COMPARABILITY OF AN INNOVATIVE DOPPLER ULTRASOUND FETAL HEART RATE MONITOR TO A PINARD FETAL STETHOSCOPE USING CARDIOTOCOGRAPHY AS A STANDARD TO ASSESS THE FETAL HEART RATE IN SINGLETON PREGNANCIES DURING LABOUR AT MOWBRAY MATERNITY HOSPITAL

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CHNLAM002

Submitted to the University of Cape Town

In partial fulfilment of the requirements for the degree

Masters of Medicine in Obstetrics and Gynaecology

Faculty of Health Sciences

University of Cape Town

Date of Submission: 21st June 2013

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DECLARATION

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ACKNOWLEDGEMENTS

I would like to acknowledge the invaluable contribution of Prof David Woods, Prof Susan Fawcus, Dr Joy Lawn and Mrs Anneke Jagau during the process of protocol development, analysis and writing up the thesis.

I acknowledge the contribution of Mrs S. Willemse and Mrs Wagiet, nurse midwives of Mowbray Maternity Hospital during data collection. I also acknowledge the help that I received from Mr Henri Carrara, Analytical epidemiologist/Biostatistician at the University of Cape Town. I am grateful to the women who accepted to be enrolled in this study. I am also grateful for the skills and support of my wife Edith Chinula.

Most of all, I would also like to acknowledge Power-free Education and Technology in allowing me to test the crank powered Doppler Ultrasound Fetal Heart Rate Monitor without undue pressure, coercion or any influence during protocol development, data collection and analysis.

Finally I would like to thank the 2013 Priorities on Perinatal Care Conference Organisers for giving me the opportunity to present the findings of this

study at the 2013 Priorities on Perinatal Care Conference held at Mpekweni Beach Resort in Eastern Cape, South Africa.

ABBREVIATIONS

AROM	Artificial Rupture of membranes
C.I	Confidence Interval
CTG	Cardiotocography
DUFRHM	Doppler Ultrasound Fetal Heart Rate Monitor
FHR(s)	Fetal Heart Rate(s)
IUGR	Intrauterine Growth Restriction
MOU	Midwife Obstetric Unit
NVD	Normal vaginal delivery
ROM	Rupture of membranes
SGA	Small for gestational age

ABSTRACT

Background

Almost four million babies die in the first four weeks of life per year worldwide, most from preventable causes. In addition a million babies die during labour and delivery (Lawn J et al., 2005). In South Africa, 'intrapartum hypoxia and birth trauma' are among the top three causes of perinatal deaths.

Severe intrapartum hypoxia is often preventable with appropriate maternal and fetal monitoring in labour. However, this remains a challenge in under-resourced settings, due to difficulties that accompany the use of a Pinard Fetal Stethoscope (PFS) which include user-dependence and lack of evidence based standardisation in taking measurements with it. Although intermittent fetal heart monitoring is as effective as continuous electronic monitoring in low risk labours (Banta DH and Thacker, 2001), the search is for reliable, robust and cheaper fetal monitoring devices. The innovative crank powered Doppler Ultrasound Fetal Heart Rate Monitor (DUFHRM) developed by Power-free Education and Technology is robust, cheaper and designed for use even in settings with no or erratic access to mains electricity and

replaceable batteries, and overcomes some of the challenges that come with the use of PFS (Banta DH and Thacker, 2001).

Aim

The aim of the study was to assess the accuracy of Fetal Heart Rates (FHRs) taken with the DUFHRM compared to FHRs taken with a PFS using a Cardiotocography (CTG) as a standard fetal heart rate monitoring device.

Method

This was a comparative diagnostic study conducted at Mowbray Maternity Hospital, a public sector maternity hospital in Cape Town during 2012. Women with singleton pregnancies in the active phase of the first stage of labour, who had consented to participation, were enrolled in the study.

Paired readings of FHRs were taken with a DUFHRM and a PFS, by two midwives and also with a CTG during the active phase of the first stage of labour before and after two preferably consecutive uterine contractions. The midwives were blinded to the CTG measurements by silencing the CTG and turning it away from their view. The FHRs taken with a PFS were done over

a 60 second period in accordance with the guidelines from professional bodies (ACOG, 1995, RANZCOG, 2002, RCOG, 2001a, Liston R et al., 2002) The DUFHRM and CTG readings were made at the start and end of each 60 second period of PFS monitoring.

The proportion agreement of FHRs taken with a DUFHRM to FHRs recorded with a CTG, and the proportion agreement of FHRs taken with a PFS to FHRs recorded with a CTG were determined and compared using McNemar Exact Significance Probability test (mcc). The protocol was approved by the University of Cape Town, Faculty of Health Sciences Research Ethics Committee.

Results

Seventy six pregnant women with singleton pregnancies in the active phase of the first stage of labour were enrolled in the study. The mean age of women enrolled was 24 years. Thirty nine women (51.3%) were multigravida. Sixty seven women (88.2%) were in labour at term. Sixty six women (86.9%) went into spontaneous labour. Labour was augmented in 32 women. Seventy two women had no medical conditions. Thus the majority of enrolled women had relatively low risk pregnancies.

Before the first contraction, the proportion agreement to CTG, at the start and at the end of the 60 second period, was 0.605 (95% CI 0.486 – 0.715) with the DUFHRM and 0.355 (95% CI 0.248 – 0.473) with a PFS (mcc =0.0034) and again 0.802 (95% CI 0.695 – 0.885) with the DUFHRM and 0.368 (95% CI 0.260 - 0.486) with a PFS (mcc = 0.000).

After the first contraction, the proportion agreement to CTG, at the start and at the end of the 60 second period, was 0.657 (95% CI 0.540 –0.762) with the DUFHRM and 0.421 (95% CI 0.308 – 0.539) with a PFS (mcc =0.0079) and again 0.789 (95% CI 0.680 – 0.874) with the DUFHRM and 0.381 (95% CI 0.272 – 0.500) with a PFS (mcc = 0.000).

Before the second contraction, the proportion agreement to CTG, at the start and at the end of the 60 second period, was 0.506 (95% CI 0.388 –.0.624) with the DUFHRM and 0.440 (95% CI 0.325 – 0.559) with a PFS (mcc =0.511) and again 0.773 (95% CI 0.662 -.0.862) with DUFHRM and 0.506 (95% CI 0.388 – 0.624) with a PFS (mcc = 0.001).

After the second contraction, the proportion agreement to CTG, at the start and at the end of the 60 second period, was 0.546 (95% CI 0.427 – 0.662) with the DUFHRM and 0.493 (95% CI 0.375 – 0.611) with a PFS (mcc =0.651) and

again 0.773 (95% CI 0.618 – 0.828) with the DUFHRM and 0.480 (95% CI 0.363 – 0.598) with a PFS (mcc =0.01).

Conclusion

The DUFHRM, compared with a CTG in assessing FHRs both before and after uterine contraction in singleton pregnancies in the active phase of the first stage of labour, performed significantly more accurately than a PFS. This study provides strong evidence for the routine use of a DUFHRM rather than a PFS for assessing FHRs before and after uterine contractions in relatively low risk pregnancies. This finding promises to improve the quality of intrapartum fetal monitoring in low risk pregnancies.

CHAPTER 1 INTRODUCTION

1.1. Background

Almost four million babies die in the first four weeks of life per year worldwide, most from preventable causes. In addition a million babies die during labour and delivery (Lawn J et al., 2005). Of the global causes of neonatal deaths, 23 per cent are caused by acute intrapartum events, specifically fetal hypoxia (Lawn J et al., 2005). Furthermore 30 per cent of stillbirths occur during labour and delivery, presumably due to fetal hypoxia. Many survivors have varying degrees of brain damage due to fetal hypoxia.

In South Africa, 'intrapartum hypoxia and birth trauma' are among the top three causes of perinatal deaths. The vast majority of these deaths are from intrapartum hypoxia as birth trauma is uncommon. The other two common causes being spontaneous preterm labour and placental disease (namely pre-eclampsia and placental abruption) accounting for 23 per cent each (Pattinson, 2009). In the latter two conditions, the fetal insult is again hypoxia.

In the vast majority of cases of perinatal mortality, at least one avoidable factor can be identified, and these are often related to medical personnel (Pattinson RC et al., 1995, Ross M et al., 2002, Van Coeverden de Groot HA and Howland, 1984). Of these personnel-associated avoidable neonatal deaths, 'intrapartum fetal distress not detected in fetuses that were being monitored in labour' accounted for 11.5 per cent of all neonatal deaths (Pattinson, 2009). This finding was largely attributed to inadequate fetal monitoring in labour.

Since early in the nineteenth century when de Kergeradee suggested that listening to the fetal heartbeat might be clinically useful to detect fetal compromise from variations in the fetal heart rate (Grant, 1989a), various methods of listening to the fetal heart have been developed and introduced in maternity care. The fetal heart can be monitored either intermittently at regular intervals during labour or continuously. The following methods are commonly used:

1. Pinard Fetal stethoscope (PFS): this is a cone shaped device. It is cheap (costs less than ZAR50) and so widely used for intermittent auscultation of the fetal heart. However it requires a fair amount of skill and experience. It can be a source of discomfort to the women on which it is being used especially during uterine contractions. There is consensus in the guidelines by professional bodies that the fetal heart

should be auscultated for at least 60 second (RCOG, 2001a, Liston R et al., 2002).

2. Hand-held Doppler ultrasound device: there are various types of hand-held Doppler devices. These are portable electronic devices and are used for intermittent monitoring of the fetal heart. They display a fetal heart rate when a Doppler ultrasound transducer is placed on the abdomen of a pregnant woman. They are user friendly, can be powered by replaceable batteries or mains electricity and they are comfortable for the woman. The currently available hand-held Doppler ultrasound costs about ZAR5000.

