AN AUDIT OF CAESAREAN SECTIONS PERFORMED FOR SUSPECTED FETAL DISTRESS AT MOWBRAY MATERNITY HOSPITAL IN 2018

Dr. Badani Moreri-Ntshabele

(MRRBAD001)

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Supervisor

Prof. Sue Fawcus

Co-Supervisors

Dr K. Kadwa

Prof. G Petro

PLAGIARISM DECLARATION

I Badani Moreri-Ntshabele declare that document is my original work, unless where it has been otherwise acknowledged. This work has not been submitted to any other university for the purpose of obtaining a degree.

I authorize the University of Cape Town to use this report in part or in its entirety for the advancement of research.

Signed

Signed by candidate

Badani Moreri-Ntshabele

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LIST OF ABBREVIATIONS

AbCTG	Abnormal CTG
APH	Antepartum haemorrhage
CTG	Cardiotocograph
GDM	Gestational Diabetes Mellitus
CS	Caesarean Section
FSBS	Fetal scalp blood sampling
GA	Gestational age
IGT	Impaired glucose tolerance
IOL	Induction of labour
IUGR	Intra-uterine growth restriction
MBRRACE	Mothers and Babies Reducing Risk through Audits and Confidential Enquiries
MMH	Mowbray Maternity Hospital
MOU	Midwife obstetric unit
MSL	Meconium-stained liquor
NICE	National Institute for Health and Care Excellence
PET	Pre-eclampsia
PPH	Post-partum haemorrhage
PPROM	Preterm pre-labour rupture of membranes

ROM	Rupture of membranes
SB	Still birth

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ABSTRACT

Background

The cardiotocograph (CTG) is used for fetal monitoring antenatally and in labour, to detect potential fetal hypoxia and thus prevent perinatal morbidity and mortality. An abnormal CTG influences decisions clinicians make in terms of timing and mode of delivery, as the type of abnormality may warrant immediate delivery by caesarean section (CS). However caesarean section rates are increasing worldwide and in South Africa, and 'fetal distress' is one of the common indications. The increased CS rate also increases the risk of maternal morbidity and mortality. At Mowbray Maternity Hospital, weekly review meetings show that 'pathological CTG' and 'non reassuring CTG' accounted for the majority of emergency CS. Therefore, this study was undertaken to see if 'fetal distress' is being over-diagnosed leading to unnecessary CS, or to affirm that the CS are correctly indicated for this diagnosis. Hence an investigation of caesarean sections done for 'fetal distress in 2018 was performed in order to audit emergency CS performed at MMH for abnormal CTG tracings.

Methods

A retrospective observational study with a comparative component was performed. The PASS 2022 software was used to calculate the sample size. The calculation was made for proportions of agreement using a kappa statistic which was calculated to be 114 cases. The study population was derived from the institutional theatre register, in which patients, who had an emergency CS for an abnormal CTG or 'fetal distress', between 01 January 2018 and 31 March 2018 were included. The CTGs were interpreted by the two obstetric specialistts (experts) and this was compared with the original interpretation made by the attending doctor. In addition, the independent experts assessed the appropriateness of the decision for CS. Data was also obtained on co-existing obstetric conditions, and perinatal and maternal outcomes. Ethics approval for the study was attained from the University of Cape Town Human Research Ethics Committee (UCT HREC) and facility approval from MMH.

Results

Ninety cases were identified from the study period and analysed. The attending doctor assessed 22 (24.4%) CTGs as suspicious and 68 (75.6%) as pathological, whereas the

experts assessed 7 (7.8%) as normal, 22 (24.4%) as suspicious and 61 (67.8%) as pathological. There was overall agreement in CTG interpretation between the experts and the attendant doctor for 61 cases (67.8%). The reliability of this agreement was measured using Cohen's Kappa and was 0.247 (CI 0.153-0.341). This is a 'fair' level of agreement. A further analysis showed that there was a higher proportion of agreement with pathological CTGs and a lower proportion of agreement for suspicious CTGs which accounted for 52 (57.8%) and 9 (10%) cases, respectively. A review of the medical records showed that 69 (77%) of patients had one or more co-existing obstetric condition such as prolonged pregnancy, hypertensive disorders, prolonged rupture of membranes and meconium-stained liquor etc. When considering these obstetric factors as well as the CTG, the experts assessed 16 women (17.8%) to have had unnecessary caesarean sections. In terms of neonatal outcomes, the mean five-minute APGAR was 8, and only 3 babies had a five-minute APGAR which was less than 7. Twelve babies (13.3%) babies were admitted to the neonatal unit and of those, 4 (4.4%) were admitted for low Apgar scores. The commonest maternal complication was PPH which affected 8.9% of the patients.

Conclusion

The inter-observer agreement in CTG interpretation at MMH was fair, which is comparable to other studies done in the world, with agreement on the indication for CS of 82.2%. The agreement in CTG interpretation was high with pathological CTGs and poor with suspicious CTGs. A second opinion for CS for abnormal CTG may reduce the number of unnecessary CS especially for suspicious CTGs. A normal CTG tends to affirm good fetal wellbeing, however an abnormal CTG does not always mean that there is fetal compromise, therefore the clinical condition must be evaluated together with the CTG to make an appropriate decision with regards to timing and mode of delivery.

1. INTRODUCTION

The Cardiotocograph (CTG) is used in the management of patients in obstetrics as a tool to monitor fetal well-being and it assists in informing the decision to perform an emergency caesarean section (CS). The role of fetal monitoring during labour is to prevent fetal hypoxia and subsequent morbidity and mortality. Fetal hypoxia is a condition of impaired blood oxygen exchange, leading to acidaemia if it persists (1).

If the hypoxia persists it may lead to birth asphyxia, where there is evidence of cardiorespiratory and neurological depression and clinically this can be suspected when an Apgar score is less than 7 at 5 minutes and there evidence of acute hypoxia. (1). Fetal monitoring helps to identify fetal heart rate patterns which are associated with fetal hypoxia. Therefore, the CTG helps in informing the decision to perform a caesarean section or to perform an operative vaginal delivery, to avoid adverse outcomes associated with fetal hypoxia. Hence, the CTG is an important tool used in fetal assessment during labour, which is used together with the overall clinical assessment of a patient to detect possible fetal hypoxia.

There is a rise in the caesarean section rate worldwide and in South Africa, with suspected 'fetal distress' or acute fetal compromise being one of the most common indications, hence the interest in this indication for emergency caesarean section at MMH (Mowbray Maternity Hospital). 'Fetal distress' is an imprecise term commonly used in maternity facilities to denote concern about possible fetal hypoxia.

Mowbray Maternity Hospital is a level 2 referral hospital in Cape Town where women are referred for obstetric complications from Midwife Obstetric units (MOUs), namely False Bay, Gugulethu, Mitchells Plain, Hanover Park and Retreat and women who reside in the surrounding suburbs from Woodstock to Claremont are managed. It is therefore expected that the caesarean section rate at this hospital will be higher than the national average as high-risk pregnancies are managed here. At MMH, weekly review meetings show that 'pathological CTG' and 'non reassuring CTG' account for the majority of emergency CS, which have increased substantially over the last decade. Therefore, it is important to review

this indication for CS, in case ‘fetal distress’ is being over diagnosed thus leading to unnecessary CS; or to affirm that the CS are correctly indicated for this diagnosis. In addition, it will be of interest to determine whether the decision for CS was made solely from the CTG pattern seen or was due to the observation of an abnormal CTG pattern in combination with concurrent obstetric conditions such as prolonged pregnancy, antepartum haemorrhage or prolonged labour.

2 LITERATURE REVIEW

The caesarean section rates worldwide are increasing. According to Betran et al, data collected from 150 countries showed the average caesarean section rate (CSR) is 18.6% of all births(2). However, this study also showed that, from 121 countries, the trend analysis showed that between 1990 and 2014, the global average CSR increased from 6.7% to 19.1% with an average annual rate of increase of 4.4% (2).

The average caesarean section rate in South Africa has increased from 18.1% in 2000/2001 to 24.4% in 2008/2009 in public hospitals, according to a study done by Monticelli (3). Monticelli further showed that there is a large variation between the different types of hospitals with district hospitals having an average CSR of 17.2% compared to 40.7% for specialized maternity hospitals in 2008/2009 (3). Data from the District Health Information System (DHIS), described in recent Saving Mothers reports for South Africa show that the mean caesarean section rate between 2014 to 2016 was 25.7%, and then 27.4% in the year 2017 in the public sector (4). However, in the private sector the caesarean section rate for women was 73.6% in 2015 (5).

The World Health Organization (WHO) suggests that at a population level the CS rates should not exceed 10-15% (6). According to the "WHO statement on caesarean section", with increasing CS rates, maternal and neonatal mortality decreased up to a threshold of 10-15% and after that no further reduction was observed (6). However, they did conclude that it is difficult to determine the ideal caesarean section rate at hospital level, which could be higher than 10-15% for certain populations(6); and also if reduction of perinatal or maternal morbidity is considered in addition to mortality. In South Africa, a study done at Tygerberg hospital showed that between 1975 and 1994 the caesarean section rates remained at 13%, however, the perinatal mortality declined from 34.7/1000 in 1975 to 18.4/1000 in 1994 (7).This study demonstrated a decline in perinatal mortality with a constant caesarean section rate. However, it is important to note that the only outcome measured was mortality and it is not known if there was an increase or decrease in perinatal morbidity.

