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Effects Of Intrapartum Nitrous Oxide Use On Comfort And Satisfaction With The Birth Experience

Tami Such

EFFECTS OF INTRAPARTUM NITROUS OXIDE USE ON COMFORT AND SATISFACTION WITH THE BIRTH EXPERIENCE

by

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This dissertation , submitted by Tami Such in partial fulfillment of the requirements for the Degree of Doctor of Philosophy in Nursing from the University of North Dakota, has been read by the Faculty Advisory Committee under whom the work has been done and is hereby approved.

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Title	Effects of Intrapartum Nitrous Oxide Use on Comfort Satisfaction with the Birth Experience
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Tami L. Such
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ABSTRACT

Background/Purpose: Increased availability of intrapartum nitrous oxide in the United States given recent Food and Drug Administration (FDA) approval of associated delivery devices has provided women an alternative intrapartum pain management strategy currently underutilized in the United States despite long standing history of effectiveness in other countries (Richardson et al., 2017b). However, the effect of pain on the experience of birth and present emphasis on patient-centered care and shared decision-making, potential improvement of women's satisfaction with the birth experience when nitrous oxide is used was an understudied concept in extant literature. Also, given the possibility of pain and comfort as coexisting forces whereby comfort is felt even in the presence of intense pain (Charles, Yount, & Morgan, 2016), study of the novel concept of comfort in response to intrapartum nitrous oxide use was warranted. Therefore, the purpose of this study was to determine if comfort and satisfaction with birth experiences differed for women who used nitrous oxide compared to epidural analgesics or no analgesics during the labor and birth process. The design of this between-subjects comparative study was guided by Kolcaba's (2001) Theory of Comfort.

Methods: Based upon the following three self-selected intrapartum pain management methods, 84 pregnant women from three Midwestern healthcare facilities were consecutively enrolled into this study: 1) epidural analgesics (may have been in combination with other analgesic options, 2) nitrous oxide and oxygen (50-50% mixture)

only, or 3) no analgesics. Study measures included: (a) the Birth Satisfaction Scale-Revised and (b) the researcher-modified version of the Childbirth Comfort Questionnaire.

Data were analyzed to determine comfort and satisfaction scores of the study participants. Differences among the comfort and satisfaction scores for the three groups of women were analyzed using ANOVA analyses.

Findings: Comfort experienced during labor and birth and satisfaction with the birth experience were similar for all study participants regardless of analgesic option used. No statistically significant differences in comfort ($F_{(2, 81)} = 1.11$, $p = .34$) or in satisfaction with the birth experience ($F_{(2, 81)} = .084$, $p = .92$) were found for women who used nitrous oxide, epidural analgesics, or no analgesics during labor and birth.

Conclusions and Implications for Clinical Practice: Findings from this study provide evidence regarding the absence of differences in comfort and satisfaction with the birth experience for women who used nitrous oxide compared to epidural analgesic or no analgesic use during the labor and birth process. Such findings are useful to inform clinical practice decisions of nurses and maternity care providers. Further, the findings support a shift in the paradigm of intrapartum pain management in the United States to include alternative pain management strategies, inclusive of routine nitrous oxide use.

CHAPTER I

INTRODUCTION

Promoting comfort, improving satisfaction, and reducing fear and anxiety are all goals of nurses for women during labor and birth. In addition, personal expectations, caregiver support, quality of caregiver-patient relationship, and involvement in decision-making have stronger influences on the labor and birth experience than pain control alone (King & Wong, 2014). Nearly four million births occur in the United States each year (Centers for Disease Control & Prevention, 2019); however, few pharmacologic pain control options exist for use during labor (American College of Obstetricians and Gynecologists, 2017). As a result, thorough understanding of the benefits and risks of the available analgesic options and utilization of those that are safe and effective for women during labor and birth is of utmost importance.

Despite high incidence of epidural analgesic use in over 60% of vaginal births in the United States (Koyyalamudi et al., 2016), availability of this option may be lacking in settings where 24 hour a day, 7 day a week coverage for in-house anesthesia care is delayed or not possible (Rooks, 2011), may be medically contraindicated, or may not be possible during rapid progression of labor and birth. Ineffective pain management, fear, and anxiety experienced during labor and birth have lasting negative effects on the woman's experience and perception of the labor and birth experience (Collins, 2015; Dammer et al., 2014). Further, in keeping with the ethical principles of autonomy, veracity, beneficence, informed consent, respect, and other obligations framed by the

ethics of caring (Carlton, Clark Callister, & Stoneman, 2005), effective pain management for women during labor and birth is an essential standard of care with particular emphasis on empowerment, shared-decision making, and patient-centered care.

Inhaled nitrous oxide and oxygen (50-50% mixture) provides an inexpensive and simple alternative labor pain management strategy that is woman-led, safe, effective and can be immediately implementable (Rooks, 2012). Further, use of this strategy allows women to feel empowered and have decreased use of opioids, better utilization of self-protective abilities, and a more active role in solving her own pain (Charles, Yount, & Morgan, 2016). First approved for use during labor in England in 1936, common use of nitrous oxide occurs in many countries, with use reported in up to two-thirds of women's labor experiences in European countries (Richardson, Lopez, & Baysinger, 2017). However, despite approval by the Food and Drug Administration (FDA) in 2012 of various intrapartum nitrous oxide delivery devices, intrapartum use of nitrous oxide in the United States is not yet widespread and knowledge is limited regarding the labor and birth experiences of women who use nitrous oxide (Crenshaw, Adams, & Amis, 2016; Hellams, Sprague, Saldanha, & Archambault, 2018; Likis et al., 2012).

Identified benefits of nitrous oxide include mild analgesia, lack of potency, decreased perception and distraction from pain, promotion of relaxation and sense of control, anxiolytic effects, rapid onset and offset, decreased restlessness, improved ability to cope, and inexpensive and non-invasive nature (Likis et al., 2014; Rooks, 2012). Despite less effectiveness for pain relief when compared to epidural analgesics, additional potential benefits of intrapartum nitrous oxide use include a potential to promote women's comfort and satisfaction with the birth experience given the possibility

of coexisting comfort and pain during labor (Charles et al., 2016). Because comfort can be provided without complete elimination of pain (Schuiling & Sampselle, 1999), comfort experienced by women when using nitrous oxide during labor and birth while still experiencing pain presented a new concept warranting further study. An exploration of women's comfort and satisfaction with the birth experience while comparing other pain management options may inform nurses and maternity care providers on how to better promote women's comfort during labor and birth and satisfaction with the birth experience.

Research Problem

Few studies examining intrapartum nitrous oxide use prior to United States FDA approval of nitrous oxide delivery devices in 2012 were of good or fair quality, and reported inconsistent concentrations ranging from as high as 80 percent nitrous oxide with 20 percent oxygen (often in combination with other inhaled medications) to 50 percent nitrous oxide with 50 percent oxygen, the current FDA approved concentration (Stewart & Collins, 2012). In addition, because pain and comfort are possible to exist within the same person at the same time (Charles et al., 2016), use of nitrous oxide during labor and birth may promote comfort during labor and birth; however, the study of the concept of comfort when nitrous oxide is used during labor and birth was not found in the literature. Because the concept of comfort involves an immediate strengthening experience whereby individual needs for relief, ease, and transcendence are met in four contexts (physical, psychological, social, and environmental) (Kolcaba, 2001), close association of comfort to overall satisfaction with the birth experience is evident.

Women have reported benefits of nitrous oxide use that contribute to their satisfaction with the birth experience including (a) maintaining self-control and the ability to focus, think and participate during labor and birth, (b) preserving bodily sensations, mobility and strength, and (c) promoting self-protective abilities (breathing techniques, personal coping skills, etc.) and a more active role in solving one's own labor pain (Richardson et al., 2017b). However, despite increased availability of FDA approved intrapartum delivery devices, few studies have examined women's satisfaction regarding analgesic effectiveness when nitrous oxide is used during labor and birth nor how this influences satisfaction with the birth experience (Attar, Feizabadi, A., Jarahi, Feizabadi, L. & Sheybani, 2016; Dammer et al., 2014; Pita et al., 2012; Richardson, Lopez, Baysinger, Shotwell, & Chestnut, 2017). Of the few extant studies examining women's satisfaction with intrapartum nitrous oxide (Attar et al., 2016; Dammer et al., 2014; Parsa, 2017; Pasha et al., 2012; Pita et al., 2012; Richardson et al., 2017b), quantitative measures of satisfaction have been reported without established instrument reliability and validity.

In health care facilities where anesthesia care is delayed or unavailable, medically contraindicated, or not possible due to rapid labor progression, use of intrapartum nitrous oxide may improve comfort and satisfaction with birth experiences, particularly given the immediate availability and implementation by the bedside Registered Nurse (RN). However, a gap in extant literature was noted regarding the effects of intrapartum nitrous oxide use on women's comfort and satisfaction with the birth experience. As a result, the current study of the effects of intrapartum nitrous oxide use on comfort and satisfaction with the birth experience was warranted.

Purpose Statement and Specific Aims

The purpose of this study was to determine if comfort and satisfaction with birth experiences differed for women who used nitrous oxide compared to epidural analgesics or no analgesics during the labor and birth process.

The specific aims examined in this study were:

Aim 1. To determine the frequencies and frequency distributions of obstetric and mental health history characteristics, current pregnancy characteristics, analgesic use, and use of non-pharmacological methods for women age 18 years and older who experienced a current spontaneous vaginal birth.

Aim 2. To determine comfort experienced during labor and birth for women who received 1) nitrous oxide and oxygen (50-50% mixture) only, 2) epidural analgesics (may have been in combination with other analgesic options), or 3) no analgesics (control group).

Aim 3. To determine satisfaction with the birth experience for women who received: 1) nitrous oxide and oxygen (50-50% mixture) only, 2) epidural analgesics (may have been in combination with other analgesic options), or 3) no analgesics (control group).

Aim 4. To compare differences in comfort between women who used nitrous oxide, those who used epidural analgesics, and those who used no analgesics during labor and birth.

Aim 5. To compare differences in satisfaction with the birth experience between women who used nitrous oxide, those who used epidural analgesics, and those who used no analgesics during labor and birth.

Significance and Background

Significance

Inhaled nitrous oxide has been used for labor analgesia worldwide for over 100 years but use in the United States is not yet widespread (Hellams et al., 2018). The established benefits of intrapartum nitrous oxide use are well understood including mild analgesic effects, decreased perception of pain, reduced anxiety and fear, rapid onset and offset, improved ability to cope, non-invasive and relatively inexpensive approach, and absence of documented adverse maternal and fetal outcomes (Collins, 2016, Likis et al.,

2014). Given the possibility of comfort and pain coexisting within the same person at the same time (Charles et al., 2016), likelihood exists for women to experience comfort and satisfaction during labor and birth while still experiencing pain. Prior to this study, research had not examined the concept of comfort when nitrous oxide is used during labor and birth and research regarding satisfaction with the birth experience when nitrous oxide is used did not report utilization of a validated satisfaction instrument; therefore, further research was warranted to inform nurses and maternity providers regarding the effects of intrapartum nitrous oxide use on comfort and satisfaction with the birth experience.

Intrapartum nitrous oxide use in the presence of limited resources, such as rural critical access hospital settings (Kester, 2014; Rooks, 2011), may provide an alternative analgesic option with a direct impact on promoting comfort and improving patient satisfaction without negative effects on obstetric and neonatal outcomes (Attar et al., 2016; Dammer et al., 2014; Parsa, 2017; Pasha et al., 2012; Pita et al., 2012; Richardson et al., 2017b; Rooks, 2011). Further, given the immediate availability and feasibility of initiation by the bedside RN, use of intrapartum nitrous oxide may provide improved comfort and satisfaction with the birth experience, particularly in situations where other options are ineffective or unavailable. In addition, systemic and regional analgesic use (epidural or spinal route) may include opioids posing increased fetal and/or neonatal risk (change in heart rate, breathing problems, drowsiness, reduced muscle tone and reduced breastfeeding) (American College of Obstetrics & Gynecology, 2017). Avoidance of side effects of opioid medications are possible when nitrous oxide is used. Findings from this study provide insight regarding differences in comfort and satisfaction with the birth

experience for those who used nitrous oxide compared to epidural analgesics or no analgesics during labor and birth. Furthermore, insights gained from this study may help inform clinical practice decisions of maternity care providers in both rural and urban settings.

Understanding of women's comfort and satisfaction with the birth experience when nitrous oxide is used during labor and birth provides increased evidence to guide clinical practice decisions surrounding availability and use of this alternative analgesic option. Further, given nurses are the individuals who primarily support the comfort and pain management needs of women in labor, they are well-positioned to provide patient education and serve as an advocate when pain management strategies are ineffective or limited. Such support, education, and advocacy provided during nursing care affords the nurse the opportunity to make positive contributions to women's childbirth experiences through engagement in practice, policy, and research arenas armed with information grounded by practice experiences and scientific evidence.

Innovation

This study was highly innovative for several reasons. First, recent FDA approval of intrapartum nitrous oxide delivery devices in 2012 with a standardized concentration of 50% nitrous oxide and 50% oxygen and subsequent availability of these delivery devices have provided women in the United States a safe alternative pain management strategy. Despite rising use in hospitals and birth centers across the United States, research studies reporting the outcomes of nitrous oxide use for labor analgesia is lacking. After completing a systematic review for the Agency for Healthcare Research and Quality, Likis et al. (2012) determined a need exists for future research regarding

nitrous oxide for the management of labor pain with specific recommendations to examine effectiveness, women's satisfaction, route of birth, harms, and health system factors. The current study was innovative given the results further the science of intrapartum pain management and presented new insight into the use of nitrous oxide as an alternative intrapartum pain management strategy.

Second, since FDA approval in 2012, only six extant studies examining women's satisfaction when nitrous oxide was used during labor and birth measured satisfaction. Measures of satisfaction included researcher generated instruments or equated satisfaction with reduced self-reported pain intensity or absence of undesired side effects (Attar et al., 2016; Dammer et al., 2014; Parsa, 2017; Pasha et al., 2012; Pita et al., 2012; Richardson et al., 2017b). This study was novel and timely given it was the first to quantify women's satisfaction with the birth experience when nitrous oxide is used during labor and birth using a validated satisfaction instrument, the Birth Satisfaction Scale-Revised (Hollins Martin & Martin, 2014). The instrument developers reported acceptable internal consistency (Cronbach's alpha 0.86) and convergent validity ($r = .94$).

Third, this study was innovative because, following a systematic search of the existing literature, no published studies were found that directly examined comfort during labor and birth when nitrous oxide is used for labor analgesia. Furthermore, to this author's knowledge, this study was the first to investigate satisfaction with nitrous oxide use in women during labor and birth using a validated measure, researcher-modified version of the Childbirth Comfort Questionnaire (Schuiling, 2002). Specifically developed to measure comfort for women undergoing childbirth, the developer of the

Childbirth Comfort Questionnaire reported established face validity (accomplished with a panel of experts) and acceptable internal consistency (Cronbach's alpha 0.71).

Finally, this study was innovative because it was the first to examine both comfort and satisfaction in the context of nitrous oxide use for labor and birth analgesia. Given the close association of comfort and satisfaction, an examination of comfort as well as satisfaction for women who use nitrous oxide during labor and birth represents a novel approach of discovery. Findings from this study may challenge and shift clinical practice regarding nitrous oxide use as an alternative intrapartum pain management strategy to promote comfort and satisfaction with the birth experience.

Gap in evidence. Within a comprehensive search of extant literature, six primary research studies since 2012, including one study conducted in the United States, focused on maternal satisfaction with the birth experience when nitrous oxide was used. Measures to explore effectiveness and satisfaction in the reviewed studies included pain intensity, maternal satisfaction, midwife satisfaction, experienced side effects, maternal hemodynamics, and birth and neonatal outcomes. Evidence to support reduced pain and improved satisfaction without negative effects on obstetric and neonatal outcomes was found in all of the reviewed studies (Attar et al., 2016; Dammer et al., 2014; Parsa, 2017; Pasha et al., 2012; Pita et al., 2012; Richardson et al., 2017b). However, despite existence of reliable and valid instruments to measure satisfaction with labor and birth experiences, valid measures of this concept were not utilized within studies measuring the effects of nitrous oxide on maternal satisfaction. As a result, use of a reliable and valid instrument to effectively measure maternal satisfaction with the birth experience when nitrous oxide is used during labor and birth in future research was of utmost importance. Considering

the close association of comfort to satisfaction and the potential for coexistence of comfort and pain, the current study examining the differences in comfort and satisfaction with the birth experience for women who used intrapartum nitrous oxide compared to epidural analgesic or no analgesic use provided new knowledge to advance the science regarding use of nitrous oxide as an alternative intrapartum analgesic option.

Theoretical Framework

Kolcaba's Theory of Comfort provided the theoretical framework for this study of women's comfort and satisfaction when nitrous oxide is used during labor and birth. Nurses meet the patient's unmet *needs for comfort* during stressful health care situations and successful nursing interventions focused on *enhancing comfort* lead patients to engage in *health-seeking behaviors* (Kolcaba, 2001). When nurses intentionally focus on enhancing comfort, unmet patient needs are identified and interventions are designed to address these needs to enhance comfort. In addition, active engagement in health-seeking behaviors and shared decision-making regarding patient and institutional outcomes directly relate *to patient satisfaction* with health care. Further, a core foundation of the Theory of Comfort is holism, which includes manipulation of the surrounding environment by nurses to enhance patient comfort and accommodate a blending of nursing and patient energy fields during therapeutic interventions (Kolcaba, 2001).

Rooted in the traditions of nursing practice, the theoretical concepts of this theory are described as humanistic, needs-related, and holistic, and relate the relationship of institutional outcomes to nursing practice with emphasis on ensuring nursing actions are visible, essential, and promote soundness of the health care institution (Kim, 1999). Major concepts in the Theory of Comfort include (a) *health care needs* (physical,

psychospiritual, social and environmental) that arise for patients in stressful health care situations, (b) *nursing interventions* (an umbrella term for commitment of nurses and institutions) to provide *comfort care*, (c*) intervening variables* that have a direct impact on outcomes, (d) *patient comfort* (the immediate state of being strengthened by having needs met in four contexts of the human experience: physical, psychospiritual, social, and environmental), (e) *health-seeking behaviors* (actions of which they may or may not be aware and which may or may not be observed) that are predictors or indicators of improved health or as a peaceful death, and (f) *institutional integrity* (the quality or state of health care corporations) that is complete, whole, sound, upright, honest and sincere. Institutional integrity can be operationalized to include *patient satisfaction*, successful discharges, cost-benefit ratios, or other outcomes essential to institutional integrity (Kolcaba, 2001) (see Figure 1).

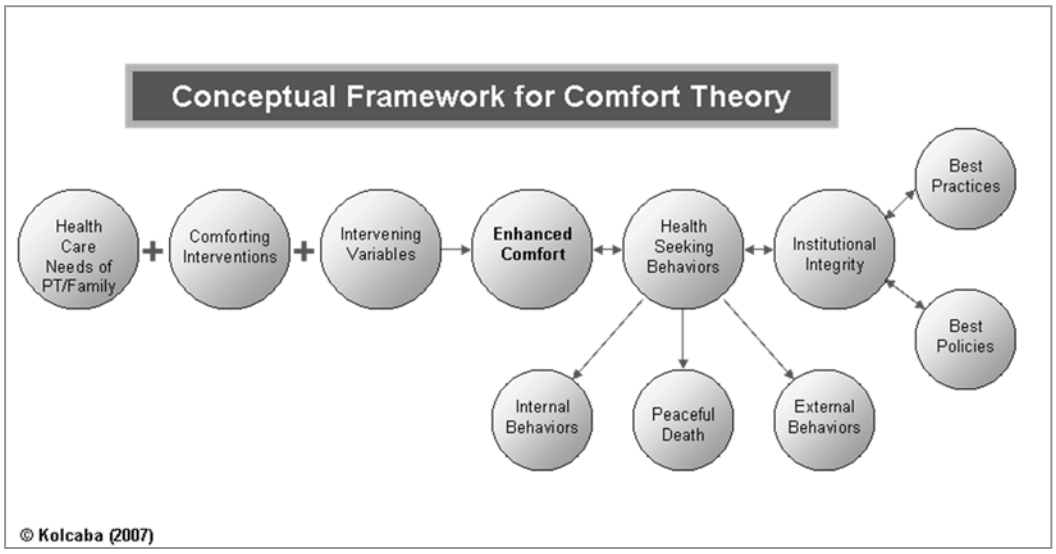

Figure 1. Model depicting Kolcaba's Theory of Comfort. Kolcaba, K. (2007). [Public Domain]. Retrieved from https://www.thecomfortline.com/

The Theory of Comfort had direct relevance to the study of comfort and satisfaction with the birth experience given women often perceive the labor experience as a stressful health care situation during which support from the bedside RN is needed to

meet their comfort care needs. Further, use of nitrous oxide as a comfort intervention, supported and guided by the nurse, promotes strength and motivation for the woman to meet her own comfort needs fostering enhanced satisfaction and improved patient and institutional outcomes.

Theoretical propositions of the Theory of Comfort include: 1) nurses identify *patients' comfort needs* that have not been met by existing support systems, 2) nurses design interventions to address those needs, 3) nurses take into account intervening variables in designing interventions and mutually agreeing on reasonable immediate (enhanced comfort) and/or subsequent (health-seeking behavior) outcomes, 4) if *enhanced comfort* is achieved, patients are strengthened to engage in *health-seeking behaviors*, 5) when patients engage in health seeking behaviors as a result of being strengthened by comforting actions, nurses and patients are more *satisfied with their health care*, and 6) when patients are satisfied with their health care in a specific institution that institution retains its integrity; *institutional integrity* has a normative and descriptive component (Kolcaba, 2001). These propositions were appropriate to guide development of new nursing knowledge regarding comfort and satisfaction with the birth experience given relevance of these statements to the provision of nursing care for women during labor and birth. Upon initiation of care, the nurse partners to determine the woman's comfort care needs and takes action to design and implement mutually agreeable comfort interventions. With active participation and shared decision-making, the woman is motivated to engage in health-seeking behaviors. Comfort interventions provide strength for the woman to remain involved and promote satisfaction with her birth experience.

Assumptions of the Theory of Comfort

Major assumptions of the Theory of Comfort include: (a) human beings have holistic responses to complex stimuli, (b) *comfort* is a desirable holistic outcome that is germane to the discipline of nursing, (c) human beings strive to meet, or to have met, their *basic comfort needs*; it is an active endeavor, and (d) *institutional integrity* has a normative and descriptive component that is based on a patient-oriented value system (Kolcaba, 2001). The major assumptions of the Theory of Comfort have direct relevance to comfort care provided to women during labor and birth. Specifically, the woman's holistic responses to the complex stimuli of labor and birth are supported by the bedside nurse and comfort is promoted as the outcome of focus for nursing interventions. *Achievement of comfort* for the woman during labor and birth is an *active endeavor* as the woman and the nurse partner to respond to various stimuli often manipulating the surrounding environment. Through this partnership and active engagement, the woman's *comfort needs* are met thus promoting *institutional integrity (patient satisfaction*). Application of the Theory of Comfort to explore nitrous oxide use as an intrapartum comfort care intervention provided a foundation upon which to generate new nursing knowledge**.**

Operational Definitions

For the purposes of this study, the following terms were defined:

Intrapartum: the period beginning with the onset of labor and ending upon completion of the third stage of labor as noted within the electronic health record.

Labor and birth experience: the experiences of the woman during the first, second, and third stages of labor as reflected in her responses to survey questions within six hours of childbirth.

Analgesia: A state of pain relief.

Analgesic: A drug used to diminish sensation to pain during labor and birth and to produce analgesia.

Intrapartum Nitrous Oxide: Nitrous oxide and oxygen (50-50% mixture) inhaled and self-administered by the woman during labor and birth under direct observation of the Registered Nurse (Richardson et al., 2017) as noted within the electronic health record.

Epidural analgesics: Initial bolus of 0.25% bupivacaine followed by continuous administration of 0.125% bupivacaine/0.9% sodium chloride within the epidural space initiated by the Anesthesiologist or Certified Registered Nurse Anesthetist for analgesia during labor consistent with the study site intrapartum epidural orderset as noted within the electronic health record.

No analgesics: no pharmacological interventions administered during labor and birth.

Comfort: An immediate strengthening experience during labor and birth whereby individual needs for relief, ease, and transcendence are met in four contexts (physical, psychological, social, and environmental) (Kolcaba, 2001) evident in the woman's responses to questions within the researcher-modified version of the Childbirth Comfort Questionnaire (Schuiling, 2002) including fourteen Likert-style questions, measured on an ordinal scale, with possible scores ranging from 14-70 and higher scores as reflective of total comfort.

Satisfaction with the birth experience: The degree to which the woman during labor and birth perceived the quality of care provision, her personal attributes, and stress experienced during labor reflected in her responses to questions within the Birth Satisfaction Scale-Revised (Hollins Martin & Martin, 2014) including ten Likert-style questions, measured on an ordinal scale, with possible scores ranging from 0-40 and higher scores as reflective of overall satisfaction with the birth experience.

Assumptions

Assumptions of this study were as follows:

1. Women bring a variety of thoughts, feelings, levels of preparation, and expectations to the labor and birth experience.
2. Behaviors of nurses and maternity providers influence the woman's decisions regarding her birth preferences.

3. The birthing environment, including unpredictable factors, contributes to the quality of the labor and birth experience creating a sense of satisfaction, ambivalence, or dissatisfaction with a pivotal life event (Carlton et al., 2005).
4. Support extended to the woman by the nurse during labor and birth impacts the woman's satisfaction with the birth experience.
5. Nurses and maternity providers have an ethical responsibility to support the woman's self-selection of pain management methods.
6. Pain relief does not necessarily improve the woman's labor and birth experience.
7. Increased comfort is not necessarily a result of pain relief (Schuiling, 2003; Charles et al., 2016).
8. Intervening to promote comfort of laboring women can empower them during labor and birth (Schuiling & Sampselle, 1999; Charles et al., 2016).
9. Comfort can exist in the presence of intense pain (Schuiling & Sampselle, 1999; Schuiling, 2003; Charles et al., 2016).
10. Women will be willing to participate in the study.
11. The acquired sample size will be adequate.
12. Study participants will be truthful in their self-reported responses of comfort and satisfaction with the birth experience within the study survey tool.
13. All birthing unit staff at the study site will support and participate in the research efforts.

Limitations

This study had several limitations:

1. The non-experimental study design limited the causal inferences that could be drawn from the study findings. However, the between-subjects comparative design used in this study does allow for exposure of each study group to a different independent variable and comparison of the dependent variables on each independent variable.
2. This study included self-selection of pain control methods and use of self-report measurement tools limiting the ability to objectively verify if participants over or under reported their experiences of comfort during labor and birth and overall satisfaction with the birth experience, if they experienced recall bias, or if they chose answers based upon their perception of social desirability for survey responses.
3. Although women in the study sample were limited to the Midwestern region of the United States, the multi-site design of this study strengthens the validity of findings because survey results represent women who underwent labor and birth experiences in three separate Midwestern hospitals within an integrated health system during a five-month period.
4. Participation in this study required fluency with the English language. Therefore, some otherwise eligible women may have been excluded from participation in the study.
5. Use of the researcher-modified Childbirth Comfort Questionnaire for this study presented a limitation because reliability and validity of this instrument had not been established prior to this study. To minimize this limitation, the researcher

evaluated the reliability of the modified instrument though pilot testing, as described in Chapter III.

Summary

Despite routine intrapartum nitrous oxide use in many countries outside of the United States, use of this option as an alternative pain management strategy in the United States is not yet widespread. Intrapartum nitrous oxide provides an alternative option with established benefits extending beyond pain management. The possibility for the woman to experience comfort when using nitrous oxide during labor and birth while still experiencing pain presented a new concept without prior study. Further, considering the close association of comfort to satisfaction and the potential for coexistence of comfort and pain, this study was the first to explore both comfort and satisfaction with the birth experience when nitrous oxide is used during labor and birth.

This dissertation is comprised of five chapters. Chapter I introduced the background, research problem, study purpose and specific aims, significance and innovation, theoretical framework, operational definitions, assumptions and limitations. Chapter II is comprised of the literature review including focus on the concepts pain and comfort during labor and birth, satisfaction with the birth experience, intrapartum pain management including ethical considerations and available analgesic methods, and various considerations regarding intrapartum nitrous oxide use. Chapter III focuses on the research design for this study. Chapter IV presents and summarizes the findings for this study. Finally, Chapter V includes a discussion of the findings and implications of this study.

CHAPTER II

LITERATURE REVIEW

The purpose of this study was to determine if comfort and satisfaction with birth experiences differed for women who used nitrous oxide compared to epidural analgesics or no analgesics during the labor and birth process.

The specific aims examined in this study were:

Aim 1. To determine the frequencies and frequency distributions of obstetric and mental health history characteristics, current pregnancy characteristics, analgesic use, and use of non-pharmacological methods for women age 18 years and older who experienced a current spontaneous vaginal birth.

Aim 2. To determine comfort experienced during labor and birth for women who received 1) nitrous oxide and oxygen (50-50% mixture) only, 2) epidural analgesics (may have been in combination with other analgesic options), or 3) no analgesics (control group).

Aim 3. To determine satisfaction with the birth experience for women who received: 1) nitrous oxide and oxygen (50-50% mixture) only, 2) epidural analgesics (may have been in combination with other analgesic options), or 3) no analgesics (control group).

Aim 4. To compare differences in comfort between women who used nitrous oxide, those who used epidural analgesics, and those who used no analgesics during labor and birth.

Aim 5. To compare differences in satisfaction with the birth experience between women who used nitrous oxide, those who used epidural analgesics, and those who used no analgesics during labor and birth.

This chapter provides a review of the literature regarding pain and comfort during labor and birth, satisfaction with the birth experience, intrapartum pain management including ethical considerations and available analgesic methods, and various considerations regarding intrapartum nitrous oxide use. Findings from the literature are discussed to frame current knowledge and gaps in understanding regarding the effects of

intrapartum nitrous oxide on comfort during labor and birth and satisfaction with the birth experience for women.

Pain during Labor and Birth

Pain and discomfort experienced by women during labor and birth are part of a normal physiologic process leading to a desired outcome, the birth of an infant. Occurring as a result of sensory receptor response and reaction, women recognize, process, and react to the pain stimulus during labor and birth influenced by emotional, social, cultural, and motivational factors. An additional contributor to a woman's perception of pain is anxiety, which can be related to fear of pain, fear of loss of control, concerns related to safety for both herself and her child, noise, and unfamiliarity of the environment (Koehn, 2000). The presence of fear and anxiety during labor activates a catecholamine stress response, which may have adverse effects during labor including increased risk for protracted labor and labor dystocia (dysfunction) (Collins, 2016). Further, inability to cope with labor pain results in higher than normal increase in maternal catecholamines leading to reduced effectiveness of uterine contractions, maternal exhaustion, fetal distress, and increased risk for posttraumatic stress disorder in the mother after birth (Rooks, 2012).

Visceral and somatic pain felt by the woman during labor contribute to the potentially unpleasant sensory and emotional experience of childbirth. Visceral pain experienced during the first stage of labor relates to tension felt as a result of cervical dilation (Czech et al., 2018). Somatic pain is experienced at the end of the first stage of labor and during the second stage in response to the force exerted on cervix, vagina, and perineum by the descending fetus (Czech et al., 2018). Given the intermittent nature as

well as the association with a normal physiologic process, labor and birth pain differs from other types of pain. Because labor generally begins with mild uterine contractions that increase in intensity over time, adaptation and identification of coping mechanisms by the woman is possible across the labor experience (Schuiling, 2003). In addition to individual expectations, support person presence, sense of control, and shared decision-making, influence pain experienced by women during labor and birth. Other factors that may influence women's perception of pain include parity, duration of labor, maternal pelvic structure, fetal presentation, position, and size, labor augmentation, and prior experiences during labor and birth (Markley & Rollins, 2017).

In response to pain, anxiety, and stress experienced during labor and birth, increased catecholamines and cortisol are released into the woman's circulation. Catecholamines (epinephrine, norepinephrine, dopamine, and serotonin) function as neurotransmitters, with the exception of epinephrine, which are chemical messengers used by neurons to communicate with one another (Schuiling, 2003). Epinephrine and norepinephrine can influence uterine function with increased epinephrine secretion associated with the reduction of uterine activity, and increased norepinephrine secretion associated with dysfunctional and uncoordinated uterine activity. In addition, endogenous analgesia occurs in response to increased norepinephrine given the effect of this hormone on pain modulation and activation of the inhibition of descending neuronal pathways (Henrique, Gabrielloni, Rodney, & Barbieri, 2018). Positive emotions as well as anxiety and fear can increase cortisol levels during labor and birth. Benefits of the increased cortisol include glucose maintenance, prevention of maternal hypoglycemia during acute stress, and a source of energy for the myometrium increasing placental transfer to the

fetus (Henrique et al., 2018). An additional consideration of the pain experience relates to the endogenous opiate system, within which opiates produce an analgesic effect. Binding of the endogenous opioids enkephalins, endorphins, and dynorphin to the specific opiate receptors may produce stress-induced analgesia (Schuiling, 2003). The actions of these neurotransmitters may account for variation seen among women experiencing pain during labor and birth.

As a powerful respiratory stimulus, the physiologic effects of pain during labor include increased ventilation and oxygen consumption during uterine contractions. Subsequently, hyperventilation causes severe respiratory alkalosis and diminished oxygen transfer to the fetus as a result of a left shift of the maternal oxyhemoglobin dissociation curve. Increases in cortisol levels also serve to maintain homeostasis when pain is experienced with release of epinephrine and norepinephrine having a direct effect on increasing the woman's pulse and respirations (Koyyalamudi et al., 2016). In addition, increased catecholamine production causes decreased blood flow to the uterus and an increase in maternal cardiac output and blood pressure (Koyyalamudi et al., 2016).

The woman's pain experience is highly individualized and closely connected to her perception of the childbirth experience (Schuiling, 2003). Considered one of the most important events in a woman's life, the childbirth experience and transition to motherhood have a substantial physical and emotional impact on the woman (Bertucci et al., 2012). The pain experiences of childbirth give meaning to the transition to motherhood by providing the woman the strength and power needed to cope with the demands of parenthood, to develop a heightened awareness, and to increase her sense of self-esteem and personal strength (Schuiling, 2003).

Comfort during Labor and Birth

Comfort can be provided to women during labor and birth without elimination of pain and through promotion of comfort, pain can be diminished (Schuiling & Sampselle, 1999). The concept of comfort, an expression of meeting present or impending (perceived) needs or desires in the body, mind, and spirit domains, results in a feeling of relief, ease, security, well-being, hope and expectation (Schuiling & Sampselle, 1999). Within her Theory of Comfort, Kolcaba described comfort as an immediate and holistic state experienced by individuals who receive comfort interventions and are strengthened through having their needs met for the three types of comfort (relief, ease, and transcendence) in four contexts (physical, psychospiritual, social and environmental) (Tomey & Alligood, 2006).

