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UNIVERSITY OF SAN DIEGO

Hahn School of Nursing and Health Science

DOCTOR OF PHILOSOPHY IN NURSING

Fetal Heart Monitoring, Nursing Surveillance, and Cesarean Birth

by

María del Carmen Colombo

A dissertation presented to the

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In partial fulfillment of the requirements for the degree

DOCTOR OF PHILOSOPHY IN NURSING

May 2014

Dissertation Committee

Cynthia D. Connelly, PhD, RN, FAAN, Chairperson

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Abstract

Purpose: Birth by cesarean delivery is a major public health issue with nearly one in three births delivered by cesarean section. Cesarean birth may be necessary to save mother or baby, but the rapid rise since 1996 without concomitant reduction in maternal and neonatal morbidity and mortality may indicate this mode of delivery may be over utilized. Cesarean births pose significant maternal and newborn health risks.

Identification of factors that may contribute to reduction in the first cesarean birth in low-risk women who are nulliparous, term gestation, with single fetus in head down position (NTSV) is a health priority. The purpose of this study was two-fold: (1) to examine nursing assessment of fetal heart rate (FHR) tracing and their interventions (nursing surveillance) in response to identification of an FHR tracing consistent with category II pattern and (2) to identify whether nursing surveillance and frequency of category II patterns contribute to the risk of cesarean birth in NTSV women.

Methodology: A descriptive, cross-sectional, correlational research design with purposive sample was used. Retrospective review of patient's electronic medical record was conducted for NTSV women who delivered at a large tertiary women's hospital between May and June 2013.

Results: Statistically significant relationships were found between maternal age, admission BMI, induced labor, and cesarean birth. The odds of having a cesarean delivery was 12% (OR = 1.12) higher among women who had an increased number of nursing interventions within four hours prior to delivery. However, when examining the

type of nursing intervention, none of the nursing interventions entered into the model were statistically significant as predictors of cesarean delivery. There was statistical significance between women who delivered vaginally and those who delivered by cesarean when examining nursing documentation of frequency of category II FHR tracing and nursing interventions.

Conclusions: The primary aims of this research study were to examine if nursing identification of a category II FHR pattern and nursing interventions were predictors of cesarean birth. The presence of category II FHR pattern was not a predictor but frequency of nursing interventions was a statistically significant predictor when entered into a logistic regression model.

María del Carmen Colombo

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2014

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Dedication

This dissertation is dedicated to my dear mother who I miss immeasurably. And to my husband who supported me every step of the way. Without his loving partnership, this would not have been possible. And to my three sons who have always been a source of inspiration.

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I am ever grateful to my Chair, Dr. Cynthia Connelly, who provided guidance, wisdom, support, and humor over the last three years. Dr. Connelly, you have been an incredible mentor and source of reassurance. Dr. Lois Howland and Dr. Mary Barger, thank you for your encouragement and advice along the way. Thank you all for your commitment to improving the health of women and newborns. It is truly inspirational.

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CHAPTER I

INTRODUCTION

The overall cesarean birth rate in the U.S. has increased nearly 60% since 1996 (Main et al., 2011) and in 2011, 32.8% of all births were by cesarean delivery (Hamilton, Martin, & Ventura, 2012). With nearly one in three pregnancies resulting in cesarean birth, cesarean delivery is now the most commonly performed major surgery in the United States (Spong, Berghella, Wenstrom, Mercer, & Saade, 2012). From 1996 to 2004, 60% of the total cesarean rate was due to an increase in primary cesareans (MacDorman, Menacker, & Declercq, 2008).

Cesarean births are not without risk and may pose substantial risk for both mother and baby (Plante, 2006). Maternal risks associated with cesarean birth include bowel and bladder injuries, infection, thromboembolism, and anesthesia complications. Risk in future pregnancies following primary cesarean include increased risk of placenta abnormalities, uterine rupture, and complications from multiple abdominal surgeries. Main et al. (2011) summarized research evidence of increased neonatal morbidity associated with cesarean birth. MacDorman, Declercq, Menacker, and Malloy (2008) found there was a 69 percent increased risk of neonatal mortality with planned cesarean

births. Healthcare costs associated with increased average length of stay, higher probability of readmission, admissions to NICU, and physician fees contribute to the rise in cost of medical care (Declercq et al., 2007; Main et al., 2011).

Strategies to reduce the number of primary cesareans have become a national priority. The Agency for Healthcare Research and Quality (AHRQ) identified research questions related to preventing the first cesarean birth (Lewis et al., 2012). Ranking as one of the top priority research questions is a need to identify components of systems interventions that are effective in reducing cesarean births. The effectiveness of nursing surveillance of fetal heart rate (FHR) tracings in reducing births by cesarean delivery is a component where gaps in the literature exist.

Background

Electronic fetal heart rate monitoring (EFM) is the expected standard of assessment of fetal well-being during labor and is the most widely used obstetric procedure in the United States (Hill, Chauhan, Magann, Morrison, & Abuhamad, 2012). More specifically, intrapartum EFM provides an assessment of fetal oxygenation during labor. Monitoring of fetal heart rate (FHR) patterns has been shown to be associated with a substantial decrease in neonatal mortality and morbidity (Chen, Chauhan, Ananth, Vintzileos, & Abuhamad, 2011). Fetal heart rate surveillance requires an evaluation of the FHR at a moment in time, as well as across time for the duration of labor within the context of the overall assessment of the clinical status of mother and fetus (Macones, Hankins, Spong, Hauth, & Moore, 2008). Maternal contraction patterns noted on the FHR tracing provide the clinician with additional information related to maternal status.

In 2008, the National Institute of Child Health and Human Development (NICHD) updated guidelines for interpretation and intervention of FHR tracings based on a three-tiered categorization (Macones et al., 2008). Category I tracings are defined as "normal," requiring no specific action and have a high predictive value of normal fetal acid-base status or fetal well-being. Category III tracings are characterized as "abnormal," requiring immediate intervention and delivery, as these tracings are predictive of abnormal fetal acid-base status. The intermediate Category II tracings have been labeled "indeterminate" requiring further evaluation, ongoing surveillance, and reevaluation. The purpose of the categorization was to standardize the language regarding FHR interpretation and to establish a standard of care in the management of this interpretation.

Spong et al. (2012) identified intrapartum fetal surveillance as having a large effect on prevention of first cesarean delivery. Preventive strategies include education on interpretation and management of patients with non-reassuring FHR tracings, additional confirmatory tests of fetal status, and intrauterine resuscitative measures. Established intrauterine resuscitative measures for Category II tracings include oxygen supplementation, maternal repositioning, increasing or supplementation of intravenous fluids, stopping oxytocin, tocolysis, and amnioinfusion. However, the indeterminate nature of category II tracings may contribute to indecisions in the management of these tracings (King & Parer, 2011).

Significance

The ambiguity of category II tracings and the wide variation in interpretation of FHR patterns and management warrant research into the relationship of nursing surveillance and cesarean birth. Macones et al. (2009) noted observational studies

focused on indeterminate category II FHR patterns and the relationship on clinical outcomes are a high priority for research. Many researchers have focused on the relationship of EFM and neonatal well-being as the clinical outcome, yet mode of birth as a clinical outcome remains less explored.

Purpose

The purpose of this study is to examine if cesarean birth among nulliparous, term, singleton, vertex (NTSV), and low-risk pregnancies can be predicted from the frequency of nursing surveillance and category II fetal heart rate (FHR) patterns. The study proposes that increased nursing surveillance as documented within the maternal medical record by the registered nurse (RN) is an effective strategy in reducing the incidence of primary cesarean births among this population of women.

Research Questions

Among women with low-risk pregnancies who are also nulliparous, term with single infant in vertex position:

1. Is there a difference in patient characteristics between mothers who give vaginal or cesarean birth?
2. Does the frequency of Category II FHR pattern predict the outcome of mode of birth (vaginal versus cesarean)?
3. Does the frequency of category II pattern and type of nursing treatment increase the odds for cesarean birth?

Specific Aims

- Aim 1. Describe a sample of women, admitted and giving birth at a large women's health medical center located in southern California.
- Aim 2. Examine the relationship between the frequencies of category II tracings, the frequency of nursing measures, and cesarean birth.
- Aim 3. Explore nursing surveillance attributes, pattern recognition and decision making, in relationship to category II tracings and association with increased risk for cesarean birth.

Conceptual Framework

The conceptual framework for this study is based upon definitions of nursing surveillance. The nursing process of continual assessing, monitoring, and intervening has been described as nursing surveillance and is a key role for nurses in the acute care setting (Dresser, 2012; Henneman, Gawlinski, & Giuliano, 2012; Kelly & Vincent, 2010; Kutney-Lee, Lake & Aiken, 2009; Shever, 2011). Surveillance as a nursing intervention is defined as "Purposeful and ongoing acquisition, interpretation, and synthesis of patient data for clinical decision making" (Bulechek, Butcher, & Dochterman, 2008, p. 687). Nursing surveillance as a concept recognizes the complexity of this intervention and defines antecedents that contribute to the nurse's ability to perform this role. These antecedents include both RN characteristics, as well as organizational characteristics (Dresser, 2012; Kelly & Vincent, 2010; Kutney-Lee et al., 2009).

