UNIVERSITY OF DERBY

The Reliability, Practicality and Acceptability of Using Ultrasonography to Monitor the Progress of Labour and Delivery

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Abstract.

Introduction: It had been suggested by a number of recent studies that ultrasonography could become an alternative to digital vaginal examination (VE) for assessing the progress of pregnant women in labour. However, no systematic review and meta-analysis on the effectiveness of ultrasonography was available.

Systematic Review: A systematic review and meta-analysis was conducted to investigate the success rate of ultrasonography in comparison with digital VE and the level of agreement between the two methods, in terms of estimating fetal head position, head station and cervical dilatation.

Systematic Review Findings: This review found that ultrasonography has a higher success rate than digital VE in estimating fetal head position. Ultrasonography was also in high agreement with digital VE in estimating cervical dilatation, with insignificant difference in the success rate of the two methods in terms of detecting cervical dilatation. There was also a significant correlation between the two methods in estimating head station. However, it was also found by the review that, existing primary studies were mainly conducted in tertiary settings of developed countries. Further research was therefore needed from the perspective of non-tertiary settings and also from developing country settings. In addition, further research was also needed to assess the diagnostic performance of ultrasound in detecting active labour, since it is associated with cervical dilatation. The diagnostic performance of ultrasound in detecting engaged fetal head had also not been investigated, which is necessary because it is associated with head station.

Primary Research Aim: As a consequence of these systematic review findings, a primary study was conducted in another clinical setting in a developing country. The aim was to investigate the reproducibility, practicality and acceptability of using ultrasonography to monitor the progress of pregnant women in labour.

Research Methods: A cross-sectional study was conducted in a teaching hospital in Ghana. The agreement between ultrasound and digital VE was statistically analysed for the estimation of fetal head position, head station and cervical dilatation. Further statistical analysis was conducted on the diagnostic performance of ultrasound in detecting

engaged fetal head, and the diagnostic performance of ultrasound in detecting active labour. A quantitative survey of mothers' acceptance of intrapartum ultrasound was also conducted. Lastly, caregivers' views on the practicality of using ultrasound in this developing country setting was also investigated in a qualitative survey.

Results of Primary Research: The results regarding reproducibility were as follows: (i) a high between-method agreement was found in the estimation of cervical dilatation, with high ultrasound sensitivity and specificity in detecting active labour; (ii) a statistically significant between-method agreement was found in the estimation of head station, with high ultrasound sensitivity and specificity in detecting engaged fetal head; (iii) a weak between-method agreement was found in the estimation of fetal head position, with ultrasound having a higher success rate than digital VE.

The results regarding acceptability showed that most mothers accepted the use of intrapartum ultrasound, and were willing to have the procedure for their future care during labour and childbirth. They also preferred ultrasound to digital VE.

With regards to practicality, the responses of caregivers indicate that the introduction of intrapartum ultrasound in this setting could serve as a good complement to digital VE in a number of ways. However, putting it into practice would require wider availability of physical and technical resources.

Conclusion: The findings of the reproducibility study were consistent with existing studies in other clinical settings which were investigated in the systematic review. This suggests that ultrasound is a reliable method for assessing the progress of pregnant women in labour. In addition, the unique contribution to existing knowledge obtained from this study was a high ultrasound sensitivity and specificity in detecting active labour and engaged fetal head which were reported for the first time. The findings on mothers' acceptability were also consistent with existing studies in other settings, which is an indication that there is high acceptance of intrapartum ultrasound by mothers from different settings and cultures. Lastly, caregivers' views on the practicality of the use of ultrasound during labour indicate that the regular use of intrapartum ultrasound for assessing the progress of labour in pregnant women may require additional resources to make it practicable in this and other similar settings.

Publications Arising From this Thesis.

- **Wiafe, Y.A.**, Whitehead, B., Venables, H. and Nakua, E.K., 2016. The effectiveness of intrapartum ultrasonography in assessing cervical dilatation, head station and position: A systematic review and meta-analysis. *Ultrasound*, *24*(4), pp.222-232.

- **Wiafe, Y.A.**, Whitehead, B., Venables, H. and Odoi, A.T., 2018. Sonographic parameters for diagnosing fetal head engagement during labour. *Ultrasound, 26(1), pp 16-21*

- **Wiafe, Y.A.**, Whitehead, B., Venables, H. and Dassah, E.T Ultrasound assessment of cervical dilatation and its value in detecting active labor. *J Ultrasound Med (ACCEPTED)*

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List of Abbreviations.

AIUM	American Institute of Ultrasound in Medicine
ALARA	As Low As Reasonably Achievable
AoP	Angle of Progression
AP	Anterior – to – Posterior
ARDMS	American Registry for Diagnostic Medical Sonography
AUC	Area under Curve
BMI	Body Mass Index
BMUS	British Medical Ultrasound Society
CINAHL	Cumulative Index of Nursing and Allied Health
DOA	Direct Occiput Anterior
DOP	Direct Occiput Posterior
EBP	Evidence Based Practice
HPD	Head-Perineum Distance
HSD	Head Symphysis Distance
LOA	Left Occiput Anterior
LOP	Left Occiput Posterior
LOT	Left Occiput Transverse
ROA	Right Occiput Anterior
ROP	Right Occiput Posterior
ROT	Right Occiput Transverse
ROC	Receiver operating characteristics

PICO	Population Intervention Comparison Outcome
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
US	Ultrasound
USA	United States of America
UK	United Kingdom
VE	Vaginal Examination
WFUMB	World Federation for Ultrasound in Medicine and Biology
WHO	World Health Organisation
2D	2 Dimensional
3D	3 Dimensional

1. Chapter One: Introduction of Thesis.

1.1 Introduction.

Ultrasonography is a widely used diagnostic imaging modality in many clinical disciplines. Particularly in obstetrics, it is the diagnostic modality of choice for many antenatal conditions that were traditionally diagnosed by the use of physical examination methods. Before the advent of ultrasound, one of the physical examination methods that was frequently used in determining the gestational age and the state of a pregnancy was by palpating the level of the uterine fundus on the maternal abdomen (Beazley and Underhill, 1970; Engstrom and Sittler, 1993). Again, with physical examination methods, clinicians diagnosed ectopic pregnancy in cases of early pregnancy bleeding by using their hands in palpating the abdomen for signs of tenderness, and by performing digital vaginal examination (digital VE) for evidence of an adnexal mass (Mol *et al*, 1999). As clinicians had no means of actually seeing the moving fetus, they used their hands in palpating the abdomen for evidence of fetal movement, in order to rule out molar pregnancy (Acosta-Sison, 1947). In cases of antepartum haemorrhage in an era where ultrasound was not available, they also used digital VE in excluding placenta previa (Eadie and Randall, 1954). The Leopold manoeuvre was the standard used in detecting fetal malpresentation (McFarlin *et al*, 1985). The list could continue with many more of such antenatal conditions which relied on physical examination methods as the standard of diagnosis before the advent of ultrasonography. However the introduction of ultrasound into obstetrics by Ian Donald and colleagues in the 1950s gradually resulted in the lesser use of these physical examination methods, as ultrasound became the established gold standard.

As a result, in modern diagnosis of such obstetric conditions, the use of physical examination methods rather than ultrasound is regarded as an obsolete practice. As Campbell (2013) noted, one can rarely find an obstetrical condition in modern practice that cannot benefit from the use of ultrasound.

The integration of ultrasonography into obstetrical care was to contribute to addressing the high level of subjectivity that was associated with physical examination methods. Due to the success achieved with ultrasonography at the antepartum stage of pregnancy, further research into advancing its use at the intrapartum stage has become a subject of discussion in recent times. It is to this debate that this study seeks to contribute.

1.2 Rationale for Study.

The interest in pursuing this research topic was conceived during the writing of a book-chapter I co-authored, which reviewed the role of ultrasound in promoting obstetric health in developing country settings, where maternal and perinatal mortality rates are still very high (Wiafe *et al*, 2011). In the course of writing, it became obvious that whilst there were clear indications and protocols for the use of ultrasound at the antenatal stage, very little was found in the literature on the use of ultrasound at the intrapartum stage. Through further reading, I came across the work of Sherer *et al* (1999) whose study on the utility of intrapartum ultrasound revealed that ultrasound was rarely used in their labour ward settings. As I was then a lead sonographer in the obstetrics and gynaecology department in a teaching hospital in Ghana, my interest was further enhanced by a subsequent article by Sherer (2007) on the advances of ultrasound in intrapartum care.

With further enquiries into the current standards of intrapartum care, I noticed that physical examination methods such as the Leopold manoeuvre and digital VE still

remained the recognised standard of intrapartum care. However, a number of publications were also found in the literature that had questioned the effectiveness of physical examination methods in intrapartum care, especially with regards to digital VE. This brought into question whether it was still relevant to continue relying solely on digital VE for assessment of the progression of labour, or whether the introduction of ultrasound could play a vital role just as it had at the antepartum stage.

In this era of evidence based practice (EBP), one question that was worth asking was whether the current use of digital VE as the main determinant of labour progress was supported by EBP standard principles. The response to this question was the most recent systematic review and meta-analysis conducted by Downe *et al* (2013), which assessed the research evidence regarding the effectiveness of digital VE in intrapartum care. The authors were disappointed to find very little evidence on the effectiveness of routine digital VE in labour which made it difficult for them to conclude on its usefulness as a routine device for assessing labour progress (Downe *et al*, 2013). In addition, contrary to the principles of EBP, they found that some mothers undergoing digital VE in labour did not like the examination for various reasons. Yet this group of mothers had no reliable alternative method available to them.

Possible alternatives to digital VE in labour discussed by Downe *et al* (2013) included ultrasonography, which they emphasised was still under investigation. After this publication by Downe *et al* (2013), new research evidence on the usefulness of ultrasound in labour kept emerging. But the fundamental question as to the reliability, practicality and acceptability of integrating ultrasonography into intrapartum care appeared not fully

addressed. In attempting to address it in a holistic context, the perspective of EBP was considered appropriate for investigating intrapartum ultrasound.

1.3 Context of the Study.

The need to subject the clinical use of ultrasonography to the effective evaluation of EBP has been advocated (Milanese and Grimmer, 2015). Sackett *et al* (1996) described EBP as 'the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients'. It goes further to explain EBP as an integration of 'individual clinical expertise with the best available external clinical evidence obtained from systematic research' (Sackett *et al*, 1996). The 'best available external clinical evidence' is only clinically relevant if it is patient centred and addresses safety issues (Sackett *et al*, 1996). Hence the three pillars of EBP are: (1) Research Evidence, (2) Individual Clinical Expertise, and (3) Patient's Values and Preferences (Sacket *et al*, 1996; Hunink *et al*, 2014).

Consequently, the present study used this context of EBP principles as an explicit measure in investigating the 'best available external clinical evidence', regarding ultrasonography as a tool for intrapartum care in comparison with digital VE. This included identifying the research evidence on the effectiveness of ultrasonography, addressing the issue regarding 'individual clinical expertise' as well as the issue regarding the 'individual patient' preferences. These three EBP principles were used in investigating ultrasonography as detailed below.

1.3.1 Research Evidence.

In the context of EBP, the research evidence regarding a medical intervention or a diagnostic method may be ranked by the study design that was used. This is often referred to as the hierarchies of research evidence by the EBP context. Generally, systematic reviews and meta-analyses are ranked as the highest form of research evidence, followed by randomised control trials, with other types of study designs following suit. However, alongside the hierarchy ranking system, EBP also accepts the use of internal validity factors in evaluating the authenticity of the research evidence by assessing how the risk of bias was addressed by the study. This could be done, for instance, by checking whether there was blinding of the examining parties between the proposed intervention under investigation and the standard it is being compared with (Milanese and Grimmer, 2015).

Currently, digital VE had to be used as the standard because it is the main intervention in use with some research evidence obtained through a recent systematic review and meta-analysis despite being declared as unsatisfactory evidence by Downe *et al* (2013). On the other hand, ultrasonography which was the proposed intervention under investigation had no major source of research evidence from the EBP standpoint of a highly ranked evidence source, such as a systematic review and meta-analysis. This is one of the reasons why it is not yet recognised for active use in intrapartum care. To address that, a systematic review and meta-analysis on the effectiveness of ultrasonography for intrapartum care was to be conducted as part of the search for research evidence regarding the diagnostic usefulness of ultrasound in labour.

1.3.2 Individual Clinical Expertise.

This refers to the experience of the caregivers in a clinical setting, which could vary from one area to another. Individual clinical expertise 'decides whether the external evidence applies to the individual patient', by evaluating 'how it matches the patient's clinical state, predicament, and preferences' (Sackett *et al*, 1996).

Hence, the second context of this study in fulfilment of the EBP concept of 'individual clinical expertise' was to investigate in a different clinical setting from the ones previously investigated by other researchers. This new clinical setting would have a new set of practitioners with 'individual clinical expertise' with the duty to decide how applicable ultrasonography could be for the 'individual patient' under their care and in their clinical context. As clinical experts, they determine how judicious employing a medical service could be in their context as was noted by EBP. These clinicians make that determination of the practicality of a medical intervention by considering the clinical state, predicament and preferences of their patient population. In this context, this study was going to find out from a new set of 'Individual Clinical Experts' regarding the practicality of using ultrasonography in labour and delivery. Secondly, conducting a primary research study with this new set of 'individual clinical expertise' in another clinical setting would be a way of assessing the reliability or the consistency of earlier research findings on the usefulness of ultrasonography in labour.

1.3.3 Patient Values and Preferences.

An EBP evaluation is incomplete without considering the perspective of the 'individual patient' (Sackett *et al*, 1996). In the context of this present study, the parturients in the selected clinical setting were regarded as a new set of 'individual patients' with their own

preferences in choosing between their acceptance of ultrasound versus digital VE in labour, probably influenced by the uniqueness of their culture, education, religion and available resources. Downe *et al* (2013) recognised the value of patient preference by including mothers' acceptability in their systematic review on digital VE. Therefore, it was necessary for this ultrasound study on intrapartum care to incorporate mothers' acceptability of ultrasonography in labour, and to also compare their view on ultrasonography versus digital VE.

1.4 Research Problem.

The principles of evidence based practice enjoins healthcare providers to employ the most efficient treatment or diagnostic intervention available, with due consideration of the 'individual clinical expertise' as well as the 'individual patient' preferences. While ultrasonography has been proposed as a potential diagnostic tool for monitoring the progress of labour and delivery, the research evidence available appeared not robust enough for high recognition in the EBP context.

In order to address this, significant research evidence was needed. There was also the need to evaluate it from the standpoint of 'individual clinical expertise' represented by the caregivers in selected clinical settings, as they have a role in deciding the practicality of a proposed intervention with due consideration of the individual patient preference. Consequently, the present study was focused on addressing this research problem which is associated with the potential usefulness of ultrasonography in monitoring the progress of pregnant women in labour.

1.5 Thesis Structure.

This thesis is composed of eight chapters. In this first chapter, a brief account of the impact of ultrasonography at the antenatal stage was recounted, regarding how it has complemented and sometimes even replaced physical examination methods. This is to establish the background for considering the possible advancement of ultrasonography for use at the intrapartum stage. It goes further to explain the rationale and context of this study by making reference to current practices and the EBP context. A reference has also been made to the most recent research evidence on the effectiveness of digital VE in labour by Downe *et al* (2013), which discusses the fact that their evidence was researched in accordance with highly ranked evidence in the EBP context. It also makes reference to the recognition of ultrasonography as a potential alternative to digital VE at the intrapartum stage, which was indicated by Downe *et al* (2013). Again, the EBP context of this present study is introduced. Lastly, the prevailing research problem is described.

Chapter Two is a systematic review and meta-analysis on the effectiveness of ultrasonography in intrapartum care. This was conducted to address the prior lack of highly ranked research evidence on the usefulness of ultrasonography in labour, in keeping with the EBP context. The discussion aspect identifies some advantages of ultrasonography as reasons why further research is important. It also identifies knowledge gaps that need further research in accordance with the EBP context.

Chapter Three is the methodology chapter. It outlines the aim, specific objectives, research questions and the methodological approach of the primary research that was conducted for this study. It also discusses the philosophical underpinning of this study in justification of the specific objectives and methodological choices made. In addition, it

also discusses the philosophical relevance of the methodology to research that is related to medical imaging.

Chapter Four provided details on the research methods of the primary study. This, include the scope of this research, the rationale for the choice of research methods, the processes used in recruiting study subjects, the procedures and protocols that were followed and the statistical analyses performed.

Chapter Five is the ethical considerations chapter. It described the ethical issues governing this study, including the safety of the ultrasound procedure for research involving pregnant women and fetuses.

Chapter Six presents the results of the primary study. Results are presented in subsections in accordance with the specific objectives of the primary study.

Chapter Seven is the discussion chapter for the primary study, where the findings from this study are discussed in relation to existing research, including their implications and relevance to clinical practice and future research. It also discusses the limitations of the primary research study.

Chapter Eight is the concluding chapter. It provides a summary of the research conducted and the findings that emerged. The implications of the findings to clinical practice and further research is briefly recounted. As a concluding statement, the original contributions this thesis provides to existing knowledge are also presented.

2. Chapter Two: Systematic Review and Meta-Analysis.

2.1 Introduction.

Chapter one introduced this thesis by discussing the current impact of ultrasonography at the antenatal stage of pregnancy, in terms of how it has complemented and sometimes even replaced physical examination methods. On this basis, it set the stage with reasons for further research on the effectiveness of using ultrasonography at the intrapartum stage.

This chapter follows with a systematic review of literature, to evaluate the existing research evidence on using ultrasound in monitoring the progress of labour. It begins by presenting the rationale for this systematic review, which also includes a discussion of what is known about the existing problem. As a systematic review and meta-analysis, it then outlines the research objectives of this review. Afterwards, it presents the chosen method for the systematic review, and continues with how the review was done. The results section presents the relevant research papers that were identified by this systematic review, as well as the meta-analyses that were conducted on the use of ultrasound in assessing cervical dilatation, fetal head station (descent) and fetal head position. The discussion section also evaluates the new research evidence which has emerged from this systematic review. In addition, new areas which required further research in a primary study are also discussed. An outline of the key findings of this systematic review and meta-analysis are also presented.

2.1.1 Rationale.

During labour, digital VE is performed routinely by the caregiver (midwife or obstetrician) at specific time intervals to monitor the progress of labour. The rationale is to provide some assurance to the caregiver and the mother on how well labour is progressing (Downe *et al*, 2013). It is also to enable the early detection of any deviation from normal progress of labour, which would then ensure early intervention to prevent maternal or fetal morbidity (Downe *et al*, 2013). The basic parameters that are assessed by the digital VE include measuring the cervical dilatation, fetal head station and fetal head position (Lavender *et al*, 2012). Although there are other means of monitoring labour progress such as assessing the descent of the fetal head by abdominal palpation; monitoring the frequency, length and strength of contractions, and by observing the appearance, vocalisation and behaviour of the mother, these methods are only used as adjuncts to digital VE rather than a replacement (WHO, 1996; Shepherd and Cheyne, 2013; Muliira *et al*, 2013). However, there are a number of limitations reported in the literature on the routine use of digital VE which then suggest that finding an effective alternative method would be useful.

The first limitation reported in the literature on digital VE is related to accuracy, which indicates that digital VE is more reliable when the initial and subsequent examinations are all performed by the same examiner (Munro and Spidy, 2005; Shepherd *et al*, 2010). However, in many labour ward facilities, it is often not possible for the same examiner to perform all the digital VEs of a particular parturient, due to overload of staff responsibilities, the shift system, and training purposes (Hassan *et al* 2012). As a result, the use of digital VE is often subjective and inaccurate (Buchmann and Libhaber, 2008).

Moreover, the findings of digital VE are less transparent, as only the examiner performing the digital VE can attest to the findings. Any second or third party interested in verifying or validating the findings of an examiner will have to repeat the digital VE, which increases the number of digital VEs to be performed. As a result, it is reported that about 70% of women in labour undergo more digital VEs than expected (Shepherd and Cheyne, 2013; Borders *et al*, 2012), and that unrecorded digital VEs are frequently performed (Stewart *et al*, 2008). This clearly increases the risk of puerperal infection manifesting following delivery (Maharaj, 2007).

Secondly, it is reported that digital VEs can raise the mother's anxiety and interrupt her focus on labour (NICE, 2014). Since the period of labour itself is already an extremely vulnerable and painful time for the woman, it is believed that undergoing a procedure as invasive as digital VE can only cause further pain which parturients often express during the examination (Dixon and Foureur, 2010). Researchers attributed the expression of discomfort by some women during digital VE as indicative of psychological problems associated with their fear and anxiety about the exam (Lai and Levy, 2002), whilst in other reports the expression was attributed to cultural and spiritual reasons (Leap and Vague, 2006). Other reporters also complained that digital VE had become too ritualistic and intimidating for some women who wish for an alternative (Hassan *et al*, 2012; Lewin *et al*, 2005).

These reported general limitations on digital VE in labour are also limitations from an EBP standpoint. As digital VE was in widespread use before the EBP concept was developed, a number of factors were not fully considered before it was introduced. From the standpoint of EBP, the first factor that was not fully considered before digital VE was

introduced is the weak research evidence supporting its use in the general population of parturients. Downe *et al* (2013) expressed their disappointment in this weak evidence base by stating the following:

'It is surprising that there is such a widespread use of this intervention without good evidence of effectiveness, particularly considering the sensitivity of the procedure for the women receiving it, and the potential for adverse consequences in some settings'. (Downe *et al*, 2013, p.2)

Hence, the need to identify the research evidence supporting an alternative method was indicated. Downe *et al* (2013) recognised the potential of ultrasonography as one of the alternative methods being considered which had been under investigation in recent times. This was not the first time a study identified the potential usefulness of ultrasound in labour for future use (Eggebo, 2013).

Again, from the EBP standpoint it was important to investigate the potential of ultrasonography because of the dislike some women have expressed about digital VE, which contradicts EBP standards on the need to consider the preferences of those women who go through the procedure without the benefit of having a choice. For such women, identifying a reliable alternative option could meet their preference in future and would then fulfil EBP standards.

As a result, a systematic review and meta-analysis was conducted to evaluate published studies on the effectiveness of ultrasonography in assessing cervical dilatation, head station and position during labour. Since systematic reviews are highly ranked by EBP standards, the research evidence to emerge from the systematic review was expected to

provide additional knowledge regarding the usefulness of ultrasonography in labour and delivery for interested healthcare providers, as there was no prior systematic review and meta-analysis on the subject.

2.1.2 Objective.

The primary objective for this review was to assess the success rate of ultrasonography in the determination of cervical dilatation, head station and head position in comparison to digital VE.

The secondary objective was to evaluate the level of agreement or correlation between ultrasonography and digital VE in the measurement of cervical dilatation, head station and position.

2.2. Method.

Systematic reviews need an agreed protocol to ensure reliability and reproducibility. Therefore, it is best practice to use an internationally agreed and accepted procedure. Consequently, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) is the structure used for this systematic review. The following section follows the headings suggested by the PRISMA checklist (Moher *et al*, 2009):

2.2.1. Protocol and Registration.

The general methods of this review and inclusion criteria were specified in advance. However, there was no registration of the review.

2.2.2. Eligibility Criteria.

Every type of primary study was eligible for inclusion, whether observational or randomised control trial. The selected study must have reported on the relationship between ultrasonography and digital VE in the measurement of either one or more of the following: cervical dilatation, fetal head station or fetal head position. There were no language and date restrictions in the search process.

2.2.3. Information Sources.

Papers included in this review were obtained from electronic searches of the following databases: PubMed (MEDLINE), CINAHL and Web of Knowledge, all of which reference international journal citations for biomedical literature. It has been demonstrated that using two or more databases will identify a greater percentage of available citations (Wilkins *et al*, 2005; Lawrence, 2008), hence the search was conducted in more than one database. In addition, there was a review of all reference lists of included studies for relevant papers that were not picked up through electronic search, as it was recognised that despite the advantages of electronic databases, they are not infallible (Armstrong *et al*, 2008).

2.2.4. Search.

The search strategy included the breaking down of the research question into component parts, for easy identification of the **P**opulation, **I**ntervention, **C**omparator and **O**utcomes (PICO), as described by Sayers (2007). Breaking down of the research question into a PICO framework was helpful in the choice of search-terms or key words for an effective search. An electronic search of subject-specific databases was then used to identify relevant articles in PubMed, Web of Knowledge, and CINAHL.

The key search-terms were logically combined in different sets of combinations, using Boolean operators “AND” and “OR”, and truncations as appropriate.

In total, nine steps of combined searches were made in PubMed, Web of Knowledge, and CINAHL on the 4th and 5th of November, 2015. Table 2.1 shows the nine steps of search conducted in PubMed.

2.2.5. Study Selection.

Records identified through database searching were exported into the EndNote citation manager. After the removal of duplicates, articles were then screened by title and abstract to determine their relevance to the research question. The primary selection criteria for all papers were: whether their results had reported on the relationship between ultrasonography and digital VE in measuring either the cervical dilatation, head station or head position. The minimum patient selection criteria for all studies was pregnant women in labour with indication for digital VE for measuring either cervical dilatation, fetal head station or head position. In some cases, all three parameters were assessed in one study. The full-text versions of all papers meeting the primary selection criteria were obtained for further evaluation.

2.2.5.1 Data Extraction and Reduction Process.

Data extraction and reduction processes were based on the following steps:

1. The mention of ultrasound in labour for assessing fetal head position, or head station/decent, or cervical dilatation in the title and/or abstract of the paper.
2. The comparison of ultrasound with digital VE for assessing fetal head position, or head station/descent, or cervical dilatation in the paper.
3. The research methods indicated blinding of between-method raters

4. The results reported the success rate of ultrasound versus digital VE
5. The results reported the relationship or agreement between ultrasound and digital VE

The adapted PRISMA Diagram (Figure 2.1) provides further details on the data extraction and reduction process.

2.2.5.2 Quality Assurance of Selection Criteria.

In ensuring that there was agreement among members of the research team on the selected papers, a second independent member of the team, who in this case was one of the two study supervisors, conducted an independent search using the same search terms and reduction process. The inclusion criteria was therefore finalised by a common agreement among two members of the research team. Any disagreements between the two team members were resolved by the opinion of the second study supervisor.

2.2.6. Data Collection Process and Data Items.

Relevant data from all selected papers were entered into a data extraction sheet. The PRISMA diagram (Figure 2.1) explains the data collection process and the quantity of papers identified by the search. Information extracted from all studies included the following: author, year of publication, country of origin, clinical setting, sample size, study design, statistical method, and results.

2.2.7. Risk of Bias in Individual Studies.

In determining the risk of bias it was assessed whether there was blinding of the two examiners performing the ultrasound examination and the digital VE.

Table 2.1 PubMed Search

Search Number	Terms	Results
S1	transperineal (ultraso* OR sonog*) AND clinical examination in labour	32
S2	transperineal (ultraso* OR sonog*) AND digital examination in labour	23
S3	transabdominal (ultraso* OR sonog*) AND clinical examination in labour	38
S4	transabdominal (ultraso* OR sonog*) AND digital examination in labour	24
S5	Intrapartum (ultraso* OR sonog*) AND rotation	10
S6	Intrapartum (ultraso* OR sonog*) AND position	48
S7	Intrapartum (ultraso* OR sonog*) AND station	18
S8	Intrapartum (ultraso* OR sonog*) AND head descent	11
S9	Intrapartum (ultraso* OR sonog*) AND cervical dilatation	48

2.2.8. Data Synthesis.

Synthesis took a narrative approach using some of the techniques described by Popay *et al* (2006) including textual descriptions, tabulations, and transformation of data into a common rubric. Studies were classified and combined in the analysis in accordance with the type of outcome measured, which included the cervical dilatation group, head station group, and head position group. The homogeneous group of studies were entered into

the RevMan 5.3 review manager, to construct forest plots for each classified group. Forest plots were analysed with the Mantel-Haenszel statistical method.

2.2.9. Risk of Bias Across Studies.

The model of analysis was performed using the random effect rather than fixed effect with the assumption that there was some amount of differences even among homogeneous groups of studies. This was considered in order to minimise the impact of selection bias, sample size bias, detection bias, and other potential sources of bias, as was evident of the true effect between studies when performing the meta-analysis ($P<0.05$).

2.3. Results.

2.3.1 Study Selection.

A total of 657 articles were identified through database searching as described, including PubMed, Web of Knowledge and CINAHL. The 657 articles were exported into the citation manager (EndNote), and duplicates were manually removed. 2 additional papers were identified by manual search of reference lists. The remaining number of articles for further screening by title and abstract was 215. The number of relevant articles for full text screening was 46, and 31 articles were found to be eligible for inclusion in the systematic review (see figure 2.1).

2.3.2 Study Characteristics

Table 2.2 shows study characteristics of articles included in the review. Thirty-one primary studies published between 2001 and 2015 met the eligibility criteria for inclusion in this review. Approximately 53% of these studies originated from Europe, 23% from Asia, 15% from North America, 6% from Africa, and 3% from Australia.

The total sample population of birthing women who have participated in these primary studies is 3370, with 47% of them from European tertiary settings, about 18% of them in Asian tertiary settings, 17% of them in the United States, 14% in a North African country and 4% in Australian tertiary clinical settings.

The thirty-one studies were all observational with a wide range of sample sizes, the least sample size being 20 subjects, and the largest sample size being 496 subjects.

2.3.3 Risk of Bias within Studies.

The various forest plots revealed a high percentage of heterogeneity amongst the classified group of studies. As a result, risk ratio was used for the forest plots rather than odd ratios.

2.3.4 Results of Individual Studies.

2.3.4.1 Fetal Head Position.

It was noted that in thirteen out of the 15 studies (87%) that reported on fetal head position, the accuracy of digital VE was defined within a range of ±45^{o} agreement limit. Other studies in the minority have used different ranges of agreement limit (other than the 45^{o} range) with one study using 60^{o} (Zahalka *et al*, 2005) and another using 180^{o} (Hidar *et al*, 2006). A zero degree agreement limit, for instance, is an absolute agreement with no provision for any margin of error. In one study, the range of agreement limit was unclear (Dimmasi *et al*, 2014). Those isolated studies were therefore excluded from forest plots to minimise the impact of heterogeneity. As the ±45^{o} range of agreement was the widely accepted one, only those studies using that range were included in the statistical analysis. Also, findings on the first stage of labour were analysed separately from the second stage of labour.

Figure 2.2 shows the forest plot of eight studies on ultrasound versus digital VE in assessing fetal head position in the first stage of labour. For the second stage of labour, seven studies qualified for inclusion in the meta-analysis as shown in the forest plot of Figure 2.3.

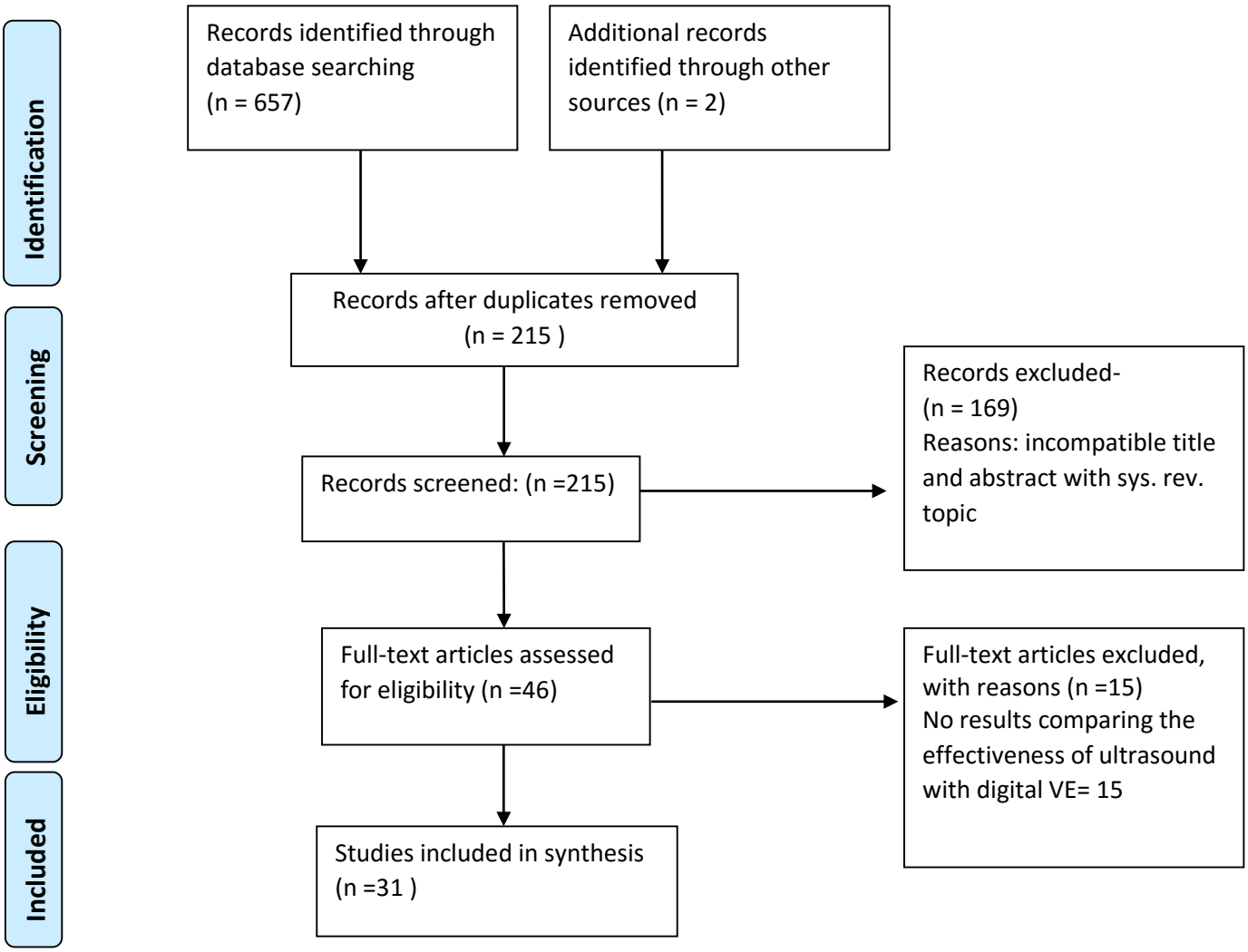

Figure 2.1 PRISMA FLOW CHART (ADAPTED) (Moher et al, 2009)

Table 2.2 Study characteristics

Author	Country	Examination	Labour Stage	Sample Size
Akmal et al (2003)	UK	Position	2nd	64
Akmal et al (2002)	UK	Position	1st	496
Barbera et al (2009b)	USA & Italy	Station	1st	88
Benediktsdottir et al (2015)	Sweden	Dilatation	1st	86
Chan et al (2014)	China	Station	1st	100
Chou et al (2004)	USA	Position	2nd	88
Dietz et al (2005)	Australia	Station	1st	139
Dimmasi et al (2014)	Tunisia	Station	1st	100
Dupuis et al (2005)	France	Position	2nd	110
Eggebo et al (2014)	UK & Norway	Position	1st	150
Ghi et al (2009)	Italy	Station	1st	60
Gilboa et al (2013)	Israel	Station	1st	65
Hassan et al (2014)	UK & Norway	Position, Station, Dilatation	1st	20
Hassan et al (2013)	UK & Norway	Dilatation	1st	21
Hidar et al (2006)	Tunisia	Position	1st	350
Kawabata et al (2010)	Japan	Position	1st	87
Kreiser et al (2001)	Israel	Position	2nd	44
Maticot-Baptista et al (2009)	France	Station	1st	45
Molina et al (2010)	UK	Station	1st	50
Rivaux et al (2012)	France	Station	1st	100
Sherer et al (2002a)	USA	Position	1st	102
Sherer et al (2002b)	USA	Position	2nd	112
Sherer et al (2003)	USA	Station	1st	222
Shetty et al (2014)	India	Position	1st	165
Souka et al (2003)	Greece	Position	2nd	148
Tutschek et al (2013)	Norway	Station	1st	106
Tutschek et al (2011)	Switzerland	Station	1st	50
Youssef et al (2013b)	Italy	Station	1st	47
Yuce et al (2015)	Turkey	Position, Station, Dilatation	1st	43
Zahalka et al (2005)	Israel	Position	1st	60
Zimerman et al (2009)	Israel	Dilatation	1st	52
Total 31				**3370**

**These primary studies were all observational studies conducted in the obstetric unit of tertiary hospitals*

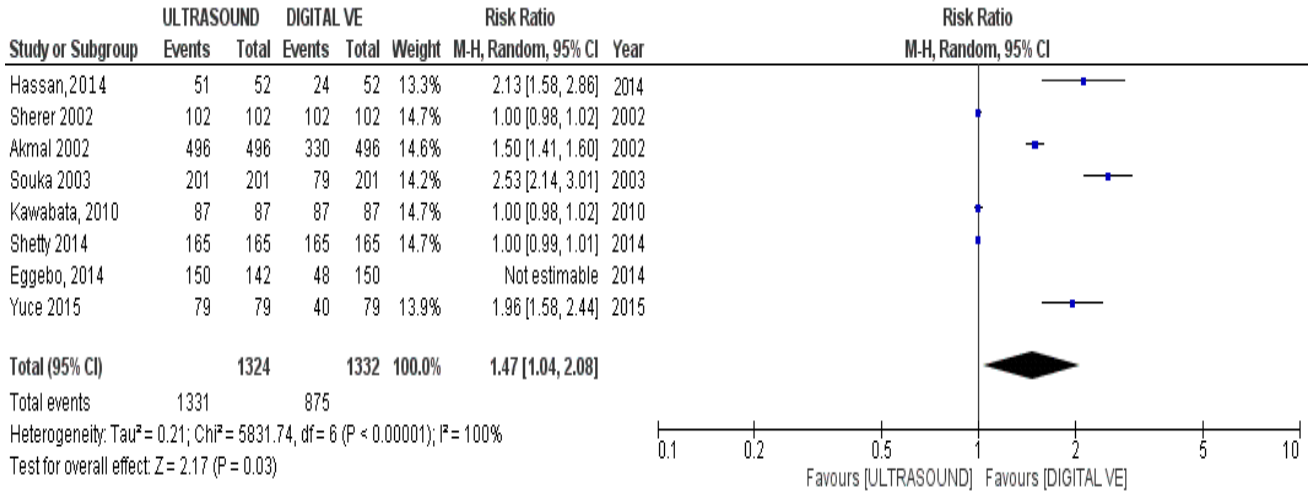

Figure 2.2 Forest plot in favour of ultrasonography on the success rate of the determination of fetal head position in the first stage of labour

Table 2.3 Agreement between ultrasound and digital VE on head position at 1st stage of labour

Author	Statistical method	Ultrasound - Digital VE agreement
Hassan et al (2014)	Simple Percentage agreement plus average mean difference with Bland-Altman plots	39%; MD: -3.9^0
Sherer et al (2002a)	Cohen's Kappa analysis	47%
Akmal et al (2002)	Simple percentage agreement	49%
Souka et al (2003)	Cohen's Kappa analysis	31%
Kawabata et al (2010)	Simple percentage agreement	40%
Shetty et al (2014)	Cohen's Kappa analysis	32%
Eggebo et al (2014a)	Cohen's Kappa analysis	32%
Yuce et al (2015)	Simple percentage agreement	24%

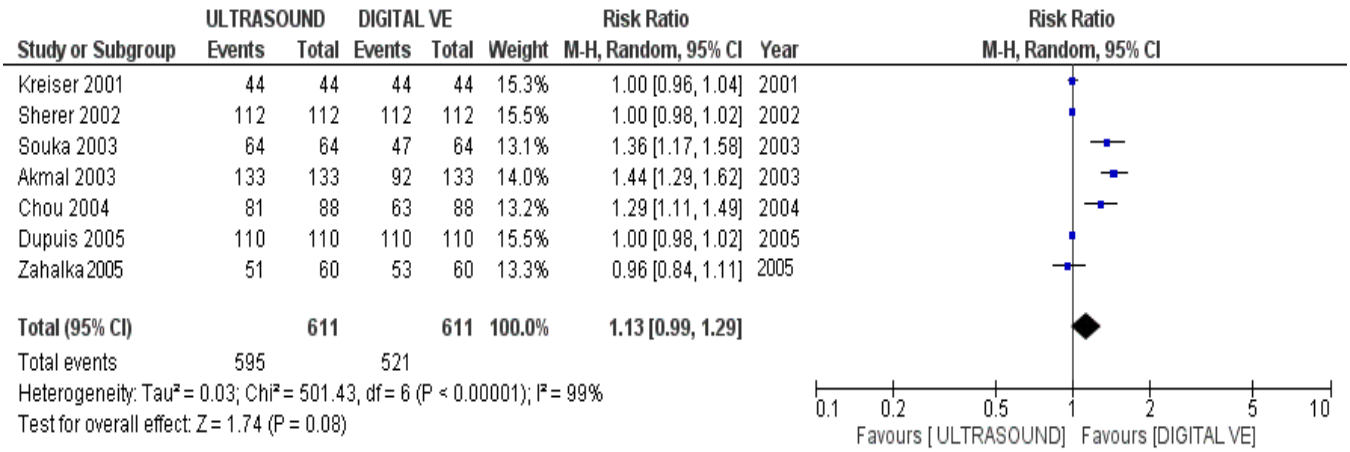

Figure 2.3 Forest plot in favour of ultrasonography on the success rate of the determination of fetal head position in the second stage of labour

Table 2.4 Agreement between ultrasound and digital VE on head position at 2nd stage of labour

Author	Statistical method	Ultrasound - Digital VE agreement
Kreiser et al (2001)	Simple percentage agreement	70%
Sherer et al (2002b)	Cohen's Kappa analysis	61%
Akmal et al (2003)	Simple percentage agreement	73%
Chou et al (2004)	Simple percentage agreement	72%
Souka et al (2003)	Cohen's Kappa analysis	65%
Dupuis et al (2005)	Cohen's Kappa analysis	80%
Zahalka et al (2005)	Simple percentage agreement	79%

2.3.4.2 Cervical Dilatation.

The forest plot of figure 2.4 shows statistically insignificant difference between the success rate of digital VE and that of ultrasound. Again, the high level of agreement reported by the five studies is presented in table 2.5.

