ORGANIZATIONAL STRUCTURE AND WORK ENVIRONMENT PREDICTORS OF ADVERSE EVENTS AS REPORTED BY NURSE ANESTHETISTS

By

SUSAN P. MCMULLAN

A dissertation submitted to the Graduate School-Newark

Rutgers, The State University of New Jersey

In partial fulfillment of the requirements

for the degree of

Doctor of Philosophy

Graduate Program of Nursing

Written under the direction of

Charlotte Thomas-Hawkins, PhD, RN

Associate Professor

And approved by

Linda Flynn

Jeannie Cimiotti

Michael J. Kremer

Newark, New Jersey

May, 2014

ABSTRACT OF THE DISSERTATION

Organizational Structure and Work Environment Predictors of Adverse Events as Reported by Nurse Anesthetists

By SUSAN P. MCMULLAN

Dissertation Director:

Charlotte Thomas-Hawkins, PhD, RN

Rationale: This study attempted to fill a gap in knowledge by analyzing the interrelationships among Certified Registered Nurse Anesthetist (CRNA) organizational structures (practice models, work setting, workload, level of education, and years of experience), perceptions of patient safety culture, and adverse anesthesia-related events in patients who receive anesthesia administered by CRNAs. There have been no studies that have assessed whether these structural and safety culture factors influence the occurrence of adverse-anesthesia events in patients cared for by CRNAs as well as an overall paucity of data related to outcomes of CRNA-administered data. As patient safety is a key feature of our healthcare system, it is paramount for CRNAs to address how work environment and safety culture influence practice**. Method**: The Nursing Organization and Outcomes Model (NOOM) and the Patient Safety Culture Framework were used to explore the interrelationships between CRNA organizational structures, perceptions of patient safety culture, and adverse event–reporting. Approval by the Internal Review Board of Rutgers University was obtained prior to commencement of the study. 500 CRNAs working in hospitals and ambulatory care settings were randomly selected to participate in this survey research; 336 participants returned surveys. **Results**: The organizational structures increased workload and less years of experience predicted inadequate ventilation and difficult extubation, as well as perception of patient safety culture and patient safety grade; higher workload and less years of experience independently predicted poorer perceptions of safety and safety grade. Lastly, patient safety grade was an independent predictor of inadequate ventilation; perception of patient safety culture was an independent predictor of inadequate ventilation, inadequate oxygenation and difficult intubation. **Conclusion**: Two organizational structures, CRNA workload and years of experience, were significantly related to CRNA-reports of adverse events and patient safety culture. The relationship between the organizational structures work setting, educational level and practice model and reports of adverse events and patient safety culture were not supported. Until this study, there was no research that examined CRNA structures, high quality work environments, and CRNA-report adverse anesthesia-related patient events. Study results indicate that the NOOM and Patient Safety Culture provides a solid framework for future research.

Dedication

To Andrew for without you I would not have made it. Thank you for being my partner, for helping me stay positive, and for all the sacrifices, and tech support.

To my boys, JB, RB, and WM: Thank you for encouraging me and loaning me your calculators.

To my mother, JP, thanks for inspiring me to become a nurse; I know that you are up there watching.

To my friends LG, LS, JS, and RJ who made my journey better!

Acknowledgements

I am extremely grateful for all the support I received during my doctoral studies.

To Dr. Michael Kremer, thank you for being there as a role model within the Nurse Anesthesia community. Thank you for being my mentor as an advanced practice nurse, researcher and educator; you were one of my biggest strengths and your wisdom is infinite.

To Dr. Charlotte Thomas-Hawkins, thank you for your emails prodding me along, your kind and supportive words, and constructive criticism. I appreciate the guidance and mentorship throughout this process. I could not have done it without you.

To my dissertation committee members, Dr. Linda Flynn and Dr. Jeannie Cimiotti for their vast knowledge and support.

To all of the Nurse Anesthesia students that have allowed me to participate in their educational process; you inspire and challenge me to improve every day.

To Seymour and Ringo Starr, a woman's best friends. Thanks for staying by my side even on the earliest mornings and the latest nights.

Table of Contents

Title i

Abstract ii

CHAPTER I. THE PROBLEM

A. Discussion of the Problem 1

B. Statement of the Problem 11

C. Sub-problems 11

D. Significance of the Study 12

CHAPTER II. REVIEW OF THE LITERATURE

A. Theoretical Frameworks

1. Nursing Organization and Outcome Model 15

2. Patient Safety Framework 16

3. Literature Review:

Independent and Dependent Variables

a. Organizational Structures and Adverse Events 17

b. Patient Safety Culture and Adverse Outcomes 31

c. Nursing Structures and Patient Safety Culture 35

d. Additional Study Variables 37

B. Hypotheses 39

C. Definitions of Terms-Theoretical and Operational 40

CHAPTER III. METHODS

A. Description of Research 42

B. Sample 43

C. Instruments 44

1. CRNA- reported Adverse Events 44

2. Patient Safety Culture 45

3. Workload 47

4. Demographics 50

D. Procedure for Data Collection 51

E. Human Subject Protection 51

F. Data Analysis Plan 52

CHAPTER IV. ANALYSIS OF THE DATA

A. Statistical Description of the Variables 56

B. Psychometric Properties of the Instruments 57

C. Results of Hypothesis Testing 63

D. Ancillary Findings 75

CHAPTER V. DISCUSSION OF THE FINDINGS

A. Hypothesis One: Relationship between CRNA Organizational Structures and CRNA-Reported Adverse Events 79

B. Hypothesis Two: CRNA Organizational Structures and Patient Safety Culture 82

C. Hypothesis Three: Patient Safety Culture and CRNA–Reported Adverse Anesthesia-Related Events 85

D. Theoretical Adequacy 87

CHAPTER VI. SUMMARY, CONCLUSIONS, IMPLICATIONS, RECOMMENDATIONS

A. Summary 87

B. Limitations of the Study 91

C. Conclusions 91

D. Implications for Nursing 93

E. Recommendations 94

REFERENCES 96

APPPENDIX

1. Appendix A Rutgers IRB 107

2. Appendix B Cover letter for Implied Consent 108

3. Appendix C Survey Tool 110

CHAPTER ONE

The Problem

Patient safety is a genuine concern in an ever changing health care system. In today's healthcare environment, it is imperative that healthcare delivery systems are both fiscally sensible and provide quality care, insuring patient protection from error and adverse outcomes. This is especially true in the high stakes field of anesthesia where advanced technologies, new information systems, and increasingly complex patient care have become the norm. Anesthesia providers are not only expected to provide high quality care under these circumstances but are pressed to operate faster and more efficiently. Since the landmark Institute of Medicine (IOM) report "To Err Is Human: Building a Safer Health System" (IOM, 1999) patient safety issues and the reduction of adverse events have been at the forefront of quality healthcare discussions. Because adverse errors in the perioperative anesthesia practice have been described as both multifactorial system errors (Cheney, 2010; Crawforth, 2002; Reason, Carthey & de Laval, 2001), and process of care problems (Metzner, Posner, Lam & Domino, 2011; Cheney, 2010; Caplan, Callahan, & Hicks, 2002; Petty, Kremer & Biddle, 2002), it is important to determine the nature of anesthesia-related adverse events and important antecedents to their occurrences.

Adverse Anesthesia-Related Events

Closed claim studies help to provide insight into the scope of the problem of adverse medical errors and near misses experienced by persons undergoing general anesthesia in our nation's operating rooms. Closed claims refer to malpractice claims resulting from a medical injury that have been dropped or settled in court (Jordan, Kremer, Crawforth & Shott, 2001; Posner, 2001). To date, the American Society of Anesthesiologists (ASA) has reviewed over 8,000 claims; 5230 of these claims were filed after 1990 (Metzner, Posner, Lamm & Domino, 2011). While closed claim reports have their limitations in that they only represent lawsuits that have been filed, they still provide critical information that cannot be found elsewhere (Cheney, 1999). It is common that medical errors are under-reported (Petty, Reason, & Sanchez, 2012). However closed claim reports provide data-based evidence on which to base need for improvement.

Prior to 1990, adverse respiratory events comprised the highest number of overall anesthesia claims (Bailie & Posner, 2011). Subsequent to this time, improved patient monitoring capabilities led to development of basic anesthesia standards of care: the development of continuous pulse oximetry, end tidal carbon dioxide monitoring capabilities, and improved anesthesia machines with fresh gas ratio protection (older machines could actually deliver lethal concentrations of nitrous oxide) significantly contributed to anesthesia patient safety (Eichorn, 2012). Claims involving adverse respiratory events (inadequate oxygenation/ventilation, difficult intubation, esophageal intubation and aspiration) decreased dramatically from 1990 to 2007, yet still comprise 17% of all anesthesia malpractice claims today (Bailie & Posner, 2011).

After 1990, the ASA Closed Claims Project (ASA-CCP) reported that death or brain damage represented almost 32% of all claims with an adverse respiratory event as the precipitating factor in 45% of those cases (Caplan, 1999; Cheney, 1997). Similarly, the American Association of Nurse Anesthetists (AANA) Foundation Closed Claims Study reported death and/or brain injury in 61% of all claims listing a respiratory event as the precipitating factor (Jordan et al., 2001). These data demonstrate that despite improvements in anesthesia monitoring standards, adverse anesthesia-related events are still significantly prevalent, with airway issues, such as difficult intubation/extubation, inadequate oxygenation/ventilation and pulmonary aspiration of gastric contents, as the leading causes of morbidity and mortality in anesthesia-related adverse outcomes today (Bailie & Posner, 2011; Metzger, Posner, Lam, and Domino, 2011).The adverse respiratory anesthesia-related events of interest to this study include CRNA-reported difficult intubation, difficult extubation, inadequate oxygenation/ventilation, and pulmonary aspiration of gastric contents.

Antecedents to Adverse Anesthesia-Related Patient Events

Organizational Structures for Certified Registered Nurse Anesthetist Care

One explanation for variations in anesthesia-related events is a set of theoretical propositions that posit that nursing organizational structures and work environment cultures have a direct influence on adverse occurrences and patient outcomes (Aiken, Clarke, & Sloane, 2002). Theorists postulate that organizational structures in healthcare institutions, such as the work setting, employee level of education, employee workload, and models of care delivery have a significant influence on the outcomes of persons who receive care in these institutions (Aiken et al., 2002; Donabedian, 1980). The relationship between organizational nursing structures for staff nurses, such as RN staffing and workload and patient outcomes in hospital environments has been studied extensively (Aiken, Clarke & Sloane, 2002; Aiken, Clarke, Sloane, Lake & Cheney, 2008; Lacey et al., 2007), and research has consistently shown that high RN staffing ratios and low workloads facilitate positive patient outcomes in hospitals (Aiken et al, 2002; Aiken et al, 2008; Wiltse-Nicely, Sloane & Aiken, 2013). Similar to staff nurses, the structural relationships of Certified Registered Nurse Anesthetists (CRNAs) in healthcare organizations vary, yet the effects of CRNA structures, such as practice models and workload, in healthcare organizations on the outcomes of patients who receive anesthesia by these practitioners have received no attention.

CRNA Practice Models. CRNA care delivery or practice models are important organizational structures in healthcare settings that may be significantly related to occurrences of adverse anesthesia-related events. CRNAs typically practice in three different practice models. The first two models are considered anesthesia care team models. One model is the medical direction model, where a CRNA works collaboratively with an anesthesiologist to provide anesthesia care to patients. In this model, an anesthesiologist may medically direct up to four CRNAs simultaneously, and this model has prescriptive requirements for the anesthesiologists to actually be present during critical parts of the procedure such as induction and emergence of anesthesia (Hogan, Seifert, Moore, & Simonson, 2010). In the next anesthesia care team model, known as the supervision model, one anesthesiologist supervises more than four CRNAs and is physically on site but does not need to be present for key parts of the procedure. A third model is autonomous or independent practice where nurse anesthesia care is delivered independently of an anesthesiologist; CRNAs are neither medically directed nor supervised. Notably, the cost effectiveness of the models demonstrates that the CRNA working independently is the most economically advantageous model both financially and in terms of time efficiency, and provides the lowest cost to the private payer (Hogan et al, 2010). Independent CRNA practice is more commonly found in rural areas with low numbers of anesthesia providers available (Dulisse & Cromwell, 2010). The medical direction 1:4 model, where one anesthesiologist provides medical direction to CRNAs for four concurrent cases, is efficient in facilities where demand is high and stable but inefficient for low demand areas (Hogan et al, 2010).

Unlike CRNA practice models, the typical care delivery model for staff nurses in inpatient hospital settings includes a “skill mix” of caregivers comprised of registered nurses, licensed practical nurses, and unlicensed assistive personnel, and research has shown that a skill mix that includes higher numbers of registered nurses is associated with positive patient outcomes and lower occurrences of adverse events (Aiken, Clarke, Cheung, Sloane, & Silber, 2003). However, there has been no research that examines the extent to which CRNA practice models are associated with adverse event occurrences in persons undergoing anesthesia. As the health care industry changes, and more emphasis is placed on cost of services, it is important to gain an understanding of the extent to which CRNA practice models affects adverse outcome occurrences as reported by CRNAS.

CRNA Work Setting. In addition to the practice model, CRNAs provide anesthesia care in a variety of settings. The type of setting in which CRNAs practice can vary and includes both inpatient and outpatient sites such as hospital operating rooms, labor and delivery, offsite and ancillary areas such as endoscopy, cardiac catheterization, interventional radiology, magnetic resonance imaging and outpatient procedural and office settings. Each of these work environments has unique features that may affect practice. For example, adverse anesthesia-related events in remote hospital locations have been linked with higher levels of serious injury and death compared with adverse anesthesia-related events in the operating room suite (Metzner, Posner & Domino, 2009).

Work settings are considered remote or “offsite” in many hospitals because the CRNA is working in an area of the hospital that is away from the traditional OR setting. In these offsite locations, ancillary personnel are frequently unfamiliar with anesthetic routines and standards of care commonly found in the OR. For example, the equipment used by anesthesia care providers in remote locations is frequently different from that found in the OR. The monitors may be different or unfamiliar to the CRNA. The anesthesia cart which contains essential medications, intravenous access supplies, and airway management equipment may be arranged differently than that in the OR; the physical space provided for the practitioner can be physically limiting to movement, and the ambient and available lighting may be reduced. Such setting differences may create situations that affect patient safety during anesthesia and can lead to errors, near misses, and adverse patient events. There has been no research that examines the extent to which CRNA work setting is associated with the occurrence of adverse anesthesia outcomes in patients.

CRNA Workload. The concept of workload varies from profession to profession. It can be defined in a variety of ways and is composed of several components (Hoonaker et al, 2011; Leerdal & Smith, 2005; Young, Zavelina & Hooper, 2008). Workload is conceptualized as a multidimensional and complex construct that is affected by external task demands, environmental, organizational and psychological factors, and perceptive and cognitive abilities (Weinger, Reddy, & Slagle, 2004). In a review of the literature, nursing workload is comprised of an intense, complex level of skill required to provide both patient care and non-patient care activities during work hours (Morris, Macneela, Scott, Treacy & Hyde, 2007). This definition is in contrast to staff nurse workload which is frequently operationalized in research as a quantification of the number of patients a nurse is responsible for or the number of hours per patient that a nurse spends providing patient care, and this conceptualization ignores the complexity, intensity, and non-patient care activities a nurse provides throughout the work period. While nursing workload is typically defined in relation to patient acuity and staffing ratios, it is often conceptualized as production pressure in anesthesia care (Gaba, Howard, and Jump, 1994; Kirsner & Biddle, 2012; Leedal & Smith, 2005).

Production pressure is defined as the pressure placed on an anesthesia provider or CRNA to work faster as a higher priority than working more safely (DeMaria & Neustein, 2010). Production pressure can differ with each anesthetic case, environment and/or type of facility. Production pressures are created by factors found within an organizational work system; the genesis of production pressure is to reduce OR downtime, maximize billable revenue, especially during times when most staff are available, e.g., 0700-1500/1700. These factors affect the care in many forms including safety of care provided (Carayon & Alvarado, 2007). Several studies indicate that increased production pressure has a negative effect on patient outcomes, in the form of more adverse outcomes and near misses (Carayon & Alvarado, 2007; DeMaria & Neustein, 2010, Gaba, Howard, & Jump, 1994). There are numerous studies that have measured workload in staff nurses and its effects on patient outcomes (Aiken, Van den Heede, Sloan, Busse, McKee, Bruyneel et al, 2012; Aiken, Cimiotti, Sloane, Smith, Flynn and Neff, 2011; Friese, Lake, Aiken, Silber & Sochalski, 2008). However, there are no studies that have examined CRNA workload and its relationship with adverse anesthesia-related events in patients who receive anesthesia by these care providers.

Demographic Characteristics. As in all occupations, demographic differences exist between CRNA providers, and research findings in samples of staff nurses suggest that low levels of CRNA education and years of experience may also be significantly associated with adverse anesthesia-related events in patients who receive CRNA-administered anesthesia. For example, research has revealed that hospitals with higher proportions of nurses educated at the baccalaureate level or above have lower rates of surgical mortality and failure to rescue (Aiken, Clarke, Cheung, Sloane & Silber, 2003). Nurse anesthesia education has changed over the past thirty years. In the 1970s all graduates had a baccalaureate degree and received a certificate in nurse anesthesia upon completion of the program. By 1998 all nurse anesthesia programs were required to confer a graduate Master's degree. At the current time, the Council on Accreditation of Nurse Anesthesia programs (COA) in conjunction with the American Association of Nurse Anesthetists (AANA) and the National Board of Certification of Nurse Anesthetists (NBCRNA) is in the process of changing CRNA educational degree to the clinical Doctorate by the year 2022 (COA, 2012). Because of these recent educational changes, there are currently practicing CRNAs with Bachelor's, Master's and Doctoral degrees. Alves (2005) found that CRNAs with a Master's degree or higher reported a greater scope of practice compared with lesser degreed CRNAs. It is important to determine whether educational level affects adverse anesthesia-related events in patients who receive anesthesia by CRNAs.

In addition to educational level, years of CRNA experience may also be associated with adverse anesthesia-related events. In an analysis of National Database of Nursing Quality Indicators (NDNQI) patient outcome data, researchers found that years of staff nurse experience was positively related to improved patient outcomes such as significant reduction in patient falls and hospital acquired pressure ulcers, emphasizing the importance of retaining experienced RNs for promotion of quality patient care and outcomes (Dunton, Gajewski, Klaus, & Pierson, 2007). Thus, it seems plausible that CRNA years of experience may have an important association with adverse anesthesia-related events in patients cared for by CRNAs. To date, no studies have examined this association.

High Quality Work Environments

Patient safety culture. In the past decade, there has been a growing awareness among health care professionals of the need to decrease the occurrence of adverse events and establish a culture of patient safety within health care organizations in the United States (U.S.) (Buerhaus, 2007; Leape, 2009). A patient safety culture reflects employees' perceptions of safety policies, procedures and practices in use within an organization and also acts as a frame of reference for their behavior and attitudes (Clarke, 2006; Mardon, Khanna, Sorra, Dyer, & Fomolaro, 2010; Mearns, Flin, Gordon, & Fleming, 2001), and there is a growing body of empirical evidence that links negative safety cultures in work environments with adverse patient events.

For example, employee's fair to failing safety culture ratings in their hospital work settings are associated with the perception that adverse patient events are more frequent with adverse patient events such as medication errors (Chang & Mark, 2011; Hofman & Mark, 2006), and iatrogenic pneumothorax and infections following surgical procedures (Mardon et al., 2010). Disturbingly, research has indicated that staff in operating rooms rate patient safety lower compared to other settings within hospitals. For example, a large multicenter study revealed that the safety culture of the operating room (OR) and the post anesthesia care units (PACU) was rated significantly lower than the safety cultures found in other areas of the same hospital (Kaafarani et al., 2009). In particular, the OR/PACU staff reported observation of unsafe patient care, lower hospital interest in quality of care, and reduced perception of understanding of clinical care by hospital administration when compared with other hospital departments (Kaafarani et al, 2009). Despite these findings, little is known regarding the impact of safety cultures, as graded by CRNAs, on adverse event occurrences and near misses in OR patients.

Research findings also suggest that nursing organizational structure variables may be important antecedents to CRNA perceptions of the extent to which the culture of safety in their work environments are positive are negative. For example, work setting, workload, and years of experience have been shown to be important predictors of health care professionals', including staff nurses, perceptions of safety in their work environments (El-Jardali, Dimassi, Jamal, Jaafar & Hemedeh, 2011; Thomas-Hawkins & Flynn, 2013a). Thus, it is important to examine the interrelationships among CRNA organizational structures, patient safety culture ratings, and their reports of adverse anesthesia-related adverse events in patients cared for by CRNAs.

The purpose of this study, therefore, was to examine the relationships among CRNA organizational structures (CRNA practice models, CRNA work setting, CRNA workload, CRNA level of education, CRNA work experience) and CRNA ratings of patient safety culture, and CRNA-reported adverse anesthesia-related events in patients receiving anesthesia by CRNAs.

Research Question

What are the relationships among CRNA organizational structures (practice models, CRNA work setting, CRNA workload, CRNA level of education, CRNA work experience), CRNA ratings of patient safety culture, and CRNA-reported anesthesia-related adverse event (difficult intubation/extubation, inadequate oxygenation/ventilation, and pulmonary aspiration of gastric contents) in patients receiving CRNA administered anesthesia?

