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Comparison of the NICE 2014 versus the NICE 2017 guidelines in predicting cord blood analysis

Ishania Mahabeer

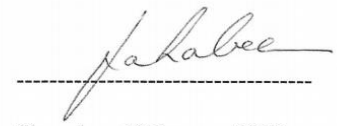
This research report is submitted to the University of the Witwatersrand Health Sciences Faculty in partial fulfilment of the requirements for the degree of Master of Medicine in Obstetrics and Gynaecology.

Johannesburg

12 January 2022

Declaration

I, Ishania Mahabeer, student number 2057437, declare that this Research Report is my own work and contains no section copied in whole or in part from any other source, unless explicitly identified in quotation marks and with detailed accurate referencing. I declare that this work has not been submitted to any other University for the purposes of a post graduate degree.



Signed on 12 January 2022

Dedication

To Yammesh,

Mahir, Keyur, and Reha.

Presentations and Publications

Journal article currently being submitted to the South African Journal of Obstetrics and Gynaecology.

Abstract

Cardiotocographic (CTG) monitoring is used to detect early signs of fetal hypoxia. However, CTG monitoring in labour, has not been shown to improve overall perinatal mortality nor cerebral palsy. In spite of the lack of evidence regarding its benefit, CTG monitoring is standard of care in many countries.

Numerous guidelines by various professional bodies, are available to assist one in the interpretation of cardiotocograph (CTG) traces. The National Institute for Health and Care Excellence (NICE) first published its guidelines on intrapartum care in 2007. These were revised in 2014 and again in 2017. There were various changes to the description of CTG features in the revised 2017 guideline. The aim of this study was to assess if these changes improve observer interpretation of CTGs by comparing the sensitivity and specificity of each version of the guideline, using the results of cord blood analysis as the standard for this study.

This was an observational study conducted at Rahima Moosa Mother and Child Hospital, a regional hospital in the City of Johannesburg, Gauteng province, South Africa. This hospital is part of the University of the Witwatersrand academic circuit.

There were 193 patient files collected for a previous study done by the co-supervisor. A total of 84 CTGs within 90 minutes of delivery, had accompanying cord blood analyses. These CTGs were assessed and categorized using the NICE 2014 and thereafter the NICE 2017 guidelines. The sensitivity and specificity for each guideline was then calculated.

The NICE 2014 guideline had a sensitivity of 11% (95% CI, 0.28-48.20), and specificity of 87% (95% CI, 76.8-93.4). The NICE 2017 guideline had a sensitivity of 22% (95% CI, 2.81-60), and a specificity of 80% (95% CI, 69.2-88.4). A limitation of this study was that cord blood pH was used as the only standard. There was no clinical correlation with low Apgar scores or need for newborn resuscitation which could have improved the sensitivity of the CTGs.

In conclusion, the NICE 2014 and the NICE 2017 guidelines performed poorly as a tool for assessing suspicious and pathological traces as determined by the accepted standard for this study i.e cord blood pH. Ultimately, CTG monitoring in labour, has not been shown to

improve overall perinatal mortality nor cerebral palsy.[1] A cord blood pH of 7.10 has been found to be significantly associated with neonatal mortality.[12]

The interpretation of baseline variability, when using either version of the guideline, often played a role in falsely assessing traces as suspicious and pathological which when compared to the accepted standard of cord blood pH, were otherwise normal.

Both versions of the guidelines had very poor sensitives compared with those calculated in other studies. Specificity calculations for both versions of the guideline fared better when compared with those calculated in other studies. There was a tendency to an improved specificity with the NICE 2014 version of the guideline when compared to the accepted standard of cord blood pH. The NICE 2014 guideline required a fetal bradycardia in addition to a prolonged deceleration to categorize a CTG as " Need for Urgent Intervention", thereby reducing its rate of false positive assessments. However, due to the very small sample size with very few poor outcomes and the wide 95% confidence intervals , a final conclusion of a better performance of the 2014 vs the 2017 guidelines, could not be made.

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List of Abbreviations

ACOG : American College of Obstetrics and Gynecology

BL : baseline

bpm : beats per minute

CTG : Cardiotocograph

Decels : decelerations

FIGO : International Federation of Obstetrics and Gynaecology

min : minutes

NICE : National Institute for Health and Care Excellence

PVB : per vaginal bleeding

RMMCH : Rahima Moosa Mother and Child Hospital

s : seconds

Journal Article

Comparison of the NICE 2014 versus the NICE 2017guidelines in predicting cord blood analysis

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Background. Cardiotocographic (CTG) tracing is a widely available tool used for intrapartum fetal monitoring. To improve assessment of CTG traces, guidelines have, over time, been revised.

Objective. To determine if recent revisions to the NICE guidelines for the Interpretation of CTGs, improves observer assessment of intrapartum CTGs.

Methods. An observational study involving the assessment of CTGs using the NICE 2014 and thereafter the NICE 2017 guidelines. These results were compared to accompanying cord blood analyses (the standard used for this study).

Results. A total of 84 CTGs within 90 minutes of delivery, had accompanying cord blood analyses. The NICE 2014 guideline had a sensitivity of 11% (95% CI, 0.28-48.20), and specificity of 87% (95% CI, 76.8-93.4). The NICE 2017 guideline had a sensitivity of 22% (95% CI, 2.81-60), and a specificity of 80% (95% CI, 69.2-88.4).

Conclusion. The NICE 2014 and the NICE 2017 guidelines performed poorly as a tool for assessing suspicious and pathological traces as determined by the accepted standard i.e cord blood pH. The interpretation of baseline variability, when using either version of the guideline, often played a role in falsely assessing traces as suspicious and pathological which when compared to the accepted standard of cord blood pH, were otherwise normal.

Both versions of the guidelines had very poor sensitives compared with those calculated in other studies. Specificity calculations for both versions of the guideline fared better when compared with those calculated in other studies. There was a tendency to an improved specificity with the NICE 2014 version of the guideline when compared with the accepted standard of cord blood pH.The NICE 2014 guideline required a fetal bradycardia in addition to a prolonged deceleration to categorize a CTG as " Need for Urgent Intervention", thereby reducing its rate of false positive assessments.

However, due to the very small sample size with very few poor outcomes and the wide 95% confidence intervals , a final conclusion of a better performance of the 2014 vs the 2017 guidelines, could not be made.

Cardiotocographic (CTG) monitoring is used to detect early signs of fetal hypoxia. However, CTG monitoring in labour, has not been shown to improve overall perinatal mortality nor cerebral palsy.[1]

Numerous guidelines are available to assist in the interpretation of CTGs. However, numerous studies have found continued inter and intra-observer variations in the interpretations of CTGs.[2,3,4] One study, found that only 30% of acidaemic babies were identified through interpretation of fetal heart rate (FHR) tracing in actual practice.[5] The 2015 RCOG "Each baby counts" report found that there were errors in the interpretation of CTGs in 27% of babies.[5] To improve the understanding of this complex tool for intrapartum fetal monitoring, various guidelines have, over time, been revised.[1,7,8,9,10]

The National Institute for Health and Care Excellence (NICE) first published its guidelines on intrapartum care in 2007.[7]These were updated in 2014 [8] and an exceptional review in 2016 resulted in a revised guideline published in 2017.[9]

These changes in the guideline included :

1. A change in the thresh-hold values for a normal baseline fetal heart rate.
2. A change in the time frame whereby variability should be considered non-reassuring or pathological.