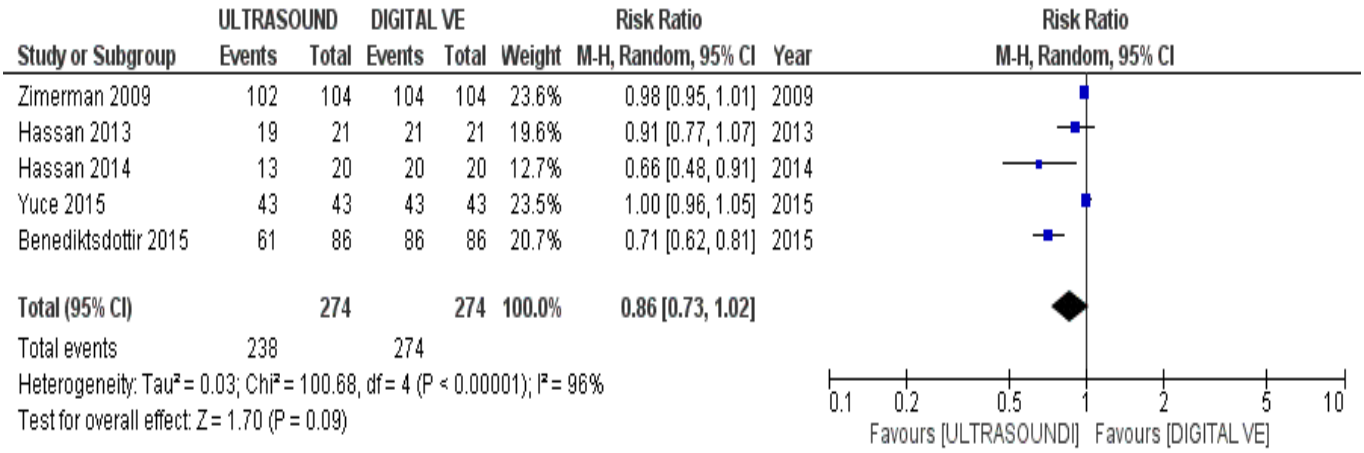

Figure 2.4 Forest plot in favour of digital VE over Ultrasonography on the success rate of the determination of cervical dilatation

Table 2.5 Results of individual studies on cervical dilatation

Author	Statistical Method	Agreement between Ultrasound and Digital VE
Benediktsdottir et al (2015)	Linear regression;	r^2=0.72
Hassan et al (2014)	Linear regression	r^2=0.68
Hassan et al (2013)	Pearson correlation coefficient	r=0.82
Yuce et al (2015)	Pearson correlation coefficient	r= 0.82
	Simple linear regression	r^2=0.61

2.3.4.3 Fetal Head station.

Of the 31 studies included in this review, fourteen reported on the relationship between ultrasonography and digital VE in the assessment of fetal head station. A total of seven different ultrasound methods for measuring fetal head station were found. However, since ultrasound and digital VE were not using the same anatomic landmarks in their estimation of fetal head station, a forest plot could not be constructed between the two methods.

The seven ultrasound methods identified in the fourteen papers which demonstrated various levels of relationship with the digital VE in the estimation of fetal head station are the following:

(1) Angle of Progression which is also known as the Angle of Descent (Barbera *et al*, 2009b; Chan *et al*, 2014; Tutschek *et al*, 2013)

(2) Head Direction (Tutschek *et al*, 2013; Ghi *et al*, 2009)

(3) Intrapartum Translabial Ultrasound (ITU) head station (Tutschek *et al*, 2011; 2013)

(4) Head Progression Distance (Dietz *et al*, 2005, Gilboa *et al*, 2013)

(5) Head Symphysis Distance (Youssef *et al*, 2013b)

(6) Ultrasound Fetal Head Engagement (Sherer *et al*, 2003)

(7) Head Perineum Distance (Chan *et al*, 2014; Dimmasi *et al*, 2014; Hassan *et al*, 2014, Maticot-Baptista *et al*, 2009; Rivaux *et al*, 2012; Yuce *et al*, 2015).

However, the widely used methods were the Angle of Progression (AoP) and the Head Perineum Distance (HPD) with details as follows:

i. **The Angle of Progression Method:** This ultrasound method reported a moderate correlation between ultrasonography and digital VE in their estimation of fetal head station (Chan *et al*, 2014; Barbera *et al*, 2009b; Tutschek *et al*, 2011). These studies

had all included multiparous and nulliparous women in their study population who were at various cervical dilatations in the first stage of active labour.

ii. **Head Perineum Distance (HPD):** Chan *et al* (2014), Hassan *et al* (2014), and Yuce *et al* (2015) have all reported moderate correlation between digital VE and the HPD in their estimation of fetal head station. Also, Dimassi *et al* (2014), Maticot-Baptista *et al* (2009), and Rivaux *et al* (2012) all reported on the diagnostic performance of the distance from the fetal head to the perineum in diagnosing fetal head engagement using digital VE as the gold standard and station 0 as their reference point. Dimassi *et al* (2014) reported sensitivity and specificity of 86.7% and 94.1% respectively for diagnosing fetal head non-engagement, using a distance of 55mm from the fetal head to the perineum as their cut-off value.

Maticot-Baptista *et al* (2009) also obtained a sensitivity of 97.8% in predicting fetal head non-engagement, using a distance of < 60mm from the fetal head to the perineum as their cut-off value. Maticot-Baptista *et al* (2009) added that whenever a distance of more than 60mm was obtained, digital VE diagnosed fetal head as 'non-engaged' with a specificity of 89.0%. Likewise, Rivaux *et al* (2012) reported that the fetal head was not engaged upon digital VE assessment whenever ultrasound recorded a mean distance of 66.4mm (±7.53mm) from the fetal head to the perineum.

2.4 Discussion.

The primary objective of this systematic review and meta-analysis was to assess the success rate of ultrasound versus digital VE in the determination of fetal head position, cervical dilatation and fetal head station. The secondary objective was to investigate the agreement or correlation between ultrasound and digital VE in the determination of fetal head position, cervical dilatation and fetal head station.

In terms of the determination of fetal head position, the forest plot (figure 2.2) indicates a statistically significant success rate in favour of ultrasound in the first stage of labour, with most studies in the review reporting poor agreement between ultrasound and digital VE on fetal head position. In the second stage of labour, the forest plot (figure 2.3) indicates a statistically insignificant success rate in favour of ultrasound, with all studies in the review reporting high agreement between ultrasound and digital VE on fetal head position.

In terms of the determination of cervical dilatation, the forest plot (figure 2.4) indicates a statistically insignificant success rate in favour of digital VE, with all studies in the review reporting high correlation between ultrasound and digital VE on cervical dilatation.

In terms of the determination of fetal head station, all studies in the review reported moderate correlation between ultrasound and digital VE. However, forest plot could not be constructed for fetal head station due to the use of different anatomic landmarks.

This is the first time these findings are reported by a systematic review and meta-analysis. They are therefore novel findings with implications for practice and future research.

2.4.1 Implications of Systematic Review Findings for Clinical Practice.

The research evidence emerging from this systematic review and meta-analysis suggests that ultrasonography can be effectively used in clinical practice for the assessment of fetal head position, cervical dilatation, and fetal head station.

1. Fetal Head Position:

In terms of fetal head position, even though most studies in the review had reported higher success rate for ultrasound, this was the first time the statistical significance of the success rate was being reported. Few studies had reported an equal success rate, whilst many others reported a success rate in favour of ultrasound. No previous study had reported a success rate in favour of digital VE. However, this systematic review and meta-analysis explicitly demonstrated the superiority of ultrasonography over digital VE in terms of success rate which is statistically significant in the first stage of labour but insignificant in the second stage of labour.

Therefore, the research evidence supported the use of ultrasound as the gold standard in assessment of fetal head position. Again, it is established by this systematic review and meta-analysis that the level of agreement between ultrasound and digital VE doubles in the second stage from approximately 35% in the first stage to 70% in the second stage. It therefore implied that since ultrasound and digital VE had good agreement in the second stage of labour, and that there is statistically insignificant difference between the two in terms of success rate, one can choose either ultrasound or digital VE for assessing fetal head position in the second stage of labour with a higher probability of attaining a similar outcome. However, the statistically significant success rate which favours ultrasound in the first stage of labour suggests that ultrasound would be more appropriate than digital

VE when looking for a reliable method for detecting fetal head position in the first stage of labour. From the safety perspective of EBP, the transabdominal approach that is used by ultrasound in determining fetal head position, compared to the transvaginal approach that is used by digital VE, also gives ultrasound an advantage in terms of minimising risk of infection.

2. Cervical Dilatation:

The insignificant statistical difference between ultrasound and digital VE in terms of success rate, and the high agreement between the two methods was suggesting that ultrasound could actually be used as an alternative to digital VE in many cases. From the safety perspective of EBP, the transperineal approach used by ultrasound compared to the transvaginal approach by digital VE arguably made the use of ultrasound in measuring cervical dilatation the safer option for minimising risk of infection. Figure 2.5 shows the anatomical location of the perineum, where the transducer is placed during transperineal ultrasound. For this reason, ultrasound could be considered as first choice over digital VE, given the insignificant statistical difference between the two methods and the likelihood of safety of the ultrasound approach.

It is also worth noting that four out of the five studies were investigated with 2D imaging. These four studies were all published after the systematic review and meta-analysis of Downe *et al* (2013), which reported that ultrasound was still under investigation. This present review is therefore the latest research evidence utilising meta-analysis which has analysed the effectiveness of intrapartum ultrasound in assessing cervical dilatation. As most of these primary studies were conducted with small sample sizes, analysing them together in this systematic review and meta-analysis made the research evidence

relatively stronger from the EBP evaluation standpoint, and also made the individual contributions of these primary researchers more relevant in terms of informing clinical practice on the effectiveness of ultrasound in assessing cervical dilatation.

3. Fetal Head Station:

Although several methods for assessing the fetal head station were found, the widely reported methods found by this review were the AoP and the HPD. The AoP is described as an angle formed by a line drawn through the long axis of the symphysis pubis and another tangential line drawn from the leading edge of the fetal head cranium. The HPD also refers to the shortest obtainable distance from the leading edge of the fetal head cranium to the skin surface of the perineum. Their level of correlation with digital VE on the fetal head station was reported by the individual studies in this review as moderate but statistically significant. Given that the digital VE itself is known to be subjective, the possible advantage ultrasound may have is that, since it has more than one measurement method, a high level of agreement amongst the ultrasound methods may indicate reliability for users who seek an alternative in clinical practice. Again, since the HSD is measured in the same plane as the AoP, it could also be measured as an additional ultrasound parameter which might increase the confidence in an ultrasound report on fetal head station if it happens to agree with the findings of HPD and AoP.

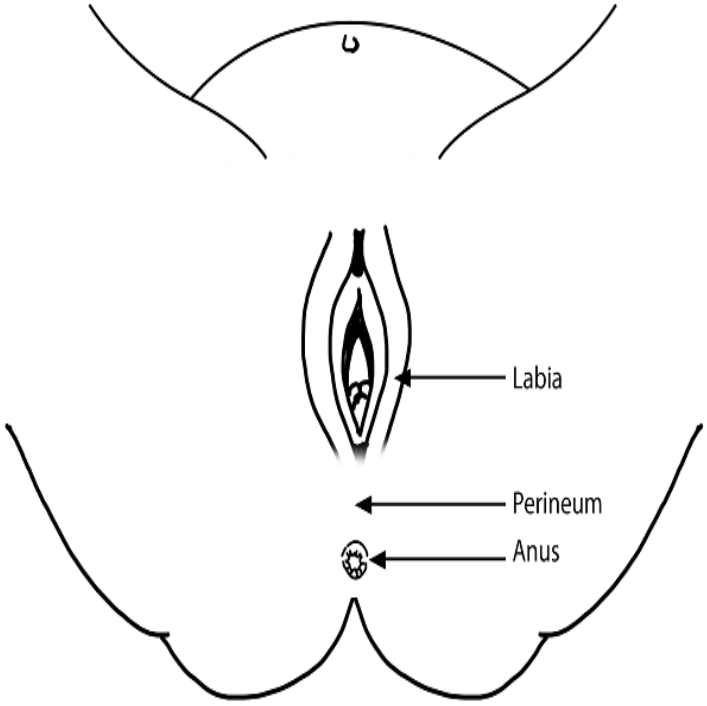

Figure 2.5 Anatomical region of the perineum

2.4.2 Implications of Systematic Review Findings for Future Research.

The findings of this systematic review and meta-analysis also had a number of implications for future research as detailed below.

1. Fetal Head Position:

Whilst the findings of the reviewed papers indicate the superiority of ultrasonography over digital VE in terms of success rate, further reading of the articles revealed conflicting findings on the factors that influenced the agreement between ultrasound and digital VE.

There was therefore the need for additional studies from the perspective of other clinical settings. It was also noted that the agreement between ultrasound and digital VE was slightly higher in studies that were analysed with simple percentage agreement statistics rather than kappa, which does not account for agreement by chance (Carletta, 1996). Given that slightly lower agreement values were obtained by studies that analysed with kappa statistics, it could be assumed that the accuracy level of ultrasound in the second stage of labour may also be slightly lower than the over 90% reported by Chou *et al* (2004) and Kreiser *et al* (2001), since these were analysed with simple percentage agreement rather than by kappa statistics. It was therefore suggested that future studies could consider investigating the accuracy level of ultrasound with a more robust statistical method in the second stage by comparing it with position at delivery.

2. Cervical Dilatation:

The debate on whether ultrasound could become a routinely used modality in labour centres, largely depends on its ability to determine cervical dilatation, as it is the major reason for the routine use of digital VE in labour (WHO, 1996; Downe *et al*, 2013).

The assessment of cervical dilatation with ultrasound was first reported in the Israeli study by Zimmerman *et al* (2009). They found significant correlation between ultrasound and digital VE in the determination of cervical dilatation. Consequently, they suggested that ultrasound could be used as an adjunct tool for monitoring selected cases of labour. However, they recommended that since their findings were only preliminary, further research should be encouraged in specific clinical settings by employing different study designs (Zimmerman *et al*, 2009). Prior to their preliminary study, it was thought that the visualisation of cervical dilatation on ultrasound was unlikely to be successful. It was also

thought that the lumen of the dilating cervix might be obscured by the bony part of the descending fetal head, which might make it difficult to differentiate the walls of the thinning or effacing cervix (Sherer, 2007). Therefore, the preliminary research findings of Zimmerman *et al* (2009) were groundbreaking as the procedure was previously considered too difficult. However, their use of 3D rather than 2D had its own disadvantages, as it meant that only settings with the means of acquiring 3D/4D systems could use it for that purpose, which leaves out the numerous settings around the globe that may be using 2D systems.

Fortunately, Hassan *et al* (2013; 2014) came across the dilating cervix on 2D when they were conducting a research on the sonographic determination of fetal head station. However, this was in a very small study population of 21 in their initial study, and 20 in their follow-up study. Subsequently, Yuce *et al* (2015) and Benediktsdottir *et al* (2015) assessed the reproducibility of previous findings in their respective Turkish and Swedish study populations.

However, since digital VE determination of cervical dilatation plays a major role in the determination of active labour, further research could be conducted to assess the research evidence on the diagnostic performance of ultrasonography in the determination of active labour. This would be an additional research evidence not previously investigated.

3. Fetal Head Station and Engagement:

It was noticed that existing studies had researched the diagnostic performance of the HPD in detecting fetal head non-engagement, but not the diagnostic performance of engaged fetal head. Future studies could therefore concentrate on exploring diagnostic

performance of the AoP and the HPD in detecting an engaged fetal head in labour, as this had not been previously investigated. In addition, since the HSD is measured in the same plane as the AoP, future studies could also consider investigating that parameter further for assessing engaged fetal head in labour.

4. *Extending Research to Non-Tertiary Settings and Developing Country Settings:*

Even though the findings of this systematic review suggested that ultrasound could be useful in clinical practice, these findings were based on studies conducted in the obstetric units of tertiary hospitals in developed countries. Its applicability in non-tertiary settings, such as the growing midwife-led units, remained unclear and needed further investigation. In addition, its applicability in developing country settings was another context that needed further research for additional research evidence.

From the EBP standpoint, investigating its use in non-tertiary settings of developed countries, and in the various clinical settings of developing countries, was important for a number of reasons. The first reason was with regards to the EBP stands on 'individual clinical expertise', which would therefore regard the caregivers of a non-tertiary setting and those from a developing country setting as having their own context-based clinical experience and expertise. Perhaps these differences in clinical context might influence the effectiveness or the practicality of ultrasonography in those clinical settings which were not yet investigated. Again, from the research evidence standpoint of EBP, it had to be established as to whether conducting the study in an entirely new setting, such as a developing country setting, would yield comparable levels of results between ultrasonography and digital VE in terms of reproducibility. In addition, that the consistency

of the findings in other settings could then imply that ultrasound is a reliable method for assessing the progress of labour in other settings.

5. Individual Patient Acceptability of Ultrasound in Labour:

The patient's value and preference for ultrasound versus digital VE still had to be investigated. It was noticed that there was inadequate information regarding mothers' acceptability of ultrasound versus digital VE from the reviewed papers. Only four out of the 31 papers of this review had provided some information on mothers' acceptability of ultrasound in labour. These papers were Hassan *et al* (2014), Barbera *et al* (2009b), Zimerman *et al* (2009) and Yuce *et al* (2015). In the case of Barbera *et al* (2009b), Hassan *et al* (2014), and Zimerman *et al* (2009), they only reported that their study participants expressed no discomfort from undergoing ultrasound in labour. They provided no further information on their ultrasound experience as either comparable or better than digital VE. Again, they provided no information on their preference between ultrasound and digital VE. The only study which provided further details on mothers' acceptability was Yuce *et al* (2015) whose finding indicated that about 86% of their participants reported that they would prefer ultrasound to digital VE in future intrapartum assessments. However the remaining 14% were neutral about their choice between ultrasound and digital VE for future intrapartum assessment. Unfortunately, no information was provided by Yuce *et al* (2015) on possible factors that might have influenced the 14% who remained neutral about their choice between ultrasound and digital VE. Again, it is also worth noting that Yuce *et al* (2015) conducted their study in Turkey, which is a clinical setting likely to comprise of significant participants with a predominantly common religious belief and culture. However, no such information was provided in their study as a possible influence

on their choices. There was also no information on possible characteristic differences between the 14% of their study population who were neutral about their preference and the other 86% who preferred ultrasound to digital VE. It therefore implied that now that there was a systematic review and meta-analysis suggesting that ultrasound could be effectively used in clinical practice, additional research on mothers' acceptability was needed to explore the 'individual patient preference' even further, as it forms an important component of EBP evaluation. Ultrasound already had a high level of acceptance at the antenatal level by mothers (Garcia *et al*, 2002), and that it was hypothetically suspected to gain acceptance by mothers if introduced at the intrapartum stage. However this had to be investigated further for research evidence in different clinical contexts.

2.5 Conclusion.

Findings suggest that ultrasonography is superior to digital VE in the assessment of fetal head position with a statistically significant difference in success rate in favour of ultrasound in the first stage of labour. This is therefore an indication that ultrasound could be effectively used as a gold standard in assessing fetal head position in the first stage and second stages of labour.

Secondly, there was no statistically significant difference between the success rate of ultrasound and digital VE in the determination of cervical dilatation. Again, there was high level of agreement on cervical dilatation between the two methods. This implied that either ultrasound or digital VE could be used in the assessment of cervical dilatation.

Lastly, whilst primary studies were in agreement on a significant but moderate correlation between ultrasound and digital VE in the assessment of fetal head station, a comparison of their success rate could not be determined.

2.6 Recommendations.

In view of the findings of this systematic review and meta-analysis, and the discussions on their implications for clinical practice the following recommendations were made for further research:

- Future studies could extend to non-tertiary settings in a much more representative general population of women in labour, including developing country settings.
- Although findings suggest no statistically significant difference in success rate between ultrasound and digital VE on cervical dilatation, future studies should target larger sample sizes to enable detailed evaluation of possible influencing factors of success rate.
- Assessing the specificity and sensitivity of ultrasonography in diagnosing active labour would add in-depth knowledge on its effectiveness. This could be defined by using a ≥4cm threshold of cervical dilatation determined by digital VE.
- Although some existing studies had assessed the diagnostic performance of the HPD in detecting non-engagement of the fetal head, future studies could also investigate the diagnostic performance of ultrasound in detecting engaged fetal head.
- Although ultrasound is highly recommended over digital VE in the assessment of fetal head position, future studies could evaluate the effectiveness further, using a much more robust statistical method.

- Lastly, in extending this research to other settings, there is the need to also investigate views of ‘individual clinical expertise’, on the practicality of using ultrasound in labour in specific settings.

2.7 Chapter Summary.

In this second chapter of the thesis, a systematic review and meta-analysis was conducted to assess the success rate of ultrasound versus digital VE in the determination of fetal head position, cervical dilatation and fetal head station. The published novel findings that were obtained from this review are as follows:

- In the first stage of labour, ultrasound has a statistically significant success rate over digital VE in the determination of fetal head position.
- In the second stage of labour, ultrasound has a statistically insignificant success rate over digital VE in the determination of fetal head position.
- In the first stage of labour, digital VE has a statistically insignificant success rate over ultrasound in the determination of cervical dilatation.

Based on these findings, implications for clinical practice and future research were discussed. Recommendations were also made for further research in a primary study.

The next chapter presents the methodology of the primary research that was conducted as part of this study in addressing some of the recommendations made for future research. Subsections in the next chapter include the aim and specific objectives of the primary research. It also presents the methodological approach of the primary research, and discusses the philosophical underpinning of the primary research.

3 Chapter Three: Methodology.

3.1 Introduction.

The preceding chapter presented the systematic review and meta-analysis conducted in this study ahead of the primary research. Based on the findings of the systematic review and meta-analysis which is now published in a peer-reviewed journal (Wiafe *et al*, 2016), recommendations were made for key areas that needed further research from the EBP perspective described in Chapter One.

This chapter presents the aims and specific objectives of the primary research. It also presents the methodological approach of the primary research. Finally, it presents the details of the philosophical underpinning of the primary research, which were also linked to their appropriateness in terms of conducting research in a diagnostic imaging field, with particular emphasis on medical ultrasound.

3.2 Aim and Objectives.

3.2.1 Main Aim.

The main aim of this primary research was to investigate the reproducibility, practicality and acceptability of using ultrasonography in monitoring the progress of pregnant women in labour.

3.2.2 Specific Objectives.

The specific objectives of this primary research were:

I. To assess the agreement between ultrasound and digital VE on fetal head position, and the intrapartum factors that may have affected the agreement.

II. To assess the agreement between ultrasound and digital VE on fetal head station, and the diagnostic performance of ultrasound in detecting engaged fetal head.

III. To assess the agreement between ultrasound and digital VE on cervical dilatation, and the diagnostic performance of ultrasound in detecting active labour.

IV. To assess the acceptance of ultrasound in labour by mothers who have experienced intrapartum ultrasound.

V. To investigate the views of caregivers on the practicality of using ultrasound to monitor the progress of labour.

3.3 Methodological Approach.

The methodological approach used by this primary research was a cross-sectional study design which assessed:

I. The fetal head position of the parturient, using ultrasound and digital VE.

II. The fetal head station, and ultrasound measurements associated with fetal head station of the parturient, using ultrasound and digital VE.

III. The cervical dilatation of the parturient, using ultrasound and digital VE.

IV. The views of mothers on the use of ultrasound in labour, using a quantitative survey.

V. The views of caregivers on the use of ultrasound in labour, using a qualitative survey.

A detailed description of the research methods continues in Chapter Four.

3.4 Philosophical Perspective of Methodological Approach.

The two major pathways for conducting scientific research are quantitative and the qualitative methods. The decision to use either a quantitative or a qualitative approach is influenced by the researcher's assumptions about reality (ontology), and his or her views about what constitutes knowledge (epistemology) (Ormston *et al*, 2014). It is also influenced by the research paradigm (Kuhn, 1970). Quantitative researchers primarily assume an ontological position which suggests that reality is not dependent of people's beliefs and understanding of it (Ormston *et al*, 2014), and that knowledge regarding a particular reality must be objective, observable and quantifiable. On the other hand, the ontological position of qualitative research is based on the primary assumption that reality is influenced by our beliefs and understanding, and that whatever is considered as a reality is only knowable through the human mind or through socially constructed meanings (Ormston *et al*, 2014; Broom and Willis, 2007).

However, some philosophers hold the view that research cannot be simply founded on one or the other of these two extremist assumptions. The position of this group of philosophers is that methodological considerations are also influenced by paradigms. Depending on the paradigm influencing a researcher, he/she may even choose to combine the two major opposing, quantitative and the qualitative assumptions, for as long as it serves the interest of the paradigm it seeks to address. Nominating the research paradigm is therefore regarded by many researchers as a necessary first step, which determines subsequent choices in terms of the methodology, methods, literature or research design (Mackenzie and Knipe, 2006). This is particularly relevant in the health sciences where research interest is often motivated by the need to address a health-

related problem which is to influence the practice of a particular specialty. Thomas Kuhn (1922-1996), who was the seminal proponent of the paradigm concept, noted that research can only be regarded by a particular scientific community as 'normal science', if it demonstrates a similar interest in the problems of that community, and shows belief in their range of possible solutions to the problem (Kuhn, 1970). According to Kuhn (1970), 'normal science' refers to a research finding that is firmly based on the past achievements of the scientific community, and supplies foundation for the practice of that paradigm. In relation to Kuhn's view on research, the methodological considerations in research are not only influenced by ontological and epistemological positions, but have also been focused on the needs that influence the practice of the scientific discipline (Broom and Willis, 2007).

Consequently, the choice of methods for this present study were also influenced by what was already in existence for the paradigm, including the tools and methods that were available to their standards of practice. For instance, the research design of this primary study was influenced by the methodological choices of similar previous studies and the existing protocols of the clinical setting.

3.4.1 Paradigms.

Chalmers (1982) defined a paradigm as consisting of the "general theoretical assumptions and laws, and techniques for their application that the members of a particular scientific community adopt". Paradigms that are in line with quantitative research are often referred to as empirical, positivist, postpositivist, or objectivist (Henrickson and McKelvey, 2002). On the other hand, paradigms that are in line with

qualitative research have been referred to as interpretive, constructive, ethnographic, critical, or post-modern, amongst others (Creswell, 2007; Cohen *et al*, 2007).

In identifying the paradigmatic stance of this present study, a review of the various paradigms was completed. Post-positivism was identified as the most appropriate paradigm to which this research could be associated.

3.4.2 Paradigmatic Stance.

As indicated above, the paradigmatic stance for this present study stems from post-positivism rather than positivism. Positivism is the conventional approach to conducting research with roots from the 17th century. The term positivism was first used by Auguste Comte (1798-1857) when he sought to apply scientific paradigm in the social world (Cohen *et al*, 2007). However, the underlying philosophy was adapted from the natural world philosophers such as Aristotle, Francis Bacon and Isaac Newton. Comte's original understanding of positivism is termed as classic positivism. In classic positivism, science referred to a finding obtained through observation of the physical senses such as by sight, hearing, tasting, touching or smelling. Anything inferred by theoretical beliefs and personal understanding could not be regarded as scientific knowledge (Bechtel, 2013). Later, the earlier view of positivism was modified into what became known as logical positivism. In this latter view of positivism, not only was it necessary for knowledge to be empirically observed, but it also had to be evaluated through a strict process of verification. They used a process known as the hypothetico-deductive method in validating what could be classified as knowledge (Bechtel, 2013). By this process, they used the inductive approach in formulating general laws and theories, which then become the basis for stating scientific hypothesis, in order to establish the basis for the research

design. Hence theoretical statements about facts had to be stated in a way that made it directly and completely testable, and that the truth or falsity of the statement had to be revealed to the researcher through empirical observation (Gjertsen, 1989; Hetherington, 2000).

Positivism has been under attack since the twentieth century. Notable philosophers such as Karl Popper (1902-1994) and Thomas Kuhn promoted the idea of thinking about science in ways other than positivism (Zammito, 2004). Consequently, there is now a clear distinction in the literature about different research paradigms (Adams, 2014).

3.5 Post-Positivism.

Post-positivism is an alternative paradigm for researchers who think in similar ways that are associated with positivism. However, whilst post-positivism has some values it shares with positivism, it is an objectivist view which does not limit itself to the positivists world view (Adam, 2014). It has 'incorporated falsificationism, fallibilism, and Feyerabend's methodological pluralism' (Hetherington, 2000). Therefore while post-positivism supports the use of quantitative methodology, it is also open to subjective interpretation of data (Adam, 2014). Post-positivists are therefore able to incorporate qualitative methods into quantitative studies when necessary for addressing a research problem that is of interest to a scientific paradigm.

3.5.1 Ontology.

Guba and Lincoln (1994) noted that unlike the naïve-realist research approach in positivism which assumes a completely objective external reality, post-positivists hold the view that 'objective reality can only be apprehended imperfectly'. This ontological position of post-positivism is rather called critical realism (Guba and Lincoln, 1994). Post-

positivists believe that although there is an objective world ‘out there’, researchers are necessarily influenced by their own subjective selves in their research. Conclusions about reality are influenced by both the investigated and the investigator (Schulze, 2003)

3.5.2 Epistemology.

Post-positivists are modified dualists. Though objectivists, they assume that ‘reality is never fully known, and that it can only be approximated’ (Guba and Lincoln, 1994). This is in contrast with the dualist view held by positivists, who assume that an investigator can determine ‘how things really are’ or ‘how things really work (Guba and Lincoln, 1994).

3.5.3 Methodology.

In post-positivism, the methodology is focused on falsification of hypotheses, rather than the positivist view of verification of hypothesis (Guba and Lincoln, 1994). This post-positivist view is partly influenced by Karl Popper’s falsifiability theory. Popper (1968) rejected the notion of theory verification in favour of the notion of falsification. In his analogy of ‘all-white swans’, Popper (1968) argued that one can never conclude that all swans are white, simply because he/she saw one million swans that were all white. Since the detection of a single black swan on another occasion completely falsifies the initial conclusion, it is better for researchers to assume a sceptical position and go out into the field of research expecting to see something different that would falsify initial claims.

This notion of falsification held by post-positivism resonates philosophically with this present research study. It suggests that although the systematic review and meta-analysis of Chapter Two may have shown statistical research evidence which is in favour of ultrasonography as an effective diagnostic imaging modality for assessing labour progress, based on a sample population of studies conducted mostly in developed

countries, it does not necessarily conclude that ultrasonography is effective in all clinical settings worldwide. Hence attempts could be made to either confirm or refute earlier research findings by testing it in another unique setting.

3.5.4 Post-Positivism and Research in Clinical Diagnostic Imaging.

The philosophical underpinning for a diagnostic imaging research, and particularly in ultrasonography, has stronger basis in post-positivism than positivism. When the various medical imaging equipment were introduced into healthcare delivery, the original idea was to promote objectivity. However, a completely objective and independent external reality was not achievable with diagnostic imaging.

From the late eighteenth century onwards, various machines were invented with the goal of rendering the senses of 'scientists' redundant, which was referred to by Daston and Galison (1992) as 'mechanical objectivity'. They invented machines that were to produce better observations than the human sensory apparatus. Some of these machines were to visualise what the human eyes cannot see, which were all intended to prevent human speculations and the use of subjective interpretations in describing the findings detected by these manufactured machines (Daston and Galison, 1992).

The invention of the X-ray in the nineteenth century which occurred in that era of positivism was among the first of such similar instruments intended for extending the 'mechanical objectivity' agenda into the diagnostic aspect of healthcare. It was to eliminate the mediating presence of the physician observer or personnel from the diagnostic process. Their initial thought was that the X-ray would provide knowledge about the otherwise invisible internal structures of the human body just 'as they actually appeared', and without the interference of human interpretation to the point of permitting

personalised opinions (Pasveer and Pauwels, 2006). The seventeenth and eighteenth century practice of healthcare which saw physicians attend to the sick by merely observing their physical appearance, body fluids and by listening to stories told by the patient or their relative was regarded highly subject to the limitations of human interpretation (Pasveer and Pauwels, 2006). Consequently, it was thought that the discovery of the X-ray was going to put an end to the old practice. With the advent of the X-ray in the nineteenth century, the expectation then was that physicians were now going to receive direct knowledge on the abnormal changes in the body of sick people without the influence of any human limitation. This idea of eliminating such influence of the human interpretation was underpinned by the positivist ontological view that, a complete knowledge about an external reality was attainable.

It was not long before they realised that 'the X-ray was not a simple, true-to-nature representation of the internal structures of the human body' (Pasveer and Pauwels, 2006). Rather, it only produced a particular perspective of the body. There were shadows to be interpreted, some of which were artefacts and did not provide direct meaning when compared to the physical human anatomy of dissected cadavers.

It was soon realised that objects to which the medical images refer were actually mediated by the very instruments and methods used in depicting them. Not even the subsequent manufacture of much more sophisticated X-ray equipment such as fluoroscopy and computed tomography would completely eliminate the external influence on the 'reality' produced by these medical images.

Ultrasonography is another type of diagnostic imaging modality that emerged after the Second World War which uses sound energy in the production of knowledge about the

internal structures of the human body. Like the X-ray, the underlying purpose for the use of ultrasound is to improve objectivity.

However, attaining ‘objective reality’ through ultrasound imaging is not without the involvement of the investigator. There is an aspect of ultrasound imaging which is supported by the basic principles of objectivity such as to ‘see’ and to ‘hear’. There is also the subjective aspect of ultrasound imaging in which the investigator is involved in the instrumentation and interpretation. This makes ultrasonography much more in association with post-positivism rather than positivism.

The objective aspect of ultrasound imaging is characterised by the production of visuals, which is supported by the objectivity principle of ‘seeing’. Even though the term ultrasound is a description for sound beyond the human hearing ability, the underlying principles of sound and hearing still hold. This is evident in the use of the Doppler-effect where the imaging of moving objects such as blood flow may be demonstrated by hearing a pattern of sound. Another aspect of objectivity is the routine measurements to be taken during ultrasound which are characteristic of quantitative studies. This characteristic of ultrasonography is similar to other diagnostic imaging practices where images produced from the anatomical as well as pathological regions of the body could be measured or quantified as a source of evidence.

There is, however, an aspect of ultrasound imaging that requires the direct involvement of the investigator, which simply occurs because of the natural principles of ultrasonography. The quality of the images produced would be affected by the properties of the tissue medium the sound wave travels through which influences what can be ‘seen’. This may result from differences in the body size of different patients, or difference in the

acoustic impedance of the pathologic region in the body. For instance, in a relatively large person, there would be higher attenuation of the sound energy traveling through the body to produce the images, making the image quality lower than the images obtained from someone who is relatively smaller in size. This limitation in ultrasonography is therefore contradictory to the positivist ontological position that objective reality can be fully attained. In this example, the principles of ultrasonography are suggesting that objective reality is not fully attained due to attenuation of ultrasound waves as they travel deeper through a medium which may cause image quality deterioration in one person and a better image in another. Hence, making the objective view often relative.

By the same ultrasound imaging principles, the positivist epistemological position that knowledge can be fully attained is not applicable. Rather, it is supported by the post-positivist position that knowledge can only be attained imperfectly. In ultrasound imaging, the attainment of full knowledge is limited by the involvement of the investigator. For instance, in the example given above on the details of ultrasound findings being affected by a patient's body habitus, the investigator would be required to select the appropriate transducer frequency for the larger patient which should be lower in terms of frequency (megahertz) than the transducer used in scanning the relatively smaller patient, in order to attain deeper sound penetration to ensure that the targeted internal structures are reached by the sound. The additional control of selecting the appropriate knobs of the ultrasound instrument such as using the GAIN settings to amplify the weakened returning echo-signals is one of the ways used in optimising the image quality which are all contributions of the external observer in the production of knowledge in diagnostic imaging, and does not make the practice supportive of the positivist view of an

independent external reality. Instead, it very much supports the post-positivist view that reality cannot be entirely independent of external influence. It is therefore imperative that the involvement of the investigator in ultrasound as a diagnostic imaging modality makes research in this field associated with post-positivism rather than positivism.

3.5.5 Implications of Post-Positivism to this Present Research.

***Research Aim* -** The purpose of inquiry for post-positivism is similar to that of positivism. It is to enable '*explanation* and deepen *understanding'*, ultimately aimed at improving the capability of 'scientists' to 'predict and control' a physical or human phenomenon that has been observed over a period of time (Guba and Lincoln, 1994). This research aim of post-positivism is essentially in agreement with the aim of the present study which began by conducting a systematic review and meta-analysis to obtain a deeper understanding of the effectiveness of intrapartum ultrasonography. The additional primary research conducted was also aimed at obtaining new knowledge that may contribute better explanation on intrapartum ultrasound, with the ultimate goal of improving the diagnostic capacity of intrapartum caregivers in equipping them to 'predict and control' labour and delivery efficiently.

On the other hand, however, post-positivists also show interest in explaining how and why individual differences between study subjects or samples may have occurred (Schulze, 2003). For example, instead of simply showing interest in the percentage of parturients which obtained high accuracy in intrapartum ultrasound, the post-positivist would also be interested in understanding the factors that may be influencing the level of accuracy. This stems from the position that the reality about that accuracy may be influenced by external factors. Consequently, as part of the aims of this study, factors that

may have influenced the results obtained by ultrasound or digital VE were also investigated.

Nature of Knowledge **-** While positivist regard knowledge as consisting of verified hypotheses that is to be accepted as facts or laws, the post-positivist regard knowledge as consisting of non-falsified hypotheses that can only be regarded as probable facts or laws (Guba and Lincoln, 1994).

In this study therefore, the knowledge obtained from the systematic review and meta-analysis which suggests that ultrasound can be effectively used in assessing labour progress was only regarded as probable facts. This is what motivated the interest in repeating the study in a different clinical setting as an attempt to 'falsify' the probable facts suggested by previous studies. The non-falsification of this probable fact in another setting is an advancement of knowledge which would then suggests that intrapartum ultrasound may be effective in another clinical setting and population. However, the falsification of it may also be regarded as new knowledge suggesting that the use of ultrasound in assessing labour progress is probably only effective in selective clinical settings and populations but not applicable in some other settings such as the present one. This is essentially in agreement with the definition of EBP as explained in Chapters one and two.

In addition, post-positivists also believe in the *intuitive* part of knowledge (O'Leary, 2004). In this present study which is influenced by post-positivism, the methodological approach also took into consideration the need to investigate the views of caregivers, as their interest in using ultrasound or digital VE may not be simply be determined by which one of them is the most effective, but may also be related to personal preference for one of

the methods. Therefore, interviewing them was considered an appropriate component for obtaining knowledge on how effective using ultrasound in labour will be considered by them.

- ***Methods -*** Using an inductive approach is acceptable in post-positivism, even though they believe that the content-specific nature of researching may not lend itself to reproducibility, they accept the importance of the research context and the need for full explication of methods, to enable others see the process leading to the conclusion made (O'Leary, 2004). Hence, the approach used by this present study was systematic and comparable to the strictness of positivist methods.
- ***The Findings -*** For the positivist, findings must be applicable to the whole of a population. Results are shown to be true beyond chance, generalisable and applicable to a population beyond the sample (O'Leary, 2004). Conversely, post-positivists recognise the uniqueness of situations, but can still seek broader value of their findings. They seek findings that are not necessarily generalisable yet have their own intrinsic worth and are transferable, such that the lessons learned from one context may be applicable to other contexts (O'Leary, 2004). Hence, even though the expectation of this present study was not to obtain knowledge that is generalisable, it was the hope of the study that research findings may be applicable in other /contexts. It also encourages other researchers to investigate the reproducibility of new research findings emerging from this present study in their own context, just as the present study assessed the reproducibility of previous findings in another clinical setting.

