that the generation of a series of recommendations would optimise the design, delivery and reporting of future training programmes. Indeed, this enabled us to structure our education package to fulfil these standards, remain compliant with ISUOG guidance (ISUOG Education

Committee, 2013) and to give specific consideration to implementation and upscale. In training midwives to perform these ultrasound scans, this work was also aligned with the WHO concept of ‘task-shifting’ (WHO, 2008).

The ease and speed at which trainees developed skills in dating pregnancies using FL, and the relatively brief training time, suggest that although not commensurate with the international ‘gold standard’, this pragmatic approach may provide a ‘real world’ context specific solution to the barriers previously encountered as a result of long training programmes (Shah et al., 2015, Kim et al., 2018, Maw et al., 2019). Likewise, we believe the proven efficacy of this approach sufficient to justify accepting the small decrease in accuracy of gestational age estimates incurred as a result of using FL as a single parameter, versus the more complex ‘gold standard’ composite measurements of AC/HC/FL.

In contrast to many other programmes developed in collaboration with groups from high income countries (Kimberley et al., 2010, Wylie et al., 2013, Boamah et al., 2014, Greenwold et al., 2014, Nathan et al., 2017,) our training was delivered exclusively by local faculty who were orientated to the programme virtually. This was a considerable strength, not only because it supported unbroken scanning experience, but also because the faculty were familiar and trusted colleagues, from whom the midwives were comfortable seeking help. Indeed, the fact that local teams with no prior knowledge or experience of this education package were able to deliver it so effectively and with so little input from the development team, is a testament to its transferability, demonstrating that with a relatively similar infrastructure this programme could potentially be delivered, largely as intended, in very similar settings. The only real requirement is access to suitable ultrasound machines, an adequate ratio of trainers to trainees and sufficient numbers of pregnant client volunteers to facilitate ample ‘hands on’ experience. That much of this work was achieved virtually, even pre-pandemic, is also a strength and an important consideration for ongoing sustainability.

Most important however, was the noticeable shift in the ownership of the project, which moved from the DIPLOMATIC collaborators responsible for developing the education package, to the team of local practitioners ultimately delivering it. As the on-site trainers rapidly gained confidence in troubleshooting and managing issues independently, there was a noticeable change in their attitude towards the programme. They appeared to assume greater ownership of activities, a factor essential for equitable partnerships and known to be an important predictor of sustainability (Netherlands Development Assistance Research Council, 2001, Costello and Zumla, 2000, Afsana et al., 2009, Swiss Commission for Research Partnership with Developing Countries, 2012, Nuffield Council on Bioethics, 2014, Larkan et al., 2016). Indeed, such is the enthusiasm for the programme, that a further 18 midwives have already been trained using this approach, after the cessation of study support, demonstrating an ongoing commitment and investment in the programme.

The studies in this Thesis are limited by the absence of longer-term follow-up studies to assess the maintenance of skills. Although a number of trainees were available for repeat testing, this only represented a third of the trainees and was undertaken just 3 months post training. Re-assessment of a greater proportion of trainees at 3, 6 and 12 month intervals would have been preferable. Likewise, the initial data set could have been strengthened by a complete set of matched pairs.

While there were undoubtedly benefits to adopting FL as a single parameter by which to determine gestational age, there were also some limitations associated with this approach. Inaccuracies in the gestational age determined by measurement of fetal parameters not only depends on the biological variability of each parameter, but also on the variability of the measurement itself. Although FL has been the parameter performed most accurately and consistently in some programmes where healthcare workers in LMICs have been taught fetal biometry, (Neufeld et al., 2009, Ohaqwu et al., 2015, Nathan et al., 2017, Shah et al., 2020), other groups have found it to be the most poorly performed parameter, with significant intra- and interobserver variability (Sarris et al., 2012) and therefore this potential source of inaccuracy should be taken into account when considering these results. This variation most likely stems from the lack of confirmatory anatomical landmarks to reassure the operator that they have imaged the bone in its entirety, risking the ends of the bone being ‘cut off’ from the image plane and the gestational age underestimated. This concept may also have limited the accuracy of the remote image review, where the reviewer cannot be totally sure that the static image presented does indeed incorporate both ends of the bone.

Practical assessment of trainee skill relied on the assumption that the trainers themselves performed the FL measurements precisely and were able to obtain an accurate representation of the 'true gestational age'. With more time, the level of agreement between the trainers' measurements could have been calculated, permitting evaluation of individual bias, be this either a systematic over or under estimation of FL.