3. An addition of increased variability as a feature
4. The addition of concerning features to describe non-reassurring decelerations
5. A change in the duration of time for which decelerations can be considered normal
6. Decelerations could be considered non-reassuring if occuring with greater than 50% of contractions OR for greater than 30minutes.

Clearly, there were many changes to the 2014 guidelines.

Clinicians rely on these guidelines and its updates to assist with decisions on operative management to improve perinatal outcomes, However, a more physiological based approach to the interpretation of CTGs is suggested by numerous authors.[11,12] Often, CTGs are assessed as pathological but important influencing variables are not added to the equation or additional evaluation methods like fetal scalp sampling are not used , resulting in a false positive rate as high as 50%.

The aim of this study, was to determine if these ongoing changes to the guidelines would improve observer analysis of intrapartum CTGs. Ultimately management decisions need to be based on the overall , individual patient setting.

The objectives of this study were :

I. To interpret CTG traces as per NICE 2014 guidelines;
II. To interpret CTG traces as per NICE 2017 guidelines
III. To compare the interpretation of CTGs as per NICE 2014 and NICE 2017 guidelines with cord blood gas analysis.

Methods

This was an observational study conducted at Rahima Moosa Mother and Child Hospital (RMMCH), a regional hospital in the City of Johannesburg, Gauteng province, South Africa. This hospital is part of the University of the Witwatersrand academic circuit. Although this is a regional hospital, a large number of antenatal clinics in the surrounding area, do not have delivery facilities. As a result, RMMCH attends to a large number of low risk deliveries.

This study is a secondary analysis of data collected for an original study done by the co-supervisor. The original study looked at cerebro-placental ratio in labour and whether it could identify , early in labour, those patients that are at higher risk of an adverse outcome.

The inclusion criteria for this original study were :

a) Ability to understand and sign consent in English
b) In latent phase of labour, cervical dilatation <4cm at recruitment
c) Spontaneous labour
d) Most recent CTG is normal as judged by the researcher

The exclusion criteria were :
a) Normal vaginal delivery contra-indicated
b) Induction of labour
c) Most recent CTG is suspicious or pathological
d) Previously diagnosed intrauterine growth restriction with abnormal dopplers
e) Known major fetal anomaly
f) Less than 18 years old
g) Two vessel cord
h) Multiple pregnancy
i) Meconium stained liquor

The files of patients being attended to in the admission area were screened and those meeting the inclusion/ exclusion criteria were recruited for the original study. Ultrasounds were done in the admission area and cerebroplacental ratios calculated were correlated with APGAR scores and cord blood analyses.

Ultimately, there were 193 files available from this original study. Some cord blood analyses were unfortunately not done and some had clotted.
CTGs and cord blood analyses from these files were screened and those meeting the inclusion and exclusion criteria for this study were assessed. Any CTG trace done within 90 min of delivery, that was

accompanied by a cord blood analysis, was included in this study. Any CTG that was not within 90min of delivery, was excluded.

CTGs that met the inclusion/exclusion criteria were assessed using the NICE 2014 and thereafter the NICE 2017 guidelines. The CTGs were assessed by the researcher only. All CTGs were first assessed using the NICE 2014 guidelines. In the following month, the researcher again reviewed all CTGS and assessed them using the NICE 2017 guidelines. The outcomes of these 2 assessments of each CTG, (using the NICE 2014 and then the NICE 2017 guidelines), were compared to the results of the accompanying cord blood analysis.

The median time between the CTG and obtaining the cord blood specimen was not reviewed . It was assumed that the cord blood sample was taken at delivery and would also therefore be within 90 min of the CTG. It is also assumed that the cord blood sample was taken from the umbilical arteries, in a heparinized syringe and processed immediately.

Umbilical cord blood analysis is an objective determinant of intrapartum fetal physiology.

In a 2010 meta-analysis [13] of fifteen studies, the association between cord blood pH and neonatal mortality was compared. A cord blood pH of 7.10 was found to be significantly associated with neonatal mortality.[13] Cord blood analysis was therefore used as the standard when comparing the NICE 2014 and NICE 2017 guidelines.

Ethics clearance (M190411) was obtained for this study and that of the co-supervisor's study (M170637).

At RMMCH, fetal scalp blood sampling is not undertaken to confirm the findings of the CTG trace. Thus, the management plans for the last two categories (Pathological and Need for Urgent Intervention) in both guidelines, are the same. These two categories were therefore merged for data analysis.

As the defining criteria for each category are the same in both guidelines, the NICE 2017 naming of categories was used. Cardiotocograph traces associated with a low umbilical cord blood pH of $\leq$ 7.10 were categorized as pathological; those associated with a cord blood pH = 7.11-7.19 were categorized as suspicious and those associated with a cord blood pH $\geq$ 7.2 were categorized as normal. For the purposes of statistical analysis, the categories of normal and suspicious were classified as non-pathological while pathological and need for urgent intervention, were classified as abnormal.

The data was analysed using the statistical software STATA® (StataCorp, 4905 Lakeway Drive, College Station, Texas 77845 USA) version 15. In order to understand the performance of these guidelines in measuring foetal distress, maximum likelihood estimate was used to calculate the sensitivity and specificity of each guideline using cord blood analysis as the accepted standard. Other outcome measures included estimates such as positive and negative predictive values. Confidence intervals were included in the reporting of results.

Sensitivity and specificity calculations were completed for each version of the guideline.

Results

There were 193 patient files available. One hundred and three CTG traces were excluded because they were either recorded more than 90 minutes from delivery or did not have an accompanying cord blood gas analysis. A further six CTG traces were excluded as two cord blood analyses had no cord blood pH recorded; a further two had no tocograph tracings which were necessary to guide CTG categorization and two CTGs were not suitable for interpretation due to significant loss of contact during the recordings. Ultimately, 84 CTG traces were categorized using the NICE 2014 and thereafter the NICE 2017 guidelines.

Umbilical cord blood analysis is an objective determinant of intrapartum fetal physiology.

In a 2010 meta-analysis [13] of fifteen studies, the association between cord blood pH and neonatal mortality was compared. A cord blood pH of 7.10 was found to be significantly associated with neonatal mortality.[13] Cord blood analysis was therefore used as this study's standard when comparing the NICE 2014 and NICE 2017 guidelines.

Most patients had a normal vaginal delivery (n=53; 63%). There were 29 (35%) caesarean section deliveries and two assisted deliveries (2%). Forty-four CTGs (52%) were recorded within 30 minutes of delivery; 26 (31%) were within 60 minutes of delivery and 14 (17%) were within 90 minutes of delivery. A cord blood pH > 7.2 was recorded in 81% of babies (n=68); 8% were between 7.11 and 7.19 (n= 7) and 11% had a cord blood pH $\leq$ 7.1 (n=9).

When CTG assessments, using the NICE 2014 guidelines, were compared with cord blood pH, 49 (86%) out of 57 CTG interpretations were correctly assessed as normal; three (19%) out of 16 CTG interpretations were correctly assessed as suspicious and one (9%) CTG out of eleven was correctly assessed as

pathological. No CTGs were assessed as Need for Urgent Intervention. These outcomes of CTG assessments (NICE 2014), when compared to cord blood pH, are charted in Table 1.