- ***Validity*** **-** Unlike the positivist who is concerned with truth value and whether conclusions made are 'correct', the post-positivist is concerned with authenticity, by recognising that multiple truths may exist (O'Leary, 2004).

3.6 Chapter Summary.

This chapter has presented the aim, specific objectives, and the methodological approach of the primary research conducted by this study. It has also detailed the philosophical underpinning of this primary research in connection with post-positivism.

The post-positivist paradigmatic stance has been explained as a philosophical position that believes in objectivism and quantitative research. However, even though post-positivism believes in objectivism, this chapter has explained how it differs from positivism. It explained that post-positivism acknowledges the potential impact of external influences on how one views the world. It went further to explain that the knowledge produced by medical ultrasound as a diagnostic imaging modality is not without the external influences of the operator, the equipment and the characteristics of the patient, which is in agreement with the post-positivist position that knowledge can only be apprehended partially and may differ from one condition to the other. Hence, the need to test knowledge under different circumstances with the view of falsification rather than verification.

The next chapter details the research methods that were used in investigating each specific objective. The scope of the primary study and the rationale for methodological choices are also explained.

4 Chapter Four: Research Methods.

4.1 Introduction.

The preceding chapter has outlined the five specific objectives of this primary study. It also presented an outline of the methodological approach that was used in investigating each specific objective.

Chapter Four now presents further details on the research methods of this primary study. It describes the process used in selecting an appropriate research design. This include the scope of this research, the rationale for the choice of research methods, the processes used in recruiting study subjects, the procedures and protocols that were followed and the statistical analyses performed. Related issues addressed in this chapter include the preliminary pilot work that was conducted ahead of the main research, and the quality assurance issues associated with this reproducibility study.

4.2 Research Design.

In selecting the appropriate research design, this primary study was fundamentally guided by the specific objectives outlined in Chapter Three. It was also guided by the need to adhere to ethical issues that are associated with conducting such a study in a clinical setting where there are existing protocols to follow with regards to the vulnerable population that was involved. This vulnerable group consisted of pregnant women going through the spontaneous process of labour in pregnancy.

With these considerations in mind, using an observational study design was considered more appropriate than using an experimental study design. Unlike an experimental study design which allows the researcher to intervene or manipulate the natural course of a phenomenon, the observational study researcher only observes outcomes rather than

interfering with the natural course of a phenomenon (Thiese, 2014). The observational study approach was therefore selected as the most appropriate option, which allows the researcher to collect data without interfering with the existing protocols of the facility in their management of pregnant women in labour.

4.2.1 Observational Study Design Considerations.

Having selected observational study as the appropriate methodological approach, the next step was to choose from three possible types of observational study designs in a biomedical research field, which includes a case-control study, a cohort study, and a cross-sectional study (Mann, 2003; Thiese, 2014). A case-control study was rejected because of the quasi-experimental approach associated with it (Thiese, 2014). A case-control study was also limited in its design for addressing all the five specific objectives this primary study had set out to investigate.

After excluding a case-control study design, the options left were to choose between a cohort study and a cross-sectional study. Selecting a cohort study design was going to require the recruitment of pregnant women with a particular type of intrapartum condition (Thiese, 2014), such as those with prolonged labour, in order to follow-up on the outcome of their condition probably to compare it with another group without that same condition. However, conducting a cohort study was rejected by this prospective primary study as it was difficult to determine how long it will take to identify prospective participants of a particular clinical condition in order to seek their consent and enrol them. It was therefore not suitable as a prospective study for an academic project. The second reason for rejecting a cohort study design was that it was not the only type of study design available

for investigating the research objectives outlined, and also because the other design appeared to be more ethically appropriate for the vulnerable population involved.

Eventually, the cross-sectional design became the remaining study design which was also appropriate for investigating all the five specific objectives outlined, including the clinical and the non-clinical aspects of the study.

4.2.2 A Cross-Sectional Study Design.

A cross-sectional study is a type of observational study which is designed to collect data at one point in time (Mann, 2003; Thiese, 2014). There are various types of cross-sectional study designs, which include prevalence studies, the estimation of sensitivity and specificity, studies of measurement validity, reliability and agreement studies, sample survey, among others (Bland *et al*, 2012). It was therefore seen as an all-encompassing approach for the specific objectives of this study.

4.3 Scope of Primary Study.

This primary study was designed to investigate 'Between-Method' agreement. It investigates ultrasound as the new method in comparison with digital VE as the old method. A study that is designed to investigate 'Between-Method' agreement is known as a reproducibility study (Barnhart *et al*, 2007; Bartlett and Frost, 2008; Watson and Petrie, 2010). This primary study can therefore be referred to as a reproducibility study. As explained in Chapter One of this thesis, the goal of this reproducibility study was to obtain further research evidence on the effectiveness of ultrasound in labour by assessing it from the context of EBP. In connection with this EBP context, the interests of patients and caregivers are seen as important counterparts of research evidence when exploring the potential introduction of ultrasonography as a medical device for assessing the

progress of pregnant women in labour. Consequently, the views of mothers as well as the views of caregivers on the use of ultrasound in labour were also investigated as part of this primary study.

There is, however, the need to differentiate the between-method agreement study, which is also called a reproducibility study, from other types of agreement studies, in order to avoid a misinterpretation of the scope of this primary study.

4.3.1 Difference between a Reproducibility Study and a Repeatability Study.

Although a reproducibility study and a repeatability study are both measures for assessing reliability, they do not mean the same (Barnhart *et al*, 2007; Bartlett and Frost, 2008; Watson and Petrie, 2010). The main difference between the two is that reproducibility investigates 'between-method' agreement, whilst repeatability investigates 'within-method' agreement (Barnhart *et al*, 2007; Bartlett and Frost, 2008; Watson and Petrie, 2010). In keeping with the scope of a reproducibility study, this primary study was conducted in order to compare its findings with similar studies conducted elsewhere. This requires using a different setting, different study subjects, a different instrument and a different observer or rater (Bartlett and Frost, 2008; Watson and Petrie, 2010).

A repeatability study on the other hand is another type of agreement study which is conducted by using the same study subjects, with the same instruments, in the same laboratory or research setting, by the same previous observer or rater, and around the same timeframe within which the underlying parameter to be measured should be considered as constant (Bartlett and Frost, 2008; Watson and Petrie, 2010). Whilst repeatability studies investigate intra-rater reliability, a reproducibility study cannot do that, since it is an investigation conducted under different circumstances. In reality, a

repeatability study was not practicable in this study because of the varying and dynamic nature of the process of labour, which makes expecting the underlying parameter to remain constant nearly impossible even in a short time. Secondly, being an observational study, ultrasounds had to be performed only when a digital VE had been clinically indicated, and since only one digital VE was allowed at a time per the protocols of the facility, only one ultrasound could also be performed at the given time.

Therefore, conducting a repeatability study was beyond the scope of this cross-sectional study, and determining intra-rater reliability was also beyond the scope of this study.

4.3.2 Difference in Between-Method Agreement versus Between-Observer/Rater Agreement.

Although ‘between-method’ agreement and ‘between-observer/rater’ agreement are both types of reproducibility, they are different methods (Bartlett and Frost, 2008). The focus of this primary study was on ‘between-method’ agreement rather than ‘between-observer/rater agreement. In this primary study, raters of digital VE were clinicians on regular duty who were not participants of the study. Digital VEs were therefore performed by different raters depending on who was on duty. On the other hand, ultrasounds were performed by one rater, a situation which was similar to almost all previous studies. Due to this lack of balance between method raters, ‘between-observer/rater’ agreement was beyond the scope of this study.

Therefore this primary study did not assess inter-rater reliability which is associated with ‘between-observer/rater agreement.

4.3.3 Study Location.

The study was conducted in Ghana, a West African country about the size of the UK. Ghana has a total land area of about 239,000 square kilometres, and a population of over 24 million (GSS, 2012). It shares borders with Togo to the East, Ivory Coast to the West, Burkina Faso to the North, and then the Atlantic Ocean (Gulf of Guinea) to the south (figure 4.1).

Figure 4.1 Geographic location of Ghana

(Reproduced with kind permission of New Internationalist https://newint.org/columns/country/2009/04/01/ghana/)

Ghana was considered an appropriate new setting for further research on intrapartum ultrasound for a number of reasons. The first reason is that, no study was identified in the systematic review and meta-analysis of Chapter Two which was conducted in a sub-Saharan African country. This makes Ghana an appropriate location for a reproducibility study since it is a sub-Saharan African country.

The selection of Ghana as a new location for further research on this subject had the potential of contributing additional knowledge, as well as providing a unique perspective on the subject of intrapartum ultrasonography.

Unlike previous studies which were mainly conducted in developed countries, Ghana was a low middle income developing country, which extends knowledge on intrapartum ultrasound beyond the existing knowledge obtained from developed country settings.

4.3.3.1 Ghana's Maternal Healthcare Profile.

Regarding maternal healthcare in Ghana, it had been reported that 96% of pregnant women access antenatal care from skilled healthcare professionals, with the majority of expectant mothers attending not less than three antenatal visits before delivery (GSS *et al*, 2009).

Ironically, it was also reported that a significant percentage of Ghanaian expectant mothers were giving birth at home with the assistance of untrained birth attendants. The most recent publication indicated that only 54% of mothers in Ghana were giving birth in the hospital or clinic, in spite of the fact that Ghana as a country had no recognised programme for home deliveries by skilled midwives (GSS *et al*, 2009).

Further reports also indicate that expectant mothers had various reasons for choosing to give birth at home, some of which include religious reasons and the fear of hospital deliveries (GSS *et al*, 2009). It remains unknown as to whether the routine digital VEs performed during hospital deliveries contributed to their 'religious' concerns and 'fears'. It is however known that the Ghanaian health insurance scheme had committed to paying for at least two routine ultrasounds in pregnancy, and that any additional scan that is clinically indicated was also paid for by the national insurance scheme (MOH, 2013). It was, however, unknown if the ultrasound services mothers received during their antenatal care was contributing to the higher patronage of antenatal services when compared to the rather lower intrapartum turn out where ultrasound is rarely used. Again, it also remained unknown if introducing ultrasound in labour might improve mothers' patronage of intrapartum services at the hospital or clinic. These are all potential areas for future research which may become relevant after determining the outcome of this explorative stage research.

4.3.3.2 Clinical Site.

Just as previous studies in developed countries began by investigating intrapartum ultrasound mainly in tertiary hospitals, this study being one of the initial or perhaps the first in sub-Saharan Africa was also conducted in a tertiary setting. The study was therefore conducted at the labour and delivery unit of the Komfo Anokye Teaching Hospital (KATH). KATH is located in Kumasi, an urbanised cosmopolitan region towards the middle part of Ghana with inhabitants from all walks of life. The hospital is the second largest teaching hospital in Ghana. It is the major referral centre for the Ashanti region and beyond. The Obstetrics and Gynaecology Department of the hospital has a bed

capacity of 160, and conducts about 13,000 deliveries a year, about 70% of which are vaginal deliveries (Dassah *et al*, 2014). The department comprises mainly of doctors and midwives and fewer other categories of staff such as anaesthetists, sonographers, administrative personnel and interns. They also have three separate labour and delivery wards with theatres attached. Each of these labour and delivery wards uses an ultrasound machine, basically for checking the presence of fetal cardiac activity, fetal presentation and the location of placenta if found necessary during labour. They never use ultrasound for determining the fetal head position or head station, or for the cervical dilatation this study was investigating.

When a mother reports to the labour ward on account of spontaneous labour, she is received by a midwife who determines whether she is in the active phase before admission to the labour ward is done. This determination of whether or not she has attained active labour is done mainly by assessing cervical dilatation and the regularity and strength of uterine contraction with other additional signs as secondary. Usually, when a midwife determines that the mother is not in active labour, she is asked to either stay in a waiting room or go back home depending on the clinical discretion exercised.

Mothers admitted to the labour ward on account of active labour would usually undergo the next digital VE in four hours after admission, and that is if she had not delivered by then. The next digital VE time would be 3 hours for parturients whose last digital VE recorded 7cm of cervical dilatation, and 2 hours for those who recorded 8cm dilatation, and again one hour for those who recorded 9cm dilatation. At 10 cm which is regarded as full dilatation, the mother is then sent to the second stage for delivery to be conducted by the midwife on duty.

If significant increase in cervical dilatation is not found by the next digital VE review time of the first stage of active labour, and especially when uterine contractions are inadequate, labour augmentation is done by either manual rupture of amniotic membranes if it is still intact, or by administering oxytocin. On the other hand, those parturients diagnosed with conditions such as cephalo-pelvic disproportion are sent for caesarean section. Caesarean section at the hospital may also be indicated in other conditions such as fetal distress.

4.3.4 Preliminary Pilot Work in Preparation for the Main Study.

Conducting a pilot project is useful in the testing of research design, study procedures, data collection tools and data analysis (Yin, 2015). Consequently, after obtaining ethical approval, a preliminary pilot project was performed ahead of the main study. This was mainly to prepare the ultrasound-rater in testing the study procedures in order to validate the data collection tools.

Before the start of this pilot work, communication was established with Professor Torbjørn Eggebø to discuss the protocols of the main study. Professor Eggebø from the Norwegian University of Science and Technology in Norway is a researcher/physician who has contributed much in the way of research on the topic of intrapartum ultrasound, with numerous published articles in ultrasound and obstetrics over a span of 28 years.

After discussing the study protocols with Professor Eggebø, I performed 20 cases of intrapartum ultrasound which were compared with digital VE findings in a non-blinded pilot study. As this pilot study was non-blinded, the ultrasound scans were performed with prior knowledge of the digital VE findings. The primary goal of this non-blinded study was to develop a consistent scanning protocol ahead of the main study, and to obtain the

basic intrapartum scanning skills that were needed, particularly with regards to the transperineal recognition of the dilating cervix. The measurement of all ultrasound parameters were also rehearsed in the process, including the use of the goniometer in measuring angles that were created from the symphysis pubis and the fetal head. Because of Professor Eggebø's guidance and suggestions specifically related to the initial images and measurements obtained for the HPD, HSD and cervical dilatation, alterations were made in subsequent scanning techniques in ensuring that I became adequately prepared for the main study.

The number of cases used for this preliminary work was influenced by the 20 cases used by Yuce *et al* (2015) when they were preparing for a similar study in Turkey. This pilot work therefore confirmed that the 20 cases used by Yuce *et al* (2015) was actually adequate for obtaining the basic intrapartum scanning skills that were needed by an ultrasound rater who is already highly experienced in performing obstetric ultrasounds.

Secondly, caregivers were engaged in oral unrecorded interviews in the course of the preliminary pilot work to identify themes of interest to be further explored during the main study. In addition, oral interviews were granted to mothers who were not having severe uterine contractions and who were willing to talk about their experiences with ultrasound in comparison to digital VE, in order to identify themes to include in the study questionnaire. These themes eventually formed the basis for the final survey questions that were used for the main study.

4.3.5 Quality Assurance of the Reproducibility Study.

The result of a between-method agreement study can be affected by the research equipment and the observers or raters that were used for the study (Bland, 2000). Whilst this limitation cannot be completely eliminated, it can be significantly minimised by using an appropriate equipment and ensuring that the observers are adequately trained raters (Santos, 2011).

These potential quality assurance issues of the reproducibility study are further addressed below.

4.3.5.1 Equipment.

As expected of a reproducibility study, the ultrasound equipment used for this study was different in terms of brand from the types used by previous investigators. Although it was a different brand of ultrasound equipment, it was by no means inferior to the others in terms of its quality. The ultrasound equipment brand used was a Siemens-Acuson P 300 (Siemens Medical Solutions, Italy) manufactured in 2014. As it was only two years old, it could be referred to as fairly-new when used in collecting the data of this study in the year 2016. In addition, the standardised sonographer-led quality assurance programme recommended by the British Medical Ultrasound Society (BMUS) was practiced to ensure the maintenance of quality (Dudley *et al*, 2014). This included protecting the machine from dust by ensuring that it was always covered when it was not in use. In order to ensure that there was no damage to the machine during the study, a daily inspection of the monitor, the transducer as well as the transducer cable was completed. A daily inspection of the grayscale bar was also done to ensure that the contrast and brightness settings were consistent with baseline calibrations. It also included a monthly assessment of air

reverberation pattern, element drop-out test and electronic noise assessment (Dudley *et al*, 2014), all of which were of high quality throughout the study period.

4.3.5.2 Digital VE Observers/Raters.

All digital VEs were performed by specialist obstetricians on duty, who had not less than five years of experience through residency training, with the majority having between ten to fifteen years of experience in clinical practice, including performing digital VE. As practitioners who were working in a teaching hospital, not only were they highly skilled in performing digital VE, but they were also involved in teaching others how to perform it. They were all members and fellows of their professional organisations including many who were fellows of the West African and Ghanaian College for Obstetricians and Gynaecologists, and a few who were members of the Royal College of Obstetricians in the UK. They therefore represented the highest quality standard available in the facility.

4.3.5.3 Ultrasound Observer/Rater.

All ultrasounds were performed by myself as a Specialist Sonographer with over ten years of experience in clinical ultrasound, and with my specialties including Obstetrics and Gynaecology ultrasound. I had maintained an ACTIVE status since my initial registration as a qualified sonographer with the American Registry for Diagnostic Medical Sonography (ARDMS) in 2005. As an Advanced Ultrasound Practitioner in a teaching hospital, not only was I registered by my professional body as highly skilled in the theory and practice of obstetric ultrasounds, which includes performing transvaginal and transperineal ultrasounds, but I also taught others how to do it. I therefore represented the highest quality standard available in the facility. I also maintained a high quality professional

standard as a member of the BMUS and the ARDMS and with a Master of Science degree in Advanced Practice Ultrasound.

4.3.5.4 Blinding of Between-Method Observers/Raters.

Double blinding was considered an aspect of the quality assurance of this study. The ultrasound-rater and the digital VE-rater were therefore blinded from each other's findings in the data collection process. This was done by ensuring that the ultrasound-rater was not with the digital VE-rater when obtaining measurements at the mother's bedside. The digital VE findings were also immediately recorded and handed over to the midwife in-charge of the labour ward and were therefore not accessible to the ultrasound-rater. Likewise, the ultrasound scanning was done in the absence of the digital VE-rater who also had no immediate access to the ultrasound findings.

4.4 Recruitment of Pregnant Women.

4.4.1 Eligibility Criteria.

In order to recruit volunteers, daily announcements were made at the antenatal clinic of KATH for voluntary participation in the upcoming study. This was done from January 2016, before the data collection began in April 2016, and continued until data collection ended in September 2016. Only mothers who were attending the antenatal clinic at KATH were eligible to participate in the study. The study information leaflets were given to potential participants who had ample time to ask questions and decide on their willingness to participate. In order to be eligible for participation, potential participants were

encouraged to bring the signed informed consent form when coming for delivery at the hospital.

4.4.2 Inclusion Criteria.

The inclusion criteria consisted of pregnancies at term (i.e. estimated gestational age of 37 weeks or more), spontaneous labour, singleton gestation, cephalic presentation, and labour ward admission. This included nulliparous, primiparous and multiparous expectant mothers.

4.4.3 Exclusion Criteria.

Women in labour with the following conditions were excluded: induction of labour, breech presentation, multiple pregnancy, polyhydramnios, sonographically detected fetal abnormalities, previous caesarean section, and any condition considered by the clinician as requiring immediate intervention which may be affected by their participation.

In addition, recruited participants were to be excluded if the ultrasound examination noticed any abnormality in the course of the study which needed to be disclosed to the management team for the appropriate care.

4.4.4 Population.

The first population set was comprised of pregnant women in labour, which was in connection with the specific objectives 1 to 3 as indicated in Chapter Three. The second population set consisted of mothers undergoing postnatal care who had experienced ultrasound in labour. The last population set was comprised of caregivers working at the labour ward of KATH.

4.4.5 Sample Size.

By regarding cervical dilatation as the primary intrapartum parameter during digital VE assessment, the estimation of the sample size was based on previous studies conducted on cervical dilatation. At the time of submitting the protocols of this study for ethical approval in 2014, the available study that could be used as a basis for estimating sample size was the multi-centre study by Hassan *et al* (2014) conducted in the UK and Norway, in which the successful ultrasound determination of cervical dilatation was said to be possible in 86.5 % of cases. Using 86.5% as ultrasound efficiency, a confidence level of 95% and a precision error of 5%, the sample size was estimated as follows:

Sample size calculation: $n = z^2pq/d^2$; where n = the estimated sample size; z = reliability coefficient of 1.96 which corresponds to 95% confidence interval (CI); p = intervention rate (the proportion of the effectiveness of the intervention) ; q = 1- p; d = precision error; z = 1.96(95% CI); p = 86.5% = 0.865; q = 1-0.865; d = 5% = 0.05 $n = (1.96)^2(0.865(1-0.865)/ (0.05)^2 = 179$.

Therefore, a minimum sample size of 179 participants was considered adequate for the quantitative study of the specific objectives 1 to 3. Regarding the fourth specific objective, which was to assess mothers' acceptance of ultrasound in labour, interviews were to be conducted with all mothers in the postpartum stage who had participated in the intrapartum study. Since the fifth objective was going to use a qualitative approach to obtain the views of caregivers on the practicality of using ultrasound in labour, no sample size calculation was done for this. Data collection was to continue until a saturation point was reached.

4.4.6 Sample Selection.

Simple random sampling was used in selecting participants for the first four specific objectives. All consenting mothers in labour had equal chance of being selected. The recruitment process began from the antenatal period where all potential participants in their third trimester of pregnancy and attending the antenatal clinic at KATH were given verbal information about the study in the local dialect (Twi). Potential participants were given the opportunity and encouraged to ask further questions about the study. Information leaflets were given to interested potential participants for further education on the study, as well as informed consent forms to be taken home for signing or thumb printing at their own convenience. Potential participants were asked to staple a copy of a signed or thumb printed informed consent form into their antenatal booklets which they usually carry along to the labour ward upon spontaneous labour. At the labour ward, all potential participants whose antenatal booklet contained the signed or thump printed informed consent form were approached for recruitment. This was, however, subject to the availability of the ultrasound-rater at the time of labour. Thus the recruitment process was completed by the availability of the ultrasound-rater during the digital VE review time of all prospective participant. The total number of participants the study was able to recruit from April to September 2016 was 201, after distributing over two thousand informed consent forms.

4.4.7 Data Collection Procedure.

Following the recruitment of a participant, digital VE was performed at the clinically indicated review time. The digital VE was done by a clinician on duty. Immediately after the digital VE, ultrasound was performed by the independent ultrasound-rater who was present at the labour ward for that sole purpose.

A specifically designed data extraction sheet was given to the labour attendant to enter the digital VE findings on cervical dilatation, head station, and position in the respective spaces provided (see Appendix 4). Other clinical details requested on the data extraction sheet were also to be provided by the digital VE-rater. The ultrasound findings were immediately entered in a separate data extraction sheet by an accompanying chaperon who was present and standing behind the ultrasound-observer during the scan.

The completed data extraction sheets for the ultrasound findings and the digital VE findings were separately submitted to the midwife in-charge of the labour ward who stapled them to the last page of the participant's folder for later collection. After delivery, recovered participants were approached by the midwife in charge to confirm their willingness to continue with the ultrasound study. Consenting participants were then asked to complete the questionnaire for investigating the mother's acceptability (see Appendix 5). The completed intrapartum data extraction sheets and the completed postpartum questionnaires on mother's acceptability of ultrasound in labour were then collected from the midwife for data entry into an Excel spread sheet. Data analysis was done with XLSTAT version 2015 for Windows.

4.5 Methods and Analyses on Fetal Head Position.

The fetal head position referred to the relationship between the reference point of the presenting fetal part and the maternal pelvis (Cunningham *et al*, 2001). Whilst the reference point could refer to the sacrum in breech presentations, or the chin in face presentations, none of these presentations were applicable in this study, as the eligibility

criteria for inclusion was limited to only cases with cephalic presentation. Consequently, the reference point in this study was the posterior fontanelle or the occiput, which is the known reference point for all cephalic presentations.

4.5.1 Preparation for Clinical Assessment of Fetal Head Position.

In accordance with the standards of the facility, the clinician performing the digital VE explained the examination to the mother, including the possible discomfort and the rarely painful experience she may have during the examination. The routine practice of the facility prior to performing vaginal examination in all parturients is to begin with an abdominal examination in order to confirm the lie of the fetus as well as the presenting fetal part. In this study, as part of the inclusion criteria the digital VE-rater was also to ensure that the presenting fetal part for all prospective participants was the head. Any doubts about the presentation was enough reason for exclusion.

In performing the digital VE, the mother was asked to lie in the supine position with her legs flexed and her knees held apart. The digital VE-rater wore sterile gloves to perform the examination. The mother's vulva and perineum were cleaned with a disinfectant, including the swabbing of both sides of the labia majora and groins as well as the introitus. This was done whilst keeping the labia majora apart with the thumb and forefinger.

4.5.2 Digital VE Procedure for the Determination of Fetal Head Position.

Whilst wearing the sterile gloves, the middle and index fingers were inserted into the vaginal canal and pushed to reach the fetal head by feeling the presenting fetal part, which in this study was expected to be the feeling of the hard skull. With the aid of the sagittal sutures, the posterior fontanelle was identified as a small triangular space whilst the anterior fontanelle was felt as a larger diamond shaped space. Upon feeling the small

triangular space called the posterior fontanelle, the clinician classified the location in relation to the mother. If the posterior fontanelle was pointing towards the anterior left of the mother, that was called left occiput anterior, or left occiput posterior when pointing to the posterior aspect of the maternal left. It was classified as left occiput transverse when pointing directly to the left side. The other possible classifications with respect to the mother were right occiput anterior, right occiput posterior and right occiput transverse, direct occiput posterior and direct occiput anterior (see figure 4.3).

4.5.3 Preparation for Ultrasound Assessment of Fetal Head Position.

Ultrasound assessment followed within five to ten minutes after the digital VE in all included cases. The ultrasound-rater washed both hands thoroughly and wore gloves before scanning. The P300 Siemens-Acuson ultrasound system (Siemens, Italy) was wheeled to the mother's bedside for the examination. The mother's information was entered onto the system, including her identification number and age. The application pre-set selected in all cases was Obstetrics (OB), and the transducer selected was a multi-frequency curvilinear probe of 2-5MHz. As part of standardised orientation measures, it was ensured that the ultrasound system's orientation icon was to the right of the screen. After wearing sterile gloves on both hands, coupling gel was poured unto the probe head to get rid of potential gas space which may prevent sound transmission from the transducer into the body. The transducer was then covered with a sterile glove. Additional coupling gel was also poured on the covered probe. The mother was then made to lie in the supine position without the flexion of legs.

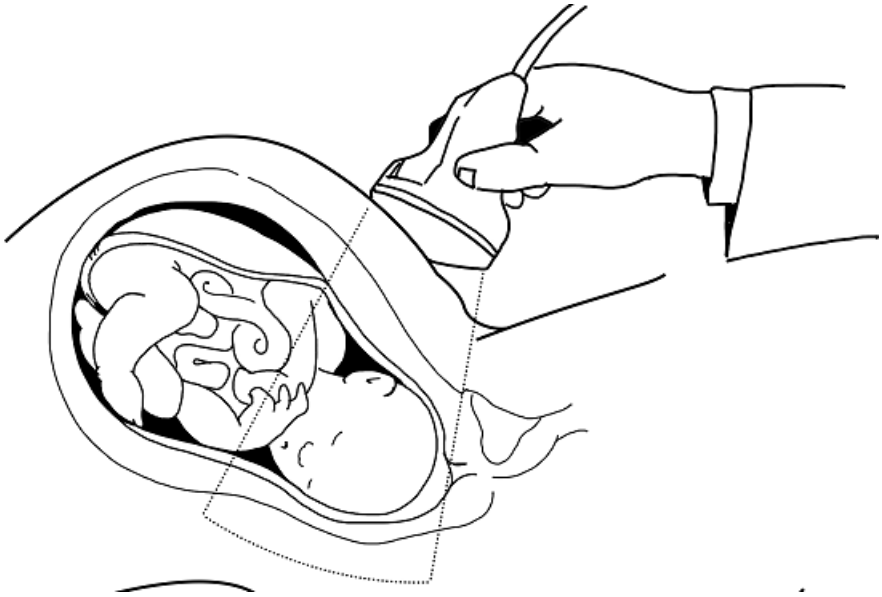

Figure 4.2 Transabdominal scan for imaging fetal head position

4.5.4 Ultrasound Procedure for the Determination of Fetal Head Position.

The transabdominal approach was used in assessing fetal head position, by placing the covered 2-5MHz transducer in transverse probe orientation at the suprapubic region of the maternal abdomen. Confirmation of cephalic presentation was made before proceeding with the study. Scan was performed in between uterine contractions by directing the transducer sound beam for an axial slice through the fetal head which was to show a number of the midline intracranial structures to serve as the anatomical landmarks for determining the occipital region of the fetal head, including the thalami, falx cerebri, cavum septum pellucidi and the cerebella hemisphere. Anterior and posterior cranial structures such as the orbits, nasal bridge, and cervical spine were also used for the identification of direct posterior position. The classification of the fetal head position was therefore determined by following guidelines of the conventional probe orientation

for transverse sonograms. Figure 4.3 shows the various classifications of fetal head position in accordance with the transverse sonographic orientation.

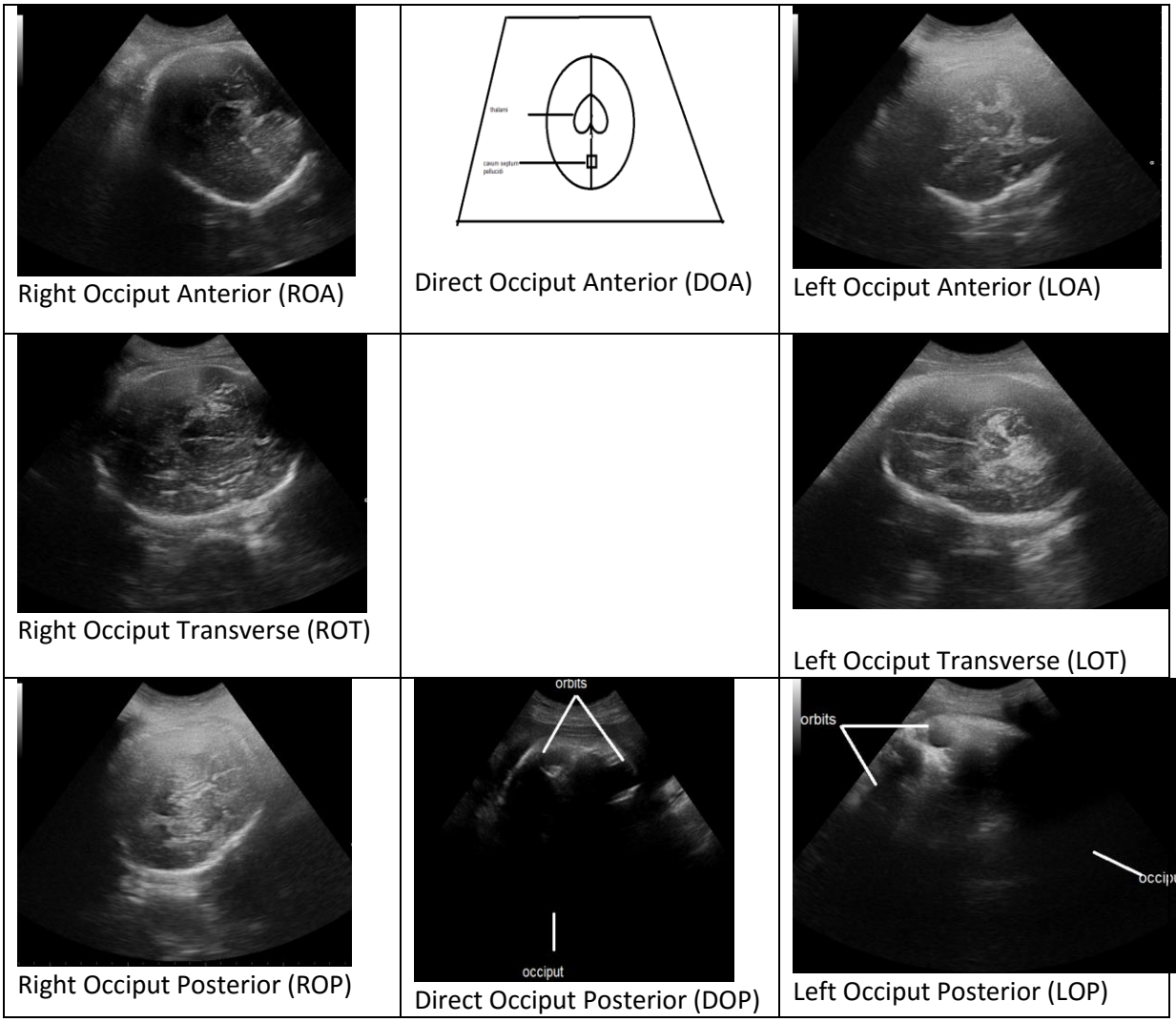

Figure 4.3 Sonograms of the various fetal head positions of some cases

(Source: from present study - No DOA case was present in the study, hence a drawing was used to represent DOA)

4.5.5 Analytic Strategy for the Research Question on Fetal Head Position.

The analytical strategy of the research question on fetal head position was primarily determined by the specific research objective. This was 'to assess the agreement

between ultrasound and digital VE on fetal head position, and the intrapartum factors that may have affected the agreement'.

Two stages of statistical analyses were therefore conducted to answer the research question on fetal head position. In the first stage of the analysis, the level of agreement between ultrasound and digital VE was analysed.

The second stage of analysis was conducted to analyse the intrapartum variables that may have affected the between-method agreement. This second component of the research question was analysed as part of this study because it was part of the initial reproducibility study conducted by Sherer *et al* (2002a) and other subsequent studies.

4.5.5.1 First Stage Analysis: Agreement on Fetal Head Position.

The appropriate analytical approach for assessing the between-method agreement on fetal head position was selected after considering two main factors. These factors are: (a) the outcome variable on fetal head position, and (b) the analytical approach that was used by similar previous studies.

a) Outcome Variable on Fetal Head Position.

The outcome variable on fetal head position is a categorical variable which has eight possible answer options, including the Left Occiput Anterior (LOA), Left Occiput Transverse (LOT), Left Occiput Posterior (LOP), Direct Occiput Posterior (DOP), Right Occiput Posterior (ROP), Right Occiput Transverse (ROT), Right Occiput Anterior (ROA), and Direct Occiput Anterior (DOA). They were therefore converted into ordinal/interval variables which are 45^{o} apart (see figure 4.4).

As these were categorical variables, the appropriate statistical method for analysing categorical outcome variables was selected. Conventionally, the statistical method for analysing the between-method agreement of a categorical outcome variable is the percent agreement, which is calculated as the number of agreement scores divided by the total number of scores (McHugh, 2012). However, this old statistical method does not account for agreement by chance. Due to this limitation in this statistical method, the most commonly used statistical method for analysing the between-method agreement of a categorical outcome variable is Cohen's Kappa statistics, which does account for agreement by chance (McHugh, 2012; Watson and Petrie, 2010).

b) Analytical Approach of Similar Previous Studies.

As shown in the Chapter Two of this thesis, in all similar reproducibility studies previously conducted, the between-method agreement on fetal head position was analysed by using either the percent agreement, the Cohen's Kappa statistics, or both. Again, in terms of the percent agreement, their definition of agreement was based on an agreement within a $\pm 45^{o}$ range.

Having considered these two factors described above, this primary study chose to analyse the between-method agreement on fetal head position by using the old statistical method of percent agreement and Cohen's Kappa which is the newer statistical method. The two types of analyses were performed in order to permit adequate comparison of this reproducibility study with all identified previous studies, as some of them were analysed by the percent agreement method only.

4.5.5.2 Second Stage Analysis – Factors Affecting Agreement on Fetal Head Position.

In this second stage of the analysis, the intrapartum factors that were analysed included:

i. digital VE cervical dilatation (3cm, 4cm, 5cm, 6cm, 7cm, 8cm, 9cm, 10cm)
ii. digital VE head station (-2, -1, 0, +1, +2, +3, +4)
iii. ultrasound head position (45^{o}, 90^{o}, 135^{o}, 180^{o}, 225^{o}, 270^{o}, 315^{o})

As these are independent variables, the Chi-square test was considered an appropriate analysis for assessing their independent relationship with the between-method agreement. The chi-square test was chosen because it is an appropriate and the most common general test that is used in analysing the effect of independent variables (Freeman and Julious, 2007). Secondly, the chi-square test was chosen because the initial reproducibility study by Sherer *et al* (2002a) was also analysed by chi-square.

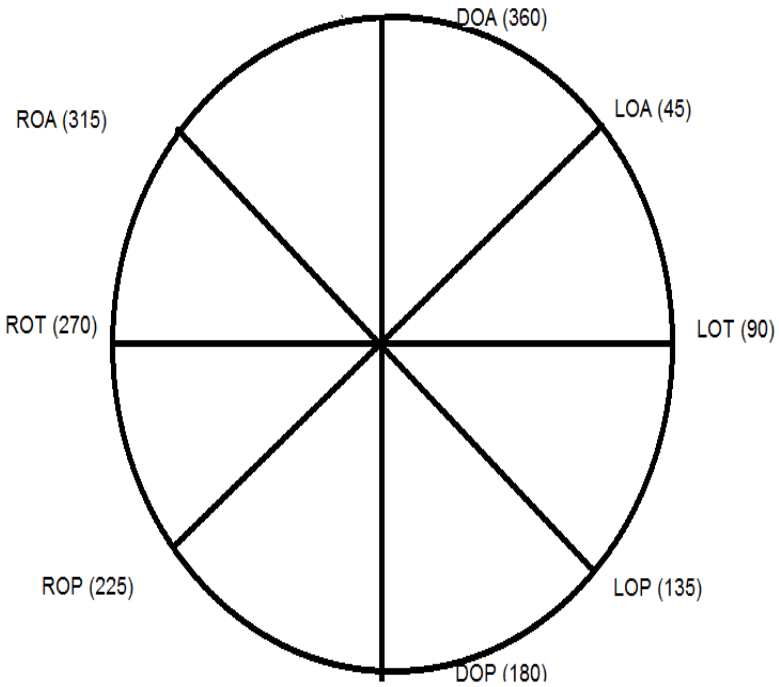

Figure 4.4 Fetal head positions in a 45^{o} range classification

4.6 Methods and Analyses on Fetal Head Station.

During labour, the head station refers to the distance (in centimetres) from the leading part of the fetus to an imaginary line at the level of the maternal ischial spines as the reference point (Cunningham *et al*, 2001). By convention, this imaginary line at the level of the ischial spines is called 'station 0', and serves as the midpoint that divides the birth canal into upper and lower halves (Cunningham *et al*, 2001). There are five stations of 1cm interval in the upper birth canal all of which are above station 0. The uppermost station in the upper birth canal is called -5, and it is 5cm above station 0 and at the entry point of the pelvic inlet. It is followed by station -4, and then stations -3, -2, and -1 which are respectively located at 4cm, 3cm, 2cm, and 1cm above station 0. In the lower birth canal which is below the ischial spines, there is another set of five stations of 1 cm interval extending from station 0 to the perineum where the baby exits. The first 1cm interval from station 0 towards the perineum is called station +1, with stations +2, +3, and +4 located at 2cm, 3cm, and 4cm respectively from station 0 towards the perineum. Station +5 is at the level of the perineum which is 5cm away from station 0 (Cunningham *et al*, 2001).

4.6.1 Preparation for Ultrasound Assessment of Fetal Head Station (Descent).

The additional preparation required for ultrasound was to ask the mother to flex the legs with her knees apart. Transperineal ultrasound examination was then performed using the same curvilinear transducer which was earlier used for the transabdominal scanning when assessing the fetal head position. The transperineal ultrasound was done immediately after the transabdominal scan. The transperineal scan was used in determining the HPD and AoP which were the two commonly used ultrasound methods

known to correlate well with the station (Wiafe *et al*, 2016). In addition, HSD was also determined along with the AoP, since the two were obtainable from the same plane.

4.6.2 Ultrasound Procedure for the Determination of Fetal Head 'Station'.

The transperineal scan was performed by placing the curvilinear transducer at the perineal space between labia and the anus. With the probe held in the sagittal plane over the perineal region, the fetal head appeared on the grayscale often with part of the symphysis pubis showing anteriorly. The probe was slightly rocked superiorly to direct the sound beam towards clear visualisation of the symphysis pubis in its longest axis as demonstrated in figure 4.5. In some cases slight rotational manoeuvres were necessary for obtaining the longest axis of the symphysis pubis.