There is a recommended classification of CS indications by Robson which groups CS into ten mutually exclusive groups (8). In 2016 an audit of CS done at MMH from January 1st to

June 30th ,showed that a total of 4727 women were delivered with 47.7 % being caesarean delivery (9). When using the Robson Ten Group Classification System, this study showed that women from group 5 (all women with a singleton, cephalic, pregnancy equal to or greater than 37 weeks gestation with a previous CS or myomectomy) and group 1 (nulliparous women in spontaneous labour at term with cephalic presentation), were the two groups which contributed most to the caesarean section rate at 31.75% and 19.51% respectively (9). It will be difficult to reduce the CS rate in group 5 (repeat CS) but more possible to reduce the high number of primary caesarean sections in group 1 which are a group that should be low risk. Although the Robson's approach does not drill down to precise reasons for CS in group I, the MMH study suggested that a large proportion were done for suspected fetal distress (9).

Caesarean sections can be done for maternal or fetal reasons. An important fetal indication is what is loosely termed 'fetal distress'. It is important to clarify what is meant by the terms fetal distress, fetal hypoxia and birth asphyxia, as the terms can be used interchangeably and often incorrectly. The following paragraph aims to clarify this. According to Parer et al, Fetal distress is a commonly used term, however it is poorly defined (10). There are characteristic fetal heart rate patterns when there is fetal hypoxia and /or acidaemia secondary to inadequate fetal oxygenation which are used in making the diagnosis of fetal distress (10). These patterns are late decelerations, variable decelerations and prolonged bradycardia (10) and clinically the presence of meconium stained liquor raises concern for fetal distress (11). The term fetal hypoxia is more precise; it results from inadequate tissue oxygenation, and leads to anaerobic metabolism, which clinically is diagnosed with high lactate levels (12). The sequelae that we need to prevent from sustained fetal hypoxia is birth asphyxia. The clinical diagnosis of birth asphyxia is based on clinical and biochemical investigations, that is, evidence of cardiorespiratory and neurological depression (defined as an Apgar score remaining less than 7 at 5 minutes after birth) and evidence of acute hypoxic compromise with acidaemia (defined as an arterial blood pH of less than 7 or base excess greater than 12 mmol/L) (1).

The use of CTG in intrapartum monitoring, has been shown to have some benefit in improving perinatal outcome. According to Ayers-de-Campos et al, in a 2015 FIGO

consensus guideline, continuous CTG monitoring has been shown to decrease neonatal seizures, however there was no difference in the occurrence of cerebral palsy or neonatal mortality (13). However, it is important to note that the information was derived from studies done in the 1980s, 1990s and early 2000s, where equipment, clinical experience and interpretation criteria were different from current practice. A Cochrane review conducted in 2017 on "Continuous cardiotocography as a form of electronic fetal monitoring for fetal monitoring during labour," showed that compared with intermittent CTG, continuous CTG made no difference to how many women had caesarean sections or instrumental births, however when the former was compared to intermittent auscultation there was an increase in caesarean section rate and operative vaginal delivery. (14). This Cochrane review included 13 studies, with more than 37 000 women involved, which compared intermittent CTG with continuous CTG in different subgroups: high risk, low risk and unspecified risk. When comparing continuous CTG to intermittent CTG in the high risk, low risk and unspecified risk groups, the risk ratio for perinatal mortality was 1.04 (95% CI 0.62-1.74), 0.87(95% CI 0.29-2.58) and 0.68(95% CI 0.38-1.24) respectively (14). Also, when comparing continuous CTG to intermittent CTG the risk ratio for neonatal seizures in the high risk, low risk and unspecified risk groups was 0.67 (95% CI 0.36-1.24), 0.36(95% 0.16-0.79) and 0.18(95% CI 0.01-3.80) respectively (14). The review showed that continuous CTG was not protective against neonatal mortality in the high-risk group, but it was protective in the low-risk group and that it was protective against neonatal seizures in all the groups. In the high-risk group, mortality was high because of the underlying condition that determined the high risk, for example, antepartum haemorrhage. Alfirevic et al further explained that the evidence for continuous CTG monitoring compared to intermittent CTG monitoring in both high-risk and low-risk labours was scientifically inconclusive as continuous CTG monitoring resulted in reduced rates of neonatal seizures, but no clear differences in cerebral palsy, infant mortality or other standard measures of neonatal wellbeing (14). The Cochrane review shows that continuous CTG is not superior to intermittent CTG in reducing neonatal mortality and cerebral palsy, however it increases the rates of operative delivery, hence the former should be used in high-risk pregnancies only. FIGO consensus guideline further recommended that continuous CTG monitoring should be considered in all cases where there is a risk for fetal hypoxia, whether due to maternal reasons such as maternal pyrexia and haemorrhage, or

fetal reasons such as intra-uterine growth restriction and meconium stained liquor and that intermittent monitoring can be used in low-risk labour (13). Ayers de Campos further recommended that since several factors such as medication can affect fetal heart rate patterns, CTG interpretation has to be considered alongside the patients clinical condition in order to have an appropriate and comprehensive management plan (13).Therefore, there is a place for intermittent CTG monitoring which together with clinical assessment of a patient, can determine whether continuous CTG is indicated.

However, in low resource settings intermittent auscultation with doptone (hand-held portable ultrasound transducer) and pinard stethoscope are used to monitor fetal well-being in labour. There was a Cochrane review done by Martis R. et al which assessed intermittent auscultation in labour as a method of fetal assessment (15). The review included three trials with a total of 6421 mothers and 6421 babies. When comparing intermittent CTG with intermittent auscultation using Pinard stethoscope in one trial, the results showed that there was no difference in low Apgar score (defined as less than 6 at 5 minutes), with a Risk Ratio (RR) of 0.66 with 95% CI 0.24-1.83. However, there were no seizures in the neonatal period in the intermittent EFM (CTG) group (0/318) compared with nine in the routine Pinard group (9/315) (RR 0.05, 95% CI 0.00 to 0.89. The incidence of hypoxic ischaemic encephalopathy was lower in the intermittent EFM (CTG) group (2/318) compared to the routine Pinard group (10/315) (RR 0.20, 95% CI 0.04 to 0.90). In the same study, women allocated to monitoring with intermittent Doptone had higher rates of caesarean section for fetal distress compared with those allocated to routine Pinard (RR 2.71, 95% CI 1.64 to 4.48) (15). According to this review the Pinard stethoscope is inferior to the CTG and intermittent Doptone when looking at subsequent fetal morbidity, but monitoring does not need to be continuous, especially in low risk pregnancies(15). According to Ayres-de-Campos et al,CTG monitoring is important in the management of high risk pregnancies intrapartum, whereas in low risk pregnancies, it has been shown to increase the risk of caesarean delivery without an improvement in neonatal outcome (13).

There is a delicate balance between risks to the mother when she delivers by caesarean section versus the benefit of expected improved fetal outcome. In South Africa, the Saving

Mothers Confidential Enquiry report on maternal mortality in the triennium 2014-2016, showed that CS was associated with three times higher mortality than vaginal delivery, and raised concerns about the increasing numbers of deaths from bleeding associated with CS, which had become the most common cause of haemorrhage related mortality (16). This then raises the question, of what is the ideal caesarean section rate, balancing the need for improved neonatal outcome against the possibility of increased risk to mothers in terms of morbidity and mortality. One way of decreasing the rate of caesarean section due to fetal distress is by ensuring that there is correct interpretation of the CTG, to avoid unnecessary caesarean sections.

At MMH, the FIGO 2015 guidelines are used for interpretation of CTG and management thereof. These guidelines are widely used to standardise CTG interpretation, however there can be inter-observer differences. A study by Rei et al, which compared interpretation of 151 CTGs amongst clinicians, using the proportions of agreement (Pa), showed that a good inter-observer agreement was found overall and there was no difference between level of expertise. The results showed that, for baseline fetal heart rate, Pa was 0.85 (0.82–0.90), for variability 0.82 (0.78–0.85), for accelerations 0.72 (0.68–0.75), for tachysystole 0.77 [0.74–0.81], for decelerations 0.92 [0.90–0.95], for variable decelerations 0.62 [0.58–0.65], for late decelerations 0.63 (0.59–0.66), for repetitive decelerations 0.73 [0.69–0.78], and for prolonged decelerations 0.81 (0.77–0.85) (17). This shows that when using the FIGO guidelines it is possible to standardised care. This does, however, require ongoing training of labour ward staff.

The CTG is not without limitations. According to Ayres-de-Campos et al, suspicious and pathological CTG have a limited capacity to predict hypoxia and acidosis in the newborn (13). There is a large percentage of pathological or suspicious CTGs which do not have these poor outcomes.This is because a CTG has a significant sensitivity in the predicting hypoxia in labour, however, it is no specific in detecting acidosis(18). A prospective study, performed in Bangladesh at Dhaka Medical College Hospital, compared normal and abnormal CTGs with fetal outcomes. In the study 50 consecutive normal and abnormal CTGs were collected an hour before delivery. The study showed that the CTG was 87% sensitive and 66% specific in the prediction of abnormal outcomes with a positive

predictive value of 54% and negative predictive value of 92% (19). Therefore a normal CTG is more predictive of normal outcomes than an abnormal CTG is for predicting abnormal outcomes (19). However, it is important to note that the aim of monitoring is to identify situations that precede hypoxia and acidosis to avoid fetal injury.