3. Cardiotocography (CTG): this device electronically records fetal heart and uterine contractions on a paper trace. It uses a Doppler ultrasound transducer to monitor fetal heart and a pressure transducer to monitor uterine contractions. These are linked to a recording machine. The fetal heart can also be monitored with the use of a scalp electrode attached to the fetal head. This use is however limited by increased prevalence of infectious diseases like Human Immunodeficiency Virus and Hepatitis. A CTG can be used intermittently or continuously in labour. However it limits mobility of the women in labour and may be a cause of discomfort when the

transducers are applied to the pregnant woman's abdomen during labour. A CTG requires electric power and skilled users and well trained staff for interpretation. It is also expensive costing up to about ZAR30000. Its use was associated with reduction in neonatal seizures, increased rates of operative deliveries and Caesarean section but with no reduction in perinatal mortality(Alfirevic Z et al., 2008).

4. Other forms of fetal monitoring are classed as 'electronic' e.g. Fetal electrocardiogram, Fetal pulse oximetry. These are unavailable in most maternity units and their clinical usefulness is still an area of extensive research.

In South Africa, the majority of births occur in community health centres and district hospitals(Pattinson, 2009). These are usually under- resourced settings where staffing is often inadequate and personnel are involved in multiple tasks. Most fetal monitoring is done intermittently with a PFS. Most intrapartum, neonatal and maternal deaths occur in these facilities.

Severe intrapartum hypoxia is often preventable with appropriate maternal and fetal monitoring in labour. However, this remains a challenge in under-resourced settings, more so with difficulties that accompany the use of a PFS. These are real challenges to achieving the fourth Millennium Development

Goal which is to reduce by two-thirds the number of deaths under 5 years of age between 1990 and 2015.

1.2. Rationale of the study

Effective intrapartum monitoring is needed to reduce perinatal and maternal morbidity, and save fetal, neonatal and maternal lives. Currently available devices for continuous intrapartum fetal monitoring are not affordable or sustainable in most low resource settings. They are also not recommended in low risk labours as intermittent fetal heart monitoring is as effective as continuous electronic monitoring in these low risk labours (Banta DH and Thacker, 2001). In South Africa, it is recommended that a Pinard Fetal Stethoscope or preferably a hand-held Doppler device is used for low risk labours and Cardiotocography is used for high risk labours (Department of Health, 2007, Ferrell E, 2005). However due to scarcity of hand-held Doppler devices due to cost, intermittent monitoring is performed, almost always with a PFS in low resource settings.

The PFS is cheap and widely available. However, in most of the low resource settings, a midwife has multiple tasks to fulfil simultaneously making it difficult for timely and appropriate fetal heart rate monitoring with a PFS.

Furthermore although there is no empirical evidence on the optimal frequency of intermittent auscultation, there is a consensus that the fetal heart should be auscultated at least every 15 minutes in the first stage of labour and at least every 5 minutes in the second stage of labour (ACOG, 1995, Liston R et al., 2002, RANZCOG, 2002, RCOG, 2001a) with each auscultation lasting at least 60 seconds (Liston R et al., 2002, RCOG, 2001a). In South Africa, it is recommended that intermittent fetal monitoring is performed every 2 hours in latent phase of the first stage of labour and every 30 minutes after a contraction in active phase of the first stage of labour, preferably with a hand-held Doppler device, in low risk labours (Ferrell E, 2005). This is challenging for midwives, who have multiple tasks, to use a PFS appropriately. This leaves most midwives resorting to 'listening to a fetal heart for a few seconds and simply multiplying by a factor to get a minute rate' as shown by anecdotal reports. The accuracy of counting the fetal heart rate with a PFS is also user-dependent. There is also lack of evidence based standardisation in taking measurements with it as it appears that auscultation protocols were developed initially in the context of clinical trials and were based on 'common sense' rather than research evidence (Alfirevic Z et al., 2008).

Given the difficulty and limitations in the use of a PFS for the healthcare worker and the discomfort for the mother in a busy midwife obstetric unit, its accuracy is questionable. Thus though intermittent fetal heart auscultation

is as safe as continuous electronic monitoring in low risk labours (Banta DH and Thacker, 2001), this may not be the case where correct auscultation with a PFS is not done.

In under-resourced settings, a hand held Doppler ultrasound fetal heart rate monitor is the most promising method of effective intermittent monitoring. A randomised trial in Zimbabwe enrolled 1255 women who were 37 weeks or more pregnant with singleton pregnancy and normal fetal heart rate before study entry. Women were randomised to intermittent intrapartum fetal monitoring by electronic monitoring, Doppler ultrasound, use of Pinard stethoscope by a research midwife or routine use of Pinard stethoscope by attending midwife. Abnormalities in fetal heart rate were more reliably detected by a Doppler ultrasound than with a Pinard Stethoscope and its use resulted in good perinatal outcome (Mahomed K et al., 1994). In a prospective study to assess the preference of women for fetal monitoring with a Pinard stethoscope, innovative wind-up Doppler ultrasound fetal heart rate monitor and cardiotocography, significantly more women preferred the innovative wind-up Doppler ultrasound fetal heart rate monitor to the other 2 methods (Mangesi L et al., 2009). However there are concerns regarding currently available hand-held Doppler devices and the feasibility of their use as intrapartum fetal monitoring devices in low- income

settings because of cost and need for replaceable batteries or mains electricity.

Power-free Education and Technology, a South African registered non-profit organisation, overcame these obstacles and developed a wind- up DUFHRM. This DUFHRM is powered by winding a hand crank and does not need replaceable batteries or charging with mains electricity. It is also cheaper (costing about ZAR1500) than the available hand-held Doppler ultrasound fetal heart rate monitors. The device uses an obstetric ultrasound probe connected to the main unit by a cord. The main unit processes the signal and displays it.

Initial field testing of the DUFHRM was conducted in 17 women in various stages of labour. Simultaneous pairs of readings of fetal heart rate were obtained using DUFHRM and cardiotocography. There was no statistical difference between readings from DUFHRM and CTG. In a survey of 97 mothers by the same authors, 72 (74%) preferred the DUFHRM to CTG or PFS as fetal monitoring tool (Bezuidenhout H et al., 2006). However, studies on comparison of performance of currently available hand-held Doppler devices to PFS in clinical settings are sparse. Furthermore there are no published studies that have compared a DUFHRM to a PFS.

The CTG was chosen for use as the standard intrapartum fetal monitoring device as it is the standard fetal heart monitor used in secondary and tertiary level hospitals in Western Cape, South Africa. Ancillary tests such as fetal blood sampling and testing are only done under special circumstances. Clinical decisions for suspected fetal compromise in labour are largely based on CTG tracings.

CHAPTER 2 HYPOTHESIS AND STUDY OBJECTIVES

2.1. Hypothesis

There is no difference in the accuracy of the DUFHRM and PFS in determining the fetal heart rate before and after contractions in labour when compared to the fetal heart rate measured by a CTG.

2.2. Primary Objective

To assess whether the DUFHRM is more accurate than a PFS in determining fetal heart rates, before and after uterine contraction, in labour when compared to a CTG.

2.3. Secondary objectives

2.3.1. Determine the proportion agreement of FHRs obtained with the DUFHRM to the FHRs recorded with a CTG before and after a contraction.

2.3.2 Determine the proportion agreement of FHRs obtained with a PFS to FHRs recorded with a CTG before and after a contraction.

2.3.3 Compare the proportion agreement of FHRs obtained with DUFHRM to FHRs recorded with a CTG, to the proportion agreement of FHRs obtained with PFS to FHRs obtained with a CTG.

2.3.4. Describe neonatal outcomes for the study population.

CHAPTER 3 METHODOLOGY

3.1. Study design

This was a comparative diagnostic study to assess accuracy of a DUFHRM and PFS when compared to a CTG in assessing the FHRs before and after contractions in singleton pregnancies during the active phase of the first stage of labour.

3.2. Study site and population

The study was conducted at Mowbray Maternity Hospital in Cape Town, South Africa. Mowbray Maternity Hospital is a public sector secondary level maternity hospital that provides maternal and newborn healthcare services for the local community requiring state health care and also receives referral cases from the following state primary level midwife obstetric units (MOU) within its catchments area: Khayelitsha, Gugulethu, and Mitchell's Plain MOUs, as well as Liesbeek Active Birth Unit.

3.3. Sample size

Sample size was calculated to show with 95% confidence whether FHRs taken with a DUFHRM were at least 95% as accurate as FHRs recorded with a CTG. The risk of a DUFHRM not being as accurate as a CTG was accepted to be 20%. Thus with $\alpha = 0.05$ and $\beta = 0.2$, sample size was estimated to be 75 women.

3.4. Recruitment and Enrolment of participants

Pregnant women admitted to the labour ward of Mowbray Maternity Hospital in the active phase of the first stage of labour, and meeting the study inclusion criteria, were approached by the two research midwives or the study investigator for recruitment and enrolment into this study. The consent forms were administered by the research midwives or the study investigator. Pregnant women meeting the following study criteria were considered for enrolment.

3.4.1. Inclusion criteria

3.4.1a. Women with singleton pregnancies in the active phase of the first stage of labour undergoing continuous CTG monitoring. This included women in preterm labour in order to allow assessment of a DUFHRM and a PFS in detecting late decelerations which are more prevalent in high risk labours than low risk labours.

