STRENGTHENING THE SCIENTIFIC BASE FOR THE UNAMBIGUOUS CATEGORY II FETAL HEART RATE TRACING ALGORITHM

A DISSERTATION SUBMITTED TO THE GRADUATE DIVISION OF THE UNIVERSITY OF HAWAI'I MĀNOA IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF

DOCTOR OF PHILOSOPHY

IN

NURSING

MARCH 2017

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Keywords: Category II fetal heart rate tracing algorithm, Donabedian theory

ACKNOWLEDGMENTS

I would like to thank my dissertation chair, Dr. John Casken, and the other members of my dissertation committee, Dr. Jeanie Flood, Dr. Karol Richardson, Dr. Stacey Roberts, and Dr. William White, for their kindness, support, and encouragement. The synergy of this committee is very special. I very much appreciate all of the time, commitment, and understanding the committee members devoted to this effort. I especially want to thank Dr. John Casken for his patience, clear guidance, and enthusiasm.

ABSTRACT

Early recognition with appropriate interventions can prevent harm for fetuses suffering from hypoxia during labor. Two preliminary studies show that utilizing a relatively simple algorithm, created by an expert consensus group in 2013, unambiguously identifies fetal heart rate baseline characteristics and deceleration patterns associated with risk for dangerous levels of hypoxia/acidemia. This algorithm, designed to help clinicians decide if, how, and when to intervene during maternal labor to safely care for fetuses who exhibit Category II fetal heart rate tracings during labor, required more research to generate more evidence regarding efficacy. The purpose of this study was to generate more evidence regarding the efficacy of the algorithm. This study used a Donabedian theoretical framework. Public access archived tracings of 552 fetal heart rates in the 30-90 minutes preceding delivery were blind analyzed using the Category II algorithm decision tree and the associated extensive clarifications for use in algorithm. Comparison of the algorithm-driven labor and delivery timing and mode, with the actual labor and delivery timing and mode measured outcome differences in newborn status, operative vs. non-operative delivery, and timing of delivery. FHR tracings of 175 out of 177 (98.9%) of the babies born with acidemia (umbilical artery pH <7.20) had conservative interventions recommended by algorithm-driven analyses for Category II FHR tracings. Earlier delivery at an average of 18.4 minutes (range 5 to 34 minutes) was recommended per algorithm-driven analyses for 17 tracings, all of which had birth pH <7.20. No increase in operative delivery was recommended for any tracings with pH ≥ 7.20.

Keywords: Category II fetal heart rate tracing algorithm, Donabedian theory

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LIST OF ACRONYMS AND ABBREVIATIONS

CTG	cardiotocography (fetal heart and uterine activity recording)
CDC	Centers for Disease Control and Prevention
EFHRM	electronic fetal heart rate monitoring
EFM	electronic fetal monitoring
FHR	fetal heart rate
NICHD	National Institute of Child Health and Human Development
OVD	operative vaginal delivery (vacuum extractor or forceps assisted delivery)

CHAPTER 1

INTRODUCTION

Early recognition with appropriate interventions can prevent harm for fetuses suffering from hypoxia during labor. Two preliminary studies (Clark et al., 2015; Clark et al., 2016) show that utilizing a relatively simple algorithm (Clark et. al., 2013) unambiguously identifies fetal heart rate (FHR) baseline characteristics and deceleration patterns associated with risk for dangerous levels of fetal hypoxia/acidemia. This 2013 algorithm was designed to help clinicians decide if, how, and when to intervene during maternal labor to safely care for fetuses who exhibit Category II FHR tracings during labor. More research was needed to generate more evidence regarding efficacy. The purpose of this study was to generate more evidence regarding the efficacy of the algorithm.

Electronic fetal heart rate monitoring in labor is widely employed throughout the country. Approximately 89% of U.S. hospital births utilize electronic FHR monitoring (Declercq, Sakala, Corry, Applebaum, & Herrlich, 2014). Electronic FHR tracing interpretation requires human visual reading of tracings, because current computer technology does not integrate a complete clinical picture into automated interpretation. Thus, interpretation and management of FHR tracings by nurses and physicians is a significant part of intrapartum patient care.

Electronic FHR monitoring was incorporated into intrapartum clinical practices throughout the U.S. without being appropriately validated with scientific evidence (Miller, 2012, p.23). In the U.S., standardized electronic FHR terminology has been slowly evolving since 1968, when the first commercially available machines became available in this country. Standardized electronic FHR terminology and interpretation are important both for patient safety related to meaningful communications between clinicians, and for consistency in research protocols. Early electronic FHR research results were difficult to compare between studies, due to variation in terminology, definitions, and protocols (Association of Women's Health, Obstetric and Neonatal Nurses [AWHONN], 2015, p. 684; National Institute of Child Health and Human Development [NICHD], 1997, p.635). As such, the National Institutes of Health and Child Development (NICHD) organized workshops for perinatal experts to create national standards for electronic FHR monitoring. These workshops took place in 1979, 1997, and the most recent one in 2008.

The 1979 workshop summary (Zuspan, Quilligan, Iams, & van Geijn, 1979) recommended specific fetal heart rate assessment standards for low-risk and for high-risk patients in labor using intermittent auscultation and/or continuous electronic fetal monitoring methods. It also called for more randomized clinical trials of electronic fetal monitoring "coordinated at the national level to provide optimum benefit from the data acquired" (p. 1029).

The 1997 workshop summary (NICHD, 1997) focused on electronic FHR monitoring research guidelines for interpretation. The goal of the 1997 workshop was to propose a standardized and rigorously "unambiguously described set of definitions that can be quantitated" (p. 636). These precise FHR definitions were seen as necessary "so that the predictive value of monitoring could be assessed more meaningfully in appropriately designed observational studies and clinical trials. Ultimately, this research direction should lead to more evidence-based clinical management of intrapartum fetal compromise" (p. 636). Many, but certainly not all, clinicians and L&D units began using the NICHD 1997 terminology, since it was mainly intended for research purposes. The impetus for a common terminology for daily clinical use largely came from The Joint Commission's 2004 Sentinel Alert #30, which recommended that nurses and physicians use standard terminology and participate in FHR interpretation education. In a study of 47 cases of perinatal death or permanent disability, 72% of cases involved communication issues, and 34% of cases had inadequate fetal monitoring involved in root causes (The Joint Commission, 2004).

The third and most recent NICHD electronic FHR monitoring workshop was to update definitions, interpretation, and research guidelines (Macones, Hankins, Spong, Hauth, & Moore, 2008a, 2008b). It will be discussed in detail later in this paper.

Significantly, in 2006, a U.S. team including three physicians, a nurse, and a nurse-midwife concluded from their systematic review, that excluding the occurrence of catastrophic events, progressively deepening recurrent late or variable decelerations with evolving reduction in fetal heart rate baseline variability "may serve as a trigger for action" for attempts to improve fetal oxygen status, since there is usually a relatively long period of "approximately one hour" to intervene prior to severe acidemia capable of inflicting serious fetal damage (Parer, King, Flanders, Fox, & Kilpatrick, 2006, p. 292). They discussed gaps in knowledge and research needs (which support this study's methodology) stating:

> Fetal heart rate monitoring is being used in virtually all delivery suites within North America. Interpretations and management decisions are often being made in a non-standardized and sometimes subjective way, unsubstantiated by

> evidence-based observations. Ideally, the relationship between specific FHR patterns and fetal acidemia should be determined in a prospectively gathered series of unselected cases that includes the full range of different FHR patterns recorded up until the time of birth, and measurements of umbilical cord arterial blood gases and acid–base state, and other measures of newborn outcome. This would enable the determination of the validity of a relationship between specific patterns and fetal acidemia. However, in the absence of such a series, we are forced to use the observational data that are available. (Parer et al., 2006, p. 292)

2008 NICHD 3-Tier System for Electronic Fetal Heart Rate Tracing Interpretation

Tremendous progress in standardizing electronic fetal monitoring clinical terminology resulted from national adoption of the 2008 Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) 3-tier system of FHR tracing definitions and recommended care (Macones et al., 2008a, 2008b). In this 3-tier classification system, FHR tracings that meet NICHD Category I criteria are considered normal and do not require special action, Category II FHR patterns are considered indeterminate, requiring continuing re-evaluation, and Category III FHR patterns are considered abnormal and require immediate intervention to promptly improve fetal oxygenation (Macones et al., 2008a, 2008b) (See Figure 1). It is important to note that *no NICHD recommendations* were in the summary statement to expedite delivery, *even with a Category III FHR tracing*. Also*, no recommendations* were in the summary statement to intervene conservatively or otherwise with a Category II FHR tracing. This absence of recommendations was the catalyst for confusion in the obstetric community.

Three-Tier Fetal Heart Rate Interpretation System

Category I

Category I fetal heart rate (FHR) tracings include all of the following:

- Baseline rate: 110–160 beats per minute (bpm)
- Baseline FHR variability: moderate
- Late or variable decelerations: absent
- Early decelerations: present or absent
- Accelerations: present or absent

Category II

Category II FHR tracings include all FHR tracings not categorized as Category I or Category III. Category II tracings may represent an appreciable fraction of those encountered in clinical care. Examples of Category II FHR tracings include any of the following:

Baseline rate

- Bradycardia not accompanied by absent baseline variability
- Tachycardia

Baseline FHR variability

- Minimal baseline variability
- Absent baseline variability not accompanied by recurrent decelerations
- Marked baseline variability

Accelerations

- Absence of induced accelerations after fetal stimulation

Periodic or episodic decelerations

- Recurrent variable decelerations accompanied by minimal or moderate baseline variability
- Prolonged deceleration ≥ 2 minutes but <10 minutes
- Recurrent late decelerations with moderate baseline variability
- Variable decelerations with other characteristics, such as slow return to baseline, "overshoots," or "shoulders"

Category III

Category III FHR tracings include either:

- Absent baseline FHR variability and any of the following:
  - Recurrent late decelerations
  - Recurrent variable decelerations
  - Bradycardia
- Sinusoidal pattern

Figure 1. The 2008 National Institute of Child Health and Human Development Workshop Report on Electronic Fetal Monitoring: Update on Definitions, Interpretation, and Research Guidelines. (Macones et al., 2008a, p. 514). Copyright 2008 by Elsevier. Reprinted under Elsevier open access content user license permission.

Category II FHR patterns include many diverse components of fetal heart tracings, some which have traditionally been considered benign, and some of which are considered very worrisome to many clinicians. Research recommendations included in the 2008 NICHD summary stated: "Areas of highest priority for research include observational studies focused on indeterminate FHR patterns, including descriptive epidemiology, frequency of specific patterns, change over time, the relationship to clinically relevant outcomes, and the effect of duration of patterns…" (Macones et al., 2008a, p. 515, 2008b, p. 665).

In the current National Institute of Child Health and Human Development (NICHD) 3-tier classification system, FHR tracings that meet criteria for NICHD Category II FHR patterns are considered indeterminate, requiring continuing bedside patient re-evaluation (Macones et al., 2008a, 2008b). *No specific recommendations for when and how to intervene when faced with specific types of Category II electronic fetal heart rate tracings were described in the 2008 NICHD workshop report.*

Category II patterns occur in more than 80% of fetuses during labor (Elliott, Warrick, Graham, & Hamilton, 2010; Jackson, Holmgren, Esplin, Henry, & Varner, 2011; Parer & King, 2010), and the NICHD recommendations are too vague for ensuring safe labor and delivery for these fetuses. Category II (indeterminate FHR tracings) data, still has not been *clearly* defined as to interpretation and recommended intervention strategies by a national authority. The NICHD 3-tier terminology system (Macones et al., 2008a, 2008b) was introduced in September 2008. Universal adoption in the United States was endorsed in position statements from professional perinatal organizations including the American College of Obstetricians and Gynecologists (American College of Obstetricians and Gynecologists [ACOG], 2009), the Association of Women's Health, Obstetric and Neonatal Nurses (Association of Women's Health, Obstetric and Neonatal Nurses [AWHONN], 2008), and the American College of Nurse Midwives (American College of Nurse Midwives [ACNM], 2011). It is notable that national universal adoption of the NICHD 3-tier system was accelerated by the simultaneous publication of the NICHD Summary Statement in September 2008 in two of the country's most esteemed and popular nursing and medical obstetrics journals (Macones et al., 2008a, 2008b). Also, in September 2008, a notification letter was sent to each Nurse Manager and to each Medical Director of every Labor/Delivery unit in the U.S., regarding the NICHD 3-tier system and terminology/recommendation as the new national standard to be instituted for practice and communications by and between *all* obstetrical personnel.

2009 and 2010 ACOG 3-Tier System Clarifications and Additions to Electronic Fetal Heart Rate Tracing Interpretation

In 2009, the American College of Obstetricians and Gynecologists (ACOG) put standards in place by giving direction on nomenclature, interpretation, and intervention best practices for Category I and Category III FHR tracings management (covering ~20% of fetuses). ACOG recommended standards (2009) were adequate for providing clear care standards for Category I and Category III FHR tracings. This 2009 ACOG Practice Bulletin added an important further intervention to the NICHD list, that of delivering the fetus, if conservative measures failed to improve the deteriorating fetus's status:

Depending on the clinical situation, efforts to expeditiously resolve the abnormal

FHR pattern may include but are not limited to provision of maternal oxygen, change in maternal position, discontinuation of labor stimulation, treatment of maternal hypotension, and treatment of tachysystole with FHR changes. If a Category III tracing does not resolve with these measures, delivery should be undertaken. (pp. 193-195)

However, management strategies for Category II FHR tracings, although somewhat clearer, were still inadequate: "In some circumstances, either ancillary tests to ensure fetal wellbeing or intrauterine resuscitative measures may be used with Category II tracings" (ACOG, 2009, p.193).

In 2010 ACOG published a landmark practice bulletin. This 2010 ACOG Practice Bulletin was authored by a collaboration of nationally renowned experts from medicine, nursing, and nurse-midwifery, and the results greatly clarified and improved standards for decreasing or discontinuing oxytocin in the setting of tachysystole (uterine contractions occurring more frequently than 5 in a 10 minute period). Also, this 2010 ACOG Practice Bulletin defined minimal variability as more than just needing continued observation with intrauterine resuscitation/non-operative interventions, stating: "Continued minimal variability (in the absence of accelerations or normal scalp pH) that cannot be explained or resolved with resuscitation should be considered as potentially indicative of fetal acidemia and should be managed accordingly" (p. 1237). With Category III FHR tracings, the 2010 ACOG Practice Bulletin stated: "…when a decision for operative delivery in the setting of a Category III EFM tracing is made, it should be accomplished as expeditiously as feasible" (p. 1237).

The 2010 ACOG Practice Bulletin also recommended that if a Category II FHR tracing was not improved with intrauterine resuscitative measures, or there is progression to a Category III FHR pattern, to consider delivery (See Figure 2). Various intrauterine resuscitative measures for Category II or Category III tracings, or both, include maternal repositioning, discontinuing uterine stimulants, administering maternal uterine relaxants and/or supplemental oxygen and/or IV fluid boluses, and/or amnioinfusion if cord compression/variable decelerations are present; and elevating the presenting fetal part until operative delivery is carried out if there is an umbilical cord prolapse (p. 1236).

A shortcoming of the ACOG 2010 Practice Bulletin was that it failed to provide any time-specific guidance for interventions, although the international literature has given time-line recommendations for when to consider minimal variability to be pathological for many years (Ayres-de-Campos & Bernardes, 2010; Federation International of Gynaecology & Obstetrics [FIGO], 1987; Liston et al., 2007; National Institute for Health and Care Excellence [NICE], 2014; NICE, 2007), and good evidence exists to justify establishing reasonable time-line standards for intervening for a deteriorating fetal status.

For example, Kamoshita et al. (2010) showed that among 19 patients with sustained fetal bradycardia due to umbilical cord prolapse, placental abruption, or uterine rupture, when the bradycardia to delivery interval was less than 25 minutes, all term pregnancies led to normal neonatal neurologic development at the age of 2 years. Leung, Leung, and Paul (1993), reviewed 106 cases of uterine rupture after previous cesarean deliver and found that significant neonatal morbidity occurred when ≥ 18 minutes elapsed between the onset of prolonged deceleration and delivery. King &

Parer (2011, p. 670) presented an opinion that a diagnosis of "risk of serious fetal acidemia" rather than of "fetal distress" is more precise in their analysis of a case where a baby was born vigorous at birth, with Apgar scores of 6 at one minute and 8 at five minutes, an umbilical arterial cord gas with a pH of 7.04, and a base excess of -8mEq/L. The electronic FHR tracing (See Figure 2) showed absent variability and recurrent late decelerations that worsened with conservative measures such as maternal position changes and supplemental maternal oxygen administration. An emergency cesarean delivery was performed. King and Parer cited this case as a good example of what would have been labeled as a "false positive test" of fetal monitoring, because the newborn did not have evidence of significant academia. However King and Parer maintained that the goal of fetal monitoring is to identify fetuses with an FHR pattern that is associated with a significant risk for academia, and to ameliorate the pattern with conservative measures, or intervene with earlier delivery if the pattern does not improve. As such, they stated that the infant likely "would have had adverse consequences of metabolic acidosis if labor had continued without intervention" (p. 669). In other words, in this case, electronic FHR monitoring worked as devised, to screen for a potential problem and to prevent harm by intervening in a timely manner. As such, a false positive rate of 100% would be the goal and ideal for Category III FHR tracings with fetal monitoring in labor.

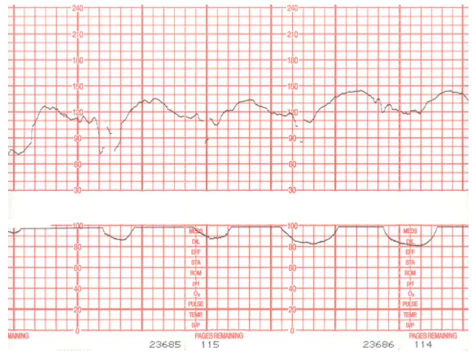


Figure 2. Category III fetal heart rate tracing (King & Parer, 2011, p.670). Copyright 2011 by Elsevier. Reprinted with permission.

Attributes of Category II Fetal Heart Rate Tracings

The NICHD's 2008 workshop report on electronic fetal monitoring terminology, interpretation and research guidelines described Category II FHR tracings as including all FHR tracings "not categorized as Category I or Category III. Category II tracings may represent an appreciable fraction of those encountered in clinical care" (Macones et al., 2008a, p. 514, 2008b, p. 665).

Dangers associated with prolonged minimal FHR baseline variability were, for the most part, ignored by the NICHD 2008 workshop recommendations, even though a great deal of evidence showed that persistent minimal base variability was a FHR tracing component that commonly occurs in deteriorating fetal status. While many healthy fetuses exhibit *limited* periods of minimal variability, virtually all sick fetuses exhibit persistent decreased, minimal variability as they deteriorate and become increasingly hypoxic.

Figure 3 emphasizes the diversity of FHR patterns and components included in Category II tracings, some of which are considerably much more worrisome than other patterns and components within the table. The components that are of high concern have been bolded and underlined.

Category II Fetal Heart Rate Tracings Include Any of the Following Examples:			
Baseline Rate	*Baseline Variability*	*Accelerations*	*Decelerations*
Bradycardia not accompanied by absent baseline variability	**Minimal baseline variability**	Absence of induced accelerations after fetal stimulation	**Recurrent variable decelerations** accompanied by **minimal** or moderate baseline variability
Tachycardia	Marked baseline variability		**Prolonged deceleration** >2 minutes but <10 minutes
	Absent baseline variability not accompanied by recurrent decelerations		**Recurrent late decelerations with minimal** or moderate baseline variability
			Variable decelerations with other characteristics, such as slow return to baseline, "overshoots," or "shoulders"

Figure 3. NICHD's description of Category II fetal heart rate tracings (Descriptions adapted from Macones et al., 2008a, p. 514. Copyright 2008 by Elsevier. Reprinted under Elsevier open access content user license permission. ***Note:*** *Category II FHR Patterns Occur in Over 80% of All Labors*.

Prior to the 2008 National Institute of Child Health and Human Development FHR tracing terminology workshop summary (Macones et al., 2008a, 2008b), normal tracings were routinely described and documented in the U.S. as "reassuring" FHR patterns. In contrast, absent variability in the FHR baseline has long been considered pathological, and was commonly described as a "non-reassuring" FHR tracing component. More ambiguous is minimal FHR baseline variability, with amplitude range from greater-than-undetectable to 5 beats per minute, peak to trough. Minimal fetal heart baseline variability may exist for limited periods, usually 20-60 minutes, in an adequately oxygenated fetus. In a normal fetus, these limited minimal FHR baseline periods are usually due to normal fetal sleep periods or due to maternal administration of narcotics or other medications. Prior to the 2008 NICHD terminology workshop summary (Macones et al., 2008ba, 2008b), minimal variability, in some circumstances, might have been described as "not reassuring, but not non-reassuring," which could be a confusing issue in the clinical setting. The 2008 NICHD guidelines noticeably did not include the terms "reassuring" or "non-reassuring" in the summary statement, instead calling Category II tracings "indeterminate," and stating that all tracings with minimal variability should be considered to be Category II tracings (Macones et al., 2008a, 2008b).