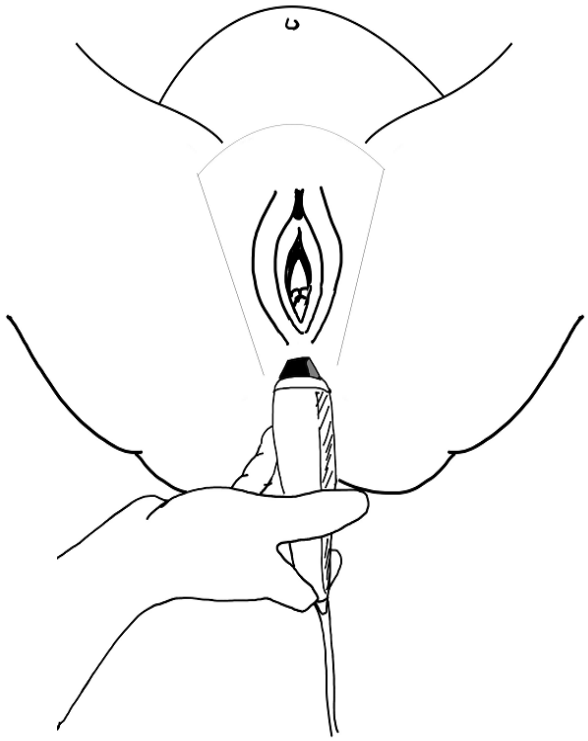

Figure 4.5 A sagittal transperineal scan with slight anterior rocking to image the AoP and HSD

The image was frozen upon visualisation of the symphysis pubis in obtaining measurements for the AoP whilst using the same plane for measuring the HSD. In measuring the HSD, the 'measure' calliper of the ultrasound system was selected and dragged to the inferior edge of the symphysis pubis to obtain a perpendicular distance from the inferior edge of the symphysis pubis to the fetal head in centimetres as demonstrated in the figure 4.6 below.

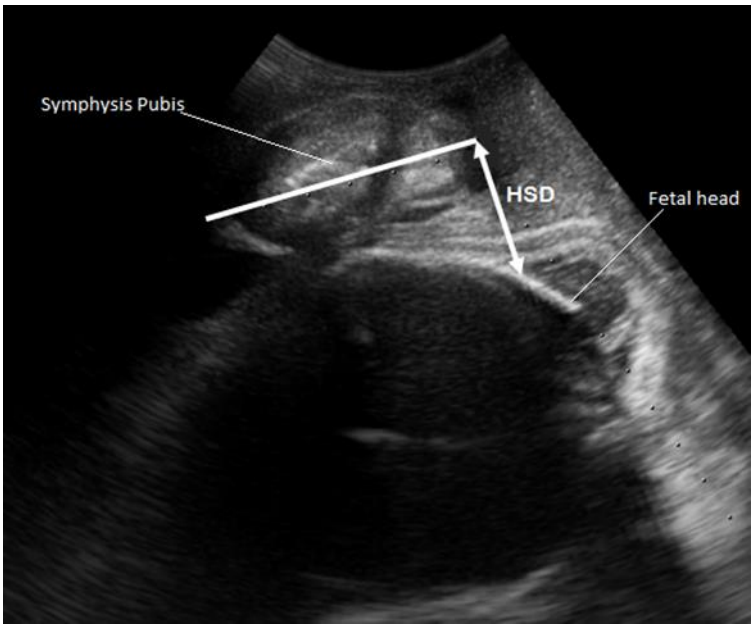

Figure 4.6 An example of HPD sonographic image (Source: Wiafe et al, 2018)

The AoP was also measured in the same plane by drawing a line through the long axis of the symphysis pubis using the 'distance' calliper on the machine. By clicking on another distance calliper a second line was then drawn from the inferior edge of the symphysis pubis to form a tangent with the leading edge of the fetal head as shown in figure 4.7. Afterwards, a goniometer was then used in measuring the angle between the two drawn lines to obtain the AoP. Depending on the level of descent, a subjective eye-ball assessment without manual measurement with the goniometer also showed the

measured AoP as either an acute angle (i.e. <90º), right angle (i.e. approximately 90º) or obtuse angle (i.e. <180º). Figure 4.7 shows an example of the appearance of AoP measurements obtained.

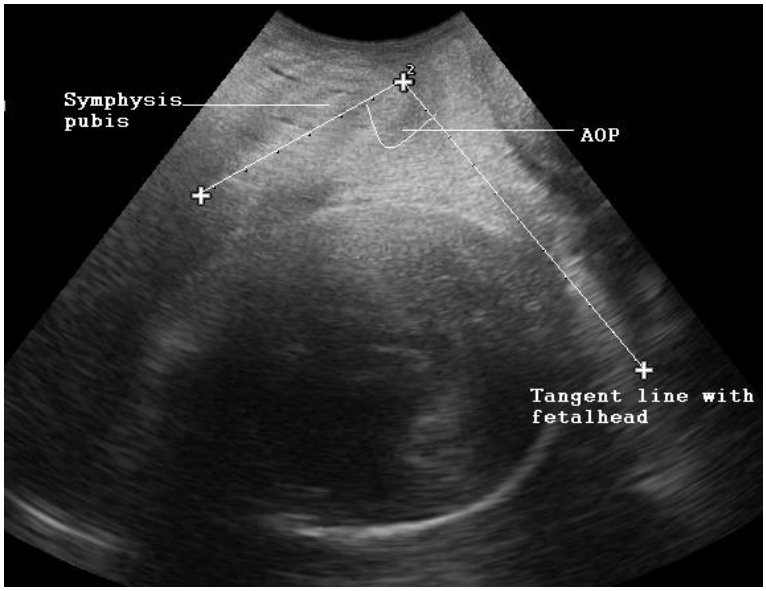

Figure 4.7 An example of AoP sonographic image (Source: Wiafe et al (2016)

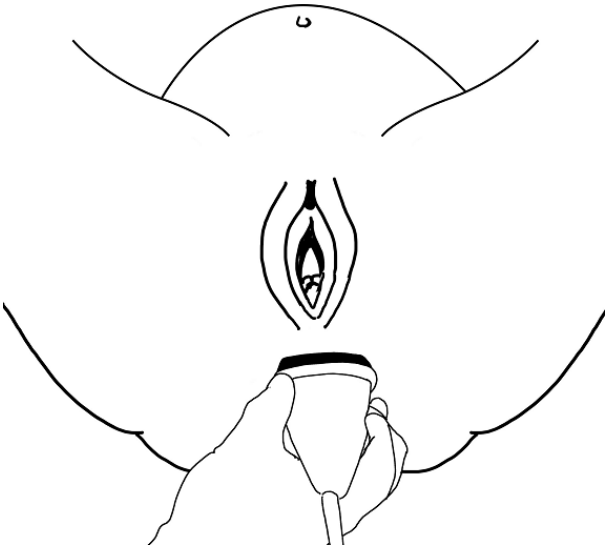

Figure 4.8 firm grip of probe to prevent sliding when imaging HPD

From the sagittal plane, the probe was turned 90^{o} anti-clockwise for a transverse plane. The probe was gripped firmly to prevent it from sliding or tilting as shown in figure 4.8. Gentle pressure was then applied until the probe hits a hard bone. The image was then frozen to measure the distance from the fetal head to the surface of the perineum, which was known as the HPD (Figure 4.9).

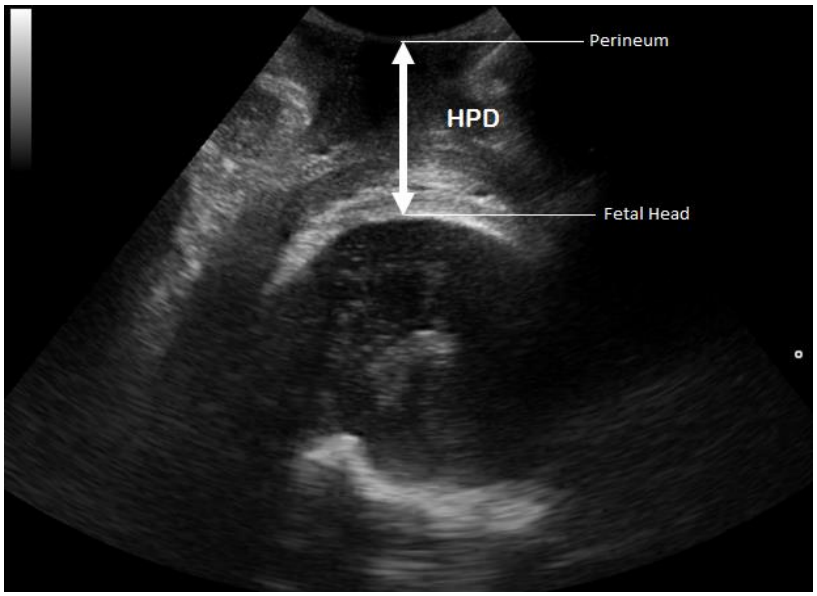

Figure 4.9 An example of HPD sonographic image (Source: Wiafe et al, 2018)

4.6.3 Analytic Strategy for the Research Question on Fetal Head Station.

The analytical strategy of the research question on fetal head station was primarily determined by the specific research objective. This was 'to assess the agreement between ultrasound and digital VE on fetal head station, and the diagnostic performance of ultrasound in detecting engaged fetal head'.

Two stages of statistical analyses were therefore conducted to answer the research question on fetal head station. In the first stage of the analysis, the level of agreement between ultrasound and digital VE was analysed. The second stage of analysis was

conducted to analyse the diagnostic performance of ultrasound in detecting engaged fetal head.

4.6.3.1 First Stage Analysis: Agreement on Fetal Head Station

The appropriate analytical approach for assessing the agreement on fetal head station was selected after considering two main factors. These factors are: (a) the outcome variable on fetal head station, (b) and the analytical approach that was used by similar previous studies.

(a) Outcome Variable on Fetal Head Station

The outcome variable of the agreement between ultrasound and digital VE on fetal head station were independent variables which can only be analysed in terms of association rather than agreement. This is because the two methods were actually not measuring the same parameters. Digital VE was measuring station which uses the ischial spines as its landmark, whilst ultrasound was also taking three different measurements which were all having their independent landmarks. It was therefore not possible to analyse their agreement since measurements were not obtained on the same ‘scale’ (Bartlett and Frost, 2008). As a result, the only possible means of establishing a relationship between the two methods was by analysing the strength of their association. Therefore, the most appropriate statistical method that could be used was the correlation coefficient which can also be converted as a linear regression (Mukaka, 2012).

(b) Analytical Approach of Similar Previous Studies

As shown in Chapter Two, in all similar previous studies the agreement on fetal head station was analysed by using either correlation coefficient or linear regression which can only assess the strength of their association.

Therefore, having considered factors (a) and (b) as explained above, the first stage analysis on fetal head station was done by the use of both linear regression and correlation coefficient in analysing the association between the fetal head station by digital VE with the HPD, the HSD and the AoP obtained by ultrasound.

4.6.3.2 Second Stage Analysis: The Diagnostic Performance of Ultrasound In Detecting Engaged Fetal Head.

This analysis was performed with digital VE as the gold standard. Engaged fetal head was defined as digital VE station 0 and below (Cunningham *et al*, 2001). Therefore all digital VE responses that were below station 0 were classified as engaged. The outcome variable of engaged fetal head was therefore classified as ordinal, and included 0, +1, +2, +3, +4 and +5. Therefore in determining the diagnostic performance of ultrasound, a cut-off value had to be selected from the range of ultrasound responses obtained from this study which corresponded with either station 0, +1, +2, +3, +4, or +5. As station 0 is the minimum level of engaged fetal head, the average ultrasound values of HPD, AoP, and HSD that were corresponding to station 0 were then selected as the cut-off values for analysing the diagnostic performance of ultrasound in detecting engaged fetal head. After selecting the cut-off values, the Receiver Operating Characteristics (ROC) curve was used in determining the sensitivity, specificity, positive predictive value and negative

predictive value of the selected cut-off values. The ROC curve was selected as the appropriate statistical method for conducting this analysis because it is the most appropriate statistical method for a diagnostic test analysis which has a continuous or numeric outcome variable (Hijian-Tilaki, 2013).

4.7 Methods and Analyses on Cervical Dilatation.

Cervical dilatation was measured in centimetres, and it referred to the diameter of the opening maternal cervix during labour. In accordance with the protocols of the facility, the digital VE-rater classified the dilatation as 1cm if the size of the cervical opening was about the size of the tip of the index finger. For a classification of 2cm cervical dilatation, a full index figure of the digital VE-rater was expected to be able to enter the cervical opening whilst also accommodating the tip of the middle finger. At 3cm the index and the middle figures were expected to enter the cervical opening lying side by side. The spreading of the index and middle finger was to be considered as equivalent to 4 to 5 cm, whilst the entry of 4 fingers was to represent 6cm to 7cm. 8 cm referred to the entry of 4 and half fingers whilst 9cm referred to 5 fingers. And 10cm, there was supposed to be additional allowance around the five fingers. The pregnant woman was classified as being in the active phase of labour when the cervical dilatation had reached 4cm or more.

In this study, the patient preparation for the digital VE determination of cervical dilatation was the same as the preparation described above for the fetal head position and the fetal head station. Essentially, the digital VE determination of the cervical dilatation, head station and head position were all examined as one set of examination by the digital VE-rater using the same patient preparation.

4.7.1 Preparation for Ultrasound Assessment of Cervical Dilatation.

No special preparation for ultrasound assessment of cervical dilatation was required other than the preparation described above for transperineal ultrasound. The ultrasound determination of cervical dilatation was done along with the measurement of the HPD, HSD, and AoP using the same preparation.

4.7.2 Ultrasound Procedure for the Determination of Cervical Dilatation.

After obtaining the AoP and HSD with the transperineal ultrasound in the sagittal plane, the cervical dilatation was then obtained along the same transverse plane as the HPD. However, a rocking movement was used in visualising the rectum as the posterior landmark as demonstrated by figure 4.10, and then a slight anterior tilt was gradually made to keep the rectum out of view as demonstrated in figure 4.11. The next region expected to be visualised by the anterior tilt which keeps the rectum out of view was expected to be the cervix. However, an extreme anterior tilt as demonstrated by figure 4.12 was avoided, as that may result in missing the dilating cervix or from a plane which will be rather too high.

After obtaining the cervical dilatation on grayscale, the image was frozen for measurements to be taken. Measurements were obtained from the right to left dimension as the actual transverse (horizontal) dimension. Measurement was also obtained from anterior to posterior (vertical) dimension as described by some previous studies (Benediktsdottir *et al*, 2015; Hassan *et al*, 2013).

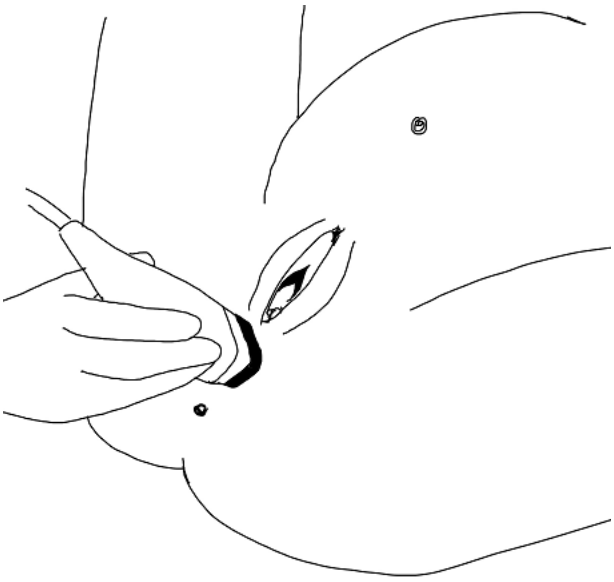

Figure 4.10 A posterior tilt of probe to identify the rectum

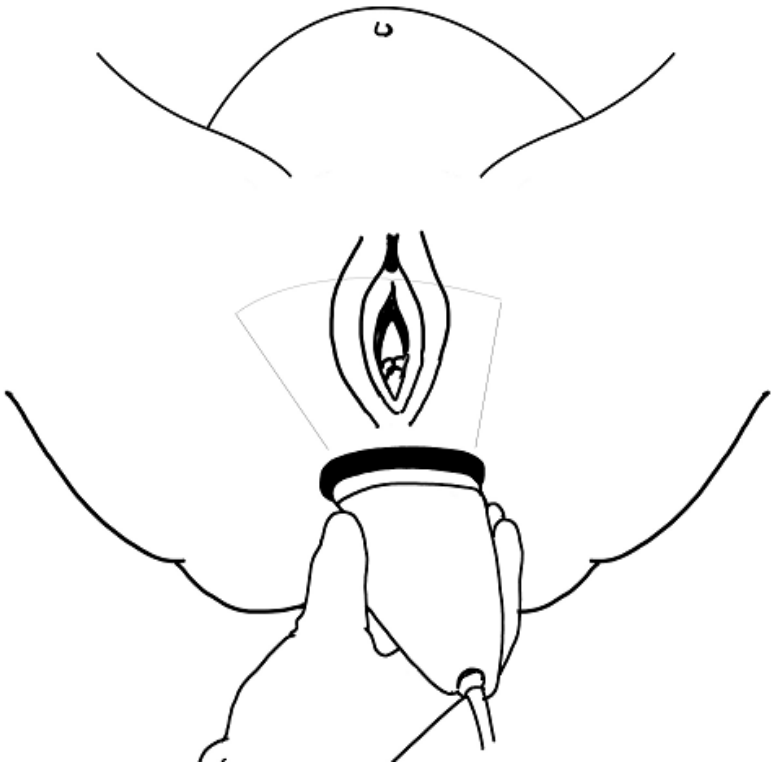

Figure 4.11 A slight anterior tilt from the rectum to visualise dilating cervix.

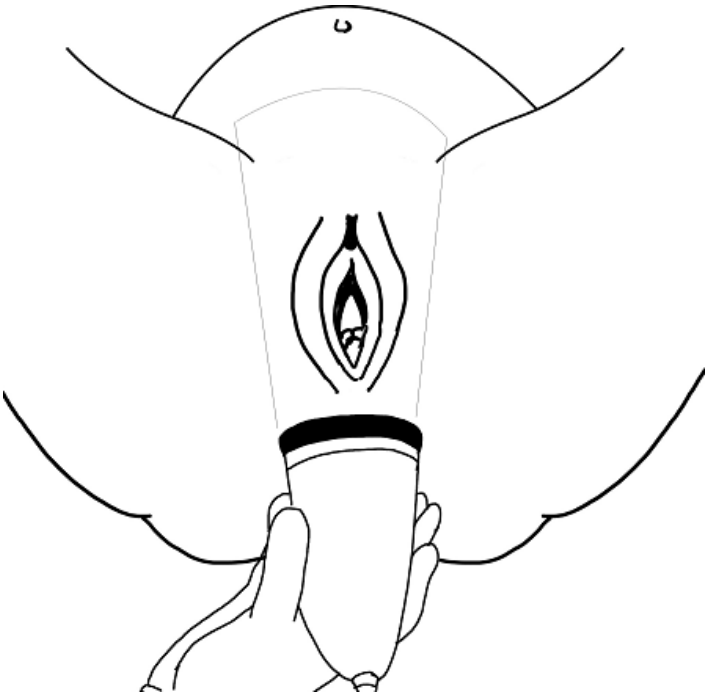

Figure 4.12 An extreme anterior tilt which may miss dilating cervix

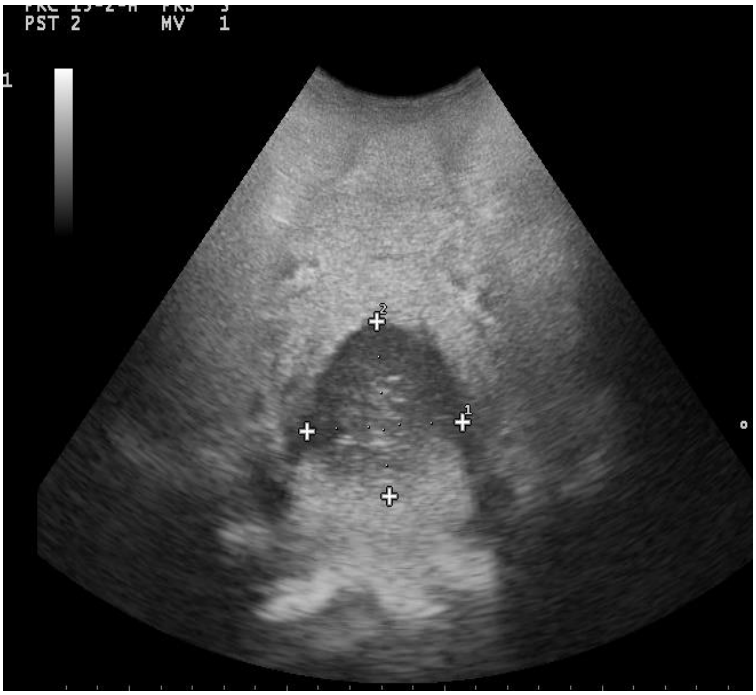

Figure 4.13 An example of cervical dilatation measurements obtained from anterior-posterior and transverse diameters (Source: Wiafe et al, 2016)

4.7.3 Analytic Strategy for the Research Question on Cervical Dilatation.

The analytical strategy of the research question on cervical dilatation was primarily determined by the specific research objective. This was ‘to assess the agreement between ultrasound and digital VE on cervical, and the diagnostic performance of ultrasound in detecting active labour’.

Two stages of statistical analyses were conducted to answer the research question on cervical dilatation. In the first stage of the analysis, the level of agreement between ultrasound and digital VE on cervical dilatation was analysed. The second stage of analysis was conducted to analyse the diagnostic performance of ultrasound in detecting active labour.

4.7.3.1 First Stage Analysis: Agreement on Cervical Dilatation.

The appropriate analytical approach for assessing the agreement on cervical dilatation was selected after considering two main factors. These factors are: (a) the outcome variable on fetal head station, (b) the analytical approach that was used by similar previous studies.

(a) Outcome Variable on Cervical Dilatation.

The outcome variable on cervical dilatation was a numeric variable which is measured in centimetres. Since the outcome variable was a numeric variable, the appropriate statistical method for analysing the agreement on a numeric variable was selected. Conventionally, the statistical method for analysing numeric variables is the correlation coefficient or a linear regression, which determines the strength of the association between two methods (Stralen *et al*, 2008). However, this old statistical method only determines association but not agreement. Since it is very possible to have two methods

with a very strong association by a weak agreement (Stralen *et al*, 2008), the Bland-Altman analysis was introduced as better measure of agreement. Bland-Altman analysis has therefore become the mostly used analytical method for assessing agreement of a numeric outcome variable (Bland and Altman, 1986; Casena *et al*, 2011; Stralen *et al*, 2008) which provides the agreement limit as well as the mean average. It then allows the reader to determine the clinical significance of the mean difference rather than the statistical significance (Stralen *et al*, 2008).

(b) Analytical Approach of Similar Previous Studies.

As shown in Chapter Two, all the previous studies analysed the agreement on cervical dilatation by using either Bland-Altman analysis or the correlation coefficient which can also be expressed as a linear regression.

Therefore, after considering factors (a) and (b), the statistical analysis of the agreement on cervical dilatation was therefore conducted by using the old correlation coefficient analysis or linear regression analysis and the Bland-Altman analysis.

4.7.3.2 Second Stage Analysis: Ultrasound Diagnostic Performance in Detecting Active Labour.

This analysis was performed with digital VE as the gold standard. In accordance with the department's protocols, active labour was defined as a cervical dilatation of 4cm and above. Therefore, all digital VE responses were classified as active labour if indicated as 4cm or above. The outcome variable of active labour was therefore classified as numeric, and included 4cm, 5cm, 6cm, 7cm, 8cm, 9cm and 10cm. Therefore, in determining the diagnostic performance of ultrasound, a cut-off value had to be selected from the range

of ultrasound responses which were 4cm and above. As 4cm was the minimum value for active labour in the facility, 4cm was also selected as the cut-off value for analysing the diagnostic performance of ultrasound in detecting active labour. After selecting the cut-off value, the Receiver Operating Characteristics (ROC) curve was used in determining the sensitivity, specificity, positive predictive value and negative predictive value. The ROC curve was selected as the appropriate statistical method for conducting this analysis because it is the most appropriate statistical method for diagnostic test analysis of a numeric outcome variable (Hijian-Tilaki, 2013).

4.8 Methods and Analyses of Mothers Acceptability of Ultrasound in Labour.

In obtaining the mothers' views on the acceptability of ultrasound in labour, a sample survey approach was used. This was done by interviewing postpartum stage mothers who had participated in the intrapartum ultrasound of this study. They were considered as the most appropriate group of mothers who could offer a legitimate opinion about the acceptability of having ultrasound in labour, as they had recently gone through the procedure whilst in labour.

After delivery, no discussion on the study was made with the mother until she received her baby and started breastfeeding. She was then approached and asked about her willingness to participate in this second part of the study. Again, she had up to this time to decide on continuing or withdrawing from the entire study. The choice of time for this second part of the study was also considered appropriate because she was more likely to recollect the memories of going through both ultrasound and digital VE in labour.

In terms of the survey design, a quantitative approach was considered most appropriate and was therefore maintained in responding to this research question, as the participant group was large enough to be analysed with a quantitative approach. Thus, the estimated sample size was all participants of the intrapartum ultrasound study.

4.8.1 Data Collection for Survey Participants.

In sample surveys, the main methods of data collection are personal interviews, telephone interviews, and questionnaires (Aday and Cornelius, 2006; Mathers *et al*, 2009). Questionnaires can be delivered by mail, through the internet, at the work-place, or other settings (Aday and Cornelius, 2006). As this study was going to gather data from mothers who were still on admission after delivery, using a questionnaire was considered more appropriate and convenient. A questionnaire was also expected to be less time consuming for them, considering the time they needed to spend on their babies.

4.8.2 Questionnaire.

In choosing the type of questionnaire for data collection, a multiple choice close-ended questionnaire was considered more appropriate than an open-ended questionnaire. This targeted group were mothers who had given birth either on the same day or the previous day. The need to avoid a time-consuming questionnaire was therefore considered from the ethical standpoint. With a multiple choice close-ended questionnaire, mothers could go through the responses and select their best answer.

4.8.3 Analytic Strategy for the Research Question on Mothers' Acceptability.

In selecting an appropriate analytical strategy, the research question and the type of questionnaire were considered. For this specific objective, the survey questionnaire

comprised of only multiple choice questions (see Appendix 5). Therefore, the outcome variables to all questions were independent categorical variables. As indicated right from the beginning, this aspect of the research was interested in the 'individual patient's' values and preferences. Therefore, it needed a description of percentage of participants or 'individual patients' who selected a particular response. Consequently, the statistical analysis needed descriptive statistics of the percentage respondents who selected a particular option, in order to present responses graphically.

4.9 Methods and Analyses of Caregivers View.

In accordance with the cross-sectional design of this primary study, a sample survey was used to investigate this fifth specific objective. This research question was asking the views of caregivers on the practicality of using ultrasound for assessing the progress of labour. In ensuring coherence with the first four specific objectives, a quantitative approach was intended for this research question. However, using a quantitative approach was considered inappropriate because of the number of caregivers in the targeted study population who were less than 30. As a result, the only option available was to use a qualitative approach. Thankfully, sample surveys can be conducted with either a quantitative or a qualitative approach (Marsland, 2001; Ponto, 2015). The use of a qualitative approach was also seen as an advantage in terms of exploring the views of the caregivers on this research question, as there was very little known from this setting with regards to the view of caregivers on the practicality of using ultrasound for assessing progress of labour. Using qualitative surveys has been found to be particularly appropriate when little knowledge exists on a research topic, as it makes it possible to generate a hypothesis for quantitative research in future (Safdar *et al*, 2016).

4.9.1 Choosing the Appropriate Qualitative Method.

In choosing the appropriate qualitative method, a number of factors were considered. The primary factor considered was the need to choose a research method that would agree with the paradigmatic stance of this primary study as detailed in Chapter Three. In connection with this postpositivist paradigmatic stance, there was the need to avoid qualitative methods that hold a purely naturalistic view or a constructivist position, as choosing those methods will be inconsistent with the quantitative aspect of this study.

In respect of this primary consideration, the qualitative content analysis method was chosen as the appropriate method for this study. As a research method, qualitative content analysis is not linked to any particular paradigmatic position, but rather embraces positivist and naturalistic paradigms (Bengtsson, 2016; Downe-Wamboldt, 1992). It is a flexible method which allows a qualitative or a quantitative analyses of data (Bengtsson, 2016; Downe-Wamboldt, 1992; Sandelowski, 1995), a position which was found to be consistent with the paradigmatic stance of this primary study as explained in Chapter Three.

4.9.2 Standards of Qualitative Content Analysis.

Qualitative content analysis allows various ways of collecting data, including face-to-face in-depth interviews, focus group interviews, one single written question, or the use of a questionnaire (Bengtsson, 2016). It can be used in analysing all types of written text, pictures or films (Bengtsson, 2016). Qualitative content analysis recommends the use of an inductive approach in situations where the previous knowledge on a research topic is restricted, or when knowledge on a research topic is fragmented (Cho and Lee, 2014; Elo and Kyngäs, 2008). On the other hand, it also allows the use of a deductive approach if

the purpose of the study is to test a hypothesis or an existing theory (Elo and Kyngäs, 2008).

In qualitative content analysis, the researcher is required to choose between analysing either the manifest content or the latent content of the source of data (Bengtsson, 2016; Elo and Kyngäs, 2008). The manifest content refers to meaning obtained from obvious statements made in the text. The latent content on the other hand refers to meaning beyond what can be 'seen' directly from the text (Bengtsson, 2016; Elo and Kyngäs, 2008).

4.9.2.1 Inductive Content Analysis.

The inductive content analysis process involves analysing data by open coding, leading to the creation of categories and then abstraction (Elo and Kyngäs, 2008). The written material is read through several times by the content analyst until he or she becomes very familiar with the text. Afterwards, the content analyst will highlight a number of passages, or statements, phrases or words in a text which contains the needed information on the research topic (Bengtsson, 2016; Elo and Kyngäs, 2008). Researchers refer to the highlighted sections in the text as the unit of analysis or the 'meaning units' (Bengtsson, 2016; Elo and Kyngäs, 2008). Once the meaning unit is identified, subheadings related to the meaning unit are written down. These subheadings are referred to as open codes (Elo and Kyngäs, 2008; Hsieh and Shannon, 2005). The open codes are collected unto a coding sheet. Afterwards, open codes are grouped into categories (Elo and Kyngäs, 2008). The creation of categories is done to enable a description of the data, and a deeper understanding of the data in order to generate knowledge (Hsieh and Shannon, 2005; Elo

and Kyngäs, 2008). An abstraction can then be made about the research topic which will be dependent on the knowledge generated by the open coding and categorisation of the meaning units. Hence, inductive content analysis is about open coding, creation of categories and abstraction (Elo and Kyngäs, 2008).

4.9.2.2 Deductive Content Analysis.

Deductive content analysis focuses on retesting existing data in a new context (Elo and Kyngäs, 2008). As a result, the first step taken after obtaining the transcript or a source of data is to develop a categorisation matrix which will be used in coding the content to correspond with the format used by a previous study (Cavanagh, 1997; Elo and Kyngäs, 2008). Therefore, the aspects of the data which fit the matrix are selected for categorisation which enables the researcher to test a hypothesis or an existing theory (Elo and Kyngäs, 2008).

4.9.3 Content Analysis Approach of this Study.

In this primary study, the inductive content analysis approach was selected, as no study was known to have used content analysis on a similar research topic.

In selecting an appropriate mode of interview, considerations included conducting either a face-to-face interview or a focus-group interview. However focus-group interview was rejected, due to the busy schedule of prospective participants who were practicing a shift system which makes it difficult meeting them as a group. Consequently, the option selected was the face-to-face interview.

4.9.3.1 Data Collection Procedure.

As part of the data collection process, the study proposal was presented to the caregivers at one of their general meetings. This was a PowerPoint presentation which explained the background and purpose of this primary study. At this presentation, caregivers were given the opportunity to ask questions on all the five specific objectives of this primary study. They were then formally invited to participate in this fifth specific objective which was to obtain their views on the practicality of assessing the progress of labour with ultrasound.

4.9.3.2 Sampling.

Purposive sampling is the commonly used sampling strategy in content analysis (Bengtsson, 2016), and was therefore considered a suitable strategy by this study. Consequently, since caregivers were working in separate teams of five, with each team assigned to a particular duty day, efforts were made to select at least one person from each team. In addition, there were a number of caregivers amongst them who showed keen interest in knowing more about the findings of this study, some of whom came to observe the data collection process from time to time. It was therefore considered appropriate to select those who had come to observe one of the intrapartum scans performed in the labour ward, as it also presented an opportunity to offer further explanation on the study to them as potential participants to the research question.

4.9.3.3 Face-to-face Interviews.

In inductive content analysis, unstructured interview is the commonly used interview approach (Bengtsson, 2016; Elo and Kyngas, 2008). Therefore, unstructured interviews were used in this primary study. All interviews were conducted at the hospital, after

successfully booking an appointment with a prospective participant. Even though interviews were unstructured, the main question of the interview was asking them to share their thoughts on the practicality of using ultrasound to monitor progress of labour in their setting. Follow up questions depended on how they responded to the initial question. This included responding to the research question from the perspective of the potential to minimise the risk of infection and complaints about discomfort from digital VE, since those were among the major issues of concern reported on digital VE.

4.9.3.4 Informed Consent Process.

Oral consent was initially obtained from prospective participants who were already well informed about the study through the presentation given at their general meeting. As a result of the explanation given to them about the study, they had shown interest in the study and had come mostly to observe one of the ultrasound in labour examinations that were performed as part of this study. Interview was granted only when a prospective participant had accepted to be interviewed by choosing a convenient date.

After the interviews, the transcripts were later sent to them individually to confirm whether they were their own words, along with the recorded voice in case they wanted it played to them. They were then asked to sign an informed consent form if they were willing to grant permission for the use of their words as data in this thesis (see appendix 7).

4.9.3.5 Analytic Strategy for the Research Question on the Practicality of Ultrasound in Labour.

The analytical strategy of this research question was primarily determined by the specific research objective, which was ‘to investigate the views of caregivers on the practicality of using ultrasound to monitor the progress of labour’. In selecting the appropriate meaning

unit for open coding and categorisation, the key which needed clear understanding was the word ‘practicality’. Consequently, the meaning of the word was obtained from the Cambridge Dictionary. In the Cambridge Dictionary, the word ‘practicality’ was explained in association with four other key words, which are ‘*suitable*’, ‘*effective*’, ‘*possible*’, and ‘*real*’.

In connection with the word ‘*suitable*’, practicality was explained in the Cambridge English Dictionary (2017) as the ‘*quality of being suitable for a particular occasion or use’*. In connection with the word ‘*effective*’, practicality was explained as ‘*approving the quality of being able to provide effective solutions to problems*’. In connection with the word ‘*possible*’, practicality was explained as ‘*the possibility of being able to put into practice’*. Lastly, in connection with the word ‘*real*’, practicality was explained in the Cambridge English Dictionary (2017) as ‘*the condition that result from an idea becoming a real situation*’.

Therefore, based on the meaning of the word ‘*practicality*’, each meaning unit selected from the responses of the caregivers was based on the following guidelines:

i. Whether or not the response of the caregiver suggests that ultrasound was suitable for use in assessing progress of labour.
ii. Whether or not the response of the caregiver approve of ultrasound as effective for assessing progress of labour, minimising risk of infection, and promoting patients interest.
iii. Whether or not the response of the caregiver suggest that it is possible to use ultrasound for assessing progress of labour in their setting.

iv. Whether or not the response identifies real situations where using ultrasound in labour may be useful.

Therefore, after transcribing recorded interviews, transcripts were read through several times to identify the manifest content from the perspective of the guidelines outlined above. Instances of manifest content were then highlighted as meaning units. The highlighted meaning unit in some instances implied the whole response to a question, while in other instances more than one meaning units were obtained from one response. For each highlighted meaning unit, open code was generated as a heading arising from the meaning unit. This was in terms of whether using ultrasound in labour was considered by the caregiver as '*suitable'*, '*effective*', '*possible*', or if they identified '*real*' (typical) conditions where it would be applicable. All open codes were collected onto a matrix and then categorised under the four main categories. Afterwards, descriptive analysis of the findings was presented in a narrative form. Lastly an abstraction was made from the findings in the discussion chapter.

4.9.4 Quality Assurance and Trustworthiness of this Content Analysis.

Qualitative content analysis has elements of validity that are universal to any qualitative study. These elements include issues about credibility, conformability, dependability, and transferability (Lincoln and Guba, 1985). In evaluating the trustworthiness of this qualitative content analysis the comprehensive review reported by Elo *et al* (2014) was used as a guide. Elo *et al* (2014) reported these guidelines which are based on their findings; extensive search of relevant databases; methodological textbooks; from their collective experience as researchers who had published several papers on content

analysis; and academics who had supervised several theses on qualitative content analysis. Therefore, their review was used as a guide in evaluating the quality and trustworthiness of this content analysis as detailed below.

4.9.4.1 Credibility:

In terms of credibility of a qualitative study, the evaluation of trustworthiness is done by assessing how well the data addressed the intended objective (Polit and Beck, 2012). In qualitative content analysis the first factor evaluated is whether the most appropriate method of data collection was used (Graneheim and Lundman, 2004). Elo *et al* (2014) found that most of the published qualitative content analysis used unstructured methods of data collection, which were mainly by interviews, observations, from diaries or other written documents. This suggest that the use of unstructured interview by this primary study is in accordance with acceptable standards of qualitative content analysis, and consequently, is credible.

The second factor to be addressed in the evaluation of credibility is whether the sampling strategy was appropriate and representative. In addition, it should be considered whether the best informants were selected through an appropriate criteria. Elo *et al* (2014) found that the mostly used sampling approach in qualitative content analysis was the purposive sampling strategy. This suggests that the use of purposive sampling by this primary study in selecting at least one person from each of the available teams was credible.

The third factor is the researcher's self-awareness, in terms of asking the appropriate questions which should be succinct and devoid of any form of manipulation. Elo *et al* (2014) suggested that interview tapes or transcripts should be carefully assessed to

examine the researcher's own actions. They also encourage conducting a pilot study. In connection with this suggestion, a preliminary pilot work was done as described above.

4.9.4.2 Conformability:

Conformability refers to whether data accurately represents responses obtained from the study participants and whether the interpretations were not the invention of the researcher. This is particularly with regards to latent content (Polit and Beck, 2012).

Elo et al (2014) noted that in qualitative content analysis the most appropriate approach is to make one researcher responsible for conducting the analysis and other researchers responsible for a careful follow-up on the whole analysis process and categorisation.

The impact of conformability in this primary study was reduced by deciding not to analyse latent content. With regards to the manifest content, follow-up on the analysis was carefully conducted by the two supervisors of the study.

4.9.4.3 Dependability:

Dependability refers to the extent to which data remain stable over time and under different conditions (Elo *et al*, 2014). A study is rated high in terms of dependability if another researcher is able to readily follow the decision trail of the initial researcher (Thomas, and Magilvy, J.K., 2011). This can be achieved by ensuring adequate and vivid description of data, including detailed description of study participants and the criteria used in selecting them which will enable readers to analyse transferability (Elo *et al*, 2014). Consequently, efforts have been made by this study to vividly describe the process used, including the characteristics of the study participants.

4.9.4.4 Transferability:

Transferability refers to whether the findings of the study could be transferred to another context or a different setting (Elo *et al*, 2008). In this primary study, the vivid description of the study should enable a reader to determine its transferability in another setting.

4.10 Chapter Summary.

This chapter has provided a comprehensive description of the research methods in this primary study which are catalogued in the table 4.1 below. It has described the scope of this reproducibility study and why an observational approach was used.

The next chapter presents the ethical issues that were addressed in recruiting pregnant women in labour.