Another way to determine if there is intrapartum hypoxia is by sampling fetal scalp blood to determine the pH and/or lactate. This test is not part of intrapartum care at MMH and in most hospitals in South Africa due to high HIV prevalence. However, studies have shown that it can decrease the number of caesarean sections done for fetal distress. Fetal scalp blood sampling (FSBS) was advocated as an 'additional test' of fetal wellbeing to reduce the false-positive rate of CTG according to Chandrahan (20). Chandrahan et al, explained that CTG has a high false positive rate of 60%, that means that 60% of fetuses diagnosed with fetal distress according to a pathological CTG, will not be hypoxic at birth. Therefore, the use of FSBS aims to identify the 60% fetuses that were not hypoxic from 40% of fetuses who were experiencing intrapartum hypoxia when the CTG was classified as 'pathological'. The aim is to avoid unnecessary operative interventions due to the false-positive rate of CTG (21).

According to Mahendru A et al, scalp pH <7.20 has a higher specificity to predict a low Apgar at 1 minute than a pathological CTG. Even so, with a pathological CTG and despite a normal fetal scalp blood pH, the risk of a low 1-minute Apgar is 30-50%. Therefore, the role of fetal scalp blood pH as a gold standard diagnostic technique is unproven; and the test has to be repeated at 30 mins intervals (22).

The interpretation of the CTG partially determines the action taken. FIGO guidelines recommend that, if a CTG is classified as "suspicious" a repeat assessment can be done in 30 minutes, whilst in the meantime a number of conservative measures can be taken to improve the situation, such as a change in position and infusion of intravenous fluids (23). If the CTG is classified as "pathological," then it should be continued, a full clinical assessment done, and if no improvement with conservative measures such as change in position, infusion, and tocolysis, the fetus should be delivered (23).

It is also important to consider whether the patient being monitored is low risk with no underlying condition that might predispose to fetal or maternal compromise. If so, a "suspicious" CTG can be observed and there is a place for intrapartum resuscitation. However, with high risk or complicated pregnancies such as intrauterine growth restriction (IUGR), hypertensive disorders of pregnancy and oligohydramnios, action may need to be taken earlier with a suspicious CTG.

Therefore, a decision for CS may be made solely on the grounds of a pathological CTG in an otherwise low risk pregnancy/labour or can be made due to an abnormal CTG (pathological or suspicious) concurrent with an obstetric complication e.g. prolonged pregnancy, IUGR, macrosomia, prior CS, APH, Pre-eclampsia, prolonged or obstructed labour, meconium in labour, meconium liquor, pyrexia in labour.

There was a study done by Aiyer et al which investigated the "Antenatal risk factors in emergency caesarean sections done for fetal distress," where a retrospective study was performed over a period of 25 months from May 2014 to May 2016 in a tertiary hospital in India. Hospital records of patients were retrieved for all patients who had emergency caesarean section, and they compared two groups; the cases were women who had caesarean section for fetal distress (these included, non-reassuring fetal status, fetal tachycardia, fetal bradycardia, and 'significant decelerations on CTG) and the controls were women who had emergency caesarean section for other indications, such as labour dystocia, deep transverse arrest, oligohydramnios, and malpresentation. The study showed that out of 669 emergency caesarean sections, 126 (18.83%) of these were due to fetal distress/ non-reassuring fetal status as denoted by the CTG, and 543 (81.17%) were for other indications. The obstetric records were reviewed to evaluate the risk factors. There were more primigravidae (61.11% vs 46.04%) in the fetal distress group (Odds Ratio 1.84, $p=0.003$). There was also a higher incidence of intra-uterine growth restriction (OR 5.44, $p<0.0001$) and antepartum haemorrhage mainly due to abruption (OR 11.19, $p <0.0001$) in this group. The study concluded that, the risk of a low APGAR was higher in the fetal distress group (12.59%) and that primiparity, intrauterine growth restriction, antepartum haemorrhage and prematurity, were shown to significantly increase the risk of emergency caesareans due to non-reassuring fetal status (24).

3 STUDY OBJECTIVES

Overall Study aim: to audit all emergency CS performed at MMH for abnormal CTG tracings.

3.1 Primary Objectives

1. To compare the assessment of the CTG tracing by two obstetric specialists (the PI and co-PI) with the initial CTG assessment by the attending doctor.

2. To document the occurrence of co-existing obstetric conditions that may have contributed to the decision for CS.

3. To compare the assessment of the decision for CS by the two specialists with the decision made by the attending doctor

3.2 Secondary objectives

To document neonatal outcome, specifically one and five minute Apgar scores, admission to ICU and mortality.

To document the occurrence of any maternal CS associated complications

4. METHODS

4.1 Study Design

The study performed was a retrospective observational study with a comparative component.

4.2 Study population

The cases were women who had caesarean sections performed at MMH during January to March 2018 for non-reassuring CTG, pathological CTG or fetal distress, according to the theatre register in which the indication for CS is documented.

4.3 Study setting

MMH is a level 2 referral hospital that offers obstetric and neonatal services. The staff comprises midwives, enrolled nurses, nursing assistants, medical interns, community service doctors, full time medical officers, registrars and full-time specialist obstetrician gynaecologists. Labour ward is managed by an on-call team which comprises of a registrar, medical officer and/or community service doctor and/or intern supervised by a specialist. The decision to perform a caesarean section can be made by the specialist on ward rounds, through telephonic consultation by the on-call team with the specialist on call, or by the registrar or the senior medical officer on call. The indication for the caesarean section is then recorded in the maternity case record, which then would be transcribed into the theatre register.

4.4 Study duration

The cases were caesarean sections done between 01 January 2018 and 31 March 2018.

4.5 Inclusion criteria

All emergency caesarean sections for pathological CTG, non-reassuring CTG and suspicious CTG were studied. Other criteria were gestational age from 28 weeks onwards, and singleton pregnancy.

4.6 Exclusion criteria

All elective caesarean sections, multiple pregnancies, gestational age below 28 weeks or those with missing maternity case record or CTGs were excluded from the study.

4.7 Data collection

The names and folder numbers of all cases of Caesarean sections performed at MMH during the first three months of 2018 for non-reassuring CTG, pathological CTG or fetal distress were obtained from the MMH theatre register where the indications for CS are documented.

The patient folders were retrieved, and basic demographic and obstetric data recorded on a purpose designed data collection sheet.

The PI and co-PI for this study are both obstetric specialists, who separately assessed the CTGs and categorised them as ‘normal’, ‘pathological/ abnormal’ or ‘suspicious / non-reassuring’ according to the criteria from the FIGO 2015 guidelines, which were used in 2018 for CTG interpretation at MMH. These two specialists (‘independent experts”) then assessed them together to get one consensus “expert opinion”.

The experts also commented on the appropriateness of the decision for CS, based on their assessment of the CTG and the associated obstetric factors.

Data was collected on newborn outcomes (one-minute and five-minute Apgar scores, admission to neonatal unit, or mortality). Data on maternal complications associated with CS was collected.

4.8 Statistical Methods

Baseline and demographic characteristics were summarized by standard descriptive summaries (e.g., means and standard deviations for continuous variables such as age, and percentages for categorical variables). Most data collected was expressed as frequencies. Statistical help was sought for correlation analysis of the CTG assessments by different observers.

4.9 Sample size

This was based on the need to achieve significance in correlating interpretation of overall CTG patterns. Interobserver agreement was measured using proportions of agreement (Pa). Then reliability was measured using a Kappa statistic, which was used to calculate the sample size. In practice, a kappa of 0.2–0.40 is regarded as a fair level of agreement, 0.41–0.60 as moderate, 0.61–0.80 as substantial and anything above 0·8 as excellent (25). The PASS 2022 software was used to calculate the sample size. This was based on the proportions of agreement using the kappa statistic. The result was a sample size of 114. The output generated by the software to calculate the sample size is on appendix 2.

Interpretation of Cohen's Kappa

When interpreting Cohen's Kappa, a value of 1 means perfect agreement and chance agreement equates to 0 (26). The table below demonstrates the commonly used scale in interpretation of Cohen's Kappa which has been adapted from Veira et al. (25).

Table 1 Interpretation of Cohen's Kappa

Kappa	Agreement
< 0	Less than chance agreement
0.01-0.20	Slight agreement
0.21-0.40	Fair agreement
0.41-0.60	Moderate agreement
0.61-0.80	Substantial agreement
0.81-0.99	Almost perfect agreement

In this study we wanted to demonstrate that kappa is better than 0·4 (so agreement is better than 'fair'). The hypothesis is that agreement is substantial, that is more than 0.60.

By using the PASS sample calculator based on an article by Flack VF et al (27), the following deductions have been made.

Table 2: Sample size calculation

	Sample size	**Kappa H0**	**Kappa H1**		**Rating categories**

Power	N	κ0	κ1	Alpha	Beta	k	Proportions
0.90030	114	0.40	0.60	0.15000	0.09970	3	0.20, 0.30, 0.50

In a test for agreement between two rates using the Kappa statistic, a sample size of 114 subjects achieves 90% power to detect a true Kappa value of 0.60 in a test of H0: Kappa = κ0, H1: Kappa ≠ κ0, when there are 3 categories with frequencies equal to 0.20, 0.30, and 0.50. This power calculation is based on a significance level of 0.15000.

MMH performs approximately 350 CS per month; of which 75% (262) are emergency; and 20% of emergency CS estimated to be done for abnormal CTGs; thus, it was anticipated that there would be 52 CS for abnormal CTG per month. Thus, collecting date for three months was thought adequate to achieve the sample size.