A fetus may have an FHR tracing which exhibits category changes over time, with or without intervention, between NICHD defined categories. As a fetus becomes stressed or hypoxic, compensatory changes (Ugwumadu, 2014) may be demonstrated with FHR patterns, which may include baseline variability initially becoming marked, or decreasing; variable or late decelerations of the FHR, and/or increases or decreases in baseline rate. Applying Ugwumadu's 2014 physiologic model to the NICHD's 3-tier system (See Figure 5), Category II tracings would indicate fetal compensatory responses to stress or oxygen deprivation. Category III tracings are somewhat analogous to the Society of Obstetricians and Gynaecologists of Canada (SOGC), and to the British National Institute for Health and Care Excellence (NICE) and to the European International Federation of Gynecology and Obstetrics (FIGO) electronic fetal monitoring tracing interpretations of abnormal or pathological patterns (NICE, 2014 & 2007; Ayers Campos & Bernardes, 2010; Liston, Sawchuck, & Young 2007). However, the U.S. NICHD 3-tier system includes minimal baseline variability of detectable-but-less-than-5 beats per minute as a Category II FHR tracing component, whereas the

SOGC, NICE and FIGO guidelines consider more than 40 to 80-90 minutes of minimal FHR baseline variability to be abnormal or pathological (Figure 4).

Moderate FHR baseline variability is associated with fetal blood pH >7.0. Fetal injury or death due to oxygen deprivation does not result unless the fetus decompensates with significant fetal metabolic acidemia with a pH less than 7.0 and a base deficit ≥12 mmol/L (ACOG, 2014; Miller, 2011). This means that clinicians usually have time to intervene with supportive care for a decompensating fetus in labor, when a Category I tracing changes to one with minimal or absent variability with significant FHR decelerations, if fetal monitoring is interpreted and actions taken in a standardized method (except with an extremely rare catastrophe, such as very rapid fetal exsanguination from a ruptured vasa previa, umbilical cord prolapse, etc. occur).

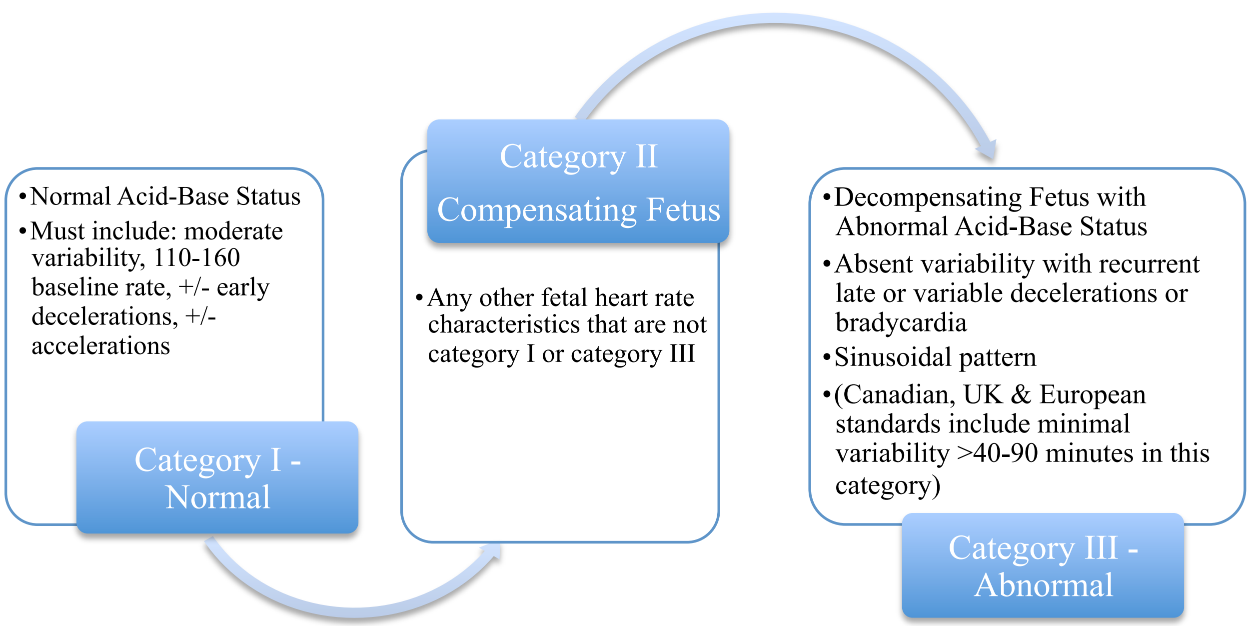


Figure 4: Physiologic Electronic Fetal Heart Rate Tracing Interpretation

In a September 2016 editorial, Vintzileos & Smulian wrote that "most fetuses are developing acidemia when their FHR tracing is still Category II… when fetuses progress from adaption to deterioration. In the absence of a correctable etiology, this may be the most appropriate time for a delivery intervention" (p. 263).

Much literature has focused on clarifying how to use the 2008 NICHD 3-tier system for effectively interpreting and managing the broad spectrum of ambiguous FHR patterns of Category II tracings (ACOG, 2009, 2010; Hamilton, Warrick, & O'Keeffe, 2012; King & Parer, 2011; Parer & King, 2010). Even when the ACOG electronic FHR practice bulletins were updated (ACOG 2009, 2010), adequate clarity was achieved for Category I and Category III tracings, yet there were still no clear timelines or comprehensive standards for managing Category II tracings. U.S. nurses and physicians lack a clear nationally sanctioned standard of care for the 80% of fetuses demonstrating Category II FHR tracings during the intrapartum period. Whereas Canadian, British, and European professional obstetric standards give variable but clearer guidance as to the maximum length of time absence of moderate variability in the FHR baseline should be observed before obstetric intervention is recommended (a Category II FHR classification in the U.S.), American nurses and physicians continue to have no national level sanctioned guidance on this issue. Consequences include a lack of improvement in U.S. neonatal mortality rates and high U.S. cesarean rates compared to other nations (See Table 1).

Table 1. Mortality rate, neonatal (per 1,000 live births)[a] -Cesarean rate (per 1,000 live births)[b]

Country	**1990 Neonatal Mortality Rate**[a]	**2015 Neonatal Mortality Rate**[a]	**2013 Cesarean Rate**[b]
Finland	4	1	158.0
Luxembourg	4	1	270.2
Israel	6	2	158.3
Sweden	4	2	164.2
Austria	5	2	287.8
Czech	10	2	248.7
Cuba	7	2	356 (2005 WHO data)[d]
Greece	10	3	169 (2006 WHO data)[d]
Italy	9.7 (UN)[e]	3	361.4
USA	6	4	327[c]

a Source World Bank (2016)
b Source Organisation for Economic Co-operation and Development (2016)
c Source Osterman & Martin (2014)
d Source World Health Organization (WHO) (2010)
e Source United Nations (UN) (2016)

Rescue during Category III FHR tracings, which are predictive of abnormal fetal acid-base status at the time of observation, may be too late to prevent permanent fetal injury or death. Conservative preventative measures before deterioration from a concerning Category II to a Category III FHR tracing may improve fetal outcomes while preventing some otherwise unnecessary cesarean or operative vaginal deliveries. If maternal position changes, maternal supplemental oxygen administration, uterine contraction suppression, or improving maternal blood pressure/placental blood flow, etc., fail to improve the FHR pattern, then earlier delivery may mitigate or prevent fetal harm.

The consensus group's algorithm (Clark et al., 2013) explains Category II FHR tracings in unambiguous, time-specific terms related to labor stage and progress. It specifies very clear timing for recommended observations and interventions that remain within the current ambiguous national standard of care while offering an option for improved patient safety and standardized professional care. According to Clark et al. (2013):

> … our algorithm does not seek to replace any established methodical approach to the management of Category II patterns. Rather, we suggest that this algorithm will be helpful in the current clinical setting in the United States in which a lack of clear direction has led to divergent decision making regarding cesarean section for FHR abnormalities… Application of the algorithm, along with the integration of future evidence-based modifications driven by additional research, will provide clinicians with a standardized, simple, rational, evidence-based, and nationally accepted approach to the management of Category II FHR patterns. (p. 96)

The Clark et al., 2013 group's algorithm helps nurses and physicians to unambiguously identify FHR baseline characteristics and deceleration patterns associated with risk for dangerous levels of hypoxia/acidemia. Early identification allows enough time to safely use conservative methods to improve the FHR patterns. If conservative methods do not ameliorate the FHR patterns then the option would be to deliver the fetus well before those levels of hypoxia/acidemia are reached, rather than waiting until the fetus is dangerously hypoxic/acidotic, then making the decision to deliver.

In the Clark group's 2013 article, which lays out the new algorithm and recommendations for standards of care for Category II fetal heart rate tracing interpretation and intervention strategies, the healthcare community is requested to test this algorithm and report on its level of efficacy. It is crucial to understand that standardization does not means throwing away professional judgment and trying to make the situation fit the standard, but rather standardization is a place and a structure from which to start, helping to lessen the possibility of preventable error through reminders, decision flow charts, and common courses of action, to cross-check and document all of the steps necessary for optimal outcomes. An example from another profession, are the standard checklists, protocols, and nomenclature used by pilots for tasks such as pre-flight, instrument checks, engine-on, take-off, level flight, landing, communication, and the mandatory training of pilots in a large number of emergency procedures. This training makes pilots able to handle common situations and emergencies almost reflexively, and makes unusual situations easier to deal with because of the comprehensive knowledge of their profession they already hold through this extensive training. An example of an airline pilot who exemplified this standard, is Chesley Sullenberger. He landed his airliner in the Hudson River in 2009, after both engines were disabled by a flight of Canada geese hitting the engines. Obviously, this particular problem is not exactly part of pilot training. However, because of his extensive training in emergency procedures, he and his crew were able to safely land the airliner in the Hudson River, without a single passenger or flight crew casualty.

This same idea holds true for the standardization of intrapartum fetal heart rate monitoring management. Training in how to react appropriately in all of the situations that can be anticipated, emergency and otherwise, only makes the medical professional more competent in handling the unusual.

Healthcare is not a static activity – changes in disorders, technologies, treatments, and environmental factors constantly change. Nurses and physicians are not above or exempt from the need to constantly retrain and adhere to regularly updated standardized care protocols anymore than airline pilots or other professionals. In the field of obstetrics, nurses, nurse-midwives, obstetricians, and perinatologists need certification and regularly scheduled recertification in electronic fetal monitoring to keep up with skills, changes, and innovations in fetal heart rate tracing interpretation and patient care management.

Purpose of the Study

The purpose of this study was to test the *Algorithm for Management of Category II Fetal Heart Rate Tracings*, created by Clark et al. (2013), to generate more evidence to evaluate its utility for improved efficacy in the interpretation and clinical management of Category II FHR tracings. This study blind tested the Clark et al., 2013 Category II FHR monitoring algorithm on 552 FHR tracings (Chudáˇcek et al., 2014) retrospectively, without reference to the original decisions made and interventions carried out at the time each strip was made. The 2013 algorithm decision tree and associated extensive "clarifications for use in algorithm," were thus tested to see if its use gave unambiguous direction on interpretation and intervention for these 552 FHR tracings*, which would potentially yield better fetal (higher Apgar scores, less acidosis, fewer admissions to NICU, less neurological and other damage, etc.) outcomes, as it has in the two Clark et al. 2015 and 2016 research efforts*.

Research Question 1. Will Clark et al.'s (2013) *Algorithm for Management of Category II Fetal Heart Rate Tracings* reliably give unambiguous direction on interpretation and intervention for Category II fetal heart rate tracings?

Research Question 2. Can using the Clark et al.'s (2013) *Algorithm for Management of Category II Fetal Heart Rate Tracings* on the 552 fetal heart rate and uterine contraction tracings result in different recommendations for management and intervention forecasting a possibly improved outcome over the actual result?

Significance of the Study

This study is significant because more research was needed to validate the Clark et al., 2013 Category II FHR tracing algorithm and the associated standards of care labor management recommendations for national use, since at this point in time, only two research efforts have been carried out with this in mind (Clark et al., 2015, 2016). This study was necessary since more research evidence was required to validate the efficacy of the 2013 algorithm. Currently there is no nationally recognized method available from which to develop a clear national standard for the unambiguous interpretation and intervention of Category II FHR tracings. The NICHD and ACOG put in place clear standards for the 20% of fetuses who have tracings that fall solely into Categories I (normal) and III (abnormal), but left fetuses who have Category II tracings, which make up at least 80% of the total fetuses, with FHR tracings classified as indeterminate. This is an ambiguous classification of fetuses with Category II heart rate tracings, which can deteriorate and enter the Category III classification, or improve and enter Category I.

The Clark group's unambiguous Category II FHR tracing algorithm is a combination of a fetal intervention decision tree and a set of recommendations (extensive "clarifications for use in algorithm") for standardizing care based on the fetal status and labor progress. Since further research efforts are necessary to provide proof that the algorithm works or does not work as posited in various clinical settings, this study helped further this process. Efforts to construct clear national standards, covering electronic FHR tracings of Category I, Category II, and Category III, are sorely needed; to facilitate various types and categories of FHR tracings to be read and interpreted intelligently, so that when interventions were indicated, they can be initiated in a timely manner, so as to yield optimum fetal and maternal outcomes. Goals should be set to achieve significantly better newborn Apgar scores, fewer NICU admissions, fewer fetal neurological problems, and fewer fetal deaths; as well as lower rates of cesarean and operative deliveries, and increased rates of spontaneous vaginal births.

Of secondary interest, this study was the first to use the 2013 Category II algorithm on electronic FHR tracings from outside the United States. This tested the algorithm to see if it was applicable in the international community, rather than only usable on FHR tracings generated in U.S. obstetrical settings.

Theoretical Framework

The theoretical framework chosen for use in this research study was the Donabedian Model. According to Donabedian (2003), how well a health care system functions, is controlled by structure, process, and outcome. Structure is how "a health care system is set up" (p. 50). Process means "quality of the process of care" (p. 52). Outcome is defined "as the consequences attributable to antecedent care" (p. 52). The relationship of these three attributes is bi-directional, but cyclical, with a feedback loop. Donabedian states that his concept of "planned reconnaissance" (p. 31) involves constant monitoring for problems, which involves the process of changing how a health care system functions, if a problem is identified (See Figure 5).

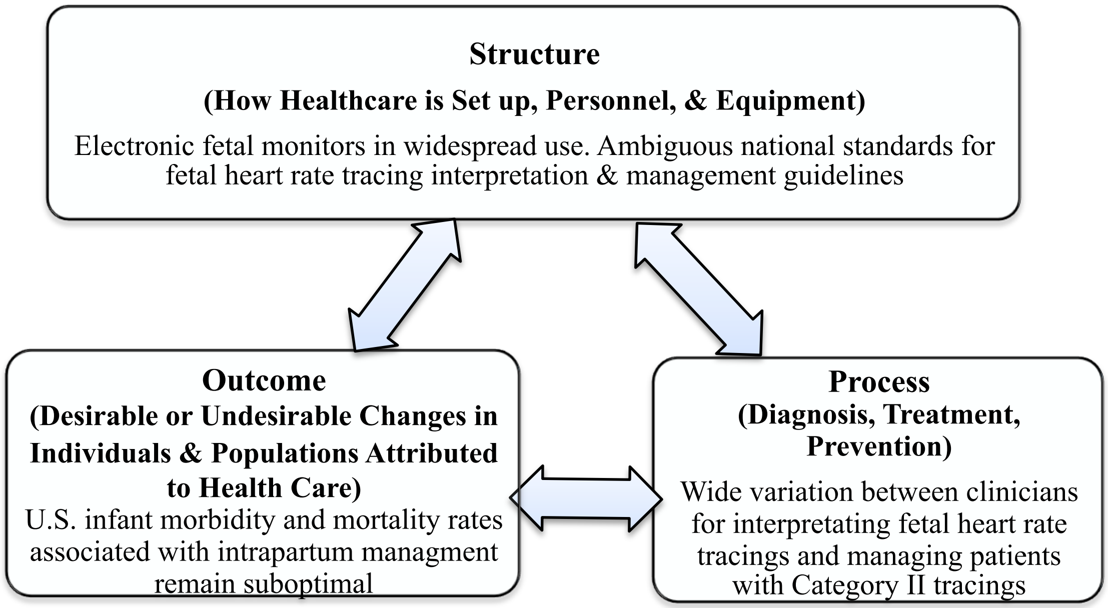


Figure 5: Donabedian (2003) Framework Applied To Category II FHR Tracings Interpretation And Intervention Problem

The structure of the U.S. obstetrics health care system has a problem. The process of caring for fetuses displaying Category II FHR tracings is the problem, since there is no evidence-based national standard for unambiguously interpreting and intervening appropriately under such conditions. The outcome is that fetuses displaying Category II FHR tracings may be given inconsistent care yielding less than optimal outcomes. The problem, at that point, is defined: Produce an evidence-based standard for unambiguously interpreting and intervening when fetuses display worrisome Category II FHR tracings.

Troubleshooting, is described by Donabedian (2003), as denoting "action in response to a clear problem by someone qualified to solve it" (p 30-31). In the case of

Category II FHR tracings, the clear problem is the inability of current NICHD terminology or fetal monitoring guidelines from U.S. medical and nursing professional organizations to give unambiguous interpretation and intervention direction for fetuses displaying Category II FHR tracings. The troubleshooting needed was for some entity to ascertain beneficial techniques and publish them, so that they might be disseminated among the U.S. obstetrical research and clinical community, and tested for efficacy and reliability. The "someone qualified to solve it" was the eighteen-member expert group who developed and published the Clark et al., 2013 algorithm, and the associated clarifications for use in algorithm. The Clark et al, 2013 consensus group was composed of representatives of the most experienced and most highly qualified national leaders in U.S. medical, nursing, and nurse-midwifery intrapartum specialties. Table 2 demonstrates the vast number of times these perinatal experts have been cited by others in the literature, regarding this groups' immense quantity of peer-reviewed publications.

Table 2. Author Information for Intrapartum management of Category II fetal heart rate tracings: towards standardization of care Clark et al., 2013)			
Author	**Current Affiliation**	**Academic Publications per Web of Science**	**Number of times Cited by others per Web of Science**
Steven L. Clark, MD	Hospital Corporation of America	189 publications	cited by others 4044
Michael P. Nageotte, MD	Long Beach Mem Hospital, Long Beach, CA	93 publications	cited by others 1659
Thomas J. Garite, MD	University of California, Irvine	148 publications	cited by others 3885
[ad] Roger K. Freeman, MD	University of California, Irvine	68 publications	cited by others 2082
[d] David A. Miller, MD	University of Southern California, L.A.	84 publications	cited by others 1575
[d] Kathleen R. Simpson, RN, PhD	Mercy Hospital, St. Louis, MO	114 publications	cited by others 443
Michael A. Belfort, MD, PhD	Baylor College of Medicine & Texas Children's Hospital	155 publications	cited by others 1859
Gary A. Dildy, MD	Baylor College of Medicine & Texas Children's Hospital	118 publications	cited by others 2037
[abcd] Julian T. Parer, MD, PhD	University of California, San Francisco	99 publications	cited by others 1959
Richard L. Berkowitz, MD	Presbyterian/Columbia University, New York	201 publications	cited by others 6335
[d] Mary D'Alton, MD	Presbyterian/Columbia University, New York	88 publications	cited by others 708
Dwight J. Rouse, MD	Brown University and Women & Infant's Hospital, RI	252 publications	cited by others 3363
Larry C. Gilstrap, MD	University of Texas, Houston	129 publications	cited by others 3368
[b] Anthony M. Vintzileos, MD	Winthrop University Hospital, Mineola, NY	295 publications	cited by others 6647
J. Peter van Dorsten, MD	Medical University of South Carolina, Charleston, SC	25 publications	cited by others 273
[b] Frank H. Boehm, MD	Vanderbilt University, Nashville, TN	54 publications	cited by others 1059
Lisa A. Miller, CNM, JD	Perinatal Risk Managment & Consultation, Portland, OR	76 publications	cited by others 209
[d] Gary D. V. Hankins, MD	University of Texas Medical Branch, Galveston	38 publications	cited by others 346

Table data retrieved on August 20, 2016 from http://apps.webofknowledge.com.eres.library.manoa.hawaii.edu/WOS_GeneralSearch_input.do?product=WOS&SID=1EFOgmxIlLAYeo53kw4&search_mode=GeneralSearch

Note: This list does not include the many authored textbooks and textbook chapters, professional association contributions to protocols and recommendations, years of contributions as presenters at local and national obstetrics conferences, and years of teaching to medical, nursing, and nurse-midwifery students in clinical and research venues.

[a] Participated in 2008 NIH Electronic Fetal Heart Rate Tracing Terminology Workshop
[b] Participated in 1997 NIH Electronic Fetal Heart Rate Tracing Terminology Workshop
[c] Chair, 1997 NIH Electronic Fetal Heart Rate Tracing Terminology Workshop
[d] Participated in 1979 NIH Electronic Fetal Heart Rate Tracing Terminology Workshop

This Donabedian (2003) Structure Process Outcome Model based study is designed to put forward evidence to further test the Clark et al. (2013) algorithm so as to alleviate the previously mentioned *structural* problem in the U.S. obstetrical health care system. This would change an important part of the obstetric management of care *process* by which fetal Category II heart rate tracings are interpreted and conditions under which intervention and types of interventions are carried out, possibly yielding improved *outcomes* for fetuses displaying Category II FHR tracings.

Implications for Research and Knowledge Development

Since, at this point in time, there have been only two published clinical research efforts to evaluate the efficacy of the Clark et al., 2013 Category II interpretation and management algorithm (Clark et al., 2015, 2016), there are many opportunities for research efforts around the world to further test and improve the efficacy of this unambiguous Category II FHR tracings interpretation and intervention algorithm. Some of these efforts could be international, so as to take advantage of the different Category I, II, and III standards that exist outside of the United States that could be melded into this algorithm and vice versa, to our mutual benefit.