Holistic comfort is experienced when all needs or desires are met in the domains of the body, mind and spirit (Schuiling & Sampselle, 1999). Comfort in the body domain is reflective of the physical needs as having been met, such as when pain relief has been achieved. Comfort in the mind domain occurs when the individual has piece of mind, a sense of security, or freedom from anxiety; and comfort in the spirit domain is evident when the individual feels a sense of being connected with a higher power which assists with transcendence to surpass physical and/or emotional pain (Koehn, 2000). Comfort measures provide strength to the person despite their remaining discomfort, and their ordinary powers are enhanced through nurse-patient relationships, patient potential, or extraordinary performance; thus, allowing for feelings of ease and relief (Kolcaba & Kolcaba, 1991). Upon elimination of the person's preoccupation with pain, disability, or other difficulties, transcendence is realized. However, the ability to receive, interpret, and

respond to critical signals from the body are required in order to transcend (Schuiling, 2003).

A synthesized meaning of comfort by Kolcaba and Kolcaba (1991) includes three classes: (a) the state sense, (b) the relief sense, and (c) the renewal sense. Absence of discomfort is not a requirement within the state sense to experience comfort given this state is relative to individual characteristics and differs from person to person with regard to how they describe and experience discomfort and ease. Within the relief sense, relief is experienced from conditions causing or contributing to discomfort, and in the renewal sense the person is strengthened and employs a positive attitude and enhanced powers to facilitate labor and birth (Kolcaba & Kolcaba, 1991).

Physical Context of Comfort

While comfort is often described with a focus on alleviation of pain, the concept of comfort during labor and birth includes consideration of pain and comfort as forces possible to coexist within the same person at the same time, where comfort can be felt even in the presence of intense pain (Charles et al., 2016). The concept of comfort over pain is important to consider when providing labor pain management interventions. Schuiling (2003) sought to describe the complex comfort needs of women during childbirth and differentiate between managing pain and experiencing comfort. This study concluded that increased comfort can be experienced by women not necessarily as a result of pain relief. In addition, the research noted epidurals, while highly effective in lowering pain, were found to have little impact on women's comfort level during labor and freedom of movement and massage were found to have greater effect on comfort than pharmacologic methods (Schuiling, 2003). Finally, Schuiling (2003) described

comfort during childbirth as complex and occurring in different contexts and senses of the experience requiring caregiver expertise in comfort assessment, evaluation, and management during labor and birth. As a result, support for further study of the concept of comfort during labor and birth with focus on goal setting, planning, and assessment of intervention effectiveness to promote comfort rather than relief of pain was apparent.

Psychospiritual and Social Contexts of Comfort

Schuilling and Sampselle (1999) conducted a review of extant nursing, midwifery, and medical literature dating back to the 1920's with focus on comfort as a concept experienced during labor. Findings of this review included recognition that interventions to promote comfort of laboring women can empower them during birthing, comfort can exist in spite of great pain, and nurses and midwives play a role in assisting women to achieve a level of comfort during labor. Additional findings included the promotion of comfort as a high priority for laboring women, increased comfort can redefine the meaning of pain in childbirth, and increased comfort may decrease the need for medical interventions and lower health care costs (Schuiling & Sampselle, 1999). As a result of the concept analysis within this review, a theory of comfort during labor was developed and subsequently incorporated within Schuiling's (2003) dissertation research study.

Garlock, Arthurs, & Bass (2017) conducted a quasi-experimental pretest/posttest comparison group study to determine if, during admission to the labor and delivery unit, providing education on comfort and comfort options available in the hospital setting increases level of comfort during labor. A convenience sample of 80 pregnant women at term gestation anticipated to undergo vaginal birth were randomly assigned to the control

and intervention groups, with the intervention group being provided a comfort education brochure and education regarding alternative options for managing comfort in the hospital setting. Utilizing the same Childbirth Comfort Questionnaire instrument and measurement intervals (Time 1 during latent phase of labor and Time 2 during active phase of labor) as in Schuiling's (2003) dissertation study, Garlock et al. (2017) did not find statistically significant differences between the comfort education group and the control group for comfort scores or pain scores at any time. However, providing comfort education to maintain comfort during labor was found to allow for women to make informed choices during labor (Garlock et al., 2017).

While only two primary research studies found in the literature focused on the study of comfort during labor and birth (Garlock et al., 2017; Schuiling, 2003), an additional study of relevance focused on promoting comfort over pain for women experiencing chronic pain exacerbated during pregnancy (Charles et al., 2016). The researchers acknowledged that medication does not correct the cause of pain; rather, it alters experiential pain perception and exposes the mother and fetus to risks associated with the pain medication effects. As a result, holistic and alternative techniques (posture and back exercises, relaxation techniques, self-hypnosis, aromatherapy, hydrotherapy, music therapy, massage, and acupressure) to increase comfort were the focus of this study whereby women received training on use of such techniques to be used across their pregnancy. Pre- and post-intervention comparison of comfort scores using a validated instrument revealed a statistically significant increase in comfort for women who used the alternative techniques. In addition, women who relieve their own pain were described as empowered and had decreased opioid use during pregnancy with resultant benefits to the

mother and fetus. The researchers concluded that reduced opioid use was related to better function of the woman's self-protective abilities; thus, allowing for increased sense of empowerment and a more active role in solving her own pain (Charles et al., 2016).

A similar study conducted by Chuntharapat, Petpichetchian, and Hatthakit (2008) examined the effects of Yoga during pregnancy on maternal comfort, labor pain, and birth outcomes. This randomized-control trial of seventy-four primigravida Thai women included a Yoga program, with six, 1-hour yoga-training sessions at prescribed intervals during pregnancy and subsequent application of this training by the woman for 30 minutes at least three times per week as the intervention. With use of a variety of instruments to measure comfort, labor pain and birth outcomes, the experimental group was found to have higher levels of comfort during labor and 2 hours post-labor, and experienced less labor pain, shorter duration of first stage of labor and total time of labor. This study concluded that while childbirth is a time of enormous stress for many women particularly, incorporation of yoga as a comfort intervention across pregnancy can assist in raising the threshold of the mind-body relationship to pain and increase in the pain threshold; thus, preventing painful stimuli from stimulating release of endogenous endorphins and serotonin. Further, with regard to measurement of comfort, pain was found to affect the level of comfort women achieved during active labor. The pain scores were consistently lower and maternal comfort was significantly higher for the experimental group compare to those of the control group over three assessment times during active labor (Chuntharapat et al., 2008). Incorporation of holistic and alternative therapies and informed decision-making for women during labor and birth promote

comfort in psychosocial and spiritual contexts while fostering a sense of empowerment and relief of one's own pain.

Environmental Context of Comfort

The woman's interaction with the environment during labor and birth is an additional consideration with regard to the holistic nature of comfort. Specifically, holistic nursing care includes attention to the interrelationships of the body, mind, and spirit in an ever-changing environment (Koehn, 2000). Kolcaba (2001) described the environmental context to include factors pertaining to the external surroundings, conditions, and influences. Originating from an external stimulus, comfort needs arise from the environment in the form of positive, obstructing, and interacting forces. In the presence of negative tension, an imbalance occurs between obstructing and facilitating forces. In the context of labor and birth, nursing care focused on identifying the changing comfort needs of the woman across the labor and birth experience with incorporation of appropriate comfort interventions allows for the negative tension naturally occurring during labor and birth to move in a positive direction (Koehn, 2000).

Kolcaba's Theory of Comfort to Inform Nursing Practice

Only two studies were found in the literature reporting use of the Theory of Comfort as a theoretical framework to guide the study of comfort for women during labor and birth (Charles et al., 2016; Schuiling, 2003). However, comfort care and the Theory of Comfort (Kolcaba, 2001) have been explored in various studies unrelated to childbirth. Application of comfort in the literature was noted within studies focused on nursing education, perianesthesia nursing, pediatric nursing, during transition from nursing school to practice, in management of epilepsy, within cancer and cardiac care, and as an

institution-wide approach across disciplines to enhance the practice environment (Cox, 1998; Egger-Rainer, Trinka, Hofler, & Dieplinger, 2017; Goodwin & Candela, 2013; Goodwin, Sener & Steiner, 2007; Kolcaba, 1994; Kolcaba, 2001; Kolcaba & DiMarco, 2005; Kolcaba, Tilton, & Drouin, 2006; Kolcaba & Wilson, 2002; Krinsky, Murillo, & Johnson, 2014; Ng, 2017). Although application of Kolcaba's Theory of Comfort to obstetric nursing practice is limited, a significant body of evidence supports its use to enhance holistic nursing care.

Congruent with the theories of comfort in labor and those of holism, trust in self and one's body relate a holistic experience during labor occurring in response to the woman's "listening to" and "going into" her own body. As a result, the woman is able to "hide in her own body" to avoid the pain of labor (Schuiling, 2003, p. 55). Direct relation of this consideration exists within Kolcaba's (1991) transcendence context of comfort which expands this consideration to also include recognition of the comfort provided by caregivers during labor and birth, the trust the woman has in the midwife/nurse and support person, and her value of support in labor in terms of one-to-one care (Schuiling, 2003) as contributing to her transcendence experience.

When comfort is used as a model of care during labor and birth, support of the physiologic process of childbirth occurs while decreasing pain and increasing other positive health related outcomes. Driven by the woman's perception of her own body and pregnancy, the link of the woman's mind and body are realized as the center of comfort care. Further, the variables the woman brings to the birth experience are considered part of the whole with each component interacting to produce a synergistic effect on the woman's health, pregnancy and birth. With focus on individual, different, and unique

outcomes for each woman and birth, labor is recognized as a holistic event with comfort understood to be a holistic phenomenon (Schuiling, 2003). Within stressful health care situations, comfort is experienced upon satisfaction (active, passive, or cooperatively) of the basic human needs for ease, relief or transcendence (Kolcaba, 1994). In addition, the expression of having met present or perceived needs or desires in three contexts of the experience (physical, psychosocial, and environmental/social) provides additional insight into the comfort experience whereby feelings of relief, ease, security, well-being, hope and expectation are realized (Schuiling & Sampselle, 1999).

Satisfaction with the Birth Experience

Beyond effectiveness of pain relief, factors such as regaining self-control, ability to focus, think and participate during labor and birth, preservation of bodily sensations, mobility and strength, and personal expectations, caregiver support, and involvement in decision-making impact overall satisfaction with the labor and experience (Richardson et al., 2017b). Satisfaction also correlates with the women's quality of care, personal attributes, and stress experienced during labor (Fleming et al., 2016). Based upon the concepts of patient-centered care and shared decision-making, greater focus on patient satisfaction in medical care and research exists today, particularly as analgesic options improve and evolve (Duale et al., 2015). Given unmet needs are an important source of dissatisfaction, people are generally satisfied when they get what they want and when their requests are honored and respected (Camann, 2017). Thus, satisfaction with the birth experience may be closely related to women's perceptions of met or unmet holistic needs.

Satisfaction as a Multidimensional Concept

As a holistic experience, women's satisfaction with labor and birth experiences is likely multidimensional, rather than related to a single factor. Hodnett (2002) described women's satisfaction with the care during childbirth as a complex concept involving both a positive attitude, an affective response to the experience, and a cognitive evaluation of the emotional response. Four factors of primary influence on women's satisfaction with care during childbirth were identified within a systematic review of 137 research reports (Hodnett, 2002) including personal expectations, amount of support from caregivers, quality of the caregiver-patient relationship, and involvement in decision-making. These four factors provide important insight regarding the potential contributors to satisfaction with the birth experience examined for this study.

Satisfaction and personal expectations. Evidence-based care processes to protect, promote, and support physiologic birth in alignment with woman's personal expectations of labor and birth allow for women to be informed in the development of their personal expectations (Carter et al., 2010). Ensuring maternity care is woman-centered, safe, effective, timely, efficient, and equitable were additional attributes described for the ideal maternity care system (Carter et al., 2010). Women whose experiences during labor and birth exceeded their expectations had higher levels of satisfaction (Hodnett, 2002). The development of a woman's personal expectations of obstetric care is influenced by various attributes and ideals of the maternity care system (Carter et al., 2010).

Personal expectations and patient perception are closely related concepts relevant to satisfaction with the birth experience. For example, the woman's perception of well-

managed pain was identified as influential on patient satisfaction following childbirth as measured within the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey (Mazurenko, Fairbanks, Collum, Ferdinand & Menachemi, 2017). Further, the woman's feeling of being in control, her ability to cope with her labor, and her perception of being treated with respect were consistently reported as contributors to the woman's satisfaction with her birth experience (Barbosa-Leiker et al., 2015; Richardson et al., 2017b; Schuiling, 2003).

Satisfaction and support from caregivers. The amount of support provided from caregivers, such as a spouse, significant other, family member and/or friend, was noted as a significant factor affecting satisfaction in various studies (Barbosa-Leiker et al., 2015; Hodnett, 2002; Hollins Martin & Martin, 2014; Lewis et al., 2016; Richardson et al., 2017b). Across the review of extant literature regarding the woman's satisfaction with her birth experience, factors consistently found to impact the woman's satisfaction included continuous support from caregivers to improve comfort, emotional support, information and advocacy, expectations as met or exceeded, quality of care provided, involvement in decision-making, and woman focused care, and systems and faculties (Barbosa-Leiker et al., 2015; Hollins Martin & Martin, 2014; Lewis et al., 2016; Richardson et al., 2017b). Such support provided by caregivers during labor and birth was an important consideration for the current study given the potential influence of caregiver support on the woman's satisfaction with her birth experience regardless of the analgesic option chosen for use during labor and birth.

Satisfaction and quality of caregiver-patient relationship. Rapport, communication, information giving, feelings of involvement in decisions about their care,

and feeling free to express feelings during labor are noted aspects influential on the quality of caregiver-patient relationships (Hodnett, 2002). In addition, when caregiver satisfaction and fulfillment are fostered (Carter et al., 2010) enhanced quality of the caregiver-patient relationship is possible (Hodnett, 2002) thus promoting increased satisfaction with the birth experience for the woman. Carter et al. (2010) described the ideal maternity care system as protecting, promoting and supporting physiologic childbirth while also promoting a satisfying and fulfilling work environment for its caregivers. An understanding of the reciprocal nature of satisfaction for both the woman and the caregiver is relevant to the current study given the potential for the quality of the caregiver-patient relationship to be influential on the woman's overall satisfaction with her birth experience.

Measurement of the quality of the caregiver-patient relationship and various factors associated with satisfaction are possible within the HCAHPS survey of which six of the eight core categories directly relate to the caregiver-patient relationship and the woman's self-report of satisfaction. Nursing communications, responsiveness of staff, doctor communication, environment, pain medication, and communication of side effects and reasons for medications are among the eight core categories of the HCAHPS survey directly related to the quality of the care-giver patient relationship and the woman's report of satisfaction with her birth experience (Mazurenko et al., 2017). However, Lewis et al. (2016) argued against the likelihood of the woman's complete satisfaction with all aspects of her birth experience given she is likely to rank the quality of her care as satisfactory but still verbally share aspects she liked and disliked when asked to reflect upon her experience. Awareness of the potential for women to verbally express aspects of

their birth experiences beyond or different from survey responses alone provide insight for researchers in the design of research study methods inclusive of both quantitative and qualitative methods when exploring the concept of satisfaction with the birth experience.

Satisfaction and involvement in decision-making. Involvement in decision-making was described as an aspect of personal control whereby the woman was permitted to have an active say in the decisions about her care (Hodnett, 2002). Carter et al. (2010) described the ideal maternity care system with optimal experiences including shared decision making and respect for informed choice, care that is coordinated, evidence-based, and evaluated for performance and quality disclosure. Direct overlap exists regarding the influence of shared decision making and choice (Carter et al., 2010) and involvement in decision-making (Hodnett, 2002).

Other factors influencing satisfaction. Additional factors beyond personal expectations, amount of support from caregivers, quality of the caregiver-patient relationship, and involvement in decision-making (Hodnett, 2002) have been described as influential of women's satisfaction with the birth experience. Age, race, ethnicity, socioeconomic status, preparation for childbirth, the birth environment, pain experienced during childbirth, immobility, medical interventions, continuity of care, the hospital's safety net status, and metropolitan location (Hodnett, 2002; Mazurenko et al., 2017) are additional factors with influence on the woman's satisfaction with her birth experience. Given the national focus on heightening the patient experience, improving overall health, and reducing health care costs, the Institute of Healthcare Improvement's "Triple Aim" provides a framework to guide United States health care providers and policy-makers regarding actions and initiatives to improve patient satisfaction with health care

(Barbosa-Leiker et al., 2015). In addition, the HCAHPS survey, a publicly reported survey of patients' perspectives of hospital care, provides an opportunity to gain feedback regarding patient satisfaction by asking discharged patients 27 questions regarding their recent hospital stay. Women who have undergone childbirth in the hospital setting are randomly selected to provide feedback regarding their recent hospital stay based upon the questions within the HCAHPS survey (Centers for Medicare & Medicaid Services, 2017). Such questions focus on critical aspects of the woman's hospital experiences including communication with nurses and doctors, the responsiveness of hospital staff, the cleanliness and quietness of the hospital environment, pain management, communication about medicines, discharge information, overall rating of hospital, and likelihood of recommending the hospital to others. Because the woman's satisfaction with her birth experience is a key factor in offering high-quality maternity care, knowledge regarding the multidimensional factors that influence satisfaction are essential to a study of satisfaction with the birth experience.

Factors Influencing Comfort and Satisfaction

Significant factors affecting comfort associated with labor and birth identified from the literature and aligned with Kolcaba's (2001) Theory of Comfort include feelings of relief, ease and transcendence, receipt of comfort interventions, the nurse-patient relationship, freedom of movement, perception of self and the pregnancy, personal attributes brought to the birth experience, sense of security, peace of mind, freedom from pain and anxiety, surpassing physical and emotional pain, and feelings of empowerment (Charles et al., 2016; Chuntharapat et al., 2008; Koehn, 2000; Kolcaba, 2001; Morse, Bottorff, & Hutchinson, 1994; Schuiling, 2003; Schuiling & Sampselle, 1999; Tomey &

Alligood, 2006). Potential factors influencing satisfaction noted in the literature and aligned with the subtheme areas of the reliable and valid Birth Satisfaction Scale-Revised self-report satisfaction instrument include quality of care provision (home assessment, birth environment, sufficient support, relationships with health care professionals), personal attributes (ability to cope during labor, feeling in control, preparation for childbirth, relationship with baby), and stress experienced during labor (distress experienced during labor, obstetric injuries, perception of having sufficient medical care, recipient of an obstetric intervention, pain experienced, long labor, health of baby) (Hollins Martin & Martin, 2014). Additional factors influencing of satisfaction mentioned in the literature include age, race, ethnicity, socioeconomic status (education, income, employment status), and prior birth experience/parity (Barbosa-Leiker et al., 2015; Bertucci et al., 2012; Charles et al., 2016; Dammer et al., 2014; Declercq et al., 2014; Duale et al., 2015; Fleming et al., 2016; Hodnett, 2002; Hollins Martin & Martin, 2014; Lewis et al., 2016; Mazurenko et al., 2017; Pasha et al., 2012; Richardson et al., 2017b). Joint consideration of factors influencing comfort as well as for satisfaction can inform future research in a manner consistent with the holistic nature of the birth experience.

Comfort Care and Satisfaction

Within the Theory of Comfort, Kolcaba (2001) proposed greater satisfaction with health care and better health-related outcomes occur when the patient and their family members are provided care aimed at promoting comfort and engagement in health-seeking behaviors (McEwen & Wills, 2014). In addition, satisfaction of patients, families, and nurses with the health care institution results in public acknowledgement about the institution's contributions to health care; thus, fostering institutional integrity including

best practices and best policies (McEwen & Wills, 2014). Comfort care entails at least three types of comfort interventions: (1) technical comfort measures designed to maintain homeostasis and manage pain, (2) coaching interventions designed to relieve anxiety, provide reassurance and information, and instill hope, listen, and help to plan for realistic and culturally sensitive outcomes, and (3) "comfort food" interventions aligned with basic nursing care which is unexpected, but very welcomed by the patient (Tomey & Alligood, 2006). While nurses of today may have less time to provide "comfort food" interventions, high patient satisfaction and transcendence are possible when the nurse uses "comfort food" interventions to make the patient feel strengthened in an intangible, personalized sort of way and to establish presence and memorable connections (Tomey & Alligood, 2006). The link of comfort care to satisfaction is apparent as noted within the key aspects of the HCAHPS patient satisfaction survey. Aspects of this survey directly aligned with the quality of comfort care provided include questions regarding nursing and doctor communications, responsiveness of staff, environmental cleanliness and quiet at night, and pain management (CMS, 2017). As a result, emphasis and attention to providing comfort care for women during their labor and birth experiences will continue to be of utmost importance to promote their satisfaction with the birth experience ongoing.

Pain Relief and Satisfaction

Based upon the concepts of patient-centered care and shared decision-making, patient satisfaction is becoming a major issue in medical care and research, particularly as analgesic options improve and evolve (Duale et al., 2015). Although pain control is a significant component, many other factors directly influence the woman's overall

satisfaction with the birth experience. Further, despite the common belief that better pain relief contributes to higher satisfaction a direct correlation has not been found (Camann, 2017).

Within a systematic review of the literature, Duale et al., (2015) sought to investigate whether maternal satisfaction had been considered as an outcome criterion in clinical research on analgesia for labor. Of the 116 articles analyzed for their scope of maternal satisfaction, type of outcome measure used, and timing of measurement, variable findings were reported across the reviewed studies. Specifically, only one of the reviewed studies reported validation of a tool to assess maternal satisfaction. While approximately 2/3 of the included articles did not use maternal satisfaction as an outcome to study analgesia during labor, of those reporting maternal satisfaction, the method used was variable, particularly regarding the aspects of satisfaction measured. As a result of this review, the authors concluded a standardized and validated tool to assess maternal satisfaction with labor analgesia is still needed (Duale et al., 2015).

Intrapartum Pain Management

Management of labor pain dates back to the 1850's during which time administration of chloroform to Queen Victoria by John Snow was based upon the novel idea that labor pain should be treated (Akerman & Dresmer, 2009). Expectations regarding intrapartum pain management continually change across the woman's pregnancy as she receives and reviews new information. Considerations such as how painful she feels labor will be, whether or not she expects labor pain to be a positive or a negative experience, what relief she perceives she will receive with available pain management methods, and how long she anticipates her labor to last (Lally, Thomson,

MacPhail, & Exley, 2014) are included within her review of information regarding intrapartum pain management.

Personal expectations, caregiver support, quality of caregiver-patient relationship, and involvement in decision-making are stronger influences on the labor and birth experience than the type or degree of pain control achieved (King & Wong, 2014). However, a variety of measures to assist women to cope with the challenges of labor and birth should be available during the birth experience (American College of Nurse-Midwives, 2010). Further, providing safe pain relief choices to women during labor and birth remains a central goal of health care providers (Markley & Rollins, 2017). While women may present to labor with a strong preference for a particular pain management method, they may end up using a method different from the original plan (Rooks, 2012). Key factors that drive maternity care provider decisions surrounding analgesic methods offered to women during childbirth relate to comparative effectiveness, availability of protocols or clinical guidelines, cost, and safety.

While women bring a variety of thoughts, feelings, levels of preparation, and expectations to the childbirth experience, the behaviors of healthcare providers influence the decisions women make regarding their birth preferences. In addition, the birthing environment contributes to the quality of the birth experience influencing the woman's sense of satisfaction, ambivalence or dissatisfaction with a pivotal life event (Carlton et al., 2005). Despite the relative predictability of the childbirth process, various unpredictable factors contribute to the overall experience such as the length of labor or a non-reassuring fetal status. In such cases, supporting a woman's birth preferences and expectations can challenge nurses and other healthcare providers; however, presence and

quality of support provided by the nurse remains central to the provision of the ethics of caring in clinical practice.

No matter the setting, maternity providers and nurses must provide pain management aligned with the ethical principles framed by the ethics of caring including autonomy, veracity, beneficence, informed consent, standard of best interest, and respect (Carlton et al., 2005). Birth preferences regarding pain management during labor and birth may include no preference, medicated or unmedicated methods, or a "wait and see" attitude, which may change across the birth experience. While pain relief does not necessarily improve the woman's experience of childbirth, awareness and support of the woman's birthing preferences by the nurse and maternity care provider is key to promoting the woman's satisfaction with the birth experience (Carlton et al., 2005).

Non-pharmacologic Methods during Labor and Birth

Non-pharmacologic labor and birth methods provide comfort interventions with low risk and cost personally initiated by the woman or in collaboration with her maternity care providers. Such comfort interventions may provide the woman with the strength she needs to work through the process of labor and allow her to be an active participant in her birth. With focus on promoting or enhancing comfort, nurses are able to fully carry out the "art" of nursing care. In addition, non-pharmacologic methods used prior to or in conjunction with analgesics may result in less total narcotic use for women during labor leading to decreased maternal and fetal risk associated with use of opioid analgesics (Schuiling, 2003).

Most women utilize at least one non-pharmacologic method to reduce pain during labor and birth. Commonly utilized non-pharmacologic labor and birth methods include

distraction therapies and alternative treatments including acupuncture, hypnotism, yoga, exercise during pregnancy, hydrotherapy, transcutaneous electronic nerve stimulation, massage and relaxation techniques (Koyyalamundi et al., 2016). Used as either the sole form of labor analgesic or as a complement to pharmacologic methods, non-pharmacologic methods can be beneficial in reducing pain perception and helping the laboring woman cope with the birth process as a whole (Markley & Rollins, 2017). Within the *Listening to Mothers III* survey of 2,400 United States women's childbearing experiences, 73% reported use of at least one non-pharmacologic method of pain relief with breathing techniques (48%) as the most common method, followed by position changes (40%), massage (22%), and relaxation (21%) (Declercq et al., 2014). With direct effect on the endogenous pain pathways activated in labor, non-pharmacologic methods have been theorized to inhibit transmission of pain fibers (tactile stimulation), reduce whole body pain via the endorphinergic system (acupuncture, acupressure, transcutaneous electrical nerve stimulation, and sterile water injection), and control the mind through attention deviation (relaxation, meditation, hypnosis, aromatherapy, and expectation management) (Marley & Rollins, 2017).

Intended to enhance the emotional experience of giving birth, non-pharmacologic methods allow women to comfort themselves, remain active and in control, and have confidence in their ability to cope with labor pain (Rooks, 2012). With an understanding that labor pain is normal and a desire to avoid the risks and side effects of pharmacologic methods, women use non-pharmacologic methods to avoid or delay use of pain mediation during labor, prior to or in conjunction with pharmacologic methods, or when pharmacologic methods are ineffective or unavailable (Rooks, 2012).

Analgesic Methods during Labor and Birth

Neuraxial analgesics (epidural, spinal, or combined spinal-epidural technique) serve as the gold standard for labor pain control (Koyyalamundi et al., 2016) with epidural use in over 60% of vaginal births today (Biel, Marshall & Snowden, 2017). However, while neuraxial analgesics may be the most effective labor analgesic option, this method may be undesired, contraindicated, unsuccessful or unavailable (Markley & Rollins, 2017). Alternative analgesic methods currently available for use by women in the United States during labor and birth include systemic analgesics (opioids and non-opioids, single dose or patient-controlled analgesics) and inhaled nitrous oxide. Within the *Listening to Mothers III* survey of 2,400 United States women's childbearing experiences conducted in 2012, while 17% of women reported using no pain medication, 83% used one or more types of pain medication for labor pain relief with epidural or spinal analgesics as the most common medication used (67%), followed by systemic analgesics (16%) and nitrous oxide gas (6%) (Declercq et al., 2014).

Despite the high incidence of epidural use, this option may not be universally available to laboring women in small community or rural hospitals where 24 hour a day, 7 day a week coverage for in-house anesthesia care is not possible (Rooks, 2011). As a result, availability of alternative labor pain management strategies that are inexpensive, simple, woman-led, safe and effective is important particularly when other options are delayed or unavailable (Rooks, 2012). Further, use of strategies that promote self-management of labor pain, and that foster empowerment, decreased use of opioids, better utilization of self-protective abilities, and a more active role in solving one's own pain (Charles et al., 2016) are of utmost importance.

Intrapartum Nitrous Oxide Use

First approved for use during labor in England in 1936 (Likis et al., 2012), nitrous oxide is widely accepted in many European countries where up to two-thirds of women use nitrous oxide as a labor analgesic modality (Richardson et al., 2017). However, United States Food and Drug Administration (FDA) approval of delivery devices to administer intrapartum nitrous oxide and oxygen (50-50% mixture) did not occur until 2012. While use in the United States is on the rise, wide availability of intrapartum nitrous oxide had not yet become usual practice in 2017, and use in 2016 was limited to just over 100 hospitals and 38 birth centers (Collins, 2016; Collins, 2017; Crenshaw, Adams, & Amis, 2016).

Likis et al. (2012), conducted a comparative effectiveness review in 2012 to determine the state of the science on effectiveness, women's satisfaction, route of birth, harms, and health system factors affecting use of nitrous oxide for the management of labor pain. However, given few studies of good or fair quality were found, the researchers concluded further study was needed in all areas included in the review (Likis et al., 2012). Scientific evidence continues to be lacking regarding use of nitrous oxide for the management of labor pain. As public awareness of intrapartum nitrous oxide expands and as alternatives for systemic opioid or neuraxial labor analgesics are sought by clinicians and consumers, close investigation of intrapartum nitrous oxide use is warranted (King & Wong, 2014). Further, creation of formalized protocols and clinical guidelines for implementing nitrous oxide during childbirth in the United States continues to be an area of great need in order to provide practice guidelines for nurses and providers despite the existence of such resources in other countries.

Recently published literature in the United States has provided recommendations for inclusion of nitrous oxide during labor and birth (Collins 2018; Hellams et al., 2018; Migliaccio, Lawton, Leeman, & Holbrook, 2017; Pinyan, Curlee, Keever, & Baldwin, 2017; Richardson et al., 2017b) and evidence exists regarding the effects of nitrous oxide use on reduction of pain with proven effectiveness and positive effects on maternal satisfaction without negative obstetric and neonatal outcomes (Attar et al., 2016; Dammer et al., 2014; Likis et al., 2012; Parsa, 2017; Pasha et al., 2012; Pita et al., 2012; Richardson et al., 2017b; Rooks, 2011). However, despite increased intrapartum nitrous oxide use in the United States, little is known regarding women's perception and satisfaction when nitrous oxide is used to manage labor pain. In addition, prior study of the concept of comfort as it relates to nitrous oxide use was not found in the literature. As a result, a need was identified for study of the effects of intrapartum nitrous oxide use on comfort and satisfaction with the birth experience.

Nitrous Oxide Use with Infrastructure and Personnel Limitations

Use of nitrous oxide and oxygen (50-50% mixture) was reported as appealing, effective and safe for management of pain during labor and useful in institutions with infrastructure and personnel limitations (Pita et al., 2012). This is particularly important to consider in health care facilities where anesthesia care is delayed or unavailable or in rural settings where 24/7 coverage for in-house anesthesia care is not possible. Implementation of nitrous oxide in labor at a small community hospital made access to immediate pain relief a reality, enabled nurses to provide safe and quick pain relief, and allowed women experiencing rapid progression of their labor to obtain pain relief before a physician was available (Kester, 2014). Further, administration of nitrous oxide by a

trained Registered Nurse (RN) allowed for immediate implementation of a pain management strategy when other pain relief options were delayed or unavailable (Dammer et al., 2014; Kester, 2014). The long life expectancy of the delivery device, the relatively inexpensive cost to deliver nitrous oxide, and the substantially reduced costs associated with administration, monitoring, and complication management compared to other analgesic options (Richardson et al., 2017), support the use of nitrous oxide as a cost-effective pain management strategy in rural hospitals. Exact cost of nitrous oxide use during labor and birth has not been documented; however, when compared to other labor analgesic modalities nitrous oxide is a notably less expensive analgesic strategy. With costs primarily associated with the disposable supplies (estimated at $20) and purchase of the re-usable delivery device (approximately $5000 per device), these cost considerations, the long life expectancy of the delivery device, and the presumed lower personnel costs suggest cost-effectiveness of nitrous oxide use for labor analgesia (Richardson et al., 2017b).

Historical Considerations of Nitrous Oxide Use

Nitrous oxide a colorless, tasteless, odorless gas, was discovered by Joseph Priestly in 1772 in Great Britain and first reported as useful for relief of a toothache in 1800 (Richardson et al., 2017). Successful establishment of nitrous oxide use during dental procedures occurred in 1846 and use as a labor analgesic was first reported in Poland in 1881 (Collins, 2015) with 80/20 mixture of nitrous oxide and oxygen. While use of inhalation analgesics in obstetrics dates back to the 1800's, the two-tank nitrous oxide self-administration device developed by Minitt in 1934 allowed for approved use during labor in England in 1936 (Agah, Baghani, Tali, & Tabarraei, 2014). Certification

of safe use of nitrous oxide for obstetric patients occurred in 1936 by the Royal College of Obstetricians and Gynecologists (Richardson et al., 2017). Further development of a single-tank cylindric container of 50% nitrous oxide and 50% oxygen allowed for commercial use in 1961 in the many European and Asian countries (Agah et al., 2014).

Although nitrous oxide was used in the United States in the 1970's, use in labor declined the following decade likely as a result of growing popularity of neuraxial analgesics (Richardson et al., 2017). However, while nitrous oxide use for surgical anesthesia has declined in the United States in the twenty-first century, a renewed interest in nitrous oxide use for labor has occurred since 2012 (Richardson et al., 2017). While nitrous oxide use in the United States is on the rise, the main reason for limited use of nitrous oxide during labor prior to 2012 likely related to the lack of an approved delivery system by the FDA (Bobb, Farber, McGovern, & Camann, 2016).

Approval of the delivery device for use during labor in the United States by the FDA in 2012 resulted in production of affordable, portable, safe, and approved delivery systems by several vendors beginning in 2013 (Bobb et al., 2016). Gaps in the literature exist regarding the effects of nitrous oxide when used during labor and birth, particularly regarding woman's comfort and satisfaction with the birth experience. Knowledge of this nature is necessary to inform decisions of nurses and maternity providers in rural hospitals surrounding optimal intrapartum pain management strategies in the presence of limited resources.

Nitrous Oxide and Intrapartum Pain and Anxiety

Nitrous oxide, entering and leaving the body through the lungs, increases the release of endogenous endorphins, corticotrophins, and dopamine (Rooks, 2012). While

the pharmacologic pathways by which nitrous oxide achieves analgesia are not well understood (Rooks, 2007), the mechanism of action for nitrous oxide is thought to result from the release of endorphins and dopamine in the brain allowing for a euphoric effect and modulation of pain stimuli via descending spinal and nerve pathways (Agah et al., 2014). Other hypotheses regarding the mechanism of action of nitrous oxide have included focus on the potential opioid-like effects in the central nervous system caused by nitrous oxide and the antagonism effect it has on the *N*-methyl-*D*-aspartate receptor (Hellams et al., 2018). As a weak anesthetic agent at 50% concentration, nitrous oxide has a very low blood/gas solubility with peak brain concentrations occurring within 60 seconds of administration in laboring patients (Richardson et al., 2017). Based upon the hypothesized release of endogenous opioid peptides in the periaqueductal gray area of the midbrain in response to nitrous oxide administration, these peptides are thought to stimulate descending noradrenergic neuronal pathways causing modulation of pain by alpha-2 receptors in the dorsal horn of the spinal cord. Further, like other volatile anesthetics, nitrous oxide has been found to have poor action at *y*-aminobutyric acid receptors but is noted to also inhibit the *N*-methyl-*D*-aspartate receptor which most likely is responsible for the anesthetic effects experienced with nitrous oxide. These anesthetic effects caused by inhibition of *N*-methyl-*D*-aspartate receptor are thought to prevent enhancement of pain sensitivity resulting in reduced pain. The combined effects of endogenous opioid release and *N*-methyl-*D*-aspartate receptor inhibition are likely responsible for the analgesic effects of nitrous oxide (Richardson et al., 2017).

