# Category II fetal heart rate characteristics and cesarean delivery outcome: Descriptors and predictions for delivery outcome in low risk labor.

Miller, Emily Ann


Miller, E. A. (2023). Category II fetal heart rate characteristics and cesarean delivery outcome: Descriptors and predictions for delivery outcome in low risk labor [University of Iowa].
https://doi.org/10.17077/etd.005231

# Category II Fetal Heart Rate Characteristics and Cesarean Delivery Outcome: Descriptors and Predictions for Delivery Outcome in Low Risk Labor

by

Emily Ann Miller

A thesis submitted in partial fulfillment
of the requirements for the Doctor of Philosophy
degree in Nursing in the
Graduate College of
The University of Iowa

December 2019

Thesis Committee: Mary K. Clark, Thesis Supervisor
Ann Marie McCarthy
Melissa Avery
Mark Santillan
Julie Vignato

This dissertation is dedicated to the hardworking heroes helping to safely deliver babies all over the world. It doesn’t matter what your title, your work is crucial and saves lives.

# ACKNOWLEDGEMENTS

First and foremost, this dissertation and the many years of work that it took to get to this point was always for my children, my life, my everything…Madison, William, and Owen. My goal has always been to provide for you, inspire you, and to show you that you can do anything if you put your mind to it and persevere through all of the forces in life that would try and shut down the achievement of your goal. I love you with all my heart. This is for you. I hope this makes you proud.

To my mother and father, my rocks and my greatest supporters, I could never have done this without you. You have inspired me to continue, to reach for the goals that are the farthest out of reach. You have carried me through the times in my life that I could not carry myself. You have inspired me to, not only surpass my own aspirations, but to also go beyond and make my mark on the world. You gave me the courage to believe that I could do such a thing. I can never thank you enough for all of the sacrifices you have made, from the day I was born, until the day I defended, to make this possible. I love you beyond measure.

To my sister, Aubree, you are my best friend. You are a consistent giver of love, friendship, chaos, laughs, and encouragement. I am forever grateful that you are my forever best friend. Your companionship in this life is one of my greatest gifts. Love you, sissy!

To my extended family in Iowa, Pennsylvania, Florida and across the United States, your love and support has meant the world to me, not only now, but throughout my entire life. No matter what life has brought me I have always felt the comfort of knowing I have a massive crew of people who genuinely love me cheering me on. My relationships with each and every one of you have made me the person I am today. I thank you wholeheartedly.

To my East Union Mennonite Church and Iowa Mennonite School (Hillcrest Academy) Family, you have inspired me, encouraged me, and rallied around me throughout my entire life. I will always see you as the source of my motivation to keep going. To have a constant source of people that love me unendingly from childhood through adulthood gives me the courage to keep going even when I feel like giving up. Even when I was at my worst, you reminded me of my best. You have nurtured not only me, but my daughter. Without the love and support of so many of you, and the stellar preparation you gave me to enter the world of nursing and post-graduate education, this would not have been possible. You are an extension of my extended family.

To my UICH labor and delivery coworkers, you made me who I am. I learned from the best in the business. I became the nurse I am because of you. I made some of the most beloved friends I have, and gained some of my most prized mentorships from physicians, nurses, and countless others working in such an amazing department in an amazing institution. You continue to inspire me today to be the best nurse I can be, and to aim high. I can never thank you enough for teaching and inspiring me to complete this research and impact the way we care for pregnant women, their unborn, and the amazing new lives I've been privileged to witness in my tenure in labor and delivery.

And to Duke, my dear K-9 companion, I love you and I'd be lost without you! Thank you for a decade of snuggles and reminders that life is about the experiences with those that you love most!

To the University of Iowa, College of Nursing, especially Mary K. Clark and the rest of my committee, you have stuck by me and pushed me through thick and thin. You have inspired me to be my best me and to keep fighting despite what life has thrown my direction. I thank you,

from the bottom of my heart, for sticking with me, pushing me, and believing in me, even when I didn’t believe in myself.

Finally, to Andy…you gave me hope when no hope was found. You carried me through the worst of times. You made me laugh in the face of death. You kept me being me. You kept me alive both in physicality and in spirit. You are one of the most important relationships in my life to date. I cannot thank you enough for carrying me through so much of this journey. I am forever in your debt. Thank you from the bottom of my heart for caring for this awkward me.

## ABSTRACT

**Background:** Cesarean delivery rates in the United States are higher than many other Western countries. Many researchers and specialists hypothesize that the use of continuous electronic fetal monitoring (CEFM) in labor may contribute to the decision to proceed with cesarean delivery. Currently, CEFM data is defined by a three-tiered category system, with the indeterminate category II encompassing 80% of all CEFM tracings. Little research exists that examines the association between the fetal heart rate (FHR) characteristics, their combinations and interactions observed in CEFM during the labor process in low risk pregnancies.

**Methods:** This study examined the category II FHR CEFM data, and maternal hospital records of low risk pregnant women who delivered at a Midwest, tertiary, academic hospital over 18 months. Category II FHR characteristics present in the two hours prior to delivery were collected by the primary investigator and a research assistant, both experienced labor and delivery nurses. All FHR characteristics were evaluated according to the definitions from the Eunice Kennedy Shriver National Institute of Child Health and Human Development. CEFM FHR data were combined with medical and demographic data taken from the maternal medical record.

**Results:** Of the 537 women included in the study, 24% delivered by cesarean for concerns with the FHR and 76% delivered vaginally. Women who delivered by cesarean had a median total time in category II of 43 minutes while women who delivered vaginally spent a median of 54 minutes in category II. The odds of cesarean delivery increased in the presence of abnormal baseline FHR (OR 3.07), variability (OR 1.68), late decelerations (OR 2.69) and prolonged decelerations (OR 1.97). After controlling for known covariates that can influence delivery method, only late and prolonged decelerations remained associated with cesarean delivery (OR 1.40, OR 1.51). Count of abnormal characteristics (which includes tachycardia, bradycardia, absent, minimal and marked variability, and variable, late and prolonged decelerations) was

significantly associated with cesarean delivery with an average of 3 abnormal characteristics increasing the odds of cesarean by 19.62 times over those with an average of 1 abnormal characteristic.

**Conclusion:** While abnormal FHR characteristics that would place a CEFM tracing in category II were associated with cesarean delivery in low risk labor, once controlling for known covariates, the only characteristics that were predictive of cesarean were late and prolonged decelerations, and a new measurement, count of abnormal FHR characteristics. This new measurement could easily be calculated in real-time on labor and delivery units. The presence of many category II FHR characteristics in low risk labor may not be indicative of fetal hypoxia and the need to proceed with cesarean delivery.

# PUBLIC ABSTRACT

Cesarean deliveries rates are higher in the U.S. than many other Western countries and are associated with adverse outcomes. One reason for the high rate provided is the use of continuous electronic fetal monitoring (CEFM) in labor. CEFM tracings are currently divided into 3 categories: category I (well-oxygenated fetus), category II (indeterminate), and category III (fetus not well-oxygenated). Roughly 80% of all CEFM tracings fall into category II.

This study examined category II CEFM tracings in the last 2 hours of labor to determine if any particular fetal heart rate (FHR) characteristics or combinations thereof in low risk patients (mothers and fetuses with no underlying health issues) were associated with cesarean.

This study found that when limiting the study to only low risk patients, very few category II FHR characteristics were good indicators of the need to proceed with a cesarean delivery when accounting for circumstances known to contribute to the increased risk for cesarean. The only FHR characteristics that were good indicators were two types of drops in the FHR, called late and prolonged decelerations, and a new measurement created for this study, count of abnormal FHR characteristics.

Having one of the decelerations increased the risk of cesarean by 1.4-1.5 times. Having 3 abnormal FHR characteristics increased the odds of a cesarean delivery over 19 times compared to having just 1 abnormal FHR characteristic.

Counting abnormal FHR characteristics can be easily done on labor and delivery units and may be a better measurement of the well-being of a low risk fetus during labor.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1: INTRODUCTION

## Problem

Cesarean delivery is the most commonly performed surgical procedure in the US. The cesarean delivery rate has risen by 53% since 1996 (CDC, 2016; Edmonds, Yehezkel, Liao, & Morre Simas, 2013). The ultimate goal of labor and delivery practitioners is to deliver a healthy infant to a healthy mother. While cesarean deliveries can be lifesaving, not all are medically indicated. If the life of the mother or fetus is in imminent danger, surgical delivery via cesarean may be the only viable option. Cesarean delivery is clearly indicated when there is deprivation of blood flow and therefore oxygen to the fetus, which can occur as a result of many complications in pregnancy (i.e., diabetes, preeclampsia, congenital abnormalities) and/or the labor process. However, cesarean sections are also associated with many adverse outcomes for mother and baby. These negative outcomes include increased maternal and newborn mortality, pain, maternal blood loss, thrombosis, infection, hysterectomy, future reproductive difficulties (uterine rupture and placental implantation problems), bladder damage, infection, newborn respiratory distress, decreased newborn Apgar scores, delayed and decreased breastfeeding and bonding, lengthened hospital stay, and increased cost (Hancerlioqullari, Yaman, Aksoy, & Tokmak, 2019). The cost of a cesarean delivery is nearly double the cost of a vaginal birth. A recent study found the average price of a cesarean delivery in the U.S. was around $50,000 versus a vaginal delivery at $30,000, with insurers paying an average of nearly $28,000 for each cesarean delivery (Truven, 2013). The high incidence of cesarean coupled with the increased cost may contribute to the overall rising cost of healthcare, especially when considering the cost of healthcare required to treat adverse outcomes related to cesarean delivery. Decreasing unnecessary (or non-medically justified) cesarean deliveries may decrease the occurrence of adverse outcomes related to cesarean and decrease the overall cost of healthcare.

One reason for the high cesarean delivery rate in the United States hypothesized by several researchers is the use of continuous electronic fetal monitoring (CEFM) (Heelan-Fancher et al., 2019; Alfirevic, Devane, Gyte & Cuthbert, 2017). CEFM is an indirect method of assessing fetal oxygenation and is currently used in approximately 80% of all women in labor (Macones, Hankins, Song, Hauth, & More, 2011). CEFM traces the fetal heart rate (FHR) in real time to allow healthcare providers to identify early signs of fetal hypoxia so timely interventions can be made which could prevent fetal and neonatal morbidities, including cerebral palsy and death (Alfirevic et al., 2017; NICHD, 1997).

CEFM involves placing two transducers on the maternal abdomen. One transducer detects the FHR while the other detects uterine contractions. Interpretation of CEFM tracings is complicated and based on identifying meaningful patterns in the FHR derived from four characteristics: FHR variability, baseline FHR, presence of accelerations in FHR, and the presence and type of decelerations in FHR. FHR variability is the normal and rapid fluctuation of the FHR over the span of one minute, with changes in rate occurring as rapidly as one heartbeat to the next. The average healthy full-term fetus has a heart rate that fluctuates 6 to 25 beats during a one-minute assessment (Miller & Miller, 2012). For example, the average fetus's heart rate may range from 125 to 145 bpm (20 bpm of variability) in the span of one minute.

Due to the variability in the FHR, the FHR baseline is the average FHR assessed at the midpoint of the variability and rounded to the nearest 5 bpm. In the above example, a fetus whose heart rate varied equally between 125 bpm and 145 bpm would have a FHR baseline of 135 bpm. Transient changes in the FHR that rise above or fall below the current FHR baseline are identified as accelerations or decelerations in the FHR. Accelerations of the FHR are transient increases in the FHR rising at least 15 bpm higher than the FHR baseline in healthy, full-term newborns, in response to fetal movement, stimulation from environmental triggers (like the maternal voice, or central nervous system signaling (Martin, 2008). A deceleration in the FHR is a transient decrease in the FHR, falling 15 bpm lower than the FHR baseline. FHR decelerations are categorized as early, variable, late or prolonged based on the duration of the deceleration and the relationship between the decelerations and maternal uterine contractions. Of these four types, only early decelerations, which occur during a contraction, mirror the duration and strength of the contraction, and are thought to arise from pressure against the fetal head, are considered benign in regards to fetal oxygenation (Nageotte, 2015).

A FHR baseline of 110 to 160 bpm is considered normal with rates above and below this range indicating hypoxemia or fetal pathophysiology. Moderate FHR variability (6 to 25 bpm) is one indicator of fetal oxygen reserve and an intact nervous system. Moderate FHR variability and the presence of accelerations in the FHR are also associated with the absence of fetal metabolic acidemia/hypoxia (Miller & Miller, 2012). In contrast, if FHR variability is low (less than 6 bpm), absent, or extremely high (greater than 25 bpm), the fetus may be responding to low oxygenation. Variable, late or prolonged FHR decelerations may be caused by an obstruction of blood flow through the umbilical cord, placental deficiencies, or as a response to other sources of hypoxemia (Nageotte, 2015) and indicate risk of fetal hypoxia (Macones et al., 2011).

Varying combinations of the FHR characteristics have produced identifiable FHR patterns that are strongly associated with positive or negative infant outcomes. Adequate fetal oxygenation and the absence of acidosis have been predicted by a pattern consisting of: moderate FHR variability, normal FHR baseline (110-160 bpm), the occurrence of FHR accelerations, and the absence of decelerations (Macones et al., 2011). This specific FHR pattern has been referred to as “normal,” “reactive” or “reassuring.” In contrast patterns that have been associated with negative or unpredictable outcomes have been labeled “non-reassuring,” “non-reactive,” or indicators of “fetal distress” (Macones et al., 2011). For example, the combinations of variable or late decelerations and decreased FHR variability (< 6 bpm) or tachycardia have been associated with an increased risk of fetal acidemia (Vintzieleos & Smulian, 2016).

Beginning in the 1960s, researchers proposed systems to categorize FHR patterns according to fetal and neonatal outcomes and recommended interventions to avoid or minimize negative outcomes. The most basic system classified the FHR pattern dichotomously as “reactive” (indicative of absence of hypoxia) and “non-reactive” (cannot rule out hypoxia). The system most widely used in the United States now is the NICHD published three-tier system (Macones et al., 2011).

The NICHD three-tier system is very similar to the previous dichotomous system. The FHR pattern previously labeled reactive was placed in “category I.” FHR patterns that were previously strongly associated with the most consistently negative outcomes (such as minimal variability and bradycardia) were placed in “category III.” FHR patterns that had conflicting or inadequate evidence of their relationship to fetal outcomes were placed in an “indeterminate” category, known as “category II.” Unfortunately, 80% of all FHR patterns in the laboring woman are classified as category II, as they do not fit the FHR pattern or characteristic criteria of categories I or III (Macones et al., 2011). The wide variety of FHR patterns and lack of clear understanding of which patterns or combinations of characteristics in category II pose the greatest risk for poor fetal oxygenation makes standardization of interventions difficult. Research suggests that the indeterminate nature of category II patterns contributes to the high cesarean rate, especially in women who otherwise had healthy pregnancies and no risk factors for negative outcomes (Jackson, Holmgren, Esplin, Henry, & Varner, 2011; Schnettler, Rogers, Barber, & Hacker, 2012; Penfield, Hong, Ibrahim, Kilpatrick, & Gregory, 2016).

Women who have had healthy pregnancies and no risk factors associated with negative outcomes are frequently labeled as having a low-risk pregnancy or low-risk labor. The NICHD guidelines recommend that the healthcare provider take clinical variables, such as maternal and fetal risk status, into considerations when interpreting FHR characteristics and patterns. However, patient risk factors are not explicitly included in the three-tier classification system, which suggests that all pregnant women are assessed, and interventions selected using identical criteria. In a low risk pregnancy, fetuses are able to withstand the periodic deoxygenation associated with occasional umbilical cord occlusion related to fetal movement, contractions and fetal compression in the birth canal. This is due to fetal oxygen reserves and the associated shunting blood flow to the heart and brain, and with fetal hemoglobin. Fetal hemoglobin binds oxygen better than the hemoglobin found in older infants, children and adults, allowing the fetus to carry oxygen more efficiently (Evans et al., 2019; Gabbe et al., 2012). In comparison, the complications associated with high risk pregnancies decrease fetal oxygen reserve, resulting in FHR characteristics different than those of fetuses in low risk pregnancies and decreased ability to adapt and compensate (Evans et al., 2019; Gabbe et al., 2012; Holmgren et al., 2013).

The compensatory mechanisms of the fetus in a low risk pregnancy allow the FHR patterns to be interpreted differently. For example, two fetuses may both have recurrent variable decelerations, but a high-risk infant with a cardiac defect and a diminished ability to circulate oxygenated blood from the placenta would be much more likely to develop hypoxia than a low risk infant. Therefore, identical CEFM FHR patterns observed in high versus low risk pregnancies can have different outcomes. With the many FHR patterns which can occur in category II and a lack of clear understanding of which of those patterns are actually indicative of fetal hypoxia in low risk labor, there is potential that these infants may be unnecessarily delivered by cesarean for suspected hypoxia when none actually exists. The US cesarean rate in low risk pregnancies is currently at 26.9%, which is considered high in comparison to other developed countries (CDC, 2016).

It is not clear which category II FHR characteristics and patterns produce adverse outcomes in women with low-risk pregnancies and labors. FHR patterns have a high false positive rate when umbilical artery pH is measured at the time of delivery (incorrectly identifying fetal hypoxia). The false positive rate has been measured as high as 99.8%, resulting in cesareans which are "performed without benefit and the potential for harm," especially when CEFM is used in low risk labor (Nelson, Dambrosia, Tiny, & Grether, 1996, p. 613, Heelan-Francher et al., 2019; Di Tommaso et al., 2013; ACOG, 2008; ACMN, 2010).

## Existing Research and the Gap

Most research evaluating the NICHD three-category CEFM classification system has examined inter- and intra-rater reliability, user-friendliness and overall ability to detect fetal hypoxia. There are published studies focused on the relationship between category II FHR classification and birth outcomes (Jackson et al., 2011; Schnettler et al., 2012; Penfield et al., 2016; Weissbach et al., 2018; Shields, Wiesner, Klein, Pelletreau, & Hedriana, 2018; Ogunyemi, Jovanovski, Friedman, Sweatman, & Madan, 2018; Cahill, Tuuli, Stout, Lopez, & Macones, 2018; Toomey & Oppenheimer, 2019). However, none of these studies specifically examines individual FHR characteristics, their combinations and interactions, and limits their studies to low risk labor only.

Schnettler, Rogers, Barber and Hacker (2012) analyzed the relationship between NICHD categories and subcategories of FHR patterns and cesarean delivery for fetal distress. The authors created two subcategories for NICHD category I FHR patterns and four subcategories for NICHD category II FHR patterns. The subcategories were as follows:

- “Ia – All of the following are met
    - Baseline FHR of 110-160 beats per minute
    - Late or variable decelerations absent
    - Early decelerations present or absent
    - Two accelerations
- Ib – All of the above are met with the exception of two accelerations present
- IIa – Baseline FHR <110 or > 160 with moderate variability
- IIb – Any of the following are met
    - Minimal variability
    - Absent variability without recurrent decelerations
    - Marked variability
- IIc – Absence of induced accelerations after fetal stimulation
- IId – Any of the following are met:
    - Recurrent variable decelerations accompanied by minimal or moderate variability
    - Prolonged decelerations
    - Recurrent late decelerations with moderate variability
    - Variable decelerations with other characteristics (i.e. slow return to baseline, overshoots or “shoulders”)” (Schnettler et al., 2012, p. 1056).

However, FHR patterns were only recorded for the first 30 minutes following admission, meaning that the effects of events during the last two hours of the tracing or of the entire tracing on the decision to proceed to cesarean delivery were not included. The results supported the predictive ability of the NICHD system, as risk of cesarean delivery for fetal distress was significantly higher for women with category II FHR patterns in the first 30 minutes after admission. However, the subcategory analyses also indicated that the risk of cesarean delivery for fetal distress was not homogenous within categories I and II, supporting the need for subcategorization of the original three-category system. Although the subcategorization of the NICHD system was an improvement, there are clinically predictive FHR characteristics that were not included in the subcategories. One example of a category II FHR characteristic which was not included in the subcategories was tachycardia. Tachycardia is important as it is often the first indicator of an infection in the uterus (chorioamnionitis, more recently called Triple I) as well as being an initial fetal response to hypoxemia (Gabbe et al., 2012). Generalization of this study to women with low risk pregnancies and labors is limited, as the minimum gestational age for inclusion was 32 weeks and the final sample had women with pre-gestational and gestational diabetes.

Penfield and colleagues (2016) also subcategorized category II of the NICHD system, adding subcategories “A”, “B” and “C”. However, their primary purpose was to evaluate the system for communication effectiveness and thus the results do not examine the relationship between having a category II FHR tracing and delivery outcomes. A third study by Jackson and colleagues (2011) limited its analyses to the amount of time the FHR fit the category II criteria of the NICHD system. The authors reported that if the FHR was classified as category II for 50% or more of the last two hours of labor, infants were significantly more likely to have a one-minute

Apgar score less than 7 or be admitted to the NICU. As with the previous two studies, the sample included women with high risk pregnancy or labor conditions. However, the results of this study further supported the need to analyze women with low risk labors or pregnancies as a separate population. The authors reported that patients whose FHR tracings were classified as category II for 25% or more of the last two hours of labor were significantly more likely to have medical-obstetric complications.

Weissbach and colleagues (2018) conducted a retrospective observational study of 271 patients delivered via cesarean for non-reassuring fetal hear rate. Duration of category II, variability, tachycardia, and deceleration frequency were analyzed and compared to postnatal outcomes (pH ≤ 7, cord base excess > 12, one- and five-minute Apgar scores ≤ 7, need for ventilation and/or chest compressions, NICU admission, hypoglycemia, and convulsions). In addition, the authors correlated meconium-stained amniotic fluid and intrapartum fever to the same outcomes. They found that longer duration of category II CEFM tracings was not associated with increased rates of adverse outcomes. They did find that decreased variability, tachycardia, and intrapartum fever were correlated with increased rates of adverse outcomes. They did not, however, limit their study to low-risk subjects and did not examine combinations or interactions of specific FHR characteristics in their study.

Shields and colleagues (2018) conducted a prospective study in which they created a standardized intervention process for category II FHRs with significant recurrent decelerations. This study was conducted at six different hospitals. Maternal and neonatal outcomes were compared between pre- and post-implementation of the standardized practice. Neonatal outcomes included: five-minute Apgar scores <7, <5, and <3, and severe unexpected newborn complications. Maternal outcomes included cesarean delivery. They found that relative to the pre-implementation, five-minute Apgar scores < 7 were reduced by 24.6% ($p < 0.05$) and severe unexpected newborn complications were decreased by 26.6% ($p < 0.05$). Primary cesarean deliveries were decreased by 1.5% which was significant ($p < 0.05$). However, this study did not limit its study subjects to low risk patients and focused on decelerations, rather than all FHR characteristics and/or combinations thereof.

Finally, Ogunyemi and colleagues (2018) studied 12,067 deliveries between 2013 and 2016. They focused their analyses on the first and last hour of labor. Outcomes included NICU admission, neonatal hypoxia and/or hypoglycemia, umbilical artery pH, and base excess. They defined abnormal FHR as variable, late, or prolonged decelerations, absent accelerations, tachycardia, bradycardia, and minimal variability. They found that accelerations occurring in the last hour had significant negative associations with adverse neonatal outcomes. Prolonged and late decelerations, tachycardia, and bradycardia in the last hour of labor had significant positive associations with adverse neonatal outcomes. The study did not limit its subjects to low risk pregnancies and did not examine all possible category II FHR characteristics and/or combinations of those characteristics.

None of the studies described above limited their population to low risk participants or stratified by risk status. Including both low and high-risk pregnancy and labor groups is problematic, as the fetus of a low risk pregnancy can potentially withstand more of the stressors of labor that might make the fetus of a high-risk pregnancy hypoxic and lead to inappropriate or unnecessary interventions.

While category II may have implications on birth outcomes, it should be studied in the context of specific FHR characteristics and patterns because previous research has indicated that some FHR characteristics and patterns are more indicative of fetal hypoxia than others

(Vintzieleos, Smulian, 2016). Overall, these three studies concluded that CEFM tracings should be subcategorized as time spent in category II or that certain category II FHR characteristics may be more highly associated with fetal hypoxia (Jackson et al., 2011 & Schnettler et al., 2012; Penfield et al., 2016). However, because of their limited focus, important patterns or combinations of patterns may have been overlooked.

An algorithm was developed to standardize interventions related to category II CEFM tracings (Clark et al., 2013). This algorithm was discussed further by Clark and Timmons (2015) and recently tested in a retrospective sample (Clark et al., 2016). This algorithm uses the two CEFM characteristics which are generally accepted as associated with adequate fetal oxygenation: moderate FHR variability and FHR accelerations. Within these two CEFM characteristics, they identified three instances when cesarean delivery is warranted in category II. Those instances are: 1) moderate variability or accelerations with significant decelerations with ≥ 50% of contractions for 1 hour in latent phase labor; 2) moderate variability or accelerations with significant decelerations with ≥ 50% of contractions for 1 hour in second stage labor (pushing) and not making normal progress; and 3) variability other than moderate or no accelerations with significant decelerations with ≥ 50% of contractions for 30 minutes. However, this algorithm has many of the same problems as those noted with the aforementioned studies: the algorithm does not distinguish between high and low risk pregnancies and fails to address all possible combinations of category II FHR characteristics, including tachycardia and prolonged decelerations.

None of the aforementioned studies or algorithms addressed known confounding variables which can increase risk for cesarean delivery. These include demographic characteristics such as age and race and medical interventions such as induction of labor and epidural analgesia, as well as provider preference to observe category II CEFM tracings or proceed to deliver (Ciriello et al., 2012; Hueston, McClaflin, & Claire, 1996; MacDorman, Menacker, & Declercq, 2008; Levine, Hirshberg, & Srinivas, 2013; Schuit et al., 2012, Haberman et al., 2013).

Research is needed to better understand the relationship between delivery method and CEFM category II tracings that focuses on low risk participants only. This research should allow for the objective evaluation of currently proposed patterns along with the exploration of additional patterns that may identify fetuses with hypoxia and aid providers in determining when to proceed with a cesarean versus expectant management.

## Purpose

The purpose of this study is to identify specific FHR characteristics and patterns that predict cesarean delivery in women with low risk pregnancies who have indeterminate category II FHR tracings in the two hours prior to delivery.

## Aims

Aim 1: To describe the distribution of specific category II FHR characteristics in low risk pregnancies in the two hours prior to delivery. These characteristics include: FHR baseline, variability, accelerations, and decelerations.

Aim 2: To examine the association between category II FHR characteristics and cesarean deliveries in the two hours prior to delivery in women with low risk pregnancies. Null hypothesis: there is no association between category II FHR characteristics and cesarean deliveries in the two hours prior to delivery in women with low risk pregnancies.

Aim 3: To determine independent associations between category II CEFM FHR characteristics and delivery method (vaginal versus cesarean) after controlling for covariates. The covariates include: method of induction or augmentation of labor if used, epidural analgesia use, and attending provider at delivery, as well as demographic characteristics. Null hypothesis: there is no association between category II CEFM FHR characteristics and delivery method after controlling for demographic characteristics and covariates.

Exploratory Aim: To identify clusters of category II FHR characteristics and associations with delivery method in the two hours prior to delivery. These characteristics include: FHR baseline, variability, accelerations, and decelerations, as well as total time spent in category II CEFM FHR patterns. Null hypothesis: there is no association between clusters and delivery outcome in the two hours prior to delivery.

## Operational & Conceptual Definitions

**Cesarean delivery:**

**Conceptual:** The only alternative method of delivery if a vaginal delivery (spontaneous or assisted with forceps or vacuum) is not possible.

**Operational:** Delivery of a fetus through an abdominal incision and hysterotomy (uterine incision).

**Fetal Oxygenation:**

**Conceptual:** An important indicator of fetal health, for which the fetus is dependent on the oxygen in the maternal circulation, placenta, and umbilical cord.

**Operational:** Oxygen level present in the fetal red blood cells, which is ideally present at levels over pH 7.2 but pH 7.1 is considered low normal (Thorp & Rushing, 1999). This is measured by the oxygen and carbon dioxide in the umbilical cord blood sample collected immediately after delivery.

**Low Risk Pregnancy:**

**Conceptual:** Those which are least likely to end with health problems or death for the mother or baby. The most likely outcome is a healthy mother-infant dyad.

**Operational:** One in which a healthy mother with no previous uterine incision is pregnant with a term (37+ week gestation), healthy, single, head-down (vertex) fetus. Absence of the following at the time of admission to labor and delivery: any fetal diagnoses (including prematurity, gastroparesis, fetal cardiac defects, neural tube defects, small for gestational age, large for gestational age, any developmental diagnosis, etc.), any maternal diagnoses complicating pregnancy (including preeclampsia, gestational diabetes, type I and type II diabetes mellitus, gestational hypertension, maternal cardiac diagnoses, premature rupture of membranes, previous uterine incision, blood clotting disorders, anemia, Rh autoimmunization, HIV/AIDS, any malignancy, oligohydramnios, polyhydramnios, etc.).

**Continuous Electronic Fetal Monitoring:**

**Conceptual**: A way of assessing fetal oxygenation which is an indicator of fetal wellbeing.

**Operational:** Using internal or external monitors to both listen to and visualize the fetal heart rate pattern and timing of uterine contractions, which is displayed on a monitor and printed on paper. Interpreted considering known fetal heart rate characteristics: baseline fetal heart rate, variability, accelerations, and decelerations.

**Operational:**

**Category I CEFM tracings:** Moderate baseline variability (>6 - <25 bpm), variable and late decelerations absent, accelerations present or absent, FHR baseline 110-160 bpm.

**Category II CEFM tracings:** Bradycardia not accompanied by absent variability, minimal (<6 bpm), marked (>25 bpm), and absent variability not accompanied by decelerations, tachycardia, no FHR accelerations after fetal scalp stimulation/vibroacoustic stimulation, FHR decelerations without absent variability, prolonged decelerations. Includes all FHR tracings not categorized as I or III.

**Category III CEFM tracings:** Absent FHR variability with recurrent variable or late decelerations or bradycardia. Sinusoidal FHR pattern.

**2 hours prior to delivery**: CEFM tracings of all study participants from delivery and 2 hours prior, divided in 15-minute segments for analysis.

**Length of labor:** sum of minutes in stage 1 and stage 2 labor, as dictated in physician's notes in electronic medical record.

# CHAPTER 2: LITERATURE REVIEW

## History of Continuous Electronic Fetal Monitoring

The fetus receives oxygen from the maternal bloodstream via the placenta. This oxygenated blood travels through the umbilical cord to the fetus. The fetus also sends deoxygenated blood back to the maternal blood stream through the umbilical cord to the placenta. Any disruption of blood flow either to or from the fetus can result in loss of oxygen to the fetus and a build-up of carbon dioxide, threatening the acid-base balance of the fetus (hypoxia). Fetal hypoxia during pregnancy or labor can result in brain and other organ injury, cerebral palsy or death, depending on the extent or degree of cell damage. Continuous electronic fetal monitoring technology was invented to screen for fetal hypoxia and acidemia, thought to contribute to cerebral palsy (Goodlin, 1979).

Continuous electronic fetal monitoring (CEFM) was proposed to provide advance warning of decreasing fetal oxygenation via identifiable changes in the FHR, thereby allowing time for intervention to increase oxygenation to the fetus or emergently deliver the baby (Alfirevic et al., 2017; NICHD, 1997). Enthusiasm for the technology was great upon its inception and electronic fetal monitors were widely disseminated before research could be conducted on its usefulness in both high and low risk pregnancies (Evans et al., 2019; Yeh, Diaz, & Paul, 1982; Erkkola, Gronroos, Punnonen, & Kilkku, 1984). By 1998, the technology was used with 84% of all US women in labor (Ventura, Martin, Curtin, Matthews, & Park, 2000). Currently CEFM technology is the most utilized form of fetal monitoring in US hospital labor regardless of a woman's risk factors and remains the "gold standard" form of fetal surveillance in perinatal care (Maso et al., 2012). Despite the widespread utilization of CEFM in intrapartum care, the rate of cerebral palsy was unchanged between 1980 and 2015 (CDC, 2018).

An alternative to CEFM is intermittent fetal monitoring (IFM), which involves periodically assessing the fetal heart rate using a Pinard stethoscope or CEFM transducer before, during, and after a uterine contraction for fetal heart rate, presence of accelerations and presence and type of decelerations. This method allows for more maternal movement, as the mother is not tethered to a monitor. This method of monitoring is endorsed by professional groups for both obstetricians and certified nurse midwives. However, the use of IFM is sporadic across the United States, and CEFM remains the most commonly used method of fetal monitoring, despite the recommendations of professional organizations (ACNM, 2010).