3.4.1b. Women with singleton pregnancies in the active phase of the first stage of labour who were undergoing continuous CTG monitoring and awaiting an emergency caesarean section for any indications e.g. failure to progress, failed vaginal birth after a previous Caesarean section, a suspicious or pathological CTG tracing. This inclusion criterion was made to include women with potential fetal heart rate abnormalities so as to allow assessment of a DUFHRM and a PFS in detecting late decelerations

3.4.1c. Ability and willingness of participants to give written informed consent

3.4.2. Exclusion criteria

3.4.2a. Women with multiple pregnancies

3.4.2b. Women in labour with an intrauterine fetal death or not requiring fetal monitoring as assessed by the attending doctor (e.g. in very preterm labour with a gestational age below 28 completed weeks or severe fetal anomalies).

3.4.2c. Women who withdraw informed consent at any time during the study.

3.4.2d. Women requiring Caesarean section for an indication that is so urgent that it could not delayed.

3.4.3. Measurements

On each participant, paired readings of the FHR were taken using a DUFHRM and PFS during two, preferably consecutive, uterine contractions by two different research midwives. At the same time the FHR was noted on the CTG and recorded by the study investigator. The two research midwives swapped devices at the second uterine contraction. The midwives were blinded to the CTG recording by silencing the CTG and turning it aside from their view by the study investigator who recorded the CTG FHR readings:

3.4.3a. In pregnant women undergoing continuous CTG monitoring, FHRs were recorded by the DUFHRM and PFS before a uterine contraction and again 30 seconds after the end of the uterine contraction while in the active phase of the first stage of labour.

3.4.3b. The fetal heart was listened to for 60 seconds using a PFS to obtain a FHR in beats per minute. Considering that the FHR obtained by a PFS required listening to the fetal heart for 60 seconds whereas the DUFHRM and CTG give a FHR within

seconds of detecting the fetal heart activity, in this study, the FHR recorded using the DUFHRM and CTG were obtained twice by recording the FHR at the beginning and again at the end of the 60 second measurement period of FHR with PFS. The midwife using the PFS would indicate when she started counting the FHR and when she finished so that corresponding readings of the FHR on the CTG and DUFHRM were noted by the other observers.

The FHR taken with the PFS and the DUFHRM were considered to be in agreement with the FHR recorded by the CTG if it was within 5 beats per minute.

National Institute for Health and Clinical Excellence guidelines (NICE, September 2007) for CTG interpretation were used to classify the CTG traces obtained as follows (Tables 1 and 2):

Table 1: Classification of FHR features

Feature	**Baseline FHR (bpm)**	**Variability (bpm)**	**Decelerations**	**Accelerations**
Reassuring	110-160	≥ 5	None	Present
Non-reassuring	100-109 161-180	<5 for 40-90 minutes	Typical variable decelerations with over 50% of contractions, occurring for over 90 minutes Single prolonged deceleration for up to 3 minutes	The absence of accelerations with otherwise normal trace is of uncertain significance
Abnormal	<100 >180 Sinusoidal pattern for ≥10min	<5 for 90 minutes	Either atypical variable decelerations with over 50% of contractions or late decelerations, both for over 30 minutes Single prolonged deceleration for more than 3 minutes	

Table 2: Definition of Normal, Suspicious and Pathological CTG traces

Category	**Definition**
Normal	A FHR trace in which all four features are classified as reassuring
Suspicious	A FHR trace with one feature classified as non-reassuring and the remaining features classified as reassuring
Pathological	A FHR trace with two or more features classified as non-reassuring or one or more classified as abnormal

Social, demographic, medical history information and pregnancy outcome data were extracted from the mothers' and the babies' hospital files after delivery.

Neonatal outcomes of pregnancies included gestational age at delivery, birth weights, Apgar scores at 1 and 5 minutes after birth, need for resuscitation, admission to the neonatal intensive care unit and baby alive on discharge of the mother from the hospital.

The data collection sheet, standard operating procedures used for the study, as well as the three fetal heart rate monitoring devices compared, are shown in Appendices 10.2, 10.3 and 10.4

3.5. Quality control

The FHR measurements taken with a PFS and the DUFHRM were done by two very experienced midwives who had been recruited as research midwives. Thus they were already trained in the use of a PFS. However, they still underwent re-training with the use of a PFS and the DUFHRM before they started taking FHR measurements on the study participants. A standard operating procedure was also prepared and adhered to during conduct of the study (Appendix 10.4). The research midwives were overseen by the investigator who is a registrar in the department of Obstetrics and Gynaecology at the University of Cape Town.

Random checks were done on non-study participants to make sure that the DUFHRM was working properly. The measurements taken in the study were double entered on the database using Epidata version 3.1 in order to minimise data entry errors before analysis. The database was also designed with checks where possible on the acceptable values for most variables.

3.6. Pilot study

A pilot study was done on 5 women in each of the CTG trace categories i.e. normal and suspicious or pathological CTG. This allowed planning for the actual study data collection and anticipation of potential problems that might have been encountered during data collection.

CHAPTER 4 STATISTICAL CONSIDERATIONS AND DATA ANALYSIS

Data were entered on a database generated on Epidata version 3.1 and converted into Microsoft Excel 2012 and later transferred into the Statistical Package for Social Sciences version 2011 (SPSS 2011) for data analysis.

Descriptive analysis of the participants' socio-demographic characteristics was done. This included frequencies of age distribution, gravidity, parity, medical history and obstetric risk factors of the enrolled women.

The proportion of CTG categories as per NICE guidelines (i.e. normal, suspicious and pathological CTG) was determined. Proportion agreement and 95% confidence intervals of the proportion agreements between FHR measurements taken with a DUFHRM to the FHR recorded with a CTG, and also between FHR measurements taken with a PFS to FHRs recorded with a CTG were determined and compared. The FHR taken with a PFS and the DUFHRM were considered to be in agreement with the FHR recorded by CTG if it was within 5 beats per minute.

Statistical significance of the proportion agreement of the FHR obtained with the DUFHRM to a CTG and proportion agreement of the FHR obtained with a PFS to a CTG was done using the Exact McNemar significance probability test as the proportions were independent of each other. Significance difference of the proportion agreements compared was considered at Exact McNemar significance probability of less than 0.05. Before and after each uterine contraction there were two FHR readings with DUFHRM and two FHR readings with CTG for each FHR reading with PFS as the other devices were used at the start and at the end of the 60 second measuring period with a PFS.

CHAPTER 5 ETHICAL CONSIDERATIONS

The research protocol was submitted for approval to the University of Cape Town, Department of Obstetrics and Gynaecology research committee before submission to the University of Cape Town, Faculty of Health Sciences Research Ethics Committee. Both committees approved the study before it was conducted.

The management of Mowbray Maternity Hospital was approached for approval that the study be conducted at the site and approval was granted accordingly. A written informed consent was sought from potential study participants. Only participants who had the ability and willingness to provide a written informed consent were enrolled in the study. Mowbray Maternity Hospital translators/ interpreters were asked by the research midwives or the investigator to translate/interpret the consent to participants who could not speak and/or read English. The informed consent form is included in Appendix 10.1

To avoid undue pressure on the potential participants, recruitment and enrolment were done once the women had been attended to and admitted by the attendant doctor and/or midwife. Potential participants who were not

sure or needed to discuss with their family members before agreeing to participation in the study were allowed to consult their family. The written informed consent was obtained by the trained research midwife or the study investigator.

Any study procedure or activity was not done if there was any need for urgent intervention in the care of the potential participants. Data collection forms were kept separate from the signed written informed consent forms. Names of enrolled participants and participant hospital folder numbers were linked in a separate name link log. All these documents were only accessible to research staff to ensure privacy and confidentiality.

CHAPTER 6 RESULTS

6.1a. Socio-demographic characteristics

We enrolled 76 women with singleton pregnancies in the active phase of the first stage of labour. Of these, 4 women were awaiting caesarian section. The mean age of the women enrolled was 24 years. Thirty seven (48.7%) of the enrolled women were primigravida and 39 women (51.3%) were multigravida. Sixty seven women (88.2%) were in labour at term (i.e. 37 completed weeks or more) and 9 (11.8%) had preterm pregnancies (Table 3).

Twenty five women (32.9%) were married and 72 (94.5%) women were unemployed. Smoking, alcohol and use of other substances were reported in 18 (23.7%), 11 (14.5%) and 2 (2.6%) respectively. Three women (3.9%) were asthmatic and 1 woman (1.3%) had epilepsy while the rest had no other medical conditions. Obstetric risk factors identified among the women were: previous Caesarean section in 5 (6.5%); gestational hypertension in 6 (7.8%); pre-eclampsia in 2 (2.6%); postdate pregnancy(Hall, 2011) in 13 (17.1%), prolonged rupture of membrane in 3 (3.9%) (Table 3).

Table 3 : Socio-demographic characteristics

Total number of participants: 76 pregnant women

Maternal Age (years) **Mean** (SD) 24 (6)

Maternal Age range (years) 13-38

Characteristic	Number	Percentage
Gravida		
1	37	48.7
2-5	37	48.7
6-7	2	2.6
Gestational age		
31-<35 weeks	3	3.9
35-<37 weeks	6	7.9
37-<41 weeks	54	71.1
41+ weeks	13	17.1
Social history		
a. Marital status		
Single	51	67.1
Married	25	32.9
Divorced	0	0
Widowed	0	0
b. Substance use		
Smoking	18	23.7
Alcohol	11	14.5
Other substances	2	2.6

c. Employment history		
Employed	3	4.0
Unemployed	72	94.7
Self-employed	1	1.3
Medical History		
Asthma	3	3.9
Epilepsy	1	1.3
Other diseases	0	0
Obstetric risk factors		
Previous Caesarean section	5	6.5
Gestational hypertension	6	7.8
Pre eclampsia	2	2.6
Chronic hypertension	0	0
Postdatism	13	17.1
Prolonged ROM	3	3.9
SGA/IUGR	0	0

6.1b. Details of current labour

Table 4 shows details of the current labour of the enrolled women. Sixty six women (86.9%) went into spontaneous labour and 10 women (13.1%) had labour induced. Labour was augmented in 32 women; in 25 women (32.8%),

augmentation of labour was by artificial rupture of membranes and in 7 women (9.2%), labour was augmented by oxytocin

The indications for induction of labour were postdate pregnancy in 4 women (36.3%); gestational hypertension in 4 women (36.3%); prolonged rupture of membranes in 1 woman (9%), pre-eclampsia in 1 woman (9%); oligohydramnios in 1 woman (9%). One woman had both postdate pregnancy and gestational hypertension (Table 4).