Sub Question(s)

1. What is the relationship between CRNA organizational structures (practice models, work setting, workload, level of education, work experience) and CRNA-reported anesthesia-related adverse events (difficult intubation, difficult extubation, inadequate oxygenation/ventilation, pulmonary aspiration of gastric contents) in patients receiving CRNA-administered anesthesia?
2. What is the relationship between patient safety culture (overall perception of safety, patient safety grade) and CRNA-reported anesthesia-related adverse events (difficult intubation, difficult extubation, inadequate oxygenation/ventilation, pulmonary aspiration of gastric contents) in patients receiving CRNA-administered anesthesia?
3. What is the relationship between CRNA organizational structures (practice models, work setting, workload, level of education, work experience) and patient safety culture (overall perception of safety, patient safety grade)?

Significance of the Study

This study attempted to fill a gap in knowledge by analyzing the interrelationships among CRNA organizational structures, perceptions of patient safety culture, and adverse anesthesia-related events in patients who receive anesthesia by CRNAs. To date there have been no studies that have assessed whether these structural and safety culture factors influence the occurrence of adverse-anesthesia events in patients cared for by CRNAs as well as an overall paucity of data related to outcomes of CRNA-administered data. As healthcare costs spiral and health care dollars dwindle, it is paramount for CRNAs to address how work environment and safety culture influence practice. The AANA motto promotes safe and effective anesthesia care (AANA, 2012). Sound evidence-based research is needed to justify clinical practice measures that insure patient safety. Moreover, changes in the healthcare system will likely demand clinical outcome data to justify costs and reimbursement. Performance measures are critical to the national effort to assure that patients receive appropriate and high-quality care. Pay for performance (P4P), or value-based purchasing, will likely link clinical outcomes with reimbursement. P4P also includes disincentives for negative consequences of care or increased costs for “never” events, e.g., wrong-site surgery, operative or postoperative complications, medication errors (AHRQ, 2012). It is not known if reimbursement mechanisms will continue to support payment for two anesthesia providers or only one provider. If the latter comes to pass, it will be especially important for CRNAs to practice at a high level and demonstrate sound outcomes in keeping with Institute of Medicine’s (IOM) report on the Future of Nursing (IOM, 2010). Hence it is necessary for CRNAs to examine how organizational factors affect their ability to provide high quality, and safe patient care.

Little research has been performed on CRNA practice models and adverse event reporting. One study suggests that there are no differences in anesthesia outcomes between independent CRNA practice in states that have opted-out of the Medicare medical supervision requirement, and the ACT model of anesthesia practice (Dulisse and Cromwell, 2010). This is important because practice model is linked to cost. Independent CRNA practice, that is anesthesia care without medical direction or supervision by an anesthesiologist, is the most cost effective type of anesthesia delivery model (Hogan et al, 2010). While cost is certainly a consideration, patient safety is also of the utmost importance to patients and insurers alike. This study sheds light on how practice model affects adverse event reporting.

CRNAs work in a variety of settings, including hospital ORs as well as off-site locations. Research has demonstrated the highest numbers of anesthesia-related legal claims today are related to adverse respiratory events that occur in remote practice areas (Metzner, Posner and Domino, 2009). Many minor surgeries and procedures can be performed for a lower cost in a non-OR setting. As cost reduction becomes a higher concern, more procedures will be performed in the non-OR setting. It is critical to determine if CRNA adverse event reporting varies by work setting.

As healthcare dollars decrease, CRNAs are being pressed to turnover cases more rapidly. Production pressure can affect the time a provider spends assessing the patient as well as the time spent preparing necessary equipment and medications in order to give a safe anesthetic (Demaria and Neustein, 2010). Work overload and time pressure increase occupational accidents in non- health care industries (Frone, 1998; Zohar, 2000). Moreover, it is estimated that half of all adverse health care errors happen in the operating room (Brennan et al., 2004). It is important to determine if production pressure as a proxy for workload, affects CRNA adverse event reporting.

CRNA educational training has changed over the past 30 years. CRNAs practicing today may have a Bachelor's, Masters or Doctoral degree. It is unknown whether adverse event reporting varies based on education. Also, experience level can vary widely from the new graduate level to the seasoned anesthetist. It is important to determine if error reporting varies by educational and/or years of experience.

Patient safety is of the utmost concern. Despite cuts in healthcare dollars, insurers and patients alike demand high quality care. CRNAs are leaders in advance practice nursing and must address patient safety culture in their workplaces, insuring patient safety during anesthesia. CRNAs must practice to highest level of their education and protect patients during the vulnerable perioperative period.

Chapter Two

Theoretical Framework and Literature Review

This research examined the relationships among 1) CRNA structures (practice models, work setting, workload, level of education, work experience); 2) patient safety culture (overall perception of safety in CRNA work environments; patient safety grade); and 3) CRNA-reported adverse event occurrences and in patients receiving CRNA administered anesthesia. Theoretical and empirical literature that helps to explain these relationships will be discussed. First, theoretical literature relevant to nursing structures, patient safety culture, and patient outcomes will be discussed. Next, research literature that provides empirical support for the theorized relationships to be tested in the proposed study will be presented. Finally, theoretical linkages and the study hypotheses will be presented.

Theoretical Framework

Nursing Organization and Outcomes Model

Based on social scientist Donabedian's (1988) Structure, Process and Outcome Model, the Nursing Organization and Outcomes Model (NOOM) (Aiken, 2002) proposes that organizational structures, attributes of high quality work environments, and processes of care influence patient outcomes. Structures are indicated by nurse supply, skill mix, skill level or experience, workload, and education or certification. One key feature of a high quality work environment is patient safety culture, and the model indicates that a positive patient safety culture aids in the reduction of adverse patient events and fosters positive patient outcomes. Specifically, the model posits positive relationships among nursing organizational structures, high quality work environments, and patient outcomes. According to the model, better staffing, lower workloads and high quality practice environments free nurses to concentrate on their patients, facilitate high quality and safe care processes, and enhance positive patient outcomes. Conversely, less staffing, higher workloads and low quality work environments impair care processes and produce adverse events and negative patient outcomes.

Although the NOOM's applicability to CRNA practice has yet to be established, this theoretical nursing model provides a solid framework to examine the extent to which CRNA structures (work setting, practice model, workload, and education/experience) and high quality practice environments in which they work (patient safety cultures) are associated with adverse events as reported by CRNAs (Figure 1).

Patient Safety Culture Framework

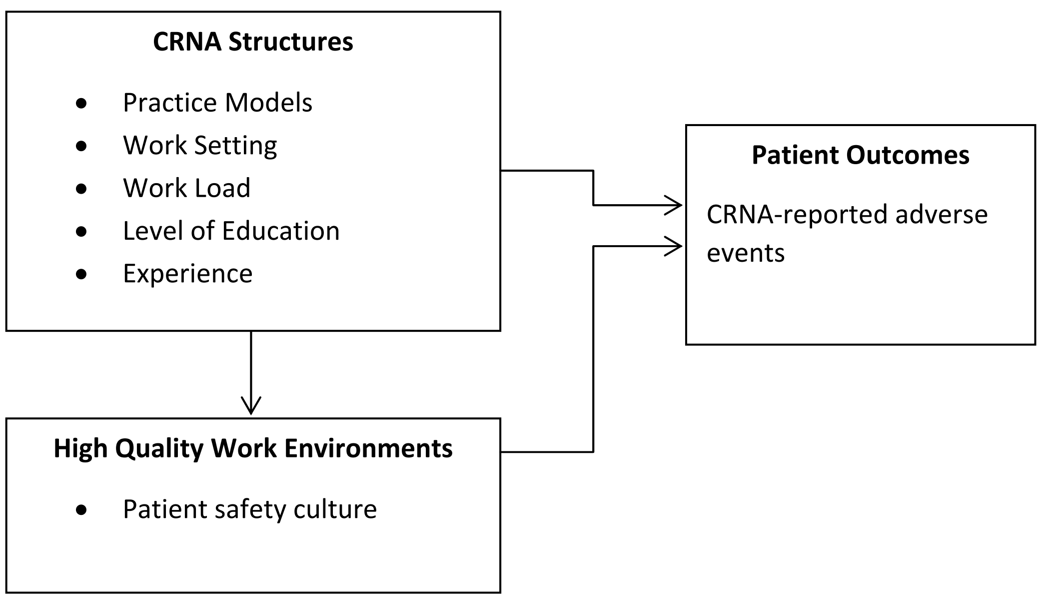
The concept of safety culture is a complex phenomenon that is not easily understood (Sammer, Lykens, Singh, Mains, & Lackans, 2010). A patient safety culture reflects employees' perceptions of safety policies, procedures and practices in use within an organization, and it also acts as a frame of reference for their behavior and attitudes (Clarke, 2006; Mearns, Flin, Gordon, & Fleming, 2001). The Agency for Healthcare Research and Quality (AHRQ) describes the concept of safety culture as an organization's commitment to safety at all levels of the organization in the face of inherently complex and potentially hazardous procedures (AHRQ 2012). AHRQ cites four key features of patient safety culture (AHRQ, 2012):

- An organization must acknowledge the high-risk nature of their activities and be determined to achieve safe operations.
- The environment must be blame-free where individuals can report errors or near-misses without fear of punishment.
- There must be collaboration across ranks and disciplines to find solutions to patient safety problems.
- There must be commitment of resources to address safety concerns.

AHRQ also conceptualizes patient safety culture as having multiple unit- and hospital-level dimensions. Two important dimensions of patient safety culture, according to AHRQ, are hospital employees' overall perception of patient safety and patient safety grade for their hospital unit. Poorly perceived safety culture has been linked to increased error rates (AHRQ, 2012). Yet, little is known regarding the state of patient safety cultures in the complex and potentially hazardous setting of the operating room, nor is there any evidence regarding the impact of safety cultures on the frequency of adverse events among patients receiving nurse administered anesthesia.

Based on the NOOM which links positive nursing work environment to improved patient outcomes and reduced mortality (Aiken et al, 2008), patient safety culture is a key dimension of high quality nursing work environments. However, there has been no research to date that have examined the associations among CRNA structures in hospital settings, CRNA perceptions patient safety culture in their work environment, and CRNA reports of adverse event occurrences in patients who receive nurse administered anesthesia.

Figure 1. Nursing Organization and Outcomes Model



Literature Review

Organizational Structures and Adverse Events

In this section an analysis and synthesis of the empirical evidence supporting the theorized relationship that nursing structures in health care organizations have a direct influence on patient outcomes is presented. Specifically, empirical research that tested the relationship between nursing and other professional employee structures and patient outcomes is presented. The literature review consists of studies that examined nursing structures to be examined in this study, that is, RN education, work setting, workload, experience, and practice models, and their relationship with patient outcomes. The search yielded fourteen studies. For each study, the nursing sample, study design, sample characteristics, variables and relevant measures and findings are summarized in Table 1.

Nurse Education and Patient Outcomes. In five of the studies reviewed, level of education of the nurse was significantly and inversely related to adverse patient outcomes in hospitalized patients (Aiken, Cimiotti, Sloane, Smith, Flynn & Neff, 2011; Aiken, Clarke, Cheung, Sloane, & Silber, 2003; Friese, Lake, Aiken, Silber & Sochalski, 2008; Kendall- Gallagher, Aiken, Sloane, & Cimiotti, 2011; Kutney-Lee, Sloane, & Aiken, 2013). In four studies, the research teams analyzed a large dataset comprised of data from diverse samples of patients including general medical, orthopedic, vascular surgery (Aiken et al, 2003, 2011; Kendall-Gallagher et al, 2011) and cancer patients (Friese et al, 2008), and the outcomes examined across the studies varied and included 30-day mortality, failure to rescue (FTR), and surgical mortality. In all of the studies, the BSN or higher educational credential of registered nurses in the samples was significantly associated with a lower likelihood of adverse patient outcomes. Specifically, Aiken et al (2003) found that a 10% increase in the proportion of nurses holding a bachelor’s degree was independently associated with a 5% decrease in both the likelihood of patients dying within 30 days of admission and the odds of FTR in general, orthopedic, and vascular surgery patients. In another analysis, Aiken and colleagues (2011) also found the same inverse and independent relationship between BSN education and 30 day FTR in hospitalized patients. Friese et al (2008) focused their analysis on the sample of persons in the dataset with head/neck, esophageal, colon/rectal, pancreatic, lung, ovary and prostate and endometrial cancer. The analysis revealed that an increased proportion of RNs with a bachelor's degree or higher was associated with a decreased likelihood of patients dying within 30 days of admission. Kendall-Gallagher et al (2011) also found a significant association between BSN or higher credential and lower odds of surgical mortality in orthopedic and vascular surgery patients. Finally, Kutney-Lee et al (2013) found that a that a ten-point increase in the percentage of nurses holding a baccalaureate degree in nursing within a hospital was associated with an average reduction of 2.12 deaths for every 1,000 patients; for a subset of patients with complications, they found an average reduction of 7.47 deaths per 1,000 patients. These large, multicenter studies support the theorized relationship between staff nurse education and patient outcomes and suggest that the level of CRNA education is likely important for the outcomes of their patients as well.

Nurse Workload and Patient Outcomes. Conceptually, workload is a phenomenon that reflects a dynamic balance between the amount of work that needs to be accomplished by an individual and the perception of one's workload or pressure to accomplish assigned work tasks. In nursing studies reviewed that have examined the relationship between nursing workload and patient outcomes, workload was operationalized largely as a measure of the number of patients assigned to a nurse or as nursing hours per patient day**.** Five studies are discussed that provide empirical evidence for the theorized relationship that nurse workload, operationalized as number of patients assigned to a nurse, is significantly associated with patient outcomes in inpatient settings

(Aiken et al, 2011; Blegen; Goode, Spetz, Vaughn & Park, 2011; Twigg et al., 2011; Wiltse-Nicely, Sloane & Aiken, 2013) and outpatient hemodialysis units (Thomas-Hawkins, Flynn, & Clarke, 2008).

Four of the studies focused on associations between nurse staffing and the outcomes of hospitalized patients. In one of these studies, Aiken et al (2011) found that higher patient-to- nurse ratios were associated with a 3% increase in the odds of inpatient mortality and FTR. Findings from a similar study (Blegen et al, 2011), revealed that, compared to high nurse staffing, low nurse staffing was significantly associated with lower odds of heart failure mortality, infections, prolonged length of stay (LOS) in general medical, surgical, and intensive care unit patients. In a third retrospective study, Similarly, Twigg and colleagues (2011) found that lower RN workload, measured as nursing hours per patient day, was associated with a 25% reduction in patient death rates, compared to patient deaths in facilities with higher RN workloads. Additionally, there were significant reductions in shock/cardiac arrest, gastrointestinal (GI), bleeding, urinary tract infections and reduced LOS with improved nursing workload. Wiltse-Nicely et al (2013) found that improved nurse staffing ratios in high volume hospitals were positively associated with improved surgical outcomes (30 day-mortality and FTR) for patients undergoing abdominal aortic aneurysm (AAA) surgery.

Finally, Thomas-Hawkins et al (2008) analyzed the relationships between RN staffing and adverse patient outcomes in outpatient hemodialysis units. Higher patient-to-RN ratios (i.e., lower levels of RN staffing) were significantly associated with the likelihood of nurse reports of frequent adverse patient events including shortened dialysis treatments, skipped dialysis treatments, and patient complaints in adjusted regression models. These studies support the theoretical premise that workload, conceptualized as nurse-to-patient ratios and nursing hours per patient day in the studies reviewed, is significantly related to a multitude of patient outcomes in both inpatient and outpatient settings. However, workloads are influenced by more than nurse-to-patient ratios and nursing hours per patient day (Cox, 2003). The extent to which CRNAs perceive their workload conditions and production pressure is an important dimension of workload, and an understanding of the relationship between CRNAs perceptions of their workload on the outcomes of patients under their care is needed.

Work setting and patient outcomes. Nurse anesthetists provide anesthesia in a variety of settings. In the hospital, CRNAs work in the operating room, labor and delivery, and other off-site or remote areas such as the gastrointestinal, cardiac catheterization, and radiology suites. Closed claim data demonstrates that claims for adverse anesthesia events are higher in off-site (non-operating room) areas of the hospital compared with those claims for operating room adverse events (Metzner, Posner, & Domino, 2009). In particular, adverse respiratory events such as inadequate oxygenation and ventilation are seven times more likely to occur, and mortality is double in the off-site areas compared with the operating room and, (Metzner et al, 2009). It is unclear what factors contribute to this unfavorable relationship. These data support the need for investigation of the relationship between CRNA work setting and adverse event reporting for patients receiving CRNA-administered anesthesia in multiple work settings.

Work experience and patient outcomes. Two studies reviewed reveal a significant, positive relationship between healthcare workers' experience and patient outcomes, and one study did not. Aiken et al (2003) found that nurse experience was significantly associated with reduced patient mortality. Moreover, the same researchers found that there was a strong, significant decrease in mortality when the operating surgeon was board-certified. Similarly, findings from a large, retrospective study (Prystowsky, Bordage, & Feinglass, 2002) revealed that a higher number of years of surgical experience for surgeons was significantly associated with reduced patient mortality for patients undergoing colorectal surgery. However, in contrast to the Aiken (2003) study, the study findings did not reveal a significant relationship between board certification and patient mortality. Conversely, Ourain and colleagues (2010) conducted a small, prospective study and found no difference in patient outcomes (length of stay, and 30-day in-hospital complications, 30-day readmission rates, and 30-day reoperation) between colorectal surgeons with less than five years in practice and those with greater than five years in practice. These equivocal findings among the three studies may be related to the differences in study size, design and outcomes measured. To date, nursing studies that have revealed the association between years of experience and patient outcomes have been conducted on staff nurses and not on advance practice nurses such as CRNAs. Since advanced practice nurses have different levels of responsibilities and scopes of practice, it is important to determine the extent to which years of practice experience is associated with the outcomes of patients who are cared for by CRNAs.

Practice models and patient outcomes. CRNAs work in one of three practice models: supervised, medically directed or independent practice. Two studies have examined associations between CRNA practice model and patient outcomes (See Table 1). In one study, “failure-to-rescue” methodology and Medicare data were used to examine associations between provider type and anesthesia outcomes, (Pine, Holt & Lou, 2003). Risk-adjusted mortality rates for patients who surgical procedures were compared as anesthesiologist-directed (AD) and non-anesthesiologist directed (NAD) cases over a three year period. Researchers found no statistical significance when comparing negative outcomes between AD and NAD cases.

The Centers for Medicare and Medicaid Services (CMS) allowed states to opt out of the requirement for reimbursement that a surgeon or anesthesiologist oversee nurse-provided anesthesia care. By 2005 fourteen states had opted out of this Medicare Part A requirement (AANA, 2013). An analysis of the data demonstrated that elimination of the oversight did not result in increased patient morbidity or mortality, and investigators recommended that CRNAs be allowed to work unsupervised in every state (Dulisse & Cromwell, 2010). Moreover, 40 states have no supervision requirements for CRNAs in the nurse practice acts, board of nursing rules and regulations, and medical practice acts or board of medicine rules and regulations (AANA, 2013). Clearly, studies that have examined or compared outcomes of CRNA practice models are few in number, and further investigations of important associations between CRNA practice models and adverse patient events are warranted.

Summary. Empirical research that examined organizational structures for professionals in healthcare organizations demonstrated significant associations between organizational structures of relevance to this study and patient outcomes. Specifically, the empirical literature supports the theoretical premises that higher levels of nursing education and lower RN workload are associated with positive patient outcomes in hospitals and dialysis settings. Moreover, research has shown that increased levels of experience for nurses and surgeons in hospital settings are associated with better outcomes for patients. Emerging data demonstrates that off-site work settings are associated with higher levels of adverse anesthesia events compared with the OR setting. Differences in CRNA practice models have not been linked to adverse patient outcomes in early studies. However, there is a paucity of research that has examined the associations between CRNA structures in healthcare organizations and the outcomes of patients who have received anesthesia by these advanced practice RNs. There is an important need to gain an understanding of these relationships in settings in which CRNAs provide care.

Table 1. Summary of studies that examined the relationship between nursing structures and adverse events.

Author	Study design	Sample characteristics	Relevant variables and measures	Relevant findings
Aiken, Clarke, Cheung, Sloane & Silber, 2003	Cross-sectional, correlational design	**Nurse sample** -50% random sample of RNs residing in Pennsylvania -Surveys completed by 10184 nurses, an average of 60 nurses per hospital with a final 52% response rate. **Hospital sample** -168 Pennsylvania hospitals: 1.reporting surgical discharges 2. Had data on structural characteristics from 2 external databases 3. had at least (10) nurse survey respondents **Patient sample** 232,342 general, orthopedic and vascular surgery patients discharged	**IV** Nurse educational level (BSN/MSN vs. Diploma) **DV** 1.Risk of mortality 30 days after admission 2. Risk of failure to rescue (deaths in surgical patients with serious complications) 30 days after admission *Controlling for patient and hospital characteristics (size, teaching, level of technology), nurse staffing, RN years of experience, board certification of surgeon **IV** 1.Nurse years of experience 2. Surgeon years of experience 3. Surgeon board certification	A 10% increase in the proportion of nurses holding a Bachelor's degree **(education)** was associated with a 5% decrease in both the likelihood of patient dying within 30 days of admission and the odds of failure to rescue [OR = 0.95 (0.91-0.99 in both cases), p= .008 The odds ratio of the effects of **nurse experience** and **physician board certification**

Author	Study design	Sample characteristics	Relevant variables and measures	Relevant findings
		from 168 non-federal adult Pennsylvania hospitals	**DV** 1.Patient mortality 2.Failure to rescue	on mortality and FTR: Nurse experience: OR 1.03, p < .009 mortality and OR 1.03, p < .009 FTR; Physician Board Certification: OR 0.51, p , .001 mortality; OR 0.61, p < .001 FTR
Friese, Lake, Aiken, Silber & Sochalski, 2008	Cross sectional, correlational	**Patient sample** 25,957 Cancer patients with head/neck, esophageal, colon-rectal, pancreas, lung, ovary, prostate and endometrium **Nurse sample:** 10,184 Pennsylvania nurses surveyed: 50% random sample of medical surgical nurses or critical care nurses in hospitals that performed surgery on cancer patients.	**IV** RN educational preparation Measure: highest nursing degree **DV** 1.30-day mortality 2. Complications (21 secondary diagnosis codes) 3.Failure to rescue (FTR) (death within 30 days of hospital admission for patient with postoperative complication	Increased proportion of RNs with Bachelor's degree or higher **(education)** was associated with a decreased odds ratio of dying within 30 days of admission (OR 0.46, p < .05)
Thomas-Hawkins, Flynn, and Clarke, 2008	Cross-sectional, correlational	422 staff RNs who worked in outpatient hemodialysis units	**IV** Nurse: Patient Ratio **DV** Adverse Patient Outcomes 1.dialysis hypotension 2. shortened dialysis treatment 3.skipped dialysis treatments 4. patient complaints	Higher patient-to-RN ratios **(less staffing)** were significantly associated with RN reports of adverse patient events: 1.dialysis hypotension (r = 0.03,ns) 2. shortened treatment (r =0.26, p< .001) 3.skipped treatment (r = 0.26, p<.001) 4.patient complaints (r = 0.11, p< .05)
Kendall-Gallagher, Aiken, Sloane & Cimiotti, 2011	Secondary analysis; correlational	**Nurse sample** 28,017 staff nurses surveyed across 4 states **Patient sample** 1,283,241 patients for first admission in 180 days for general, orthopedic	**IV** -Nurse level of education -Nurse certification status **DV** 1.30-day inpatient mortality 2.Failure to rescue	A 10% increase in hospital proportion of baccalaureate and certified baccalaureate staff nurses **(education)**, respectively, decreased the odds of adjusted inpatient 30 day mortality by 6% and 2%; results for failure to rescue were identical.