## Physiology Underlying FHR and Fetal Oxygenation

Assessing fetal oxygen status is critical in determining fetal well-being. Appropriate oxygenation is necessary for growth and development of the fetus, but also for maintaining function of each fetal organ system, including the cardiac system.

The fetus receives oxygen from the maternal circulating blood. The maternal blood is circulated through the uterus where oxygen and nutrients are filtered from the maternal vessels into the placenta. Additionally, the placenta releases fetal waste into the maternal circulation for the maternal kidneys and liver to dispose of. Once oxygen crosses the placenta it enters the fetal blood stream and moves through the vein of the umbilical cord and into the fetus. Fetal oxygenation can be disrupted at many levels: the maternal lungs, maternal circulation, placenta, and umbilical cord or the fetus itself. Any disruption in the ability of the maternal lungs to oxygenate the blood including illnesses and pulmonary emboli can impact the fetus. Examples of interruptions in the maternal circulation include: anemia, hyper/hypotension, and thromboses. The placenta can be rendered less efficient for multiple reasons including but not limited to: maternal smoking, diabetes, preeclampsia, and uterine abruption (detachment of a portion or the entire placenta) (Rychek, 2004). The umbilical cord can be impacted by abnormal growth and abnormal insertions into the placenta, which can place the umbilical cord at a high risk of shearing off the placenta. Additionally, the umbilical cord can be kinked, knotted, or wrapped around the fetus. Finally, the fetus can have congenital abnormalities or illnesses which cause a decreased ability to oxygenate the cells (Murray, 2006).

The placenta receives about 50% of the combined cardiac output of the fetal heart and is responsible for metabolic exchange (Rychek, 2004). Vascular resistance of the placenta decreases with increasing gestation, but this can be altered due to differing disease states. Altering this placental resistance can have drastic effects on the cardiac and circulatory systems of the fetus, decreasing the ability of the fetal blood to nourish the fetal body and rid the fetus of metabolic waste resulting in lagging growth and development (Rychek, 2004).

Fetal oxygenation is usually assessed indirectly. The primary method of assessing fetal oxygenation is assessing the FHR. The FHR can be auscultated with a stethoscope-like device called a fetoscope, doppled using ultrasound, or electronically monitored. Continuous electronic fetal monitoring (CEFM), or cardiotocography, involves placing an ultrasound transducer and another transducer which measures uterine contractions on the maternal abdomen. Monitors can also be placed through the vagina and cervix, placed directly on the fetal head and in the uterus when necessary, if the amniotic sac has been ruptured. The transducers/monitors send data to a computer which will play audio of the heart rate as well as display of visual of the heart rate characteristics as well as uterine contractions on a computer monitor and print the display on graph paper. This visualization of the FHR is interpreted considering known FHR characteristics: baseline FHR, variability, accelerations, and decelerations.

The FHR is controlled by the autonomic nervous system, with the sinoatrial node generating the baseline rate. At earlier gestational ages the sympathetic nervous system (in charge of increasing the heart rate) is more developed, so the FHR is higher. As gestational age increases the parasympathetic portion of the autonomic system, controlled by the medulla oblongata, develops further (MSRCD, 2015). This causes the FHR to decrease. The FHR at around the ninth week of gestation is approximately 175 bpm and begins to decrease to approximately 140 bpm at the end of normal pregnancy (Pillai, James, 1990). The difference between a fetus around 28 weeks gestation and term (at or over 38 weeks) is approximately 10 beats per minute (AWHONN, 2009). These decreases in the FHR are mediated by an increase in parasympathetic activity which overrides the accelerating influence of the sympathetic nervous system (Parer, 1983). A gestational week of significance is the 32-week mark because it coincides with structural and functional neuromaturational changes in the central and autonomic nervous system. This includes increasing cortical control (MSRCD, 2015). The maturation of the fetal nervous system also increases biologic feedback to the fetus. This can include feedback from chemoreceptors, baroreceptors, the vagal nerve, as well as external stimuli, all of which can influence the FHR patterns and characteristics (Van Leeuwen, Lange, Bettermann, Gronemeyer, & Hatzmann, 1998).

Extrinsic factors such as maternal stress, maternal physical conditioning and external stimuli (sounds and maternal voice) can all influence FHR patterns and characteristics (MSRCD, 2015; Sandman, Wadhwa, Hetrick, Porto, & Peeke, 1997). Presence of stress hormones and the maternal response to stress can impact the fetus. Some hormones, like cortisol, can cross the placenta and enter the fetal circulation, creating a stress response in the fetus including increased heart rate and variability within the FHR. Changes in maternal blood pressure can impact placental blood flow. Maternal blood pressures on both extremes, either too high or too low, can decrease the ability of the placenta to extract oxygen and nutrients from the maternal circulation as well as minimize the ability of the placenta to return fetal waste and carbon dioxide to the maternal circulation (Sarkar, Bergman, Fisk, O'Connor, & Glover, 2007). Increased maternal physical conditioning can decrease fetal exposure to stress hormones, and more consistent placental perfusion. Finally, fetuses can be startled by noises upon the development of the auditory system, which can increase the FHR. Conversely, FHRs have been observed to decrease, in an apparent calming effect, of the maternal voice. It has also been observed that the fetus has the ability to habituate to auditory stimuli, especially with increasing gestational age. So, for example, while a dog barking may initially cause the FHR to increase, the fetus can develop the ability to effectively ignore the dog barking with increased exposure to the sound, which is observed by minimal change in the FHR after habituation has occurred (Sandman et al., 1997). Also, fewer FHR normal increases in the FHR (accelerations) were noted in pregnant women of a lower socioeconomic standing, again contributing to the argument that increased maternal stress can negatively impact the fetal cardiac system (MSRCD, 2015).

Aside from periodic or episodic changes to the FHR (which will be discussed at length later), the FHR is comprised of two primary characteristics: FHR variability and baseline FHR. Competition between the sympathetic and parasympathetic fetal nervous system results in what is known as FHR variability. The sympathetic nervous system causes cardio acceleration while the parasympathetic nervous system causes cardio deceleration. This competition causes a push pull effect, resulting in frequent changes in the FHR. Specifically, FHR variability measures fetal oxygen reserve (Murray, 2006). Maturation of the vagal system also contributes to increased FHR variability with advancing gestational age (Van Leeuwen et al., 1998).

**Variability**

FHR variability is the irregular, frequent fluctuation of the baseline FHR and is visually quantified as difference in peak to trough in beats per minute (bpm) as the FHR increases and decreases around the baseline FHR, and can be classified as moderate, absent, minimal and marked. Moderate variability is considered normal. This is the fluctuation of the baseline FHR of at least 6 bpm and less than 25 bpm. Absent variability is undetectable fluctuation of the FHR, appearing as a straight line in CEFM. Minimal variability is greater than undetectable but fluctuates by less than 6 bpm. Moderate FHR variability can decrease to minimal or absent FHR variability related to hypoxia and acidosis, maternal drug consumption, a fetal sleep state, fetal arrhythmia, and extreme prematurity (Gabbe et al., 2012). As mentioned previously, maternal stress can impact the FHR. FHR variability has been observed as decreased in fetuses of socioeconomically disadvantaged women when comparing to similar gestational ages in more advantaged pregnant women (MSRCD, 2015).

Marked variability is the fluctuation of the FHR by more than 25 bpm. Given the extreme fluctuation of marked variability it is impossible to determine baseline FHR (Macones et al., 2011). Normal variability can increase to the pathologic marked variability related to hypoxia, increased catecholamines, hyper-oxygenation, fetal stimulation, and increased parasympathetic activity. However, the premature FHR variability will increase from minimal to moderate variability during normal fetal maturation process. Additionally, exposure to catecholamines, hyper-oxygenation, and fetal stimulation can increase the variability of the FHR to moderate when the fetus displays absent or minimal variability at the time of exposure (Gabbe et al., 2012). Marked variability can be associated with fetal stimulation. This stimulation can be achieved via maternal sympathetic neural stimulation, stimulating the fetus through audial and manual processes (i.e. maternal voice or pressure on fetal body parts felt through the maternal abdomen). However, marked variability can also be one of the cardinal signs of increased deoxygenation in the fetus (Polnaszek et al., 2019). Marked variability, therefore, is ambiguous in nature, either indicating a stimulated fetus, or a fetus threatened by deoxygenation.

When examining the visual representation of the FHR, if absent, minimal, or moderate variability is noted, an imaginary line can be drawn across the middle of the bounce (or lack thereof in absent variability) of the FHR variability. This imaginary line is an approximated baseline FHR. Baseline FHR is an approximate mean heart rate rounded to increments of 5 beats per minute (bpm) excluding periods of acceleration or deceleration of the FHR or when the FHR varies by more than 25 bpm. At least two minutes of baseline FHR must be present in at least 10 minutes of CEFM to determine FHR baseline. The normal FHR baseline is between 110 and 160 bpm (Macones et al., 2011). The baseline FHR is determined by the maturity of the autonomic nervous system and medulla oblongata and is higher at younger gestational ages due to an immature parasympathetic system. Baseline FHR varies somewhat between fetuses. However, stability of the FHR has been documented in individual fetuses. Autonomic regulation of cardiac patterns is retained as gestation increases. Earlier 20$^{th}$-century studies noted that fetuses with increased baseline FHR and variability in earlier gestational ages also had increased baseline FHR and variability in later gestational ages, relative to their peers (Sontag & Richards, 1938; Welford, Sontag, Phillips, & Phillips, 1967).

**Tachycardia and Bradycardia**

Tachycardia is a baseline FHR over 160 bpm. Causes of fetal tachycardia include: maternal fever, drugs in the maternal circulation, and fetal supraventricular tachycardia. Bradycardia is a FHR below 110 and can be caused by fetal cardiac issues (i.e. heart block), drugs in the maternal circulation, and severe deoxygenation (Macones et al., 2011). The adult nervous and circulatory systems respond to hypoxia by increasing the heart rate. The opposite occurs in the fetus. “Chemoreceptors in the fetal aorta respond to ascending aortic blood p02 values below 18 or 19 Torr by inducing bradycardia" (Rychik, 2004, p. 205). Shunting blood flow away from all organs except for the heart and brain allows the fetus to conserve oxygen in a hypoxic environment. A low FHR can supply oxygen to the heart and brain (Rychik, 2004).

**Accelerations**

Periodic and episodic changes include both FHR accelerations and decelerations. FHR accelerations are transient increases in the FHR associated with a well-oxygenated fetus. Similar to children and adults, the FHR will increase with stimulation. Fetal stimulation can occur with fetal movement, uterine contractions, umbilical vein compression, and the startling of a fetus related to loud noises or touching the fetus (either through the maternal abdomen by palpation or during a cervical exam) (Sweha, Hacker & Nuovo, 1999). Accelerations of the FHR, or visually apparent, abrupt increases in the FHR, take less than 30 second from onset to peak, and in fetuses over 32 weeks gestation must be at least 15 bpm greater than baseline (Macones et al., 2011). Prior to 32 weeks gestation, accelerations are defined as a rise 10 bpm from baseline and last 10 seconds. The reason for the change in criteria for an acceleration at gestational ages post-32 weeks is the maturation of the autonomic nervous system, as mentioned above. FHR accelerations elicited by exposure to external stimuli including noises, vibration and fetal scalp stimulation via a cervical exam are an indicator of fetal well-being. Additionally, the combination of moderate FHR variability and spontaneous accelerations is indicative of a well-oxygenated fetus (Macones et al., 2011).

**Decelerations**

Early decelerations are a gradual (taking at least 30 seconds from onset to nadir), symmetrical decrease and return of the FHR. The low point of the deceleration (nadir) occurs with the peak of the contraction. Early decelerations are considered benign and can indicate fetal head descent into the maternal pelvis and vaginal canal (Macones et al., 2011). Early decelerations are caused by head compression and require an intact vagal response. This head compression occurs with contractions, which alters the cerebral blood flow, stimulating the central vagus nerve. This causes a decrease in the FHR which resolves as soon as the head compression ceases (Gabbe et al., 2012). Fetal head pressure, as noted in early decelerations, may trigger a temporary bradycardia related to increased intracranial pressure, thus causing a temporary reduction in cerebral perfusion (Westgate et al., 2007).

Variable decelerations are abrupt decreases (taking less than 30 seconds from onset to nadir), dropping at least 15 bpm and lasting at least 15 seconds but not more than 2 minutes (Macones et al., 2011). Variable decelerations are caused by compression of the umbilical cord. Umbilical cord compression causes abrupt drops in the FHR. The umbilical cord can be compressed by various methods. Cord compression causes an immediate increase in the fetal blood pressure which triggers the fetal baroreceptors. This causes a vagal response and a drop in the FHR (Richardson, Carmichael, Homan, Johnston, & Gagnon, 1996). Compression of the umbilical cord can be caused by the cord being lodged between the uterine wall and the fetus, especially when amniotic fluid levels drop, knots in the umbilical cord, and even the fetus grasping its own umbilical cord while exploring its surroundings en utero (Gabbe et al., 2012).

Late decelerations are the gradual decreases (duration of at least 30 seconds from onset to nadir) and return of the FHR to baseline with the nadir of the deceleration occurring after the peak of the uterine contraction (Macones et al., 2011). Late decelerations are caused by uteroplacental insufficiency. Any condition impacting maternal circulation, or the placenta can cause late decelerations. Maternal hyper- or hypotension, placentas impacted by conditions like post-dates gestation, diabetes, preeclampsia and maternal smoking, and tachysystole (contractions too frequent to allow for adequate uterine blood flow) are all issues that can impact uteroplacental insufficiency (Sweha, Hacker & Nuovo, 1999).

Prolonged decelerations are decreases in the FHR by at least 15 bpm and lasting between 2 and 10 minutes. Accelerations and decelerations lasting longer than 10 minutes are considered a baseline FHR change (Macones et al., 2011). Prolonged decelerations can be caused by fetal head compression, umbilical cord compression, or uteroplacental insufficiency. The trigger causing the deceleration is not relieved, causing the FHR to not return to baseline (Gabbe et al., 2012).

FHR decelerations during periods of hypoxia are thought to be an adaptation believed to reduce work of the fetal myocardium and oxygen requirements. Initially the drop in FHR is mediated by the chemoreflex of the fetus. The parasympathetic blockade can prevent this drop (Westgate et al., 2007). A brief deceleration in labor is an indication that the fetus has responded to hypoxia with a temporary bradycardia mediated vagally. Decelerations cause a myriad of changes in the fetal circulation. The fetus has a tremendous ability to withstand FHR decelerations due to a large reserve of placental capacity, intended to accommodate the fetus during periods of decreased oxygen transfer of the placenta during uterine contractions (Westgate et al., 2007). The fetal circulation diverts from all the tissues and is shunted to the brain and heart. If prolonged, the decreased blood flow to the other organs, muscles and skin can cause lactic acid build-up and thus metabolic acidosis, placing the fetus at risk of injury or death (Richardson, et al., 1996).

FHR variability, baseline FHR, accelerations, and decelerations can be interpreted together to assess the oxygenation of the fetus and risk of injury or death related to hypoxia. The presence of moderate variability and FHR accelerations is a reliable predictor of a well-oxygenated fetus and can reliably rule out metabolic acidemia. Variable, late, and prolonged decelerations signal health care providers that an interruption of oxygen transfer to the fetus has occurred (Gabbe et al., 2012). However, generally each of these FHR characteristics considered alone make it difficult to decipher the oxygenation of a fetus. Therefore, experts in the field of obstetrics and perinatology met to discuss how categorizing FHR patterns might assist in assessing fetal oxygenation and standardizing interventions (Macones et al., 2011).

## Classification of Fetal Heart Rate Patterns

Since the initiation of CEFM, multiple systems for classifications of the FHR tracings have been proposed. In the 1990s the Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD) met with the American College of Obstetricians and Gynecologists (ACOG) as well as the Society for Maternal-Fetal Medicine to develop standardized definitions of FHR decelerations, which could help to meaningfully assess the FHR tracing, promoting the development of evidence-based interventions for the fetus during the intrapartum period (NICHD, 1997). This workshop resulted in a two-tier classification of the CEFM tracing: “reassuring” and “non-reassuring.” These early definitions were widely accepted by groups like ACOG and the Association of Women’s Health & Neonatal Nurses (AWHONN) but provided no guidance for standardized interpretation and responses to the two FHR types.

This two-tier system was used widely in practice for approximately 10 years. Clinically, the response to non-reassuring CEFM tracings was based on provider preference. Individual providers had to clinically decide whether to use conservative measures (maternal position changes, IV fluid boluses, maternal oxygen administration, discontinuing oxytocin) or proceeding to an expedited delivery (cesarean or instrumental vaginal delivery) (Macones et al., 2011). Subsequently, several research studies demonstrated that the two-tiered system resulted in rather large false positive rates. One study found a false-positive rate of 89% in low risk patients

(Sameshima, Ikenoue, Ikeda, Kamitomo, & Ibara, 2004). A second study found that using the NICHD two-tier system did not increase agreements on FHR features beyond what was expected by chance (Devoe et al., 2000).

In response to the problems identified within the two-tiered system, multiple alternative classification systems which were intended to aide in the assessment and interpretation of the CEFM tracing were introduced but not widely accepted or used in perinatal care in the United States (Gyamfi-Bannerman, Grobman, Antoniewicz, Hutchinson, & Blackwell, 2011).

In April 2008, a two-day NICHD workshop designed to review and update the nomenclature, interpretations and research recommendations related to intrapartum CEFM was held with ACOG and the Society for Maternal-Fetal Medicine and included participants from various groups involved in the care of pregnant and laboring women (Macones et al., 2011). The 2008 NICHD workshop's goals were three-fold. The first was to review the definitions for the CEFM patterns and update where necessary. The second was to assess the classification and interpretive systems in use in the United States and around the world and come to a consensus recommendation for use of a classification system in the United States. The third goal was to discuss recommendations for research related to CEFM (Macones et al., 2011).

The 2008 NICHD workshop resulted in adopting the current three-tier system. This system classifies FHR patterns into three categories. Table 1 describes the FHR characteristics in each category, the significance of the findings, and NICHD management recommendations. Category I is indicative of normal fetal acid-base balance and is characterized by moderate FHR baseline variability (variability between 6 and 25 beats per minute), absence of variable and late FHR decelerations, and a normal FHR baseline (between 110-160 beats per minute). Category III is indicative of the potential for abnormal fetal acid-base balance and is characterized by absent FHR baseline variability with recurrent variable or late FHR decelerations or bradycardia (less than 110 beats per minute), or a sinusoidal patter, which resembles a saw-tooth pattern and indicates serious fetal hypoxia. Category II includes all FHR patterns not included in Category I or Category III and is deemed indeterminate (Macones et al., 2011).

**Table 1** - NICHD Categories

| | Category I | Category II | Category III |
|---|---|---|---|
| **CEFM Findings** | Moderate baseline variability (>6 - <25 bpm), variable and late decelerations absent, accelerations present or absent, FHR baseline 110-160 bpm | Bradycardia not accompanied by absent variability, minimal (<6 bpm), marked (>25 bpm) and absent variability not accompanied by decelerations, tachycardia, no FHR accelerations after fetal scalp stimulation/vibroacoustic stimulation, FHR decelerations without absent variability, prolonged decelerations<br><br>Includes all FHR tracings not categorized as I or III | Absent FHR variability with recurrent variable or late decelerations or bradycardia.<br><br>Sinusoidal FHR pattern |
| **Significance** | Normal fetal arterial pH and fetal wellbeing | Tachycardia: medication, maternal anxiety, infection and fever<br>Bradycardia: ROM, OP position, post-term pregnancy, congenital anomalies<br>Variability changes: medications, fetal sleep cycle, change in maternal position, change in FHR monitoring technique, possible fetal hypoxia/acidemia<br>No accelerations: possible fetal hypoxia/acidemia<br>Variable: umbilical cord compression or prolapse<br>Late: possible uteroplacental insufficiency, epidural hypotension, tachysystole | Uteroplacental insufficiency, fetal hypoxia/acidemia |
| **Management** | Continue current monitoring method (IFM or CEFM) | Conservative measures: cervical exam, check maternal vital signs, administer O2, change maternal position, IV fluid bolus, fetal scalp stimulation/ vibroacoustic stimulation, discontinue oxytocin<br>Change monitoring method, amnioinfusion, consider expedited delivery if abnormalities persist and do not respond in reaction to interventions | Conservative measures<br>Expedite delivery |

bpm= beats per minute, ROM= rupture of membranes (Macones et al., 2011, p. 665; Bailey, 2008)

Category II encompasses multiple FHR characteristic that can be present in multiple combinations including: bradycardia without absent variability, minimal (<6 beats per minute (bpm)), marked (>25 bpm) and absent variability without decelerations, tachycardia, no FHR accelerations after fetal scalp stimulation/vibroacoustic stimulation, FHR decelerations without absent variability, and prolonged decelerations. Some of these FHR patterns within category II may be benign, while the others may not, however currently there is no way to discriminate the benign patterns from the patterns indicative of fetal hypoxia (Macones et al., 2011).

Since the publication of the three-tier system, ACOG, the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN), the Society of Maternal Fetal Medicine (SMFM), the American College of Nurse Midwives (ACNM) and the Joint Commission have endorsed the classification system and incorporated the NICHD terminology into their guidelines for fetal monitoring and these guidelines in the form of practice bulletins influence care across the nation (AWHONN, 2009). Despite this wide-spread adoption there is inconsistency in CEFM tracing interpretation and how the resulting interventions are applied among providers across the country (Di Tommaso et al., 2013).

> "The limit of the NICHD guideline, which classifies 80% of tracings in the second category is that it does not provide elements for the management of FHR trace and the intervention that should be applied to a specific pattern…the NICHD classification leads in most cases to uncertainty in the interpretation of the tracings…" (DiTommaso et al., 2013, p. 490).

The indeterminate nature of category II is also reflected in the interventions suggested in the 2009 NICHD workshop. The interventions for category II FHR patterns include interventions used in both category I and category III. Category I treatment recommendations include expectant management, which includes continued surveillance and evaluation of the CEFM tracing while allowing labor to progress without intervention (Macones et al., 2011). Category III treatment recommendations include conservative measures, which consist of maternal position changes, oxygen administration, IV fluids and discontinuing oxytocin administration, and expedited delivery if conservative measures do not resolve suspected fetal hypoxia, as evidenced by the CEFM tracing (Macones et al., 2011). Category II treatment recommendations include everything from continuing to monitor without intervention (expectant management), conservative measures, to expedited delivery. Expedited delivery can include operative vaginal delivery and emergency cesarean delivery. Operative vaginal deliveries include vacuum extraction, assisting the birth of the fetal head with a vacuum, and forceps deliveries, assisting the birth of the fetal head with forceps, both of which are only possible if the fetal head is descended low enough in the birth canal (Ali & Norwitz, 2009). Emergency cesarean delivery, as discussed earlier, is associated with multiple poor outcomes for both the mother and baby as well as increased health care costs. Therefore, if CEFM tracings are erroneously indicating a fetus is hypoxic or at risk for hypoxia, the mother, her baby and the healthcare system as a whole may be placed at a disadvantage.

## Risk Status and Use of CEFM

Both the American Congress of Obstetricians and Gynecologists (ACOG) (2008) and the American College of Nurse Midwives (ACNM) (2010) recommend against using CEFM in low risk fetuses. Low-risk pregnancies conceptually are those which are least likely to end with health problems or death for the mother or baby. They are most likely to end in a healthy mother-infant dyad. Operationally, low-risk pregnancies are those in which a healthy mother with no previous uterine incision is pregnant with a healthy, single, head-down fetus. Conversely, high-risk pregnancies are just the opposite: those with maternal or fetal diagnoses placing the health or life of mother, fetus or both at risk. Nearly all high-risk conditions can potentially impact the development of the fetus and/or the placenta, which impacts the oxygenation of the fetus. Healthy fetuses are able to withstand the periodic deoxygenation associated with occasional umbilical cord occlusion related to movement, or with labor due to fetal oxygen reserves, associated with shunting blood flow to the heart and brain, and with fetal hemoglobin. Fetal hemoglobin binds oxygen better than the hemoglobin found in older infants, children and adults (Gabbe et al., 2012). High-risk fetuses have less reserve related to the maternal or fetal diagnoses and therefore will display FHR characteristics different than those of low-risk pregnancies. It becomes difficult to judge low and high-risk pregnancies by the same standards using CEFM.

### False Positives in CEFM Category II

False-positives, or CEFM tracings which indicate possible fetal hypoxia when hypoxia is not present, have been observed in relation to CEFM for decades (Prentice &Lind, 1987). Researchers have raised concern that the false positive rate, which has been found to be as high as 99.8%, of CEFM, may result in cesarean sections with are “performed without benefit and the potential for harm” (Nelson et al., 1996, p. 613; Di Tommaso et al., 2013).

Di Tommaso and colleagues (2013) examined 97 CEFM tracings and compared the three-tiered NICHD classification systems to four other CEFM classification systems to determine sensitivity, specificity, positive and negative predictive values and the capacity of each classification system to predict neonatal pH, as evidenced by umbilical cord gasses collected immediately after birth. They found that 80% of all tracings interpreted with the three-tiered NICHD categorical system were indeterminate. They also that found the sensitivity of the three-tiered system to detect acidemia related to fetal hypoxia was 67%; specificity was 92%, a positive predictive value of 80% and a negative predictive value of 86% (Di Tommaso et al., 2013, p. 489). At first glance these numbers may seem impressive. However, the rates reported were for all three categories combined in the NICHD 3-tiered system. They concluded that the widely accepted relatively poor sensitivity of the NICHD category II to detect fetal hypoxia is directly related to the large majority (80%) of FHR patterns in the indeterminate category II.

"This can contribute to a higher rate of intervention, leading to an increased incidence of cesarean delivery" (DiTomasso et al., 2013, p. 489).

Other recent studies comparing the 2008 NICHD categories to other CEFM classification systems found similar results to the DiTommaso (2013) study (Coletta, Murphy, Rubeo, & Gyamfi-Bannerman, 2012; Gyamfi-Bannerman et al., 2011). Coletta and colleagues (2012) examined 24 cases with a fetal arterial pH <7 (poor) and 24 controls with a fetal arterial pH > 7.2 (good) and studied the CEFM tracings of each using both the NICHD three-tiered categorization system and another five-tiered CEFM categorization system. They found that virtually the same proportion of cases (83.3%) and controls (79.2%) were classified as category II. But NICHD category II did not differentiate fetal acidemia (hypoxia) compared with non-acidemic fetuses (Coletta et al., 2012). More recently, Evans and colleagues (2019) developed the Fetal Reserve Index (FRI), a combination of traditional CEFM variables with risk factors (maternal, obstetrical and fetal) and uterine contraction characteristics. "The FRI has high performance metrics in the identification of cases entering labor with apparently normal status and unharmed fetus who: (1) went on to have a baby with cerebral palsy, (2) would require an emergency operative delivery, (3) its real-time use has appeared to lower the risk of emergency operative delivery" (p. 2). They studied 248 singleton, term, high-risk pregnancies. Each subject had umbilical artery cord blood collected and examined pH, base excess and pO2. They created an eight-point scale based on normality of each of the criterion which make up the FRI (heart rate, variability, accelerations, decelerations and uterine activity, medical risk factors, obstetrical risk factors, and fetal risk factors). Normal parameters were given 1 point, while abnormal parameters were given 0 points. These scores were then compared to CEFM tracings and umbilical cord gases. The study found FRI showed a correlation with umbilical cord base excess and pH. The three-tiered CEFM categorization system was less predictive than FRI ($p < 0.05$). Category II cases in the study had FRI scores across the spectrum of severity of FRI scores and provided little clinical discrimination. The exclusion of low-risk pregnancies does not allow this study to address the question of impact of category II FHR characteristics and their relation to delivery method in low-risk labor.

**Limitations of Category II FHR Designation**

The indeterminate nature of category II may be influenced by the breadth of FHR characteristics within the category. Category II is very broad and multiple combinations of the many FHR characteristics results in many potential category II patterns that may indicate hypoxia or be benign. There are very few studies that have attempted to look at specific FHR characteristics in category II. Three recent studies examined category II FHR patterns based on either FHR patterns within category II or the amount of time spent in category II, in some cases offering potential subcategories for category II CEFM tracings (Jackson et al., 2011; Schnettler et al., 2012; Penfield et al., 2016). In addition to studies, groups of clinicians have used clinical expertise and available research to build algorithms which are built around specific FHR characteristics observed in category II CEFM tracings. These algorithms attempt to standardize provider responses to category II CEFM patterns (Clark et al., 2013; Timmins & Clark, 2015). Another study examined category II FHR characteristics, but is of limited use because it compares the three-tiered system to other categorization systems which are not widely used in practice (Gyamfi-Bannerman et al., 2011).

Schnettler and colleagues (2012) divided category II into four subcategories: a) bradycardia or tachycardia with variability; b) minimal or marked variability or absent variability without recurrent decelerations; c) lack of accelerations after stimulation; and d) recurrent variable decelerations with minimal or moderate variability, prolonged decelerations, recurrent late decelerations with moderate variability or variable decelerations. The study found that there was more than a 2 times increased risk of cesarean delivery for categories IIb and IId than for category IIa. The major limitation with this study is that the sample was not limited to low risk women. Including high risk mothers or fetuses could have biased the results and not be applicable to low risk mothers/fetuses. For example, fetuses below a gestational age of 37 weeks, or with underlying health issues may have FHR characteristics that a healthy, term fetus would not have in labor.

Another study created subcategories of study participants based on the amount of time spent in category II (Jackson et al., 2011). Jackson and associates (2011) subcategorized category II tracings based on the amount of time in the last 2 hours prior to delivery a fetus spent in category II. The categories were based on quartiles (<25%, 25-49%, 50-74% >75%). The study found that the more time spent in category II the greater the likelihood for poor neonatal outcomes including Apgar scores, resuscitation, and NICU admissions. Again, this study sample was not limited to low risk pregnancies. Additionally, it did not control for the different FHR patterns within the designated time period.

Penfield and colleagues (2015) subcategorized category II CEFM tracings into three predefined subcategories based on a CEFM categorization system created by Parer and Ikeda (2007). These three predefined categories contain multiple FHR characteristic combinations (see Table 2). These subcategories offer far more FHR characteristic combinations than any of the other studies. This study surveyed different healthcare providers in a labor and delivery unit about the effectiveness of communication and on the level of agreement between providers on the CEFM tracing interpretation for first the standard NICHD three-tiered system and then with the subcategorized system. The study also included pre- and post-implementation surveys of the labor and delivery staff as well as phone notification surveys when off-site providers were called about the CEFM tracings of the patients cared for by the study-participants. Most of the data collected focused on outcome data such as agreement of interpretation, arrival to labor unit when alerting off-site providers, and provider preference for the differing systems. The study did examine delivery method and NICU admissions when comparing the two systems. However, these data were only collected when a provider was called in from off-site. One potential way to improve the study methods would be to collect this data on all study participants. The study found that the subcategorization system was preferred and was considered more effective than the standard NICHD three-tiered system (80% for subcategorized vs 43% for NICHD, $p < 0.01$). Greater agreement of interpretation was found for the subcategorized (79%) than NICHD (64%, $p = 0.046$). Off-site physicians were found to arrive more quickly to the labor unit with the subcategorized system (44%) versus the NICHD system (20%, $p < 0.01$). There was no difference in delivery method found in this study (total of 95 deliveries included in the study). This study highlights the notion that using a more comprehensive subcategorization system could have benefits including increased potential for agreement in interpretation. The study also found the more comprehensive subcategorization system resulted in decreased NICU admissions. However, the total number of phone notification surveys was 146, a remarkably small sample size. This study used both the NICHD three-tiered system and the modified subcategorization system on both high and low risk pregnancies. Finally, the subcategories, while more comprehensive than many other studies, were predefined rather than emerging from the data. Future studies could collect many of the same variables with a larger sample size and collect all variables on all study participants.