Within a 2002 systematic review (Rosen, 2002), the variable concentrations of nitrous oxide used for women during labor in the included studies which took place from

1961 to 1995 made drawing conclusions regarding analgesic effectiveness difficult. Additional challenges associated with drawing conclusions from this review related to the varied methods of administration, methods and timing of effectiveness assessments, and comparator modalities (Richardson et al., 2017). A subsequent systematic review conducted 12 years later (Likis et al., 2014) faced similar challenges adding very little new information regarding the analgesic effectiveness of nitrous oxide with the inclusion of only one new study in this review. While both systematic reviews found insufficient evidence to make conclusions regarding analgesic effectiveness of nitrous oxide as a result of unsatisfactory study design, most studies identified subsets of women who reported significant analgesic effectiveness from nitrous oxide with many expressing a desire for future use (Richardson et al., 2017).

Even though awareness of pain may still exist, relaxation, a sense of control, and reduced perception of pain are all possible when nitrous oxide is used by women during labor (Rooks, 2011). In addition, relief of anxiety and fear experienced during labor and particularly during the second stage of labor when self-doubt, question regarding one's ability to complete the birth, and a decreased ability to cope can occur may result with nitrous oxide use. The anxiolytic effect of nitrous oxide is thought to occur as a result of increased prolactin levels and decreased cortisol levels occurring in response to nitrous oxide use (Collins, 2015). Further, because nitrous oxide has an effect on consciousness, women may feel a sense of detachment, pleasure, euphoria, relaxation, nightmares, or sleepiness (Hellams et al., 2018). Other common side effects reported by women who have used nitrous oxide during labor and birth include dizziness, nausea, and vomiting

although many of the side effects associated with nitrous oxide use may also be associated with natural progression of labor (Collins, 2016; Rooks, 2007).

Safety of intrapartum nitrous oxide use for both the woman and fetus has been established (Rooks, 2007; Rooks, 2011). Eliminated through the lungs and not the liver, the effects of nitrous oxide are transient and noncumulative (Rooks, 2007). Because nitrous oxide is self-administered by the laboring woman via a face mask during contractions, control of when and how much nitrous oxide is used is possible. Also, given the rapid onset and end of action, women who do not like the effects of nitrous oxide or who find it inadequate for pain management can quickly discontinue use of nitrous oxide and switch to another pain management method (Likis et al., 2012). Despite less effectiveness for pain relief compared to epidural analgesics, nitrous oxide has other benefits including mild analgesic effects, decreased perception of pain, helpful anxiolytic effects, rapid onset and offset, decreased restlessness and improved ability to cope, and is inexpensive and non-invasive without documented adverse maternal or fetal outcomes (Collins, 2016; Likis et al., 2014; Rooks, 2012). Also, unlike epidural analgesics, nitrous oxide is not associated with maternal fever, prolonged second stage of labor, or increased incidence of occiput-posterior position of the fetus at birth which call all impact the incidence of cesarean delivery or vacuum or forceps-assisted vaginal delivery and associated third and fourth degree lacerations (Rooks, 2007).

Nitrous Oxide and Comfort

Given interventions to promote comfort and active participation can facilitate the woman's connection to her body, emotions, and experience during labor and birth while also decreasing the power inequity between the woman and the health care provider

(Schuiling & Sampselle, 1999), the concept of comfort over pain is an important consideration. Nitrous oxide provides an alternative comfort strategy that allows for active participation, self-control, preservation of mobility and strength and shared decision-making for the woman during labor and birth. However, absence of research regarding comfort experienced by women when nitrous oxide is used offered support for this study to determine the effects of nitrous oxide on promoting comfort for women during labor and birth and offer nurses and maternity providers new insight regarding an alternative intrapartum pain management strategies with the potential to promote comfort.

Research has not been found examining both concepts of comfort and satisfaction when intrapartum nitrous oxide is used, thus providing support for this study to inform nurses and maternity providers regarding the effects of nitrous oxide use on comfort and satisfaction with the birth experience. Schuiling (2003) offered insight relevant to this study including explanation of the increased potential for comfort to be experienced when the perception of pain is blunted, rather than obliterated. When the perception of pain is blunted, the woman is able to continue to react to noxious stimuli; thus, allowing for continued self-assessment of wellbeing and increased sense of self-confidence, security and reassurance (Schuiling, 2003). Blunting of the perception of pain and continuous self-assessment of wellbeing is possible when nitrous oxide is used by women during labor and birth offering further support for this study.

Nitrous Oxide and Satisfaction with the Birth Experience

Satisfaction with the birth experience may be multifaceted rather than unilaterally determined based on pain relief alone. Since FDA approval in 2012, few studies have

examined women's satisfaction regarding analgesic effectiveness when nitrous oxide is used nor how this influences satisfaction with the birth experience (Attar et al., 2016; Dammer et al., 2014; Pita et al., 2012; Richardson et al., 2017b). A possible reason for the limited number of current studies relates to recent FDA approval of the delivery device used to administer intrapartum nitrous oxide in the United States in 2012 and availability of approved delivery devices for this purpose in 2013. Themes identified within studies of satisfaction when nitrous oxide is used included report of greater satisfaction when compared to other analgesic options, report of tolerable side effects associated with nitrous oxide use, likelihood of future use, and an overall reduction of pain with nitrous oxide use. Each of these themes are described in detail in the following sections.

Report of Satisfaction with Nitrous Oxide

Richardson et al. (2017b) retrospectively analyzed prospectively gathered survey data of 6507 women on their first day postpartum to compare nitrous oxide and/or neuraxial labor analgesia on analgesic effectiveness and satisfaction. Those women who used nitrous oxide alone expressed satisfaction similar to those who received neuraxial analgesics even though they were "less likely to report excellent analgesia" (Richardson et al., 2017b, p. 548). Regaining self-control, ability to focus, think and participate during labor and birth, preservation of bodily sensations, mobility and strength, and personal expectations, caregiver support, and involvement in decision-making were described by these authors as additional contributors to maternal satisfaction reported by study participants. Pita et al. (2012), within a prospective observational pilot study, analyzed the benefits of inhaled analgesics over intrapartum pain and the degree of satisfaction of

using this method. Of the 126 women who used nitrous oxide at a low-income hospital in Ecuador, 92.6% rated their degree of satisfaction with the nitrous oxide-oxygen mixture as good/excellent.

A randomized clinical trial conducted by Pasha et al. (2012) assessed maternal expectations and experience of labor analgesia for ninety-eight Iranian women. Comparison of Entonox (50% nitrous oxide/50% oxygen mixture) to oxygen alone resulted in 98% of participants (n = 47) reporting satisfaction with use of the nitrous oxide/oxygen mixture, only 2% (n = 1) expressed being unsatisfied with nitrous oxide, and 49% (n = 24) described their experience with the nitrous oxide mixture as good or excellent. A similar randomized clinical trial conducted in Iran by Attar et al. (2016) evaluated the analgesic effects of 50% nitrous oxide with 50% oxygen (referred to as Entonox by the researchers) compared to oxygen alone and found the majority of participants in the nitrous oxide group reported complete satisfaction 67% (n = 134) and 33% (n = 66) reported relative satisfaction (p = 0.019). A final randomized clinical trial conducted in Iran by Agah et al. (2014) investigated the effects of continuous use of inhaled 50% nitrous oxide with 50% oxygen (referred to as Entonox by the researchers) in comparison to intermittent use (reported as received during each uterine contraction) on obstetric outcomes. While the continuous nitrous oxide group reported a higher satisfaction rate (96%) in comparison with the intermittent method, 70% (n = 50) of the intermittent group reported an acceptable level of satisfaction (Agah et al., 2014). Studies of satisfaction when nitrous oxide is used during labor and birth have shown maternal satisfaction extends beyond analgesic effects alone with report of positive patient experiences in response to intrapartum nitrous oxide use.

Tolerance with Side Effects of Nitrous Oxide Use

Within their prospective observational pilot study of 126 women in Ecuador, Pita et al. (2012) noted dizziness as the most commonly reported side effect associated with nitrous oxide use (reported by 43.7%; $n = 55$); however, this side effect was described by study participants as mild and tolerable. Within a similar prospective observational study conducted in Germany, Dammer et al. (2014) found 82% ($n = 54$) report of well to very well tolerance of nitrous oxide. Further, the majority of participants who used nitrous oxide reported no side effects (65%, $n = 43$). Of those who reported side effects, dizziness ($n = 8$), nausea ($n = 5$), raspy/dry throat ($n = 3$), vomiting and feeling woozy ($n = 2$) or a feeling of euphoria and powerlessness ($n = 2$) were among the mentioned side effects (Dammer et al., 2014). Finally, within a randomized clinical trial conducted in Iran to evaluate the analgesic effects of inhaled mixture of 50% nitrous oxide with 50% oxygen (referred to as Entonox by the researchers) during labor, Attar et al. (2016) reported side effects including nausea, vomiting, dizziness, and drowsiness in 25% of the intervention (nitrous oxide/oxygen) group and 23% of the control (Oxygen only) group ($p = 0.640$). Despite the possibility of intermittent side effects with nitrous oxide use, the majority of women in the included studies reported tolerance of the side effects associated with intrapartum nitrous oxide use.

Likelihood of Future Nitrous Oxide Use

Two studies reported findings associated with likelihood of future nitrous oxide use. Within a randomized clinical trial conducted in Iran including 98 pregnant women in the active phase of labor, Pasha et al. (2012) assessed maternal expectations and experience of labor analgesia with nitrous oxide. Of the 49 participants who used nitrous

oxide, 80.9% indicated that they would request this intervention in the future. Dammer et al. (2014) reported similar findings within their prospective observational study conducted in Germany to investigate acceptance of inhaled nitrous oxide and oxygen. Of the 66 participants, 68% (n = 45) reported that it was quite to very likely they would use nitrous oxide again in the future with a higher likelihood of future use for those who tolerated nitrous well (p = 0.0129). Current evidence suggests a likelihood of future nitrous oxide use during subsequent labor and birth experiences.

Pain Reduction with Nitrous Oxide Use

Pain scores were reported as a measure of satisfaction in three studies of women who used nitrous oxide during labor and birth. Pasha et al. (2012), within a randomized clinical trial in Iran, assessed maternal expectations and their experience of labor analgesia with nitrous oxide compared to those who do not use nitrous oxide. Important findings of this study regarding labor pain included 91.8% of those who used nitrous oxide experienced less pain, with report of pain for this group as moderate (46.94%), severe (40.82%), and very severe (10.2%) compared to reports of severe (55.10%) and very severe (26.53%) pain in the group who did not use nitrous oxide (p = 0.004). In a similar randomized clinical trial, Attar et al. (2016) reported significantly reduced pain during delivery when nitrous oxide was used with mean pain scores of 4.5+1.2 reported for the nitrous oxide (intervention) and 5.2+1.4 in the control group (p = 0.001). Finally, Dammer et al. (2014) reported a statistically significant reduction of pain when nitrous oxide was used (p = <0.001) during labor and birth.

Review of current research revealed very few primary research studies focused on maternal satisfaction of the birth experience when nitrous oxide is used. Despite

conducting a comprehensive search using multiple databases, a number of related search terms, SCOPUS and the reference lists of reviewed articles, only 6 studies published in English in peer-reviewed journals since FDA approval of the intrapartum nitrous oxide delivery devices in 2012 were found reporting intermittent use of only nitrous oxide and oxygen (50-50% concentration) during childbirth for pain management and measurement of satisfaction as it relates to nitrous oxide use. Three of the six reviewed studies were conducted in Iran with the remaining studies conducted in the United States (n = 1), Germany (n = 1), and Ecuador (n = 1) resulting in great diversity with regard to the country in which the reviewed studies took place. A possible reason for the limited number of current studies in the United States relates to the recent approval of the delivery devices used to administer nitrous oxide in labor by the FDA in 2012. Given studies completed prior to this time reported findings based upon inconsistent concentrations of nitrous oxide and oxygen that are not reflective of the approved 50-50% nitrous oxide and oxygen mixture, further study related to the use of nitrous oxide with the FDA approved concentration is necessary.

As a result of the recent increased availability of nitrous oxide as a pain management strategy in labor in the United States, further research regarding women's satisfaction and the role of the nurse when nitrous oxide is used for labor pain management continues to be needed. In a *Comparative Effectiveness Review*, Likis et al. (2012) supported this need for future research with specific recommendations including the need to study effectiveness, women's satisfaction, route of birth, harms, and health system factors affecting use of nitrous oxide for the management of labor pain. Based on these recommendations and given the lack of evidence of current research related to the

impact of nitrous oxide on women's satisfaction during childbirth, further research in this area is necessary. The review of the literature identified no studies that incorporated the use of reliable and valid instruments to measure women's satisfaction when nitrous oxide was used in labor. Thus, exploration and identification of reliable and valid instruments to effectively measure maternal satisfaction in labor when nitrous oxide is used was an important consideration used to inform this study. Satisfaction with the birth experience is a multifaceted concept not solely determined by pain relief alone. Given the gaps in the literature regarding analgesic effectiveness when nitrous oxide is used and the influence of this analgesic option on satisfaction with the birth experience, further study of the effects of intrapartum nitrous oxide use on women's comfort and satisfaction with the birth experience was warranted.

Summary

Despite increasing intrapartum use of nitrous oxide in the United States, knowledge is limited regarding the differences in women's comfort and satisfaction with the birth experience when nitrous oxide is used compared to epidural analgesics or no analgesics during the labor and birth. Of the extant studies, while satisfaction with intrapartum nitrous oxide use has been suggested, the absence of use of validated instruments to measure satisfaction within these studies warranted further study using an instrument to measure satisfaction with established reliability and validity. In addition, while the concept of comfort had been studied within and beyond childbirth, prior study of the relationship of intrapartum nitrous oxide use and comfort experienced during labor and birth was not found in the literature. Further, given the close association of comfort and satisfaction with the birth experience, both of these concepts had direct relevance to

the study of the differences in comfort and satisfaction with the birth experience for women who used nitrous oxide compared to epidural analgesics or no analgesics during the labor and birth process. Therefore, the purpose of this study was to determine if comfort and satisfaction with birth experiences differed for women who used nitrous oxide compared to epidural analgesics or no analgesics during the labor and birth process.

CHAPTER III

METHODS

The purpose of this study was to determine if comfort and satisfaction with birth experiences differed for women who used nitrous oxide compared to epidural analgesics or no analgesics during the labor and birth process.

The specific aims examined in this study were:

Aim 1. To determine the frequencies and frequency distributions distribution of obstetric and mental health history characteristics, current pregnancy characteristics, analgesic use, and use of non-pharmacological methods for women age 18 years and older who experienced a current spontaneous vaginal birth.

Aim 2. To determine comfort experienced during labor and birth for women who received 1) nitrous oxide and oxygen (50-50% mixture) only, 2) epidural analgesics (may have been in combination with other analgesic options), or 3) no analgesics (control group).

Aim 3. To determine satisfaction with the birth experience for women who received: 1) nitrous oxide and oxygen (50-50% mixture) only, 2) epidural analgesics (may have been in combination with other analgesic options), or 3) no analgesics (control group).

Aim 4. To compare differences in comfort between women who used nitrous oxide, those who used epidural analgesics, and those who used no analgesics during labor and birth.

Aim 5. To compare differences in satisfaction with the birth experience between women who used nitrous oxide, those who used epidural analgesics, and those who used no analgesics during labor and birth.

This chapter presents the methodology for this study including the study design, sample and setting, procedures, protection of human subjects, tests and measures, and data management and analysis plan.

Study Design

A prospective between-subjects comparative design was used to determine if comfort and satisfaction with birth experiences differed for women who used nitrous oxide compared to epidural analgesics or no analgesics during the labor and birth process. Key components of a between-subjects comparative design include (a) random assignment to study groups or because of a particular participant attribute or experience; (b) enrollment in only one group; (c) exposure of each group to different values of the independent variable; (d) comparison of responses of all members of one group to those of another group; and, (e) expectation of the groups to differ (Brink & Wood, 1998). A between-subjects comparative design was appropriate to determine if comfort and satisfaction with birth experiences differed for women who used nitrous oxide compared to those who used epidural analgesics or no analgesics during the labor and birth given this design allowed for comparison of comfort and for satisfaction scores among all three study groups and extended support for causal relationships without manipulation of the independent variable. Further, use of this design allowed for observation in a natural environment and control of the independent variable(s) through sample selection (allowing for discrimination of the group based upon presence, absence, or amount of the independent variable) (Brink & Wood, 1998). Figure 2 depicts an overview of the study research design.

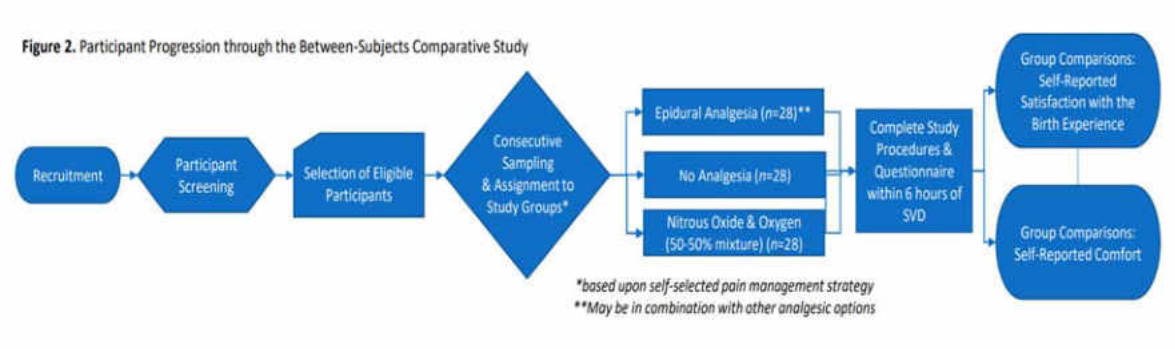

Figure 2. Overview of the Study Research Design

Limitations of the between-subjects comparative design included: (a) a descriptive rather than experimental nature, (b) inability to control for internal validity and make causal inferences given the independent variable were not manipulated, (c) impossibility for random assignment of study participants to the groups to create equivalent groups, (d) challenges with matching participants across the groups as an alternative to randomization given the extraneous variables to match were unknown and the sample was not large enough to match all extraneous variables, and (e) complexity of matching beyond that of matching of pairs with more than two study groups (Brink & Wood, 1998). Predominant threats to the study between-subjects comparative design validity included bias in sample selection to be minimized through use of consecutive sampling of a representative sample, bias in data collection procedures to be minimized by maintaining consistent study conditions, careful training of nurse research assistants and study site staff, systematic monitoring by the Principal Investigator, and participant survey response bias and the Hawthorne effect to be minimized through use of pre-intervention strategies to satisfy participants' desire to look competent or please the researcher, and through account and control of extraneous variables (Wood & Ross-Kerr, 2011; Polit & Beck, 2017).

Sample and Setting

A consecutive sample of pregnant women in their last trimester of pregnancy and who were planning vaginal delivery using pharmacologic and non-pharmacologic pain management was planned for study recruitment. Participants were recruited from three facilities within an integrated health system in the upper Midwest region of the United States. With similar standards of care and standardized intrapartum order sets across all three facilities, the largest of the three facilities was a joint commission accredited 380-bed teaching medical center with Level I Adult/Level II Pediatric Trauma Center designation (referred to as Site #3 in future sections). The Birthplace within this facility includes 15 labor and delivery rooms each with private bathrooms, whirlpool tubs and spacious atmosphere conducive to family centered care and Baby Friendly Designation. The second largest facility was also a joint commission accredited 133-bed medical center with designation as a Level II Trauma Center and Comprehensive Stroke Center (referred to as Site #1 in future sections). The Birthplace of this study site includes 9 labor and delivery rooms also each with private bathrooms, whirlpool tubs and spacious atmosphere conducive to family centered care and Baby Friendly Designation. The third, and smallest of the three study sites, was a 34-bed hospital with designation as a Level III Trauma Center and includes seven labor and delivery rooms with atmosphere similar to that of the other study sites (referred to as Site #2 in future sections). The health system research institute and birthing unit staff at all three facilities were supportive and agreeable to serving as one of three settings for this study.

Population and Sample

Following University and study site Institutional Review Board (IRB) approvals, consecutive sampling over a five-month period was used to enroll eligible pregnant women who consented to participate. The consecutive sampling approach, involving recruitment of all eligible participants from the accessible population over a specific time interval (Polit & Beck, 2017), included a five-month enrollment period derived from estimates based upon the 2018 birth rates for each of the three study sites (S. Skogen personal communication, October 22, 2018; A. Vogt personal communication, March 3, 2019; J. Shelton personal communication, August 5, 2019). A five-month period reflected the timeframe estimated as necessary to obtain the desired sample size for each study group to achieve statistical significance. Further, according to the United States Census Bureau (2016) statistics, demographic estimates for the available population of pregnant women 18 years and older included 88-90% white, 3-5% African American, 1-3% Asian, 2-3% Hispanic, and 1-4% two or more races.

Sample size. The birth rates in 2018 for the three study sites totaled 3399 live births. The estimated total sample population available over a five-month period included 1416 pregnant women based upon study site estimates. Additional study site statistics included an average monthly cesarean birth rate of 26% and estimated intrapartum pain management use as follows: (1) 75% epidural analgesics (includes epidural-only, nitrous oxide with conversion to epidural, or systemic analgesics with conversion to epidural), (2) 5-15% nitrous oxide only, (3) 5-15% systemic analgesics only, and (4) 5% use of no labor analgesics (S. Skogen personal communication, October 22, 2018; A. Vogt personal communication, March 3, 2019; J. Shelton personal communication, August 5,

2019). In consideration of these study site statistics, the anticipated number of participants available for each study group over a five-month recruitment period included: (1) 787 for the epidural group (including epidural-only, nitrous oxide with conversion to epidural, and systemic analgesics with conversion to epidural), (2) 52-157 for the nitrous oxide only study group, and (3) 52 for the no labor analgesic group.

Sample power. The G*Power 3.1 software (Faul et al., 2007) was used to determine the sample size needed to achieve statistical power based upon the anticipated number of groups (n = 3) to be used for an ANOVA statistic. The power for this sample calculation was set at .80, with an alpha of .05, and a conservative estimate of the effect size of .35 to detect significant differences for a total sample size of 84 participants evenly distributed across the three study groups. The effect size was determined based upon recommendations from Cohen (1992) and Faul et al. (2007) to estimate the effect size for one-way ANOVA analysis using .10 for small effects, .25 for medium effects, and .40 for large effects. Further, use of a .35 effect size for this power calculation was supported by Richardson et al. (2017) who found women who used nitrous oxide alone were 2.5 times more likely to report high levels of satisfaction compared epidural analgesia alone reflective of a .40 effect size (N= 6242; n = 1246 nitrous oxide only) and given satisfaction with nitrous oxide for labor was reported by 49% to 93% of women in several previous investigations (Richardson et al., 2017; Dammer et al., 2014; Attar et al., 2016; Pita et al., 2012; Pasha et al., 2012). Enrollment of at least 28 participants to each of the three study groups was necessary to achieve statistical power. Anticipating potential refusal (5%) and attrition (10%) rates estimated by review of relevant literature,

oversampling of four additional participants for each study group occurred resulting in initial enrollment of 32 participants in each group.

Inclusion Criteria

Screening of potentially eligible participants occurred using the following inclusion criteria: (1) age of at least 18 years, (2) current full-term pregnancy (at least 37 weeks gestation), (3) anticipated spontaneous vaginal delivery, (4) vertex fetal presentation, (5) singleton pregnancy, (6) fluency with the English language, and (7) absence of current pregnancy complications.

Exclusion Criteria

Participants were excluded if they had: (1) anticipated current pregnancy cesarean birth, (2) planned vaginal birth after cesarean, (3) current multiple gestation pregnancy, (4) fetal presentation other than vertex, (5) current non-viable pregnancy, or (6) diagnosis and/or medical treatment of anxiety or psychiatric disorder during the current pregnancy. Data from enrolled participants was also excluded if a stressful childbirth event (i.e. neonatal resuscitation or infant transfer to intensive care), operative vaginal birth (vacuum or forceps-assisted delivery), or cesarean birth occurred as part of the current childbirth experience. Finally, exclusion occurred if the study participant received opioid or other narcotic postpartum pain medication prior to survey completion and once the required number of participants (n = 28) who completed all study procedures for each analgesic group was met.

Procedures

The following section describes the procedures followed within this research study. Procedures for human subjects protection and informed consent, sampling and

recruitment, communication with the healthcare team, staff training, data collection, instruments and measurements, and data analysis are described within the following sections.

Human Subjects Protection

This study sought to determine if comfort and satisfaction with birth experiences differed for women who used nitrous oxide compared to epidural analgesics or no analgesics during labor and birth, and was conducted in three facilities, all within an integrated health system in the upper Midwest region of the United States following receipt of study support and approval (see Appendix A). Approvals were obtained from both the University and health system Institutional Review Board prior to pilot study initiation. A detailed description of the procedures conducted regarding the protection of human subjects is provided in Appendix A.

Informed Consent

Based on inclusion and exclusion criteria, women were invited to participate in the study. If interested, eligible women were provided a handout explaining the purpose of the study, what participation entails, participant rights, answers to frequently asked questions, and contact information for the Principal Investigator (PI). Explanation and documents describing informed consent for study participation and release of medical information were provided by the Principal Investigator or PI-trained nurse research assistants and questions were answered. Upon agreement to participate, two consent forms were signed by the participant. The participant was provided one of the signed forms and the other was retained by the Principal Investigator. The physical paper consent forms will be destroyed via university system paper destruction services within

five years of study completion. A copy of the forms used to obtain informed consent are provided in Appendix A.

Sampling and Recruitment Process

Recruitment strategies. Recruitment of 84 pregnant women ages 18 or older occurred within study site clinic settings during a third trimester prenatal care visit, prior to or following childbirth preparation class attendance, or upon admission to the birthing unit for anticipated childbirth with care taken not to recruit women while they were experiencing active labor pain. Written materials regarding the study were provided to potential participants with enrollment of eligible participants following informed consent. Relationships were established with key stakeholders within each study site prior to study initiation. To overcome the potential barrier of mistrust of the researcher, initial support for the study was gained from the health system and study site nurse leaders and administrators, from the obstetricians and nurse midwife providers, and three nurses employed at the study sites who were approached by the Principal Investigator to serve as research assistants. To overcome barriers associated with reluctance to participate, referrals of potential participants were made to the Principal Investigator by maternity care providers based upon study inclusion and exclusion criteria, and recruitment during prenatal classes and clinic visits in the presence of nurses employed at the study site helped to promote study participation. Three nurses employed at the study sites were hired and trained by the Principal Investigator to serve as research assistants to assist with study procedures and minimize potential to miss the opportunity to survey participants within the study timeframe, to provide an on-site research team member to complete study protocols, and to minimize logistic challenges.

Retention strategies. Potential burden on participants posed by survey completion was reduced thorough use of a single survey conducted during participant hospitalization for childbirth at a time convenient to the participant within six hours of childbirth. The within six-hour timeframe was selected to minimize interruption of maternal rest, bonding with the newborn, and necessary health care while still allowing for ready recall of intrapartum pain management experiences. Research assistants were trained by the Principal Investigator to assist with the following study procedures: screening for eligibility, obtaining informed consent and enrollment of participants, and facilitation of survey completion following the birth experience. In addition, a pilot study prior to study initiation was conducted to evaluate the processes to access and gain consent from study participants, the process of questionnaire administration, and to ensure adequacy of instrumentation and variable selection.

Support gained from the study site staff and nurse research assistants increased the likelihood of continued study participation. As an employee of the health care organization of the study sites, the Principal Investigator avoided a conflict of interest through the use of study site nurses as members of the research team and collaboration with the health information team to ensure electronic health record access privileges were consistent with those allowed according to obtained approvals. In the event the nurse research assistant was involved in the labor care for the recent birth experience or had a significant personal relationship with a participant another nurse research assistant or the Principal Investigator was responsible for participant informed consent and data collection. Across recruitment and data collection, the Principal Investigator and PI-trained nurse research assistants modeled genuine interest and concern, openly shared

study information, and established trust with all stakeholders. In addition, a $20 gift card was provided following survey completion as compensation for participant time completing study procedures.

Communication with the Healthcare Team

A notification added to the participant's electronic health record alerted the unit secretary and nursing staff to contact the Principal Investigator by phone upon the participant's admission for anticipated childbirth to allow for survey completion within six hours of vaginal birth. Enrollment of eligible participants who had not been informed of the study prior to hospital admission was facilitated by study site staff who notified the Principal Investigator upon potential participant arrival to the unit, with care taken not to recruit women while they are experiencing active labor pain. The Principal Investigator was available to the unit staff across the study duration to address needs or issues regarding study procedures and provided purposeful, open, honest and consistent, communication. Maintaining a reciprocal wheel of communication across study planning, implementation, and evaluation fostered development of a connection and working relationship with key leaders, providers, nurses, and participants.

Staff Training

The purpose and procedures of the study were shared with study site maternity care providers and nurses within a routine staff meeting prior to study initiation by the Principal Investigator. An opportunity was provided for provider and staff questions to be answered and additional information or guidance was provided as necessary. The Principal Investigator provided education via email for newly hired staff and as needed for individuals unable to attend the routine staff meeting. In addition, informal face-to-

face meetings with the birthing unit secretaries occurred to provide training regarding identification of patients as study participants and their role in facilitating communication of study participation with the Principal Investigator, PI-trained nurse research assistants, and appropriate unit staff.

Data Collection Procedures

The Principal Investigator or PI-trained nurse research assistant administered the electronic survey via iPad to study participants within six hours of spontaneous vaginal birth and prior to postpartum opioid or other narcotic pain medication administration to allow for timely recall of labor and birth pain experiences unmasked by opioid or other narcotic analgesics. Gathering of electronic survey responses via Qualtrics allowed for anonymity of study participants, ease of distribution and data aggregation, and secure and economic data collection procedures. Use of available study site iPads with previously established wireless network access minimized risk of device malfunction. Survey administration, approximately 5-10 minutes in duration, took place in the participant's hospital room after facilitating a calm and quiet atmosphere. Following survey completion, participants were thanked for their participation and provided a $20 gift card.

Data collection from the electronic health record by the Principal Investigator or PI-trained nurse research assistant occurred for each study participant following survey completion based upon the Electronic Health Record Data Collection Tool (see Appendix B) and data documented in electronic form within the Qualtrics system. The same unique code was denoted within the participant survey and entered within the Electronic Health Record Data Collection Tool to allow for match of participant survey and electronic health record data as necessary during data analysis. Data collected from the electronic

health record was de-identified prior to removal from the research site with the exception of the consent form, which was secured at all times and filed in a locked cabinet in the office of the Principal Investigator. The electronic data will be erased from the servers of the computer with help of university system information technology support professionals and physical paper consent forms destroyed via university system paper destruction services within five years of study completion.

Tests and Measures

This study measured comfort and satisfaction with the birth experience for women who received epidural analgesics, nitrous oxide and oxygen (50-50% mixture), or no analgesics during labor and birth. Following informed consent, data collection included electronic survey of study participants within six hours of spontaneous vaginal birth to measure comfort and satisfaction. The electronic survey included questions focused on demographic data, obstetric and mental health history characteristics, current pregnancy characteristics, current labor and birth use of analgesic and non-pharmacological methods, comfort experienced during labor and birth, and overall satisfaction with the birth experience. Data extraction from the electronic health record of each study participant by the Principal Investigator or nurse research assistant followed survey completion. Table 1 summarizes the various instruments utilized in this study including the variables, their measurement and the timing of data collection.

Table 1

Study Variables and Instruments

Variables	Indicator or Instrument	Data Source	Level of Measurement	Timing of Measurement
Dependent Variables				
Comfort	RM-CCQ	Participant Report	Ordinal	Within six hours of birth
Satisfaction	BSS-R	Participant Report	Ordinal	Within six hours of birth
Independent Variables				
Pain Management Strategy				
Nitrous Oxide Epidural Analgesics No Analgesics	EHR-DCT	EHR Review	Nominal	After survey completion
Potential Covariate Variables				
Maternal age, parity	EHR-DCT	EHR Review	Continuous	After survey completion
Race, ethnicity, income, education, employment status	PIS	Participant Report	Nominal, Ordinal	Within six hours of birth

Note. Nitrous Oxide = Inhaled nitrous oxide and oxygen (50%-50% mixture); EHR-DCT = Electronic Health Record Data Collection Tool; RM-CCQ = researcher-modified version of the Childbirth Comfort Questionnaire (Schuiling, 2002); BSS-R = Birth Satisfaction Scale-Revised (Hollins Martin & Martin, 2014); PIS = Prenatal Information Survey.

Pain Management Strategy

Data were recorded regarding the self-selected analgesic option utilized during the labor and birth experience as documented in the electronic health record (See Appendix B). In keeping with the key components of between-subjects comparative design, study participants were assigned to only one study group, each group being exposed to a different pain management option, and responses of groups were compared (Brink & Wood, 1998).

Inhaled nitrous oxide and oxygen (50%-50% mixture) use was measured based upon data gathered from the electronic health record. Data extraction regarding duration of intermittent nitrous oxide use (in minutes) via the FDA approved Pro-Nox

delivery device allowed for meaningful data analysis and interpretation. As supported by current literature recommending self-administration of intrapartum nitrous oxide by the woman under direct oversight of the RN (Collins, 2018; Richardson et al., 2017b; Pinyan et al., 2017; Migliaccio et al., 2017; Hellams et al., 2018), participant self-administration of intrapartum nitrous oxide was supervised by RNs within the study sites. The obstetrician or maternity care provider order for intrapartum nitrous oxide was provided within the standardized intrapartum orderset or as a separate nitrous oxide panel order. Included within this provider order was the prescribed route, concentration, dose, and indication including self-administration of inhaled 50% nitrous oxide and 50% oxygen to be used intermittently as needed for analgesia during each uterine contraction and/or painful intrapartum procedures.

Epidural analgesic use was measured based upon data extracted from the electronic health record. Data extracted included analgesic type, bolus dose, continuous infusion rate, duration of placement procedure, and duration of epidural use (in minutes). Over 60% of women use epidural analgesics during labor, which is considered the gold standard for labor pain management administered by a trained anesthesia provider (Koyyalamudi et al., 2016; Biel et al., 2017).

Participants for the epidural-only group were recruited from the same study site with epidural analgesic administration by a Certified Registered Nurse Anesthetist or Anesthesiologist based upon the study site's established labor and delivery epidural infusion orderset. This orderset included standardized approaches for epidural analgesic use regarding nursing assessments and interventions, diet, instances of required anesthesia provider notification, and medications. Specific to epidural analgesics,

bupivacaine (Marcaine or Sensorcaine) 0.25% (Preservative-Free) injection 1-30 mL was administered once in the epidural space as the initial epidural bolus followed by continuous epidural infusion of bupivacaine 0.125% (Preservative-Free) in 0.9 sodium chloride at 12-15mL/hour, as per the established labor epidural protocol within the study site health system. Based upon individual anesthesia provider preference, addition of fentanyl (Sublimaze) injection of 50-100mcg once given as part of the initial epidural bolus occurred for particular participants.