Table 4.1 Summary of Research Methods and Analyses

SPECIFIC OBJECTIVE	RESEARCH METHOD	ANALYTIC STRACTEGY	
		VARIABLES	**ANALYSIS**
To assess the agreement between ultrasound and digital VE on fetal head position, and the intrapartum factors that may have affected the agreement.	A cross sectional design to obtain fetal head position from the parturient, using ultrasound and digital VE.	Stage 1: -Outcome Variable of agreement : **Categorical** 45^o,90^o,135^o,180^o,225^o, 270^o,315^o, 360^o	1. Statistical analysis for categorical outcome variables on agreement: A. Percentage agreement B. Cohen's Kappa statistics
		Stage 2: -Outcome variable of agreement: **Categorical** vs -Intrapartum factors (US head position, VE dilatation, VE head station) : **Independent**	2. Statistical analysis for assessing the effect of independent variables: chi-square test
To assess the agreement between ultrasound and digital VE on fetal head station and the diagnostic performance of ultrasound in detecting engaged fetal head.	A cross sectional design to obtain fetal head station, and ultrasound measurements associated with fetal head station from the parturient, using ultrasound and digital VE.	Stage 1: Outcome Variables of Correlation: **Independent Variables -** HPD (cm); HSD (cm); AoP (cm)	1. Statistical analysis for independent numerical outcome variables on correlation: A. Correlation coefficient B. Linear regression
		Stage 2: Assessing Diagnostic Performance of US on Engaged Fetal Head: - Gold standard test: **digital VE Station ≥ 0** - Outcome variable of gold standard – **Dichotomous:** Engaged/Not engaged -New Method Test: US Cut- off values for HPD, AoP and HSD which are corresponding to **digital VE Station ≥ 0**	2. Statistical analysis on the diagnostic performance of a Dichotomous outcome variable: The ROC curve
To assess the agreement between ultrasound and digital VE on cervical dilatation and the diagnostic	A cross sectional design to obtain cervical dilatation from the parturient,	Stage 1: Outcome Variables of agreement – **numerical:** Cervical dilatation (cm)	1. Statistical analysis for numerical outcome variables on agreement: A. Bland-Altman analysis B. Correlation coefficient C. Linear regression

performance of ultrasound in detecting active labour.	using ultrasound and digital VE.	Stage 2: Assessing Diagnostic performance of US on active labour: - Gold standard test: **Cervical Dilatation ≥ 4cm** - Outcome variable of gold standard – **Dichotomous:** Active/not active -New Method Test: US Cervical dilation of ≥4cm	2. Statistical analysis on the diagnostic performance of a Dichotomous outcome variable: The ROC curve
To assess the acceptance of ultrasound in labour by mothers who have experienced intrapartum ultrasound in the assessment of labour progress.	A cross sectional design to obtain the views of mothers on the use of ultrasound in labour in a quantitative survey.	Outcome Variable of mothers views – **Categorical**	Statistical Analysis: Descriptive Statistics – frequency distribution tables and bar charts
To investigate the views of caregivers on the practicality of using ultrasound to monitor the progress of labour in Ghana.	A cross sectional design to obtain the views of caregivers on the use of ultrasound in labour in a qualitative survey.	Qualitative (Inductive) content analysis – open coding and categorisation of manifest content from face-to-face interview transcripts	Descriptive analysis of open codes and categories

5 Chapter Five: Ethical Considerations.

5.1 Introduction.

The previous chapter presented on the detailed research methods of the primary research. The major group that participated in this study was pregnant women in labour. However, most of the ultrasound measurements obtained were relating a fetal body part to maternal anatomy. This made both mother and fetus research subjects of this study. Pregnant women and fetuses are regarded as vulnerable groups whose rights and safety as research participants must be highly protected. Therefore, a separate chapter is devoted to addressing the ethical considerations of this study.

In this chapter, the various topics discussed included the ethical review process, risk and safety issues, privacy and confidentiality issues and the informed consent process.

5.2 Ethical Approval.

Following the Helsinki declaration, all research involving human subjects are expected to go through the scrutiny of an ethics committee (Zion *et al*, 2000). Therefore, this study was taken through the ethical clearance process of the ethics committee at KATH in Ghana. The ethics committee of KATH is a joint board comprising of members from the hospital staff and other members from the academic staff of the affiliated medical school, known as the Committee on Human Research Publication and Ethics (CHRPE).The research protocols and other related documents were therefore submitted to the KATH ethics committee for evaluation. Approval was finally given by CHRPE, after recommendations arising from the review were dully addressed to their satisfaction (approval letter in appendix 1). In addition, ethics approval was sought from the Subject Research Ethics Committee (SREC) of the College of Health and Social Care at the

University of Derby. This was also approved after recommendations arising from the committee's review were satisfactorily addressed. The ethical considerations of this study was therefore finalised after addressing and incorporating the ethics recommendations made by the two independent ethics committees (Approval letter in Appendix 2).

5.3 Patient Safety.

One safety concern addressed by this study was the possible biologic effect that may result from exposing a pregnant mother and her fetus to ultrasound examination. The second safety concern was with regards to the potential infection transfer that could be associated with undergoing both digital VE alongside transperineal ultrasound, and how they were addressed.

5.3.1 Biologic Effect Considerations.

No adverse effect has been found regarding the use of diagnostic ultrasound in pregnancy since the 1950s. However, in-vitro and in-vivo experiments suggest that ultrasound may not be entirely safe when used without caution. Experiments involving plants have shown that when the gas-filled channels within a plant cell are exposed to high frequency sound waves, the rapid changes in pressure of the sound waves may cause the formation of bubbles in the gas-filled channels, which can disorganise and destroy the plant cell (Miller, 1983). This formation of bubbles (cavities) resulting from the rapid changes in pressure of a high frequency sound waves may occur in all forms of fluid mediums, and is referred to as cavitation (Kremkau, 2005). Cavitation is a mechanical biologic effect which was also found in vivo studies involving animal subjects (mammalians). In animals, the mechanically induced side effect from cavitation was found to be occurring at tissue-gas interfaces (as found in the intestine or lungs), and was

causing haemorrhage and rupture of capillaries (Miller *et al*, 2008; Kremkau, 2005). Fortunately, the likelihood of cavitation can be estimated and prevented by choosing the appropriate mechanical index. Diagnostic ultrasound, is a high frequency longitudinal mechanical pulse wave with regions of rarefaction and compression. The mechanical index can be calculated from the peak rarefactional pressure at the point of maximum pulse intensity, divided by the square root of the transducer frequency in megahertz (Kremkau, 2005).

Secondly, apart from the mechanical biologic effect from cavitation, thermal biologic effect may also result from the attenuation of sound waves as they travel through a tissue interface. During the transmission of ultrasound into the body, some amount of sound waves may be absorbed by the various tissue interfaces in the pathway. The amount of absorption depends on the characteristics of the various tissue interfaces that are in the pathway of sound transmission. It also depends on the sound wave intensity, the transducer frequency, and the duration of travel. When the sound waves are absorbed by the tissue, they are then converted to thermal energy, which would cause temperature rise within the tissue. For as long as the temperature rise remain less than 2^{o}C, in vivo studies suggest that the ultrasound exposure time could go as far as 50 hours without causing any adverse effect to the body tissue (Kremkau, 2005). However, the exposure time should not be more than 250 minutes if the temperature rise goes beyond 2^{o}C (Barnett *et al*, 2000; Kremkau, 2005). In fact, at a temperature rise of 4^{o}C and 6^{o}C, safety can only be guaranteed when exposure time is limited to 16 minutes and one minute respectively (Kremkau, 2005).

Even though the above knowledge on biologic effects are based on studies conducted in plants and animals rather than in humans, it offers guidelines on the appropriate output power levels in preventing tissue damage for a given diagnostic ultrasound examination. It also offers a guide on the acceptable length of time for an ultrasound examination to be performed.

In view of this, professional organisations such as the World Federation for Ultrasound in Medicine and Biology (WFUMB), the American Institute of Ultrasound in Medicine (AIUM) and the British Medical Ultrasound Society (BMUS) have developed safety guidelines for using ultrasound in clinical practice.

Consequently, efforts were made by this study in ensuring that power output levels and exposure time were in accordance with the **A**s **L**ow **A**s **R**easonably **A**chievable (ALARA) principles of diagnostic ultrasound imaging, which was adopted from the guidelines of BMUS (2009).

The BMUS (2009) guidelines recommend that performing an ultrasound scan for pregnant women and neonates should generally not take more than sixty minutes. For scans that take up to sixty minutes, thermal and mechanical indices of the output power should not exceed 1.0 and 0.7 respectively. However, the thermal index could go as high as 2.5 if the scan would take less than four minutes to complete. Fortunately for this study, all scans took less than the four minutes, and most scans were actually completed in one minute. In this study, the application preset for obstetric ultrasound examination on the Siemens-Acuson P300 was used in performing all scans. The output power levels prescribed by the application preset for obstetric ultrasound examination was maintained throughout the examination for all study participants. This ensured that the mechanical

index was always less than 0.7, and that the thermal index was always ≤ 1.3. It therefore implies that the ultrasound output power levels for this study, as well as the duration per scan, were within approved limits, and far too low to cause any adverse effect on both mother and fetus.

5.3.2 Infection Control.

In order to minimise the risk of infection resulting from digital VE, midwives and obstetricians are expected to only perform the examination when there is an obvious clinical need. The digital VE aspect of this study was therefore arranged to coincide with the participant's clinically indicated review time for digital VE. It ensured that participants would not undergo more digital VEs than clinically indicated on account of this research. Recruitment was therefore tied to the availability of the ultrasound investigator who was required to be present at the digital VE review time, in order to scan and obtain the ultrasound data immediately after the digital VE was performed. Consequently, many potential candidates were not recruited for the study (even though they had consented) due to the non-availability of the ultrasound investigator at the digital VE review time.

The ultrasound examinations were also done in compliance with the facility's standard protocol for infection control, which included wearing scrubs and gloves before performing intrapartum examinations and washing hands (as well as the ultrasound probe) with soap and water immediately before and after an examination. In addition, the ultrasound probe was covered with a disposable additional barrier for preventing possible infection transfer.

5.4 Risk.

With the safety issues addressed above, no harm to the mother or fetus was anticipated in connection with their participation in this research. Ultrasound transmits sound waves rather than ionising radiation. As detailed above, it has a safety track record especially when used in accordance with ALARA principles.

Moreover, unlike the digital VE which is transvaginal, the ultrasound examinations were rather performed by the non-invasive transabdominal and transperineal methods. With this scanning approach, it was anticipated that the ultrasound examination would even be more tolerable for participants than the indicated digital VE which they were all to undertake regardless of the research. However, in preparing the mind of participants, mothers were cautioned that although the intrapartum ultrasound was really not expected to be painful, it might not be entirely free from discomfort.

5.5 Privacy and Confidentiality.

Each participant had a screen around her bed during the digital VE and ultrasound examination. During the ultrasound examinations, only one midwife or clinician was allowed to stand by the ultrasound investigator or rater in serving as a chaperon.

In terms of ensuring optimal patient privacy, the ultrasound examination was actually ‘less intrusive’, given that the transducer was only placed at the perineal region, compared to the indicated digital VE which was transvaginal.

With regards to confidentiality, participants’ identification information were given code numbers. No name, address, contact numbers or any other information which directly identifies the participant was recorded on the data collection sheet or on the sonogram. This ensured that data collected could not be linked to a particular participant.

5.6 Informed Consent

Informed consent is a process that enables a prospective participant to decide on whether or not to participate in a study. It ensures that the competent individual obtains the necessary information they would need about a research study before deciding on participation. It assures the prospective participant that the decision to participate in the study is out of free will, and that they would not be victimised for refusing to participate. They should also be informed that they can withdraw their participation in the course of the study even after previously consenting.

As part of the informed consent process of this study, general information about the research was provided at the antenatal clinic to all potential participants. Interested participants obtained an information leaflet to be taken home for further reading. A page was provided on the information leaflet for signing or thumb printing by those interested in participating in the research (see Appendix 3). This was done to ensure that prospective participants had ample time before the onset of labour, to enable them to decide on whether or not they were willing to participate in the research.

5.6.1 Language.

Informed consent must be written in a language the prospective participant can read and understand. It should avoid the use of technical words that may be difficult for a lay reader to comprehend.

In this study, prospective participants were initially given the general information about the study in the Twi Language. Twi is a local Akan dialect spoken by most Ghanaians. With Kumasi being the native region of the language, almost all the prospective

participants could speak Twi fluently. A prospective participant could also request for further explanation in another Ghanaian language or in English.

However, as English is the official language in Ghana, the additional information leaflet for interested prospective participants was written in English, including the consent page. A copy of the information leaflet and consent form were given to interested prospective participants to enable those wishing to ask a trusted person for personalised interpretation to do so.

5.6.2 Comprehension.

Prospective participants were encouraged to ask further questions at all levels of the study. The mobile number of the primary investigator was also provided on the informed consent sheet to encourage prospective participants to call and ask further questions (see Appendix 3). Recruited participants were regularly briefed about what was happening at any level of the study, including the purpose of the transabdominal ultrasound examination, the transperineal ultrasound examination and also at the postpartum stage where questionnaires were given.

5.6.3 Documentation of Consent.

Prospective participants documented consent by signing or thumb-printing the provided documentation page. An additional signing or thumb-printing was also provided by a witness of their choice.

5.6.4 Benefit (s).

Prospective participants had no assurance of direct benefit for their participation. However, they were informed that there might be some benefit in future for them or for another person in labour, if ultrasound turns out to be useful and effective for monitoring

labour progress. They were also informed that even though it was a blinded study, their quality of care was paramount, and that if an incidental finding was detected during the scan which could potentially influence the course of their management, a disclosure of the incidental information would be made available to management. This would be a direct benefit to them other than the study, as they would cease to be participants of the study under such a circumstance.

5.6.5 Compensation.

Whilst no assurance of compensation was given to any prospective participant, it was suggested by the local ethics committee that some token should be given for their time and corporation. Consequently, three cakes of baby soap were given to them after the postpartum questionnaire. These were offered to them without their prior knowledge.

5.6.6 Withdrawal from the Research.

Participants had the opportunity to withdraw their participation from the study. This was possible up to the postpartum stage where the questionnaire was administered. Participants were therefore asked about their willingness to continue as study subjects after delivery. Although there was no such instance in the study where a participant decided to withdraw, the protocol was to remove the data of any participant who withdraws from the study by not including the data available on them in the analysis.

5.6.7 Consequence for Withdrawal.

Participants were informed that the ultrasound in labour would not in any way contribute to their management, except in the rare case of an incidental finding which may be beneficial to their management. They were also informed that they had nothing to lose if they decided to withdraw from the study.

5.7 Chapter Summary.

This chapter has addressed the ethical issues that were associated with the recruitment of pregnant women to participate in this primary study. It was discussed that in terms of biologic effects, the ALARA principles observed by this study ensured the optimum safety of both mothers and fetuses as study subjects. It has also described the ethical approval processes this study was taken through in ensuring that it met the requirements of the local review board as well as the academic review board. The informed consent process of the study has also been described.

The next chapter presents the results of the primary research conducted by this study.

6 Chapter Six: Results

6.1 Introduction.

In this chapter, the results obtained from the various analyses described in Chapter Four are presented. These results were obtained in response to the specific objectives outlined for the primary research. The chapter is divided into five main sections, with each section addressing a specific research objective.

6.2 Participant Demographics.

Table 6.1 shows the general demographics of the intrapartum ultrasound participants. In total, 201 parturients participated in the study. Data analysis was however possible in 196 participants, due to some missing data in 5 participants. Participants were in the age range of 19 to 39 years, which included 47% nulliparous women, 22% primiparous, and 31% multiparous. Their average gestational age before spontaneous onset of labour was 39 weeks 4days. Also, their body mass index (BMI) was in the range of 20kg/m^2 to 42kg/m^2 with the average being approximately 28kg/m^2.

In fourteen percent of participants, labour had been augmented with oxytocin on account of slow progress of labour before the ultrasound and digital VE examinations for this research were performed. Also, 36% of the participants had ruptured membranes before the ultrasound and digital VE examinations for this research were performed. In the 127 participants whose membranes had not ruptured prior to the ultrasound and digital VE investigation, the membranes of one-third of them were reported by the clinicians as slightly bulging.

The longest duration of a participant from the time of ultrasound investigation to delivery was approximately 11 hours, and the shortest duration recorded for a participant was approximately 20 minutes. Figure 6.1 shows the various cervical dilatations that were reported by digital VE immediately before the ultrasounds were performed.

Table 6.1 Demographics of Intrapartum Participants

Variables	Frequency	Percentage (%)
Age (Mean ± SD) years	26.79 ± 4.86	
Age Group		
<20	9	4.5
20-29	134	68.0
30-39	55	27.5
Parity		
Nulliparous	92	47.0
Primiparous	43	22.0
Multiparous	61	31.0
Ruptured Membranes		
Yes	69	36.0
No	127	64.5
Epidural		
Yes	1	0.5
No	195	99.5
Oxytocin		
Yes	26	13.5
No	170	86.5
Gestation age (Mean ± SD) weeks	39.60 ± 1.07	
Birthweight (kg)	3.22 ± 0.43	
Body mass index	27.80 ± 3.49	
Mode of delivery		
Caesarean delivery	26	13.0
Spontaneous vaginal delivery	170	87.0

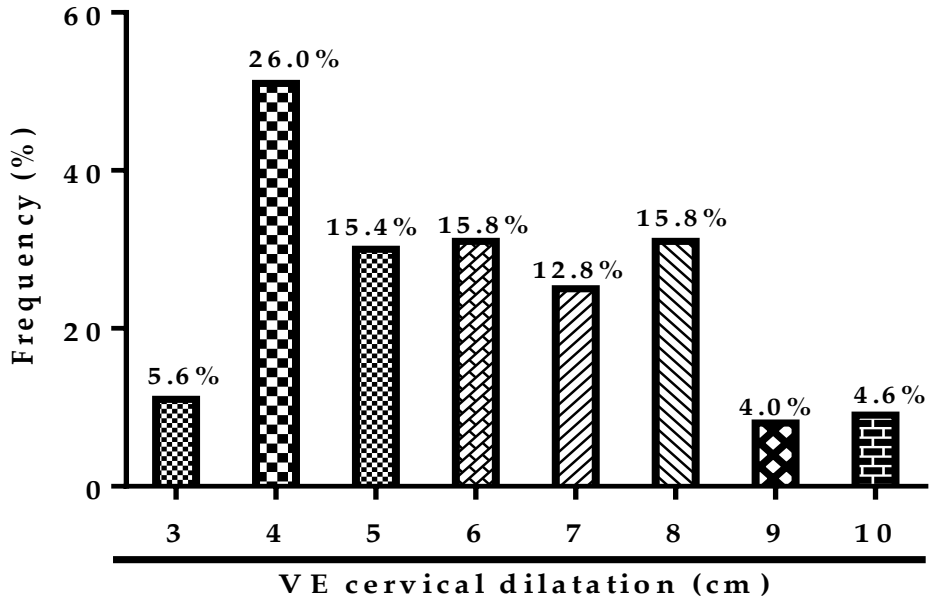

Figure 6.1 Digital VE Percentage Distributions of the Estimated Cervical Dilatations.

6.3 Findings Obtained from the Analyses Conducted on Fetal Head Position

The determination of fetal head position was obtainable with ultrasound in all participants, but obtainable with digital VE in 67% of participants. The various fetal head positions were presented in degrees as described in Chapter Four. The highest percentage of participants were determined by ultrasound as being in the LOT (45^{o}) position, followed by the LOP (90^{o}) position, and the ROT (270^{o}) position respectively (Figure 6.2). The DOP (180^{o}) was the lowest in percentage reported by ultrasound. No participant was reported by ultrasound as being in the DOA (360^{o}) position. Ultrasound and digital VE were generally in agreement on the fetal head position of 47.2% participants, including 12.9 % of perfect agreement and 34.3% in the ±45^{o} agreement range (Figure 6.3).

However, digital VE could not determine the fetal head position of 33.3% of cases, which was captured as missing data (Figure 6.3).

In addition to the simple percentage agreement statistics, Cohen's kappa analysis was done to investigate agreement occurring by chance. The concordance analysis for Kappa coefficients between ultrasound and digital VE is shown in figure 6.4.This showed a significant poor agreement between ultrasound and digital VE determination of fetal head position (k=0.23). Figure 6.4 also demonstrates that whenever ultrasound predicted a fetal head position as being LOA, which is depicted here as 45^{o}, there was only 34% chance of digital VE predicting the same LOA. Based on an LOT (90^{o}) determination made with ultrasound, there was only about 10% chance of digital VE predicting the same. Again, based on an LOP (135^{o}) determination made with ultrasound, the chances of digital VE predicting the same was also just 10%. Digital VE had 0% chance of predicting DOP (180^{o}) determination made by ultrasound. Digital VE also had a little over 20% chance of predicting ROP (225^{o}) made by ultrasound, and about 15% chance of predicting ROT (270^{o}) made by ultrasound. Lastly, digital VE had about 20% chance of predicting ROA (315^{o}) determination made by ultrasound.

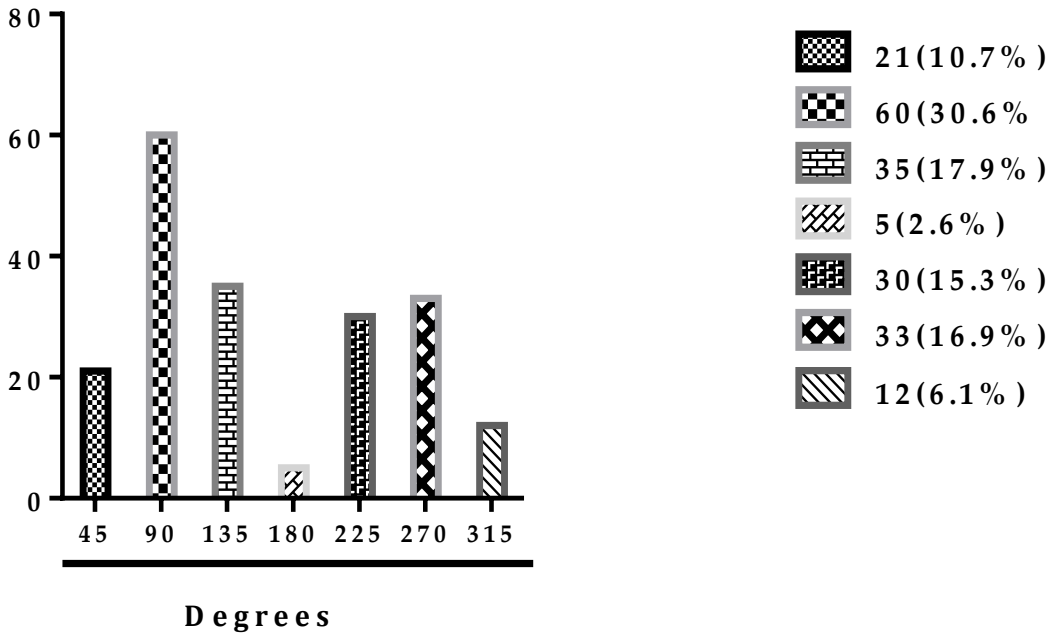

Figure 6.2 Percentage distribution of fetal head positions determined by ultrasound

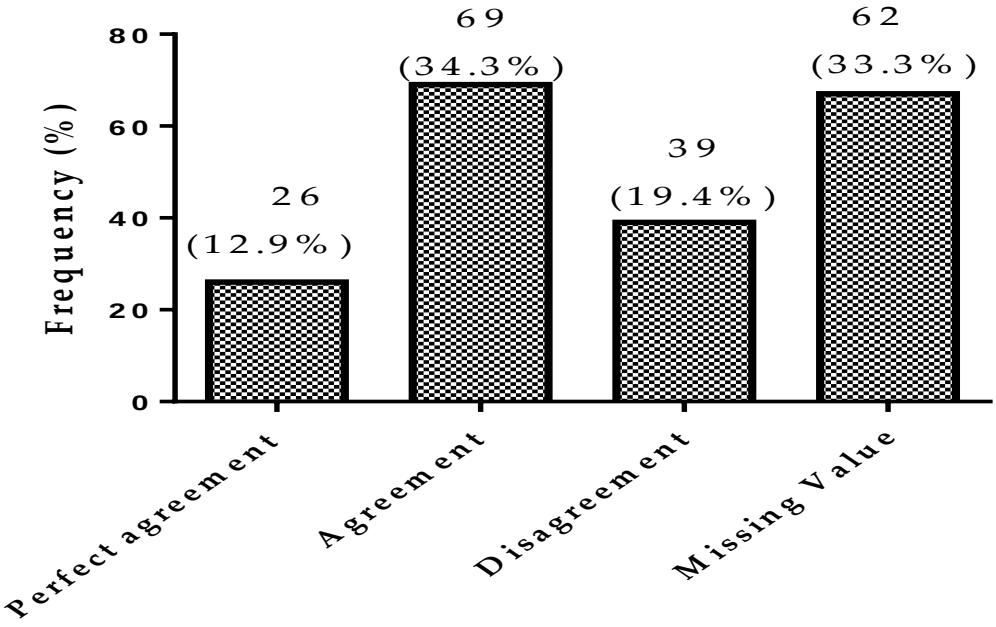

Figure 6.3 Simple Percentage Agreement between Ultrasound and Digital VE on Fetal Head Position

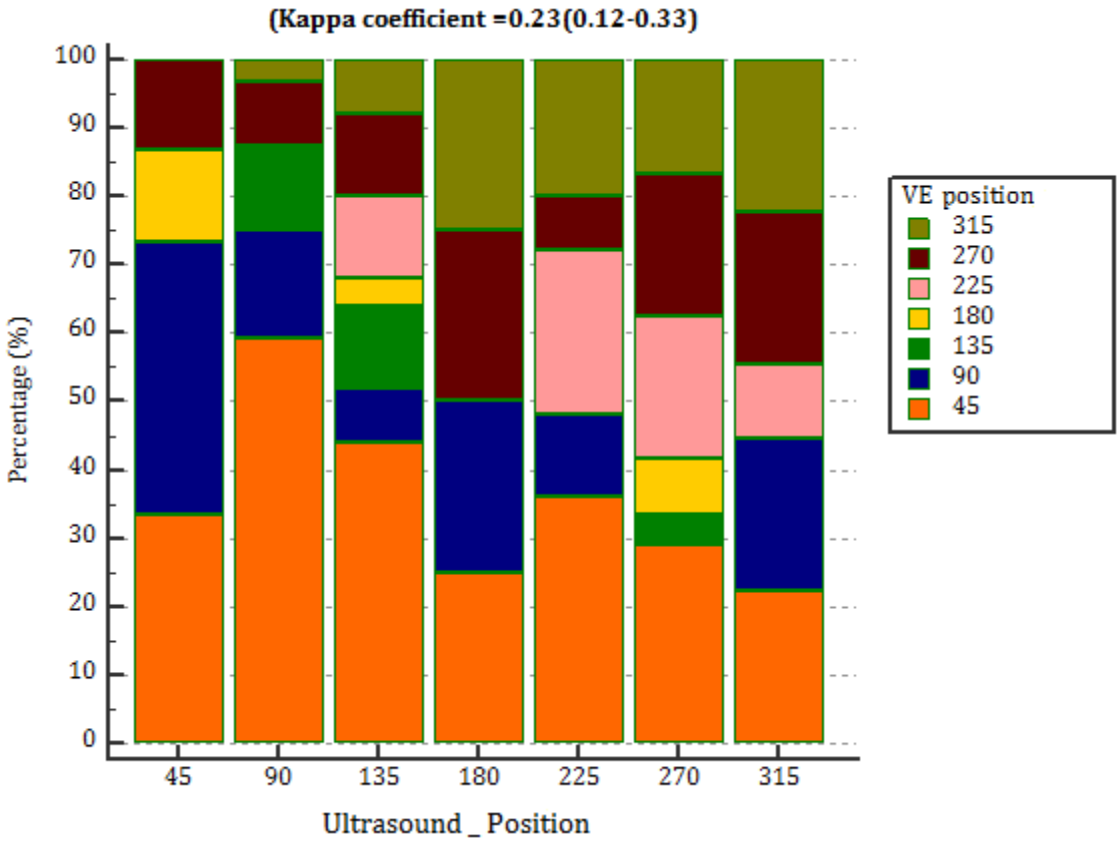

Figure 6.4 Between-Method Agreement of Ultrasound versus Digital VE on Fetal Head Position

6.3.1 Findings on Intrapartum Variables That May Affect the Between-Method Agreement.

The findings of this study did not show any statistically significant effect of the intrapartum variables considered in relation to the between-method agreement. As indicated in Chapter Four, these intrapartum variables considered included the VE cervical dilatations, the VE head stations, and the US head position (p=0.266). Table 6.2 shows the chi-square statistical analysis of these categorical numeric variables in association with the between-method agreement.

Table 6.2 Intrapartum variable that may be effected by the agreement between US Position and VE Position

Agreement				
Variables	Yes (n, %)	No (n, %)	X^2, df	p-value
US position (degrees)			7.64, 6	0.266
45	11(10.8%)	10(9.6%)		
90	35(34.3%)	25(25.5%)		
135	15(14.7%)	20(21.3%)		
180	2(2.0%)	3(3.2%)		
225	10(10.8%)	20(21.3%)		
270	20(19.6%)	13(13.8%)		
315	8(7.8%)	4(5.3%)		
VE cervical Dilatation (cm)			5.62, 7	0.584
3	6(6.4%)	4(3.9%)		
4	26(27.7%)	25(24.5%)		
5	10(10.6%)	19(18.6%)		
6	16(17.0%)	20(19.6%)		
7	15(15.0%)	9(8.8%)		
8	13(13.8%)	17(16.7%)		
9	4(4.3%)	3(2.9%)		
10	4(4.3%)	5(4.9%)		
VE Station			4.56, 4	0.336
<-1	26(27.7%)	35(34.3%)		
0	11(11.7%)	17(16.7%)		
1	11(11.7%)	5(4.9%)		
2	1(1.1%)	1(1.0%)		
3	45(47.9%)	44(43.1%)		

Data is presented as frequency (%), X^2= Chi-Square value, df = degree of freedom, $p<0.05$ is statistically significant

6.4 Findings Obtained from the Analyses Conducted on Fetal Head Station

Figure 6.5 shows the percentage distribution of the various fetal head stations that were determined by digital VE. The highest percentage of the parturients were diagnosed by digital VE as being at station 0, followed by station -1. Generally, 46% were diagnosed as being above the ischial spines which suggests that there was no head engagement, and 54% were diagnosed as being at the level of the ischial spines or below which suggest that there was fetal head engagement.

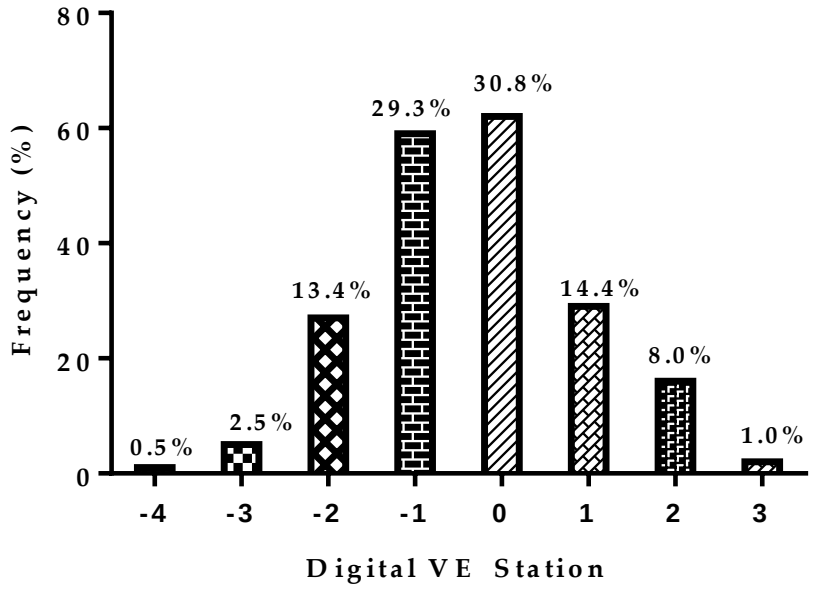

Figure 6.5 Percentage distribution of fetal head stations determined by ultrasound

The ultrasound parameters assessed in relation to fetal head station included the HPD, HSD and AoP, all of which were obtainable in all recruited participants. Table 6.3 shows

the average HPD, HSD and AoP values that were obtained by ultrasound in these participants, and the corresponding fetal head station that was reported by digital VE. Generally, an average HPD of 3.6cm was likely to be at station 0 which is the minimum level of engaged fetal head. Again, an average HSD of 2.8cm corresponded with station 0. Lastly, an average AoP of 101^{o} also corresponded with station 0.

Table 6.3 Mean levels of HPD, HSD and AoP in relation to fetal head station by digital VE (The highlighted region shows correspondence between station 0 and 3.6cm HPD, 2.8cm HSD and 101^{o} AoP).

VE Head Station	-4	-3	-2	-1	0	1	2	3
N=196	N=1	N=5	N=27	N=57	N=62	N=29	N=13	N=2
HPD (cm)								
Mean ± SD	5.9 ± 0.0	4.16 ± 1.05	4.42 ± 0.60	4.17 ± 0.86	3.64 ± 0.94	3.27 ± 0.60	3.08 ± 0.42	2.45 ± 0.07
95% CI	-	(2.86 to 5.46)	(4.17 to 4.66)	(3.94 to 4.39)	(3.40 to 3.88)	(3.04 to 3.50)	(2.85 to 3.29)	(1.82 to 3.09)
HSD (cm)								
Mean ± SD	3.9 ± 0.0	3.16 ± 1.15	3.47 ± 0.52	3.36 ± 0.64	2.83 ± 0.64	2.43 ± 0.74	2.13 ± 0.53	1.50 ± 0.57
95% CI	-	(1.73 to 4.58)	(3.26 to 3.67)	(3.19 to 3.53)	(2.67 to 2.99)	(2.15 to 2.71)	(1.84 to 2.42)	(-3.58 to 6.58)
AoP (deg)								
Mean ± SD	80 ± 0.0	93.60 ± 15.04	88.52 ± 7.23	91.92 ± 13.60	101.4 ± 13.4	108.2 ± 14.7	108.6 ± 8.58	147.5 ± 17.6
95% CI	-	(74.5 to 112.3)	(85.6 to 91.3)	(88.3 to 95.46)	(98.0 to 104.8)	(102.6 to 113.8)	(104 to 113.1)	(113.3 to 306.3)

Values are presented as mean standard deviation and 95% confidence interval of mean

6.4.1 Relationship between the HPD and Digital VE Head Station.

As indicated in Chapter Four, linear regression and correlation coefficient were used in analyzing the strength of the relationship between HPD and fetal head station (figure 6.6). This showed a significant negative relationship with a correlation matrix of 0.493 (r=-0.493; p<0.0001) obtained between HPD and fetal head station. The coefficeint of determination (R^2 value) was also 0.243. In addition, it demonstrated that a one unit increase in centimetre of the fetal head station corresponded to a decrease in HPD by 0.360 cm. The regression equation was HPD (cm) = 3.697-0.360*VE head Station.

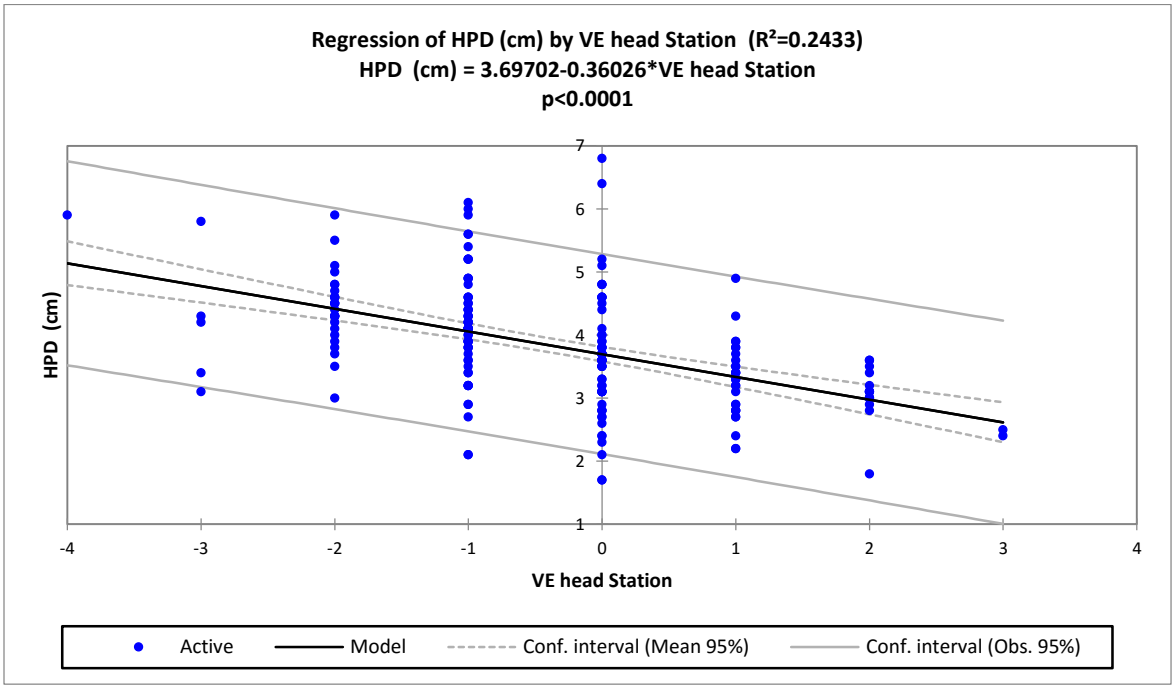

Figure 6.6 Scatterplot with linear regression analysis showing HPD measured by ultrasound against fetal head station assessed by digital VE

6.4.2 Relationship between the HSD and the Digital VE Head Station.

Linear regression and correlation coefficient were used in analysing the relationship between the HSD and fetal head station as shown in figure 6.7. This showed significant negative relationship with a correlation matrix of 0.551 (r=-0.551; p<0.0001) between the HSD and fetal head station. Also, the coefficient of determination (R^2 value) was 0.304. In addition, it demonstrated that a one unit increase in centimetre of fetal head station corresponded to a decrease in HSD by 0.342 cm. The regression equation was HSD (cm) = 2.847-0.342*VE head station.

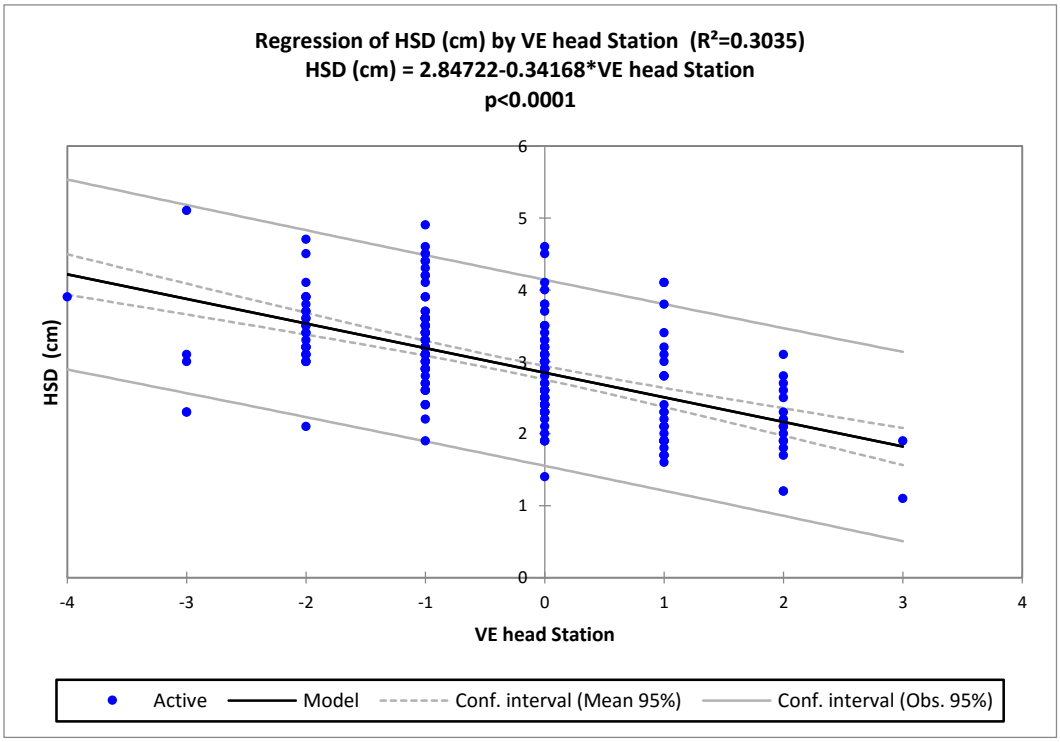

Figure 6.7 Scatterplot with linear regression analysis showing HSD measured by ultrasound against fetal head station assessed by digital VE

6.4.3 Relationship between the AoP and Digital VE Fetal Head Station.

Linear regression and correlation coefficient were used in analysing the relationship between the AoP and fetal head station as shown in figure 6.8. This showed significant positive relationship with a correlation matrix of 0.460 (r=0.460; p<0.0001) obtained between AoP and fetal head station. Also, the coefficient of determination (R^2 value) was 0.212. In addition, it demonstrated that a one unit increase in fetal head station corresponded to increase in AoP by 6.112 degrees. The regression equation was AoP (deg) = 100.04+6.112*VE head station.