**Table 2** - A Modified Subcategorization System to Interpret CEFM

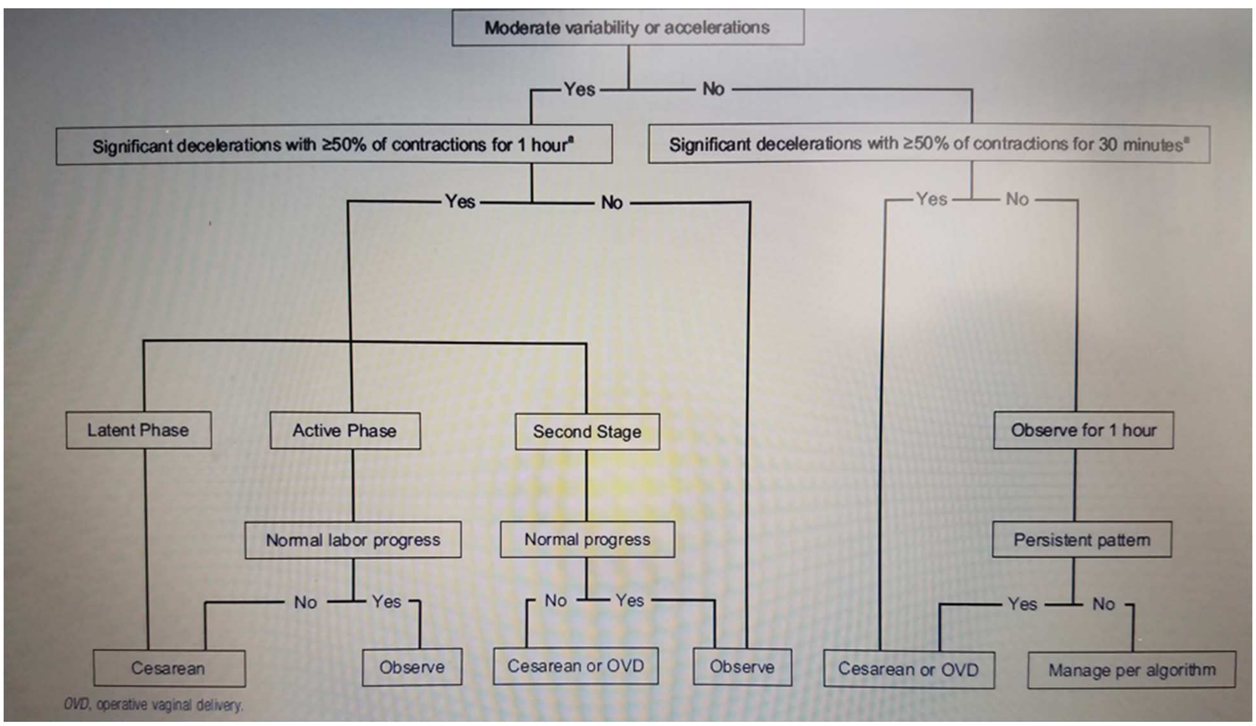
| Category[a] | Fetal heart rate tracing characteristics[b] |
| --- | --- |
| Blue/Category IIA | • Moderate variability + tachycardia + any of the following: no decelerations or presence of early or mild variable decelerations<br>• Moderate variability + normal baseline + moderate variable decelerations<br>• Moderate variability + normal baseline + mild late decelerations<br>• Minimal variability + tachycardia + no decelerations<br>• Minimal variability + normal baseline with no decelerations or with early decelerations |
| Yellow/Category IIB | • Moderate variability + tachycardia + any of the following: moderate variable decelerations, mild or moderate late decelerations, mild or moderate prolonged decelerations<br>• Moderate variability + normal baseline + any of the following: severe variable decelerations, moderate or severe late decelerations, mild or moderate prolonged decelerations<br>• Moderate variability + mild bradycardia + any of the following: no decelerations, early decelerations, mild or moderate variable decelerations, mild or moderate late decelerations, mild or moderate prolonged decelerations<br>• Moderate variability + moderate with no decelerations or with decelerations<br>• Minimal variability + tachycardia + early decelerations or mild variable decelerations.<br>• Minimal variability + normal baseline + mild variable decelerations<br>• Marked variability |
| Orange/Category IIC | • Moderate variability + tachycardia or mild bradycardia + any of the following: severe variable, late, or prolonged decelerations<br>• Moderate variability + normal baseline + severe prolonged decelerations<br>• Moderate variability + moderate bradycardia + any of the following: severe variable decelerations, moderate or severe late decelerations, or severe prolonged decelerations<br>• Moderate variability + severe bradycardia with or of the following: no decelerations, early decelerations, severe variable, severe late, or severe prolonged decelerations<br>• Minimal variability + tachycardia + any of the following: moderate or severe variable decelerations, mild or moderate late decelerations, or mild, moderate or severe prolonged decelerations<br>• Minimal variability + normal baseline + any of the following: moderate or severe variable decelerations, mild or moderate late decelerations, mild or moderate prolonged decelerations<br>• Minimal variability + mild bradycardia with no decelerations or with early decelerations<br>• Minimal variability + moderate bradycardia with no decelerations or with early decelerations<br>• Absent variability with normal baseline and no decelerations |

Taken from Penfield et al. (2015) as adapted by Parer and Ikeda (2007).

Gyamfi-Bannerman and colleagues (2011) subcategorized category II based on variability and presence of accelerations and compared the three-tiered systems to two other categorization systems, the old two-tiered NICHD system and the aforementioned Parer and Ikeda system (2007). The authors did not provide any information on how the subcategorization process occurred. They simply stated they "grouped category II tracings based on FHR variability and accelerations" (p. 288.e2). They do not discuss the number of subcategories they created. There are some findings from this study which are applicable to this proposed study. The study found that after sub-categorization based on variability and accelerations, 70% of tracings were consistent with normal acid-base balance and 30% of tracings were consistent with abnormal acid base balance. All methods of subcategorization were selected prior to the initiation of both of the studies and did not emerge from the author's data causing a potential to overlook potential category II FHR characteristics and patterns, again making the study not comprehensive. The authors also did not examine delivery outcomes other than umbilical cord gases. Additionally, the study did not exclude high risk mother-infant dyads.

More recently, Timmins and Clark (2015) discussed an algorithm developed by Clark, Nageotte, Garite and colleagues in 2013. This algorithm uses the two CEFM patterns which are known to be associated with optimum fetal oxygenation, moderate variability and FHR accelerations (see Figure 1). Once determining if these patterns are present or absent, the algorithm asks the provider to determine if there are significant decelerations with 50% or more of uterine contractions for 1 hour in patterns with moderate variability and accelerations, or 30 minutes for patterns without moderate variability or accelerations. If moderate variability and accelerations are present and there are not significant decelerations with at least 50% of contractions for an hour or if, in the absence of either moderate variability or accelerations, there are not significant decelerations with at least 50% of contractions for 30 minutes, the algorithm calls for the provider to continue to observe the FHR as displayed on CEFM. In the absence of moderate variability or accelerations after observing for an hour the algorithm calls for the prover to determine if a persistent pattern of abnormal variability, lack of accelerations or continued repeated decelerations exists. If so, the algorithm recommends cesarean or operative vaginal delivery. If not, the algorithm says, "manage per algorithm." Conversely, according to the algorithm in the absence of moderate variability or accelerations with significant decelerations with at least 50% of contractions for 30 minutes, the provider should proceed with a cesarean or operative vaginal delivery. If moderate variability and accelerations are present but significant decelerations are present with at least 50% of contractions the algorithm calls for the provider to determine the phase of labor the patient is in. In latent phase (early labor, not adequately changing the maternal cervix) the algorithm calls for cesarean delivery. In the active phase of labor, if labor is progressing normally (cervix changing and baby descending into the maternal pelvis) the algorithm calls for continued observation; however, if labor is not progressing normally the algorithm calls for cesarean delivery. Finally, in the second stage of labor (pushing phase) if the baby is descending normally, observation is deemed appropriate in the algorithm. But if the baby is not descending normally, the algorithm calls for cesarean or operative vaginal delivery (Clark et al., 2013; Timmins & Clark, 2015).

**Figure 1** - Clark's Algorithm



(Clark, Nageotte, & Garite, 2013)

There are some problems with this algorithm. First is the definition of "significant" decelerations. Prolonged decelerations are not adequately discussed in either article and would be extremely difficult to observe for even 30 minutes if they were occurring with at least 50% of contractions and not responding to conservative measures like maternal position change, oxygen administration and discontinuation of oxytocin. While conservative management methods are discussed in both articles, conservative measures are not included in the algorithm.

The issue of delineating the low-risk from the high-risk fetus is of great importance and is not mentioned in either article. The low-risk fetus will have significantly more oxygen reserve than the high-risk fetus. A low-risk fetus with minimal variability without accelerations could be in a sleep cycle. Deep variables are often seen with contractions when the fetal head begins to descend into the maternal pelvis. It may be important to understand the fetal ability to withstand the insults of labor, especially advanced labor. Therefore, risk status of the pregnancy is an important factor when creating an algorithm. Standardizing care to the two different risk-statuses may be appropriate.

Finally, this algorithm fails to examine all of the potential FHR characteristics that may be present (or absent) in category II CEFM. There is no mention of baseline FHR or baseline changes, type of variability other than not moderate, or type of deceleration (only “significant”). The algorithm also fails to quantify total time spent in category II other than the occurrence of decelerations in relation of at least 50% of contractions. Could the time spent in category II regardless of decelerations in at least 50% of contractions be significant? These articles fail to address this question. There are too many questions left unanswered to accept this algorithm as the “gold standard” for obstetrical care in both high and low risk labor, and it needs to be tested further with quality research studies to be considered field tested.

More recently, the algorithm was tested by Clark, Hamilton and colleagues (2017). The case control study compared a study group with fetal metabolic acidemia (n= 120) and a control group with normal umbilical cord gases (n=120) (Clark et al., 2017). While the study does limit the sample to term deliveries, the investigators did not limit the study sample to only low-risk pregnancies. The CEFM tracings for each of the cases were retrospectively, blindly assessed using the algorithm created by Timmins and Clark (2015) and the following questions were asked:

- How did algorithm-based decisions differ from those made in practice?
- What was the nature of CEFM tracings in infants born with metabolic acidemia that were potentially prevented or predicted with CEFM assessment by the study experts?
- What limits exist related to the ability of CEFM to predict/prevent fetal hypoxia and metabolic acidemia during labor?

In clinical practice, this study had 36 cesarean deliveries for abnormal CEFM tracings (30%) compared with 55 recommended cesarean deliveries in the expert analysis using the Timmons and Clark algorithm (45.8%, p=.016). While this finding was significant, the study also found that use of the Timmons and Clark (2015) algorithm did not indicate earlier delivery in 65 of the 120 participants in the case group (presence of umbilical cord gas acidemia). The authors concluded "Our data suggest that, of infants who are born with metabolic acidemia, only approximately one half could be identified potential and have delivery expedited, even under ideal circumstances…" (Clark et al., 2017, p.163.e5).

While the algorithm may have the ability to identify some fetuses at risk of hypoxia and metabolic acidemia, it failed to identify at least half of the cases of metabolic acidemia it studied. This could possibly be related to including some high-risk pregnancies in the study; however this effect can never be known. In addition, the relatively small sample size may indicate a need for a larger study to validate the results.

Shields and colleagues (2018) modified the Clark et al. (2017) algorithm. They defined active labor as ≥ 4 cm dilation. They defined significant decelerations as "severe" variable decelerations, late decelerations, or recurrent prolonged decelerations occurring with > 50% of contractions for 30 minutes. Severe variable decelerations were defined as lasting at least 60 seconds and dropping at least 60 beats per minute below baseline or below 60 beats per minute. The authors chose to define normal variability as moderate and marked, while absent and minimal variability were defined as abnormal. The authors were primarily interested in the effect of significant decelerations, so they limited their study to subjects with marked and moderate variability with significant decelerations. Six hospitals agreed to utilize the modified Clark algorithm to standardize treatment. Data were collected on pre-implementation (the six months prior to implementation) and post-implementation outcomes. Those outcomes included: delivery method, 5-minute Apgar scores, and severe unexpected newborn complications. Use of the algorithm was also collected during the 11-month post-implementation period. Of the 3799 eligible deliveries, 361 patients met the criteria for recurrent significant fetal heart rate decelerations. They found a significant decrease in primary cesarean delivery of 1.5% ($p=0.04$). They did find, however, that within the group of patients with significant FHR decelerations in the post-implementation period the rate of vaginal birth dropped from 75.8% to 57.9% ($p < 0.01$) and primary cesarean rates increased from 18.3% to 23.7% ($p<0.01$). The post-implementation data showed a 24.6% reduction in the rate of 5-minute Apgar scores <7 ($p<0.05$) and a 24.5% reduction in unexpected newborn complications ($p<0.05$).

While this study did exclude preterm, multiple gestation (twins, triplets, etc.) and vaginal birth after cesarean (VBAC) patients from their study, they did not exclude all high-risk pregnancy complications from their sample. In addition, by choosing to focus on significant decelerations in the presence of marked or moderate variability, they eliminated many FHR characteristic and combinations thereof that would fit into category II. This study does show, however, that greater standardization of responses to certain FHR characteristics may decrease adverse neonatal outcome (Shields et al., 2018).

Ogunyemi and colleagues (2018) studied 12,067 singleton deliveries with at least two hours of CEFM tracing occurring between 2013 and 2016. They examined abnormal CEFM tracings, which they defined as absent accelerations, variable, late or prolonged decelerations, tachycardia, bradycardia, or minimal variability. Data were collected from the first and last hour of CEFM tracing for each subject. Outcome data collected included: NICU admission, neonatal hypoxia, neonatal hypoglycemia, umbilical artery pH, and base excess. They did find that any abnormal CEFM during the last hour was independently associated with each of the neonatal outcomes ($p<0.05$). They also found that throughout labor increasing accelerations were negatively correlated with all adverse neonatal outcomes and increasing frequency of late, variable, and prolonged decelerations were positively correlated with each adverse neonatal outcome ($p<0.05$). Tachycardia and bradycardia contributed 0.8% to the variance in umbilical artery pH and base excess. Increasing frequency of abnormal FHR patterns contributed 0.6% to the variance in umbilical artery pH and base excess ($p<0.05$). Their study did demonstrate that accelerations may be protective and increasing frequency in abnormal FHR characteristics may be related to adverse neonatal outcome. However, the authors did not collect delivery method data and failed to include all potential FHR characteristics/combinations which can be defined as category II (Ogunyemi et al., 2018).

Weissbach and colleagues (2018) conducted a retrospective, observational study of the medical records of 271 patients delivered by cesarean for non-reassuring FHR at a tertiary medical center from 2015-2017. Data collected included: duration of category II, variability, tachycardia, and deceleration frequency. These data was compared to outcome data which included: umbilical artery pH $\leq 7$, cord base excess > 12, 1- and 5-minute Apgar scores $\leq 7$, need for neonatal ventilation and/or chest compressions, NICU admission, hypoglycemia, and convulsions. Data were also collected on meconium-stained amniotic fluid and intrapartum fever. They found the mean duration of category II CEFM tracings was 146 minutes (range 17-553 minutes). However longer duration of category II did not result in increased rates of adverse neonatal outcomes. Minimal or absent variability was associated with an 11.5% increase in umbilical artery pH $\leq 7$ ($p=0.0006$) and an 11.2% increase in cord base excess > 12 ($p=0.004$). Fetal tachycardia was associated with a 7.2% increase in 5-minute Apgar scores of 7 or less ($p=0.04$) and a 29% increase in the need for neonatal ventilation support. Intrapartum fever was associated with an 8% increase in cord base excess > 12 ($p=0.035$), a 9.3% increase in 5-minute Apgar scores of 7 or less ($p=0.005$), a 13.9% increase in the need for neonatal ventilation ($p=0.042$), a 6.45% increase in neonatal chest compressions ($p=0.013$) and a 10.4% increase in NICU admissions ($p=0.018$). This study suggests that duration of category II FHR characteristics may not predict fetal hypoxia and further adds to the evidence that variability may be a better indicator of fetal oxygenation than some other FHR characteristics (Weissbach, et al., 2018). The study was not limited to low risk study subjects. While frequency of decelerations was collected, types of decelerations were not, and combinations of FHR characteristics were not considered.

Finally, two quite recent studies examined CEFM FHR characteristics (or categories) and the connection to fetal hypoxia. Cahill and colleagues (2018) conducted a prospective cohort study of over 8500 pregnant women examining the CEFM tracings in the two hours prior to delivery. They found that decelerations were the best predictor of fetal acidemia (AUC 0.77, 95% CI 0.75-0.79). They found that once their threshold of decelerations was reached the number of cesareans needed to prevent one case of fetal hypoxia (acidemia) was five. However, they did not limit the study participants to those with low risk pregnancies. Toomey and Oppenheimer (2019) conducted a case-control study in which cases were newborns with an umbilical artery pH ≤ 7.05 and controls were those with a pH ≥ 7.15 and were matched for gestational age, maternal age, and parity. They examined 190 case-control pairs and the CEFM tracing in the two hours prior to delivery. This study examined the specific FHR characteristics and excluded most high-risk comorbidities and conditions in pregnancy. The study found that fetal tachycardia was the most specific (Point estimate 3.4, 95% CI 1.14-10.14) in predicting neonatal acidemia while variable and late decelerations were the most sensitive (Point estimate 1.12, 95% CI 1.07-1.16). No combinations or interactions of FHR characteristics were examined in this study.

Ultimately, it is not clear which FHR characteristics associated with category II are the most common or the most ominous. Until this is understood, category II CEFM classifications may not be helpful in diagnosing true fetal hypoxia and understanding the best clinical care. Addressing risk status by conducting studies limited to low risk pregnancies remains a need in the literature related to the use of the NICHD three-tiered system and its usefulness at accurately predicting fetal hypoxia in labor. Because the available literature sampled participants from both high and low risk pregnancies, it remains unknown how to interpret CEFM tracings when taking risk status into account. Subcategorizing based on emergent data, rather than on predefined categories or using clinician opinion, is also a need in the literature related to the use of a subcategorized form of the 2008 NICHD three-tiered system. Failure to use emergent data, and instead using preconceived categories, allows for different FHR patterns to be overlooked. Many

FHR characteristics make up the complete FHR pattern. To truly understand the relationship between all individual characteristics and fetal hypoxia, all potential combinations of FHR characteristics must be accounted for. This is important to understand how each individual characteristic of the FHR represented on CEFM impacts the risk for fetal hypoxia. For confidence that the CEFM subcategories adequately identify fetal hypoxia, data is needed to support which FHR pattern characteristics (and combinations of characteristics) belong in which subcategory, related to risk for fetal hypoxia and decision on delivery method.

Well-designed studies focusing on indeterminate FHR patterns were identified as a priority for research into CEFM and FHR tracings at the 2008 NICHD workshop (Macones et al., 2011). Specific recommendations for future research included: “descriptive epidemiology, frequency of specific patterns, and change over time, the relationship to clinically relevant outcomes, and the effect of duration of patterns on clinical outcomes” (Macones et al., 2011, p. 665). However, there has been little research since the 2008 NICHD workshop studying the association between specific category II tracing characteristics and outcomes like cesarean delivery.

## Alternative Methods of Monitoring Fetal Oxygenation

There are alternative methods to monitor the oxygenation of a fetus. One method is fetal scalp sampling. This involves creating a shallow cut to the fetal scalp using a lancet inserted transvaginally to collect the blood from the capillaries cut on the fetal scalp. This method of monitoring has not been widely used in labor and delivery units worldwide. This is, in part, due to the trauma caused to the fetal scalp and because of the limited value it provides in predicting adverse outcomes in fetuses. Fetal scalp sampling is a good method to rule out an uncompromised fetus but not to rule in those fetuses at risk for asphyxia (Al Wattar et al., 2019).

In a recent study of 1422 fetal scalp blood samples, the sensitivity of the fetal blood to predict academia was 22% with a positive predictive value of 4.9% (Al Wattar et al., 2019).

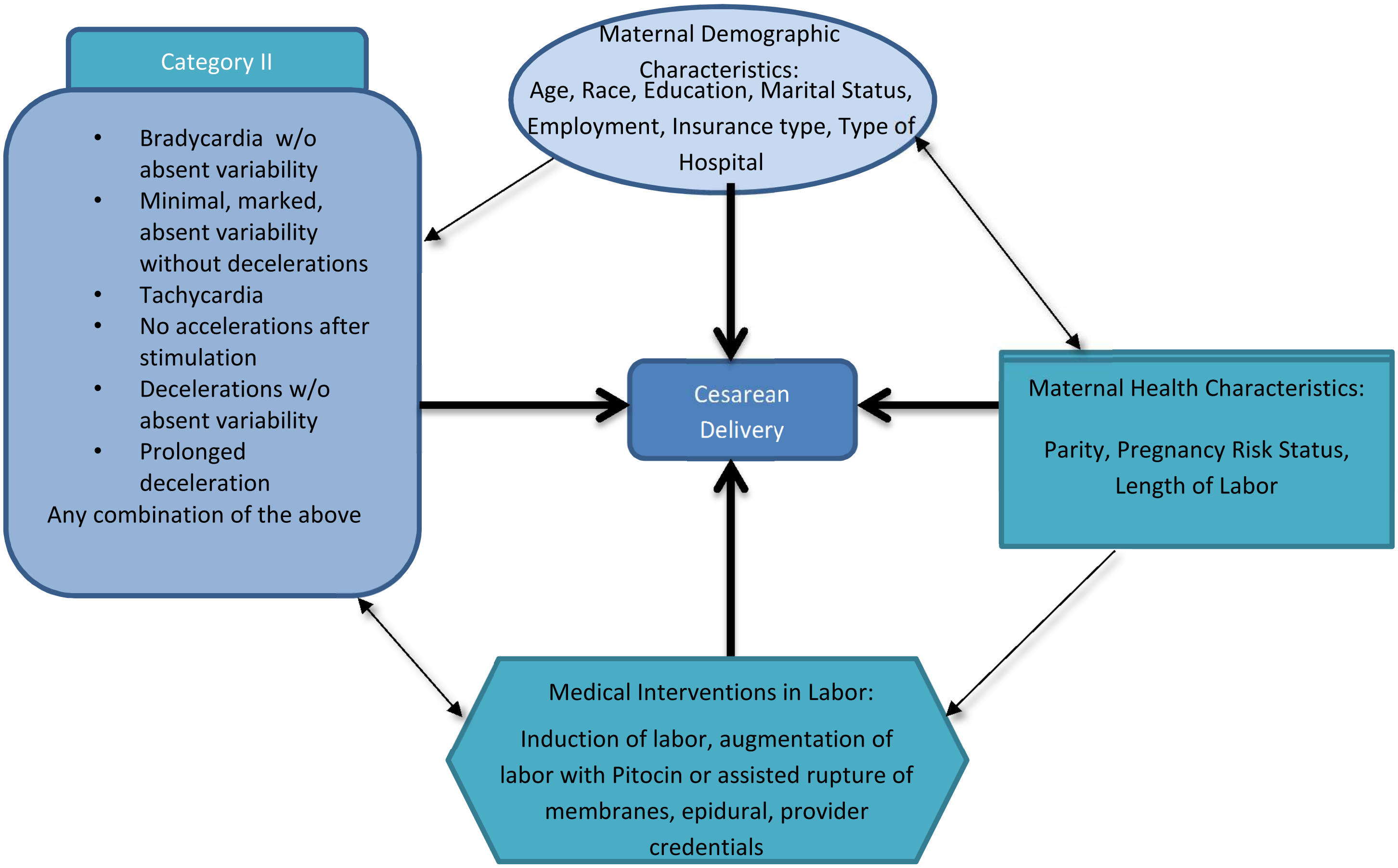
Another method to monitor fetal oxygenation is fetal pulse oximetry. This method uses a probe which sits on the fetal scalp during labor. The probe is inserted transvaginally. A review of seven trials involving over 8000 pregnant women found that the use of fetal pulse oximetry did not improve cesarean rates or improve outcomes for both mother and infant. In fact, in at least one study the use of fetal pulse oximetry increased cesarean rates (East, Begg, Colditz & Lau, 2014).

## Factors Influencing Delivery Method

### Overview

Figure 2 depicts multiple factors that could influence delivery method. In addition to the already discussed category II FHR characteristics, maternal demographic characteristics, maternal health status characteristics, and medical interventions during labor have been related to delivery outcome.

**Figure 2** - Factors Influencing Cesarean Delivery




**Maternal Demographic Characteristics**

Researchers have identified certain demographic variables like age, race, and socioeconomic status as risk factors for cesarean delivery (Heelan-Fancher, et al., 2019, Ciriello, et al., 2012, Hueston, McClaflin, & Claire, 1996; MacDorman et al., 2008).

Age has been identified as an independent risk factor for cesarean delivery. Advanced maternal age, age 35 years and over, has been observed to more than double the risk for cesarean delivery when comparing to mothers aged 20-29 years old (Lialios, Kaponis & Adonakis, 1999). In a study conducted between 1994 and 1998 cesarean rates were noted at 14.83% for mothers aged 20-29, 19.85% for others aged 30-34, and 33.99% for mothers over the age of 35. In a second study the cesarean rate was also observed to increase with age, with the cesarean rate of women less than 25 years at 11.6% while women over 40 delivered by cesarean at a rate of 43.1%. The authors of this study noted that with increasing age came an increase of history of myomectomies or mal-presentation, which are both risk factors for cesarean delivery without labor. The study also found diagnoses of fetal distress and failure to progress increase with age, which are both risk factors for cesarean with labor (Ecker, Chen, Cohen, Riley, & Lieberman, 2001). This result was duplicated in a 2019 study of 3513 nulliparous women. The study found a statistically significant increase in the risk of emergency cesarean delivery in women over 35 compared to women less than 30 (adjusted OR: 1.805, CI 1.347, 2.418). They also found cesareans for non-reassuring FHR was increased in mothers over 40 years of age (adjusted OR 5.354, CI 2.386, 12.017) (Kim et al., 2019).

Race is a significant risk factor for cesarean delivery even when controlling for significant confounding variables. In a five-year study, African-American women had higher rates of cesarean delivery than spontaneous vaginal delivery when controlling for confounders (OR: 1.43, 95% CI: 1.07, 1.91, $p<0.01$). Asian women were also observed to have higher rates of cesarean (OR: 1.49, 95% CI: 1.01, 2.17, $p <0.04$). Caucasian and Hispanic women were not found to have statistically significant difference in delivery type. Compared to Caucasian women, African-American women are at a significant risk of cesarean delivery for fetal distress (Heelan-Fancher et al., 2019; Edmonds et al., 2013). In another study analyzing data from over 20 years, African-American women were observed to have a 1.48 times greater risk of delivering by cesarean than their Caucasian counterparts, with Latina women having a 1.48 times greater risk of cesarean than Caucasian women (Bryant, Washington, Kuppermann, Cheng, & Caughey, 2009).

Maternal level of education is also related to risk for cesarean delivery. Multiple studies on maternal level of education and cesarean delivery have been conducted outside the United States. One such study found the higher the level of education of a mother, the lower the risk for cesarean delivery and the higher the rates of spontaneous vaginal delivery (Cammu, Martens, & Keirse, 2011). Another study, conducted in Italy, found that women with a high school diploma had a 24% (95% CI: 12-37) increased risk of cesarean delivery compared to women with a 4-year college degree (Cesaroni, Forastiere, Perucci, 2008). A Norwegian study conducted over nearly 40 years found that risk for cesarean delivery was inversely related to level of education, with the highest educated mothers having the lowest risk for cesarean delivery and vice versa (Tollanes, Thompson, Daltveit, & Irgens, 2007).

Marital status has been studied in relation to cesarean outcome. A Puerto Rican study found that unwed mothers had higher rates of cesarean delivery than married mothers when controlling for age (Vazquez-Calzada, 1997). However, other studies have found increased risk of cesarean delivery in married women. One study conducted in the US between 1965 and 1986 found married women had a cesarean rate per 100 deliveries of 14% versus never married women at a rate of 7.8% per 100 (Shepard, Saftlas, Leo-Summers, & Bracken, 1998). Another study found married women had a cesarean rate of 11.4% while unmarried women had a primary cesarean rate of 9.4% (Amini, Catalano, & Mann, 1996). However, this difference was not statistically significant. It is possible that marital status could be directly related to age, which may explain the increase in cesarean delivery with age.

When comparing homemakers with white collar workers, employment outside the home has been observed to be associated with an increased risk for cesarean for fetal distress (Smith, Brix, & Heaton, 1988). Another study confirmed this finding of decreased risk of cesarean for homemakers (Simoes, Kunz, Bosing-Schwenkglenks, & Schmahl, 2005). Little data exists on risk for cesarean delivery and unemployment status.

When controlling for other demographic factors as well as clinical and hospital factors, patients with Medicaid had a lower risk of cesarean delivery when compared with those with private insurance (OR: 0.91) (Kozhimannil, Shippe, Adegoke, & Vernig, 2013). These results were confirmed in another study which found a statistically significant increase in risk for cesarean when privately insured versus public insurance (Movsas, Wells, Mangoven, & Grigorescu, 2012). A third study found that the cesarean rate is higher in privately insured women compared to the uninsured as well (Onion, Meyer, Wenneberg, & Soule, 1999). The association of WIC participation and cesarean delivery has not been studied and the relationship is not understood.

## Medical Interventions in Labor

Induction of labor is a risk for cesarean delivery. In a 2013 study both nulliparous and multiparous women undergoing an induction of labor had a cesarean delivery rate which was more than double that of spontaneous labor (Levine, Hirshberg, & Srinivas, 2013). Risk for cesarean delivery was doubled in another study comparing elective induction with spontaneous labor (OR: 2.5, 95% CI: 1.4-4.2) (Jonsson, Cnattingius, & Wikstrom, 2013). Augmentation of labor is often achieved with exogenous oxytocin and assisted rupture of membranes. A 2010 study found oxytocin augmentation greatly increased the odds of cesarean delivery (OR: 4.678) (Indraccolo et al., 2010). Assisted rupture of membranes (or amniotomy) is associated with a decreased length of labor but also an increase in cesarean delivery (OR: 1.26, 95% CI: 0.96-1.66) (Fraser, Turcot, Krauss, & Brisson-Carrol, 2000). A 2019 study of 3513 nulliparous women found that induction of labor increased the risk for emergency cesarean (OR: 2.489, CI 2.043, 3.033) (Kim et al., 2019). However, a systematic review of seven randomized control trials with

7598 total study participants did find that induction of labor at or around 39 weeks was not associated with an increased risk of cesarean delivery. Uncomplicated, full-term, singleton gestation subjects were randomized into induction during the 39th week of the pregnancy. The induction group had a cesarean rate of 21.4% while the control (expectant management) group had a cesarean rate of 20.3% (RR: 0.96, CI 0.78, 1.19), an insignificant difference (Saccone et al., 2019).

Epidural analgesia has also been observed to be associated with a significant increase in cesarean delivery. In a 2012 study cesarean delivery was observed at an odds ratio of 2.46 when compared to spontaneous vaginal delivery in patients with an epidural (95% CI: 1.82-3.33) (Schuit et al., 2012). This study's findings reflected an earlier study which found a 5.8 increased odds of cesarean with epidural analgesia (95% CI: 4.1-8.1) (Eriksen, Nohr, & Kjaergaard, 2011).

Health care provider training and differences between providers of the same type have been studied more in the decision to perform a vaginal birth after cesarean (VBAC). However, studies have observed trends that may be related to provider training. One such study found that during evening hours, patients were at a statistically significant increased chance for cesarean delivery (Haberman et al., 2013). Another study conducted in 2004 found obstetricians believed women had the right to request a cesarean without maternal or fetal complications, with midwives believing the opposite. The findings of this study were significant ($p<0.001$) (Reime et al., 2004). This indicates different provider groups may approach labor from differing paradigms, indicating provider training may play a large role in the decision making in labor. Finally, a 1999 study found that patients treated by resident physicians had greater number of cesarean deliveries than private physicians ($p<0.0001$), but that alternative action plans were suggested more often by private physicians ($p<0.0001$) (Peipert, Hogan, Gifford, Chase, & Randall, 1999). This suggests private physicians and resident physicians may use differing criteria to decide to deliver by cesarean.

Potential confounding or modifying variables related to the induction or augmentation of labor, epidural status, and provider preference have been identified as increasing the risk of cesarean delivery. To understand the relationship between the differing FHR patterns and potential combinations of patterns within category II CEFM and cesarean delivery outcome, the variables which may contribute to cesarean delivery should be controlled for.

It is also important to note that regional, and even hospital, differences exist in the use of cesarean delivery types. United States cesarean delivery rates varied from 4 - 65% across differing communities. A study by Little, Orav, Robinson, and Jha (2016) utilized a population-based, observational study that used multiple national sources of data, including birth certificates and Medicaid data. The study found 28.6% of the variation in the rates of cesarean were explained by differences in health care patterns in usage, 16.6% by obstetric procedure differences, 7.9% by the hospital structure, and 2.3% by variations in the malpractice environment of the area. Therefore, it is possible private and public hospitals may have differing practices related to obstetric intervention even in the same community. Differences in payer time, demographic characteristics, types of provider and provider training, and community characteristics can have an impact on delivery practices in individual labor and delivery units.

**Maternal Health Characteristics**

Researchers have observed drastically increased risk of cesarean delivery in mothers with a body mass index (BMI) greater than 30 (OR: 9.558, 95% CI: 5.92-17.27) (Jain, Khuteta, Chaturvedi, & Khuteta, 2012). Likelihood of cesarean delivery seems to increase with BMI. A 2013 study found that morbidly obese women delivered by cesarean at a rate of 60.6% compared to women of normal BMI at 25% (Crane, Murphy, Burrage, & Hutchens, 2013). These findings have been confirmed by other studies, including one study that found while 31.4% of normal weight women required cesarean delivery, 39.1% of overweight, 40.8% of obese and 56.6% of morbidly obese women required cesarean delivery (Berendzen & Howard, 2013).