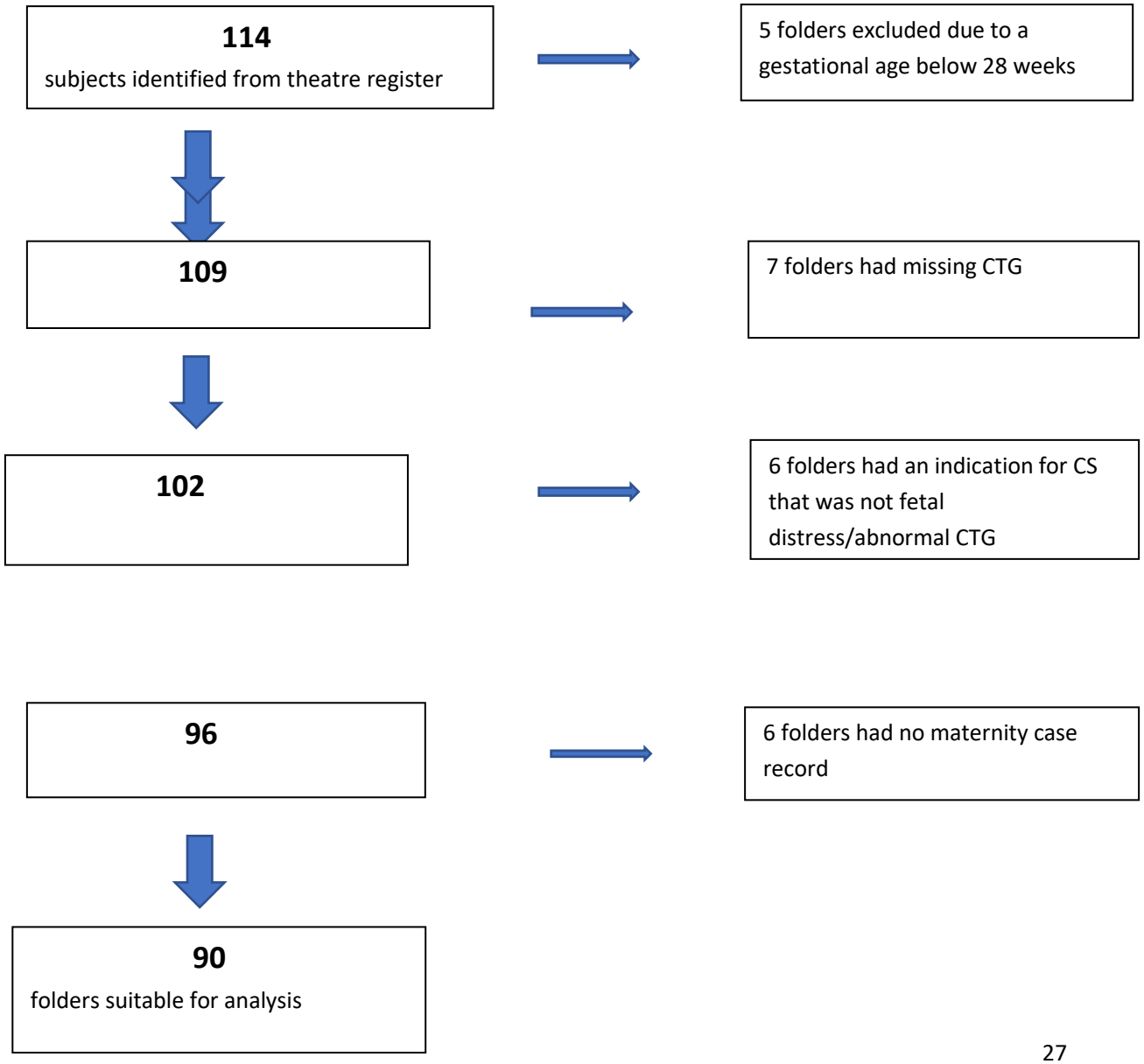
4.10 ETHICAL CONSIDERATIONS

Since this was a retrospective folder review, individual patient consent was not required. All data was anonymized and kept confidential and secure. Ethics approval for the study was attained from the University of Cape Town Human Research Ethics Committee (UCT HREC 122/2019) and facility permission obtained from MMH.

5 RESULTS

The theatre delivery register was used at MMH to collect folder numbers of patients who had delivered by caesarean section because of an abnormal CTG. The indications were recorded in the register as fetal distress, or abnormal CTG which included both pathological and suspicious CTG. Identified cases included those where the register specified an abnormal CTG / fetal distress only (e.g. 'CS for abnormal CTG') or in combination with another specified condition (e.g. CS for abnormal CTG and previous CS). The estimated sample size was 114 folders. A list of 114 folders from the register starting with deliveries on the 1st of January 2018 was made and the folders retrieved. Of these, 24 did not meet the inclusion criteria for reasons shown in Figure 1 and thus 90 folders were included in the study.

Figure 1. Identification of cases



5.1 PATIENT DEMOGRAPHICS

There were 90 cases analysed in the study. Demographic features are shown in Table 3. The mean age was 27 years with a range of 16 to 43 years. Most patients were primigravidae (41.1%). The median parity was 1 with a range from 0 to 4. Almost all (98.9%) were booked for antenatal care and their mean booking gestational age was 17 weeks. There were 15.6% of patients who were HIV positive and two of the patients screened positive for syphilis using the TPHA test, however the confirmatory RPR test was negative indicating that neither had active syphilis. The gestational age at Caesarean section ranged from 30 weeks and 4 days to 42 weeks and 2 days.

Table 3: Patient demographics (N=90)

Parameter	**N (%), Range**
Mean Age in years (range)	27 (16 to 43)
Median parity	1
Range of parity	0 to 4
Booked for antenatal care	89 (98.9%)
Mean gestational age at booking (weeks)	17
Number of women who booked before 20 weeks	55 (61.1%)

Range of booking gestation (weeks)	6 to 37
HIV positive	14 (15.6%)

5.2 DESCRIPTION OF OBSTETRIC FACTORS

Table 4: Previous obstetric history of the patients (N=90)

Previous obstetric problem	**N (%)**
Previous Pre-eclampsia	3 (3.3%)
One previous caesarean section	14 (15.5%)
Previous Stillbirth	4 (4.4%)
Previous preterm labour	6 (6.7%)
Nil (Multigravidae)	31 (34.4%)
N/A (Primigravidae)	37 (41.1%)
TOTAL	**90**

There were only 22 (24.4%) patients who had a complicated past obstetric history shown by Table 4. The commonest complication was a history of a previous caesarean section at 15.5%, followed by previous preterm labour at 6.7% and then previous stillbirth at 4.4%. Five patients had two prior obstetric complications. Out of the 14 patients with a prev ious caesarean delivery two patients had pre-eclampsia, one patient had a still birth and one patient a preterm delivery in their previous pregnancies. One patient had a previous preterm

delivery and she had a still born baby. Hence the total number of patients is 90. The remaining 68 (75.6%) patients were admitted to MMH labour ward due to antenatal complications in the index pregnancy or labour complications as demonstrated by Table 5 and Table 8.

The most common antenatal complications were prolonged pregnancy (16.7%), and hypertensive disorders (16.7%) which included pre-eclampsia, gestational hypertension, and chronic hypertension for 7.8%, 4.4% and 4.4% respectively. Forty-nine patients (54.4%) had no antenatal complications.

Table 5: Antenatal complications (N=90)

Antenatal complication	**N (%)**
Prolonged pregnancy	15 (16.7%)
Preterm labour	4 (4.4.%
Pre-eclampsia	7 (7.8%)
Gestational hypertension	4 (4.4.%)
Chronic hypertension	4 (4.4.%)
Polyhydramnios	1 (1.1%)
Oligohydramnios	2 (2.2%)
IUGR	4 (4.4.%)
APH	5 (5.6%)
Total number of antenatal complications	46 (51.1%)
Number of patients with more than one complication	5 (5.6%)

Number of patients with complications	41 (45.6%)
No antenatal complication	49 (54.4%)
Total	90

Table 6. Onset of labour and delivery details (N=90)

Gestational age at delivery	
Mean GA (weeks)	39
Range of GA at delivery (weeks)	30 + 4 days to 42 + 2 days
Labour onset	
Spontaneous labour prior to admission	49 (54.4%)
Spontaneous labour after admission	11 (12.2%)
Number of patients in active labour after IOL*	8 (50% of IOL)
Never laboured (CS before active labour)	22 (24.4%)
Total	90

** 16 had IOL, of which 8 went into active labour (Cervix fully effaced and 4 cms dilated)*

There were 49 (54.4%) women who had spontaneous labour, 16 (17.8 %) were induced but of these, only 8 (50%) went into labour. After administration of misoprostol half of the patients had abnormal fetal heart tracings before they were in active labour. Therefore, 22 patients (24.4%) had the emergency CS for CTG abnormality before the onset of active labour defined as a cervix fully effaced and 4cms dilated.