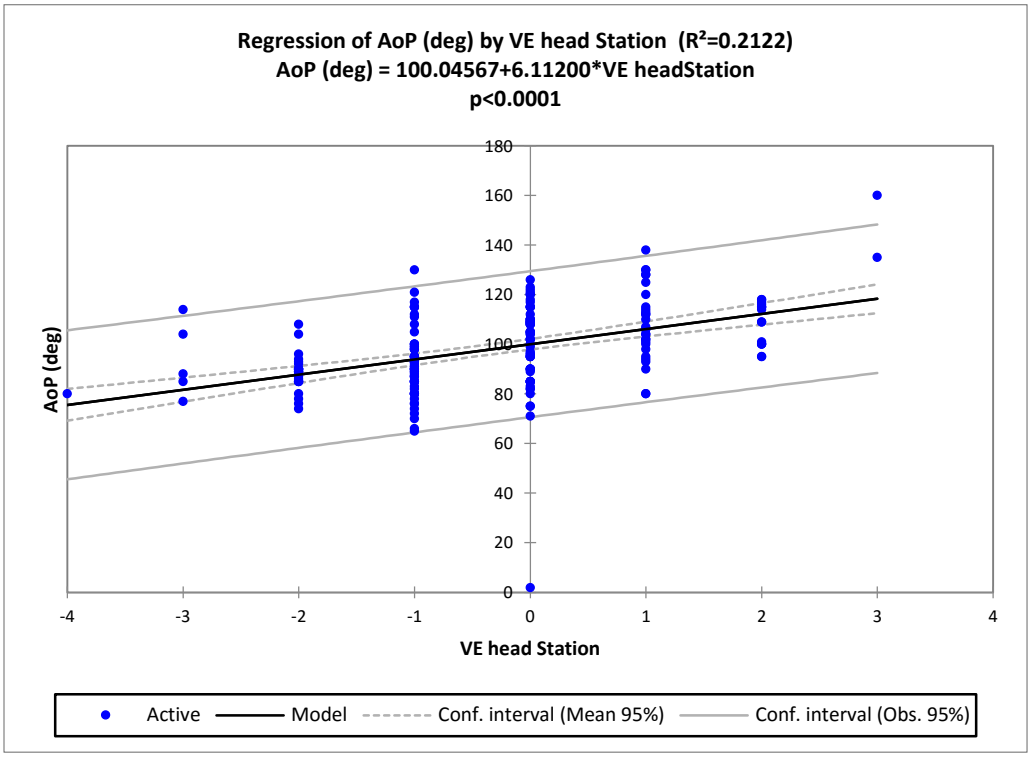

Figure 6.8 Scatterplot with linear regression analysis showing AoP measured by ultrasound against fetal head station assessed by digital VE

6.4.4 Findings on the Diagnostic Performance of HPD, HSD and AoP in Determining Engaged Fetal Head.

With the digital VE station 0 as the gold standard, the corresponding average values of HPD, HSD and AoP were selected as the cut-off values for testing the diagnostic performance of ultrasound in diagnosing engaged fetal head. As highlighted in table 6.3, these cut-off values are 3.6cm, 2.8cm and 101^{o} for HPD, HSD and AoP respectively. These cut-off values were therefore used in the ROC curve analyses. Figures 6.9, 6.10 and 6.11, and Table 6.4 show the diagnostic performance of HPD, HSD and AoP in the detection of engaged fetal head.

Using the ROC curve, the cut-off for HPD below which head engagement would be diagnosed was 3.6cm. On the basis of this threshold, the results obtained showed an AUC of 0.7946, a sensitivity of 78.7%, a specificity of 72.3%, a positive predictive value of 49.0% and a negative predictive value of 92.0% in the HPD diagnosis of engaged fetal head.

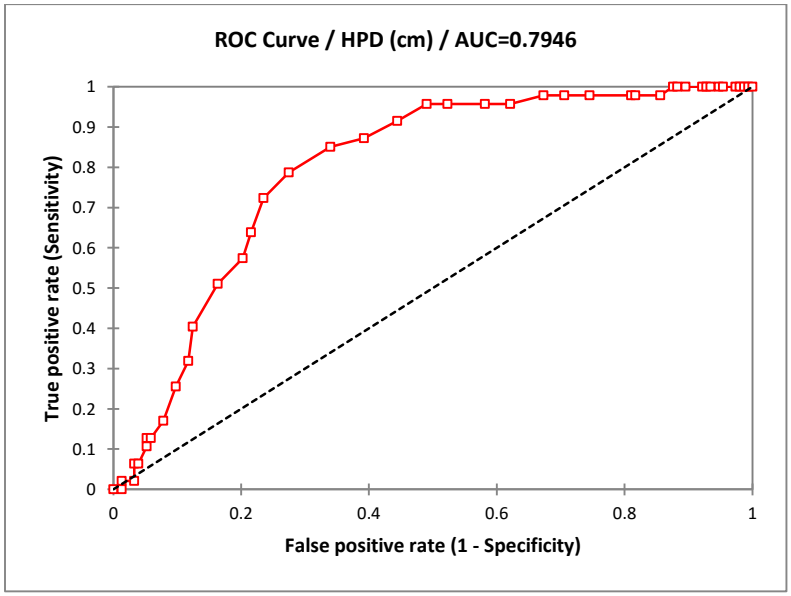

Figure 6.9 ROC Curve showing the diagnostic performance of HPD on engaged fetal head

Secondly, with HSD cut-off value of 2.8cm for diagnosing engaged fetal head, the ROC curve obtained an AUC of 0.8265, a sensitivity of 74.5%, and a specificity of 70.8%.

The positive predictive value and negative predictive values were 44.0% and 90.0% respectively.

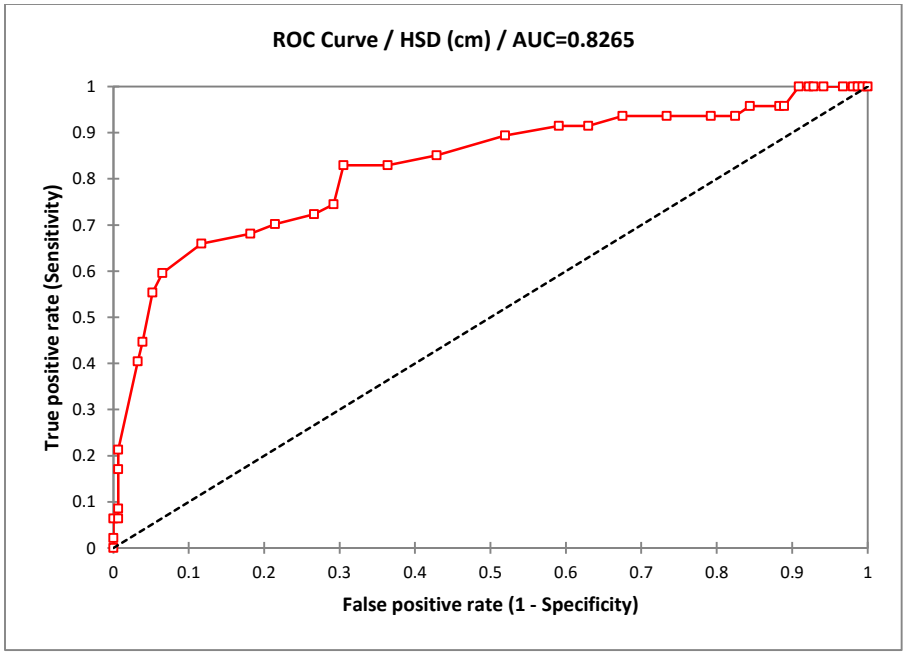

Figure 6.10 ROC Curve showing the diagnostic performance of HSD on engaged fetal head

Thirdly, with an AoP cut-off value of 101º, the ROC curve obtained an AUC of 0.7729, a sensitivity of 68.1%, and a specificity of 68.2%. The positive predictive value and negative predictive value were 39.5% and 87.5% respectively.

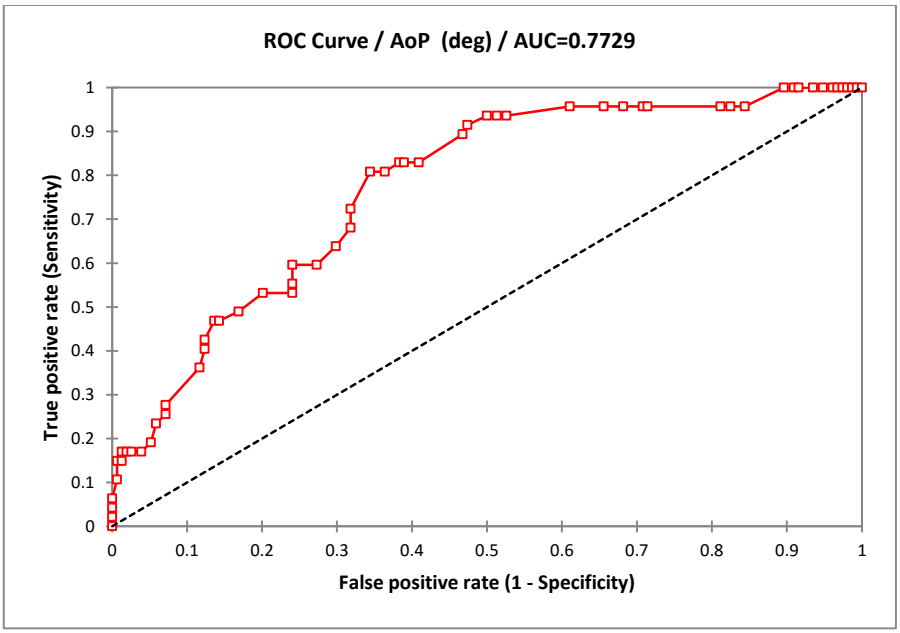

Figure 6.11 ROC Curve showing the diagnostic performance of AoP on engaged fetal head

Table 6.4 Diagnostic performance of HPD, HSD and AoP on fetal head engagement

Ultrasound Methods	Cut-off points	Sensitivity (95%CI)	Specificity (95%CI)	PPV	NPV	TP	TN	FP	FN	Accuracy
HPD(cm)	3.60	78.7(65.0-88.1)	72.3(65.0-79.0)	49.0	92.0	37	111	42	10	74.0
HSD cm)	2.80	74.5(60.0-84.0)	70.8(63.1-77.4)	44.0	90.0	35	109	45	12	71.6
AoP (deg)	101.0	68.1(54.0-79.6)	68.2(60.4-75.0)	39.5	87.5	32	105	40	15	68.2

6.5 Findings Obtained from the Analyses Conducted on Cervical Dilatation.

Three ultrasound measurement methods for cervical dilatation were assessed in relation to digital VE measurement for cervical dilatation. The ultrasound measurement methods assessed were named here as the anterior-to-posterior (AP) measurement method, transverse measurement method, and the average diameter method.

Statistical analysis was based on 175 participants with clearly visualised sonographic anatomical landmarks for measuring cervical dilatation.

6.5.1 Relationship between the Ultrasound AP Diameter and the Digital VE on Cervical Dilatation.

Linear regression and correlation coefficient were used in analysing the relationship between the ultrasound AP diameter measurement and the digital VE on cervical dilatation. This showed a significant positive relationship ($r=0.731$; $p<0.0001$) between the two, with a correlation matrix of 0.731 (figure 6.12). Also, the coefficient of determination (R^2 value) was 0.535. Again, it was noted that a 1cm increase in the ultrasound AP measurement corresponded to an increase in digital VE measurement by 1.009 cm. The regression equation was VE Cervical Dilatation (cm) = 0.201+1.009*US cervical dilatation AP diameter (cm) as shown in figure 6.12.

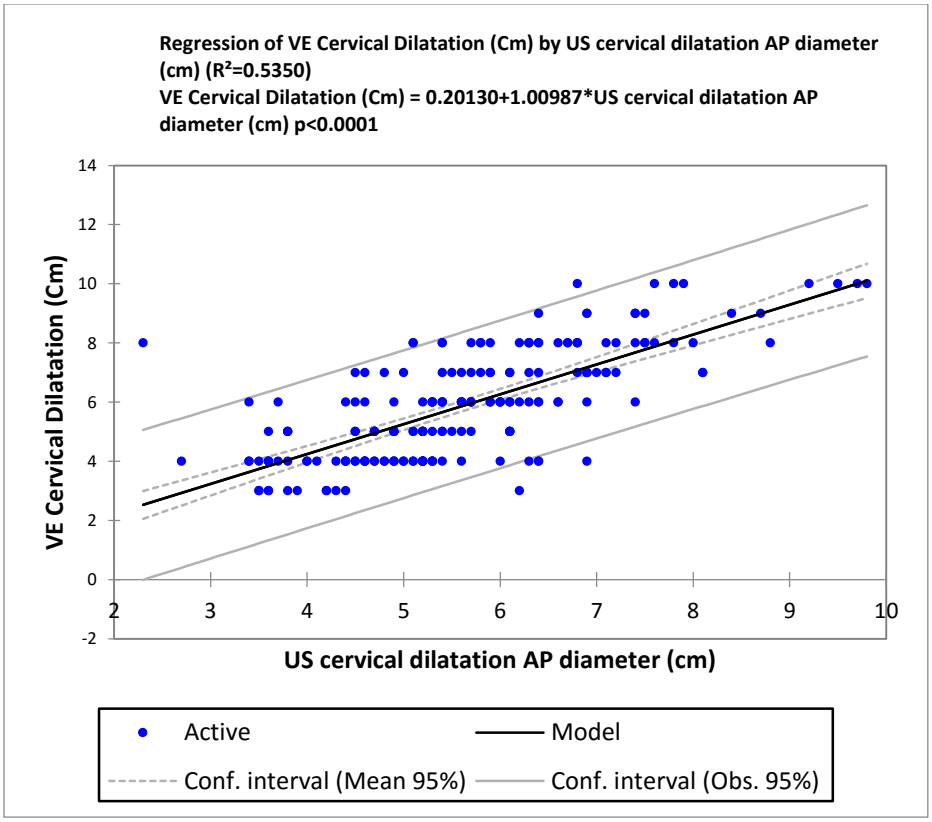

Figure 6.12 scatterplot with linear regression analysis showing US AP and digital VE dilatation.

The Bland-Altman plot was also used in calculating the mean difference and agreement limits between the two methods. This showed an average mean difference of 0.26cm between the ultrasound AP measurement and the digital VE results on cervical dilatation. The limit of agreement was 0.08 to 0.43 (figure 6.13)**.** This mean difference obtained was statistically significant (p=0.0045).

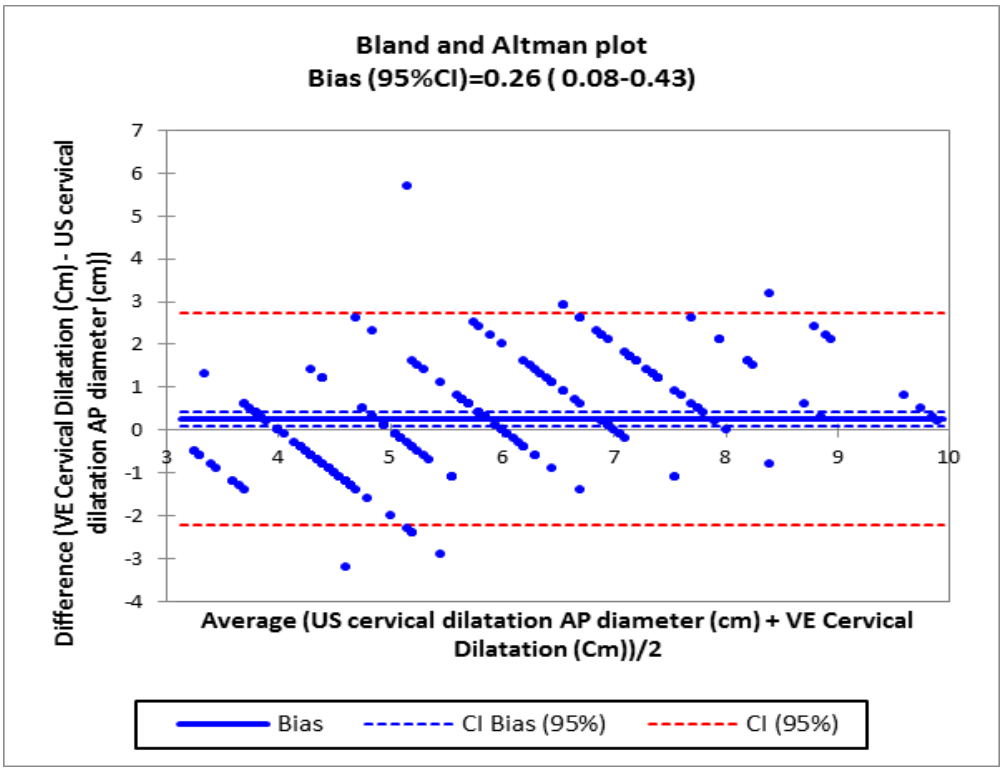

Figure 6.13 Bland-Altman analysis on of US dilatation AP diameter

6.5.2 Relationship between the Ultrasound Transverse Diameter and the Digital VE on Cervical Dilatation.

Linear regression and correlation coefficient analysis were used in analysing the relationship between the ultrasound transverse measurement and the digital VE on cervical dilatation. This showed a significant positive relationship ($r=0.758$; $p<0.0001$) between the two methods with a correlation matrix of 0.758. The coefficient of determination (R^2 value) was 0.574. It was also noted that a 1cm increase in the ultrasound transverse diameter on cervical dilatation corresponded to an increase in digital VE by 1.061 cm (figure 6.14). The regression equation was VE Cervical Dilatation (Cm) = -0.180+1.061*US Cervical dilatation in transverse as shown in figure 6.14.

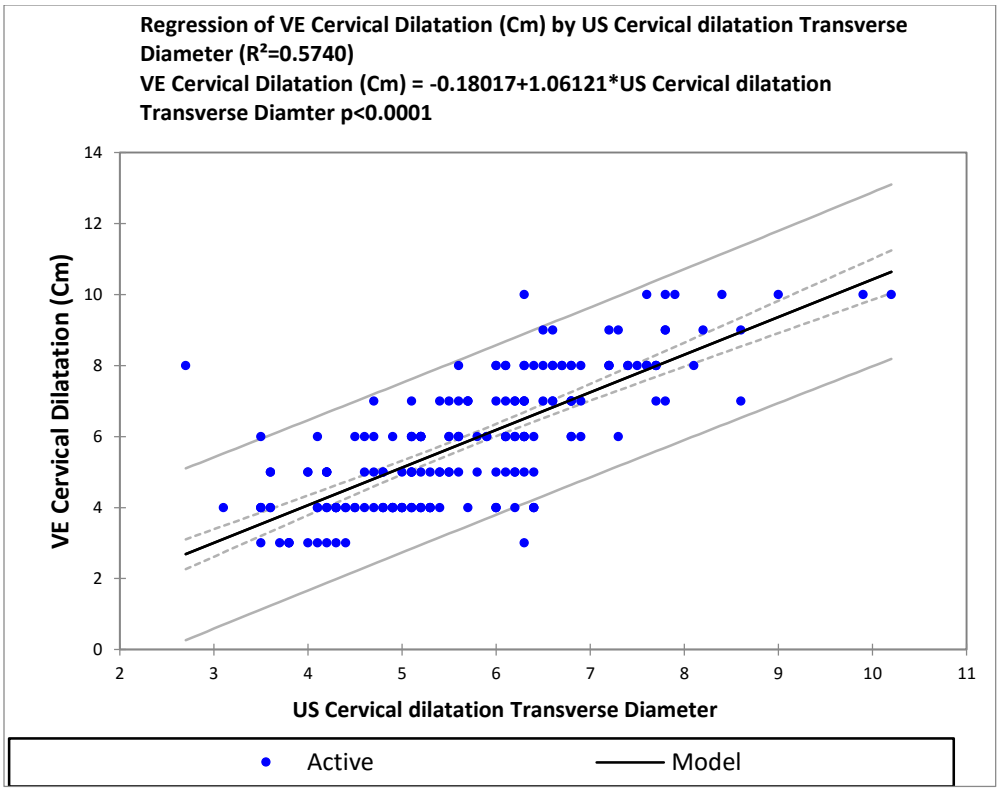

Figure 6.14 scatterplot with linear regression analysis showing US Transverse diameter and digital VE dilatation

In addition, the Bland-Altman plot was used in calculating the mean difference and agreement limits between the two methods. This showed an average mean difference of 0.17cm between the ultrasound transverse measurement and the digital VE on cervical dilatation. The limit of agreement was 0.0 to 0.33 (figure 6.15). Again, this mean difference was statistically significant (p=0.049).

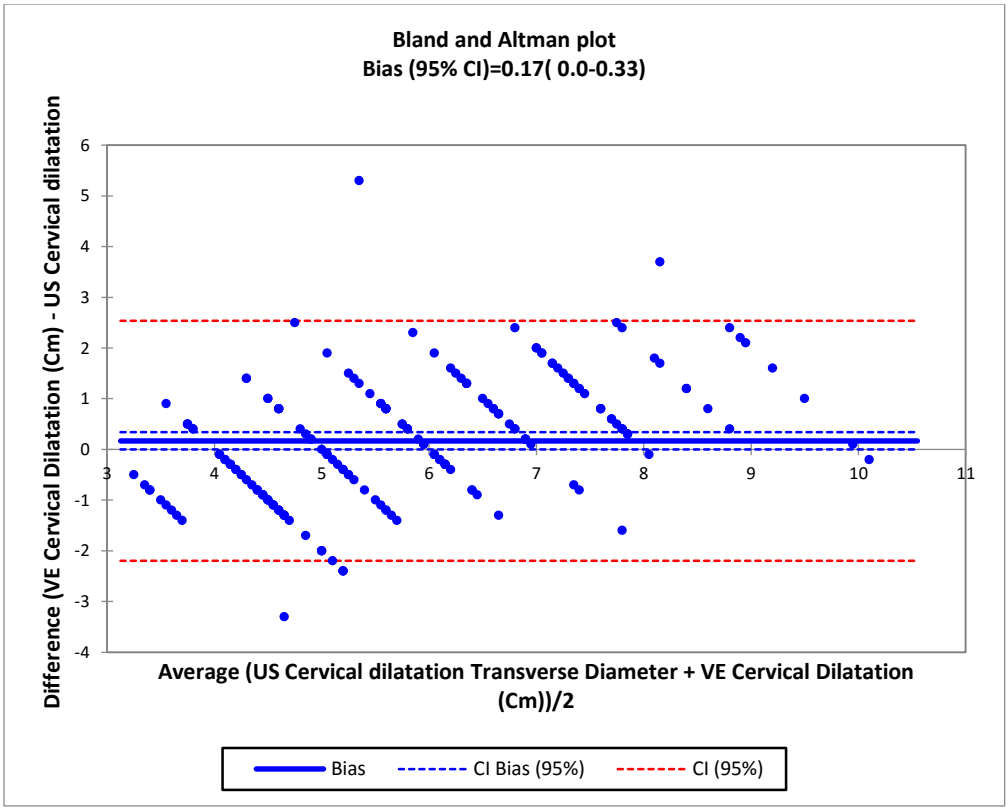

Figure 6.15 Bland-Altman graph of US transverse and digital VE dilatation.

6.5.3 Relationship between the Ultrasound Average Diameter and Digital VE Cervical Dilatation.

Linear regression and correlation coefficient were used in analysing the relationship between the ultrasound average diameter and digital VE on cervical dilatation. This showed a significant positive relationship ($r=0.758$; $p<0.0001$) with a correlation matrix of 0.758. The coefficient of determination (R^2 value) was 0.575. It was also noted that a 1cm increase in ultrasound average diameter corresponded to an increase in digital VE by 1.058 cm.

The regression equation was VE Cervical Dilatation (cm)= -0.121+1.058*Average US dilatation (cm) as shown in figure 6.16.

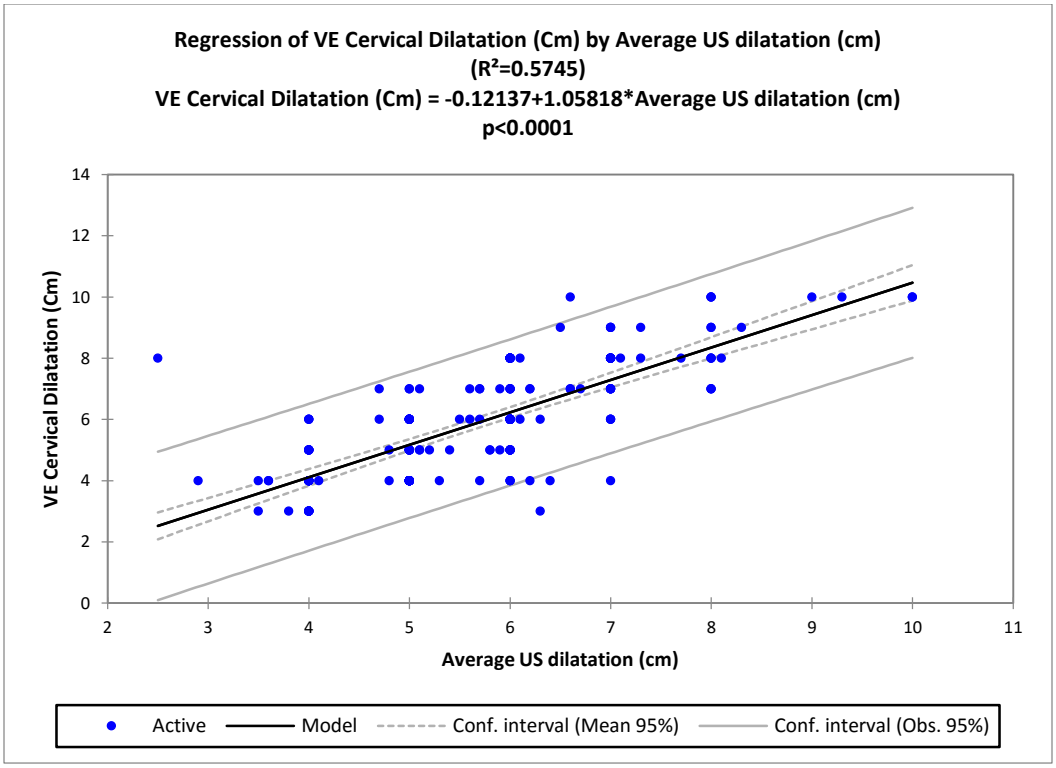

Figure 6.16 scatterplot with linear regression analysis showing US average diameter and digital VE dilatation.

In addition, the Bland-Altman plot was used in calculating the mean difference and agreement limits between the two methods. This showed an average mean difference of 0.21 between the ultrasound average diameter and digital VE on cervical dilatation. The limit of agreement was 0.04 to 0.38 (figure 6.17)**.** Again, this mean difference was statistically significant (p=0.016).

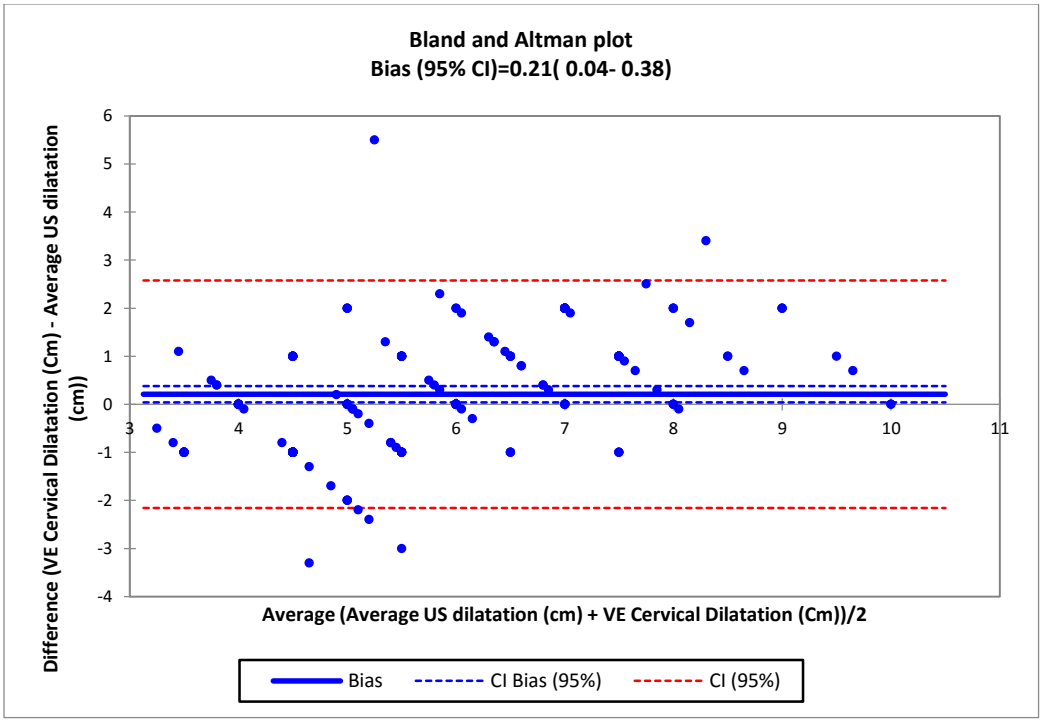

Figure 6.17 Bland-Altman graph of US average diameter and digital VE dilatation.

6.5.4 Diagnostic Performance of Ultrasound Methods in Determining Active Labour.

Using the ROC curve, and a digital VE cervical dilatation threshold of ≥ 4cm, the diagnostic performance of all the ultrasound methods in determining active labour was assessed as follows:

i. The sensitivity, specificity, positive predictive value and negative predictive value of using the ultrasound AP diameter in diagnosing active labour was 87%, 91%, 99% and 29% respectively (figure 6.18).

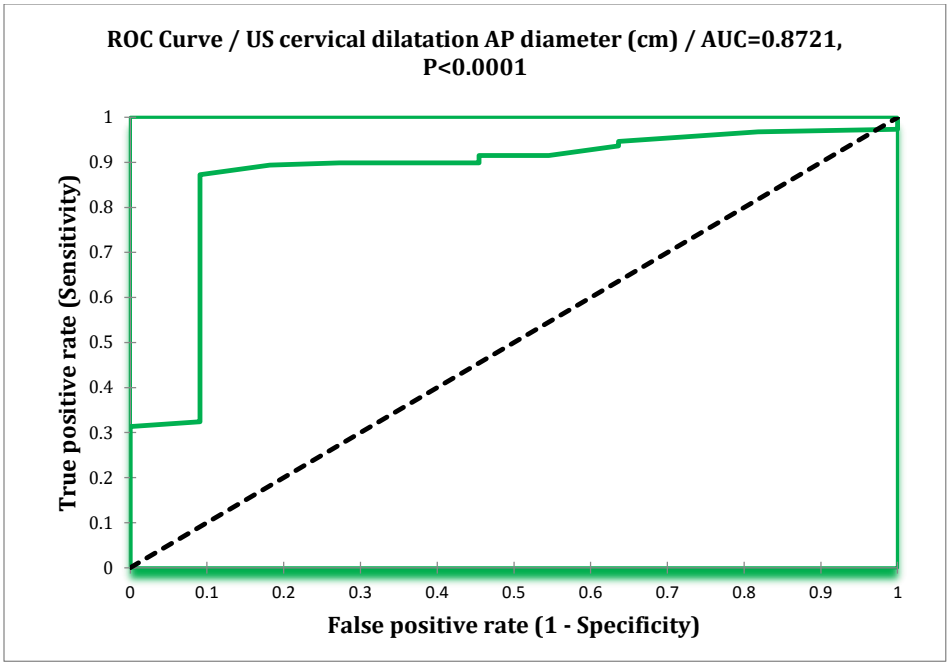

Figure 6.18 ROC Curve showing US diagnostic performance of Active Labour

ii. The sensitivity, specificity, positive predictive value and negative predictive value of using the ultrasound transverse diameter in diagnosing active labour was 85%, 91%, 99% and 27% respectively (figure 6.19).

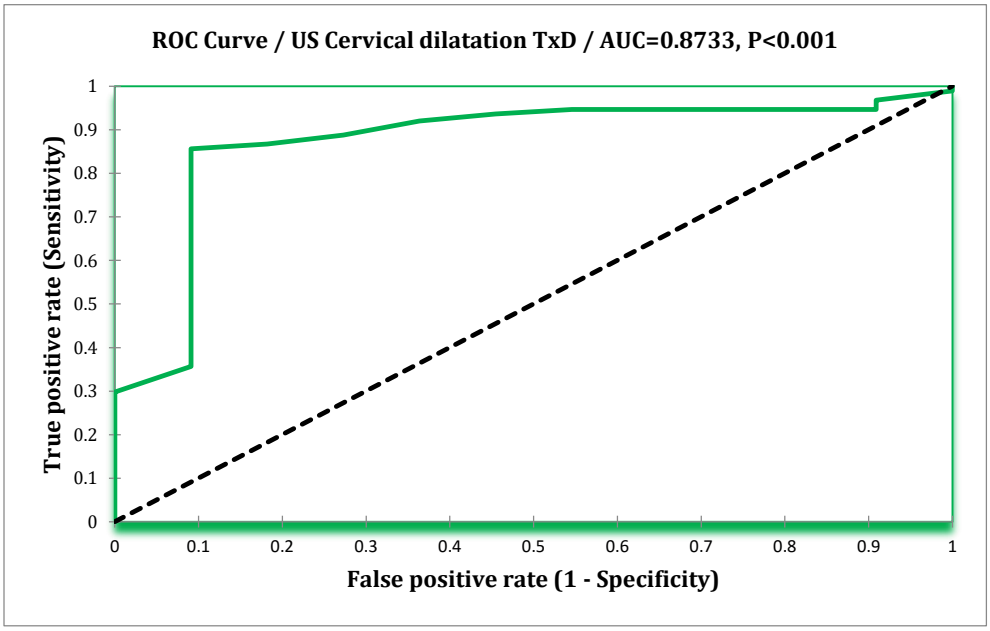

Figure 6.19 ROC Curve showing US diagnostic performance of Active

iii. The sensitivity, specificity, positive predictive value and negative predictive value of using the ultrasound average diameter in diagnosing active labour was 86%, 91%, 99% and 27% respectively (figure 6.20).

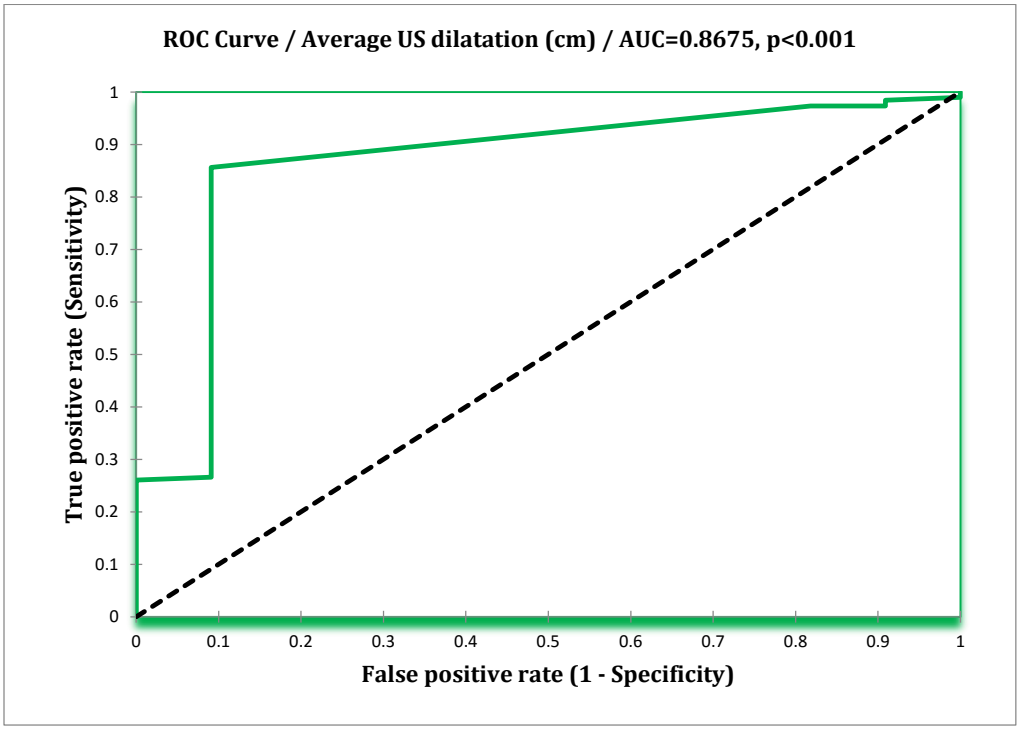

Figure 6.20 ROC Curve showing US diagnostic performance of Active Labour

6.6 Findings Obtained from the Analysis of Mothers' Acceptability of Ultrasound in Labour.

Table 6.5 shows demographics of mothers who completed questionnaire after delivery. The results of 196 completed questionnaire were analysed. This included 21% of mothers who were educated up to the tertiary level, and 26% of mothers who had gone through secondary school education. The rest had undergone basic education including those who dropped out of basic school at some point. All participants had undergone at least one ultrasound scanning during the antenatal period (figure 6.21). The majority of participants belonged to the Christian faith (83%), with the rest being Muslims. Most of the participants were from the Akan Tribe, followed by various Northern tribes with the minority from other Southern tribes.

Table 6.5 Demographics of postpartum participants

Variable	Frequency	Percentage
Level of Education		
Basic	104	53.0
Secondary	51	26.0
Tertiary	41	21.0
Tribe		
Akan	122	62.0
Northern tribes	62	31.0
Ga	5	3.0
Ewe	7	4.0
Religion		
Christianity	163	83.0
Islamic	33	17.0

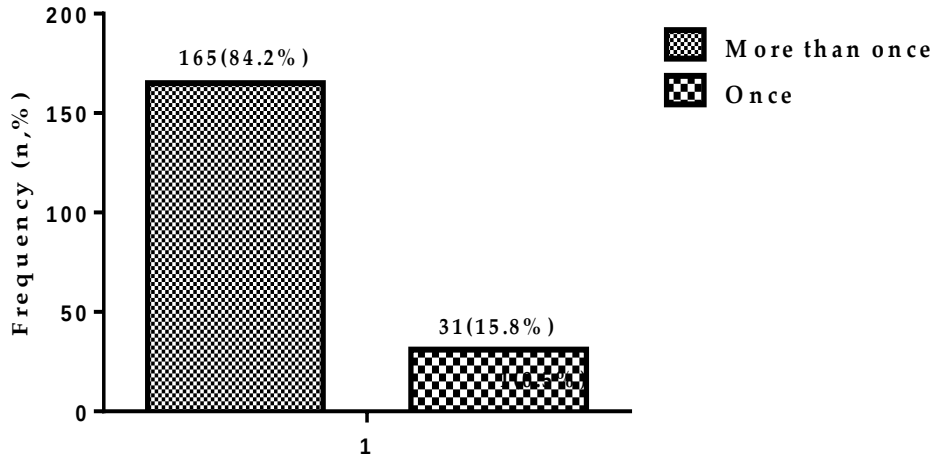

Figure 6.21 Number of antenatal scans

6.6.1 Mothers' View on How Uncomfortable Intrapartum Ultrasound Was.

When asked how uncomfortable intrapartum ultrasound was, 32% of mothers thought it was slightly uncomfortable, whilst 3% thought it was very uncomfortable. However, the majority (66%) thought it was not uncomfortable (see figure 6.22).

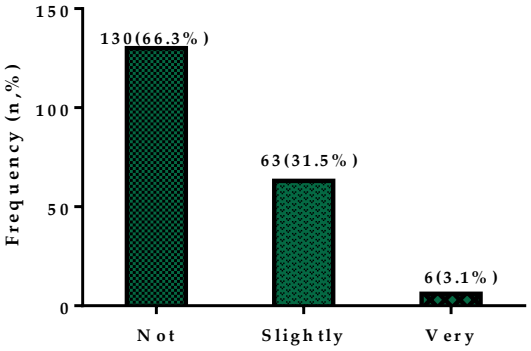

Figure 6.22 Level of ultrasound discomfort

6.6.2 Mothers' Comparison of their Experience and Prior Expectation from Ultrasound in Labour.

When asked whether intrapartum ultrasound was as uncomfortable as they had thought it would be, about 40% thought it was actually better than they had thought. However, forty-six thought the level of discomfort was within their expectation, whilst about thirteen percent thought it was actually worse than they anticipated. Figure 6.23 is a graphic representation of mothers' expectations and their views of what it turned out to be.

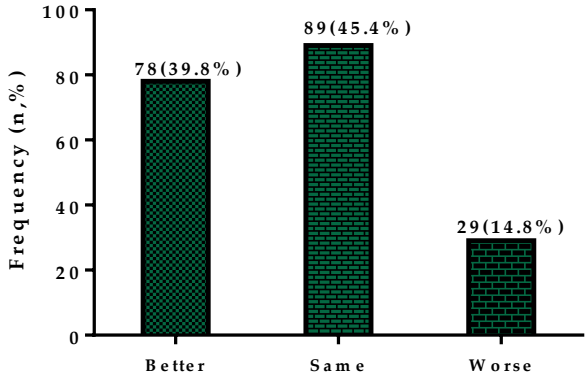

Figure 6.23 Ultrasound experience compared with expectation

6.6.3 Mothers' View of Intrapartum Ultrasound in Comparison with Digital VE.

When asked about their view on how they felt about the intrapartum ultrasound compared to digital VE, about 98% of mothers noted that the ultrasound was a better experience for them than the digital VE. But one mother indicated that there was no difference between the two, whilst three indicated that ultrasound was actually worse than digital VE (see figure 6.24).