CHAPTER 2

REVIEW OF THE LITERATURE

Initial Literature Search

A literature to investigate the response to Category II FHR tracing definitions and recommendations from the 2008 NICHD's introduction of the 3-tier system was carried out. Medline, Google Scholar, ProQuest, Science Direct, and Academic Search Complete were searched to find peer-reviewed articles, which related to improving Category II FHR tracing interpretation and management. The reference lists and any sources in the "cited by" areas of the included articles' online sources were also searched. Search parameters included being written in English and published in academic journals between September, 2008 and August, 2013. Search keywords included: Category II FHR management, Category 2 fetal heart rate tracing, and electronic fetal heart rate monitoring standards of care.

During this first search, the *Algorithm for Management of Category II Fetal Heart Rate Tracings* (Clark et al., 2013) was identified as the basis for this ongoing research effort. Additional literature was identified dating from September, 2008 to August, 2013, which provided material showing the research progress which made possible the creation of the important break-through developed and written up by Steven Clark and his colleagues, and which was published in August, 2013.

Inclusion criteria. Initially, articles that discussed application of the 2008 NICHD 3-tier system fetal heart rate tracing interpretation or management recommendations were included. This search produced 95 articles. To focus on Category II issues of interpretation and management strategies, only articles, which gave new strategies or examples of Category II definitions or management recommendations, were included. While each included article had to contain novel concepts concerning Category II fetal heart rate tracing interpretation or management, the novel concept, information, or example did not have to originate with that article; it could contain secondary sources for explaining the new concept. This decreased the number of articles for the initial literature search to three, including the Clark et al., 2013 algorithm article, for the initial literature search.

Exclusion criteria. Those articles, which did not discuss, use, or reference the 2008 NICHD 3-tier system of fetal heart rate tracing interpretation or management criteria or recommendations, and further, did not contain novel solutions to the Category II fetal heart rate tracings interpretation, management, and intervention problem were excluded.

The Second Focused Literature Review

To investigate the response to and level of adoption in the field, of the *Algorithm for Management of Category II Fetal Heart Rate Tracings* (Clark et al., 2013), a second, more focused literature search was undertaken. Medline, Google Scholar, ProQuest, Science Direct, and Academic Search Complete were searched to find peer-reviewed articles, which either discussed or referenced the above algorithm and/or the associated article. The reference lists and any sources in the "cited by" areas of the included articles' online sources were also searched. Search parameters included, articles written in English and published in academic journals, between August, 2013 to April, 2016. Search keywords included: Category II fetal heart rate management algorithm, Category II fetal heart rate tracing management algorithm, Category 2 fetal heart rate tracing, and electronic fetal heart rate monitoring standards of care.

Inclusion criteria. Only articles, which discussed the adoption of, or research to test, the Clark, et al., 2013 algorithm's efficacy were considered. This search produced 22 articles, from which seven articles were selected as most relevant, for a total, including those three articles from the initial search, of ten total articles.

Exclusion criteria. Those articles, which did not discuss, use, or reference the Intrapartum Management Of Category II Fetal Heart Rate Tracings: Towards Standardization Of Care (Clark et al., 2013) or the associated fetal heart rate tracings algorithm, were excluded. Because of the specificity of the search criteria as to the above-mentioned algorithm and article, and the associated date of 2013 or newer, all seven articles picked for in-depth review were published in 2013, 2014, 2015, or 2016.

Findings

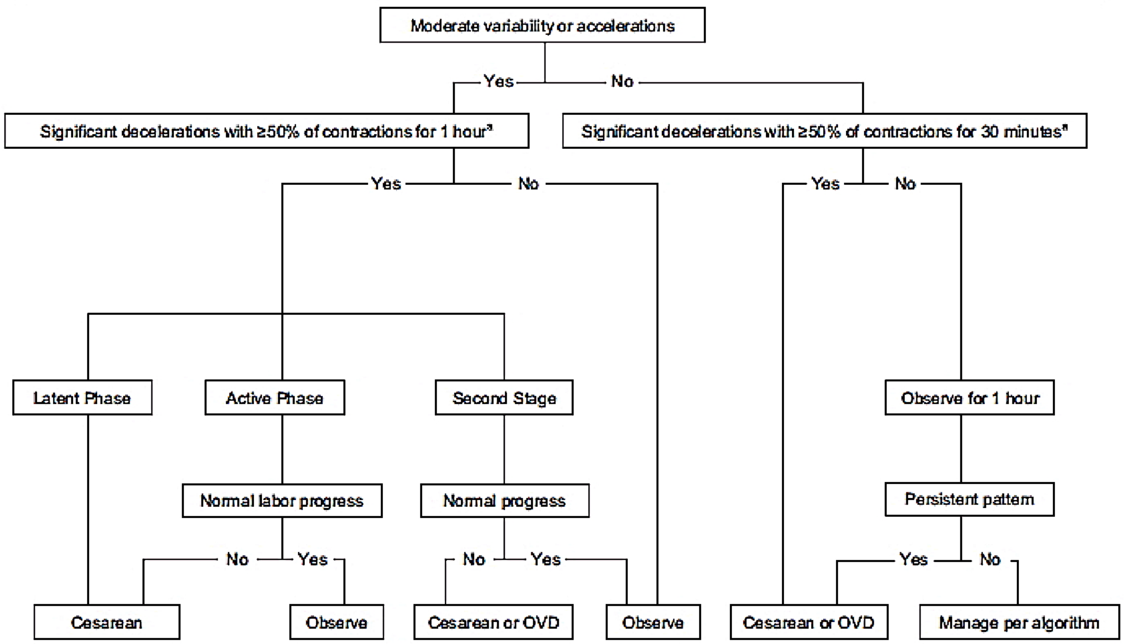
The first and most important article, the *Intrapartum Management Of Category II Fetal Heart Rate Tracings: Towards Standardization Of Care* (Clark et al., 2013), was the focus of this literature search and research effort, and the basis against which to evaluate the other nine papers. In addition, the importance of the fetal heart rate tracings algorithm, explained in the 2013 Clark et al. paper, and the associated recommended standards of care cannot be overemphasized as a tool to clarify and improve the management of the more than 80% of fetuses who have heart rate tracings that come under Category II classification.

In 2013, eighteen national experts from medicine, nursing, and nurse-midwifery came together with a goal to put together a Category II FHR tracings algorithm, a combination of a FHR tracings interpretation and intervention decision tree and a set of recommendations for an associated standard of care based on the algorithm. The reason for this activity was the fact that there had never been a straightforward national standard for the management of Category II FHR tracings patterns, despite the fact that Category II patterns occur in over 80% of fetuses during labor. The basis of this algorithm was the synthesis of the knowledge of these 18 experts, using the best currently existing science and the best available evidence-based research in the field of FHR tracings interpretation and intervention, as well as their varied and wide experience. This model was assembled and published by this group, to be tested by other healthcare professionals in the field of obstetrics, so that the model could be verified, and recommendations for improvement, standardization, and general adoption could be made. The standards for Category II FHR tracings interpretation and intervention, up to this point, had been relatively vague and inadequate. The final sentence from the article, provided the rationale for this paper, as well as providing justification for further research on this topic: "Application of the algorithm, along with the integration of future evidence-based modifications driven by additional research, will provide clinicians with a standardized, simple, rational, evidence-based, and nationally accepted approach to the management of Category II FHR patterns" (Clark et al., 2013, p. 96).

It is noteworthy that six of those in this group of eighteen were past participants of the 2008 NICHD FHR tracing terminology 43-member U.S./Canadian/UK workshop (Macones et al., 2008a, 2008b), and two others in the group had participated in either the 1997 U.S./Canadian/UK (NICHD, 1997) or in the 1979 U.S./Canadian/UK (Zuspan, Quilligan, Iams, & van Geijn, 1979) NICHD electronic fetal monitoring terminology consensus workgroups. One member of the Clark et al. 2013 group participated in all three workgroups, including chairing the 1997 workgroup. All eighteen participants had published multiple works on electronic fetal monitoring in peer-reviewed journals and most had been authors, editors, or contributors for numerous medical or nursing textbooks on electronic fetal monitoring and/or obstetrics. The Clark et al., 2013 consensus group was composed of representatives of the most experienced and most highly qualified national leaders in U.S. medical, nursing, and nurse-midwifery intrapartum specialties.

The Clark et al., 2013 Category II FHR tracing algorithm is a combination of a fetal intervention decision tree and a set of recommendations for standardizing care based on the fetal status and labor progress. The decision tree starts with Category II FHR tracings, which do or do not exhibit moderate variability or accelerations. A major difference from the NICHD 3-tier system is that in the algorithm by Clark et al. (2013), minimal FHR baseline variability is managed the same as absent variability (Druzin & Peterson, 2014). Also, the 2008 NICHD definitions combined all variable decelerations that were not recurrent (occurring with less than 50% of the uterine contractions) *and* accompanied by absent baseline FHR variability, as Category II patterns. Instead, the Category II algorithm subcategorizes all late or prolonged decelerations, as well as variable decelerations lasting more than 60 seconds with nadir less than 60 beats per minute or less than 60 beats per minute below the baseline, into "significant decelerations" (Clark et al., 2013). This Category II algorithm by Clark et al., (2013), uses several time-dependent decision steps to arrive at several possible actions: Manage Per

Algorithm, Observe, Cesarean or Operative Vaginal Delivery, or Cesarean Delivery. The algorithm proposed by Clark et al. (2013), for patient care of Category II fetal heart tracings gives more specific interpretation and management recommendations (See Figure 6 and Appendix).



OVG, operative vaginal delivery

[a]That have not resolved with appropriate conservative corrective measures, which may include supplemental oxygen, maternal position changes, intravenous fluid administration, correction of hypotension, reduction or discontinuation of uterine stimulation, administration of uterine relaxant, amnioinfusion, and/or changes in second stage breathing and pushing techniques.

Clark. Category II FHRT. Am J Obstet Gynecol 2013.

Figure 6: The Algorithm for Management of Category II Fetal Heart Rate Tracings (Clark et al., 2013). Copyright 2013 by Elsevier. Reprinted with permission.

The second paper is authored by Simpson (2014a), *Labor Management Evidence Update - Potential to Minimize Risk of Cesarean Birth in Healthy Women*. Simpson discusses the Category II FHR tracings algorithm, speculating that using the algorithm would help in lowering the current 32.8 per 100 birth rate of cesarean births in the United States, which Simpson says is both dangerous and unnecessary. Simpson explains that the high cesarean rate has come about because the maternal birthing population is both older and has a noticeably higher BMI, and induction of labor is much more prevalent. Simpson also notes in comparing women in spontaneous labor, with a single vertex baby, an increase of +2.6 hours in first-stage labors compared to 50 years ago. This article also points out that the most common reason for cesarean birth (up to 50%) is labor dystocia/failure to progress/cephalopelvic disproportion. Interestingly, Simpson states that many women are never actually in labor when this diagnosis is made. Instead, they are generally diagnosed before they even go into active labor, since recent data suggest active labor more likely begins at 6 cm, vs. the traditionally accepted 4 cm dilatation. Thus, many women really haven't been given enough time to progress during a labor induction/augmentation. The paper then goes on to explain the dangers of cesarean section vs. vaginal delivery, particularly the heightened dangers of repeat cesarean sections. Simpson also states that cesarean section has all of the dangers of major surgery, and should not be done, unless there are immediate and compelling reasons to do so. Simpson does not mention fear of malpractice as one of the reasons for cesarean section, although she mentions that the care provider income from cesarean section is double that of vaginal birth. The main focus of Simpson's paper is advocating the use of the Category II FHR tracings algorithm as a way to avoid cesarean section, except when medically necessary. Simpson explains that by using the algorithm, longer birthing times at all stages can be more safely done, and the goal of a successful vaginal birth with a normal, viable baby can be reached more often. Simpson stresses the importance of being knowledgeable of updated evidence, of being well-versed regarding improvements in safe labor management, and of being aware that "patience is underrated as a patient safety strategy" (Simpson, 2014a, p 115).

The third paper reviewed is *Managing an Indeterminate (Category II) Fetal Heart Rate Tracing During Labor* (Simpson, 2014b). Simpson summarizes the main points of the Clark group's 2013 article. In this summary, Simpson points out that identifying FHR tracings as Category II, has limited value since Category II FHR tracings cover a large range of physiological characteristics which have varying levels of concern, depending on how far along a mother is in labor and how stable the status of fetus. Simpson then explains how the new 2013 Category II FHR algorithm can give the healthcare professional tools to overcome the seeming indeterminate nature of Category II FHR tracings through the use of the Category II FHR tracings decision tree and the associated management standards of care. Using these two tools, gives the healthcare professional guidance on when to: observe, manage per the algorithm (i.e. intervene to take steps to correct a developing problem), or initiate steps to expedite birth of the fetus quickly by cesarean or operative vaginal delivery (OVD). The basic goal is to resolve problems as they arise, before they become serious, so that normal labor continues, resulting in a spontaneous vaginal birth of a vigorous, healthy, baby; or if necessary, to intervene in a timely fashion and deliver the fetus by cesarean or operative vaginal delivery, to result in the birth of a vigorous, healthy, baby.

The fourth article, an electronic fetal monitoring case review by Druzin and Peterson (2014), discusses the 2013 Clark et al. article and algorithm. Druzin and Peterson contrast the major differences in intervention strategies between the National Institute of Child Health and Human Development recommendations, and those described in the Clark, et al., 2013 article. Druzin and Peterson note that in the Clark group's algorithm: "moderate variability and/or accelerations are required to diagnose a nonacidotic fetus. The distinction between minimal and absent variability becomes irrelevant" (p. e255). The basic idea is that looking for signs of a nonacidotic fetus who is not in trouble, is key to deciding on routine management or observation. Conversely, looking for signs that the visibly decompensating fetus is in deadly trouble is wasting precious time.

Druzin and Peterson's (2014) case study involves a mother at 39 $^{2/7}$ weeks gestation, admitted to Labor & Delivery, requesting a repeat cesarean, with a 24 hour history of decreased fetal movement. It is probable that had the 2013 algorithm been used when this patient's initial fetal heart pattern showed a Category II tracing of minimal baseline variability with recurrent late decelerations, that delivery would have been expedited, occurring more than 2 hours sooner. While sooner delivery would not necessarily have brought a normal outcome, it probably would have made for an improved outcome for this newborn. The Apgar scores were 1, 1, 6, & 8 at 1, 5, 10 & 15 minutes respectively, and there was a neonatal hemoglobin level of 3 g/dL (normal newborn level = 19.3±2.2 g/dL). Druzin and Peterson's incisiveness in noting the key advances inherent in the new algorithm in interpretation and hence timely intervention as it concerned this case study, demonstrates how on a case-by-case basis, this new technique is winning credibility among those astute enough to understand and realize the power of its application.

The fifth article, *Standardization of Intrapartum Management and Impact on Adverse Outcomes* (Pettker, 2011), discusses improved patient outcomes from applying protocols, guidelines, and checklists, and praises the Minkoff & Berkowitz (2009) concept of the FHR monitoring "bundle" of checklists/organized activities. Pettker (2011) suggests that electronic health records might be enabled with computerized warning flags or pop-ups generated in real-time when abnormal FHR tracing components are documented. Futhermore, Pettker's (2011) description of a standardized labor progress note from Yale-New Haven Hospital is somewhat akin to a concept of forcing providers to more completely and accurately describe electronic FHR tracings by hardstops in the electronic health record that require completion of at least 5 critical FHR assessment components: "baseline, variability, accelerations, decelerations, and Category" (p. 3).

The sixth paper, by Flood Chez and McMurtry Baird (2011), *Electronic Fetal Heart Rate Monitoring: Where Are We Now?* gives a history of past and current controversies and challenges related to intrapartum evaluation and management of fetal heart rate tracings. The authors point out that the 2004 Joint Commission Sentinel Event Alert No. 30: *Preventing Infant Death and Injury during Delivery* and The Joint Commission (2004) recommendation for institutions to follow the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists advice to: "a. Develop clear guidelines … including nursing protocols for the interpretation of FHR tracings. b. Educate nurses, residents, nurse midwives, and physicians to use standardized terminology to communicate abnormal FHR tracings," (American Academy of Pediatrics & American College of Obstetricians and Gynecologists, 2002, pp. 127, 133-134). Flood Chez and McMurtry Baird (2011) summarize the frustrations of more than 30 years of the obstetric community to clearly define and classify electronic fetal monitoring parameters – which has resulted in the continuing interobserver variability in interpretation and management of various FHR patterns. The authors also gave an explanation of Parer and Ikeda's 2007 five-tier system of 134 identified FHR patterns, color-coded from green (no threat of acidemia), blue-yellow-orange (3 intermediate categories corresponding to NICHD Category II), and red (severe threat of acidemia). This inclusion of Parer and Ikeda's 2007 5-tier system is significant since numerous U.S. and Japanese facilities, textbooks, researchers and others use or refer to the 5-tier system.

The seventh published writing which quotes a portion of the Clark et al., 2013 article, is the April, 2015 *ACOG Committee Opinion number 629, Clinical Guidelines and Standardization of Practice to Improve Outcomes.* The quoted text is as follows:

> The adoption by the clinical care team of one appropriate specific management plan will, by virtue of standardization alone, yield results superior to those achieved by random application of several individually equivalent approaches. This is particularly true at the facility level. (p. 2)

The ACOG committee opinion is congruent with the Clark et al., 2013 article, emphasizing that clinically valid reasons for not following standardized protocols or checklists should be documented in the clinical record when deviations purposefully occur or are planned.

This eighth reviewed paper, by Timmins and Clark, (2015), is a very detailed explanation of the great necessity for the development of a standard such as the Category II FHR tracings unambiguous interpretation, management, and intervention algorithm with its clarifications for use in algorithm; the history leading up to this development, the reasons why use of this particular Category II algorithm is particularly advantageous, and as well as a series of very complete directions on the clinical use of this algorithm with conservative advice on managing and improving fetal oxygenation, and improving fetal outcomes. The paper further explains the necessity for finding a solid standard to displace the current wide variation in practice currently existing for the care of fetuses manifesting Category II heart rate tracings. The lack of practice standards for this majority of fetuses yields an undo amount of less than desirable results. Timmins and Clark (2015) note:

> In 1990, Roger Freeman observed that the saga of electronic FHR monitoring had been "a disappointing story" in that such monitoring had failed to result in any significant reduction in rates of neonatal encephalopathy and subsequent neurologic impairment but had contributed to the rise in cesarean section delivery rate. A quarter of a century later, the situation remains unchanged, yet the approach to FHR interpretation and management has remained static. Recent data suggest that variation in interpretation and response to abnormal FHR patterns is largely to blame and that, as in many other areas of medicine, standardization will yield improved outcomes. (p. 371)

The paper also states that up until the 2013 algorithm was developed, electronic fetal monitoring wasn't living up to its potential. With the use of the unambiguous algorithm, the picture is much better, showing lower rates of cesarean deliveries, lower oxytocin use rates, better Apgar scores, less NICU admissions, and better labor outcomes in general, as demonstrated in the next paper below in this literature review.

The ninth paper reviewed is authored by Clark et al. (2015), *Recognition and Response to Electronic Fetal Heart Rate Patterns: Impact on Newborn Outcomes and Primary*

Cesarean Delivery Rate in Women Undergoing Induction of Labor. The Clark et al., 2015 study provides solid evidence that the unambiguous definitions for Category II fetal heart rate tracings in the Clark et al., 2013 algorithm do make a measureable, positive difference in how the labor is managed, and that through its use, the fetus and mother also do measurably better as well.

The 2015 published study was a very large study involving 14,398 women and the results of this study were significant. Also significant was the practical use to which the algorithm was put, allowing the algorithm to be tested in the field with significant positive newborn and maternal outcome results. The paper by Clark et al. (2015), provides clear proof that the Category II FHR tracings algorithm does make a measureable, positive difference in how the labor is managed, and that through its use, the fetus and mother also do measurably better as well. The significant results were: a significantly reduced rate of neonatal intensive care unit admission (3.8% vs. 5.2%, P = 0.01), a significantly reduced rate of Apgar scores less than 7 at 1 and 5 minutes (4.9% vs. 6.4%, p = 0.01, 0.6% vs. 1.1%, p = 0.04), and a significant reduction in cesarean delivery rate (15.8% vs. 18.8%, p = 0.00).

The study population came from the 110 Hospital Corporation of America affiliated hospitals with obstetrical and newborn services in 21 states with a total annual delivery volume of approximately 207,000 (5-6% of U.S. deliveries). From April 1, 2013 until September 30, 2013, a total of 14,398 patient charts from singleton, term fetuses undergoing labor induction with oxytocin were examined sequentially in a non-random, prospective manner, by a Hospital Corporation of America regional nurse, certified as a Fetal Heart Rate Monitor instructor by the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN). Each 30-minute segment of the FHR tracing, where oxytocin was infused, was examined and the FHR tracing data was compared to an evidence-based oxytocin/FHR tracing safety checklist. Unless each segment met the oxytocin/FHR tracing safety checklist standard, the oxytocin dose was to be reduced. The every-30-minute FHR and uterine activity safety checklist elements used were:

1. At least 1 acceleration of 15 bpm x 15 seconds in 30 minutes is observed, or adequate variability is present for 10 of the previous 30 minutes.
2. No more than 1 late deceleration occurred in the previous 30 minutes.
3. No more than 2 variable decelerations exceeding 60 seconds in duration and decreasing greater than 60 bpm from the baseline occurred within the previous 30 minutes.
4. No more than 5 uterine contractions in 10 minutes for any 20-minute interval.
5. No 2 contractions greater than 120 seconds duration.
6. Uterus palpates soft between contractions.
7. If intrauterine pressure catheter is in place, Montevideo units must calculate less than 300 mm Hg and the baseline resting tone must be less than 25 mm Hg (Clark et al., 2015, Table 1, p. 494.e2).