Surveillance is an ongoing process that requires assessment of the patient, monitoring of patient laboratory values, medication efficacy, assimilation of the findings into immediate action, alerting others, and then advising or advocating for a change in

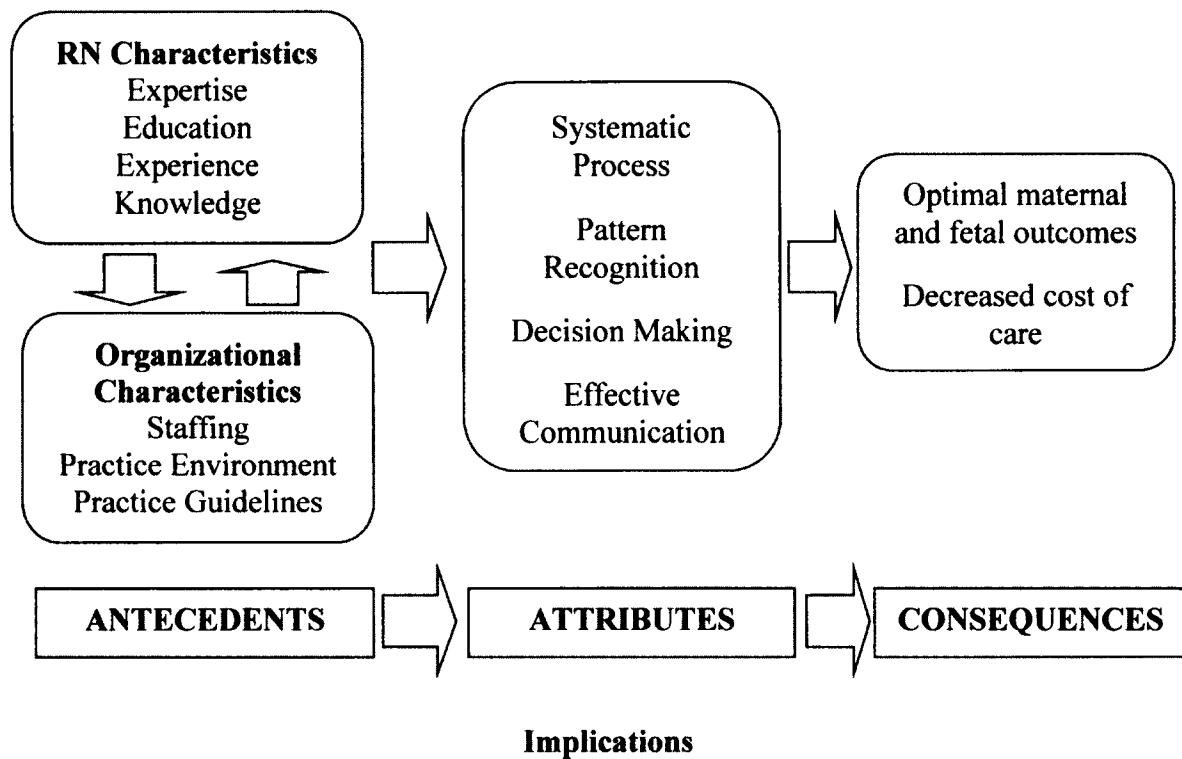
plans or direction to prevent harm (Kelly & Vincent, 2010; Kutney-Lee et al., 2009). Dresser (2012) included pattern recognition as a key attribute of nursing surveillance. This key component is not just recognition of repeated occurrences, but stresses the importance of the nurse's ability to make sense of these occurrences as signals of impending harm. The nurse's ability to identify relationships and similarities will assist in recognition of potential risks to an individual patient, as well as across patients. Nursing surveillance is not solely attributable to a single nurse at a specific time, but should be viewed as a process that occurs over time and across nurses.

Surveillance in obstetrical nursing is also noted in *Nursing Interventions Classification* (Bulechek et al., 2008) as surveillance: late pregnancy. Activities identified are similar to those previously noted but include activities related to maternal-fetal status that guide the nurse to treat, observe, or admit the patient. The activities are related to triage nursing and do not describe nurse actions for a woman who was in active labor. A more common surveillance procedure in obstetrical nursing during active labor is EFM surveillance. Activities within EFM surveillance have not been well-defined in the literature.

However, the conceptual framework of nursing surveillance can be applied to nursing care during active labor, may affect route of birth, and prevent harm to both the mother and baby(s). See Figure 1. Edmonds and Jones (2013) identified themes related to nurses' perceived influence on route of birth and outcomes. The themes of expert knowledge and nurse-physician relations, as well as patient advocacy (Sleutel, Schultz, & Wyble, 2007) can be found within the nursing surveillance conceptual model. Practice environment, resources, and nurse-physician communication were also identified as

contributing to the nurses' ability to prevent cesarean births in another study examining nurses' view of their intrapartum care.

Figure 1. *Summary of the Concept of Nursing Surveillance in Obstetrical Settings*



Registered nurses (RN) have the primary responsibility for the management of women in labor. This is especially true in hospitals where physicians may not be on site for the majority of the time from when a woman presents in labor until the time of delivery. Because of this relative autonomy, the RN is in a key role to influence the medical management of the laboring patient and the route of birth. Nursing surveillance plays a critical role in the nurse's ability to affect safe patient outcomes. In an obstetrical care setting, the consequences of nursing surveillance have been identified as maternal and fetal well-being.

There has been very little research conducted on the nurses' role and cesarean birth. Exploration and clarification of nursing surveillance antecedents and attributes in the obstetrical setting offer opportunities for research on the relationship between nursing care and cesarean birth. Identification of areas of influence may direct resources towards education for nurse educators in identifying priorities and strategies to improve or enhance the nurses' ability to conduct nursing surveillance. Identifying an operational definition of nursing surveillance within the obstetrical care setting may increase the ability of nurse researchers to study the influence of nursing surveillance on route of birth.

CHAPTER II

REVIEW OF LITERATURE

The percentage of births by cesarean delivery rose nearly 60% from 1996 through 2009 with a total cesarean rate of nearly 33% between 2010 and 2011 (Hamilton, Martin, & Ventura, 2012). It is the most commonly performed major surgery in the United States (Spong, et al., 2012). The alarming trend in the percentage of women having cesarean births is a public health issue because of the implications for maternal and newborn well-being, as well as the impact on health care utilization and cost.

As with any major surgery, cesarean births are not without medical risk. Using data from the Nationwide Inpatient Sample (NIS) of the Healthcare Cost and Utilization Project (HCUP), Kuklina et al. (2009) analyzed maternal morbidity among all delivery hospitalizations from 1998-2005 and found rates of severe obstetric complications were higher among cesarean deliveries, primary and repeat, than with vaginal deliveries. Specifically, the increasing cesarean rate may be a factor in the increase of renal failure, respiratory distress syndrome, shock, pulmonary embolism, and need for blood transfusions in the obstetric patient. These outcomes are in addition to the previously reported maternal complications associated with cesarean births including infection,

complications from anesthesia, injuries to genitourinary tract, and intraperitoneal adhesions. Complications associated with each recurring cesarean include abnormal insertion of the placenta, placenta previa or accreta, uterine rupture, hemorrhage, emergency peripartum hysterectomy, and unexplained stillbirth (Declercq et al., 2007; MacDorman, et al., 2008b; Main et al., 2011; Plante, 2006).

Using data from birth certificates, fetal death records, and birth-related hospital discharge records, Declercq et al. (2007) categorized low-risk mothers into one of two groups: planned primary cesarean delivery or planned vaginal birth. Low-risk mothers were those women who had no prior cesarean delivery, singleton, vertex, and 37 to 41 weeks gestation. Mothers in the planned vaginal births category included vaginal births with and without documented labor risk and primary cesarean births with documented labor risk. The planned primary cesarean group were mothers with no documented labor risk. Among this population of women, the rate of maternal rehospitalization within 30 days was more than twice as likely as for planned vaginal group. Surgical wound complications and postpartum infection were the primary reasons for rehospitalization.

The neonate is also at risk for complications associated with cesarean births including higher rates of respiratory distress, increased admission to the neonatal intensive care unit, increased length of stay, and iatrogenic prematurity (Kamath, Todd, Glazner, Lezotte, & Lynch, 2009; Main et al., 2011; Plante, 2006). MacDorman et al. (2008a) examined neonatal mortality risk by delivery method for low-risk women. Birth and infant death data in the U.S. from 1999 to 2002 were used to examine infant mortality among low-risk women. Low-risk was defined as no prior cesarean or identified prior medical risk, singleton, vertex, term (37-41 weeks' gestation), and no

reported placenta previa. Using an intent-to-treat methodology, vaginal births and cesareans with labor complications or procedures were combined to form a planned vaginal delivery category. Cesareans with no labor complications or procedures formed the comparison category of planned cesarean delivery. Adjusting for sociodemographic and medical risk factors, the results of the multivariable logistic regression method indicated an unadjusted neonatal mortality rate for cesarean deliveries with no labor complications or procedures of 2.4 times than for planned vaginal deliveries with an adjusted odds ratio for neonatal mortality of 1.69 (95% CI 1.35-2.11).

Examining birth records and hospital discharge data for singleton, live-born, cephalic neonates with a gestational age between 24 and 34 weeks, Werner, Han, Savitz, Goldshore and Lipkind (2013) found infants who delivered vaginally had decreased odds of neonatal morbidity. Among the 20,321 infants who met the study criteria, the study found neonates born by cesarean delivery had a higher risk of respiratory distress syndrome, sepsis, seizure, 5-minute Apgar score less than 7, and death compared to those who delivered vaginally. Using logistic regression and adjusting for maternal age, race, parity, education, insurance status, prepregnancy weight, diabetes, hypertension, smoking, gestational age at delivery, and indication for delivery, the study found when compared to vaginal delivery, infants delivered by cesarean delivery had increased odds of respiratory distress.

Several studies have sought to determine an explanation for the increase in cesarean births and have found the causes are multifactorial. Maternal and fetal medical conditions have long been associated with need for cesarean delivery, yet all of the studies indicate these conditions do not fully explain the dramatic rise in birth by

cesarean delivery. Sociocultural factors may include physician fear of litigation, overall public acceptance of birth by cesarean, lack of education of risks, lack of training of physicians in use of operative vaginal delivery techniques such as forceps or vacuum, and lack of nurse training in advocacy and support of women in labor (MacDorman et al., 2008a; Main et al., 2011; Plante, 2006; Zhang et al., 2010). Maternal request for elective cesarean delivery may contribute to the overall cesarean delivery rate and reasons may include fear of childbirth, fear of pain, and concern for safety of self and infant, as well as convenience (Miesnik & Reale, 2007).

The review of the literature will provide a summary of studies related to cesarean births among low-risk mothers and why preventing the first cesarean among this population is important. Next, the definitions of characteristics associated with fetal heart monitoring and the implications of interpretation will be outlined. The use of electronic Fetal Heart Rate monitoring (EFM) and the nurses' role in interpreting and managing will be addressed. And finally, a conceptual framework for examining the relationship between EFM, nursing surveillance, and cesarean birth outcome will be reviewed.

Maternal Population

Low-risk and Primary Cesarean Birth

MacDorman et al. (2008b) examined over four million U.S. birth certificates from 1989 to 2004 and found from 1996 to 2004, increases in primary cesareans contributed to

cesarean delivery offers a significant opportunity for reducing the overall cesarean birth rate.