Two recent, applicable studies identified the potential for other maternal characteristics to affect the delivery method. Those variables included maternal age, BMI, parity, smoking, and diabetes (Schnettler et al., 2012; Jackson et al., 2011). Jackson et al. (2011) found that nulliparous participants spent more time in category II than multiparous participants. No other potential confounders, modifiers or significant risk factors were identified in any of the applicable studies released since the 2008 NICHD CEFM workshop.

Research has highlighted the indeterminate nature of category II as evidenced by inconsistency in interpretation the broad range of FHR characteristics within the category and the lack of interventions specific to the category. However, one cannot deduce that category II FHR patterns are related to cesarean in low risk labor without considering the potential effect of demographic variables, modifiers, and confounders on cesarean as an outcome.

Few studies have examined the specific FHR characteristics of category II, and none have limited the study sample to low risk laboring women. There are a few studies which have attempted to break category II into subcategories, however the fetal heart rates characteristics of the subcategories were determined prior to initiation of the study and not determined by the data from their studies. No studies about the 2008 NICHD categories have been identified which control for potential confounding characteristics which may influence delivery outcome, aside from parity.

## Conclusion

The ultimate goal of labor and delivery practitioners is the delivery of a healthy infant to a healthy mom, with no harm done to either mother or fetus. The high cesarean delivery rate in the United States may be directly related to a vague category II CEFM tracing, and the lack of standardization of interventions related to those CEFM categories. The American Congress of Obstetricians and Gynecologists and the American College of Nurse Midwives both agree that the use of CEFM in low risk labor can increase unnecessary intervention and negatively impact mother and baby (ACOG, 2005; ACNM, 2010). However, it is also possible that the cesarean rate may be influenced by other confounders, modifiers, and risk factors. In order to understand the relationship between FHR pattern characteristics within category II and cesarean delivery, it is necessary to study low risk pregnancies to help control potential modifying/confounding variables associated with high risk pregnancies. It is also important that potential subcategories emerge from the data so that all potential FHR pattern combinations can be accounted for. In other words, subcategories should be based on observed FHR pattern combinations that are associated with poor delivery outcomes rather than preconceived notions. This will prevent practitioners from biasing CEFM tracings based less on their specific training, paradigm and personal experience, and more upon what the individual FHR characteristics tell us about the oxygenation of a fetus. And finally, it is necessary for research on category II CEFM patterns to control for variables which may potentially influence delivery outcome, even in low risk pregnancies.

# CHAPTER 3: METHODS

## Design and Overview

The purpose of this retrospective longitudinal study was to identify specific FHR characteristics and patterns within the NICHD indeterminate category II that are associated with cesarean for low risk pregnancies in the two hours prior to delivery. This research attempted to identify fetal heart rate (FHR) characteristics which may be associated with negative outcomes including cesarean delivery. The study included 537 low risk pregnant women and their fetuses/newborns with category II FHR tracings (indeterminate risk for hypoxia) based on continuous electronic fetal monitoring (CEFM.) The participants, low risk women, delivered at a large Midwestern academic tertiary care center between 1/2014 and 6/2015, either vaginally (n = 408) or by primary cesarean for fetal intolerance to labor (n = 129). Variables collected include: category II FHR characteristics in the two hours prior to delivery (time spent in category II, baseline FHR, variability, accelerations, decelerations), credentials of delivery provider, epidural status, labor induction methods, labor augmentation, and demographic characteristics (age, marital status, race/ethnicity, insurance status). The overall goal of this program of research is reducing the cesarean delivery rate in low risk mothers and improving birth outcomes.

## Purpose

The purpose of this study was to identify FHR characteristics and patterns within the indeterminate category II that increase odds for cesarean for low risk pregnancies in the two hours prior to delivery.

## Aims

Aim 1: To describe the distribution of specific category II FHR characteristics in low risk pregnancies in the two hours prior to delivery. These characteristics include: FHR baseline, variability, accelerations, and decelerations.

Aim 2: To examine the association between category II FHR characteristics and cesarean deliveries in the two hours prior to delivery in women with low risk pregnancies. Null hypothesis: there is no association between category II FHR characteristics and cesarean deliveries in the two hours prior to delivery in women with low risk pregnancies.

Aim 3: To determine independent associations between category II CEFM FHR characteristics and delivery method (vaginal versus cesarean) after controlling for covariates. The covariates include: method of induction or augmentation of labor, if used, epidural analgesia use, attending provider at delivery, as well as demographic characteristics. Null hypothesis: there is no association between category II CEFM FHR characteristics and delivery method after controlling for demographic characteristics and covariates.

Exploratory Aim: To identify clusters of category II FHR characteristics and associations with delivery method in the two hours prior to delivery. These characteristics include: FHR baseline, variability, accelerations, and decelerations, as well as total time spent in category II CEFM FHR patterns. Null hypothesis: there is no association between clusters and delivery outcome in the two hours prior to delivery.

## Setting and Sample

Mother and infant medical record data were obtained from the University of Iowa Hospitals and Clinics (UIHC). UIHC is a large Midwestern academic tertiary care center. Patients admitted to the labor and delivery unit at UIHC range from low risk mother infant dyads to the highest risk, highest acuity patients in the state of Iowa, and some of the surrounding states. The labor and delivery unit employs midwives, resident obstetrician-gynecologists, staff obstetrician-gynecologists, maternal-fetal medicine fellows and maternal-fetal medicine staff physicians, masters- and doctorally-prepared clinical nurses, staff nurses, and support staff.

The target population for this study included low risk pregnant mothers and their fetuses at 37 weeks to 41 weeks 7 days, who delivered at UIHC between 1/2014 and 6/2015, anticipating a vaginal delivery. For this study, low risk pregnant mothers were defined as mothers who had a singleton pregnancy with the fetus in the vertex (head presenting in the maternal pelvis) position and who did not have medical complications (examples include but are not limited to: preeclampsia, diabetes, hypertension, and fetal anomalies). High risk fetuses may have a decreased ability to respond to the periods of decreased oxygen associated with the contractions of active labor and, therefore, the FHR patterns of high risk and low risk fetuses may not be comparable.

**Inclusion Criteria**

Specific inclusion and criteria and related rationale are as follows:

1. Women ages 16-42 with: term (37+ weeks, < 42 weeks) gestation.
    - The majority of women delivering babies are between ages 16-42. After age 35 the mother is considered of advanced maternal age. However, many of these babies are born with no abnormalities. Any fetus diagnosed with complications prior to delivery was considered high risk and therefore, excluded (Gabbe et al., 2012).
    - The fetus is considered term at 37 weeks, placing an otherwise uncomplicated pregnancy at low risk. The term fetus is considered neurologically intact and should, therefore, be capable of withstanding the normal stress of labor and delivery (Gabbe et al., 2012).

2. Low risk women who labored, for at least two hours, in anticipation of a vaginal delivery at UIHC and had CEFM tracings that fell into category II FHR tracing at any point during the two hours prior to delivery.
    - The two-hour time frame was chosen to capture the data a provider would be using to influence their decision to proceed with delivery. In 2005 a study examined the use of fetal pulse oximetry in addition to CEFM and the “decision-to-incision” time. The 177 study participants which were part of the control group (CEFM alone) had a decision-to-incision time of 27.7 minutes ±13.9 and 58% of the control group having a decision-to-incision time of 30 minutes or less (Klauser et al., 2005). The Klauser and colleagues (2005) study used high-risk participants. It is possible that pregnancy risk status may influence decision-to-deliver. Therefore, using this study as a frame of reference, expanding the collection the FHR data to two hours prior to delivery should capture the majority of CEFM data influencing the decision to proceed with a cesarean delivery.
    - The two-hour time frame was also chosen by Gyamfi-Bannerman and colleagues (2011). This study, as discussed earlier, examined the FHR tracings of both high and low risk participants and categorized the tracings using a subcategorized version of the NICHD three-tier system, as well as other FHR monitoring methods. This data was then compared with umbilical cord gases. Using the same two-hour time frame allowed for outcome comparisons.
3. Any mother-fetus dyad that did not have any diagnoses that would place either the mother or fetus in a high-risk status at the time of admission to the labor and delivery unit. (This did not eliminate mothers that developed a fever during their labor.)

- In two quite recent studies (Cahill et al., 2018; Toomey & Oppenheimer, 2019) the CEFM tracings in the two hours prior to delivery were studied. The Toomey and Oppenheimer study also focused on low-risk labor, and can serve as a comparison study.

**Exclusion Criteria**

Exclusion criteria included:

1. Women with a preterm delivery or high-risk pregnancy.
    - Examples of high-risk pregnancy conditions include, but are not limited to: preeclampsia, eclampsia, diabetes, chronic or gestational hypertension, multiple gestation (twins, triplets, etc.), fetal anomalies, maternal diabetes, maternal/fetal cardiac diagnoses, and previous uterine incision. Excluding preterm and high-risk pregnancies minimizes the chance that early gestation and maternal or fetal diagnoses could influence the CEFM tracing and decision regarding the best method for delivery.
2. Any study participant that did not have a category II CEFM tracing in the two hours prior to delivery was excluded.
    - Some potential study participants delivered shortly after arrival to the labor and delivery unit. Additionally, some low risk participants had intermittent fetal monitoring. These potential participants did not have the CEFM records necessary to make an appropriate comparison to the other study participants meeting inclusion criteria.
3. Mothers delivering by cesarean for any reason other than fetal distress were excluded.

- The focus of this study was how the CEFM tracing influences the decision to allow a vaginal delivery or proceed with a cesarean in the event of perceived fetal distress. Other reasons for proceeding to cesarean delivery are related to failure for the fetus to descend properly, maternal exhaustion, or other reasons unrelated to the FHR and therefore those mother-infant dyads receiving a cesarean delivery for any other reason than fetal distress were excluded from the study.

4. Age below 16 years or greater than 42 years.

## Sample Size Calculation

Currently, no literature exists regarding specific category II FHR characteristics and the decision to proceed with cesarean delivery. Estimated sample size was calculated for multiple logistic regression using G-Power software. Estimating the proportion of cesarean deliveries (the lowest occurring event) at .24 with multiple covariates, a sample size of 536 women composed of 129 cesarean deliveries and 407 normal vaginal deliveries will allow the detection of a minimal Odds Ratio of 1.5, with significance of 0.05 and a power of 0.8.

## Participant Pool

In 2014, there were 2112 total births to women between 16 and 40 at UIHC. Of those, 936 were low risk as defined in this study (both vaginal and cesarean deliveries). Approximately 75 participants were eliminated due to not having two hours of CEFM tracing. Another 60 women were eliminated for other reasons (high risk status not included in delivery summary, thus making it into the report), leaving 801 eligible participants. Of those, 625 did deliver vaginally. This study sample size required at least 536 participants with 407 vaginal deliveries.

There were 176 low risk cesarean deliveries at UIHC in 2014. Of the low risk cesarean deliveries, 100 were for reasons other than fetal intolerance to labor (fetal hypoxia) and were thus eliminated prior to obtaining the data report from the study hospital, leaving 76 of the remaining cesarean deliveries for fetal intolerance to labor (risk of fetal hypoxia) for inclusion in the study. Since the sample size for this study required 129 cesarean deliveries, acquisition of participants having a primary cesarean delivery for fetal distress was extended to the first six months of 2015. In all of 2015 there were 197 cesarean deliveries that meet the inclusion criteria. This was sufficient to meet the required sample size of 129 primary cesarean deliveries for fetal distress, needing 53 cesareans in the first 6 months of 2015 to minimize the impact of a new resident class entering the study. There were no changes in practice standards regarding when to perform a cesarean delivery that would bias the study results.

It was anticipated that the number of vaginal deliveries necessary for inclusion in the study sample will be 407. This is less than the number of low risk deliveries which would meet inclusion criteria available. The medical record numbers (MRN) of each potential participant were placed in alphabetical order and printed, with between 25 – 30 MRNs per page. Names were deleted upon receipt to maintain confidentiality. Pages of MRNs were given to the PI and research assistant to guide data collection. Distribution of pages was: one page taken from top of pile of MRN pages (early alphabet), one from the bottom (late alphabet), and one from the middle of the pile (mid-alphabet) until the target number of 407 vaginal deliveries was reached.

## Instruments and Data Collection

All data were obtained from two electronic medical record systems: *OBTraceVue* (otherwise known as *Phillips IntelliSpace Perinatal*) and *Epic*. *Epic* medical record data for this study was downloaded as an electronic spreadsheet from the delivery summary and demographic overview and included demographic and some medical variables. Length of labor was manually extracted from Epic, as it did not populate on the reports run from the delivery summary or demographic overview. Length of labor was calculated by taking the length of the 1$^{st}$ and 2$^{nd}$ stage of labor from the physician's notes in the medical record. The FHR characteristics were abstracted from *OBTraceVue*, computer software which displays the FHR and uterine contraction activity characteristics as lines on a grid, enabling the provider to decipher FHR baseline, variability, accelerations, and decelerations. Data abstraction was completed by the PI (a practicing labor and delivery nurse) and another labor and delivery nurse (research assistant) working at UIHC.

The study hospital used *Epic* electronic medical record, which is utilized by at least 274 healthcare organizations (Epic, 2015). Data that were extracted from the *Epic* electronic medical record included: demographic characteristics, descriptive data relating to maternal health and obstetric history, outcomes data, and situational labor and delivery data that may have influenced the CEFM FHR tracings (see Appendix). Most of the data was collected from the delivery summary using the "Report" function in *Epic* to select the desired variables and download them, matched to the participant, in an electronic spreadsheet format. Much of the data collected from the *Epic* medical record was available on a single electronic form, the delivery summary in *Epic* (see Appendix) Per UIHC policy and *Epic* electronic protocols, the delivery summary must be filled out completely and signed by the nurse caring for the patient. Therefore, most of the variables of interest were available in the *Epic* electronic medical record for collection in this study. However, if data was missing from the delivery record, the history and physical and clinician's delivery notes were examined for the missing data. No background data exists to document the accuracy of the medical records on the labor and delivery unit at UIHC.

**Demographic Variables**

The following demographic characteristics were collected: maternal age, and race. Age is calculated by *Epic* using the birthdate listed in the medical record. Birthdate was either self-reported when the patient came to UIHC for services, was reported by a transferring health care center, or came from a birth record if the participant was born at UIHC. Race/ethnicity information was self-reported. Race was part of the admission flow sheet. Data on these characteristics was available for each study participant. For any missing demographic data, study participants were included and marked as “unknown,” eventually being placed in the “other” category. Approximately 1.5% of race data was missing or unknown.

**Obstetric History**

Obstetric history data (descriptive data) collected included parity (number of previous deliveries), and gestational age (in weeks and days). Parity and gestational age were included in all *Epic* medical records including the physicians’ notes. Both characteristics were recorded at the first prenatal visit and entered by the nurse. If the study participant delivered previously at UIHC, *Epic* automatically updated parity based on the delivery summary. Medical records from other institutions were collected whenever possible to validate claims of parity. In rare cases, most notably for participants who previously delivered overseas, parity data was only based on the participant’s report of their obstetrical history. *Epic* medical records at UICH had three options for recording gestational age: date by last menstrual period, date by ultrasound, and date by maternal report. The date deemed most accurate was bulleted by the practitioner and populated into the information on the electronic medical record. Gestational age is generally calculated as 40 weeks from the last menstrual period, but may be modified by the provider if significant difference in fetal development in relation to gestational age is noted on ultrasound. For the purpose of this study, the gestational age bulleted by the practitioner was used to define gestational age.

**Outcomes**

The outcome of interest is method of delivery. Data included: spontaneous vaginal delivery, or primary cesarean for fetal distress. Data were also requested for assisted vaginal delivery (forceps or vacuum delivery). Too few assisted vaginal deliveries met the inclusion criteria to be included in the study. This data was available from the delivery summary and can be collected in a report.

### Interventions and Care in Labor

Data were also collected on interventions during labor that may influence CEFM FHR patterns and included: induction and augmentation of labor (cervical ripening, oxytocin administration, and assisted rupture of membranes), and epidural use. These variables were entered by the nurse caring for the patient into the delivery summary on *Epic* and were collected in a report. The delivery summary cannot be signed without filling in the sections pertaining to all of the interventions of interest in this study. Therefore, this data was available on 100% of study participants. However, it should be noted that if multiple interventions were used it is possible that not all options may have been selected on the delivery summary. No data exists to determine the accuracy of charting on UIHC's labor and delivery unit.

### Health Care Provider Characteristics

Finally, to determine if decision to deliver varies among clinicians, the delivering clinicians and their credentials were also collected. The name of the delivery provider must be included in the delivery summary before the delivery summary could be signed by the nurse. The name of the provider is found directly after the date and time of delivery. These names and credentials can be abstracted from the delivery summary and were entered by the nurse caring for the patient. The names of physicians and midwives were all coded numerically to protect the clinicians' privacy. Coding the credentials of the delivering provider (CNM, Family Practice Physician, general Obstetrician-Gynecologist, and High-risk Obstetrician/Maternal-Fetal Medicine Specialist) also decreased the number of variables collected assisting with the analysis of the results of the study. At UIHC there were three attending providers on the unit at any given time, one attending from OB (this could be either a GOB or MFM), a family practice attending physician, and a midwife. Whichever provider type was caring for the patient at the time of decision for delivery was documented as the health care provider for this study.

**Fetal Heart Rate Characteristics**

The CEFM data were archived on the CEFM software Philips *IntelliSpace Perinatal*, otherwise known as *OBTraceView*. If the computer system went offline during a study participant's labor, it was protocol for the hospital to save paper copies of the CEFM tracing. No study participants' CEFM tracings were removed from labor and delivery, and all records were examined in a private area to protect the participant's privacy and confidentiality.

Two hours of CEFM tracings immediately prior to delivery were examined for each study participant. Data collected from the CEFM tracings included: length of time spent in category II, baseline FHR, and variability during the category II tracings, as well as presence of FHR accelerations and decelerations and type of decelerations noted during category II tracings. Each FHR characteristic was also subcategorized as normal or abnormal. Baseline FHR was considered normal when between 110-160 bpm and abnormal when outside those parameters. Variability was considered normal when meeting NICHD criteria for the moderate classification, all other classifications were considered abnormal. Accelerations were considered normal when present with other category and abnormal when absent. Early and absent decelerations were considered normal, while variable, late, and prolonged decelerations were considered abnormal. Given the amount of artifact and difficulty identifying decelerations just prior to the vaginal birth of a baby, the 15 minutes prior to delivery was left out of multivariate analyses.

CEFM tracings are dependent upon the proper application of the ultrasound transducer and tocodynamometer. The CEFM tracing does, at times, actually pick up the maternal pulse. These periods of maternal tracing are usually obvious to those trained in CEFM interpretation. If it appeared the maternal pulse is being traced instead of the FHR that data from that period was not be included in the interpretation of category II CEFM tracings. If it was unclear if the CEFM tracing is reading the FHR or the maternal pulse the data was not included.

**Abstracting Process/Inter-rater Reliability**

CEFM tracings data were extracted by the PI and one labor and delivery nurse working at UIHC. The PI is an experienced labor and delivery nurse, having taken advanced fetal monitoring classes and passed examinations required by the unit educator in order to complete the class. The labor and delivery nurse recruited for data extraction for this study had at least three years' experience as a practicing labor and delivery nurse and had taken the same 8-hour advanced fetal monitoring class. The course covered individual FHR characteristics and the etiology behind the FHR characteristics, uterine contractions, medication management and interventions for abnormal FHR characteristics. The test was a 5-page assessment of 20 CEFM tracings. Nurses were required to decipher FHR baseline, FHR variability, presence of accelerations, presence and type of decelerations, and assessment of timing between and during contractions. This class was required for all labor and delivery nurses after completing basic fetal monitoring and intermediate fetal monitoring classes.

To ensure interrater reliability the research assistant extracted the same data from five two-hour CEFM strips which are unrelated to this study and have been examined by a Maternal-Fetal Medicine (MFM) Specialist. Data extracted included: total time spent in category II in eight 15-minute segments (equaling two hours of CEFM tracing), baseline FHR, type of variability, presence of accelerations, and presence of decelerations (and type of decelerations). This data was entered into RedCAP (see Appendix). The PI and research assistant matched the assessment of the MFM at 95% or better before abstracting the study data. Initially, 1 in 5 of the CEFM tracings reviewed by the research assistant were reviewed by the PI until agreement of 90% or greater was achieved. Disagreements were reviewed and resolved by the PI and the nurse research assistant. The tracing in question was examined together by both the PI and nurse research assistant to come to an agreement on the FHR characteristics in question. If no agreement was made, a Maternal-Fetal Medicine Specialist involved in this study would have been brought in to help determine the correct assessment of the tracing, however this was not necessary. This process continued until an agreement of 90% or greater was achieved. A 90% agreement was achieved very early in the study, therefore the PI continued to review 20% of all of the CEFM study tracings collected by the research assistant.

## Procedures

A list of the medical record numbers (MRN) of pregnant women with live, singleton pregnancies at 37 weeks or greater during the study period was compiled by *Epic* Information Technology (IT) specialists, which was immediately de-identified upon receipt. A Microsoft Excel report of all vaginal deliveries from 2014 and cesareans for fetal distress in 2014 – June 2015 was collected excluding delivery summaries with any high-risk conditions noted on the delivery summary. The IT specialist was given a list of all of the high-risk conditions that appear on the delivery summary to exclude when creating the report. Using the medical record numbers for the resulting deliveries, demographic data as well as parity and gestational age were added to the report. Variables such as epidural status, labor induction and augmentation methods, and delivery provider were collected in the report from the delivery summary as well. From this report the PI and research assistant examined the *Epic* medical record to ensure the participant met inclusion criteria and did not meet any of the exclusion criteria using the history and physical and provider's delivery note. In addition, the PI and research assistant extracted total time of labor from the provider's delivery note.

The two hours of CEFM strips were broken down into eight 15-minute segments or intervals. Each 15-minute interval was examined for total minutes spent in category II. If category II tracing characteristics were noted in an interval the baseline FHR, variability, presence of accelerations, and presence/type of decelerations were collected for that interval category II tracing. By breaking the two hours of data into 15-minute intervals and collecting the category II FHR characteristics present in each of the resulting eight intervals, analyses were conducted to see how the characteristics occur over time.

Permission to access the medical records of pregnant mothers and their infants to determine study eligibility and to abstract medical record data from eligible participants was obtained from the institutional IRB.

**Data Management and Analysis**

All data were de-identified and accessed via computers on the labor and delivery unit at the study hospital or by the PI's secure, password-protected laptop computer. All data were entered directly into the data management system RedCAP. Any notes taken were shredded after being entered into RedCAP (see Appendix). RedCAP data was combined with data from an Excel file created by the *Epic* reporting team at UICH using medical record numbers (MRNs) as the identifier using the V Look-up feature in Excel. In rare instances data including delivery method, race, age, and parity were missing from the combined data. In these instances, the MRN identified with the subject was searched using the *Epic* medical record and the missing data was corrected.

Data was compiled from two sources: the report provided by the *Epic* Report Team and RedCAP database. In rare instances, MRNs with transposed numbers were identified and combined as appropriate For example, the MRN entered into RedCAP may have had one number transposed which did not match with the MRN from the data set provided by the UIHC *Epic* Report Team. In these instances, it was evident that data from one of the sources was missing.

Using a control+F function in Excel the transposed MRN was identified and combined with the correct MRN creating a correct record.

Occasionally extreme or impossible results were recorded on the RedCAP database (example, baseline FHR of 1600). In these instances, the record in question was identified by the record number and the impossible outcome was compared to the medical record and corrected. The impossible results were all identified in the RedCAP database and were a result of duplication of numbers (example a baseline FHR of 1600 was in reality 160) or transposition of numbers in the MRN (example 0123456 was recorded as 0123455). Each line of data was examined for appropriateness of outcome. This process resulted in the cleaning of all data for this study.

Statistical analysis of data was completed using *SAS* version 9.4 statistical software. Descriptive statistics were conducted on all variables including mean, median, range, and standard deviation for normally distributed variables (i.e. age). Frequencies and percentages were computed on categorical study variables (i.e. race). T-tests were used to test bivariate associations for continuous normally distributed data. Chi-square was used to test bivariate associations between categorical variables. Non-parametric Wilcoxon Rank Sum tests were used to test non-normally distributed continuous data. Logistic regression analysis was the major multivariable analytic approach when the dependent variable was categorical (vaginal vs. cesarean delivery).

Specific statistical approaches for each study aim were as follows:

Aim 1: To describe the distribution of specific category II FHR characteristics in low risk pregnancies in the two hours prior to delivery. These characteristics include: FHR baseline, variability, accelerations, and decelerations.

Time spent in category II is a continuous variable and was described in medians and ranges, as it was non-parametric data. Baseline fetal heart rate was initially a continuous variable and was described in means and standard deviations. The other FHR characteristics (variability, accelerations, and decelerations) were categorical. Variability had four categories: absent, minimal, moderate, and marked. Accelerations had two categories: present, not present. Decelerations had four categories: early, variable, late, prolonged. Categorical variables were described in numbers, percentages, and ranges.

Initial analysis of the numbers and percentages for each FHR characteristic at the interval level resulted in collapsing of the FHR characteristic variables. This was done for two reasons. First, a number of the cells had too few subjects to be useful in the analysis (e.g. only five cesarean subjects had minimal variability in interval 3). The second reason for collapsing variables was that any subject without category II FHR characteristics in a given interval was captured as missing during the initial analysis. Given there was no category III FHR tracing included in this study it is presumed that these subjects with missing data were in category I, or there was an interruption in FHR monitoring. Therefore, these subjects were providing normal data that wasn't being captured. Therefore, each individual category II FHR characteristic (baseline FHR, FHR variability, FHR accelerations and decelerations) was collapsed into normal (WNL) and abnormal (NWNL). Baseline FHR was grouped into normal = 110-160 bpm with abnormal being outside of those parameters. Variability was grouped into normal = moderate and blanks. Moderate variability is considered a normal FHR characteristic. The absence of any variability data in a given interval indicates a Category I tracing (and therefore moderate variability) during that interval and was, therefore, considered normal (WNL). Any intervals with absent, minimal, or marked variability were grouped into abnormal variability (NWNL). If accelerations were present in the absence of other category II FHR characteristics they would have not been documented in this particular study. Therefore, when accelerations were identified or left blank, those observations were considered normal (WNL). When accelerations were noted as absent (or none), this was collapsed into abnormal (NWNL). Lastly, when no FHR variables or early decelerations (which are considered normal during labor) were observed they were classified as normal (WNL) versus variable, late, or prolonged decelerations being classified as abnormal (NWNL).

Also upon considering this data the decision was made to create three new continuous descriptive variables: Onset Interval (the interval in which the first category II characteristic was observed), Total Number of Intervals (the total number of intervals with category II FHR characteristics present [range from 1-8]), and Total Number of Characteristics Per Interval (the number of characteristics present in a given interval [range from 1-4]).

Aim 2: To examine the association between specific category II FHR characteristics and cesarean deliveries in the two hours prior to delivery in women with low risk participants. Null hypothesis: there is no association between specific category II FHR characteristics and cesarean deliveries in the two hours prior to delivery in low risk participants. These characteristics include: time spent in category II (continuous data), baseline FHR (categorical data), FHR variability (categorical data), FHR accelerations (dichotomous data), FHR decelerations (categorical data), and delivery method (categorical data).

Initially FHR characteristics were visually evaluated by delivery method using figures and plots across all intervals. FHR characteristics were described for each interval separately. Analyses of each FHR characteristic and new variables were conducted to detect a significant difference in each characteristic and delivery method. Categorical variables were examined using chi-square, odds ratios, and confidence intervals. Continuous variables were examined using t-tests.

Aim 3: To determine independent associations between category II CEFM FHR characteristics and delivery method after controlling for covariates. The covariates include: method of induction or augmentation of labor, if used, epidural analgesia use, and credentials of the delivering provider, as well as maternal demographic characteristics. Null hypothesis: there is no association between category II CEFM FHR characteristics and delivery method after controlling for demographic characteristics and covariates. The dependent variable is delivery method (vaginal vs. cesarean delivery). The FHR characteristics of interest include all those identified in Aim 1.

Upon the descriptive analysis of covariates, the decision was made to collapse certain variables based on the low number of study subjects which were assigned each category. Race was collapsed into Caucasian and all others (African American, Hispanic/Latino, Asian, Other). These groups were combined to aid in analyses given the low volume of each group represented in the study.

In addition, method of induction and augmentation were collapsed into one group: Intervention in Labor. This combined group contained the following categories: cervical ripening (Cytotec and Cervidil), Oxytocin, and A-ROM. Again, this was in response to categories with too few subjects in the cells and to decrease the number of variables to assist in conducting the multivariate analyses. Collapsing variables in this manner is justifiable as the methods of cervical induction, while different in ingredients and dose, both work to stimulate prostaglandins to induce labor. Oxytocin and assisted rupture of membranes (AROM) are both administered the same regardless of use in induction or augmentation. Therefore, it was deemed appropriate to collapse these variables.

Initially bivariate associations between all potential covariates were identified using either T-test or Chi-square tests as described in Aim 2. Those that were associated with delivery method at the 0.05 level were included in the multivariable analysis along with FHR characteristics. In addition, cumulative odds ratios for FHR characteristics across intervals were examined using the Breslow-Day test for Homogeneity of Odds Ratios and Mantel-Haenszel odds ratios. It was determined that baseline FHR, variability and accelerations did not have statistically significant differences in odds ratios. Therefore, to decrease the number of variables for the multivariate analyses the decision was made to collapse each variable for all intervals and utilize the Mantel-Haenszel odds ratio, which is a summary statistic that defines the odds ratio across all intervals.

In examining decelerations a significant difference in abnormal decelerations was noted across intervals (OR: 1.3471, CI: 1.1602, 1.5642, $p < .0001$). There was a clear increase in abnormal decelerations in those who delivered vaginally in intervals 6, 7, and 8. This makes clinical sense. The fetus experiences head pressure and decreased blood flow from descending through the birth canal, which can cause variable decelerations. Therefore, it was determined decelerations could be collapsed into two categories: abnormal decelerations in intervals 1-6 and abnormal decelerations in intervals 7-8. Collapsing the eight intervals for decelerations into two helps minimize the number of variables in the model for multivariate analysis.

Sequential logistic regression was used to develop multivariate models with delivery method as the outcome variable. Models were first developed to identify independent and interactive associations between FHR characteristics and delivery method. For this, the first model included all the FHR characteristics. Subsequent models tested two-way interactions between FHR characteristics. All FHR characteristics and interactions, significant at the 0.05 level, were retained and tested along with previously identified significant confounding/modifying variables.

Exploratory Aim: To identify clusters of category II FHR characteristics and associations with delivery method in the two hours prior to delivery. These characteristics include: FHR baseline, variability, accelerations, and decelerations, as well as total time spent in category II CEFM FHR patterns. Null hypothesis: there is no association between clusters and delivery outcome in the two hours prior to delivery. Cluster analysis was performed using the cluster package R3.5.2 (Maechler et al., 2018). Since the data for this analysis includes continuous, ordinal, and nominal variables, Gower distance was used to define the dissimilarity between observations (Gower, 1971). The clustering algorithm used was partitioning around medoids, a more robust version of K-means clustering (Kaufman & Rosseeuw, 2005). The number of clusters was chosen to maximize the silhouette width, an aggregated measure of how similar an observation is to its own cluster compared to the closest neighboring cluster (Rosseeuw, 1987). The clustering was performed in R3.5.2 using the cluster package (Maechler et al., 2018). Chi-square tests were used to determine whether clusters were associated with delivery method. Multiple logistic regression was used to determine the association between the clusters and delivery method after adjusting for important covariates: labor interventions, epidural analgesia use, parity, and credentials of the delivering provider, age, and race. The type I error rate was set to 5% for all tests.

In each interval, baseline FHR ranged from 1 to 190. FHR variability was classified as either absent, minimal, moderate, or marked. Accelerations were recorded as present with category II FHR characteristics or absent. There were four categories for decelerations; early, variable, late, and prolonged. The FHR characteristics could be classified as present in more than one category in any given interval.

**Human Participants**

Approval by the University's Institutional Review Board was achieved prior to initiating the study (IRD ID# 201506806). All patient identifiers were kept on a password protected laptop, with a back-up copy kept on a USB file which was stored in a locked fire safe. No participant identifiers were placed in the RedCAP database, instead study participants were assigned a number which only the research team members were able to connect with the participants' medical record number. After conclusion of the study all patient identifiers were permanently deleted.

Given the nature of the study, a medical chart review, risk to potential study participants was limited. However, all participants' medical records were reviewed in a private area to protect participant confidentiality and privacy.