Table 7a: Indication for induction of labour (N=16) *

Indications	**N (%)**
Chronic hypertension	1 (6.3%)
Pre-eclampsia	5 (31.3%)
Prolonged pregnancy	7 (43.8%)
Prolonged rupture of membranes	7 (43.8%)
Decreased fetal movements at term	2 (12.5%)

***** *Some patients were induced for more than one indication.*

Table 7b: Method used for induction (N=16) *

Method	**N (%)**
Intracervical balloon catheter	8 (50%)
Oral Misoprostol	13 (81.3%)
Oxytocin infusion	2 (12.5%)
Artificial rupture of membranes	5 (31.3%)

**Most patients had more than one method*

A total of 16 patients underwent induction of labour. The two main indications for induction of labour were prolonged pregnancy and prolonged rupture of membranes at 43.8% each. The other indications were pre-eclampsia, decreased fetal movements at term and chronic hypertension at 31.3%, 12.5% and 6.3% respectively. Some patients were induced for more than one indication.

Misoprostol was used for most induced patients (81.3%). Other methods used were intra-cervical foley catheter, artificial rupture of membranes, and oxytocin at 50%, 31.3% and 2% respectively. Some patients were induced with more than one method.

Of the 16 who were induced, 8 went into active labour and 8 had a CS for a CTG abnormality before active labour (i.e. cervical dilation < 4cms with length)

In total, 68 women experienced labour (49 admitted already in labour, 11 went into labour during hospital stay after admission, and 8 progressed to labour after IOL). Labour complications are shown in Table 8.

Table 8: Labour Complications N=68

Labour complication	**N (%)**
Prolonged labour	5 (7.4%) *****
Maternal pyrexia (temperature > 37.5 °C in labour)	1 (1.5%)
Hyperstimulation	2 (2.9%)
Prolonged rupture of membranes	8 (11.8%)
Meconium-stained liquor	21 (30.8%) ******
Offensive liquor	1 (1.5%)
Total number of complications	38
Total number of women with complications	32 (47.1%) *******
No labour complication (other than CTG	36 (52.9%)

abnormality)	

***Prolonged first stage=1, prolonged second stage=1, CPD =3*

****msl grade 1=5, msl grade 2=12, msl grade 3=4*

*****6 women had more than 1 complication*

The most common labour complication was meconium stained liquor (MSL), which occurred in 21 women (30.8%) followed by prolonged rupture of membranes (more than 24 hours) in 11.8% and prolonged labour in 7.4%. The other complications included maternal pyrexia and offensive liquor at 1.5% each. There were 36 women (52.9%) with no labour complication, other than the CTG abnormality for which the CS was performed.

Table 9: Analgesia in labour (N=68)

Analgesic method	**N (%)**
Morphine	8 (11.8%)
Entonox	5 (7.4%)
Epidural	0
None	55 (80.1%)

Most women (80.1%) did not have analgesia in labour as shown in table 9. If analgesia was given it was mainly intramuscular morphine (11.8%).

5.3 ASSESSMENT OF CTGs

All patients, by case definition, had a CS for an abnormal CTG. This was detected before active labour in 22 (24.2%) and during labour in 68 (75.6%). Table 8 describes the CTG assessments performed by the attendant doctor and documented in the patient's folder.

Table 10: CTG assessment by attending doctor (N=90)

CTG assessment	**N (%)**
Suspicious	22 (24.4%)
Pathological	68 (75.6%)

The attending doctor interpreted 75.6% of the CTGs as pathological and 24.4% as suspicious as shown in table 10.

Table 11: CTG assessment by experts

CTG assessment	**N (%)**
Normal	7 (7.8%)
Suspicious	22 (24.4%)
Pathological	61 (67.8%)

The experts assessed 7.8% of CTGs to be normal, 24.4% as suspicious and 67.8% as pathological as shown in table 11. An analysis was performed to assess the proportion of agreement between the experts (seen as the 'gold standard') and the attendant doctors, with respect to CTG interpretation, see table 12.

Table 12 shows inter-observer agreement for the three different categories of CTGs. For pathological and suspicious CTGs there was agreement for 52 (57.8%) cases and 9 (10%) cases respectively. There was no agreement for normal CTGs as only CTGs categorised as

abnormal by the attending doctor were included in the study. There was agreement in overall interpretation for 61 cases (67.8%).

Table 12: Inter-observer agreement between the attending doctor and experts for CTG interpretation

		Attending doctor		**Total** (experts)
		Suspicious	Pathological	
Experts	Normal	4	3	7
	Suspicious	9	13	22
	Pathological	9	52	61
Total (attending doctor)		22	68	90

However, this figure is not corrected for agreement that could be due to chance especially because one variable was prevalent (pathological CTG). Cohen's Kappa was then used to determine agreement excluding that which was due to chance, as shown in Section 4.9 of the Methods.

Table 13: Determination of Cohen's Kappa Symmetric Measures for assessment of agreement on CTG interpretation

	Value	**Asymptotic Standard Error**	**Approximate T[b]**	**Approximate Significance**
Measure of Agreement Kappa	**0.247**	**0.094**	**2.728**	**0.006**
N of Valid Cases	**90**			

Table 13 shows the calculated value of Cohen's Kappa. Reliability was measured using a Kappa statistic, which is 0.247 (CI 0.153-0.341). This finding is statistically significant as

the P value is less than 0.05 (as noted above the approximate significance is 0.006). A kappa of 0.2–0.40 is regarded as a 'fair' level of agreement**.**

5.4 ASSESSMENT OF CO-EXISTING OBSTETRIC CONDITIONS IN RELATION TO CTG ASSESSMENTS BY EXPERTS.

The experts assessed 7 (7.8%) CTGs as normal, 22 (24.4%) as suspicious and 61 (67.8%) as pathological. Table 14 below shows how each category was assessed in relation to co-existing obstetric conditions These co-existing obstetric conditions were not mutually exclusive with several women having more than one condition as demonstrated in table 14. For the 7 women with normal CTGs 3 patients had co-existing obstetric conditions (prolonged rupture of membranes and MSL); with no co-existing conditions identified in 4 women.

Table 14: CTG classification by experts and co-existing obstetric conditions*

Co-existing obstetric condition	Normal N=7	Suspicious N=22	Pathological N=61	TOTAL N=90
Previous CS	2 (28.6%)	2 (9.1%)	10 (16.4%)	14 (15.6%)
Previous SB	0	1 (4.5%)	3 (4.9%)	4 (4.4%)
IUGR	0	1 (4.5%)	3 (4.9%)	4 (4.4%)
Oligohydramnios	0	0	2 (3.3%)	2 (2.2%)
Prolonged pregnancy	0	6 (27.3%)	9 (14.8%)	15 (16.6%)
APH	1 (14.3%)	1 (4.5%)	3 (4.9%)	5 (5.6%)
GH, PET,	1 (14.3%)	1 (4.5%)	9 (14.8%)	11 (12.2%)
CH HYP	0	0	4 (6.6%)	4 (4.4%)
Prolonged ROM	2 (28.6%)	1 (4.5%)	5 (8.2%)	8 (8.9%)
Decreased fetal movements	0	2 (9.1%)	0	2 (1.1%)

Hyperstimulation	0	1 (4.5%)	1 (1.6%)	2 (2.2%)
Prolonged labour / CPD**	0	1(4.5%)	3 (4.9%)	5 (5.6%)
Delayed second stage	0	0	1 (1.6%)	1 (1.1%)
MSL	2 (28.6%)	5 (22.7%)	14 (23.0%)	21 (23.3%)
Maternal pyrexia	0	0	1 (1.6%)	1 (1.1%)
Offensive liquor	0	1 (4.5%)	0	1 (1.1%)
Preterm labour	0	0	4 (6.6%)	4 (4.4%)
No factor identified	4 (57.1%)	7 (31.8%)	10 (16.4%)	21 (23.3%)

**Some women had ≥ one co-existing condition; ** 4 had oxytocin augmentation (2 in susp + 2 in path group).*

For women with suspicious CTGs, the most common co-existing conditions were prolonged pregnancy, MSL, and prolonged labour present in 6 (27.3%), 5 (22.7%), 4 (18.2%) cases respectively. There were women 7 (31.8%) with no co-existing condition.

For women with pathological CTGs, a co-existing condition was present in 51 (83.6%). The main co-existing conditions were meconium-stained liquor, followed by previous CS, prolonged pregnancy and hypertensive disorder of pregnancy (gestational hypertension plus Pre-eclampsia) with 14 (23.0%), 10 (16.4%), 9 (14.8%) and 9(14.8%) respectively.

Sixteen women were induced. The majority of these women, developed a pathological CTG, and five had suspicious CTG. Of those women whose labour was augmented, half had suspicious CTGs and the other half had pathological CTGs.

5.5 ASSESSMENT OF DECISION FOR CAESAREAN SECTION

Table 15: Status of Doctor who made Decision for caesarean section

Doctor status	**N (%)**
Specialist	16 (17.8%)
Registrar	54 (60.0%)
Medical officer	20 (22.2%)

The decision for caesarean section as documented in patient folders was made in consultation with the specialist in a ward round or through telephone consultation for 17.8%; and by the registrar and medical officers for 60% and 22.2% of patients respectively (Table 14).

From the documented indications in the patient record and theatre register, it appears that most caesarean sections were done solely for an abnormal CTG (84.4%), as shown in table 16.

Table 16. Indication for CS by attending doctor as documented in the clinical record. (N=90)

Indication for CS	**N (%)**
Abnormal CTG (AbCTG) only	76 (84.4%)
AbCTG plus Uncontrolled BP	1 (1.1%)
AbCTG plus Failure to progress	3 (3.3%)
AbCTG plus Meconium-stained liquor grade 3	3 (3.3%)
AbCTG plus CPD	4 (4.4%)
AbCTG plus Failed induction of labour	1 (1.1%)
AbCTG plus APH	1 (1.1%)
AbCTG plus Previous CS with impending rupture	1 (1.1%)

The decision for CS was assessed to be appropriate by the independent experts in 82.2%, but not for 17.8% (table 17). For the latter group, the experts thought that the patients could

have been monitored for longer (suspicious CTG only) or have routine management (normal CTGs), see Table 18.