Author	Study design	Sample characteristics	Relevant variables and measures	Relevant findings
		or vascular surgery		In the model adjusted for hospital and patient characteristics the OR were the same for both surgical mortality and FTR: Percentage of nurses with BSN or higher (OR 0.94, $p < .001$) Percentage of BSN (or higher) degree nurses who are certified (OR 0.98, $p <.01$)
Aiken, Cimiotti, Sloane, Smith, Flynn & Neff, 2011	Cross-sectional, correlational	**Hospitals (665) grouped** according to size, teaching status, technology level **Nurse sample n = 39,038** **Patient sample n = 1,262,120**	**IV** 1.Nurse Staffing Measure: average number of patients reported divided by average number of nurses on unit 2. Nurse Education Measure: Percentage of staff nurses in each hospital holding baccalaureate degree or higher **DV** 1.Patient 30 day mortality 2.Failure to Rescue	Better staffing and better Nurse educational level improve patient outcomes. **Staffing** Higher patient-to-nurse ratios decrease the odds of pt mortality and FTR 1. Odds ratio for nurse staffing and patient mortality (OR 1.033, $p < .005$) 2. Odds ratio for nurse staffing and FTR (1.031, $p < .01$ **Education** Higher nurses percentages of educated at the baccalaureate level or higher decrease the odds of pt mortality and FTR 1.Odds ratio for nurse education and pt mortality (OR .957, $p < .0001$) 3. Odds ratio for nurse education and FTR (or .955, $p < .0001$)
Kutney-Lee, Silber, and Aiken, 2013	Retrospective survey, patient discharge data and the American Hospital Association annual survey	134 Pennsylvania Hospitals 1999: 42,000 RNs 2006: 25,000 RNs	**IV** Percentage of BSN prepared RNs **DV** 1.Surgical mortality 2.Failure to rescue	Increased percentages of BSN were significantly associated with reduced surgical mortality (-2.12, $p < .01$) and FTR (-7.47, p,.001)
Wiltse-Nicely, Sloane, and Aiken, 2013	Cross-sectional; -Multi-State Nursing	517 hospitals, 20,409 patients and 25,265 staff nurses working	**IV** 1.Nurse staffing ratio 2. Volume level **DV**	Reduced mortality in AAA repairs is contingent upon nurse staffing ratios in high volume hospitals

Author	Study design	Sample characteristics	Relevant variables and measures	Relevant findings
	Care and Patient Safety survey data (CA, PA, NJ and FL) in 2006-2007 – Hospital discharge administrative data sets from four states – AHA Annual Survey data	in the study hospitals • Volume dichotomized into low/medium volume and high volume hospital groups	1. 30 day mortality 2. FTR	OR Estimating Effects of Nursing & Volume on Mortality Staffing: OR .085, p < .05 Hospital volume 0.09, p < .001 Staffing and Volume interaction: OR 1.35, p < .001
Blegen, Goode, Spetz, Vaughn and Park, 2011	Cross-sectional model testing using 2 hospital data from the University Health System Consortium	Data for 1.1 million adult non-obstetric patient discharges Staffing for 872 patient care units from 54 hospitals: 1.Adult general medical /surgical 2. Adult ICU	**IV** 1.Total hours of nursing care (RNs, LPNs and assistants) per inpatient day Measure: (TotHPD) 2.RN skill mix Measure: **DV** AHRQ risk-adjusted safety and quality indicators Measures: 1.Heart failure(HF) mortality 2.FTR 3. infections 4.prolonged length of stay (LOS) greater than expected	1. TotHPD in **general units** was associated with –lower rates of HF mortality (OR = -0.087, p< .05), and -Infections (OR = -0.233, p < .001), and - prolonged LOS (OR = -.002, p < .001) 2.RN skill mix in **general units** was negatively associated with FTR (OR = -.008, p < .001) and Infections (OR = -.027, p < .05) 3.TotHPD in **ICUs** was associated with fewer infections (OR = -.134, p < .05) 4. RN skill mix in **ICU**s was associated with -fewer cases of sepsis (OR = -.040, p < .01 And -reduced FTR (OR = .011, p < .05)

Author	Study design	Sample characteristics	Relevant variables and measures	Relevant findings
Twigg, Duffield, Bremner, Rapley and Finn, 2011	Retrospective, Interrupted time series design	Patient and staffing data from 3 adult tertiary care hospitals in Perth, Australia 236,454 patient records 150,925 nurse staffing records	**IV** Workload: Measure: Nursing hours per patient day (NHPPD) Categorized as: A= 7.5 NHPPD B= 6NHPPD C=5.75 NHPPD D=5 NHPPD **DV** 14 Nursing-sensitive outcomes (NSOs) 1.Central nervous system (CNS) complications 2.Wound infections 3. Pulmonary failure 4.UTI 5.Pressure ulcer 6.Pneumonia 7. Deep Vein thrombosis (DVT) 8.ulcer/gastritis/upper gastrointestinal bleed 9.Sepsis 10.Physiologic/ metabolic derangement 11.Shock/cardiac arrest 12.Mortality 13. FTR 14.Length of stay (LOS) *wound infect, pulm. failure and phys/metab derangements were measured in surgical pts.	Improved **workload** reduces pt death rates. Death rates for all patients decreased 25% in stage 2 (increase in NHPPD staffing) compared with stage 0 (prior to increase in NHPPD staffing). Category A: Outcome after increase in NHPPD compared to pre-increase period Shock/cardiac arrest decreased (Rate ratio = 0.42, $p < .05$) GI bleed decreased in surgical pts (0.42, p , .05) Category B: Outcome after increase in NHPPD compared to pre-increase period Shock/cardiac arrest decreased (Rate ratio = 0.43, $p < .001$) Mortality decreased (Rate ratio = 0.72, $p < .05$) Category C: Outcome after increase in NHPPD compared to pre-increase period Mortality rates decreased (Rate ratio = 0.72, $p < .05$) Category D: Outcome after increase in NHPPD compared to pre-increase period Decreases in UTI (Rate ratio = 0.75, $p < .05$) Decreases in LOS (Rate ratio = --2.19, $p < .05$)

Author	Study design	Sample characteristics	Relevant variables and measures	Relevant findings
Metzner, Posner & Domino, 2009	Review of closed claim malpractice data 1990-	8496 anesthesia claims from 1990-2007. 87 remote locations and 3287 operating room claims	**IV:** 1.Remote location 2.Operating room **DV:** 1.Mortality 2.Inadequate oxygenation or ventilation	Closed claim studies revealed that mortality claims in off-site anesthetizing locations were double those in the operating room (54% compared with 29%, $p < .001$) Further, an adverse respiratory event of inadequate oxygenation and ventilation was seven times greater in the off-site location compared with the operating room (21% compared with 3%, $p <.001$).
Prystowsky, Bordage and Feinglass, 2002	Retrospective hospital admission data	15,427 patient admissions for segmental colon resection by 514 surgeons in Northeastern Illinois.	**IV:** 1.American Board of Surgery (ABS) Certification 2.years of experience **DV:** 1.Inpatient mortality 2.Complications	Certification and years of experience were related to reduced mortality, and fewer complications : 1.ABS 4.2 % mortality rate compared with 7.1% for Non- ABS ABS complication rate 23.8 % compared with non-ABS 30.7% 2. 5-20 years' experience 4.1 % mortality 20+ years of experience 3.9% (Compared with less than 5 years' experience 5.6%)
Ourian, Nasseri, Murrell, Gewertz, Magner, Burel et al, 2010	Prospective	300 patients for colorectal procedures; 8 surgeons	**IV:** Years of surgeon experience Group A less than 5 years Group B more than five years **DV:** 1.Inhospital complications within 30 days (wound, GI, cardiopulmonary, other) 2.LOS 3.unplanned admission within 30 days 4.return to OR within 30 days	No significant difference in short term outcomes between colorectal surgeons with less than versus more than 5 years' experience

Author	Study design	Sample characteristics	Relevant variables and measures	Relevant findings
Pine, Holt, & Lou, 2003	Risk adjusted mortality rates by provider	404,194 Hospitalized Medicare patients form 1995-19997 in 22 states undergoing a selected operation (carotid endarterectomy, cholecystectomy, herniorrhaphy, Hysterectomy ,knee replacement, laminectomy, mastectomy, prostatectomy)	**IV:** Type of provider: 1.Anesthesiologist alone 2.CRNA alone 3. Anesthesia care team **DV:** Risk-adjusted mortality rate	No significant differences in risk-adjusted mortality by type of anesthesia provider and by hospital type of anesthesia practice
Dulisse and Cromwell, 2010	Mortality rates and complications compared stratifying by year and anesthesia practice arrangement.	12,696 non-opt out and 26,876 opt out hospitalizations Medicare part A and B data from 14 states opting out of the Medicare supervision requirement 1999-2005	**IV:** 1.Opt-out states by provider CRNA solo, Anesthesiologist solo, Anesthesia Care team (ACT) 2.Non-opt-out states by provider CRNA solo, Anesthesiologist solo, ACT **DV:** 1.Inpatient mortality rate 2.AHRQ Complications (7): Death from low-mortality diagnosis, FTR, iatrogenic pneumothorax, or collapsed lung, postop physiologic and metabolic, postop chemical imbalance derangement, postop respiratory failure, transfusion reaction	Despite a shift to more anesthetics performed by CRNAs no increase in adverse outcome was found in either opt-out or non opt-out states. The odds ratio of mortality in opt out states before and after opt-out: MDA solo 0.797, 0.788 CRNA solo 0.651, 0.689 ACT 0.708, 0.565 The odds ratio of complications before and after opt-out: MDA solo 0.824, 0.818 CRNA solo 0.798, 0.813 ACT 0.927, 0.903

Patient Safety Culture and Adverse Outcomes

In this section, a synthesis and analysis of the empirical evidence that supports the theorized relationship between high quality work environments, conceptualized as patient safety culture in this study, and patient outcomes is presented. The literature review was delimited to articles that examined relationships between dimensions of patient safety culture or patient safety climate and patient outcomes. Four studies met these criteria and are summarized in Table 2. Two of the four studies (Mardon, Khanna, Sora, Dyer, & Famolaro, 2010; Thomas-Hawkins &Flynn, 2013a) used the AHRQ Hospital Survey on Patient Safety Culture (HSOPS) tool as the measure of patient safety culture. Mardon et al (2010) found that hospitals with better HSOPS scores (e.g., positive patient safety culture) had lower rates of documented AHRQ Patient Safety Indicators (PSIs) including iatrogenic pneumothorax, selected infections due to medical care, postoperative hemorrhage or hematoma, postoperative physiologic and metabolic derangements, postoperative respiratory failure, postoperative sepsis, postoperative wound dehiscence in abdominopelvic surgical patients and accidental puncture and laceration. Moreover, patient safety grade was significantly and negatively correlated with the PSI composite score.

Similarly, Thomas-Hawkins and Flynn (2013a), in an analysis that examined the association between 422 hemodialysis nurses' ratings of patient safety (patient transition safety and unit safety grade) in dialysis units and adverse patient events, found that nurse reports of unsafe patient transitions and fair to failing safety grades were associated with an increased likelihood of their reports of frequent adverse patient occurrences (see Table 2) such as vascular access infections and thrombosis, medication error, and hospital admission. Both of these studies demonstrate that negative safety culture is adversely associated with patient outcomes.

Hofman and Mark (2006) examined associations between patient safety climate and medical and surgical patient outcomes. They found that negative ratings of unit safety climate significantly predicted both medication errors and UTIs. Furthermore, they found that the relationship between overall safety climate of the unit and medication errors was significant and negative when patient conditions were complex, suggesting that patient complexity likely moderated the relationship between safety climate and medication errors. In a similar study, Valentin, Schifflinger, Streyer, Huber & Strunk (2012) found that patient safety climate was a significant predictor of medical errors in ICU patients. Moreover, increased patient complexity or acuity was associated with more medication errors and reduced safety climate.

Summary. These empirical data provide strong support for the NOOM proposition that low quality work environments are associated with adverse events and negative patient outcomes. Across the studies, safety culture/climate of hospital and outpatient dialysis settings was negatively associated with adverse patient outcomes. Moreover, patient complexity appears to moderate this relationship. To date, no research exists on CRNA practice, patient safety culture and adverse patient outcomes. As CRNAs care for complex surgical patients on a daily basis, it is imperative to examine the relationship between perceived safety culture and adverse event reporting.

Table 2. Summary of studies that examined the relationship between patient safety culture and adverse outcomes.

Author/Yr.	Study design	Sample characteristics	Relevant variables and measures	Relevant findings
Hofman and Mark, 2006	Correlation; Exploratory factor analysis and negative binomial regressions of survey data and archival records	Outcomes Research in Nursing Administration project II (ORNA-II) 2004: 1,127 nurses working in 81 general medical-surgical units in 42 randomly selected non-government hospitals with more than 150 beds	**IV:** Safety climate Measure**:** 1. Revised Safety Climate (9) items 2.Error Orientation Scale (13) Items *Scores aggregated at the unit level **DV**: 1.Medication Errors Measure: frequency of medication error resulting in harm 2.Urinary tract infections (UTI) Measure: Nosocomial UTIs during the 3 month outcome period **Moderating Variable**: Complexity of patient condition Measure:14 item patient complexity 5 item Likert scale **Control Variable:** Hospital size	1.Overall **safety climate** of unit **predicted medication errors** ($r = -1.51$, $p < .05$) and UTIs ($r = -1.27$, $p < .05$) 2. The relationship between the **overall safety climate of the unit** and medication errors (slope = -3.47, $z = -3.82$, $p < .01$) **was significant and negative when patient conditions were complex**. (Patient complexity moderated the relationship between safety climate and medication errors).
Mardon, Khanna, Sorra, Dyer, and Famolaro, 2010	Correlational	179 hospitals from the HSOPS 2007database with signed data use agreements and AHRQ Patient Safety Indicators (**PSI**s)	**IV** 1. **Patient Safety Culture** Measure: **Measure: Hospital Survey on Patient Safety Culture** -HSOPS 12 patient safety composites, -an estimated unit safety grade (A-E), -an estimated number of adverse events reported and -a final HSOPS composite score **DV**	Hospitals with **better HSOPS scores (more positive pt safety culture)** tend to have **lower rates of PSIs** (fewer documented events). 12 of the 15 HSOPS variables were negatively correlated with the PSI composite score and significant **Patient Safety grade** was significantly, negatively correlated with PSI composite

Author/Yr.	Study design	Sample characteristics	Relevant variables and measures	Relevant findings
			AHRQ PSI Composite Score (A **PSI** is an administrative data-based indicator that identifies an in-hospital patient safety event) **<u>Covariate</u>** **Hospital** characteristics (size, teaching status, ownership)	(r = -.17, p< .05)
Thomas-Hawkins, Flynn, 2013	Cross-sectional, Correlational	422 staff nurses who worked in outpatient hemodialysis units	**IVs:** Patient transitions safety Measure: (modified HSOPS Handoffs and Transitions Scale) Patient safety grade Measure: (HSOPS patient safety grade item) **DV**: Dialysis outcomes	In adjusted logistic regression models, nurse reports of unsafe patient transitions was associated with an increased likelihood of nurse reports of skipped dialysis treatments (OR=1.97, p<.03); shortened dialysis treatments (OR 2.06, p<.01), vascular access infection (OR 1.59, p<.05), vascular access thrombosis (OR 2.07, p<.05), vascular access bleeding (OR 1.61, p<.05), and patient complaints (OR 2.72, p<.001). In adjusted logistic regression models, nurse reports of fair to failing patient safety grade was associated with an increased likelihood of nurse reports of skipped dialysis treatments (OR=4.65, p<.01); vascular access infection (OR 2.20, p<.01), patient complaints (OR 2.85, p<.001), medication error (OR 2.72, p<.01), ER use (OR 1.96, p<.05), and hospital admission (OR 1.82, p<.05)
Valentin, Schiffinger, Steyrer, Huber & Strunk, 2012	Prospective, observational, multinational, correlational	45 ICUs in Austria, Switzerland, and Germany; 795 patients 549 nurses 185 physicians	**IV:** Safety Climate Measure: Vienna Safety Climate Questionnaire (VSCQ) **DV:** number of medical errors	**Safety climate score is a significant predictor of medical error** (beta = -0.02, p < .01; OR = 0.98, p < .01)

Nursing Structures and Patient Safety Culture

According to the NOOM, the organizational structure in which nurses practice in health care organizations influence the extent to which the workplace is perceived by staff as a safe, high quality practice environment. This section will provide empirical evidence to support this theoretical relationship. Three studies were found which met these criteria, and they are summarized in Table 3. The structures examined in these studies include work setting, years of experience, and workload. The dimensions of patient safety culture varied across the studies and included event reporting, patient safety grade, overall perceptions of patient safety, and patient transitions safety.

El-Jardali, Dimassi, Jamal, Jaafar & Hemedeh (2011) examined the association between work setting and years of experience and patient safety culture variables (frequency of events reported, overall perception of patient safety culture, patient safety grade, and number of events reported) in a sample of nearly 7000 hospital employees. Significant differences were found between hospital departments (work settings) and overall perception of safety. Specifically, diagnostics departments had the highest mean patient safety score compared to surgical and medical units. Additionally, years of employee experience was significantly associated with the overall employee perception of patient safety. In fact, respondents with less than one year of experience were less likely to give an excellent/very good safety grade but this increased as years of experience increased. In a second study, Thomas-Hawkins and Flynn (2013b) examined the associations between RN workload, RN staffing and patient safety culture and they found that nurse reports of high workloads was significantly associated with a decreased likelihood of their reports of safe patient transitions in the dialysis unit and good to excellent safety grades for their dialysis units. Finally, in a large, international study Aiken and colleagues (2012) found that as patient-to-nurse ratios increased (i.e., low RN staffing), with each additional patient per nurse, the odds of nurses reporting poor or failing safety grades increased (see Table 3).

Summary. These studies support the NOOM theoretical premise that nursing structures that strengthen the organization of nurses in health care organizations are associated with safe and high quality practice environments. However, empirical examinations of the extent to which CRNA practice environments reflect a positive patient safety culture and important antecedents to high quality CRNA practice environments are conspicuously absent from this literature. There is a need to understand the extent to which CRNA organizational structures influence the extent to which CRNAs perceive their practice environments as safe.

Table 3. Summary of studies that examine the relationship between nursing structures and patient safety culture.

Author/Yr.	Study design	Sample characteristics	Relevant variables and measures	Relevant findings
El-Jardali, Dimassi, Jamal, Jaafar & Hemedeh, 2011	Cross-sectional correlational	68 Hospitals 6807 employees surveyed	**IV**: 1.10 composite scores of the Arabic version of HSOPS 2. position 3.accreditation status 4.hospital size 5. years of experience **DV**: 4 outcome variables 1.Frequency of events reported 2.Overall perception of patient safety culture 3.Patient safety grade 4.Number of events reported	1. Significant differences were noted between different hospital units (**work setting**) and the overall perception of safety. Significantly higher mean scores were observed for diagnostics (M = 3.96, p<.001)) compared to surgical (3.82, p<.001)) and medical units (3.83, p<.001)) units. 2. Years of **experience** were significantly associated with overall perceptions of patient safety. Respondents with less than 1 year of experience were less likely to give excellent/very good patient safety grade but this increased as years of experience increased. After experience

Author/Yr.	Study design	Sample characteristics	Relevant variables and measures	Relevant findings
				exceeded 16 years, patient safety grade scores gradually decreased.
Thomas-Hawkins & Flynn, 2013	Cross-sectional correlational mailed survey design	422 registered nurses working in US outpatient dialysis facilities	**IV:** 1.Workload Measure: workload scale of the Individual Workload Perception Scale (IWPS) 2. RN –to-Patient ratio Measure: staffing items questionnaire **DV:** Patient Safety Culture Measure: 1.AHRQ HSOP Patient Safety Grade scale 2. AHRQ HSOP handoff and transitions scale	In adjusted logistic regression models, nurse reports of high workloads (OR=.534, p<.01), unsupportive practice environment (OR .364, p<.01), and 3 or more tasks undone (OR .235, p <.001) was associated with a decreased likelihood of safe patient transitions. In adjusted logistic regression models, nurse reports of high workloads (OR=.211, p<.05) and unsupportive practice environment (OR .080, p<.001) was associated with a decreased likelihood of nurse reports of good to excellent safety grades.
Aiken, Sermeus, Van den Heede, Sloane, Busse, McKee et al, 2012	Cross-sectional correlational, international survey	33,659 European nurses from 12 countries; 27,509 US nurses (all working in acute care hospitals)	**IV:** Nurse staffing ratio Measure: The patient -to-nurse ward ratio on the last shift worked (low ratio indicates favorable staffing) **DV**: Patient safety grade Measure: AHRQ HSOP patient safety grade item	1.Each additional patient per nurse **(staffing ratio)** increased the odds of nurses reporting poor or failing safety grades (OR 1.10, 1.05-1.16 Europe) and (OR 1.05, 1-1.1 US)

Additional Study Variables

Several organizational variables, including hospital type (university-affiliated, not university-affiliated) magnet status (magnet certification, no magnet certification), and hospital size (number of beds), may be confounders in the proposed study since there is empirical support for the association between these variables and adverse patient outcomes in healthcare institutions (Aiken et al., 2003, 2011; Friese et al, 2008; Kendall et al., 2011; Mardon et al., 2010). Therefore, these variables were also analyzed in the study.

