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Factors Influencing Pediatric Sedation Safety

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CHAPTER ONE

Factors Influencing Pediatric Sedation Safety

Abstract

Every year, thousands of children require sedation for diagnostic and interventional procedures. Despite regulations by accreditors and guidelines by professional organizations, adverse sedation events and variations in how sedation care is delivered continue to occur. Differences in sedation care may be related to the type of specialist providing sedation, their scope of sedation practice, and methods used to induce sedation. Sedation is performed by a variety of health care providers including registered nurses (RNs), but there are limited data on current regulations governing RN sedation, descriptions of RN sedation practice, or comparisons of outcomes of sedation by different types of providers. This study presents a review of sedation standards shaping RN practice and exemplars of state Boards of Nursing sedation regulations in the United States. The Pediatric Sedation Research Consortium (PSRC) database was used to learn more about RN sedation practices in diagnostic radiology; findings revealed that RNs often plan to achieve deep levels of sedation and administer combinations of two or more sedative medications for diagnostic procedures. Outcomes of sedation for cases where RNs monitored and delivered sedation alone were compared to outcomes of RN and physician teams and physicians working alone to deliver sedation. Cases in which RNs alone provided sedation had similar American Society of Anesthesiologists risk scores compared to cases with physicians alone and RN and physician sedation teams. Findings revealed that cases in which RNs alone or physicians alone monitored and delivered sedation had lower odds of experiencing adverse events than when sedation was administered by RN and physician teams. This study revealed inconsistencies in state Board of Nursing regulations and in RN sedation care standards in the U.S. Data from this

study could be used to improve RN sedation care processes, and guide the development of consistent nursing sedation licensing regulations, hospital standards, and policies.

Factors Influencing Pediatric Sedation Safety

Annually, thousands of children are sedated by registered nurses (RNs) for diagnostic and interventional procedures (Couloures, Beach, Cravero, Monroe, & Hertzog, 2011). However, there is a lack of clinical outcomes research in the specialty area of pediatric sedation in general and particularly on RN administered sedation. Sedation is a "technique of administering sedatives or dissociative agents with or without analgesics to induce an altered state of consciousness that allows the patient to tolerate unpleasant procedures while preserving cardiorespiratory function" (Godwin et al., 2005, p. 178). Compared to adults, children require sedation more frequently and are sedated more deeply because their cognitive and developmental level limits their ability to cooperate during diagnostic and interventional procedures (Cravero et al., 2006). Children are also at a higher risk than adults of developing airway complications due to anatomical differences and the need to maintain a higher respiratory rate (Coté & Wilson, 2006). Components of adequate sedation, including deep sedation, necessary to minimize the pain and distress associated with medical procedures, have been evaluated by the American Academy of Pediatrics, and are included in the current standard of care for the management of acute pain in infants, children, and adolescents (American Academy of Pediatrics Committee on Psychosocial Aspects of, Family, Task Force on Pain in Infants, & Adolescents, 2001).

Demand for Sedation Care

The demand for sedation services has exceeded the supply of anesthesiologists available to provide such services for many procedures (Havidich & Cravero, 2012; Wachtel, Dexter, & Dow, 2009). Thus, non-anesthesiologists, that is, those who are not anesthesiologists or certified registered nurse anesthetists, often provide sedation. Sedation practice has moved beyond the

operating room setting to a complex system of care provided in a variety of locations by multiple specialists for procedures ranging from endoscopy to pediatric dentistry (Cravero et al., 2006).

Many types of non-anesthesiologists, including RNs, routinely administer sedation to patients. However, non-anesthesiologist sedation providers have varying knowledge, training, and skills in pediatric sedation, often developing competency outside their formal basic and advanced professional education. The rapid growth in sedation services combined with few regulatory standards has led to several pediatric deaths from avoidable sedation complications (Coté, Notterman, Karl, Weinberg, & McCloskey, 2000). The deaths of several sedated children in a single dental office focused national attention on the dangers of sedation by inexperienced providers and unsafe practices such as inadequate patient monitoring, administration of sedative medications by unqualified providers such as parents, and a lack of familiarity with the basic skills and equipment to perform resuscitation if necessary (Coté et al., 2000).

Pediatric Sedation Safety

The Joint Commission, formerly the Joint Commission on Accreditation of Hospitals, and the American Academy of Pediatrics developed the current minimum safety standards for patient monitoring and sedation provider competency; as a result there has been a decrease in the number of serious adverse sedation events in some health care settings (Hoffman, Nowakowski, Troshynski, Berens, & Weisman, 2002; Pitetti et al., 2006). Even so, adverse event rates in sedated children range from 0.4% to 20.1% in the U.S., and include cases of desaturation, inadequate sedation, and respiratory depression requiring bag valve mask ventilation (Bluemke & Breiter, 2000; Shah et al., 2011). One multi-site study reported an overall adverse event rate of 5.3% in 30,037 pediatric sedation cases by physician anesthesiologist and non-anesthesiologist sedation providers performing a variety of procedures (Cravero et al., 2006). The rate of sedation

adverse events when RNs provide sedation is unknown, due to small sample sizes and few RNs participating in reported studies. Limitations of most investigations regarding pediatric sedation include frequent use of single site samples, reporting on only one type of procedure, and using sample sizes that are underpowered to detect sedation adverse events that are estimated to occur once in many thousands of cases (Cravero et al., 2006).

RN Sedation Practice

Many studies of RN sedation practice have examined a particular aspect of sedation care, such as determining differences in outcomes of sedation using different sedative medication regimens or the number of failed sedations; these outcomes are not compared to other sedation provider outcomes (Heistein et al., 2006). As a result, these studies provide limited information on the safety of RN administered procedural sedation, the factors that increase the likelihood of adverse sedation events, and the differences in sedation administered by RNs compared to other sedation providers. The lack of data on RN sedation practice and safety hinders the development of evidence-based regulations (National Council of State Boards of Nursing, 2007).

Although minimum competency standards for all sedation providers exist, there is disagreement among professional organizations and state Boards of Nursing regarding the appropriate scope of practice for RNs providing sedation. Restrictions on sedation practice and conflicting standards by professional organizations such as the American Nurses Association and the American Association of Nurse Anesthetists may cause variations in how sedation is practiced by RNs depending on the state and specialty in which they practice (American Association of Nurse Anesthetists, 2004; American Nurses Association, 2008). No data are available regarding sedation safety when different regulatory strategies are used to regulate RN sedation practice.

Improving RN Sedation Practice

The purpose of this dissertation was to examine pediatric RN sedation regulation, practice, and outcomes to inform regulation and potentially impact pediatric sedation safety in the United States. This dissertation presents a proposal for the research exploring how RN pediatric sedation outcomes compared to other non-anesthesia sedation providers using secondary data from the Pediatric Sedation Research Consortium (PSRC) database for diagnostic radiology procedures. However, in order to fully understand sedation safety and outcomes, factors influencing the sedation care delivery system such as the regulations governing RN sedation and the practices that RNs use to deliver sedation care must also be understood. There are three manuscripts presenting a different aspect of sedation by RNs: (1) regulation of RN sedation practice, (2) a description of RN sedation practices and (3) outcomes of RN sedation compared to other non-anesthesiologist providers.

RN Sedation Standards and Guidelines

There are many standards and guidelines that have been developed to guide sedation care practices by subspecialty groups such as anesthesiologists and pediatricians (Cravero et al., 2006). Most of these standards and guidelines were developed via the consensus method using literature reviews, weighing the level of evidence from published studies on sedation, and the expert opinion of physicians in the subspecialty group; by and large they specifically address physician sedation providers (Coté & Wilson, 2006). Several RN subspecialty organizations have adopted sedation position statements limiting RN practices such as the administration of anesthetic agents, while others have endorsed the administration of anesthetic agents for sedation by RNs not otherwise credentialed to deliver anesthesia (American Association of Nurse Anesthetists, 2004; American Nurses Association, 2008). Therefore, there are currently several

conflicting standards of RN sedation practice. However, RN practice is regulated at the state level through each state's respective Board of Nursing (Guido, 2010).

Regulation of RN Sedation Practice

The first manuscript, *Procedural Sedation in the United States: A Review of Nursing Regulations,* prepared for submission to the Journal of Nursing Regulation (Appendix 1), describes the current regulatory environment of RN sedation practice in the U.S. by using one exemplar of Board of Nursing sedation regulation from each region of the U.S. Exemplars were used to demonstrate the variation in RN sedation regulation depending on the state. Sedation regulations may influence how RNs provide sedation care, for example the medications they administer to induce sedation and the required skills necessary for RNs to manage sedation, such as Advanced Cardiac Life Support (ACLS) training. In order to develop effective regulations, there must be evidence that supports or dismisses the practices used by RNs to sedate patients. However, there is a paucity of evidence from large multi-site samples on current sedation practices used by RNs.

The PSRC database, a research collaborative that collects data from 35 member institutions on pediatric sedation using a standard web based data collection tool, was used to investigate the current practices of RNs monitoring and delivering sedation to children in diagnostic radiology (Langhan, Mallory, Hertzog, Lowrie, & Cravero, 2012). There were several reasons that this sample was chosen to explore this topic. First, diagnostic, not interventional procedures were chosen to reduce the introduction of variables other than sedation, such as the effect of analgesics and the procedural intervention that would make results more difficult to interpret. Second, interventional procedures include a provider performing the intervention, which is likely to be a physician or advanced practice provider, so it is more likely that an RN

and physician team not an RN alone would provide sedation services. Last, the type of diagnostic radiology procedure performed requires different levels of sedation (moderate or deep) and different types of medication or monitoring strategies to complete the procedure and that may also affect the types of adverse events RNs must manage. The second manuscript, *Pediatric Sedation: A Descriptive Study of Registered Nurse Practice in Radiology,* prepared for submission to Pediatric Nursing (Appendix 2), is the first study to use the PSRC database to report sedation practices and adverse events when RNs provide sedation in diagnostic radiology.

Description of RN Sedation Practice

Only cases in which RNs monitored and delivered sedation were included in this study. Comparison data from prior studies of physician sedation practice using the PSRC database were provided to underscore the similarities and differences in sedation care practices by different providers (Cravero et al., 2006; Langhan et al., 2012). Data on RN sedation practices are important to obtain, such as the frequency with which RNs are providing deep sedation, the types of medications they are administering, and the types of adverse events their patients are experiencing. These data can be used to consider whether or not the current sedation safety standards are being met by RNs, such as the acuity of the patients they sedate or the monitoring equipment they use during sedation. However, descriptions of RN practice are insufficient to determine whether these practices translate to increased or decreased sedation safety. Outcomes of RN sedation must be compared to the outcomes of other sedation providers to determine how safe RN sedation practice is; this comparison is done in the third manuscript, *Registered Nurse and Physician Procedural Sedation Practices and Adverse Events in Pediatric Diagnostic Radiology,* prepared for submission to Pediatrics (Appendix 3).

Outcomes of RN Sedation

The purpose of the third manuscript included herein was to understand differences in adverse events related to the type of sedation provider delivering and monitoring sedation: RN alone; non-anesthesiologist physicians only; or RN and non-anesthesiologist physician teams in the pediatric diagnostic radiology setting. The study aims were:

1. To describe the influence of types of sedation providers on safety and the type of adverse events in children when the influence of patient risk factors, radiologic procedure type, and sedation care processes are considered.
2. To determine the influence of patient risk factors radiologic procedure type, sedation care processes and types of sedation providers on inadequate and prolonged sedation in children.

Logistic regression models were used to compare outcomes of RN sedation adverse events and four specific types of adverse sedation events (neurologic, respiratory, other, and emergent). The findings from this study may be used to identify patient or procedural characteristics that could increase the likelihood of an adverse sedation event. In addition, findings of this study may provide evidence that supports, expands, or questions some of the current methods used to regulate RN sedation practice. Results of this study are not generalizable because it only considers diagnostic radiologic procedures and only includes pediatric patients. However, the study can provide a framework for other researchers to use the PSRC database to obtain more evidence about other types of RN sedation providers, such as advanced practice nurses, and about outcomes of interventional and other types of procedures.