Clinical outcomes in the experimental population included a significant reduction in low 1 and 5 minute Apgar scores, a significant reduction in cesarean births, as well as a significant reduction in NICU admissions when the oxytocin infusion rate was reduced during periods of uterine tachysystole (more than 5 contractions in a 10 minute period). Of great interest on many levels, the authors state that the study results:

> …stand in contrast to several previous reports comparing EFHRM (electronic fetal heart rate monitoring) with intermittent auscultation…Most studies comparing EFHRM to intermittent auscultation were designed with the assumption that those clinicians interpreting and acting upon the information gleaned from EFHRM were interpreting and acting correctly. Yet no attempt was made to validate these assumptions; in fact, no unambiguous definition of either correct interpretation or proper clinical response was provided. This assumption of uniform expertise and appropriate reaction to abnormal FHR tracings is especially surprising in light of the well-established inability even of individuals identified as experts to agree on FHR interpretation. In contrast, for purposes of this study we defined abnormal FHR patterns in a completely unambiguous manner and similarly defined a specific appropriate reaction when such patterns were observed. (pp. 494e2-494e3)

As noted in this 2015 article, the data gathered in this study, show a clear congruence between the process outlined in *Intrapartum Management Of Category II Fetal Heart Rate Tracings: Towards Standardization Of Care* (Clark et al., 2013), and the results described in *Recognition and Response to Electronic Fetal Heart Rate Patterns – Impact on Newborn Outcomes and Primary Cesarean Delivery Rate in Women Undergoing Induction of Labor* (Clark et al., 2015).

The objective of the study was to see if unambiguous definitions of abnormal FHR could improve patient outcomes when applied to women in induced labor using oxytocin. This study was the first attempt to use the Category II FHR tracings algorithm on a wide scale with one of the controversial areas in obstetrics, oxytocin induced labor.

The idea of the study design was to simultaneously seek possible evidence that use of the unambiguous definitions of abnormal FHR tracings, which are a part of the Clark et al., 2013 Category II FHR tracings algorithm, is effective, and to see if it can be applied successfully to give safer control to healthcare personnel over the use of oxytocin. So that IV oxytocin is properly administered at ideal rates of infusion, the patients, mother and fetus, are closely monitored using electronic FHR monitoring, for signs of FHR compensatory patterns or tachysystole, so that oxytocin infusion rates can be reduced or stopped, if necessary, in an effort to bring the FHR tracings back into a Category I pattern. As mentioned by Simpson (2014a), the cesarean delivery rate is expected to exceed 50% by 2020 in the United States. Elective induction of labor has declined from 23.8% in 2010, to 23.3% in 2012, but is still very common (Centers for Disease Control and Prevention, 2014; Osterman & Martin, 2014). What this means is that patients who are not in labor are sometimes scheduled by their healthcare providers, either for medical indications or for elective reasons, to attempt stimulating labor, using a cervical ripening agent, mechanical induction with a silicone cervical balloon or cervical Foley catheter, or artificial rupture of the amniotic membranes treatment, and/or intravenous oxytocin, rather than waiting to go into spontaneous labor. The study published in 2015 by Clark et al., looked at improving neonatal outcomes and lowering cesarean birth rates for induced labors by finding ways to protect the fetus during labor, and help labors to progress to a successful outcome by more skillfully intervening in a timely manner. Using unambiguous methods for Category II FHR tracings interpretation with the associated standards of care, and the in-use checklist used by this study encouraged appropriate conservative corrective measures for Category II FHRs, which could include supplemental oxygen, maternal position changes, intravenous fluid administration, correction of hypotension, reduction or discontinuation of uterine stimulation, administration of a uterine relaxant, amnioinfusion, and/or changes in second stage breathing and pushing techniques.

The results demonstrated statistically significant correlation between the recognition of danger to the fetus based on an unambiguous interpretation of Category II FHR tracings revealing the need to intervene, and the act of reducing or discontinuing oxytocin, when indicated. This relationship of cause and effect significantly lowered the rate of neonatal NICU admission by one third, resulted in fewer low one and five minute Apgar scores < 7, as well as significantly lowered the cesarean birth rate from 18.8% to 15.8%. The large size of the study was also important, since this helped point up significant results that might have either not been identified or been difficult to recognize. This evidence answers those who questioned the Category II FHR tracings algorithm when first published, as having no evidence to support it, as well as helping answer those who felt that continuous intrapartum electronic fetal monitoring was not useful. With this study, there is now stronger evidence of the validity of the Category II FHR tracings algorithm and continuous electronic FHR monitoring during induced labors. It is also clear that more and varied studies are necessary to further validate these methods, particularly from researchers outside the group that conceived and constructed the Category II FHR tracings algorithm. This is necessary to test its universality, and its applicability for general use among the obstetrical community. In the conclusion by Clark et al. (2015), it is stated, "electronic FHR monitoring improves neonatal outcomes when unambiguous definitions of abnormal FHR and tachysystole are coupled with specific interventions."

The tenth research paper, written by Clark et al. (2016), entitled *Use of a Standardized Protocol for the Management of Category II Fetal Heart Rate Tracings Leads to Earlier Intervention in Infants Born with Metabolic Acidosis*, is also important. It looks at the idea of producing better outcomes, by blind analyzing 240 births, using the Clark et al., 2013 algorithm, after the fact, to see if by using the algorithm, earlier intervention would have happened, yielding an improved outcome for the 120 fetuses with significant metabolic acidosis. This smaller study, of 240 fetuses, half of whom were born with prolonged hypoxia evidenced by significant metabolic acidosis (umbilical artery base deficit >12mM/L), and half of whom had normal umbilical artery base deficit levels (<8mM/L), showed that use of the algorithm would have resulted in a significantly higher rate ($p=0.016$) of earlier delivery of infants with significant metabolic acidosis. This study also noted that in the case of the 120 fetuses without significant acidosis, also blind analyzed, using the Clark, et al., 2013 algorithm, that using the algorithm would not have resulted in significantly earlier intervention ($p=1.0$).

It is clear that the Clark et al., 2013 consensus group has a clear vision of where they want to go. They want to put in place a standard for accurately interpreting FHR tracings, and for specific standards for fetal and maternal interventions based on those unambiguous FHR tracings interpretations. This 2015 manuscript of Clark et al. is clearly constructed to validate the FHR tracings algorithm and the associated recommendation for standards of care using a large number of clinical cases, so that the value of the concept can be proven and the construct may be more readily adopted by the rest of the healthcare community. With the 2015 and 2016 manuscripts, Clark and his colleagues made major contributions to the health and safety of mothers, fetuses, and families, and have raised the bar for intrapartum quality care. It is now even more clear that more research is needed to further test, improve, and validate this Category II FHR tracings algorithm, and work for national adoption of a clear and effective set of standards and recommendations for patient care in the setting of Category II FHR tracings.

Discussion

Because of the recentness of publication of the 2013 Category II FHR tracings algorithm, very little research has been done to validate and improve the technique. Within the first 3 years of publication, using a Web of Science Database search, the 2013 Clark et al. article was found to have been cited in a mere 22 publications. Only seven published writings were found which discussed, used, or referenced the algorithm in any depth. Of those, five of them discussed or inferred possible uses for the algorithm in clinical settings, and only two (Clark et al., 2015), (Clark et al., 2016) were actual research efforts, though one was a rather large one, which utilized the unambiguous definitions for Category II FHR tracings, and produced strong evidence of its efficacy of use (Clark et al., 2015).

The Category II FHR tracings algorithm (Clark et al., 2013) was only published in 2013, in answer to a need to address the necessity for a way to unambiguously interpret Category II FHR tracings, and when needed, carry out prompt and meaningful interventions to benefit the fetus and the mother during labor. Without the 2013 Category II FHR tracing algorithm, the situation can be chaotic, with individuals or small groups using various interpretation methods, which may be at odds with each other. The situation for interventions based on those disparate interpretations of Category II FHR tracings can also be in disarray, since there is no current national standard on deciding what to do and when to do it appropriately for Category II FHR tracings. With the NICHD 3-tier system, Category I was classed as normal, Category III was classed as abnormal, and Category II was simply classed as indeterminate (ACOG, 2009, 2010; Druzin, 2010; Macones et al., 2008a, 2008b). Clinicians in obstetrics have clear national recommendations on what to do when the 16-20% of fetuses have heart rate tracings that are purely Category I, or for the relatively few fetuses that have Category III tracings, but not so when the 80% of fetuses who have FHR tracings which are Category II are in labor and delivery.

In 2013, eighteen of some of the foremost U.S. experts in the field of FHR tracings interpretation, headed by Clark, collaborated and published a journal article to alleviate this problem. They went through the existing science and research related to Category II electronic FHR tracing interpretation and intervention, and pooling their decades of experience, developed an unambiguous Category II FHR tracings algorithm. Out of that process was built a Category II FHR tracings decision tree to guide users of the algorithm in how to decide when and how to intervene appropriately in the labor and birthing process. In addition to this decision tree, a table was created, with a series of ten recommendations for standards of care based on the Category II FHR tracings algorithm, called "Management of Category II FHR patterns: clarifications for use in algorithm," which goes into great detail on how and when to use the algorithm in clinical settings. Also in the 2013 algorithm paper, are sixteen further useful recommendations and cautions related to using the algorithm (See Appendix).

The strength of the algorithm is that the people who developed the algorithm have had wide and profound experiences in the field, and are authors of many hundreds of far-reaching pieces of applicable obstetrics research over the past 2 to 5 decades. They also came from many different backgrounds, and had tremendous amounts of the accumulated science and clinical knowledge about electronic fetal monitoring interpretation and intervention available to them. Lastly, they came together determined to solve the crisis over Category II FHR tracings interpretation and intervention, and discovered a system for re-classifying Category II FHR tracings from ambiguous to unambiguous, and standardizing Category II FHR tracings interpretation and intervention.

The main weakness with the 2013 unambiguous algorithm and its recommendations for standards of care and use, was that as written, it had never been tested in a large scale research effort in a clinical setting to see if it worked, and to see if it would make a significant positive difference in fetal and maternal outcomes. This aspect was discussed in the original paper recommending that research be done using the algorithm in clinical settings to see how it fared. Others in the research community also pointed to the need for scientific evidence of its efficacy.

Some authors subsequently wrote suggesting various scenarios in which the algorithm might prove itself useful, but no one actually published a research effort providing scientific evidence gathered from a clinical setting.

In April of 2015, the American Journal of Obstetrics and Gynecology published the findings of a very large research effort spear-headed by Clark, one of the authors of the original 2013 algorithm. This 33-page article described a clinical research effort involving 14,398 subjects, a massive research effort. This study used the algorithm and recommendations authored by Clark et al. (2013) to compare clinical outcomes of patients in which the algorithm was followed, with control patients in which the components of the 2013 algorithm were not followed. For example, in the experimental group, when specific Category II FHR tracings were identified, and oxytocin was consequently reduced or discontinued, there were less substandard newborn outcomes. As a result, the number of NICU admissions also dropped significantly by one third. Lastly, the cesarean delivery rate also dropped significantly from 18.8% to 15.8%, due to better labor management based on unambiguous use of the Category II FHR tracings algorithm. The inverse relationship between cesarean birth rates and healthy neonates need not hold true when careful adherence to unambiguous definitions of abnormal FHR patterns and standardized patient safety recommendations are followed. It is then possible to lower the cesarean delivery rate, while simultaneously taking good care of the fetuses, yielding much lower adverse outcome risks for the mothers and for the babies. Since the Clark et al. (2015) clinical study dealt exclusively with a group of oxytocin induced women, the results may not be applicable to other dissimilar groups of women in labor.

In the most recent 2016 published clinical study, the algorithm was used post-facto to blind review FHR tracing data from 120 fetuses with severe metabolic acidosis. The methodology in the 2016 study is thus similar to the methodology outlined by Van Hoose (2014), which is the basis for this dissertation research (See Chapter III).

As more research efforts using the 2013 unambiguous Category II FHR tracings interpretation and intervention algorithm are carried out, the algorithm will have appropriate validation with regarding its efficacy. In the Clark group's 2013 article, which explains the new algorithm and recommendations for standards of care for Category II FHR tracing interpretation and intervention strategies, the healthcare community is requested to test this algorithm and report on its level of efficacy.

Implications for Research and Knowledge Development

Since, at this point in time, there have been only two published clinical research efforts to evaluate the efficacy of the Clark et al., 2013 Category II interpretation and management algorithm (Clark et al., 2015, 2016), there are many opportunities for research efforts around the world to further test and improve the efficacy of this unambiguous Category II FHR interpretation and intervention algorithm. Some of these efforts could be international, so as to take advantage of the different Category I, II, and III standards that exist outside of the United States that could be melded into this algorithm and vice versa, to our mutual benefit. The two research opportunities used in this research effort are discussed below.

An opportunity to test the algorithm on a different set of fetal heart rate tracings from those used by Clark, et al., 2015. This allowed the production of further evidence as to the efficacy of the Clark et al. 2013 unambiguous Category II FHR algorithm decision tree and the associated list of ten main "management of Category II FHR patterns: clarifications for use in algorithm," as well as the sixteen additional management per algorithm recommendations for care based on the fetal status and labor progress.

An opportunity to test the algorithm against other regions' standards, and

using electronic fetal heart rate monitors output used in other regions. There are electronic fetal heart rate monitors built and used in regions outside the United States, designed for fetal heart rate tracings interpretation and intervention standards different from those used in the United States. Research on the efficacy of the Clark et al., 2013 Category II fetal heart rate tracings algorithm when used on other regions' electronic fetal heart rate monitors, in concert with the other regions' fetal heart rate tracings standards, might yield an international standard better than either alone.

CHAPTER 3

METHODOLOGY

Purpose of the Study

The purpose of this study was to test the *Algorithm for Management of Category II Fetal Heart Rate Tracings*, created by Clark et al. (2013), to generate more evidence to evaluate its utility for improved efficacy in the interpretation and clinical management of Category II fetal heart rate tracings.

Specific Aim 1. The first specific aim of this study was to test the Clark et al. Category II fetal heart rate monitoring algorithm on 552 fetal heart rate tracings (Chudáˇcek et al., 2014) without reference to the original decisions made and interventions carried out at the time each strip was made, to see if the algorithm decision tree and associated extensive "clarifications for use in algorithm," gave unambiguous direction on interpretation and intervention for these 552 fetal heart rate tracings*, which would potentially yield better fetal (higher Apgar scores, less acidosis, fewer admissions to NICU, less neurological and other damage, etc.) and maternal (fewer cesarean births, fewer operative vaginal deliveries, more successful spontaneous vaginal deliveries) outcomes, as it has in the two Clark et al. 2015 and 2016 research efforts*.

Research Question 1. Will Clark et al.'s (2013) *Algorithm for Management of Category II Fetal Heart Rate Tracings* reliably give unambiguous direction on interpretation and intervention for Category II fetal heart rate tracings?

Specific Aim 2. The second specific aim of this study was to generate more evidence regarding the efficacy of the Clark et al. Category II fetal heart rate tracing algorithm.

Research Question 2. Can using the Clark et al.'s (2013) *Algorithm for Management of Category II Fetal Heart Rate Tracings* on the 552 fetal heart rate and uterine contraction tracings result in different recommendations for management and intervention forecasting a possibly improved outcome over the actual result?

Research Design

This study design was a blind retrospective secondary analysis of an anonymous set of public access archived files of 552 fetal heart rates tracings in the 30-90 minutes preceding delivery, acquired in the obstetrics ward at the University Hospital in Brno, Czechoslovakia (Chudá˘cek et al., 2014). The database is located online at: http://physionet.org/physiobank/database/ctu-uhb-ctgdb/. The electronic fetal heart rate and uterine contraction tracings were stored in OB TraceVue® form. Exclusion criteria used by Chudá˘cek et al. (2014) to reduce the number of tracings to 552 before being uploaded for availability in an open access intrapartum CTG database were: Maternal age < 18 years, fetal weeks of gestation ≦ 37, known fetal diseases – congenital defects or intrauterine growth restriction. Inclusion criteria were for only singleton, uncomplicated pregnancies. Chudá˘cek et al. (2014) also provided umbilical artery blood pH with each of the fetal heart rate tracings.

Research Methodology

Each of the 552 fetal heart rate tracings and associated maternal uterine contraction tracings was blind analyzed using the Clark et al. (2013) Category II algorithm decision tree and associated standards of care. The fetal heart rate tracings were blind analyzed without access to or reference to the original outcomes, decisions made, and interventions carried out at the time each strip was recorded. The analyses evaluated the fetal heart rate tracings related to maternal uterine contraction patterns, and made notations when any of the following were visible:

1). Absence of moderate variability or accelerations in the baseline that continue for ≥ 30 minutes.

2). Recurrent late decelerations of the fetal heart rate.

3). Recurrent significant variable decelerations of the fetal heart rate (lasting > 60 seconds, decelerations deeper than 60 beats per minute below the baseline rate, or going lower than 60 beats per minute).

4). Any prolonged deceleration (algorithm use should be discontinued until prolonged deceleration is resolved) (See Figure 7).

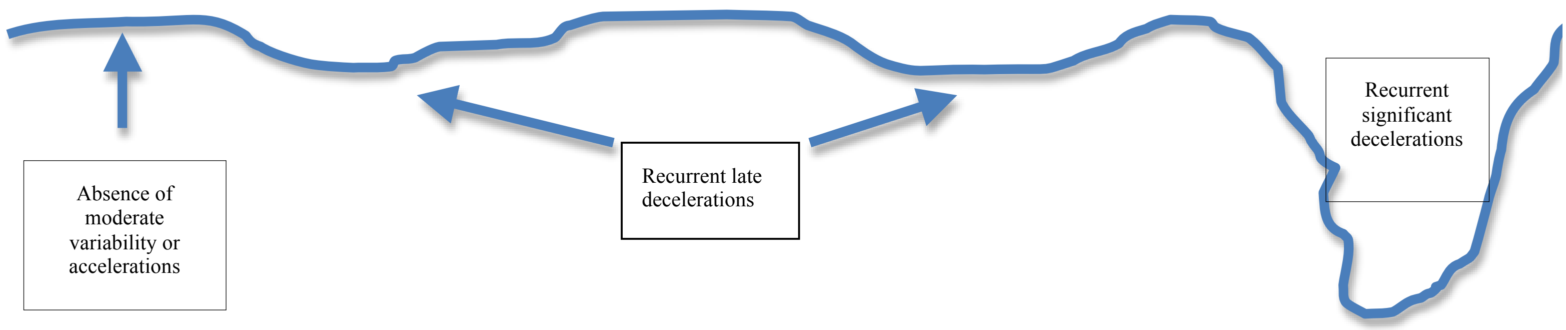


Figure 7. Criteria for data collection

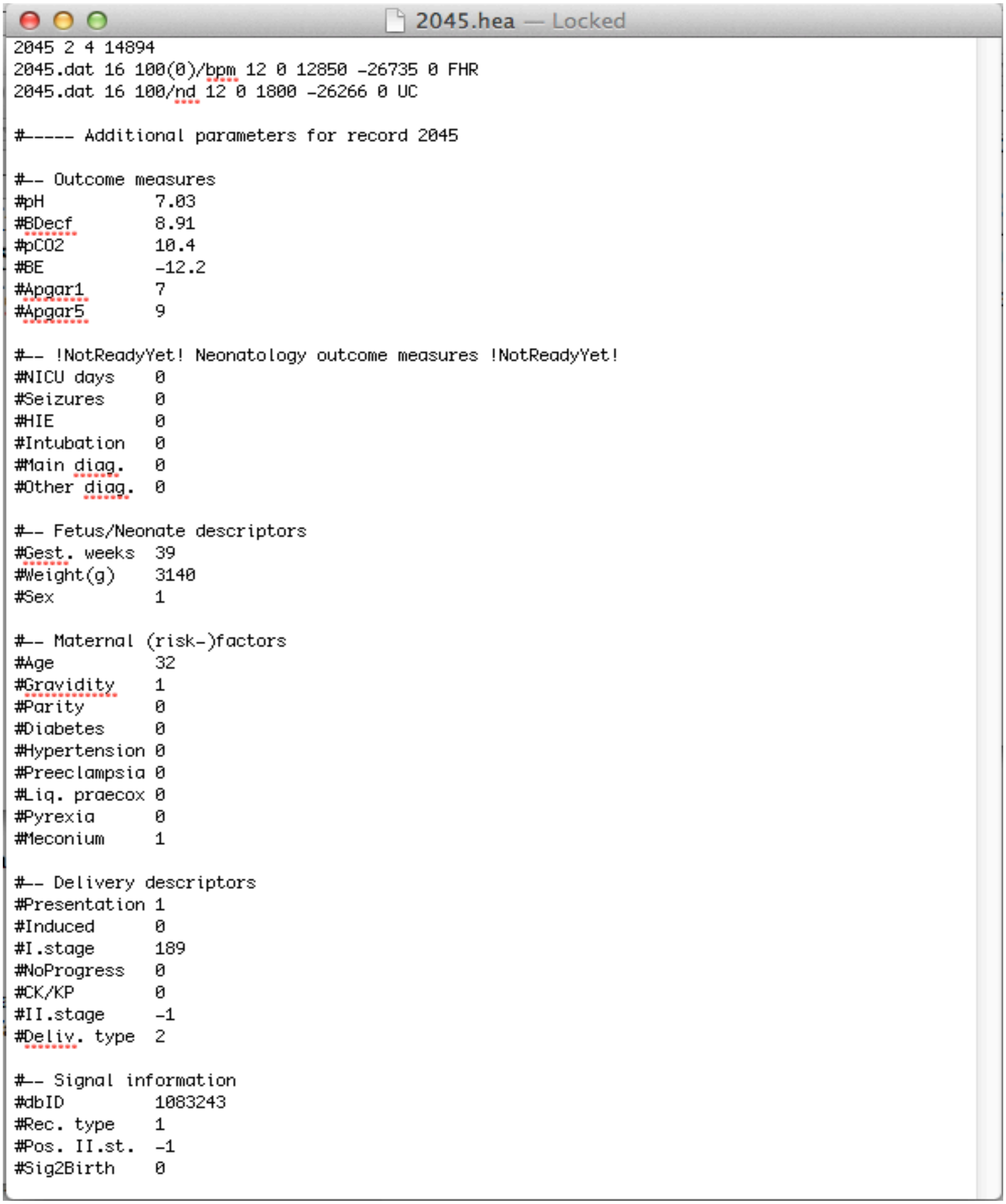
Based upon the presence of any of the four above characteristics, analyses also noted movement from one action state to another on the algorithm decision tree

(*Manage Per Algorithm, Observe, Cesarean or Operative Vaginal Delivery, or Cesarean Delivery*), and on that basis, recommended a specific intervention or set of interventions to be carried out at each of those points in time along the tracing. This was done for each of the 552 fetal heart rate tracings until the endpoint of the actual delivery, the end of the tracing, or an analysis per algorithm recommended delivery point was reached. The fetal heart rate tracings had no annotations, notes, or any other information on them. All of the notes, outcomes, labor, and birthing information, etc., are contained in a separate text file with the same file number as the associated fetal and maternal heart rate tracing file. After the analyses per algorithm had been completed on all 552 fetal heart rate tracings, a comparison of the algorithm-driven fetal, labor, delivery management and probable outcome with actual labor and delivery timing and mode from the associated separate information text file were made to estimate fetal, labor management and outcome differences in newborn status, operative vs. non-operative delivery, and timing of delivery. This methodology made possible comparisons between the actual labor management, intervention(s), and outcome; and the algorithm-driven labor management, intervention(s), and outcome. The most important statistically measureable set of outcomes were how much earlier the algorithm-driven delivery time is for each of the fetuses with problematic fetal heart rate tracings, compared to the actual delivery time for this same set of fetuses. Also possible was that of more algorithm-driven operative vaginal and cesarean deliveries than in the actual outcomes group as described in the associated information header files. These same statistical comparisons were also made with those fetuses with non-problematic fetal heart rate tracings, to see if unnecessary interventions were produced, by using the algorithm-driven analyses. This comparison yielded potentially superior labor-process management, better and more timely intervention(s), and an improved neonatal and maternal outcome. Further proof of the efficacy of the Clark et al. fetal heart rate tracing algorithm and its associated extensive "clarifications for use in algorithm" (Clark et al., 2013) was one of the products of this study.