Current State of Knowledge and Gaps

The Nursing Organization and Outcomes Model proposes that organizational structures and attributes of high quality work environments influence patient outcomes. Structures are indicated by nurse supply, skill mix, skill level or experience, workload, and education or certification. Patient safety culture is a key component of a high quality work environment and the model stipulates that a positive patient safety culture aids in the reduction of adverse patient events and fosters positive patient outcomes. The empirical evidence reviewed in this section supports the NOOM and provides clear evidence that RN staffing, level of education and workload are significantly associated with patient outcomes. Additionally, data supports the relationship between patient safety culture and adverse patient events. Finally, while minimal, research suggests that work setting, years of experience, and workload influence perceived patient safety culture.

To date, research on the NOOM has only been conducted with staff nurses. It is imperative that as advanced practice nurses such as CRNAs take on a larger role in the healthcare system, research is conducted to evaluate the organizational structures, work environments, and processes of care that influence the outcomes of patients under the care of theses practitioners. Additionally, there is no existing research on advanced practice nurse practice models as an organizational structure that potentially influences patient outcomes. The purpose of this study was to examine the complex relationships among CRNA organizational structures (practice model, work setting, workload, level of education, work experience) and patient safety culture, and CRNA-reported adverse patient events.

Hypotheses

The following hypotheses were examined in this study:

1. CRNA organizational structures are significantly related to CRNA-reported adverse patient events in patients receiving CRNA administered anesthesia.
    a. CRNA practice models are significantly associated with CRNA-reported adverse events in patients receiving CRNA administered anesthesia.
    b. CRNA work setting is associated with CRNA-reported adverse events in patients receiving CRNA administered anesthesia.
    c. Higher CRNA workload is associated with higher numbers of CRNA-reported adverse events in patients receiving CRNA administered anesthesia.
    d. Lower levels of CRNA education are associated with higher numbers of CRNA-reported adverse events in patients receiving CRNA administered anesthesia.
    e. Less CRNA years of experience is associated with higher numbers of CRNA-reported adverse events in patients receiving CRNA administered anesthesia.
2. CRNA organizational structures are significantly associated with patient safety culture.
    a. CRNA practice models are significantly associated with patient safety grades and overall patient safety as rated by CRNAs.
    b. CRNA work setting is significantly associated with patient safety grades and overall patient safety as rated by CRNAs

c. Higher CRNA workload is significantly associated with fair to failing patient safety grades and negative overall patient safety as rated by CRNAs.

d. Higher level of CRNA education is associated with good and excellent patient safety grades and overall positive patient safety as rated by CRNAs.

e. Increased years of experience are associated with good and excellent patient safety grades and overall positive patient safety as rated by CRNAs.

3. Patient safety culture is significantly associated with CRNA-reported adverse event reporting in patients receiving CRNA administered anesthesia.

    a. Fair to failing patient safety grades as rated by CRNAs are significantly associated higher with numbers of CRNA-reported adverse events in patients receiving CRNA administered anesthesia

    b. Negative overall patient safety as rated by CRNAs is significantly associated with higher numbers of CRNA-reported adverse events in patients receiving CRNA administered anesthesia

Theoretical and Operational Definitions

Organizational structures are represented in this study as practice models, work setting, workload, level of education, years of experience.

Practice model: CRNA practice models are defined as the employment arrangement in relationship to the anesthesiologist in the practice setting. There a two types of practice models that will be explored in this study. The **Anesthesia Care Team**

(ACT) practice model is comprised of the practice model type in which the CRNA works in a collaborative relationship with anesthesiologist to provided anesthesia care. There are two types of ACTs: medical direction and supervision. **Medical direction** is when an anesthesiologist is personally involved during key points of the anesthetic such as induction, and emergence; **Supervision** is when an anesthesiologist is available but does not actually have to be physically present in the room during the anesthetic (Hogan et al, 2010).The **Independent Practice (IP)** model is defined as a CRNA who works independently of an anesthesiologist but collaboratively with other clinicians such as surgeons, dentists, podiatrists and proceduralists to provide anesthesia care (Hogan et al, 2010). For this study, CRNA practice model is operationally defined as participant's response to the "practice model type" item (medical direction, supervision, independent) on the demographic data sheet.

Work setting is defined as the place in which CRNAs are employed. For this study, work setting is operationally defined as the participant's response to the "work setting" item (hospital operating room, ambulatory surgical center or both) on the demographic data sheet.

Workload is defined as a dynamic balance between the challenge of a task and an individual's response to that task (Leedal & Smith, 2005) and covert and or overt pressures and incentives on personnel to place production, not safety as their primary priority (Gaba, Howard, & Jump, 1994). Workload is operationalized as a participant's score on the Individual Workload Perception Scale (IWPS) workload subscale (Lacey, Cox, Lorfing, Teasley, Carroll & Sexton, 2007) and a score on the NASA Task Load Index (NASA TLX) (Hart, 2006).

Level of education is defined as the highest level of formal nursing education and is operationalized as a participant's response to the "highest level of formal nursing education" item on the demographic data sheet.

Years of experience is defined as the number of years of experience in the CRNA role and is operationalized as the participant's response to the "number of years of experience in the CRNA role" item on the demographic data sheet.

Patient Safety Culture is defined as complex phenomenon that 1) reflects employees' perceptions of safety policies, procedures, and practices in use within an organization; 2) acts as a frame of reference for employee behavior and (Clarke et al, 2006); Mearns et al, 2001); and 3) reflects an organization's commitment to safety at all levels in the face of inherently complex and potentially hazardous procedures (AHRQ, 2012). Patient safety culture is operationalized as a participant's score on Hospital Survey on Patient Safety Culture's overall patient safety scale, and patient safety grade item.

Adverse event is defined as an untoward respiratory occurrence in a patient who has received CRNA-administered anesthesia and includes difficult intubation/extubation, inadequate oxygenation and ventilation, and pulmonary aspiration. In this study, adverse events are operationalized as the surveyed number of CRNA-reported adverse patient events in patients cared for by the CRNA in the past twelve months.

Chapter 3

Methods

This chapter describes the research setting and design for this study including the sampling methods, sample, instruments and procedure for data collection and analysis. This study used descriptive, correlational research design to investigate the relationships among CRNA organizational structures (practice model, work setting, workload, level of education, work experience, hospital size, magnet status, teaching/non-teaching status) and patient safety culture, and CRNA-reported adverse patient events.

Research Setting

The subjects were recruited through the use of a membership mailing list of all currently certified, active nurse anesthetists in the U.S. This list of CRNAs was obtained from the American Association of Nurse Anesthetists (AANA).

Sampling Methods

The American Association of Nurse Anesthetists (AANA) is the professional association representing more than 47,000 Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists nationwide (AANA, 2013). The AANA promotes education and practice standards and guidelines, and provides consultation to both private and governmental entities regarding nurse anesthetists and their practice. Their mission is to advance patient safety, and practice excellence through member excellence (AANA, 2013). The association focuses on patient safety, care for the whole patient from a nursing perspective, professional excellence and well-being, healthcare policy and collaboration as well as integrity and quality for all professional and clinical settings (AANA, 2013). Over 90% of all CRNAs belong to the AANA (AANA, 2014).

The investigator requested a mailing address list of 500 randomly selected CRNAs from the organization. The AANA selected the sample via computer generated random selection mechanism. The selection algorithm is based on a uniform distribution, that is, there was an equal probability for each one of the targeted pool to be selected (AANA, 2013). The target pool was defined by the parameters certified, recertified, all states of residence, primary employment in a hospital based, or ambulatory surgical center clinical practice base. Inclusion criteria was as follows: 1) must be a CRNA; and 2) is employed as a CRNA in a hospital based or ambulatory surgical center in the U.S. In addition to the mailing list request, a copy of Rutgers University IRB approval, the study protocol including a description of the study purpose, hypotheses, methods, survey instruments, survey packet cover letter, data analysis plan, and plan for dissemination of the results, and endorsement letter from my dissertation chairperson accompanied the application for mailing list rental per AANA policy.

Power analysis for correlational and regression analysis was calculated to determine the appropriate sample size to yield sufficient power for these statistical techniques. For correlational analysis, using a moderate effect size ($r = .25$) based on the literature for nurse staffing ratios and RN reports of adverse events (Thomas-Hawkins et al, 2008) and patient safety culture and patient outcomes (Valentin et al, 2012), a sample size of 126 subjects was required to obtain statistical power of 0.80 at a .05 significance level (Cohen, 1988). For regression analysis using the moderate ($f = .15$) effect size based on the literature (Valentin et al., 2012) and 11 independent variables, a minimum sample size of 143 was needed to obtain a power of .80 power at a significance level of .05 (Cohen, 1988). Based on Dillman's estimate of response rates repeated mailings, a minimum sample size of 250 is anticipated which will provide more than sufficient power for correlational and regression analyses.

Instruments

Anesthesia-related adverse patient events.

CRNA-reported anesthesia-related adverse patient events. Five CRNA-reported anesthesia-related adverse patient events were measured including difficult intubation, difficult extubation, inadequate oxygenation/ventilation, and pulmonary aspiration of gastric contents. These events were selected because they are common adverse occurrences among patients who receive general anesthesia (Metzner et al, 2011), sensitive to anesthesia care (MacRae, 2007); and their reduction has been identified as important quality indicators in perioperative environments (Eichorn, 2012). These events are not reportable, and no data registries are available on adverse anesthesia-related events in U.S. hospitals. Therefore, nurse reports of adverse anesthesia-related events were measured and have been used previously in health outcomes research as appropriate estimates of adverse patient events (Ausserhofer, Schubert, Desmedt, Blegen, De Geest, and Schwendimann, 2013; Schubert et al., 2008; Thomas-Hawkins et al., 2008).

CRNA-reported anesthesia-related adverse patient events were operationalized as a series of questions designed to capture the number of times in the past year the CRNA participant has experienced adverse anesthesia-related patient events that occur from the anesthesia induction period up through the postoperative recovery period as monitored by the CRNA. For each adverse anesthesia-related event, participants were asked to report the number of occurrences they experienced in the past 12 months on the following 6-point scale: (1) none; (2) 1 to 2; (3) 3 to 5; (4) 6 to 10; (5) 11 to 20; and (6) 21 or more.

Patient Safety Culture

Hospital Survey on Patient Safety Overall Perceptions of Safety and Patient Safety Grade Scales. The AHRQ Hospital Survey on Patient Safety (HSOPS) is a multidimensional survey tool which assesses hospital and staff perceptions of patient safety in their workplace. The tool was developed by researchers under contract for use by the AHRQ (Sorra and Dyer, 2010). The tool consists of 42 items which measure 12 dimensions of patient safety culture, and two outcome questions.

Psychometric properties of the tool were initially established by Nieva and Sorra (2004) in 21 hospitals with a sample 1,400 staff respondents, including staff RNs, MDs employed primarily in the hospital setting, and pharmacists. Composite scores were calculated for each of the dimensions, and correlational analysis was used to determine the initial construct validity of HSOPS dimensions. Correlation coefficients between dimensions ranged .23 to .60; indicating that the HSOPS dimensions were relatively distinct dimensions of patient safety culture (Nieva and Sorra, 2004). The reliability for the HSOPS subscales ranged from 0.63 to 0.84; internal consistency reliability for the Overall Perceptions of Patient Safety scale was acceptable with an alpha reliability coefficient of .74.

In addition to initial HSOPS psychometric testing, the AHRQ Comparative Database was used to further examine the psychometric properties of the survey (Sorra & Dyer, 2010). The final data set included 331 hospitals with 2,267 units and 50,513 hospital staff respondents, almost half of which were RNs or Licensed Vocational Nurses (LPNs). Internal consistency reliability was examined for all dimensions and ranged from 0.62 to 0.85 for all dimensions; all were greater than 0.70 except staffing. In addition, the Patient Safety Grade item responses were significantly correlated with all HSOPS dimensions at the individual (r =.48), unit (r = .55), and hospital level (r = .54).

The AHRQ HSOPS is a valid and reliable tool to assess patient safety culture at the individual, unit and hospital level. For the proposed study, two of the HSOPS scales will be used, The Overall Perceptions of Patient Safety scale and the single-item Patient Safety Grade question.

The Overall Perceptions of Patient Safety Scale consist of four items that focus on the extent to which one agrees or disagrees that procedures and systems are good at preventing errors and that there is a lack of patient safety problems (Nieves and Sorra, 2004). The respondent is asked to respond to each item on a five-point Likert scale ranging from 1 = strongly disagree to 5 = strongly disagree. The scores are added (negatively worded questions are reverse scored) and a higher score indicates a better safety culture perception. For the HSOPS Patient Safety Grade item, respondents are instructed to assign an overall grade for patient safety in their work setting (A-excellent, B-very good, C-acceptable, D-poor, E-failing). Good the excellent grades represent positive ratings of safety, and poor to failing grades represent negative safety ratings.

Workload

NASA Task-Load Index. The NASA Task-Load Index (NASA-TLX) was used as one measure of CRNA workload, and it is a widely used, multi-dimensional scale designed to measure subjective workload (Hart and Staveland, 1988). The instrument is a self-reported survey tool. It consists of 6 subscales that represent independent variable clusters: Mental, Physical and Temporal Demands, Frustration, Effort and Performance (Hart, 2006). Each of the subscales is a 20-point bipolar scale resulting in a score between 0-100. The assumption is that overall workload is a combination or sum of these scales, and a higher score indicates an increased workload. Initially, the subscales were weighted but more recently researchers have used the raw score (RTLX) where the subscale scores are averaged or added to create an overall workload estimate (Hart, 2006). However, because the subscales are independent, researchers can analyze them separately when evaluating specific workload dimensions. Designed originally to operationalize workload in the field of aviation, the tool has been well-described, tested, and employed for over twenty-five years in over 550 studies in diverse areas including air traffic control, operating rooms, nuclear power plant control rooms, simulated combat and website design (Hart, 2006). Recently, the tool has been used to operationalize workload for intensive care unit RNs (Hoonakker et al, 2012).

The psychometric properties for the NASA-TLX were originally investigated by Hart and Staveland (1988) during tool development. Hart and Staveland (1988) demonstrated content validity of the tool during initial development. Stability of the instrument was demonstrated using the test-retest method; the test-retest reliability was found to be 0.77 in a sample of pilots (Batisse and Bortolussi, 1988). Hoonakker et al (2012) tested internal consistency reliability of NASA-TLX in secondary analysis of 757 ICU nurses working in multiple settings, and they reported a Cronbach's alpha of 0.72 in this population.

Convergent validity was demonstrated by researchers who compared the NASA-TLX with other established subjective workload scales. Rubio, Diaz, Martin and Puente (2004) compared scores on the NASA-TLX with those on the Subjective Workload Assessment Technique (SWAT) and the Workload Profile (WP) in a study of 36 University students. They found that the NASA-TLX was highly correlated with the two other workload scales ($r = .97, .98, p < .001$) respectively. Hoonakker et al (2012) found that the NASA-TLX scores correlated highly with those on the Perceived Workload Scale PWS and the Rating Scale Mental Effort (RSME) (($r=.81$ and $r=.77$ $p < .01$) respectively in a two large studies of workload in ICU nurses.

Rubio et al (2004) also compared the three subjective workload instruments (NASA TLX, SWAT, WP) and showed that all three instruments had high correlations (between 0.73 and 0.79, $p < .05$) with performance measure, but that NASA-TLX demonstrated a higher correlation than the two other instruments with a second measure of performance. The NASA TLX concurrent validity was found to be higher than the concurrent validity of the two other workload instruments. Finally, discriminant validity was demonstrated by Hoonakker et al, (2012). The results of the comparison between patient-based (staffing) and subjective measures of workload show that nurse patient ratio is not significantly related to the subjective measures of workload ($r = .10$, ns).

In summary, the reliability and validity of the NASA-TLX has been established in a variety of disciplines. Most recently, the tool has been shown to be both a reliable and valid to measure subjective workload in RNs working in the intensive care setting.

The Workload Scale of the Revised Individual Workload Perception Scale. The Workload Scale of the Revised Individual Workload Perception Scale (IWPS-R) was used as a second measure of workload in this study. It is a 32-item Likert scale instrument that has been used widely to measure workload in nursing research. It is a self-report survey tool that has six subscales: manager support, unit support, peer support, workload, intent-to-stay, and nurse satisfaction. The 6-item workload subscale of the IWPS will be used to measure workload in this study. Each item is comprised of a 5 point summated rating scale ranging from strongly disagree to strongly agree. Scores can range from 6- 30 with a higher score indicating a higher workload. Sample items include “my current workload is reasonable” and “I am able to take at least a 30 minute meal break during my shift.”

The psychometric properties of the tool have been established in multiple studies involving staff RNs (Cox, Teasley, Zeller, Lacey, Parsons, Carroll, Ward-Smith, 2006; Flynn, Thomas-Hawkins, and Clarke, 2009; Lacey et al, 2007). Content validity was established by 3 nurse executives and 2 experts in the field of psychometrics (Cox et al, 2006). Reliability of the scale has been demonstrated by several nurse researchers. Cox et al (2006) reported a Cronbach’s alpha of 0.75 for the workload subscale of the IWPS-R in a large study of pediatric staff RNs. Similarly, in a study of 3337 nurses in magnet, magnet-aspiring and non-magnet hospitals, Lacey et al (2007) reported a reliability coefficient of .70 for the workload subscale and Flynn et al (2009) reported 0.78 in 422 dialysis RNs. If the IPWS is highly correlated with the NASA-TLX in the proposed study, only one workload measure will be used for hypothesis testing.

Demographic Characteristics: Practice Model, Work Setting, Years of CRNA experience, Level of Education

Demographic Questionnaire. CRNA practice model, years of CRNA experience, work setting, and level of education was operationalized as a single-item questions on the demographic questionnaire. In addition, hospital type (teaching vs. non-teaching), magnet status, and hospital size (number of beds) was assessed using single items questions on the demographic questionnaire.

Procedure for Data Collection

Data was collected via the Tailored Design Method (TDM) (Dillman, 2009) that consists of a repeated mailing, multiple contact design in order to maximize the survey response rate. Strict adherence to the TDM generally yields a mailed survey response rate of 50-70% (Dillman, 2009). Initially, participants received a standard prenotice letter via first class mail. The following week the participants received the mailed survey packet. Each packet contained the study instrument, and a cover letter from the principal investigator (PI) that includes (a) an explanation of the study and an invitation to participate (b) an assurance of confidentiality and the participants right to choose not to participate or to terminate at any time, (c) a summary of risks and benefit, (d) contact information for the PI and the Rutgers IRB , and (e) instructions to place the completed survey in the self-addressed stamped envelope provided in the packet for return to the PI. CRNAs were informed in the cover letter that completion of the survey served as their consent to participate. Each survey was pre-coded with a unique identifier number to facilitate tracking of survey return and follow up mailings to non-respondents.

One week after the survey mailing, a reminder letter/thank you card was sent to participants. The PI maintained a record of non-responders. A second questionnaire package was be sent to non-responders 3 weeks after the initial survey packet was mailed. Also, a postcard reminder was sent to non-responders one week after the second survey mailing. A final survey packet was sent to non-responders seven weeks after the initial study packet was sent.

Human Subject Protection

This study was submitted to the Institutional Review Board of Rutgers, The State University of New Jersey to ensure protection of human subjects prior to data collection.

Risks to CRNA participants were no greater than minimal, and harm or discomfort anticipated in the proposed research was not greater than that which is encountered in ordinary daily life, or during the participation in any routine psychological examination or test.

A computer list of participants' names, addresses, and survey code numbers was maintained by the investigator. The files were password protected, and password access was only available to the PI. Data was entered into Statistical Package for the Social Sciences (SPSS), and only code numbers were used to identify each subject's response. Data was backed up onto a CD, which was kept in a locked cabinet in the PI's office accessible only to the PI.

Data collected in the study is presented only as an aggregate, and therefore participants are unidentifiable. All computer files and backup discs will be destroyed after completion of the research study, and in compliance with the mandatory 3 year IRB maintenance period.

Data Analysis Plan

A statistical database was created by the PI using SPSS version 21 (SPSS, 2012). Demographic data and participant responses to study instruments were entered into the SPSS database by the PI. Data analysis included descriptive statistics, including means and standard deviations, to describe sample characteristics. Frequency tables, histograms, and scatterplots were used to assess distribution of study variables for normality. Tests for skewness and kurtosis were also conducted. Data was inspected for inconsistencies, outliers, and wild data entry codes. A code book which included copies of the original data set and the cleaned data set, basic descriptive data, correlations, regressions, syntax and output as well as PI notes was generated to document analyses.