Table 1: Outcomes of CTG assessments (NICE 2014) when compared to cord blood pH

CTG assessments	Cord blood pH $\leq$ 7.1	Cord blood pH =7.11-7.19	Cord blood pH $\geq$ 7.2
Normal n = 57 (67.9%)	n = 6 (7.1%)	n = 2 (2.4%)	n = 49 (58.3)
Suspicious n = 16 (19.0%)	n = 2 (2.4%)	n = 3 (3.6%)	n = 11 (13.1)
Pathological n = 11 (13.1%)	n = 1 (1.2%)	n = 2 (2.4%)	n = 8 (9.5)

Cord blood pH was found to be pathological in two CTGs assessed as suspicious according to the NICE 2014 guideline. The time to delivery could have played a role here. One of these CTGs was within 30 minutes of delivery and the other within 60 minutes of delivery.

Cord blood pH was found to be normal in eleven CTGs assessed as suspicious according to NICE 2014 guidelines. Nine of these eleven CTGs were assessed as suspicious based on variability alone.

Eleven CTGs were assessed as pathological, but only one was confirmed pathological by cord blood pH. Five of the ten assessments, not confirmed as pathological by cord blood pH, were assessed as pathological based on abnormal variability; three had abnormal variable decelerations, and two CTGs had non-reassuring variability accompanied by non-reassuring decelerations. Clearly, the assessment of baseline variability, played a major role in the interpretation of these CTGs as pathological.

For the purposes of statistical analysis, the categories of normal and suspicious were classified as non-pathological, while pathological and need for urgent intervention, were classified as abnormal. Seventy-

three CTGs were assessed as non-pathological according to the NICE 2014 guideline and eleven were assessed as abnormal. Only one (9%) CTG assessment was identified as a true positive. Ten (91%) were identified as false positives. Sixty-five (89%) were identified as true negatives and eight (11%) were identified as false negatives. These values for the components of sensitivity and specificity calculations, for the NICE 2014 guideline are displayed in table 2. These percentages calculated are charted in Graph 1. The percentages calculated for the NICE 2017 guidelines are also included in Graph 1.

Table 2: Values for the components of Sensitivity and Specificity Calculations for the NICE 2014 guideline

		Cord blood analysis		
		Pathological (n / %)	Non-Pathological (n / %)	Total (n / %)
CTG Assessment	Abnormal	True positive = 1 (9%)	False positive = 10 (91%)	11 (13%)
	Non-pathological	False Negative =8 (11%)	True Negative =65 (89%)	73 (87%)
	Total	9 (11%)	75 (89%)	84 (100%)

Of these eight false negatives, four CTGs had variable decelerations, but were not assessed as pathological; one had a single deep deceleration ; one had a suspicious fetal heart rate and no other features to support an assessment of Pathological; one had no features of a pathological trace (this CTG was within 30min of delivery); one had decreased variability but did not persist for more than 90 minutes. The four CTGs with variable decelerations that were not categorized as pathological, either did not take > 60s to recover or drop by > 60bpm from baseline. Two of these CTGs with variable decelerations did not occur in > 50% of contractions.

The sensitivity and specificity of the NICE 2014 guidelines for the interpretation of CTGs was calculated at 11% (95% CI, 0,28-48.20), and 87 % (95% CI, 76.8-93.4), respectively. The positive predictive value was 9% (95% CI, 0.23-41.3) and the negative predictive value was 89% (95% CI, 79.5-95.1). The positive likelihood ratio (LR) was 0.83 and the negative LR was 1.03.

When CTG assessments, using the NICE 2017 guidelines, were compared with cord blood pH, 45 (87%) out of 52 CTG interpretations were correctly assessed as normal ; two (13%) out of 15 CTG interpretations were correctly assessed as suspicious; two (17%) out of 12 were correctly assessed as pathological and zero out of five were correctly assessed as Need for Urgent intervention. The outcomes of this comparison between CTG assessments according to NICE 2017 guidelines and cord blood pH, are illustrated in Table 3.

Table 3: Outcomes of CTG assessments (NICE 2017) when compared to cord blood pH, according to the standard classification of CTGs.

CTG assessments n (%)	Cord blood pH $\leq$ 7.1 n (%)	Cord blood pH =7.11-7.19 n (%)	Cord blood pH $\geq$ 7.2 n (%)
Normal 52 (61.9)	5 (6.0)	2 (2.4)	45 (53.6)
Suspicious 15 (17.9)	2 (2.4)	2 (2.4)	11 (13.1)
Pathological 12 (14.3)	2 (2.4)	2 (2.4)	8 (9.5)
Need for Urgent Intervention 5 (6.0)	0 (0)	1 (1.2)	4 (4.8)

Seven CTGS were incorrectly assessed as normal. When compared to cord blood pH, five were pathological and two were suspicious.

Fifteen CTGs were assessed as suspicious. Two were confirmed suspicious by cord blood pH and 13 CTGS were incorrectly assessed when compared to cord blood pH. Two were pathological and the remaining eleven were normal. One of the two CTGs confirmed as pathological on cord blood pH, had variable decelerations with concerning features, but these decelerations did not occur in more than 50% of contractions. The other had only a suspicious FHR. Of the eleven suspicious CTGs that had normal cord blood pH, five were incorrectly assessed as suspicious based on baseline variability; five were based on non-reassuring variable decelerations and one on a non-reassuring baseline fetal heart rate. The identification of non- reassuring variable decelerations played an equal role in the incorrect assessment of CTGs as did baseline variability.

Twelve CTGs were assessed as pathological. Two CTGs were correctly assessed as pathological when compared to cord blood pH. Ten CTGs were incorrectly assessed as pathological, of which, two CTGs were suspicious on cord blood pH and eight were normal on cord blood pH. Seven of the ten CTGs were incorrectly assessed as pathological based on the presence of abnormal variability as defined by the NICE 2017 guidelines, and three were incorrectly assessed based on the presence of abnormal variable decelerations.

Five CTGs were assessed as "Need for Urgent Intervention". None were confirmed on cord blood pH. All five CTGs presented with a single prolonged deceleration lasting $\geq$ 3 minutes. A baseline FHR of less than 100 was not part of the criteria required to identify this as an abnormal feature in the NICE 2017 guideline, but was required in the NICE 2014 guideline.