# CHAPTER 4: ANALYSES

## Overview

The overall goal of this study was to identify specific FHR characteristics and patterns that are associated with cesarean delivery in women with low risk pregnancies who had category II FHR tracings in the two hours prior to delivery and also to determine independent associations between category II CEFM FHR characteristics and delivery method after controlling for known covariates. The known covariates included: labor intervention use, epidural analgesia use, parity, and credentials of the delivering provider, as well as demographic characteristics of age and race. The fetal heart rate characteristics included: FHR baseline, variability, accelerations, and decelerations. The dependent variable was delivery method (vaginal vs. cesarean delivery).

## Characteristics of the Population

Of the 537 women included in the study, 129 (24%) delivered by cesarean, and 408 (76%) delivered vaginally. The mean age was 28.5 years (SD 5.1), and ranged from 16 to 40 years. Women who delivered vaginally were on average 1.3 years older than women having cesarean deliveries, with a mean age of 28.8 (SD 4.9) years for women who delivered vaginally as compared to 27.5 (SD 5.5) years for those who delivered by cesarean (p=0.01). The majority of women were White (65.5% n= 352) followed by African-Americans at 13.2% (n=71), Hispanic/Latino at 8.8% (n=47) and "Other" at 12.5% (n=67). There was a significant difference in the proportion of cesarean deliveries by race with the lowest proportions among white (20.2%, n=71) and Hispanic/Latino women (23.4%, n=11). The highest proportions among women classified as "Other" (34.3% n=23), and African-American (33.8%, n=24). These differences were statistically significant (p= 0.01) across all race categories (Table 3). Although the majority of women were multiparous (53.8%, n= 289) the majority of cesarean deliveries were to nulliparous women (60.5%, n= 78, p= 0.00). The overall proportion of cesarean deliveries to nulliparous women was of 31.5% (n= 78), while the proportion of cesarean deliveries to multiparous women was 17.7% (n= 51, p= 0.00) (Table 3).

**Length of Labor and Frequency of Category II FHR Characteristics in Low Risk Women**

Aim 1 was to describe the distribution of specific category II FHR characteristics in low risk pregnancies during the two hours prior to delivery. Aim 2 was to examine the association between category II FHR characteristics and cesarean deliveries in the two hours prior to delivery. Fetal heart rate characteristics included: base FHR, variability, accelerations and decelerations, as well as total time spent in category II CEFM FHR patterns.

The mean length of labor ($1^{st}$ and $2^{nd}$ stage) for all women in the study was 519 (SD 215) minutes. Length of labor was similar for both women who delivered vaginally and via cesarean. The mean length of labor for vaginal deliveries was 513 minutes (SD 215.5) and for cesarean deliveries was 536.3 minutes (SD 214.5) (Table 3). Overall, the total number minutes of with category II CEFM FHR characteristics in the two hours prior to delivery ranged from 1 minute to 120 minutes. Women who delivered vaginally demonstrated a significantly lower median total time in category II (42.8, range 1-120 mins. vs. 54, range 3-120 mins., p=0.0006) (Table 3).

With the exception of marked variability, the fetuses delivered by cesarean had a significantly higher proportion of abnormal FHR characteristics than those who delivered vaginally. Overall 17.1% (n=92) of fetuses had abnormal baseline FHR (tachycardia and/or bradycardia) in the two hours prior to delivery. Fetuses delivered via cesarean had a significantly higher proportion of abnormal baseline FHR (n=32, 24.8% vs. n=60, 14.7%, p=0.001).

Abnormal variability includes absent, minimal, and marked variability. Combined, 83.4% (n=448) of fetuses exhibited abnormal variability in the two hours prior to delivery. Absent and marked variability were uncommon. Only 4 fetuses (0.74%) had absent variability, with each instance of absent variability observed among fetuses delivered by cesarean. Of the 16 fetuses with marked variability, 5 (5.4%) were delivered by cesarean and 9 (3%) were delivered vaginally ($p=1.06$). Minimal variability was observed in nearly 80% ($n=428$) of fetuses. Minimal variability was observed in 87% ($n=112$) of fetuses delivered by cesarean, which was significantly greater than fetuses delivered vaginally ($n=316$, 77%) ($p=0.02$).

Accelerations in the presence of other category II FHR characteristics were extremely common, observed in 98% ($n=527$) of fetuses. Although the difference in accelerations between vaginal and cesarean delivery methods was statistically significant, the difference was not clinically meaningful ($n=399$, 97.8% vs. $n=128$, 99.2%, $p<0.0001$).

Abnormal decelerations included variable, late, and prolonged decelerations. Late and prolonged decelerations were significantly higher among fetuses delivered by cesarean. Late decelerations were present in 69% ($n=89$) of those delivered by cesarean as compared to 48% ($n=195$) of those delivered vaginally ($p<0.00$). Prolonged decelerations were present in 59% ($n=76$) of those who delivered by cesarean compared to 37% ($n=152$) of those who delivered vaginally ($p<0.0001$). However, fetuses who were delivered by cesarean had a proportion of variable decelerations of 89% ($n=115$) which was lower than those who delivered vaginally ($n=394$, 97%, $p=0.001$).

**Table 3** - Demographic and FHR Characteristics of Low Risk Women by Delivery Method

| | **Total n=537** | | **Vaginal** n=408 | | **Cesarean** n= 129 | | | |
|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD | | p-value |
| Age | 28.5 | 5.05 | 28.8 | 4.87 | 27.5 | 5.5 | | 0.01 |
| Total Length of Labor | 518.6 | 215.3 | 513.0 | 215.5 | 536.3 | 214.5 | | 0.28 |
| | Median | Range | Median | Range | Median | Range | | |
| Total Time in Category II | 37.0 | 1-120 | 42.8 | 1-120 | 54.0 | 3-123 | | 0.0006 |
| | **n** | **%** | **n** | **%** | **n** | **%** | **Chi-Sq (DF)** | **p-value** |
| **Race** | | | | | | | 10.5 (3) | 0.015 |
| Caucasian | 352 | 65.5 | 281 | 79.8 | 71 | 20.2 | | |
| African-American | 71 | 13.2 | 47 | 66.2 | 24 | 33.8 | | |
| Hispanic | 47 | 8.8 | 36 | 76.6 | 11 | 23.4 | | |
| Other | 67 | 12.5 | 44 | 76.6 | 23 | 34.3 | | |
| **Parity** | | | | | | | 13.9 (1) | 0.0002 |
| Primigravida | 248 | 46.2 | 170 | 68.6 | 78 | 31.5 | | |
| Multiparous | 289 | 53.8 | 238 | 82.4 | 51 | 17.7 | | |
| **FHR Characteristics (2hrs)** Baseline FHR (abnormal) | 92 | 17.1 | 60 | 14.7 | 32 | 24.8 | 26.1 (8) | 0.001 |
| Variability | 434 | 80.8 | 320 | 78.8 | 114 | 88.4 | 17.5 (8) | 0.03 |
| Absent | 4 | 0.74 | 0 | 0.00 | 4 | 3.1 | 12.7 (1) | 0.0004 |
| Minimal | 428 | 79.7 | 316 | 77.5 | 112 | 86.8 | 5.3 (1) | 0.02 |
| Moderate | 429 | 79.9 | 331 | 81.1 | 98 | 76.0 | 1.6 (1) | 0.20 |
| Marked | 16 | 3.0 | 9 | 2.2 | 7 | 5.4 | 3.5 (1) | 1.06 |
| Accelerations | 527 | 98.1 | 399 | 97.8 | 128 | 99.2 | 47.0 (8) | <0.0001 |
| Decelerations | 528 | 98.3 | 403 | 98.8 | 125 | 97.0 | 18.5 (8) | 0.02 |
| Early | 164 | 30.5 | 140 | 34.3 | 24 | 18.6 | 11.4 (1) | 0.0004 |
| Variable | 509 | 94.8 | 394 | 96.6 | 115 | 89.2 | 10.9 (1) | 0.001 |
| Late | 284 | 52.9 | 195 | 47.8 | 89 | 69.0 | 17.7 (1) | <0.0001 |
| Prolonged | 228 | 42.5 | 152 | 37.3 | 76 | 59.0 | 18.8 (1) | <0.0001 |

### Abnormal Fetal Heart Rate Characteristics and Delivery Status in 15 Minute Intervals Over Two Hours

FHR characteristics are commonly collected every 15 minutes in active labor (MSCRD, 2015). In order to track trends over the two hours prior to delivery each category II FHR characteristic was documented in eight 15-minute segments, mimicking the clinical documentation. Figure 3 depicts the differences in proportion of abnormal FHR characteristic across the eight 15-minute intervals prior to delivery by delivery method. With the exception of decelerations in intervals 6, 7, and 8, the individual FHR characteristics, when abnormal, were consistently significantly greater among cesarean deliveries than vaginal deliveries but were relatively stable over time.

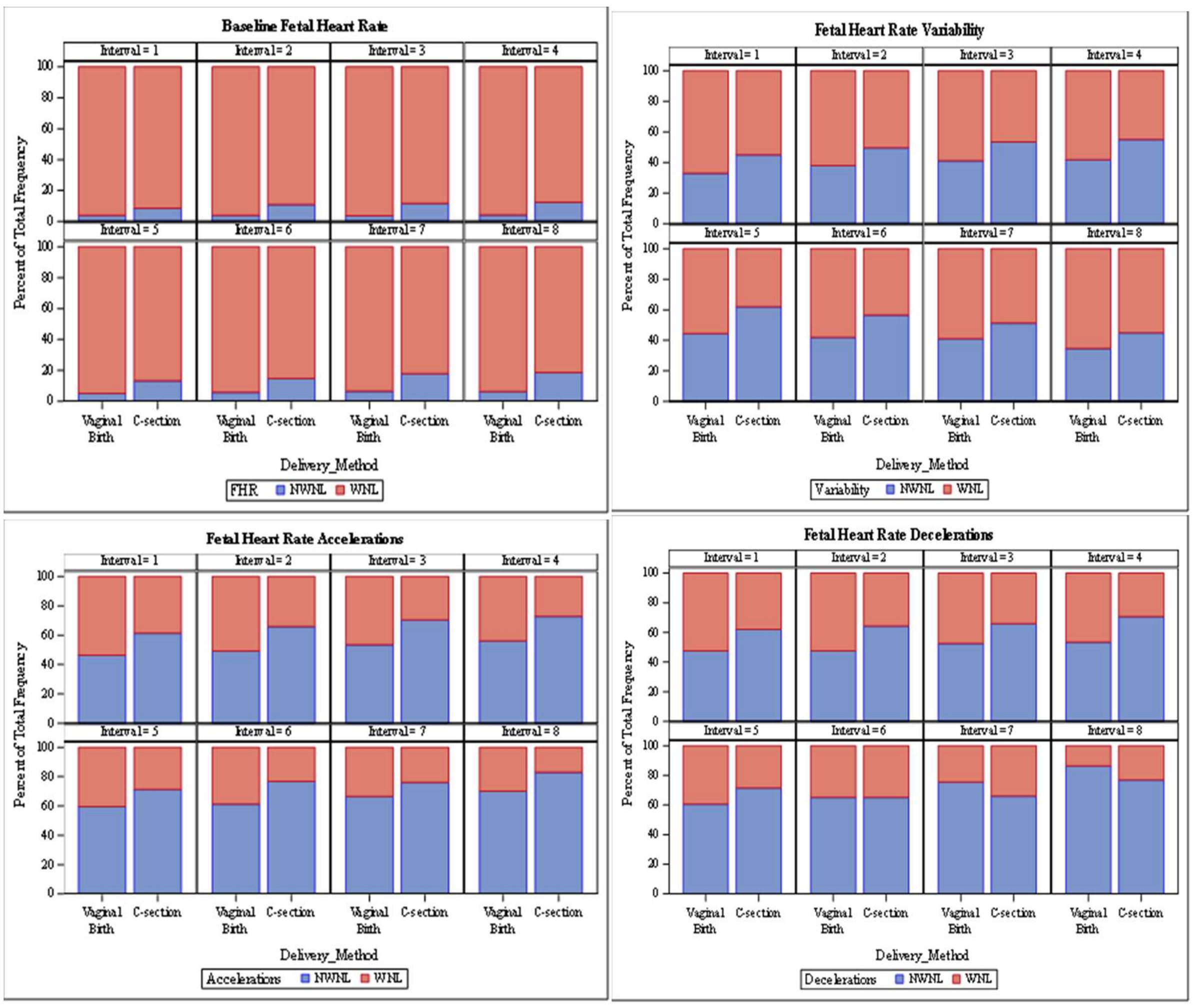
There were significantly higher proportions of abnormal FHR characteristics among those who were delivered via cesarean than those who delivered vaginally. Among fetuses delivered by cesarean the proportion of abnormal baseline FHR ranged from 8.53% (n=11) to 18.6% (n=24, $p = 0.04$) as compared to 3.9% (n=16) and 6.1% (n=25, $p > 0.0001$) in those who delivered vaginally. The range for abnormal variability was 45% (n=58) to 62% (n=80, $p=0.005$) for fetuses delivered via cesarean as compared to a range of 34% (n=134) to 44% (n=181, $p < 0.03$) for vaginal deliveries. The proportion of women who had cesarean deliveries with abnormal variability remained roughly similar or increased across all intervals with the exception of interval 7, in which the lowest proportion was observed.

Abnormal decelerations were common ranging from 62% (n=80) to 71% (n=92) for cesarean deliveries as compared to 48% (n=194) and 61% (n=247) of those who delivered vaginally ($p=0.004$ and 0.02 respectively). The proportion of women who had cesareans with abnormal decelerations remained roughly similar or increased across most of the first 5 intervals.

However, this trend switched. The proportion of vaginal deliveries with abnormal decelerations increased after interval 6.

Among those who delivered by cesarean the proportion of absent accelerations ranged from a low of 61% (n=79) to 83% (n=107) as compared with those who delivered vaginally at 46% (n=189) and 70% (n=286) (p= 0.003 and p=0.004, respectively).

**Figure 3** - Differences in the proportion of abnormal FHR characteristics across 15 minute intervals by vaginal and cesarean delivery



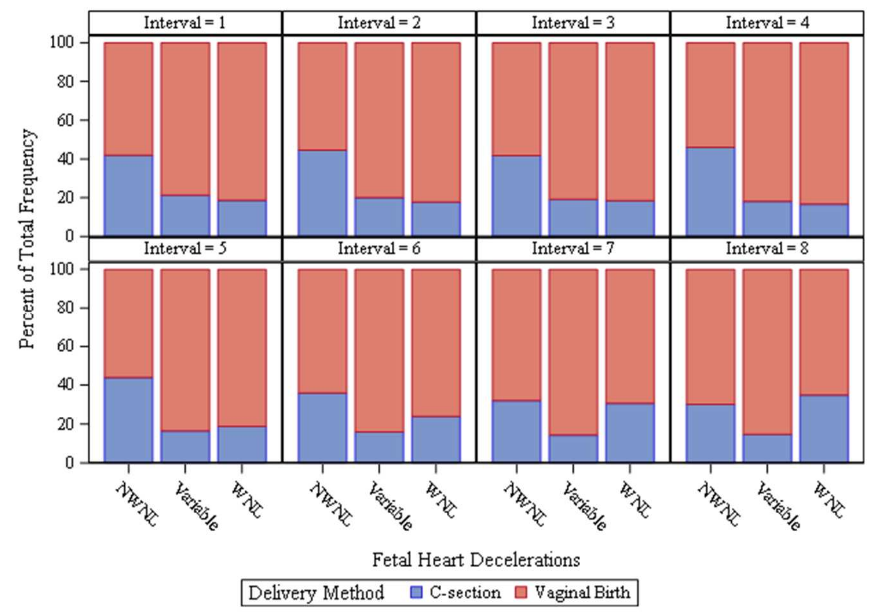
**Impact of Variable, Late and Prolonged Decelerations on Delivery Method**

Since nearly 95% (n=509) of all fetuses had at least one variable deceleration during the two hours of labor prior to delivery, the decision was made to reevaluate decelerations in two additional ways. First, decelerations were reclassified into three groups as: normal (none or early), variable decelerations, and abnormal decelerations, which included late and prolonged decelerations. Secondly, late and prolonged decelerations were separated and evaluated individually, as variable decelerations were common during the pushing phase of labor and may have skewed the association of late and prolonged decelerations with delivery method. Late decelerations are caused by placental insufficiency while prolonged decelerations are caused by prolonged umbilical cord compression or placental insufficiency; neither are common at any time during labor, unlike variable decelerations.

**Comparison of Normal, Variable, and Combined Late and Prolonged Decelerations**

As can be seen in Figure 4, abnormal (late and prolonged) decelerations were greater in those with cesarean deliveries while variable decelerations occurred more frequently among fetuses delivered vaginally. Abnormal decelerations ranged from a low of 30% (n=64) to a high of 46% (n=54) in cesarean deliveries as compared to 55% (n=62) and 70% (n=148) in vaginal deliveries. Variable decelerations ranged from a low of 14% (n=33) to 21% (n=36) in cesarean deliveries and 79% (n=133) to 86% (n=198) in vaginal deliveries. In fact, when examining the variable deceleration group the proportion of cesarean deliveries trended down across all intervals. Normal decelerations (none and early decelerations) ranged from 17% (n=38) to 35% (n=30) in cesarean deliveries while vaginal delivery normal deceleration proportions ranged from 65% (n=56) to 83% (n=190). Chi-squares were calculated on a 2x3 table, given the addition of a third group to the analysis. All intervals had a significant delivery method difference between deceleration types with p-values <0.00.

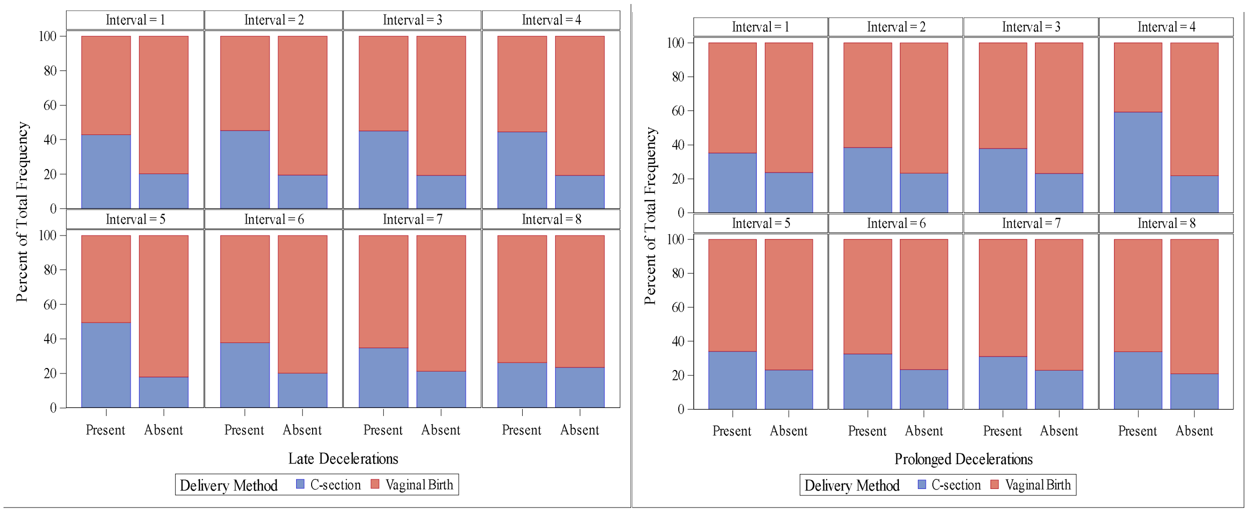
**Figure 4** - Differences in Proportion of Delivery Method between Normal (WNL/None and Early) Decelerations, Variable and Abnormal Decelerations (NWNL/Late and Prolonged Decelerations) per Interval




## Late and Prolonged Decelerations

When late and prolonged decelerations were analyzed individually, late decelerations were significantly associated with delivery method in all intervals except interval 8. As seen in Figure 5 the proportion of late decelerations in cesarean deliveries ranged from a low of 26% (n=28) to a high of nearly 50% (n=51) (p =0.0001).

**Figure 5** - Frequency of Delivery Method for Late and Prolonged Decelerations per Interval

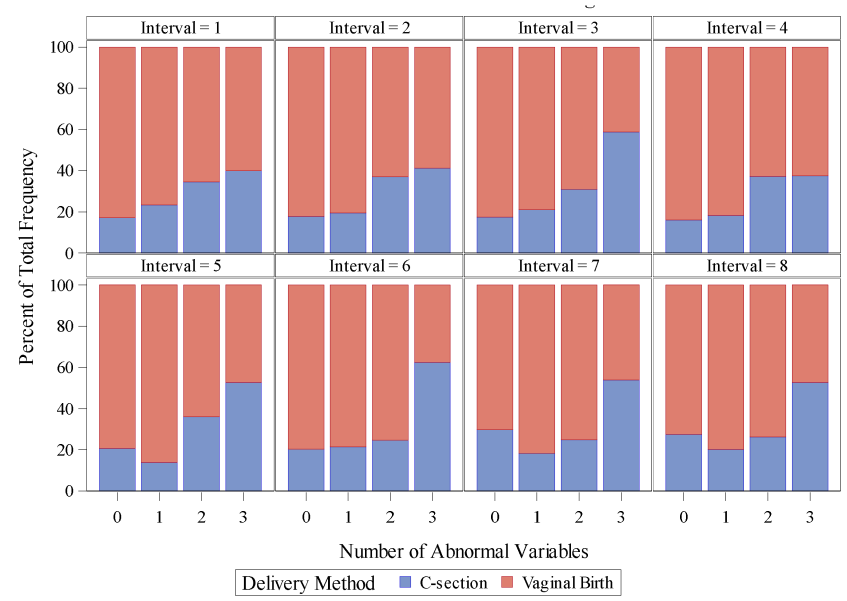



## Total Abnormal FHR Characteristics

In order to determine whether having multiple, simultaneous abnormal FHR characteristics increased risk for cesarean delivery, a new variable representing the total number of abnormal category II FHR characteristic occurring in each interval was created. Since the presence or absence of accelerations does not, in itself, place a CEFM tracing into category II, accelerations were not counted, leaving 0-3 as the possible total for each interval. Overall, the average number of abnormal FHR characteristics across all intervals was 1.12 (SD 0.58). Women who delivered via cesarean had significantly more abnormal FHR characteristics with an average of 1.33 (SD 0.68) while the women who delivered vaginally had a mean of 1.05 (SD 0.52) (p=0.00).

Figure 6 demonstrates the number of abnormal characteristics per interval by delivery status. The proportion of cesarean deliveries was greatest across all intervals when three abnormal FHR characteristics were present and doubled or nearly doubled the proportion of cesarean deliveries when no abnormal FHR characteristics were present in a given interval. When 3 abnormal fetal heart rate characteristics were present the proportion of cesarean deliveries ranged from 37.5% (n=6) to 62.5% (n=15) as compared to 16 % (n=24) to 30% (n= 26) when no abnormal FHR characteristics were present. P-values ranged from <0.00 to 0.01 for each interval, indicating a significant difference in delivery outcome based on number of abnormal variables in each interval (Table 4).

**Figure 6** - Number of Abnormal Variables and Delivery Method




## FHR Characteristics and Risk for Cesarean

To determine whether any of the abnormal FHR characteristics increased the risk for cesarean delivery, odds ratios were calculated for each characteristic and at each 15-minute interval. The Breslow-Day Test of Homogeneity was used to determine whether the odds ratios differed across intervals for each of the FHR characteristics. For three of the four FHR characteristics (baseline FHR, variability, and accelerations), the odds ratios across intervals were not significantly different and the risk of cesarean could be represented by the overall Mantel-Haentzel odds ratio. As can be seen in Table 4 the greatest risk for cesarean was when abnormal baseline FHR was present, (OR 3.07, CI 2.42, 3.91), followed by accelerations at 1.92

(CI 1.65, 2.24) and variability at 1.68 (CI 1.46, 1.94). Decelerations were not homogenous across intervals and were subsequently categorized into two groups, representing intervals 1 through 5 and 6 through 8. Once categorizing decelerations into two groups, a decreased risk for cesarean delivery was observed for fetuses with abnormal decelerations in intervals 6-8 (OR 0.25, CI 0.10, 0.67). There were no significant associations between decelerations in intervals 1-5 and risk for cesarean delivery.

The amount of artifact on the CEFM display due to pushing in the 15 minutes prior to delivery is large and can make identifying true late decelerations difficult. Given this fact, and the potential for placental insufficiency as the fetal head is crowning, the decision was made to exclude interval 8 from any multivariate analyses. Odds ratios for cesarean in the presence of late decelerations ranged from 1.99 (CI 1.26, 3.13) to 4.48 (CI 2.83, 7.07) in intervals 1-7. The Breslow-Day Test for Homogeneity of Odds Ratios resulted in a Mantel-Haentzel odds ratio of 2.69 (CI 2.29, 3.16) ($p=0.00$), indicating a significant difference in odds ratios across intervals. Prolonged decelerations were only significantly associated with delivery method in intervals 4 and 8 when analyzed by themselves. In interval 4 the proportion of those with prolonged decelerations who delivered by cesarean was 59% ($n=19$) and 34% ($n=44$) in interval 8. Odds ratios for cesarean delivery were 5.25 (CI 2.51, 10.96) and 1.94 (CI 1.25, 2.99) respectively.

**Interactions of FHR Characteristics and Risk for Cesarean Delivery**

In order to identify whether combinations of FHR characteristics increased the odds of cesarean, all bivariate interactions were tested between accelerations, variability, and decelerations. The only significant interactions were between variability and accelerations and these interactions occurred only in intervals 6, 7, and 8. In interval 7, normal variability with accelerations decreased the odds of cesarean delivery (OR 0.17, CI 0.04, 0.73) while abnormal variability with accelerations increased the odds of cesarean delivery nearly two-fold in intervals 6, 7, and 8 (Table 4).

**Table 4** - Mantel-Haentzel Odds of Cesarean Delivery across Intervals for Each Abnormal FHR Characteristic and Interactions between Accelerations and Variability

| FHR Characteristic | OR | 95% Confidence Limits | |
|---|---|---|---|
| **Baseline FHR** | 3.0748 | 2.4179 | 3.9102 |
| **Variability** | 1.6843 | 1.4621 | 1.9402 |
| **Accelerations** | 1.9203 | 1.6454 | 2.2412 |
| **Total Decelerations 1-5** | 0.685 | 0.332 | 1.413 |
| **Total Decelerations 6-8** | 0.254 | 0.096 | 0.672 |
| **Late Decelerations 1-7** | 2.69 | 2.29 | 3.16 |
| **Prolonged Decelerations 1-8** | 1.97 | 1.57 | 2.48 |
| **Interaction Tests** | **OR** | **95% Confidence Limit** | |
| **Accels*WNL Variability** | | | |
| **Interval 7 (n=42)** | 0.17 | 0.04 | 0.73 |
| **Accels*NWNL Variability** | | | |
| **Interval 6 (n=192)** | 2.09 | 1.28 | 3.41 |
| **Interval 7 (n=191)** | 2.13 | 1.32 | 3.45 |
| **Interval 8 (n=150)** | 1.91 | 1.22 | 3.00 |

### Independent Associations between Labor Characteristics, FHR Characteristics, and Cesarean Delivery

Aim 3 was to determine independent associations between category II CEFM FHR characteristics and delivery method (vaginal vs cesarean) after controlling for covariates. The covariates included: method of induction or augmentation of labor, if used, epidural analgesia use, attending provider at delivery as well as demographic characteristics.

**Associations between Provider-Type, Labor Interventions, and Cesarean Delivery**

Prior to multivariable modeling, bivariate associations between delivery method and all covariates were evaluated in order to determine statistically and clinically significant covariates. Four delivery provider types were responsible for the decision to proceed to cesarean delivery: certified nurse midwives, family practice physicians, general obstetricians-gynecologists (GOB), and high-risk obstetricians, otherwise known as maternal-fetal medicine specialists (MFM). The GOB group attended to the majority of deliveries (n= 290, 54%) followed by certified nurse-midwives (n= 99, 18%), MFMs at 16.8% (n= 90), and family practice physicians at 10.8% (n= 58). There was a significant difference in cesarean delivery rate according to provider type (p=0.0016). Approximately 23% (n=30) of deliveries attended by MFMs were cesarean as compared to 57% (n=74) for general obstetrician-gynecologists, 12% (n=15) for family practice physicians and 8% (n=10) for midwives (table 5).

Medical interventions during labor or to initiate labor were divided into four categories: no interventions, cervical ripening (Cervidil and Cytotec), oxytocin (Pitocin) administration, and assisted rupture of membranes (AROM). Use of oxytocin and AROM were initially intended to be categorized into induction with oxytocin, augmentation with oxytocin, induction with AROM, and augmentation with AROM. However, the cell values for augmentation with oxytocin and augmentation with AROM were too small to be meaningful. Therefore, the variables were collapsed into use of oxytocin and use of AROM. Overall, cervical ripening was used in 13% (n= 69) of women to initiate labor, oxytocin was used in 40% (n= 214) of women, and AROM to induce labor or expedite delivery in 38% (n= 203) of women. Of the cesarean deliveries in the study, 48% (n=62) had been given oxytocin in labor as compared to 40% (n=161) of those who delivered vaginally. Approximately 21% (n=27) of those who delivered via cesarean had their labor induced with cervical ripening medications while just 11% (n=45) of those who delivered vaginally received cervical ripening agents. When AROM was used to induce or augment labor similar delivery proportions were observed between cesarean (n=18, 14%) and vaginal deliveries (n=45, 11%). Cervical ripening and AROM were significantly associated with cesarean delivery (p=0.0044 and p=0.02, respectively) (Table 5).

Local anesthesia (epidural/spinal injection) prior to the decision to deliver was used in 80% (n= 428) of the deliveries in this study. Of the women with anesthesia the proportion of cesarean deliveries was nearly 30% (n=128) compared to only 1% (n=1) of those with no anesthesia prior to the decision to deliver via cesarean (p> 0.0001) (Table 5).

**Table 5** - Prevalence of Interventions in Labor by Delivery Method

| | **Total n=537** | | **Vaginal** n=408 | | **Cesarean** n= 129 | | | |
|---|---|---|---|---|---|---|---|---|
| | **n** | **%** | **n** | **%** | **n** | **%** | **Chi-Sq (DF)** | **p-value** |
| **Provider** | | | | | | | 15.2 (3) | 0.0016 |
| Midwife | 99 | 18.4 | 89 | 21.8 | 10 | 7.8 | | |
| FP | 58 | 10.8 | 43 | 10.5 | 15 | 11.6 | | |
| GOB | 290 | 54.0 | 216 | 52.9 | 74 | 57.4 | | |
| MFM | 90 | 16.8 | 60 | 14.7 | 30 | 23.3 | | |
| **Interventions in Labor** | | | | | | | | |
| None | 179 | 33.3 | 157 | 38.5 | 22 | 17.1 | | |
| Cervical Ripening | 69 | 12.8 | 45 | 11.0 | 27 | 20.9 | 8.09 (1) | 0.0044 |
| Pitocin | 214 | 39.9 | 161 | 39.5 | 62 | 48.1 | 0.90 (1) | 0.3434 |
| AROM | 203 | 37.8 | 45 | 11.0 | 18 | 14.0 | 5.48 (1) | 0.0193 |
| **Anesthesia** | | | | | | | 40.0 (1) | <0.0001 |
| None | 109 | 20.3 | 108 | 26.5 | 1 | 0.8 | | |
| Epidural | 428 | 79.7 | 300 | 73.5 | 128 | 99.2 | | |

### Risks for Cesarean Delivery After Controlling for Known Covariates

Initially multivariable models were developed with delivery method as the outcome variable and significant covariates which included race, age, parity, provider type, cervical ripening, AROM, and anesthesia prior to the decision to deliver. Total length of labor and total time spent in category II were considered as potential covariates but were not significantly associated with delivery. Next each FHR characteristic (baseline FHR, variability, accelerations, and decelerations (all categorizations)), interactions between variability and accelerations or decelerations, and average number of abnormal FHR characteristics were added in separate models to determine whether they contributed to the variation in cesarean proportions. With the exception of late and prolonged decelerations and number of abnormal FHR characteristics there were no significant associations between any abnormal FHR characteristics, their interactions and cesarean delivery. Because late and prolonged decelerations are included in the number of FHR characteristics and therefore could not be modeled together, two final models were created to identify independent associations between the FHR characteristics and delivery (Tables 6 and 7).

**Model 1: Average Number of Abnormal FHR Characteristics and Risk for Cesarean Controlling for Known Covariates**

Logistic regression was performed with delivery method as the outcome variable. Based on an exploratory plot of the observed log odds by the average number of abnormal characteristics, a quadratic term was included in the model for this variable due to a non-normal distribution (Figure 7).