Correlation analysis of the study variables was conducted using Pearson Product Moment Correlation. In line with a conservative approach, a two-tailed test of significance set at 0.05 level was employed even if the hypothesis was directional (Polit, 2012). The correlation matrix was examined to determine if there were any demographic variables that were significantly correlated with the dependent variables and that needed to be controlled for in subsequent analysis. The correlation matrix was examined to determine if CRNA structures and patient safety culture variables were significantly associated to adverse event reporting. To test study hypotheses, multiple regression analysis was conducted for each anesthesia-related adverse event. The control variables significantly related to the adverse event were entered on the first step, and the CRNA structural and patient safety variables significantly related to the adverse event were entered on the second step.

Chapter 4

Data Analysis

The purpose of this study was to investigate the relationships among CRNA organizational structures (practice models, work setting, workload, level of education, work experience), CRNA ratings of patient safety culture, and CRNA-reported adverse anesthesia-related events in patients receiving anesthesia administered by CRNAs. Five hundred CRNAs practicing in hospital and/or surgery centers were randomly selected from the American Association of Nurse Anesthetist database to receive the mailed survey. Three hundred and thirty six (336) surveys were returned with an overall response rate of 67%. The survey instrument included (1) a demographic questionnaire developed by the principle investigator (PI) for this study to collect data on participants' age, gender, race, years of experience, employment status, highest level of education completed, anesthesia practice model, work setting, work location, hospital type, size, and magnet status as well as number of anesthetics provided in a two-week period; (2) five nurse-reported adverse anesthesia-related event items; (3) the AHRQ Hospital Survey on Patient Safety (HSOPS) Overall Perceptions of Patient Safety Scale; (4) the HSOPS single-item Patient Safety Grade; (5) the NASA Task-Load Index (NASA-TLX) workload scale and (6) the Workload Scale of the Revised Individual Workload Perception Scale (IWPS).

The survey design method for this study included a process of repeated mailings and multiple contacts in accordance with a modified Tailored Design Method (TDM) (Dillman, 2009). Each of the 500 potential participants was sent a pre-notice postcard introducing them to the study. This was followed by a research survey packet with a cover letter containing elements of informed consent with a brief explanation of the study. Each survey was pre-coded with a unique identifier known only to the PI to facilitate tracking and follow-up mailings to non-responders. Subsequent contacts included a thank you/ reminder postcard, a second survey to non-responders three weeks after the first survey, a second thank you/reminder postcard and a final third survey sent seven weeks after the initial survey packet was sent. All follow-up reminders were scheduled at weekly intervals (each respective Monday) in accordance with the modified TDM. An electronic list of participants' contact information including names and addresses were stored and password protected. Data collected for the study were entered into SPSS version 21 using an identification number assigned to each survey questionnaire. Analyses of the data are presented in this chapter.

Demographics of the Study Sample

A description of the study sample is presented in Table 1**.** The final sample size was 336 participants. The mean age of the sample participants was 48.5 (*SD*=11.02) ranging from 27 to 72 years. The majority of participants were female (57%), white/Caucasian (91%), worked full-time (86.1%), administered an average of 34 (*SD*=17.7) anesthetics in a two week period, and had an average of 16 years (*SD*=11.46) experience as a CRNA. Eighty-one percent worked in the hospital only setting, 61.7% worked in a teaching hospital, 50.3 % worked in a non-magnet hospital, and 51.2 % worked in a hospital with > 250 beds. The average hospital-based CRNA reported spending 78% of their time in the main operating room and 21% of their time in an off-site location.

Table 1.

Sample Demographic Characteristics (n= 336*)

Variable		**Mean**	**SD**
Age		48.5	11.02
Years in Practice		16	11.46
Number of Anesthetics in two week period		34	17.7
		N	**%**
Gender	Male	139	41
	Female	190	57
Work location	% time in main OR		78%
	% time in offsite location		21%
Race	White	306	91
	African American	9	2.7
	Hispanic/Latino	6	1.8
	Asian	7	2.1
	Native American	1	.3
	Other	2	.6
Employment Status	Full Time	285	86.1
	Part Time	46	13.7
Hospital Type	Teaching	198	61.7
	Non-Teaching	121	37.7

Hospital Size	< 100 beds	60	17.9
	100-250 beds	88	26.2
	>250 beds	172	51.2
Hospital Magnet Status	Magnet	129	38.4
	Non Magnet	169	50.3

*sample size varies for variables in the table due to missing data

Description of the Study Variables

Descriptive statistics (mean, standard deviation, range) for study variables are presented in Table 2. CRNA organizational structures will be discussed first. The majority of participants (75%) were masters-prepared. The mean number of years of experience as a CRNA was 16.25 years with a range of experience from one year to 42 years. The majority of nurses (82%) worked in a hospital setting. A majority of nurses worked in either a medically-directed (41%) or supervised (29%) practice model. Participants reported, on average, a high mean workload score for the NASA-TLX (M=66.88, range = 32.5 yrs. to 92.5 yrs.) and a high mean workload score for the IWPS (M=24.2, range = 8 to 30). Mean scores for CRNA-reported adverse anesthesia-related events in a 12 month period were low for all five dependent variables. The difficult intubation (M=2.73, SD=1.18) mean score corresponds to 3-4 events in a year, on average. Similarly, in a one-year period, the difficult extubation mean score (M=1.87, SD=0.93) corresponds to 1-2 events, the inadequate ventilation mean score (M=2.04, SD= 1.12) corresponds to 1-2 events, the inadequate oxygenation mean score (M=2.08, SD=1.13) corresponds to 1-2 events, and the pulmonary aspiration mean score (M=1.25, SD=0.49) corresponds to between zero and 2 events. The mean overall perception of patient safety score was 3.88 out of a possible range of one to four, and the mean score of 4.1 for patient safety grade reflected, on average, a very good patient safety grade rating among study participants. The composite scores for patient safety culture variables reflect the percent of the sample who positively endorsed the patient safety culture dimension in the workplace. The composite score for overall patient safety culture was 74%, indicating that a majority of CRNAs in the sample positively endorsed overall patient safety in their work settings. In addition, the composite score for patient safety grade of 82% indicated a majority of the sample graded patient safety positively as reflected in an A grade endorsed by 31% of nurses and a B grade endorsed by 51% of the nurses (Table 2).

Table 2.

Descriptive Statistics of the Study Variables

Variable		**N**	**%**
Educational Level	Certificate/Diploma	23	6.8
	Bachelor's Degree	46	13.7
	Master's Degree	248	74.9
	Clinical Doctorate	13	3.9
	Research Doctorate	1	.3
Work Setting	Hospital	275	81.8
	Ambulatory Surgery Center	22	6.5
	Both	39	11.6
Practice Model	Supervised	100	29.8
	Medical Directed	139	41.4
	Independent practice	44	13.1
	Other	53	15.8
	Mean	**SD**	**Range**
Years of Experience	16.25	11.46	1 – 42
Difficult Intubations	2.73	1.18	1 – 6
Inadequate Ventilation	2.04	1.12	1 – 6
Inadequate oxygenation	2.08	1.13	1 – 6
Pulmonary Aspiration	1.25	0.49	1 – 3
Difficult Extubation	1.87	0.93	1 – 6
NASA -TLX	66.88	11.90	32.5 – 92.5
IWPS	24.2	4.40	8 – 30
Overall Perception of Safety	3.88	0.83	1 – 4
Patient Safety Grade	4.1	0.75	1 – 5
		N	***%***
A		103	30.7
B		171	50.9
C		53	15.8
D		9	2.7

Internal consistency reliability coefficients for the study are presented in Table 3. A satisfactory level of reliability is dependent upon how the measure is used (Nunnally, 1978). Some researchers have stated that 0.7 is the cut-off for acceptable reliability (Kerlinger & Lee, 2000). In nursing research, a measure that achieves a reliability coefficient greater than .70 is satisfactory, but coefficients greater than .80 are preferred (Polit & Beck, 2011). Reliability was not calculated for the Patient Safety Grade due to the single item dimension of the scale. The reliability coefficients for each of the remaining study variables are listed in Table 4. The reliability coefficient for the HSOPs Overall Perception of Safety scale was .840, and for the IWPS Workload Scale was .763, indicating acceptable reliability and good internal consistency. The reliability for the NASA-TLX scale was .623 in this study, which is lower than the reported .72 found in an earlier study of Intensive Care Unit (ICU) nurses (Hoonaker et al, 2011).

Table 3.

Alpha Coefficients for Study Instruments

Study Instrument	Cronbach's alpha coefficient
NASA-TLX	.623
IWPS	.763
Overall Perception of Safety	.840

Data management consisted of a series of data checking methods. The data were cleaned and verified as recommended by Polit and Beck (2011). Data were inspected and checked for invalid and missing values, and identifiable patterns of expectancy, such as inconsistencies in individual variable range. Data were examined for missing variable scores. Of the 336 respondents, three of the participants returned surveys with missing complete NASA-TLX scores and were therefore included in hypothesis testing that pertained to this variable. There was also one survey with missing data for the IWPS and that was not included in hypothesis testing for this variable. Missing data for nurse-reported adverse events was minimal: inadequate ventilation data were missing on two surveys; inadequate oxygenation data were missing on five surveys; and both difficult extubation and pulmonary aspiration data were missing on two surveys.

Data quality was further examined to assess variable scores for symmetry, approximation to normal distributions, and extreme skewness. The distribution of scores for all study variables were assessed by visually inspecting for skewness (evidence of central tendency) and kurtosis (evidence of tail heaviness relative to the total variance in the distribution). Fisher's skewness coefficient (measure of skewness/standard error of skewness) results in a z-statistic. Z-statistic values that fall between +1.96 and -1.96 are considered normally distributed (Tabachnik & Fidell, 2006). As presented in Table 4, only the NASA-TLX workload scores were normally distributed. Scores for CRNA-reported adverse anesthesia events, years of experience, practice models, IWPS workload were positively skewed, and scores for level of education, NASA-TLX workload, and overall perceptions of safety were negatively skewed. For these non-normally distributed, data transformation could be considered. However, data transformation is not universally recommended as transformed data may be more difficult to interpret (Tabachnik & Fidel, 2006). Therefore data transformations were not done.

Table 4.

Distribution of Scores for Study Variables

	Skewness	S. E. Skewness	Kurtosis	S. E. Kurtosis	Fisher's Skewness Coefficient (Z- score)
Education level	-1.243	.134	2.265	.267	-9.28
Year of Experience	.385	.134	-1.085	.267	2.87
Work Setting	1.967	.133	2.173	.265	14.79
Practice Model	.598	.133	-.726	.265	4.50
Difficult Intubation	.553	.133	-.182	.265	4.158
Difficult Extubation	1.445	.133	2.887	.266	10.86
Inadequate Ventilation	1.212	.134	1.325	.266	9.04
Inadequate Oxygenation	1.071	.134	.596	.267	7.99
Pulmonary Aspiration	1.858	.133	2.658	.266	13.97
NASA-TLX	-.178	.134	-.413	.266	-1.33
IWPS	-.951	.133	.848	.266	7.15
Overall Perception of Safety	-.795	.133	.661	.265	-5.97

Results of Hypothesis Testing

A correlation matrix of the main study variables is presented in Table 5. Pearson product- moment correlations were computed to examine the hypothesized relationships between CRNA organizational structures (practice model, work setting, workload, level of education and years of experience), patient safety culture, and CRNA-reported adverse anesthesia-related events. As noted in Table 5, age was highly correlated with years of experiences ($r = .87$, $p < .01$), indicating that older age was highly associated with more years of experience. Therefore, age was not entered as a covariate in multivariate regression models that included years of experience as an independent variable. In addition, two hospital characteristics were significantly associated with several main study variables. Hospital size was significantly related to workload as measured by the NASA-TLX ($r = .157$, $p < .01$), indicating that larger hospitals (bed size > 250) were associated with higher workloads. Hospital magnet status was significantly related to overall patient safety grade ratings ($r = -.115$, $p < .05$), indicating that Magnet hospitals were associated with positive patient safety grades. Hospital magnet status was also significantly related to CRNA reports of inadequate ventilation adverse events ($r = .115$, $p < 05$), indicating that non-Magnet hospitals were associated with higher occurrences of these events as reported by CRNAs. Therefore, these hospital characteristics were controlled for in the appropriate regression models. Additionally, NASA-TLX and IWPS workload variables were significantly correlated, as expected. However, the magnitude of the correlation (-.358) between these variables indicate that they are relatively distinct and represent different dimensions of workload. Therefore, these variables were entered together into appropriate regression models. Lastly, the demographic variable employment status, which refers to full-time versus part-time employment was correlated with two of the five adverse anesthesia-related events. Employment status was significantly, and negatively correlated with difficult intubations ($r = -.109$, $p = .049$) and inadequate oxygenation ($r = -.118$, $p = .033$), indicating that full-time employment was significantly associated with these adverse events. Therefore, employment status was controlled for in regression models that included these adverse events. No other demographic variables (gender, race, number of anesthetics delivered in a 2-week period) or hospital characteristics (hospital size or type) were correlated with patient safety variables or adverse anesthesia-related events, and they are not listed in Table 5.

Table 5.

Correlation Coefficients for Study Variables

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
1 Age	1																	
2 Years of Experience	.871**	1																
3 Employment Status	.095	.160**	1															
4 Education Level	-.459**	-.598**	-0.085	1														
5 Practice Model	.001	-.016	-.054	.020	1													
6 Work Setting	-.025	.015	.111*	-.023	.031	1												
7 Hospital Type	.149**	.122*	-0.078	-.138*	.131*	-.057	1											
8 Hospital Size	-.266**	-.197**	0.064	.192**	-.247**	.065	-.519**	1										
9 Hospital Magnet Status	.087	.030	-.047	-.093	.095	-.080	.394**	-.421**	1									
10 Difficult Intubation	.006	.001	-.109*	.017	-.041	.018	-.016	.000	.048	1								
11 Difficult Extubation	-.176**	-.122*	-0.047	.073	-.040	.038	-.060	.042	-.038	.489**	1							
12 Inadequate Ventilation	-.082	-.139*	-0.088	.066	-.024	-.057	-.027	.072	.115*	.256**	.294**	1						
13 Inadequate Oxygenation	-.040	-.046	-.118*	.107	-.022	-.049	.029	.014	.046	.244**	.317**	.545**	1					
14 Pulmonary Aspiration of Gastric Contents	-.113*	-.088	-.095	.072	-.032	.004	-.102	.099	-.074	.036	.129*	.059	.029	1				
15 Overall Safety Perception	.078	.121*	0.072	-.064	.086	.022	.053	-.058	-.061	-.133*	-.082	-.298**	-.170**	-.029	1			
16 Overall Patient Safety grade	-.018	.039	.087	-.028	.044	.057	.039	-.022	-.115*	-.042	-.016	-.185**	-.063	.007	.727**	1		
17 NASA-TLX	.047	.014	-.017	.051	-.007	-.045	-.100	.157**	.008	.050	.034	.034	.008	-.019	-.214**	-.149**	1	
18 IWPS	-.086	-.049	.126*	-.078	-.104	.022	-.098	.088	-.097	-.075	-.126*	-.006	.020	-.032	.415**	.393**	-.358**	1

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

HYPOTHESIS ONE

Hypothesis 1 indicated that CRNA organizational structures (practice model, work setting, workload, education and years of experience) were significantly related to CRNA-reported adverse patient events.

Hypotheses 1a-b indicated that CRNA practice models and work setting were significantly associated with CRNA-reported adverse anesthesia-related events. As shown in Table 5, neither CRNA practice model nor work setting was significantly associated with any of the five CRNA-reported adverse anesthesia-related events. Therefore, hypotheses 1a and 1b were not supported.

Hypothesis 1c indicated that CRNA workload was significantly associated with CRNA-reported adverse anesthesia-related events. As shown in Table 5, NASA-TLX total scores were not significantly related to any adverse event. However, the IWPS workload score was significantly and negatively correlated with difficult extubation ($r = -.126$, $p = .022$), indicating that high workload was significantly associated with difficult extubation. Therefore, hypothesis 1c was partially supported.

Hypothesis 1d indicated that level of education was significantly associated with CRNA-reported adverse anesthesia-related events. As shown in Table 5, this relationship was not significant. Therefore, hypothesis 1d was not supported.

Hypothesis 1e indicated that fewer years of CRNA experience is related to higher numbers of CRNA-reported adverse events. As noted in Table 5, bivariate correlational analysis revealed that CRNA years of experience was inversely related to two adverse events including difficult extubation ($r = -.122$, $p = .027$) and inadequate ventilation ($r = -.139$, $p = .011$), indicating more years of experience was significantly related to lower CRNA-reported adverse events of difficult extubation and inadequate ventilation. Since years of experience was significantly related to two of five adverse events, hypothesis 1e was partially supported.

Multivariate analysis was undertaken to examine the independent effect of years of experience on difficult extubation and inadequate ventilation. Since hospital magnet status was also significantly related to inadequate ventilation ($r = .115$, $p < .05$), and a hierarchical regression analysis was conducted to examine the independent effect of years of CRNA experience on inadequate ventilation, controlling for the effect of magnet status on this CRNA-reported adverse event. The survey responses for the magnet status variable (1 = magnet hospital; 2 = non-magnet hospital) were recoded (0 = non-magnet hospital; 1 = magnet hospital) for regression analysis. Magnet status was entered into the regression model in the first step, and years of experience was entered in the second step. As shown in Table 6, both magnet status and years of CRNA experience were independently associated with inadequate ventilation. However, the effect of both of these variables on inadequate ventilation was small. Magnet status contributed only 1% of the variance in this adverse event, and years of CRNA experience contributed only an additional 2% of variance in inadequate ventilation.

Table 6.

Independent Effects of Years of Experience on Inadequate Ventilation

Model 1	**Standardized Beta**	**Adjusted R^2**	**p-value**
Magnet Status	-.124	.012	.035

Model 2		**R^2 change** .020	
Magnet Status	-.126		.031
Years of Experience	-.140		.016

IWPS workload was significantly related to difficult extubation, ($r = -.127$, $p < .05$) so a hierarchical regression analysis was performed to determine the independent effects of years of experience on difficult extubation controlling for workload. IWPS was entered into the regression model in the first step, and years of experience was entered into the second step. As shown in Table 7, both IWPS workload ($r = -.133$, $p = .015$) and years of experience (-.128, $p = .020$) were found to be independently associated with difficult extubation as reported by CRNAs. IWPS explained 1 % of the variance and years of experience contributed an additional 2% of the variance above the effect of workload.

Table 7

Independent Effects of Years of Experience on Difficult Extubation

Model 1	**Standardized Beta**	**Adjusted R^2**	**p-value**
IWPS workload	-.127	.013	.021
Model 2		**R^2 change** .016	
IWPS Workload	-.133		.015
Years of Experience	-.128		.020

HYPOTHESIS TWO

Hypothesis two indicated that CRNA organizational structures (practice models, work setting, workload, education, years of experience) were significantly related to patient safety culture variables (overall perception of safety and patient safety grade).

Two nurse organizational structures, workload and years of experience, were significantly related to patient safety culture variables.

Hypothesis 2a indicated that CRNA practice model was significantly associated with overall perception of patient safety and patient safety grade. As noted in Table 5, practice model was not significantly associated with either patient safety variable, and this hypothesis was not supported.

Hypothesis 2b indicated that CRNA work setting was significantly associated with overall perception of patient safety and patient safety grade. As noted in Table 5, work setting was not significantly associated with either patient safety variable, and this hypothesis was not supported.

Hypothesis 2c indicated that high CRNA workload was significantly associated with a fair to failing patient safety grade and a negative rating of overall patient safety by CRNAs. As noted in Table 5, CRNA workload, operationalized both as NASA-TLX and IWPS, was significantly related to CRNAs overall perception of patient safety culture ($r = -.214$, $p = .000$ and $r = .415$, $p = .000$, respectively) and patient safety grade ($r = -.149$, $p = .000$ and $r = .393$, $p = .000$, respectively). Therefore, hypothesis 2c was supported.

To determine the independent effects of workload dimensions on these patient safety variables, two regression analyses were performed. First, the independent effects of both workload dimensions on CRNAs perceptions of overall patient safety in their work setting was examined. Since years of experience was related to overall patient safety as well, a hierarchical analysis was conducted. Years of experience was entered in the first step, and workload variables (NASA-TLX and IWPS) were entered in the second step. As shown in Table 8, years of experience ($\beta = .142$, $p = .004$) and IWPS workload (β =.402, p = .000) were independently associated with overall perception of patient safety when all variables were in the regression model together. However, the NASA-TLX dimension of workload (β = -.076, p = .155) was not independently associated with overall perception of patient safety when the effects of IWPS workload scores and years of experience were controlled for in the model. Years of experience accounted for 1% of variance in CRNA ratings of overall patient safety, and workload dimensions contributed an additional 12% of the variance in CRNA overall perceptions of patient safety culture above the variance accounted for by years of experience.

Table 8

Independent Effects of CRNA Workload on Overall Perception of Patient Safety

Model 1	**Standardized Beta**	**Adjusted R^2**	**p-value**
Years of experience	.119	.011	.031
Model 2		**R^2 change**	
		.118	
Years of Experience	.142		.004
NASA-TLX	-.076		.115
IWPS Workload	.402		.000

Secondly, the independent effect of workload on patient safety grade was examined. Since hospital magnet status was significantly related to patient safety grade, a hierarchical regression analyses was conducted to determine the independent effect of workload variables on patient safety grade, controlling for the effects of hospital magnet status. As shown in Table 9, the IWPS dimension of workload was the only variable that was independently associated with patient safety grade (β = .357, p = .000) when the effects of the NASA-TLX workload and hospital magnet status were controlled for in the model. Neither magnet status (r = .093, p = .090) or NASA-TLX (r = -.011, p = .849) was independently associated with patient safety grade. The models indicate that hospital magnet status only contributes about 1% of the variance in patient safety grades, and workload variables contribute an additional 13% of the variance, above that of magnet status, in patient safety grade.