Table 17. Assessment for decision for CS by expert (N=90)

Assessment of decision for CS	N (%)
Decision appropriate for CS	74 (82.2%)
Not appropriate for CS	16 (17.8%)

The experts interpreted 7 CTGs as normal, but in three of these they assessed the decision for CS was appropriate because of the clinical condition. Two patients were in labour; one with severe pre-eclampsia and the second with poor progress of labour. The third patient had prolonged rupture of membranes and a significant antepartum haemorrhage prior to labour. For the remaining 4 with normal CTGs, the experts assessed the indication for CS to be inappropriate.

Table 18: Analysis made by experts on appropriateness of caesarean section according to their CTG classification (N=90)

Decision for CTG	**N (%)**
Normal CTG	7 (7.8%)
Appropriate decision for CS	3 (42.9%)
Inappropriate decision for CS	4 (57.1%)
Suspicious CTG	22 (24.4%)
Appropriate decision for CS	10 (45.5%)
Inappropriate decision for CS	12 (54.5%)
Pathological CTG	61 (67.8%)
Appropriate decision for CS	61 (100%)
Inappropriate decision for CS	0

The experts assessed 10 patients with a suspicious CTG to have had an appropriate decision for CS, because of co-existing obstetric indications. Three (13.6%) patients had prolonged rupture of membranes, three (13.6%) patients had prolonged pregnancies, two (9.1%) had prolonged labour and two (9.1%) patients had IUGR. The decision for CS was deemed inappropriate for 12 (54.5%) patients with suspicious CTG as there was not enough clinical reason for expedited delivery. For example, for two patients the CTG tracing was too short, one patient's CTG had improved by the time she had the caesarean section and for one patient there was only one variable deceleration in the entire tracing. There was no co-existing condition factor identified for 7 (31.8%) patients who had suspicious CTG. Caesarean section was appropriate for all patients with pathological CTGs. Co-existing obstetric conditions occurred for 51 (83.6%) of this group as shown in Table 12. The commonest co-existing condition in this group was meconium-stained liquor, hypertensive disorder, prolonged rupture of membranes and previous CS. There were 11 patients (18.0%) who had been induced.

5.6 NEONATAL AND MATERNAL OUTCOMES

Neonatal outcomes

Table 19 shows the neonatal outcomes. The mean gestational age of the patients was 38 weeks and 3 days with a range of 30 weeks 4 days to 42 and 2days days which correlates with the birth weights of the neonates. The average birthweight was 3091g with a range of 1240g to 4300g. The average 1-minute Apgar was 8, with a range of 1 to 10. The average 5-minute Apgar was 9 with a range of 5 to 10.

Table 19 Neonatal outcomes (N=90)

Neonatal parameter	
Average birthweight (gms)	3091

Range (gms)		1240 - 4300
APGAR scores		
1 minute Apgar	Mean	8
	Mode	9
	Range	1-10
5-minute Apgar	Mean	9
	Mode	10
	Range	5-10
	Apgar < 7	3 (3.3%)

All babies born were immediately assessed in theatre by a doctor from the paediatric department. Only three babies (3.3%) had 5-minute Apgars less than seven. There were 78 babies assessed to be well and therefore, allowed to accompany their mothers to the postnatal ward. Twelve (13.3%) were admitted to the neonatal unit, for reasons shown in Table 20. There were no still births and no mortality within the first 24 hours.

Table 20: Neonatal Outcomes per CTG category (CTG interpreted by experts)

Type of CTG	Number of cases	Admission to NICU
Normal	7	0
Suspicious	22	0
Pathological	61	12 (19.7%) *

**prematurity = 6, Low Apgar = 4, Not clearly documented, however the Apgar scores were low = 2*

Characteristics of patients whose babies were admitted for prematurity

There were 6 babies who were admitted to the neonatal unit for prematurity. The minimum gestational age was 32 weeks and 1 day and the maximum was 36 weeks and 3 days. The range of birth weights was from 1240g to 1980g.

Characteristics of patients whose babies were admitted for low Apgar scores

Low Apgar score was clearly documented in the maternal records as the reason for admission for four neonates. The reason for admission was not documented for the other two neonates, it was documented that babies were immediately transferred to NNU. Both neonates had 5-minute Apgars which were more than 7, they were delivered at term with a normal birth weights. Three neonates from the total of four admitted for 'low apgars,' had 5-minute Apgars which were less than 7 as noted in table 19. One neonate had a low 1-minute Apgar and a normal 5-minute Apgar but was admitted to NNU, nonetheless. All patients booked between 7 to 20 weeks. Three (75%) patients were HIV positive. In terms of previous obstetric history, 1 (25%) patient had previous pre-eclampsia and 1 (25%) patient had a caesarean section in a previous pregnancy. In the index pregnancies, 2 (50%) patients had pre-eclampsia, 1 (25%) patient had gestational hypertension, 1 (16.7%) patient had prolonged pregnancy and 1 (25%) patient had preterm labour at 32 weeks. Some patients had more than one co-existing obstetric or medical conditions. The diagnosis prior to delivery made by the attending doctor was suspicious CTG for 1 patient (25%) and pathological for 3 patients (75%). The experts analysed all the 4 CTGs as pathological and deemed all caesarean sections to be appropriate for this group of neonates.

5.7 MATERNAL OUTCOMES

Maternal outcomes are illustrated in the table 21. The most common morbidity was post-partum haemorrhage. Eight (8.9%) patients had estimated blood loss of 1000ml or more. Puerperal sepsis was the second commonest complication which affected four patients (4.4%) who all responded well to antibiotic treatment.

Table 21: Maternal outcomes (N=90)

Maternal outcome	**Finding or N (%)**
Mean blood lost (ml)	267 (range 150 – 2000)
PPH (>=1000 mls)	8 (8.9%)
Blood transfusion	2 (2.2%)
Treatment for sepsis	4 (4.4%)

Investigation for injury to ureter	2 (2.2%), *no injury found*
HELLP syndrome /Referral to Groote Schuur Hospital	1 (1.1%)
Renal impairment with Pre-eclampsia	1 (1.1%)
Hospital stay	
Average hospital stay post caesarean section (days)	4
Range of hospital stay (days)	3- 11

Two women required blood transfusion following PPH, and two patients had investigations for ureteric injury as they had had difficult surgery, however the results showed there was no injury. The usual hospital stay post caesarean section post caesarean section is 3 days. The average hospital stay in this study was 4 days, with a range of 3 to 11 days, with 68 (75.6%) patients being discharged on day 3. Out of the remaining 22 (24.4%), the commonest reason for a prolonged hospital stay was treatment for sepsis for 4 patients, which was followed by 3 patients who were waiting for their babies to be discharged. Other reasons included patients who were awaiting results following intervention such as blood transfusion, to see improvement of renal function in patients with pre-eclampsia, or to see results of intra-venous pyelogram to rule out ureteric injury. All the results showed that the patients did not require further intervention and they were discharged home. None of the patients required a hysterectomy and there were no maternal deaths.

6 DISCUSSION

Ninety women undergoing emergency CS for abnormal CTGs were assessed. The independent experts' assessment of the CTGs gave a fair correlation with that of the attendant doctor, and this was significant. The experts assessed the decision for CS to be appropriate for 82.2% of the cases. Of note, many of the women (77 %) had one or more co-existing obstetric conditions which are likely to have influenced the decision to perform CS. This contrasts with the attendant doctors' entries in the files where they documented 84.4%

of CS being performed on the basis of the CTG alone. There were no major neonatal or maternal adverse outcomes.

Timing of caesarean sections

Most women (75.6%) in the study had intrapartum CS. Two-thirds of the women (66.6%) had spontaneous labour, whereas 8 (8.9%) women were in labour after induction. A significant number of women, 22 (24.4%) had CS prior to labour. These findings are comparable to the results by Khanum et al (28), where an analysis of 260 women who underwent emergency CS for fetal distress was done in a tertiary hospital, which showed that almost half (48%) of the women presented with spontaneous onset of labour. More women (43%) had induction of labour in that study as compared to our MMH study where only 17.8% were induced. Also, the Khanum study had 8.8% with CS before labour which is much less than the 24.4% in our MMH study. Although almost half of the patients were induced in the study by Khanum et al, this may not have been possible at MMH because 15.5% of patients had previous caesarean delivery and thus were not candidates for induction of labour and some women had an admission CTGs which was abnormal hence induction was contra-indicated.

Comparison of CTG interpretation between the experts and the attendant doctor.

The attending doctor assessed 22 (24.4%) CTGs as suspicious and 68 (75.6%) as pathological. The documented decision for caesarean section was based on CTG alone for 76 (84.4%) patients and for 24 (26.6%) of the patients there was abnormal CTG and another medical condition as indications for the CS. However, analysis of the medical records by the researcher showed that co-existing obstetric conditions were found in 69 (77%) women. The attendant doctor may have recognised the risk factors, but not documented it under the indication for CS. Co-existing obstetric factors were not present in almost a quarter of the cases (23.3%). This differs from results of a study of 270 women who had caesarean section for fetal distress at SZ Hospital and Gandhi Medical college in India, which showed that

there was no underlying obstetric condition contributing to fetal distress for 16 cases (5.9%), which is much less compared to our study (29). This could be because, admission CTG is done for significant number of patients at MMH, which may increase the number of emergency CS. Other research suggests that performing routine admission CTG can increase the caesarean section rate by up to 20% even in low risk women (30).