Table 6 provides odds ratio estimates, 95% confidence intervals and p-values for all variables in the model. The quadratic effect of average number of abnormal FHR characteristics was highly significant ($p = 0.0068$). To analyze the odds ratios of the quadratic effect, contrasts were performed for all possible combinations of an average of one, two, and three abnormal characteristics. The odds of cesarean for a woman averaging two abnormal characteristics was 1.86 times the odds of cesarean for a woman averaging one abnormal characteristic ($p = 0.0001$).

The odds of cesarean for women that averaged three abnormal characteristics was nearly 20 times higher than the odds of cesarean for women that averaged one abnormal characteristic (p = 0.0001), and 10 times higher than the odds of cesarean for women that averaged two abnormal characteristics compared to those that averaged one abnormal characteristic (p = 0.0001)

The odds of cesarean decreased with age. A one-year increase in age was associated with 0.95 times the odds of cesarean (p = 0.02). Figure 5 displays the probabilities of cesarean by age for the different numbers of average abnormal FHR characteristics (1-3) when controlling for the covariates including parity. As can be seen, there is a general association of increased age with decreased probability of cesarean, as well as increased average number of abnormal FHR characteristics and increased probability of cesarean across all ages.

There are several statistically significant differences in cesarean delivery between types of delivering clinicians (Table 6). The reference group for the type of delivering clinician was GOB but contrasts for all pairwise comparisons are provided. Midwives had the lowest odds of cesarean delivery with family practice doctors 2.9 times, GOB 2.32 times, and high-risk obstetricians 3.76 times more likely to order a cesarean than midwives (p = 0.0001, p = 0.03 and p = 0.0001, respectively). The odds of cesarean ordered by a high-risk obstetrician are 1.62 times the odds of cesarean ordered by a GOB (p = 0.04). Figure 8 displays the probabilities of cesarean by the average number of abnormal FHR characteristics for each type of delivering clinician. As can be seen, the probability of cesarean delivery was lower for midwives regardless of the total number of abnormal FHR characteristics than high-risk obstetricians, who had the highest probability of ordering a cesarean delivery.

The use of anesthesia increased the odds of cesarean by an estimated 43 times (p = 0.0001), although the extreme magnitude of this effect was related to only one woman in the data-set who had a cesarean and also did not receive anesthesia prior to the decision to deliver. Interestingly, the use of cervical ripening decreased the odds of cesarean when controlling for the covariates, including parity. Women that did not receive cervical ripening had 1.87 times the odds of cesarean than women that received cervical ripening ($p = 0.01$). The other two type of labor interventions (Pitocin, AROM) were tested in the model but were found to be non-significant and removed.

Overall, race was significantly associated with cesarean delivery; however the only significant odds ratio for race was between African-American women and white women. The odds of cesarean for African-American women are 1.85 times the odds of cesarean for white women ($p = 0.02$). Parity was not found to be significant in the model.

**Table 6** - Odds Ratios for Average Abnormal FHR Characteristic Model Variables

| **Odds Ratio Estimates** | | | | |
|---|---|---|---|---|
| **Effect** | **Point Estimate** | **95% Wald Confidence Limits** | | **Pr > ChiSq** |
| Average Number of Abnormal FHR | | | | |
| 1 vs 2 | 1.8558 | 1.2122 | 2.8409 | 0.0001 |
| 1 vs 3 | 19.6233 | 3.8962 | 98.8328 | 0.0001 |
| 2 vs 3 | 10.5743 | 2.8944 | 38.6320 | 0.0001 |
| Age | 0.949 | 0.907 | 0.993 | 0.02 |
| Delivering clinician | | | | |
| Family Practice Doctor vs Standard | 1.2499 | 0.7208 | 2.1675 | 0.43 |
| MFM vs Standard OB | 1.6182 | 1.0267 | 2.5506 | 0.04 |
| Midwife vs Standard OB | 0.4306 | 0.2413 | 0.7685 | 0.0001 |
| Family practice vs MFM | 0.7724 | 0.3353 | 1.7792 | 0.54 |
| Family practice vs Midwife | 2.9025 | 1.0956 | 7.6889 | 0.03 |
| MFM vs Midwife | 3.7577 | 1.5655 | 9.0196 | 0.0001 |
| Anesthesia used | 43.434 | 5.685 | 318.597 | 0.0001 |
| 1 or More Pregnancies vs 1st | 0.665 | 0.415 | 1.065 | 0.09 |
| Race | | | | |
| African-American vs White | 1.8499 | 1.1065 | 3.0927 | 0.02 |
| Hispanic/Latino vs White | 0.8134 | 0.4201 | 1.5750 | 0.54 |
| Other vs White | 1.1399 | 0.6820 | 1.9051 | 0.62 |
| African American vs. Hispanic | 2.2743 | 0.8304 | 6.2286 | 0.11 |
| African American vs. Other | 1.6229 | 0.7033 | 3.7446 | 0.26 |
| Hispanic vs. Other | 0.7136 | 0.2564 | 1.9860 | 0.52 |
| Labor Intervention – cervical ripening | 0.5360 | 0.291 | 0.989 | 0.01 |

**Figure 7** - Number of Abnormal FHR Characteristics and Probability of Cesarean Delivery by Age

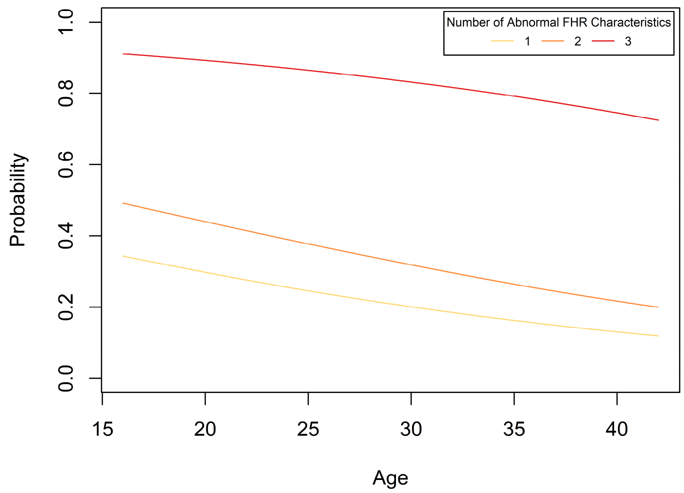
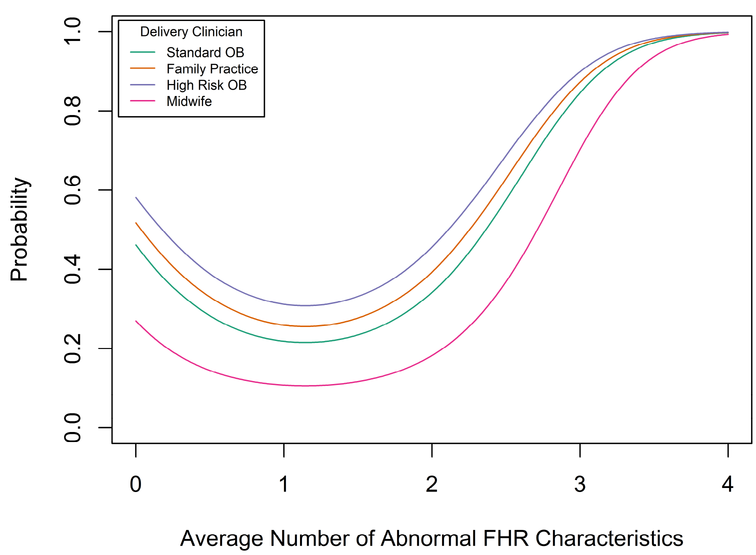



**Figure 8** - Average Number of FHR Characteristics and Delivery Provider Type




**Model 2: Late and Prolonged Decelerations and Risk for Cesarean Controlling for Known Covariates**

Table 7 shows odds ratio for the regression model that included covariates and combinations of late and prolonged decelerations. Because artifacts on the CEFM strip were common while the fetus was in the birth canal and can make properly identifying late decelerations more difficult, interval 8 was removed from this analysis. Having either late or prolonged decelerations significantly increased the odds of cesarean when they were considered independently. The odds of cesarean delivery were 1.51 (CI 1.19, 1.91) when prolonged decelerations were present and 1.4 (CI 1.10, 1.77) when late decelerations were present. There was no significant increase in the odds of cesarean delivery in any combination of late and prolonged decelerations. As seen in the previous model, anesthesia, any race other than white, and birth attendance by a MFM were the most significantly associated covariates with cesarean delivery in this model.

The R-square for the prolonged and late decelerations model was 0.2076 and the R-square for the average abnormal characteristics model was 0.1936, making both models essentially equivalent in explaining the difference in delivery method.

**Table 7** - Odds Ratios for Late and Prolonged Decelerations, Demographic and Labor Characteristics and Risk for Cesarean Delivery

| **Odds Ratio Estimates** | | | |
|---|---|---|---|
| **Effect** | **Point Estimate** | **95% Wald Confidence Limits** | |
| Family Practice Doctor vs General Obstetrician-Gynecologist | 0.967 | 0.460 | 2.032 |
| MFM vs General Obstetrician-Gynecologist | 1.478 | 0.821 | 2.662 |
| Midwife vs General Obstetrician-Gynecologist | 0.373 | 0.173 | 0.803 |
| Anesthesia Yes vs None Prior to Delivery Decision | 42.717 | 5.758 | 316.908 |
| 1 or More Pregnancies vs 1st Pregnancy | 0.721 | 0.449 | 1.158 |
| African-American vs White | 3.090 | 1.561 | 6.114 |
| Hispanic/Latino vs White | 1.526 | 0.625 | 3.729 |
| Other vs White | 1.893 | 1.001 | 3.579 |
| Age | 0.944 | 0.901 | 0.988 |
| Cervical Ripening Yes vs Non | 0.479 | 0.258 | 0.890 |
| Prolonged Decelerations without Late Decelerations | 1.5071 | 1.189 | 1.9102 |
| Late Decelerations without Prolonged Decelerations | 1.3982 | 1.1027 | 1.7729 |
| Prolonged Decelerations in the Presence of Late Decelerations | 1.1570 | 0.8770 | 1.5263 |
| Late Decelerations in the Presence of Prolonged Decelerations | 1.0734 | 0.7736 | 1.4893 |

**FHR Characteristic Clusters and Association with Cesarean Delivery**

The exploratory aim was to identify clusters of category II FHR characteristics in the two hours prior to delivery and how those clusters were associated with delivery outcome. To achieve this a cluster analysis was conducted. The category II FHR characteristics included were FHR baseline, variability, accelerations, decelerations, and total time spent in category II CEFM FHR patterns. FHR baseline, variability, accelerations, and decelerations were measured every 15 minutes in the two hours prior to delivery. If the FHR patterns were not classified as category II in any interval, the FHR characteristics were not recorded. All women included in this study each had at least 1 minute in category II in the two hours prior to delivery.

Table 8 depicts the degree of missingness for each FHR characteristic over time. To account for the missing values, the following steps were taken. First, missing FHR characteristics were imputed for intervals in which the patterns were not classified as category II and assumed to be category I. Missing baseline FHR values indicated that the baseline FHR value was in the interval 110 – 160, so the mean value of 135 was imputed. Missing variability was classified as moderate variability. Missing accelerations did not necessarily indicate that there were no accelerations, so a new category of accelerations unknown was created. Any missing decelerations were considered absent.

The silhouette width was maximized for two clusters, so two clusters were used in subsequent analyses. Tables 9 through 12 summarize the FHR characteristics in each cluster over time. Cluster 1 had higher baseline FHR, more minimal variability, more non-missing accelerations, and more decelerations present in all categories, indicating that this cluster has more abnormal FHR characteristics than cluster 2. Cluster 2 was essentially the opposite of cluster 1. Generally, it contained lower baseline FHR, more moderate variability, more unknown accelerations, less decelerations of any type, and less time spent in category II. In general changes in FHR characteristics were not significantly different and did not contribute to the cluster identification. Table 12 represents the proportion of individuals in each cluster that had specific decelerations in each interval. Decelerations of all types were higher in cluster 1 than cluster 2. Therefore, it does not appear that any specific type of decelerations was more important in the clustering. Of note, early decelerations, while considered normal, were included in the cluster analysis. This is because the goal of the cluster analysis was to examine which FHR characteristics are related, regardless of their classification as "normal" and "abnormal."

Table 13 shows the bivariate association between cluster and delivery method and Table 14 gives the odds ratio estimates, 95% Wald confidence intervals and p-values for each variable included in the logistic regression model. After considering covariates known to be related to delivery method, the cluster effect is no longer significant (p = 0.6715).

There was a significant difference in cesarean delivery between clusters. The odds of cesarean for a woman in cluster 1 were 1.67 times the odds of a cesarean for a woman in cluster 2 (Table 14). The chi-squared test with 1 degree of freedom was 5.55 (p = 0.02).

**Cluster Data Summaries**

**Table 8** - Percent Missing for Each FHR Characteristic at Each Interval

| % Missing | | | |
|---|---|---|---|
| **Interval** | Baseline FHR | Variability | Accelerations |
| **Interval 1** | 35 | 35 | 35 |
| **Interval 2** | 33 | 33 | 33 |
| **Interval 3** | 28 | 28 | 29 |
| **Interval 4** | 26 | 26 | 27 |
| **Interval 5** | 21 | 22 | 22 |
| **Interval 6** | 20 | 19 | 21 |
| **Interval 7** | 15 | 16 | 17 |
| **Interval 8** | 10 | 10 | 12 |

**Cluster Summaries**

**Table 9 -** Summaries of Baseline FHR and Total Time Spent in Category II by Cluster

| | Cluster 1 | | | Cluster 2 | | |
|---|---|---|---|---|---|---|
| | Min | Mean | Max | Min | Mean | Max |
| **Baseline FHR** | | | | | | |
| **Interval 1** | 4 | 139.50 | 190 | 0 | 134.40 | 165 |
| **Interval 2** | 100 | 140.76 | 190 | 80 | 134.87 | 165 |
| **Interval 3** | 110 | 141.49 | 190 | 0 | 134.53 | 165 |
| **Interval 4** | 110 | 142.44 | 185 | 80 | 135.13 | 165 |
| **Interval 5** | 100 | 142.25 | 185 | 13 | 134.54 | 170 |
| **Interval 6** | 100 | 142.50 | 195 | 80 | 134.91 | 170 |
| **Interval 7** | 3 | 141.55 | 190 | 100 | 135.36 | 175 |
| **Interval 8** | 95 | 141.65 | 180 | 100 | 135.78 | 175 |
| **Total Mins. of Cat II** | 9 | 61.32 | 213 | 1 | 23.46 | 158 |

**Table 10 -** Counts and Percentages in Each Variability Category by Cluster

| Variability | Cluster 1 | | | n (%) | Cluster 2 | | | |
|---|---|---|---|---|---|---|---|---|
| **Interval** | Absent | Minimal | Moderate | Marked | Absent | Minimal | Moderate | Marked |
| **Interval 1** | 0 (0) | 154 (49) | 157 (5) | 3 (1) | 0 (0) | 35 (16) | 189 (84) | 0 (0) |
| **Interval 2** | 2 (0.01) | 169 (54) | 142 (45) | 1 (0) | 0 (0) | 47 (21) | 176 (79) | 1 (0) |
| **Interval 3** | 0 (0) | 192 (61) | 120 (38) | 2 (1) | 0 (0) | 43 (19) | 180 (8) | 1 (0) |
| **Interval 4** | 1 (0) | 182 (58) | 130 (41) | 1 (0) | 0 (0) | 59 (26) | 165 (74) | 0 (0) |
| **Interval 5** | 2 (1) | 193 (61) | 118 (38) | 1 (0) | 0 (0) | 65 (29) | 158 (71) | 1 (0) |
| **Interval 6** | 0 (0) | 182 (58) | 130 (41) | 2 (1) | 0 (0) | 58 (26) | 163 (73) | 3 (1) |
| **Interval 7** | 0 (0) | 166 (53) | 147 (47) | 1 (0) | 0 (0) | 65 (29) | 158 (71) | 1 (0) |
| **Interval 8** | 0 (0) | 132 (42) | 180 (57) | 2 (1) | 0 (0) | 63 (28) | 158 (71) | 3 (1) |

**Table 11** - Counts and Percentages in Each Accelerations Category by Cluster

| Accelerations | Cluster 1 | | n (%) | Cluster 2 | | |
|---|---|---|---|---|---|---|
| **Interval** | No | Yes | Unknown | No | Yes | Unknown |
| **Interval 1** | 226 (72) | 57 (18) | 31 (10) | 43 (19) | 22 (10) | 159 (71) |
| **Interval 2** | 232 (74) | 52 (17) | 30 (10) | 55 (25) | 23 (10) | 146 (65) |
| **Interval 3** | 243 (77) | 51 (16) | 20 (6) | 67 (30) | 23 (10) | 134 (60) |
| **Interval 4** | 248 (79) | 44 (14) | 22 (7) | 76 (34) | 27 (12) | 121 (54) |
| **Interval 5** | 249 (79) | 52 (17) | 13 (4) | 87 (39) | 29 (13) | 108 (48) |
| **Interval 6** | 248 (79) | 48 (15) | 18 (6) | 101 (45) | 26 (12) | 97 (43) |
| **Interval 7** | 241 (77) | 50 (16) | 23 (7) | 128 (57) | 28 (13) | 68 (30) |
| **Interval 8** | 237 (75) | 51 (16) | 26 (8) | 156 (70) | 30 (13) | 38 (17) |

**Table 12** - Percent with Decelerations Present by Cluster

| Decelerations | Cluster 1 | | | % | Cluster 2 | | | |
|---|---|---|---|---|---|---|---|---|
| **Interval** | Early | Variable | Late | Prolonged | Early | Variable | Late | Prolonged |
| **Interval 1** | 10 | 64 | 25 | 25 | 3 | 12 | 5 | 5 |
| **Interval 2** | 12 | 66 | 26 | 26 | 3 | 12 | 7 | 7 |
| **Interval 3** | 14 | 68 | 26 | 26 | 4 | 18 | 8 | 8 |
| **Interval 4** | 15 | 72 | 26 | 26 | 5 | 18 | 9 | 9 |
| **Interval 5** | 11 | 75 | 27 | 27 | 6 | 26 | 8 | 8 |
| **Interval 6** | 11 | 70 | 31 | 31 | 5 | 35 | 10 | 10 |
| **Interval 7** | 9 | 73 | 29 | 29 | 4 | 52 | 9 | 9 |
| **Interval 8** | 3 | 71 | 25 | 25 | 4 | 66 | 12 | 12 |

**Cluster Association with Delivery Method**

**Table 13** - Bivariate Association between Cluster and Delivery Method

| Cluster | Delivery Method n (%) | | |
|---|---|---|---|
| | C-section | Vaginal Birth | Total |
| **Cluster 1** | 87 (27.8%) | 226 (72.2%) | 313 (100%) |
| **Cluster 2** | 42 (18.75%) | 182 (81.25%) | 224 (100%) |
| **Total** | 129 (24%) | 408 (76%) | 537 (100%) |

**Table 14** - Logistic Regression Odds Ratio Estimates, 95% Wald Confidence Limits, and p-values

| **Odds Ratio Estimates** | | | | |
|---|---|---|---|---|
| **Effect** | **Point Estimate** | **95% Wald Confidence Limits** | | **Pr > ChiSq** |
| Cluster | 1.1068 | 0.6925 | 1.7688 | 0.6715 |
| Age | 0.941 | 0.900 | 0.984 | 0.0071* |
| Anesthesia used | 45.8266 | 6.1600 | 340.9204 | 0.0002* |
| 1 or More Pregnancies vs 1st Pregnancy | 0.7406 | 0.4799 | 1.1428 | 0.1748 |
| Labor Intervention – cervical ripening | 1.8284 | 0.9978 | 3.3506 | 0.0508 |
| Labor Intervention - AROM | 1.3297 | 0.8460 | 2.0902 | 0.2168 |
| Delivering clinician | | | | |
| Family Practice Doctor vs GOB | 1.0836 | 0.5266 | 2.2299 | 0.8274 |
| MFM vs GOB | 1.4603 | 0.8230 | 2.5629 | 0.1890 |
| GOB vs Midwife | 2.6289 | 1.2286 | 5.6251 | 0.0128* |
| MFM vs Family practice | 1.3476 | 0.5937 | 3.0590 | 0.4756 |
| Family practice vs Midwife | 2.8487 | 1.0921 | 7.4311 | 0.0324* |
| MFM vs Midwife | 3.8390 | 1.6279 | 9.0537 | 0.0021* |
| Race | | | | |
| African-American vs White | 2.9254 | 1.5146 | 5.6501 | 0.0014* |
| Hispanic/Latino vs White | 0.3505 | 0.5769 | 3.1613 | 0.4887 |
| Other vs White | 2.0664 | 1.1103 | 3.8458 | 0.0220* |
| African American vs. Hispanic | 2.1662 | 0.8117 | 5.7810 | 0.1227 |
| African American vs. Other | 1.4157 | 0.6206 | 3.2295 | 0.4087 |
| Other vs. Hispanic | 1.5301 | 0.5700 | 4.1072 | 0.3985 |

* Indicates significant finding

# CHAPTER 5: DISCUSSION

This chapter includes an integrated discussion of the most notable results, as well as limitations, and implications for research and practice.

Some of the study results were consistent with the available, applicable research. Other results were inconsistent with some of the available, applicable research, while additional results appear to provide new, previously unstudied data. This new data can inform thought, interpretation and practice.

## Distribution of Specific Category II FHR Characteristics in Low Risk Labor

Perhaps the most interesting finding was the high prevalence of abnormal variability and variable decelerations in all study subjects, regardless of delivery outcome. This finding may indicate that clinicians need to evaluate the usefulness of these FHR characteristics in assessing a low risk fetus in labor. Macones and colleagues (2011) have reported that the combination of moderate variability and accelerations indicates adequate fetal oxygenation. However, in low risk labor, minimal variability was observed in nearly 85% of all subjects. This may indicate that abnormal variability is less indicative of fetal oxygenation when there are no fetal or maternal risk factors present. In addition, variable decelerations, especially during the pushing phase of labor, may be normal in low risk labor. This would be a shift in the classification of variable decelerations, as they have been classically classified as abnormal, requiring intervention (Macones et al., 2011).

To date, this study is the first to comprehensively describe the incidence of each individual FHR characteristic specifically in low risk labor. Very few studies were identified that could be used as a comparison in low risk labor. Cahill and colleagues (2019) found that nearly 60% of fetuses in low risk labor had “mostly moderate variability” while only 25% of those in low risk labor “always” had moderate variability. They also found that nearly 70% of those in low risk labor had at least one acceleration in the two hours prior to delivery (Cahill et al., 2019). Most studies that examine the prevalence of FHR characteristics tend to examine those characteristics in the three-tiered category (i.e., Mean minutes in category II) (Jackson et al., 2011). Therefore, this study provides a record for FHR characteristic statistics that can be used as a comparison for further studies.

**Association of Category II FHR Characteristics and Cesarean Deliveries**

Several significant bivariate associations were found between category II FHR characteristics and cesarean delivery. Tachycardia and bradycardia were associated with cesarean delivery, causing a 10% increase in cesarean deliveries in this study. In fact, abnormal baseline FHR was associated with a 3 times increase in cesarean, which is consistent with the existing literature (Toomy & Oppenheimer, 2019). Absent variability, while rare, had a 100% cesarean rate, while marked variability was observed more in those who delivered vaginally. This is likely caused by rapid FHR changes and difficulty tracing the FHR as the fetus descends through the birth canal and is a similar finding to another study. In a case-control study, absent variability occurred too infrequently to estimate an association (Toomy & Oppenheimer, 2019). Minimal variability was observed for at least 1 minute in 80% of all those included in this study and was associated with a 10% increase in cesarean deliveries. Abnormal variability was associated with a nearly 2 times increase in cesarean delivery. While Macones and colleagues (2011) and others have discussed the importance of variability in assessing fetal oxygenation, this study may support the argument that it is not as indicative of fetal hypoxia in low risk labor (Ogunyemi et al., 2018, Weissbach et al., 2018). It should be noted, however, that the protective interaction of moderate variability and accelerations mimicked the literature and confirmed that when these two FHR characteristics are observed together in an interval they are protective and indicate adequate fetal oxygenation (Macones et al., 2011).

The risk for cesarean with abnormal baseline FHR and FHR variability was not significantly different when comparing in which interval the abnormal characteristic was observed. This was a surprising finding. One might expect that if the abnormal characteristic was occurring in earlier intervals that the cesarean rate would be higher. In other words, a provider having to watch an abnormal FHR characteristic for longer may be influenced to proceed to cesarean. However, this was not the case and may add to the argument that the data collected on low risk CEFM tracings in the two hours prior to delivery is less useful in determining the oxygenation of the low risk fetus.

Abnormal decelerations were common in both those who delivered vaginally and those who delivered via cesarean. This was directly related to the high prevalence of variable decelerations in both fetuses delivered via cesarean and those which delivered vaginally. Abnormal decelerations included variable, late, and prolonged decelerations. Late and prolonged decelerations were significantly associated with cesarean delivery, which supports the existing literature (Toomy & Oppenheimer, 2019). Late decelerations were associated with greater than 2.5 times increased risk of cesarean when present in the first seven intervals. Given the artifact present during the final interval in vaginal deliveries, late decelerations were more difficult to identify. However, in this study variable decelerations were significantly associated with vaginal delivery. This may be a result of limiting the study to low risk patients. The presence of fetal hemoglobin likely protected the fetus from the temporary oxygen restriction provided by variable decelerations and occurred most frequently in the later intervals, when the woman was in the pushing phase of a vaginal delivery (Evans et al., 2019). The last three intervals prior to delivery were different when comparing odds ratios across all intervals. This is likely related to the association of variable decelerations with the pushing phase of labor (Ogunyemi et al., 2018).

This makes sense, given all babies born vaginally are subject to head compression and decreased blood flow through the umbilical cord when descending through the birth canal, often causing variable decelerations, which are considered abnormal. These statistics may indicate that observing variable decelerations on CEFM tracing in low risk labor may not indicate fetal hypoxia and that intermittent monitoring for late or prolonged decelerations may be more appropriate for low risk patients.

Prolonged decelerations were only significantly associated with delivery method in intervals 4 and 8 in this study. The presence of prolonged decelerations in interval 8 makes sense, likely the provider expedited delivery via cesarean based on a prolonged deceleration, but interval 4 is harder to interpret. It could be that many women began pushing in interval 4 to try and expedite a vaginal delivery because of the presence of prolonged decelerations, however this is a hypothesis. Larger studies would need to be conducted similarly to validate the finding.

Total number of abnormal characteristics is a new measurement that has not been previously studied and may be a clinically useful tool in assessing the oxygenation of the low risk fetus in labor. When three total abnormal characteristics were present in a given interval the cesarean proportion was doubled from when no abnormal characteristics were present. This measurement could be easily calculated in real time on labor and delivery units without purchasing new equipment and warrants further research. This new variable was created in this study and adds to the science and may be helpful in the future.

### Independent Associations Between Category II FHR Characteristics While Controlling for Covariates

In multivariate models only late and prolonged decelerations were significantly associated with cesarean delivery. This may be one of the most important findings of this study. Another significant characteristic associated with cesarean delivery was the average number of abnormal FHR characteristics. This does seem to confirm the stances of both the ACNM and ACOG that CEFM is not the best method for monitoring the low risk fetus in labor. Both groups support the use of intermittent fetal monitoring (IFM) in low risk labor. This study did not examine IFM and cannot state which method of fetal monitoring in low risk labor is better.

Since both late and prolonged decelerations are captured by the average number of abnormal FHR characteristics, two separate multivariate models were created to assess the relationship between significant FHR characteristics and cesarean delivery while controlling for known covariates. The average number of abnormal FHR characteristics model is the preferred model because it has more clinical utility.

**Model 1- Average Number of Abnormal FHR Characteristics and Cesarean Delivery**

This model found that the average number of abnormal FHR characteristics is a clear indicator of the risk of cesarean in low risk labor, while being easily calculated in 15-minute increments during labor, thus making this variable easy to calculate and useful to providers during labor. This study found that women that averaged three abnormal FHR characteristics had 20 times the risk of those that had one, and two abnormal FHR characteristics had 10 times the risk of those that had one. These findings add to the results of the bivariate analyses of the abnormal FHR characteristics. A count of abnormal FHR characteristics may be a better indicator of cesarean delivery than all of the individual FHR characteristics and their interactions or any other measure of the CEFM FHR. Counting abnormal FHR characteristics, to date, has not been suggested or studied prior, contributing to the advancing of the science.

In Model 1, unlike results from the literature, age was inversely associated with cesarean delivery. An increase in age was associated with a decreased risk of cesarean delivery (Lialios et al., 1999). This may have been due to parity and the effect of a history of an uncomplicated vaginal delivery. This finding could also be related to older patients, with higher education levels, seeking the care of midwives and younger patients seeking care by the physicians at an academic institution, however this trend needs to be studied further to determine if this a true trend or reflects a selection bias in this study. In this low risk population each year of increased age resulted in 0.95 times decrease in risk for cesarean. In addition, model 1 showed that provider type had one of the most significant impacts on method of delivery with patients of MFMs having nearly 4 times the risk of cesarean than patients of midwives.

Interestingly, when controlling for covariates, cervical ripening was actually protective against cesarean delivery with women who did not receive cervical ripening have twice the risk of cesarean than those who received it. This finding contradicts much of the literature on studies that combined both low and high-risk pregnancies (Kim et al., 2019, Fraser et al., 2000). However, the results of the bivariate analyses do support the findings of one study that found induction of labor at 39 weeks was not associated with cesarean delivery (Saccone et al., 2019). This may indicate that labor induction after 39 weeks does not pose a significant threat to achieving a vaginal delivery, and is a potentially safe method of induction for low risk patients.

Finally, race was significantly associated with cesarean delivery when comparing African-American women to white women, with African-American women being nearly twice as likely to delivery by cesarean when controlling for all other covariates. This finding is on trend with the literature (Heelan-Fancher et al., 2019).

Parity, however, was not significantly associated with cesarean when controlling for other covariates, which is a different finding than many other studies (Schnettler et al., 2012; Jackson et al., 2011). This is a new finding and may highlight the differences, or lack thereof, when eliminating the effects of high-risk conditions in pregnancy that influence delivery outcomes.

**Model 2- Late and Prolonged Decelerations and Cesarean Delivery**

Late and prolonged decelerations were the only two FHR characteristics found to be associated with delivery method. Prolonged decelerations increased the odds of cesarean delivery 1.5 times and late decelerations increased the odds by nearly 1.5 times. This study highlights these characteristics as being more accurate in assessing fetal oxygenation in low risk labor. However, they were only significant when they appeared without the presence of the other. A much larger study sample may be needed to have to enough subjects with both late and prolonged decelerations in a given interval. Having anesthesia prior to the decision to deliver, being any race other than white, and having a high-risk obstetrician attend the delivery significantly all increased the odds for cesarean delivery.

Given the similar R-square for the models, they both appear to be equivalent in explaining the differences in delivery method. However, given the consistent findings of anesthesia, race, and provider type, these three variables may be more important in predicting cesarean delivery than any specific FHR characteristic. The increased risk for cesarean when using count of abnormal FHR characteristics seems to have, arguably, the highest association with cesarean delivery, and would include the risks related to both late and prolonged decelerations. Therefore, it does seem that Model 1 is the most clinically useful model and could inform the decision to deliver. While the main purpose of this aim was not to assess and evaluate demographic and labor characteristics and their relationship to cesarean delivery, when multivariate models were created, some clear associations were observed.

## Demographic and Labor Characteristics and Cesarean Delivery

Increased age in previous studies has been associated with increased risk for cesarean delivery, as discussed in chapter 2. However, in this study increasing age was actually protective against cesarean delivery. This can potentially be explained by the exclusion criteria. The oldest patients that delivered at UIHC during the study period were excluded from the study sample. In addition, it is known that high risk pregnancy conditions can increase with age (i.e., gestational diabetes, blood pressure disorders, fetal genetic abnormalities, etc.), as can fetal malpresentation and failure to progress in labor (Evans et al., 2019). Any of these conditions would have excluded the woman from inclusion in the study. However, it should be noted that the mean age of 28.5 years and normal distribution indicates the study sample does to some degree mimic that of the population of interest. The study's finding of a decreased odds of cesarean with an increase of 5 years in age may indicate that otherwise low risk women over the age of 35 are not at an increased risk of cesarean. It may also reflect the choice of older patients to receive care from a midwife (Reime et al., 2004).