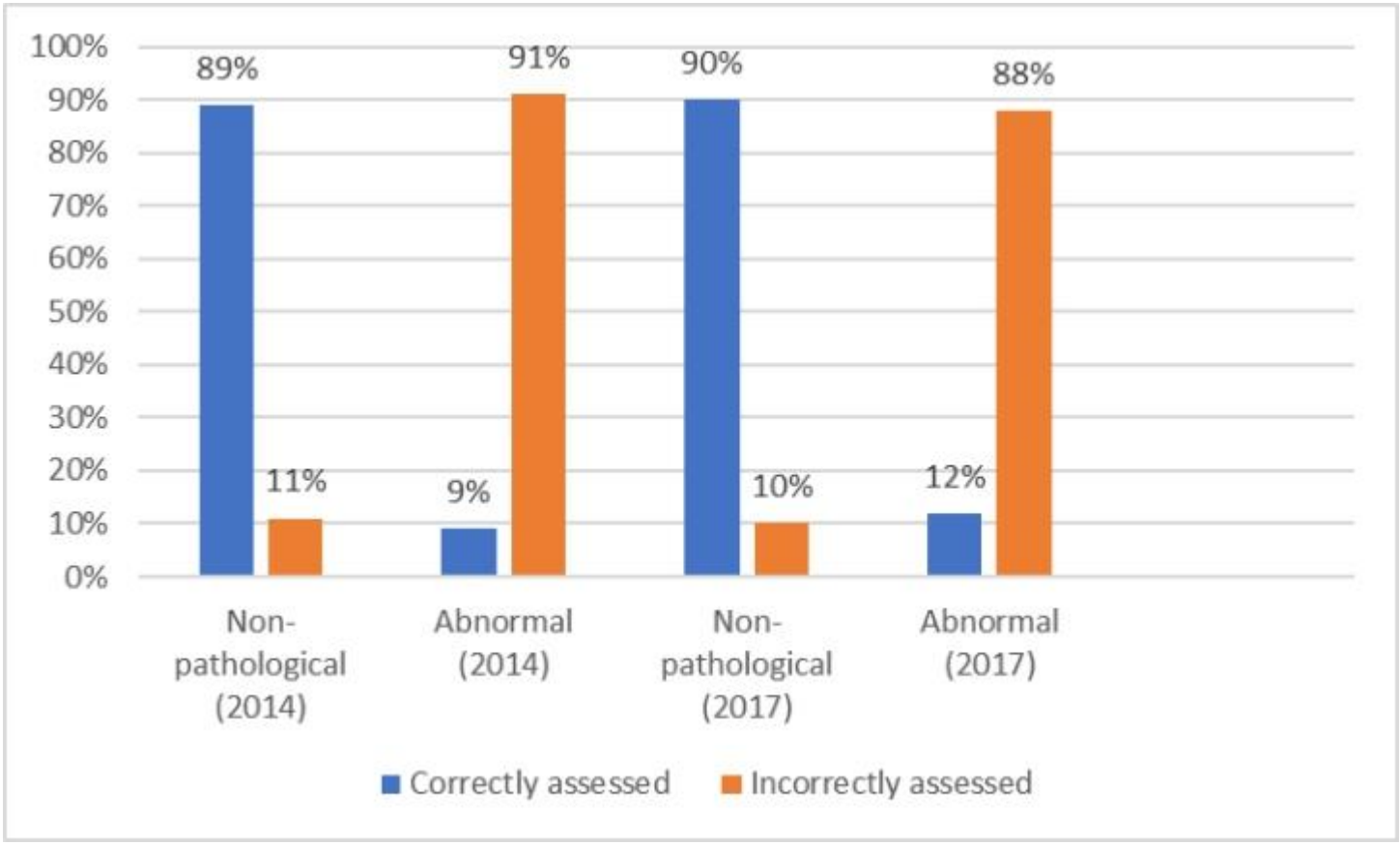
For the purposes of statistical analysis, the categories of normal and suspicious were classified as non-pathological, while pathological and need for urgent intervention, were classified as abnormal. Sixty-seven CTGs were assessed as non-pathological and 17 CTGs were assessed as abnormal. Two (12%) CTG assessments were identified as true positives. Fifteen (88%) were identified as false positives. Sixty CTG assessments (90%) were identified as true negatives and seven (10%) were identified as false negatives. These values for the components of sensitivity and specificity calculations, for the NICE 2017 guideline are displayed in table 4. These percentages calculated are charted in Graph 1, where the percentages calculated for the NICE 2014 guidelines are also included.

The sensitivity and specificity of the NICE 2017 guideline was calculated at 22 % (95% CI, 2.81- 60) and 80 % (95% CI, 69.2-88.4), respectively. The positive predictive value was 12% (95% CI, 1.46-36.4) and the negative predictive value was 90% (95% CI, 79.7-95.7). The positive likelihood ratio (LR) was 1.11 and the negative LR was 0.97.

Table 4: Values for the Components of Sensitivity and Specificity Calculations for the NICE 2017 guideline

		Cord blood analysis		
		Pathological (n/%)	Non-Pathological (n/%)	Total (n/%)
CTG	Abnormal	True positive = 2 (12%)	False positive = 15 (88%)	17 (20%)
Assessment	Non-Pathological	False Negative =7 (10%)	True Negative = 60 (90%)	67 (80%)
	Total	9 (11%)	75 (89%)	84 (100%)

Graph 1: Outcomes of CTG assessments when compared to cord blood pH, when CTG categories are combined for statistical analysis



Discussion

The sensitivity and specificity of the NICE 2014 guideline for the interpretation of CTGs was calculated at 11% (95% CI, 0,28-48.20), and 87 % (95% CI, 76.8-93.4), respectively. The sensitivity and specificity of the NICE 2017 guideline was calculated at 22 % (95% CI, 2.81- 60) and 80 % (95% CI, 69.2-88.4), respectively.

The sensitivity of both guidelines was much lower than values calculated in other studies. In a study done by Santo *et al,* sensitivities of the FIGO 1987, NICE 2007, and ACOG 2010 guidelines were calculated at 89%, 97% and 32% respectively.[14] Their CTGs were within 5 min of vaginal delivery and within 20 min of caesarean deliveries.[14] In this study, CTGs were within 30-90min of delivery. Sixty-six percent of CTGs in the false negative group, were stopped more than 30 minutes before delivery. This study also had a larger percentage of acidemic new-borns (4.6% of new-borns with acidaemia in Santo's study vs 11% in our study). The combination of CTG recordings further from time of delivery and more babies being acidemic at birth could have contributed to more false negatives. The majority of our acidemic babies (56%), were delivered via caesarean section, all of which took >30 minutes from decision for caesarean section to arrival in theatre. This delay to theatre could have possibly contributed to the higher number of acidemic babies in our study. The reasons for these delays was not investigated in our study, however a study done at Chris Hani Baragwnath Academic hospital, a tertiary hospital in the city of Johannesburg, reported a backlog of emergency caesarean sections and theatres blocked by complicated cases as reasons.[15] Their decision to anaesthetic interval for caesarean sections for fetal compromise was reported as 354.5 minute.[15]

Both the guidelines had poor sensitivities compared to other studies. This may be the result of a very small sample size with very few poor outcomes. Also, only cord blood pH was used as the accepted standard for this study. There was no clinical correlation with low Apgar scores or need for newborn resuscitation which could have improved the sensitivity of the CTGs.

The 95% confidence intervals are also very wide. It is therefore not possible to compare the sensitivies of the 2 versions of the NICE guideline.

The specificities of the NICE 2014 and NICE 2017 guidelines were calculated at 87% (95% CI, 76.8-93.4) and 80% (95% CI, 69.2-88.4) respectively. In the study done by Santo *et al*, specificities for the FIGO 1987, NICE 2007, and ACOG 2010 guidelines were 63%, 95% and 66% respectively.[14] Our specificities fare

reasonably in comparison. However, in view of the wide confidence intervals calculated, the two versions of the guideline cannot be compared with each other.