The proportion of agreement between the attendant doctor and the experts, in interpretation of the CTGs was 67.8%. In other words, there was agreement in interpretation of 61 cases from a total of 90. Similar findings were obtained by Rei et al where the overall proportion of agreement on interpretation of 151 CTG's by six clinicians was 0.60 (CI 0.56-0.64)(17).

However, the agreement was higher for pathological CTGs with 52 cases (85.2%) where the denominator is 61 cases (since the gold standard is CTG interpretation by experts). Similar findings were reported in Rei et al, where agreement was higher for pathological CTGs. this could be because pathological CTGs are easier to recognise as the abnormalities are more obvious. A similar study on inter-observer interpretation CTG using proportion of agreement as the measure, showed that agreement was good (Pa 71.5%, 95% CI 67.5-75.2) for normal CTGs, moderate (Pa 57.4%, 95% CI 51.3-63.5) for pathological CTGs and poor (Pa 36.4%, 95% CI 30.9-41.9) for suspicious CTGs (31).

Reliability was measured using a Kappa statistic, to assess whether the interobserver agreement was not due to chance. For overall CTG interpretation the proportion of agreement was 67.8% with a Kappa of 0.247 (CI 0.153-0.341) and it was statistically significant. According to Veira et la, Kappa of 0.21 to 0.40 shows a fair agreement, whereas a Kappa of 1 shows perfect agreement and a Kappa of 0 shows agreement only due to chance (26). Another study of interobserver agreement in CTG interpretation of 105 CTG showed an overall agreement of 60% with a kappa of 0.39 (0.33-0.45) (17). This is comparable to our study as it also showed a fair level of agreement

A second opinion may reduce caesarean section rate for fetal distress. An evaluation by experts in our study showed that 16 (17.8%) caesarean sections were done inappropriately. Having a second opinion could be even more helpful for CTGs which are interpreted as

suspicious as the inter-observer agreement for this group has been shown to be poor. Althabe et al suggest that, in hospitals that apply the second opinion rule before performing an emergency caesarean section, 20 caesarean sections could be prevented for every 1000 caesarean sections (32). The WHO also recommends mandatory second opinion from a senior clinicians to reduce unnecessary caesarean sections (33). At MMH, the specialist was documented to have been involved in the decision for CS in only17.8%, indicating an area for improvement. However, it is possible that consultation with a specialist could have been made without it being documented.

According to MBRRACE-UK perinatal mortality surveillance report of 2017, one of the recommendations for reducing perinatal morbidity and mortality is by focusing on assessment of fetal growth and intrapartum fetal monitoring (34). However, the high number (77%) of co-existing obstetric conditions in this study illustrates the importance of CTG interpretation in the clinical context and the need for situational awareness. Early identification and appropriate management of these co-existing conditions may reduce operative deliveries due to fetal distress (24). The most common co-existing obstetric conditions in our study were previous CS, prolonged pregnancy, prolonged rupture of membranes, hypertensive disorders of pregnancy and meconium-stained liquor. These are all conditions which require referral from primary maternity units to hospital in Metro West and are indications for continuous CTG monitoring.

Neonatal outcomes

Only 4 (4.4%) neonates required admission to the neonatal unit for low Apgar. This illustrates the poor predictive value of the CTG and raises the question as to whether other tests of fetal wellbeing such as fetal blood sample should be considered? Alternatively, it could be argued that MMH is timeously delivering babies who would have developed hypoxia?

Most of the neonates (86.7%) assessed by doctors from paediatrics immediately post-partum were assessed as normal and therefore joined their mothers in the postnatal ward. Twelve (13.3%) babies were admitted to the neonatal unit; of these 6 (6.7%) were admitted for

prematurity and 4(4.4%) were admitted for low Apgars. All of these neonates are from the pathological CTG group. Forty-nine neonates (80.3%) of the neonates from the pathological CTG group were well and joined their mothers post-delivery. All babies from the normal CTG group had a normal 5-minute Apgars and only one baby from the suspicious CTG group had a 5-minute Apgar less than 7. However, that baby responded to basic resuscitation and did not require admission to the neonatal unit. This suggests that there is a low correlation between the suspicious CTGs abnormality and fetal outcome, but better for pathological ones. This is also demonstrated by other researchers that show there is significant correlation between pathological CTG and fetal condition at birth (35,36). In a study by Gangwar et al, 146 caesarean sections were done for fetal distress in a referral hospital in India and it reported that 21(14.4%) babies had a 5 minute Apgar less than 7 and were subsequently admitted to NICU (37). Although our total admissions are comparable to the ones in this study, admissions due to low Apgars are lower at MMH. This shows that CTG has low specificity as to abnormal fetal outcome (38).It is important to assess the level of risk to determine the type of monitoring that would be required intrapartum. Low risk women can have intermittent monitoring and high risk women should be monitored using the CTG. Where fetal hypoxia is suspected on the basis of an abnormal CTG fetal scalp blood gas should be sampled to determine if there is acidosis or not, which will inform the mode and timing of delivery. (39). This would have been very useful in this study as a way of correlating newborn outcome with CTG findings. At MMH, although the surgeon routinely takes a loop of cord blood at CS, due to shortage of resources, blood gas examination is only actually performed when the baby has low 5 minute Apgar and/or is admitted to the Neonatal unit. This means that the majority of neonates in this case series would not have had cord blood gas analysis. For the 12 admitted to the neonatal unit, it would have been done but was not recorded in the maternal record or in the data collection sheet for this study. As described later, this is a limitation of the study.

Another procedure that has been coupled with CTG monitoring is fetal blood sampling (FBS) to reduce the rate of caesarean sections for fetal distress. FBS provides more accurate information on fetal metabolic reserve in addition to CTG and can aid in decision making on urgency of operative delivery and type of anaesthesia to be used for CS (40). According to

Visser et al, the CS rate is high when CTG monitoring is done without FBS (41). A trial which compared CTG with and without FBS showed that the caesarean delivery rates were 11% and 18% respectively, however this difference was not statistically significant (41). Furthermore, a Cochrane review done in 2013 based on seven trials which compared CTG with intermittent auscultation showed that where FBS was an adjunct to CTG compared to CTG only that relative risk of caesarean delivery was 1.34 and 1.63 respectively (41). A multicentre study showed that the negative predictive value of FBS for the occurrence of arterial cord pH less than 7.15 was 89%, with a specificity of 89% but the positive predictive value was 40% (42). This means it is useful when the pH is normal to identify fetuses which do not require immediate delivery; however, a positive test does not always mean that there is fetal hypoxia.

There are some disadvantages in using FBS. The procedure is invasive, repeated sampling may need to be done to get sufficient volumes and it may cause prolonged bleeding, haematoma or abscess at the incision point (41,43). The procedure is contraindicated in conditions where infections such as HIV and Herpes can be transmitted to the baby or where coagulation disorders are suspected in the fetus(43). Fetal blood sampling is currently not performed at MMH, due to the high HIV prevalence.

In South Africa, the Perinatal Problem Identification Programme (PPIP) was designed to audit perinatal deaths at facility level, in order to improve maternal and perinatal care(44). According to Rhoda et al, in 2016, the main causes of neonatal deaths were complications of prematurity (47.9%), intrapartum related events, mainly intrauterine hypoxia (24.3%) and infections (44). Fetal distress not detected and lack of fetal monitoring intrapartum were identified as some of the main avoidable factors causing perinatal mortality (45). This means that some abnormal CTGs may not be recognized at the time of review or that there is inadequate monitoring of high-risk pregnancies resulting in intrapartum hypoxia. One of the strategies suggested in the “Reducing neonatal deaths in South Africa” report is reducing incidences of asphyxia by appropriate monitoring of mother and fetus during labour as well as proper interpretation of data from the monitoring tools(45). Obviously, our study was not designed to detect abnormal CTGs which were not identified by the birth attendants and thus delivery not expedited by CS.

Maternal Outcomes

The commonest maternal morbidity was PPH (8.9% of patients). The other important complication was puerperal sepsis which affected 4 patients. All patients were ultimately discharged. There was no maternal mortality in this study

A systematic review done on maternal and perinatal mortality associated with caesarean delivery in low and middle income countries in 2017 reported that a quarter of all mothers who died had undergone caesarean section (46). In South Africa, in 2017 there were 362 maternal deaths associated with caesarean sections that is, the case fatality rate was 145.7 per 100,000 caesarean deliveries (4). Caesarean section can also cause severe maternal morbidity. An audit on maternal near-misses in Southern Gauteng province showed that for a period of six months in 2014 there were 93 near misses and 7 maternal deaths from obstetric haemorrhage during or after caesarean delivery from a total of 20,527 caesarean deliveries (47). Hence it important to avoid unnecessary CS, which have implications also for future pregnancies

7 STUDY LIMITATIONS

The sample size of 114 was not achieved due to exclusions, but the results on CTG correlation were still significant.