Robson (2001) proposed a classification table for the obstetric patient comprised of 10 standard groups. Group 1 defines the low-risk population segment as nulliparous (first birth) with single cephalic (vertex) pregnancy, ≥ 37 weeks gestation (term) in spontaneous labor. Studies indicate cesarean births among this population with and without prior medical risk factors or complications during labor and delivery have been increasing. A study examining maternal outcomes among Massachusetts women who delivered between 1998 and 2003 found the cesarean birth rate among women in this category increased from 7.6% to 9.9% (Declercq et al., 2007).

Main et al. (2011) also reported hospital cesarean rates were highly correlated with the cesarean rate of nulliparous, term, singleton, vertex presentation (NTSV) cesarean rates. The Consortium of Safe Labor conducted a retrospective observational study of births between 2002 and 2008 among 19 teaching and non-teaching hospitals across the U. S. and found mothers had a nearly 15% intrapartum cesarean rate (Zhang et al., 2010). A study using data from the Flemish birth register compared mode of birth among women classified into each of the 10 Robson categories and found while there was an overall increase in cesarean births across all categories, the increase was most notable in Group 1 (Delbaere et al., 2012).

Fetal Heart Rate Monitoring

Definition

Electronic fetal heart rate monitoring (EFM) provides an auditory signal of fetal heart tones that are converted into a visual waveform. The output is a visual representation of both fetal heart rate and maternal uterine contraction patterns. The first commercial use of the electronic fetal heart rate monitor was in 1960's and has become the standard of care for measuring fetal status (Tucker, Miller, & Miller, 2009). Continuous EFM is the most widely used technological procedure in the intrapartum period with more than 85% of pregnancies in 2004 monitored using EFM (Anath, Chauhan, Chen, D'Alton, & Vintzileos, 2013).

Electronic fetal monitoring as introduced as an advanced method for assessing fetal well-being in the antepartum and intrapartum period. In a recent study examining use of EFM in the United States, Anath et al. (2013) conducted a retrospective study of more than 55 million nonanomalous singleton live births between 24 and 44 weeks gestation. The purpose of the study was to examine if neonatal morbidity and mortality risks and rates of primary cesarean delivery between 1990 and 2004 were affected by EFM use. Data was extracted from birth certificate data on file with the National Center for Health Statistics of the Centers for Disease Control and Prevention. Log-binomial regression models were used to adjust for maternal age, live-born parity, education, maternal race or ethnicity, smoking, and marital status. In this temporal study, EFM use was associated with a decrease in early and late neonatal mortality of 2 to 5%. An increase of 2 to 4% cesarean delivery for fetal distress was also associated with EFM use.

Interpretation

Standardization of interpretation and management of EFM has evolved over the years. In 2008, the definitions for interpretation were updated during a workshop sponsored by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development along with the American College of Obstetricians and Gynecologists, and the Society for Maternal-Fetal Medicine. A three-tiered categorization for interpretation and management of FHR patterns was recommended by this group: Category I FHR tracings are normal, strongly predictive of normal fetal acid-base status at the time of observation, and do not require specific action. Category II FHR tracings are not predictive of fetal-base status and require continued surveillance and ongoing evaluation. Category III FHR tracings are abnormal, predictive of abnormal fetal acid-base status, and require prompt evaluation and action to resolve the abnormal FHR pattern (Macones, et al., 2008).

Category II. Characteristics of fetal heart rate patterns include baseline fetal heart rate and variability in the fluctuations in the heart rate from baseline. Variability is further defined as either absent, minimal, moderate, or marked. Other characteristics include accelerations and decelerations which are respectively abrupt increases or decreases in the fetal heart rate. Category II FHR tracings characteristics are noted in Table 1.

Table 1. Category II FHR Tracing Characteristics

FHR Characteristic	Description
Baseline Heart Rate	Bradycardia not accompanied by absent baseline variability Tachycardia
Baseline Variability	Minimal baseline variability Absent variability not accompanied by recurrent decelerations Marked baseline variability
Accelerations	Absence of induced accelerations after fetal stimulation
Periodic or episodic decelerations	Recurrent variable decelerations accompanied by minimal or moderate baseline variability Prolonged decelerations ≥ 2 minutes but < 10 minutes Recurrent late decelerations with moderate baseline variability Variable decelerations with other characteristics, such as slow return to baseline, "overshoot," or "shoulders"

Category II tracings are commonly referred to as indeterminate because the pattern has not been associated with fetal acidemia, a known indicator of poor fetal outcome. The ambiguity of category II tracings has raised concerns because of a lack of consensus of management when these patterns present. A specific area of concern is the broad spectrum of tracings within category II which may present challenges in management for nurses and other providers (Parer, Ikeda, & King, 2009). A five-tier system has been proposed in an effort to provide clinicians with improved management

guidelines to minimize poor fetal outcomes and to reduce interventions (Parer & King, 2010).

This ambiguity may be reflected in the use of the term, non-reassuring fetal heart pattern. Non-reassuring fetal heart rate or fetal distress accounted for 27.3% of the intrapartum cesarean births in the Consortium of Safe Labor group (Zhang et al., 2011). A similar finding of fetal intolerance of labor as characterized by EFM patterns contributing as much as 20% of the proportion of the total cesarean rate, was reported by Main et al. (2011). Non-reassuring fetal status as an indication for cesarean birth has received attention as an area for potential target for reduction in the overall cesarean rate, but in particular for preventing the first cesarean delivery (Main et al., 2011; Meikle, Steiner, Zhang, & Lawrence, 2005; Spong et al., 2012).

Chiossi et al. (2011) conducted a study using standardized patients to examine the factors that prompted physician notification and subsequent intervention to expedite delivery. They examined multiple factors including providers age, education, experience, score on fear index, patient insurance, etc., and found only detection of category II tracings was strongly correlated with physician notification and subsequent intervention ($p < 0.001$). Cesarean delivery was the intervention of physician choice given the standardized patient scenarios with category II tracings.

A recent study conducted by Jackson, Holmgren, Esplin, Henry, and Varner (2011) reviewed fetal heart rate data to examine the relationship between the percentage of time in category II tracing and newborn outcome as measured by 5-minute Apgar score. The study examined data from 10 hospitals and yielded a sample of 48,444 women who had been in labor for at least 2 hours, were 37 weeks or greater gestation, singleton

pregnancy with an intent to deliver vaginally. Category II tracings were found in 84.1% of the patients with 22.1% of the overall time in labor in category II. The time in category II increased for women for whom this was their first birth (23.8%) and in all women in the two hours just prior to delivery (39.1%). Only the last two hours of labor were compared in relation to time in category II pattern and 5-minute Apgar score. It wasn't until more than 75% of the last two minutes were spent in category II was there a 5-minute Apgar score less than 7 with an increased admission rate to the NICU. Severity of low Apgar score and NICU admission were not examined in this study. The authors concluded the predominance of category II tracings with no short-term neonatal morbidity supported the description of category II patterns as indeterminate.

Management

Nurses have primary responsibility for the monitoring, interpretation, management of labor, fetal response to labor, and intervening appropriately to prevent harm to the fetus and mother. FHR patterns are not static and may move in and out of a category reflecting the fetal physiologic response to maternal contractions and placenta function. Notably, the medical management of category II tracings is not well-defined. Recently, Clark et al. (2013) provided some guidance with the development of an algorithm for the management of category II tracings. The authors argue category II tracings may have varying significance dependent upon the stage of labor. The initial management includes intrauterine resuscitative measures. These measures are standardized in professional practice guidelines for obstetrical nurses (AWHONN, 2009; Tucker, Miller, & Miller, 2009). These intrauterine resuscitative techniques or corrective measures are outlined in Table 2.

Table 2. Nursing Interventions for Category II FHR Characteristics

Nursing Intervention	Rationale
Oxygen supplementation	Promote fetal oxygenation
Maternal Reposition	Promote fetal oxygenation
	Reduce uterine activity
	Alleviate cord compression
	Correct maternal hypotension
Amnioinfusion (Infusion of sterile, normal saline solution through the cervix)	Alleviate cord compression
Fluid Bolus (Intravenous infusion of at least 500 ml of lactated Ringer's solution)	Promote fetal oxygenation
	Reduce uterine activity
	Correct maternal hypotension
Reduce or discontinue Pitocin (synthetic oxytocin)	Promote fetal oxygenation
	Reduce uterine activity

Fetal Surveillance. In addition to the interventions noted above, nurses and other providers are guided to provide ongoing FHR surveillance when presented with a category II tracing (AWHONN, 2009; Macones et al., 2008; Spong et al., 2012).

Techniques for fetal surveillance provided by three national guidelines, American Congress of Obstetricians and Gynecologists (ACOG), Society of Obstetricians and Gynaecologists of Canada (SOGC), and the Royal Australian and New Zealand College

of Obstetrician and Gynaecologists (RANZCOG), vary in the management of FHR tracings and do not provide a clear definition of fetal surveillance (Hill et al., 2012). Tucker et al. (2009) provide a definition of surveillance in terms of a surveillance system that offers care providers with alerts and alarms.

Nursing Surveillance

Nursing surveillance has also been described as a process by which nurses are on the alert to detect early warning signs in the patient's condition. These warning signs may signal a worsening in the patient's condition and provide the nurse with an opportunity to quickly intervene to ameliorate further deterioration (Institute of Medicine, 2004). Surveillance in this context is not simply the act of monitoring or watching, but making a decision(s) or clinical judgment based on these observations or nursing assessments and intervening to prevent harm (Perry, 2006).

Four attributes of surveillance were consistently noted in nursing in general and obstetrical nursing: systematic process, pattern recognition, effective communication, and decision making leading to intervention.

Systematic Process

In 2009, Kutney-Lee, Lake, & Aiken proposed the development of a profile that describes a hospital's nurse surveillance capacity. Nursing surveillance was defined as a process containing four components: (1) ongoing observation and assessment of a patient's physical and mental status, (2) recognition of change in patient status including change in laboratory values, (3) interpretation and synthesis of clinical data in the context of changes in the patient status, and (4) decision-making or acting upon the information.

During the care of the intrapartum patient, this process always involves at least two patients, mother and fetus, and may include more than one fetus.

Kelly and Vincent (2010) further described nursing surveillance in the acute care setting as a systematic process used by nurses to evaluate patient status and intervene appropriately to provide safe patient care. They also noted this was a 24-hour responsibility with frequent occurrence. The authors stressed nursing surveillance was not solely attributable to a single nurse at a specific time, but should be viewed as a process that occurs over time and across nurses. Behavioral and cognitive process components include data collection and data interpretation, as well as other activities that allow the nurse to make clinical judgments in a systematic fashion (Dresser, 2012).