Table 4: Labour details

Characteristic	Number	Percentage
Labour		
Spontaneous labour	66	86.9
Induced labour	10	13.1
AROM	25	32.8
Oxytocin use	7	9.2
CTG category		
Normal CTG	43	56.6
Suspicious	24	31.6
Pathological	9	11.8
Indication for induction of labour		
Prolonged ROM	1	9.0
Pre-eclampsia	1	9.0
Gestational hypertension	4	36.3
Postdatism	4	36.3
Oligohydramnios	1	9.0

NB: One participant was induced for both gestational hypertension and postdatism

6.2. Fetal heart rate measurements

Data for fetal heart rate measurements were available for 76 women at the time of the first uterine contraction and for 75 women at the time of second uterine contraction. At the time of fetal heart rate measurements taken in this study, 43 women (56.6%) had a normal CTG trace, 24 women (31.6%) had a suspicious trace and only 9 women (11.8%) had a pathological CTG trace (Table 4).

6.2.1 The proportion agreements before and after first contraction by CTG category.

Table 5 shows the proportion agreements of FHRs obtained by the DUFHRM to FHRs recorded with a CTG compared with the proportion agreements of FHRs obtained by a PFS to FHRs recorded with a CTG, done before and after the first contraction by CTG category. The proportion agreements of FHRs obtained by the DUFHRM to FHRs recorded with a CTG are consistently higher than proportion agreements of FHRs obtained by a PFS to FHRs recorded with a CTG both before and after the first contraction.

Table 5: The proportion agreement of FHRs obtained by DUFHRM to FHRs recorded with CTG compared with proportion agreement of FHRs obtained by PFS to FHRs recorded with CTG done before and after the first contraction by CTG category

Variable	Pathological CTG	Suspicious CTG	Normal CTG
Number of participants	9	24	43
	Before contraction		
DUFHRM/CTG1	0.778	0.625	0.556
PFS/CTG 1	0.333	0.250	0.419
DUFHRM/CTG 2	0.889	0.667	0.860
PFS/CTG 2	0.333	0.250	0.442
	After Contraction		
DUFHRM/CTG 1	0.667	0.791	0.581
PFS/CTG 1	0.556	0.208	0.512
DUFHRM/CTG 2	0.667	0.792	0.814
PFS/CTG 2	0.556	0.250	0.419

DUFHRM/CTG 1= proportion agreement of FHRs obtained with DUFHRM to FHRs recorded with a CTG at the start of 60 second FHR measurement period with PFS; PFS/CTG 1= proportion agreement of FHRs obtained with PFS to FHRs recorded with CTG (FHRs recorded with CTG at the start of 60 second FHR measurement period with PFS);

DUFHRM/CTG 2= proportion agreement of FHRs obtained with DUFHRM to FHRs recorded with a CTG at the end of 60 second FHR measurement period with PFS ;PFS/CTG 2= proportion

agreement of FHRs obtained with PFS to FHRs recorded with CTG (FHRs recorded with CTG taken at the end of 60 second FHR measurement period with PFS)

6.2.2 The proportion agreements before and after second contraction by CTG category

Table 6 shows the proportion agreements of FHRs obtained by the DUFHRM to FHRs recorded with a CTG compared with the proportion agreements of FHRs obtained by a PFS to FHRs recorded with a CTG, done before and after second contraction by CTG category. Before the second contraction, the proportion agreement to FHRs recorded with a CTG, at the start of 60 second measuring period, was 0.222 with the DUFHRM and 0.556 with a PFS for a pathological CTG tracing, 0.522 with the DUFHRM and 0.435 with a PFS for a suspicious CTG tracing, 0.558 with the DUFHRM and 0.419 with a PFS for a normal CTG tracing. After the end of the second contraction, the proportion agreement to FHRs recorded with CTG, at the end of the 60 second measuring period, was 0.814 with the DUFHRM and 0.512 with a PFS for a normal CTG tracing, 0.652 with the DUFHRM and 0.435 with a PFS for a suspicious CTG and 0.556 with the DUFHRM and 0.444 with a PFS for a pathological CTG.

The proportion agreement of FHRs obtained by the DUFHRM to the FHRs obtained by CTG at the start of 60 second FHR measurement period with PFS for the pathological CTG category in tables 5 and 6 were 0.778 and 0.222 respectively. Likewise the proportion agreements of FHRs obtained by PFS to FHRs obtained by CTG at the start of the 60 second FHR measuring period, PFS/CTG1, were 0.333 and 0.556 respectively in the same tables. Similar large discrepancies in proportion agreements were noted in the suspicious CTG category for the proportion agreements of FHRs obtained by PFS to FHRs obtained by CTG at the start of the 60 second FHR measuring period, PFS/CTG1 and also in the proportion agreements of FHRs obtained with PFS to FHRs recorded with CTG taken at the end of 60 second FHR measurement period with PFS, when compared at the first and second uterine contractions. In contrast, the respective proportion agreements were similar in the normal CTG category for the first and second uterine contractions.

Table 6: The proportion agreement of FHRs obtained by DUFHRM to FHRs recorded with CTG compared with proportion agreement of FHRs obtained by PFS to FHRs recorded with CTG done before and after second contraction by CTG category

Variable	Pathological CTG	Suspicious CTG	Normal CTG
Number of participants	9	24	43
	Before contraction		
DUFHRM/CTG1	0.222	0.522	0.558
PFS/CTG 1	0.556	0.435	0.419
DUFHRM/CTG 2	0.778	0.652	0.837
PFS/CTG 2	0.778	1.000	0.488
	After Contraction		
DUFHRM/CTG 1	0.667	0.435	0.581
PFS/CTG 1	0.556	0.435	0.512
DUFHRM/CTG 2	0.556	0.652	0.814
PFS/CTG 2	0.444	0.435	0.512

DUFHRM/CTG 1= proportion agreement of FHRs obtained with DUFHRM to FHRs recorded with a CTG at the start of 60 second FHR measurement period with PFS; PFS/CTG 1= proportion agreement of FHRs obtained with PFS to FHRs recorded with CTG (FHRs recorded with CTG at the start of 60 second FHR measurement period with PFS);

DUFHRM/CTG 2= proportion agreement of FHRs obtained with DUFHRM to FHRs recorded with a CTG at the end of 60 second FHR measurement period with PFS ;PFS/CTG 2= proportion agreement of FHRs obtained with PFS to FHRs recorded with CTG (FHRs recorded with CTG taken at the end of 60 second FHR measurement period with PFS)

6.2.3 The proportion agreements before and after first contraction for all CTG categories

Table 7 shows the proportion agreements of FHRs taken with the DUFHRM to FHRs recorded with a CTG compared with the proportion agreements of FHRs taken with a PFS to FHRs recorded with a CTG before and after first contraction for all CTG categories. The data were available for all 76 enrolled women.

Before the first contraction, the proportion agreement to CTG was 0.605 (95% CI 0.486 – 0.715) with the DUFHRM and 0.355 (95% CI 0.248 – 0.473) with a PFS, at the start of the 60 second measuring period, and 0.802 (95% CI 0.695 – 0.885) with the DUFHRM and 0.368 (95% CI 0.260 – 0.486) with a PFS, at the end of the 60 second measuring period. The proportion agreement of the DUFHRM to a CTG was statistically significantly different from the proportion agreement of a PFS to a CTG (*mcc = 0.0034 and mcc =0.000*) (Table 7).

Table 7: The Proportion agreement of FHRs obtained by DUFHRM to FHRs recorded with CTG compared with proportion agreement of FHRs obtained by PFS to FHRs recorded with CTG before and after first contraction for all CTG categories

Variable	Number of participants	Proportion agreement	95% CI	mcc
		Before contraction		
DUFHRM/CTG1	76	0.605	0.486-0.715	
PFS/CTG 1	76	0.355	0.248-0.473	0.0034
DUFHRM/CTG 2	76	0.802	0.695-0.885	
PFS/CTG 2	76	0.368	0.260-0.486	0.00
		After Contraction		
DUFHRM/CTG 1	76	0.657	0.540-0.762	
PFS/CTG 1	76	0.421	0.308-0.539	0.0079
DUFHRM/CTG 2	76	0.789	0.680-0.874	
PFS/CTG 2	76	0.381	0.272-0.500	0.00

DUFHRM/CTG 1= proportion agreement of FHRs obtained with DUFHRM to FHRs recorded with a CTG at the start of 60 second FHR measurement period with PFS; PFS/CTG 1= proportion agreement of FHRs obtained with PFS to FHRs recorded with CTG (FHRs recorded with CTG at the start of 60 second FHR measurement period with PFS); DUFHRM/CTG 2= proportion agreement of FHRs obtained with DUFHRM to FHRs recorded with a CTG at the end of 60 second FHR measurement period with PFS; PFS/CTG 2= proportion agreement of FHRs obtained with PFS to FHRs recorded with CTG (FHRs recorded with CTG at the end of 60 second FHR measurement period with PFS; mcc = Exact McNemar significance probability; C.I = Confidence Interval

After the first contraction, the proportion agreement to a CTG was 0.657 (95% CI 0.540 – 0.762) with the DUFHRM and 0.421 (95% CI 0.308 – 0.539) with a PFS, at the start of the 60 second measuring period, and 0.789 (95% CI 0.680 – 0.874) with the DUFHRM and 0.381 (95% CI 0.272 – 0.500) with a PFS, at the end of the 60 second measuring period. The proportion agreement of the DUFHRM to a CTG was statistically significantly different from the proportion agreement of a PFS to a CTG (*mcc = 0.0079 and mcc = 0.00*) (Table 7).