No analgesic use was measured based upon data extracted from the electronic health record. Data extracted included the types of non-pharmacological pain management strategies used in the absence of any analgesics (epidural or intrathecal, systemic, or nitrous oxide) throughout labor and birth. Absence of analgesic use was confirmed through review of the pain assessment and intervention sections of the labor flowsheet, the medication administration record, and the anesthesia record (noted as an absence of such record).

Survey of Comfort

Comfort was measured within six hours of spontaneous vaginal birth using the researcher-modified version of the Childbirth Comfort Questionnaire (see Appendix C) included as part of the single participant electronic survey. In a comprehensive review if the literature, three primary research studies were found reporting measure of comfort during labor and birth. Within these studies, one dissertation study (Schuiling, 2003) utilized the Childbirth Comfort Questionnaire, a 14-item researcher generated scale, to measure comfort; one quasi-experimental pretest/posttest comparison study also measured comfort using the Childbirth Comfort Questionnaire (Garlock et al., 2017), and

one randomized control trial (Chuntharapat et al., 2008) measured comfort using a researcher generated 35-item maternal comfort questionnaire. While Schuiling (2003) thoroughly described her efforts to establish reliability and validity of her newly created scale, Garlock et al. (2017) did not report additional testing of reliability and validity of the Childbirth Comfort Questionnaire and Chuntharapat et al. (2008) did not describe reliability and validity testing for their comfort questionnaire. Given the 14-item Childbirth Comfort Questionnaire was the only identified instrument specific to comfort and labor and birth experiences with established reliability and validity, this instrument was selected for use, with modification, for this study.

Childbirth Comfort Questionnaire. The Childbirth Comfort Questionnaire (Schuiling, 2002) was adapted from Kolcaba's General Comfort Questionnaire (Kolcaba, 1992) to measure comfort of primiparous women during latent and active phase of labor. With input from midwives and women who had experienced labor and birth, items from the General Comfort Questionnaire were revised and new items added to align with content domains relevant to childbirth and reflective of the comfort needs of women during childbirth. The Childbirth Comfort Questionnaire includes 14 Likert-style questions, each measured on an ordinal scale, to quantify comfort for women during childbirth. Scoring of the instrument includes reverse coding of negative responses (items numbered 2, 4, 6, 9 and 12-14), with a higher summed total equating to higher comfort. Psychometric testing of the Childbirth Comfort Questionnaire led to established content validity through expert review and associated modifications to select questions within the instrument, face validity established through instrument review by expert nurse-midwives and women who had experienced labor and vaginal birth, and internal consistency

established through preliminary data analysis (Cronbach's alpha .69 at Time 1 [latent phase] and .73 at Time 2 [active phase], n=25) and subsequent study data analysis (Cronbach's alpha of 0.67 for Time 1 and 0.75 for Time 2 [n=64]) (Schuiling, 2003).

Within the subsequent dissertation study including 64 participants, internal consistency was validated for the Childbirth Comfort Questionnaire with a Crohbach's alpha 0.67 for Time 1 and 0.75 for Time 2, yielding 0.71 as the final Cronbach's alpha for the instrument (Schuiling, 2003). Use of the Childbirth Comfort Questionnaire beyond Schuiling's (2003) dissertation study has occurred in only one other study (Garlock et al., 2017); however, further testing of reliability and validity for this instrument was not reported.

Instrument modification. Given the absence of other identified reliable and valid instruments to measure comfort during childbirth and the direct relevance of the questions within the Childbirth Comfort Questionnaire to this study, permission was obtained from the instrument creator to modify the instrument for use in this study. Modification of the instrument to reflect past tense of each question allowed for questionnaire completion within the first six hours following the vaginal birth experience (See Appendix C). Pilot testing of the researcher-modified Childbirth Comfort Questionnaire occurred prior to study initiation to establish reliability and validity of the researcher-modified instrument when used within six hours of childbirth.

Survey of Satisfaction

Birth Satisfaction Scale-Revised. Satisfaction with the birth experience was measured within six hours of spontaneous vaginal birth using the United States translation of the Birth Satisfaction Scale-Revised (Hollins Martin & Martin, 2014)

included as part of the single participant electronic survey. Ten Likert-style questions, each measured on an ordinal scale, are included in the Birth Satisfaction Scale-Revised to quantify birth satisfaction in three areas (1) stress experienced during labor, (2) quality of care, and (3) women's personal attributes (see Appendix D). Within the Birth Satisfaction Scale-Revised participants are asked to rate their level of agreement with each of the 10 items (strongly disagree=0 to strongly agree=4; items numbered 2, 4, 7 and 8 are reverse-coded) with higher scores indicating higher satisfaction with the birth experience. The Birth Satisfaction Scale-Revised was developed from the 30-item original Birth Satisfaction Scale (BSS) (Hollins Martin & Fleming, 2011) developed and psychometrically validated in the United Kingdom (UK). Refinement of the scale for cultural relevance in the United States indicated the subscales and total scale were reliable for the United States sample (n = 181); total Cronbach's alpha of 0.89, and subscale scores of 0.75 (stress experienced during labor), 0.85 (quality of care) and 0.74 (women's personal attributes) (Barbosa-Leiker et al., 2015) and reaffirmed within a subsequent study (n = 2229; total Cronbach's alpha score of 0.86 and subscale scores of 0.74 (quality of care), 0.80 (women's personal attributes), and 0.76 (stress experienced during labor) (Fleming et al., 2016).

Demographics

Prenatal Information Survey. A researcher created prenatal information survey, included as part of the single participant electronic survey, was administered to study participants within six hours of spontaneous vaginal delivery (see Appendix E). The survey included questions to obtain demographic characteristics needed to describe the sample and determine the frequency distribution of obstetric and mental health history

characteristics, current pregnancy characteristics, analgesic use, and use of non-pharmacological methods. Included within this survey were questions regarding the participant's race, ethnic origin, socioeconomic status (annual household income, employment status, level of education) history of anxiety or psychiatric disorders, history of past negative birth experiences, participation in formal childbirth preparation classes, presence of support person during labor and birth, and use of non-pharmacologic methods used to manage labor pain. Additional demographic data extracted from the electronic health record included the participant's age, gravida, para, pregnancy gestation at time of birth, duration of first and second stages of labor, non-pharmacologic methods used to manage labor pain, presence of occiput posterior fetal position during labor, use of oxytocin for labor induction or augmentation, prior diagnosis of anxiety or psychiatric disorders, and previous birth complications.

Electronic health record review. Data extraction from the electronic health record following childbirth and participant survey completion included the questions noted within the Electronic Health Record Data Collection Tool (See Appendix B). Data gathered within this review included participant age, gravida, para, pregnancy gestation at time of birth, marital status, duration of first and second stages of labor, use of non-pharmacologic methods to manage labor pain, occiput posterior fetal position during labor, and oxytocin induction or augmentation of labor, previous diagnosis of anxiety or psychiatric disorders, previous birth complications. This data was used to describe the study participants and to determine the frequencies and frequency distributions of obstetric and mental health history characteristics, current pregnancy characteristics,

analgesic use, and use of non-pharmacological methods for study participants as described in detail within Chapter IV.

Pilot Study

Following IRB approval of both the pilot and current studies, the initial pilot study was conducted based upon data gathered for 11 participants who completed all study procedures without discrimination of the particular self-selected pain management method used. Psychometric testing of the researcher-modified instrument included steps to re-establish face validity, content validity, internal consistency by calculating Cronbach's alpha, and construct validity through exploratory factor analysis. Outcomes of the pilot study in evaluation of the feasibility of the research plan, instrument adequacy, and variable selection are described within the following pilot study results section.

Feasibility of the research plan. Across the pilot study, recruitment, enrollment, and data collection procedures previously described for this study were implemented. The Principal Investigator was available to the unit staff across the pilot study to address needs or issues regarding study procedures.

Adequacy of instrumentation. Psychometric testing to establish reliability and validity of the researcher-modified version of the Childbirth Comfort Questionnaire (Schuiling, 2002) occurred prior to study initiation using pilot study data gathered for this instrument. Preliminary data analysis was conducted on participant responses provided for the researcher-modified version of the Childbirth Comfort Questionnaire following completion of the study procedures by 11 participants without discrimination of the particular self-selected pain management method used during labor and birth. Given the

researcher-modified version of the Childbirth Comfort Questionnaire was an adapted instrument it was necessary to re-establish face validity, content validity, internal consistency and construct validity early in the data collection phase to ensure modified instrument would continue to measure the concept of comfort similar to the original Childbirth Comfort Questionnaire.

Consistency of participant responses were verified through estimation of the reliability coefficient by calculating Cronbach's alpha for the researcher-modified version of the Childbirth Comfort Questionnaire. The extent to which the instrument is reliably measuring the critical attribute and the intercorrelations of all items within the instrument can be estimated by calculating Cronbach's alpha (Polit & Beck, 2017). With the normal range of values between .00 and +1.00, calculation of Cronbach's alpha is useful to assess homogeneity of the items in the scale to determine if the scale is measuring one construct with an alpha of 0.70 considered acceptable for newly developed or modified instruments (Polit & Beck, 2017). This measure of internal consistency was selected primarily given this was the same measure used to assess the internal consistency of the researcher-modified version of the Childbirth Comfort Questionnaire.

Face validity of the researcher-modified version of the Childbirth Comfort Questionnaire was tested to establish the readability, appropriateness to the level of the participants, and completeness of the instrument through review of the instrument by a panel of expert maternity care providers and women who have undergone labor and vaginal birth. Content experts, including five obstetric providers (three obstetricians and two certified nurse midwives) and five women who had experienced labor and vaginal birth reviewed face validity of the researcher-modified version of the Childbirth Comfort

Questionnaire utilizing a five-item Likert scale including strongly agree to strongly disagree responses to rate overall impression of instrument readability, clarity, appropriate language, appropriateness for use within six hours of childbirth, and completeness.

Content validity of the instrument was validated through judgements of content relevance made by the panel of experts, including calculation of the content validity index for both the items and the scale, and in response to theoretical understanding and evidence in the literature regarding the concept of comfort (Tabachnick & Fidell, 2013). The panel of experts rated content validity, or relevance of each item in the scale to the concept of comfort, on a five-point scale of relevance (strongly agree to strongly disagree). Content validity index was calculated for each item to determine the proportion in agreement about relevance, and for the scale by averaging the item-content validity index scores. An item-content validity index of .80 or greater is considered acceptable and a value of .90 or greater for the scale-content validity index is suggestive of excellent content validity (Polit & Beck, 2017).

Construct validity of the researcher-modified version of the Childbirth Comfort Questionnaire was tested utilizing exploratory factor analysis to determine the extent to which the structure of the multi-item scale adequately reflects the hypothesized dimensionality of the construct being measured (Polit & Beck, 2017). Exploratory factor analysis was selected as the measure to identify the minimum number of common factors required to explain the relationships among a set of characteristics, indicators or items given this was the same measure used to assess construct validity for the Childbirth Comfort Questionnaire. Exploratory factor analysis is a useful method to identify

clusters of related items, how they cluster together to form a unidimensional construct, to determine complex interrelationships among items, and to identify items that can be combined as unified concepts (Polit & Beck, 2017). Through exploratory factor analysis, underlying variables, or factors, can be identified that explain the pattern of correlations within a set of variables, and highly correlated factors are grouped into a factor; thus, providing clarification of the underling dimensionality of a set of items and an initial estimate of the variance for each variable (Polit & Beck, 2017).

Bartlett's Test of Sphericity was conducted to determine if the correlation matrix was suitable for factor analysis, evident for variables found to have a p-value < 0.05. Next, within the factor extraction phase of factor analysis, identified communalities indicated the amount of variance in each variable that was accounted for by the variables with higher values useful in indicating the variables were well represented by the extracted components. Eigenvalues, or the amount of variance in the original variable accounted for by each component, were then computed to determine the amount of variance in all items that could be explained by a given principle component (Polit & Beck, 2017). Selection of the initial number of factors was based upon those factors whose eigenvalues were greater than 1.00, as these accounted for the highest amount of the total variance in the items. Next, within the second phase of exploratory factor analysis, factor rotation, unrotated factors were identified in their order of importance and rotated utilizing Varimax orthogonal rotation method to improve their meaningfulness and interpretation and maintain independence of the factors. Utilization of the steps described for exploratory factor analysis allowed for comparison of the findings of the factor analysis of the Childbirth Comfort Questionnaire to those of the researcher-

modified version of the Childbirth Comfort Questionnaire and are described within the following pilot study results section.

Variable selection. The sample studied was intended to reflect a population of healthy pregnant women who underwent spontaneous vaginal birth following receipt of typical labor and birth care in the hospital setting. Based upon findings in the literature and researcher practice experiences, interventions typically encountered in this setting were anticipated to have a direct effect on the outcome variables of interest for this study: woman's comfort and satisfaction with the birth experience. Examination of both outcome variables was possible within the pilot study utilizing the researcher-modified version of the Childbirth Comfort Questionnaire and the Birth Satisfaction Scale-Revised administered to study participants within six hours of spontaneous vaginal birth.

Pilot Study Results

Evaluation of the feasibility of the research plan, instrument adequacy, and variable selection occurred within a pilot study prior to current study initiation including 11 participants who completed all study procedures without discrimination of the particular self-selected pain management method used. Psychometric testing of the researcher-modified instrument included steps to re-establish face validity, content validity, internal consistency by calculating Cronbach's alpha, and construct validity through exploratory factor analysis. The pilot study was conducted to evaluate the research plan, instrument adequacy, and variable selection. Of the 11 included participants, seven participants used epidural analgesics only, two participants used nitrous oxide only, and two participants used systemic analgesics only during labor and birth.

Feasibility of the Research Plan

Across the pilot study, recruitment, enrollment, and data collection procedures previously described for this study were implemented. The Principal Investigator was available to the unit staff across the pilot study to address needs or issues regarding study procedures. Procedures for recruitment and data collection originally planned for study implementation were found to be adequate following pilot study completion with the exception of one necessary modification. Given that 28 potentially eligible participants were excluded from study participation within the two-week timeframe utilized for the pilot study, modification of one item within the exclusion criteria was necessary. Following IRB approval of the requested protocol change (see Appendix A), the exclusion criteria "history of anxiety or psychiatric disorders" was modified to "diagnosis and/or medical treatment of anxiety or psychiatric disorder during current pregnancy." All other study procedures were found to be adequate in response to the pilot study resulting in continued implementation of the previously described procedures across the study.

Adequacy of Instrumentation

Internal consistency. Consistency of participant responses were verified through estimation of the reliability coefficient by calculating Cronbach's alpha for the researcher-modified version of the Childbirth Comfort Questionnaire. The Cronbach's alpha for the researcher-modified version of the Childbirth Comfort Questionnaire during the pilot study was 0.85 reflective of acceptable internal consistency reliability of this instrument when used to measure comfort within six hours of childbirth.

Face validity. Face validity of the researcher-modified version of the Childbirth Comfort Questionnaire was established by a panel of experts, including five obstetric providers (three obstetricians and two certified nurse midwives) and five women who had experienced labor and vaginal birth to establish the readability, appropriateness to the level of the participants, and completeness of the instrument. Readability, clarity, appropriate language, appropriateness for use for women within six hours of childbirth, and completeness of the instrument was reported as "strongly agree" by all panel experts (10/10) reflective of high readability, appropriateness, and completeness of the instrument. Clarity was reported as "strongly agree" or "agree" by all panel experts, with majority responses (6/10) reflective of strong agreement with instrument clarity. As a result, face validity was confirmed for the researcher-modified version of the Childbirth Comfort Questionnaire.

Content validity. Content validity of the instrument was validated through judgements of content relevance made by the panel of experts, including calculation of the content validity index for both the items and the scale. The item content validity index proportion in agreement about relevance included 100% agreement, with "strongly agree" or "agree" responses, by all panel experts for items numbered 2, 4, 5, 7, 10, 11, and 14. Items numbered 1, 3, 6, 8, 12, and 13 reflected 90% agreement, evident given the "strongly agree" or "agree" responses (neutral response $n = 1$ for each item) provided by all panel experts for these items. One item, number 9, revealed 80% agreement with "strongly agree" or "agree responses" by 8/10 panel experts (neutral response $n = 2$). Content validity index for the scale, calculated by averaging the item-content validity index scores, was found to be .94.

Construct validity. Construct validity of the researcher-modified version of the Childbirth Comfort Questionnaire was confirmed utilizing exploratory factor analysis to determine if loadings would be similar to that of the Childbirth Comfort Questionnaire (Schuiling, 2003). A correlation matrix was generated and found suitable for factor analysis. The initial and extracted communalities were found to be reasonable (all were >.65) indicating a relationship existed among the 14 items of the researcher-modified version of the Childbirth Comfort Questionnaire. The factors were then rotated using a Varimax orthogonal five-factor solution of the researcher-modified version of the Childbirth Comfort Questionnaire with all factor loadings across the five factors found to be greater than .50. These five factors with eigenvalues greater than 1.00 accounted for 85.8% of the variance similar to the same five factors with eigenvalues greater than 1.00 in the factor analysis for the Childbirth Comfort Questionnaire which accounted for 64.8% of the variance at Time 1 (latent phase of labor, <5cm dilation) and 67% of the variance at Time 2 (6 or more cm dilated). The factor loadings for Varimax orthogonal five-factor solution of the researcher-modified version of the Childbirth Comfort Questionnaire are show in Table 2.

Table 2

Factor Loadings of the Researcher Modified Childbirth Comfort Questionnaire for Varimax Orthogonal Five-Factor Solution

Item	Factor Loadings
Factor 1	
1. I worried I would lose control.	.93
12. I felt like giving up.	.91
2. My pain was difficult to endure.	.85
8. I felt confident I could birth my baby.	.79
4. I didn't think I could do it without the help of others.	.74
10. The pain of the contractions motivated me to be strong.	.62
Factor 2	
6. The chair (bed) made me hurt.	.78
3. I felt empowered by those around me.	.73
Factor 3	
14. I needed to feel better informed about my progress.	.85
9. The room made me feel weak and helpless.	.78
Factor 4	
11. This was a safe place to be.	.95
1. I had enough privacy.	.83
Factor 5	
5. I worked well with my body.	.91
7. I rose above my pain because it helped me birth my baby.	.60

Note. n = 11 and alpha = .85. Five factors with eigenvalues > 1.00 accounted for 85.8% of the variance.

Variable Selection

The participants studied for the pilot study reflected a sample of healthy pregnant women who underwent spontaneous vaginal birth following receipt of typical labor and birth care in the hospital setting. Interventions typically encountered in this setting were provided with assumed effect on the outcome variables of interest for this study: woman's comfort and satisfaction with the birth experience. Examination of both outcome variables was possible within the pilot study utilizing the researcher-modified version of the Childbirth Comfort Questionnaire and the Birth Satisfaction Scale-Revised administered to study participants within six hours of spontaneous vaginal birth. Given the established feasibility of the research study plan, the identified reliability and validity

of the researcher-modified version of the Childbirth Comfort Questionnaire, and adequacy of variable selection, initiation of the current study began immediately following pilot study completion. While internal consistency, face validity, content validity, and construct validity were all found acceptable for the researcher-modified version of the Childbirth Comfort Questionnaire further testing of reliability and validity for this instrument is needed.

Data Analysis and Management

Given the desire to determine differences in comfort and satisfaction with birth experiences for women who use nitrous oxide compared to epidural analgesics or no analgesics during the labor and birth Analysis of Variance (ANOVA) was selected to allow for testing of mean group differences on comfort and on satisfaction. Within ANOVA analysis, total variability in the dependent variable is broken down into two components: 1) variability attributed to the independent variable and 2) all other variability and the variation between groups is contracted to the within groups variation reported as the *F*-ratio (Polit & Beck, 2017).

To facilitate descriptive and multivariate analyses of study data, data gathered within the participant survey and electronic health record extraction were downloaded from Qualtrics and entered within the Statistical Package for the Social Science software, version 25. Creation of a dataset within the statistical software occurred with accuracy of data entry confirmed using a double entry procedure. In preparing the data for analysis, screening through the Statistical Package for the Social Science explore feature and subsequent cleaning of the data occurred as necessary to ensure the assumptions for univariate and multivariate analyses were met. A detailed description of the data

screening and cleaning techniques used to prepare the data for analysis is provided below. Consultation of a statistician occurred across data preparation and statistical analysis to ensure the final dataset was appropriate for analysis.

Univariate Assumptions

Univariate assumptions including the absence of missing data and outliers and normal distribution of the continuous variables were tested and missing values were treated based upon their pattern of missingness, outliers were treated if they altered the normal distribution, and continuous variables were transformed if skewness or kurtosis was found. The findings of data screening and treatment, as necessary, of missing data, outliers, and variable transformation are described below.

Missing data. Improper handling of missing data in research, posing specific threat to the external validity of the study findings, can lead to inaccurate conclusions regarding the study population (El-Masri & Fox-Wasylyshyn, 2005). Initial data screening steps included sorting of data within the statistical software in both ascending and descending approaches and simple frequency analysis to identify out of expected range and plausibility of values, with subsequent double check of data entry. Given the Qualtrics survey format included automatic notices provided to the participant and the Principal Investigator or PI-trained nurse research assistant in the presence of a missing response and inability to move on and/or to submit survey responses, survey completion for both the participant survey and the electronic health record data collection tool was not possible without entering a value for each question or item within the survey and tool. Missing data within the participant electronic health record was not found to be an issue particularly given many of the items included within the electronic health record

data collection tool could be found in multiple locations within the participant electronic health record and duplication of needed information was often documented in multiple areas by the bedside nurse, the nurse midwife, and/or the physician. As a result, no issues with missing data were found requiring subsequent treatment of missing data.

Outliers. Identification of outliers or data values different from the majority of cases in the data set occurred for all continuous variables (age, cumulative comfort score and total satisfaction score) to avoid inflation or deflation of the study results. Assessment of *z*-scores and graphical assessment allowed for detection of outliers for this study. For any identified outliers, return to the data to correct any data entry errors, invalid missing data coding, and confirmation of participant characteristics aligned with the sampling criteria occurred. A total of four outlier cases were explored in detail, three identified on the cumulative comfort score variable and one identified on the total satisfaction score variable. All four cases, following exploration were determined to be valid observations and subsequently were included in the analysis without transformation of the associated data. Detailed explanation of the outlier cases and associated data are described below.

Of the three outlier cases identified for cumulative comfort score, two cases included report of a low cumulative comfort score (36 and 39) and one reported a high comfort score (64) whereas cumulative comfort scores for all participants ranged from 36 to 66 with a mean score of 53.29 (*SD* 5.96). Common themes for both outlier cases with low comfort scores included both cases were primiparous (experienced their first live birth after 20 weeks as an outcome of the current pregnancy), both had a history of an anxiety disorder without current treatment during pregnancy and one also had a history of

depression, both were currently employed, and both had an annual household income less than $75,000. Also, one outlier case with a low comfort score received no analgesics during labor and birth but experienced rapid duration first and second stage of labor (39 and 25 minutes, respectively), particularly for a primiparous woman, and the other outlier case received epidural analgesics and an occiput posterior fetal position at the time of birth. Total satisfaction scores for both outlier cases with low cumulative comfort scores were also noted to be well below the established mean for all study participants, with scores of 24 and 25 (M = 30.79, SD 4.88).

The third outlier case identified for cumulative comfort score included a participant who received no analgesics during labor and birth and was multiparous (experienced two live births after 20 weeks gestation including the current pregnancy), had no history of anxiety or psychiatric disorders, was currently employed with an annual household income greater than $75,000 and had a total satisfaction score of 38. Regarding the outlier case identified for total satisfaction score, the associated participant received no analgesics during labor and birth and was multiparous (experienced four live births after 20 weeks gestation including the current pregnancy), had a history of anxiety, depression and Bipolar disorder, was not currently employed with an annual household income <$25,000, and provided a cumulative comfort score of 52. Given exploration of all three outlier cases for cumulative comfort scores and for the outlier case identified for total satisfaction score yielded valid findings aligned with those of expected norms and capture the population intended for study, all four cases were included in the data analysis without transformation of the associated data.

Normality distribution. Normal distribution of the continuous variables within the data set was explored by testing for skewness and kurtosis for each group variable. Fisher's skewness coefficient, a measure of symmetry used to determine whether the distribution was symmetrical with respect to the dispersion from the mean, was used to determine presence or absence of skewness for the data set. In addition, Fisher's coefficient of kurtosis was used as a measure of kurtosis to determine whether the data in the data set were peaked or flat relative to a normal distribution. Mild skewness (-2.349) and kurtosis (4.54) found on the cumulative comfort score variable for the no analgesics group aligned with expected findings given the inclusion of the above outlier cases. Both the epidural analgesic and nitrous oxide groups for the cumulative comfort score variable and all three groups for the age and total satisfaction score variables had a Fisher's skewness and kurtosis co-efficient $\pm$1.96 evident of the absence of skewness or kurtosis on the given variable by study group. Graphical assessment, including review of the histograms, stem and leaf plots, normal probability plots, and detrended normal probability plots for the data set also allowed for visualization of the described mild skewness and kurtosis for the cumulative comfort score for only the no analgesic group.

Multivariate Assumptions

Multivariate assumptions of ANOVA include mutually exclusive groups, the assumption of homoscedasticity or homogeneity of variance, and normal distribution of the dependent variables. The findings of data screening and treatment, as necessary, for each of these multivariate assumptions are described below.

Mutually exclusive groups. Observations were considered independent when participant scores on the dependent variable were not influenced by other participants in

the study group (Grimm & Yarnold, 2010). Given other participants in this study were not able to affect another participant's responses at the time the dependent variables were measured independence of observations was assumed for this study. Specifically, individual pain management strategies provided during labor and birth and survey of participants within six hours of childbirth fostered independence of observations thus allowing for the multivariate assumption of mutually exclusive groups to be met.

Multivariate outliers. Given the potential for outlier cases to impact the value of statistical parameters greater than other scores (Polit, 2010), exploration of the continuous variables within the data set for multivariate outliers was necessary. Specifically, assessment of Mahalanobis distance, Cook's distance, and graphical display allowed for detection of multivariate outliers for this study. The Mahalanobis distance was evaluated using the chi-square distribution such that cases with values exceeding the critical x^2 value (df = number of independent variables included in the analyses) at p <.001 were considered multivariate outliers (Tabachnick & Fidell, 2013). Exploration of the minimum and maximum values for Mahalanobis distance within the statistical software occurred based upon the critical x^2 value of 13.82 ($df = 2$, $p = 0.001$). Given the maximum and minimum Mahalanobis distances for all three continuous variables were lower than the critical value (0 and 1.482, respectively), it was concluded that there were no influential outlier cases. Cook's distance, as a measurement of the influence of a case on the change in the regression coefficient upon deletion of that case (Tabachnick & Fidell, 2013), was examined with a Cook's distance value for a case of greater than one deemed as an influential data point. Because .166 was the highest Cook's distance of the three continuous variables, further evidence indicating that influential multivariate

outliers were not a concern was noted. Graphical display of the histogram, linear P-P plots of expected and observed cumulative probabilities of the residuals, and a scatter plot were examined for each of the continuous variables and will be described in detail within the next section.

Multivariate normality. The assumption of multivariate normality includes the following criterion: (a) normal distribution of the individual independent variables, (b) normal distribution of any linear combination of the dependent variables, and (c) multivariate normal distribution of all subsets of the variables (Grimm & Yarnold, 2010). Multivariate normality was evaluated visually for all three continuous variables (age, cumulative comfort score and total satisfaction score) for each study group through visual examination of the histogram, stem-and-leaf plot, normal and detrended normal Q-Q plots, and a box plot. Visual inspection of each of these graphs for each study group revealed an overall sense of normal distribution for both of the dependent variables (cumulative comfort score and total satisfaction score) and for the covariate variable age despite visualization of the four outlier cases described earlier.

For each of the continuous variables, homoscedasticity was assessed though visualization of a scatter plot and based upon Levene's Test of Equality of Variance used to determined equal variance between the groups if non-significant values result (Polit, 2010). Visualization of the scatter plot for each continuous variable indicated the assumption of homoscedasticity was met since overall the scatter plot took the shape of a rectangular with scores concentrated in the center (Tabachnick and Fidell, 2013). However, the Levene's test for the comfort variable was significant, $F(2, 81) = 3.510$, $p = .035$. The assumption of homoscedasticity was met for the age ($F(2, 81) = .003$, $p =$

.997) and satisfaction (F (2, 81) = .094, p = .910) variables given non-statistically significant findings for the Levene's test.

Further exploration of the assumption of homoscedasticity was conducted based upon the Kolmogrov-Smirnov and Shapiro-Wilk tests of normality. For both the satisfaction and age variables, both tests of normality did not report statistically significant findings supporting the assumption of homoscedasticity or homogeneity of variance as being met for these variables. As noted within the Levene's test for the comfort variable, statistically significant findings were noted for both the Kolmogrov-Smirnov (statistic = .165, df = 28, p = .048) and the Shapiro-Wilk (statistic = .902, df = 28, p = .013) tests for the no analgesic group with findings for the other study groups noted as not statistically significant for both tests of normality. Given the small number of observations within the study sample, the similarity of mean scores across the study groups for all three continuous variables, the similarities of boxplots visualization with no obvious differences, and the high number of binary/dichotomous variables included in the analysis, violation of the homogeneity of variance assumption for the comfort variable only for the no analgesic group was noted. However, a decision was made to proceed with the data analysis without transformation of the study data since ANOVA analysis is robust to mild violations of multivariate assumptions.

Data Analysis Techniques

Psychometric testing of the researcher-modified version of the Childbirth Comfort Questionnaire and scoring of both the researcher-modified version of the Childbirth Comfort Questionnaire and the Birth Satisfaction Scale-Revised occurred prior to data analysis. Scoring of participant cumulative comfort scores for the researcher-modified

version of the Childbirth Comfort Questionnaire and cumulative satisfaction scores for the Birth Satisfaction Scale-Revised included reverse coding of items with negative responses. For the researcher-modified version of the Childbirth Comfort Questionnaire items numbered 2, 4, 6, 9, and 12-14 were reverse coded, for the Birth Satisfaction Scale-Revised reverse coding occurred for items numbered 2, 4, 7 and 8. Further, the dataset was screened in the statistical software and cleaned, as determined necessary, to ensure the assumptions for univariate and multivariate analyses were met. When conducting the statistical analyses, statistical significance (two-tailed) for data analysis was set at $p < 0.05$. The following aims were examined to determine if comfort and satisfaction with birth experiences differed for women who used nitrous oxide compared to those who used epidural analgesics or no analgesics during labor and birth. Data analysis conducted for each study specific aim is discussed in the following section.

Aim 1. To determine the frequencies and frequency distribution of obstetric and mental health history characteristics, current pregnancy characteristics, analgesic use, and use of non-pharmacological methods for women age 18 years and older who experienced a current spontaneous vaginal birth. Frequencies were addressed through evaluation of descriptive statistics, including percentage, means, standard deviation, and range where appropriate and frequency distributions of were evaluated for normality through graphical and statistical methods. Significance levels were set at .05 ($\alpha = .05$, 2-tailed).

Aim 2. To determine comfort experienced during labor and birth for women who received 1) nitrous oxide and oxygen (50-50% mixture) only, 2) epidural analgesics (may have been in combination with other analgesic options), or 3) no analgesics (control group). Comfort was quantified using the researcher-modified version of the Childbirth

Comfort Questionnaire, which scored from 14 to 70 (Schuiling, 2002) administered to study participants within six hours of spontaneous vaginal birth and prior to postpartum opioid or other narcotic pain medication administration. Cumulative item scores were calculated and totaled for each participant. Cumulative comfort scores were also grouped by pain management method to allow for group comparisons. Descriptive statistics, including group means, were calculated and greater satisfaction noted with higher mean scores noted as reflecting greater comfort.

Aim 3. To determine satisfaction with the birth experience for women who received: 1) nitrous oxide and oxygen (50-50% mixture) only, 2) epidural analgesics (may have been in combination with other analgesic options), or 3) no analgesics (control group). Satisfaction with the birth experience was measured using the Birth Satisfaction Scale-Revised, which is scored from 0 to 40 (Hollins Martin & Martin, 2014) administered to study participants within six hours of spontaneous vaginal birth and prior to postpartum opioid or other narcotic pain medication administration. Cumulative item scores were calculated and totaled for each participant. Total satisfaction scores were also grouped by pain management method to allow for group comparisons. Descriptive statistics, including group means, were calculated and greater satisfaction noted with higher mean satisfaction scores.

Aim 4. To compare differences in comfort between women who used nitrous oxide, those who used epidural analgesics, and those who used no analgesics during labor and birth. One-way Analysis of Variance (ANOVA) was used to test the significance of group mean differences for comfort. Wilks' lambda, noted as the *F*-ratio, was used to report the significance of group mean differences (Polit & Beck, 2017). Statistical

significance was determined using a *p*-value <0.05 and are described in detail in Chapter IV. Should the overall ANOVA results suggest the group means were significantly different, Ad hoc tests to examine the difference across each pair of groups would have been performed (Polit & Beck, 2017).

Aim 5. To compare differences in satisfaction with the birth experience between women who used nitrous oxide, those who used epidural analgesics, and those who used no analgesics during labor and birth. One-way Analysis of Variance (ANOVA) was used to test the significance of group mean differences for satisfaction with the birth experience. Wilks' lambda, noted as the *F*-ratio, was used to report the significance of group mean differences (Polit & Beck, 2017). Statistical significance was determined using a *p*-value <0.05 and are described in detail in Chapter IV. Should the overall ANOVA results suggest the group means were significantly different, Ad hoc tests to examine the difference across each pair of groups would have been performed (Polit & Beck, 2017).

Summary

The purpose of this prospective study was to determine if comfort and satisfaction with birth experiences differed for women who used nitrous oxide compared to epidural analgesics or no analgesics during the labor and birth process. The between-subjects comparative design was appropriate to compare differences in comfort and satisfaction with birth experiences for women who used nitrous oxide compared to epidural analgesics or no analgesics during the labor and birth given this design allowed for comparison of comfort and for satisfaction scores among all three study groups and extended support for causal relationships without manipulation of the independent

variable. This chapter presented the methodology used for this study including the study design, sample and setting, procedures, protection of human subjects, tests and measures, and data management and analysis. The findings of this study following data analysis are described in detail within Chapter IV.

CHAPTER IV

RESULTS

The purpose of this study was to determine if comfort and satisfaction with birth experiences differed for women who used nitrous oxide compared to epidural analgesics or no analgesics during the labor and birth process.

The specific aims examined in this study were:

Aim 1. To determine the frequencies and frequency distributions of obstetric and mental health history characteristics, current pregnancy characteristics, analgesic use, and use of non-pharmacological methods for women age 18 years and older who experienced a current spontaneous vaginal birth.

Aim 2. To determine comfort experienced during labor and birth for women who received 1) nitrous oxide and oxygen (50-50% mixture) only, 2) epidural analgesics (may have been in combination with other analgesic options), or 3) no analgesics (control group).

Aim 3. To determine satisfaction with the birth experience for women who received: 1) nitrous oxide and oxygen (50-50% mixture) only, 2) epidural analgesics (may have been in combination with other analgesic options), or 3) no analgesics (control group).

Aim 4. To compare differences in comfort between women who used nitrous oxide, those who used epidural analgesics, and those who used no analgesics during labor and birth.

Aim 5. To compare differences in satisfaction with the birth experience between women who used nitrous oxide, those who used epidural analgesics, and those who used no analgesics during labor and birth.

This chapter presents results of this dissertation research study.