Data Collection

The 552 tracings data files and the associated 552 tracings information files from the Chudáˇcek et al. (2014) open access intrapartum CTG database were downloaded to the database folder on an Apple Macintosh computer for organizing, processing, transfiguring, optimization, and display. The tracings data files each contain a fetal heart rate tracing with the maternal uterine contraction tracing. The separate associated information files each contain data on fetal gestational age, maternal parity and gravidity, maternal age, known perinatal diseases, type of delivery, fetal sex, risk factors, intrapartum drugs, induced vs. spontaneous labor, fetal presentation, intrapartum risks or diagnoses umbilical artery pH and base excess/base deficit, newborn weight, Apgar scores, and amount of missing signal time for each associated data file (See Glossary). Each information header file (.hea) was matched with a unique file number to each data file's (.dat) matching unique file number.

Each of the 552 tracings information header files (See Figure 8) have a separate matching 30-90 minute heart rate tracings/maternal uterine contraction tracings data file (See Figure 9).



2045.hea — Locked

```
2045 2 4 14894
2045.dat 16 100(0)/bpm 12 0 12850 -26735 0 FHR
2045.dat 16 100/nd 12 0 1800 -26266 0 UC

#----- Additional parameters for record 2045

#-- Outcome measures
#pH           7.03
#BDecf        8.91
#pCO2         10.4
#BE           -12.2
#Apgar1       7
#Apgar5       9

#-- !NotReadyYet! Neonatology outcome measures !NotReadyYet!
#NICU days    0
#Seizures     0
#HIE          0
#Intubation   0
#Main diag.   0
#Other diag.  0

#-- Fetus/Neonate descriptors
#Gest. weeks  39
#Weight(g)    3140
#Sex          1

#-- Maternal (risk-)factors
#Age          32
#Gravidity    1
#Parity       0
#Diabetes     0
#Hypertension 0
#Preeclampsia 0
#Liq. praecox 0
#Pyrexia      0
#Meconium     1

#-- Delivery descriptors
#Presentation 1
#Induced      0
#I.stage      189
#NoProgress   0
#CK/KP        0
#II.stage     -1
#Deliv. type  2

#-- Signal information
#dbID         1083243
#Rec. type    1
#Pos. II.st.  -1
#Sig2Birth    0
```

Figure 8: Example Of an Associated Fetal Heart Rate Tracing Information File 2045.hea. Copyright 2014 by Chudáˇcek. Reprinted under terms of the Creative Commons Attribution License.

The maternal uterine contraction tracing runs parallel with the fetal heart rate tracing in the same tracings data file. When displayed, each data file has the fetal heart rate tracing along the top of the tracing and the maternal uterine contraction tracing running along parallel just below the fetal heart rate tracing. The interaction of the two parallel tracings was compared and contrasted with each other along the entire length of each tracing. A curser-driven readout allowed accurate fetal heart rate numerical reading at any point of the tracing (See Figure 10).

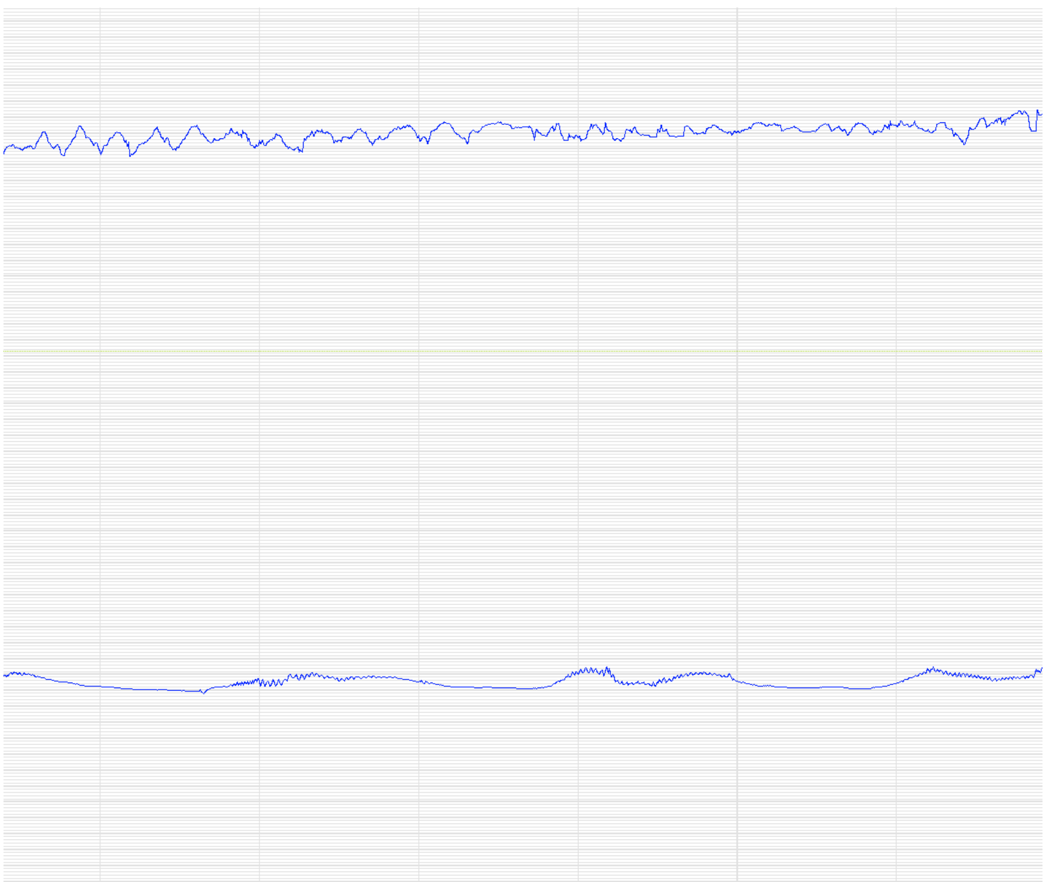


Figure 9: Short Example Of Fetal Heart Rate & Maternal Uterine Tracings Data File Number 2045.dat (fetal heart rate varies from 123 bpm to 151 bpm in this trace). Copyright 2014 by Chudáˇcek. Reprinted under terms of the Creative Commons Attribution License.

Each of the 552 fetal heart rate tracings and each parallel maternal uterine contraction tracings were blind analyzed using the Clark, et al. unambiguous Category II algorithm decision tree and the associated list of ten main “management of Category II fetal heart rate patterns: clarifications for use in algorithm,” as well as the sixteen additional management per algorithm recommendations for care based on the fetal status and labor progress (For a thorough discussion of the above algorithm, ten clarifications, and sixteen recommendations, see Appendix). Each of the 552 analyses followed the method described at length in the previous research design area of this paper. Briefly, each of the 552 fetal heart rate tracings/maternal uterine contraction tracings, was blind analyzed using the Clark et al., 2013 algorithm decision tree, the associated list of ten main “management of Category II fetal heart rate patterns: clarifications for use in algorithm,” as well as the sixteen additional management per algorithm recommendations for care based on the fetal status and labor progress. The algorithm-driven analysis of each fetal heart rate tracing was compared to the actual outcome information contained in the separate information header file associated with each of the 552 fetal heart rate tracings/maternal uterine contraction tracings data files. The algorithm-driven analyses comparisons were made to see if there was, or was not, a significant difference in the time to delivery in the case of fetuses showing evidence of lack of moderate variability/accelerations lasting >30 minutes with recurrent late decelerations, recurrent variable decelerations lasting >60 seconds with nadirs less than 60 bpm or > 60 bpm below baseline, or with prolonged decelerations in their fetal heart rate tracings. If moderate variability/accelerations were present, then up to 1 hour of significant decelerations could be observed before an early delivery intervention. There was a difference between the total number of earlier delivery times of algorithm-driven births, and the total number of actual delivery times described in the information header files. Each of the 552 per algorithm analyses was entered into an array using the original tracings data file number for identification. This was necessary to avoid confusion, as the tracings data file numbers and header information file numbers both start at 1001, run sequentially up to 1506 and stop; start again at 2001 and run sequentially through to 2046 and end there. After the 552 tracings data files had been analyzed with the Clark et al., 2013 unambiguous Category II algorithm and associated extensive "clarifications for use in algorithm," then the 552 header information files were entered into the analysis array next to the tracings data file analysis with the same file number. At that point, each header information file was compared each associated tracing data file per algorithm analysis, with the actual outcomes information from each tracings header information file with the same file number. When all of the comparisons between the analysis per algorithm decisions and management information, versus the actual outcome information were made, there was a noticeable improvement when contrasting the unambiguous algorithm probable outcomes over the associated actual outcomes, as the algorithm driven analyses worked as predicted. When the earlier time to delivery percentages were compared, there was an important, but non-statistically significantly shorter time to delivery difference in favor of the algorithm-driven analyses in the earlier delivered group. There was higher rate of operative deliveries recommended in the algorithm-driven group as well, potentially yielding better fetal and maternal outcomes.

Description of Data from Chudáˇcek et al., 2014 Open Access intrapartum CTG Database

The 552 fetal heart rate tracings/maternal uterine contraction tracings in the public access database created by Chudáˇcek et al. (2014), were selected from the 14,492 deliveries gathered between April 2010 and August 2012 at the obstetrics department of the University Hospital at Brno, located in the Czech Republic. The data was of two types; intrapartum fetal heart rate tracings/maternal uterine contraction tracings, and for each set of tracings there was an information header file containing the associated clinical data. The tracings were collected using a variety of fetal monitoring machines: STAN S21 and STAN S31 made by Neoventa Medical, Sweden; and Avalon FM40 and FM50 made by Phillips Healthcare, USA. A total of 9,164 individual tracings were recorded, from which the 552 tracing were meticulously selected using the following clinical and technical criteria: Women's age, greater than 18 years old; weeks of gestation, more than 37 weeks; no known fetal diseases, no congenital defects or intrauterine growth restriction; type of gravidity, only uncomplicated, singleton pregnancies allowed; and exclude records with missing umbilical artery pH; and type of delivery. The 552 deliveries included 417 vaginal (pH>7.15), 89 vaginal (pH≤7.15), 30 cesarean (pH>7.15), 16 cesarean (pH≤7.05). Other clinical criteria were: Fetuses of both genders are included; risk factors included were gestational diabetes, preeclampsia, maternal fever (>37.5 °C), hypertension, meconium stained fluid; and information on why operative delivery was used was not included, if there was induced labor, presentation type (occipital/breech), no labor progress, dystocia cephalocorporal (incoordinate uterine activity, and dystocia cephalopelvic). The fetal heart and maternal uterine signal criteria were: Signal length, the ninety minutes before the delivery (Stage I maximum sixty minutes, Stage II maximum thirty minutes); missing signal, no more than fifty percent of the tracing; noise and artifacts, some recordings contain maternal heart rate sometimes present (typically when ultrasound doppler probe is used); and fetal tracings instrument used, a mix of ultrasound doppler probe and/or direct scalp measurement. Since, according to the authors, these sorts of tracings are typical of the obstetrics department at University Hospital at Brno (and in hospitals around the U. S. as well), they can be interpreted in that context by healthcare personnel skilled in fetal heart rate tracings/maternal uterine contraction tracings analysis. This Physiobank (Goldberger et al., 2000) database (http://physionet.org/physiobank/database/ctu-uhb-ctgdb/) was designed to be used by researchers as a basis for studies, which can be cross-compared with one another, or as the basis for research comparing this database to other similar databases of fetal heart rate tracings/maternal uterine contraction tracings. The database consists of 552 fetal heart rate tracings/maternal uterine contraction tracings data files (.dat), and 552 associated separate tracings information files (.hea). The Chudáˇcek et al., 2014 open access intrapartum CTG Database on physionet.org, consists of a listing of 1104 alternating data and information files in MIT Waveform Database format. To decode and display this data as fetal heart rate tracings/maternal uterine contraction tracings electronic digital waveforms, it is necessary to unpack, install, and properly configure Open Source WFTD Processing GNU-Based Unix software (this process is complex and outside the scope of this paper).

Sample Characteristics

The data is comprised of 552 electronic fetal heart rate tracings/maternal uterine contraction tracings data files and associated separate tracings information files.

Inclusion criteria. The data includes only the 552 data and separate information files from the Chudáˇcek et al., 2014 open access intrapartum CTG Database.

Exclusion criteria. Exclusion criteria used by Chudáˇcek et al. to reduce the number of tracings from 14,492 to 552 before being uploaded for availability in an open access intrapartum CTG database are: Exclude maternal age < 18 years, weeks of gestation - include only fetal weeks of gestation ≥ 37, exclude known fetal diseases – congenital defects or intrauterine growth restriction, include type of gravidity - only singleton, uncomplicated pregnancies and excluded records with missing umbilical artery pH.

Detailed information on inclusion, exclusion and other criteria are discussed in the *Description of Data* section above.

Statistical Approach For Analysis Of The Data

The two-sample z-test for proportions was one of the two statistical methods, which were utilized in this research. This approach was used to compare two different percentage/proportion outcomes of some phenomena involving two sub-groups of a larger group. The z-test yields a 'p' score, which is a measure of the significance of the relationship between the two proportions (percentages). The second statistical method was the 2X2 Fischer's Exact Test. This statistical method also yields a 'p' score, which is also a measure of the significance of the relationship between the two percentages (proportions). These two statistical methods were very useful individually and in combination to address those data which lent themselves to statistical analysis. When used in parallel, they yielded the same significant ‘p’ scores, thus cross-validating those results.

On a side note, Clark, et al. (2016) used Chi-Square for trends, and for tests of proportions, they used Fischer’s Exact Test (personal communication from E. Hamilton, MD, on 09/19/2016) on their somewhat similar datasets. The statistical method and the associated statistical test used by Clark et al., 2016, also produce ‘p’ scores, which can be compared. A 2x2 table for each of Clark et al., 2016 statistical methods was used to generate a pair of percentages (proportions), which can be used to calculate the ‘p’ score in each instance. Since both of their ‘p’ scores are significant (at the 0.05 level), then the findings can be seen as valid. Normally, however, Chi-Square is used on large datasets, greater than 1000, and Fischer’s Exact Test is used on smaller datasets, less than 1000.

Protection of Human Subjects

The University of Hawai’i Human Studies Program and Institutional Review Board did not require IRB approval of this study, because it utilized digital recordings and data from a currently existing, publically available database and did not include any individual identifiers or involve human subjects (University of Hawai’i Human Studies Program, 2015 p. 2).

CHAPTER 4

RESULTS

This section provides the results of the statistical data analysis carried out on the research data generated. The study aimed to verify if using the Clark et al., 2013 fetal heat rate monitoring algorithm and associated ten main clarifications for use in algorithm, plus the sixteen additional clarifications for fetal and maternal labor management would result in improved outcomes when blind analyzing the 552 fetal heart and maternal uterine contraction electronic tracings from the Chudáˇcek et al., 2014 open access intrapartum CTG Database.

Database Clinical Parameters

Table 3: Main Clinical Parameters Of Vaginal Delivery
(Chudáˇcek et al., 2014, File#1471-2393-14-16-S1). Copyright 2014 by Chudáˇcek.
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Main clinical parameters of the vaginal delivery part of the CTG database – pH related

	pH ≤ 7.05 # cases: 38			pH > 7.05 # cases: 468			pH > 7.15 # cases: 412			pH > 7.25 # cases: 261		
	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
Maternal age (years)	29.97	19	42	29.79	18	46	29.76	18	43	30.08	18	43
Parity	0.18	0	2	0.45	0	7	0.48	0	7	0.56	0	5
Gravidity	1.37	1	5	1.44	1	11	1.47	1	11	1.57	1	11
Gestational age (weeks)	39.97	38	42	40.00	37	43	39.98	37	43	40.03	37	43
pH	6.98	6.85	7.04	7.25	7.05	7.47	7.27	7.15	7.47	7.31	7.25	7.47
BE	-16.63	-26.80	-8.30	-5.68	-13.30	-0.20	-5.07	-11.70	-0.20	-4.12	-8.10	-0.20
BDecf (mmol/l)	13.74	6.76	26.11	3.99	-3.40	10.92	3.51	-3.40	9.70	2.81	-3.41	7.03
Apgar 1min	6.53	1	10	8.4	1	10	8.53	2	10	8.84	3	10
Apgar 5min	7.92	4	10	9.15	4	10	9.25	4	10	9.43	4	10
Neonate's weight (g)	3357	2570	4200	3412	1970	4750	3411	1970	4750	3404.6	1970	4750
Neonate's sex (F/M)	16 / 22			223 / 245			195 / 217			124 /137		

Table 4: Main Clinical Parameters Of SC Delivery
(Chudáˇcek et al., 2014, File#1471-2393-14-16-S2). Copyright 2014 by Chudáˇcek.
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Main clinical parameters of the SC delivery part of the CTG database – pH related.

	pH ≤ 7.05 # cases: 9			**pH > 7.05 # cases: 37**			**pH > 7.15 # cases: 32**			**pH > 7.25 # cases: 22**		
	Mean	**Min**	**Max**	**Mean**	**Min**	**Max**	**Mean**	**Min**	**Max**	**Mean**	**Min**	**Max**
Maternal age (years)	27.44	21	34	29.7	20	46	29.25	20	39	30.32	20	39
Parity	0	0	0	0.35	0	2	0.32	0	2	0.55	0	2
Gravidity	1	1	1	1.62	1	8	1.72	1	8	2.05	1	8
Gestational age (weeks)	40.33	38	41	39.8	37	43	39.84	37	43	39.86	37	43
pH	6.99	6.95	7.04	7.26	7.08	7.43	7.28	7.15	7.43	7.32	7.25	7.43
BE	-18.67	-23.70	-12.00	-6.17	-12.10	-1.30	-5.32	-10.40	-1.30	-4.58	-7.00	-1.30
BDecf (mmol/l)	15.91	7.92	22.52	4.54	0.82	9.75	3.81	0.82	8.45	3.45	0.82	5.61
Apgar 1min	7.67	5	10	8.03	5	10	8.16	5	10	8.45	5	10
Apgar 5min	8.44	7	10	8.81	4	10	8.94	4	10	8.95	4	10
Neonate's weight (g)	3220	2600	4100	3296	2150	3810	3297	2150	3810	3281	2150	3720
Neonate's sex (F/M)		5 / 4			20 / 17			15 / 17			7 / 15	

Table 5: Clinical Parameters (Risk Factors and Means of Measurement) Vaginal
(Chudáˇcek et al., 2014, File#1471-2393-14-16-S3). Copyright 2014 by Chudáˇcek.
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Clinical parameters (risk factors and means of measurement) – vaginal delivery part of the CTG database – pH related. In description of presentation – O stands for occipital and B for breech.

	pH ≤ 7.05	**pH > 7.05**	**pH > 7.15**	**pH > 7.25**
Total number	**38**	**468**	**412**	**261**
Diabetes	30	364	313	188
Fever	3	29	28	16
Hypertension	0	6	6	4
Preeclampsia	3	39	34	21
Meconium	1	16	14	8
Induced	13	183	165	116
Presentation O	35	425	336	239
Presentation B	1	13	7	7
No progress	7	44	33	27

Table 6: Clinical Parameters (Risk Factors and Means of Measurement) Cesarean (Chudáˇcek et al., 2014, File#1471-2393-14-16-S3). Copyright 2014 by Chudáˇcek. Reprinted under terms of the Creative Commons Attribution License.