Table 9

Independent Effects of CRNA Workload on Patient Safety Grade

Model 1	**Standardized Beta**	**Adjusted R^2**	**p-value**
Magnet Status	.126	.012	.031
Model 2		**R^2 change**	
		.129	
Magnet Status	.093		.090
NASA-TLX	-.011		.849
IWPS Workload	.357		.000

Hypothesis 2d indicated that higher level of CRNA education was associated with an overall positive rating of patient safety and a good to excellent patient safety grade. As noted in Table 5, CRNA education was not significantly related to patient safety culture variables, and this hypothesis was not supported.

Hypothesis 2e indicated that increased years of experience was significantly associated with overall positive ratings of patient safety culture and good to excellent patient safety grades. As noted in Table 5, years of experience was significantly related to CRNA overall perceptions of patient safety (r = .121, p = .028) but not related to their patient safety grade ratings. Therefore, hypothesis 2e was partially supported. In addition, as noted in Table 8, years of experience was an independent predictor of overall perception of patient safety (r = .142, p = .004) in multivariate analysis.

HYPOTHESIS THREE

Hypothesis three stipulated that patient safety culture was significantly associated with CRNA-reported adverse anesthesia–related events in patients receiving CRNA-administered anesthesia.

Hypothesis 3a indicated that negative ratings of CRNAs overall perception of patient safety in the work setting was significantly associated with their reports adverse anesthesia-related events. As shown in Table 5, overall safety perception is significantly and inversely related to three adverse events. Specifically, negative ratings of overall patient safety was significantly associated with increased reports of difficult intubation ($r = -.133$, $p = .014$), inadequate ventilation ($r = -.298$, $p = .000$) and inadequate oxygenation ($r = -.170$, $p = .002$) by CRNAs. Thus hypothesis 3a was supported. Employment status (full- or part-time) CRNA years of experience, and hospital magnet status were also significantly associated with one or two of these adverse events and were controlled for in multivariate analyses.

To determine the independent effects of CRNAs overall perception of patient safety culture on their reports of the inadequate ventilation adverse event, hierarchical regression was undertaken to control for the effects of years of experience and magnet status on inadequate ventilation as noted in Table 6. Specifically, less years of experience and non-magnet status was associated higher numbers of inadequate ventilation events. Years of experience and recoded magnet status scores were entered in the first step, and overall safety perception was entered in the second step. As shown in Table 10, CRNA overall perception of patient safety remained a significant and independent predictor of inadequate ventilation when the effect of years of experience and magnet status were controlled for. In addition, years of experience and magnet status remained significant when overall patient safety was in the model. Taken together, years of experience and magnet status accounted for nearly 3% of the variance in inadequate ventilation scores, and overall perception of patient safety culture contributed an additional 8% of variance in the scores for this adverse event.

Table 10

Independent Effects of Overall Perception of Safety on Inadequate Ventilation

Model 1	**Standardized Beta**	**Adjusted R^2**	**p-value**
		.028	
Years of experience	-.140		.031
Magnet Status	-.126		.016
Model 2		**R^2 change**	
		.081	
Years of experience	-.113		.045
Magnet status	-.113		.041
Overall perception of patient safety	-.286		.000

A second hierarchical regression was conducted to determine the independent effect of overall safety perception on difficult intubation, controlling for the effect of employment status on this adverse event. Specifically, full-time employment was significantly associated with higher CRNA reports of difficult intubation. Since employment status was coded 1 = full-time and 2 = part-time, this variable was recoded for regression analysis to 0 = part-time and 1 = full-time. Employment status was entered in the first step, and overall perception of safety was entered in the second step. As shown in Table 11, overall perception of patient safety remained a significant and independent predictor of difficult intubation when controlling for employment status. When employment status was in the model with overall perception of patient safety, it was no longer related to CRNA reports of difficult intubation. Employment status accounted for only 1% of the variance in difficult intubation, and overall perception of patient safety contributed little additional variance (1%).

Table 11

Independent Effects of Overall Perception of Safety on Difficult Intubation

Model 1	**Standardized Beta**	**Adjusted R^2**	**p-value**
		.009	
Employment status	.109		.049
Model 2		**R^2 change**	
		.015	
Employment status	.100		.069
Overall perception of patient safety	-.125		.023

A third hierarchical regression was conducted to determine the independent effect of overall safety perception on inadequate oxygenation, controlling for the negative effect of full-time employment status on this adverse event. The recoded employment status variable was entered in the first step, and overall perception of safety was entered in the second step. As shown in Table 12, overall perception of patient safety remained a significant and independent predictor of difficult intubation when controlling for employment status. When employment status was in the model with overall perception of patient safety, it was no longer related to CRNA reports of difficult intubation. Employment status accounted for only 1% of the variance in difficult intubation, and overall perception of patient safety contributed only an additional 1% of variance.

Table 12

Independent Effects of Overall Perception of Safety on Inadequate Oxygenation

Model 1	**Standardized Beta**	**Adjusted R^2**	**p-value**
		.011	
Employment status	-.118		.033
Model 2		**R^2 change**	
		.026	

Employment status Overall perception of patient safety	-.105 -.161		.055 .003

Hypothesis 3b indicated that fair to failing patient safety grades as rated by CRNAs are significantly associated with higher numbers of CRNA-reported adverse events. As shown in Table 6, patient safety grade was significantly and negatively correlated with one adverse event, inadequate ventilation ($r = -.185$, $p = .001$). Thus hypothesis 3b was supported. As shown in Table 6, years of experience and magnet status were also correlated with inadequate ventilation, indicating that less years of experience and non-magnet status was a higher number of CRNA reports of inadequate ventilation. To control for these effects, a hierarchical regression analysis was performed to determine if patient safety grade was an independent predictor of inadequate ventilation. The recoded magnet status variable and years of experience were entered in the first step, and patient safety grade was entered in the second step. As shown in Table 13, patient safety grade was independently associated with inadequate ventilation when the effects of magnet status and years of experience were controlled. For the covariates, years of experience remained significant, however magnet status was no longer significant when patient safety grade was in the model. Taken together, magnet status and years of experience contributed nearly 3% of the variance in inadequate ventilation scores, and patient safety grade ratings contributed an additional 4 % of the variance when added to the model.

Table 13

Independent Effects of Patient Safety Grade on Inadequate Ventilation

Model 1	**Standardized Beta**	**Adjusted R^2**	**p-value**
		.028	

Magnet status	-.126		.031
Years of experience	-.140		.016
Model 2		**R^2 change** .039	
Magnet status	-.106		.066
Years of experience	-.133		.020
Patient safety grade	-.198		.001

Summary of Hypothesis Testing

In summary, of the 15 hypotheses tested, five were supported, as noted in Table 14. For hypothesis one, only two of five organizational nurse structures were significantly related to adverse anesthesia-related events. High workload, as measured by the IWPS (and not the NASA-TLX dimension) was significantly associated with one of five CRNA-reported adverse anesthesia-related events measured, i.e., difficult extubation, and it was an independent predictor of this event in multivariate analysis. A second nurse structure, less years of experience, was significantly associated with two (inadequate ventilation, difficult extubation) of five CRNA-reported adverse anesthesia-related events. Magnet designation was also related to less inadequate ventilation events, and this effect was controlled for in multivariate analysis. CRNA years of experience independently predicted both inadequate ventilation and difficult extubation.

For hypothesis two, only two (workload, years of CRNA experience) of the five organizational nurse structures were significantly related to patient safety culture variables (overall perceptions of patient safety, patient safety grade), as shown in Table 14. Both dimensions of workload (IWPS and NASA-TLX) were significantly related to both overall perceptions of patient safety and patient safety grade ratings in bivariate analyses. In addition, magnet status designation and more years of CRNA experience were associated with positive overall perceptions of patient safety, and magnet designation was associated with positive patient safety grades. These effects were controlled for in multivariate analysis. Multivariate analyses revealed that only one workload dimension, operationalized as IWPS scores, and years of CRNA experience independently predicted overall patient safety culture and patient safety grade ratings.

For hypotheses 3, patient safety grade was significantly associated with one (inadequate ventilation) of five CRNA-reported adverse anesthesia-related event in bivariate analysis, and it was an independent predictor of the adverse event in multivariate analysis, when the effects of employment status and magnet status on this event were controlled for. The second patient safety culture variable, overall perceptions of patient safety, was significantly associated with three (inadequate ventilation, difficult intubation, inadequate oxygenation) of five CRNA-reported adverse anesthesia-related events in bivariate analysis. In multivariate analyses, controlling for the effects of employment status, years of experience, and magnet status as appropriate, CRNAs overall perception of patient safety was also an independent predictor of the three adverse events.

Table 15. Summary of Hypothesis Testing

Hypothesis 1a	Practice model is associated with adverse events	Not supported
Hypothesis 1b	Work setting is associated with adverse events	Not supported
Hypothesis 1c	High workload is associated with adverse events	Supported
Hypothesis 1d	Lower level of education associated with adverse events	Not supported
Hypothesis 1e	Less years of experience associated with adverse events	Supported
Hypothesis 2a	Practice model is associated with patient safety variables	Not supported

Hypothesis 2b	Work setting is associated with patient safety variables	Not supported
Hypothesis 2c	High workload is associated with negative patient safety culture ratings	Supported.
Hypothesis 2d	High level of education associated with positive patient safety culture ratings	Not supported
Hypothesis 2e	More years of experience associated with positive patient safety culture ratings	Supported
Hypothesis 3a	Negative patient safety grades associated with adverse events	Supported
Hypothesis 3b	Negative overall patient safety ratings associated with adverse events	Supported

Ancillary Analysis

In the field of anesthesia, production pressure can be a proxy for workload. Production pressure is the pressure placed on a provider to work faster as a higher priority than working more safely (DeMaria & Neustein, 2010). Production pressure can vary depending on an organizational work system but generally the goal is to reduce OR downtime, thereby maximizing billable hours. The NASA-TLX scale is a multidimensional scale that has been used to generate both an overall and single dimension workload scores. The NASA-TLX workload dimension subscales (mental, physical, temporal, effort, performance, and frustration level) are considered fairly independent and consequently can be analyzed separately (Hart, 2006). Therefore, in order to further test for production pressure, bivariate correlations were performed with the temporal subscale (time pressure or “production pressure) and the five adverse anesthesia-related events. The temporal demand subscale was found to be significantly associated with only one adverse event, difficult extubation ($r = .118$, $p = .031$).

Extubation occurs during emergence, one of the busiest times of an anesthetic (Leedal & Smith, 2005). As this occurs just prior to transfer of care of the patient from the anesthesia provider to the post anesthesia care unit, there may be pressure on the anesthesia provider to perform this too early and at the cost of readiness of the patient for extubation.

Additionally, production pressure reduces safety during anesthetic care by encouraging providers to deviate from usual care, and to encourage haste which may increase unintentional error (Gaba, Howard, & Jump, 1994). In bivariate correlation, the temporal subscale was found to be significantly, and negatively associated with both overall perception of patient safety ($r = -.251$, $p = .000$) and patient safety grade ($r = -.213$, $p = .000$), demonstrating moderate correlation and a high level of significance. This provides further support for hypothesis 2c, high workload is associated with negative patient safety culture ratings.

Chapter 5

Discussion of the Findings

The purpose of this study was to examine the relationships among CRNA organizational structures, CRNA ratings of patient safety culture, and CRNA-reported adverse anesthesia-related events in patients receiving anesthesia administered by CRNAs. The findings in this chapter are discussed in the context of the theoretical propositions derived from the Nursing Organization and Outcome Model (Aiken, 2002), and the Patient Safety Culture Framework (AHRQ, 2012).The Nursing Organization and Outcome Model (NOOM) proposes that organizational structures, attributes of high quality work environments and processes of care influence patient outcomes.

Patient safety culture is a key component of a high quality work environment and the model stipulates that a positive patient safety culture assists in the reduction of adverse patient events and promotes positive patient outcomes. According to both the theoretical and empirical literature, nursing organizational structures, such as workload, are significantly associated with patient outcomes and nurses' perceptions of the culture of patient safety in their work settings (Aiken et al, 2003; El-Jardali et al, 2011; Metzner et al, 2009; Pine, Holt & Lou, 2003; Thomas-Hawkins & Flynn, 2013. Furthermore, the empirical literature reveals an important association between patient safety culture in healthcare settings and adverse patient outcomes (Hofman & Mark, 2006; Mardon et al, 2010; Thomas-Hawkins & Flynn, 2013). A discussion of the findings from this study related to the relationships among CRNA organizational structures, patient safety culture, and CRNA-reported adverse-anesthesia related events are presented.

CRNA- Reported Adverse Anesthesia-Related Events

The number of adverse anesthesia events as reported by CRNAs was low for all five events in a twelve month period. For four out of the five adverse events measured (difficult extubations, inadequate ventilation, inadequate oxygenation, pulmonary aspiration of gastric contents), a majority of CRNAs (75% to 97%) reported adverse event frequencies of either no occurrences or only 1 to 2 occurrences in the past year. Only one adverse event, difficult intubations, was reported by 51% of CRNAs as occurring three or more times in a year.

These findings are consistent with existing data about adverse anesthesia related events. Closed claim analyses have been performed by both the American Society of Anesthesiologists (ASA) and the American Association of Nurse Anesthetists (AANA) in order to shed light on current patterns and predictors of adverse patient events. As a result of continuous improvement efforts initiated by the Anesthesia Patient Safety Foundation (APSF) in the 1980s, the overall number of anesthetic adverse events remains low (Eichorn, 2012). Claims involving adverse respiratory events (inadequate oxygenation/ventilation, difficult intubation, esophageal intubation and aspiration) decreased dramatically from 1990 to the present (Bailie & Posner, 2011).

Despite the low numbers of adverse events (AE) reported by CRNAs in this study, the significance of potential morbidity and mortality associated with such serious events cannot be ignored. For example, one episode of pulmonary aspiration can result in a life-threatening pneumonia with multiple days of hospitalization and accompanying medical treatments (Limper, 2011). Although CRNAs individually reported low numbers of adverse anesthesia-related events in the past year, collectively, the potential harm to patients is not inconsequential because of the large numbers of patients who receive anesthesia by CRNAs in the United States; 32 million anesthetics are delivered by CRNAs each year (AANA, 2009). There are little to no data that exist that convey the economic burden of anesthesia-related adverse events and these data are sorely needed. On the other hand, pay for performance (P4P), or value-based purchasing, will likely link clinical outcomes with reimbursement. P4P also includes disincentives for negative consequences of care or increased costs for “never” events, e.g., wrong-site surgery, operative or postoperative complications, medication errors (AHRQ, 2012). Hence, in the current evidence-based, outcomes driven healthcare environment, it is critical for anesthesia practitioners to strive to eliminate these events. This can be accomplished by monitoring adverse event occurrences and implementing strategies to prevent any future occurrences.

Relationship between CRNA Organizational Structures and CRNA-Reported Adverse Events

Hypothesis one indicated that CRNA organizational structures (practice model, work setting, workload, education and years of experience) were significantly related to CRNA-reported adverse patient events. Only two of five organizational nurse structures were significantly related to adverse anesthesia-related events; workload and years of experience.

In this study, workload was operationalized in two different ways. First, the workload subscale (IWPS) of the Revised Individual Workload Perception Scale was used. The items on this subscale focus on whether nurses receive a meal break, feel assignments are fairly distributed and workload reasonable, voice concerns to their manager about heavy workload, and intend to stay at the place of employment. Workload was also operationalized as CRNA scores on the NASA Task-Load Index (NASA-TLX). This instrument measures CRNA subjective reports of mental effort, temporal demands, as well as feelings of frustration, job satisfaction and overall job performance. NASA-TLX and IWPS workload scores were significantly related in this study, but the magnitude of the correlation (-.358) between these variables indicated that they are relatively distinct and represent different dimensions of workload. Interestingly, only IWPS scores were significantly related to one AE, difficult extubation, in both bivariate and multivariate analyses in this study, and this finding is consistent with previous research in samples of staff nurses in that high workload was significantly associated with adverse patient events in outpatient dialysis (Thomas-Hawkins et al, 2008) and hospital settings (Aiken et al, 2011; Wiltse-Nicely et al, 2013). On the other hand, the NASA-TLX total score was not significantly related to any AE in hypothesis testing. However, the NASA-TLX temporal workload subscale, which measures production pressure, was significantly correlated with the AE difficult extubation in ancillary analysis. These findings may underscore both similarities and differences in dimensions of workload for the CRNA compared to other nurses. For example, the CRNA may not be able to take a meal break, similar to staff nurses, because of workload. On the other hand, in the field of anesthesia, production pressure, that is, the pressure to work faster to turn over cases as a higher priority than working more safely, is well-described (Carayon & Alvarado, 2007; DeMaria & Neustein, 2010; Gaba et al, 1994; Kirsner & Biddle, 2012). Thus, it is important to capture this aspect of workload in CRNA practice. For example, extubation, or removal of the endotracheal tube, occurs at the culmination of the surgical or procedural event. It may be that the anesthetist feels rushed to perform this task when workload and/or production pressure is high. The IWPS may not measure particular aspects of CRNA workload that are distinctive for this role. Because the reliability for NASA-TLX was less than desirable in this study, future work is needed to develop and test a reliable and valid workload measure that captures unique aspects of CRNA workload such as production pressure. In addition, future comparisons of IWPS and NASA-TLX workload dimensions in CRNAs is warranted.

Hypothesis one also stipulated that less years of experience was related to CRNA reports of adverse event occurrences, and study findings revealed that years of experience was inversely related to both inadequate ventilation and difficult extubation in both bivariate and multivariate analyses. These findings are consistent with research that has shown that more years of staff nurse experience is a significant predictor of reduced mortality and failure-to-rescue in hospitalized patients (Aiken et al, 2003). Additionally, the findings are also consistent with research that indicates that more years of surgeon experience is associated with reduced mortality and fewer complications (Prystowsky et al, 2002). It is important to investigate this relationship further as these findings have important implications for CRNA practice. Less experienced CRNAs may require added support during early years of practice in order to minimize the occurrence of inadequate ventilation and difficult extubation. Similarly, less experienced CRNAs may benefit from working in a setting where additional support is available prior to accepting a position in an independent practice model.

CRNA level of education was not significantly related to anesthesia-related adverse events as expected. In the study sample, 75% of the sample were Master's prepared; thus there was little variability in level of education among nurses in the sample. Thus, the homogeneity in level of education in this study could have accounted for the non-significant findings in this relationship.

Study findings also did not reveal a significant relationship between CRNA practice model and CRNA-reported adverse anesthesia-related events, and this finding is consistent with research that revealed a non-significant relationship between CRNA practice model and risk adjusted mortality for patients receiving CRNA- administered anesthesia (Dulisse & Cromwell, 2010; Pine, Holt & Lou, 2010). However, adverse event data in these studies were actual patient outcomes, that is, objective data, retrieved from medical reports. The current healthcare system demands clinical outcome data to justify costs and reimbursement. Future research that examines actual patient adverse outcomes is needed to evaluate the relationship between CRNA practice model and adverse anesthesia-related objective outcomes in patients cared for by CRNAs. Additionally, there was little variability in practice models in the study sample; 71% of participants worked in the anesthesia care team model. It is not known if the practice model proportions in this study are representative of the true population CRNA practice models, and further work is needed in this area,

Work setting, that is hospital or ambulatory surgery setting, was also not associated with adverse patient events. Despite this finding, empirical data, while minimal, indicate that offsite mortality claims are double those in the operating room, and that inadequate ventilation and oxygenation are seven times greater in the off-site location compared with the operating room (Metzner, Posner & Domino, 2009). A majority of CRNAs in the sample (82%) worked in the hospital setting, and a lack of variability in work setting in the sample may account for the negative finding in this study. Moreover, this study operationalized work setting as hospital-based and outpatient work settings. Future research is needed that examines differences in work settings in hospital-based nurses; that is operating room and offsite settings within hospitals.

CRNA Organizational Structures and Patient Safety Culture.

The study findings revealed that two of five nursing organizational structures, years of experience and workload, were significantly related to patient safety culture variables. There was a significant association and positive association between years of experience and CRNAs overall perception of safety in their work setting in both bivariate and multivariate analyses, indicating that more years of CRNA experience are associated with positive perceptions of patient safety culture. The relationship between greater of years of experience and reports of positive patient safety culture has been documented in one study of 700 hospital-based employees (El-Jardali et al, 2011). This is the first study to investigate this relationship in a sample of CRNAs, and the paucity of findings that reveal a significant association between years of experience and patient safety culture point to a need for further work in this area to fully understand the nature of this relationship.

In bivariate analyses, the two dimensions of workload (as measured by IWPS and NASA-TLX) were significantly and inversely related to both patient safety culture dimensions examined in this study; that is CRNAs' overall perception of patient safety in their work setting and their patient safety grade ratings. High workload scores were significantly associated with CRNAs' overall perceptions that their work setting was not safe and with their fair to failing patient safety grade ratings. These findings are consistent with research in both dialysis (Thomas-Hawkins & Flynn, 2013) and hospital settings (Sermeus et al, 2012) that revealed significant relationships between high workload scores and low safety grade ratings and perceptions of overall patient safety by nurses. However, in multivariate analysis, only the dimension of workload captured by the IWPS was independently associated with patient safety culture variables. Conceptually, it appears that the dimension of workload assessed by IWPS may be more important for CRNAs perceptions of patient safety in their work environments compared to the dimension of workload assessed by the NASA-TLX. However, the significant bivariate relationship between NASA-TLX scores and patient safety culture variables in this study underscore the need for further research focused on the nature of CRNA workload. In addition, a rigorous development and testing of an anesthesia workload scale that captures the full domain of CRNA workload that likely differs in some ways from the workload of staff nurses is needed.