6.2.4 The proportion agreements before and after second contraction for all CTG categories

Before the second contraction, the proportion agreement to a CTG was 0.506 (95% CI 0.388 – 0.624) with the DUFHRM and 0.440 (95% CI 0.325 – 0.559) with a PFS, at the start of the 60 second measuring period, and 0.773 (95% CI 0.662 – 0.862) with the DUFHRM and 0.506 (95% CI 0.388 – 0.624) with a PFS, at the end of the 60 second measuring period. The proportion agreement of the DUFHRM to a CTG was statistically significantly different from the proportion agreement of a PFS to a CTG for FHRs taken at the end of the 60 second measuring period with a PFS (*mcc= 0.001*) and not statistically different for the FHRs taken at the start of 60 second measuring period with a PFS (*mcc = 0.511)* (Table 8).

Table 8*: *The proportion agreement of FHRs obtained by DUFHRM to FHRs recorded with CTG compared with proportion agreement of FHRs obtained by PFS to FHRs recorded with CTG before and after second contraction for all CTG categories

Variable	Number of participants	Proportion agreement	95% CI	mcc
		Before contraction		
DUFHRM/CTG1	75	0.506	0.388-0.624	
PFS/CTG 1	75	0.440	0.325-0.559	0.511
DUFHRM/CTG 2	75	0.773	0.662-0.862	
PFS/CTG 2	75	0.506	0.388-0.624	0.001
		After Contraction		
DUFHRM/CTG 1	75	0.546	0.427-0.662	
PFS/CTG 1	75	0.493	0.375-0.611	0.651
DUFHRM/CTG 2	75	0.773	0.618-0.828	
PFS/CTG 2	75	0.480	0.363-0.598	0.001

DUFHRM/CTG 1= proportion agreement of FHRs obtained with DUFHRM to FHRs recorded with a CTG at the start of 60 second FHR measurement period with PFS; PFS/CTG 1= proportion agreement of FHRs obtained with PFS to FHRs recorded with CTG (FHRs recorded with CTG taken at the start of 60 second FHR measurement period with PFS); DUFHRM/CTG 2= proportion agreement of FHRs obtained with DUFHRM to FHRs recorded with a CTG at the end of 60 second FHR measurement period with PFS; PFS/CTG 2= proportion agreement of FHRs obtained with PFS to FHRs recorded with CTG (FHRs recorded with CTG taken at the end of 60 second FHR

measurement period with PFS; mcc = Exact McNemar significance probability, C.I = Confidence Interval

After the second contraction, the proportion agreement to CTG was 0.546 (95% CI 0.427 – 0.662) with the DUFHRM and 0.493 (95% CI 0.375 – 0.611) with a PFS, at the start of the 60 second measuring period, and 0.773 (95% CI 0.618 – 0.828) with the DUFHRM and 0.48 (95% CI 0.363 – 0.598) with a PFS, at the end of the 60 second measuring period. The proportion agreement of the DUFHRM to a CTG was statistically significantly different from the proportion agreement of a PFS to a CTG for FHRs taken at end of 60 second measuring period (*mcc =0.001)* and not statistically different for the FHRs taken at the start of the 60 second measuring period after first contraction (*mcc = 0.651)* (Table 8).

The DUFHRM gave significantly more comparable FHRs to a CTG than a PFS at 6 out of 8 time point measurements of FHRs.

6.3. Pregnancy outcomes

Of the enrolled participants, 46 women (63.2%) progressed to normal vaginal delivery, 27 women (35.5%) required a Caesarean section and one woman

(1.3%) required an assisted vaginal delivery with a vacuum extractor (Table 9).

The birth weight range of babies born to enrolled women was 1520 – 4555 grams. 72 babies (94.74%) born had birth weight of at least 2500 grams and only 4 (5.26%) had birth weight less than 2500 grams. No baby was born with an Apgar score of below 7 at 1 minute and 5 minutes after delivery. Only one baby was admitted to the neonatal intensive care unit. This baby was preterm, born to a mother who had no antenatal care and the baby's birth weight was 1520grams. All babies born were alive at the time of the mother's discharge from hospital (Table 9). One baby required some resuscitation for poor respiratory effort after birth by vacuum extraction. Of the 9 women who had pathological CTGs, 4 had normal vaginal delivery and 5 had caesarian section done.

Table 9: Pregnancy outcomes for 76 enrolled women

Characteristic	Number	Percentage
Mode of delivery		
Normal vaginal delivery	48	63.2
Caesarian section	27	35.5
Vacuum extraction	1	1.3
Birth weight range 1520-4555grams		
2500 or more grams	72	94.7
Less than 2500grams	4	5.3
Apgar score less than 7 at 1 minute	0	0
Apgar score less than 7 at 5minutes	0	0
Neonatal resuscitation done	1	1.3
Admission to NICU	1	1.3
Baby alive at discharge	76	100

CHAPTER 7 DISCUSSION

This study showed that the DUFHRM was more accurate than a PFS in assessing the FHR in singleton pregnancies in the active phase of the first stage of labour when compared to a CTG as a standard intrapartum fetal monitoring device. In this study, 67 of the women (88.2 %) enrolled had term pregnancies with only 9 (11.8%) preterm. Most women had no medical problems, 66 women (86.9%) went into spontaneous labour and only 10 women required induction of labour. This reflects the low risk status of the study population on which the devices were tested in assessing FHR in labour. Twenty seven women (35.5%) delivered by caesarean section. However this caesarian section rate was inflated by referral bias and including the normal deliveries at the referring MOUs would result in a much lower rate, thus reflecting the low risk nature of the study population. The low risk nature of the study population was also reflected in the high percentage of babies weighing 2500 grams or more (94.7%), no babies born with low Apgar scores and only 1 baby needing admission to the neonatal intensive care unit.

The study population reflected pregnancies that would meet criteria for intermittent fetal heart rate monitoring. As expected for low risk pregnancies, most women 43 (56.6%), had a normal CTG trace with only 24

women (31.6%) and 9 women (11.8%) having a suspicious and pathological CTG trace respectively. This was therefore an appropriate population for testing the comparability of the DUFHRM and a PFS to a CTG for assessing fetal heart rate in relatively low risk labours where intermittent fetal monitoring would be appropriate. Intermittent fetal heart monitoring is as effective as continuous electronic monitoring in such low risk labours.

The DUFHRM gave significantly more comparable FHRs to a CTG than a PFS at 6 out of 8 time point measurements of FHRs. This was not surprising considering that the DUFHRM uses the same basic principle, the Doppler effect, which the cardiotocography uses to measure FHRs. It also recorded the measurement of FHR at the same time and displays the heart rate. It may be argued that the comparability of PFS to CTG was compromised by continuous use of CTG throughout the time that FHR readings were taken with PFS in contrast to typical use of PFS where the abdomen of women is free from any CTG probes and their supporting elastic bands. However, FHR readings with DUFHRM were also taken with CTG monitoring in progress. This study did not assess formally the difficulties of use of PFS and DUFHRM with the CTG monitoring in progress. Further studies will need to look at this aspect.

In this study a PFS was used for measuring the FHR over 60 seconds. This is in contrast to the typical use of PFS in a busy midwife obstetric unit where most midwives count the FHR for 15 seconds only and get the rate by multiplying by a factor of 4 (anecdotal reports), which has a potential for error. Thus the proportion agreements of FHRs taken with a PFS to FHRs recorded with a CTG in this study might actually have over-estimated the accuracy of a PFS compared to a typical clinical setting where a PFS is commonly used. We also recruited the services of two well experienced midwives who followed standard operating procedures in assessing FHRs using both of the fetal heart rate measuring devices (i.e. DUFHRM and PFS). This contrasts to the typical use of PFS in a busy midwife obstetric unit where often no standard operating procedure for taking the FHR with a PFS would be found leaving every midwife to use PFS in a way s/he was taught while in nursing school. This potentially brings about significant inter-individual variation in the FHRs obtained.

In the field study comparing DUFHRM and CTG, Bezuidenhout et al showed no significant difference between readings from the DUFHRM compared to the CTG (Bezuidenhout H et al., 2006). To date there is no published study that compared FHRs taken with the DUFHRM to FHRs recorded with a CTG and also FHRs taken with a PFS compared with FHRs recorded with a CTG.

This study was done in a clinical setting where women were in labour at a hospital that also serves women with relatively low risk pregnancies in addition to women referred with other obstetric or intrapartum complications. It also compared in the most practical way, simultaneous measurements of FHRs taken using three devices.

The timing of assessing the FHRs by the DUFHRM and a CTG during the 60 seconds needed to obtain a FHR with a PFS gives scope to bias. Therefore we compared FHRs obtained by the DUFHRM and a PFS with that recorded with the CTG at the start and at the end of the 60 second period. Given the difficulty in comparing readings taken by PFS which requires a period of time (at least 30 seconds) to CTG and DUFHRM which give a FHR reading instantly, this design of comparing the 3 devices was the best one arrived at with consultation from experts in the field.