Pattern Recognition

Pattern recognition is identified as a key attribute not specified in earlier definitions of nursing surveillance (Dresser, 2012). This key component is not just recognition of repeated occurrences, but emphasizes the importance of the nurse's ability to make sense of these occurrences as signals of impending harm. The nurse's ability to identify relationships and similarities will assist in recognition of potential risks to an individual patient, as well as across patients.

Fetal heart pattern recognition is an example of a critical skill required by obstetric nurses providing antepartum and intrapartum care. Fetal heart rate monitoring may be either intermittent or continuous and provides an overall assessment of fetal well-being and tolerance of labor. Maternal contraction patterns noted on the FHR tracing provide the nurse with additional information related to maternal status. Fetal heart rate surveillance requires an examination of the FHR at a moment in time, as well as across

time for the duration of labor within the context of the overall assessment of the clinical status of mother and fetus (Macones, Hankins, Spong, Hauth, & Moore, 2008).

Effective Communication

Effective communication in the labor and delivery setting has been defined as timely, direct, specific, and patient-centered, and occurring between all health care team members and the laboring woman and her family (Lawrence et al., 2012). During high stress situations such as those that may occur during intrapartum care, effective communication with team members, including physicians, has been identified as a critical characteristic of nursing surveillance (Forster et al., 2006; Lyndon, Zlatnik, & Wachter, 2011; Simpson, 2005; Simpson, James, & Knox, 2006). The nurse's ability to engage in ongoing communication with the patient and family may assist the nurse in decision-making (Adams & Bianchi, 2008; Dresser, 2012; Henneman et al., 2012).

Decision Making

The collection of data and information from multiple sources including the FHR tracing allows the nurse to make decisions in the plan of care. The nurse may decide to continue with the original plan of care or to take action utilizing knowledge from previous experience and incorporating evidence-based research, standardized protocols, and expert resources (Melnik & Fineout-Overholt, 2005). The course of action would be discussed with the patient and family, as well as other health care team members. This decision making process is central to nursing surveillance to effect safe patient outcomes.

Antecedents within the nursing surveillance framework include RN and organizational characteristics.

RN Characteristics

Registered Nurse characteristics include expertise, experience, education, and knowledge (Dresser, 2012). Kelly and Vincent (2010) described RN expertise, intuition, and early recognition skills as necessary antecedents to surveillance. The nurse's ability to recognize changes in patient condition, a key attribute of nursing surveillance, depends upon education, clinical expertise, and years of experience and knowledge to accurately interpret the situation (Henneman et al., 2012; Kutney-Lee et al., 2009). Similar characteristics, such as RN certification, being a member of the perinatal safety team, or being a day shift RN, a proxy for RN experience, were identified in obstetrical settings as influencing RNs' FHR pattern recognition skill (Davis, Kenny, Doyle, McCarroll, & von Gruenigen, 2013). Experienced labor and delivery RNs identified knowledge of labor and physician practice as key antecedents to effective communication and their decision-making ability (Edmonds & Jones, 2012). For example, experienced nurses would alter their communication with physicians based on their experience of how that physician would respond; knowing what they said and how they said it might very well increase the woman's chance to deliver vaginally.

Organizational Characteristics

Nurse staffing. Organizational characteristics include nurse staffing in terms of adequacy, skill mix and/or hours per patient day (HPPD), and nurse-to-patient ratio (Dresser, 2012; Forster et al., 2006; Henneman et al., 2012; Kelly & Vincent, 2010; Kutney-Lee et al, 2009; Simpson, 2009; Wilson & Blegen, 2010). Nurse staffing in an obstetrical setting was examined in an alternative manner by Gagnon, Meier, and Waghorn (2007). The researchers conducted a retrospective medical record review to

determine the number of times during a laboring woman's hospital stay nursing care changed from one nurse to another. The likelihood of cesarean birth increased with the number of times care changed from one nurse to another. Another measure of nurse staffing in an obstetrical setting was examined in terms of nursing effort; the hourly quantity of nursing care received by each patient, captured through analysis of nurse documentation in the patient medical record (Hall, Poyton, Narus, & Thornton, 2008).

Practice Environment. Kutney-Lee et al. (2009) used the five domains of the Practice Environment Scale of the Nursing Work Index (PES-NWI) to define the organizational characteristics of nurse surveillance. The five domains of the PES-NWI are: nurse participation in hospital affairs; nursing foundations for quality of care; nurse manager ability, leadership, and support of nurses; staffing and resource adequacy; and collegial nurse-physician relations (Lake, 2002). Dresser (2012) included the elements of the PES-NWI but added clarification to some of the PES-NWI components. For example, Dresser clarified nursing foundations for quality as an organization's ability to provide nursing preceptor programs as well as continuing education to increase RN knowledge and expertise.

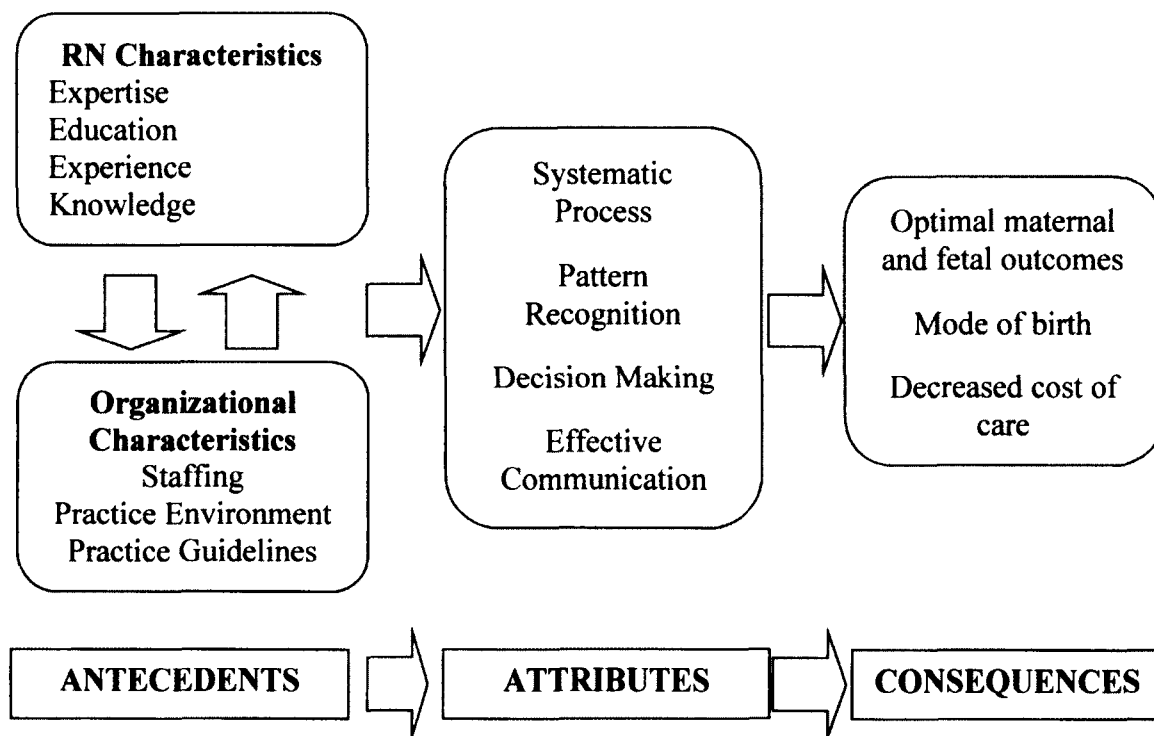
Dresser distinguished collegial relationships with physicians as relationships that enhance effective communication. Effective communication does not occur within a vacuum. An environment of trust, respect, and collaboration is necessary to support effective communication (Henneman et al., 2012; Lawrence et al., 2012; Lyndon et al., 2011). Labor and delivery nurses identified teamwork and collaboration with physicians and nurse-midwives as integral to their ability to communicate effectively and advocate for their patients (Sleutel, Schultz, & Wyble, 2007).

Practice Guidelines. Evidenced-based practice guidelines or protocols support decision-making and standardize interventions while allowing for flexibility for individual patient variation (Melnik & Fineout-Overholt, 2005). These practice guidelines may be established by national professional organizations or may be hospital-specific, but all are directed to establishing nursing care practices to maximize patient outcomes (Association of Women’s Health, Obstetric, and Neonatal Nurses [AWHONN], 2009, Macones et al., 2008; Pettker et al., 2009). Use of a standardized guideline for communication within the organization assists with effective communication with other healthcare team members including nurse midwives and physicians (Lawrence, et al., 2012; Lyndon, et al., 2011).

Conceptual Framework

Surveillance has been identified as a process, system, or program that involves the early detection of risk to an individual, group, or population. Within this systematic process exists an ability to recognize pattern(s), communicate observations effectively, and take action to limit or prevent harm. Registered nurse and organizational characteristics that influence nursing surveillance were also identified in the literature. In an obstetrical care setting, the consequences of nursing surveillance have been identified as maternal and fetal well-being as well as cost of care. Mode of birth may be added as a consequence of nursing surveillance. Figure 2 provides a revised diagram of nursing surveillance in the perinatal setting with mode of birth included.

Figure 2. Revised Summary of the Concept of Nursing Surveillance in Obstetrical Settings



Summary

Research related to nursing surveillance has been conducted examining the antecedents of nursing surveillance such as staffing, RN experience and education, nurse practice environment, relationships with physicians, etc. However, there is a gap in the literature in the examination of the influence of nursing surveillance attributes on patient care outcomes. This gap may be explained because previous literature has not described nursing surveillance well in terms of attributes that are measurable, and most of the research has been conducted in acute care settings.

This research study will utilize a retrospective review of the patient's medical record to examine nursing surveillance attributes in relationship to the assessment of category II tracings, nursing assimilation of that assessment into action or intervention,

and mode of birth; cesarean or vaginal delivery. Documentation of nursing interventions or actions should indicate the nurse assimilated the information gathered from her interpretation of the tracings. Subtle changes in patient status would be documented and either standardized procedures initiated and/or the physician alerted before the situation became critical. This study seeks to add mode of birth as an outcome influenced by nursing surveillance of fetal heart monitoring specifically in relationship to assessment and action in response to pattern recognition of category II tracing.