Clinical parameters (risk factors and means of measurement) – sectio caesarea delivery part of the CTG database – pH related. In description of presentation – O stands for occipital and B for breech.

	$pH \leq 7.05$	$pH > 7.05$	$pH > 7.15$	$pH > 7.25$
Total number	**9**	**37**	**32**	**22**
Diabetes	9	27	22	12
Fever	1	2	1	1
Hypertension	0	0	0	0
Preeclampsia	0	1	1	1
Meconium	0	2	2	1
Induced	2	23	21	16
Presentation O	9	35	31	21
Presentation B	0	2	1	1
No progress	5	5	4	3

Patient Characteristics

Table 7: Patient And Labor Outcome Statistics
(Chudáˇcek et al., 2014, p. 7). Copyright 2014 by Chudáˇcek. Reprinted under terms of the Creative Commons Attribution License.

Patient and labor outcome statistics for the CTG-UHB cardiotocography database

506 – Vaginal (44 – operative); 46 – Caesarean Section
US = 412; DECG = 102; US-DECG = 35; N/A = 3

	Mean (Median)	Min	Max	Comment
Maternal age (years)	29.8	18	46	Over 36y: 40.
Parity	0.43 (0)	0	7	
Gravidity	1.43 (1)	1	11	
Gestational age (weeks)	40	37	43	Over 42 weeks: 2
pH	7.23	6.85	7.47	
BE	-6.36	-26.8	-0.2	
BDecf (mmol/l)	4.60	-3.40		
Apgar 1min	8.26 (8)	1	10	AS1 < 3: 18
Apgar 5min	9.06 (10)	4	10	AS5 < 7: 50
Neonate's weight (g)	3408	1970	4750	SGA: 17; LGA: 44
Neonate's sex (F/M)	259 / 293			

Abbreviations: AS1, AS5 – Apgar score at 1st and 5th minute respectively; SGA, LGA – fetus small, large for gestational age.

CTG Signal Characteristics

Table 8: CTG Signal Characteristics for the CTG-UHB Database (Chudáˇcek et al., 2014, p. 8). Copyright 2014 by Chudáˇcek. Reprinted under terms of the Creative Commons Attribution License.

CTG signal statistics for the CTG-UHB cardiotocography database

506 – Vaginal (44 – operative); 46 – Caesarean Section
US = 412; DECG = 102; US-DECG = 35; N/A = 3

	Mean	Min	Max	Comment
Length of I. stage (min)	225	45	648	
Length of II. stage (min)	11.87	0	30	
Dist. SignalEnd to Birth (min)	2.70	0	29	Over 10 min: 9
Noisy data W1 (%)	12.38	0	74	
Missing data W1 (%)	3.59	0	87	
Overall W1 (%)	15.98	0	89	Over 50%: 18
Noisy data W2 (%)	13.42	0	49	
Missing data W2 (%)	0	0	0	
Overall W2 (%)	13.14	0	49	Over 25%: 98
Noisy data II. stage (%)	22.62	0	91	
Missing data II. stage (%)	8.47	0	100	
Overall II. stage (%)	31.26	0	100	Over 50%: 97

W1 – 30 minute-long window beginning 60 minutes before end of the first stage of labor, W2 – 30 minute-long window beginning 30 minutes before end of the first stage of labor.

Statistical Analysis Software

The IBM Statistical Package for the Social Sciences (SPSS) Apple Macintosh Version 22 with the Confidence Interval Proportion Tool was used for data analysis.

Comparison of Ratios. The two research questions explored the differences between the ratios/percentages of two sets of analyses outcomes from the same dataset. The final decision to use the two-sample Z-test for proportions and the 2 X 2 table Fischer's Exact Test was based on the data generated, as well as the form of the comparison of the blinded and un-blinded analyses used. Both of these methods detected a statistically significant difference between two proportions/percentages. The decision to use both statistical analysis methods, was to compare the two statistical results to see if they were significant at a similar level as a form of cross-validation.

Sample Characteristics

The final analyses samples either are or were extracted from the entire Chudáˇcek et al. 2014 open access intrapartum CTG Database.

Each of the 552 fetal heart rate tracings came from babies who had no severe morbidity, no NICU days, no seizures, no diagnosis of hypoxic ischemic encephalopathy (HIE), and no intubation. However, very vigorous resuscitation and support required at delivery can be assumed for the 37 babies in the dataset with one-minute Apgar scores of 5 or less. Twenty babies also had 5 minute Apgar score of 6 or less.

A very significant predictive effect of the presence of Category II FHR was observed in all but two of the 177 fetal heart rate tracings from babies with umbilical artery pH at birth less than 7.20 (the traditional definition of fetal academia).

As the 552 fetal monitoring strips were being blind analyzed, the strips looked typical regarding the amount of missing data (fetal heart rate and uterine contraction), the differences when shifting between external fetal heart rate monitoring and fetal scalp lead monitoring and probable oxytocin use detection.

Data Analyses Parameters

Because of the nature and structure of the Clark et al., 2013 FHR monitoring algorithm, and ten main, and the sixteen additional clarifications for use in algorithm, the blind analyses per algorithm were carried out at several different, yet related and connected levels.

The first level, was identifying those FHR monitoring strips which, according to the algorithm, were identified as having urgent Category II status, which recommended an earlier radical intervention, per algorithm, of either an operational vaginal delivery (vacuum extractor or forceps), or a cesarean delivery. In actual practice, in the case of Category II status fetuses, conservative methods should be tried earlier in the tracing, unless a sentinel event has occurred, requiring immediate, radical action, to save the patient(s). Unfortunately, in the analysis of post-facto strips such as these, it was not possible to use conservative interventions to improve the fetuses' Category II status, as would be the case, if they were currently in progress, due to the need for immediate action.

The second level of analysis, was identifying those FHR monitoring strips, which required a conservative intervention, per algorithm, to rescue the fetus from Category II status (indeterminate), and return it to Category I status (normal). Conservative interventions include, but are not limited to: supplemental oxygen, maternal position changes, intravenous fluid administration, correction of hypotension, reduction or discontinuation of uterine stimulation, administration of a uterine relaxant, amnioinfusion, and/or changes in second stage breathing and pushing techniques.

A third level of analysis, was to explore the supposition that use of the algorithm could potentially reduce the number of OVD's and cesarean deliveries, and instead allow more normal spontaneous vaginal deliveries.

Specific Aim 1

The first specific aim of this study was to test the Clark et al., 2013 Category II fetal heart rate monitoring algorithm on 552 fetal heart rate tracings (Chudá˘cek et al., 2014) without reference to the original decisions made and interventions carried out at the time each strip was made, to see if the algorithm decision tree and associated extensive "clarifications for use in algorithm," gave unambiguous direction on interpretation and intervention for these 552 fetal heart rate tracings*, which would potentially yield better fetal (higher Apgar scores, less acidosis, fewer admissions to NICU, less neurological and other damage, etc.) and maternal (fewer cesarean births, fewer operative vaginal deliveries, more successful spontaneous vaginal deliveries) outcomes, as it has in the two Clark et al., 2015 and 2016 research efforts*.

Research Question 1

Will Clark et al.'s (2013) *Algorithm for Management of Category II Fetal Heart Rate Tracings* reliably give unambiguous direction on interpretation and intervention for Category II fetal heart rate tracings?

Research question 1 sought to ascertain if Clark et al.'s (2013) *Algorithm for Management of Category II Fetal Heart Rate Tracings*, algorithm decision tree and associated extensive "clarifications for use in algorithm," gave unambiguous direction on interpretation and intervention for Category II FHR tracings.

Highly significant algorithm-driven evidence was discovered giving very useful unambiguous direction for interpreting and intervening when observing Category II FHR tracings.

Post facto reading comparison of the actual results showed eighteen of the 177 header files with pH less than 7.20 had severe fetal metabolic acidosis base deficit extracellular fluid levels (BDecf) over 12.0, and another 45 header files reported fetal metabolic acidosis evidenced by abnormally high base deficit extracellular fluid levels (BDecf) over 8 but less than 12. Seven of the 177 data files with pH less than 7.20 had missing base deficit extracellular fluid levels (BDecf) records.

The blind analysis per algorithm correctly identified all but two of the 177 FHR tracings with a pH below 7.20 as Category II, requiring interventions to relieve the stressors on the fetuses and return them to Category I (Normal) status. In this study, the algorithm-driven conservative interventions recommended, were found to be indicated in all except two of the 177 FHR tracings with pH less than 7.20 for Category II FHR tracings. These blind analyses conservative interventions, discovered by utilizing the Clark et al. (2013) algorithm decision tree and associated extensive "clarifications for use in algorithm with Category II FHR tracings, could potentially for improve fetal pH, base deficit, Apgar scores, and non-operative delivery rates. There were a total of 17 algorithm-driven recommended radical interventions (OVD or cesarean), all with a birth pH of 7.18 or less (8 had pH less than 7.0, with the other 9 babies having umbilical artery pH from 7.0 to 7.18). An additional 11 FHR tracings with pH ≤7.20 were found to meet the criteria for radical intervention per algorithm within 5 minutes of the tracing end. These findings and others are described in more detail under Research Question 2. The sensitivity of the algorithm makes these levels of findings and the solutions to them finally possible. Without the algorithm, these Category II FHR tracings could remain indeterminate, and possible interventions, and when and what to use, might not be utilized. The database contained only forty-six cesarean deliveries, and the forty-four OVD deliveries included were not identified in the information header files, nor was the reason given why the cesarean deliveries were done. If the reason for doing the cesarean deliveries had been failure to progress when adequate labor has not been well established, maternal preference, or failure to allow a trial of labor after a previous cesarean in appropriate patients in appropriate settings, then conservative measures per algorithm could have been utilized if indicated, and the patients could have been allowed to have a normal spontaneous vaginal delivery. This would have spared them having a cesarean delivery with all of the risks of major surgery that that entails. In the case of OVD's the risk for the fetus is also higher, because using a vacuum extractor or forceps has potential for harm.

The Clark et al.'s (2013) *Algorithm for Management of Category II Fetal Heart Rate Tracings,* algorithm decision tree and associated extensive "clarifications for use in algorithm," definitively gave unambiguous direction on interpretation and intervention for Category II FHR tracings. In blind analyzing the 552 Chudáˇcek et al., 2014 open access intrapartum CTG Database FHR tracings using the above algorithm, unambiguous interpretation came much more easily as the blind analyses progressed. Another aspect of this research effort, was the experience of how this algorithm would work to give structure to experienced experts to expand and reinforce their professional judgment. Rather than the algorithm's structured approach getting in the way of professional judgment, it rather instead reinforced and added to professional competence and judgment by providing a set of basic ideas from which to reason in reaching evidence-based and reasonable sets of decisions for care and management of labor and delivery patients. The algorithm would give new practitioners a basis on which to build trustworthy professional judgment for interpretation and management of Category II FHR tracings, and would give a boost and reinforcement of the professional judgment of experienced practitioners in the same area. As this research effort progressed through the blind analyses per algorithm of the 552 FHR tracings, the task of analysis quickly became easier, as the algorithm's logic is melded with decades of experience. This is not a small thing. It is easy to see the power of such a useful tool, as it is used over time, it becomes an expansion of skill levels, clearing up ambiguity, and substituting clarity. The evidence can be found in the results following Research Question 2. This potential should be examined more fully in clinical settings, by clinical practitioners in real-time, now that post-facto research is demonstrating its practicality.

Specific Aim 2

The second specific aim of this study was to generate more evidence regarding the efficacy of the Clark et al., 2013 Category II fetal heart rate tracing algorithm.

Research Question 2

Can using the Clark et al.'s (2013) *Algorithm for Management of Category II Fetal Heart Rate Tracings* on the 552 fetal heart rate and uterine contraction tracings result in different recommendations for management and intervention forecasting a possibly improved outcome over the actual result?

Research question 2 sought to ascertain if using Clark et al.'s (2013) *Algorithm for Management of Category II Fetal Heart Rate Tracings*, algorithm decision tree and associated extensive "clarifications for use in algorithm," would result in different recommendations for management and intervention forecasting a possibly improved outcome over the actual result.

Highly significant evidence was discovered which would potentially have resulted in improved outcomes over the actual results.

The first illustration was when the actual results, with their associated blind analyses were sorted by pH, and the results with pH levels below 7.20 were examined; it was found that all but two FHR tracings had an algorithm-driven recommendation of conservative intervention. The Z-Score was -18.3897. The p-value was 0. The result was significant at $p<0.01$. The proportion of responses for Observation 1 was 0.011. The proportion for Observation 2 was 0.989. The Fischer Exact Test statistic value was 0. The result was significant at $p<0.01$. This algorithm-driven recommendation, which if acted upon at the time the FHR tracings were generated, would have potentially ameliorated the acidemic condition of the fetuses, resulting in improved fetal status during labor, and upon delivery, resulting in improved overall newborn health status. This algorithm-driven method can also improve fetal status to the point of potentially making an OVD or cesarean delivery unnecessary, and allowing a normal spontaneous vaginal delivery to occur with better fetal status as a result. There were seventeen possible examples of this in this pH levels below 7.20 group.

The second illustration was also when the actual results, with their associated blind analyses outcomes were sorted by pH, and the results with pH levels below 7.20 were examined; it was found that all of the FHR tracings with algorithm-driven recommendations for earlier radical intervention (OVD or cesarean) were in this group. The earlier algorithm-driven radical intervention ranged from 5 minutes to 34 minutes. The average was 18.4 minutes. In fetuses with this status, severe metabolic acidosis can be ameliorated or prevented by earlier recognition and intervention. "Barring a sentinel event, use of this algorithm would result in birth of a severely depressed infant with metabolic acidosis in less than 1/5000 labors, which probably represents a technical threshold for visually interpreted fetal heart rate monitoring" (Clark et al., 2016). In the case of those fetuses identified per algorithm in blind analyzing the 552 Chudáˇcek et al., 2014 open access intrapartum CTG Database FHR tracings for earlier radical intervention, this is certainly true, as intervening even a few minutes earlier can make a large difference in the fetal outcome, such as when a shoulder dystocia, umbilical cord prolapse, uterine rupture, or significant placental abruption occur.

A third illustration was when the actual results, with their associated blind analyses outcomes were sorted by base deficit in extracellular fluid level (BDecf), all 17 of the FHR tracings with algorithm-driven recommendations for earlier radical intervention (OVD or cesarean) had pH less than 7.20 and 47% (8 out of 17) had severe metabolic acidosis with base deficit in extracellular fluid level above 12. Indeed, the algorithm was sensitive enough to identify and recommend early, conservative intervention to prevent fetal harm before pH fell to dangerous levels, yet did not result in early delivery intervention recommendations for any tracings with normal pH.

CHAPTER 5

DISCUSSION

This section discusses the study's findings as related to the two research questions, with specific considerations of limitations, significance for practice, and recommendations for future research. All results supported the efficacy of using the Clark et al., 2013 algorithm as a simple and quick means for identifying and treating fetuses with Category II FHR tracings to improve pH during labor and birth. The algorithm is particularly good in identifying fetuses with potentially low pH during labor, and is very helpful in assessing positive fetal responses to conservative interventions for suspect fetal heart rate tracings.

Research Question 1

Will Clark et al.'s (2013) *Algorithm for Management of Category II Fetal Heart Rate Tracings* reliably give unambiguous direction on interpretation and intervention for Category II fetal heart rate tracings?

Comparing the blind analysis per algorithm data with the actual outcome header files data confirmed the interpretation and intervention efficacy of the Clark et al. 2013 algorithm in identifying Category II FHR tracings, and giving meaningful, clear direction for useful intervention strategies to potentially change those tracings to Category I (Normal) tracings. The algorithm decision tree is easy to use and memorize, and the various options for moving through the tree to decide what must be done in reaction to the various types of tracings made sense in context. The 'clarifications for use in algorithm' are clear, and provide expert guidance, which complements and enhances professional judgment. The results when using the algorithm on blinded post facto FHR tracings, gave a clear path for improvement over the actual outcome. In the final analysis, during this research effort, the algorithm has fulfilled its promise giving a set of techniques for correctly identifying Category II FHR tracings, and giving unambiguous direction for correcting the problems associated with fetuses manifesting those same Category II FHR tracings, potentially returning those fetuses to Category I status.

Research Question 2

Can using the Clark et al.'s (2013) *Algorithm for Management of Category II Fetal Heart Rate Tracings* on the 552 fetal heart rate and uterine contraction tracings result in different recommendations for management and intervention forecasting a possibly improved outcome over the actual result?

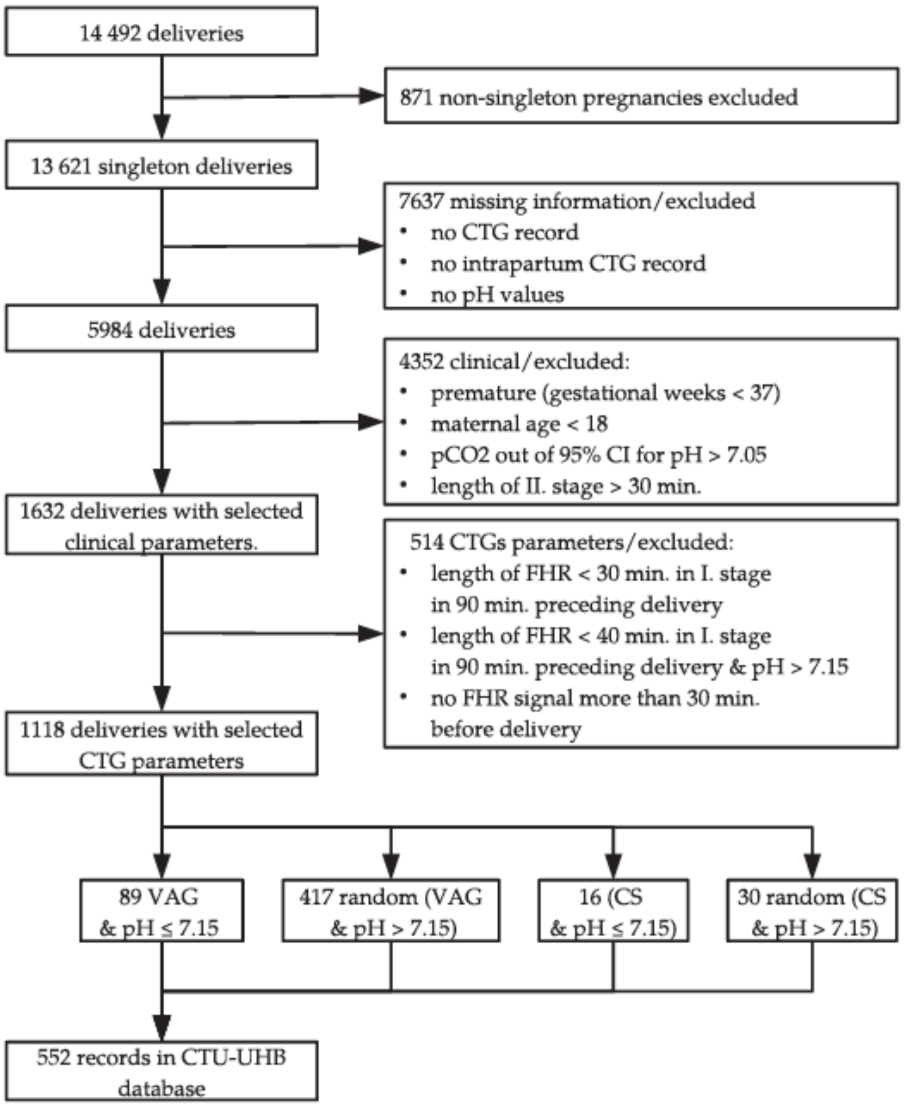
Using the Clark et al.'s (2013) *Algorithm for Management of Category II Fetal Heart Rate Tracings* on the blind analyses of the 552 fetal heart rate and uterine contraction tracings in this research study, resulted in significantly different interpretation and intervention recommendations for management and intervention. Virtually all (98.9%) of the fetuses which in the actual results, had a pH below 7.20 (below normal) were identified previously during the blind analyses per algorithm as requiring either conservative (as described earlier) or radical (OVD or cesarean) intervention. This illustrates the sensitivity of the algorithm-based method. With this level of sensitivity, most fetuses manifesting a low pH and other associated problems, may be identified, and proper intervention applied to improve the situation, and potentially return the fetus to normal, healthy status.

Limitations

There are several limitations to this study. Only one publicly available database exists of the size needed for this research. While this database restricted the size and variety of populations that were studied, it also validates the worthiness of publishing future large(r) datasets, especially including FHR tracings from populations with significant neonatal morbidities that might be attributable to health care management during the intrapartum period.

The database was produced using exclusion criteria by Chudáˇcek et al. (2014) to reduce the number of tracings from 14,492 to 552 before being uploaded for availability in the open access intrapartum CTG database. Some of the exclusions were: Exclude maternal age < 18 years, weeks of gestation - include only fetal weeks of gestation ≥ 37, exclude known fetal diseases – congenital defects or intrauterine growth restriction etc., include type of gravidity - only singleton, uncomplicated pregnancies and exclude records with missing umbilical artery pH.
Detailed information on inclusion, exclusion and other criteria are discussed in the *Description of Data* section of Chapter III.