We found significantly higher proportion agreements with the DUFHRM compared with a PFS, at the start and at the end of the 60 second period, both before and after the first uterine contraction. In contrast, we found that the proportion agreements of FHRs taken with the DUFHRM to a CTG were greater but not significantly different from the proportion agreements of FHRs taken with a PFS to a CTG at the start of the 60 second period, both before and after the second uterine contraction. As with the first contraction,

we found significantly higher proportion agreements with the DUFHRM compared to a PFS at the end of the 60 second period, both before and after the second uterine contraction. There is no obvious explanation as to why the proportion agreements should differ in this manner (Table 8).

There were large discrepancies in the proportion agreements, specifically DUFHRM/CTG1, PFS/CTG1 and PFS/CTG2 compared at the first and second uterine contractions for the pathological CTG category and suspicious CTG category. Noteworthy, the respective proportion agreements were similar in the normal CTG category for the first and second uterine contractions (Tables 5 and 6). The large discrepancies in the proportion agreements could be attributed to the smaller numbers of pathological CTG traces and suspicious CTG traces compared to normal CTG traces (Table 4). It could also be attributable to the large variations in the abnormalities that could be observed in the features of CTG e.g. types of decelerations and their duration which could vary widely.

This study could not establish with certainty the reliability of the DUFHRM in detecting the presence or absence of late decelerations as only 9 women had pathological CTG tracings. This was possibly attributable to the high proportion of women with relatively low risk pregnancies who were enrolled in the study. Enrolling women who already had a pathological CTG would

however have brought about bias as the observer might have suspected a pathological CTG as intrauterine resuscitation would have been instituted on the participants with pathological or suspicious CTG. Blinding the observers by delaying intrauterine resuscitation where CTG tracing was suspicious or pathological in order to assess the reliability of these devices to detect late decelerations would be unethical as that would mean delaying or denying the women standard of care. Thus the only practical way to assess reliability of the DUFHRM to detect late decelerations was a chance finding of women with late decelerations, again not a common occurrence in low risk pregnancies as has been shown in this study population. It would also require enrolling large numbers of women to identify possibly enough sample study to draw conclusions on.

The DUFHRM also lacks the ability to assess baseline variability of the FHR, which is one of the four features of the FHR that the CTG is able to assess. For this reason, as well as the continuous nature of the CTG, it is not recommended that DUFHRM be the method of choice for fetal assessment in labour of high risk pregnancies.

Another limitation in this study was the use of a CTG as the standard fetal monitoring device for assessing fetal well-being. It is recognised that while specific abnormalities of the fetal heart rate pattern on a CTG are proposed as

being associated with cerebral palsy, the specificity of a CTG for prediction of cerebral palsy is low with reported false positive rates as high as 99.8% even in the presence of late decelerations and decreased variability(Nelson KB et al., 1996). This was however the best available device used for monitoring fetal heart in the setting in which the study was done.

Regardless of the limitations cited above, we demonstrated that the DUFHRM compares with a CTG in assessing the FHR in singleton pregnancies in labour significantly more accurately than a PFS. This would suggest that the DUFHRM would also be more accurate in detecting late decelerations and therefore be a preferable method of identifying mothers who need active fetal resuscitation and possible delivery intervention and neonatal resuscitation.

CHAPTER 8 CONCLUSION

This study documents that the DUFHRM is more accurate than the PFS in determining the FHR both before and after uterine contractions in low risk pregnancies in the active phase of the first stage of labour. The DUFHRM also gives an objective rate rather than relying on the midwife counting the FHR over a minute. The data provides strong evidence for the routine use of a DUFHRM rather than a PFS for monitoring the FHR during labour in low risk singleton pregnancies. This would apply in many district hospitals and most clinics where low risk pregnancies are managed in South Africa.

The additional cost of a DUFHRM when compared to cost of a PFS needs to be balanced against the more accurate measurement in FHR which forms the basis of assessing fetal wellbeing in labour. Improved intrapartum fetal monitoring promises to reduce the risk of fresh stillbirths and decrease both neonatal morbidity and mortality.

There is need for further research on comparing DUFHRM to CTG in the diagnosis of fetal distress if the DUFHRM is to realise the full potential of preventing severe fetal compromise. Further research will also need to assess

any difficulties that may come about with use of DUFHRM with CTG monitoring in progress.

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CHAPTER 10 APPENDICES

10.1 Informed consent form

Consent to Participate in a Research Study

Comparability of an innovative Doppler ultrasound fetal heart rate monitor to a Pinard fetal stethoscope using cardiotocography as a standard to assess the fetal heart rate in singleton pregnancies during labour at Mowbray Maternity Hospital

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Prof David Woods, University of Cape Town

HREC REF: 091/2012

INTRODUCTION

You are being asked to volunteer for the research study named above because you are or you will be in labour. Dr Lameck Chinula, a registrar in the department of obstetrics and gynaecology at the University of Cape Town, is in charge of the study supported by Prof Susan Fawcus, Prof David Woods and Dr Joy Lawn. Before you decide to be a part of this study we want you to know about the study.

This is a consent form. It gives you information about this study. The research staff will talk with you about this information. You are free to ask questions about this study at any time. If you agree to take part in this study, you will be asked to sign this consent form. You will be offered a copy of this consent form to keep.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to see whether your baby's heart rate, which is an indirect measure of your baby's wellbeing, can be accurately assessed

with a Doppler ultrasound fetal heart rate monitor or a Pinard stethoscope while using the cardiotocography as a standard testing tool.

In low resource settings, cardiotocography monitoring is unavailable and not affordable. Most monitoring of the fetal heart is thus done using a Pinard stethoscope. There are concerns that fetal heart monitoring using a Pinard stethoscope may not be as accurate as using the newly developed Doppler ultrasound fetal heart rate monitor. We would like to find out if the new monitor is more accurate than a Pinard stethoscope. (Potential participant will be shown all the three fetal heart rate monitoring tools mentioned here)

Information obtained in this study may help in recommending the more reliable method to use in monitoring FHR of women in labour in low resource setting.

WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?

If you decide to join this study, the research staff will ask you to sign a written informed consent form. While you are in labour and your baby is being monitored by a cardiotocograph, two research midwives will also

listen to the baby's heart rate using the two different devices. You will be subjected to the same management as any other pregnant woman in labour.

HOW MANY PEOPLE WILL PARTICIPATE IN THE STUDY?

A total of at least 75 pregnant women in labour at Mowbray Maternity Hospital will participate in this research study.

ARE THERE ANY REASONS WHY YOU CANNOT PARTICIPATE?

You cannot participate if:

You cannot give a written informed consent

You have decided at any point in the study to withdraw your participation

WILL YOU BE ASKED TO PAY OR BE PAID ANYTHING TO PARTICIPATE?

You will not be paid or asked for payment to participate in the study. No penalty will be charged by withdrawing or refusing participation in the study.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Apart from the discomfort of the pressure associated with the use of Pinard stethoscope and cardiotocograph, there are no additional risks associated with the use of the ultrasound monitor and Pinard stethoscope.

WHAT ARE THE POSSIBLE BENEFITS?

Your baby will be carefully monitored using three devices rather than just one device. You and others may benefit in future from what can be learnt in this study. You may also be satisfied for participating in this study and contributing to knowledge about the accuracy of the newly designed Doppler ultrasound fetal heart monitor

What if you have questions about this study?

If you have questions about the study, contact Dr Lameck Chinula on 0725796225 or Prof Susan Fawcus 0723354823 or Prof David Woods 0217865369

What if you have questions about your rights as a participant?

If you have questions about your rights as a study participant, contact the University of Cape Town, Faculty of Health Sciences Research Ethics Committee, E52 Room 24, Old Main Building, Groote Schuur Hospital, Observatory. Tel. 27214066338 Fax 27214066411

Comparability of an innovative Doppler ultrasound fetal heart rate monitor to a Pinard fetal stethoscope using cardiotocography as a standard to assess the fetal heart rate in singleton pregnancies during labour at Mowbray Maternity Hospital

SIGNATURES

If you have understood this information, and you have voluntarily agreed to participate in the study, please sign your name or put your mark below.

_____ _____ _____

Participant Name Participant Signature Date

(print)

_____ _____

Study Staff Conducting Study Staff Signature

Date Consent Discussion (print)

Participant is literate ☐ illiterate ☐

Witness name, signature and date are required on this form only when the consenting participant is illiterate/not able to read.