This study's findings on race are consistent with multiple studies discussed in chapter 2. African-American women and Asians delivered at a 14% increased cesarean proportion than white women, with white women and those of Hispanic ethnicity only differing by 3%. This study found an even greater odds of cesarean when comparing low risk African-American women to low risk white women than other studies (2.91 vs 1.48) (Bryant et al., 2009). This could be related to demographic differences in patients at UIHC versus other U.S. hospitals, or related to the exclusion criteria. UIHC is a tertiary care center where the majority of midwife patients are likely educated, white, and of higher income. UIHC also sees lower income Medicaid patients which may explain the increased odds of cesarean observed in women of a lower socio-economic status, as reviewed in chapter 2. Similar to race, the trends observed in parity were consistent with the research. Primiparous (or nulliparous) women had a higher risk of cesarean delivery than multiparous women (Nisenblat et al., 2006; MacDorman et al., 2008; Holmgren et al., 2013).

The use of epidural anesthesia in low risk labor prior to the decision to deliver was significantly associated with cesarean delivery which is on trend with the existing literature. Only 1 subject delivered by cesarean without having an epidural prior to deciding to deliver. The strict definition of low risk subjects for this study likely contributed to this finding. This study would have to be replicated on a much larger scale with the same definition of low risk labor to confirm the strength of the association, to attempt to capture more women who delivered via cesarean but did not have an epidural prior to that decision to deliver.

Cervical ripening, oxytocin, and AROM were all associated with cesarean delivery, however only cervical ripening and AROM were significantly associated. This is consistent with the literature (Saccone et al., 2019). To be included in this study the patient must be low risk which would limit rationale for induction for the subjects included in this study, likely meaning when inductions occurred, they occurred after 39 weeks.

Delivery provider type at the decision to deliver was one of the most interesting findings of the study. Delivery provider type ultimately ended up having one of the highest associations with cesarean delivery. While nearly 75% of the subjects were attended to by the general obstetrician-gynecologist (GOB) group or the midwife group, 33% of those patients attended to by the high-risk obstetricians delivered by cesarean, and 10% of those attended to by midwives. This is consistent with the current literature showing a lower cesarean rate for midwives than physicians. However, it should be noted that midwives see low risk patients while physicians, especially obstetricians, see patients that are both low and high risk. MFMs may be influenced by their training in treating the highest risk women and fetuses when attending to the labor and birth of a low risk patient. In other words, when a provider sees high risk patients on a daily basis, they may be more inclined to view the labor of a low risk patient as equivalent to a high-risk patient the MFM sees in their clinic duties. In addition, certified nurse midwives will transfer care of high-risk patients to obstetricians, therefore, pregnant women choosing a midwife for their prenatal care are generally of a lower-risk status than the wide array of patients that see GOBs or MFMs for their prenatal care. This is the first study that examined only low risk patients and categorized physicians into GOB, high risk and family practice, and therefore adds new information to the data collected on provider type and delivery method.

## Clusters of Abnormal FHR Characteristics and Cesarean Delivery

The cluster analysis seemed to confirm Model 1 as the superior model for associating with cesarean when controlling for the multiple covariates. Cluster 1 (higher baseline FHR, minimal variability, and decelerations) was associated with a greater than 1.5 times increased odds of cesarean than those in cluster 2. This finding seems expected as it contains more abnormal FHR characteristics. Cluster analyses have not been used to examine the individual FHR characteristics in labor in any of the available literature. While the bivariate analyses of the clusters was significant, once multivariate analyses were used to control for covariates the significance was eliminated. This likely means the covariates have better associations with cesarean than the clusters or the cluster variable doesn't explain any additional variability in delivery method, than is already explained by the covariates.

## Limitations

This study was a retrospective longitudinal study, with the data collected from the medical record. Because the data was not being collected prospectively, in real time, some data desired for this study may have been missing from the medical record, or was incomplete. A prospective longitudinal design would have been stronger, given the control over the type of data collected instead of having to work with what is available. For example, in a prospective study one could actively track and monitor maternal cervical dilation and interventions implemented to address concerning FHR characteristics. This data is often charted by the nurse caring for the patient; however, it is not known when the cervix actually changed unless the cervix is checked regularly despite labor characteristics (Gabbe et al., 2012). In addition, when interventions are implemented the nurse caring for the patient is often busy and can inadvertently forget to chart each intervention.

Another limitation of the study was having only one study hospital. Regional, community, and even hospital differences exist. While the study hospital treats a variety of patients, ranging from low-risk midwife patients to the sickest mother-infant dyads in the state, having study participants from multiple institutions (public and private) in multiple states would make the findings much more generalizable to low-risk mother-infant dyads across the country. However, the recruiting of multiple hospitals from multiple states was not feasible for the time and funding of this study. The generalizability of the study findings was minimized to low risk mother-infant dyads at the study hospital.

Some variables were not collected in this study that may influence the FHR and the decision to proceed to cesarean delivery. Some of those variables include cervical dilation and maternal temperature. Cervical dilation would be an indicator of the progression of labor. If abnormal FHR characteristics are observed and the maternal cervix is 5 cm the provider may treat that patient differently than if the maternal cervix is completely dilated. Maternal temperature can indicate a uterine infection, can cause fetal tachycardia, and uterine dysfunction (Gabbe et al., 2012). Including assisted vaginal deliveries may also have influenced the outcomes of this study. However, in order to achieve a meaningful result, studies focusing on assisted vaginal deliveries in low risk labor must be undertaken.

As mentioned earlier, it is possible to trace the maternal pulse instead of the FHR (Macones et al., 2011). If the CEFM is obviously tracing the maternal pulse, or questionably tracing the maternal pulse, these segments of CEFM tracing were not included in the study. Additionally, if the nursing staff was busy or unable to quickly reposition the ultrasound transducer there were varying periods of time in the two hours prior to delivery in which there was missing data. In these periods of missing data it is possible that category II CEFM tracings may have been occurring. This study was interested in examining the relationship between category II CEFM tracing and the decision on method of delivery. If CEFM data was missing or the maternal pulse was being recorded, the data itself would not have influenced the decision on method of delivery, but the inability to acquire a FHR could have potentially influenced a decision to expedite delivery. None of the CEFM tracings examined had greater than two intervals with missing data.

Some of the study participants from the participant pool received only intermittent fetal monitoring (IFM) during the two hours prior to delivery. These participants could have potentially been at the lowest risk of mediating variables affecting the FHR or decision to deliver, as IFM is only done when the participant is low risk, does not have an epidural or medications for induction and augmentation (cervical ripeners and oxytocin) at the study hospital (AWHONN, 2009). If a potential study participant did not receive any CEFM in the two hours prior to delivery they were excluded from the study. It is possible that if these participants were to receive CEFM, given their minimized risk of mediating variables affecting the FHR and delivery method, the results of the study may have been altered. However, given the aims of the study, exclusion of those participants only receiving IFM was appropriate.

The two-hours prior to delivery time frame of the CEFM strips examined for this study had some limitations as well. Some labors, especially those which are induced, can be significantly longer than two hours. If labor is long, increased stress could be placed on the fetus impacting the FHR characteristics on the CEFM tracing (Gabbe et al., 2012). Additionally, the second-stage of labor (pushing stage) may be longer than two hours. In these cases, the entire two-hour CEFM strip was in the pushing phase of labor when the fetal head is descending through the maternal pelvis and into the birth canal, causing stress on the fetus. Both of the above scenarios could have an impact on the FHR characteristics, and therefore the study results. To aid in understanding how the length of labor might impact the FHR characteristics, total length of labor was collected in minutes from each study participant.

Given that cell values for induction with oxytocin, augmentation with oxytocin, induction with AROM, and augmentation with AROM were too small to be meaningful, the decision was made to collapse them into use of oxytocin and use of AROM. There is a difference between intervening in spontaneous labor, and intervening to induce labor. Therefore, the use of both oxytocin and AROM may impact the labor of a woman in differing ways depending on their use prior to, or after labor begins. Therefore, the collapsing of these variables in this way may have had an impact on the variable outcomes. However, it should be noted that despite the collapsing of these variables, induction of labor with cervical ripeners, which was not collapsed, had the most significant association with delivery outcome.

The decision to proceed to cesarean delivery clearly differs between both provider types and individual providers. The decision to proceed to cesarean delivery does not necessarily mean the fetus is actually hypoxic, it simply represents a fear that the fetus may be at risk of hypoxia. There are few ways of actually determining a fetus's true oxygenation in labor. One way of confirming the hypoxia in labor is fetal scalp sampling. Hypoxia can be confirmed after delivery by sampling the blood from the umbilical cord. Many providers might argue that they try and intervene prior to the fetus actually becoming hypoxic (Nelson et al., 1996). This study did not examine the umbilical cord gases of each newborn to confirm fetal hypoxia because umbilical cord blood sampling did not occur with most of the vaginal deliveries. Therefore, this study did not examine true fetal hypoxia, but rather the fear that fetal hypoxia was imminent by deciding to deliver via cesarean. In other words, this study examined the FHR characteristics that influenced the provider's decision to deliver by cesarean and not the FHR characteristics that actually placed the low risk fetus at risk of hypoxia.

The use of electronic medical records has inherent limitations. This includes errant data entered by hospital staff. This could include forgetting to mark specific maternal or fetal diagnoses, or errant entries, such as time of birth, birth weight, etc. Physicians, midwives and nurses are human and will occasionally make mistakes in medical record charting. Any of the medical records reviewed for this study could have had erroneous charting, which could potentially influence the outcomes of this study.

The low R-square value in this study indicated that approximately 20% of the variance between Model 1 and Model 2 of the multivariate analyses was explained. This is a relatively low explanation of variance. This study should be completed on a grander scale, with multiple institutions to confirm the models' findings are consistent and valid.

Finally, while using only one research team member to collect all of the data helps inter-rater reliability, it is possible that the interpretation of the CEFM tracings could be inconsistent with how another clinician might interpret the tracings. To address this concern, as mentioned before, the PI independently interpreted 10% of the CEFM tracings abstracted by the research assistant with an acceptable agreement of 90% or greater required.

**Implications for Practice**

This study adds to the evidence that CEFM is not appropriate for use in low risk labor, as the individual FHR characteristics are not significantly associated with cesarean delivery once controlling for covariates. In fact, a low risk woman's race, anesthesia status, and the type of provider attending her delivery may have the best association with delivery outcome. However, resistance to using IFM in low risk labor remains an issue on labor and delivery units across the country. If IFM is not used and a woman is instead placed on CEFM it may be more beneficial to collect simply a count of the abnormal FHR characteristics in the presence of category II. Nurses and other providers on labor and delivery units may want to first assess which category a low risk fetus falls into in a given 15-minute interval in active labor. If it is determined a fetus is in category II, perhaps simply document the number of abnormal FHR characteristics, rather than the actual baseline FHR, type of variability, presence of accelerations, and type of decelerations. Perhaps when two abnormal FHR characteristics are present interventions can be implemented to try and reverse the number. When three abnormal FHR characteristics are present the team may want to discuss the need for proceeding to cesarean delivery with the woman and her family. However, to confirm these findings, more research must be done on count of abnormal characteristics.

It is important for labor and delivery providers to understand the differences between low and high-risk pregnancies and evaluate them differently. Low risk patients may be better identified as at risk for cesarean delivery by their covariates (race, anesthesia status, and provider type) and the number of abnormal FHR characteristics than any combination of specific FHR characteristics. Cesarean is a life-saving procedure that is critical to save lives of both mothers and fetuses. However, many agree that the cesarean rate needs to decrease. The goal should be to deliver via cesarean only when it is absolutely necessary to prevent adverse outcomes for the mother or the infant.

## Future Research Needed

The strength of the relationship between counts of abnormal FHR characteristics needs to be researched further in both retrospective, observational studies and prospective randomly controlled trials. In addition, qualitative studies on provider opinions on the use of count of abnormal characteristics in labor should be conducted to ascertain the willingness of nurses, midwives, and physicians to use the measurement in practice.

Repeating this study in multiple states and in both academic and private, community hospitals would aid in making the results of this study applicable to a larger population. Additionally, this study highlights that more research needs to be conducted that separates high risk patients from low risk patients and that it is possible they need to be monitored differently.

Future studies should be conducted to flush out the mechanism for low income disparities and the manner in which the impact of Medicaid assignments to practitioners may impact delivery outcomes.

Cluster analyses of similar variables should be conducted on a larger sample size to determine if more specific clusters of individual FHR characteristics emerge. This could inform the interpretation of the CEFM strip and help to identify benign combinations of FHR characteristics and potentially injurious combinations of FHR characteristics in low risk labor.

## Conclusion

While there were significant associations between specific FHR characteristics and cesarean delivery, those associations frequently became insignificant once the characteristics were controlled for by multiple covariates or confounding variables. In low risk labor, race, epidural status, and provider type are actually better associated with cesarean delivery than most individual FHR characteristics. Count of abnormal FHR characteristics is the best measurement from the CEFM strip to determine risk of cesarean delivery in low risk labor. Count of abnormal FHR characteristics should be examined further and considered as a potential measurement of low risk fetal status in labor. There is a need to further codify both the interpretation of CEFM and the interventions to address specific FHR characteristics. Consistency in interpretation and practice will help to decrease the disparities between providers and institutions and create a safer environment for labor and birth around the world.

REFERENCES

Aboulghar, W., Ibrahim, M., Allam, I., Hosny, W., & Otify, M. (2013). Validity of cardiotocography in the diagnosis of acute fetal hypoxia in low resource settings. *Internet Journal of Gynecology & Obstetrics, 17*(1), 1.

Afors, K., & Chandraharan, E. (2011). Use of continuous electronic fetal monitoring in a preterm fetus: Clinical dilemmas and recommendations for practice. *Journal of Pregnancy,* 2011, 1-7.

Alfirevic, Z., Devane, D., Gyte, G., & Cuthbert. (2017). Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour. *Cochrane Database of Systematic Reviews 2017, 2*. DOI: 10.1002/14651858.CD006066.pub3.

Ali, U.A., & Norwitz, E.R. (2009) Vacuum-assisted vaginal delivery. *Review of Obstetrics and Gynecology, 2*(1), 5-17.

Al Wattar, B.H., Lakhiani, A., Sacco, A., Siddharth, A., Bain, A., Calvia, A., . . .Castling, Z. (2019). Evaluating the value of intrapartum fetal scalp blood sampling to predict adverse neonatal outcomes: A UK multicentre observational study. *European Journal of Obstetrics & Gynecology & Reproductive Biology. 240*, 62-67.

American College of Nurse Midwives. (2010). Intermittent auscultation for intrapartum fetal heart rate surveillance. *Journal of Midwifery & Women's Health, 55*(4), 397-403.

American College of Obstetricians and Gynecologists. (2008). *Intrapartum Fetal Heart Rate Monitoring: A Standardized Approach to Interpretation and Management* [PDF Document]. Retrieved from mail.ny.acog.org/website/EFMInterpretation.pdf.

American College of Obstetricians and Gynecologists. (2005). ACOG practice bulletin: Clinical management guidelines for Obstetrician-Gynecologists, Number 70 (Replaces practice bulletin Number 62). *Obstetrics & Gynecology, 106*(6), 1453-1460.

American College of Obstetricians and Gynecologists and American Academy of Pediatrics. (2019). Committee opinion on the Apgar score. *Pediatrics, 126*: e52-5.

American Congress of Obstetricians and Gynecologists Task Force on Neonatal Encephalopathy and Cerebral Palsy, American College of Obstetricians and Gynecologists, American Academy of Pediatrics Neonatal Encephalopathy and Cerebral Palsy. (2003). *Defining the Pathogenesis and Pathophysiology.* Washington D.C.: ACOG.

Amini, S.B., Catalano, P.M., & Mann, L.I. (1996). Births to unmarried mothers: trends and obstetric outcomes. *Women's Health Issues, 6*(5), 264-272.

Association of Women's Health, Obstetric and Neonatal Nurses. (2009). On NICHD workshops I (1997) and II (2008) on electronic fetal monitoring. *Journal of Obstetric, Gynecologic and Neonatal Nursing, 38*(3), 255-257.

Berendzen, J.A., & Howard, B.C. (2013). Association between cesarean delivery rate and body mass index. *Tennessee Medicine, 106*(1), 35-37.

Berg, J., Tymoczko, J., & Stryer, L. (2002). "10.2". *Biochemistry* (5th ed.) New York, NY: W. H. Freeman. ISBN 0-7167-3051-0.

Bryant, A.S., Washington, S., Kuppermann, M., Cheng, Y.W., & Caughey, A.B. (2009). Quality and equality in obstetric care: racial and ethnic differences in caesarean section delivery rates. *Paediatric Perinatal Epidemiology, 23*(5), 454-462.

Cahill, A.G., Tuuli, M.G., Stout, M.J., Lopez, J.D., & Macones, G.A. (2018). A prospective cohort study of fetal heart rate monitoring: Deceleration area is predictive of fetal acidemia. *American Journal of Obstetrics and Gynecology, 218*(5), 523.e1-523.e12.

Cammu, H., Martens, G., & Keirse, M.J. (2011). Mothers' level of education and childbirth interventions: A population-based study in Flanders, Northern Belgium. *Birth, 38*(3), 191-199.

Cantu, J., Szychowski, J., Li, X., Biggio, J., Edwards, R.K., & Andrews, W. (2014). Predicting fetal acidemia using umbilical venous cord gas parameters. *Obstetrics & Gynecology, 124*(5), 926-932.

Centers for Disease Control and Prevention. (2012). *Births – Method of delivery* [Data file]. Retrieved from http://www.cdc.gov/nchs/fastats/delivery.htm.

Centers for Disease Control and Prevention. (2016). *Trends in low-risk cesarean delivery in the United States, 1990-2013.* Retrieved from https://nchstats.com/2016/11/05/trends-in-low-risk-cesarean-delivery-in-the-united-states-1990-2016/.

Centers for Disease Control and Prevention. (2018). *Data and statistics for cerebral palsy.* Retrieved from https://www.cdc.gov/ncbddd/cp/data.html.

Cesaroni, G., Forastiere, F., & Perucci, C.A. (2008). Are cesarean deliveries more likely for poorly educated parents? A brief report from Italy. *Birth, 35*(3), 241-244.

Ciriello, E., Locatelli, A., Incerti, M., Ghidini, A., Andreani, M., Plevani, C., & Regalia, A. (2012). Comparative analysis of cesarean delivery rates over a 10-year period in a single institution using 10-class classification. *Journal of Fetal Neonatal Medicine, 25*(12), 2717-2720.

Clark, S., & Hankins G. (2003). Temporal and demographic trends in cerebral palsy-fact and fiction. *American Journal of Obstetrics and Gynecology, 188*, 628-633.

Clark, S., Hamilton, E., Carite, G., Timmins, A., Warrick, P., & Smith, S. (2017) The limits of electronic fetal heart rate monitoring in the prevention of neonatal metabolic acidemia. *American Journal of Obstetrics and Gynecology, 216*, 163.e1-6.

Clark, S., Nageotte, M., Garite, T., et al. (2013). Intrapartum management of category II fetal heart rate tracings: Towards standardization of care. *American Journal of Obstetrics and Gynecology, 209*(2), 89-97.

Coletta, J., Murphy, E., Rubeo, Z., & Gyamfi-Bannerman, C. (2012). The 5-tier system of assessing fetal heart rate tracings is superior to the 3-tier system in identifying fetal acidemia. *American Journal of Obstetrics and Gynecology, 226*, 226.e1-226.e5.

Crane, J.M., Murphy, P., Burrage, L., & Hutchens, D. (2013). Maternal and perinatal outcomes of extreme obesity in pregnancy. *Journal of Obstetrics and Gynaecology Canada, 35*(7), 606-611.

Devoe, L., Golde, S., Kilman, Y., Morton, D., Shea, K., & Waller, J. (2000). A comparison of visual analyses of intrapartum fetal heart rate tracings according to the new National Institute of Child Health and Human Development guidelines with computer analyses by an automated fetal heart rate monitoring system. *American Journal of Obstetrics and Gynecology, 183*(2), 361-366.

Di Tommaso, M., Seravalli, V., Cordisco, A., Consorti, G., Mecacci, F., & Rizzello, F. (2013). Comparison of five classification systems for interpreting electronic fetal monitoring in predicting neonatal status at birth. *The Journal of Maternal-Fetal and Neonatal Medicine, 26*(5), 487-490.

East, C., Begg, L., Colditz, P., & Lau, R. (2014). Fetal pulse oximetry for fetal assessment in labour (Review). *Cochrane Database of Systematic Reviews*, 10, DOI: 10.1002/14651858.CD004075.pub4.

Ecker, J.L., Chen, K.T., Cohen, A.P., Riley, L.E., & Lieberman, E.S. (2001). Increased risk of cesarean delivery with advancing maternal age: Indications and associated factors in nulliparous women. *American Journal of Obstetrics and Gynecology*, *185*(4), 883-887.

Edmonds, J.K, Yehezkel, R., Liao, X., & Moore Simas, T.A. (2013). Racial and ethnic differences in primary, unscheduled cesarean deliveries among low-risk primiparous women at an academic medical center: a retrospective cohort study. *BMC Pregnancy and Childbirth*, *13*, 168.

Elliott, C., Warrick, P., Graham, E., & Hamilton, E. (2010). Graded classification of fetal heart rate tracings: Association with neonatal metabolic acidosis and neurologic morbidity. *American Journal of Obstetrics and Gynecology, 202*(3), 258.e1-258.e8.

Epic. (2015). Organizations of the care everywhere network. Retrieved from http://www.epic.com/CareEverywhere/.

Epstein, A., Twogood, S., Lee, R., Opper, N., Beavis, A., & Miller, D. (2012). Interobserver reliability of fetal heart rate pattern interpretation using NICHD definitions. *American Journal of Perinatology, 30*(6), 463-468.

Eriksen, L.M., Nohr, E.A., & Kjaergaard, H. (2011). Mode of delivery after epidural analgesia in a cohort of low-risk nulliparas. *Birth, 38*(4), 317-326.

Erkkola, R., Gronroos, M., Punnonen, R., & Kilkku, P. (1984). Analysis of intrapartum fetal deaths: Their decline with increasing electronic fetal monitoring. *Acta Obstetricia et Gynecologica Scandinavica, 63*, 459–62.

Evans, M., Britt, D., Eden, R., Gallagher, P., Evans, S., & Schifrin, B. (2019). The fetal reserve index significantly outperforms ACOG category system in predicting cord blood base excess and pH: A methodological failure of the category system. *Reproductive Sciences,* 1-6, DOI: https://doi.org/10.1177/1933719119833796.

Fraser, W.D., Turcot, L., Krauss, I., & Brisson-Carrol, G. (2000). Amniotomy for shortening spontaneous labour. *Cochrane Database of Systematic Reviews,* (2), CD000015.

Gabbe, S., Niebyl, J., Galan, H., Jauniaux, E., Landon, M., Simpson, J., & Driscoll, D. (2012). *Obstetrics: Normal and problem pregnancies* (6th ed.). Philadelphia, PA: Saunders.

Goodlin, R. (1979). The history of fetal monitoring. *The American Journal of Obstetrics and Gynecology, 133*(3), 323-352.

Gower, J. C. (1971) A general coefficient of similarity and some of its properties. *Biometrics, 27*, 857–874.

Grivell, R.M., Aflrevic Z., Devane, D. & Gyte, G. (2013). Antenatal cardiotocography for fetal assessment. *Cochrane Database of Systematic Reviews, 12*(9), 1-59.

Gyamfi-Bannerman, C., Grobman, W., Antoniewicz, L., Hutchinson, M., & Blackwell, S. (2011). Assessment of the concordance among 2-tier, 3-tier, and 5-tier fetal heart rate classification systems. *American Journal of Obstetrics and Gynecology, 205*(3), 288.e1-288.e4.

Haberman, S., Saraf, S., Zhang, J., Landy, H.J., Branch, D.W., Burkman, R., Gregory, K.D., Ramirez, M.M., Bailit, J.L., Gonzalez-Quintero, V.H., Hibbard, J.U., Hoffman, M.K., Kominiarek, M., Lu, L., Van Veldhuisen, P., & Von Gruenigen, V.; for the Consortium on Safe Labor. (2013). Nonclinical parameters affecting primary cesarean rates in the United States. *American Journal of Perinatology,* May [Electronically published ahead of print].

Hancerlioqullari, N., Yaman, S., Aksoy, R.T., & Tokmak, A. (2019). Does an increased number of cesarean sections result in greater risk for mother and baby in low risk, late preterm and term deliveries? *Pakistani Journal of Medicine, 35*(1), 10-16.

Healthcare Cost and Utilization Project. (2006). *Hospitalizations Related to Childbirth, 2003* [Data file]. Retrieved from http://www.ncbi.nlm.nih.gov/books/NBK63491/.

Heelan-Fancher, L., Shi, L., Zhang, Y., Cai, Y., Nawai, A, & Leveille, S. (2019). Impact of continuous electronic fetal monitoring on birth outcomes in low-risk pregnancies. *Birth, 00*, 1-7.

Holmgren, C., Esplin, M., Jackson, M., Porter, R., Horne, H., & Varner, M. (2013). A risk stratification model to predict adverse neonatal outcome in labor. *Journal of Perinatology*, *33*(12), 914-918.

Hueston, W., McClaflin, R., & Claire, E. (1996). Variations in cesarean delivery for fetal distress. *Journal of Family Practice, 43*(5), 461-467.

Indraccolo, U., Calabrese, S., Di Iorio, R., Corosu, L., Marinoni, E., & Indraccolo, S.R. (2010). Impact of the medicalization of labor on mode of delivery. *Clinical and Experimental Obstetrics and Gynecology, 37*(4), 273-277.

Jackson, M., Holmgren, C., Esplin, S., Henry, E., & Varner, M. (2011). Frequency of fetal heart rate categories and short-term neonatal outcome. *Obstetrics and Gynecology, 118*(4), 803-808.

Jain, D., Khuteta, R., Chaturvedi, V., & Khuteta, S. (2012). Effect of body mass index on pregnancy outcomes in nulliparous women delivering singleton babies: Observational study. *Journal of Obstetrics and Gynaecology India, 62*(4), 429-431.

Jonsson, M., Cnattingius, S., & Wikström, A.K. (2013). Elective induction of labor and the risk of cesarean section in low-risk parous women: A cohort study. *Acta Obstetricia et Gynecologica Scandinavica, 92*(2), 198-203.

Kaufman, L., & Rousseeuw, P. (2005). *Finding groups in data*. New York: Wiley.

Kim, S., Park, J., Bak, S., Jang, Y., Wie, J., & Ko, H. (2019). Effect of maternal age on emergency cesarean section. *The Journal of Maternal-Fetal & Neonatal Medicine,* DOI: 10.1080/14767058.2019.1593958.

Klauser, C.K., Christensen, E.E., Chauhan, S.P., Bufkin, L., Magann, E.F., Bofill, J.A., & Morrison, J.C. (2005). Use of fetal pulse oximetry among high-risk women in labor: A randomized clinical trial. *American Journal of Obstetrics and Gynecology, 192*(6), 1817-1819.

Kozhimannil, K.B., Shippee, T.P., Adegoke, O., & Vemig, B.A. (2013). Trends in hospital-based childbirth care: The role of health insurance. *American Journal of Managed Care, 19*(4), e125-132.

Levine, L.D., Hirshberg, A., & Srinivas, S.K. Term induction of labor and risk of cesarean delivery by parity. *Journal of Maternal-Fetal & Neonatal Medicine,* November [Electronically published ahead of print].

Lialios, G., & Kaponis, A. (1999). Maternal age as an independent risk factor for cesarean delivery. *International Journal of Gynecology & Obstetrics*, *67*(3), 187-188.

Little, S., Orav, E., Robinson, J., Caughney, A., & Jha, A. (2016). The relationship between variations in cesarean delivery and regional health care use in the United States. *American Journal of Obstetrics & Gynecology, 214*(6), 735.e1-8.

MacDonald, D., Grant, A., Sheridan-Pereira, M., Boylan, P., & Chalmers, T. (1985). The Dublin randomized controlled trial of intrapartum fetal heart rate monitoring. *American Journal of Obstetrics and Gynecology, 152*, 425-539.

MacDorman, M., Menacker, F., & Declercq, E. (2008). Cesarean birth in the United States: Epidemiology, trends and outcomes. *Clinics in Perinatology, 35*(2), 293-307.

MacLennan, A. (2000). A template for defining a causal relationship between acute intrapartum events and cerebral palsy: International consensus statement. *Journal of Obstetrics and Gynecology, 40*, 13-21.

Macones, G., Hankins, G., Spong, C., Hauth, J., & More, T. (2011). The 2009 National Institute of Child Health and Human Development workshop report on electronic fetal monitoring. *Obstetrics and Gynecology, 112*(3), 661-666.

Maechler, M., Rousseeuw, P., Struyf, A., Hubert, M., & Hornik, K. (2018). Cluster: Cluster Analysis Basics and Extensions. R package version 2.0.7-1.

Martin, C. B. (2008). Normal fetal physiology and behavior, and adaptive responses with hypoxemia. *Seminars in Perinatology, 32*, 239-242. doi: 10.1053/j.semperi.2008.04.003.

Martin, J.A., Hamilton, B.E., Sutton, P.D., Ventura, S.J., Menacker, F., Kirmeyer, S., & Munson, M.L. (2009). Births: Final data for 2006. *National Vital Statistics Reports*, *57*(7). Hyattsville, MD: National Center for Health Statistics.

Maso, G., Businelli, C., Piccoli, M., Monico, M., De Seta, F., Sartore, A., & Alberico, S. (2012). The clinical interpretation and significance of electronic fetal heart rate patters 2 h before delivery: An institutional observational study. *Archives of Gynecology and Obstetrics, 286*(5), 1153-1159.

Menacker, F., & Hamilton, B. (2010). NCHS data brief: Recent trends in cesarean delivery in the United States. *National Vital Statistics Reports, 35*. Hyattsville, MD: National Center for Health Statistics.

Miller, D.A., & Miller, L.A. (2012). Electronic fetal heart rate monitoring: Applying principles of patient safety. *American Journal of Obstetrics & Gynecology, 206*, 278-283. doi: 10.1016.j.ajog.2011.08/016.

Mires, G., Williams. F., & Howie, P. (2001). Randomized controlled trial of cardiotocography versus Doppler auscultation of fetal heart at admission in labour in low risk obstetric population. *BMJ, 322*, 1457-1462.

Mitchell, K. (2008). The effect of the labour electronic fetal monitoring admission test on operative delivery in low-risk women: a randomized control trial. *Evidence Based Midwifery, 6*(1), 18-26.

Monographs of the Society for Research in Child Development. (2015). V. Fetal heart rate and variability. *Monographs of the Society for Research in Child Development*, *80*(3), 23-32. doi:10.1111/mono.12175

Movsas, T.Z., Wells, E., Mongoven, A., & Grigorescu, V. (2012). Does medical insurance type (private vs. public) influence the physician's decision to perform caesarean delivery? *Journal of Medical Ethics, 38*(8), 470-473.

Murray, M. (2006). *Antepartal and intrapartal fetal monitoring (3rd ed.).* New York, NY: Springer Publishing Company.

Nageotte, M.P. (2015). Fetal heart rate monitoring. *Seminars in Fetal & Neonatal Medicine, 20*, 144-148. doi: 10.1016/j.siny.2015.02.002.

National Institute of Child Health and Human Development Research Planning Workshop. (1997). Electronic fetal heart rate monitoring: Research guidelines for interpretation. *American Journal of Obstetrics and Gynecology, 177*(6), 1385-1390.

Nelson, K., Dambrosia, J., Ting, T., & Grether, J. (1996). Uncertain value of electronic fetal monitoring in predicting cerebral palsy. *The New England Journal of Medicine, 334*(10), 613-618.

Nisenblat, V., Barak, S., Griness, O.B., Degani, S., Ohel, G., & Gonen, R. (2006). Maternal complications associated with multiple cesarean deliveries. *Obstetrics and Gynecology*, *108*, 21–26.

Ogunyemi, D., Jovanovski, A., Friedman, P, Sweatman, B., & Madan, I. (2018). Temporal and quantitative associations of electronic fetal heart rate monitoring patterns and neonatal outcomes. *The Journal of Maternal-Fetal & Neonatal Medicine, 4*(6), 1-10.

Onion,, D.K., Meyer, D.L., Wennberg, D.E., & Soule, D.N. (1999). Primary cesarean section rates in uninsured, Medicaid and insured populations of predominantly rural northern New England. *Journal of Rural Health, 15*(1), 108-112.

Parer, J.T., (1983). Fetal heart rate. In R.K. Creasy, & R. Resnik, (Eds.), *Maternal-fetal medicine: Principles and practice.* Philadelphia: W.B. Saunders.

Parer, J., & Ikeda, T. (2007). A framework for standardized management of intrapartum fetal heart rate patterns. *American Journal of Obstetrics and Gynecology, 197*(1), 26.e1-26.e6.