Need for Sedation Research

This dissertation provides data on regulations, practices, and outcomes of sedation by RNs. The complex nature of sedation care delivery in the U.S. has made it difficult to study and

has led to many gaps in research in this area. However, as the need for sedation continues to increase, the availability of more sedative medications grows, more diagnostic tests become available, care continues to expand to the out-patient setting, changes in reimbursement occur and care delivery in the U.S. changes through the Affordable Care Act, there will be an ongoing need for research in this area.

References

American Academy of Pediatrics. Committee on Psychosocial Aspects of Child Family Health Task Force on Pain in Infants, Children, & Adolescents. (2001). The assessment and management of acute pain in infants, children, and adolescents. *Pediatrics, 108*(3), 793-797.

American Association of Nurse Anesthetists. (2004). AANA-ASA Joint Position Statement Regarding Propofol Administration. Retrieved June 29, 2012, from http://www.aana.com/resources2/professionalpractice/Pages/AANA-Position-Statements,-Advisory-Opinions,-and-Considerations.aspx

American Nurses Association. (2008). Procedural Sedation Consensus Statement. Retrieved June 28, 2012, from http://www.nursingworld.org/MainMenuCategories/Policy-Advocacy/Positions-and-Resolutions/ANAPositionStatements/Position-Statements-Alphabetically/Procedural-Sedation-Consensus-Statement.html

Bluemke, D. A., & Breiter, S. N. (2000). Sedation procedures in MR imaging: safety, effectiveness, and nursing effect on examinations. *Radiology, 216*(3), 645-652.

Coté, C., Notterman, D. A., Karl, H. W., Weinberg, J. A., & McCloskey, C. (2000). Adverse sedation events in pediatrics: a critical incident analysis of contributing factors. *Pediatrics 105*(4 part 1), 805-814.

Coté, C. J., & Wilson, S. (2006). Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures: An update. *Pediatrics, 118*(6), 2587-2602. doi: 10.1542/peds.2006-2780

Couloures, K. G., Beach, M., Cravero, J. P., Monroe, K. K., & Hertzog, J. H. (2011). Impact of provider specialty on pediatric procedural sedation complication rates. *Pediatrics, 127*(5), e1154-1160. doi: 10.1542/peds.2010-2960

Cravero, J. P., Blike, G. T., Beach, M., Gallagher, S. M., Hertzog, J. H., Havidich, J. E., & Gelman, B. (2006). Incidence and nature of adverse events during pediatric sedation/anesthesia for procedures outside the operating room: report from the Pediatric Sedation Research Consortium. *Pediatrics, 118*(3), 1087-1096. doi: 10.1542/peds.2006-0313

Godwin, S. A., Caro, D. A., Wolf, S. J., Jagoda, A. S., Charles, R., Marett, B. E., . . . American College of Emergency, P. (2005). Clinical policy: procedural sedation and analgesia in the emergency department. *Annals of Emergency Medicine, 45*(2), 177-196. doi: 10.1016/j.annemergmed.2004.11.002

Guido, G. W. (2010). *Legal and Ethical Issues in Nursing* (Fifth ed.). Upper Saddle River, NJ: Pearson Health Science.

Havidich, J. E., & Cravero, J. P. (2012). The current status of procedural sedation for pediatric patients in out-of-operating room locations. *Current Opinion in Anaesthesiology, 25*(4), 453-460. doi: 10.1097/ACO.0b013e32835562d8

Heistein, L. C., Ramaciotti, C., Scott, W. A., Coursey, M., Sheeran, P. W., & Lemler, M. S. (2006). Chloral hydrate sedation for pediatric echocardiography: physiologic responses, adverse events, and risk factors. *Pediatrics, 117*(3), e434-441.

Hoffman, G. M., Nowakowski, R., Troshynski, T. J., Berens, R. J., & Weisman, S. J. (2002). Risk reduction in pediatric procedural sedation by application of an American Academy

of Pediatrics/American Society of Anesthesiologists process model. *Pediatrics, 109*(2 part 1), 236-243.

Langhan, M. L., Mallory, M., Hertzog, J., Lowrie, L., & Cravero, J. (2012). Physiologic monitoring practices during pediatric procedural sedation: a report from the Pediatric Sedation Research Consortium. *Archives of Pediatrics & Adolescent Medicine, 166*(11), 990-998. doi: 10.1001/archpediatrics.2012.1023

National Council of State Boards of Nursing. (2007). Guiding principles of nursing regulation. Retrieved June 29, 2012, from https://www.ncsbn.org/1325.htm

Pitetti, R., Davis, P. J., Redlinger, R., White, J., Wiener, E., & Calhoun, K. H. (2006). Effect on hospital-wide sedation practices after implementation of the 2001 JCAHO procedural sedation and analgesia guidelines. . *Archives of Pediatric and Adolescent Medicine, 160*(2), 211-216.

Shah, A., Mosdossy, G., McLeod, S., Lehnhardt, K., Peddle, M., & Rieder, M. (2011). A blinded, randomized controlled trial to evaluate ketamine/propofol versus ketamine alone for procedural sedation in children. *Annals of Emergency Medicine, 57*(5), 425-433 e422. doi: 10.1016/j.annemergmed.2010.08.032

Wachtel, R. E., Dexter, F., & Dow, A. J. (2009). Growth rates in pediatric diagnostic imaging and sedation. *Anesthesia and Analgesia, 108*(5), 1616-1621. doi: 10.1213/ane.0b013e3181981f96

CHAPTER TWO

Research Proposal

Specific Aims

Children are sedated for diagnostic procedures, such as magnetic resonance imaging (MRI), due to developmental factors, which can result in uncooperative behavior that decreases exam quality. Non-interventional diagnostic radiologic procedures, such as MRI alone, pose little risk to the patient. Use of sedation during these exams increases the risk of sedation-related complications. The rates of sedation-related adverse events in children, including desaturation and decreased blood pressure, range from 0.4% to 20.1% in the United States (Malviya, Voepel-Lewis, & Tait, 1997; Sanborn et al., 2005). The number of children requiring sedation is growing, increasing the need for nurses (RNs) to provide this service (Barbi et al., 2003; Lininger, 2004). Yet, differences in frequency and types of sedation-related adverse events when sedation is provided by an RN or physician (MD) are unknown. Pediatric sedation-related complications, based on multi-center data from 30,037 records in a sample of MD-provided sedation, found 339.6 per 10,000 total sedation adverse events and 111.9 per 10,000 unplanned treatments (Blike et al., 2006). MDs in this study were from various specialties, such as pediatrics and radiology, and had varying sedation experience, but whether this was significant was not examined. The role the RN had in sedations was not described, although RNs often sedate children alone or with an MD.

Accreditors such as the Joint Commission (TJC), formerly the Joint Commission on Accreditation of Hospitals, requires evidence of sedation provider competence, but does not specify how competence is established (Patterson, 2002; Pitetti et al., 2006). As a result, RNs (excluding Certified Registered Nurse Anesthetists [CRNA]) and MDs (excluding

anesthesiologists) with varying training in sedation often provide sedation care (American Society of Anesthesia House of Delegates, 2005). RN-provided sedation includes assessment of risk, administration of sedatives, monitoring (vital signs and level of consciousness throughout and after sedation), and intervention if an adverse event occurs (American Association of Nurse Anesthetists, 2010). RN sedation practices, competencies, and training vary, and the safety of RN-provided sedation compared to other non-anesthesiology providers (radiologists, pediatricians, emergency medicine, intensivists, fellows, house staff, and surgeons) is unknown (Agrawal, Feldman, Krauss, & Waltzman, 2004; Mace et al., 2004).

The purpose of this study was to understand sedation care processes of RNs providing and monitoring sedation and to examine the relationship of their practices to safety (occurrence of unexpected adverse events), compared to MD practices and sedation safety. The Systems Engineering Initiative for Patient Safety (SEIPS) model was used as the framework for this study and is detailed later in this proposal. Study variables were derived from model components, and include work system, care processes, and outcomes (Carayon et al., 2006). The work system comprises elements that interact, such as people (patients/providers), technology and tools, environment, and organization. These elements affect care processes, such as monitoring patients during care delivery that are facilitated by the work system. Model outcomes are quality and patient safety. Data from this study could be used to improve RN sedation care safety, and guide development of consistent sedation standards and policies. A retrospective cross sectional design using secondary data from the Pediatric Sedation Research Consortium (PSRC) was used. The specific aims of this study were to:

1. Describe the influence of type of sedation providers (RN, MD, RN and MD) on safety (the occurrence of any unanticipated adverse events) and category of unanticipated adverse event

(neurologic, respiratory, emergent, other) in children when the influence of patient risk factors (age, weight, anesthesia risk using ASA class, co-existing medical conditions), radiologic procedure type (CT, MRI, Ultrasound) and sedation care processes (medications and monitoring type) are considered.

2. Determine the influence of patient risk factors (age weight, anesthesia risk using ASA class, co-existing medical conditions), radiologic procedure type (CT, MRI, Ultrasound), sedation care processes (medications and monitoring type) and sedation provider type (RN, MD, MD and RN) on inadequate sedation, unexpected bag-valve-mask-ventilation, and prolonged sedation in children.

Background and Significance

In 1985, the American Academy of Pediatrics (AAP) developed guidelines for monitoring children under sedation by non-anesthesiologists (MDs and RNs) in response to a series of pediatric sedation-related deaths in 1983 in a single dental office in California (Coté, 2002). Sedation practices considered safe were derived through the examination of practices that improved anesthesia safety, expert opinion, and consensus of physicians from organizations such as the American Society of Anesthesia (ASA) and the AAP (Hoffman, Nowakowski, Troshynski, Berens, & Weisman, 2002). Application of an ASA guided risk assessment and adherence to AAP guidelines have been shown to decrease adverse outcomes in pediatric procedural sedation (Hoffman et al., 2002; Pitetti et al., 2006). A detailed explanation of the ASA class (an anesthesia risk assessment) was included in this proposal in the section on Incidence and Prevalence of Adverse Events. TJC sedation standards are applied to children in the U.S., although these standards were developed in response to data from adverse events in hospitalized adults (Brennan et al., 1991; Kohn, Corrigan, & Donaldson, 1999; Leape et al.,

1991; Slonim, LaFleur, Ahmed, & Joseph, 2003). Studies of adverse events in pediatric settings have found that the types and rates of errors affecting hospitalized children differ from those reported for adults (Mace et al., 2004; Stucky, American Academy of Pediatrics Committee on Drugs, & American Academy of Pediatrics Committee on Hospital Care, 2003). The most common adverse events in the pediatric population are birth and diagnostic related, rather than surgically preventable adverse events often described in adults. The effect of the implementation of TJC sedation standards on adverse event occurrences in sedated patients has been reported. In a recent study, 7.6% of adult and pediatric patients had an adverse event during sedation after implementation of TJC guidelines for procedural sedation (Pitetti et al., 2006). A change in the incidence of adverse events was measured over a three-year period; the incidence of adverse events was correlated to each month of the study. The strength of the correlation between incidence of adverse event and study month was determined via Pearson correlation. A downward trend in the incidence of adverse events in a sample of 14,386 patients over a three-year period (Pearson product moment correlation, -0.68) was reported indicating that there was a negative correlation between the study month and adverse sedation events. This suggests that a standardized approach to sedation can reduce adverse events (Pitetti et al., 2006). TJC sedation standards implemented on January 1, 2001 guide sedation practice for non-anesthesiology providers (RNs and MDs).

Qualifications of non-anesthesiology sedation providers mandated by TJC sedation standards differ depending on the planned depth of sedation, and require that the provider be competent to rescue the patient from unintentional slips into deeper levels of sedation such as general anesthesia (Patterson, 2002). TJC sedation standards also outline requirements for care processes such as pre-, post-, and inter-procedural monitoring of physiologic parameters (vital

signs and level of sedation) (Patterson, 2002). Several sedation delivery systems such as sedation units, nurse-led programs, programs with nurses overseen by various physician specialties, or anesthetist-led programs have been implemented by hospitals to improve compliance to TJC sedation standards (Catalano, 2002; Lalwani & Michel, 2005; Lowrie, Weiss, & Lacombe, 1998).