CHAPTER III

METHODOLOGY

The study examined the relationship between multiple independent variables described within the context of FHR nursing surveillance, including interpretation of FHR tracing, nursing interventions, and cesarean birth. Preventing the first cesarean delivery may contribute to an overall reduction in cesarean births and the associated maternal and neonatal morbidity and mortality. Nursing surveillance of electronic fetal heart rate monitoring (EFM) in relationship to the incidence of cesarean birth has not been explored. This study explored the unique contribution of nursing surveillance of category II fetal heart rate (FHR) patterns as defined by the National Institute of Child Health and Human Development (NICHD) on the incidence of cesarean birth in nulliparous, term, singleton, vertex, (NTSV), low-risk pregnancies.

The study proposed that increased nursing surveillance as documented within the maternal medical record by the registered nurse (RN) was an effective strategy in reducing the incidence of primary cesarean births among this population of women. Nursing surveillance attributes include assessment of FHR tracings, recognition of category II characteristics, and nursing interventions to address category II pattern.

This chapter includes a description of the research questions, study aims, research design, sample and sampling, data collection, and analytic procedures. Protection of human subjects will also be presented.

Research Questions

Among women with low-risk pregnancies who are also nulliparous, term with single infant in vertex position:

1. Is there a difference in patient characteristics between mothers who give vaginal or cesarean birth?
2. Does the frequency of Category II FHR pattern predict the outcome of mode of birth (vaginal versus cesarean)?
3. Does the frequency of category II pattern and type of nursing treatment increase the odds for cesarean birth?

Specific Aims

- Aim 1. Describe a sample of women, admitted and giving birth at a large women's health medical center located in southern California.
- Aim 2. Examine the relationship between the frequencies of category II tracings, the frequency of nursing measures, and cesarean birth.
- Aim 3. Explore nursing surveillance attributes, pattern recognition and decision making, in relationship to category II tracings and association with increased risk for cesarean birth.

Research Design

This study used a descriptive, cross-sectional, correlational research design to examine relationships between independent variables and the outcome variable, cesarean birth. Retrospective review of the patient's chart, also known as the patient's electronic medical record (EMR), was conducted to examine the frequency of RN documentation of FHR nomenclature consistent with category II tracings, the types and frequency of nursing treatments in response to category II tracing, and the mode of birth, vaginal or cesarean.

Sample and Sampling

A purposive sample of women meeting inclusion criteria who delivered at a nonprofit community hospital in Southern California was obtained. The hospital has a large delivery volume of over 8,000 births per year. The hospital's Perinatal Download database (PDD) was used to identify initial case selection. Cases were selected from a three month period of time to ensure adequate sample size. Inclusion criteria: nulliparous (first birth) with single cephalic (vertex) pregnancy, ≥ 37 weeks' gestation (term) in labor (spontaneous or induced) with continuous EFM for at least two hours during labor. Exclusion criteria: scheduled cesarean delivery, previous birth, multiple gestation, < 37 weeks' gestation, and fetal presentation other than head down (vertex). The PDD provided information related to each inclusion criterion except length of EFM which was obtained from the patient's EMR.

Power, Effect and Sample Size

Determination of sample size, power, and effect can be complex in logistic regression analysis. Polit (2010) makes a recommendation of 10 to 20 cases for each predictor variable with 20 or more preferable to achieve adequate sample size. However, an alternate method for calculating sample size is to have at least 10 outcomes or subjects for every independent variable (Katz, 2011). A post hoc method for determining if the sample size is sufficient in logistic regression is to examine the model fit. If there is not a good model fit, then either the sample size needs to be increased or the number of independent variables needs to decrease. Katz (2011) provides three methods for decreasing the number of independent variables: exclude variables that did not have a statistically significant association with the outcome (p value ≥ 0.05); choose one variable to represent two or more variables that are moderately correlated; and/or combine multiple variables. A sufficient sample size for the outcome variable, cesarean birth, was obtained within two months of data analysis.

Similarly there is no single accepted method for determining effect size for logistic regression. Statistical Package for the Social Sciences (SPSS) will compute two effect size indices, the Cox and Snell R^2 and the Nagelkerke R^2 . These values may be used as a substitute for the R^2 value used to evaluate effect size in multiple regression (Polit, 2010). However neither of these tests is run a priori but may be used in post-hoc analysis. The post-hoc Nagelkerke R^2 was the method used to examine effect size in this study.

Procedures

Initial case selection came from the hospital's PDD and was used as a source for identification of inclusion criteria: parity, gestational age, fetal presentation, and single fetus as well as mode of birth outcome, vaginal or cesarean delivery. Cases selected from the PDD were matched by hospital visit number to the patient's EMR. Demographic data, maternal physical characteristics, and medical interventions were then obtained from the EMR. The EMR was also the source for determination of length of time of electronic fetal heart rate monitoring (EFM).

Labor and delivery (L&D) registered nurses (RN) are required to follow national professional guidelines and hospital policies reflecting those guidelines in the care of women in labor and their fetus (AWHONN, 2009). Within these guidelines are standards for EFM assessment and documentation of fetal heart rate characteristics and treatments or interventions by the L&D RN. The key attribute of nursing surveillance, pattern recognition, was captured by RN documentation of fetal heart rate characteristics including baseline fetal heart rate, fetal heart rate variability, presence of accelerations, and decelerations. The L&D RN documentation of EFM assessment and FHR characteristics in the EMR was used to identify tracings consistent with NICHD category II characteristics (Macones, et al., 2008). Table 3 provides a description of category II fetal heart rate characteristics and a description of RN documentation within the EMR.

Table 3. RN Documentation of Category II Fetal Heart Rate Characteristics

Characteristic	RN Documentation
Baseline FHR	Bradycardia or Tachycardia May include numerical value for FHR
FHR Variability	Absent, Minimal, Marked
Accelerations	Acoustic or scalp stimulation Presence or absence of accelerations
Decelerations	Late, Variable, Prolonged

The EMR was also used to obtain data on nursing action in response to pattern recognition of category II tracings. Registered nurse documentation of these interventions, commonly referred to as intrauterine resuscitation, was used as a measure of nurse decision making. Table 4 provides an overview of the rationale for the intervention, as well as a description of the common nursing interventions as outlined within the professional standards for L&D RNs (AWHONN, 2009). While not considered an intrauterine resuscitative intervention, the L&D RN may, in the presence of absent or minimal variability, apply fetal scalp stimulation or vibroacoustic stimulation to elicit a fetal response.

Table 4. RN Documentation of Nursing Treatments for Category II FHR Characteristics

Nursing Treatment/Intervention	Rationale	RN Documentation
Oxygen supplementation	Promote fetal oxygenation	Oxygen at 10 L/min via mask
Maternal Reposition	Promote fetal oxygenation Reduce uterine activity Alleviate cord compression Correct maternal hypotension	Left or right lateral position Reposition
Amnioinfusion (Infusion of sterile, normal saline solution through the cervix)	Alleviate cord compression	Amnioinfusion and amount of fluid infused
Fluid Bolus (Intravenous infusion of at least 500 ml of lactated Ringer's solution)	Promote fetal oxygenation Reduce uterine activity Correct maternal hypotension	IV bolus LR
Reduce or discontinue Pitocin (synthetic oxytocin)	Promote fetal oxygenation Reduce uterine activity	Pitocin ↓ Pitocin off
Fetal Scalp Stimulation	May provide an indication of fetal well-being	Fetal Scalp Stimulation
Vibroacoustic Stimulation	As above	Vibroacoustic Stimulation

In this institution, the RN documentation guidelines for continuous EFM include documentation of FHR baseline, variability, and accelerations/decelerations at 30-minute intervals in the active phase. In the second stage of labor, FHR, variability, and

accelerations/decelerations are documented at 30-minute intervals but baseline FHR is to be documented every 15 minutes. Patients with high-risk conditions or who have changes in their condition require more frequent assessments and documentation of FHR baseline. Documentation of nursing interventions may be completed on the fetal monitor tracing or within the electronic medical record. This study only included review of RN documentation within the EMR.

Within each hour of the four hours before birth, any RN documentation of FHR baseline, variability, and decelerations as noted in Table 3 was counted as an occurrence of RN recognition of a category II FHR characteristic. For example, if the RN documented a FHR of 105 and selected from the FHR baseline description pick list “bradycardia”, this was noted as an occurrence of category II pattern. If only the FHR was noted, then this was not noted as an occurrence because there wasn’t any indication that this was the baseline FHR for a 10-minute period of time. Similarly, frequent contiguous RN documentation of “variable” deceleration was not counted as an occurrence of recurrent variable deceleration. Only RN documentation of “recurrent variable” from the deceleration pick list was counted.

The documentation of RN interventions was also captured within each hour of the four hours before birth. RN documentation of interventions could be found in the comment section as free text, in the vital sign section for administration of oxygen, in the intravenous medication section for Pitocin adjustment, and in the fetal monitoring section. The fetal monitoring section had a pick list for deceleration interventions which included all of the interventions noted in Table 4 except for vibroacoustic stimulation which could be found in the free text comment section. On many occasions, RN

interventions were documented in multiple areas for the same patient. Not all RN interventions could be associated with the identification or presence of category II FHR tracing. Some of the documentation of nursing intervention was clearly in response to category II pattern such as choosing from the pick list or free text documentation of “decel intervention...” however, often times there was documentation of deceleration intervention in the free text section when there was no documentation of FHR pattern consistent with category II deceleration pattern.

RN interventions were only counted if there was clear indication that the intervention was associated with RN recognition of category II pattern. If the mother was repositioned for example, and there was no documentation in either the comment section or in the FHR monitoring section of category II pattern, then this was not counted as an intervention. If the mother was repositioned more than once for a single episode of intervention, this was only counted as an occurrence. Initiation of oxygen in response to category II tracing was often continued for a length of time that exceeded more than one event documentation of category II tracing. Pitocin adjustment was combined with discontinuation therefore occurrence was not counted as each but rather yes/no. Pitocin discontinued as a result of a decision to proceed with a cesarean delivery was excluded from the analysis. RN interventions were captured as yes/no within each hour but totaled as a frequency count for the two to four hours of EFM before birth.

Data Analysis

Data analysis was conducted using SPSS version 21 software. Descriptive statistics (mean, mode, standard deviation, and percentages) were reported for independent and dependent variables. A one-way ANOVA and chi-square test was computed to examine the differences in means or observed frequencies within and among the two groups, vaginal versus cesarean birth. The dependent or outcome variable, presence or absence of cesarean birth, was measured on a nominal scale and was not expected to have a normal distribution. Therefore, a chi-square analysis was completed to examine the observed frequencies of the predictor variables among the two groups. An unadjusted logistic regression was used to examine the extent to which frequency of category II characteristics, and nursing treatments in response to category II tracings within the four hours prior to birth estimated the likelihood of cesarean delivery. Table 5 provides a summary of the variables.