Following is the selection flowchart (See figure 10) used by Chudáˇcek et al. (2014) to reduce the number of tracings from 14,492 to 552 before being uploaded for availability in the open access intrapartum CTG database.



Selection of recordings for the final database. Flowchart diagram describing the process of data selection for the final database.

Figure 10: Selection Flowchart For The Final Public Database (Chudáˇcek et al., 2014, p. 6). Copyright 2014 by Chudáˇcek. Reprinted under terms of the Creative Commons Attribution License.

As can be seen, many important varieties of delivery types usually seen in the larger population have been excluded. This flowchart illustrates the need for many more, larger, and varied FHR tracings databases are needed to do substantive and meaningful research in electronic FHR monitoring, as well as to find and substantiate significant new, improved ways to interpret and intervene on the basis of electronic

FHR monitoring results.

A second, and important limitation to this study, was that none of the 552 laboring mothers in the dataset had any narcotic or synthetic narcotics during the fetal heart rate recordings. As such, the results may be generalizable only to non-systemically medicated birthing populations. Of the 16 women with preeclampsia, 4 of their babies were born with a pH <7.20, and there was no information given if maternal magnesium sulfate or other medications that might affect FHR were administered.

The third important limitation to this study is the possible inaccuracy of the pH, base excess, and base deficit in extracellular fluid results in the data. It was not specified if all umbilical artery sampling for blood gases was performed within a specified time, was from double clamped umbilical cord segments vs. from unclamped umbilical cords or from placental arteries, etc. Both pH and base excess results from non-clamped cords, or from placenta, will significantly exponentially decrease if drawn at 30, 60, and 90 minutes after delivery (Mokarami, Wiberg, & Olofsson, 2013). Also, possible lab, transcription, or inadvertent umbilical vein instead of artery sampling errors may occur, and even samples drawn immediately or from double clamped cord segments will give inaccurate results if contaminated with ambient air (Pomerance, 2004).

Last, while FHR and uterine pressure signal loss complicated to varying degrees analyzing 123 of the 177 tracings where pH was less than 7.20, the signal loss was comparable to that in many U.S. settings. Some of the more challenging analyses occurred where uterine contraction monitoring had been discontinued at the start of or during second stage, a problem that still occurs in too many U.S. hospitals.

Significance for Practice

Because nurses and physicians make ongoing labor management decisions both independently and jointly for each patient, it is important to have a common understanding and set of parameters guiding assessment, intervention, and communication for early recognition and appropriate management of Category II and Category II fetal heart rate tracings. This study has provided more evidence that the Clark et al. (2013) algorithm decision tree and associated extensive "clarifications for use in algorithm with Category II FHR tracings does give unambiguous direction on interpretation and intervention based upon the secondary analyses of these 552 fetal heart rate tracings. The results showed that a significant proportion >98.8% (n=175) of different recommendations for management and conservative, non-operative intervention for the 177 FHR tracings where abnormal pH <7.20. There was an average earlier delivery recommendation of 18.4 minutes (range 5 to 34 minutes) per algorithm for 17 of the 552 tracings, all of which had pH <7.20 (range 6.85 to 7.18), forecasting a probable improved outcome over the actual result.

The longest FHR tracing used in this study was 90 minutes of recording. There were no Category III tracings found. Review for Category I FHR tracings took on average, less than five minutes. Up to 30 minutes was required to analyze each of the more complicated Category II FHR tracings, especially when significant sections had missing or poor signal recording, or when patient history and prior parts of the tracing would have certainly added clarity and greatly decreased review time required. This is very important, since ease of application was very reasonable for using the Clark et al. (2013) algorithm decision tree and associated extensive "clarifications for use in algorithm with Category II FHR tracings". The value of an easy-to-use algorithm for assessing and managing Category II FHR tracings is key to successful evaluation, recommendation, and standardization for adoption in the obstetrical setting.

The speed and extent to which general adoption will occur, in the U.S., of the Clark et al. (2013) algorithm decision tree and associated extensive clarifications for use in algorithm with Category II FHR tracings, will likely depend on several factors. The most important is more and varied research, using larger and more variegated databases, and also its use in many different clinical situations, by many different clinicians.

Future Research

There is a current need for open-access databases of electronic fetal heart rate tracings with associated newborn outcome data from at least five different populations of maternal-fetal groups within the United States. This would provide resources to collect and work with the needed electronic fetal heart rate tracings and associated data from multiple birthing hospitals in the United States. It would be the first open-access database of U.S. fetal heart rate tracings for research purposes. This would give researchers opportunities to use relatively large commonly shared databases of fetal heart rate tracings from fetuses with normal outcomes, adverse outcomes, and from preterm, term, drug or condition specific exposed fetuses, induced vs. spontaneous labors, etc. At the present time, it is very difficult to gather population-specific electronic fetal heart rate tracings in sufficient numbers and with standardized data to allow for successful comparative research.

Summary

This study has helped validate, for possible universal adoption, a relatively uncomplicated yet very specific algorithm. The algorithm was created by eighteen renowned obstetrical leaders, from medicine, nursing, and nurse-midwifery. It specifically addresses the most challenging issue in electronic fetal monitoring - the gray areas of indeterminate fetal heart rate tracings known as Category II fetal heart rate tracings, which occur with varying attributes, severity, and duration with most fetuses during the labor/delivery process. A huge need exists for a nationally recognized, unambiguous electronic fetal heart rate interpretation and management standard for intrapartum care in the United States.

The speed and extent to which general adoption will occur, in the U.S., of the Clark et al. (2013) algorithm decision tree and associated extensive clarifications for use in algorithm with Category II FHR tracings, will likely depend on several factors. This Category II FHR tracing unambiguous interpretation, decision and intervention algorithm has a growing group of people behind it, and it looks like an answer to a large problem in maternal/fetal labor management. This innovation adoption movement is being initiated by healthcare researchers doing studies, and practitioners doing personal testing, utilizing the Category II FHR tracing unambiguous interpretation, decision, and intervention algorithm in practice situations at hospitals and birthing centers to test the efficacy of the technique in many varied real-world situations. This process of early adopters personally professionally testing a new technique, machine, or prescription drug is typically how the diffusion of innovation adoption process begins and spreads in the healthcare world. Testing by various authorities such as government entities and corporations is not enough to convince physicians and nurses to wholesale adopt a new technique. The new technique must be tested, tried, and accepted by the leading practitioners in each area of the country. Then the process of diffusion of the new and innovative technique can expand, as the early adopters, who have thoroughly tested the new technique and are satisfied that it performs up to their personal standards, spread the news of the new innovation to their peers. These peers then test the technique themselves, and if it measures up to their expectations, they then spread it to their peers, and so on, until the "tipping point" is reached, and the innovation spreads with almost geometrical speed throughout the population of possible users (Rogers, 2003).

Given the closely-knit connectivity of the healthcare world, the acceleration of this diffusion of a new healthcare innovation can be breath-taking in its speed of adoption, if the innovation is of such a nature as to solve a serious problem in an efficiently thorough and successful fashion, such as the Category II FHR tracing unambiguous decision and intervention algorithm seems to be; and if it is promoted properly through interpersonal diffusion channels. The power of interpersonally communicated positive experience through near peers cannot be underestimated. Human beings value the personal experience acquired information related to them by valued friends and colleagues over that of information related to them by entities who are distant and seen as less able to relay their information in a fashion palatable to healthcare practitioners in particular and is seen as a less personal set of practice parameters. Necessarily, information relayed to them by people practicing in areas and situations similar to themselves, whom they respect as local leaders in their field, is much more likely to have the respect of, and is more likely to be listened to with close interest, if the earlier adopters are enthusiastic about a new healthcare innovation they have personally tested.

This Category II FHR tracing unambiguous interpretation, decision, and intervention algorithm also has the advantage of being a significant improvement of an already accepted innovation, that of electronic fetal monitoring. Because of the higher perceived relative advantage of the improvement, both electronic fetal monitoring and the Category II FHR tracing unambiguous interpretation, decision, and intervention algorithm assist each other in driving symbiotic validation and verification of mutual usefulness. With the addition of this innovative Category II interpretation and intervention algorithm, electronic fetal monitoring suddenly gains traction as a technology and technique, which can positively influence labor outcomes in a number of significant ways, including decreasing the cesarean rates, and lessening the severity and rate of less-than-optimal births. The final and most significant point to take away from this research effort, is that the Clark et al. (2013) Category II FHR tracing algorithm, the interpretation and intervention decision tree, the ten main 'clarifications for use in algorithm', and the additional sixteen clarifications, together form a toolset which is uniquely capable of detecting fetuses with low pH below 7.20, and providing direction for interventions to return the fetuses to normal pH levels and recover Category I (Normal) status, thus potentially putting them on the path to a normal, spontaneous vaginal delivery.

APPENDIX

Intrapartum management of category II fetal heart rate tracings: towards standardization of care

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There is currently no standard national approach to the management of category II fetal heart rate (FHR) patterns, yet such patterns occur in the majority of fetuses in labor. Under such circumstances, it would be difficult to demonstrate the clinical efficacy of FHR monitoring even if this technique had immense intrinsic value, since there has never been a standard hypothesis to test dealing with interpretation and management of these abnormal patterns. We present an algorithm for the management of category II FHR patterns that reflects a synthesis of available evidence and current scientific thought. Use of this algorithm represents one way for the clinician to comply with the standard of care, and may enhance our overall ability to define the benefits of intrapartum FHR monitoring.
Key words: fetal heart rate monitoring, neonatal encephalopathy, patient safety

Interpretation and management of fetal heart rate (FHR) patterns during labor remains one of the most problematic issues in obstetrics. Multiple basic science investigations and clinical trials have been published since the introduction of this technique in the late 1950s.[1-7] Unfortunately, this body of work has primarily served to raise more questions than it has answered-as a medical community, we seem to know less than we thought we did 30 years ago regarding the utility of this ubiquitous technique.

In recent years, several specific issues relating to the interpretation and management of FHR patterns have received considerable attention in the medical literature. These include the lack of agreement in interpretation even among recognized experts, the role of FHR patterns as a primary driver of a rising cesarean rate, and the explosion of litigation involving FHR patterns, despite the consistent absence of scientific evidence to support the contention that intervention based on any single FHR pattern or combination of FHR patterns in fact prevents cerebral palsy or other types of neurologic impairment.[8-12] Against this background, however, there remains in many of us suspicion (albeit based primarily upon anecdotal experience and the original basic science investigations) that at least a portion of the conflicting evidence regarding the clinical utility of intrapartum FHR monitoring results from ad hoc interpretation of terminology, and the lack of standardized protocols for management and intervention based on what are often challenging patterns. In a very real sense, the FHR monitor is a medical device that was introduced into clinical practice without an instruction manual, without the now common premarket testing to support the unrealistic expectations of efficacy, and without clearly defined parameters for use. Under such circumstances, it would be difficult to demonstrate clinical efficacy even of a device with immense intrinsic value, since there has never been a standard hypothesis to test dealing with interpretation and management of abnormal patterns.

With respect to the assessment of the clinical value of FHR monitoring, an evolving consensus exists in the maternal-fetal medicine community that it is time to start over and establish some common language, standard interpretation, and reasonable management principles and guidelines.[13-19] A Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) consensus panel in 2008 proposed a uniform system of terminology in which any FHR pattern is classified as category I, II, or III, based on the presence or absence of well-defined aspects of the FHR.[20] Once universally adopted in clinical practice, these definitions should serve as an important first step in both the investigation of the significance of various FHR patterns, and the development of a uniform standard of care in the interpretation and management of such patterns.

With this in mind, subsequent recommendations have been developed by the American Congress of Obstetricians and Gynecologists (ACOG) for the management of category I (normal) and category III (pathologically abnormal) FHR patterns.[20,21] Although useful, these recommendations remain insufficient since _ 80% of fetuses in labor demonstrate FHR patterns that fall into category II, patterns for which no specific ACOG management recommendations exist.[21,22]

The management of category II FHR patterns remains the most important and challenging issue in the field of FHR monitoring, and is arguably second only to preterm birth as the most pressing issue in clinical obstetrics. In addition, the overall cesarean delivery rate exceeded 32% in the United States in 2011, and exceeds 50% of all births in some US hospitals.[23] While dystocia and prior cesarean delivery remain the leading indicators for such surgical intervention, the presence of a category II or III FHR in labor is a frequent indication as well.[11,24] For cesarean deliveries, there is a wide variance in the reported indications and their frequency, both between hospitals and among members of the medical staff practicing obstetrics.[24.] Concern regarding FHR patterns is perhaps the indication that has the greatest such variance; we believe this observation is directly related to the absence of defined management protocols for category II patterns.

Accordingly, we present a suggested algorithm for the management of category II FHR patterns (Figure 1) along with several important specific clarifications (Table). As outlined in Figure 1, it is reasonable to initiate management of a category II FHR pattern with an assessment of variability and accelerations, thus allowing the clinician to immediately rule out the presence of clinically significant metabolic acidemia. For nonacidemic fetuses, the focus then shifts to assessing the likelihood of developing significant acidemia prior to delivery. While no algorithm can predict all cases of sudden deterioration due to sentinel events, even with category I FHR patterns, analysis of the frequency and nature of decelerations and the progress in labor provides the clinician with a reasonable approach to such decision making (Figure 1). With category II FHR tracings that do not exhibit moderate variability or accelerations, but do exhibit patterns of persistent late or significant variable decelerations, as defined in the Table, significant metabolic acidemia cannot be excluded. Further, these deceleration patterns signify the presence of physiologic stresses that increase the risk of developing such acidemia. In such cases, we recommend expeditious delivery. Examples of the application of this algorithm are demonstrated in Figures 2-5. These examples assume that the 20-minute period shown in the figures is representative of the 30-60 minute observation period referred to in the algorithm. Should the pattern either improve or deteriorate during this time frame, management should be changed accordingly.

In assessing and implementing this algorithm, we wish to bring specific attention to a number of considerations which we consider to be particularly germane.

1. This algorithm follows the foundational NICHD definitions and recommendations.[20,21]
2. This algorithm should be understood as a next step in the development of management recommendations for category II FHR patterns. The effectiveness and associated intervention rates of this algorithm may be further defined and refined in future studies.
3. Category II patterns identify fetuses that may potentially be in some degree of jeopardy but are either not acidemic, or have not yet developed a degree of hypoxia/acidemia that would result in neonatal encephalopathy.[12,20,21] However, we believe one important goal of intrapartum care is delivery of the fetus, when possible, prior to the development of damaging degrees of hypoxia/acidemia.

We offer this algorithm to assist the attending physician in accomplishing this goal. We recognize that adherence to the algorithm cannot alter the course for an already injured fetus, or one that experiences an unexpected catastrophic event during labor.

However, since any algorithm for the management of category II patterns will apply to the majority of fetuses during labor, the algorithm must also avoid unnecessary intervention, and encourage vaginal delivery in women whose FHR patterns suggest minimal risk of significant deterioration prior to delivery. We designed this algorithm with both goals in mind, but with a primary focus on the avoidance of preventable injury.

4. The appropriateness of select conservative attempts to relieve certain category II patterns is well established.[25-29] However, valid scientific evidence affirming the effectiveness of such measures varies widely. For example, while amnioinfusion for relief of oligohydramnios-associated variable decelerations is well supported in the literature, no evidence exists to support the efficacy of maternal oxygen administration in commonly achievable concentrations in increasing fetal tissue oxygenation, or in improving newborn outcomes regardless of oxygen concentration.[28,29] Nevertheless, any of the commonly accepted approaches to relief of abnormal FHR patterns may be appropriately attempted in specific situations.

Their effect should be apparent within 30 minutes of application (Figure 1). If the FHR tracing remains category II following these efforts, the algorithm is applied to the pattern observed following these attempts at therapeutic intervention.

Attention should be given to the prompt elimination of excessive uterine activity including tachysystole or prolonged contractions, especially when uterine stimulants (oxytocin or prostaglandin-containing agents) are being applied.[30,31] Oxytocin infusion should be reduced or discontinued in the presence of excessive uterine activity and a persistent category II FHR pattern.[21] Acceptable approaches to monitoring of uterine activity are well described in available literature.[30,31]

5. Recent data suggest that no single quantitative value of fetal arterial pH serves to defi ne a point of hypoxia-induced damage applicable to all fetuses.[32] However, the literature is consistent in its demonstration that for any individual fetus, baseline variability and accelerations will reliably be depressed before the pH has reached a level of acidemia associated with neurologic injury for that fetus, regardless of its quantitative value.[33,34] Hence this algorithm relies strongly on the presence of moderate baseline variability or accelerations. In contrast, conflicting data exist regarding the significance of variability within deceleration nadirs.[35,36] Variability within decelerations alone cannot be reliably used to exclude fetal acidemia and accordingly is not addressed in this algorithm. 6. FHR patterns cannot be interpreted in isolation. Accordingly, we have incorporated labor progress as described in traditional terms (stage I latent phase, stage I active phase and second stage) into this algorithm. This is of significance since the expected remaining length of labor may influence the likelihood of, and response to, deterioration of category II patterns. A category II pattern may have a different indicated management when presenting in early first-stage labor than an identical pattern presenting in the late second stage. We acknowledge recent data suggesting that cesarean delivery based on classic definitions of protracted active phase, arrest of dilatation, or arrest of second-stage descent alone may not be necessary, and that longer periods of observation may yield lower intervention rates.[10,37] However, data demonstrating the safety of these more conservative approaches in the presence of persistent category II FHR patterns are lacking. For example, we hesitate to recommend nonintervention for an arrest of active phase dilatation of 4 hours in the presence of recurrent late decelerations, even in the presence of moderate variability. The superb reliability of accelerations and moderate variability in excluding any degree of hypoxia-related central nervous system depression or risk of ongoing hypoxic injury would allow observation of patterns with these features and adequate labor progress regardless of the deceleration pattern (Figure 1). However, intervention in patients with certain category II patterns and slow, but technically adequate labor progression may also be an appropriate option.

7. Some well-defined features of category II patterns (eg, fetal tachycardia or marked variability) are not included in the algorithm based decision tree for intervention. This does not signify that such patterns are innocuous indeed, it may be exactly these features of a tracing that mandate consideration as a category II pattern, and the use of this algorithm. However, in such cases, it is our expectation that other concerning patterns included in the algorithm will appear prior to the need for intervention.

8. This algorithm is intended to address the challenge of progressive intrapartum hypoxia/acidemia due to the effects of labor contractions on a susceptible fetus. Neither this, nor any other management approach to labor, will ever predict, or prevent, unexpected sentinel events that may occur without warning and rapidly change a FHR pattern from category II to category III. In such situations, even the most expeditious response may be insufficient to avoid neonatal encephalopathy and its sequelae.[38,39]

However, 2 clinical situations exist in which category II patterns, while excluding ongoing hypoxia/acidemia, may be harbingers of sentinel events that may rapidly lead to profound hypoxia. These conditions are vaginal bleeding sufficient to suggest possible placental abruption, and any woman undergoing a trial of labor after a previous cesarean.[40-42] In both cases, this algorithm does not apply, as expeditious cesarean delivery is often indicated based on the sudden appearance of decelerations in a context (moderate variability and accelerations) that would be otherwise reassuring.

9. This algorithm does not address the issue of prolonged deceleration, as defined by the NICHD. This definition is too broad to be clinically useful in isolation.[20,21] A 121-second deceleration to 90 beats/min and a 9-minute and 59-second deceleration to 50 beats/min are, from a clinical standpoint, very different, yet both are, by definition, prolonged decelerations. The situations associated with prolonged decelerations also greatly impact the decision making - a prolonged deceleration following an epidural should give rise to a completely different set of management considerations than an identical pattern in a woman laboring with a scarred uterus.[40,42,43] Such variations are legion and cannot be adequately addressed with a single algorithm - indeed, their rarity and physiologic heterogeneity probably preclude meaningful study as a group. We can only comment that tolerance for such recurrent patterns remote from delivery ought to be small unless the etiology is apparent and can be promptly ameliorated.

10. The current NICHD classification system uses the classic descriptions of deceleration patterns initially developed by Kulbi and colleagues.[1]

However, because different types of decelerations have unique etiologies, a given fetus may have > 1 pathologic process ongoing during labor. One example would be a growth-restricted fetus with oligohydramnios demonstrating both variable decelerations secondary to cord compression and late decelerations due to hypoxia during contractions based on uteroplacental insufficiency. This may give rise to a less well-defined, hybrid pattern of decelerations - for example, late decelerations superimposed upon variable decelerations. Because relatively benign variable decelerations are visually more dramatic than the subtle, yet more concerning, late decelerations - the latter may be easily overlooked. In such cases, the patient should be managed with a focus on the late, rather than the variable decelerations. Such hybrid deceleration patterns differ from the more commonly seen " atypical" variable decelerations that have no correlation with fetal acidemia.[35] It is important for clinicians to carefully evaluate any atypical-appearing variable decelerations in this light.

11. The algorithm presented authorizes judgment in some situations between cesarean delivery and operative vaginal delivery. We wish to emphasize that operative vaginal delivery is not universally applicable, but rather depends on the patient meeting appropriate criteria for vacuum or forceps, as well as operator expertise in use of these techniques.[44,45] Because delivery based on this algorithm will be principally driven by concern for fetal well-being, and because variable levels of expertise in operative vaginal delivery exist among practitioners, we anticipate that cesarean delivery will be the most common procedure elected in many situations. In contrast to some types of category III tracings in which the urgency of intervention may occasionally justify acceptance of some degree of risk for trauma, the vast majority of category II tracings in which delivery is indicated only warrant initiation of delivery within 30 minutes of the decision for delivery. A limited attempt at operative vaginal delivery by an experienced clinician may represent optimal care in some circumstances. However, the physician with limited experience in operative vaginal delivery should not delay preparations for cesarean, nor persist in attempts at operative vaginal delivery without progressive descent with each contraction.