Hospital sedation policies differ in the methods used to meet TJC standards, such as determining competence of non-anesthesiology sedation providers, restricting sedative medication use depending on provider (RN or MD), and patient selection criteria (American Association of Nurse Anesthetists, 2010; Bates, Vanderveen, Seger, Yamaga, & Rothschild, 2005; Landrum, 1997). Nevertheless, RNs may be the sole care provider monitoring sedated patients who are receiving medications such as Propofol (an anesthetic) via continuous infusion started by an MD. RNs also may monitor sedated patients while an MD administers and supervises administration of the sedative medication, or RNs may administer and monitor approved sedative agents themselves (Barbi et al., 2003; Bates et al., 2005; Hasan, Shayevitz, & Patel, 2003). Sedation practices such as these remain controversial, but little evidence regarding the safety or risk of these RN practices exist (Clark, Flick, & Litman, 2005; Kingston, 2000; Lalwani & Michel, 2005; Mohr et al., 2003; Simmons, 2005; Zeigler & Brown, 1997).

The lack of evidence related to sedation safety and the increasing utilization of sedation, particularly in the pediatric population, led health care professionals from various pediatric specialties, including anesthesia, gastroenterology, emergency medicine, radiology, and nursing, to form a consortium to examine factors that contribute to sedation-related risk and to develop a system of data collection to encourage research in the area of pediatric sedation. This effort, supported through a National Patient Safety Foundation grant, led to the creation of the Pediatric

Sedation Research Consortium (PSRC) and the PSRC database (Cravero, Blike, Beach, Gallagher, & Weiss, 2005). Several studies using PSRC data have been published, on topics ranging from rates of sedation-related adverse events and adverse events associated with various sedatives such as propofol and etomidate (Beach, Cravero, Blike, & Gelman, 2005; Blike et al., 2006; Cravero, 2009). Although the PSRC database includes data on RN providers, the PSRC data have not been analyzed to determine the incidence of adverse events when RNs provide sedation, the practices RNs use when they sedate children, the medications used, or how RN-provided sedation may differ from sedation provided by MDs. The availability of the PSRC database provides an opportunity to investigate the practices and adverse events associated with pediatric sedation by nurses.

Research methods such as health services research (HSR) were developed to understand the individual dimensions of quality, how they interact to affect outcomes in healthcare, and to discover how outcomes could be improved (Aday, 2001). HSR is a "multidisciplinary field of inquiry, both basic and applied, that examines the use, cost, quality, accessibility, and delivery of healthcare services to increase knowledge and understanding of the structure, process and effects of health services for individuals and populations" (Aday, 2001, p. 183). Donabedian's original framework from 1966 for healthcare quality has been adapted by health service researchers to guide a health services research agenda that considers the effects of health policy on the health care delivery system and on outcomes at the individual (microsystem) level or population (macrosystem) level (Donabedian, 1966). This is further described in the conceptual framework section of this proposal (Aday, 2001). Nursing research in the area of quality patient care served as the basis for patient safety research (Blegen, 2006). Safety has been identified as a prerequisite to quality patient care (Walshe & Boaden, 2005). Nurse researchers have used a

variety of methods to understand patient safety in order to improve the delivery and safety of healthcare (Merwin & Thornlow, 2006). Some of the research methods employed include qualitative interviews, primary data collection of patient specific data, surveys, and secondary data analysis, used to evaluate practice changes and identify factors associated with safety (Merwin & Thornlow, 2006). Nursing health services research (N-HSR) studies using administrative data sets have provided evidence in areas such as models of care delivery, quality of care, and cost of care; some of these studies have provided evidence for changes in health policy (Bland & Mark, 2005). This study used N-HSR to understand factors that influence pediatric sedation safety using a secondary, multi-site data set collected by the PSRC. This method was selected for this study because delivery of sedation care involves many aspects of a healthcare system and this method facilitated the consideration of the multiple components associated with safety.

The lack of evidence pertaining to adverse events during RN-provided sedation, and practices in general, has prevented state boards of nursing and nursing professional organizations from setting practice standards to regulate nursing sedation practices. Several state nursing licensing boards have amended or added restrictions to RN-provided sedation practice to safeguard patients. However, inconsistencies in licensing regulations and lack of evidence related to the safety of RN-provided sedation form the basis for this study. Although various commentaries exist, no study has been completed regarding differences in RN state board of licensing regulations and professional organization standards in sedation or the possible effect these have in areas such as safety, moral distress, or job satisfaction (Davidson, Bloomberg, & Burnell, 2007).

RN Sedation Standards and Licensing Regulation

Nursing professional and state regulatory standards related to the role, competencies, and limitations applied to the delivery of sedation by nurses vary widely. For example, in 2002 the Maryland Board of Nursing provided a declaratory statement specifying the theoretical requirements for sedation education for nurses, requirements for training in advanced life support, institutional sedation policy requirements, methods, and specific circumstances in which the nurse may administer anesthetic agents such as propofol, thiopental, and ketamine (Maryland Board of Nursing, 2002). However, in May 2008, this declaratory statement was withdrawn and the Maryland Board of Nursing currently provides no guidance in this area. Several state boards of nursing including Virginia and Florida provide no specific guidelines related to the administration of sedative or anesthetic agents by an RN or any specific requirements for its administration (Landrum, 1997; Percy, 2006). Conversely, several states including Georgia and Texas provide specific guidance on practice related to sedation by an RN, including specifically prohibiting administration of medications such as propofol (American Society for Gastrointestinal Endoscopy, Society for Gastroenterology Nurses and Associates, & The American College of Gastroenterology, 2009; Texas Board of Nursing, 2009). Variations of position statements from professional organizations also exist; for example, the Emergency Nurses Association position statement on procedural sedation and analgesia in the emergency department states that nurses may deliver medications including etomidate, propofol, ketamine, fentanyl, and midazolam for procedural sedation and analgesia once credentialed and while working under the direct supervision of an emergency physician (Emergency Nurses Association, 2005). The American Association of Nurse Anesthetists however, states, “registered nurses who are not qualified anesthesia providers should not administer agents classified as anesthetics, including but not limited to ketamine, propofol, etomidate and sodium thiopental”

(American Association of Nurse Anesthetists, 2010, p. 3). Conflicting professional standards and state regulation of sedation practice make it difficult for nurses to determine what their scope and standards of sedation practice should be. Furthermore, the information used to determine the limitations of RN sedation practice by boards of nursing are based on little evidence because data on the types of adverse events experienced by patients who are sedated by nurses, and other risk factors associated with adverse events during sedation by RNs, have not been available. The limitations that state licensing agencies have imposed on sedation practice by RNs, and whether these limitations decrease adverse events for sedated patients, have not been studied. A description and analysis of the current regulatory limitations imposed by state boards of nurses on sedation practice compared to data on the types of adverse events experienced by sedated patients, and the risk factors that were associated with adverse events, is necessary to explore regulatory policies that could lead to improved sedation safety.

Incidence and Prevalence of Adverse Events

Data on the incidence and epidemiology of adverse events in the pediatric acute care setting are limited (Thomas, Orav, & Brennan, 2000). A recent study investigating the incidence of adverse events and preventable adverse events in children reported a 1% incidence of adverse events during pediatric hospitalizations (approximately 70,000 per year); 60% of these were preventable (Pitetti et al., 2006; Woods, Thomas, Holl, Altman, & Brennan, 2005). Although the incidence of adverse events in non-elderly patients, 20 to 65 years of age, was comparable (1.5%), the epidemiology of adverse events was different for children than adults (Woods et al., 2005). The most common adverse events in the pediatric population are birth and diagnostic related, rather than preventable surgical adverse events often described in adults (Woods et al., 2005). Hospital-reported medical errors have also been investigated to determine the

characteristics of children most at risk of an adverse event (Slonim et al., 2003). The highest error rates were found for children aged 6 to 12 years. Those with special medical needs due to co-morbid conditions, or dependence on medical technology, also had significantly higher rates of hospital- reported medical errors than other groups of children (Slonim et al., 2003). Children admitted for urgent or emergent conditions had lower medical error rates than those admitted electively (Slonim et al., 2003). Children with developmental delay have been identified as having an increased risk of adverse events during sedation, such as hypoxia (Slonim et al., 2003). The effect of the patient's developmental delay persisted despite controlling for other patient-level characteristics, such as age, that could contribute to the increased risk for adverse events (Slonim et al., 2003). Other factors, such as institutional characteristics including hospital size, were not related to medical error rate (Slonim et al., 2003). The percentage of preventable adverse events in other studies may indicate that 60% of adverse events in pediatrics are preventable (Pitetti et al., 2006; Woods, Thomas et al., 2005). Data on safety (the occurrence of unexpected adverse events), and the specific type of adverse event, such as inadequate sedation, unexpected bag-valve-mask ventilation, and prolonged sedation in children sedated by MDs alone, RNs alone, and MD and RN sedation teams for diagnostic radiology procedures, have not been reported. These data are needed to identify the competency areas that should be required for sedation providers to safely manage sedated children. The following sections provide a review of literature related to sedation risk factors, care processes, and provider types.

This study significantly increases knowledge of the occurrence of adverse events in children receiving RN-provided sedation, and the factors that influence the occurrence of these events as compared to MDs. Findings from this study can assist health care systems and state

licensing boards in the evaluation and implementation of better sedation policies, safer sedation practices, and evidence based regulatory practices.

Conceptual Framework

Historically, errors in health care and other industries were viewed as a failure of the individual (Institute of Medicine, 2004). The traditional organizational safety program sought to control workers through strict enforcement of company regulations focusing on individual punishment after an error occurred (Garcia Herrero, Mariscal Saldana, Manzanedo del Campo, & Ritzel, 2002). However, these programs did not improve safety, because the focus was on technical requirements and they were not integrated with other functions of the organization (Garcia Herrero et al., 2002; Leape, Berwick, & Bates, 2002).

In contrast, a systems view of errors and error prevention from fields such as accident investigation and engineering indicate that poor outcomes occur due to failures at multiple points within a system caused by several factors (Cook, Woods, & Miller, 1998; Institute of Medicine, 2004). A system is defined as a set of elements that are interconnected to aid in driving toward a defined goal (Gibson, Scherer, & Gibson, 2007). Research on safety, human contribution to safety, and safety failure has been most prominent in areas outside of health care, such as the aviation and power generation industries (Cook et al., 1998; Donabedian, 1978; Helmreich, 2000; Pronovost, Holzmueller, et al., 2006; Pronovost, Miller, & Wachter, 2006; Reason, 2000). Knowledge gained through the study of human, technological, and organizational contributors to normal functioning in complex work environments and accidents have led to changes in the conceptual frameworks used to examine quality, safety and risk. These are also being applied to health care systems (Carayon et al., 2006; Cook et al., 1998; Molloy & O'Boyle, 2005; Pronovost, Miller, et al., 2006; Reason, 2000). Latent factors are decisions, policies, and

procedures that are unrecognized within an organization until an error occurs (Clark et al., 2005). TJC identifies the importance of latent factors related to sedation safety in the National Patient Safety Goals and attempts to address these through sedation standards (Chai, 2005; Simmons, 2005). The National Patient Safety Foundation (NPSF) and the Dartmouth Summit on Pediatric Sedation describe the need to consider the regulatory environment in which complex systems develop organizational policies to better understand safety (Blike & Cravero, 2001; Cook et al., 1998). TJC and state licensing regulations are external to the individual system but directly affect hospital sedation policies by governing sedation care processes. Organizational failures, conflicts in interactions among individuals, and suboptimal systems are cited as major contributors to risk by the Institute of Medicine (IOM) (Nemeth , Nunnally, O'Connor, Klock, & Cook, 2005). The IOM proposes the use of engineering concepts and methods such as system engineering to improve the design of health care delivery systems (Carayon et al., 2006).

Thinking in the area of patient safety as a system problem was further advanced by Cook's sharp-end-blunt-end model, which conceptualizes safety as a wedge with both sharp and blunt ends (Cook et al., 1998). The sharp end of the wedge consists of practitioners (operators) who apply expertise and actions in their work to attain results, while the blunt end (managers) use policies, procedures, resources, and constraints that shape the work at the sharp end (Cook et al., 1998). The blunt end of the system is the source of the resources and constraints that form the environment in which practitioners work (Cook et al., 1998). Examination of failures in healthcare systems consistently show that the ability of sharp end operators to prevent against failure depends directly and indirectly on blunt end factors (Cook et al., 1998). Nurses play a significant role in the healthcare system through their involvement in both the sharp and blunt end of healthcare. Nurses represent the largest portion of the healthcare workforce, often have

the most frequent and longest contact with patients, deliver care in various settings (acute care, community health, home health), and also influence care delivery through administrative and policy-making roles.