Sample Demographics and Characteristics

Of the 146 pregnant women identified as eligible for study participation according to eligibility criteria, a total of 145 pregnant women were enrolled for study participation according to the eligibility criteria. Enrollment procedures at Site #1 and Site #2 occurred

over a five-month period (June 2019-October 2019) and at Site #3 over a two-month period (August 2019-October 2019). Of eligible woman approached for study participation at Site #1, one woman refused to participate (0.7%, $n = 1$) with "not feeling well" expressed as her reason for refusal.

A total sample of 145 pregnant women 18 years or older who were planning a vaginal birth experience in the next three months or who were presently admitted to the birthing unit for anticipated childbirth agreed to participate in this study across the three study sites. Of the 145 pregnant women enrolled for study participation, 117 were enrolled from Site #1 and 14 were enrolled from each of the other two study sites. A total of 90 participants completed all study procedures, 62 of whom completed the study within Site #1, and 14 completed all study procedures at each of the other two study sites. Given the researcher-modified version of the Childbirth Comfort Questionnaire was identified as reliable and valid within the pilot study, data collected for all pilot study participants were included within the total number of participants for the current study. Further, as a result of established feasibility of the research study plan and adequacy of variable selection, the initiation of the current study began immediately following pilot study completion.

For the epidural analgesic study group, all 28 participants were enrolled at Site #1; for the nitrous oxide only group 14 were enrolled at Site #1, 11 were enrolled at Site #2 and three were enrolled at Site #3; and for the no analgesic (control) study group 14 were enrolled at Site #1, three were enrolled at the Site #2, and 11 were enrolled at Site #3. Six women were withdrawn after examination of the data following completion of all study procedures given receipt of systemic analgesics only ($n = 5$) and the associated

protocol change, or after having received intrathecal rather than epidural analgesics (n = 1). An additional 55 enrolled participants from Site #1 were withdrawn from study participation based upon study exclusion criteria reexamined following labor and birth. Table 3 below describes the reasons for withdrawal of participants following initial enrollment (n = 61).

Table 3

Characteristics of Pregnant Women Withdrawn from Study Participation Following Initial Enrollment (n = 61)[a]

Characteristic	*n*	Percentage (%)
Cesarean Delivery for Current Pregnancy		
Failure to Progress	5	8.2
Breech Presentation	2	3.3
Fetal Intolerance of Labor	1	1.6
Fetal Distress Prior to Labor Onset	1	1.6
Vacuum-Assisted Vaginal Delivery	1	1.6
No Analgesics During Labor and Birth		
Prior to Study Protocol Change	8	13.2
Use of Nitrous Oxide and Systemic Analgesics	2	3.3
Use of Epidural Analgesics		
After Study Group Filled	34	55.6
Administrative Reasons		
Missed 6 Hour Survey Window[b]	1	1.6
Use of Intrathecal Analgesics[c]	1	1.6
Use of Systemic Analgesics only[c]	5	8.2

Note. [a] Total number of enrolled participants excluded following admission to the birthing unit for anticipated childbirth or following the childbirth experience (n = 55) and those excluded after examining study data following participant survey completion (n = 5 systemic analgesics only, n= 1 intrathecal analgesics). [b]Number of participants excluded for administrative reasons in the presence of intermittent study support by research assistants during the first week of study implementation. [c]Participants excluded following completion of all study procedures following review of survey data and study protocol change excluding use of only systemic analgesics.

Exclusion Characteristics

A total of 957 potentially eligible pregnant women were screened for study participation across the three study sites, including screening of 506 pregnant women at

Site #1, screening of 257 pregnant women at Site #3, and screening of 194 pregnant women at Site #2. Of the 957 pregnant women screened, 145 were subsequently enrolled for study participation and 812 were excluded for the reasons outlined within Table 4 below.

Table 4

Characteristics of Pregnant Women Excluded from Study Participation[a]

Characteristic	*n*	Percentage (%)
History of Anxiety or Psychiatric Disorder[b]	32	3.9
Current medications and/or treatment of Anxiety or Psychiatric Disorder	91	11.2
Nitrous Oxide Analgesic Only[c]		
After Study Group Filled	3	0.4
Epidural or Intrathecal Analgesics[d]		
Site #1	92	11.3
Site #2	83	10.2
Site #3	126	15.5
No Analgesics[e]	39	4.8
Systemic Analgesics Only[f]		
Following Protocol Change	4	0.5
Primary Cesarean Birth	47	5.8
Planned VBAC or Repeat Cesarean Birth[g]	173	21.3
Pregnancy Gestation < 37 weeks	36	4.4
Multiple Gestation Pregnancy	17	2.1
Age < 18 years	4	0.5
Current Fetal or Newborn Complications	4	0.5
Prior Stress in Childbirth	4	0.5
Current Stressful Childbirth Event	4	0.5
Current Vacuum or Forceps Assisted Delivery	5	0.6
Pregnancy Complications		
Magnesium Sulfate during Labor and Birth	2	0.25
Illicit Drug Use during Pregnancy[h]	35	4.3
Absence of English Language Proficiency	7	0.9
Combined Use of Analgesics		
Nitrous Oxide and Systemic Analgesics	3	0.4
Refusal to Participate	1	0.10

Note. [a] Total screened for study participation *N*=957, 812 excluded for above reasons. [b]Excluded without consideration of currency of anxiety or psychiatric disorder diagnosis and/or treatment (prior to study protocol change/exclusion criteria modification during pilot study). [c-d]Excluded after securing desired number of participants for the study groups. [e]Excluded prior to study protocol change to begin including participants for this study group. [f]Includes participants who used only systemic analgesics after the study protocol change to no longer include enrollment to this study group. [g]VBAC = Vaginal Birth After Cesarean. [h]Illicit drug use of marijuana or methamphetamine during pregnancy confirmed with positive drug screen following initial prenatal clinic visit.

Sample Characteristics

A sample of 84 pregnant women who met study eligibility criteria were enrolled over a five-month period (June 2019 - October 2019) from three facilities within an integrated health system in the upper Midwest region of the United States. Enrollment occurred during a third trimester prenatal care clinic visit, prior to or following childbirth preparation class attendance, or upon admission to the birthing unit for anticipated childbirth with care taken not to recruit women while they were experiencing active labor pain. All participants who completed the study experienced spontaneous vaginal birth, without assistance of vacuum or forceps, had no existing health concerns for the newborn following birth or at the time of survey completion, and completed the study survey within six hours of spontaneous vaginal birth and prior to postpartum opioid or other narcotic pain medication administration. Table 5 outlines the participant demographic characteristics. The mean age for the study sample ($N = 84$) was 28 years ($M = 28.62$, $SD = 4.9$) with age ranging from 18 to 39 years. The vast majority of the participants were married ($n = 59$; 70%) and of White race ($n = 72$, 85.7%), with the next largest race self-reported as Black or African American alone ($n = 4$, 4.8%) or as two or more races ($n = 4$, 4.8%). Overall, the sample was homogenous in nature and reflected very little ethnic diversity. Over 80% of participants reported to have continued their education beyond high school ($n = 68$; 80.9%) with nearly half reporting to have completed a Bachelor's degree or higher ($n = 38$; 45.2%). The majority of study participants reported current employment ($n = 86$; 81%) with annual household income greater than $75,000 for half of the participants ($n = 42$; 50%).

Table 5

Demographic Characteristics of Pregnant Women 18 Years or Older who Experienced a Current Spontaneous Vaginal Birth[a]

Characteristic	*n*	Percentage (%)
Race		
White alone	72	85.7
Black or African American alone	4	4.8
American Indian or Alaska Native alone	2	2.4
Asian alone	0	0
Native Hawaiian or other Pacific Islander alone	0	0
Some other race alone	2	2.4
Two or more races	4	4.8
Ethnicity		
Not Hispanic or Latino	79	94
Hispanic or Latino	5	6
Marital status		
Single	16	19
Married	59	70.2
Widowed	0	0
Divorced	0	0
Separated	0	0
Living with partner	9	10.7
Other living arrangement	0	0
Annual Household Income		
Under $25,000	11	13.1
$25,000 to $49,999	14	16.7
$50,000 to $74,999	17	20.2
$75,000 to $99,999	20	23.8
$100,000 and over	22	26.2
Employment Status		
Currently Employed	68	81
Not Currently Employed	16	19
Highest level of education		
Less than high school graduate	2	2.4
High school graduate (including GED or other equivalent)	14	16.7
Some college or associate's degree	30	35.7
Bachelor's degree or higher	38	45.2

Note. Data were collected within six hours of the childbirth experience. [a]$N = 84$, including women who used epidural analgesics ($n = 28$), nitrous oxide only ($n = 28$), or no analgesics ($n = 28$) during labor and birth. Age range of participants 18 to 39 years ($M = 28.62$, $SD = 4.9$).

Specific Aim 1

To determine the frequencies and frequency distributions of obstetric and mental health history characteristics, current pregnancy characteristics, analgesic use, and use of non-pharmacological methods for women age 18 years and older who experienced a current spontaneous vaginal birth.

The frequencies and frequency distributions of the obstetric and mental health history characteristics were calculated for study participants. Over half of the study participants experienced a current first or second pregnancy (n = 50; 59.5%) with the majority giving birth to their first or second birth after 20 weeks gestation (n = 55; 65.5%). Three participants self-reported a past negative birth experience within the participant survey not otherwise noted in the electronic health record (n = 3, 2.4%) with newborn transfer to the neonatal intensive care unit (n = 2) or shoulder dystocia (n = 1) noted as the cause of the negative birth experience. Nearly half of the participants had never attended a childbirth preparation class (n = 39; 46.4%) with the remaining majority reporting participation during a past pregnancy (n = 28; 33.3%). The majority of study participants reported no history of anxiety or psychiatric disorders (n = 64; 76.2%); however, for those reporting such history a diagnosis of anxiety disorder was most frequently reported (n = 11; 13.1%). Table 6 presents the obstetric and mental health history of all study participants.

Table 6

Obstetric and Mental Health History Characteristics of Pregnant Women 18 Years or Older who Experienced a Current Spontaneous Vaginal Birth[a]

Characteristic	*n*	Percentage (%)	*M (SD)*
Gravida (total number of confirmed pregnancies)			2.69 (1.61)
1 pregnancy	23	27.4	
2 pregnancies	27	32.1	
3 pregnancies	9	10.7	
4 Pregnancies	9	10.7	
5 Pregnancies	10	11.9	
Greater than 5 pregnancies	6	7.1	
Para (total number of births after 20 weeks gestation)			2.27 (1.27)
No prior births after 20 weeks gestation	29	34.5	
2 births	26	31	
3 births	12	14.3	
4 births	12	14.3	
5 births	4	4.8	
Greater than 5 births	1	1.2	
Participation in formal childbirth preparation classes			
Never Attended	39	46.4	
During past pregnancy	28	33.3	
During current pregnancy	17	20.2	
History of Past Negative Birth Experiences			
No history	82	97.6	
Traumatic birth/delivery	1[b]	0.2	
Transfer of newborn to Neonatal Intensive Care Unit/NICU	2	2.2	
History of Anxiety or Psychiatric Disorder			
No history	64	76.2	
Anxiety	11	13.1	
Depression	1	1.2	
Anxiety and Depression	6	7.1	
Anxiety and Bipolar Disorder	1	1.2	
Anxiety, Depression, and Bipolar Disorder	1	1.2	

Note. Data were collected within six hours of the childbirth experience. [a]$N = 84$, including women who used epidural analgesics ($n = 28$), nitrous oxide only ($n = 28$), or no analgesics ($n = 28$) during labor and birth. Age range of participants 18 to 39 years ($M = 28.62$, $SD = 4.9$). [b]Traumatic birth resulting from shoulder dystocia.

The frequencies and frequency distributions of the current pregnancy characteristics for study participants were calculated. Current pregnancy gestation for study participants at the time of birth ranged from 37 to 41 weeks gestation ($M = 39$, $SD = 1.064$; $n = 84$). Mean duration of first and second stage of labor for study participants were 317 minutes ($M = 317$; $SD = 203.74$) and 24.89 ($M = 24.89$; SD 28.38) respectively,

with the majority requiring no intravenous oxytocin administration for labor induction or augmentation (*n* = 54; 64.3%). Of those requiring oxytocin administration, intravenous oxytocin was administered to 11 participants (13.1%) for labor induction and to 19 participants (22.6%) for labor augmentation. Occiput posterior fetal position was noted at time of birth for 3 participants (*n* = 3; 3.6%) and the majority of participants reported having a spouse present as their only support person during labor and/or birth (*n* = 55, 65.5%) followed by their significant other as the next most common support person during labor and/or birth (*n* = 12, 14.3%). Three participants reported support provided by a doula in addition to their spouse, significant other, and/or friend. Tables 7 and 8 present the current pregnancy characteristics of all study participants.

Table 7

Current Pregnancy Characteristics of Pregnant Women 18 Years or Older who Experienced a Current Spontaneous Vaginal Birth[a]

Characteristic	*n*	Percentage (%)	Mean (*SD*)	Range
Pregnancy Gestation at Time of Birth (in weeks)			39 (*1.064*)	37-41
37 weeks gestation	7	8.3		
38 weeks gestation	21	25		
39 weeks gestation	26	31		
40 weeks gestation	25	29.8		
41 weeks gestation	5	6		
Duration first stage of labor (in minutes)			317 *(203.74)*	38-1140
Duration second stage of labor (in minutes)			24.89 *(28.38)*	1-140

Note. Data were collected within six hours of the childbirth experience. [a]*N* = 84, including women who used epidural analgesics (*n* = 28), nitrous oxide only (*n* = 28), or no analgesics (*n* = 28) during labor and birth.

Table 8

Additional Current Pregnancy Characteristics of Pregnant Women 18 Years or Older who Experienced a Current Spontaneous Vaginal Birth[a]

Characteristic	*n*	Percentage (%)
Use of Oxytocin		
No Oxytocin Use	54	64.3
For Induction	11	13.1
For Augmentation	19	22.6
Fetal position at time of birth[b]		
Occiput Anterior	81	96.4
Occiput Posterior	3	3.6
Presence of Support Person during Labor and/or Birth		
No support person present	0	0
Spouse	55	65.5
Significant other	12	14.3
Family member	2	2.4
Friend	0	0
Other[c]	1	1.2
More than one support person[d]	15	17.9

Note. Data were collected within six hours of the childbirth experience. [a]*N* = 84, including women who used epidural analgesics (*n* = 28), nitrous oxide only (*n* = 28), or no analgesics (*n* = 28) during labor and birth. [b]Denotes fetal position at time of birth noted on delivery summary. [c]Other noted as "father of baby" within participant comment. [d]Presence of more than one support person reported as spouse and family member (*n*=7); significant other and family member (*n*=3); spouse and friend (*n*=1); spouse or significant other and doula (*n*=2); significant other, friend and doula (*n*=1); or significant other, family member, and friend (*n*=1).

Frequencies and frequency distributions were calculated for the analgesic method utilized by each study participant and reported by study group. All study participants experienced a spontaneous vaginal birth for the current pregnancy and utilized one of the following during labor and birth: 1) nitrous oxide and oxygen (50-50% mixture) only, 2) epidural analgesics (may have been in combination with other analgesic options), or 3) no analgesics (control group). For participants within epidural analgesic study group, 26 used only epidural analgesics (*n* = 26; 92.9%) and two used nitrous oxide for 30 or 275 minutes prior to epidural conversion (*n* = 2; 7.1%). Epidural bolus doses ranged from 0-17ml (*M* = 9.25; *SD* 4.32) and continuous epidural infusion rates ranged from 12-15ml/hr. Duration of the epidural placement procedure ranged from 2-42 minutes (*M* = 18; *SD* 13.5) and duration of epidural infusion ranged from 52-950 minutes (*M* = 294; *SD*

212). For participants within the nitrous oxide only group the duration of nitrous oxide use ranged from 10-412 minutes (*M* = 96.5; *SD* 94.55). Sample characteristics regarding the analgesic method used by the study participants during labor and birth are described in Table 9.

Table 9

Analgesic Methods Utilized by Pregnant Women 18 Years or Older who Experienced a Current Spontaneous Vaginal Birth[a]

Characteristic	*n*	Range	*M(SD)*
Epidural Analgesics Group	28		
Epidural Analgesics only	26		
Nitrous Oxide and Epidural Analgesics[b]	2		
Epidural Bolus Dose	27	0-17ml[c]	9.25(*4.32*)
No Epidural Bolus	1		
Continuous Epidural Infusion (15ml/hr)[d]	15		
Continuous Epidural Infusion (12ml/hr)[d]	12		
Continuous Epidural Infusion (13ml/hr)[d]	1		
Duration of Epidural Placement Procedure (in minutes)	28	2-42	18*(13.5)*
Duration of Epidural Use (in minutes)	28	52-950	294*(212)*
Nitrous Oxide Group			
Duration of Nitrous Oxide Use (in minutes)	28	10-412	96.5*(94.55)*
No Analgesic Group	28		

Note. Data were collected following the childbirth experience. [a]*N* = 84, including women who used epidural analgesics (*n* = 28), nitrous oxide only (*n* = 28), or no analgesics (*n* = 28) during labor and birth. [b]Duration of nitrous oxide use 30 and 275 minutes prior to epidural conversion. [c]Epidural bolus dose utilizing Bupivacaine 0.25% injection (*n* = 13), Bupivacaine 0.25% injection and Fentanyl 100mcg (*n* = 10), Bupivacaine 0.125% injection and Fentanyl 100mcg (*n* = 1), Ropivacaine 0.2% injection (*n* = 2), or Bupivacaine 0.75% injection and Fentanyl 30mcg (*n* = 1). [d]Continuous epidural infusion of Bupivacaine 0.125% infusion.

Frequencies and frequency distributions were calculated for the non-pharmacological method utilized by each study participant and reported by study group. A variety of non-pharmacological methods were utilized during labor and birth by study participants identified by participant self-report and confirmed by electronic health record documentation. For both the nitrous oxide only (*n*=17; 61%) and no analgesic (*n*=19;

68%) study groups, focused/paced breathing was noted as the most frequently utilized non-pharmacological method. Hydrotherapy/whirlpool tub use and exercise/walking were consistently noted across all three study groups within the top three most frequently utilized non-pharmacological methods (epidural group: exercise/walking *n* = 15, 54% and hydrotherapy/whirlpool tub *n* = 12, 43%; nitrous oxide group: exercise/walking *n* = 10, 36% and hydrotherapy/whirlpool tub *n* = 12, 43%; no analgesic group: both exercise/walking and hydrotherapy/whirlpool tub *n* = 12, 43%). Table 10 presents the frequencies and percentages for utilization of non-pharmacological methods utilized during labor and birth by each study group.

Table 10

Non-pharmacological Methods Utilized by Pregnant Women 18 Years or Older who Experienced a Current Spontaneous Vaginal Birth[a]

Characteristic	*n*	Percentage (%)[b]
Non-pharmacologial Methods Used		
Epidural Group		
Exercise/walking	15	54
Massage	4	14
Focused/paced breathing techniques	8	29
Hydrotherapy/whirlpool tub	12	43
Guided Imagery	0	
Meditation	0	
Yoga/Birthing Ball	4	14
No alternative therapies used	7	25
Other[c]	6	21
Nitrous Oxide Group		
Exercise/walking	10	36
Massage	6	21
Focused/paced breathing techniques	17	61
Hydrotherapy/whirlpool tub	12	43
Guided Imagery	0	
Meditation	2	7
Yoga/Birthing Ball	3	11
No alternative therapies used	3	11
Other[c]	2	7
No Analgesic Group		
Exercise/walking	12	43
Massage	7	25
Focused/paced breathing techniques	19	68
Hydrotherapy/whirlpool tub	12	43
Guided Imagery	1	4
Meditation	2	7
Yoga	3	11
No alternative therapies used	4	14
Other[c]	2	7

Note. Data were collected within six hours of the childbirth experience. [a]$N = 84$, including women who used epidural analgesics ($n = 28$), nitrous oxide only ($n = 28$), or no analgesics ($n = 28$) during labor and birth. [b]Percentage reported by study group ($n = 28$). [c]No comments were provided by participants who chose a response of "other".

Specific Aim 2

To determine comfort experienced during labor and birth for women who received 1) nitrous oxide and oxygen (50-50% mixture) only, 2) epidural analgesics (may have been in combination with other analgesic options), or 3) no analgesics (control group).

Cumulative item scores for the researcher-modified Childbirth Comfort Questionnaire. Comfort scores for participants were quantified using the researcher-modified version of the Childbirth Comfort Questionnaire (Schuiling, 2002). Calculation of cumulative item scores and totaling of scores for all items in the scale resulted in the participant total comfort score. Comfort scores for participants within six hours of childbirth utilizing the researcher-modified version of the Childbirth Comfort Questionnaire ranged from 36 to 66 with a mean score of 53.29 (*SD* 5.96, *N* = 84). Aligned with scoring by Schuiling (2003), participant scores of low comfort across the study groups ranged from 33-50 (*n* = 23; 27%) and scores of high comfort ranged from 58-66 (*n* = 61; 73%). Mean item scores for the researcher-modified version of the Childbirth Comfort Questionnaire were found to be similar and within one point when compared across the study groups. Tables 11-13 present the results of item scores for the researcher-modified version of the Childbirth Comfort Questionnaire for each study group including the mean, standard deviation, and range.

Table 11

Cumulative Item Scores for the Researcher Modified Childbirth Comfort Questionnaire for Pregnant Women 18 Years or Older who Received Nitrous Oxide only[a]

Item	M (*SD*)	Range
1. I had enough privacy.	4.61 (*.57*)	3-5
2. My pain was difficult to endure.*	2.36 (*.91*)	1-4
3. I felt empowered by those around me.	4.46 (*.64*)	3-5
4. I didn't think I could do it without the help of others.*	1.89 (*.99*)	1-4
5. I worked well with my body.	4.04 (*.69*)	2-5
6. The chair (bed) made me hurt.*	3.07 (*1.12*)	1-5
7. I rose above my pain because it helped me birth my baby.	4.14 (*.71*)	2-5
8. I felt confident I could birth my baby.	4.11 (*.88*)	2-5
9. The room made me feel weak and helpless.*	4.21 (*.83*)	1-5
10. The pain of the contractions motivated me to be strong.	3.64 (*.83*)	2-5
11. This was a safe place to be.	4.82 (*.39*)	4-5
12. I felt like giving up.*	3.29 (*1.38*)	1-5
13. I worried I would lose control.*	3.43 (*1.20*)	1-5
14. I needed to feel better informed about my progress.*	3.89 (1.10)	2-5

Note. Data were collected within six hours of the childbirth experience. [a]*n* = 28 participants. Scores for each item ranged from 1 (strongly disagree) to 5 (strongly agree). *Denotes reversed coding prior to scoring.

Table 12

Cumulative Item Scores for the Researcher Modified Childbirth Comfort Questionnaire for Pregnant Women 18 Years or Older who Received Epidural Analgesics[a]

Item	M (*SD*)	Range
1. I had enough privacy.	4.71 (*.46*)	4-5
2. My pain was difficult to endure.*	2.96 (*1.20*)	1-5
3. I felt empowered by those around me.	4.50 (*.64*)	3-5
4. I didn't think I could do it without the help of others.*	2.00 (*1.22*)	1-5
5. I worked well with my body.	3.86 (*.80*)	2-5
6. The chair (bed) made me hurt.*	3.54 (*1.20*)	1-5
7. I rose above my pain because it helped me birth my baby.	3.61 (*.92*)	1-5
8. I felt confident I could birth my baby.	4.07 (*.86*)	2-5
9. The room made me feel weak and helpless.*	4.86 (*.36*)	4-5
10. The pain of the contractions motivated me to be strong.	3.32 (*.86*)	2-5
11. This was a safe place to be.	4.64 (*.83*)	1-5
12. I felt like giving up.*	3.79 (*1.23*)	1-5
13. I worried I would lose control.*	4.00 (*1.09*)	1-5
14. I needed to feel better informed about my progress.*	4.39 (.99)	2-5

Note. Data were collected within six hours of the childbirth experience. [a]*n* = 28 participants, including two participants who utilized nitrous oxide and epidural analgesics. Scores for each item ranged from 1 (strongly disagree) to 5 (strongly agree). *Denotes reversed coding prior to scoring.

Table 13

Cumulative Item Scores for the Researcher Modified Childbirth Comfort Questionnaire for Pregnant Women 18 Years or Older who Received No Analgesics[a]

Item	M (*SD*)	Range
1. I had enough privacy.	4.79 (*.42*)	4-5
2. My pain was difficult to endure.*	1.96 (*.79*)	1-4
3. I felt empowered by those around me.	4.32 (*.72*)	2-5
4. I didn't think I could do it without the help of others.*	1.93 (*.98*)	1-4
5. I worked well with my body.	4.36 (*.68*)	2-5
6. The chair (bed) made me hurt.*	3.36 (*1.06*)	1-5
7. I rose above my pain because it helped me birth my baby.	4.43 (*.63*)	3-5
8. I felt confident I could birth my baby.	4.21 (*1.00*)	1-5
9. The room made me feel weak and helpless.*	4.61 (*.63*)	3-5
10. The pain of the contractions motivated me to be strong.	3.43 (*1.10*)	1-5
11. This was a safe place to be.	4.79 (*.42*)	4-5
12. I felt like giving up.*	3.46 (*1.32*)	1-5
13. I worried I would lose control.*	3.89 (*1.03*)	1-5
14. I needed to feel better informed about my progress.*	4.12 (1.23)	1-5

Note. Data were collected within six hours of the childbirth experience. [a]*n* = 28 participants. Scores for each item ranged from 1 (strongly disagree) to 5 (strongly agree). *Denotes reversed coding prior to scoring.

Cumulative comfort scores for the researcher-modified Childbirth Comfort Questionnaire. Cumulative comfort scores were also grouped by pain management method to allow for group comparisons. Descriptive statistics, including group means, standard deviation and range, were calculated and greater comfort noted with higher mean scores reflective of greater comfort. Table 14 presents the cumulative comfort scores for study participants based upon cumulative item scores from the researcher-modified version of the Childbirth Comfort Questionnaire.

Table 14

Cumulative Comfort Scores for the Researcher Modified Childbirth Comfort Questionnaire for Pregnant Women 18 Years or Older who Experienced a Current Spontaneous Vaginal Birth[a]

Study Group	M (*SD*)	Range
Nitrous oxide and oxygen (50-50% mixture) group (*n* = 28)	51.96 (*6.47*)	38-62
Epidural analgesic group[b] (*n* = 28)	54.25 (*6.06*)	39-66
No analgesic group (*n* = 28)	53.64 (*5.28)*	36-64

Note. Data were collected within six hours of the childbirth experience. [a]*N* = 84, including women who used epidural analgesics (*n* = 28), nitrous oxide only (*n* = 28), or no analgesics (*n* = 28) during labor and birth. Two participants in the epidural analgesics group also received nitrous oxide prior to epidural conversion. Total comfort score possible for the researcher-modified Childbirth Comfort Questionnaire = 70 with higher scores indicating greater comfort.

Specific Aim 3

To determine satisfaction with the birth experience for women who received: 1) nitrous oxide and oxygen (50-50% mixture) only, 2) epidural analgesics (may have been in combination with other analgesic options), or 3) no analgesics (control group).

Cumulative item scores for the Birth Satisfaction Scale-Revised. Scores for participant satisfaction with the birth experience were quantified using the Birth Satisfaction Scale-Revised (Hollins Martin & Martin, 2014). Calculation of cumulative item scores and totaling of scores for all items in the scale resulted in the participant total satisfaction score. Satisfaction with the birth experience scores for participants within six hours of childbirth utilizing the Birth Satisfaction Scale-Revised ranged from 15 to 40 with a mean score of 30.79 (*SD* 4.88). Mean item scores for the Birth Satisfaction Scale-Revised were found to be similar and within one point when compared across the study groups. Tables 15-17 present the results of item scores for the Birth Satisfaction Scale-Revised for each study group including the mean, standard deviation, and range.

Table 15

Cumulative Item Scores for the Birth Satisfaction Scale-Revised for Pregnant Women 18 Years or Older who Received Nitrous Oxide only[a]

Item	M (*SD*)	Range
1. I came through childbirth virtually unharmed.	3.75 (*.52*)	2-4
2. I thought my labour was excessively long.*	3.32 (*1.02*)	1-4
3. The delivery room staff encouraged me to make decisions about how I wanted my birth to progress.	3.61 (*.79*)	1-4
4. I felt very anxious during my labour and birth.*	2.36 (*1.19*)	0-4
5. I felt well supported by staff during my labour and birth.	3.96 (*.19*)	3-4
6. The staff communicated well with me during labour.*	3.86 (*.36*)	3-4
7. I found giving birth a distressing experience.*	2.00 (*1.15*)	0-4
8. I felt out of control during my birth experience.*	2.46 (*1.17*)	0-4
9. I was not distressed at all during labour.	1.25 (*1.11*)	0-4
10. The delivery room was clean and hygienic.	3.96 (.19)	3-4

Note. Data were collected within six hours of the childbirth experience. [a]*n* = 28 participants. Scores for each item ranging from 1 (strongly agree) to 5 (strongly disagree) were recoded to align with instrument scoring criteria ranging from 0 (strongly disagree) to 4 (strongly agree). *Denotes reversed coding prior to scoring.

Table 16

Cumulative Item Scores for the Birth Satisfaction Scale-Revised for Pregnant Women 18 Years or Older who Received Epidural Analgesics[a]

Item	M (*SD*)	Range
1. I came through childbirth virtually unharmed.	3.36 (*1.03*)	1-4
2. I thought my labour was excessively long.*	2.93 (*1.27*)	0-4
3. The delivery room staff encouraged me to make decisions about how I wanted my birth to progress.	3.64 (*.68*)	2-4
4. I felt very anxious during my labour and birth.*	2.29 (*1.27*)	0-4
5. I felt well supported by staff during my labour and birth.	3.96 (*.19*)	3-4
6. The staff communicated well with me during labour.*	3.89 (*.31*)	3-4
7. I found giving birth a distressing experience.*	2.57 (*1.07*)	0-4
8. I felt out of control during my birth experience.*	3.21 (*.96*)	0-4
9. I was not distressed at all during labour.	1.36 (*1.19*)	0-4
10. The delivery room was clean and hygienic.	3.86 (.36)	3-4

Note. Data were collected within six hours of the childbirth experience. [a]*n* = 28 participants, including 2 participants who utilized nitrous oxide and epidural analgesics. Scores for each item ranging from 1 (strongly agree) to 5 (strongly disagree) were recoded to align with instrument scoring criteria ranging from 0 (strongly disagree) to 4 (strongly agree). *Denotes reversed coding prior to scoring.

Table 17

Cumulative Item Scores for the Birth Satisfaction Scale-Revised for Pregnant Women 18 Years or Older who Received No Analgesics[a]

Item	M (*SD*)	Range
1. I came through childbirth virtually unharmed.	3.57 (*.69*)	1-4
2. I thought my labour was excessively long.*	3.29 (*1.30*)	0-4
3. The delivery room staff encouraged me to make decisions about how I wanted my birth to progress.	3.46 (*.88*)	1-4
4. I felt very anxious during my labour and birth.*	2.64 (*1.37*)	0-4
5. I felt well supported by staff during my labour and birth.	3.71 (*.85*)	0-4
6. The staff communicated well with me during labour.*	3.50 (*1.17*)	0-4
7. I found giving birth a distressing experience.*	2.32 (*1.12*)	0-4
8. I felt out of control during my birth experience.*	2.82 (*1.28*)	0-4
9. I was not distressed at all during labour.	1.64 (*1.10*)	0-4
10. The delivery room was clean and hygienic.	3.79 (*.79*)	0-4

Note. Data were collected within six hours of the childbirth experience. [a]*n* = 28 participants. Scores for each item ranging from 1 (strongly agree) to 5 (strongly disagree) were recoded to align with instrument scoring criteria ranging from 0 (strongly disagree) to 4 (strongly agree). *Denotes reversed coding prior to scoring.

Total satisfaction scores group comparisons. Total satisfaction with the birth experience scores were also grouped by pain management method to allow for group comparisons. Descriptive statistics, including group means, standard deviation, and range, were calculated and greater satisfaction noted with higher mean scores reflective of greater satisfaction with the birth experience. Table 18 presents the total satisfaction scores for study participants based upon cumulative item scores from the Birth Satisfaction Scale-Revised.

Table 18

Total Satisfaction Scores for the Birth Satisfaction Scale-Revised for Pregnant Women 18 Years or Older who Experienced a Current Spontaneous Vaginal Birth[a]

Study Group	M (*SD*)	Range
Nitrous oxide and oxygen (50-50% mixture) group (*n* = 28)	30.54 (*4.29*)	21-40
Epidural analgesic group[b] (*n* = 28)	31.07 (*4.79*)	20-40
No analgesic group (*n* = 28)	30.75 (*5.63*)	15-39

Note. Data were collected within six hours of the childbirth experience. [a]*N* = 84, including women who used epidural analgesics (*n* = 28), nitrous oxide only (*n* = 28), or no analgesics (*n* = 28) during labor and birth. Two participants in the epidural analgesic group also received nitrous oxide prior to epidural conversion. Total satisfaction score possible for the Birth Satisfaction Scale-Revised = 40 with higher scores indicating greater satisfaction. Each item for the Birth Satisfaction Scale-Revised is scored from 'Strongly Agree' = 4 to 'Strongly Disagree' = 0, with reverse coding of items 2, 4, 7 and 8.

Specific Aim 4

To compare differences in comfort between women who used nitrous oxide, those who used epidural analgesics, and those who used no analgesics during labor and birth.

The differences in mean comfort scores for women who used nitrous oxide (*M* = 51.96, *SD* = 6.47, range = 38-62), epidural analgesics (*M* = 54.25, *SD* = 6.06, range = 39-66), or no analgesics (*M* = 53.64, *SD* 5.28, range = 36-64) during labor and birth were explored using one-way Analysis of Variance (ANOVA). The assumption of homogeneity of variance was met for comfort scores ($p = .19$) and the Wilks' lambda, noted as the *F* ratio, was used to report the significance of group mean differences. As shown below in Table 19, findings of the ANOVA analysis indicated there were no statistically significant differences in comfort for women who used nitrous oxide, epidural analgesics, or no analgesics during labor and birth ($F_{(2, 81)} = 1.11$, $p = .34$).

Table 19

Between-Subject Differences in Comfort for Pregnant Women 18 Years or Older who used Nitrous Oxide, Epidural Analgesics, or No Analgesics during Labor and Birth[a]

Variable	*M*	*SD*	*F-ratio*	*p*-value*
Nitrous Oxide Group (*n* = 28)	51.96	6.47	1.11	.34
Epidural Analgesic Group (*n* = 28)	54.25	6.06		
No Analgesic Group (*n* = 28)	53.64	5.28		

Note. *Significant group mean differences were determined at $p \leq 0.05$. [a]*N* = 84, including women who used epidural analgesics (*n* = 28), nitrous oxide only (*n* = 28), or no analgesics (*n* = 28) during labor and birth.

Given the ANOVA results did not suggest statistically significant group means differences for comfort, Ad hoc tests were not conducted to further examine differences across each pair of groups (Polit & Beck, 2017).

Significance of group mean differences. Analysis of Covariance (ANCOVA) was used as an extension of ANOVA (Leech et al., 2005) to test the significance of group mean differences for comfort after accounting for the following covariates of comfort described in the literature (Charles et al., 2016; Schuiling & Sampselle, 1999; Kolcaba, 2001): (1) parity/number of live births after 20 weeks gestation, (2) income and (3) education. The Wilks' lambda, noted as the *F*-ratio, was used to report the significance of group mean differences and eta squared computed to summarize the magnitude of the adjusted effect of the independent variable on the dependent variable (See Tables 20 and 21).