CRNA level of education was not associated with patient safety culture dimensions. As discussed in an earlier section, 75% of the study sample were Master's prepared; there was little variability in level of education among nurses in the sample. Thus, the homogeneity in level of education in this study could have accounted for the non-significant findings in this relationship.

CRNA practice model also was not associated with patient safety culture dimensions in this study. To date, there have been few studies investigating the relationship between CRNA practice model and patient outcomes, and no studies examining the relationship between CRNA practice model and patient safety culture. Researchers have not found a relationship between adverse patient events and the practice models of CRNAs (Dulisse & Cromwell, 2010; Pine, Holt & Lou, 2010), and it may be that practice model has no influence on CRNA perception of patient safety culture as well. However, since a majority of participants worked in one practice model, more work is needed in this area before such a conclusion can be made with certainty.

Lastly, work setting was also not associated with patient safety culture in this study. Little research exists in this area. Only one study could be found (El-Jardali et al, 2011) that supports the relationship between work setting, as measured by hospital unit, and patient safety culture. The El-Jardali et al. study examined patient safety culture (using the same safety culture measures as in this study) in a variety of hospital departments. In this study, work setting was operationalized as hospital-based and ambulatory surgery settings. CRNAs provide anesthesia as a service in a variety of departments within the hospital setting, and are not always tied to one location. For example, CRNAs provide anesthesia services in off-site locations within the hospital but outside of the operating room such as the cardiac catheterization, gastroenterology, obstetric, and radiology suites. Closed claim studies revealed that mortality claims in off-site anesthetizing locations were double those in the operating room and that the adverse respiratory events of inadequate oxygenation and ventilation was seven times greater in the off-site location compared with the operating room (Domino & Posner, 2009). These findings are concerning. It is likely that more personnel and equipment are available in the main operating room and ambulatory surgery setting, as measured in this study, so that patient safety may not be jeopardized. Further research that examines the relationship between hospital operating room versus hospital offsite CRNA work settings and patient safety culture is needed.

Patient Safety Culture and CRNA–Reported Adverse Anesthesia-Related Events.

The theorized relationship between high quality work environments, conceptualized as patient safety culture in this study**,** and adverse anesthesia-related patient events (AEs) was supported in this study. Patient safety grade ratings by CRNAs was significantly and inversely associated with one adverse event, inadequate ventilation, in bivariate and multivariate analysis. Moreover, CRNAs overall perception of patient safety in their work setting was also significantly and inversely associated with three of the adverse events: inadequate ventilation, difficult intubation, and inadequate oxygenation in both bivariate analysis and multivariate analysis. These findings are consistent with research findings that revealed that hospitals with positive safety culture scores were found to have less patient morbidity (Mardon et al, 2010), fewer urinary tract infections and reduced medication errors (Hofman & Mark, 2006), less adverse event reporting (Thomas-Hawkins & Flynn, 2013) and fewer medical errors in the ICU setting (Valentin et al, 2012). The findings also suggest an important association between patient safety cultures in CRNA work settings and adverse anesthesia-related event occurrence in patients cared for by CRNAs, and future research is needed that examines these relationships with objective patient outcome data.

Study findings also revealed that 74% of CRNAs in the sample positively endorsed overall patient safety in their work settings, and 82% graded patient safety as good (B) or excellent (A). Conversely, approximately one out of four CRNAs (26%) did not positively endorse patient safety in their work environments, and 18% gave their work setting a fair to failing (C, D, or E) safety grade. What is important to note is that, in general, most CRNAs rate patient safety positively, and this may represent a culture in their work settings that fosters positive patient outcomes and the low occurrence of events as reported by CRNAs in this study. However 18% to 26% of the sample did not rate or grade patient safety positively. These results have important implications for organizations in which CRNAs practice. The focus of healthcare today underscores improved patient safety and better patient outcomes. Routine patient safety culture assessments in CRNA practice settings may uncover potential problems. Assessments could lead to the development and testing of strategies designed to improve patient safety culture and ultimately reduce adverse event occurrence in patients receiving anesthesia by CRNAs.

Adequacy of the Nursing Organization and Outcomes Model (NOOM) and Patient Safety Culture Framework for Explaining the Organizational and Work Environment Predictors of Adverse Events as Reported by CRNAs.

The study findings provided support for the NOOM and the Patient Safety Culture framework in the examination of theorized interrelationships among CRNA structures, patient safety culture, and CRNA-reported adverse anesthesia-related patient events. The NOOM links high quality work environment with improved patient outcomes; this proposition was supported in this study. CRNA workload, years of experience and perceptions of patient safety culture were all significantly related to CRNA adverse event reports. Additionally, the proposition that patient safety is a key dimension of a high quality work environment that is linked to patient outcomes was supported by the significant relationship between CRNA perceptions of patient safety in their work setting and their reports of adverse anesthesia-related patient events. Until this study, there was no research that examined CRNA structures, high quality work environments, and CRNA-report adverse anesthesia-related patient events. It is important to investigate these relationships further. Study results indicate that the NOOM and Patient Safety Culture provides a solid framework for future research.

Chapter Six

Summary, Conclusions, Implications, and Recommendations

Summary

Guided by the Nursing Organization and Outcomes Model (Aiken, 2002) and the Patient Safety Culture Framework (AHRQ, 2012), this study examined the relationships among CRNA organizational structures (practice models, work setting, workload, level of education, years of experience), CRNA ratings of patient safety culture, and CRNA-reported adverse anesthesia-related events in patients receiving anesthesia administered by CRNAs. The following hypotheses were examined in a sample of CRNAs practicing in the hospital and ambulatory surgical setting:

1. CRNA organizational structures (practice model, work setting, workload, education and years of experience) are significantly related to CRNA-reported adverse patient events in patients receiving CRNA- administered anesthesia.
2. CRNA organizational structures (practice models, work setting, workload, education, and years of experience) are significantly related to patient safety culture variables (overall perception of safety and patient safety grade).
3. Patient safety culture (overall perception of safety and patient safety grade) is significantly associated with CRNA-reported adverse anesthesia–related events in patients receiving CRNA- administered anesthesia.

The study sample consisted of 336 participants who were certified or recertified by the American Association of Nurse Anesthetists (AANA) and worked in the United States. Inclusion criteria was primary employment as a CRNA in a hospital and/or ambulatory surgical center. Participants meeting the inclusion criteria were randomly selected from the AANA member database. Data were collected using self-report surveys provided to participants using the Tailored Design Method (Dillman, 2009). Instruments included in the study were (1) a demographic questionnaire developed by the principle investigator that included the participants' age, gender, race, CRNA practice model, years of CRNA experience, work setting, and level of education as well as hospital type, magnet status, and hospital size; (2) a CRNA- reported adverse event tool with a series of questions related to the number of occurrences in a 12-month period; (3) Hospital Survey on Patient Safety Overall Perceptions of Safety and Patient Safety Grade Scales (HSOPS) tools (Sorra & Dyer, 2010); (4) the NASA-Task Load Index (NASA-TLX) (Hart and Staveland, 1988); (5) the Workload Scale of the Revised Individual Workload Perception Scale (IWPS) (Cox et al, 2006).

The mean age of the sample was 48.5 (*SD*=11.02) years. The sample was 57% female. The majority of the participants were white/Caucasian (91%). The majority worked full-time (86.1%), administered an average of 34 (*SD*=17.7) anesthetics in a two week period, and had an average of 16 years (*SD*=11.46) experience as a CRNA. Eighty-one percent worked in the hospital only setting, 61.7% worked in a teaching hospital, 50.3 % worked in a non-magnet hospital, and 51.2 % worked in a hospital with > 250 beds. The average hospital-based participant reported spending 78% of their time in the main operating room and 21% of their time in an off-site location.

For hypothesis 1 inferential statistics revealed significant relationships between two organizational structures (workload and years of experience) and CRNA-reported adverse events (inadequate ventilation and difficult extubation). Significantly correlated variables were subjected to further tests using multiple regression analysis. Regression analysis revealed a significant and independent effect of high workload on difficult extubation, and a significant and independent effect of years of experience on both inadequate ventilation and difficult extubation.

For hypothesis 2, two (workload, years of CRNA experience) of the five organizational nurse structures were significantly related to patient safety culture variables (overall perceptions of patient safety, patient safety grade). Both dimensions of workload (IWPS and NASA-TLX) were significantly related to both overall perceptions of patient safety and patient safety grade ratings in bivariate analyses. Additionally, magnet status designation and more years of CRNA experience were associated with positive overall perceptions of patient safety, and magnet designation was associated with positive patient safety grades. These effects were controlled for in multivariate analysis. Multivariate analyses revealed that only one workload dimension (IWPS scores) and years of CRNA experience independently predicted overall patient safety culture and patient safety grade ratings.

For hypothesis 3, patient safety grade was significantly and inversely associated with inadequate ventilation in bivariate analysis, and was shown to be an independent predictor of inadequate ventilation in multivariate analysis. In bivariate analysis, CRNAs overall perception of patient safety was correlated with three adverse events (inadequate ventilation, difficult intubation, inadequate oxygenation). In multivariate analysis, controlling for the effects of employment status, years of experience, and magnet status as appropriate, CRNAs overall perception of patient safety was also an independent predictor of the three adverse events.

In summary, two organizational structures, CRNA workload and years of experience, were significantly related to CRNA-reports of adverse events and patient safety culture. The relationship between the organizational structures work setting, educational level and practice model and reports of adverse events and patient safety culture were not supported in this study.

Limitations

In statistical analysis, correlation does not prove causation. When testing relationships between variables with statistical analysis, an artificial environment is created in order to isolate and test whether or not one variable is influenced by another. It is not clear whether this relationship will continue to exist in the natural setting. This study was limited by its cross-sectional design and the dependence on power analysis based on a paucity of literature regarding the relationship between CRNA organizational structures, adverse event reporting, and patient safety culture. The cross-sectional design does not establish a sequence of events, allow for longitudinal analysis of change over time, and it does not yield incidence (Hulley, Cummings, Browner, Grady & Newman, 2007). Generalizability of the sample to other populations is limited to those CRNAs who agreed to participate, and may not be representative of the general population of practicing CRNAs. Finally, the study relied on CRNA reports of adverse events rather than real patient data. The recall of adverse events over 12 months may not be reliable, and some events such as pulmonary aspiration may not be discovered immediately. Actual patient data related to adverse events may reveal different information than that found in this study. The difficulty with collecting actual patient data related to adverse anesthesia events is whether or not it will be discoverable in the patient chart if it did not result in patient harm.

Conclusions

The results of this study partially support the theorized relationship between CRNA organizational structures and CRNA-reported adverse events. Two of the five structures (workload and years of experience) were significantly related to the adverse events inadequate ventilation and difficult extubation. Workload was an independent predictor of difficult extubation; years of experience was an independent predictor of inadequate ventilation and difficult extubation. In ancillary analysis, the temporal subscale of the NASA-TLX which measures production pressure as a proxy for workload was also related to the adverse event difficult extubation. On the other hand, three of the structures (work setting, level of education and practice model) were not related to reports of adverse events. Closed claim analysis reveals that adverse respiratory event claims are double in the off- site work setting (Metzner, Posner, & Domino, 2009). Hospital –based CRNAs in this study spent an average of 21% or nearly a quarter of their time in an off-site area; this study did not independently measure adverse events reported in the off-site areas so this may be a reason for a lack of a relationship between work setting and adverse events. The educational level of the study CRNAs was very similar (75% held Master's degrees); this homogeneity may have accounted for a lack of relationship between level of education and adverse event reporting. As CRNA education is moving to the clinical doctorate level, it will be interesting to determine if a relationship between higher levels of CRNA education and fewer adverse events reported develops over time. Finally, practice model was not associated with CRNA-reported adverse events. Other studies using actual patient data (Dulisse and Cromwell, 2010; Pine, Lou & Holt, 2010), demonstrate that the independent practice model has not been associated with higher patient morbidity and mortality. Although this study did not use actual patient data, it is important that CRNAs did not report any difference in number of adverse events based on practice model. These study findings provide additional support for CRNAs to work independently.

The theorized relationship between CRNA organizational structures and patient safety culture was also partially supported. Interestingly, two organizational structures (workload and years of experience) were related to both CRNA-reported adverse events and patient safety culture. However, workload, measured by the IWPS, contributed 12 % of the variance in CRNA overall perceptions of patient safety and 13% of the variance in CRNA patient safety grade ratings, while years of experience accounted for only 1% of variance in patient safety ratings. Thus, workload appears to be a more important determinant of CRNA perception of patient safety in their work setting than years of experience.

Lastly, hypothesis testing also revealed that the theorized relationship between patient safety culture and CRNA-reported adverse events was supported. Both patient safety grade and perception of patient safety were inversely related to, and independent predictors of inadequate ventilation; perception of patient safety was inversely related to and a predictor of 3 adverse events (inadequate ventilation, inadequate oxygenation and difficult intubation). Importantly, the findings suggest an important association between positive patient safety cultures in CRNA work settings and reduced adverse anesthesia-related event occurrence in patients cared for by CRNAs. Future research is needed that examines these relationships with objective patient outcome data.

Implications for Nursing

The Nursing Organization and Outcomes Model and Patient Safety Culture Framework posit that the interrelationships among CRNA organizational structures, patient safety culture and CRNA-reported adverse anesthesia-related events are complex. This study provides support for theoretical propositions that CRNA organizational structures and patient safety culture may be important antecedents to adverse anesthesia-related event in patients cared for by CRNAs. The findings in this study that reduced workload and greater years of experience are associated with fewer reports of adverse events and positive ratings of patient safety culture provide opportunities for the implementation of nursing strategies and interventions aimed at CRNA workload reduction when appropriate; clinical support for new graduate CRNAs; periodic monitoring of patient safety culture in departments of anesthesia; and improved documentation and review of adverse anesthesia-related events. Furthermore, evidence-based interventions designed to improve patient safety culture and reduce CRNA workload may foster positive patient anesthesia-related outcomes, a goal of today's performance driven health care system.

Recommendations

Recommendations for future research based on the findings from this study include:

1. <u>Qualitative exploration of the CRNA workload experience.</u> An in-depth inductive exploration of the workload experience of CRNAs is needed to understand the full domain of CRNA workload.
2. <u>Development and psychometric testing of a CRNA workload tool</u>. Based on the findings from this study, there is a need to develop and test a valid and reliable workload scale that captures the full domain of CRNA workload.
3. <u>Examination of relationship between CRNA hospital-based work settings and anesthesia-related patient outcomes</u>. A measure of work setting that is operationalized as hospital based operating room and off-site locations instead of hospital versus ambulatory surgery center is warranted.

4. Replication of study with use of patient outcome data. The use of patient chart review to quantify actual adverse anesthesia-related patient events rather than nurse-reported events is needed.

References

AANA. (2014). Retrieved March 8, 2014 from http://www.aana.com/aboutus/Documents/executivesummary.pdf

AANA (2014). Retrieved March 12, 2014 from http://www.aana.com/aboutus/Pages/Who-We-Are.aspx

AANA (2013). Supervision of CRNAs. Retrieved June 7, 2013 from http://www.aana.com/advocacy/stategovernmentaffairs/Pages/Federal-_Supervision-Rule-opt-Out-Information.aspx

AANA (2013). Advocacy. Retrieved June 21, 2013 from http://www.aana.com/myaana/Advocacy/stategovtaffairs/Pages/06-21-13---Rhode Island- Removes-Supervision-Requirement-for-CRNAs.aspx

AANA (2012). AANA Motto. Retrieved December 14, 2012 from http://www.aana.com/aboutus/Pages/Who-We-Are.aspx.

Agency for Healthcare Policy and Research (2012). Patient safety network. PSNet. Available at http://psnet.ahrq.gov/glossary.aspx?indexLetter=P

AHRQ (2012). Agency for Healthcare Research and Quality: Never Events. Retrieved December 12, 2012 from http://psnet.ahrq.gov/primerHome.aspx.

AHRQ (2012). Patient Safety Primer. Retrieved February 19, 2013 from http://psnet.ahrq.gov/primer.aspx?primerID=5

Aiken, L., Cimiotti, J., Sloane, D., Smith, H., Flynn, L. & Neff, D. (2011). Effects of nurse staffing and nurse education on patient deaths in hospitals with different nurse work environments. *Medical Care*, 49, 1047-1053.

Aiken, L., Clarke, S., Cheung, R., Sloane, D. & Silber, J. (2003). Educational levels of hospital nurses and surgical mortality. *JAMA*, 290, 1617-1623.

Aiken, L., Clarke, S. & Sloane, D. (2002). Hospital staffing, organization, and quality of care: cross national findings. International Journal for Quality in Health Care, 14(1), 5-13.

Aiken L, Clarke S., Sloane D., Lake E., & Cheney, T. (2008). Effects of hospital care environments on patient mortality and nurse outcomes. *Nursing Administration*, 38, 223-229.

Aiken, L., Sermeus, W., Van den Heede, K., Sloane, D., Busse, R., McKee, M., et al. (2012). Patient safety, satisfaction, and quality of hospital care: cross sectional surveys of nurses and patients in 12 countries in Europe and the United States. *BMJ*, 344, e1717, 1-14.

Alves, S. (2005). A study of occupational stress, scope of practice, and collaboration in nurse anesthetists practicing in anesthesia care team settings. *AANA Journal,* 73, 6, 443-452.

Ausserhofer, D., Schubert, M., Desmedt, M., Blegen, M.A., De Geest, S., Schwendimann, R. (2013). The association of patient safety climate and nurse-related organizational factors with selected patient outcomes: A cross-sectional survey. International Journal of Nursing Studies, 50, 240-252.

Bailie, R., & Posner, K. (2011). New trends in adverse respiratory events. *American Society of Anesthesiologists Newsletter*, 75, p.28-29.

Batisse, V. & Bortolussi, M. (1988). Transport pilot workload: a comparison of two subjective techniques. Paper presented at Human Factors Society Thirty-Second Annual Meeting.

Blegen, M., Goode, C., Spetz, J., Vaughn, T. & Park, S. (2011). Nurse staffing effects on patient outcomes. Safety- net and non-safety-net hospitals. *Medical Care*, 49, 406-414.

Brennan, T., Leape, L., Laird, N., Heber, L., Localio, A., Lawthers, A., Newhouse, J., Weiler, P., & Hiatt, H. (2004). Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. *Quality and Safety in Healthcare,* 13, 145-151.

Buerhaus, P.I. (2007). Changes in the nurse workforce. Journal of Nursing Scholarship, 31(2), 160.

Caplan, R. (1999). The Closed Claims Project: looking back, looking forward. *American Society of Anesthesiologists Newsletter*, *63,* 7-9.

Carayon, P., & Alvarado, C. (2007). Workload and patient safety among critical care nurses. *Critical Care Nursing Clinics of North America*, 19, 121-129.

Chang, Y. & Mark, B. (2011). Effects of learning climate and registered nurse staffing on medication errors. *Nursing Research*, 60(1), 32-39.

Chang, Y. & Mark, B. (2011). Effects of learning climate and registered nurse staffing on medication errors. *Nursing Research*, 60(1), 32-39.

Cheney, F. (1997). Anesthesia patient safety and professional liability continue to improve. *American Society of Anesthesiologists Newsletter, 61*, 18-20.

Cheney, F. (1999). The American Society of Anesthesiologists Closed Claims Project: What have we learned, how has it affected practice, and how will it affect practice in the future? *Anesthesiology*, 91, p.552-556.

Cheney, F. (2010). The American Society of Anesthesiologists closed claims: the beginning. *Anesthesiology*, 113: p. 957-960.

Clarke, S. (2006). The relationship between patient safety *climate* and safety performance: A meta-analytic review. *Journal of Occupational Health Psychology, 11(4),* 315-327.

Clancy, C.M. (2011). New research highlights the role of patient safety culture and safer care. *Journal of Nursing Care Quality*, 26(3), 193-196.

Cohen, J. (1988). Statistical power analysis for the behavioral sciences. 2nd ed. Hilldale, NJ: Lawrence Erlbaum Associates.

Council on Accreditation (COA) of Nurse Anesthetists (2013). Standards for accreditation of nurse anesthesia programs. Retrieved May, 25, 2013 from http://home.coa.us.com/accreditation/Documents/Standards%20for%20Accreditation%20of%20Nurse%20Anesthesia%20Education%20Programs_January%202013.pdf

Cox, K., Teasley, S., Zeller, R., Lacey, S., Parsons, L., Carroll, C., Ward-Smith, P. (2006). Know staff's "intent-to-stay." *Nursing Management*, 37, 13-5.

Crawforth, K. (2002). The AANA Foundation Closed Malpractice Claims study: obstetric anesthesia. *AANA Journal*, 76, p.97-104.

DeMaria, S. & Neustein, S. (2010). Production pressure, medical errors and the pre-anesthesia checkout. *Middle Eastern Journal of Anesthesia*, 20, 631-638.

Dillman, D., Smyth, J., & Christian, L. (2009). Internet, Mail, and Mixed-mode Surveys: The Tailored Design Method. Hoboken, New Jersey: John Wiley and Sons.

Donabedian, A. (1988). The Quality of Care: How Can It Be Assessed? *JAMA*, 60, 1743-1748.

Donabedian, A. (1980). *Explorations in quality assessment and monitoring: the definitions of quality and the approaches to its assessment*. Ann Arbor, MI: Health Administration Press.

Dunton, N., Gajewski, B., Klaus, S., & Pierson, B. (2007). The relationship of nursing workforce characteristics to patient outcomes. *Online Journal of Issues in Nursing,* 12(3), 4.