Table 5. Conceptual and Operational Definitions of Variables

Variable Name	Variable Definition	Variable Type and Operational Definition
Age	Age of patient at time of hospital admission	Continuous
Race/Ethnicity	Race/ethnicity as reported by patient and documented in EMR upon admission	Categorical: 0 = White 1 = Non-Hispanic black 2 = Hispanic 3 = Asian/Pacific Islander 4 = Other

Maternal BMI	Body mass index calculated in terms of patient's weight and height; documented upon admission to hospital	Continuous
Induction	Noted at time of admission to hospital as scheduled induction	Categorical: 0 = no 1 = yes
Pitocin augmentation	IV administration of synthetic oxytocin to increase labor contraction pattern	Categorical: 0 = no 1 = yes
Artificial rupture of membranes	Stripping of the amniotic membrane usually as a method to induce labor	Categorical: 0 = no 1 = yes
Epidural analgesia	Continuous infusion of pain medication in the epidural space via catheter	Categorical: 0 = no 1 = yes
Category II tracing	Count of total number of category II terms documented by L&D RN	Continuous
Oxygen	Supplemental maternal oxygenation via mask	Continuous
Maternal reposition	Maternal reposition	Continuous
Amnioinfusion	Infusion of sterile, normal saline solution through the cervix	Categorical: 0 = no 1 = yes
Fluid Bolus	Intravenous infusion of at least 500 ml of lactated Ringer's solution	Continuous
Pitocin adjustment	Reduce or discontinue Pitocin (synthetic oxytocin)	Continuous
Fetal stimulation	Scalp or vibroacoustic stimulation	Continuous
Mode of birth	Vaginal (spontaneous or operative) versus cesarean	Categorical: 0 = not cesarean 1 = cesarean

A concern with logistic regression is a high correlation among the predictor variables similar to any multiple regression. It is important to identify and delete variables that are essentially measuring the same thing. SPSS can provide a tolerance statistic or measure of collinearity among the predictor variables. Mertler and Vannatta (2010) provide two methods for addressing multicollinearity: deletion of the problematic variable(s), or combine like variables into a single predictor variable. Table 6 provides an overall summary of research aims, questions, and statistical methods.

Table 6. Research Aims, Questions, and Statistics

Aims	Research Question	Statistics
1. Describe the patient population and examine differences among those who delivered vaginally and those who delivered by cesarean section.	Is there a difference in patient characteristics between groups of vaginal versus cesarean delivery?	ANOVA Chi-square
2. Examine the relationship between the frequency of category II tracings, the frequency of nursing measures, and cesarean birth.	Is there a relationship between the frequency of category II tracings, the frequency of nursing measures and cesarean birth?	Logistic Regression
3. Explore the factors of category II tracings, nursing surveillance attributes and increased risk for cesarean birth.	Does the frequency of category II FHR pattern as determined by nursing assessment and type of nursing treatment increase the odds for cesarean birth?	Logistic Regression

Protection of Human Subjects

Institutional Review Board approval was obtained from the University of San Diego and from the associated hospital. All data was obtained retrospectively from medical record review and did not require any patient contact. Patient confidentiality and privacy in accordance with the Health Insurance Portability and Accountability Act was maintained throughout the research study. All patient identification data and protected health information was de-identified in the data collection process and prior to data analysis.

CHAPTER IV

RESULTS

The purpose of this study was to examine if cesarean birth among nulliparous, term, singleton, and vertex (NTSV), low-risk pregnancies can be predicted from the frequency of nursing surveillance and category II fetal heart rate (FHR) patterns. The results are presented in this chapter including a descriptive profile of the sample followed by results related to the specific aims and research questions.

- Aim 1. Describe a sample of women, admitted and giving birth at a women's health medical center located in southern California.
- Aim 2. Examine the relationship between the frequencies of category II tracings, the frequency of nursing interventions, and cesarean birth.
- Aim 3. Explore nursing surveillance attributes, pattern recognition and decision making, in relationship to category II tracings and association with increased risk for cesarean birth.

Specific Aim #1

Describe a sample of women, admitted and giving birth at a large women's health medical center located in southern California.

Data were collected through a retrospective audit of patient electronic medical records. The hospital's administrative data base was used to identify women who were giving birth for the first time (nulliparous), with a single fetus (singleton) whose presentation was head down (vertex), and with a gestational age of ≥ 37 weeks' gestation (term). Women who were admitted and delivered between May and June 2013 were included in the sample. A total of 510 cases identified from the database as nulliparous, term, with singleton in vertex position (NTSV) were assessed for eligibility and 53 were excluded. Reasons for exclusion were scheduled cesarean section, multiple gestation pregnancy, fetal presentation other than vertex, and continuous electronic fetal monitoring (EFM) for less than two hours. There were 457 women included in the analysis.

As shown in Table 7, the majority of the women in this study were white, non-Hispanic. The mean age was 28.8 (*SD* 5.65) years, range 15-44. The maternal body mass index (BMI) ranged from 21 to 50 kg/m² (mean 30.2, *SD* 5.01). Nearly 31% had their labor induced with either a cervical ripening agent and/or with Pitocin, a synthetic oxytocin. Labor was augmented with Pitocin in approximately 40% of the women and more than half were still receiving Pitocin at least 4 hours prior to birth. Nearly 90% of women received an epidural and about half had their membranes artificially ruptured. Among this sample population of NTSV pregnant women, approximately 30% had a cesarean delivery.

Table 7. Demographics and Medical Intervention Characteristics of the Study Population (N = 457)

Characteristic	Mean (SD)	n	%
Mean age in years	28.8_(5.65)		
Mean BMI (kg/m ²)	30.2 (5.01)		
Race			
White		207	45.4
Black/African American		25	5.5
Asian/Pacific Islander		61	13.4
American Indian or Alaskan Native		5	1.1
Other		158	34.6
Ethnicity			
Hispanic		145	31.7
Non-Hispanic		310	67.8
Induction*		140	30.6
AROM		208	45.9
Epidural		410	89.7
Pitocin Augmentation**		185	40.5
Pitocin at 4 hours before birth		248	54.4
Cesarean birth		135	29.5

*Includes both cervical ripening agent and Pitocin

**Excludes patients who received Pitocin as induction method

Research Question #1

Among women with low-risk pregnancies who are also nulliparous, term with single infant in vertex position, is there a difference in patient characteristics between mothers who deliver vaginally or by cesarean birth? The ANOVA and chi-square tests were applied to examine the differences in means of observed frequencies within and among the two groups, vaginal versus cesarean birth. Chi-square was computed individually for each medical intervention. As shown in Table 8, statistically significant differences were found for age and maternal admission BMI between the two groups of women. The percentage of women who had an induction was higher for women who delivered by cesarean than those who delivered vaginally and this was difference was statistically significant ($p < .05$).

Table 8. Characteristics of Subjects by Mode of Birth (N=457)

	Vaginal (n = 322)	Cesarean (n = 135)	<i>F</i> (<i>df</i>)	χ^2	<i>p</i> ^a
Demographic Characteristics					
Mean age in years (SD)	28.2 (5.6)	30.27 (5.7)	12.46(1)		<.01
Mean body mass index (kg/m ²) (SD)	29.5 (4.6)	31.83 (5.5)	20.17(1)		<.01
Race (%)				3.35(4)	.50
White	141 (43.8)	66 (49.3)			
Black	21 (6.5)	4 (3.0)			

Asian/ Pacific Islander	45 (14.0)	16 (11.9)		
American Indian/ Native Alaskan	3 (0.9)	2 (1.5)		
Other	112 (34.8)	46 (34.3)		
Ethnicity (%)			.004(1)	.95
Non-Hispanic	219 (68.2)	91 (67.9)		
Hispanic	102 (31.8)	43 (32.1)		
Medical Intervention Characteristics (%)				
Induction	89 (27.6)	51 (37.8)	4.60(1)	.03
Artificial Rupture of Membranes	151 (47.5)	57 (42.2)	1.06(1)	.30
Pitocin Augmentation	130 (40.4)	55 (40.7)	.01(1)	.94
Epidural	293 (91)	117 (86.7)	1.93(1)	.17

*ANOVA or chi-squared test

Specific Aim #2

Examine the relationship between the frequencies of category II tracings, nursing interventions, and cesarean birth.

Category II fetal heart rate (FHR) tracings are defined by characteristics of fetal heart rate, baseline variability, decelerations, and presence or absence of accelerations. Table 9 provides the distribution by hour of the percentage of women who had each type of category II FHR characteristic documented by the RN in the EMR. The percentage of women with category II FHR pattern increased in every category within the last hour

before birth. Among this sample population nearly 68% of the women had documentation of FHR characteristic consistent with category II tracing. Approximately 43% of the women had documentation of minimal baseline variability and approximately 21% had recurrent variable decelerations.

Table 9. Percentage of Women with Category II FHR Characteristic by Hour of Labor before Birth

	Hour 4	Hour 3	Hour 2	Hour 1	Total
Bradycardia	1.3	1.3	2.4	4.4	8.3
Tachycardia	2.0	3.9	7.2	14.2	16.2
Absent Baseline Variability	0	0.2	0.4	0.4	0.9
Minimal Baseline Variability	16.2	18.4	19.5	21.9	43.3
Marked Baseline Variability	0.2	0.7	0.4	1.3	2.4
Recurrent Variable Deceleration	4.4	4.8	7.2	14.2	20.6
Prolonged deceleration (≥ 2 but < 10 minutes)	2.6	4.6	5	8.5	17.3
Recurrent late decelerations with moderate baseline variability	0.2	1.1	1.3	2.4	4.2

Nursing measures or interventions for category II FHR tracing include oxygen supplementation, maternal reposition, amnioinfusion, intravenous fluid bolus, and reduction or discontinuation of Pitocin. Among this sample population of women, nearly

75% had at least one nursing intervention. Oxygen supplementation and maternal reposition were the most frequently documented nursing interventions. See Table 10.