Organizations such as the IOM and Agency for Health Care Research and Quality (AHRQ) have recognized the significant role nurses play in patient safety in areas such as patient monitoring, medication errors, and nurse vigilance (Institute of Medicine, 2004; Wachter, 2008). The IOM report entitled "Crossing the Quality Chasm" discussed patient safety in the context of quality care, emphasizing a system orientation (Institute of Medicine, 2001a). A system/organizational view of safety considers elements or factors such as the work environment, organization management, organization processes, and staff training, as well as individual behaviors in understanding safety (Cook et al., 1998; Institute of Medicine, 2004; Pronovost, Miller, et al., 2006; Reason, 2000). The IOM defines quality care as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and that are consistent with current professional knowledge" (Institute of Medicine, 2001a). Donabedian, a physician and professor of public health, published a framework for assessing quality health care that is the basis for most healthcare quality management and assessment today (Donabedian, 1966). Donabedian's framework of structure-process-outcome has been used to understand the dimensions of quality at the organizational level (Iezzoni, 1997). Donabedian's three dimensions of quality are defined as (1) structure, or the characteristics of a healthcare setting, for example the physical environment, available technologies, and staffing patterns; (2) process, or what is done to the patients, for example the policies and practices that guide the patient through the system of care; (3) outcome, or how patients do after health care interventions (Blike & Cravero, 2001; Donabedian, 1978). The SEIPS model (Figure 1) explains

how work system design can affect patient safety and organizational outcomes, building on models of quality, such as Donabedian's structure-process-outcome framework (Carayon et al., 2006; Donabedian, 1978). This study focused on the impact of work system and processes on patient safety.

The SEIPS model considers three major components: (1) work system, (2) process, and (3) outcomes (Carayon et al., 2006). Table 1 lists the variables used for this study and how they fit into the SEIPS model components.

Work System. The work system consists of the interactions between system components, which include the person (knowledge, skills, involvement in the system) who performs job tasks (job content) using technology and tools (e.g., diagnostic radiologic procedures) within a physical environment under specific organizational conditions (policies and procedures) (Carayon et al., 2006). Two persons are at the center of the work system in this study, the sedation provider (MD, RN) and the patient. Patients fit into the SEIPS model as recipients of care (Carayon et al., 2006). Individual patient characteristics affect work systems particularly when these characteristics influence the occurrence of adverse events; these patient characteristics are referred to as risk factors. In this study risk factors including patient age, weight, American Society of Anesthesia (ASA) class (an anesthesia risk score) and co-existing medical conditions were considered as part of the work system. Interactions among work system components subsequently influence care processes by the sedation provider type (RN alone, MD alone and MD and RN team) (Carayon et al., 2006; Pronovost, Miller, et al., 2006).

Care Processes. Care processes are the tasks performed, such as sedation monitoring (assessing the patient for response to sedation and identification of complications) using technology such as pulse oximetry, electrocardiogram, and capnography. Medication administered during sedation is

another task required for sedation. Care processes differ depending on the interaction among work system components. In this study the care processes studied were the medications administered and monitoring used to care for sedated patients. Work system components should enhance and facilitate performance of care processes by the individual to prevent poor outcomes (adverse events) (Carayon et al., 2006). This study investigated the influence of sedation care processes such as type of sedative medication used and type of monitoring done on patient outcomes depending on the type of sedation provider (RN alone, MD alone and MD and RN team).

Outcomes. The way care is delivered to patients by providers via care processes directly affects organizational outcomes which are quality and patient safety in the SEIPS model (Carayon et al., 2006). In this study unexpected adverse sedation events reported on the PSRC database were used to measure patient safety. Organizational outcomes were not included in this study.

Feedback. Feedback loops from processes to work systems and from outcomes to work systems can be used to design or redesign work systems (Carayon et al., 2006). Poor processes and outcomes can trigger system redesign. Quality and safety programs collect pertinent data that is qualitative and quantitative to identify process and work system components that increase and decrease risk and determine whether changes are necessary and which part of the system may need redesign. Feedback is a continuous process due to the interaction of components, which cause changes in outcome when any part of the system is changed. This research provided evidence regarding the influence of sedation providers (work system) on patient safety (unexpected adverse events) and descriptive data on sedation care (processes) that may be used to improve sedation care. However, the feedback loop will not be considered in this study.

Table 1 provides a brief description of the SEIPS model components and the study variables that were used in this study. The study variables were organized under each of the model components to illustrate the relationship between study variables and how they relate to SEIPS model components. Although the external context (regulatory) in which complex systems function are not depicted in the SEIPS model, regulations such as state licensing restrictions on nurse sedation practice and TJC accreditation standards were considered in this study. TJC regulations associated with sedation care have affected work system and process components by setting accreditation standards that have directly affected hospital sedation policies and procedures by providing minimum standards for monitoring of sedated patients, requiring the use of sedation risk assessment and documentation of sedation provider competencies (Devers, Pham, & Liu, 2004; Duckett, 1983).

Differences in patient characteristics such as age, weight, ASA class (an anesthesia risk classification) and co-existing medical conditions have been shown to increase adverse event risk and affect the interactions between work system components (Beach, Cravero, Blike, & Gelman, 2005; Coté, Karl, Notterman, Weinberg, & McCloskey, 2000). Regulatory and organizational standards and policies use patient characteristics such as age, weight, ASA and co-existing medical condition to pre-determine sedation care processes such as medications used, type of monitoring, and type of sedation provider (RN alone, MD alone or MD and RN team) (Baxter, Mallory, Sujit, Frellich, & Spandorfer, 2006; Green, Kuppermann, Rothrock, Hummel, & Ho, 2000; Heistein et al., 2006; Hoffman et al., 2002). However, limitations imposed by work system components such as the type of procedure being performed (technology and tools), may hinder the provider's ability to complete required care processes, such as certain monitoring processes, and will affect patient outcome.

Work System Components

Person

Risk Factors. The SEIPS conceptual model work system component includes "person"; in sedation this person may be the sedation provider or the patient. Patient risk factors such as age, weight, and co-existing medical conditions contribute to system errors/adverse events. In this study, the term patient risk factors was used to describe individual patient characteristics (age, weight, ASA class, and co-existing medical conditions) that may increase the likelihood of adverse events (American Society of Anesthesia House of Delegates, 2005; American Society of Anesthesiologists, 1996; American Society of Anesthesiologists, 2002; Beach, Cravero, Blike, & Gelman, 2005; Beach, Cravero, Blike, Gallagher, & Weiss, 2005; Menke, Klein, John, & Junginger, 1993). Care process components, such as sedative medication choice and monitoring practices, may also contribute to or prevent adverse events (American Society of Anesthesia House of Delegates, 2005; American Society of Anesthesiologists, 1996; American Society of Anesthesiologists, 2002; Beach, Cravero, Blike, & Gelman, 2005; Beach, Cravero, Blike, Gallagher, et al., 2005; Coté, 2002; Coté, Karl, et al., 2000; Coté, Notterman, Karl, Weinberg, & McCloskey, 2000; Hoffman et al., 2002; Malviya et al., 1997; Menke et al., 1993). Risk may be managed through the development of several layers, or barriers and safeguards, within work systems to diminish risk through administrative and procedural control (organizational work system component) (Reason, 2000). Sedation policymakers use organizational components (policies and procedures) to implement regulations intended to decrease sedation-related adverse events. Patient risk factors associated with sedation-related adverse events were derived from research findings on anesthesia safety and expert consensus (Hoffman et al., 2002). TJC requires sedation providers (RNs and MDs) to complete an assessment prior to sedation, including a history and physical, and a pre-sedation risk assessment immediately prior to administration of

the sedative agent (Chai, 2005; Patterson, 2002). Most sedation providers use the ASA class to meet this TJC requirement (Beebe, 2000; Cravero & Blike, 2004; Patterson, 2002). The ASA class is a preoperative classification system that predicts post-operative morbidity and mortality using the number of co-morbid conditions as an indicator of patient risk (Keats, 1978; Menke et al., 1993; Wolters, Wolf, Stutzer, & Schroder, 1996). As the number of co-morbid conditions increases, the ASA class increases, and patients are considered to be at higher risk for post-operative morbidity and mortality (American Society of Anesthesia House of Delegates, 2005; Castellano & Lopez-Escamez, 2003; Keats, 1978; Menke et al., 1993). The effectiveness of the ASA class as a pre-sedation assessment of adverse event risk has not been established (Heistein et al., 2006; Keats, 1978). However, the ASA class is often used in sedation policies to assign the sedation provider (i.e., nurse or anesthesiologist), or sedative medication (Chai, 2005; De Jong & Abraham-Inpijn, 1994; Green et al., 2000; Hasan et al., 2003; Jackson & Johnson, 2002; Lalwani & Michel, 2005; Miller, Levy, & Patel, 2005). Although the ASA class has been widely accepted for use as a pre-sedation screening tool, findings of several studies evaluating the accuracy of the ASA class score found it had no predictive value or the studies had limited sample size (Amundsen et al., 2005; Green et al., 2000; Miller et al., 2005).

Few patient risk factors and care processes used to develop sedation policy have been derived from research specifically on sedated children (Sedman et al., 2005; Shojania, Duncan, McDonald, & Wachter, 2002; Sloane, 2004). Licensing regulations, TJC standards, and hospital policies use patient risk factors to limit patients selected for sedation by certain providers, and use care process requirements to specify the medications and monitoring that may be used during sedation (Brennan et al., 1991; Kohn et al., 1999; Mohr et al., 2003; Patterson, 2002). For example, sedation policies limit the use of certain medications by RNs, or use ASA class as

criteria to determine the type of patient an RN may sedate (Lalwani & Michel, 2005; Tohda, Higashi, Sakumoto, Sumiyoshi, & Kane, 2006). However, weaknesses in safety systems exist, usually due to the real life situations that may allow errors to occur in sedation. One such weakness in the radiology environment is the type of procedure being performed, which makes it difficult to follow TJC standards for sedation and organizational sedation policies. The type of diagnostic radiology procedure performed may increase the risk of adverse events because it may cause monitoring problems. For example in order to complete MRI procedures, the patient is required to lie flat in an enclosed space similar to a tunnel in the machine. The location of the patient in the machine limits the ability for sedation providers to visualize the patient throughout the procedure. The MRI machine also uses magnetic fields that presents a hazard to patients if metal containing equipment are brought into the MRI environment, so only MRI compatible electronic monitoring devices such as cardiac monitors and infusion pumps can be used. However, if children are being monitored during the procedure the monitoring equipment must also be the appropriate size for the patient. Monitoring type in this study refers to differences among methods used by practitioners. Monitoring practices may be altered during sedation due to restrictions imposed by the diagnostic procedure (Blike & Cravero, 2001; Hasan et al., 2003). Few studies have been conducted to determine whether variations in care processes (i.e., medication, procedure, and monitoring) increase adverse events in sedated children (American Association of Nurse Anesthetists, 2010; Mace et al., 2004; Sedman et al., 2005; Shojania et al., 2002; Sloane, 2004). Current TJC sedation standards require providers to decrease risk using criteria such as ASA class (which considers co-morbidities to identify patients at risk for adverse sedation events). Other risk factors for adverse events in children include age; anatomical differences in the airway at different stages of development may increase the risk of airway

adverse events, and affect the choice of medications that a provider may use to reach an adequate level of sedation (Coté, 2002). Sedation safety may be improved if children at risk for adverse sedation events are identified prior to sedation, or if the appropriate monitoring and medication is used, and if these findings are incorporated into organizational policies that guide sedation practice in acute care settings. Further discussion of monitoring patients during sedation is provided in the monitoring section.