Although variability was the major feature contributing to the assessment of suspicious and pathological CTGs, variable decelerations were also often present. The NICE 2017 guideline identifies five concerning features of variable decelerations. The commonest concerning feature identified, was “taking >60s to recover”. Other concerning features did not contribute to identifying more pathological CTGs.

The limitations of this study include the small sample size, a single observer for the assessment of CTGs, and there was no clinical correlation with low Apgar scores or need for newborn resuscitation which could have improved the sensitivies of the CTGs. Also,this was a secondary analysis of a previous study, and therefore the limitations of such a study are inherent in this study.

In conclusion, the NICE 2014 and the NICE 2017 guidelines performed poorly as a tool for assessing suspicious and pathological traces as determined by the accepted standard for this study i.e cord blood pH. Ultimately, CTG monitoring in labour, has not been shown to improve overall perinatal mortality nor cerebral palsy.[1] A cord blood pH of 7.10 has been found to be significantly associated with neonatal mortality.[13]

The interpretation of baseline variability, when using either version of the guideline, often played a role in falsely assessing traces as suspicious and pathological which when compared to the accepted standard of cord blood pH, were otherwise normal.

The sensitivity of both the NICE 2014 and NICE 2017 guidelines, in identifying pathological CTGs, was extremely poor as this was a very small sample size with very few poor outcomes. Specificity calculations for both versions of the guideline fared better when compared with those calculated in other studies. There was a tendency to an improved specificity with the NICE 2014 version of the guideline when compared to the accepted standard of cord blood pH that was used in the this study.The NICE 2014 guideline required a fetal bradycardia in addition to a prolonged deceleration to categorize a CTG as “ Need for Urgent Intervention”, thereby reducing its rate of false positive assessments. However, due to the very small sample size with very few poor outcomes and the wide 95% confidence intervals , a final conclusion of a better performance of the 2014 vs the 2017 guidelines, could not be made.

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Appendix A : Approved Research Protocol

Comparison of the NICE 2014 versus the NICE 2017 guidelines in predicting cord blood analysis

1. Introduction

1.1. Background literature search and analysis critique

Cardiotocographic monitoring during labour, is used to detect early signs of fetal hypoxia so that steps can be taken to prevent perinatal morbidity and mortality. Numerous guidelines by various professional bodies, are available to assist one in the interpretation of cardiotocograph (CTG) traces. The three most popular guidelines worldwide are those published by the International Federation of Gynecology and Obstetrics (FIGO), the American College of Obstetricians and Gynecologists (ACOG) and the National Institute for Health and Care Excellence (NICE) in the United Kingdom.

The use of these guidelines has assisted greatly in standardizing the interpretation of cardiotocographs over the centuries, however numerous studies have found continued inter and intra-observer variations in the interpretations of CTGs(1–3). One study, found that only 30% of acidaemic babies were identified through interpretation of fetal heart rate tracing in actual practice(4). The 2015 RCOG “Each baby counts” report found that there were errors in the interpretation of CTGs in 27% of babies (5). In an attempt to improve the understanding of this complex, but widely available tool for intrapartum fetal monitoring, guidelines by various professional bodies have, over time, been revised.

1.2. Review of the FIGO guidelines

The FIGO guidelines were first published in 1987 and recently revised in 2015 (6). The FIGO 2015 guidelines, classify CTG traces as normal, suspicious and pathological. This classification is simple and therefore very easy to remember in the practical setting, however, in its simplicity it classifies all repetitive decelerations occurring for more than 30min as pathological. (This would include early repetitive

decelerations occurring for more than 30min as well as V-shaped variable decelerations occurring for more than 30min. V-shaped variable decelerations are described, in their guidelines, as being "seldom associated with an important degree of fetal hypoxia/acidosis" (6).

1.3. Review of the ACOG in collaboration with NICHHD guidelines:

ACOG wrote their guidelines in 1997 and, in collaboration with NICHHD (National Institute of Child Health and Human Development) updated their guidelines in 2008 (7). ACOG classifies CTGs as Category 1, Category 2 and Category 3 and subclassifies variability into absent, mild, moderate and marked.

ACOG is essentially similar to FIGO except for its categorization of variability. A pathological trace using the ACOG guidelines, would have absent baseline variability (amplitude range undetectable) as compared FIGO where a pathological trace would have variability < 5 bpm. ACOG also does not give a time frame for recurrent decelerations.

1.4 Review of the NICE guidelines:

The National Institute for Health and Care Excellence (NICE) first published its guidelines on intrapartum care in 2007, the NICE clinical guideline CG 55. The guidelines were updated (NICE clinical guideline CG 190) in 2014. The 2014 guidelines then underwent an exceptional review in 2016 and the revised guideline was published in 2017 (8).

In 2007, the NICE guidelines introduced the terms typical and atypical to describe decelerations. This was confusing health care professionals, so in the 2014 guidelines, the use of these words to describe decelerations, was removed (14). In 2014 , NICE then classified CTG features as Normal/Reassuring, Non-reassuring and Abnormal (9) and decelerations were described as early, variable or late. Non-reassuring variable decelerations were described as a decline in fetal heart rate by more than 60 beats per minute for less than 60 seconds, occurring for greater than 90 minutes or a decline in fetal heart rate by more than 60 beats per minute for greater that 60 seconds for up to 30 minutes (9). Non- reassuring late decelerations were described as being present for up to 30 minutes in greater than 50% of contractions (9).

Criticism of this guideline highlighted that the decline in fetal heart rate by 60 beats per minute was based on consensus and not scientific evidence (10). Subsequently, NICE revised its guidelines in 2017 (11).

The differences between the NICE 2014 description of CTG features and the NICE 2017 description of CTG features, are discussed below. The features described are baseline fetal heart rate, baseline variability and decelerations.

In 2014, a re-assuring baseline FHR was considered to be between 100-160 bpm, but in 2017, a re-assuring baseline FHR was described as between 110-160 bpm. A baseline FHR between 100-109 bpm was then classified as a non-reassuring feature in the 2017 guidelines.

With regards to variability, non-reassuring variability was considered to be variability of less than 5bpm in both versions of the guidelines, but the time frame after which it was considered non-reassuring, changed. In 2014, reduced variability occurring for 30-90min was non-reassuring, but in 2017, reduced
variability occurring for 30-50min was non-reassuring. Also included as a non-reassuring feature of variability in the 2017 guidelines, and not the 2014 guidelines, was variability greater than 25bpm occurring for 15- 25min. Thus, the description of abnormal variability changed as well. Abnormal variability in 2014, was considered variability of < 5 bpm , occurring for more than 90min and in 2017, variability was considered abnormal if it was < 5 bpm for more than 50 min or more than 25bpm for more than 25 min.

With regards to decelerations, the 2014 guidelines, as noted above, described non-reassuring variable decelerations as having a decline in fetal heart rate by 60 bpm. The 2017 guidelines changed this description of non-reassuring variable decelerations, and instead described non-reassuring variable decelerations as decelerations with or without concerning features. These concerning features were, variable decelerations lasting more than 60 seconds; reduced baseline variability within the deceleration; failure to return to baseline; biphasic (W) shape and no shouldering.
The 2017 guidelines also included variable decelerations, with no concerning features , lasting for less than 90min, in its normal/ re-assuring category. In the past, only early decelerations were considered normal/ re-assuring.