Table 10. Percentage of Women with Nursing Interventions by Hour of Labor before Birth

	Hour 4	Hour 3	Hour 2	Hour 1
Oxygen Supplementation	18.6	25.2	30.9	37.9
Maternal Reposition	21.7	25.8	23.0	16.4
Amnioinfusion	0.7	0.0	0.2	0.7
Intravenous Fluid Bolus	9.6	10.5	12.9	11.6
Decrease/Discontinue Pitocin	7.6	9.0	9.6	8.3
Vibroacoustic or fetal scalp stimulation	0.9	2.2	1.5	3.1

A one-way ANOVA was computed to examine the differences among women who delivered vaginally with regards to the frequency means of category II FHR tracings and nursing interventions. There was statistical significance between the two groups when examining nursing documentation of the frequency of category II FHR tracing and frequency of occurrence of nursing interventions (Table 11).

Table 11. One-way ANOVA Results for Frequency of Category II FHR Tracings and Nursing Intervention by Mode of Birth

	Vaginal	Cesarean	<i>F</i> (<i>df</i>)	<i>p</i>
	Mean (SD)	Mean (SD)		
Frequency of Category II FHR	2.28 (2.93)	3.07 (3.43)	6.301(1)	.01
Frequency of Nursing Interventions	2.57 (2.63)	3.59 (2.87)	13.634(1)	<.001

Research Question #2

Among women with low-risk pregnancies who are also nulliparous, term with single infant in vertex position, does the frequency of category II FHR pattern predict the outcome of mode of birth (vaginal versus cesarean)? A logistic regression analysis estimated the relations of the two predictor variables, frequency of category II FHR tracings and frequency of nursing measures recommended as interventions for category II FHR pattern, to the risk of cesarean birth. The predictor variables were entered simultaneously.

Table 12 presents the logistic regression and indicates the overall model of two predictors (frequency of category II tracing and nursing documentation) was statistically reliable with a good fit in distinguishing between mothers who delivered by cesarean section and those who did not (- 2Log Likelihood = 540.401; χ^2 (2) = 14.32, $p = .001$). The Hosmer and Lemeshow test also indicated that the model was a good fit to the data ($\chi^2 = 3.44$, $p = .84$). Wald statistics indicate increased number of nursing interventions within four hours prior to delivery was associated with increased odds for cesarean birth

(8.37, $p = .004$, OR 1.12, 95% CI 1.038, 1.213). The model correctly classified 70.2% of the cases. The overall effect size was small, with Nagelkerke R^2 equal to .04.

Table 12. Logistic Regression Results Predicting the Probability of a Cesarean Birth (N = 457)

Predictor	b(SE)	Wald	Odds Ratio	95% Confidence Interval		p
				Lower	Upper	
Category II	.40(.03)	1.38	1.04	.973	1.114	.241
Nursing Intervention	.12(.04)	8.37	1.12	1.038	1.213	.004

Model (likelihood ratio) chi-square = 14.32, $df = 2$, $p = .001$

Nagelkerke $R^2 = .04$

Percent correctly classified = 70.2%

Specific Aim #3

Explore nursing surveillance attributes, pattern recognition and decision making, in relationship to category II tracings and association with an increased risk for cesarean birth.

Attributes within the concept of nursing surveillance include pattern recognition as part of the overall patient assessment, and decision-making including interventions taken in relation to assessment. A small to moderate statistically significant correlation ($r = .39$, $p < .01$) was found between the documentation of the frequency of total category II tracings and total nursing interventions within the four hours prior to delivery indicating nursing interventions were associated with recognition of category II pattern.

Research Question #3

Among women with low-risk pregnancies who are also nulliparous, term with single infant in vertex position, does the frequency of category II pattern and type of nursing treatment increase the odds for cesarean birth? A logistic regression examining predictors for cesarean birth tested the strength of association of the following predictors: frequency of documentation of characteristics consistent with category II FHR tracings and type of nursing intervention with mode of birth. The nursing interventions included in the model were oxygen supplementation, maternal reposition, intravenous (IV) fluid bolus, and decreasing or discontinuing Pitocin. Amnioinfusion and vibroacoustic or fetal scalp stimulation were not included in the model as there were less than 20 cases of these predictors per cesarean birth. The predictor variables were again entered simultaneously. Multicollinearity was not a problem as all tolerance values were $> .2$.

Table 13 presents the logistic regression indicating the overall model of five predictors (frequency of category II tracing, oxygen supplementation, maternal reposition, IV fluid bolus, and Pitocin adjustment) was statistically reliable with a good fit in distinguishing between mothers who delivered by cesarean section and those who did not ($-2\text{Log Likelihood} = 15370.415$; $\chi^2(5) = 17.14$, $p = .01$). The Hosmer and Lemeshow test also indicated the model was a good fit to the data ($\chi^2 = 4.61$, $p = .71$). The model correctly classified 70.2% of the cases. The overall effect size was small, with Nagelkerke R^2 equal to .05. Type of nursing intervention was not statistically significant as a predictor of cesarean delivery. Although, maternal reposition approached statistical significance.

Table 13. Logistic Regression Results Estimating the Probability of a Cesarean Birth by Frequency of Category II FHR Tracing and Type Nursing Intervention (N=457)

Predictor	<i>b</i> (SE)	Wald	Odds	95% CI, Odds Ratio		<i>p</i>
			Ratio	Lower	Upper	
Category II FHR	.04(.04)	1.41	1.04	.97	1.12	.235
O2 Supplementation	-.14(.26)	.29	.87	.52	1.45	.592
Maternal Reposition	-.43(.25)	2.94	.65	.40	1.06	.087
IV Fluid Bolus	-.30(.25)	1.46	.74	.46	1.21	.227
Decrease/Discontinue Pitocin	-.15(.23)	.43	.86	.55	1.35	.512

Model (likelihood ratio) chi-square = 17.14, *df* = 5, *p* = .01

Nagelkerke R^2 = .05

Percent correctly classified = 70.2%

CHAPTER V

DISCUSSION OF FINDINGS

The purpose of this study was to examine if the frequency of nursing surveillance and category II fetal heart rate (FHR) patterns predicted cesarean birth among nulliparous, term, singleton, and vertex (NTSV), low-risk pregnancies. A nursing surveillance conceptual model provided the framework for this study. Attributes within the framework include pattern recognition and nursing action or intervention in response to pattern recognition assessment. In this chapter, a discussion of the findings and implication for nursing practice, education, research, and policy are presented.

Study Summary

Data were abstracted retrospectively from the electronic medical records of women who had delivered between May and June 2013 at a large urban women's hospital in southern San Diego. The hospital's administrative data base was used to identify women who were giving birth for the first time (nulliparous), with a single fetus (singleton) whose presentation was head down (vertex), and with a gestational age of ≥ 37 weeks' gestation (term). The dependent variable was risk for cesarean birth.

Independent variables included fetal heart rate (FHR) characteristics consistent with category II pattern and standardized nursing interventions within four hours prior to delivery.

There were 457 women included in the analysis. The majority of the women described themselves as white (45.4%) and nearly a third with Hispanic ethnicity (31.7%). Age ranged from 15 to 44 with a mean age of 28.8 years (SD 5.65). The mean BMI was 30.2(SD 5.01) with a range of 21 to 50 kg/m². Women who delivered by cesarean had a statistically significant higher mean age 30.3 (SD 5.7) and mean BMI 31.8 (SD 5.49) compared to women who delivered vaginally; mean age 28.2 (SD 5.6) and mean BMI 29.5 (SD 4.6). These findings support the work of Zhang et al. (2010) who reported similar findings in their review of more than 200,000 electronic medical records from births across the U.S., 2002 to 2008.

Among the current group of women, 31% had their labor induced, 40% had their labor augmented with Pitocin, approximately 90% had an epidural, slightly less than half (45.5%) had their amniotic membrane artificially ruptured, and nearly a third (29.5%) had a cesarean birth. These findings are somewhat consistent with other research that report rates of primary cesarean delivery rate of 21.7% to 30% (Barber, et al., 2011; Main, et al, 2011; Osterman & Martin, 2014, & Zhang, et al, 2010) but well above the Healthy People 2020 target of 23.9% for this population of women (Healthy People 2020).

When evaluating medical interventions, only induction was found to be statistically significant between those who delivered by cesarean and those who did not. This finding is consistent with findings conducted by the Consortium on Safe Labor

which found cesarean births were twice as likely among women who had their labor induced (Zhang et al., 2010). Labor augmentation, artificial rupture of membranes, and labor analgesia were not found to have any effect on differences in this group of women. Spong, Berghella, Wenstrom, Mercer, and Saade (2012) noted similar findings in their examination of labor practices that may have an effect on first cesarean delivery.

The presence of category II pattern was determined by nurse documentation of the following fetal heart tracing characteristics: bradycardia, tachycardia, absent, minimal, or marked variability, recurrent variable deceleration with minimal or moderate variability, prolonged deceleration, and recurrent late deceleration with moderate baseline variability. A FHR characteristic with category II pattern was documented as occurring in the fetal tracing for nearly 68% of women in this study. This percentage is lower than what has been documented in a larger study using software to analyze the fetal tracing of 48,444 women. Among this group of women, a category II pattern was identified more than 80% of the time (Jackson, Holmgren, Esplin, Henry, & Varner, 2011).

When examining the frequency of documentation of category II FHR tracing, there was statistical significance between women who delivered vaginally and those who delivered by cesarean section. Women who delivered by cesarean had a higher mean number of category II FHR patterns compared to women who delivered vaginally. Logistic regression was used to estimate the effect of frequency of category II FHR pattern on estimating the risk of having a cesarean delivery. Frequency of category II FHR pattern was not statistically significant in predicting the likelihood of a cesarean delivery.

Nursing interventions included in the overall analysis were supplemental oxygen, maternal reposition, amnioinfusion, intravenous fluid bolus, decrease or discontinue Pitocin, and vibroacoustic or fetal scalp stimulation. Among this sample of women, nursing documentation indicated nearly 74% received at least one of these nursing interventions. The most frequent interventions were oxygen supplementation, maternal reposition, and bolus of intravenous fluid. The percentage of women who had an amnioinfusion, or fetal stimulation was less than 2% and 8% respectively. When the frequency of documentation of nursing interventions was examined, there was statistical significance between those who delivered via cesarean and those who did not. Women who delivered vaginally had fewer nursing interventions than women who delivered by cesarean section. Women who had an increase in the number of nursing interventions documented did have an increased odds of having a cesarean birth (OR = 1.12, 95% CI = 1.038, 1.213). However, the overall effect size was small (Nagelkerke $R^2 = .04$). When type of nursing intervention was entered into the logistic regression, none of the nursing intervention types were statistically significant.