Provider Type

Sedation can be administered and monitored by MDs alone, RNs alone, or a team consisting of an MD and RN. Sedation providers also come from sub-specialties of disciplines such as radiology, or emergency and critical care, with varying amounts of experience and training providing sedation. Sedation regulations include guidelines related to specific competencies required to deliver sedation and to monitor the patient (Berkenbosch, Lubisch, Gallagher, & Cravero, 2006; Coté & Wilson, 2006). Personnel administering moderate sedation must be able to rescue patients who progress to a higher than intended level of sedation; minimal requirements include providing bag-valve-mask ventilation and other techniques to manage complications (Coté & Wilson, 2006). During moderate sedation in which a provider is responsible for treatment, such as completing bone marrow aspiration or endoscopy, a second support person, capable of providing and assisting in basic life support and resuscitation measures, who is responsible for monitoring the patient, must be present (Coté & Wilson, 2006). During deep sedation, one person must be responsible for observing vital signs, patency of the airway, ventilation, and the administration of medications (Coté & Wilson, 2006). At least one of the individuals present must be able to provide pediatric advanced life support, airway

management, and cardiopulmonary resuscitation for patients receiving deep sedation (Coté & Wilson, 2006).

A study by the PSRC on overall sedation complications analyzed differences among physicians who were not anesthesiologists, from various sub-specialties such as emergency medicine, radiology, or gastroenterology. The study used data from 10,552 sedations and 24 sites, and found an overall complication rate of 5.6% for all sedation providers excluding RNs and CRNAs (Beach, Cravero, Blike, Gallagher, et al., 2005). Patient age, ASA class, or urgency of procedure did not account for differences in sedation complications found among different sub-specialties of the providers (Beach, Cravero, Blike, Gallagher, et al., 2005). An analysis of types of complications, medication, and monitoring practices contributing to observed differences among providers was not included in the study (Beach, Blike, Cravero, Gallagher, & Weiss, 2005; Beach, Cravero, Blike, Gallagher, et al., 2005). While studies regarding MD sedation providers have compared adverse event rates among various sub-specialties providing sedation, they have not been compared to sedation providers such as nurses.

Research on sedation by nurses usually has been limited to a particular sub-specialty, such as sedation team nurses or emergency department nurses. However, nurses may deliver sedation to patients in the hospital as long as they meet minimum competencies required by organizational policies, state licensure, and TJC sedation standards. The practices of specialized radiology sedation nurses were studied using a sample of 6,093 adult and pediatric patients. Data were collected over an 8-year period; 75% of the sample was 9 years of age and younger (Bluemke & Breiter, 2000). Nurses providing the majority (76%) of MRI sedations had shorter and less variable procedure times when compared to general radiology and floor nurses (Bluemke & Breiter, 2000). In this study the overall adverse event rate was (0.42%) (Bluemke &

Breiter, 2000). There were no comparisons among radiology sedation nurses and other non-anesthesiology providers, and this study was conducted in only one site, prior to implementation of the 2001 Joint Commission sedation regulations, using a stringent sedation protocol for patient and medication selection (Bluemke & Breiter, 2000). The investigators also noted that bias was a limitation of this study; the specific sedation provider was identified, and the data were collected by the nurses providing sedation (Bluemke & Breiter, 2000).

Although sedation is often provided to patients by a team (RN and MD), studies describing or comparing the differences in adverse events, medication, or monitoring practices when both an RN and MD, an MD alone, or an RN alone sedates the patient have not been reported. The type of adverse events that occur when children are sedated by RN providers, and how these differ from the sedation-related adverse events with physicians, is unknown (Beach, Blike, et al., 2005; Beach, Cravero, Blike, Gallagher, et al., 2005). Nursing research addressing outcomes of pediatric sedation have focused on the implementation of different care delivery systems, such as pediatric sedation units, satellite sedation teams, and sedation services provided in the critical care and emergency departments (Bennett, 2003; Catalano, 2002; Dresser & Melnyk, 2003; Kingston, 2000; Lininger, 2004; Smallman, 2003). Published reports of nurses as sedation providers include descriptions of organizational methods of assuring sedation nurse competency, descriptions of nurse-driven sedation protocols including pre-sedation risk assessment, and criteria for referral to higher level providers (Bennett, 2003; Dresser & Melnyk, 2003; Kingston, 2000; Lalwani & Michel, 2005; Lininger, 2004; Pettinicchi, 2005; Zeigler & Brown, 1997). Policies related to the practice and regulation of sedation by nurses has primarily come from studies of anesthesia safety. The AAP guidelines for monitoring and management of children during and after sedation for diagnostic and therapeutic procedures are consistent with

TJC sedation standards; however, the AAP specifically describes nurses as qualified providers and monitors of sedation (American Academy of Pediatrics, 2002). Several studies describe risk factors such as sedative medications, length of procedure, and physician experience associated with adverse sedation events; these studies also state that nurses' monitoring and experience with sedated children are an integral part of decreasing adverse events. However, there are no data presented to support this conclusion (Arepally, Oechsle, Kirkwood, & Savader, 2001; Beebe, 2000; Malviya, Voepel-Lewis, Prochaska, & Tait, 2000; Mason et al., 2004; Sanborn et al., 2005).

Sedation protocols developed by health care organizations usually describe the roles of and limits placed on nurses providing sedation within the organization. Three factors that determine the success of nurse-delivered sedation in MRI are: appropriate screening of patients who are likely to be sedated adequately and safely, medication choice (type and dose), and training and experience of nurses (Woodthorpe, Trigg, Gurney, & Sury, 2007). An evaluation of nursing care processes used for the delivery of pediatric sedation and the effect these processes have on safety have not been reported in the literature.

In conclusion, research has been conducted on MD alone, RN alone and MD and RN teams of sedation providers, but descriptions and comparisons of adverse event rates and types, complications, medication, and monitoring processes when MD and RN teams provide sedation have not been reported. The sedation provider (MD alone, RN alone, or RN and MD teams) is integral to the work system component of sedation care, and differences in adverse event rate have been found within each discipline. However, what these differences are and how much influence the type of provider has on pediatric sedation-related adverse events are unknown.

Organization

Evidence regarding the importance of hospital characteristics, such as hospital ownership (teaching hospital versus privately owned), number of beds, and location have been found to inconsistently affect quality of care, including the prevention of adverse events, depending on the measures used (Thomas et al., 2000; Thornlow & Stukenborg, 2006; Woodthorpe et al., 2007). One study investigating the effect of institutional characteristics on the occurrence of patient safety indicators (PSIs) in a large administrative data set found virtually no difference in outcomes among four models, three that controlled for institutional characteristics and one that did not (Slonim et al., 2003; Slonim, Marcin, Turenne, Hall, & Joseph, 2007). Because a limited number of measures are available to assess pediatric health care quality, it is difficult to discern which organizational characteristics may result in risk for adverse events in hospitalized children (Beal et al., 2004). While organization-level research can be conducted using secondary data, it may be limited to the broadest levels of description, such as location, size, teaching affiliation, or specialty (e.g., children's hospital versus a general medical center). Despite limitations, this research may discover which organizations have developed best practices that could be further evaluated using primary data collection methods. The PSRC does not include organization-level information such as number of beds, geographic location, or average daily census. Therefore, the influence of these characteristics was not considered in this study.

Technology and Tools

Procedure Type

An increase in the number of diagnostic and therapeutic procedures requiring sedation, such as computerized tomography (CT) and MRI, is reported in several studies (Beebe, 2000; Malviya et al., 2000; Sanborn et al., 2005). The purpose of sedation is to increase cooperation and immobilize the child so that the procedure can be successfully completed (Malviya et al.,

2000; Mason et al., 2004). The risk of MRI and CT procedures themselves on children is nominal; however, when children are sedated, the risk of adverse events increases, and a prolonged period of sedation after a procedure may also increase risk (Malviya et al., 2000; Malviya et al., 1997). One study of adverse events in 922 children sedated for either CT or MRI found a 2.9% incidence of hypoxemia, and a 7% rate of sedation failure (Malviya et al., 2000). Another study found that 30.4% of preventable adverse events in children occurred in diagnostic-related medical care; a child is 1.35 times more likely than an adult to experience a preventable diagnostic adverse event (Woods et al., 2005). A 3-year study of 14,386 children receiving procedural sedation found that 7.6% of patients had an adverse event (Pitetti et al., 2006). The radiology department had the highest number of sedations; 48.5% of the sample and 37.6% of the study sample required sedation for MRI (Pitetti et al., 2006). Interventional procedures such as fracture reductions and cardiac catheterization had the highest rate of adverse events (10% and 16% respectively). Although these patients received sedative and analgesic medications for the procedures, patients undergoing MRI and CT scans received only sedatives but still had adverse event rates of 7.3% and 6.8%, respectively (Pitetti et al., 2006). Nurses frequently provide and monitor sedation in MRI and CT scan procedures (Bluemke & Breiter, 2000). However, because diagnostic procedures require varying levels of cooperation from the patient, the depth and length of time required for sedation in children varies. For example, because MRI procedures generally take longer to complete, patients may be sedated longer, which may also translate into deeper levels of sedation. However, whether this increases adverse sedation-related events is not clear. Although these differences in diagnostic procedures are known, they are not considered in regulatory standards, so guidelines for the monitoring and competencies of providers are consistent no matter where sedation is performed. However, the types and frequency of adverse

events associated with diagnostic radiology procedures, and the monitoring practices and medication choices used during these procedures, should be investigated as part of preventing adverse sedation-related events in children.

Care Process Component

Medication Type

There are many types of medications that may be used for sedation. The type of medication used during a procedure depends on the duration of the procedure, the available routes of administration and the depth of sedation needed. Sedative medications may also be administered in many different combinations. Some investigators have found that the number of medications administered had the most affect on sedation critical incidents such as cardiac arrest (Coté, Notterman, et al., 2000).

Sedative agents such as propofol, ketamine, and nitrous oxide may be administered and/or monitored by a nurse outside the operating room, depending on state licensing and organizational policies. The lack of consistent sedation administration policies amongst hospitals and boards of nursing allows some nurses to administer medications that are likely to place patients at a deep level of sedation (Malviya et al., 2000; Malviya et al., 1997; Roback, Wathen, Bajaj, & Bothner, 2005). The definition of moderate and deep sedation provided by TJC and the method of assessing sedation level of the patient is poorly validated in the pediatric population (Coté, Karl, et al., 2000; Coté, Notterman, et al., 2000; Polaner et al., 2001). Several small studies have evaluated the effectiveness and complications associated with anesthetics, including propofol and etomidate, when used by non-anesthesiology providers not certified in anesthesiology (Berkenbosch et al., 2006; Cravero et al., 2009). However, the occurrence of sedation adverse events related to provider type, including RNs, and factors influencing safety in

diagnostic radiology, have not been examined. Results of research on complications associated with particular sedative agents, such as chloral hydrate, require further investigation. One study in which the AAP and ASA guidelines were used to decrease risk of sedation complications found that the only medication associated with an increased risk of complications was chloral hydrate, which is used frequently in nurse-directed sedation protocols (Hoffman et al., 2002). The influence that medication type, such as opioids, non-opioids, or anesthetics, has on sedation safety in children is unclear from the pediatric nursing literature, which may be due to small sample sizes. State licensing bodies often limit sedation practice by RNs according to medication type; however, it is not clear whether this increases patient safety. In addition, as new sedatives become available, the effectiveness of regulating practice based on traditional medication categories may be diminished. Determining the types of medications nurses administer during pediatric sedation, and the associated adverse events, must occur to evaluate whether limiting RN sedation practice by medication type decreases sedation-related adverse events.

Monitoring Type

Studies of sedation-related adverse events in children assume that nurses are monitoring patients in accordance with TJC sedation guidelines (vital signs and level of sedation every 5 minutes) during all radiology procedures. However, research on barriers to monitoring imposed by radiology equipment during procedures, such as limited views of the patient preventing assessment of their level of sedation, is lacking (Arepally et al., 2001; Beebe, 2000; Malviya et al., 2000; Sanborn et al., 2005). Adequate patient monitoring to identify early signs of problems is imperative in preventing adverse events, but may be affected by aspects of the type of procedure performed, such as noise level and monitor artifact produced by some diagnostic equipment; this has not been studied. Three common diagnostic radiology procedures (CT scan,

MRI, and ultrasound) were studied because nurses frequently provide sedation for these procedures, and because each procedure presents similar monitoring challenges.

Monitoring standards for sedation vary depending on the level of sedation achieved by the patient. Sedation levels range from minimal sedation in which patients respond normally to verbal commands with some impaired cognition and coordination, to general anesthesia in which patients are unresponsive and often require assistance to maintain their airways (American Society of Anesthesiologists, 2002). The definitions of sedation level by the American Society of Anesthesia (ASA) have been adopted by TJC, professional organizations, and sedation researchers. The most frequently required levels of sedation in children are moderate and deep sedation.