Furthermore, in the 2014 guidelines, non-reassuring variable decelerations lasting more than 60 seconds had to occur for up to 30min in more than 50% of contractions. The 2017 guidelines added that variable decelerations with concerning features could still be non-reassuring even if they occurred for less than 30 min, provided they occurred in more than 50% of contractions.

Clearly, there were numerous changes to the NICE 2014 guidelines. It would be interesting to determine if these changes to the NICE 2014 guidelines have improved intra-observer interpretation of intrapartum cardiotocographic monitoring.

Clinicians rely on these guidelines and its updates to assist with decisions on operative management to improve perinatal outcomes, However, a more physiological based approach to the interpretation of CTGs is suggested by numerous authors.[11,12] Often, CTGs are assessed as pathological but important influencing variables are not added to the equation or additional evaluation methods like fetal scalp sampling are not used , resulting in a false positive rate as high as 50%.

The NICE guidelines are the most popular guidelines used in our academic circuit and the most popular guidelines used at RMMCH. If these changes to the guidelines are shown to improve intra-observer interpretation of CTG traces, it would be valuable promoting the use of the revised guidelines within our circuit.

1.5. Umbilical cord blood pH analysis.

Both the NICE 2014 and the NICE 2017 guidelines suggest fetal blood sampling to confirm the findings of a pathological trace. However fetal blood sampling is contra-indicated when there is a risk of maternal-to-fetal transmission of infection or a risk of fetal bleeding disorders (11).

In South Africa we have a high prevalence of HIV and other sexually transmitted infections and therefore fetal blood sampling would be contra-indicated in our setting. In order to validate our categorization of CTG traces, this study will use umbilical cord analysis instead. Umbilical cord blood analysis is an objective determinant of intrapartum fetal physiology. It

was established as early as 1958 as being able to recognise intrapartum fetal hypoxic stress (12).

In 2010, a meta-analysis was done, looking at the strength of association of acidosis at birth with neonatal mortality, morbidity (hypoxic ischaemic encephalopathy, intraventricular haemorrhage or periventricular leucomalacia) and long term outcomes (cerebral palsy). It included 51 cohort and case-control studies, with over 480 000 infants (13). The individual studies included in the metanalysis had different outcome thresholds for cord blood pH ranging from 7.00 to 7.27. Fifteen studies compared the association between cord pH and neonatal mortality and the results for a threshold of 7.10 achieved significance. Thirty one studies compared the association between cord pH and a variety of neonatal outcomes. The most substantial association was at a pH threshold of 7.00. Only one study examined three thresholds : $\leq$ 7.00, $\leq$ 7.10 and $\leq$ 7.20 and its outcome measure was death within the neonatal period (14). A clear dose-response relation was apparent within this study , with the strongest association at a threshold of 7.00 and the weakest at a threshold of 7.20.

It would therefore be useful to use umbilical cord blood analysis as an objective assessment of the changes to the NICE guidelines for the interpretation of CTG traces.

2. Aim

In this study, we would like to determine if the changes to the NICE guidelines, will improve observer analysis of intrapartum cardiotocographic monitoring.

3. Objectives:

a) To interpret CTG traces as per NICE 2014 guidelines.
b) To interpret CTG traces as per NICE 2017 guidelines.
c) To compare the interpretation of CTGs as per NICE 2014 and NICE 2017 guidelines with cord blood gas analysis.

4. Method

This study is a secondary analysis of data collected for an original study done by the co-supervisor. The original study looked at cerebro-placental ratio in labour and whether it could identify , early in labour, those patients that are at higher risk of an adverse outcome.

The inclusion criteria for this original study were :

a) Ability to understand and sign consent in English
b) In latent phase of labour, cervical dilatation <4cm at recruitment
c) Spontaneous labour
d) Most recent CTG is normal as judged by the researcher

The exclusion criteria were :
a) Normal vaginal delivery contra-indicated
b) Induction of labour
c) Most recent CTG is suspicious or pathological
d) Previously diagnosed intrauterine growth restriction with abnormal dopplers
e) Known major fetal anomaly
f) Less than 18 years old
g) Two vessel cord
h) Multiple pregnancy
i) Meconium stained liquor

The files of patients being attended to in the admission area were screened and those meeting the inclusion/ exclusion criteria were recruited for the original study. Ultrasounds were done in the admission area and cerebroplacental ratios calculated were correlated with APGAR scores and cord blood analyses.

CTGs and cord blood analyses from these files will be screened and those meeting the inclusion and exclusion criteria for this study will be assessed.

1. Sample

The sample should comprise of 200 CTG traces which will be obtained from files of patients previously studied by the co-supervisor.

4.1.1. Inclusion criteria

a) Any CTG trace done within 90 min of delivery, that is accompanied by a cord blood analysis.

4.1.2. Exclusion criteria

a) CTG traces that are not within 90min of delivery.

4.2. Setting

Rahima Moosa Mother and Child Hospital is a regional hospital in the City of Johannesburg, Gauteng province, South Africa. This hospital is part of the Wits Academic circuit.

4.3. Study design and Data collection

This study is an observational study involving the assessment of CTG traces using the NICE 2014 and NICE 2017 guidelines. The outcome of these assessments will be compared to the results of cord blood analysis. About 200 CTG traces are available with corresponding cord blood analysis. The CTGs, data collection tools, and corresponding cord blood analysis will be paired and numbered serially. There will be no patient identifiers used on the data collection tools. In order to avoid investigator bias, the cord blood analysis will be separated from the CTG.

In the first month of data collection, the CTG traces will be assessed by the principal investigator, using the 2014 data collection tool. In the second month of data collection, the same CTG traces will be re-assessed using the 2017 data collection tool.

Once all data collection is complete, the interpretation of the CTGs as obtained from the data collection tools will be re-matched with the cord blood analysis for that trace and all data will be entered into a RedCap program.

At RMMCH, management decisions are based on a combination of clinical findings, CTG assessments, as well as with patient input. No further testing (fetal blood sampling), is offered to confirm the findings of the CTG trace. Thus, the management plans for the last two categories in both guidelines, (the "Non- Reassuring category and indicates the need for conservative management and further testing" and the "Abnormal and indicates the need for urgent intervention" categories in the 2014 NICE guidelines, and the "Pathological" and "Need for urgent Intervention" categories of the 2017 NICE guidelines), are similar. Therefore, these two categories, will be merged for data analysis.

The NICE 2017 naming of the various categories of CTG traces (Normal/Suspicious/Pathological/ Need for urgent intervention), is more user-friendly. As the defining criteria for each category are the same in both guidelines, the NICE 2017 naming of categories will be used to assist with comparisons. CTG traces associated with a low umbilical cord blood pH of $\leq$ 7.10 will be categorized as pathological. A cord blood pH between 7.11 and 7.19 will be categorized as suspicious and a cord blood pH $\geq$ 7.2 will be categorized as normal. Study data will be captured in a RedCap program.

4.4. Confidentiality

Patient names recorded on CTG traces will not be collected as part of data. Instead, CTG traces will be numbered and only this numbering system will assist in pairing data collection tools and cord blood analyses.

4.5. Endpoints

The results of the assessments as normal, suspicious, pathological or need for urgent intervention, based on each guideline.