Table 20

Means, Adjusted Means, Standard Deviations and Standard Errors for Comfort for Pregnant Women 18 Years or Older who used Nitrous Oxide, Epidural Analgesics, or No Analgesics during Labor and Birth by Study Group[a]

Study Group	Mean (*SD*)	Estimated Marginal Mean	95% Confidence Interval	Standard Error
Nitrous Oxide Analgesic (*n* = 28)	51.96 (*6.47*)	52.67	[50, 54]	1.034
Epidural Analgesics (*n* = 28)	54.25 (*6.06*)	54.07	[52, 56]	1.025
No Analgesics (*n* = 28)	53.64 (*5.28)*	53.12	[51, 55]	1.025

Note. [a]*N* = 84. Significant group mean differences were determined at $p \leq 0.05$.

Table 21

Nitrous Oxide, Epidural Analgesics, and No Analgesics Group Mean Differences for Comfort after Accounting for Significant Covariate Variables[a]

Source	Type III SS	*df*	MS	*F*-ratio	*p*-value	Partial eta squared
Covariate						
Parity	122.30	1	122.30	4.21*	.04	.05
Income	232.72	1	232.72	8.01*	.01	.09
Education	58.41	1	58.41	2.01	.16	.03
Group[b]	28.05	2	14.03	.438	.62	.01
Error	2265.19	78	29.04			
R squared = .232	Adjusted R squared = .183					

Note. *Significant group mean differences were determined at $p \leq 0.05$. [a]Significant covariate variables accounted for within the ANCOVA analysis included education, income and parity/number of live births after 20 weeks gestation. [b]Group variable includes nitrous oxide analgesic (*n* = 28), epidural analgesics (*n* = 28), or no analgesics (*n* = 28).

As noted within the ANCOVA analysis, group mean differences for comfort were not found to be statistically significant across the study groups after accounting for the significant covariates of parity, income and education ($F_{(2,78)} = .438$; $p = .619$). Given the results of the between-group comparisons within the ANCOVA did not identify statistically significant group means differences for comfort, ad hoc tests were not

conducted to further examine differences across each pair of groups (Polit & Beck, 2017).

Specific Aim 5

To compare differences in satisfaction with the birth experience between women who used nitrous oxide, those who used epidural analgesics, and those who used no analgesics during labor and birth.

The differences in mean satisfaction scores for women who used nitrous oxide (*M* = 30.54, *SD* = 4.29, range = 21-40), epidural analgesics (*M* = 31.07, *SD* = 4.79, range = 20-40), or no analgesics (*M* = 30.75, *SD* 5.63, range 15-39) during labor and birth were explored using one-way Analysis of Variance (ANOVA). The assumption of homogeneity of variance was met for satisfaction scores ($p = .32$) and the Wilks' lambda, noted as the *F*-ratio, was used to report the significance of group mean differences. Findings of the ANOVA analysis indicated there were no statistically significant differences in satisfaction with the birth experience for women who used nitrous oxide, epidural analgesics, or no analgesics during labor and birth ($F_{(2, 81)} = .084$, $p = .92$; see Table 22).

Table 22

Between-Subject Differences in Satisfaction with the Birth Experience for Pregnant Women 18 Years or Older who used Nitrous Oxide, Epidural Analgesics, or No Analgesics during Labor and Birth[a]

Variable	*M*	*SD*	*F-ratio*	*p*-value*
Nitrous Oxide Group (*n* = 28)	30.54	4.29	.084	.92
Epidural Analgesic Group (*n* = 28)	31.07	4.79		
No Analgesic Group (*n* = 28)	30.75	5.63		

Note. *Significant group mean differences were determined at $p \leq 0.05$. [a]*N* = 84, including women who used epidural analgesics (*n* = 28), nitrous oxide only (*n* = 28), or no analgesics (*n* = 28) during labor and birth.

Given the ANOVA results did not suggest statistically significant group means differences for satisfaction with the birth experience, ad hoc tests were not conducted to further examine differences across each pair of groups (Polit & Beck, 2017).

Significance of group mean differences. Analysis of Covariance (ANCOVA) was used as an extension of ANOVA (Leech et al., 2005) to test the significance of group mean differences for satisfaction after accounting for the following predictors of satisfaction with the birth experience described in the literature (Charles et al., 2016; Schuiling & Sampselle, 1999; Kolcaba, 2001): (1) age, (2) income and (3) education. The Wilks' lambda, noted as the *F* ratio, was used to report the significance of group mean differences and eta squared was computed to summarize the magnitude of the adjusted effect of the independent variable on the dependent variable (See Tables 23 and 24).

Table 23

Means, Adjusted Means, Standard Deviations and Standard Errors for Satisfaction with the Birth Experience for Pregnant Women 18 Years or Older who used Nitrous Oxide, Epidural Analgesics, or No Analgesics during Labor and Birth by Study Group[a]

Study Group	Mean (*SD*)	Estimated Marginal Mean	95% Confidence Interval	Standard Error
Nitrous Oxide Analgesic (*n* = 28)	30.54 (*4.29*)	31.15	[29, 32]	.83
Epidural Analgesics (*n* = 28)	31.07 (*4.79*)	30.88	[29, 32]	.82
No Analgesics *(n* = 28)	30.75 (*5.63*)	30.32	[28, 31]	.82

Note. Significant group mean differences were determined at $p \leq 0.05$. [a]$N = 84$. Significant covariate variables accounted for within the ANCOVA analysis included education, income and parity/number of live births after 20 weeks gestation.

Table 24

Nitrous Oxide, Epidural Analgesics, and No Analgesics Group Mean Differences for Satisfaction with the Birth Experience after Accounting for Significant Covariate Variables[a]

Source	Type III SS	df	MS	*F*-ratio	*p*-value	Partial eta squared
Covariate						
Age	1.387	1	1.387	.075	.79	.00
Income	204.01	1	204.01	10.97*	.001	.12
Education	79.73	1	79.73	4.29*	.04	.05
Group[b]	9.60	2	4.80	.258	.77	.01
Error	1451.18	78	18.61			
R squared = .266	Adjusted R squared = .219					

Note. *Significant group mean differences were determined at $p \leq 0.05$. [a] $N = 84$. Significant covariate variables accounted for within the ANCOVA analysis included age, income and education. [b]Group variable includes nitrous oxide analgesic ($n = 28$), epidural analgesics ($n = 28$), or no analgesics ($n = 28$).

As noted within the ANCOVA analysis, group mean differences for satisfaction with the birth experience were not found to be statistically significant across the study groups after accounting for the significant covariates of age, income, and education ($F_{(2,78)} = .258$; $p = .77$). Given the results of the between-group comparisons within the ANCOVA did not suggest statistically significant group means differences for satisfaction with the birth experience, ad hoc tests were not conducted to further examine differences across each pair of groups (Polit & Beck, 2017).

Summary of Results

ANOVA analyses allowed for comparison of group mean scores for comfort, based upon the cumulative researcher-modified version of the Childbirth Comfort Questionnaire comfort score, and for satisfaction with the birth experience, based upon the total Birth Satisfaction Scale-Revised satisfaction score, across all three study groups (nitrous oxide only, epidural analgesics, and no analgesics). In summary, group mean differences for comfort and for satisfaction with the birth experience were not found to be

statistically significant across the study groups. The purpose of this study was to determine if comfort and satisfaction with birth experiences differed for women who used nitrous oxide compared to epidural analgesics or no analgesics during the labor and birth process.

CHAPTER V

DISCUSSION

The purpose of this study was to determine if comfort and satisfaction with birth experiences differed for women who used nitrous oxide compared to epidural analgesics or no analgesics during the labor and birth process.

The specific aims examined in this study were:

Aim 1. To determine the frequencies and frequency distributions of obstetric and mental health history characteristics, current pregnancy characteristics, analgesic use, and use of non-pharmacological methods for women age 18 years and older who experienced a current spontaneous vaginal birth.

Aim 2. To determine comfort experienced during labor and birth for women who received 1) nitrous oxide and oxygen (50-50% mixture) only, 2) epidural analgesics (may have been in combination with other analgesic options), or 3) no analgesics (control group).

Aim 3. To determine satisfaction with the birth experience for women who received: 1) nitrous oxide and oxygen (50-50% mixture) only, 2) epidural analgesics (may have been in combination with other analgesic options), or 3) no analgesics (control group).

Aim 4. To compare differences in comfort between women who used nitrous oxide, those who used epidural analgesics, and those who used no analgesics during labor and birth.

Aim 5. To compare differences in satisfaction with the birth experience between women who used nitrous oxide, those who used epidural analgesics, and those who used no analgesics during labor and birth.

The final chapter presents a summary of this study and important conclusions drawn from the data presented in Chapter IV, describes the study limitations, and provides an interpretation of major findings and their significance for nursing science, practice, policy and education.

Summary of the Study

The current study utilized a between-subjects comparative design, guided by Kolcaba's Theory of Comfort (2001), to determine if comfort and satisfaction with birth experiences differed for women who used nitrous oxide compared to epidural analgesics or no analgesics during the labor and birth process. A total of 84 women who had experienced spontaneous vaginal birth within the past six hours at one of three hospitals within an integrated health system completed all study procedures during the months of June 2019 and October 2019. Within the study sample, women were assigned to one of three study groups based upon self-selected analgesic option used during labor and birth including the following groups: 1) nitrous oxide and oxygen only, 2) epidural analgesics (may have been in combination with other analgesic options) or 3) no analgesics (control group).

A participant survey completed in the patient room within six hours of spontaneous vaginal birth and prior to postpartum opioid or other narcotic pain medication administration, allowed data collection to quantify comfort experienced during labor and birth based upon questions included within the researcher-modified and tested version of the Childbirth Comfort Questionnaire (Schuiling, 2002) described in detail in Chapter 3. Participant responses regarding satisfaction with the birth experience were also obtained within the participant survey and quantified using the reliable and valid Birth Satisfaction Scale-Revised (Hollins Martin & Martin, 2014). Comparison of differences in comfort and in satisfaction with the birth experience for women who received 1). nitrous oxide and oxygen (50-50% mixture) only, 2). epidural analgesics (may be in combination with other analgesic options), or 3). no analgesics (control group)

was possible utilizing the ANOVA analysis. Discussion and interpretation of the significance of the findings of the current study are provided in the following section.

Major Findings

Frequency of Sample Characteristics Relevant to Comfort and Satisfaction

The first aim of this study examined the frequencies and frequency distributions of obstetric and mental health history characteristics, current pregnancy characteristics, analgesic use, and use of non-pharmacological methods for women age 18 years and older who experienced a current spontaneous vaginal birth.

Prior birth experiences. Prior birth experience, or parity, was identified in the literature as a factor influencing women's satisfaction with the birth experience, particularly if the woman previously experienced stress during labor and birth such as: 1) perceived or actual distress during labor, 2) an obstetric injury, 3) perceived insufficient medical care, 4) undesired obstetric intervention, 5) uncontrolled pain, 6) long labor duration, or 7) concerns for the health of baby (Barbosa-Leiker et al., 2015; Bertucci et al., 2012; Charles et al., 2016; Dammer et al., 2014; Declercq et al., 2014; Duale, 2015; Fleming et al., 2016; Hodnett, 2002; Hollins Martin & Martin, 2014; Lewis et al., 2016; Mazurenko et al., 2017; Pasha et al., 2012; Richardson et al., 2017b). In the current study 23 participants experienced a first-time pregnancy (n = 23, 27%), 27 experienced their second pregnancy (n = 27; 32%), and the remaining 34 participants had experienced 2 or more prior pregnancies (n = 34, 41%). While diligent efforts were made in the current study to exclude women who had prior stressful birth experiences based upon established exclusion criteria, it is possible prior birth experiences of study participants influenced

their current satisfaction with the birth experience rather than the presence or absence of analgesic use alone.

Personal attributes. In addition to prior birth experiences, the woman's personal attributes brought to the birth experience such as the ability to cope during labor, feeling in control, preparation for childbirth, and relationship with the baby were described in the literature as significant factors affecting comfort associated with labor and birth and satisfaction with the birth experience (Charles et al., 2016; Chuntharapat et al., 2008; Hollins Martin & Martin, 2014; Koehn, 2000; Kolcaba, 2001; Morse, 1994; Schuiling, 2003; Schuiling & Sampselle, 1999; Tomey & Alligood, 2006). In this study, nearly half of the pregnant women (n = 39, 46%) who experienced a current spontaneous vaginal birth had never attended a childbirth preparation class, and the remaining majority reported childbirth preparation class attendance during a past pregnancy (n = 28, 33%). Given only 17 of 84 (20%) pregnant women in this study had current pregnancy childbirth preparation class experiences the majority relied upon prior knowledge or experiences, alternative sources of information, and/or available support persons to identify and utilize comfort strategies during labor and birth experiences. This is an important finding for nurses providing labor and birth care to consider given the strong influences of personal expectations, caregiver support, quality of caregiver-patient relationship, and involvement in decision-making on women's perceptions of the labor and birth experience and satisfaction (Hodnett, 2002).

Support from caregivers. Continuous support from caregivers across the labor and birth experience to improve comfort, emotional support, information sharing and advocacy was identified in the literature as a significant factor affecting satisfaction with

the birth experience (Barbosa-Leiker et al., 2015; Hollins Martin & Martin, 2014; Lewis et al., 2016; Richardson et al., 2017b). Specific to support persons utilized by current study participants, most women reported the presence of their spouse (n = 55, 65.5%) or significant other (n = 12, 14.3%) as their only support person during labor and/or birth with three participants reporting additional support provided by a doula in addition to their spouse, significant other, and/or friend. Such support provided by caregivers during labor and birth was an important consideration for the current study given the potential influence of caregiver support on the woman's comfort and satisfaction with her birth experience regardless of the analgesic option chosen for use during labor and birth. The findings of this study suggest women may rely upon a variety of sources of comfort and to promote satisfaction with the birth experience.

Anxiety or psychiatric disorders. Kohen (2000) described anxiety as a potential contributor to increased pain and decreased comfort during labor and birth often resulting from fear of pain, fear of loss of control, concerns related to safety for both herself and her child, noise, and unfamiliarity of the environment. Further, a woman's feeling of being in control, her ability to cope with her labor, and her perception of being treated with respect across the labor and birth experience were noted as contributors to the woman's satisfaction with her birth experience (Barbosa-Leiker et al., 2015; Richardson et al., 2017b; Schuiling, 2003). Considering these findings, the presence or absence of an anxiety or psychiatric disorder during pregnancy has the potential to influence the woman's comfort experienced during labor and birth and her satisfaction with the birth experience.

While the majority of study participants reported no history of anxiety or psychiatric disorders (*n* = 64; 76.2%), an important study finding relates to the number of study participants who had a current anxiety or psychiatric disorder diagnosis not requiring medication or treatment during the current pregnancy, identified through self-report by study participants and verified within electronic health record review. Given 11 study participants (*n* = 11; 13.1%) had a current anxiety disorder diagnosis and an additional six participants had current diagnoses of both anxiety and depressive disorders (*n* = 6; 7.1%), the potential influence of past and/or current anxiety or psychiatric disorders on comfort and satisfaction with the birth experience for women who used nitrous oxide, epidural analgesics or no analgesics during labor and birth cannot be overlooked. Because holistic comfort is experienced when all needs or desires are met in the domains of the body, mind and spirit (Schuiling & Sampselle, 1999) and comfort in the mind domain occurs when the individual has piece of mind, a sense of security, or freedom from anxiety (Koehn, 2000), participant variations regarding history or current anxiety or psychiatric disorders and the potential influence these disorders have on the woman's self-report of comfort and satisfaction with the birth experience are important considerations when applying the current study findings within clinical practice and future research studies.

Non-pharmacological methods considerations. Additional considerations with potential influence on the woman's self-report of comfort and satisfaction with the birth experience relate to the use of non-pharmacological methods during labor and birth. While it is difficult to determine the exact influence of the self-selected non-pharmacological methods on comfort and satisfaction with the birth experience, use of

non-pharmacologic methods, prior to or in conjunction with analgesics may result in less total analgesic use and greater comfort and satisfaction with the birth experience (Schuiling, 2003). The current study participants utilized a variety of non-pharmacological methods during labor and birth, identified by participant self-report and confirmed by EHR documentation. Focused/paced breathing was the most frequently utilized non-pharmacological method for participants in both the nitrous oxide only (*n*=17; 61%) and no analgesic (*n*=19; 68%) study groups, and hydrotherapy/whirlpool tub use and exercise/walking were consistently noted across all three study groups as the top three most frequently utilized non-pharmacological methods (epidural group: exercise/walking *n* = 15, 54% and hydrotherapy/whirlpool tub *n* = 12, 43%; nitrous oxide group: exercise/walking *n* = 10, 36% and hydrotherapy/whirlpool tub *n* = 12, 43%; no analgesic group: both exercise/walking and hydrotherapy/whirlpool tub *n* = 12, 43%). Further, given the theorized actions of non-pharmacologic methods including inhibiting transmission of pain fibers, reducing whole body pain via the endorphinergic system, and controlling the mind through attention deviation (Markley & Rollins, 2017), the potential influence of various non-pharmacological methods on participant report of comfort and satisfaction with the birth experience must be considered.

Comfort Experienced during Labor and Birth

The second aim of this study evaluated comfort during labor and birth for women who received nitrous oxide, epidural analgesics, or no analgesics. As Schuiling (2003) found, women in the current study identified comfort as present during their labor and birth experience. Further, the cumulative comfort scores varied only slightly across groups for the current study regardless of the particular analgesic option used during

labor and birth. This finding was similar to that of Schuiling (2003) who found women's level of comfort changed very little over the course of labor regardless of intervention used. The presence of subtle changes in comfort scores despite use of different comfort measures in the current study also noted by Schuiling (2003).

Comfort in the presence of analgesics. Mean comfort scores from the researcher-modified version of the Childbirth Comfort Questionnaire varied only slightly between the nitrous oxide and epidural analgesic groups (M = 51.96; SD 6.47 and M = 54.25; SD 6.06, respectively). These findings are consistent with that of Schuiling (2003) who found, while pain scores of women receiving epidural analgesics fell dramatically across labor, comfort scores for women who received epidural analgesics did not change significantly. The current study findings provide evidence to further the science of the concept of comfort rather than pain intensity alone particularly for women who use various analgesic options during labor and birth, and provide insight regarding the effects of the analgesic option on promoting comfort rather than on pain reduction alone. In addition, like Schuiling (2003), the findings of this study support the need for further research examining the relationship between comfort and pain, and consideration of pain and comfort as phenomenon possible to coexist (Charles et al., 2016).

Comfort in the absence of analgesics. Interestingly, comfort scores for women who used no pain medication were similar to those who used nitrous oxide or epidural analgesics (nitrous oxide group, M = 51.96, SD = 6.47, range = 38-62; epidural analgesics group, M = 54.25, SD = 6.06, range = 39-66 ; no analgesics group, M = 53.64, SD 5.28, range = 36-64). Possible physiologic explanation exists regarding the similarities of mean comfort scores for the no analgesic group compared to those who received pharmacologic

analgesic methods given the natural endorphin response occurring when sensory stimulation is altered utilizing various comfort measures during labor and birth (Darra & Murphy, 2016; Hadley, 2000). Opiate-like activity of endorphins, generated within the brain and pituitary gland, along with the effects of the endogenous opioids, beta-endorphin and the peptide enkephalin also produced within the pituitary, allow for a natural analgesic response from the woman's own body during labor and birth (Cahill, 1989; Hadley, 2000) resulting in a blunting rather than obliterating effect on labor pain (Schuiling & Sampselle, 1999). Further, the natural effects of increased beta-endorphins on decreasing labor pain (Bacigalupo, Sabine, Rosendahl & Saling, 1990; Chan et al., 1993; Darra & Murphy, 2016; Hadley, 2000) and the coexistence of comfort and pain during labor (Charles et al., 2016) may have resulted in a positive effect of these natural hormones to increase maternal comfort in the absence of analgesic use during labor and birth.

Factors influencing comfort. Study of the concept of comfort experienced during labor and birth is limited in extant literature with no prior studies identified that reported measurement of comfort experienced by women who used intrapartum nitrous oxide. Findings from two research reports were identified with relevance to the current study. One study used a randomized clinical trial design to explore the effects of the non-pharmacologic intervention of Yoga on comfort scores in 74 primigravid Thai women (Chuntharapat et al., 2008) and the other was a quasi-experimental study to determine the effect of prenatal comfort education on comfort and pain scores (Garlock et al., 2017) during labor and birth. Chuntharapat et al. (2008) utilized a randomized clinical trial design, to study the effect of Yoga on comfort experienced by 74 primigravid Thai

women, beginning with prenatal classes inclusive of Yoga practices to be used across pregnancy and throughout labor and birth. While Chuntharapat et al. (2008) found higher levels of maternal comfort for the Yoga intervention group across labor and 2 hours after birth, Garlock et al. (2017) found no significant difference in maternal comfort scores for the participants in the intervention group who received comfort education and the control group. There is some initial evidence to support utilization of the non-pharmacologic method of Yoga during labor and birth. In the current study, participants utilized a variety of different self-selected non-pharmacologic methods and had varied prenatal care and prenatal education experiences. Therefore, it is difficult to draw any conclusions regarding the role of non-pharmacologic methods used and prenatal education received by participants in the current study on reported comfort scores.

Variations in comfort may exist due to the influence of other factors, such as, demographics, current and past birth experiences or events, caregiver support provided during labor and birth, and the patient-caregiver relationship (Charles et al., 2016; Chuntharapat et al., 2008; Koehn, 2000; Kolcaba, 2001; Schuiling, 2003; Schuiling & Sampselle, 1999) regardless of analgesic use during labor and birth. However, between-group comparisons of mean comfort scores in the current study, while controlling for significant covariates of comfort including (1) parity/number of live births after 20 weeks gestation, (2) income and (3) education, did not suggest statistically significant group mean differences for comfort. While the findings of the current study suggest little variation in comfort for women who use nitrous oxide, epidural analgesics, or no analgesics during labor and birth, further study of comfort experienced by women during labor and birth with consideration of the various non-pharmacological methods, prenatal

education experiences, and other influential factors is necessary to determine the effect of each of these considerations on women's comfort during labor and birth experiences.

Satisfaction with the Birth Experience

The third aim of this study evaluated satisfaction with the birth experience for women who received nitrous oxide, epidural analgesics, or no analgesics. Satisfaction with the birth experience was similar for all study participants regardless of analgesic option used. Total satisfaction scores for the Birth Satisfaction Scale-Revised ranged from 15 to 40, of 40 possible points, with a mean score of 30.79 (*SD* 4.88, *n* =84). Specific to each study group, the satisfaction scores for the nitrous oxide group ranged from 21-40 (*M* = 30.54; *SD* 4.29; *n* = 28); for the epidural analgesic group (including 2 participants who also received nitrous oxide prior to epidural conversion) ranged from 20-40 (*M* = 31.07; *SD* 4.79; *n* = 28); and for the no analgesic group ranged from 15-39 (*M* = 30.75; *SD* = 5.63; *n* = 28).

The total satisfaction scores varied only slightly for the current study regardless of analgesic option used during labor and birth. Similarities in total satisfaction scores across the study groups align with the belief that many factors beyond pain control directly influence the woman's overall satisfaction with the birth experience (Camann, 2017). Further, the findings of a systematic review of 137 research reports by Hodnett (2002) examining factors influencing women's satisfaction with their childbirth experiences identified four factors more important than pain, pain relief, and intrapartum medical interventions on subsequent satisfaction including: 1) personal expectations; 2) amount of caregiver support; 3) quality of caregiver-patient relationship; and 4) involvement in decision making. Consideration of each of these four factors was

important when examining the total satisfaction scores of study participants. Given the chosen reliable and valid Birth Satisfaction Scale-Revised instrument utilized in the current study measured satisfaction with the birth experience using 10 Likert-style questions reflective of three subscale areas: 1) quality of care provision; 2) women's personal attributes; and 3) stress experienced during labor, examination of participant satisfaction was possible utilizing questions aligned with the four factors as identified by Hodnett (2002) as influencing women's satisfaction with their childbirth experiences. Major findings of satisfaction with the birth experience for study participants based upon the total satisfaction score utilizing the Birth Satisfaction Scale-Revised will be described in the following sections.

Satisfaction in the presence of analgesics. Mean total satisfaction scores for the Birth Satisfaction Scale-Revised varied only slightly for the nitrous oxide and epidural analgesic groups (M = 30.54; SD 4.29 and M = 31.07; SD 4.79, respectively), and the range of scores for both groups were nearly identical (nitrous oxide group range 21-40; epidural group range 20-40). Similarities in satisfaction with the birth experience identified in the current study mirror the findings of Richardson et al. (2017b) who found women who used nitrous oxide alone were as likely to express satisfaction as those who received neuraxial analgesics despite less likelihood to report excellent analgesia with nitrous oxide use alone. Additional studies have consistently reported participant satisfaction with nitrous oxide use during labor and birth (Attar et al., 2016; Dammer et al., 2014; Parsa, 2017; Pasha et al., 2012; Pita et al., 2012), often through participant verbal report of satisfaction with yes/no responses and expressed likelihood of future use. However, it is important to note the absence of prior studies identified in the literature

reporting use of an instrument with established reliability and validity to measure satisfaction when nitrous oxide is used during labor and birth. Further, while various studies have reported participant satisfaction with epidural analgesics (Atienzar et al., 2008; Bang et al., 2012; Cooper et al., 2010; Haydon et al., 2011; Howell & Concato, 2004; Koyyalamundi et al., 2016; Salim et al., 2005; Vetter, Ivankova, & Pittet, 2013); Duale et al. (2015) within a systematic review of 116 articles reporting maternal satisfaction as an outcome criterion on analgesia for labor, identified only one study reporting use of a validated questionnaire to assess maternal satisfaction after neuraxial blockade for labor analgesia. Findings from the current study provided evidence regarding satisfaction with the birth experience with data obtained from a reliable and valid instrument.

Satisfaction in the absence of analgesics. Satisfaction with the birth experience in the absence of analgesics was evident in the current study given the similarities in mean total satisfaction scores of the Birth Satisfaction Scale-Revised for participants for the no analgesic group (M = 30.75; SD = 5.63; n = 28) compared to the nitrous oxide (M = 30.54; SD 4.29; n = 28) and epidural analgesics (M = 31.07; SD 4.79; n = 28) groups. Some researchers have concluded satisfaction may be higher in women who choose to utilize non-pharmacologic methods during labor and birth without analgesics. Czech et al. (2018) who found women who used non-pharmacologic methods alone during labor and birth had higher satisfaction compared to those who used epidural analgesics with highest satisfaction reported by women who used water immersion. However, satisfaction with the chosen pain management technique within this study was assessed by measuring the likelihood of future use of the technique (Czech et al., 2018). The finding that

satisfaction is higher for women in the absence of analgesics supports the multidimensional nature of the concept of satisfaction involving a positive attitude, an affective response to the experience, and a cognitive evaluation of the emotional response (Hodnett, 2002) useful when applying the current study findings to clinical practice and future research.

Differences in Comfort by Analgesic Option

The fourth aim of this study sought to compare differences in comfort between women who used nitrous oxide, those who used epidural analgesics, and those who used no analgesics during labor and birth. ANOVA analyses allowed for comparison of group means across the study groups. Findings of the ANOVA analyses revealed no statistically significant differences in comfort across the three study groups ($F_{(2, 81)} = 1.11$, $p = .34$).

Similar to the findings of Schuiling (2003), the absence of differences in comfort across the three study groups in the current study may be related to the woman's active efforts to maintain her own level of comfort across the labor and birth experience. For example, the woman may have asked for additional support from a significant other, or other support person, in the form of a backrub, may have changed her position spontaneously or with assistance, or may have utilized available pharmacological or other non-pharmacological interventions. In keeping the woman as the center of the childbirth experience, a focus on fostering her locus of control across the labor and birth experience while providing one-to-one support by nurses, maternity care providers and/or other labor support persons likely had a direct effect on the level of comfort experienced by the woman despite the analgesic option used during labor and birth (Charles et al., 2016). When comfort measures are provided by nurses to women during labor and birth a

strengthening experience is facilitated even though the woman may remain uncomfortable. Ordinary abilities to cope are enhanced through the nurse-patient relationship, patient potential, or extraordinary performance; thus, allowing for feelings of ease and relief, and elimination of preoccupation with labor pain and associated discomforts leading to transcendence (Kolcaba, 1991). As a result, further research is warranted examining women's comfort during labor and birth, particularly related to the woman's own efforts to maintain her comfort across the labor and birth experience and the effect of comfort interventions provided by the nurse across the labor and birth experience to promote the woman's comfort.

An additional consideration relates to the multiple contexts of comfort for which nurses, maternity care providers, and other support persons provide comfort interventions. When nurses are committed to providing holistic comfort, incorporation of interventions in the physical, psychospiritual, social, and environmental contexts routinely occur to promote comfort during labor and birth. As described by Kolcaba and DiMarco (2005), nurses move back and forth among these contexts of comfort with the ultimate goal to promote transcendence through promotion of relief and ease while eliminating the woman's preoccupation with her pain or other discomforts of labor (Kolcaba, 1991). However, determining the exact interventions needed at the time given the context of need is of utmost importance. Use of the researcher-modified version of the Childbirth Comfort Questionnaire to measure comfort experienced by women during labor and birth in the current study allowed for reliable and valid measurement of comfort across all four contexts of comfort.

Differences in Satisfaction with the Birth Experience by Analgesic Option

The fifth aim of this study sought to compare differences in satisfaction with the birth experience between women who used nitrous oxide, those who used epidural analgesics, and those who used no analgesics during labor and birth. Comparison of group mean scores within ANOVA analyses for the current study revealed group mean differences for satisfaction with the birth experience were not statistically significant across the three study groups ($F_{(2, 81)} = .084$, $p = .92$).

Measurement of Satisfaction. Satisfaction with nitrous oxide, epidural analgesics, and use of no analgesics during labor and birth has been reported in the literature. However, findings from studies examining the outcome of satisfaction with the birth experience utilizing reliable and valid instruments was not found for studies exploring intrapartum nitrous oxide use and only one study exploring epidural analgesics during labor and birth reported measurement of satisfaction using a reliable and valid instrument (Duale et al., 2015). Satisfaction was reported in prior studies as having been measured based upon likelihood of future use or the level of satisfaction reported based upon a 5-point Likert scale of strongly agree to strongly disagree. Given satisfaction is a multidimensional concept, simple report of satisfaction in this manner does not capture the multitude of considerations necessary when exploring this concept. Report of satisfaction based upon the Birth Satisfaction Scale-Revised in the current study allowed for capture of participant experiences across the multiple dimensions of satisfaction utilizing a reliable and valid instrument lending support for the current study findings of similarities in women's satisfaction with the birth experience no matter the chosen analgesic option.

Factors influencing satisfaction with the birth experience. Regaining self-control, ability to focus and think, participation during labor and birth and involvement in decision-making, preservation of bodily sensations, mobility and strength, personal attributes and expectations, caregiver support, quality of care and the caregiver-patient relationship, and stress experienced during labor are described in the literature as primary factors influencing satisfaction with the birth experience. (Fleming et al., 2016; Hodnett, 2002; Lewis et al., 2016; Richardson et al., 2017b). Use of the Birth Satisfaction Scale-Revised in the current study to measure participant satisfaction with the birth experience allowed for measurement of similar influencing factors and quantification of total satisfaction scores for women who used nitrous oxide, epidural analgesics, or no analgesics during labor and birth. Further, between-group comparisons of mean satisfaction scores in the current study, while controlling for significant covariates of satisfaction including (1) age, (2) income and (3) education, did not suggest statistically significant group mean differences for satisfaction. While findings of the current study suggest there are no significant differences in satisfaction with the birth experience for women regardless of analgesic option used during labor and birth, continued study of satisfaction with the birth experience for women who use various pharmacologic and non-pharmacologic methods with close investigation of each of the mentioned primary influencing factors is necessary to determine the effect of these influencing factors on satisfaction with the birth experience for women who use varied analgesic options.

Given the absence of statistically significant differences in mean satisfaction scores across the three study groups, the current study findings suggest the chosen analgesic option was not a primary factor influencing a woman's satisfaction with the

birth experience. Further, similarities in the mean satisfaction scores regardless of the analgesic option used during labor and birth support the need for focused attention of nurses and maternity care providers on promoting satisfaction utilizing a multidimensional approach rather than with focus on pain relief alone (Carter et al., 2010; Hodnett, 2002; Mazurenko et al., 2017; Richardson et al., 2017b).

Aligning nursing care with the woman's personal expectations, encouraging involvement of her spouse, significant other, or other caregivers across labor and birth, establishing quality nurse-patient relationships, and actively involving the woman in decision-making throughout the childbirth experience are all essential interventions to provide nursing care across the multiple dimensions of satisfaction (Hodnett, 2002). Further, satisfaction with the birth experience can be promoted by incorporating specific interventions focused on promoting comfort and holistic care rather than on pain management alone. When comfort is used as a model of care during labor and birth, the physiologic process of childbirth is supported while decreasing pain and producing a synergistic effect on the woman's health, pregnancy and birth (Schuiling, 2003). With focus on individual, different, and unique outcomes for each woman and birth, holistic care is realized, and greater satisfaction with health care, engagement in health-seeking behaviors, and improved health-related outcomes result when comfort care is provided (Kolcaba, 2001). Further, satisfaction of patients, families, and nurses with the health care institution results in public acknowledgement about the institution's contributions to health care which is integral to institutional integrity (McEwen & Wills, 2014). This study highlights the need for nursing care to be focused on the multiple dimensions of

satisfaction regardless of analgesic option used during labor and birth in order to promote high levels of satisfaction with the birth experience.

This was the first study to report no significant difference in satisfaction with the birth experience among women who used nitrous oxide, epidural analgesics, or no analgesics during labor and birth. The finding of no significant differences in satisfaction between the three groups suggests the use of nitrous oxide as an intrapartum analgesic option does not negatively impact satisfaction with the birth experience despite pain relief differences. Studies of satisfaction when nitrous oxide is used during labor and birth have shown maternal satisfaction extends beyond analgesic effects alone with report of positive patient experiences in response to intrapartum nitrous oxide use (Agah et al., 2014; Attar et al., 2016; Pasha et al., 2012; Pita et al., 2012; Richardson et al., 2017b). The findings of the current study support the inclusion of intrapartum nitrous oxide as an analgesic option that assists in efforts to minimize adverse effects, foster holistic care, and promote satisfaction with the birth experience.

While awareness of pain may still exist in the presence of nitrous oxide use, relaxation, a sense of control, and reduced perception of pain are all possible when nitrous oxide is used for labor analgesia (Rooks, 2011). In addition, immediate availability and bedside administration (Dammer et al., 2014; Kester, 2014) possible with intrapartum nitrous oxide use enables the nurses to provide safe (Rooks 2007; Rooks, 2011) and quick pain relief especially helpful for women experiencing rapid progression of their labor or when other pain relief options are delayed or unavailable (Kester, 2014). Further, cost-effectiveness of intrapartum nitrous oxide use compared to epidural analgesics may be improved since the cost of nitrous oxide is primarily associated with

the disposable supplies (estimated at $20) and purchase of the re-usable delivery device (approximately $5000 per device). In addition, other cost savings associated nitrous oxide use relate to the long-life expectancy of the delivery device and presumed lower personnel costs for administration compared to epidural analgesics (Richardson et al., 2017b). Altered pain awareness, reduced anxiety and fear, immediate availability and administration, and cost effectiveness are all potential benefits of intrapartum nitrous oxide use relevant to strategies for minimizing adverse effects, fostering holistic care, and promoting satisfaction with the birth experience.