Without real expertise in operative vaginal delivery, a deteriorating category II FHRT will often be best managed by prompt cesarean delivery.

12. The most vexing issue in the development of this algorithm was the issue of decreased vs. absent variability. We accept the accuracy of data concluding that FHR variability must be absent to reliably reflect a high degree of correlation with severe fetal acidemia.[20,21]

However, we caution against delaying delivery of a deteriorating FHR pattern because criteria indicating probable severe metabolic acidemia have not yet been met. We have chosen to treat persistent minimal and absent variability as one for the following reasons.

a. Variability cannot be considered to be a strictly binary feature of a FHR pattern. It is evident that a fetus with moderate variability (thus excluding concurrent fetal metabolic acidemia) that devolves to a state of frank asphyxia and severe metabolic acidemia with absent variability as a result of episodes of intrapartum hypoxia must first pass through a stage of minimal variability, unless the deterioration is abrupt and catastrophic as seen in a sentinel event.

b. While it is possible for apparent variability to be exaggerated with the use of a first-generation external, ultrasound-based heart rate monitoring device, autocorrelation techniques employed with most current monitoring systems have minimized this tendency.[46] Unfortunately erratic signal detection or transient artifact may give rise to periods of apparent " minimal variability" that could be falsely reassuring to some clinicians and lead to delay in delivery. If technically feasible, the fetus with a category II pattern and poor FHR signal quality should be monitored with a fetal scalp electrode.

c. An external FHR monitor that yields a consistent high-quality tracing, or a continuous fetal scalp lead tracing, will generally allow the qualified clinician to distinguish different degrees of variability, even in the presence of classic late or variable decelerations. Unfortunately, such a determination may be rendered more difficult by many of the category II patterns actually encountered in clinical practice.

Such difficulties are especially common in the presence of atypical variable decelerations, in which determination of return to baseline may be difficult.

In such cases, a " baseline" apparently exhibiting some degree of variability may in fact still be a part of a recovering deceleration. With exceptional expertise, most of these situations can be appropriately delineated. However, that level of expertise is not universal among practicing obstetricians. Indeed, even among recognized experts there is significant interobserver variation in the differentiation of FHR patterns with minimal vs. absent variability.[9]

A basic principle of any safety protocol is the direction of such guidelines to the least, not the greatest expected level of user competence.
Thus, we have used moderate rather than moderate or minimal variability as a defining reassuring feature of our algorithm. While we acknowledge that such a decision will lead to intervention in cases that, in hindsight, might be proven to be unnecessary, we believe that following the algorithm as written will avoid preventable neurologic injury due to lack of intervention for a category II FHR pattern, and will be associated with an appropriate intervention rate. Cases of fetal hypoxia/acidemia during labor due to unexpected sentinel events remain largely unpreventable.[38,39]

13. A fetus presenting with persistent minimal to absent FHR variability and absent accelerations but without significant decelerations poses a significant diagnostic and management dilemma. In many of these cases, such a pattern represents preexisting central nervous system injury with marked metabolic acidemia. In other cases, intrauterine events leading to the injury may have resolved (eg, umbilical cord compression) and the fetus will have recovered metabolically, but not neurologically. Developmental anomalies unrelated to hypoxia/acidemia may give rise to a similar picture. Although the benefit of cesarean delivery in improving neurologic outcome in such fetuses has never been demonstrated, these fetuses may be less likely to tolerate the additional hypoxia and acidemia that accompanies even normal labor without intrapartum demise. In the absence of significant decelerations however, the clinician may be assured that while the fetus may be damaged, it is not being damaged. Under these circumstances, a limited period of observation is appropriate, and is embraced in the algorithm.

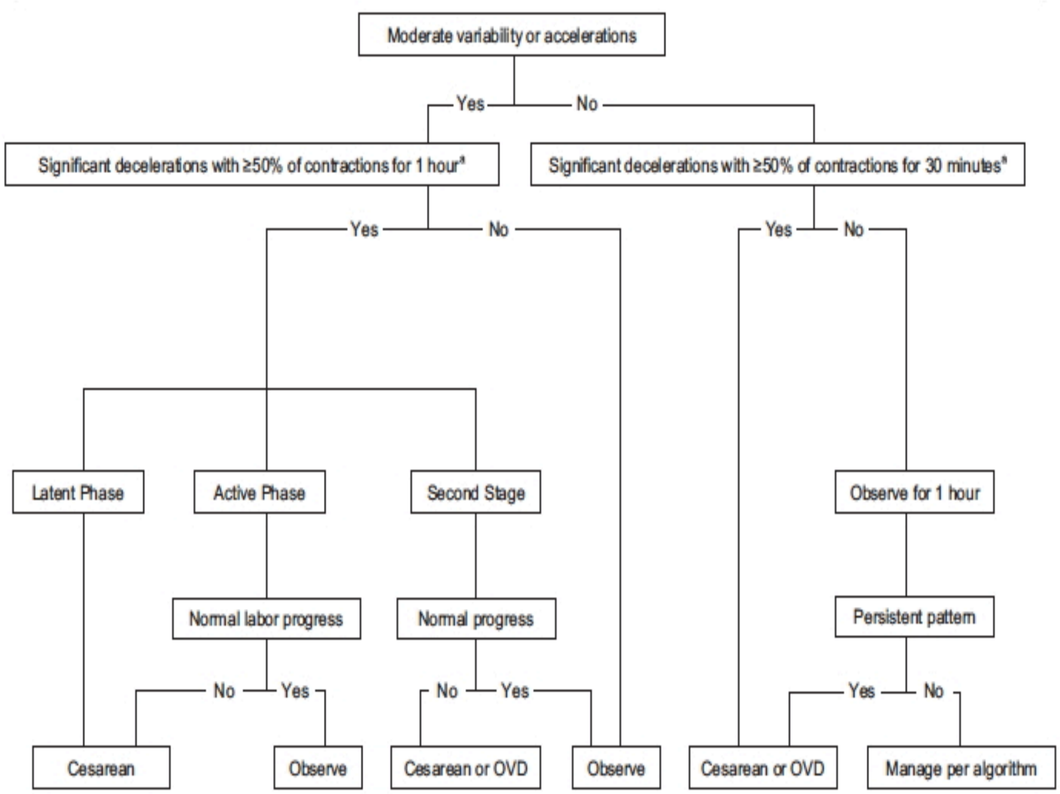
14. The algorithm presented here represents a consensus of the best thoughts of 18 authors regarding one reasonable approach to category II FHR patterns given our present scientific understanding. All authors are highly experienced clinicians with significant peer reviewed research experience and publications in the area of fetal evaluation. They also represent a broad geographic spectrum and experience in both the academic and private practice worlds and represent the disciplines of medicine, nursing, and midwifery. As such, it is reasonable for clinicians to utilize this algorithm in the management of category II FHR patterns; compliance with this protocol is one way to meet the standard of care in the United States. Importantly, as with most other areas of medicine, the establishment of this algorithm as one way to comply with the standard of care does not exclude the existence of other equally acceptable approaches. While the authors uniformly agree on the appropriateness of this model for any laboring patient, each of us can think of numerous situations in which alternative approaches to any branch of the algorithm would be equally acceptable.

15. This algorithm is supported by available clinical experience, a substantial body of basic science evidence, and indirect clinical data. Given the current state of obstetric knowledge, we do not believe it is possible to simultaneously eliminate preventable fetal neurologic injury and significantly reduce the cesarean delivery rate for abnormal FHR patterns - several decades of such attempts have resulted in the current state of Brownian motion in which neither goal has been measurably achieved. Our goal in developing this algorithm has been to fix one variable in this equation by presenting an algorithm, which if implemented as one component of good obstetrical care, will assist the clinician in avoiding preventable intrapartum fetal hypoxia, metabolic acidemia, and hypoxic injury based on failure to deliver in the face of certain persistent category II FHR patterns. Of course, as with any set of recommendations, clinical studies directly applying this algorithm both retrospectively to large series of category II patterns, and prospectively to large populations, are needed to potentially improve the efficacy of the algorithm, and to better ascertain the actual intervention rate associated with its application. It is anticipated that such studies may facilitate refinement of this basic algorithm to reduce the intervention rate without incurring preventable morbidity or mortality.

16. We make no claim of the superiority of this algorithm over other approaches that might have been developed. We began with the premise that standardization and simplification of critical care processes are fundamental principles of patient safety. In virtually any human endeavor, particularly one that relies on the performance of multiple team members in an effort to achieve an optimal result, standardization will yield improved results.[47-50] As such, unless one ideal approach to care has been demonstrated to be superior to all others by virtue of well-performed clinical trials, it is not necessary to demonstrate the superiority of one specific approach over others that are, when considered individually, likely to be equivalent. Rather, the adoption by the clinical care team of one appropriate specific management plan will, by virtue of standardization alone, yield results superior to those achieved by random application of several individually equivalent approaches. This is particularly true at the facility level.[47-50]

For example, protocols used to guide the provision of cardiopulmonary resuscitation have not been demonstrated to be superior to all others in randomized clinical trials.[51] Yet the near universal adoption of these standard approaches has resulted in improved outcomes for cardiac arrest patients. Such algorithms have, over time, also undergone modification due to advances in clinical understanding based on new data. It is also important to note that in this instance, our algorithm does not seek to replace any established methodical approach to the management of category II patterns. Rather, we suggest that this algorithm will be helpful in the current clinical setting in the United States in which a lack of clear direction has led to divergent decision making regarding cesarean section for FHR abnormalities.[24]

Adoption of this algorithm for the management of category II FHR patterns by the clinician is one approach to achieving compliance with the current standard of care. Application of the algorithm, along with the integration of future evidence-based modifications driven by additional research, will provide clinicians with a standardized, simple, rational, evidence-based, and nationally accepted approach to the management of category II FHR patterns.



[a] **That have not resolved with appropriate conservative corrective measures, which may include supplemental oxygen, maternal position changes, intravenous fluid administration, correction of hypotension, reduction or discontinuation of uterine stimulation, administration of uterine relaxant, amnioinfusion, and/or changes in second stage breathing and pushing techniques.**

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Figure 11: Clark, et al. (2013). Algorithm for Management of Category II Fetal Heart Rate Tracings. Copyright 2013 by Elsevier. Reprinted with permission.

Table 9: Clarifications for Use in Algorithm. Copyright 2013 by Elsevier. Reprinted with permission.

TABLE

Management of category II fetal heart rate patterns: clarifications for use in algorithm

1. Variability refers to predominant baseline FHR pattern (marked, moderate, minimal, absent) during a 30-minute evaluation period, as defined by NICHD.
2. Marked variability is considered same as moderate variability for purposes of this algorithm.
3. Significant decelerations are defined as any of the following:
   - Variable decelerations lasting longer than 60 seconds and reaching a nadir more than 60 bpm below baseline.
   - Variable decelerations lasting longer than 60 seconds and reaching a nadir less than 60 bpm regardless of the baseline.
   - Any late decelerations of any depth.
   - Any prolonged deceleration, as defined by the NICHD. Due to the broad heterogeneity inherent in this definition, identification of a prolonged deceleration should prompt discontinuation of the algorithm until the deceleration is resolved.
4. Application of algorithm may be initially delayed for up to 30 minutes while attempts are made to alleviate category II pattern with conservative therapeutic interventions (eg, correction of hypotension, position change, amnioinfusion, tocolysis, reduction or discontinuation of oxytocin).
5. Once a category II FHR pattern is identified, FHR is evaluated and algorithm applied every 30 minutes.
6. Any significant change in FHR parameters should result in reapplication of algorithm.
7. For category II FHR patterns in which algorithm suggests delivery is indicated, such delivery should ideally be initiated within 30 minutes of decision for cesarean.
8. If at any time tracing reverts to category I status, or deteriorates for even a short time to category III status, the algorithm no longer applies. However, algorithm should be reinstituted if category I pattern again reverts to category II.
9. In fetus with extreme prematurity, neither significance of certain FHR patterns of concern in more mature fetus (eg, minimal variability) or ability of such fetuses to tolerate intrapartum events leading to certain types of category II patterns are well defined. This algorithm is not intended as guide to management of fetus with extreme prematurity.
10. Algorithm may be overridden at any time if, after evaluation of patient, physician believes it is in best interest of the fetus to intervene sooner.

FHR, fetal heart rate; *NICHD*, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development.

Clark. Category II FHRT. Am J Obstet Gynecol 2013.

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Received Jan. 21, 2013; revised March 27, 2013; accepted April 24, 2013. Management recommendations discussed in this document reflect the opinions of the authors. They do not necessarily reflect endorsement by affiliated institutions or organizations.
The authors report no conflict of interest.
Reprints not available from the authors.

GLOSSARY OF TERMS

Acidemia: Low pH of the blood. May be due to continuing low oxygen levels preventing normal aerobic metabolism with anaerobic metabolism unable to completely break down glucose and instead producing the anaerobic metabolic byproduct of lactic acid. Lactic acid build-up may result in tissue damage to the nervous system and to other tissues, and if severe, may cause permanent brain damage or possibly death.

Amnioinfusion: Infusion of normal saline or lactated Ringer's solution into the uterus through the cervical opening after rupture of membranes to increase intra-amniotic fluid to cushion the umbilical cord during labor when cord compression causes variable FHR decelerations to occur.

Augmentation of labor: Administration of a uterotonic agent, such as oxytocin, during the course of an already established labor to stimulate the uterus to contract more vigorously.

Apgar score: A measure of the physical condition of a newborn infant usually performed at 1 and at 5 minutes of life. It is obtained by adding points (2, 1, or 0) for heart rate, respiratory effort, muscle tone, response to stimulation, and skin color; scores ≥7 are normal.

Avalon FM40 and FM50 Fetal Monitor: A standard fetal monitors made by Phillips Healthcare, USA.

BDecf: base deficit calculated from the whole extracellular fluid, which will not be as affected by high CO_2 levels as measured from blood (BDblood). Critical neonatal umbilical artery BDecf > 10-12 mmol (normal 4-7 mmol/L).

BE: Base excess. Critical neonatal umbilical artery bases excess > -12 mEq/L.

BPM: Beats per minute.

Breech presentation: Fetal presentation in which the buttocks or lower extremities are located in or over the maternal pelvis.

Category I fetal heart rate patterns: Normal - the fetal heart rate tracing shows ALL of the following:
Baseline FHR 110-160 BPM, moderate FHR variability, accelerations may be present or absent, no late or variable decelerations, may have early decelerations.
Strongly predictive of normal acid-base status at the time of observation. Routine care.

Category II fetal heart rate patterns: Indeterminate - the fetal heart rate tracing shows ANY of the following: tachycardia, bradycardia without absent variability, minimal variability, absent variability without recurrent decelerations, marked variability, absence of accelerations after stimulation, recurrent variable decelerations with minimal or moderate variability, prolonged deceleration ≥ 2minute but less than 10 minutes, recurrent late decelerations with moderate variability, variable decelerations with other characteristics such as slow return to baseline, and "overshoot". Not predictive of abnormal fetal acid-base status, but requires continued surveillance and reevaluation.

Category III fetal heart rate patterns: Abnormal. the fetal heart rate tracing shows EITHER of the following: Sinusoidal pattern OR absent variability with recurrent late decelerations, recurrent variable decelerations, or bradycardia.
Predictive of abnormal fetal-acid base status at the time of observation. Depending on the clinical situation, efforts to expeditiously resolve the underlying cause of the abnormal fetal heart rate pattern should be made.

Cephalic presentation: Head-first fetal presentation.

Cephalopelvic disproportion: A mismatch between the dimensions of the presenting part and the capacity of the pelvis.

CTG: Cardiotocography (CTG) is a technical means of recording the fetal heartbeat and the uterine contractions during pregnancy. The machine used to perform the monitoring is called a cardiotocograph, more commonly known as an electronic fetal monitor (EFM)

Dystocia: Difficult labor or abnormally slow progress of labor. Other terms that are often used interchangeably with dystocia are dysfunctional labor, failure to progress (lack of progressive cervical dilatation or lack of fetal descent), and cephalopelvic disproportion (CPD).

Early fetal heart rate deceleration: Gradual decrease in FHR with onset of deceleration to nadir ≥30 seconds. The nadir occurs with the peak of a contraction. They are due to a vagal response from fetal head compression and considered benign.

EFM: Electronic fetal monitor

EFHRM: Electronic fetal heart rate monitor

Episodic fetal heart rate patterns: Those not associated with maternal uterine contractions

Fetal heart rate baseline variability: Visual fluctuations in the fetal heart rate, termed as absent (undiscernable to the eye), minimal (discernable up to 5 beats per minute peak to trough), moderate (6-25 beats per minute/normal), or marked (>25 beats per minute)

Fetal heart rate acceleration: An abrupt increase in FHR above baseline with onset to peak of the acceleration less than < 30 seconds and less than 2 minutes in duration. The peak of acceleration must be at least 15 bpm above the baseline and last at least 15 seconds. An acceleration lasting ≥2 minutes but < 10 minutes is a prolonged acceleration. Longer than 10 minutes would constitute a baseline rate change. Before 32 weeks of gestation accelerations are defined as having a peak ≥10 bpm and a duration of ≥10 seconds.

FHR: Fetal heart rate

Gestation: Term gestation is 40 weeks, < 38 weeks preterm, >42 weeks is post-term

Gravity/Gravida: Total number of times a woman has been pregnant

HIE: Hypoxic Ischemic Encephalopathy (HIE) is a type of hypoxic brain damage

Hypoxia: Deficiency of oxygen in the tissues

Hypoxemia: A low concentration of oxygen in the blood

Intrapartum: The period from the onset of labor to the end of the third stage of labor

Late fetal heart rate deceleration: gradual decrease in FHR with onset of deceleration to nadir ≥30 seconds. Onset of the deceleration occurs after the beginning of the contraction, and the nadir of the contraction occurs after the peak of the contraction. They are due to uteroplacental insufficiency / lack of enough oxygen to the fetus.

Liq. Praecox: Premature rupture of the amniotic sac

Meconium: Fetal or neonatal bowel movement / stool

Nadir: Lowest point

NICU: Neonatal intensive care unit

NSVD: Normal spontaneous vaginal delivery

Operative Vaginal Delivery (OVD): Vacuum extractor or forceps assisted vaginal delivery

pCO_2 (kPa): Normal newborn umbilical artery pCO_2 (kPa) 5.4-8

Parity/Para: The number of births that a woman has had after 20 weeks gestation

Periodic fetal heart rate patterns: Those associated with maternal uterine contractions

pH: Critical neonatal umbilical artery pH < 7.0

Preeclampsia: Perinatal disorder usually involving maternal hypertension, may be mild or severe enough to cause fetal and/or maternal harm or death

Prolonged fetal heart rate deceleration: A decrease in FHR of $\geq$15 beats per minute measured from the most recently determined baseline rate. The deceleration lasts >= 2 minutes but less than 10 minutes

Pyrexia: Temperature greater than 37.5 ˚C (99. 5 ˚F)

Recurrent fetal heart rate decelerations: Occurring with 50% or more of uterine contractions in a 20 minute tracing

Significant fetal heart rate decelerations: Are defined by Clark et al. (2013) as any of the following:

- Variable decelerations lasting longer than 60 seconds and reaching a nadir more than 60 bpm below baseline.
- Variable decelerations lasting longer than 60 seconds and reaching a nadir less than 60 bpm regardless of the baseline.
- Any late decelerations of any depth.
- Any prolonged deceleration (algorithm use should be discontinued until prolonged deceleration is resolved)

STAN fetal monitors: Made by Neoventa in Sweden, FDA approved in the USA, is used in addition to a standard electronic fetal monitor, giving additional information on elevations and depressions of the S-T segment of the fetal EKG that suggests anaerobic metabolism in the fetus, and thus hypoxemia. This technology is used in a few U.S. hospitals currently.

Stage 1 labor: From 0 cm until 10 cm cervical dilation in labor

Stage 2 labor: From 10 cm cervical dilation until birth of the baby (maternal pushing)

SVD: Spontaneous vaginal delivery

Tachysystole: Uterine contractions occurring more frequently than 5 in a ten minute period

Umbilical cord prolapse: If the fetal umbilical cord slips down into the vagina ahead of the presenting fetal part, or becomes trapped and compressed between the fetal presenting part and the incompletely dilated uterine cervix, pressure on the umbilical cord can stop blood and oxygen flow from the placenta to the fetus and may result in fetal harm unless the pressure on the cord is relieved or the fetus is quickly delivered.

Variable fetal heart rate deceleration: Abrupt decrease in FHR of $\geq$15 beats per minute measured from the most recently determined baseline rate. The onset of deceleration to nadir is less than 30 seconds. The deceleration lasts $\geq$ 15 seconds and less than 2 minutes. A shoulder, if present, is not included as part of the deceleration. Usually due to umbilical cord compression.

Vasa previa: A defect where fetal blood vessels, which normally are protected within the umbilical cord and placenta, instead run between the amniotic membranes as they enter the umbilical cord from the placenta or if the placenta has an accessory lobe with these unprotected fetal blood vessels. If the unprotected fetal blood vessels are over or near the cervix and the amniotic membranes rupture, fetal hemorrhage may ensue.

Vertex: crown or top of the head. A vertex presentation is the most common and most uncomplicated fetal presentation during labor, whereby the fetal head is flexed and the occiput (back part of the head) is the leading fetal part into the vagina.

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