4.6. Bias

The study done by the co-supervisor included CTGs and blood gas analyses of patients that delivered vaginally as well as patients that delivered by caesarean section. All paients were believed to be low risk. Thus, by including patients that had a normal vaginal delivery, a sampling bias towards patients taken for caesarean section due to a pathological trace, will be avoided. Strict adherence to the description of CTG features as per 2014 and 2017 guidelines, will be maintained by use of the data collection tools. This will restrict the principal investigator's bias towards diagnosing pathological traces.

5. Data analysis

According to the guidelines, CTG traces are categorized as normal, suspicious and pathological and need for urgent intervention. However, for the purposes of statistical analysis the categories of normal and suspicious will be classified as normal while pathological and need for urgent intervention, will be classified as abnormal.

The data will be analysed using the statistical software STATA® (StataCorp, 4905 Lakeway Drive, College Station, Texas 77845 USA) version 13 (or more recent version). In order to understand the performance of these guidelines in measuring foetal distress, maximum likelihood estimate will be used to calculate the sensitivity and specificity of each guideline using cord blood analysis as gold standard. Other outcome measures will include estimates such as positive and negative predictive values. Confidence intervals will be included in the reporting of results.

A table that will assist in sensitivity and specificity calculations will be completed for each version of the guideline as below :

Table 5.1. Table for Sensitivity and Specificity calculations :

True Positive : The CTG is assessed as pathological and the cord blood pH is $\leq$ 7.1.	**False Negative :** The CTG is assessed as normal/suspicious, but the cord blood pH is $\leq$ 7.1.
False Positive : The CTG is assessed as pathological, but the cord blood pH is >7.1.	**True Negative :** The CTG is assessed as normal/ suspicious and the cord blood pH is > 7.1

6. Ethics

To be submitted to the WITS Health Research Ethics Committee after the protocol has been reviewed. The data collection tools will have no participant identifiers. Each participant will be given colour coded stickers which will link the two data collection tools. There will be no link between the informed consent and the data collection tools. Permission to do the study will be obtained from the CEO at RMMCH. (to be attached).

7.Timing

2018	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Protocol development									X	X	X	X
2019	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Submission	X											
Correction		X										
Ethics			X									
Data Collection				X	X							
Analysis						X	X					
Write up								X	X			
Marking										X		
Corrections											X	

8. Funding

All costs incurred, with regards to printing of data collection tools, travelling costs , re-imbursement of a biostatistician, publication fees and presentation at a conference, will be at the expense of the researcher.

Item	**Amount**
Photocopying of data collection tools	R 350
Travelling costs	R 500
Re-imbursement of biostatician	R 3000
Publication fee	R 5250
Conference costs	R 8000
Total cost	**R 17 100**

9. Problems

The sample comprises of 200 CTG traces which will be obtained from files of patients previously studied by the co-supervisor. Not all CTG traces may meet the inclusion criteria, thereby reducing the sample size, which may affect the statistical analysis of data.

This is a secondary analysis and therefore the limitations of such a study will be inherent in this study.

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Appendix B: Data collection tool using the NICE 2014 Interpretation of CTG guidelines

Tool serial number : _____

Mark with an X

Feature	**Re-assuring**	**Non-Re-assuring**	**Abnormal**
Baseline FHR	100- 160bpm	161-180bpm	Above 180bpm
Variability	≥ 5bpm	< 5bpm for 30- 90 min	< 5bpm for > 90 min
Decelerations	None or early	Variable , dropping from baseline by, ≤ 60bpm and taking ≤ 60s to recover, present for > 90min, in > 50% of contractions	Non-reassuring variable decels still observed 30min after starting conservative measures in > 50% of contractions.
		Variable, dropping from baseline by > 60 bpm or taking >60s to recover, present for up to 30min, occurring in > 50% of contractions	
		Late decelerations, present for up to 30 min, in > 50% of contractions	Late decelerations , present for > 30 min, that do not improve with conservative measures, in > 50% of contractions
			Bradycardia or single prolonged deceleration with a BL below 100bpm, lasting ≥ 3min.

ASSESSMENT :

Please circle the category that best describes this trace (circle a, b, c, or d)

A. Normal / Reassuring = All features are re-assuring

B. Non- Reassuring and suggests need for conservative management

= 1 non-re-assuring feature and 2 reassuring features

C. Non- Reassuring and indicates the need for conservative management and further testing

= One abnormal or two non-reassuring features

D. Abnormal and indicates the need for urgent intervention

= Bradycardia or single prolonged deceleration lasting $\geq$ 3min.

Appendix C: Data collection tool using the NICE 2017 Interpretation of CTG guidelines

Tool serial number : _____

Mark with an X

Feature	**Re-assuring**	**Non-Re-assuring**	**Abnormal**
Baseline	110- 160	100-109 or 161-180	<100 or >180
Variability	5-25	< 5 for 30-50min or > 25 for 15-25min	>25 for 25min or < 5 for > 50 min
Decelerations	None or early	Variable with no concerning features for ≥ 90 min	Variable with any concerning features in > 50 % of contractions for 30min. (or less if risk factors are present)
	Variable for <90min with no concerning features	Variable with concerning features for ≥ 30min in up to 50% of contractions	
		Variable with concerning features in >50% of contractions, for < 30 min	
		Late decelerations for < 30min in > 50% of contractions.With no risk factors eg PVB or	Late decelerations for 30 min (or less than 30min if risk factors are present)

		significant meconium	Bradycardia or a single prolonged deceleration lasting ≥ 3 min.

ASSESSMENT : Please circle the category that best describes this trace

NORMAL = All features are re-assuring

SUSPICIOUS = One non-re-assuring feature and two reassuring features

PATHOLOGICAL = One abnormal or two non-reassuring features

NEED FOR URGENT INTERVENTION = Bradycardia or single prolonged deceleration lasting ≥ 3min.

Appendix D: Data collection tool for cord blood analysis and further paediatric outcomes

Tool serial number : _____

1. Type of Delivery : Caesarean section / Normal vaginal delivery / Assisted vaginal delivery
2. Cord blood analysis
   2.1. pH : _____
   2.2. Base excess _____
   2.3. Lactate _____
3. Apgar scores
   2.1 At 5 minutes _____
   2.2. At 10 minutes _____

3. Admission to Ward 16 (Nursery) Yes / No

4. Reason for admission to Ward 16 :

4. NICU admission Yes / No

5. Reason for NICU admission :

Appendix E: Ethics Clearance Certificate

Note : Dr. A. Wise has been my supervisor since conceptualization of this study, however during the time of submission of my proposal to Ethics, Dr.Wise was not available for her signature, and thus the Ethics clearance certificate only includes Professor Lombaard as supervisor.