Moderate sedation is defined as a drug-induced depression of consciousness in which patients respond to verbal or light tactile stimulation but require no interventions to maintain airway patency or adequate ventilation (Coté & Wilson, 2006). Sedation providers must obtain baseline vital signs prior to administration of sedative medications and perform continuous monitoring of oxygen saturation and heart rate, with intermittent recording of respiratory rate and blood pressure, during moderate sedation (Coté & Wilson, 2006). Monitoring of vital signs continues until appropriate discharge criteria have been met, including a return to pre-sedation level of consciousness (Coté & Wilson, 2006).

In contrast, deep sedation is a drug-induced depression of consciousness during which the patient is not easily roused but responds after repeated verbal or painful stimulation. The ability to maintain ventilatory function may be impaired requiring assistance in maintaining airway patency (Coté & Wilson, 2006). Monitoring of patients who are deeply sedated includes obtaining baseline vital signs, and continuous observation of oxygen saturation and heart rate

with documentation at least every 5 minutes. The post-procedure monitoring of deeply sedated patients is the same as those for moderately sedated patients (Coté & Wilson, 2006).

Sedation in children differs from adult sedation because children are sedated to control behavior that would otherwise interfere with the ability to safely complete a procedure (Coté & Wilson, 2006). The ability to control behavior and cooperate in completing a procedure varies based on both chronological and developmental age; however, children younger than 6 years and those with developmental delays often require deep sedation (Coté & Wilson, 2006).

Advances in monitoring technology related to sedation, such as pulse oximetry, noninvasive carbon dioxide, and sedation level monitoring continue to change the nursing care processes involved in sedation (Agrawal et al., 2004; American Society of Anesthesiologists, 2002). However, there is little evidence that use of these monitoring systems improve the safety of sedated children. Sedation monitoring procedures are sometimes altered due to limitations presented by the type of exam (Hasan et al., 2003). MRI in particular presents difficulties such as movement artifact, noise that could be frightening, and lack of ability to observe children while they are in the machine (Hasan et al., 2003), which may prevent monitoring for changes in sedation level. Monitoring procedures such as tactile stimulation to determine level of sedation could interfere with obtaining an adequate examination. The most recent guideline for monitoring sedation in children encourages the use of capnography for difficult-to-observe patients, especially during MRI; however, capnography has not been mandated by any regulatory agency such as TJC (Coté & Wilson, 2006). Studies investigating adverse events in children sedated for MRI have focused on medications used for sedation. Sample sizes for these studies ranged from 376 to 16,467 (Malviya et al., 2000; Sanborn et al., 2005). Although Sanborn et al. (2005) noted the importance of trained and experienced nurses in their study of 16,467 children

sedated for diagnostic imaging, the monitoring procedures used were not discussed. Monitoring type referred to differences among methods used by practitioners to monitor patients during sedation. Monitoring practices are altered during sedation due to restrictions imposed by diagnostic procedure (e.g., difficulty in observing patients during MRI) (Blike & Cravero, 2001; Hasan et al., 2003). Whether monitoring methods used by RNs differ from those used by MDs, and how these affect adverse events, is unknown. However, appropriately monitoring patients during sedation is necessary to determine whether an adverse event is occurring, and to allow intervention to decrease the amount of harm to the patient.

Outcome Component

Safety and Adverse Events

One of the difficulties in developing pediatric quality indicators stems from the diversity of the population due to normal developmental processes, so that quality indicators for one age group may not apply to another (McDonald et al., 2006). Another difficulty is that quality indicators often apply to chronic disease states which are less common in children than adults (McDonald et al., 2006). One study reviewing quality measures for children's health care used the IOM framework to develop four domains of pediatric quality, one of which was safety. Safety included missed and incorrect diagnoses, treatment error, and safety from injury in health care settings (Beal et al., 2004). This study identified 19 health care quality-measure sets, such as the Medical Expenditure Panel Survey (MEPS), and categorized measures of quality that applied to children; only 14.4% of the quality measures applied to safety (Beal et al., 2004). Safety measures identified focus on errors in health care delivery, and emphasize medical and surgical error (Beal et al., 2004).

The IOM defines safety as freedom from accidental injury (Havens & Boroughs, 2000; Institute of Medicine, 2001b). In this study, sedation safety was measured using the occurrence of unexpected adverse events to understand the safety of current practices by sedation providers (RN alone, MD alone, RN and MD teams), as well as other risk factors associated with sedation safety in pediatric radiology. Errors are defined as the failure of a planned action to be completed as intended, or to use a wrong plan to achieve an aim (Institute of Medicine, 2001b).

Although a reduction in error is important in order to improve patient safety, not all errors in care lead to patient harm (Institute of Medicine, 2001b). When harm or injury from a medical intervention occurs it is considered an adverse event (Institute of Medicine, 2001b). Research on sedation-related adverse events in hospitalized children has primarily concerned medication errors. Adverse events in pediatric sedation are reported in the general pediatric, anesthesia, and radiology literature (Coté, Karl, et al., 2000; Coté, Notterman, et al., 2000; Cravero & Blike, 2004; Dresser & Melnyk, 2003; Hoffman et al., 2002; Kingston, 2000; Lowrie et al., 1998; Mace et al., 2004; Malviya et al., 2000; Malviya et al., 1997). Research supports the opinion that children are at an increased risk of adverse events during sedation, due to factors such as: the limited availability of safe and easily administered sedatives for children; differences in anatomy of the pediatric airway; developmental factors, such as lack of cooperation with procedures; and limited availability of pediatric health care providers (Coté, Karl, et al., 2000; Coté, Notterman, et al., 2000; Cravero & Blike, 2004; Hoffman et al., 2002; Lowrie et al., 1998; Malviya et al., 2000; Malviya et al., 1997; Polaner et al., 2001). The most frequently reported sedation-related adverse events in children include inadequate sedation, causing delay, cancellation, or poor-quality diagnostic exams; respiratory complications requiring bag-valve-mask ventilation that may involve further intervention; and prolonged sedation, which may delay discharge or become

evident after discharge (Malviya et al., 2000; Malviya et al., 1997; Roback et al., 2005). A study of adverse events, such as death and permanent neurological injury, in 95 cases of sedated children used a critical incident analysis and found that these events were associated with all routes and classes of medications administered; inadequate Cardiopulmonary Resuscitation (CPR) skills; drug overdose; inadequate monitoring; inadequate recovery; and transcription or prescription errors (Coté, Notterman, et al., 2000). Adverse events were more likely when sedation occurred outside of the hospital environment (Coté, Notterman, et al., 2000). Practices implemented to improve the safety of sedated children include provider education and training to increase familiarity with administration of sedative agents, and use of pulse oximetry for all procedures (Fernandez & Gillis-Ring, 2003; Sedman et al., 2005). In this study adverse events included any unanticipated adverse events, and adverse event types listed on Table 2. Few large databases contain sufficient detail to reveal factors that influence the occurrence of adverse events in the pediatric population (Blike & Cravero, 2001; Ferguson, 2001). This study used the PSRC database to study adverse events depending on the provider (RN alone, MD alone and MD and RN teams) while considering other factors that may influence their occurrence (refer to the research design section for detailed information about the PSRC database) (Blike & Cravero, 2001; Cook et al., 1998; Cravero et al., 2005).

In summary, there are many factors that may influence pediatric sedation safety. The SEIPS model was used to gain a better understanding of patient sedation safety by considering the system components involved in delivering safe pediatric sedation. A detailed explanation of the study variables and definitions used for this study are listed in the variables section Table 2. Some of these factors include: patient characteristics such as age, weight, ASA class, and co-existing medical conditions, the type of procedure, and requirements the procedure may have

that influence the care processes used during sedation, such as the ability to appropriately monitor the patient, and the choice of medication used to sedate the patient. The influence of the type of sedation provider on whether or not an adverse sedation event occurs, and differences in the types of adverse events, such as inadequate sedation, prolonged sedation, and unexpected need for bag-valve-mask ventilation, will be compared among providers. The care processes used by different sedation providers (RN alone, MD alone, and RN and MD teams), such as medication type and monitoring used will also be described. This study also provided descriptive data about the practices and adverse sedation events associated with different sedation providers (RN alone, MD alone, and MD and RN teams) in diagnostic radiology. Data from this study could be used to improve RN sedation care processes, and guide the development of consistent nursing sedation licensing regulations, hospital standards, and policies.

Preliminary Studies

The applicant has not conducted any preliminary studies.

Research Design and Methods

A retrospective, cross-sectional, correlational design will be employed to determine differences in sedation risk factors, medication types, procedure types, monitoring, occurrence of adverse events depending on the type of sedation provider, and the relationship of these factors to safety in children sedated for diagnostic radiology in the United States. The PSRC database was used for this study. A description of the proposed study database is provided in the following section. Data collection procedures for the PSRC database are also presented, followed by descriptions of the setting and the study sample. Finally, the study variables are described, followed by the data management and data analysis plans.

PSRC Database

The PSRC database was developed by a group of pediatric experts led by primary investigator Joseph Cravero, MD, Director of Pediatric Anesthesiology, Children's Hospital at Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire. The purpose of development was to gather enough data so that sample size and power would allow accurate estimation of the efficacy, efficiency, and safety of pediatric sedation practice. Permission for access to the database was obtained by the investigator. The PSRC database consists of data collected from various departments selected by the 30 participating organizations, including radiology, intensive care, emergency, and sedation units. Each participant organization has a pediatric sedation service that specifically treats children and focuses professional practice in this area. PSRC members include 15 freestanding children's hospitals, and 15 children's hospitals within hospitals in the United States (Cravero et al., 2005). Data include demographics, risk (i.e., ASA class), medications administered, procedures, co-morbid conditions, adverse events, and provider information (including provider responsible, provider administering medication, and provider monitoring). The consortium partners developed and defined data elements collected via a Web-based tool consisting of 324 questions in 24 question sets that were identified as relevant to pediatric sedation.

Data Collection

Each hospital has an identified primary investigator and must agree to a standardized methodology for data collection (Cravero et al., 2005). All participating institutions and primary investigators from the institution are blinded from data submitted from individual institutions except their own. Institution primary investigators assure accuracy of data transmitted by performing data audits on 10 charts every 6 months, review independently recorded total counts of sedations performed in their institution, and compare these to the number of records submitted

to the PSRC (Cravero et al., 2005). Member organizations answer questions on each case. Regular inventories are performed by the primary investigator at each data collection site to reduce the chance of selective under-reporting of adverse events (Cravero et al., 2005). A review of the total counts of sedations performed via independent tracking in each institution is checked by the institutional investigator to assure the number of sedations coincide with the number of records submitted to the database to assure data integrity (Cravero et al., 2005).

The web-based data collection tool consists of 25 primary screens that contain one question per screen and bases subsequent questions on responses (Cravero et al., 2005). The system validates data entry and prevents logic errors. The data are collected via the Sybase data management system (Cravero et al., 2005). Each participant is authenticated and has access only to portions of the web site that are relevant to the institution, so that collected data conform to Hospital Insurance Portability and Accountability Act requirements (HIPAA) (Cravero et al., 2005).

Three of the questions on the web-based tool collect data on complications, including those occurring during a procedure. Subsequent questions prompt the respondent to provide detailed information about the selected complication, such as the duration of the event. In addition all categories of data collection allow for free text entries.

A limitation of the database is the difficulty in extracting data on advanced nurse providers; the questionnaire codes advanced registered nurse practitioners, pediatric nurse practitioners, and physician assistants into one category. Physician providers are coded by sub-specialty, while registered nurse providers are coded into one category.

Psychometric testing of the web-based PSRC data collection tool has not been reported. However, content validity was established at the Dartmouth Summit on pediatric sedation on

September 9, 2000 after a four-lecture plenary session and a four-hour round table discussion resulted in six major themes that were incorporated into the tool. Strengths of this data set are the availability of multi-center data specific to the topic of pediatric sedation and the sample size.

Setting

Thirty institutions contribute data to the PSRC database. Sites range in size from 95 to 1,764 beds with an average of 413 beds. PSRC member organizations are located across the U.S. (six sites in the Northeast, fourteen in the South, nine in the Midwest, and one in the West) (Cravero et al., 2005). Each site selects departments to report sedations, which may include radiology, intensive care, and sedation units.