The study was a retrospective descriptive study, therefore relied on documentation in patient files which was not always complete. The study design also did not enable a determination of the risk factors for abnormal CTGs to be identified. The study focussed on subjects who had a CS for suspected fetal hypoxia, thus it could not address the question of whether some abnormal CTGs in labouring women could have been misinterpreted or not done, so the necessary CS was not done, thus resulting in adverse perinatal outcomes. The SA PPIP reports shows that a common avoidable factor for perinatal mortality is 'fetal distress not having been recognised because the fetus was not monitored or CTG misinterpreted'. Of note, some CTGs assessed as suspicious by the attending doctors were thought to be pathological by the experts. The proportion of babies for whom cord blood gas analysis was

performed and the findings were not recorded in the mothers folders and not retrieved from neonatal notes. This was an omission; it would have improved the study's assessment of neonates delivered by emergency CS for abnormal CTG/fetal distress. However only 12 neonates were admitted to the neonatal unit, mostly for prematurity and only 4 for a low Apgar score. No babies developed neonatal encephalopathy, and none died.

8 CONCLUSIONS

The independent experts' assessment of the CTGs gave a fair correlation with that of the attendant doctor; this was significant, and comparable with other studies (67.8% agreement with kappa coefficient of 0.25). The experts assessed the decision for CS to be appropriate for the majority of women but 17.6% were inappropriately performed. Of note, three-quarters of the women had one or more co-existing obstetric conditions which are likely to have influenced the decision to perform CS. There were no major neonatal or maternal adverse outcomes.

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Appendix A: Data Collection Sheet

Data collection Sheet

Research number _____

1. Demographic Data on admission

Date of birth (patient)			Age		
Gravidity		Parity		Miscarriage	
Gestational age		weeks		days	

Date Of admission	Date		Time	

2. Booking Bloods

Booked	Yes		No								
Gestational age at Booking											
HIV	Positive		Negative		Unknown						
Syphilis											
TPHA	Positive		Negative								
RPR	Reactive		Non-Reactive								
Blood group	O		A		B		AB		unknown		
Rhesus	Positive		Negative								
Abnormal antibodies	Positive		Negative								

3. Previous obstetric History

	yes	No
Prolonged pregnancy		
Induction of labour		
Preterm delivery		
Gestational proteinuric hypertension(pre-eclampsia)		
Gestational hypertension		
Chronic hypertension		
Unclassified hypertension		

Eclampsia		
Previous still birth		
Previous antepartum haemorrhage		
Previous C/s x 1		
Previous C/S x 2m		
Previous C/s x 3		

4. Admission

Labour				Yes			No	
Labour	Spontaneous			Yes			No	
Labour	Induction			Yes			No	
If in labour, stage of labour	1st stage			2nd Stage				
Membranes intact	Yes			No				
Date and Time of ROM	Date			time				
Meconium(Grade)	none		Gr1		Gr2		Gr 3	
Meconium	Blood Stained			Yes			No	
Antepartum haemorrhage	Yes			No				

5. Analgesia prior to C/S

Intramuscular opiates (morphine)	Yes		No	
Entonox	Yes		No	
Epidural	Yes		No	

6. Antenatal complications

	Yes	No		Yes	No
Prolonged pregnancy (>41 wks)			Gestational DM		
Preterm labour			Type II DM		
Unclassified HPT			Impaired GTT		
Gestational proteinuric HPT (PET)			IUGR		
Gestational HPT			Oligohydramnious		
Chronic HPT			Polyhydramnious		
Eclampsia					

7. Intrapartum complications

	Yes	NO		Yes	No
Abruptio placentae			Pre labour ROM(term >36+6		
Cord prolapse			Prolonged ROM>24hrs		
Uterine rupture			Preterm Prelabour ROM		
Prolonged labour(>41wks)			Maternal pyrexia(>37.5C)		
Hyperstimulation			CPD		
Augmentation of labour			Delayed second stage		

8. Induction of labour Yes NO

Indication	Yes	No		Yes	No
Chronic HPT			APH		
Gestational HPT			Prolonged preg(>41wks)		
GPH (PET)			ROM		
Unclassified HPT			Decreased fm		
Eclampsia			IUGR		
Polyhydramnious			Oligohydramnious		

9. Method of IOL

	Yes	No		Yes	No
Intracervical Balloon			Oxytocin		
Misoprostol			AROM		
Prandin					

10. Labour

	Date	time		

Onset of first stage				
Onset second stage				
Delivery				

Was the patient in labour at the time of C/S _____Yes or No

11. Indication For CTG

Indication	Yes	No		Yes	No
Chronic HPT			APH		
Gestational HPT			Prolonged preg(>41wks)		
GPH (PET)			ROM		
Unclassified HPT			Decreased fm		
Eclampsia			IUGR		
Augmentation of labour			Oligohydramnious		
IOL			undocumented		

12. CTG description by attending doctor

Parameter	Description	
Baseline heart-rate Beats/min	Below 110	
	110-160	
	More than 160	
Variability beats/min	5-25	
	Less than5	
	More than 25	
	Pseudo sinusoidal	
	Sinusoidal pattern	
Decelerations	none	
	Early	

	Variable	
	Late	
	Prolonged	

Overall CTG classification by attending doctor	normal
	Suspicious/Non-reassuring
	pathological

12. Caesarean section

Decision for CS made by	Medical officer alone	Yes or No
	Registrar alone	
	Registrar or medical officer in consultation with specialist	
	Specialist	

Time between decision for CS	Date		Time			
Delivery	Date		Time			

Reasons for delay	Theatre busy			No second theatre		unexplained

Anaesthesia	Spinal		General	

5. Neonate

Birth weight					
Apgars	One		Five		Ten
Cord blood pH					
Admission to nursery/ICU	Yes		No		
Still birth	Yes		No		

HIE Score:

Mortality in the first week Yes or No

6. Maternal complications

Maternal complications	Estimated blood lost	mls			
	Blood transfusion	yes		no	
	Re-look lap	yes		no	
	Bowel injury	Yes		no	
	Bladder injury	yes		no	
	Ureteric injury	yes		no	
	hysterectomy	yes		no	
	Rx sepsis (>1 days of IV Antibiotics)	yes		no	
	death	yes		no	

Length of hospital stay post delivery	Date of discharge	Time of discharge

Appendix B: Sample size calculation

Kappa Test for Agreement Between Two Raters

Numeric Results

Solve For: Sample Size

Test Type: Two-sided Z test

Hypotheses: H0: Kappa = κ0 vs. H1: Kappa ≠ κ0

	Sample Size	Kappa|H0	Kappa|H1			Rating Categories	
Power	N	κ0	κ1	Alpha	Beta	k	Proportions
0.9003	114	0.4	0.6	0.15	0.0997	3	0.2, 0.3, 0.5

Power The probability of rejecting a false null hypothesis when the alternative hypothesis is true.

N The total sample size.

κ0 The value of Kappa under the null hypothesis, H0.

κ1 The value of Kappa under the alternative hypothesis, H1.

Alpha The probability of rejecting a true null hypothesis.

Beta The probability of failing to reject the null hypothesis when the alternative hypothesis is true.

k The number of rating categories.

Proportions Gives the rating category proportions. The number of categories is equal to k.

Summary Statements

In a test for agreement between two raters using the Kappa statistic, a sample size of 114 subjects achieves 90%

power to detect a true Kappa value of 0.6 in a test of H0: Kappa = κ0 vs. H1: Kappa ≠ κ0 when there are 3

categories with frequencies equal to 0.2, 0.3, and 0.5. This power calculation is based on a significance level of

0.15.

Kappa Test for Agreement Between Two Raters

Dropout-Inflated Sample Size

Dropout Rate	Sample Size N	Dropout-Inflated Enrollment Sample Size N'	Expected Number of Dropouts D
20%	114	143	29

Dropout Rate The percentage of subjects (or items) that are expected to be lost at random during the course of the study and for whom no response data will be collected (i.e., will be treated as "missing"). Abbreviated as DR.

N The evaluable sample size at which power is computed. If N subjects are evaluated out of the N' subjects that are enrolled in the study, the design will achieve the stated power.

N' The total number of subjects that should be enrolled in the study in order to obtain N evaluable subjects, based on the assumed dropout rate. After solving for N, N' is calculated by inflating N using the formula N' = N / (1 - DR), with N' always rounded up. (See Julious, S.A. (2010) pages 52-53, or Chow, S.C., Shao, J., Wang, H., and Lokhnygina, Y. (2018) pages 32-33.)

D The expected number of dropouts. D = N' - N.

Dropout Summary Statement

Anticipating a 20% dropout rate, 143 subjects should be enrolled to obtain a final sample size of 114 subjects.

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Kappa Test for Agreement Between Two Raters: Procedure Input Settings

Design Tab

Solve For: Sample Size

Alternative Hypothesis: Two-Sided

Power: 0.90

Alpha: 0.15

κ1 (Kappa|H1): 0.6

κ0 (Kappa|H0): 0.4

Specify Using: List Input

P (Frequencies): 0.2 0.3 0.5

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room 553-45 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

25 March 2019

HREC REF: 122/2019

Prof S Fawcus
Department of Obstetrics and Gynaecology
H-Floor
OMB

Dear Prof Fawcus

PROJECT TITLE: AN AUDIT OF CAESAREAN SECTIONS AT NOWBRAY MATERNITY HOSPITAL (MMH) PERFORMED FOR ABNORMAL CARDIOTOCOGRAPHIC TRACINGS IN 2017 (MMeD-candidate Dr B Ntshabele)

Thank you for your response letter dated 18 March 2019, addressing the issues raised by the Human Research Ethics Committee (HREC).

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 March 2020.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student: Dr B Ntshabele will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.

NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.