Nursing Implications

Nursing Practice

The framework for this study was a nursing surveillance conceptual model. Four attributes of surveillance are identified in this model and have specific implications for obstetrical nursing. These four attributes include a systematic process, pattern recognition, effective communication, and decision making leading to intervention. A primary role of the obstetrical nurse in the labor and delivery setting is fetal heart

monitoring and recognition of patterns that may indicate a maternal or fetal risk of poor outcome.

This research study evaluated risk of harm in terms of cesarean delivery in a low risk group of women. A category II FHR pattern was not associated with an increased risk of cesarean delivery in this study, nor in the literature. However, the indeterminate nature of a category II FHR pattern may serve as a proxy for non-reassuring fetal status or fetal intolerance of labor. Fetal intolerance of labor (non-reassuring FHR) and failure to progress have been cited as one of two indications that account for almost 90% in the variation in cesarean delivery rates (Main, et al., 2011) and may contribute 20 to 32% to the increase in primary cesarean rate (Barber, et al., 2011; Main, et al.; Zhang, et al.).

The frequency of category II characteristics may have been underreported in this study. Frequently nursing interventions were documented without documentation of category II FHR characteristic. When this researcher spoke with experienced labor and delivery nurses, they reported nurses were responding to the FHR tracing and would not always document what they saw because they considered the FHR tracing a primary source document. Additionally, nurses reported that the documentation of recurrent variable or late decelerations would often be delayed because the fetal tracing frame of reference was only 10 to 15 minutes and identifying contiguous variable or late deceleration as recurrent requires the nurse to retrospectively examine the fetal tracing.

Nursing interventions in response to recognition of category II FHR pattern has been standardized within nursing practice guidelines (Association of Women's Health, Obstetric and Neonatal Nurses, 2009). These interventions, often referred to as intrauterine resuscitative measures, may promote fetal oxygenation, improve

uteroplacental blood flow, reduce uterine activity, and alleviate umbilical cord compression. One or more of these conditions may be associated with one or more category II FHR characteristic. The American College of Obstetricians and Gynecologists (2010) provided a framework for nursing management of specific category II FHR patterns.

Oxygen supplementation and intravenous (IV) fluid bolus were two of the most frequently used nursing interventions. There is little data to support the effectiveness of supplemental oxygen and IV fluid bolus (American College of Obstetricians and Gynecologists, 2014). The two least frequently used interventions, amnioinfusion and fetal scalp stimulation, may have some effect in reducing rate of cesarean delivery, especially in the presence of recurrent variable decelerations or minimal variability (American College of Obstetricians and Gynecologists, 2014; American College of Obstetricians and Gynecologists and Society for Maternal-Fetal Medicine, 2014; Spong, Berghella, Wenstrom, Mercer, & Saade, 2012).

Amnioinfusion however, at this institution is only indicated as an intervention for recurrent variable decelerations after other methods of treatment including IV fluid bolus, maternal reposition, and oxygen administration have failed to resolve pattern. Fetal scalp stimulation although indicated on the deceleration pick list is not noted in the institution's policy as an assessment procedure for fetal well-being in the presence of minimal variability, a category II characteristic.

Nurses play a key role in the evaluation of maternal and fetal status during labor, continued surveillance, initiation of corrective measures when indicated, and reevaluation. Nurses may benefit from a more clearly defined algorithm in determining

nursing intervention as proposed by Clark et al. (2013) and King (2012). The algorithm proposed by Clark et al. (2013) includes levels of FHR surveillance based on stages of labor. The algorithm begins with an assessment of the presence of moderate variability or accelerations followed by an evaluation for the presence of significant decelerations with $\geq 50\%$ of contractions within a defined timeframe based on the stage of labor. King (2012) proposes a 5-tier algorithm that also begins with an assessment of FHR variability but then distinguishes between categories IIA, IIB, and IIC to guide interventions. The current 3-tier system for FHR tracing interpretation developed in 2008 (Macones, Hankins, Spong, Hauth, & Moore, 2008) may not only contribute to a much broader interpretation of category II tracings but doesn't provide the practitioner with a systematic process for evaluating when and what nursing interventions are appropriate.

A key attribute of nursing surveillance is that it is a systematic process for assessment, intervention, and evaluation. Nursing practice would benefit from a more well-defined process in the evaluation of FHR tracing as their interventions may reduce the risk of cesarean birth due to the presence of an indeterminate FHR pattern. Simpson (2005) developed a standardized process for evaluating appropriate nursing response to fetal heart patterns however, the broad interpretation of category II pattern may limit the usefulness of this tool.

Education

Obstetrical nurses may benefit from ongoing education related to recognition of category II FHR pattern and nursing interventions specific to the FHR pattern. More importantly, nurses may need a more holistic approach to nursing surveillance, including recognition that increased frequency of nursing interventions may not be an indication for

a cesarean delivery (American College of Obstetricians and Gynecologists and Society for Maternal-Fetal Medicine, 2014). Efforts at increasing awareness of NTSV cesarean births and the concomitant risks to both mother and baby should be integral to any obstetrical practice environment.

Research and Policy

Findings of this study must be viewed in the context of several limitations. The limitations of this study were the sample size and the use of nurse documentation of fetal heart pattern and nursing intervention. The small size may have contributed to the finding of nursing intervention by type not having statistical significance in estimating the risk of cesarean birth. However, the *b* coefficients were all negative indicating an inverse relationship as a predictor of cesarean delivery. A larger sample size may demonstrate nursing intervention by type may play a role in reducing cesarean delivery. Examination of the fetal heart tracing was not used in this study, however nursing documentation of the nurse's interpretation of the tracing may have been more useful, as fetal heart tracings are known to have some subjectivity in interpretation.

Despite these limitations, the study does add new knowledge regarding the frequency of category II FHR tracings, nursing interventions, and the outcome of cesarean delivery. Nursing interventions were defined as those standardized in the literature and within nursing profession guidelines. However, further research should include labor support interventions or behaviors within the context of nurse decision making (Adams & Bianchi, 2008; Barrett, S, & Stark M., 2010). Further research should focus on nursing surveillance antecedents including RN education, expertise, experience, and knowledge in interpretation and management of category II FHR tracings (Davis et

al., 2013). In addition, organizational characteristics such as nurse staffing, collaborative nurse-physician environment, and a nurse practice environment that allows for increased nursing support of labor, should be researched to more clearly explicate their contributions to mode of birth.

This research study examined the presence of category II FHR characteristics and frequency of nursing interventions within four hours prior to delivery. Further research could examine if there is a difference by the hour. Research has shown that increasing time in category II in the last two hours of labor may be associated with increased short-term newborn morbidity (Jackson, et al., 2011; Maso, et al., 2012). Additional research could examine what proportion of category II tracings were improved with nursing intervention and if there was a difference in the frequency of category II characteristics among women who had an induced versus spontaneous labor.

The indeterminate nature of category II FHR tracings and the continued lack of clearly defined interpretive management guidelines may contribute to an overutilization of nursing interventions, such as oxygen supplementation and IV fluid bolus and an underutilization of other nursing interventions, such as amnioinfusion and fetal stimulation. This research indicates that increased nursing interventions was a predictor of cesarean birth but type of nursing intervention, while not statistically significant, had an inverse predictor relationship to cesarean birth. Current guidelines for nursing intervention may need to be more clearly defined and associated with occurrence as well as type of category II FHR pattern.

Conclusion

Nursing surveillance guides identification of priorities and strategies to improve the nurse's ability to accurately assess and intervene to promote optimal maternal and fetal outcomes. Nursing surveillance plays a critical role in the nurse's ability to effect safe patient outcomes. This study demonstrated that nurse recognition of category II FHR pattern and subsequent nursing interventions, while not predictors of cesarean birth, were statistically significantly correlated with a difference between women who delivered by cesarean and those who did not.

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Appendix B



Institutional Review Board
 8695 Spectrum Center Blvd
 San Diego, CA 92123
 P (858) 499-4836 / F (858) 499-3105
<http://sharpnet/irb/> www.sharp.com/research
 E-mail: research@sharp.com

130881
 Colombo
 08/21/2013
 8-1

August 23, 2013

Maria Colombo, Nursing Administration
 5296 Soledad Rd.
 San Diego, CA 92109

**RE: IRB #130881 /
 Fetal Heart Monitoring, Nursing Surveillance and Cesarean Birth**

Dear RN Colombo:

The Sharp HealthCare Institutional Review Board (IRB00000920; FWA00000084) has reviewed and approved your application for the above-referenced research activity in accordance with 45CFR46.110(b)(1) Category 5. This approval includes:

- Appendix A: Data Collection Form
- Waiver of authorization is allowed in accordance with 45 CFR 164.512(l)(2)

This action will be reported to all committee members at the August 21, 2013 meeting.

The following site(s) and site personnel are approved:

Site:
 Mary Birch

Principal Investigator: Maria Colombo, Nursing Administration

Study Coordinator: none

Sub-Investigator and Other Site Personnel:

The IRB reference number is 130881 Colombo. Please include this reference number in all future correspondence relative to this research activity.

As a reminder, it is the responsibility of the Principal Investigator to submit periodic status reports to the IRB. Periodic review of this research activity may be conducted via an expedited process and is scheduled for inclusion on the August 20, 2014 IRB meeting agenda. Approval for this research activity will expire if periodic review is not conducted on or before 8/21/2014. Please provide a completed Continuation Request with required supporting documentation to research@sharp.com no later than 08/05/2014 to assure timely review and continuation of this research activity.

Changes or amendments to the research activity protocol, informed consent documents, and to other research activity-related documents, as well as new documents, tools or advertisements to be utilized as part of this research activity, must be reviewed and approved by the IRB before changes are implemented.

It is the policy of Sharp HealthCare IRB that the investigator(s) submit a copy of any abstracts, papers, manuscripts, posters, presentations, articles, etc. to the IRB prior to publication or dissemination. Sharp HealthCare would expect that if the results of the research project came to publication, their role would be properly recognized in the research or have the opportunity to have the organization's name withheld. This also gives the organization the opportunity to prevent disclosure of data or information that is beyond the scope of the research agreement.

Thank you and please feel free to contact me at (858) 499-4836, if you have any questions.

Sincerely,

Lois Collier, CIP
IRB Specialist

Enc.