Important factors must be considered when examining the similarities in satisfaction scores for women who used epidural analgesics compared to those who used nitrous oxide for analgesia in the current study. While initial perceptions of nurses and maternity care providers may include thoughts of a woman experiencing greater satisfaction with the birth experience when epidural analgesics are used, unlike epidural analgesics, nitrous oxide is not associated with maternal fever, prolonged second stage of labor, or increased incidence of occiput-posterior position of the fetus at birth which can all impact the incidence of cesarean delivery or vacuum or forceps-assisted vaginal delivery and can be associated third and fourth degree lacerations (Rooks, 2007). Further, similarities in satisfaction with the birth experience for women who use nitrous oxide compared to epidural analgesics for labor analgesia may exist given active participation, self-control, preservation of mobility and strength, and shared decision-making are all possible for women who use nitrous oxide during labor and birth (Collins, 2016; Likis et al., 2014; Rooks, 2012) and may be less likely for women who use epidural analgesics. Given these important considerations, the current study findings provide evidence to

inform nurses and maternity care providers regarding the similarities in the woman's satisfaction with the birth experience despite use of either nitrous oxide or epidural analgesics.

Study Limitations

Thoughtful consideration was given to the design of this study, including efforts to identify and minimize potential study limitations. While the non-experimental study design limited the causal inferences that could be drawn from the study findings, the between-subjects comparative design allowed for exposure of each study group to a different independent variable and comparison of the dependent variables on each independent variable.

Given the inability to objectively verify participant responses provided utilizing self-report measurement tools, a limitation may exist if participants over or under reported their experiences of comfort during labor and birth and overall satisfaction with the birth experience, if they experienced recall bias, or if they chose answers based upon their perception of social desirability for survey responses (Polit & Beck, 2017). However, given the concepts of study were personally experienced by the study participants and the diligent efforts of the researcher and nurse-research assistants to survey participants within six hours of childbirth, the limitation of self-report was minimized. Further, the self-report measures chosen for this study were validated in previous studies of women during and/or following childbirth experiences, which also helped to minimize this potential limitation.

Although women in the study sample were limited to the Midwestern region of the United States, the multi-site design of this study strengthens the validity of findings

because survey results represent women who underwent labor and birth experiences in three separate Midwestern hospitals within an integrated health system during a five-month period. In addition, due to the population limitations and nature of the population in the study site region, the sample lacked cultural diversity with the majority of study participants in the current study of White race. Further, participation in this study required fluency with the English language. Therefore, some otherwise eligible women may have been excluded from participation in the study. However, of the 812 participants excluded from study participation for the current study, less than one percent (n = 7; 0.9%) were excluded for a lack of fluency with the English language.

In addition, use of the researcher-modified version of the Childbirth Comfort Questionnaire for this study presented a limitation given reliability and validity of this instrument had not been established prior to this study. This limitation was minimized through evaluation of the reliability and validity of the modified instrument within a pilot study described in Chapter III.

Summary and Conclusions

This between-subjective comparative study expands the limited scientific knowledge of the effects of intrapartum nitrous oxide use on women's comfort and satisfaction. The results provide: 1). a determination regarding the frequencies and frequency distributions of obstetric and mental health history characteristics, current pregnancy characteristics, analgesic use, and use of non-pharmacological methods for women age 18 years and older who experienced a current spontaneous vaginal birth; 2) a determination regarding comfort experienced during labor and birth for women who received 1) nitrous oxide and oxygen (50-50% mixture) only, 2) epidural analgesics (may

have been in combination with other analgesic options), or 3) no analgesics (control group); 3) a determination regarding satisfaction with the birth experience for women who received: 1) nitrous oxide and oxygen (50-50% mixture) only, 2) epidural analgesics (may have been in combination with other analgesic options), or 3) no analgesics (control group); 4) a comparison of comfort experienced by women who used nitrous oxide compared to epidural analgesics or no analgesics during labor and birth; and 5) a comparison of satisfaction with the birth experience for women who used nitrous oxide compared to epidural analgesics or no analgesics during labor and birth. Further, the results from this study contribute to the evidence base regarding reliable and valid measurement of comfort and satisfaction with the birth experience for women who use nitrous oxide during labor and birth.

Kolcaba's Theory of Comfort provided an excellent framework upon which to base study of women's comfort and satisfaction when nitrous oxide is used during labor and birth. Nurses meet the patient's unmet needs for comfort during stressful health care situations and successful nursing interventions focused on enhancing comfort lead patients to engage in health-seeking behaviors (Kolcaba, 2001). When nurses intentionally focus on enhancing comfort, unmet patient needs are identified and interventions designed to address these needs to enhance comfort. In addition, active engagement in health-seeking behaviors and shared decision-making regarding patient and institutional outcomes directly relate to patient satisfaction with health care. Further, a core foundation of the Theory of Comfort is whole person holism, which includes manipulation of the surrounding environment by nurses to enhance patient comfort and

accommodate a blending of nursing and patient energy fields during therapeutic interventions (Kolcaba, 2001).

Rooted in the traditions of nursing practice, the theoretical concepts of the Theory of Comfort (Kolcaba, 2001) are described as humanistic, needs-related, and holistic and relate the relationship of institutional outcomes to nursing practice with emphasis on ensuring nursing actions are visible, essential, and promote soundness of the health care institution (Kim, 1999). The Theory of Comfort (Kolcaba, 2001) had direct relevance to the current study of comfort and satisfaction with the birth experience given women often perceive the labor experience as a stressful health care situation during which support from the bedside Registered Nurse (RN) is needed to meet their comfort care needs. Further, use of nitrous oxide as a comfort intervention, supported and guided by the nurse, promotes strength and motivation for the woman to meet her own comfort needs fostering enhanced satisfaction and improved patient and institutional outcomes. Further, upon initiation of care, the nurse partners to determine the woman's comfort care needs and takes action to design and implement mutually agreeable comfort interventions.

With active participation and shared decision-making, the woman is motivated to engage in health-seeking behaviors. Comfort interventions provide strength for the woman to remain involved and promote satisfaction with her birth experience. Achievement of comfort for the woman during labor and birth is an active endeavor as the woman and the nurse partner in response to various stimuli often manipulating the surrounding environment. Through this partnership and active engagement, the woman's comfort needs are met thus promoting institutional integrity (patient satisfaction). Application of the Theory of Comfort to explore nitrous oxide use as an intrapartum

comfort care intervention provided a foundation upon which to generate new nursing knowledge for the current study.

Significance for Nursing Science, Practice, Policy, and Education

Based upon study findings and conclusions, the significance and associated recommendations are provided for nursing science, practice, policy, and education in the following section.

Significance for nursing science. This study contributes to the growing evidence regarding the differences in comfort and satisfaction with the birth experience for women who used nitrous oxide compared to epidural analgesics or no analgesics during the labor and birth process. In addition, this study was the first to quantify women's satisfaction with the birth experience when nitrous oxide is used during labor and birth using a validated satisfaction instrument and no prior studies were found in the literature that directly examined comfort during labor and birth when nitrous oxide is used for labor analgesia. Further, this study was the first to examine both comfort and satisfaction in the context of nitrous oxide use as a labor and birth analgesic. Future research is needed to expand the understanding of women's comfort and satisfaction with the birth experience when nitrous oxide is used during labor and birth to further support application of the current study findings to practice.

Nurses who provide labor and birth nursing care must be actively involved in the generation and dissemination of new knowledge. Given that nurses provide 1:1 care to women across the labor and birth experience they are in a key position to recognize necessary areas of further study specific to pharmacological and non-pharmacological methods utilized during labor and birth and in promoting women's comfort and

satisfaction with the birth experience. Research questions regarding the effects of intrapartum nitrous oxide use on women's comfort and satisfaction with the birth experience were formulated based upon 1:1 care provided to women across the labor and birth experience by the researcher.

Additional research is needed for in-depth study of the patient experiences specific to comfort and satisfaction with the birth experience. Triangulation of qualitative studies of comfort and satisfaction with the birth experience with quantitative studies that use the researcher-modified version of the Childbirth Comfort Questionnaire and the Birth Satisfaction Scale-Revised would allow for validation of the researcher-modified version of the Childbirth Comfort Questionnaire in measuring comfort during labor and birth and allow for greater explanation of women's comfort and satisfaction experienced during labor and birth. Within the current study, qualitative data provided by study participants following survey completion was not captured given the quantitative study design. However, participants freely spoke of their experiences immediately following survey completion and demonstrated a willingness to share associated experiences with the researcher or nurse-research assistant. Future study to determine if comfort and satisfaction with birth experiences differ for women who use nitrous oxide compared to epidural analgesics or no analgesics during labor and birth should include a mixed-method study design.

In addition, an intervention study over a longer study period, including a larger sample size, and utilizing a standardized comfort-enhancing childbirth education intervention may elicit more useful information. Further, standardization of teaching to all women who are anticipating a vaginal birth should be provided in the clinic setting

during a third trimester visit, during childbirth preparation classes, and upon admission to the hospital for anticipated childbirth. The influence of teaching and learning on comfort and satisfaction with the birth experience following use of pharmacological and/or nonpharmacological pain management methods should be studied and the results utilized to improve future education provided to pregnant women prior to childbirth. Inclusion of a larger sample size in a future study would also allow for further validation of the researcher-modified version of the Childbirth Comfort Questionnaire to measure comfort and the Birth Satisfaction Scale-Revised to measure satisfaction with the birth experience when nitrous oxide, epidural analgesics, and no analgesics are used during labor and birth.

Future research is also needed to address comfort and satisfaction with the birth experience for women from different cultures. Given culture often shapes our birthing patterns and prior studies have demonstrated women in some cultural groups rate their pain levels much lower compared to others, the same may be true for comfort and satisfaction scores. Due to the population limitations and nature of the population in the study site region, the sample for the current study lacked cultural diversity. To date, there are no studies measuring comfort and satisfaction with the birth experience when nitrous oxide is used in different populations of birthing women. Further, cultural differences regarding labor pain management and in promoting comfort and satisfaction with the birth experience should be an area of future study. Because the African American race constituted the second largest ethnic group identified in this research study, focus on cultural differences and preferences of this culture's beliefs and practices associated with labor and birth in future research may provide insight regarding unique cultural variations

important for understanding by nurses and maternity care providers when planning labor and birth interventions. Pain management methods and comfort intervention awareness, pain management beliefs, specific factors contributing to satisfaction with the birth experience, and teaching and learning differences associated with childbirth experiences are areas of potential future study across cultures. Further, nurses who provide labor and birth care must be aware of cultural differences and foster achievement of the woman's individual cultural needs and expectations during the labor and birth experience to promote comfort and satisfaction with the birth experience for women across cultures.

Future study of women's comfort and satisfaction when nitrous oxide is used during labor and birth should also closely consider participant variations regarding past history or current anxiety or psychiatric disorders and the potential influence these disorders may have on the woman's self-report of comfort and satisfaction with the birth experience. Initial exclusion of a significant number of otherwise eligible participants who had a history of anxiety or psychiatric disorders resulted in a protocol change for the current study to modify the original exclusion criteria for exclusion to occur only if the woman was receiving treatment for the anxiety or psychiatric disorder during the current pregnancy. While this modification to the originally planned exclusion criteria did allow for greater study enrollment, nearly one-fourth of study participants in the current study had a history of an anxiety or psychiatric disorder not currently necessitating treatment during the pregnancy. The potential influence of past and/or current anxiety or psychiatric disorders on comfort and satisfaction with the birth experience for women who use nitrous oxide during labor and birth would be important to consider when planning future research in this area.

Significance for practice. Findings from this study provide great insight to inform nurses who care for women during labor and birth experiences. While epidural analgesics have shown to be highly effective in lowering labor pain (Koyyalamudi et al., 2016), this analgesic option has a similar effect on a woman's comfort experienced during labor and birth and her overall satisfaction with the birth experience when compared to other safe, less invasive, and more affordable analgesic options such as nitrous oxide. Given the role of the bedside nurse to provide primary support for the comfort and pain management needs of women in labor, they are well-positioned to provide patient education regarding available pharmacological and non-pharmacological pain management options and serve as an advocate when pain management strategies are ineffective or limited. Such support, education, and advocacy provided during labor and birth care affords the nurse the opportunity to make positive contributions to women's childbirth experiences through engagement in practice, policy, and research arenas armed with information grounded by practice experiences and scientific evidence.

When providing support of the comfort and pain management needs of women in labor, the bedside nurse should engage discussion with the woman and maternity care provider regarding all available pharmacological and non-pharmacological options, inclusive of nitrous oxide. Further, within facilities where nitrous oxide for labor analgesia is not yet available or of limited use, given the current study findings including similarities in comfort and satisfaction with the birth experience for women who used nitrous oxide compared to epidural analgesics and no analgesics, nurses should advocate for the initiation of intrapartum nitrous oxide as an alternative analgesic option for use by women during labor and birth within their facility. The current study offers nurses and

maternity care providers who may have limited experience or who are new to offering nitrous oxide during labor evidence suggesting no significant difference in comfort and satisfaction with the birth experience for women regardless of analgesic option selected for use during labor and birth.

While the provision of safe pain relief choices for women during labor and birth remains a central goal of health care providers (Markley & Rollins, 2017), nurses must recognize the influence they have on the pain management method choices of women and realize they often are a driving force when such decisions are made. Further, despite the variety of experiences, perceptions, and expectations women bring to the childbirth experience, the behaviors of nurses and other healthcare providers influence the decisions they make regarding their birth preferences (Carlton et al., 2005). Because women admitted to the birthing unit in active labor may rapidly progress to complete dilation, the role of the nurse in providing patient education regarding available analgesic options at point of care and in providing subsequent supportive interventions is of utmost importance particularly given the resultant effect of these interventions on women's comfort and satisfaction with the birth experience.

Incorporation of holistic and alternative therapies and informed decision-making for women during labor and birth must remain priorities for nurses who provide care for women during labor and birth to promote their comfort in psychosocial and spiritual contexts while fostering a sense of empowerment and relief of their own pain (Charles et al., 2016). The results of this study provide evidence regarding the importance of nursing efforts focused on providing women open access to available analgesic options, including

nitrous oxide, without delay during active labor to promote comfort and satisfaction with the birth experience.

More importantly, nurses need to remain fully engaged and attentive to the woman's comfort care needs throughout the labor and birth experience and offer various comfort strategies across this experience to promote comfort and satisfaction with the birth experience. While the current study did not explore the effects of intrapartum nitrous oxide and other analgesic options on relieving labor pain, the findings of this study align with those of Charles et al. (2016) who suggested the possibility of comfort and pain coexisting within the same person at the same time whereby comfort is experienced even in the presence of extreme pain. The findings of the current study offer insight regarding the similarities of comfort experienced during labor and birth and satisfaction with the birth experience for women during labor and birth potentially while still experiencing pain regardless of analgesic option used**.**

Significance for policy. Primary focus of health care policy development in the United States is focused on safety and risk reduction within the health care system. Use of analgesic options during labor and birth with limited or no risk to the woman and her fetus, such as with intrapartum nitrous oxide use, align with this current focus for policy development. Reducing risk associated with analgesic options utilized during labor and birth, including decreasing epidural use and exposure to narcotic or other opioid medications often provided during labor and birth as epidural or systemic analgesics, is an area of necessary focus for future policy development. Public health policies must be written with consideration of findings such as those identified within this study

supporting use of alternative options for pain management during labor and birth beyond epidural analgesics.

Although the findings of this study may not directly drive a major policy change, other studies have provided caution regarding the risks associated with epidural use during labor and birth, particularly for obese women. Over one-third of childbearing women in the United States are obese (BMI > 30 kg/m2) placing them at increased risk for slower labor progression, altered labor management, high frequency of epidural use, and increased incidence of epidural complications and cesarean delivery regardless of parity (Biel et al., 2017; Carlson, Hernandez, & Hurt, 2015; Kim et al., 2016; Kawakita et al., 2016). Given current use of epidurals in over 60% of vaginal deliveries in the United States (Biel et al., 2017), use of safe and effective alternative analgesic options such as intrapartum nitrous oxide (Stewart & Collins, 2012; Kester, 2014; King & Wong, 2014; Rooks, 2012; Richardson et al., 2017, Collins, 2018), may allow additional time to complete the first stage of labor before proceeding to cesarean delivery for slow labor progress, may eliminate or delay use of regional analgesics, and may improve comfort and satisfaction with the birth experience for obese women. Review of the findings from this and other related studies, in addition to expert opinion, is necessary as United States public health policy development continues surrounding labor and birth analgesia and use of low-risk analgesic options.

Hospital policy considerations in response to the current study findings include a recommendation to develop policies outlining available pharmacological and nonpharmacological pain management methods and the associated standardized education to be provided to women upon admission for anticipated childbirth. Similarly,

clinic policies should also outline available pharmacological and nonpharmacological options available in the birthing unit and the associated standardized education to be provided to women during a third trimester prenatal clinic visit and during childbirth preparation classes. Such approaches to ensure women are consistently informed of available options for pain management and to promote comfort and satisfaction with the birth experience will be instrumental in streamlining information provided to women prior to childbirth and in fostering informed decision-making for women during labor and birth.

Significance for education. Educational programs play a critical role in preparing new nurses for future clinical practice. Knowledge of various pharmacological and non-pharmacological options for pain management during labor and birth and how these interventions promote comfort and satisfaction with the birth experience must be conveyed to nursing students within program curricula. The educational experience should include both didactic and direct care experiences during which knowledge development and practical application is fostered. First hand experiences of students in observation of the labor and birth experience with reflection upon the available and actual pharmacological and nonpharmacological methods used by women during labor and birth will allow nursing students to explore various pain management and comfort strategies and their effect on promoting women's comfort and satisfaction with the birth experience. Further, nurse education curricula must focus on the role of the nurse in promoting women's comfort and satisfaction with the birth experience. Ensuring nursing students are provided opportunities to observe nursing interventions provided by nurses focused on promoting comfort and satisfaction and to practice such interventions in

laboratory and/or clinical settings are essential to knowledge and skill development for new nurses who provide nursing care in labor and birth settings.

Conclusion

This study contributed to the science of intrapartum pain management and expanded knowledge regarding comfort and satisfaction with the birth experience particularly for women who used nitrous oxide, a self-administered, alternative pain management strategy, during labor and birth. Findings from this study provide evidence regarding the differences in comfort and satisfaction with the birth experience for women who used nitrous oxide compared to those who used epidural analgesics or no analgesics during labor and birth useful to inform clinical practice decisions of nurses and maternity care providers. The new knowledge gained from this quantitative study can be used to shift the paradigm of intrapartum pain management in the United States to include alternative pain management strategies, such as nitrous oxide, given the similarities in comfort and satisfaction with the birth experience identified within the current study for women regardless of the analgesic option utilized during labor and birth.

APPENDICES

Appendix A: Protection of Human Subjects

The research study site was conducted within the three largest facilities within an integrated health system located in the upper Midwest region of the United States. All three facilities provide normal and high-risk obstetric and neonatal care to women.

The following procedures regarding the protection of human subjects were utilized for this study:

1. Participants were recruited from a total population of pregnant women who were in their last trimester of pregnancy and planning a vaginal birth. Eighty-four women with singleton pregnancies who met inclusion criteria were consented to participate. Ability to read, understand, and speak English was verified through participant verbal report to allow for completion of study surveys. Participants were surveyed in the first 6 hours following spontaneous vaginal birth with exclusion from study participation occurring if the woman's physician or nurse midwife felt study participation placed the mother at a higher risk. Precautions were taken to minimize fatigue or emotional distress for the woman during data collection. Participants were informed of their ability to withdraw from study participation at any time. Pregnant woman who were at least 18 years of age who did not have history of complications in the current pregnancy were selected for study participation given their lower prenatal risk and greater likelihood of spontaneous vaginal birth. All ethnic groups of pregnant women receiving prenatal and/or maternity care at the study site and who were eligible according to the specified eligibility criteria were provided equal opportunity to participate.

2. Pregnant women who had confirmation of an uncomplicated pregnancy, verified through electronic heath record review and clinic or birthing center staff confirmation, and who were in their third trimester of pregnancy were recruited for the study from the study site populations. The Principal Investigator or PI-trained nurse research assistants (employees of the study site who collaborated as members of the research team who were trained in the protection of human subjects and in screening, enrollment and consenting of participants, and data collection procedures) partnered with the study site clinic staff, maternity providers, and birthing unit staff to identify potentially eligible participants. Access to potentially eligible study participants was gained within a third trimester prenatal care visit, prior to or following childbirth preparation class attendance occurring at the study site, and upon admission to the birthing unit with care taken not to recruit women while they are experiencing active labor pain. Handout materials were distributed across the study site and to potential study participants including the purpose and significance of the research, why the site was chosen, what the research entailed, how ethical guidelines will to be maintained, how the results will be reported, and what stakeholders and others at the site have to gain from the study. Eligibility for participation was determined based upon established inclusion and exclusion criteria and eligible participants were invited to participate in the study. Explanation and documents describing informed consent for study participation and release of medical information was provided by the Principal Investigator or PI-trained nurse research assistant during a meeting occurring with the potential participant prior to or following a clinical

visit, a prenatal class, or following admission to the birthing unit. At this meeting, informed consent forms were signed by eligible participants agreeable to study participation if the participant felt comfortable with providing consent at that time. Follow-up by the Principal Investigator or PI-trained nurse research assistant occurred during a future prenatal care visit or later in the hospital stay if delay in providing consent for participation by the potential participant was desired. During the initial and delayed enrollment meetings, participants were reminded by the Principal Investigator or PI-trained nurse research assistant of their right to refuse participation or to withdraw from the study at any time without consequences to their maternity care. The Principal Investigator or the PI-trained research assistant provided participants with a copy of the consent form, information regarding the purpose of the study, the study procedures and the rights and responsibilities associated with study participation, and the opportunity to have questions about the research study answered prior to obtaining informed consent (the informed consent procedure is described in detail in the following section). A pilot study including 11 participants prior to study initiation was conducted to evaluate the processes to access and gain consent from study participants, the process of questionnaire administration, and to ensure adequacy of instrumentation and variable selection with study initiation occurring following pilot study completion.

3. Prior to initiating the study survey, the purpose of the project and details of the study were once again explained to the participants. Questions were answered by the Principal Investigator or PI-trained nurse research assistants. Participants were

then guided to complete the electronic survey via the iPad provided to them. Diligent efforts allowed for survey completion to occur at a time most convenient to the participant, her newborn, and her family within the first 6 hours following childbirth.

4. Training of nurse research assistants by the Principal Investigator was provided within a 4-hour orientation to standardize study procedures and verify nurse research assistant completion and understanding of human subject protection training.
5. Potential inconveniences or risks to the participants. The Principal Investigator did not anticipate any adverse effects to the participant from study participation. Potential physical and emotional risks of participation included possible fatigue following childbirth and emotional distress with or without an undisclosed anxiety or psychiatric disorder or stressful experience during childbirth. To minimize these risks, the Principal Investigator and PI-trained nurse research assistants visited with staff prior to survey administration, conducted passive surveillance for developing fatigue, discomfort, or emotional distress during survey completion, and informed the participant study participation is voluntary and could be discontinued at any time. In the event of physical or emotional distress, the Principal Investigator or PI-trained nurse research assistant was prepared to end survey completion and to notify staff so the participant needs could be immediately addressed. The health of the participant was of utmost importance. The Principal Investigator and PI-trained nurse research assistants also remained attentive in conducting general surveillance on the environment to ensure the

needs of the newborn were met while the participant was completing the study survey. Reattempt for survey completion upon resolution of the distressing event was to be attempted only once within the 6-hour timeframe following childbirth designated for data collection. No situations of distress by study participants were experienced across survey processes within this study.

6. Information regarding the participants was confidential. Participant responses were gathered electronically within Qualtrics with a unique random code assigned prior to survey initiation. This unique code was important because of the possibility of needing to re-visit the data collected during data analysis. HIPAA requirements were satisfied with use of random codes assigned to the survey data and de-identification of data collected from the electronic health record. The privacy of the participant was protected via password protected computers and physical consent forms locked in a cabinet in the Principal Investigator's office. Data were made available only to research team members and collaborator(s) as needed to complete the research procedures. However, the data is subject to the United States legal jurisdiction and will follow the legal routine if subpoenaed. Electronic version of the data collected will continue to be stored on the University's secured servers via the Principal Investigator's office/University system issued computer. The paper version of the consent form will continue to be stored in a separate locked cabinet in the Principal Investigator's office. Only the Principal Investigator and research team members/collaborators assisting with data analysis for the study will have access to the data. Data from the study are reported in aggregate and in de-identified form.

7. There were no direct benefits to participants as a result of participation in this study. However, a $20 gift card was given following study completion to help compensate women for time given to study participation. Participant health care was not altered and was provided exactly as if they were not study participants. Therefore, all study participants received the same benefits as a result of participation. Benefits to the participant included the monetary incentive and being offered a report of the study results. Benefits to society and maternity care providers included expanded understanding of the effects of inhaled nitrous oxide (50-50% mixture) to guide decisions regarding intrapartum pain management options during labor and birth experiences. The overall goal for this study was to determine the effects of intrapartum nitrous oxide use on comfort and satisfaction with the birth experience for women following spontaneous vaginal birth.
8. The risks anticipated from this type of study were very minimal. Participation in the study did not interfere with maternity care. Previous studies including women who used nitrous oxide during childbirth received IRB approval by different universities and/or hospitals. No complications were reported in the literature for any of these prior studies.
9. IRB approval from the University of North Dakota and the study site research institute was received prior to study initiation and prior to each study protocol change. Verification of these approvals is included within Appendix B. Additional support for the project was obtained from the study site administration and nursing leadership, maternity care providers and nurses. Also, the Principal

Investigator and PI-trained nurse research assistants successfully completed the University and study site requirements for human subject protection training.

Participant Informed Consent Form

Study Site Identifiers Removed

Such Study
Version Date: 06/03/2019

PATIENT CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

TITLE:	**Exploring the Effects of Pain Medication on Comfort and Satisfaction with the Birth Experience**
SPONSOR:	Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN)
INVESTIGATORS:	Tami L. Such, MSN, RNC-OB, PHN [redacted]

You are invited to participate in a research study sponsored by University of North Dakota PhD Candidate, Tami Such, MSN, RNC-OB, PHN. Your participation in this study is voluntary. Please read the information below, and ask questions about anything you do not understand, before deciding whether to participate.

KEY INFORMATION
Things you should know:

- The purpose of the study is to explore different pain medications used during labor and birth and how they affect the woman's comfort and satisfaction with her vaginal birth experience. If you choose to participate, you will be asked to complete an electronic survey within six hours of the birth of your baby while you are in the hospital at [redacted]. This will take approximately 5-10 minutes.
- We want to make sure you know about a few key risks right now. We give you more information in the "What possible risks can I expect from taking part in this study?" section. Risks or discomforts from this research include that you may get tired as you complete the survey questions. While not anticipated, the researcher will notify your nurse and maternity care provider if you experience any emotional upset or psychological issues related to your participation in the research study.
- The study will not have any direct benefits to you as a participant in the study.
- A $20 gift card will be provided to you following completion of the study to help compensate for your time.
- If you decide not to participate in this research, your other choices may include:
  - Getting maternity care without being in a study
  - Taking part in another study

PURPOSE OF THE STUDY
The purpose of this research study is to determine the effects of different pain medications used during labor and birth on women's comfort and satisfaction with their vaginal birth experiences. The researcher

PURPOSE OF THE STUDY
The purpose of this research study is to determine the effects of different pain medications used during labor and birth on women's comfort and satisfaction with their vaginal birth experiences. The researcher hopes the knowledge from this study will provide information that can be used to help guide decisions about pain medication options for women during labor and birth experiences.

PROCEDURES

You are asked to participate in the study because you are currently pregnant and planning to deliver your baby vaginally in the next 3 months and are age 18 years or older. Approximately 90 pregnant women will take part in this study. If you are willing to join, a member of the research team will meet with you at a convenient time for you. This meeting will take about 30 minutes. The purpose of the project and details for the study will be explained.

The study will last up to six hours after your baby is born. You and your maternity care provider will be able to choose the pain medication you want or need during your birth experience. Whether or not you choose to participate, you will receive pain management according to the usual hospital practices. The researcher or member of the research team will ask you to complete an electronic survey using an iPad provided to you within the first six hours after your baby is born. This survey will take an estimated 5-10 minutes and will be completed in your hospital room. The doctors, nurse midwives, and nurses will treat you as they usually do while you are in the hospital. Your consent to review your medical record will also be requested to obtain additional information about you, as explained on the HIPAA Authorization for the Use & Disclosure of PHI form (below).

POTENTIAL RISKS AND DISCOMFORTS
There are low risks with this study. After the birth of your baby, you may get tired as you complete the survey questions. This study does not test any medications or their side effects. We will protect your privacy while you are answering the questions. The researcher will notify your nurse and maternity care provider if emotional upset or psychological issues develop related to your participation in the research study.

WHAT ARE THE BENEFITS OF THIS STUDY?
It is hoped that you or other future patients might benefit from this study because of a better understanding of the effects of different pain medications used during labor and birth on women's comfort and satisfaction with their vaginal birth experiences.

ALTERNATIVES TO PARTICIPATING IN THIS STUDY
You may choose not to participate in this study, and the researcher will not contact you and you may still receive your healthcare at [redacted].

COST TO PARTICIPATE
The procedures that will be performed only for the study will be provided at no cost to you and will not be billed to your health insurer or Medicaid. All costs that are part of your usual medical care that you could or will incur regardless of your enrollment in the study will be billed to your health insurer or Medicaid. You are responsible for all co-pays and deductibles. Please ask the study staff if you have questions about this.

PAYMENT FOR PARTICIPATION
You will receive an appreciation gift of $20 Gift Card, after you complete this research study.

PARTICIPATION AND WITHDRAWAL
If you decide you no longer wish to participate in this study, you are free to quit at any time without penalty or loss of benefits to which you are otherwise entitled. However, the information that has been gathered up to that time will be used in the study. This information will not have your name on it. There will be no costs to you for being in this research study.

WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR
The investigator may withdraw you from the study if you cannot safely continue, if you can't answer the questions, if your vaginal birth requires assistance of a vacuum or forceps, if you require a cesarean section for delivery of your baby, if the birth of your baby is a stressful experience, or if you receive opioid or other narcotic pain medication after the birth of your baby before you are able to complete the survey.

CONFIDENTIALITY
We will do our best to make sure that the personal information in your medical record will be kept confidential. However, we cannot guarantee total confidentiality. Your personal information may be given out if required by law. Your name and other personal information will not be used if information from this study is published or presented at scientific meetings.

You will also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) Authorization for Release of Information form because this study involves the use of your protected health information.

By signing this consent form and the attached authorization, you agree that the following organizations may look at and/or copy your medical records for research, quality assurance, and data analysis:

- Office for Human Research Protections or other federal, state, or international regulatory agencies
- The [redacted] Institutional Review Board
- The University of North Dakota Institutional Review Board
- Authorized research staff at [redacted]
- The sponsor supporting the study, their agents, or study monitors

You may also choose to reveal protected information about yourself under certain circumstances—for example, if you or your guardian requests the release of information about you in writing (through, for

To protect your privacy, your consent form will be held in a locked file in the researcher's private office. After five years the consent forms will be shredded. Your survey responses and the information obtained from your medical record will be stored electronically on the University's secure server and accessed only using a University issued computer with password protection. This information will not become part of your medical records. Your personal information will not be included on the researcher's worksheets or computer files. The researcher will "code" the information by a randomly assigned number that will be known only to the researcher and university officials whose job is to protect your rights in research. Confidentiality of participants will be maintained by the researcher.

NEW FINDINGS
During the course of the study, if any significant new findings are identified, such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study, the researcher will tell you about it and then ask you if you still want to stay in the study. If you choose to stay in the study, you will sign another consent form.

WILL MY RESEARCH INFORMATION BE USED FOR FUTURE RESEARCH OR SHARED WITH OTHERS?
Your private information collected as part of the research, even after identifiers are removed, will not be used or distributed for future research studies.

WILL THE RESEARCHERS PROVIDE INFORMATION TO ME ABOUT WHAT THEY LEARN FROM ANALYZING MY RESEARCH RESULTS?
We may learn things about your health as part of the research, however we will not share this information with you.

CONTACTS AND QUESTIONS
The researcher conducting this study is **Tami L. Such**. You may ask any questions you have now. If you later have questions about the study, please contact **Tami L. Such** by email, tami.such@ndus.edu or phone, **(218) 205-6380; [redacted] by email, [redacted] or phone, [redacted]; or Dr. Dawn L. Denny (PhD Student Advisor) by email, dawn.denny@ndus.edu or phone, (701)777-2699.**

If you have questions regarding your rights as a research subject, you may contact the [redacted] Human Protections Administrator at [redacted], **or** the University of North Dakota Institutional Review Board at **(701) 777-4279 or UND.irb@UND.edu**.

- You may call this number about any problems, complaints, or concerns you have about this research study
- You may also call this number if you cannot reach research staff, or you wish to talk with someone who is independent of the research team.

SIGNATURE OF RESEARCH PARTICIPANT

SIGNATURE OF RESEARCH PARTICIPANT

I have read the information provided above. I have been given an opportunity to ask questions and all my questions have been answered to my satisfaction. I have been given a copy of this form. I have been given enough time to consider participating. I agree to participate.

_____
Name of Participant (Please print)

_____ _____
Signature of Participant Date

SIGNATURE OF WITNESS
I have discussed the above points with the participant. My signature as witness certifies that the participant signed this consent form in my presence as her voluntary act and deed.

_____
Name of Witness (Please print)

_____ _____
Signature of Witness Date

I have discussed the above points with the participant.

_____ _____
Signature of Person Who Obtained Consent Date

Bill of Rights for Research Participants

As a participant in a research study, you have the following rights:

- To have enough time to decide whether or not to be in the research study and to make that decision without any pressure from the people who are conducting the research.
- To refuse to be in the study at all, and to stop participating at any time after you begin the study.
- To be told what the study is trying to find out, what will happen to you, and what you will be asked to do if you are in the study.
- To be told about the reasonably foreseeable risks or discomforts of being in the study.
- To be told about the possible benefits of being in the study.
- To be told whether there are any costs associated with being in the study and whether you will be compensated for participating in the study.
- To be told who will have access to information collected about you, how the information will be used and how your confidentiality will be protected.
- To be told where to go with questions about the research, about research-related injury, and about your rights as a research subject.

If the study involves treatment or therapy:

- To be told about the other non-research alternative treatment choices you have.
- To be told where treatment is available should you have a research-related injury, and who will pay for the research-related treatment.

HIPAA Authorization for the Use & Disclosure of PHI

Study Title: Exploring the Effects of Pain Medication on Comfort and Satisfaction with the Birth Experience

Subject's Name: _____

The Health Insurance Portability and Accountability Act (HIPAA) requires protection of your health and medical information so that it is kept as private and confidential as possible. Protected Health Information (PHI) is any health information that identifies you. It includes information collected about you as part of this study and health information that is stored in your medical record.