_____

Participant name (print)

_____ _____ _____

Witness Name Witness Signature Date

(PRINT)

10.2. Data Collection Sheet

Comparability of an innovative Doppler ultrasound fetal heart rate monitor to a Pinard fetal stethoscope using cardiotocography as a standard to assess the fetal heart rate in singleton pregnancies during labour at Mowbray Maternity Hospital

Question #	Question	Response
	SECTION 1: DEMOGRAPHICS AND SOCIAL HISTORY	
1.1	Participant folder number: ☐☐☐☐☐☐☐☐☐☐	
1.2	Date of birth (DD-MM-YY) ☐☐ - ☐☐ - ☐☐	
1.3	Gravida ☐☐	
1.4	Parity ☐☐	
1.5	Weight (kg) ☐☐☐	
1.6	Height (meters) ☐.☐☐	

1.7	Gestation age (weeks): *Enter on response 1 = early ultrasound (<24weeks), 2 = Late ultrasound (>24weeks, 3 = Last menstrual period (LMP), 4 = Booking symphysis fundal height* ☐☐☐	☐
1.8	Marital status: *Enter 1=Single, 2=married, 3=divorced, 4= widowed*	☐
1.9	Employment history: *Enter 1 = employed, 2 = unemployed, 3 = self- employmen*t	☐
	2. SUBSTANCE USE *Enter 1= Yes, 2 = No*	☐
2.1	Smoking	☐
2.2	Alcohol	☐
2.3	Other substances	☐
	3. MEDICAL HISTORY: *Enter 1=Yes or 2=No*	
3.1	Hypertension	☐
3.2	Diabetes mellitus	☐
3.3	Thyroid disease	☐
3.4	Cardiac disease	☐

3.5	Asthma	☐
3.6	Epilepsy	☐
	4. OBSTETRIC RISK FACTORS: *Enter 1=Yes or 2=No*	
4.1	Previous Caeserian section	☐
4.2	Gestational Hypertension	☐
4.3	Pre- eclampsia	☐
4.4	Chronic hypertension	☐
4.5	Postdate pregnancy/prolonged pregnancy	☐
4.6	Prolonged rupture of membranes (>24hours)	☐
4.6	Intrauterine growth restriction (IUGR)/small for gestational age (SGA)	☐
	5. LABOUR HISTORY: *Enter 1 = spontaneous, 2 = induced* *If 1, jump to Q#6, if 2 enter 1= Yes, 2=No for 5.1 – 5.6*	
5.1	Prolonged rupture of membrane	☐
5.2	Pre-eclampsia	☐
5.3	Gestational Hypertension	☐

5.4	Chronic hypertension	☐
5.5	Gestational diabetes (GDM)/Impaired Glucose Tolerance (IGT)	☐
5.6	IUGR/SGA	☐
5.7	Postdate pregnancy/Prolonged pregnancy	☐
5.8	Oligohydramnios	☐
	6. AUGMENTATION OF LABOUR: *Enter 1=Yes or 2=No*	
6.1	Artificial rupture of membranes	☐
6.2	Oxytocin use	☐
	7. FETAL HEART RATE MEASUREMENTS	
7.1a	Cervical dilatation at time of fetal heart rate (FHR) measurement (cm) ☐☐	
7.1b	Awaiting Caesarian section *Enter 1 = yes, 2 = No*	☐
	7.2a. FHR MEASUREMENTS BEFORE FIRST CONTRACTION: *Beats/min (bpm)*	
7.2a1	FHR with Cardiotocograph (at beginning of FHR measurement by PFS) ☐☐☐	

7.2a2	FHR with Doppler Ultrasound FHR monitor (DUFHRM) (at beginning of FHR measurement by PFS): ☐☐☐	
7.2a3	FHR with Pinard Fetal stethoscope (PFS) (taken in 60seconds): ☐☐☐	
7.2a4	FHR with Cardiotocograph (at the end of FHR measurement with PFS) ☐☐☐	
7.2a5	FHR with Doppler Ultrasound FHR monitor (DUFHRM) (at the end of FHR measurement by PFS): ☐☐☐	
7.2a6	FHR with Pinard Fetal stethoscope (PFS) (taken in 60seconds): enter same FHR as in 7.2a3 ☐☐☐	
	7.2b. FHR MEASUREMENTS AFTER FIRST CONTRACTION: *Beats/min (bpm)*	
7.2b1	FHR with Cardiotocograph (at beginning of FHR measurement by PFS) ☐☐☐	
7.2b2	FHR with Doppler Ultrasound FHR monitor (DUFHRM) (at beginning of FHR measurement by PFS): ☐☐☐	
7.2b3	FHR with Pinard Fetal stethoscope (PFS) (taken in 60seconds) : ☐☐☐	
7.2b4	FHR with Cardiotocograph (at the end of FHR measurement	

	with PFS) ☐☐☐	
7.2b5	FHR with Doppler Ultrasound FHR monitor (DUFHRM) (at the end of FHR measurement by PFS): ☐☐☐	
7.2b6	FHR with Pinard Fetal stethoscope (PFS) (taken in 60seconds): enter same FHR as in 7.2b3 ☐☐☐	
	7.2c. CTG FEATURES (NICE Guidelines as in table 1) at time of FHR MEASUREMENTS IN 7.2a AND 7.2b *Enter 1=reassuring, 2= non-reassuring, 3 = abnormal*	
7.2c1	Baseline Fetal heart rate (FHR)	☐
7.2c2	Variability	☐
7.2c3	Accelerations	☐
7.2c4	Decelerations	☐
7.2d	**CTG CATEGORY (NICE guidelines as in table 2)** *Enter 1 = Normal, 2 = suspicious, 3 = pathological*	☐
	7.2e. FHR MEASUREMENTS BEFORE SECOND CONTRACTION: *Beats/min (bpm)*	
7.2e1	FHR with Cardiotocograph (at beginning of FHR measurement by PFS) ☐☐☐	

7.2e2	FHR with Doppler Ultrasound FHR monitor (DUFHRM) (at beginning of FHR measurement by PFS): ☐☐☐	
7.2e3	FHR with Pinard Fetal stethoscope (PFS) (taken in 60seconds) : ☐☐☐	
7.2e4	FHR with Cardiotocograph (at the end of FHR measurement with PFS) ☐☐☐	
7.2e5	FHR with Doppler Ultrasound FHR monitor (DUFHRM) (at the end of FHR measurement by PFS): ☐☐☐	
7.2e6	FHR with Pinard Fetal stethoscope (PFS) (taken in 60seconds): enter same FHR as in 7.2e3 ☐☐☐	
	7.2f. FHR MEASUREMENTS AFTER SECOND CONTRACTION: *Beats/min (bpm)*	
7.2f1	FHR with Cardiotocograph (at beginning of FHR measurement by PFS) ☐☐☐	
7.2f2	FHR with Doppler Ultrasound FHR monitor (DUFHRM) (at beginning of FHR measurement by PFS): ☐☐☐	
7.2f3	FHR with Pinard Fetal stethoscope (PFS) (taken in 60seconds) : ☐☐☐	
7.2f4	FHR with Cardiotocograph (at the end of FHR measurement	

	with PFS) ☐☐☐	
7.2f5	FHR with Doppler Ultrasound FHR monitor (DUFHRM) (at the end of FHR measurement by PFS): ☐☐☐	
7.2f6	FHR with Pinard Fetal stethoscope (PFS) (taken in 60seconds): enter same FHR as in 7.2f3 ☐☐☐	
	7.2g. CTG FEATURES (NICE Guidelines as in table 1) at time of FHR MEASUREMENTS IN 7.2a AND 7.2b *Enter 1=reassuring, 2= non-reassuring, 3 = abnormal*	
7.2g1	Baseline Fetal heart rate (FHR)	☐
7.2g2	Variability	☐
7.2g3	Accelerations	☐
7.2g4	Decelerations	☐
7.2h	**CTG CATEGORY (NICE guidelines as in table 2)** *Enter 1 = Normal, 2 = suspicious, 3 = pathological*	☐
8	**Mode of delivery:** *Enter 1 = Normal vaginal delivery (NVD), 2 = Caeserian section, 3 = Vacuum extraction, 4 = Forceps delivery*	☐
	9. PREGNANCY OUTCOME	☐
9.1	Birth weight (grams) ☐☐☐☐	

9.2	Apgar score at 1 min: ☐☐	
9.3	Apgar score at 5 min: ☐☐	
9.4	Admission to neonatal care unit: *enter 1 = Yes, 2 = No*	☐
9.5	Neonatal resuscitation required*: enter 1 = Yes, 2 = No*	☐
9.6	Neonate alive on discharge from hospital: *enter 1 = Yes,* *2 = No*	☐
9.7	Indications for admission to neonatal care unit _____ _____	

Table 1: CTG Features (mark 1 = Reassuring, 2 = non-reassuring, 3 = abnormal)

Feature	**Baseline FHR(bpm)**	**Variability (bpm)**	**Decelerations**	**Accelerations**
Reassuring	110-160	≥ 5	None	Present
Non-reassuring	100-109 161-180	<5 for 40-90 minutes	Typical variable decelerations with over 50% of contractions, occurring for over 90 minutes Single prolonged deceleration for up to 3 minutes	The absence of accelerations with otherwise normal trace is of uncertain significance
Abnormal	<100 >180 Sinusoidal pattern ≥10min	<5 for 90 minutes	Either atypical variable decelerations with over 50% of contractions or late decelerations, both for over 30 minutes Single prolonged deceleration for more than 3 minutes	

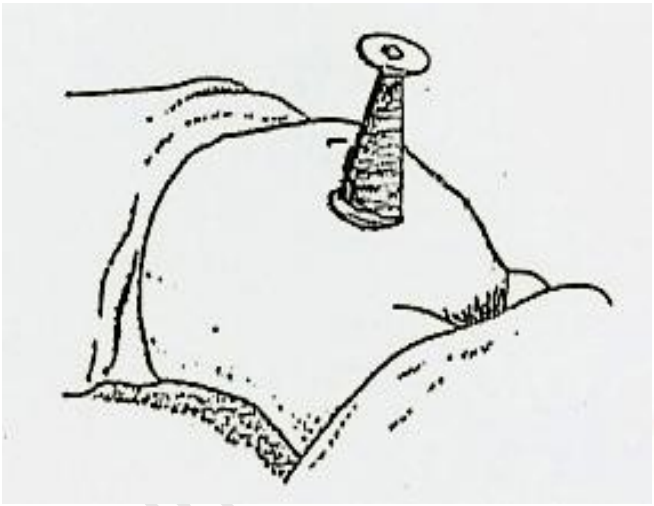
Table 2: Definition of Normal, Suspicious and Pathological CTG traces

Category	**Definition**
Normal	A FHR trace in which all four features are classified as reassuring
Suspicious	A FHR trace with one feature classified as non-reassuring and the remaining features classified as reassuring
Pathological	A FHR trace with two or more features classified as non-reassuring or one or more classified as abnormal