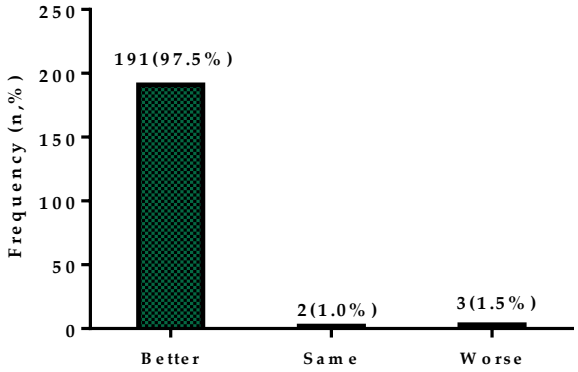

Figure 6.24 ultrasound experience compared with digital VE

6.6.4 Mothers' First Choice Preference between Ultrasound and Digital VE

When mothers were asked about their preferred first choice between ultrasound and digital VE for future intrapartum care, almost 99% said they would like to have ultrasound in future and would choose ultrasound ahead of digital VE (see figure 6.25).

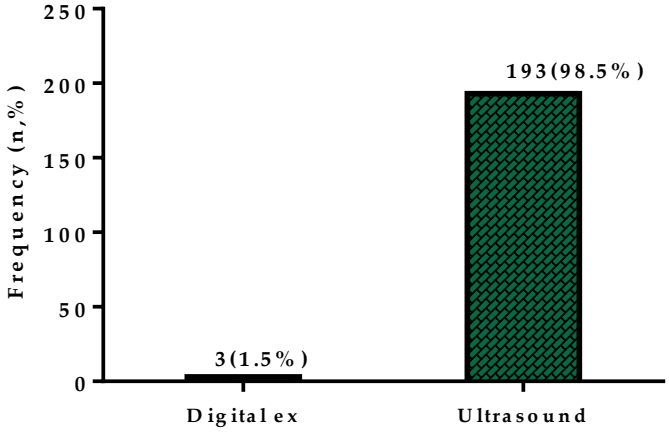

Figure 6.25 Preference between ultrasound and digital VE

6.6.5 Mothers Choice of Multiple Examinations in Labour

When asked to choose between ultrasound and digital VE regarding which one of them they would like to have many times than the other in labour, 99% of mothers said they would choose to have ultrasound many times than digital VE (see figure 6.26).

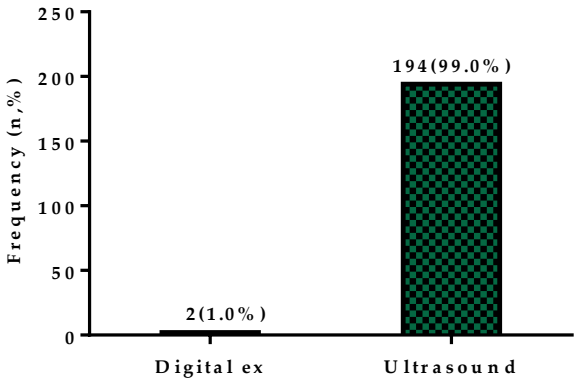

Figure 6.26 Modality of choice for multiple examination

6.6.6 Mothers Choice If They Could Decide Which of the Examinations Not to Have

When asked to choose between ultrasound and digital VE, if they could decide to avoid one, almost 99% chose digital VE over ultrasound as the one they would like to avoid if given the option (see figure 6.27).

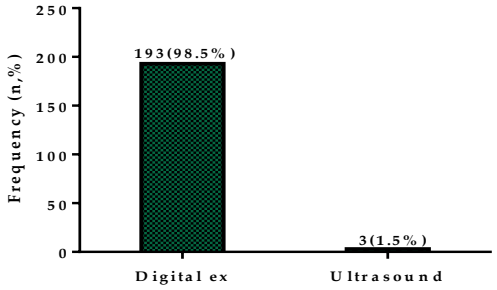

Figure 6.27 Mothers wish in case they could reject digital VE for ultrasound

6.7 Findings Obtained From the Analysis of Caregivers View on the Practicality of Ultrasound in Labour.

Table 6.6 shows the demographics of the caregivers who were interviewed on the practicality of using ultrasound for assessing the progress of labour. All consenting caregivers for the interview were obstetricians who had practiced for not less than 5 years as specialists. A total of seven caregivers were interviewed. However, the response of one caregiver was later excluded, as she was not available to sign the informed consent form which was sent to all caregivers along with the transcribed audio recording. Therefore, the findings presented below are from the transcripts of six caregivers who signed the informed consent form after reading through the transcribed audio recording and confirming that they were their own words.

Table 6.7 shows the open codes and the four categories that were generated from the responses of the six caregivers who participated in this study. A total of 22 open codes were generated. Open codes 1 to 8 are responses related to whether using ultrasound to assess labour progress in the clinical setting will be possible. Open codes 9 to 12 are responses related to whether ultrasound will be a suitable option to digital VE in assessing progress of labour in the clinical setting. Open codes 13 to 19 are related to caregivers' approval of ultrasound being able to provide effective solutions to a number of problems that are associated with monitoring the progress of labour. Open codes 20 to 22 are related to the perception of caregivers' on real situations where using ultrasound in labour will serve a good purpose.

Each open code addresses a specific detail under the four main categories. Quotes from caregivers are also presented under each open code.

Table 6.6 Demographics of caregiver participants

CAREGIVER	RANK	GENDER	YEARS OF EXPERIENCE AS SPECIALIST
1	SPECIALIST	FEMALE	8 YEARS
2	SENIOR SPECIALIST	MALE	10 YEARS
3	CONSULTANT	MALE	15 YEARS
4	CONSULTANT	MALE	15 YEAS
5	SPECIALIST	FEMALE	5 YEARS
6	SENIOR SPECIALIST	MALE	10 YEARS

1. Quotes Associated with Open Code 1

In open code 1, the responses of 4 out of 6 caregivers suggest that using ultrasound in labour was not possible now, due to limited scanning skills among caregivers. Below are quotes associated with open code 1.

(Caregiver 1):

'For now as it is in the labour ward, not many people are trained to have the skills to operate it'.

(Caregiver 2):

'There will be the need for every personnel to have the skill in operating the ultrasound machine to avoid a situation whereby those who are skilled in the use of ultrasound machine happens not to be on duty to use it.'

(Caregiver 3):

'I will say that the personnel who have the skills is what can hinder its use, as they may not be available all the time.'

(Caregiver 6):

'Also if you introduce the ultrasound it means that all clinicians must be equipped in the skill of using it.'

2. Quotes Associated with Open Code 2

In open code 2, the response of 4 out of 6 caregivers suggest that using ultrasound in labour will be possible, but not until caregivers receive adequate US training.

(Caregiver 1):

'…but with training and education we will be able to operate it'

(Caregiver 2):

'…*so I think all our residents should have the basic skills in ultrasound scanning as early as possible'*

(Caregiver 3):

'But it could be possible with adequate ultrasound skills for all labour ward personnel'

(Caregiver 5):

'The challenge is that we should be trained to use the ultrasound but the residency program did not make it compulsory for all residents. So it should be possible if that limitation is addressed '

Table 6.7 Open code and Categories

#	OPEN CODES	CATEGORY	NUMBER OF RESPONDENTS
1	Not possible now, because of limited scanning skills	POSSIBLE?	4 out of 6
2	Possible, but not until caregivers receive adequate US training		4 out of 6
3	Possible, but only if it is cost-effective for management		2 out of 6
4	Possible, but only if it is at no cost to mothers		2 out of 6
5	Possible, but only if covered by health insurance		1 out of 6
6	Possible, but for limited use in selective cases		3 out of 6
7	Possible, but not until we get enough research evidence		4 out of 6
8	Possible, but not until more portable equipment become widely available		3 out of 6
9	Not suitable for the size and current set-up of the labour ward if using larger US equipment	SUITABLE?	2 out of 6
10	Suitable as adjunct but not a replacement for digital VE, because with VE we can also check moulding		3 out of 6
11	Suitable as adjunct because with digital VE we can also check amniotic fluid colour		2 out of 6
12	Suitable as adjunct because with VE we can also check cord compression		1 out of 6
13	Approve of US for effective detection of head position	EFFECTIVE?	4 out of 6
14	Approve of US for effective follow-up on VE to detect Active Labour and minimise multiple ves		2 out of 6
15	Approve of US as effective for limiting risk of infection		3 out of 6
16	Non-approval of US limiting risk of infection		1 out of 6
17	Non-approval of US for dilatation and station		1 out of 6
18	Approve of US in estimating fetal weight prolonged labour		1 out of 6
19	Approve of US in checking placenta location of women who report bleeding		4 out of 6
20	A real (typical) case is when abnormal progress is suspected	REAL?	2 out of 6
21	A real (typical) case for US is to determine head position for instrumental delivery		1 out of 6
22	A real (typical) case for US is for women who resist digital VE		2 out 6

3. Quotes Associated with Open Code 3

In open code 3, the response of 2 out of 6 caregivers suggest that using ultrasound in labour will be possible, but only if it is cost-effective for management. Below are quotes from caregivers.

(Caregiver 2):

'I think the cost of introducing ultrasound should be studied, because when a woman have 3 digital VE what will be the cost? But with the ultrasound there will be machine cost, electricity cost and are you going to use disposable gloves always?'

(Caregiver 3):

'It depends on the management administration, if they have the desire and zeal to purchase and maintain more equipment and also ensuring that supplies are available.'

4. Quotes Associated with Open Code 4

In open code 4, the response of 2 out of 6 caregivers suggest that using ultrasound in labour will be possible, but only if it is cost-effective or free for mothers. Below are quotes from caregivers.

(Caregiver 5):

'It's alright to use ultrasound if it's for free, but if the patients are to pay for it then it brings an extra cost to the patient which may affect its feasibility'.

(Caregiver 4):

'There may be cost implications on the side of the patient for the use of ultrasound'

5. Quotes Associated with Open Code 5

In open code 5, the response of 1 out of 6 caregivers suggest that using ultrasound in labour will be possible, but only if it is covered by the health insurance scheme. Below is a quote from caregiver.

(Caregiver 2):

'…*beyond that, is the health insurance ready to pay for that?'*

6. Quotes Associated with Open Code 6

In open code 6, the response of 3 out of 6 caregivers suggest that using ultrasound in labour will be possible, but for limited use in selective cases. Below are quotes from caregivers.

(Caregiver 3):

'I wouldn't want to use it for every case, but it should be possible in selective high risk cases'

(Caregiver 4):

'It will be feasible in high risk cases… we had an issue with the use of CTG, it was supposed to be used in high risk pregnancy but not routinely for every pregnancy.

(Caregiver 6):

'On routine basis I wouldn't admit unless there is a certain high risk case where you want to be more objective about your findings'

7. Quotes Associated with Open Code 7

In open code 7, the response of 4 out of 6 caregivers suggest that using ultrasound in labour will be possible, but not until they get enough research evidence. Below are quotes from caregivers.

(Caregiver 1):

'…because it's new there will be need for more research on it, to know how evidential it is in supporting its use'.

(Caregiver 2):

'There has not been much study on ultrasound in labour…but if I'm sure that ultrasound will give me the same or superior results, then yes, I will prefer the ultrasound'

(Caregiver 4):

'When we start slowly with ultrasound and then realise that it is superior, it will then minimise the use of digital VE it, not replacing it. So when we realise that there is some discrepancies in the ultrasound and the VE then there is the need for an experience person to re-examine so that we will find out which one is correct. So ultrasound should be used to complement the VE for now'.

(Caregiver 6):

'But first of all, there should be enough research evidence supporting the use of ultrasound. If statistics shows that what the fingers can do is much better than with the ultrasound it will limit its use, and if the ultrasound happens to be the best one statistically then it will be feasible,

8. Quotes Associated with Open Code 8

In open code 8, the response of 3 out of 6 caregivers suggest that using ultrasound in labour will be possible, but not until portable equipment become widely available. See below.

(Caregiver 3):

'I will say that the inadequate number of portable ultrasound machines will restrict its use'

(Caregiver 2):

'Given the size of the labour ward, more portable equipment will be needed'

(Caregiver 6):

'But our problem is that it should be with mobile ultrasound machine, and there is no enough of that for now'.

9. Quotes Associated with Open Code 9

In open code 9, the response of 2 out of 6 caregivers suggest that the limited space and set-up of the labour ward is not suitable for regular use of ultrasound. See comments below.

(Caregiver 2):

'The space in the labour ward is not that big, so moving the mounted ultrasound machine to every bedside will be difficult'

(Caregiver 3):

'One other issue is that the movement of the equipment, looking at the set-up of the labour ward will be restricted'

10. Quotes Associated with Open Code 10

In open code 10, the response of 3 out of 6 caregivers suggest that ultrasound may not be a suitable replacement for digital VE because with VE they can also check moulding. See comments below.

(Caregiver 1):

'… also you can determine moulding'

(Caregiver 2):

'…beyond that we also use digital VE to rule out significant moulding, since we need not prolong the delivery to avoid brain damage if moulding is 2 plus'.

(Caregiver 4):

'…because even if you do the ultrasound you have to asses other things like moulding which I don't know if the ultrasound can do it.'

11. Quotes Associated with Open Code 11

In open code 11, the response of 2 out of 6 caregivers suggest that ultrasound may not be a suitable replacement for digital VE because with VE they can also check amniotic fluid colour. See comments below.

(Caregiver 1):

'I wouldn't want to see people now shifting to ultrasound alone but the two should run hand in hand because each one has its advantages, the digital V examination provides the opportunity to be close to the patient and also to know the colour of the amniotic fluid which will also tell you something.'

(Caregiver 3):

'…also, the digital VE enables you to inspect the liquor with your fingers to know the nature of the liquor.'

12. Quotes Associated with Open Code 12

In open code 12, the response of 1 out of 6 caregivers suggest that ultrasound may not be a suitable replacement for digital VE because with VE they can also check cord compression. See comments below.

(Caregiver 2):

'…one of the things we look for is prolapse of the umbilical cords, I don't know whether so far you have considered it because anytime the membrane is ruptured we must exclude cord compression or prolapse of the cord which during digital exams we are able to feel …, but I don't know how that will be done with the use of ultrasound.'

13. Quotes Associated with Open Code 13

In open code 13, the response of 4 out of 6 caregivers suggest that they approve of ultrasound for effective detection of head position. See comments below.

(Caregiver 1):

'With respect to the parameters, I think the position of fetal head is where it will be much beneficial because with the ultrasound you will be able to determine position with much accuracy. But with the digital VE even with the most experienced personnel there have been errors.'

(Caregiver 2):

'In instances of prolonged labour where you want to find out the position. And that may be difficult sometimes because the head may be high or excessive caput may be present so you are not able to locate the occiput, the ultrasound would be needful than the digital VE.'

(Caregiver 3):

'I think using the ultrasound to determine the position will be appropriate.'

(Caregiver 5):

'In all the prolonged labour cases the cause is to be determined to enable intervention as soon as possible. Using ultrasound may be much easier to determine the position, if you have the skill.'

14. Quotes Associated with Open Code 14

In open code 14, the response of 2 out of 6 caregivers suggest that they approve of ultrasound for effective follow-up on VE to detect Active Labour and minimise multiple ves. See comments below.

(Caregiver 2):

'For example we have some women who come in with symptoms of labour. But you will examine and realise that she is really not yet in active labour. Instead of doing multiple examinations to find out if they are in active labour, you can use the ultrasound. And if it tells you that they are 4/5cm then you can admit them to the labour ward. By doing this, you would have spared them some vaginal examination and as I said earlier, multiple vaginal examination can lead to infections so you may have spared them from that too.'

(Caregiver 1):

'If you are going to depend on ultrasound to do sonographic monitoring in the process of labour definitely it will reduce the risk of infection because if the patient report and the first assessment is done for the cervical dilatation it can then be followed up with the ultrasound and if it is properly done, of course the number of infections can be reduced.'

15. Quotes Associated with Open Code 15

In open code 15, the response of 3 out of 6 caregivers suggest that they approve of ultrasound as effective for limiting risk of infection. Below are quotes from two participants.

(Caregiver 2):

'Also doing multiple vaginal examinations can lead to infections so using ultrasound will reduce the risk of infection.'

(Caregiver 6):

'The use of ultrasound will reduce the number of vaginal examination which will also reduce risk of infection because we know that the frequency of vagina examination can lead to infection, especially when the membranes are ruptured.'

16. Quotes Associated with Open Code 16

In open code 16, the response of 1 out of 6 caregivers suggest non-approval of ultrasound as effective for limiting risk of infection. See comment below.

(Caregiver 3):

'So in terms of invasiveness ultrasound will not introduce any probe inside, but in doing digital VE one have to observe certain principles of infection control. So what I'm saying is that when you compare the digital VE and ultrasound, the mere fact that ultrasound is not going to be invasive might reduce risk of infection but as to how significant I'm not sure. For me, it's rather about observing infection prevention practices effectively and not using ultrasound per se.'

17. Quotes Associated with Open Code 17

In open code 17, the response of 1 out of 6 caregivers suggest non-approval of ultrasound as effective for assessing cervical dilatation and fetal head station. See comment below.

(Caregiver 3):

'I think using the ultrasound to determine the position will be possible but for station and dilatation I don't see that being feasible.'

18. Quotes Associated with Open Code 18

In open code 18, the response of 1 out of 6 caregivers suggest approval of ultrasound in estimating fetal weight in cases of prolonged labour

(Caregiver 4):

'In suspected macrosomic cases where we think prolonged labour in a referred case may be resulting from a big baby, ultrasound is done to estimate fetal weight.'

19. Quotes Associated with Open Code 19

In open code 19, the response of 4 out of 6 caregivers suggest that they approve of ultrasound as effective for checking placenta location of women who report bleeding. See comments below.

(Caregiver 5):

'Rarely do we use ultrasound …. But when someone present bleeding in labour we do ultrasound before we attempt to do a vaginal examination'.

(Caregiver 6):

'We mostly use the ultrasound when a patient has come and she is bleeding, we quickly use the ultrasound to locate the placenta to know whether there is placenta previa.'

(Caregiver 1):

'If someone is bleeding you need to make sure where the placenta is.'

(Caregiver 2):

'In a woman who is bleeding, normally you do the ultrasound to locate the placenta.'

20. Quotes Associated with Open Code 20

In open code 20, as a real situation where using ultrasound in labour will be needful, the response of 2 out of 6 caregivers suggest situations of abnormal progress as a typical example. Below are their quotes.

(Caregiver 4):

So I will advise that we limit ultrasound to abnormal progression of labour cases so that we don't use it for all labour cases.'

(Caregiver 5):

'In all the prolonged labour cases, the cause is to be determined to enable intervention as soon as possible. Using ultrasound may be much easier to determine the position, if you have the skill.'

21. Quotes Associated with Open Code 21

In open code 21, as a real situation where using ultrasound in labour will be needful, the response of 1 out of 6 caregivers suggest situations where instrumental delivery is indicated. See comment below.

(Caregiver 3):

'As I said, the determination of the position it is very important when you want to do instrumental delivery, so for me it will be very beneficial if we apply the ultrasound before the instrumental delivery.'

22. Quotes Associated with Open Code 22

In open code 22, as a real situation where using ultrasound in labour will be needful, the response of 2 out of 6 caregivers suggest situations a woman is resisting digital VE in labour.

(Caregiver 5):

'Yes, because vaginal examination is not comfortable for everyone and I had one client who refused the VE. So for such a person ultrasound might help.'

(Caregiver 3):

…particularly in those who resist the VE.

6.8 Chapter Summary.

In this chapter, the results obtained upon investigating the five specific objectives of this primary study were presented.

With regards to the first specific objective which sought to investigate the between-method agreement on fetal head position and the intrapartum factors that may affect the agreement, the result has shown a percentage between-method agreement of 47% and a kappa concordance of 0.23 with statistically insignificant influence of the intrapartum parameters analysed.

With regards to the second specific objective which sought to investigate the between-method agreement on fetal head station and the diagnostic performance of ultrasound in detecting engaged fetal head, the result has shown statistically significant correlation between ultrasound and digital VE on fetal head station and a high ultrasound specificity and sensitivity in detecting engaged fetal head.

With regards to the third specific objective which sought to investigate the between-method agreement of cervical dilatation and the diagnostic performance of ultrasound in detecting active labour, the results has shown a statistically significant correlation and a good agreement between the two methods. It also found a high ultrasound specificity and sensitivity in terms of detecting active labour.

With regards to the fourth specific objective which sought to investigate mothers' view on the acceptability of ultrasound in labour, the results show high acceptance by mothers.

Lastly, with regards to the fifth specific objective which sought to investigate caregivers view on the practicality of using ultrasound for assessing progress of labour, the results

indicate that using ultrasound for the said purpose in labour will not be possible now, due to limited ultrasound equipment and scanning skills among the caregivers in this Ghanaian setting. However, this could be possible if there is enough research evidence to boost the confidence of caregivers, which will motivate caregivers to improve on their scanning skill limitations. In addition, the cost effectiveness of using ultrasound was also considered a potential limitation which needs further investigation. Again, caregivers generally thought replacing digital VE entirely with ultrasound may not be suitable for various reasons they indicated. However they mostly are in favour of using ultrasound for an adjunct role. They also identified a number of typical situations where the use of ultrasound could play a paramount role.

7 Chapter Seven: Discussion.

7.1 Introduction.

In Chapter Six, the results of the primary research of this thesis were presented. This seventh chapter now discusses these results. It evaluates each specific objective of the present study in comparison with other existing studies. It also discusses new findings that have emerged from this primary study. Again, it discusses the implications of the findings of this study to clinical practice. In addition, it discusses the limitations of this study, and identifies new areas for future research.

There are ten sections in this chapter which includes this introductory section. The next five sections will address the findings of the five specific objectives that were investigated in this primary research. It then follows with sections on the implications of this study to clinical practice, the limitations of this research, and then the recommended areas for future research. It then ends with a chapter summary which outlines the key findings of this thesis.

7.2 Agreement on Fetal Head Position and the Factors of Influence.

As the first specific objective, this study set out to assess the agreement between ultrasound and digital VE on fetal head position and the intrapartum factors that may affect the agreement. The results have shown that digital VE was unable to detect fetal head position in 33% of the study population, whilst ultrasound was able to determine fetal head position in the entire study population. Secondly, it was found that there was poor agreement between ultrasound and digital VE on fetal head position. Lastly, it was also found that the between-method agreement on fetal head position was not

significantly influenced by the different levels of cervical dilatation, the different levels of fetal head station, or by the various fetal head positions in the study population. These findings are reported for the first time from the Ghanaian population and clinical context. As of the time this present study was being conducted, no published study was found by the systematic review of Chapter Two that had emerged from a sub-Saharan African population since the initial study conducted by Sherer *et al* (2002a) in the USA. After this initial study by Sherer *et al* (2002a), similar studies have been conducted, which include: Akmal *et al* (2002), UK; Souka *et al* (2003), Greece; Kawabata *et al* (2010), Japan; Shetty *et al* (2014), India; and Yuce *et al* (2015), Turkey. This present study conducted in Ghana has therefore extended the series of reproducibility studies so far conducted on the between-method agreement on fetal head position in the first stage of labour.

The findings presented from this new study population are broadly consistent with the results of earlier studies. It is therefore an additional research evidence which confirms a poor agreement between the two methods in another clinical setting and a new ethnic population. The lower success rate of digital VE which was found by this study was also found in most previous studies as reported by the published systematic review and meta-analysis of this thesis (Wiafe *et al*, 2016).

This high level of comparability between the current and previous studies suggests that the ethnic differences in the wider sample populations, as well as the rater differences of these reproducibility studies, did not significantly influence the between-method agreement.

In addition, the consistently poor agreement between the two methods suggest that one of the two methods has been consistently unreliable for the diagnosis of fetal head

position whilst the other has been consistently reliable. Reliability appears to be in favour of ultrasound, given the consistently higher success rate it obtained over digital VE.

7.2.1 Examination of Findings on Fetal Head Position in Relation to Existing Research.

One similarity noted between the present and all previous studies was that the fetal head position was reported by ultrasound as predominantly towards the left side of the mother.

The initial study of Sherer *et al* (2002a) attributed this predominance of the left side position in their study population to the typical female pelvis called gynecoid, and by that Sherer *et al* (2002a) referred to the earlier study by Caldwell *et al* (1934), who found that in the typical gynecoid pelvis, the fetal head was mostly located on the left side of the mother in the first stage of labour than on the right side, with as high as 58.5% towards the left, and 40.5% towards the right side. However, this present study noticed that the confirmation of this trend by Sherer *et al* (2002a) in the USA study population was not a peculiar finding to their USA study, and that subsequent studies including this one has shown the same trend of left side predominance over the right side, regardless of the type of population or ethnic group involved. While this study can hardly confirm as to whether all the study subjects were having a gynecoid pelvis, the similar trend of a predominant left side occiput position is undisputedly found in all similar studies.

In terms of the percent agreement between ultrasound and digital VE, the present study is in concordance with previous studies on a <50% between-method agreement. This <50% between-method agreement includes agreement by chance. The only study which disagrees with the present study on the <50% between-method agreement is Souka *et al* (2003) who reported a percent agreement of 80% in their study. A closer comparison

between this study and Souka *et al* (2003) however revealed that their study population comprised of only participants with ruptured amniotic membrane. However the present study as well as all other similar studies which obtained the <50% between-method agreement were all comprising of participants with ruptured membrane and some without ruptured membranes. It therefore suggests that it is probably more accurate to examine with digital VE when the membranes are ruptured. On the other hand it also suggests the superiority of ultrasound which has maintained consistent results even when the membranes are not ruptured.

In terms of inter-method kappa concordance which accounts for agreement by chance, similar previous studies that has provided results from their kappa analysis include Sherer *et al* (2002a), Souka *et al* (2003) and Shetty *et al* (2014). Again, with the exception of Souka *et al* (2003) who reported a moderate inter-method agreement of 0.59 kappa value, both Sherer *et al* (2002a) and Shetty *et al* (2014) reported a poor agreement of 0.16 and 0.15 kappa values respectively. The present study obtained a kappa value of 0.23, which is only slightly above the borderline of poor agreement.

In terms of the factors that influenced the poor agreement, the findings of the present study was in contrast with Akmal *et al* (2002) and Kawabata *et al* (2010) who reported a significant influence of cervical dilatation on the between-method agreement. However, a closer comparison of the findings of this study with theirs revealed that there was higher occiput anterior positions in their study populations, which occurs with advancing cervical dilatation (Fitzpatrick *et al*, 2001, Phipps *et al*, 2015). It is therefore debatable as to whether the between-method agreement was actually influenced by the cervical dilatation or by the anterior rotation of the fetal head which occurs with advancing cervical dilatation.

The validity of this argument is enhanced by the fact that Souka *et al* (2003) who obtained a better inter-method agreement also had a higher percentage of anterior occiputs than the present study and other similar studies which obtained a poorer between-method agreement. This argument on the influence of the anterior occiput position rather than the cervical dilatation is further enhanced by Souka *et al* (2003) who repeated the between-method assessment at the second stage of labour in the same study population. While Souka *et al* (2003) obtained a significantly better between-method agreement in their repeated scans at full cervical dilatation, it was also at a stage where most of the fetal head positions had rotated towards the anterior position, which makes it debatable as to whether the improved between-method agreement was due to the cervical dilatation or the anterior positions.

Again, it was also noticed that in all previous studies which obtained a poorer between-method agreement than the present one, the DOP population in their study was about 50% higher than the DOP population of the present study. This suggest that having a higher DOP population may have contributed to the poorer between-method agreement in those studies. However, this can only be proven by observation rather than statistics due to the generally lower DOP percentages in every study population. Souka *et al* (2003) also reported the impact of the posterior occiput on the between-method agreement of their study. It therefore suggest that there is usually a disagreement between ultrasound and digital VE on DOP determination which contributes to the poorer agreement in studies with higher DOP populations.

7.3 Agreement on Fetal Head Station and the Diagnostic Performance of Ultrasound in Detecting Engaged Fetal Head.

This second specific objective and research question was set out to investigate the between-method agreement of ultrasound versus digital VE in the determination of fetal head station and the diagnostic performance of ultrasound in detecting engaged fetal head.

The findings of this study indicate that there is a statistically significant correlation between the ultrasound HPD and the digital VE head station. With an HPD cut-off of 3.6cm, ultrasound could detect engaged fetal head with a sensitivity of 78.7% and a specificity of 72.3%.

Secondly, there is a statistically significant correlation between the ultrasound HSD and the digital VE head station. Also, with an HSD cut-off of 2.8cm, ultrasound could detect engaged fetal head with a sensitivity of 74.5% and a specificity of 70.8%.

Thirdly, there is a statistically significant correlation between the ultrasound AoP and the digital VE head station. Also, with an AoP cut-off of 101^{o}, ultrasound could detect engaged fetal head with a sensitivity of 68.1% and a specificity of 68.2%.

7.3.1 Examination of Findings on HPD in Relation to Existing Research.

In examining the findings on HPD in relation to existing research, a comparison was made with similar studies that were identified by the systematic review and meta-analysis of the Chapter Two of this thesis. These previous studies included Tutschek *et al* (2013), Hassan *et al* (2014), Chan *et al* (2014) and Yuce *et al* (2015). The study of Hassan *et al* (2014) was a multi-centre study involving participants from Norway and the UK and comprising of 20 parturients. In this study, Hassan *et al* (2014) reported a significant but

moderate linear correlation (r^2= 0.33) between the ultrasound HPD and the digital VE head station. Subsequent reproducibility studies conducted in Turkey and China by Yuce *et al* (2015) and Chan *et al* (2014) were both conducted in larger study populations than Hassan *et al* (2014). Yuce *et al* (2015) reported a correlation coefficient of r= 0.42 in their Turkish study population, whilst Chan *et al* (2014) obtained a correlation coefficient of r= 0.49 in their Chinese population.

As of the time this present study was being conducted, no similar published study had been reported on the correlation between the HPD and fetal head station in a black African population. The present study is therefore the first to be conducted in a Black African population (Wiafe *et al*, 2018). In the case of this present study, a correlation coefficient of r=0.49 was obtained, which was in perfect agreement with Chan *et al* (2014) in their study conducted in a Chinese study population. This study was also highly comparable to Hassan *et al* (2014) and Yuce *et al* (2015). It therefore shows consistency in the findings from one population to the other, which also suggests that the ultrasound HPD could be reliably used for assessing the head station in a population not previously investigated.

In addition, this study also obtained average HPD values for the various head stations in the studied population. As part of this average HPD values, it was found that an HPD of 3.6cm corresponded to head station 0. This correlation between 3.6cm HPD and station 0 was in perfect agreement with the findings of Tutschek *et al* (2013). However, it was found that station +1 corresponded with an HPD of 3.3cm in the present study, rather than the 3.1cm reported by Tutschek *et al* (2013), and that it was rather station +2 which

corresponded to 3.1cm HPD in this present study. In addition, the present study also found station +3 to be corresponding to 2.5cm HPD.

Again, there is a disparity between sonographic HPD at station 0 and the actual distance from the perineum to the ischial spine at station 0 which needs clarification. In the literature, it is established that the distance from the perineum to the station 0 is 5cm (Eggebø *et al*, 2006, WHO, 2017), but both the present study and the findings of Tutschek *et al* (2013) obtained a shorter distance from the perineum to station 0 which is 3.6cm on the average. This shorter value obtained by both studies was because the ultrasound measurement was obtained as a straight line, even though in reality that distance is known to be a curve (Barbera *et al*, 2009b). Because it is a curve, measuring it as a straight line will result in a shorter distance as obtained by the present study and in the earlier study by Tutschek *et al* (2013).

7.3.2 HPD Diagnosis of Engaged Fetal Head.

Earlier studies by Maticot-Baptista *et al* (2009) and Dimassi *et al* (2014) reported that an HPD of 5.5cm or higher was predictive of fetal head non-engagement with high sensitivity and specificity, but provided no HPD predictive value for an engaged fetal head. Given that the distance from the perineum to the maternal ischial spines is reported to be 5cm apart (Eggebo *et al*, 2006; WHO, 2017), an HPD value for an engaged fetal head would be expected to be ≤5cm, since engagement occurs around station 0 or at a station further below (Cunningham *et al*, 2001). However, in the 62 parturients of this primary study whose digital VE head station was 0, the HPD obtained was in the range of 3.4cm to 3.9 cm and with 3.6cm as the average (see Table 6.3). Consequently, the 3.6cm was used as the cut-off value for predicting an engaged fetal head. It therefore suggests that this

primary research is the first to report the diagnostic performance of the HPD in engaged fetal head. This new knowledge obtained by the present study is therefore an assurance that HPD of ≤3.6cm could now be used as a determinant of an engaged fetal head (Wiafe *et al*, 2018), just as an HPD of ≥5.5 cm is already reported for being predictive of non-engagement.

7.3.3 Examination of Findings on AoP in Relation to Existing Research.

In examining the findings on the AoP in relation to existing research, a comparison was made with similar studies that were identified by the systematic review and meta-analysis of the Chapter Two of this thesis. These previous studies included Barbera *et al* (2009b), Tutschek *et al* (2011), Chan *et al* (2014) and Yuce *et al* (2015).

The study of Barbera *et al* (2009b) was a multi-centre study involving participants from Italy and the USA. In this initial study, Barbera *et al* (2009b) reported a significant but moderate linear correlation (r^2= 0.2650) between ultrasound AoP and the digital VE head station.

As of the time this present study was being conducted, no similar published study had been reported on the correlation between the AoP and fetal head station in a black African population. The present study is therefore the first to be conducted in a Black African population on the correlation between the AoP and the fetal head station (Wiafe *et al*, 2018). In the case of this present study, a coefficient of determination of r^2 =0.212 was obtained, which was highly comparable to Barbera *et al* (2009b) in their multi-center study population. The correlational matrix of r=0.460 obtained by the present study is also comparable to with the Chinese study by Chan *et al* (2014) which obtained a correlational matrix of r=0.579, and the Turkish study by Yuce *et al* (2015) which obtained r=0.55 . It

is also not significantly different from the r^2=0.24 obtained by Tutschek *et al* (2011) in the Norwegian study.

Even though the results of the present study showed a slightly weaker correlation than previous studies, this was probably because it had a relatively larger sample size with a wider range of all stations which can potentially increase the error margin. However, it still confirms the consistency of previous findings in another population even though the sample size was relatively larger in this newer study population. The high comparability of the current study with previous ones carried out across continents in a variety of study populations and clinical settings, and by independent investigators, also attest to the reliability of the AoP as an alternative method for estimating fetal head station. On the other hand, the closeness of the findings of independent researchers in different study populations suggests that the AoP is probably more reliable than the digital VE.

This study also noted that digital VE station 0 averagely corresponded with an AoP of 101^o. This AoP value obtained by this study in correlation with station 0 is apparently lower than the 123^o reported by Chan *et al* (2014) in the Chinese study population, and the 116^o reported by Tutschek *et al* (2013) in the Norwegian study population. It is however closer to the 99^o obtained by Barbera *et al* (2009a) when they compared the AoP to CT scan findings in a separate non-gravid population.

With regards to AoP diagnosis of head engagement, no published study had reported the diagnostic performance of the AoP for detecting engaged fetal head. This makes this present study the first to report on the diagnostic performance of the AoP in detecting engaged fetal head (Wiafe *et al*, 2018).

7.3.4 Examination of Findings on HSD in Relation to Existing Research.

In examining the findings of this study in relation to existing research, a comparison was made with similar studies that were identified by the systematic review and meta-analysis of Chapter Two of this thesis. These previous studies included Youssef *et al* (2013b), and Tutschek *et al* (2013).

The study of Youssef *et al* (2013b) was conducted in Italy and comprised of 47 nulliparous participants. In this initial study, Youssef *et al* (2013b) reported a significant correlation coefficient of r= -0.894 between ultrasound and the fetal head station.

As of the time this present study was being conducted, no similar published study had been reported on the correlation between the HSD and fetal head station from other parts of the world apart from Europe. The present study is therefore the first to be conducted outside of Europe on the correlation between the HSD and fetal head station (Wiafe *et al*, 2018).

In the case of this present study, a correlation coefficient of r= -0.551 was obtained. Whilst this is a statistically significant negative correlation, it is lower than the initial finding of Youssef *et al* (2013b). A number of possible reasons may have accounted for the difference between the two studies. The first possible factor is that Youssef *et al* (2013b) recruited only nulliparous cases, unlike the present one which included other types of parity cases (i.e. primiparous and multi-parous). It is believed that every delivery causes some alteration of the symphyseal bone and fibrocartilage (Putschar, 1976; Rustamova *et al*, 2009), but the extent to which this may cause differences in HSD in different study populations cannot be established by this study.

The second possible factor worth discussing is that, the mean age of the present study population was about 26 years, whereas that of Youssef *et al* (2013b) was 29 years. In connection with age, it is believed that age causes changes in the symphysis pubis, regardless of the parity (Putschar, 1976; Rustamova *et al*, 2009). However, the extent to which this may cause differences in HSD in different study populations cannot be established by this study.

The third possible factor that may have accounted for the wider difference between the results of this study and Youssef *et al* (2013b) is perhaps the larger sample used by this study. However, this later reason is unlikely to be significant, since the other parameters discussed above were highly comparable to previous research findings.

This study also noted that digital VE station 0 averagely corresponded with HSD of 2.8cm. This HSD value obtained by this study in correlation with station 0 is apparently lower than the 3.4 cm reported by Tutschek *et al* (2013) in the Norwegian study population. In connection with the possible causes of this difference as discussed above, it is known that the study population of Tutschek *et al* (2013) also comprised of nulliparous cases only, and the mean age in their study population was 42 years.

Lastly, unlike the HPD, no published study had reported the diagnostic performance of the HSD for diagnosing engaged fetal head. This makes this study the first to report the HSD for diagnosing engaged fetal head (Wiafe *et al*, 2018).

7.4 Agreement on Cervical Dilatation and the Diagnostic Performance of Ultrasound in Detecting Active Labour.

As the third specific objective, this study has investigated the between-method agreement of ultrasound versus digital VE in the determination of cervical dilatation and the diagnostic performance of ultrasound in detecting active labour.

The findings of this study indicate that there is a statistically significant correlation of r= 0.731 between the ultrasound AP diameter measurement and digital VE cervical dilatation. The Bland-Altman analysis also obtained a mean difference of 0.26 which suggest clinically insignificant difference. Also, in terms of detecting active labour, the AP diameter has a sensitivity of 87% and a specificity of 91%.

Secondly, there is a statistically significant correlation coefficient of r= 0.758 between the ultrasound transverse diameter measurement and digital VE cervical dilatation. The Bland-Altman analysis also obtained a mean difference of 0.17 which suggest clinically insignificant difference. Also, in terms of detecting active labour, the transverse diameter has a sensitivity of 85% and a specificity of 91%.

Thirdly, there is a statistically significant correlation coefficient of r= 0.758 between the ultrasound average diameter measurement and digital VE cervical dilatation. The Bland-Altman analysis also obtained a mean difference of 0.21 which suggest clinically insignificant difference. Also, in terms of detecting active labour, the average diameter has a sensitivity of 86% and a specificity of 91%.

7.4.1 Examination of Findings on Cervical Dilation in Relation to Existing Research.

In examining the findings on cervical dilatation in relation to existing research, a comparison was made with similar studies that were identified by the systematic review and meta-analysis of Chapter Two of this thesis. These previous studies included Zimmerman *et al* (2009), Hassan *et al* (2013; 2014), Yuce *et al* (2015) and Benediktsdottir *et al* (2015).

As of the time this present study was being conducted, no similar published study had been reported on the between-method agreement on cervical dilatation in a black African population. It therefore suggests that the present study is probably the first to be conducted in a Black African population on the agreement between ultrasound and digital VE on cervical dilatation. In the case of this present study, the AP diameter and the transverse diameter were separately analysed in relation to digital VE. In addition, an average of the two dimensions was also analysed in relation to digital VE.

The AP diameter correlation coefficient obtained by the present study ($r= 0.731$; $r^2=535$) is highly comparable to the findings of Hassan *et al* (2013; 2014) who obtained their measurements in the AP dimension. Again, the mean difference obtained from the Bland-Altman plot was also highly comparable to their findings.

Secondly, the average diameter correlation coefficient obtained by the present study ($r=0.758$; $r^2=575$) is comparable to the findings of Zimmerman *et al* (2009) and benediktsdottir et al (2015) who obtained their measurements from an average diameter. In addition, the present study has also included a correlation coefficient of the transverse dimension which was not provided by previous studies.