Dullisse, B. & Cromwell, J. (2010). No harm found when nurse anesthetists work without supervision by physicians. *Health Affairs*, 29, 1469-1475.

Eichorn, J. (2012). The Anesthesia Patient Safety Foundation at 25: A pioneering success in safety, 25th anniversary provokes reflection, anticipation. *International Anesthesia Research Society*, 114, 791-800.

El-Jardali, F., Dimassi, H., Jamal, D., Jaafar, M., & Hemadeh, N. (2011). Predictors and outcomes of patient safety culture in hospitals. *BMC Health Services Research*, 11:45, 1-12.

Flynn, L., Thomas-Hawkins, C. & Clarke, S. (2009). Organizational traits, care processes, and burnout among chronic hemodialysis nurses. *Western Journal of Nursing Research,* 31, 569-582.

Friese, C., Lake, E., Aiken, L., Silber, J. & Sochalski, J. (2008). Hospital nurse practice environments and outcomes for surgical oncology patients. *Health Services Research*, 43, 1145-1163.

Frone, M. (1998). Predictors of work injuries among employed adolescents. *Journal of Applied Psychology,* 83, 564-576.

Gaba, D., Howard, S., & Jump, B. (1994). Production pressure in the work environment. California anesthesiologists' attitudes and experiences. *Anesthesiology,* 81, 488-500.

Hart, S. (2006). NASA-Task Load Index (NASA-TLX); 20 Years Later. Proceedings of the Human Factors and Ergonomics Society 50th Annual Meeting, 904-908. Santa Monica: HFES.

Hofman, D.A. & Mark. B. (2006). An investigation of the relationship between safety climate and medication errors as well as other nurse and patient outcomes. *Personnel Psychology*, 59, 847-869.

Hogan, P., Seifert, P., Moore, C. & Simonson, B. (2010). Cost effectiveness analysis of anesthesia providers. *Nursing Economics*, 28, 159-169.

Hoonakker, P., Carayon, P., Gurses, A., Brown, R., McGuire, K., & Khunlerkit, A. (2012). Measuring workload of ICU nurses with a questionnaire survey: the NASA task load index. *IIE Transactions on healthcare Systems Engineering*, 1(2), 131-143.

Hulley, S., Cummings, S., Browner, W., Grady, D. & Newman, T. (2007). Designing clinical research, 3rd Edition. Philadelphia: Lippincott William & Wilkins.

Institute of Medicine (IOM). (1999). To err is human: building a safer health system. Retrieved October 29, 2012 from: http://www.iom.edu/Reports/1999/To-Err-is-Human-Building-A-Safer-Health-System.aspx

Institute of Medicine (IOM). (2004). Near miss analysis. In P. Aspden, J. Corrigan, J. Wolcott & S. Erickson (Eds.), *Patient safety achieving a new standard of care.* (pp. 226-246). Washington, D.C.: National Academy Press.

Institute of Medicine. (2010). The future of nursing: leading change, advancing health. Retrieved July 21, 2013 from: http://www.iom.edu/Reports/2010/The-Future-of-Nursing-Leading-Change-Advancing-Health.aspx

Jordan, L., Kremer, M., Crawforth, K., & Shott, S. (2001). Data-driven practice improvement: The AANA Foundation closed malpractice claims study. *AANA Journal*, 69, p.301-311.

Kendall-Gallagher, D., Aiken, L., Sloane, D., Cimiotti, J. (2011). Nurse specialty certification, inpatient mortality, and failure to rescue. *Journal of Nursing Scholarship*, 43, 188-194.

Kerlinger, F. & Lee, H. (2000). *Foundations of Behavioral Research, 4th Edition*: Belmont, California: Cengage Learning.

Kirsner, K. & Biddle, C. (2012). Production pressure and a culture of deviance in the insular operating room and the consequences of their “normalization”: Have we reached a Hooper moment? *The Internet Journal of Law, Healthcare and Ethics*, 8, 1.

Kutney-Lee, A., Sloane, D., & Aiken, L. (2013). An increase in the number of nurses with baccalaureate degrees is linked to lower rates of post-surgery mortality. *Health Affairs*, 32, 3, 579-586.

Lacey, S., Cox, K., Lorfing, K., Teasley, S., Carroll, C. & Sexton, K. (2007). Nursing support, workload, and intent to stay at magnet, magnet-aspiring, and non-magnet hospitals. *Journal of Nursing Administration*, 37, 199-205.

Leape, L. (2009). New world of patient safety: 23rd Annual Samuel Jason Mixter lecture. *Archives in Surgery*, 144(5), 394-398.

Leedal, J. & Smith, A. (2005). Methodological approaches to anesthetists' workload in the operating theatre. British Journal of Anesthesia, 94,702-709.

Limper A. (2011). Overview of pneumonia, Chapter 97. In: Goldman L, Schafer AI, eds. *Goldman's Cecil Medicine.* 24th ed. Philadelphia, PA: Elsevier Saunders.

MacRae, M. (2007). Closed claim studies in anesthesia: a literature review and implications for practice. *AANA Journal*, 75, 4, 267-275.

Mardon, R., Khanna, K., Sorra, J., Dyer, N., & Famolaro, T. (2010). Exploring relationships between hospital patient safety culture and adverse events. Journal of Patient Safety, 6, 226-232.

Mearns, K., Flin, R., Gordon, R., & Fleming, M. (2001). Human and organizational factors in offshore safety. *Work and Stress, 15,* 144-160.

Metzner, J., Posner, K., & Domino, K. (2009). The risk and safety of anesthesia at remote locations: the US closed claims analysis. Current Opinions in Anesthesiology, 22, 502-508.

Metzner, J., Posner, K., Lam, M., & Domino, K. (2011). Closed claims' analysis. *Best Practice and Research Clinical Anesthesiology*, 25, 263-276.

Morris, R., MacNeela, P., Scott, A., Treacy, P., Hyde, A. (2007). Reconsidering the conceptualization of nursing workload: literature review. *Journal of Advanced Nursing*, 57, 463-471.

Nunnally, J. (1978). *Psychometric theory, 2nd Edition* .New York: McGraw-Hill.

Petty, Reason, Sanchez, J. (2012). Patient safety. *Surgical Clinics of North America*, *92,* xvii- xix.

Pine, M., Holt, K., & Lou, Y. (2003). Surgical mortality and type of anesthesia provider. *AANA Journal,* 70, 193-202.

Polit, D & Beck, C. (2011). *Essentials of Nursing Research: appraising evidence for nursing practice, 7th Edition.* Philadelphia: Wolters Kluwer Lippincott Williams & Wilkins.

Posner, K. (2001). Closed Claims Project shows safety evolution. *Anesthesia Patient Safety Foundation Newsletter, 16*, p.1-3.

Reason, J., Carthey, J, & de Leval, M. (2001). Diagnosing "vulnerable system syndrome": an essential prerequisite to effective risk management. *Quality in Healthcare*, 10, Supp 2, ii21-ii25.

Rubio, S., Díaz, E., Martín, J., Puente, JM. (2004). Evaluation of Subjective Mental Workload: A Comparison of SWAT, NASA-TLX, and Workload Profile Methods. *Applied Psychology: an International Review*, 53, 61–86.

Sammer, C., Lykens, K., Singh, K., Mains, D., Lackan, N. (2010). What is patient safety culture? A review of the literature. *Journal of Nursing Scholarship*, 42, 156-165.

Schubert, M., Glass, T.R., Clarke, S.P., Aiken, L.H., Schaffert-Witvliet, B., & DeGeest, S. (2008). Rationing of nursing care and its relationship to patient outcomes: the Swiss extension of the International Hospital Outcomes Study. International Journal for Quality in Health Care, 20(4), 227-237.

Sorra, J. & Dyer, N. (2010). Multilevel psychometric properties of the AHRQ hospital survey on patient safety culture. *BMC Health Services Research*, 10:199.

Tabachnik, B. & Fidell, L. (2006). *Using Multivariate Statistics, 5th Edition.* Philadelphia:Pearson.

Thomas-Hawkins, C. & Flynn, L. (2013a). Patient safety culture and nurse-reported adverse patient events in outpatient hemodialysis facilities [Abstract]. *Nephrology Nursing Journal, 40(2),* 170.

Thomas-Hawkins, C. & Flynn, L. (2013b). RN staffing and workload, dialysis work environment, processes of nursing care, and patient safety culture in outpatient hemodialysis facilities [Abstract]. *Nephrology Nursing Journal, 40(2),* 170.

Thomas-Hawkins, C., Flynn, L., & Clarke, S. (2008). Relationships between registered nurse staffing, processes of care, and nurse-reported patient outcomes in chronic hemodialysis units. *Nephrology Nursing Journal*, 35, 123-145.

Twigg, D., Duffield, C., Bremner, A., Rapley, P., & Finn J. (2011). The impact of the nursing hours per patient day (NHPPD) staffing method on patient outcomes: a retrospective analysis of patient and staffing data. *International Journal of Nursing Studies*, 48, 540-548.

Valentin, A., Schiffinger, M, Steyrer, J., Huber, C., & Strunk, G. (2013). Safety climate reduces medication and dislodgement errors in routine intensive care practice. *Intensive Care Medicine*, 39, 391-398.

Weinger, M., Herndon, O., Zornow, M., Paulus, M., Gaba, D., & Dallen, L. (1994). An objective methodology for task analysis and workload assessment in anesthesia providers. *Anesthesiology*, 80, 77-92.

Weinger, M., Reddy, S., Slagle,J. (2004). Multiple measures of anesthesia workload during teaching and nonteaching cases. *Anesthesia and Analgesia*, 98, 1419-1425.

Wiltse-Nicely, K., Sloane, D., & Aiken, L. (2013). Lower mortality for abdominal aortic aneurysm repair in high-volume hospitals is contingent upon nurse staffing. *Health Services Research*, 48,3, 972-991.

Young, G., Zavelina, L., Hooper, V. (2008). Assessment of workload using NASA-Task Load Index in perianesthesia nursing. *Journal of Perianesthesia Nursing*, 23, 102-110.

Zohar, D. (2000). A group-level model of safety climate: Testing the effect of group climate on microaccidents in manufacturing jobs. *Journal of Applied Psychology,* 85, 587-596.

Appendix A Rutgers IRB

RUTGERS UNIVERSITY
Office of Research and Sponsored Programs
ASB III, 3 Rutgers Plaza, Cook Campus
New Brunswick, NJ 08901

September 30, 2013

P.I. Name: McMullan
Protocol #: 14-049M

Susan P McMullan
180 University Ave
Newark NJ 07102

Dear Susan McMullan: ✓

(Initial / Amendment / Continuation / Continuation w/ Amendment)

Protocol Title: "Organizational Structure and Work Environment Predictors of Adverse Events as Reported by Nurse Anesthetists"

This is to advise you that the above-referenced study has been presented to the Institutional Review Board for the Protection of Human Subjects in Research, and the following action was taken subject to the conditions and explanations provided below:

Approval Date:	8/22/2013	**Expiration Date:**	8/21/2014
Expedited Category(s):	7	**Approved # of Subject(s):**	250

This approval is based on the assumption that the materials you submitted to the Office of Research and Sponsored Programs (ORSP) contain a complete and accurate description of the ways in which human subjects are involved in your research. The following conditions apply:

- **This Approval-**The research will be conducted according to the most recent version of the protocol that was submitted. **This approval is valid ONLY for the dates listed above;**
- **Reporting-**ORSP must be immediately informed of any injuries to subjects that occur and/or problems that arise, in the course of your research;
- **Modifications-**Any proposed changes MUST be submitted to the IRB as an amendment for review and approval prior to implementation;
- **Consent Form(s)-**Each person who signs a consent document will be given a copy of that document, if you are using such documents in your research. The Principal Investigator must retain all signed documents for at least three years after the conclusion of the research;
- **Continuing Review-**You should receive a courtesy e-mail renewal notice for a Request for Continuing Review before the expiration of this project's approval. However, it is your responsibility to ensure that an application for continuing review has been submitted to the IRB for review and approval prior to the expiration date to extend the approval period;

Additional Notes: **Expedited Approval per 45 CFR 46.110**

Failure to comply with these conditions will result in withdrawal of this approval.
Please note that the IRB has the authority to observe, or have a third party observe, the consent process or the research itself. The Federal-wide Assurance (FWA) number for the Rutgers University IRB is FWA00003913; this number may be requested on funding applications or by collaborators.

Respectfully yours,
Margaret Cooper
Acting For--
Dr. Beverly Tepper, Ph.D.
Professor
Chair, Rutgers University Institutional Review Board

cc: Dr. Charlotte Thomas-Hawkins

Appendix B Cover Letter of Informed Consent

Rutgers, The State University of New Jersey
180 University Avenue
Newark, NJ 07102-1897
973-353-5293

Dear Fellow CRNAs:

You are one of 500 subjects invited to participate in a research study that is being conducted by Susan McMullan, a doctoral candidate in the College of Nursing at Rutgers University in Newark. The purpose of this research is to examine relationships among CRNA organizational structures (practice models, work setting, workload, level of education, work experience) and CRNA ratings of patient safety culture, and CRNA-reported adverse anesthesia-related events in patients receiving anesthesia administered by CRNAs.

While you will not experience any direct benefits from participation, information collected in this study may benefit the profession of anesthesia through better understanding of how organizational factors affect CRNA's ability to provide high quality, and safe patient care.

Participation in this study is voluntary. You may choose not to participate. You may withdraw at any time during the study without penalty. The survey should take less than 15 minutes to complete.

This research is confidential. Any contact information that is obtained about you will not be used as part of the research data. That is, no information will be recorded about you that could identify you in the study. The research team and the Institutional review Board of Rutgers University are the only parties that will be allowed to see the data, except as may be required by law. The results of the study may be published, or presented at a professional conference. Findings from the study will only be reported in the aggregate, that is, only group results will be reported; your name will not be disclosed. All study data will be maintained in a secure location for a minimum of three years.

If you have any questions concerning the research study or about being a participant, you may contact me at
(708) 415-2544 or email: spmcrna@pegasus.rutgers.edu, or contact the Rutgers College of Nursing, 180 University Avenue, Newark, NJ 07102

For questions about your rights as a research subject, you may contact the Institutional Review Board for the Protection of Human Subjects at Rutgers University (a committee that reviews research to protect those who participate) at:

Rutgers, The State University of New Jersey
Institutional Review Board for the Protection of Human Subjects
Office of Research and Sponsored Programs
3 Rutgers Plaza, New Brunswick, NJ 08901-8559
Tel: 848-932-4058
Email: humansubjects@orsp.rutgers.edu

Returning the completed survey in the postage pre-paid envelope implies your consent (agreement) to be a study subject. **DO NOT write your name on any of the study materials.**

Your participation is appreciated. You may keep a copy of this assent form for your records.

This informed consent form was approved by the Rutgers University Institutional Review Board for the Protection of Human Subjects on 8/22/13; approval of this form expires on 08/21/14.

Appendix C Survey Tool

Section 1: Participant Demographic Information

1a.	**Age (years)**	☐	
1b.	**Gender**	**Male** ☐	**Female** ☐
1c.	**Years employed as a CRNA**	☐	
1d.	**Race**	**White / Caucasian**	☐
		African American	☐
		Hispanic / Latino	☐
		Asian	☐
		Native American	☐
		Other Pacific Islander	☐
1e.	**Employment Status**	**Full-time** ☐	**Part-time** ☐
1f.	**Highest level of education completed.**	**Certificate/Diploma**	☐
		Bachelors Degree	☐
		Masters Degree	☐
		Clinical Doctorate	☐
		Research Doctorate	☐

1g. Anesthesia Practice Model

- **Anesthesia care team** ☐

  Supervised ☐

  Medically directed ☐

OR

- **Independent practice** ☐

1h. Work Setting

Hospital	Ambulatory Surgical Center
☐	☐

If work setting is a hospital, please complete the following:

1i.

• **Hospital Type**	**Teaching**	**Non-teaching**	
	☐	☐	
• **Hospital Size**	**<100 beds**	**100-250 beds**	**>250 beds**
	☐	☐	☐
• **Hospital Magnet Status**	**Magnet**	**Non-Magnet**	
	☐	☐	

1j. How many anesthetics do you provide in a typical two week period? (Please fill in the number below).

____

1k. Work Setting - % Time in Work Locations

(please make total % adds up to 100 %)

% time in Main OR	% time Off-site

If work is performed in Off-site locations, please complete the following with respect to Off-site work.

1l. Work Setting - % Time in Off-site work locations	**% time in Location**
o **GI**	
o **Radiology**	
o **Cardiac Cath.Lab**	
o **MRI**	
o **Other location in hospital**	

(please make sure total % adds up to 100 % of the off-site time listed in 1k.)

Section 2: CRNA Reported Anesthesia-related Adverse Patient Events

Please report the number of **occurrences** you have experienced in the last 12 Months using the check boxes below.

Use the following definitions to select your answer:

Difficult intubation: more than two attempts at laryngoscopy using direct laryngoscopy, glidescope or fiberoptic bronchoscope

Difficult extubation: desaturation following extubation requiring more than routine airway management in the PACU, and/or reintubation

Inadequate ventilation: inadequate or inability to mask ventilate patient without assistance of another clinician, including use of an oropharyngeal /nasopharyngeal airway or placement of a laryngeal mask airway (LMA) in order to ventilate

Inadequate oxygenation: oxygen saturations less than 95% despite routine airway management

Pulmonary aspiration of gastric contents: actual witnessing of gastric contents in endotracheal tube, LMA or face mask at any time during an anesthetic, and/or postoperative chest xray indicating aspiration.

	Type of Adverse Event	Number of Occurrences experienced in the last 12 Months					
		None	1-2	3-5	6-10	11-20	21 or more
1.	Difficult Intubation	☐1	☐2	☐3	☐4	☐5	☐6
2.	Difficult extubation	☐1	☐2	☐3	☐4	☐5	☐6
3.	Inadequate ventilation	☐1	☐2	☐3	☐4	☐5	☐6
4.	Inadequate oxygenation	☐1	☐2	☐3	☐4	☐5	☐6
5.	Pulmonary aspiration of gastric contents	☐1	☐2	☐3	☐4	☐5	☐6

Section 3: Overall Perceptions of Patient Safety

Please indicate your level of agreement with the statements regarding patient safety at your work area / unit.

		Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
1.	Patient safety is never sacrificed to get more work done.	☐1	☐2	☐3	☐4	☐5
2.	Our procedures and systems are good at preventing errors from happening	☐1	☐2	☐3	☐4	☐5
3.	It is just by chance that more serious mistakes don't happen around here.	☐5	☐4	☐3	☐2	☐1
4.	We have patient safety problems in this unit.	☐5	☐4	☐3	☐2	☐1

Section 4: Patient Safety Grade

Please give your work area / unit at your facility an overall grade on patient safety.

☐	☐	☐	☐	☐
A	**B**	**C**	**D**	**E**
Excellent	**Very Good**	**Acceptable**	**Poor**	**Failing**

Section 5: Workload

The following questions deal with the workload that you experience in your job. Please put an 'X' on each of the following six scales at the point that matches your overall experience of workload.

1.	**Mental Demand.** How much mental activity is required to perform your job (e.g., thinking, deciding, calculating, remembering, looking, searching, etc.)?	Low — High
2.	**Physical Demand.** How much physical activity is required to perform your job (e.g., pushing, pulling, turning, controlling, activating, etc.)?	Low — High
3.	**Temporal Demand.** How much time pressure do you feel due to the rate or pace at which the tasks or task elements occurred?	Low — High
4.	**Effort.** How hard do you have to work (mentally and physically) to accomplish your level of performance?	Low — High
5.	**Performance.** How satisfied are you with your performance at your job?	Low — High
6.	**Frustration level.** How insecure, discouraged, irritated, stressed and annoyed versus secure, gratified, content, relaxed and complacent do you feel about your job?	Low — High

Think about your typical daily workload over the past six months and answer the following questions.

		Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
1.	I am able to take at least a 30 minute meal break during my shift.	☐1	☐2	☐3	☐4	☐5
2.	Individual assignments are fairly distributed within the unit given the available resources.	☐1	☐2	☐3	☐4	☐5
3.	Most days I feel my workload is reasonable,	☐1	☐2	☐3	☐4	☐5
4.	My current workload will cause me to look for a new position.	☐5	☐4	☐3	☐2	☐1
5.	I have voiced concerns about my workload being too heavy to the manager.	☐5	☐4	☐3	☐2	☐1
6.	My current work environment makes me want to stay and work here.	☐1	☐2	☐3	☐4	☐5

Curriculum Vitae

Susan Parry McMullan PhDc, MSN, APN, CRNA

October 13, 1962
Smyrna, Tennessee

Education

Doctorate, PhD Candidate, currently part-time doctoral student at Rutgers College of Nursing

Certified Registered Nurse Anesthetist (CRNA) 1988
American Association of Nurse Anesthetists

Masters, Anesthesia Nurse Practitioner Program 1988
Rush University College of Nursing

Bachelors, Nursing, 1984
University of Michigan School of Nursing

Experience

2012-Present	Staff CRNA, Ann and Robert H. Lurie Children's Hospital of Chicago
2009-2012	Staff CRNA, Continental Anesthesia, Chicago, Illinois
2010-2011	Interim Program Director/Program Director, and
2009-2010	Assistant Program Director, Nurse Anesthesia, Rosalind Franklin University, North Chicago, Illinois
2004-2009	Chief CRNA, Hinsdale Anesthesia Associates, Hinsdale, Illinois
1992-2004	Staff CRNA, Hinsdale Anesthesia Associates, Hinsdale, Illinois
1988-1992	Staff CRNA, Rush University Medical Center, Chicago, Illinois

Professional Activities

2012- Present	CRNA Representative to the Illinois Society for Advanced Practice Nurses
2007-2009	Region 2 Director, Illinois Association of Nurse Anesthetists Board