Sample

Inclusion criteria for this study are children up to and including age 14 sedated by non-anesthesiology sedation providers such as non-anesthesiologist physicians and licensed registered nurses (RN) not certified to deliver anesthesia for diagnostic CT, MRI/MRA/MRV/MRS, or ultrasound, from January 1, 2005 through December 31, 2007. Exclusion criteria are all children over the age of 14, cases sedated by anesthesiologists or CRNAs, cases in which a Licensed Practical Nurse (LPN), advanced registered nurse (ARNP), Pediatric Nurse Practitioners (PNP), or Family Nurse Practitioners (FNP) sedated the patient, sedation for any procedure other than diagnostic CT, MRI/MRA/MRV/MRS, or ultrasound from January 1, 2005 to December 31, 2007. Data on interventional radiology studies, were excluded due to the difficulty in differentiating the affects of practices such as concomitant use of analgesic medications, increased sedation time required for interventional procedures, and adverse events from the intervention in the procedure (such as needle biopsy/aspiration) that might increase the risk of adverse events and would not be performed by a nurse. Sedation

provided by anesthesiologists and CRNAs was excluded due to the differences in the sedation practices standards and guidelines in place for anesthesia providers (American Society of Anesthesia House of Delegates, 2005). Racial and ethnic composition of the sample is unknown because it is not collected for the PSRC database.

Adequacy of the sample size was determined after new variables were created, and frequencies per cell of at least 5 cases in more than 20% of the cells were used to determine adequacy (Tabachnick & Fidell, 2007). If the sample was inadequate (fewer than 5 frequencies in more than 20% of the cells) the investigator considered collapsing categories. Power estimates were made once all new variables were created.

Variables

Covariate, dependent, and independent variables were obtained from the PSRC database codebook; these are presented in Table 2. Several new variables were also created from existing variables for this study, and are also included on Table 2. A variable named "any unanticipated adverse event" was created; cases were categorized into those with any adverse event (coded 1) or without any of the 27 possible adverse events (coded 0).

Four variables named "unanticipated adverse event type" were also created; the variable categories were neurologic, emergent, respiratory and other events. Each category was coded so that cases with adverse events meeting the category criteria listed in Table 2 were coded 1, and those cases without an unexpected adverse event meeting the category criteria were coded 0. Table 2 is provided to further clarify how cases were categorized into these variables.

A new dichotomous variable, "high ASA" was created, ASA scores greater than II were considered to be high. A new variable was created because the PSRC database variable for ASA scoring includes ten levels of ASA scoring. Due to the high number of possible ASA scores, and

because the study population consisted of relatively healthy children requiring non-interventional procedures in radiology, there were an insufficient number of cases classified with higher ASA risk scores to model adverse events. However, because ASA scores indicate patients with a higher risk for sedation complications it was important to retain these cases in the models. The cutoff ASA score of greater than two was selected because sedation guidelines often categorize ASA scores greater than two as higher risk for adverse events than cases categorized with ASA one and two scores (American Society of Anesthesiologists, 2002).

The "comorbid conditions" variable uses the number of comorbid conditions counted in each sedation case and ranges from none to greater than two comorbidities. This variable was created due to the large number of types of coexisting conditions (nines type) on the PSRC database and the number of cases in which several comorbid conditions could exist, creating overlaps in the data, making interpretation difficult. All nine of the coexisting condition variables were retained to be used for descriptive statistics but the comorbid conditions variables was used in logistic regression.

The "provider type" variable was derived using data from the "provider administering medication" and "provider monitoring medication" question. Cases were categorized into three groups. The MD alone group consisted of cases in which only a non-anesthesiology physician administers and monitors the patient, MD and RN sedation teams consisted of cases in which a non-anesthesiology physician and nurse administer and/or monitor the patient, and the RN alone group consisted of cases in which only a nurse administered and monitored the patient. A list and description of study variables are provided on Table 2.

"Any MRI" is a dichotomous variable that includes any case that had any diagnostic MRI. This variable was used in logistic regression models of adverse events and types of adverse

events. Multicollinearity testing demonstrated that the PSRC variable "MRI/MRA/MRV/MRS" and for "any diagnostic CT" were highly negatively correlated. For example, cases with diagnostic CT were unlikely to have an "MRI/MRA/MRV/MRS", this relationship was so strong that knowing the result of one variable (having a diagnostic CT) could predict that that case would not have an MRI/MRA/MRV/MRS. The number of ultrasounds was so low that only one variable "any MRI" was used to represent procedure type. MRI was selected because of the environmental factors such as monitoring difficulties and length of the procedure that could have an affect on adverse events. All procedure type variables were retained and used to obtain descriptive statistics on the study sample.

The "medications administered" variable uses the count of the number of medications administered in each sedation case and ranges from none to greater than two medications administered. This variable was created due to the large number of combinations of types of sedative medications that providers used and the number of cases in which several different types of medications were used (e.g. opioids and non-opioids), creating overlaps in the data and making interpretation difficult. All of the "medication type" variables were used to obtain descriptive statistics but the "medications administered" variables were used in logistic regression.

Data Management

An encrypted data file was obtained from the PSRC containing one record for each case meeting the study inclusion criteria. The data file was downloaded into a password-protected directory on the University of Virginia UNIX system. Data was examined and cleaned while checking for data errors. A data set for analysis was prepared using Statistical Analysis System (SAS) 9.1, to translate data into a file for analysis. Cases and variables were screened for missing data. If there were more than 5% cases with missing data, the cases were evaluated for patterns

of missing data. All cases missing data on ASA scores were excluded from the study. If a case was missing data on variables that were not being considered in the study, it was retained. Variables with more than 5% missing data were correlated to study variables that had less than 5% missing data. If a variable with fewer than 5% missing data was highly correlated to a variable with more than 5% missing data, the variable with more than 5% missing data was removed from the analyses (Mertler & Vannatta, 2005; Tabachnick & Fidell, 2007).

Data Analysis Plan

Aim 1

Describe the influence of type of sedation providers (RN alone, MD alone, RN and MD teams) on safety (the occurrence of any unanticipated adverse events), and type of unanticipated adverse event (four categories) in children when the influence of patient risk factors (age, weight, high ASA class, comorbid conditions), radiologic procedure type (any MRI), and sedation care processes (medications administered and monitoring type) are considered.

Hypothesis 1.1

After controlling for variables related to person (age, weight, high ASA, comorbid conditions), technology and tools (any MRI), and care process (medications administered, monitoring type), the provider type (RN alone, MD alone, RN and MD teams) will predict unanticipated adverse events in children sedated for diagnostic radiology procedures.

Plan

Descriptive statistics for all variables including means, median, and range was obtained for continuous variables (age and weight) and for the total number of adverse events. Frequency distribution was obtained on categorical data (unanticipated adverse event type, any unanticipated adverse event, ASA class, high ASA, co-existing medical conditions, comorbid

conditions, procedure type, any MRI, medication type, medications administered, monitoring type, and provider type). Cases were categorized by sedation provider type:
1) RN alone, defined as cases with only non-anesthesiology nurses delivering medication and monitoring sedation, 2) MD alone, defined as only cases with non-anesthesiology physicians delivering medication and monitoring sedation, and 3) RN and MD teams, defined as cases with non-anesthesiology nurses and physician delivering medication and/or monitoring sedation. Descriptive statistics for all variables described previously were also obtained for each provider type.

A hierarchical logistic regression model was used to predict the presence of any unanticipated adverse event depending on the provider (RN alone, MD alone, RN and MD teams), with the RN and MD team serving as the reference variable. The regression proceeded in the following manner: block 1- person (age, weight, high ASA, and comorbid conditions), block 2 - technology and tool (any MRI), block 3 - care process (medications administered and monitoring type), and block 4 - provider types. Assumptions tested included linearity of the logit; if violated, the predictor was transformed: tolerance to determine multicollinearity of discrete predictors was examined. If violated, all predictors were evaluated and redundant variables eliminated, and residuals for outliers were also examined (Tabachnick & Fidell, 2007). Overall model fit was evaluated by examination of -2 log likelihood, goodness-of-fit statistic. Chi-squares, 95% confidence intervals, parameter and odds ratio estimates were evaluated to determine the amount of variance in unanticipated adverse events accounted for by the model variables (Mertler & Vannatta, 2005). Correct classification by the model was compared to the actual values. The Wald statistic $p<.01$ was used to determine the significance of the contribution by each variable to the model, (Mertler & Vannatta, 2005).

Hypothesis 1.2

After controlling for variables related to person (age, weight, high ASA, comorbid conditions), technology and tools (any MRI), care process (medications administered, monitoring type), and the provider type (RN alone, MD alone, RN and MD teams) the interaction of high ASA and provider type and the interaction of medications administered and provider type will predict unanticipated adverse events in children sedated for diagnostic radiology procedures.

Plan

A hierarchical logistic regression was used to predict the presence of any unanticipated adverse event depending on the interaction of high ASA and provider type, and the interaction of medications administered and provider type. The regression was developed in the same manner described in the hypothesis 1.1 plan (blocks 1- 4). Two additional blocks (5 and 6) were added to the model. Block 5 consisted of the interaction of provider type (RN alone, MD alone, RN and MD teams), and high ASA. Block 6 consisted of the interaction of provider type (RN alone, MD alone, RN and MD teams), and medications administered. Block 5 and 6 was analyzed to determine the contribution to the presence of unanticipated adverse events. The data analysis (screening, assumptions, distribution and overall model fit) as described for hypothesis 1.1 were completed. Chi-square and parameter estimates were examined to determine significance of the interactions, but odds ratio estimates were not obtained.

Hypothesis 1.3

After controlling for variables related to person (age, weight, high ASA, comorbid conditions), technology and tools (any MRI), and care process (medications administered, monitoring type), the provider type (RN alone, MD alone, RN and MD teams) will predict

unanticipated adverse event type (neurologic, cardiovascular, emergent, respiratory, other events) in children sedated for diagnostic radiology procedures.

Plan

Four hierarchical logistic regression models for prediction, one for each unanticipated adverse event type (neurologic, emergent, respiratory, other events) were estimated. Each regression proceeded in the following manner: block 1 - person (age, weight, high ASA, and comorbid conditions); block 2 - technology and tool (any MRI); block 3 - care process (medications administered and monitoring type); and block 4 - provider types (RN alone, MD alone, RN and MD teams). Assumptions tested included linearity of the logit; if violated, the predictor was transformed: tolerance to determine multicollinearity of discrete predictors was examined. If violated, all predictors were evaluated and redundant variables eliminated, and residuals for outliers were also examined (Tabachnick & Fidell, 2007). Overall model fit was evaluated by examination of -2 log likelihood, goodness-of-fit statistic. Chi squares, 95% confidence intervals, parameter and odds ratio estimates were evaluated to determine the amount of variance in unanticipated adverse events accounted for by the model variables (Mertler & Vannatta, 2005). Correct classification by the model was compared to the actual values. The Wald statistic $p<.01$ was used to determine the significance of the contribution by each variable to the model, (Mertler & Vannatta, 2005).

Hypothesis 1.4

After controlling for variables related to person (age, weight, high ASA, comorbid conditions), technology and tools (any MRI), care process (medications administered, monitoring type), and the provider type (RN alone, MD alone, RN and MD teams) the interaction of high ASA and provider type, and the interaction of medication administered and

provider type will predict unanticipated adverse event types (neurologic, emergent, respiratory, other events) in children sedated for diagnostic radiology procedures.

Plan

Four hierarchical logistic regression models for prediction, one for each unanticipated adverse event type (neurologic, emergent, respiratory, other events) were planned. Preliminary analysis found that several adverse event types numbered in the hundreds. Although preliminary analysis of interactions were conducted, the addition of interaction variables increased the number of variables to be included in the model, raising concerns of unstable models due to small cell sizes (Mertler & Vannatta, 2005). In the future a larger subset of the PSRC database with more years of data, could be used to obtain this information.

Aim 2

Determine the influence of patient risk factors (age, weight, high ASA, comorbid conditions), procedure type (any MRI), care processes (medications administered, monitoring type), and sedation provider type (RN alone, MD alone, RN and MD teams) on inadequate sedation, unexpected bag-valve-mask-ventilation, and prolonged sedation in children sedated for diagnostic radiology procedures.