Peipert, J.F., Hogan, J.W., Gifford, D., Chase, E., & Randall, R. (1999). Strength of indication for cesarean delivery: Comparison of private physician versus resident service labor management. *American Journal of Obstetrics and Gynecology, 181*(2), 435-439.

Penfield, C., Hong, C., Ibrahim, S., Kilpatrick, S., & Gregory, K. (2016). Easy as ABC: A system to stratify category II fetal heart rate tracings. *American Journal of Perinatology* [Electronic publication ahead of print]. Retrieved from http://www-ncbi-nlm-nih-gov.proxy.lib.uiowa.edu/pubmed/?term=Penfield%2C+C.%2C+Hong%2C+C.%2C+Ibrahim%2C+S.%2C+Kilpatrick%2C+S.%2C+Gregory%2C+K.+(2015).+Easy+as+ABC%3A+A+system+tt+stratify+category+II+fetal+heart+rate+tracings.+American+Journal+of+Perinatology.

Pillai, M., & James, D. (1990). The development of fetal heart rate patterns during normal pregnancy. *Obstetrics & Gynecology, 76*, 812-216.

Polnaszek, B., Lopez, J.D., Clark, R., Raghuraman, N., Macones, G.A., & Cahill, A.G. (2019). Marked variability in intrapartum electronic fetal heart rate patterns: Association with neonatal morbidity and abnormal arterial cord gas. *Journal of Perinatology,* doi: 10.1038/s41372-019-0520-9 [Epub ahead of print].

Prentice, A., & Lind, T. (1987). Fetal heart rate monitoring during labour – Too frequent intervention, too little benefit? *The Lancet, 330*(8572), 1375-1377.

Read, A.W., Prendiville, W.J., Dawes, V.P., & Stanley, F.J. (1994). Cesarean section and operative vaginal delivery in low-risk primiparous women, Western Australia. *American Journal of Public Health, 84*(1), 37-42.

Reime, B., Klein, M.C., Kelly, A., Duxbury, N., Saxell, L., Liston, R., Prompers, F.J., Entjes, R.S., & Wong, V. (2004). Do maternity care provider groups have different attitudes towards birth? *British Journal of Obstetrics and Gynecology, 111*(12), 1388-1393.

Richardson, B., Carmichael, L., Homan, J., Johnston, L., & Gagnon, R. (1996). Fetal cerebral, circulatory and metabolic responses during heart rate decelerations with umbilical cord compression. *American Journal of Obstetrics and Gynecology, 175*(4), 929-936.

Rousseeuw, P. J. (1987). Silhouettes: A graphical aid to the interpretation and validation of cluster analysis. *Computational and Applied Mathematics, 20*, 53–65. doi:10.1016/0377-0427(87), 90125-90127

Royal College of Obstetricians and Gynecologists. (2001). *The use of electronic fetal monitoring: the use and interpretation of cardiotocography in intrapartum fetal surveillance.* (Evidence based guideline number 8). London, UK: author unnamed.

Rychik, J., (2004). Fetal cardiovascular physiology. *Pediatric Cardiology, 25*, 201-209.

Saccone, G., Della Corte, L., Maruotti, G.M., Quist-Nelson, J., Raffone, A., De Vivo, V., Esposito, G., Zullo, F., & Berghella, V. (2019). Induction of labor at full-term in pregnant women with uncomplicated singleton pregnancy: A systematic review and meta-analysis of randomized trials. *Acta Obstetrica Gynecologica et Scandinavia,* DOI: 10.1111/aogs.13561.

Sameshima, H., Ikenoue, R., Ikeda, R., Kamitomo, M., & Ibara, S. (2004). Unselected low-risk pregnancies and the effect of continuous intrapartum fetal heart rate monitoring on umbilical blood gases and cerebral palsy. *American Journal of Obstetrics and Gynecology, 190*(1), 118-123.

Sandman, C.A., Wadhwa, P., Hetrick, W., Porto, M., & Peeke, H.V.S., (1997). Human fetal heart rate dishabituation between thirty and thirty-two weeks gestation. *Child Development, 68*(6), 1031-1040.

Sarkar, P., Bergman, K., Fisk, N.M., O'Connor, T.G., & Glover, V. (2007). Ontogeny of foetal exposure to maternal cortisol using midtrimester amniotic fluid as a biomarker. *Clinical Endocrinology, 66*(5), 636-640.

Schnettler, W., Rogers, J., Barber, R., & Hacker, M. (2012). A modified fetal heart rate tracing interpretation system for prediction of cesarean section. *The Journal of Maternal-Fetal and Neonatal Medicine, 25*(7), 1055-1058.

Schuit, E., Kwee, A., Westerhuis, M.E.M.H., Van Dessel, H.J.H.M., Graziosi, G.C.M., Van Lith, J.M.M., Hijhuis, J.G., Oei, S.G., Oosterbaan, H.P., Schuitemaker, N.E.W., Wouters, M.G.A.J., Visser, G.H.A., Mol, B.W.J., Moons, K.G.M., & Groenwold, R.H.H. (2012). A clinical prediction model to assess the risk of operative delivery. *British Journal of Obstetrics and Gynaecology, 119*(8), 915-923.

Shepard, M.J., Saftlas, A., Leo-Summers, L., & Bracken, M. (1998). Maternal anthropometric factors and risk of primary cesarean delivery. *American Journal of Public Health, 88*(10), 1534-1538.

Shields, L., Wiesner, S., Klein, C., Pelletreau, B., & Hedriana, H. (2018). A standardized approach for category II fetal heart rate with significant decelerations: Maternal and neonatal outcomes. *American Journal of Perinatology, 35*(14), 1405-1410.

Simoes, E., Kunz, S., Bosing-Schwenkglenks, M., & Schmahl, F.W. (2005). Occupation and risk of cesarean section: Study based on the perinatal survey of Baden-Württemberg, Germany. *Acta Obstetricia et Gynecologica Scandinavica, 271*(4), 338-342.

Smith, M.A., Brix, K.A., & Heaton, C.J. (1988). The influence of work on the outcome of low-risk pregnancies. *Journal of the American Board of Family Practice Physicians, 1*(3), 167-174.

Society of Obstetrics and Gynaecologists of Canada. (2007). *Fetal health surveillance: Antepartum and intrapartum consensus guideline.* Ottawa, ON: Liston, R. & Sawchuck, D.

Sontag, L.W., & Richards, T.W. (1938). Fetal heart rate as a behavior indicator. *Monographs of the Society for Research in Child Development, 3*(4), 1-67.

Sweha, A., Hacker, T., & Nuovo, J. (1999). Interpretation of the electronic fetal heart rate during labor. *American Family Physician, 59*(9), 2487-2500.

Thorp, J.A., & Rushing, R.S., (1999). Umbilical cord blood gas analysis. *Obstetrics and Gynecology Clinicians of North America, 26*(4), 695-709.

Timmons, A., & Clark, S. (2015). How to approach intrapartum category II tracings. *Obstetrics and Gynecology Clinics of North America,* 42, 363-375.

Tollånes, M.C., Thompson, J.M., Daltveit, A.K., Irgens, L.M. (2007). Cesarean section and maternal education; Secular trends in Norway, 1967-2004. *Acta Obstetricia et Gynecologica Scandinavica, 86*(7), 840-848.

Toomey, P.C., & Oppenheimer, L. (2019). Prediction of hypoxic acidemia in last 2 hours of labour in low-risk women. *Journal of Obstetrics and Gynecology, 41*(11), 1564-1570.

Truven Health Analytics. (2013). The cost of having a baby in the U.S. Retrieved from http://transform.childbirthconnection.org/wp-content/uploads/2013/01/Cost-of-Having-a-Baby1.pdf.

United States Department of Health and Human Services. (2013). *Summary of Objectives: Maternal, Infant and Child Health* [Data file]. Retrieved from http://www.healthypeople.gov/2020/topicsobjectives2020/pdfs/MaternalChildHealth.pdf.

The University of Iowa Carver College of Medicine. (2014). Obstetrics and Gynecology. Retrieved from https://www.medicine.uiowa.edu/obgyn/welcome/.

Van Leeuwen, P., Lange, S., Bettermann, H., Gronemeyer, D., & Hatzmann, W. (1998). Fetal heart rate variability and complexity in the course of pregnancy. *Early Human Development, 54*, 259-269.

Vázquez-Calzada, J.L. (1997). Cesarean childbirth in Puerto Rico: The facts. *Puerto Rican Health Sciences Journal, 16*(4), 395-400.

Ventura, S., Martin, J., Curtin, C., Mathews, T., & Park, M. (2000). Births: Final data for 1998. *National Vital Statistics Reports, 48*(3). Hyattsville, MD: National Center for Health Statistics.

Vintzieleos, A.M., & Smulian, J.C. (2016). Decelerations, tachycardia, and decreased variability: have we overlooked the significance of longitudinal fetal heart rate changes for detecting intrapartum fetal hypoxia. *American Journal of Obstetrics & Gynecology, 215*, 261-264. doi: 10.1016/j.ajog.2016.05.046.

Weissbach, T., Heusier, I., Ovadia, M., David, L., Daykan, Y., Schreiber, F., & Biron-Shental, T. (2018). The temporal effect of category II fetal monitoring on neonatal outcomes. *European Journal of Obstetrics and Gynecology and Reproductive Biology, 229*, 8-14.

Welford, N.T., Sontag, L.W., Phillips, W., & Phillips, D. (1967). Individual differences in heart rate variability in the human fetus. *American Journal of Obstetrics and Gynecology, 98*(1), 56-61.

Westgate, J., Wibbens, B., Bennet, L., Wassink, G., Parer, J., & Gunn, A. (2007). The intrapartum deceleration in center stage: A physiologic approach to the interpretation of fetal heart rate changes in labor. *American Journal of Obstetrics and Gynecology, 197*(3), 236.e1-236.e11.

World Health Organization. (2009). *Monitoring Emergency Obstetric Care: A Handbook*. Geneva, Switzerland: World Health Organization Press.

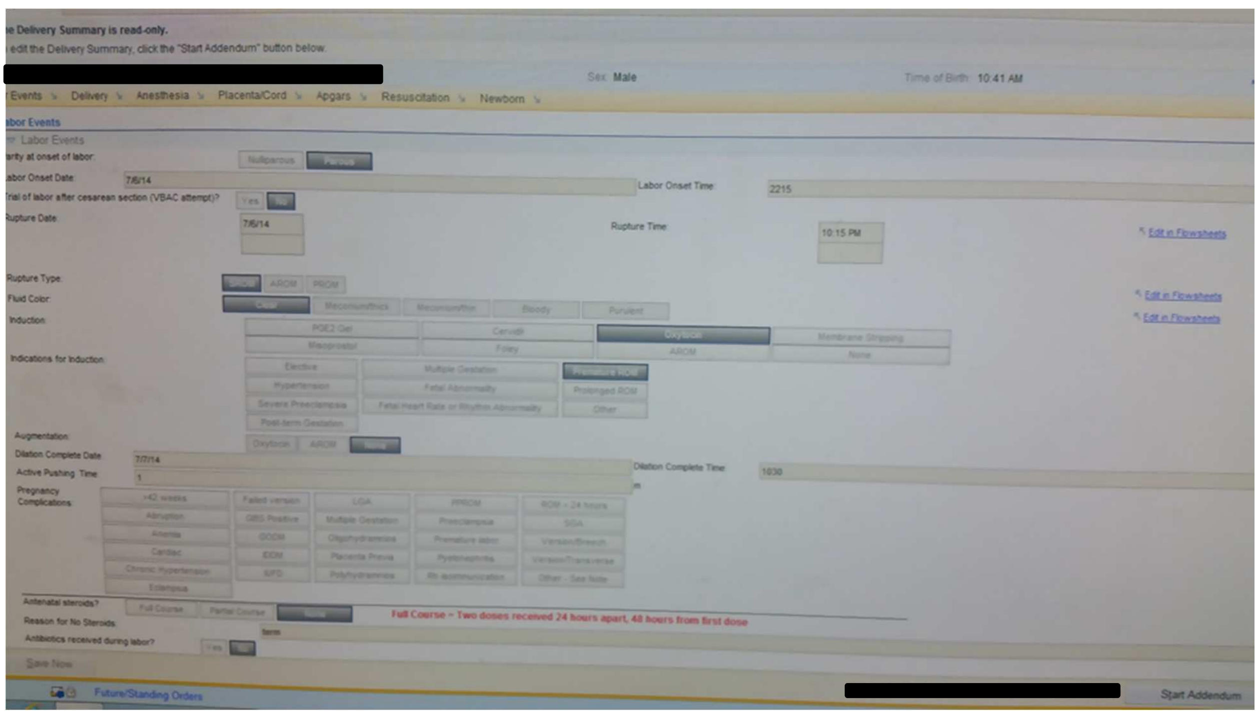
Yeh, S., Diaz, F., & Paul, R. (1982). Ten-year experience of intrapartum fetal monitoring in Los Angeles County/University of Southern California Medical Center. *American Journal of Obstetrics and Gynecology, 143*, 496–500.

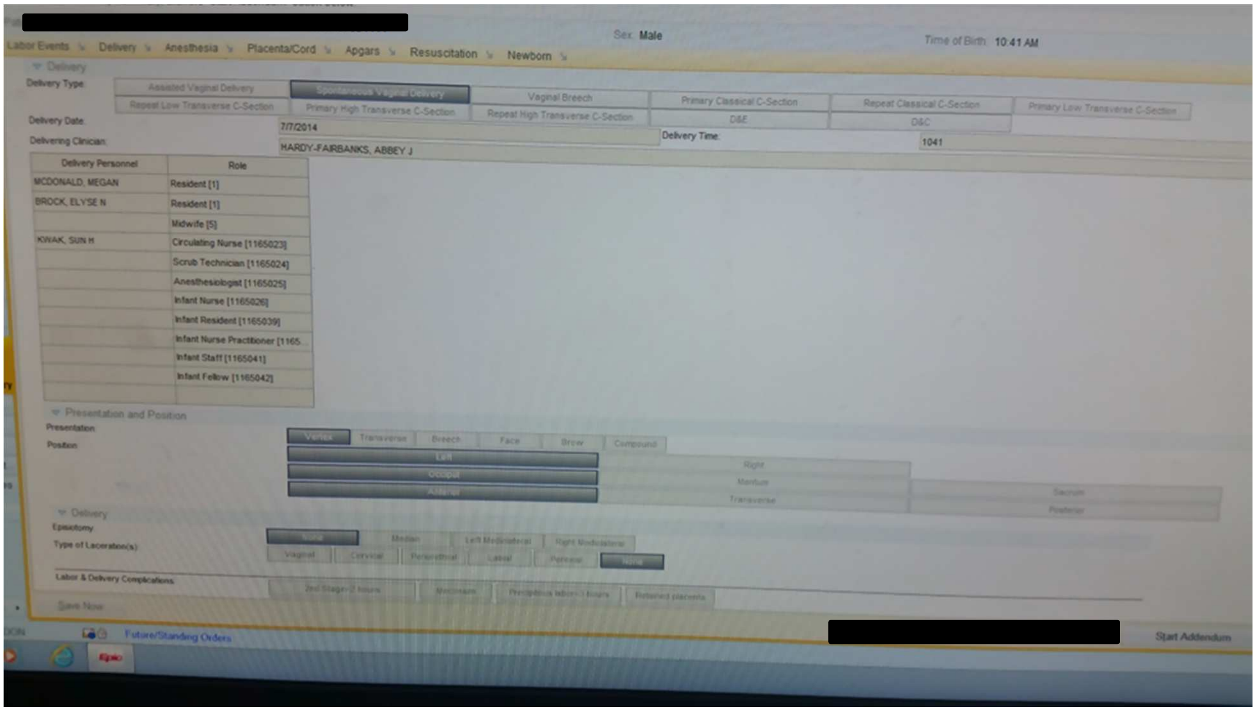
APPENDIX

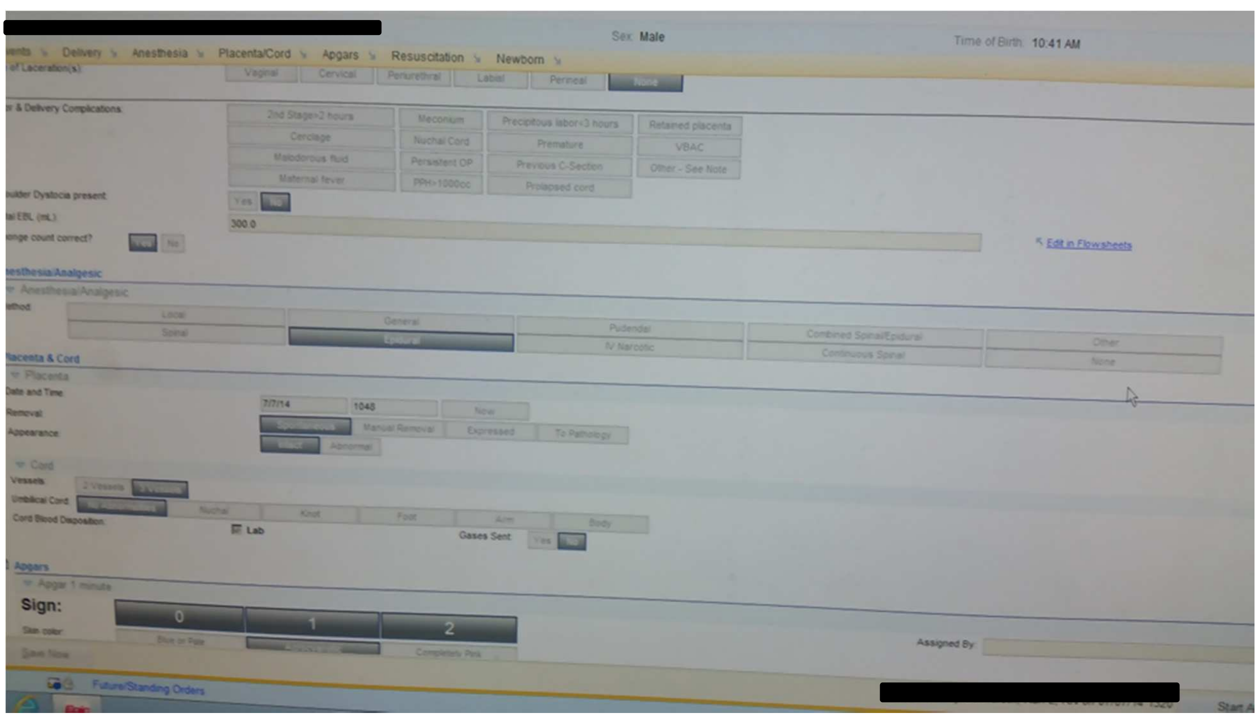
## Data Extracted from Medical Report from Epic

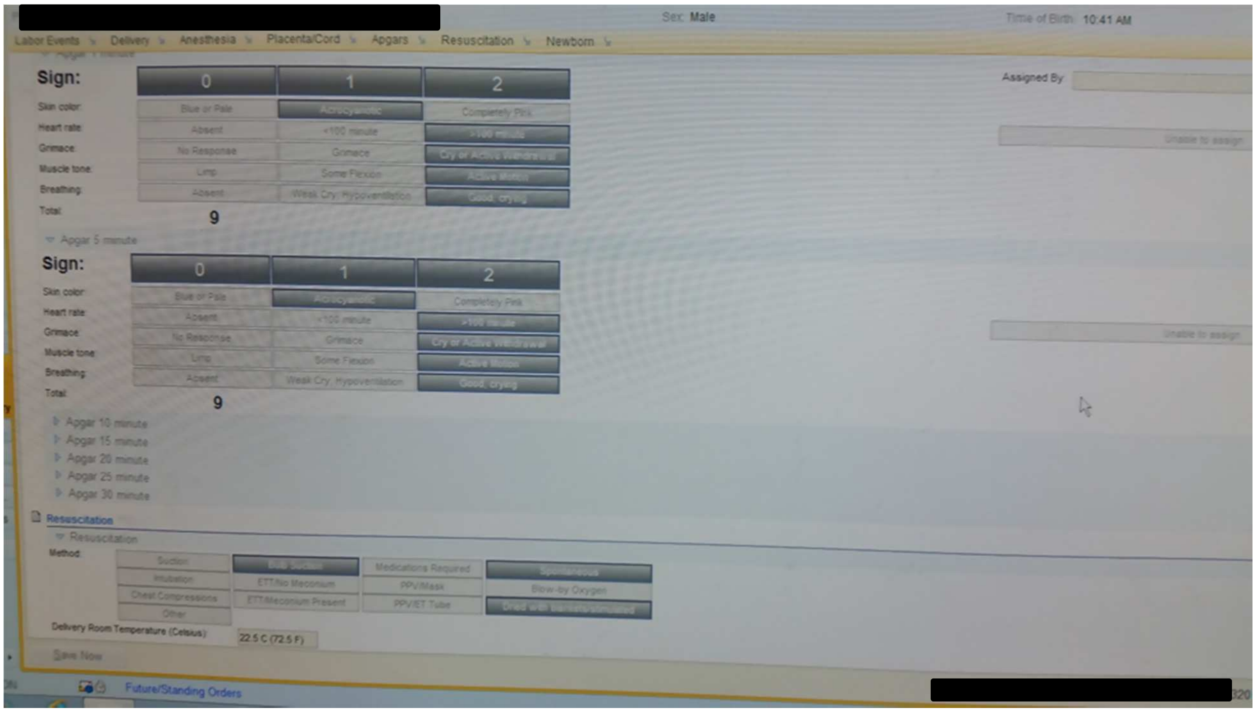
| |
|---|
| **Delivery Method** |
| **Delivering Clinician** |
| **Augmentation with AROM** |
| **Augmentation with Oxytocin** |
| **Induction with Cervidil** |
| **Induction with Cytotec** |
| **Induction with Oxytocin** |
| **Induction with AROM** |
| **Anesthesia** |
| **Prior Parity** |
| **Age** |
| **Patient Race** |
| **Apgar 1minute** |
| **Apgar 5 minute** |

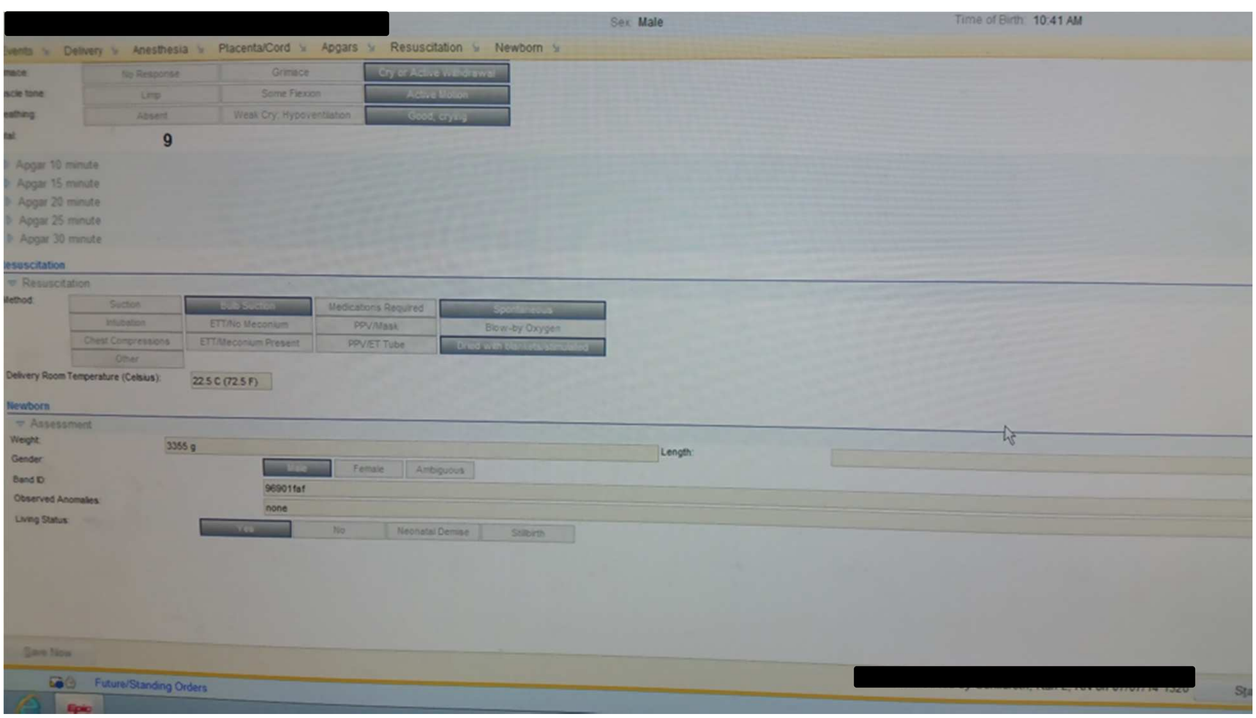
## Electronic Delivery Summary Used for Data Extraction




[redacted]
Sex: Male
Time of Birth: 10:41 AM
Labor Events
Delivery
Anesthesia
Placenta/Cord
Apgars
Resuscitation
Newborn
Delivery Type
Assisted Vaginal Delivery
Spontaneous Vaginal Delivery
Vaginal Breech
Primary Classical C-Section
Repeat Classical C-Section
Primary Low Transverse C-Section
Repeat Low Transverse C-Section
Primary High Transverse C-Section
Repeat High Transverse C-Section
D&E
D&C
Delivery Date
7/7/2014
Delivery Time
1041
Delivering Clinician
HARDY-FAIRBANKS, ABBEY J
Delivery Personnel
Role
MCDONALD, MEGAN
Resident [1]
BROCK, ELYSE N
Resident [1]
Midwife [5]
KWAK, SUN H
Circulating Nurse [1165023]
Scrub Technician [1165024]
Anesthesiologist [1165025]
Infant Nurse [1165026]
Infant Resident [1165039]
Infant Nurse Practitioner [1165
Infant Staff [1165041]
Infant Fellow [1165042]
Presentation and Position
Presentation
Position
Delivery
Episiotomy
Type of Laceration(s)
Labor & Delivery Complications
Future/Standing Orders
[redacted]
Start Addendum


[redacted]
Sex: Male
Time of Birth: 10:41 AM
Delivery
Anesthesia
Placenta/Cord
Apgars
Resuscitation
Newborn
Vaginal
Cervical
Periurethral
Labial
Perineal
None
2nd Stage>2 hours
Meconium
Precipitous labor<3 hours
Retained placenta
Cerclage
Nuchal Cord
Premature
VBAC
Malodorous fluid
Persistent OP
Previous C-Section
Other - See Note
Maternal fever
PPH>1000cc
Prolapsed cord
300.0
Edit in Flowsheets
Local
General
Pudendal
Combined Spinal/Epidural
Other
Spinal
Epidural
IV Narcotic
Continuous Spinal
None
Placenta
Date and Time
Removal
Appearance
7/7/14
1048
Manual Removal
Expressed
To Pathology
Abnormal
Cord
Vessels
Umbilical Cord
Cord Blood Disposition
2 Vessels
Nuchal
Knot
Foot
Arm
Body
Lab
Gases Sent
Apgars
Sign:
0
1
2
Skin color
Completely Pink
Assigned By
Future/Standing Orders
[redacted]


[redacted]
Sex: Male
Time of Birth: 10:41 AM
Labor Events
Delivery
Anesthesia
Placenta/Cord
Apgars
Resuscitation
Newborn
Sign:
0
1
2
Assigned By
Skin color
Heart rate
Grimace
Muscle tone
Breathing
Total
Blue or Pale
Acrocyanotic
Completely Pink
Absent
<100 minute
>100 minute
No Response
Grimace
Cry or Active Withdrawal
Limp
Some Flexion
Active Motion
Absent
Weak Cry; Hypoventilation
Good, crying
9
Apgar 5 minute
Sign:
0
1
2
9
Apgar 10 minute
Apgar 15 minute
Apgar 20 minute
Apgar 25 minute
Apgar 30 minute
Resuscitation
Method
Suction
Bulb Suction
Medications Required
Spontaneous
Intubation
ETT/No Meconium
PPV/Mask
Blow-by Oxygen
Chest Compressions
ETT/Meconium Present
PPV/ET Tube
Dried with blankets/stimulated
Other
Delivery Room Temperature (Celsius):
22.5 C (72.5 F)
Save Now
Future/Standing Orders
[redacted]


[redacted]
Sex: Male
Time of Birth: 10:41 AM
Delivery
Anesthesia
Placenta/Cord
Apgars
Resuscitation
Newborn
No Response
Grimace
Cry or Active Withdrawal
Limp
Some Flexion
Active Motion
Absent
Weak Cry; Hypoventilation
Good, crying
9
Apgar 10 minute
Apgar 15 minute
Apgar 20 minute
Apgar 25 minute
Apgar 30 minute
Resuscitation
Suction
Bulb Suction
Medications Required
Spontaneous
Intubation
ETT/No Meconium
PPV/Mask
Blow-by Oxygen
Chest Compressions
ETT/Meconium Present
PPV/ET Tube
Dried with blankets/stimulated
Other
Delivery Room Temperature (Celsius):
22.5 C (72.5 F)
Newborn
Assessment
Weight:
3355 g
Length:
Gender:
Male
Female
Ambiguous
Band ID:
96901faf
Observed Anomalies:
none
Living Status:
Yes
No
Neonatal Demise
Stillbirth
Save Now
Future/Standing Orders
[redacted]

**RedCAP Data Collection Tool**

Confidential

*Determining Specific Category II Continuous Electronic Fetal Monitoring Heart Rate Patterns Associated with Cesarean Delivery in Low Risk Labor*

*Page 1 of 3*

## Category II Characteristics and ACBG

Record ID ______________________

MRN ______________________

Category II cEFM 0-15 minutes - Time spent ______________________

cEFM Baseline 0-15 ______________________

cEFM Variability 0-15
- ○ Absent
- ○ Minimal
- ○ Moderate
- ○ Marked

cEFM Accelerations 0-15
- ○ Yes
- ○ No

cEFM Decelerations 0-15
- ☐ Early
- ☐ Variable
- ☐ Late
- ☐ Prolonged

Category II cEFM 15-30- Time spent ______________________

cEFM Baseline 15-30 ______________________

cEFM Variability 15-30
- ○ Absent
- ○ Minimal
- ○ Moderate,
- ○ Marked

cEFM Accelerations 15-30
- ○ Yes
- ○ No

cEFM Decelerations 15-30
- ☐ Early
- ☐ Variable
- ☐ Late
- ☐ Prolonged

Category II cEFM 30-45 - Time spent ______________________

cEFM Baseline 30-45 ______________________

cEFM Variability 30-45
- ○ Absent
- ○ Minimal
- ○ Moderate
- ○ Marked

cEFM Accelerations 30-45
- ○ Yes
- ○ No

cEFM Decelerations 30-45
- ☐ Early
- ☐ Variable
- ☐ Late
- ☐ Prolonged

Category II cEFM 45-60 - Time Spent ______________________

cEFM Baseline 45-60 ______________________

12/30/2016 2:54pm www.projectredcap.org REDCap cEFM Variability 45-60

○ Absent
○ Minimal
○ Moderate
○ Marked

cEFM Accelerations 45-60

○ Yes
○ No

cEFM Decelerations 45-60

☐ Early
☐ Variable
☐ Late
☐ Prolonged

Category II cEFM 60-75 - Time spent ______________________

cEFM Baseline 60-75 ______________________

cEFM Variability 60-75

○ Absent
○ Minimal
○ Moderate
○ Marked

cEFM Accelerations 60-75

○ Yes
○ No

cEFM Decelerations 60-75

☐ Early
☐ Variable
☐ Late
☐ Prolonged

Category II cEFM 75-90 - Time spent ______________________

cEFM Baseline 75-90 ______________________

cEFM Variability 75-90

○ Absent
○ Minimal
○ Moderate
○ Marked

cEFM Accelerations 75-90

○ Yes
○ No

cEFM Decelerations 75-90

☐ Early
☐ Variable
☐ Late
☐ Prolonged

Category II cEFM 90-105 - Time spent ______________________

cEFM Baseline 90-105 ______________________

cEFM Variability 90-105

○ Absent
○ Minimal
○ Moderate
○ Marked

cEFM Accelerations 90-105

○ Yes
○ No

cEFM Decelerations 90-105

☐ Early
☐ Variable
☐ Late
☐ Prolonged

Category II cEFM 105-120 - Time spent ______________________

cEFM Baseline 105-120 ______________________

cEFM Variability 105-120

- ○ Absent
- ○ Minimal
- ○ Moderate
- ○ Marked

cEFM Accelerations 105-120

- ○ Yes
- ○ No

cEFM Decelerations 105-120

- ☐ Early
- ☐ Variable
- ☐ Late
- ☐ Prolonged

Arterial Cord Blood Gases

- ○ WNL
- ○ Not WNL