10.3 The three fetal heart rate monitoring devices

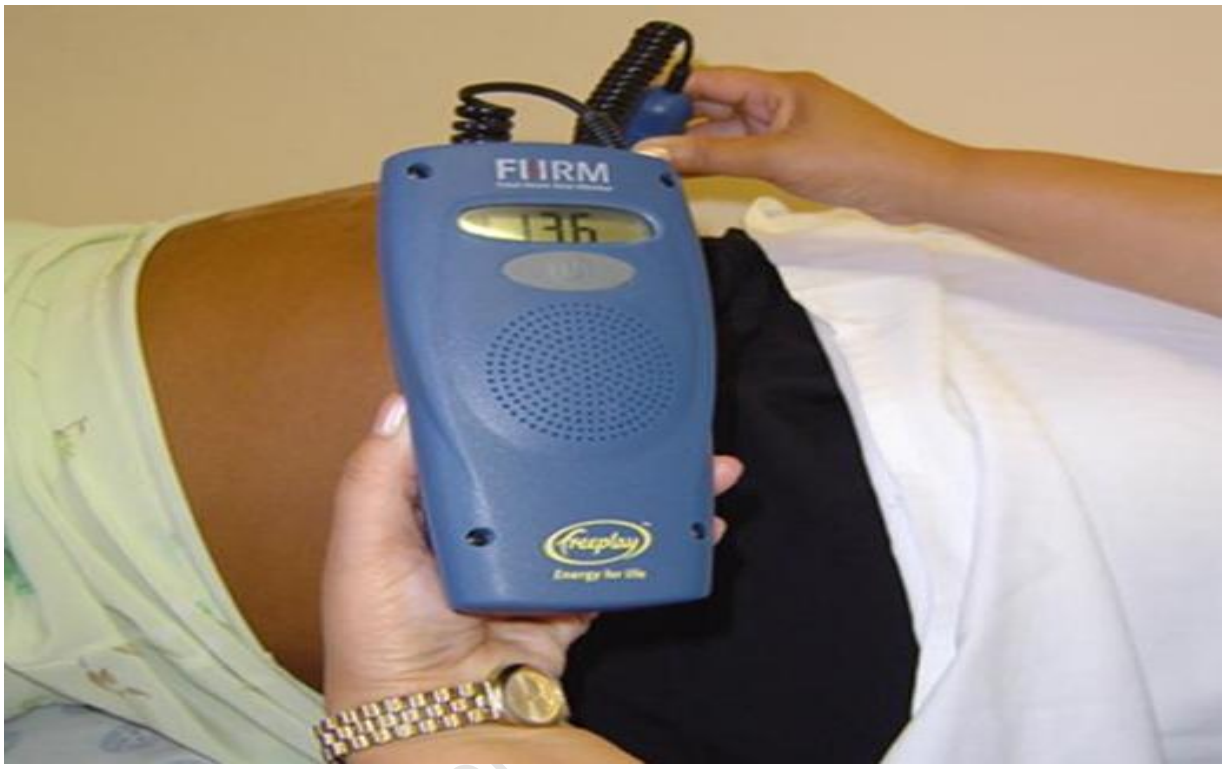
Comparability of an innovative Doppler ultrasound fetal heart rate monitor to a Pinard fetal stethoscope using a cardiotocography as a standard fetal heart rate monitor to assess the fetal heart rate pattern of singleton pregnancies during labour at Mowbray Maternity Hospital

A: Pinard Fetal stethoscope (PFS): cone shaped device used to measure fetal heart rate



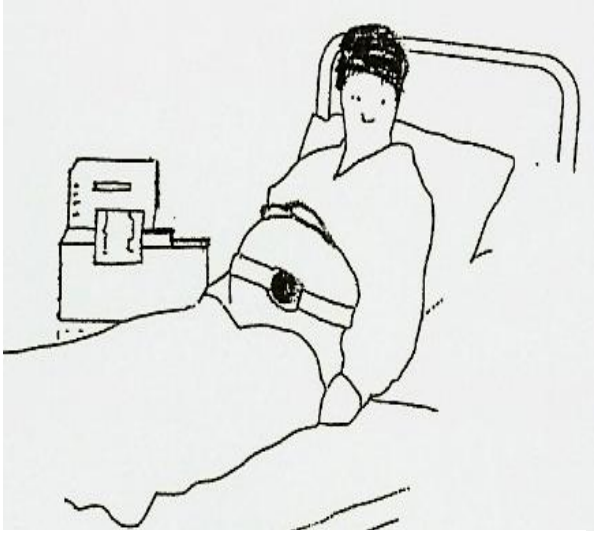
Courtesy of Power-free Education and Technology

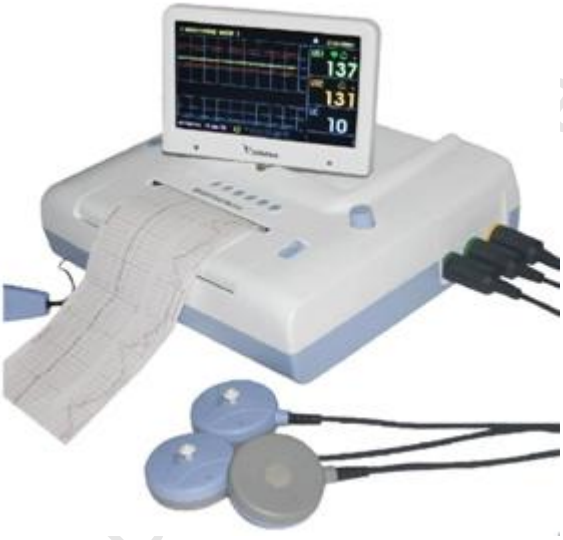
B: Doppler Ultrasound Fetal Heart Rate Monitor (DUFHRM): Portable electronic device that displays fetal heart rate



Courtesy of Power-free Education and Technology

C: Cardiotocograph (CTG): electronic device that provides a continuous visual and printed record of the fetal heart rate and uterine contractions





Courtesy of Power-free Education and Technology

10.4. The Standard operating procedures (SOP)

Comparability of an innovative Doppler ultrasound fetal heart rate monitor to a Pinard fetal stethoscope using cardiotocography as a standard to assess the fetal heart rate in singleton pregnancies during labour at Mowbray Maternity Hospital

SOP No. 1

Title: SOP for Eligibility Determination, recruitment and enrollment

Original Effective Date: 12 May 2012 **Revision Effective Date:** Not Applicable

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Purpose

To define eligibility determination procedures for the study

Scope

This procedure applies to all study staff

Responsibilities

The study staff who performs eligibility determination, recruitment and enrollment procedures, and measurements and documentation for the study is responsible for understanding and following this SOP.

Procedures

- **Eligibility criteria**

Inclusion criteria

a. Women with singleton pregnancies in the active phase of the first stage of labour undergoing continuous CTG monitoring

b. Women with singleton pregnancies in the active phase of the first stage of labour and awaiting an emergency caesarean section for any indications e.g. failure to progress, failed vaginal birth after caesarean section

c. Ability and willingness of participant to give written informed consent

Exclusion criteria

a. Women with multiple pregnancies

b. Women in labour with an intrauterine fetal death or not requiring monitoring as assessed by the attending doctor (e.g. in very preterm labour with a gestational age below 28 completed weeks, severe fetal anomalies)

c. Inability or unwillingness of participant to give written informed consent

d. Women who withdraw informed consent at any time during the study

e. Women requiring caesarean section for an indication that is so urgent that it cannot delay

- **Eligibility Determination / Screening**

1. Review potential study participant's folder on admission or in labour ward for eligibility determination.

2. Approach potential participant and determine ability and willingness to provide a written informed consent if meets other inclusion criteria.

3. Administer a written informed consent.

4. If consent obtained, document the participant's name and folder number on the name link log.

5. Proceed to completing the data collection sheet and organize the setting for FHR measurements using the three fetal heart rate monitoring devices.

- **Socio-demographic, medical and past medical history**

1. Social, demographic, medical history information data will be extracted from the participants' hospital files.

2. Where more information is needed on the above, the investigator will interview the participant to obtain the required information.

- **Measurements**

1. Identify area on the patient's abdomen where the FHR is easiest picked up by the observers with Pinard fetal stethoscope (PFS) and mark this area. Identify with the Innovative Doppler Ultrasound monitor with another area on the patient's abdomen, where the Innovative Doppler Ultrasound monitor (DUFHRM) can pick up the fetal heart rate and mark the point upon obtaining verbal consent from the patient.

2. Palpation for a contraction will then be done, once absence of contraction is confirmed, proceed as below:

   a. The observer with a PFS measures the FHR (i.e. counts the FHR for 60seconds)

b. The second observer notes the FHR on the DUFHRM at the start and at the end of the PFS measurement (i.e. at the start and at the end of the 60 second period). The third observer also notes the FHR on the CTG at the same time point (i.e. at the beginning of counting FHR with PFS and at the end of the PFS measurement).

c. To ensure that the measurements above are taken at the appropriate time, the observer using the PFS will signal to the other 2 observers when she starts counting the FHR and when she finishes counting.

d. The measurements in 2a, 2b and 2c will then be recorded on the data collection sheet.

3. A contraction will then be palpated again. 30 seconds after the palpable contraction ends, proceed as in 2a, 2b and 2c above and record the measurements on the data collection sheets.

4. Before the next contraction, proceed again as in 2 and 3 above. The observers using the PFS and DUFHRM will swap the devices at the measurements before and after the second contraction

- **Mode of delivery and Neonatal outcomes**

  Mode of delivery and neonatal outcomes will be extracted from the patient's file once this information becomes available

References of the SOP

Study Protocol

Approval

_____ _____

Lameck Chinula, MBBS Date

Principal Investigator