Individual Health Information to be Used or Disclosed
The researchers and research staff may use and/or share the following health information about you:

- Demographic information (such as your age, ethnicity, gender, etc.)
- Health information from your medical record that includes, but may not be limited to, your medical history and the details of your pregnancy and delivery, such as:
  - pain medications
  - date and time of birth
  - mode of delivery
  - number of weeks completed in your pregnancy
- Additional medical and health-related information gathered from you within the electronic survey.

Purposes for Using and/or Sharing Your Health Information
Your health information may be used and/or shared to . . .

- Confirm that you are eligible to enroll in a study.
- Conduct the study and make certain that the study is being carried out properly.
- Ensure that the information collected during the study is accurate and complete.
- Analyze the study results.
- Protect your safety and rights as a research subject.

Parties Who May Disclose Your Individual Health Information
To carry out this research study, the researcher and the researcher's staff may obtain your individual health information from other healthcare providers, such as laboratories, which are a part of this research, as well as health care providers who are not part of this research (other doctors, hospitals, and/or clinics).

Parties Who May Receive or Use My Individual Health Information
The parties described in the paragraph above may disclose your health information to the following persons and organizations for their use in connection with this research study:

- Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services
- Governmental, regulatory bodies

- [redacted] Institutional Review Board (IRB) and administrative office
- University of North Dakota Institutional Review Board (IRB) and administrative office
- Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN)

The researchers and the sponsor (if applicable) agree to protect your health information by using and sharing it only as authorized by you and required by law. There are other laws that may require disclosure of your individual health information for public purposes. Examples include potential disclosures required for mandated reporting of abuse or neglect, judicial proceedings, health oversight activities, and public health measures. Once your PHI is shared with someone outside the research team, your information may no longer be protected by HIPAA regulations.

Right to Refuse to Give Authorization (Permission)
You do not have to sign this authorization. If you decide not to give your authorization and not to sign this document, you will not be able to take part in this research study or receive any research-related treatment provided through the study. But your decision will not affect any other treatment, payment, health plans, or eligibility for benefits.

Right to Revoke Your Authorization (Permission)
You can change your mind and revoke (withdraw) your authorization at any time. If you revoke your authorization in the future:

- The researcher may use and disclose the protected health information already collected for this research study, but no more information will be added to the research records.
- You will not be allowed to continue to participate in the study.

To withdraw your authorization, you must notify the researcher in writing to inform him or her of your decision. If you wish to revoke your authorization, send a letter to the researcher at the address below:

[redacted]/Tami Such, PhD Candidate, MSN, RNC-OB, PHN
[redacted]

When Access to Your Information May Be Limited
You have the right to see and copy your medical records and PHI related to this study for as long as the study team or institution holds this information. But to ensure the scientific integrity of the study, you may not be able to see or copy some of the study information until after the study has been completed. (When the study is over, you will have the right to access the information again.) The Notice of Privacy Practices available in the hospital, clinic, or office where the research is being conducted provides general information on your rights to review, copy, and correct your health information.

Expiration
This authorization to use and share your PHI in connection with this study does not have an expiration date.
You will receive a signed copy of this form.

Signature
I am the research participant or representative authorized to act on behalf of the participant, and I authorize the researcher and the researcher's staff to use and disclose (share) my individual health information for the purposes of carrying out this research study.

Signature of Study Participant (Subject) Date

Signature of Legally Authorized Representative (if applicable) Date

Description of the Representative's Authority to Act for Subject

Recruitment Materials: Participant Flyer

Script for Invitation of Pregnant Women for Research Study Participation

UND NURSING
UNIVERSITY OF NORTH DAKOTA

RESEARCH STUDY OPPORTUNITY AT [redacted]

With your upcoming childbirth, you may be eligible to participate in a labor and birth pain study being conducted at [redacted] by a doctoral nursing student, Tami Such, from the University of North Dakota. Your participation in this study is voluntary. If you choose not to participate you may still receive your healthcare from [redacted] and your labor and birth care will not change. The findings from this study will provide information to help guide decisions about pain medication options for women during their labor and birth experiences.

If you are interested in this opportunity, your name and contact information will be shared with Ms. Such so she can contact you to provide you with detailed information about the study.

If you are interested in this opportunity, you may contact Ms. Such using the contact information included below to learn more about study participation.

If you prefer, we will contact Ms. Such so she can contact you to discuss the study.

Researcher contact information:
Tami L. Such, PhD Candidate, MSN, RNC-OB, PHN
(218)205-6380
University of North Dakota
Tami.such@mayvillestate.edu

Participant Information Handout

Participant Information

Such Labor and Birth Pain Study

Researcher: Tami L. Such, PhD Candidate (University of North Dakota), MSN, RNC-OB, PHN and Birthing Center Nursing Professional Development Specialist at [redacted]

Research Title: Exploring the Effects of Pain Medication on Comfort and Satisfaction with the Birth Experience

Research Topic: Labor and birth pain and pain medication effects

PURPOSE: To explore different pain medications used during labor and birth and how they effect the woman's comfort and satisfaction with her vaginal birth experience.

RECRUITMENT: Pregnant women who are at least 18 years of age and planning a vaginal birth in the next 3 months may be eligible to participate in this study. Eligibility screening will occur before or after a prenatal care clinic visit, before or after childbirth preparation classes, or when the woman is admitted to the hospital for the birth of her baby. If you are eligible for the study you will be invited to participate and you will be asked for your written to participate.

ELIGIBILITY: Participants must (1) be at least 18 years of age, (2) have a full-term pregnancy (at least 37 weeks) at time of the birth, (3) be planning a spontaneous vaginal birth, (4) have a head-down position of the baby, (5) have a single baby pregnancy, (6) be able to speak and understand English, and (7) have no current pregnancy problems. Women will not be able to participate if (1) a current cesarean birth is planned, (2) a vaginal birth after cesarean (VBAC) is planned, (3) the current pregnancy includes two or more babies, (4) the baby's position is not head down (5) concern for the health of the baby exists, or (6) the woman has a history of an

anxiety or psychiatric disorder. You will also be unable to participate in the study if you have a stressful event during the birth of your baby, if a vacuum or forceps is used during the birth, if you need a cesarean birth, or if you receive opioid, or other narcotic pain medications, after the birth and prior to completing the study survey.

NUMBER OF PARTICIPANTS: 84 participants over a period of up to 8 months, including pregnant women who use the following pain medications during labor and birth: (1) epidural, (2) inhaled nitrous oxide, or (3) intravenous (IV) medication.

STUDY PROCEDURES: The study will last up to six hours after your baby is born. You and your maternity care provider will be able to choose the pain medication you want or need during your birth experience. Whether or not you choose to participate, you will receive pain management according to the usual hospital practices. The researcher or research assistant will ask you to complete an electronic survey using an iPad provided to you within the first six hours after your baby is born. This survey will take an estimated 5-10 minutes and will be completed in your hospital room. You will be given a $20 gift card when you complete the survey as a thank you for study participation. The doctors, nurse midwives, and nurses will provide the usual maternity care while you are in the hospital. The researcher or research assistant will request your consent to review your medical record.

Researcher Contact information:

Tami L. Such, PhD Candidate, MSN, RNC-OB, PHN

Phone: (218)205-6380 Email: tami.such@mayvillestate.edu

University of North Dakota Initial IRB Letter of Approval

UNIVERSITY OF NORTH DAKOTA

DIVISION OF RESEARCH & ECONOMIC DEVELOPMENT

UND.edu

Institutional Review Board
Twamley Hall, Room 106
264 Centennial Dr Stop 7134
Grand Forks, ND 58202-7134
Phone: 701.777.4279
Fax: 701.777.6708
UND.irb@research.UND.edu

December 13, 2018

Principal Investigator:	Tami Such
Project Title:	Exploring the Effects of Intrapartum Nitrous Oxide Use on Comfort and Satisfaction
IRB Project Number:	IRB-201812-127
Project Review Level:	Expedited 7
Date of IRB Approval:	12/10/2018
Expiration Date of This Approval:	12/09/2019
Consent Form Approval Date:	12/10/2018

The application form and all included documentation for the above-referenced project have been reviewed and approved via the procedures of the University of North Dakota Institutional Review Board.

Attached is your original consent form that has been stamped with the UND IRB approval and expiration dates. Please maintain this original on file. ***You must use this original, stamped consent form to make copies for participant enrollment. No other consent form should be used.*** It must be signed by each participant prior to initiation of any research procedures. In addition, each participant must be given a copy of the consent form.

Prior to implementation, submit any changes to or departures from the protocol or consent form to the IRB for approval. No changes to approved research may take place without prior IRB approval.

You have approval for this project through the above-listed expiration date. When this research is completed, please submit a termination form to the IRB. If the research will last longer than one year, an annual review and progress report must be submitted to the IRB prior to the submission deadline to ensure adequate time for IRB review.

The forms to assist you in filing your project termination, annual review and progress report, adverse event/unanticipated problem, protocol change, etc. may be accessed on the IRB website: http://und.edu/research/resources/human-subjects/

Sincerely,

Michelle L. Bowles, M.P.A., CIP
IRB Manager

MLB/sb
Enclosures

Cc: Dawn Denny, Ph.D., RN, ONC

University of North Dakota IRB Approval:

Protocol Change for Study Site Required IRB Modifications

UNIVERSITY OF NORTH DAKOTA.

UND.edu

Institutional Review Board
Tech Accelerator, Suite 2050
4201 James Ray Drive Stop 7134
Grand Forks, ND 58202-7134
Phone: 701.777.4279
Fax: 701.777.2193
Email: UND.irb@UND.edu

June 4, 2019

Principal Investigators:	Tami Such
Project Title:	Exploring the Effects of Intrapartum Nitrous Oxide Use on Comfort and Satisfaction
IRB Project Number:	IRB-201812-127
Project Review Level:	Expedited 5, 7
Date of IRB Approval:	06/04/2019
Expiration Date of This Approval:	12/09/2019
Consent Form Approval Date:	06/04/2019

The Protocol Change Form and all included documentation for the above-referenced project have been reviewed and approved via the procedures of the University of North Dakota Institutional Review Board.

Attached is your revised consent form that has been stamped with the UND IRB approval and expiration dates. Please maintain this original on file. ***You must use this original, stamped consent form to make copies for participant enrollment. No other consent form should be used.*** It must be signed by each participant prior to initiation of any research procedures. In addition, each participant must be given a copy of the consent form.

You have approval for this project through the above-listed expiration date. When this research is completed, please submit a termination form to the IRB. If the research will last longer than one year, an annual review and progress report must be submitted to the IRB prior to the submission deadline to ensure adequate time for IRB review.

The forms to assist you in filing your project termination, annual review and progress report, adverse event/unanticipated problem, protocol change, etc. may be accessed on the IRB website: http://und.edu/research/resources/human-subjects/

Sincerely,

Michelle L. Bowles, M.P.A., CIP
IRB Manager

MLB/sb

Enclosures

Cc: Dawn Denny, Ph.D., RN, ONC

University of North Dakota IRB Approval:

Protocol Change for Exclusion Criteria Modification

UND UNIVERSITY OF NORTH DAKOTA

UND.edu

Institutional Review Board
Tech Accelerator, Suite 2050
4201 James Ray Drive Stop 7134
Grand Forks, ND 58202-7134
Phone: 701.777.4279
Fax: 701.777.2193
Email: UND.irb@UND.edu

July 9, 2019

Principal Investigator:	Tami Such
Project Title:	Exploring the Effects of Intrapartum Nitrous Oxide Use on Comfort and Satisfaction
IRB Project Number:	IRB-201812-127
Project Review Level:	Expedited 5, 7
Date of IRB Approval:	06/26/2019
Expiration Date of This Approval:	12/09/2019

The Protocol Change Form and all included documentation for the above-referenced project have been reviewed and approved via the procedures of the University of North Dakota Institutional Review Board.

You have approval for this project through the above-listed expiration date. When this research is completed, please submit a termination form to the IRB. If the research will last longer than one year, an annual review and progress report must be submitted to the IRB prior to the submission deadline to ensure adequate time for IRB review.

The forms to assist you in filing your project termination, annual review and progress report, adverse event/unanticipated problem, protocol change, etc. may be accessed on the IRB website: http://und.edu/research/resources/human-subjects/

Sincerely,

Michelle L. Bowles, M.P.A., CIP
IRB Manager

MLB/sb

Cc: Dawn Denny, Ph.D., RN, ONC

University of North Dakota IRB Approval:

Protocol Change for Study Group Modificaiton

UNIVERSITY OF NORTH DAKOTA

UND.edu

Institutional Review Board
Tech Accelerator, Suite 2050
4201 James Ray Drive Stop 7134
Grand Forks, ND 58202-7134
Phone: 701.777.4279
Fax: 701.777.2193
Email: UND.irb@UND.edu

September 12, 2019

Principal Investigator:	Tami Such
Project Title:	Exploring the Effects of Intrapartum Nitrous Oxide Use on Comfort and Satisfaction
IRB Project Number:	IRB-201812-127
Project Review Level:	Expedited 5, 7
Date of IRB Approval:	09/04/2019
Expiration Date of This Approval:	12/09/2019

The Protocol Change Form and all included documentation for the above-referenced project have been reviewed and approved via the procedures of the University of North Dakota Institutional Review Board.

You have approval for this project through the above-listed expiration date. When this research is completed, please submit a termination form to the IRB. If the research will last longer than one year, an annual review and progress report must be submitted to the IRB prior to the submission deadline to ensure adequate time for IRB review.

The forms to assist you in filing your project termination, annual review and progress report, adverse event/unanticipated problem, protocol change, etc. may be accessed on the IRB website: http://und.edu/research/resources/human-subjects/

Sincerely,

Michelle L. Bowles, M.P.A., CIP
IRB Manager

MLB/sy

Cc: Dawn Denny, Ph.D., RN, ONC

Appendix B: Electronic Health Record Data Collection Tool

*Tool was created in Qualtrics to allow for electronic storage and aggregation of the data as well as export to Excel and transfer to SPSS for data analysis. Data collection using this tool was conducted by the Principal Investigator or PI trained nurse research assistant. The same unique study code was assigned to the participant survey and the data collection tool to allow for match and revisit of the data within Qualtrics and the Electronic Health Record as needed during data analysis.

Participant Study Code (assigned by the PI or PI trained nurse research assistant):_____

Date of birth (baby's): _____

Time of birth:_____

Note: Codes planned for use during data analysis are referenced following each item.

Mode of delivery: spontaneous vaginal (0), vacuum assist (1), forceps assist (2), cesarean section (3)

Receipt of any opioid or other narcotic pain medications since delivery: yes (1), no (0)

Participant age (in years) Range 18-XX years

Gravida (total number of confirmed pregnancies, 1-5; greater than 5 coded as 6)

Para (total number of births after 20 weeks gestation, 1-5; greater than 5 coded as 6)

Pregnancy gestation at time of birth (in weeks)

Duration of first stage of labor (in minutes)

Duration of second stage of labor (in minutes)

Non-pharmacologic methods to manage labor pain:

- Acupuncture (1)
- Hypnotism (2)
- Yoga (3)
- Exercise/walking (4)
- Hydrotherapy/whirlpool tub (5)
- Transcutaneous electronic nerve stimulation (TENS) (6)
- Massage (7)
- Meditation (8)
- Guided imagery (9)
- Focused/paced breathing techniques (10)
- Other_____(comment option to be included) (11)

Occiput posterior fetal position during labor: Yes (1), No (0)

Oxytocin/Pitocin induction of labor: Yes (1), No (0)

Oxytocin/Pitocin augmentation of labor: Yes (1), No (0)

Previous diagnosis of anxiety or psychiatric disorders
- No history of anxiety or psychiatric disorder (0)
- Anxiety (1)
- Depression (2)
- Panic disorder (3)
- Bipolar disorder (4)
- Post-traumatic stress disorder (5)
- Obsessive-compulsive disorder (6)
- Eating disorder (7)
- Schizophrenia (8)
- Other disorder (9) (include text option)

Obstetric history
As noted in Obstetric History section or the prenatal record or prior delivery summaries in the Electronic Health Record:

Previous birth complications
- No history of previous birth complications (0)
- Traumatic birth/delivery (1)
- Need for neonatal resuscitation (2)
- Transfer of newborn Neonatal Intensive Care Unit/NICU (3)
- Fetal or neonatal death (4)
- Other stressful birth experience (5) (include text option)

Data Collection on one of the following pain control methods (based upon self-selection):

Inhaled nitrous oxide and oxygen (50%-50% mixture): Yes (1), No (0)
Duration of use (in minutes)

Systemic analgesic: Yes (1), No (0)
Analgesic type (per study site standard of care):
- Sublimaze/Fentanyl Citrate (1)
- Other (include text option) (2)

Analgesic dose (each dose) (50mg = 1; 100 mg = 2; other = 3)
Total number of doses received (1-5; greater than 5 doses = 6)

Epidural analgesic: Yes (1), No (0)
Analgesic type (per study site standard of care):
- Bolus dose: Bupivacaine (Marcaine, Sensorcaine) 0.25% injection (1-30 ml)

Other bolus medication: Yes (1), No (0) and dose (in mg) (include text option for name of medication)
Continuous infusion: Bupivacaine 0.125% infusion (15 ml/hr) Yes (1), No (0)
Other infusion medication Yes (1), No (0) and dose (in mg) (include text option name of medication)
Duration of placement procedure (in minutes)
Duration of epidural use (in minutes)

Nitrous oxide and oxygen (50-50% mixture) with conversion to epidural analgesic
Duration of nitrous oxide use (in minutes)
Epidural Analgesic type (per study site standard of care):
Bolus dose: Bupivacaine (Marcaine, Sensorcaine) 0.25% injection (1-30 ml)
Other bolus medication: Yes (1), No (0) and dose (in mg) (include text option for name of medication)
Continuous infusion: Bupivacaine 0.125% infusion (15 ml/hr) Yes (1), No (0)
Other infusion medication Yes (1), No (0) and dose (in mg) (include text option name of medication)
Duration of epidural placement procedure (in minutes)
Duration of epidural use (in minutes)

Systemic analgesic with conversion to epidural analgesic
Analgesic type (per study site standard of care):
Sublimaze/Fentanyl Citrate (1)
Other (include text option) (2)
Analgesic dose (each dose) (50mg = 1; 100 mg = 2; other = 3)
Total number of doses received (1-5; greater than 5 doses = 6)
Epidural Analgesic type (per study site standard of care):
Bolus dose: Bupivacaine (Marcaine, Sensorcaine) 0.25% injection (1-30 ml)
Other bolus medication: Yes (1), No (0) and dose (in mg) (include text option for name of medication)
Continuous infusion: Bupivacaine 0.125% infusion (15 ml/hr) Yes (1), No (0)
Other infusion medication Yes (1), No (0) and dose (in mg) (include text option name of medication)
Duration of epidural placement procedure (in minutes)
Duration of epidural use (in minutes)

No analgesic used during labor and birth (only non-pharm methods used)

Appendix C: Researcher Modified Childbirth Comfort Questionnaire

For the next section of the survey you will be provided 14 statements to describe your feelings during labor and birth. Please rate each statement from 1 to 5 with "1" meaning you 'strongly disagree' and "5" meaning you 'strongly agree' to describe how you felt during labor and birth.

Example:
I am glad I am being asked these questions…… 1 (strongly disagree) to 5 (strongly agree).

Question	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. I had enough privacy.	**1**	**2**	**3**	**4**	**5**
2. My pain was difficult to endure.	**1**	**2**	**3**	**4**	**5**
3. I felt empowered by those around me.	**1**	**2**	**3**	**4**	**5**
4. I didn't think I could do it without the help of others.	**1**	**2**	**3**	**4**	**5**
5. I worked well with my body.	**1**	**2**	**3**	**4**	**5**
6. The chair (bed) made me hurt.	**1**	**2**	**3**	**4**	**5**
7. I rose above my pain because it helped me birth my baby.	**1**	**2**	**3**	**4**	**5**
8. I felt confident I could birth my baby.	**1**	**2**	**3**	**4**	**5**
9. The room made me feel weak and helpless.	**1**	**2**	**3**	**4**	**5**
10. The pain of the contractions motivated me to be strong.	**1**	**2**	**3**	**4**	**5**
11. This was a safe place to be.	**1**	**2**	**3**	**4**	**5**
12. I felt like giving up.	**1**	**2**	**3**	**4**	**5**
13. I worried I would lose control.	**1**	**2**	**3**	**4**	**5**
14. I needed to feel better informed about my progress.	**1**	**2**	**3**	**4**	**5**

Note: The questions above reflect modification of the Childbirth Comfort Questionnaire (CCQ) to reflect past tense for each question to allow for survey within the first four hours following childbirth.

The Childbirth Comfort Questionnaire (CCQ) was developed and tested in 2002-2003. Face validity was accomplished by a panel of experts: midwives, obstetricians, labor and delivery nurses and women who had given birth. The instrument has a 0.71 Cronbach's (sample size n = 64). The instrument is administered twice during labor: latent & active phase. To score, reverse code the negative responses and total the sum. Higher totals mean higher comfort. This instrument was used in a population of primiparous women who gave birth in the United States. Further testing of the instrument is ongoing. For comments or questions please contact: kschuili@nmu.edu. Please see the original Childbirth Comfort Questionnaire (CCQ) included below.

*Permission for use and modification of the Childbirth Comfort Questionnaire (CCQ) was obtained from the author. Please see email communication also included below.

Childbirth Comfort Questionnaire

Data Collectors please read the statement below at each data collection time point. Circle her score.
Thank-you VERY MUCH for helping in this study about the feelings women experience during labor. I am going to ask you to rate how you feel about 14 statements. Please rate each statement from 1 to 5 with "1" meaning you 'strongly disagree' and "5" meaning you 'strongly agree' at this moment.

Example:
I am glad I am being asked these questions……1 (strongly disagree) to 5 (strongly agree).

1. I have enough privacy. 1…2…3…4…5
2. My pain is difficult to endure. 1…2…3…4…5
3. I feel empowered by those around me. 1…2…3…4…5
4. I don't think I can do this without the help of others. 1…2…3…4…5
5. I am working well with my body. 1…2…3…4…5
6. This chair (bed) makes me hurt.* 1…2…3…4…5
7. I can rise above my pain because it helps me birth my baby. 1…2…3…4…5
8. I feel confident I can birth my baby. 1…2…3…4…5
9. This room makes me feel weak and helpless. 1…2…3…4…5
10. The pain of the contractions motivates me to be strong. 1…2…3…4…5
11. This is a safe place to be. 1…2…3…4…5
12. I feel like giving up. 1…2…3…4…5
13. I worry I will lose control. 1…2…3…4…5
14. I need to feel better informed about my progress. 1…2…3…4…5

Note: The Childbirth Comfort Questionnaire (CCQ) was developed and tested in 2002-2003. Face validity was accomplished by a panel of experts: midwives, obstetricians, labor and delivery nurses and women who had given birth. The instrument has a 0.71 Cronbach's (sample size n = 64). The instrument is administered twice during labor: latent & active phase. To score, reverse code the negative responses and total the sum. Higher totals mean higher comfort. This instrument was used in a population of primiparous women who gave birth in the United States. Further testing of the instrument is ongoing. For comments or questions please contact: (kschuili@nmu.edu) or 906-227-2834 or via mail:

Kerri Durnell Schuiling, PhD, CNM, FACNM
Professor & Associate Dean
Northern Michigan University School of Nursing
1401 Presque Isle Ave.
2301 NSF
Marquette, MI 49855

Such, Tami

From: Kerri Schuiling <kschuili@nmu.edu>
Sent: Monday, November 12, 2018 8:33 AM
To: Such, Tami
Subject: Re: Request for Use and Modification of the Childbirth Comfort Questionnaire

Hello Tami,
This email is to confirm you have my permission to use the Childbirth Comfort Scale and to modify it as needed for your study. Your research sounds fascinating and I will be very interested to learn of the outcomes. Best of luck!

Kerri D. Schuiiling, PhD, CNM, FACNM, FAAN
Provost, Northern MI Univ

On Sun, Nov 11, 2018 at 6:51 PM Such, Tami <tami.such@mayvillestate.edu> wrote:

> Hello Dr. Schuiling,
>
> My name is Tami Such and I am a third year doctoral student in the PhD in Nursing program at the University of North Dakota. I would like to thank you for your contributions to advance nursing science regarding comfort for women during childbirth through your dissertation study, "Exploring the Presence of Comfort within the Context of Childbirth" including creation and use of the Childbirth Comfort Questionnaire.
>
> I am emailing to request your permission for use and modification of your Childbirth Comfort Questionnaire within my dissertation study, "Exploring the Effects of Intrapartum Nitrous Oxide Use on Comfort and Satisfaction." Specifically, I am requesting your permission to modify the questions included within your questionnaire to reflect past tense to allow for survey of women within the first four hours following childbirth. Upon modification of your instrument, I would conduct a pilot study over a 1-month period to reestablish reliability and validity of the modified instrument.
>
> Please let me know if you need any additional information to consider my request. Thank you, in advance, for your consideration. I look forward to your response when possible.
>
> Best Regards,
>
> Tami Such
>
> --
>
> **Tami Such, MSN, RNC-OB, PHN**

Chair & Associate Professor, Division of Nursing

Mayville State University

330 Third Street NE Mayville, ND 58257

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--
Kind regards,

Kerri D. Schuiling, PhD, CNM, FACNM, FAAN
Provost & VPAA
Northern MI University
Office: (906) 227-2922
FAX: (906)
Email: kschuili@nmu.edu

Appendix D: Birth Satisfaction Scale-Revised (BSS-R)

Edinburgh Napier UNIVERSITY

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Birth Satisfaction Scale-Revised (BSS-R)

(Hollins Martin and Martin, 2014)

(VALIDATED UNITED STATES VERSION)

Tips for filling in the questionnaire

(a) Find a quiet place where you will be undisturbed.

(b) Read each statement carefully and once you understand what is being asked, respond fairly quickly. Do not ponder too long over each statement.

(c) The statements are structured as follows. Please circle one of the following.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

(d) Please do not miss out any of the items and try to be as honest as possible.

Please respond to the following statements:

(1) I came through childbirth virtually unharmed.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

(2) I thought my labour was excessively long.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

(3) The delivery room staff encouraged me to make decisions about how I wanted my birth to progress.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

(4) I felt very anxious during my labour and birth.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

(5) I felt well supported by staff during my labour and birth.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

(6) The staff communicated well with me during labour.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

(7) I found giving birth a distressing experience.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

(8) I felt out of control during my birth experience.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

(9) I was not distressed at all during labour.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

(10) The delivery room was clean and hygienic.

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

Edinburgh Napier UNIVERSITY

UNIVERSITY OF HULL

Scoring the Birth Satisfaction Scale-Revised (BSS-R)

The Birth Satisfaction Scale-Revised (BSS-R) is easily scored. A score of 0 represents no birth satisfaction and 40 most (range 0-40). Each item is scored on a descending rating from 'Strongly Agree' with a score of '4' to 'Strongly 'Disagree' with a score of '0'. However, items 2, 4, 7, 8 are reverse scored. The following scoring grid details the score that should be given for each individual item.

BSS-R Item	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
Item 1	4	3	2	1	0
Item 2	0	1	2	3	4
Item 3	4	3	2	1	0
Item 4	0	1	2	3	4
Item 5	4	3	2	1	0
Item 6	4	3	2	1	0
Item 7	0	1	2	3	4
Item 8	0	1	2	3	4
Item 9	4	3	2	1	0
Item 10	4	3	2	1	0

The BSS-R comprises the following three sub-scales:

Sub-scale	Sub-scale items	Score range
Stress experienced during labour	1, 2, 7, 9	0 - 16
Women's personal attributes	4, 8	0 - 8
Quality of care provision	3, 5, 6, 10	0 - 16

It is entirely acceptable to calculate a total BSS-R score of the 10 items in order to give an overall birth satisfaction score.

An **optional** 'comments' section (two lines) may be placed *following the response categories* to each BSS-R question for additional qualitative insights if required.

The BSS-R is free for use in clinical practice, routine outcomes measurement, and clinical research but requires permission from the developer. Please contact: Prof Caroline J. Hollins Martin (c.hollinsmartin@napier.ac.uk) to obtain permission to use the measure and an official copy of the instrument or to inquire about translations.

The Birth Satisfaction Scale-Revised (BSS-R) was created by:
(1) Professor Caroline J Hollins Martin, Edinburgh Napier University (UK). Contact: c.hollinsmartin@napier.ac.uk
(2) Professor Colin Martin, University of Hull (UK).

The original development and validation reference for the BSS-R below must be cited in any published output that has used this original version, or any translated, modified or non-UK version of the measure:

Hollins-Martin, C.J., Martin, C. (2014). Development and psychometric properties of the Birth Satisfaction Scale-Revised (BSS-R). Midwifery. 30: 610-619 http://dx.doi.org/10.1016/j.midw.2013.10.006

Reference for the United States version of the BSS-R:

Barbosa-Leiker, C., Fleming, S., Hollins Martin, C.J., Martin, C.R., 2015. Psychometric properties of the Birth Satisfaction Scale-Revised (BSS-R) for US mothers. Journal of Reproductive and Infant Psychology 33 (5), 504-511.

*Permission was obtained from the authors for use of the Birth Satisfaction Scale-Revised (BSS-R). Please see email communication included below.

Such, Tami

From: Hollins Martin, Caroline <C.HollinsMartin@napier.ac.uk>
Sent: Thursday, November 15, 2018 10:58 AM
To: Such, Tami
Cc: Colin R Martin
Subject: RE: Request for use of your BSS-R
Attachments: Birth Satisfaction Scale Revised_Hollins Martin and Martin 2014_UNITED STATES VERSION_ver1.3.pdf; (14) JRIP BSS-R USA Washington.pdf

Dear Tami,

I attach the US validated version of the BSS-R and validation paper for your use. I wish you every success with the study. I have copied in my research partner Prof Colin Martin. If there are any questions, please feel free to contact us.

Best Cj

Prof Caroline J Hollins Martin
PhD MPhil BSc RM RGN (MBPsS) Senior Fellow HEA
School of Health and Social Care
Edinburgh Napier University (Sighthill Campus)
Email: C.HollinsMartin@napier.ac.uk
Mobile: 07500443427

Currently on secondment to NHS Education Scotland (NES) as Head of Programme for Women, Children, Young People and Families (WCYPF), NMAHP NHS Education for Scotland, Westport, 102 Westport, Edinburgh, EH3 9DN.
Email: Caroline.Hollins-Martin@nes.scot.nhs.uk

To view publications:
http://researchrepository.napier.ac.uk/view/people/Hollins_Martin=3ACaroline_J=3A=3A.html

Research impact: The Birth Satisfaction Scale-Revised (BSS-R) developed by Hollins Martin and Martin (2014) now recommended as the key clinical measure of birth satisfaction globally: www.ichom.org/medical-conditions/pregnancy-and-childbirth/

Research impact: The Birth Satisfaction Scale-Revised (BSS-R) developed by Hollins Martin and Martin (2014) is to be incorporated into the European-wide Medical Data Models (MDM) meta-data registry for academic medical research developed by the Institute of Medical Informatics, University of Münster in Germany: www.medical-data-models.org/

Research impact: The Birth Satisfaction Scale-Revised Indicator (BSS-RI; Martin, Hollins Martin and Redshaw, 2017) development and validation paper, a short-form version of the BSS-R developed by Hollins Martin and Martin (2014), is available from the Nuffield Department of Population Health, Medical Sciences Division, University of Oxford, website https://www.ndph.ox.ac.uk/publications/726242

From: Such, Tami <tami.such@mayvillestate.edu>
Sent: 12 November 2018 00:12
To: Hollins Martin, Caroline <C.HollinsMartin@napier.ac.uk>
Subject: Request for use of your BSS-R

1

Hello Dr. Hollins-Martin,
My name is Tami Such and I am a third year doctoral student in the PhD in Nursing program at the University of North Dakota. I would like to thank you for your great contributions to advance nursing science regarding women's satisfaction with their birth experience through creation of the Birth Satisfaction scale-Revised (BSS-R) and multiple subsequent compelling and meaningful studies using this instrument. I am emailing to request permission for use of the US translation of your Birth Satisfaction scale-Revised (BSS-R) within my dissertation study, "Exploring the Effects of Intrapartum Nitrous Oxide Use on Comfort and Satisfaction."

Please let me know if you need any additional information to consider my request. Thank you, in advance, for your consideration. I look forward to your response when possible.
Best Regards,
Tami Such
--

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Appendix E: Prenatal Information Survey

*Survey was completed by the participant in Qualtrics to allow for electronic storage and aggregation of the data as well as export to Excel and transfer to SPSS for data analysis. Participant survey included questions from the Prenatal Information Survey, the researcher-modified version of the Childbirth Comfort Questionnaire and the Birth Satisfaction Scale-Revised. The same unique study code was assigned to the participant survey and the data collection tool to allow for match and revisit of the data within Qualtrics and the Electronic Health Record as needed during data analysis.

Prenatal Information Survey Questions

Participant Study Code:_____ (assigned/entered by the PI or PI trained nurse research assistant)

Note: Codes planned for use during data analysis are referenced following each item.

Race:

- White alone (0)
- Black or African American alone (1)
- American Indian or Alaska Native alone (2)
- Asian alone (3)
- Native Hawaiian or other Pacific Islander alone (4)
- Some other race alone (5)
- Two or more races (6)

Ethnicity:

- Not Hispanic or Latino (0)
- Hispanic or Latino (1)

Marital status:

- Single (0)
- Married (1)
- Widowed (2)
- Divorced (3)
- Separated (3)
- Living with partner (5)
- Other living arrangement (6) (include text option)

Annual Household Income:

- Under $25,000 (0)
- $25,000 to $49,999 (1)
- $50,000 to $74,999 (2)
- $75,000 to $99,999 (3)
- $100,000 and over (4)

Currently employed: Yes (1), No (0)
Highest level of education:
- Less than high school graduate (0)
- High school graduate (1) (including GED or other equivalent)
- Some college or associate's degree (2)
- Bachelor's degree or higher (3)

History of anxiety or psychiatric disorders:
- No history of anxiety or psychiatric disorder (0)
- Anxiety (1)
- Depression (2)
- Panic disorder (3)
- Bipolar disorder (4)
- Post-traumatic stress disorder (5)
- Obsessive-compulsive disorder (6)
- Eating disorder (7)
- Schizophrenia (8)
- Other disorder (9) (include text option)

History of past negative birth experiences:
- No history of past negative birth experiences (0)
- Traumatic birth/delivery (1)
- Assistance for baby to breathe or stay alive after birth (neonatal resuscitation) (2)
- Transfer of newborn to intensive care (Neonatal Intensive Care Unit/NICU) (3)
- Fetal or neonatal death (4)
- Other negative birth experience (5) (include text option)

Participation in formal childbirth preparation classes:

- Never attended (0)
- During past pregnancy (1)
- During current pregnancy (2)

Presence of support person during labor and/or birth:
- No support person present (0)
- Spouse (1)
- Significant other (2)
- Family member (3)
- Friend (4)
- Other (5) (include text option)

During my labor and birth, I used the following to help with my pain (check all that apply):

Non-medication or Alternative therapies for pain
Acupuncture (1)
Hypnotism (2)
Yoga (3)
Exercise/walking (4)
Hydrotherapy/whirlpool tub (5)
Transcutaneous electronic nerve stimulation (TENS) (6)
Massage (7)
Meditation (8)
Guided imagery (9)
Focused/paced breathing techniques (10)
Other_____(comment option to be included) (11)

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