Even though the results of the present study on cervical dilatation showed a slightly weaker correlation than previous studies, this was probably because the sample size of this study was larger than all previous ones put together, which can potentially increase the error margin. However it still confirms the consistency of previous findings in another population even though the sample size was larger in this newer study population. The high comparability of the current study with previous ones carried out across continents in a variety of study populations and clinical settings and by independent investigators also attest to the reliability of ultrasound as an alternative method for estimating cervical dilatation. On the other hand, the closeness of the findings of independent researchers in different study populations suggests that ultrasound is probably the better option.

7.4.2 Ultrasound Diagnosis of Active Labour.

The diagnosis of onset of labour is reported as one of the most difficult diagnosis for caregivers (Hanley *et al*, 2016). As a result, about 30% to 45% of women are admitted to the labour ward before onset of active labour (Ball and Washbrook, 1996; Cheney *et al*, 2006). The consequence of which include avoidable interventions such as labour augmentations and caesarean sections (Cheney *et al*, 2006). This does not only contribute to morbidity but also to the overall cost of healthcare and the national economy as well. In ensuring that only women in active labour get admitted to the labour ward, the conventional measure include performing digital VE to determine cervical dilatation which must be ≥4cm before admission to the labour ward is granted (Neal *et al*, 2010). Unfortunately, as caregivers perform digital VEs to determine onset of active labour, some end up performing multiple digital VEs to decide on labour ward admission, with some

women undergoing up to 3 or 4 digital VEs prior to confirmation of active labour (Dixon, 2005; Stewart, 2008). This increases the frequency of digital VEs before delivery which contributes not only to the mothers' discomfort but to the increasing risk of infection as well.

The present study has now demonstrated a high diagnostic performance of ultrasound in playing the role of digital VE for the diagnosis of active labour. Ultrasound obtained over 85% sensitivity and over 90% specificity in diagnosing a cervical dilatation in more than one dimension, making it a very reliable alternative to digital VE in the diagnosis of active labour. This is the first time the diagnostic performance of the ultrasound in detecting active labour has been reported. Previous studies probably did not analyse this because of the smaller sample sizes of their study population.

7.5 Mothers' Views on the Acceptability of Ultrasound in Labour

The findings of this fourth specific objective of the primary research has shown that most mothers (66%) reported no discomfort associated with intrapartum ultrasound, but about 31% reported mild discomfort whilst another 3% (6 participants) reported significant discomfort.

Also, whilst 97.5% of mothers felt that ultrasound was a better experience than digital VE, and 1% felt that there was no difference between the two methods, there were 3 participants (1.5%) who indicated that ultrasound was actually worse in terms of discomfort than digital VE.

Yet, in spite of the discomfort some women reported about ultrasound in labour, approximately 99% of mothers said they would like to have ultrasound in future as their first choice over digital VE. This 98.5% of mothers indicated that they would like to have ultrasound many times than Digital VE. This same percentage of women stated that they would reject digital VE if allowed to choose between the two methods. It therefore suggests that most of these women actually go through digital VE out of acquiescence.

7.5.1 Examination of Findings on Mothers Acceptance in Relation to Existing Research.

In examining the findings on mothers' acceptance of intrapartum ultrasound, a comparison was made with two related studies that were identified. This include the study of Iliescu *et al* (2015) which was conducted in Romania, and the study of Chan *et al* (2016) which was conducted in China.

The study of Iliescu *et al* (2015) was similar to the present study in many ways. Their findings were obtained from 192 participants, which is closely related to the 196 participants that were analysed by the present study. However, their study was a longitudinal observational study while this was a cross sectional observational study.

In the present study, the 98.5% acceptance rate of ultrasound in labour is highly comparable to the 97.4% obtained by Iliescu *et al* (2015) in the Romanian study population. This confirms the high acceptance of ultrasound in labour by mothers in different countries across continents, which suggests that cultural differences did not influence the response of women in the two independent studies. Again, while the study of Iliescu *et al* (2015) comprised of over 50% women on epidural analgesia the

acceptance rate of ultrasound was almost the same as the present one which had only one person on epidural analgesia.

Secondly, in the present study over 65% of women said they did not experience any discomfort from ultrasound in labour. This is comparable to the findings of Chan *et al* (2016) who reported that 75% of women in their study population also reported of no discomfort. The use of epidural analgesia was insignificant between the study of Chan *et al* (2016) and the present one, as there were only two women on epidural analgesia in their study. Iliescu *et al* (2015) also added that 79% of women who were not on epidural analgesia did not complain of discomfort associated with the ultrasound examination.

It is however worth adding that the 31% of women in this study who reported mild discomfort from ultrasound is comparable to the 21% of women in the study of Iliescu *et al* (2015) who made a similar report. This mild discomfort reported by the present study, and also by the previous study, may have resulted from the gentle pressure applied to reach the pelvic bone when obtaining the HPD. However, in spite of this minimal pain, a very high percentage of women in between similar studies were satisfied with intrapartum ultrasound and willing to have one in future.

7.6 Caregivers Views on the Practicality of Ultrasound in Labour.

The content analysis of caregivers view has shown that the Ghanaian clinical setting cannot put ultrasound in labour into practice now, because of limited ultrasound scanning skills among caregivers.

Their response indicates that there are a number of physical and technical challenges in this developing country setting which ought to be addressed before the active use of ultrasound in labour can be introduced. According to them, this would include ensuring that all caregivers receive the minimum scanning skills that is required in undertaking intrapartum ultrasound. Their response suggests that equipment and supplies are currently not widespread and portable enough to allow the introduction of ultrasound in labour, which ought to be addressed. The affordability of introducing ultrasound in labour is a related issue the caregivers wanted addressed, as it is not clear how affordable introducing ultrasound in labour would be in comparison to the current use of digital VE, and who would bear the cost. In view of that, some suggested that a limited introduction of intrapartum ultrasound for selective cases would be the advisable approach, which may include clients who opt for the service. However, they indicate that the extent of its use will also depend on the strength of available research findings that supports its use.

On the basis of the amount of research evidence available, the caregivers did not regard ultrasound suitable to replace digital VE, due to other uses of digital VE. This includes detecting the presence of moulding which tells about the risk of damage to the fetal brain whenever there is prolonged labour, and the amniotic fluid colour which tells them about

the risk of fetal distress, and also, checking whether the umbilical cord from which the fetus obtains its oxygen is being compressed unduly.

Nevertheless, caregivers were in agreement on the need to introduce ultrasound which they recognise would solve some current problems they encounter. Most caregivers acknowledged the difficulty in determining fetal head position with digital VE which they believe the introduction of ultrasound would solve, especially when excluding DOP as the possible cause of prolonged labour, and also for confirming the position before every instrumental delivery. They were generally not sure about using ultrasound to assess fetal head station and cervical dilatation, but were mostly of the view that if ultrasound can actually detect cervical dilatation, then it would help minimise the number of VEs they sometimes do to simply confirm onset of active labour which increases risk of infection. However, the use of ultrasound in limiting risk of infection was considered debateable and requiring further research. Caregivers also indicated that they currently do employ ultrasound on few occasions in labour, when they need to confirm estimated fetal weight, presentation and the placenta location of referred labour cases.

7.6.1 Examination of Findings on Caregivers View in Relation to Existing Research.

In examining the findings on caregivers view on the practicality of ultrasound in labour, no paper with a similar qualitative survey design was found. However, one related quantitative survey was found which was conducted in Italy by Youssef *et al* (2013a). In this previous study, Youssef *et al* (2013a) obtained the views of 264 caregivers from Europe who completed an on-line questionnaire about their current utility of ultrasound in

labour. A number of similar views were found between these caregivers in Italy and Ghana, in spite of the fact that the latter was in a developing country setting.

Similar to the Italian study, which reported that 68.7% of caregivers were using ultrasound for assessing fetal head position, their Ghanaian counterparts were optimistic about using ultrasound to assess fetal head position, even though they indicated that more resources were still needed to put that into practice.

Secondly, similar to the Italian study which reported that only 23.5% of caregivers used ultrasound in assessing fetal head station or descent, their Ghanaian counterpart did not sound confident about using ultrasound to assess head descent even if they had the resources. However, only one paper on cervical dilatation was available at the time of this publication by Youssef *et al* (2013a). Therefore, unlike the present study, their study did not ask caregivers about using ultrasound to assess cervical dilatation.

Thirdly, Youssef *et al* (2013a) recognised that ultrasound in labour was still not significantly utilised by caregivers in their European setting, which they attributed to the accessibility of ultrasound equipment in their ward setting. This situation was alluded to by their Ghanaian counterparts in this present study who are working in a developing country setting.

Lastly, Youssef *et al* (2013a) also recognised that the inadequate amount of research evidence at the time was contributing to the limited use of ultrasound in labour. Again, this was alluded to by their Ghanaian counterparts.

7.7 Implications of this Research to Clinical Practice.

Based on the findings of this primary research and the comparison made with other existing research, a number of recommendations can be made to clinical practice.

With regards to the assessment of fetal head position, ultrasound should be regarded as the gold standard. Therefore, ultrasound should be employed for the assessment of fetal head position, especially when the detection of DOP is needed.

Secondly, with the additional information obtained from the current study, concerning the diagnostic performance of ultrasound in detecting engaged fetal head, caregivers could consider ultrasound for detecting engaged fetal head whenever needed. This could be used as an adjunct to digital VE initially, until caregivers appreciate its use and value for detecting engaged fetal head.

Thirdly, ultrasound could gradually be introduced as a validation tool for detecting onset of active labour, through the measurement of cervical dilatation.

Fourthly, in keeping with EBP standards, which advocates patient value and preference, the interest of parturients for the use of ultrasound in labour should be given its due recognition and consideration. Previous studies have shown that the historic practice of rectal examination in the assessment of labour progress was discontinued after it became obvious that mothers preferred digital VE (Downe *et al*, 2013; Lewin *et al*, 2005). The comparison made between rectal examination and digital VE enabled mothers to choose digital VE as the most tolerable option. The findings of the present study and other similar

studies conducted in Europe and China suggest that most women will choose ultrasound over digital VE, just as they previously chose digital VE over rectal examination in labour.

Lastly, in view of the increasing evidence that supports the reliability of ultrasound in monitoring labour progress, it is worth suggesting that resources should be made widely available. This implies that management should ensure that intrapartum ultrasound training, and equipment and supplies are adequately provided for labour cases that may need or request for ultrasound.

7.8 Limitations of this Primary Research.

The limitation of the reproducibility study conducted in this primary research is that, it focused on between-method agreement rather than between-rater agreement. Being an observational study design, the difficulty in finding the same number of raters for ultrasound and digital VE did not allow the determination of inter-rater reliability. This situation was a similar challenge in most previous studies. However, the high comparability of the findings of this study to other similar studies from different settings suggest that there is a good agreement among raters of ultrasound.

Secondly, in this study the assessment of mothers' acceptance of ultrasound in labour was based on a cross-sectional study design. Therefore, there was lack of uniformity in the number of times they had ultrasound in labour in comparison to the number of times they had digital VE, as some mothers underwent more than one digital VE in the course of labour. This may have influenced their responses in terms of comparing their experience between ultrasound and digital VE after delivery. The use of a longitudinal

study would have ensured that parturients received as many ultrasound examinations as digital VEs before delivery. However, there was still no significant difference between the responses of mothers in this cross-sectional study in comparison to the longitudinal study conducted by Iliescu et al (2015) which ensured that mothers had the same number of ultrasounds as digital VE. It therefore suggests that using a longitudinal study may not have resulted in a significant change in mothers responses.

7.9 Recommendations for Future Research.

Further research could continue in the meantime by selecting sites for introduction of routine ultrasound in labour over a period of time. This could be a multi-centre study comprising of different clinical settings from developed and developing countries, as well as tertiary and non-tertiary settings. Areas of research in connection with the findings of this study may include the following:

1. A control study could investigate the incidence of morbidity in a population with access to routine ultrasound in labour versus another with no access to routine ultrasound in labour.
2. The incidence of reported signs and symptoms of puerperal infection within 72 hours of delivery could be investigated in a control study of routine ultrasound users versus non-routine users in labour.
3. The cost effectiveness of using ultrasound in labour could be investigated by comparing cost incurred by routine users versus non-routine users.
4. The effectiveness of ultrasound in assessing other intrapartum conditions that are traditionally assessed by digital VE could also be investigated, such as using ultrasound to grade moulding and assessing the presence of meconium stain with the ultrasound transducer.

5. To investigate whether the routine use of ultrasound improves mothers' interest in accessing the services of skilled professionals during labour and delivery in developing countries.

7.10 Chapter Summary of Key Findings.

The key findings obtained from investigating the five specific objectives are presented below.

1. Fetal head position: On the basis of the systematic review and meta-analysis presented in Chapter Two, this reproducibility study on fetal head position is the first to be conducted in a Black African population. The findings has shown comparable results with other similar studies from different ethnic backgrounds and geographic locations, that there is less than 50% agreement between ultrasound and digital VE in the determination of fetal head position. Secondly, although the present study did not find a statistically significant cause of the poor agreement, it noticed that the present study obtained a better between-method agreement than most similar studies that were having more DOPs in their study population.
2. Fetal head station: It has been found for the first time in this population that there is statistically significant correlation between ultrasound and digital VE on fetal head station. This finding is comparable to the findings of similar studies from different ethnic background and geographic location (Wiafe *et al*, 2018).
3. Engaged fetal head: This study reports the diagnostic performance of ultrasound in detecting engaged fetal head for the first time, which has shown higher sensitivity and specificity when the HPD is ≤3.6cm; AoP is ≥101^{o}; and HSD is ≤ 2.8cm (Wiafe *et al*, 2018).

4. It has been found in this new population that there is statistically significant agreement between ultrasound and digital VE on cervical dilatation. This finding is comparable to the findings of similar studies from different ethnic backgrounds and geographic locations.
5. Diagnosis of active labour: With the largest sample population than all similar studies conducted on cervical dilatation, this study reports the diagnostic performance of ultrasound in detecting active labour for the first time in this thesis, which has shown a high sensitivity and specificity from using ultrasound.
6. Mothers' acceptance of ultrasound: This reports high acceptance rate by mothers in this population, which is comparable to the findings of similar studies from different ethnic background and geographic location.
7. Caregivers view on the practicality of ultrasound in labour: This study reports for the first time that inadequate technical and physical resources are unlikely to make the use of ultrasound in labour practicable in this setting for now. It also reports the view of caregivers in this setting on how ultrasound in labour will be useful to their practice.

8 Chapter Eight: Conclusion.

8.1 Introduction.

This thesis aimed at investigating ultrasonography as a tool for intrapartum care, with digital VE as the reference standard. It investigated the evidence regarding ultrasonography from the EBP context as follows: (1) investigating the effectiveness of ultrasonography in assessing the progress of pregnant women in labour; (2) investigating the acceptance of ultrasound by mothers; (3) investigating the view of caregivers about using ultrasound for assessing progress of labour. This concluding chapter presents a summary of the research process and the original contributions it has made.

8.2 Systematic Review and Meta-Analysis.

With regards to the effectiveness of ultrasonography in assessing labour progress, a systematic review and meta-analysis was initially carried-out to assess existing research findings. The main objective of this systematic review was to assess the success rate of ultrasonography versus digital VE in the determination of fetal head position, fetal head station and cervical dilatation. Secondly, it was to review the between-method agreement of ultrasound versus digital VE. The PRISMA format was selected as an appropriate methodological approach for this systematic review and meta-analysis.

The results showed that with regards to the intrapartum assessment of fetal head position, success rate was in favour of ultrasound over digital VE, and that this success rate was statistically significant in the first stage of labour, but not significant in the second stage of labour. The results also showed that with regards to cervical dilatation, success rate was in favour of digital VE over ultrasound, however this success rate was not statistically significant. With regards to fetal head station, success rate could not be established, since

the two methods were not measuring the same parameters in their determination of head descent.

This results obtained from the systematic view was interpreted in the discussion section of the review as implying that, given the statistically significant success rate of ultrasound over digital VE in the determination of fetal head position, ultrasonography becomes the better option for assessing fetal head position particularly in the first stage of labour. However, the statistical insignificance of the success rate in the second stage assessment of fetal head position implied that either ultrasound or digital VE could be used in second stage, since the difference between them was not significant in the second stage. Moreover, there was good agreement between the two methods in the second stage but but not in the first stage. Secondly, with regards to the determination of cervical dilatation, the findings implied that since there was good agreement between the two methods and the success rate between the two was not statistically significant, one can choose to use either ultrasound or digital VE for assessing cervical dilatation.

It was however unclear as to whether these findings and interpretations were applicable to non-tertiary settings and developing country settings, since existing studies were mainly conducted in tertiary settings of developed countries. This question needed to be addressed from the EBP context, by investigating the reproducibility of these findings in other settings which had so far not been investigated. Again, the EBP context also needed an answer to the individual patient value and preference for ultrasonography versus digital VE. It also needed to address the views of the clinical experts who make prudent choices for these women, in terms of the practical issues that will influence their choice between

ultrasound and digital VE for their clients. A primary research was therefore designed to investigate such issues.

8.3 Primary Research.

The aim of the primary research was to investigate the reproducibility, practicality and acceptability of using ultrasonography to monitor the progress of pregnant women in labour.

In terms of investigating the reproducibility of ultrasonography, the agreement between ultrasound and digital VE was assessed in a similar manner as previous studies. It therefore required the use of an observational cross-sectional study approach as used by previous studies, since an experimental approach was actually not ethically feasible for investigating the population involved. In addition, as part of the analysis of the research findings, a number of related diagnostic test were also analysed, which were not analysed by previous studies. With regards to the between-method agreement on fetal head station, the diagnostic performance of ultrasound for detecting engaged fetal head was a related issue that was statistically analysed. Also, with regards to the between-method agreement on cervical dilatation, the diagnostic performance of ultrasound for detecting active labour was a related issue that was statistically analysed. The results of this reproducibility study showed a comparable between-method agreement in another clinical setting and study population, which then suggested that previous findings on ultrasonography were consistent with the present one and therefore reliable. Results on the diagnostic performance of ultrasound in detecting engaged fetal head and detecting active labour were additional findings reported by this study.

In terms of investigating the acceptance of ultrasonography by mothers, a cross-sectional survey was considered an appropriate approach. A survey questionnaire was therefore completed by mothers after delivery for a descriptive quantitative analysis. The results showed high acceptance of ultrasonography as a preferred choice by mothers over digital VE. The findings were also comparable to related studies conducted in other populations.

In terms of investigating caregivers' view on the practicality of using ultrasound in labour, a qualitative survey approach was used. This was considered appropriate because there were not as many caregivers to allow a viable statistical analysis. Qualitative content analysis was chosen as the appropriate method, as choosing other qualitative views may contradict the paradigmatic stance of this predominantly quantitative study. The results showed that caregivers appreciated the value of using ultrasonography as a complement to digital VE in providing solutions to challenges associated with the conventional practice. However, in order to make the use of ultrasound in labour practicable, a number of physical and technical resources had to be addressed to make it possible.

8.4 Implications.

The high level of comparability between this study and other existing studies is a demonstration of the consistency of ultrasonography for assessing the labour progress parameters investigated in this study. This suggest that ultrasonography can be reliably used for intrapartum care in terms of assessing the progress of labour, just as it has often been used in antenatal care for assessing important parameters such as fetal growth rate. However, the inadequate physical and technical resources in many settings may not permit its regular use in settings such as the current study location. Therefore, in order to address the individual patient value and preference, as advocated by EBP standards,

adequate provision has to be made for the accessibility of intrapartum ultrasonography. In the meantime, further research should continue on unanswered questions about intrapartum ultrasonography as listed in Chapter Seven.

8.5 Concluding Statement.

This study makes an important contribution to the existing knowledge on intrapartum ultraonography. It conducted the first systematic review and meta-analysis on the success rate of ultrasonography versus digital VE in intrapartum care. The original key findings of the systematic review regarding the success rate of ultrasonography were:

(1) That ultrasonography has a statistically significant success rate over digital VE in the assessment of fetal head position in the first stage of labour;
(2) That ultrasonography has a statistically insignificant success rate over digital VE in the assessment of fetal head position in the second stage of labour; and
(3) That digital VE has statistically insignificant success rate over ultrasonography in the assessment of cervical dilatation.

Secondly, a primary study was conducted in a population that had previously not been investigated. This also revealed new findings about intrapartum ultrasound which were previously not reported. These original findings from this primary study are as follows:

(1) That the between-method agreement of ultrasound versus digital VE in assessing fetal head position, fetal head station and cervical dilatation in the Black African population of Ghana is highly comparable to most similar studies conducted in other populations of different geographic locations.

(2) That an HPD value of ≤3.6cm; AoP value of ≥ 101^{o}; and HSD value of ≤2.8cm have high diagnostic performance for detecting engaged fetal head.

(3) That ultrasound has high diagnostic performance in detecting active labour.

(4) That mothers' accept intrapartum ultrasound over digital VE, just as they historically chose digital VE over rectal examination.

(5) That limited physical and technical resources are the main setbacks of the use of intrapartum ultrasound by caregivers in a developing country setting.

These key findings add originality, importance and value to ultrasonography as an effective diagnostic imaging tool for assessing the progress of labour in intrapartum care which is highly accepted by most mothers. It also provides basis for further research on ultrasonography in intrapartum care.

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Appendix 1

Ethical Approval from Research Site

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY
COLLEGE OF HEALTH SCIENCES
SCHOOL OF MEDICAL SCIENCES / KOMFO ANOKYE TEACHING HOSPITAL
COMMITTEE ON HUMAN RESEARCH, PUBLICATION AND ETHICS

Our Ref: CHRPE/AP/231/15

16th June, 2015.

Mr. Yaw Amo-Wiafe
Department of Sonography
Faculty of Allied Health Sciences
KNUST-KUMASI

Dear Sir,

LETTER OF APPROVAL

Protocol Title: "The Reliability, Practicality and Acceptability of Using Ultrasonography to Monitor the Progress of Labour and Delivery"

Proposed Site: Komfo Anokye Teaching Hospital, the Directorate of Obstetrics and Gynaecology.

Sponsor: Department of Sonography.

Your submission to the Committee on Human Research, Publications and Ethics on the above named protocol refers.

The Committee reviewed the following documents:

- A notification letter of 20th November, 2014 from Komfo Anokye Teaching Hospital (study site) indicating approval for the conduct of the study in the Hospital.
- A Completed CHRPE Application Form.
- Participant Information Leaflet and Consent Form.
- Research Protocol.
- Questionnaire.

The Committee has considered the ethical merit of your submission and approved the protocol. The approval is for a fixed period of one year, renewable annually thereafter. The Committee may however, suspend or withdraw ethical approval at any time if your study is found to contravene the approved protocol.

Data gathered for the study should be used for the approved purposes only. Permission should be sought from the Committee if any amendment to the protocol or use, other than submitted, is made of your research data.

The Committee should be notified of the actual start date of the project and would expect a report on your study, annually or at the close of the project, whichever one comes first. It should also be informed of any publication arising from the study.

Thank you Sir, for your application.

Yours faithfully,

Rev. Prof. John Appiah-Poku
Honorary Secretary
FOR: CHAIRMAN

Room 7 Block J, School of Medical Sciences, KNUST, University Post Office, Kumasi, Ghana
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Appendix 2

Ethical Approval from Research Ethics Committee (Rec), College of Health and Social Care, University Of Derby

UNIVERSITY of DERBY

Approval with Recommendations Letter

Date: 22 July 2015
Name: Yaw Wiafe

Dear Yaw

Topic: THE RELIABILITY, PRACTICALITY AND ACCEPTABILITY OF USING ULTRASONOGRAPHY TO MONITOR THE PROGRESS OF LABOUR AND DELIVERY

Thank you for submitting your application to the College of Health and Social Care Research Ethics Committee.

The recommendation of the committee was that the application be approved subject to the following:

- Re-consider whether part 2 of questionnaire is necessary given the aims of the study.

Please submit your response to the committee secretary via email to j.dean1@derby.ac.uk for our records.

Once the study commences if any changes to the study described in the application or to the supporting documentation are necessary, you are required to make a resubmission to the College of Health and Social Care Research Ethics Committee.

We will also require an annual review of the progress of the study and notification of completion of the study for our records.

Yours sincerely,

Martyn Harling
(Vice-Chair, College of Health and Social Care REC)

Appendix 3

UNIVERSITY *of* DERBY

Participant Information Leaflet and Consent Form

This leaflet is given to all prospective participants to enable them know enough about the research before deciding to or not to participate

Title of Research: The Reliability, Practicality and Acceptability of Using Ultrasonography To Monitor The Progress Of Labour And Delivery

Name(s) and affiliation(s) of researcher(s): This study is being conducted by Mr Yaw Amo Wiafe, a PhD research student of University of Derby in UK, with Dr Bill Whitehead and Ms Heather Venables as academic supervisors. In addition, Prof. Alexander Odoi of the Komfo Anokye Teaching Hospital is also involved in the provision of local oversight for the conduct of the study.

Background (Please explain simply and briefly what the study is about):

When you come to the labour ward to give birth, the traditional practice is for your doctor to examine you with their fingers, and obtain certain measurements. These measurements help them to know if your baby is coming out progressively as expected, and to assess if you can give birth by yourself without getting hurt or hurting your baby. We want to know if an ultrasound scan can also take the same measurements your labour-ward doctor is going to make with their fingers.

Purpose(s) of research:

The purpose of this research is to find out whether using ultrasound can make the same measurements your labour-ward doctor will be using their fingers to measure. The idea is to find out about the possibility of replacing certain traditional examinations done with the fingers with the use of the ultrasound machine.

Procedure of the research, what shall be required of each participant and approximate total number of participants that would be involved in the research:

During labour, your doctor is required to insert his/her fingers in the vagina to assess how well your cervix is expanding, and whether the rate of expansion and the descent of the baby can allow

your baby to come out successfully without the need for an operation. As part of this routine examination your labour-ward doctor will be doing, we will also do an ultrasound scan for you. However, unlike your labour-ward doctor who is required to insert the finger in the vagina, the ultrasound will only be placed on the vagina without inserting it into the vagina. The ultrasound will be done by using the same kind of instrument they used in scanning your abdomen during the antenatal stage. The scan will take around five to ten minutes, and it will be used in checking all the things your labour ward doctor will check with their fingers, and will also measure the size of your baby.

Risk(s): We do not anticipate any significant risk, as the ultrasound is even less invasive than the routine examination your labour-ward doctor will be doing anyway. Again, ultrasound is a very safe imaging technique that does not involve ionising radiation or any known risk used in this way. The researcher is a well-trained ultrasound user who holds a recognised ultrasound qualification.

Benefit(s):

The goal of this research is to find ways of reducing the need for vaginal examination with the fingers. We hope that if this study turns out positive for the use of ultrasound, it may help reduce the frequency of vaginal examinations done with the fingers, and other pregnant women after you may benefit from that without you necessarily benefiting directly. On the other hand, it is rarely possible that in the course of the scanning we may find something outside of this research which may help your labour-ward doctor in managing your child birth, and this will then become beneficial to you directly but not for the research.

Confidentiality: All information collected in this study will be given code numbers. No name will be recorded. Data collected cannot be linked to you in anyway. No name or identifier will be used in any publication or reports from this study. However, as part of our responsibility to conduct this research properly, we may allow the ethics committees to have access to your records.

Voluntariness: Taking part in this study should be out of your own free will. You are not under obligation to. Research is entirely voluntary.)

Alternatives to participation: If you choose not to participate, this will not affect your treatment in this hospital/institution in any way.)

Withdrawal from the research: You may choose to withdraw from the research at anytime without having to explain yourself. You may also choose not to answer any question you find uncomfortable or private).

Consequence of Withdrawal: There will be no consequence, loss of benefit or care to you if you choose to withdraw from the study. Please note however, that some of the information that may have been obtained from you without identifiers (name etc), before you chose to withdraw, may have been modified or used in analysis reports and publications. These cannot be removed anymore. We do promise to make good faith effort to comply with your wishes as much as practicable.

Debriefing: In case you encounter any problem for participating in this study, do not hesitate to inform the midwife in-charge of the labour ward immediately after your delivery

Costs/Compensation: We do not intend to compensate you for this study. However, it will be our pleasure if you will accept a token of two cakes of baby soap as our way of saying welcome to the baby

Contacts: If you have any question concerning this study, please do not hesitate to contact Mr. Yaw Wiafe (Name of Researcher or PI) on 020 8226290.

Further, if you have any concern about the conduct of this study, your welfare or your rights as a research participant, you may contact:

The Office of the Chairman

Committee on Human Research and Publication Ethics,

Kumasi

Tel: 03220 63248 or 020 5453785

Consent Form

Statement of person obtaining informed consent:

I have fully explained this research to _____ and have given sufficient information about the study, including that on procedures, risks and benefits, to enable the prospective participant make an informed decision to or not to participate.

DATE: _____ NAME: _____

Statement of person giving consent:

I have read the information on this study/research or have had it translated into a language I understand. I have also talked it over with the interviewer to my satisfaction.

I understand that my participation is voluntary (not compulsory).

I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it.

I understand that I may freely stop being part of this study at any time without having to explain myself.

I have received a copy of this information leaflet and consent form to keep for myself.

NAME:_____

DATE: _____ SIGNATURE/THUMB PRINT: _____

Statement of person witnessing consent (Process for Non-Literate Participants):

I _____ (Name of Witness) certify that information given to

_____ (Name of Participant), in the local language, is a true reflection of what l have read from the study Participant Information Leaflet, attached.

WITNESS' SIGNATURE (maintain if participant is non-literate): _____

Appendix 4

UNIVERSITY of DERBY

Data Collection Form

To be completed by Clinician/Midwife on-duty.

Please provide information on the following or tick [√] the appropriate answer in the space provided:

1) Participant's ID----------
2) Participant's Age:----------
3) Height:----------cm
4) Weight:----------kg
5) BMI----------
6) Parity----------
7) Gestational Age by early USG/LMP.....

❖ **DIGITAL EXAMINATION (TIME:)**

8) Had patient been given epidural analgesia prior to digital examination? **Yes [ ] No [ ]**
9) Was Patient on oxytocin prior to this examination? **Yes [ ] No [ ]**
10) Was membrane ruptured? **Yes [ ] No [ ]**
11) Was membrane bulging? **Yes [ ] No [ ] N/A[ ]**
12) Did patient express any sign of discomfort towards the VE? **Yes [ ] No [ ]**

13) What was the station?

-5	**-4**	**-3**	**-2**	**-1**	**0**	**+1**	**+2**	**+3**	**+4**	**+5**

14) What was the cervical dilatation?

3cm	4cm	5cm	6cm	7cm	8cm	9cm	10cm

15) What was the fetal position?

[ ]Direct occiput anterior
[ ]Right occiput anterior
[ ]Left occiput anterior
[ ]Right occiput transverse
[ ]Left occiput transverse
[ ]Direct occiput posterior
[ ]Right occiput posterior
[ ]Left occiput posterior
[ ]Not Obtainable

16) What is the rank of the clinical examiner? **[ ]**Senior Specialist /Consultant **[ ]**Senior resident/Specialist **Signature**.....

To be completed by Research-Sonographer.

❖ **1ST ULTRASOUND EXAM (TIME:)**

17) Was cervical dilatation obtainable? **Yes [ ] No [ ]**

18) Was the AoP obtainable? **Yes [ ] No [ ]**

19) Was the HPD obtainable? **Yes [ ] No [ ]**

20) Was caput present? **Yes [ ] No [ ]**

21) Was moulding present? **Yes [ ] No [ ]**

22) Did patient express any sign of discomfort towards the US exam? **Yes [ ]** **No [ ]**

23) Fetal position:

[ ]Direct occiput anterior
[ ]Right occiput anterior
[ ]Left occiput anterior
[ ]Right occiput transverse
[ ]Left occiput transverse
[ ]Direct occiput posterior
[ ]Right occiput posterior
[ ]Left occiput posterior
[ ]Not Obtainable

24) Cervical dilatation A-P diameter:.....cm

25) Cervical dilatation right-to-left diameter:.....cm

26) Cervical dilatation (Ellipse-guided)……cm

27) HPD.....cm

28) HSD.....cm

29) AoP.....degrees

Appendix 5

UNIVERSITY of DERBY

Post-Delivery Questionnaire for Mothers

1) We would like you to tell us how acceptable you found the scan had whilst in labour.

2) Was this your first time having this kind of scan in labour? **Yes [ ] No [ ]**

3) How often did you scan in the antenatal period? **Never [ ] once [ ] more than one [ ]**

4) Compared to the scan you had in the antenatal period, was this **Worse[ ] Better [ ] Same [ ] ?**

5) How uncomfortable/sore was this scan you had in labour? **Very [ ] Slightly [ ] Not [ ]**

6) Compared to what you thought it would be like, was it **Worse [ ], Better, [ ] or Same [ ] ?**

7) Compared to the digital vaginal exam you had around the same time, was this
Worse [ ] Better[ ] Same[ ] ?

8) If you happen to be pregnant again would you mind having ultrasound in labour ? **Yes [ ] No [ ]**

9) Between having ultrasound in labour and having digital VE, which would you choose first ?
Digital exam [ ] ultrasound [ ]

10) Between ultrasound and digital exam which would you want to have many times?
Digital exam [ ] Ultrasound [ ]

11) Between ultrasound and digital exam which would you rather not have at all?
Digital exam [ ] Ultrasound [ ]

Appendix 6

UNIVERSITY of DERBY

Content Analysis of Caregivers View.

The list of generated open codes from the six transcripts:

#	OPEN CODES	CATEGORY
1	Not possible now, because of limited scanning skills	POSSIBLE?
2	Possible, but not until caregivers receive adequate US training	
3	Possible, but only if it is cost-effective for management	
4	Possible, but only if it is at no cost to mothers	
5	Possible, but only if covered by health insurance	
6	Possible, but for limited use in selective cases	
7	Possible, but not until we get enough research evidence	
8	Possible, but not until more portable equipment become widely available	
9	Not suitable for the size and current set-up of the labour ward if using larger US equipment	SUITABLE?
10	Suitable as adjunct but not a replacement for digital VE, because with VE we can also check moulding	
11	Suitable as adjunct because with digital VE we can also check amniotic fluid colour	
12	Suitable as adjunct because with VE we can also check cord compression	
13	Approve of US for effective detection of head position	EFFECTIVE?
14	Approve of US for effective follow-up on VE to detect Active Labour and minimise multiple VEs	
15	Approve of US as effective for limiting risk of infection	
16	Non-approval of US limiting risk of infection	
17	Non-approval of US for dilatation and station	
18	Approve of US in estimating fetal weight prolonged labour	
19	Approve of US in checking placenta location of women who report bleeding	
20	A real (typical) case is when abnormal progress is suspected	REAL?
21	A real (typical) case for US is to determine head position for instrumental delivery	
22	A real (typical) case for US is for women who resist digital VE	

Transcript of Caregiver 1:

Q1. What do you think about using ultrasound to monitor the progress of labour?

A1. For now as it is in the labour ward, not many people are trained to have the skills to operate it[1] but with training and education we will be able to operate it[2] and the machines too are available

Q2. What are the potential benefits you expect from using ultrasound for the assessment of labour progress?

A2. With respect to the parameters, I think the position of fetal head is where it will be much beneficial because with the ultrasound you will be able to determine position with much accuracy[13]. But with the digital VE even with the most experienced personnel there have been errors.

Q3. How important is identifying the position in the first stage of labour

A3. It is important to know the position especially when we are looking at occiput posterior position so that if the patient is in the first stage of labour and is not progressing, and the position remain the same we can then know what to do[20]. So when we are writing our report we have to state the position.

Q4. So have you started using ultrasound to determine fetal head position already?

A4. Not yet though

Q5. Recent studies suggest that ultrasound could be used in labour for determining not only head position, but the station and dilatation as well. Will you consider a shift from digital VE to ultrasound in your setting in that regard?

A5. I wouldn't want to see people now shifting to ultrasound alone but the two should run hand in hand because each one has its advantages. The digital V examination provides the opportunity to be close to the patient and also to know the colour of the amniotic fluid which will also tell you something. Also, you can determine moulding[10, 11].

Q6. So can the introduction of ultrasound improve your management protocol in anyway?

A6. The ultrasound can complement some areas when it comes to digital vagina examination, for instance if you are not sure of your fetal position. So I see ultrasound being important, that is why we use it when we see the

need. Because if someone is bleeding you need to make sure where the placenta is[19]. And it can also perfect our digital examination.

Q7. Can adding ultrasound help reduce the number of digital VE for detecting dilatations?

A7 Looking at the protocol we are using in labour, if labour progresses normally you can have only 3 vaginal examinations which is done every 4 hours before you deliver. But if you are close to full dilatation then we will look at the number of centimeters left to determine whether we will do it hourly or more. So supposing one is 8cm we will schedule the vagina examination in 2 hours. By then, we will be able to take a decision. So if we stick to the protocol there shouldn't be a lot of vaginal examination

Q8. In terms of infection control, it is reported that the VE increases risk. Could introducing ultrasound play a role in minimising risk of infections?

A8. If you are going to depend on ultrasound to do sonographic monitoring in the process of labour, definitely it may reduce the risk of infection. Because if the patient report and the first assessment is done for the cervical dilatation, it can then be followed up with the ultrasound and if it is properly done, of course the risk of infection will be reduced[14,15].

Q9. So let's get back to the issue of skill limitations. Do you consider it as the major problem regarding the practicality of ultrasound in labour?

A9. As it is now the skill of using ultrasound is not wide spread and in my department no one is using it for that purpose, so it will require training and acceptance to use the ultrasound

Q10. When you say 'acceptance', are you referring to caregivers or the mothers?

A10. I am referring to the caregivers in particular. The old ways are there, so for them to use ultrasound which is new as their main way, it needs to be accepted by them that it is the best and most convenient way to go.

Q11. So you are saying that skill will be the hindrance to acceptance?

A11. Yes if you don't have the skill you cannot use it

Q12. How sustainable will using ultrasound in labour be?

A12. First I will say that sustainability will be ensured once people have the skill. Also people getting convinced based on enough research evidence that the ultrasound has an advantage over the digital VE[7].

Q13. Comparing the two, I mean ultrasound versus VE, which of them do you think would be more evidence based ?
A13. Well, I guess ultrasound and it's the most recent one and also because it's new there will be need for more research on it to know how evidential[7] it is in supporting its use.

Q14. Are there other potential setbacks you can think of, if you should consider regular use of ultrasound in labour?
A14. In settings where ultrasound machines are available at the labour ward it will be much easier, but in the cases where it is not, acquiring the machines will result in some cost implication because ultrasound machines are not cheap.

Q15. So between skill and cost implication, which one will you consider a major concern?
A15. I think Skill is more of an issue than cost though. For our setting skill is the most important to address

Q16. So finally, to what extent do you want to see the use of ultrasound in the labour ward. As a complement to digital VE or replacement
A16. In the future, I see ultrasound complementing but in the long term there will be a possibility of it replacing the digital VE.

Thank you very much

Appendix 7

Caregivers Informed Consent

Dear Dr xxxxxxx

I write to thank you for the interaction we had at the labour ward, during my data collection on the intrapartum ultrasound study. I also thank you for the subsequent interview you granted. I have attached a transcribed copy of the recorded interview.

I would like to include excerpts from this transcript in my thesis, if you agree with the content as representative of the interview you granted. You may also withdraw your participation at this stage, if you do not want your words to be quoted in the thesis. As I believe you are aware, your participation is voluntary, and there are no consequences for deciding to withdraw your consent. I also confirm that all quotations in the thesis will be anonymous.

If you are willing to grant me the permission, please complete the attached informed consent form. Thank you.

Yours faithfully,

Yaw Amo Wiafe.

Consent Form for Caregivers

I have read the information presented in the cover letter about the study being conducted by **Mr Yaw Amo Wiafe,** a PhD student of University of Derby. I have had the opportunity to ask any questions related to this study, and have received satisfactory answers to my questions.

I was informed that my interview will be tape recorded to ensure an accurate recording of my responses.

I have also read through the transcribed version of the recording and confirm that they are my own words.

I am also aware that excerpts from the transcribed interview may be included in the thesis and/or publications to come from this research, with the understanding that the quotations will be anonymous.

I was informed that I can withdraw my consent without fear of any penalty by advising the researcher.

With full knowledge of all foregoing, I agree to the use of anonymous quotations in the thesis or publication from this research.

☐ YES ☐ NO

Name of participant (please print) _____

Signature of participant _____ Date _____

Name of Witness (please print) _____ Date_____

Signature of Witness _____ Date _____

Study Title: The Reliability, Practicality and Acceptability of Using Ultrasonography to Monitor the Progress of Labour and Delivery.

Research Student: Yaw Amo Wiafe.

Director of Studies: Dr Bill Whitehead.