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

R14/49 Dr I Mahabeer

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M190411

NAME: (Principal Investigator)	Dr I Mahabeer
DEPARTMENT:	School of Clinical Medicine Department of Obstetrics and Gynaecology Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	Comparison of NICE 2014 versus NICE 2017 guidelines in predicting fetal cord blood analysis
DATE CONSIDERED:	2019/04/26
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Professor H Lombaard
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2019/06/20

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the 3rd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **April** and will therefore reports and re-certification will be due early in the month of **April** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

Date 21/08/2019

PLEASE QUOTE THE CLEARANCE CERTIFICATE NUMBER IN ALL ENQUIRIES

Appendix F: Turnitin Report



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ORIGINALITY REPORT

4%	4%	5%	4%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

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2	Submitted to University of Newcastle upon Tyne Student Paper	1%
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4	www.nice.org.uk Internet Source	1%
5	Diogo Ayres-de-Campos, Catherine Y. Spong, Edwin Chandraharan. "FIGO consensus guidelines on intrapartum fetal monitoring: Cardiotocography", International Journal of Gynecology & Obstetrics, 2015 Publication	1%
6	Sara Paterson-Brown, Tracey A. Johnston. "Fetal Monitoring During Labour", Wiley, 2018 Publication	1%

Appendix G: Plagarism declaration

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

FACULTY OF HEALTH SCIENCES

PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I Ishania Mahabeer (Student number: 2057437) am a student registered for the degree of Master of Medicine in the academic year 2020.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.
- I have included as an appendix a report from "Turnitin" (or other approved plagiarism detection) software indicating the level of plagiarism in my research document.

Signature: Mahabeer Date: 16/08/2020

1

Appendix H : Author Guidelines for SAJOG

Author Guidelines

Author Guidelines

Please view the Author Tutorial for guidance on how to submit on Editorial Manager.

To submit a manuscript, please proceed to the SAJOG Editorial Manager website: http://www.editorialmanager.com/sajog

To access and submit an article already in production, please see the guidelines here.

Author Guidelines

Please take the time to familiarise yourself with the policies and processes below. If you still have any questions, please do not hesitate to ask our editorial staff (tel.: +27 (0)21 532 1281, email: submissions@samedical.org).

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Authorship

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General:
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• Please make your article concise, even if it is below the word limit.
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• Abbreviations should be spelt out when first used and thereafter used consistently, e.g. 'intravenous (IV)' or 'Department of Health (DoH)'.
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- Please ensure that all genes are in italics, and proteins/enzymes/hormones are not.
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- Use the latest approved gene or protein symbol as appropriate:
o Human Gene Mapping Workshop (HGMW): genetic notations and symbols
o HUGO Gene Nomenclature Committee: approved gene symbols and nomenclature
o OMIM: Online Mendelian Inheritance in Man (MIM) nomenclature and instructions
o Bennet et al. Standardized human pedigree nomenclature: Update and assessment of the recommendations of the National Society of Genetic Counselors. J Genet Counsel 2008;17:424-433: standard human pedigree nomenclature.

Preparation notes by article type

Research
Guideline word limit: 3 000 words (excluding abstract and bibliography)
Research articles describe the background, methods, results and conclusions of an original research study. The article should contain the following sections: introduction, methods, results, discussion and conclusion, and should include a structured abstract (see below). The introduction should be concise – no more than three paragraphs – on the background to the research question, and must include references to other relevant published studies that clearly lay out the rationale for conducting the study. Some common reasons for conducting a study are: to fill a gap in the literature, a logical extension of previous work, or to answer an important question. If other papers related to the same study have been published previously, please make sure to refer to them specifically. Describe the study methods in as much detail as possible so that others would be able to replicate the study should they need to. Where appropriate, sample size calculations should be included to demonstrate that the

study is not underpowered. Results should describe the study sample as well as the findings from the study itself, but all interpretation of findings must be kept in the discussion section. The conclusion should briefly summarise the main message of the paper and provide recommendations for further study.

• May include up to 6 illustrations or tables.
• A max of 20 - 25references

Structured abstract

• This should be no more than 250words, with the following recommended headings:
o Background: why the study is being done and how it relates to other published work.
o Objectives: what the study intends to find out
o Methods: must include study design, number of participants, description of the research tools/instruments, any specific analyses that were done on the data.
o Results: first sentence must be brief population and sample description; outline the results according to the methods described. Primary outcomes must be described first, even if they are not the most significant findings of the study.
o Conclusion: must be supported by the data, include recommendations for further study/actions.
• Please ensure that the structured abstract is complete, accurate and clear and has been approved by all authors. It should be able to be intelligible to the reader without referral to the main body of the article.
• Do not include any references in the abstracts.

Illustrations/photos/scans

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• Tables should be constructed carefully and simply for intelligible data representation. Unnecessarily complicated tables are strongly discouraged.
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• Footnotes must be indicated with consecutive use of the following symbols: * † ‡ § ¶ || then ** †† ‡‡ etc.

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Some examples:

• Journal references: Price NC, Jacobs NN, Roberts DA, et al. Importance of asking about glaucoma. Stat Med 1998;289(1):350-355. http://dx.doi.org/10.1000/hgjr.182
• Book references: Jeffcoate N. Principles of Gynaecology. 4th ed. London: Butterworth, 1975:96-101.
• Chapter/section in a book: Weinstein L, Swartz MN. Pathogenic Properties of Invading Microorganisms. In: Sodeman WA, Sodeman WA, eds. Pathologic Physiology: Mechanisms of Disease. Philadelphia: WB Saunders, 1974:457-472.
• Internet references: World Health Organization. The World Health Report 2002 - Reducing Risks, Promoting Healthy Life. Geneva: WHO, 2002. http://www.who.int/whr/2002 (accessed 16 January 2010).
• Legal references
• Government Gazettes:

National Department of Health, South Africa. National Policy for Health Act, 1990 (Act No. 116 of 1990). Free primary health care services. Government Gazette No. 17507:1514. 1996.
In this example, 17507 is the Gazette Number. This is followed by :1514 - this is the notice number in this Gazette.
• Provincial Gazettes:
Gauteng Province, South Africa; Department of Agriculture, Conservation, Environment and Land Affairs. Publication of the Gauteng health care waste management draft regulations. Gauteng Provincial Gazette No. 373:3003, 2003.
• Acts:
South Africa. National Health Act No. 61 of 2003.
• Regulations to an Act:
South Africa. National Health Act of 2003. Regulations: Rendering of clinical forensic medicine services. Government Gazette No. 35099, 2012. (Published under Government Notice R176).
• Bills:
South Africa. Traditional Health Practitioners Bill, No. B66B-2003, 2006.
• Green/white papers:
South Africa. Department of Health Green Paper: National Health Insurance in South Africa. 2011.
• Case law:
Rex v Jopp and Another 1949 (4) SA 11 (N)
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1949: Date of decision (or when the case was heard)
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SA: SA Law Reports
11: Page or section number
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From submission to acceptance

Submission and peer-review

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• The following are required for your submission to be complete:
o Anonymous manuscript (unless otherwise stated)
o Author Agreement form
o Manuscript

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Peer Review Process

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The following process should usually take between 4 - 6 weeks:
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3. If the CE has an author queries, he/she will contact the corresponding author and send them the copyedited Word doc, asking them to solve the queries by means of track changes or comment boxes.
4. The authors are typically asked to respond within 1-3 days. Any comments/changes must be clearly indicated e.g. by means of track changes. Do not work in the original manuscript - work in the copyedited file sent to you and make your changes clear.
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6. Once typeset, the CE will send a PDF of the file to the authors to complete their final check, while simultaneously sending to the 2nd-eye proofreader.
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• Full detail of proposed correction and rationale

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