Although a proportion of images were available for remote review following the training, this was significantly less than anticipated as a result of the challenges encountered utilising the bespoke app. It had been intended to review all images in the 6 weeks following the training and 10% thereafter, but instead it was only possible to access 130. Not only did this impact on the quality of the individual feedback provided to the midwives, but also limited the capture of the total number of scans performed within that period and by whom. Although previous groups have successfully utilised remote image review (Sarris et al., 2013, Wylie et al., 2013, Boamah et al., 2014, Kinnevey et al., 2016, , Nathan et al., 2017, Millar et al., 2018, AMANHI Group, 2020, Shah et al., 2020, Toscano et al., 2021), these have often been supported by greater resources and established within more robust infrastructures (Sarris et al., 2013, Kinnevey et al., 2016 , Nathan et al., 2017, Millar et al., 2018, AMANHI Group, 2020). In trying to create our own 'simple' system however, we inadvertently complicated this process and impaired our ability to achieve the desired objective. This served as a valuable lesson in avoiding trying to employ new, unpiloted systems, when there may be already be a pre-existing one that could potentially be modified or re-purposed.

Although explored to some extent as part of the wider DIPLOMATIC work, important additional contextual information regarding the current provision and practice of ultrasound, and the potential barriers and facilitators to its use, could have been ascertained by performing additional in-depth interviews and focus-group discussions with a range of other healthcare workers, policy makers and clients. Indeed, it would be especially valuable to explore attitudes towards the task-shifting of ultrasound to lower cadres of healthcare worker, for example Community Health Workers, which may offer the potential to avoid further overburdening midwives, an issue highlighted as a concern by many of the midwives interviewed. The strength of the implementation data could also have been enhanced by the inclusion of structured observations of training sessions to facilitate improved understanding of adaptations to implementation and fidelity, and in-depth interviews with the training faculty to augment the measure of ‘adoption’ and to enrich the interpretation of the qualitative data.

6.5 Future Directions

Evidence pertaining to the implementation of ultrasound training initiatives in LMICs, and the subsequent upscale of ultrasound is limited, largely due to the key objectives of evaluation often focussed towards establishing efficacy. To maximise both study resources and learning opportunities, a greater emphasis should be placed on embedding implementation research into the development of such interventions, be this via pragmatic trials, participatory action research or via more novel trial methodology, for example hybrid effectiveness-implementation designs. In allowing for the simultaneous evaluation of both the impact of the intervention, introduced in a ‘real world’ setting, and the implementation strategy itself, these implementation specific research methods are more likely to provide researchers with additional contextual understanding and thus enhance their understanding of the factors contributing to uptake and generalisability.

Although much of the recent work to try to improve access to ultrasound dating in LMICS has been focussed on automated measurements (Maraci et al., 2017, Van de Heuvel et al., 2019, Maraci et al., 2020, Von Dadelszen et al., 2020), (undoubtedly the future of ultrasound dating in this setting), these are not yet available out with the research setting. As this is likely to require significant financial and human investment before being widely available, this 10-day programme offers the potential to widen access to accurate determination of gestational age in the meantime, and future work should therefore explore the generalisability of this education package in the absence of any additional resources, and when delivered by a team completely removed from the DIPLOMATIC group. Although delivered by a team removed from the development process, the trainers still had access to advice and support from the development group, and the provision of the training was still supported by the resources endowed by the study setting. As such, this may have positively influenced the success of the programme and therefore this should be further evaluated in the absence of this additional support.

Given that the most recent Emergency Obstetric and Neonatal Needs Assessment, undertaken in 2014, revealed substantial staff shortages across all cadres, especially within maternity services (Malawi Ministry for Health, 2015), consideration should be given to the possibility of training other cadres of health provider, for example Community Health Workers (CHW). While evidence from previous groups suggests that this would be possible (Rijken et al., 2009), preliminary qualitative data would be valuable before embarking on this, ensuring that, based on accepted cultural and workplace norms, lower cadres performing such examinations would be acceptable to both clients and healthcare workers.

The limitations in re-assessing the trainees, suggest that future work should also explore the ongoing retention of ultrasound skills, ensuring those who have experienced this educational package are able to maintain their skills to the required standard. While most would argue ultrasound skills should improve over time (Tolsgaard et al., 2013, Tolsgaard et al., 2018), this is reliant on opportunities to maintain regular scanning experience and those unable to achieve this may experience a depreciation in their ability to perform accurate measurements over time. By formally re-evaluating trainees, any requirement for ‘refresher training’ may be identified.

Despite the challenges encountered with the development of the bespoke app to facilitate image review, there remains a paucity of evidence as to how to best approach remote supervision. Unfortunately, for many practitioners working and training in remote geographical locations, commitment to lengthy or continuous in person follow-up supervisory sessions is unrealistic and there is therefore a pressing need to establish robust systems to facilitate this in the absence of pre-existing methods or significant financial investment.

6.6 Concluding remarks

This Thesis found that it is possible to train practitioners with no previous experience of ultrasound to successfully date pregnancies using measurement of the fetal femur length in less than 2 weeks, and that it was feasible to deliver this education programme across multiple sites in Malawi. Although difficulties were encountered, by formally evaluating these in the context of an implementation framework, it was possible to identify the specific areas which were problematic, offering areas for ongoing targeted focus and improvement

With increasing onus on the importance of improving estimates of gestational age in low-income settings, this work offers a potential solution to expand the provision of sustainable training in basic obstetric ultrasound in LMICs and to optimise the determination of gestational age in this setting.

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