Hypothesis 2.1

After controlling for variables related to person (age, weight, high ASA, comorbid conditions), technology and tools (any MRI), and care process (medications administered, monitoring type), the provider type (RN alone, MD alone, RN and MD teams) will predict inadequate sedation, unexpected bag-valve-mask ventilation, and prolonged sedation.

Plan

Three hierarchical logistic regression models for prediction, one for each (inadequate sedation, unexpected bag-valve-mask ventilation, and prolonged sedation) were planned. However, there was a low frequency of these types of adverse events. Preliminary analysis found that prolonged sedation adverse event types numbered less than forty; no further analysis was completed on this variable due to the low frequency of this event. Preliminary analysis of inadequate sedation and unexpected bag-valve-mask variables found that these events occurred hundreds of times in the sample. In order to complete the regressions, the model was limited to the variables that were the most significant in the any adverse event model. Each regression proceeded in the following manner: block 1- person (weight, high ASA, any comorbid conditions); block 2 - technology and tool (any MRI); block 3 - care process (medications administered, administration of propofol, two combinations of monitoring); and block 4 - provider types (RN alone, MD alone, RN and MD teams). Overall model fit was evaluated by examination of -2 log likelihood, goodness-of-fit and R^2 but due to the small cell sizes the model remained unstable (Mertler & Vannatta, 2005). In the future a larger subset of the PSRC database with more years of data, could be used to obtain this information.

Limitations

Limitations of this study were that data from 30 institutions was not representative of all hospitals throughout the United States, so results were not generalizable. Generalizability may also be affected by the over-representation of children's hospitals and a lack of uniform distribution of contributing sites across US regions. Difference in terms of organizational policies, procedures, and training that may affect complication rates; sedative medication choice; and provider expertise may be present that cannot be controlled for in this study because there

are no specific data available about sedation providers (e.g., years of experience). No data were collected on race in the study sample, so it may not be a racially representative sample.

Summary

Results of this study could be used to determine the influence of factors such as sedation risk factors, procedure types, medication type, co-existing medical conditions, and monitoring common adverse events for children sedated for diagnostic radiology, and provide data describing the types of adverse events that occur, the influence of provider type on any adverse events, and total number of adverse events. Data from this study could provide evidence to inform managers, regulators, and policymakers about the factors that are most relevant in determining the occurrence of adverse events, and assist in the development of improved sedation delivery systems, evidence based policies, and consistent practice standards that could improve sedation safety.

Protection of Human Subjects

The applicant successfully completed a course on research ethics including content on the protection of human subjects and integrity of scholarship. This study used secondary data collected from the Pediatric Sedation Research Consortium (PSRC) database. This database meets Health and Human Services regulation exemption 4 of 45 CFR part 46 because it involves data that are recorded in a manner in which the subjects cannot be identified. The database contains demographic (age and gender only), procedural, provider, medication, and adverse event data on sedated children from several institutions throughout the United States. The applicant only used retrospective data from the database for this study. Data collected for the PSRC was observational, and did not impose any additional risks on study participants. The data sources for the PSRC database were 30 institutions in the United States. Each of the sites obtained Institutional Review Board approval, and met the additional protections for children

involved as subjects in research prior to starting data collection. The database is available to members of the PSRC and interested researchers with approval from a steering committee designated by the consortium. The major human subject risk possible in this study is a breach in confidentiality; this was avoided through maintenance of de-identified data. In the unlikely event that the applicant inadvertently identifies a case on the database, confidentiality will be maintained. The following protections are in place to guard against this risk. All data collected from individual institutions are de-identified, the records are given a unique identifying number to the institution and the department within the institution providing the data, but no information is collected that allows the data to be connected with any specific patient. This study was approved by the University of Virginia Institutional Review Board prior to initiation. Data is stored on a secure UNIX server at the University of Virginia; hard copies of any data analysis will be stored in a locked cabinet that can only be accessed by the applicant and study sponsor. Database files are saved on the UNIX server hard drive at the University of Virginia; access to data files is restricted to the applicant, sponsor, and data manager. A large database, such as the PSRC database, provides a large multi-center sample for the study of sedated children. The potential benefit of this study is the improvement in the safe delivery of care to sedated children by RNs and MDs. The knowledge gained from this study is important to determine the occurrence and which factors influence the safety of children sedated by RNs and MDs for diagnostic radiology procedures.

Inclusion of Women and Minorities

This study included patients of both genders, thus the database met the human subjects criteria for exemption four. This study used the PSRC database, which did not include data on race or ethnicity. However, data were obtained from 30 sites across the United States consisting

of 15 free-standing children's hospitals, and 15 children's hospitals within hospitals and general medical centers. Several sites are located in major metropolitan areas with racially diverse populations. Although the individual race/ethnicity of the individual patients is unknown, based on the location and the ethnic composition of the population around the sites, it is expected that the data includes minority patients, roughly in proportion to the minority composition of the city or state in which the site is located. Several study sites are located in urban areas such as Atlanta, Miami, New York, Philadelphia, Cleveland, and Denver. There are 6 locations in which the Hispanic population represents at least 10% of the total population, 11 locations have at least a 15% black population, and 6 with Asian populations of at least 3%. Table 3 depicts the city and bed size of the PSRC sites contributing data, the ethnic composition of the city (when available) or state for each site is listed. The lack of data on race is a limitation of this database. However, there is no other multi-center database on this population. The applicant believes that the potential contribution of this study justified the use of the PSRC database despite this limitation. This information is used to estimate the number of subjects by gender, race, and ethnicity in the Targeted/Planned Enrollment Table 3.

Inclusion of Children

Only children up to and including age 14 were included in this sample. The sample included children from age 0 to 14 years representing a wide range of developmental, anatomic, and physiologic developmental stages of children. The sites providing data for this study are part of a pediatric consortium consisting of free standing children's hospitals, children's hospitals within hospitals, and general hospitals that provide diagnostic imaging and sedation to children; therefore, they have access to both the equipment and expertise necessary to provide care to children. The consortium database consists of data collected from 30 sites providing a large multi-center sample for the applicant to investigate.

Vertebrate Animals

There are no vertebrate animals included in this study.

Figure 1. The SEIPS conceptual framework model. Reproduced from [Quality and Safety in Health Care, Carayon, Hundt, Karash, Gurses, Alvarado, Smith, Brennan, volume number 15, page i51 2006]with permission from BMJ Publishing Group LTD.

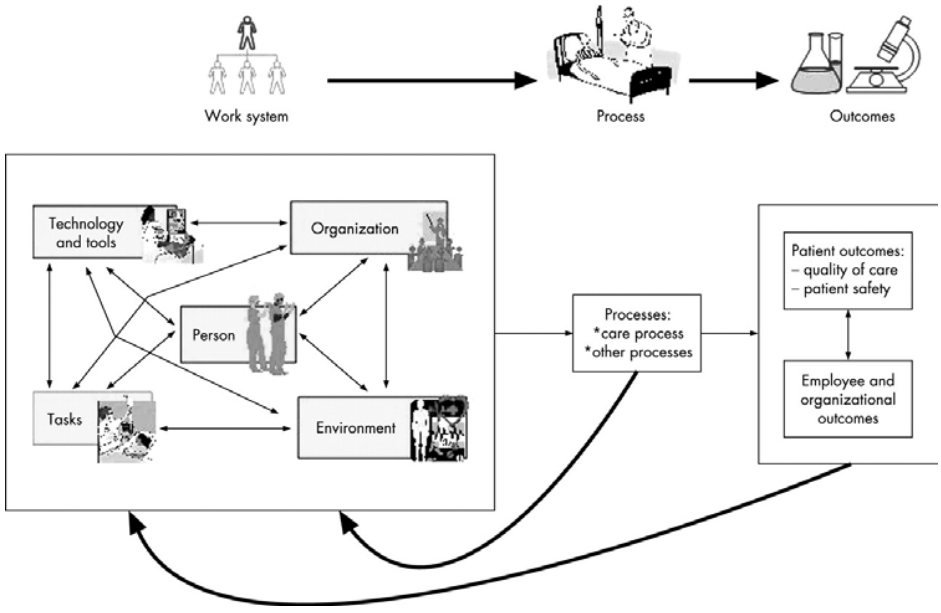

Table 1. Systems Engineering Initiative for Patient Safety Model Components

Work System	Care Process	Outcome
1. Person Patient *Risk Factors Age, Weight, ASA class, co-existing medical conditions that interact with other work system components and result in altered care processes. Provider Provider Type May include sedation provided and monitored by an RN alone, an MD alone or both (RN and MD). Care processes change depending on provider type. 2. **Organization** Hospitals develop sedation care policies to comply with licensing and accrediting regulations. Work systems components (person, technology and tools; task, environment) are established to carry out care process in keeping with hospital policies. 3. **Technology and tools** Procedure Type Care processes are altered due to limitations posed by radiologic equipment and exam requirements. 4. **Task and environment** Organizational policies and procedures delineate required tasks (obtain consent, verify NPO status), to be used to provide sedation care in all organizational environments.	1. Medication Type Sedative medications given based on organizational and regulatory policies. 2. Monitoring Type There may be differences between the methods used by practitioners to monitor patients during sedation. Monitoring practices are altered during sedation due to restrictions imposed by the diagnostic procedure.	1. Safety Sedation adverse events, (unanticipated sedation, and unanticipated adverse events) reported on the Pediatric Sedation Research Consortium Database will be used as measures of safety.

***Study variables are underlined.**

Table 2. System Component, Model Component, Variable Name and Description

System Component Variable Name	**Model Component** Operational Descriptions	
Work System	**Person – Patient Risk Factors**	
Age	Age in months (0-180)	
Weight	Weight in kilograms	
High ASA	1= ASA score of greater than two including eight levels of ASA scores ranging from ASA three (ASA III) to ASA five including emergency modifiers (ASA VE) 0= ASA scores of one (ASA I) and two (ASA II)	
Coexisting Medical Condition	Each co-existing medical condition is defined using 5-20 medical diagnoses, symptoms or anatomical conditions. These are listed via drop down menus on the PSRC database web based data collection tool for each condition. An aggregate list of 9 major co-existing medical conditions are provided here. 1. None 6. Cardiovascular 2. Congenital 7. Craniofacial 3. GI 8. Metabolic/Genetic (includes obesity) 4. Neurologic 9. Prematurity Related 5. Respiratory	
Comorbid Conditions	Total number of comorbid conditions in a sedation case None Two One Greater than two	
Any Comorbids	1= Any case that includes a comorbid condition 0=Cases without comorbid conditions	
Work System	**Person – Provider Type**	
MD Alone	Only cases with non-anesthesia physician delivering medication and monitoring sedation.	
RN-MD Team	Cases with non-anesthesia physician and nurse that deliver medication and/or monitor sedation.	
RN Alone	Only cases with non-anesthesia nurses delivering medication and monitoring sedation.	
Work System	**Technology and tools –Procedure Type**	
Procedure Type	1. Any diagnostic CT 3. Ultrasound 2. MRI/MRA/MRV/MRS 4. Radiology Other	
Any MRI	1= Any case that included a diagnostic MRI/MRA/MRV/MRS 0= Case without any MRI/MRA/MRV/MRS	
Care Process	**Medication Type**	
Medication Type	1. Non-opioids 4. Anticholinergics 2. Opioids 5. Inhaled Medications 3. Anesthetics	
Medications Administered	Total number of medications administered during a sedation case None Two One Greater than two	
Care Process	**Monitoring Type**	
Monitoring type	1. None 6. End-Tidal CO2 2. BIS or other sedation depth monitor 7. Inspired oxygen monitor 3. Blood Pressure 8. Pleth (Impedance Plethysmography) 4. Direct observation 9. SPO2 5. Electrocardiogram 10. Other	
Outcome	**Safety (Dependent Variable)**	
Unanticipated Adverse Event Type (1-4) *Individual sedation unanticipated adverse events. These adverse event types are listed in specific aim 2.	1. Neurologic • Agitation/delirium • Prolonged recovery time • Prolonged sedation * • Unintended deep sedation • Inadequate sedation* 2. Emergent • Cardiac Arrest • Death • Use of reversal agents • Emergency anesthesia consultation • Unexpected need for bag-valve mask ventilation * • Unplanned intubation • Allergic reaction	3. Respiratory • Airway Obstruction • Apnea>15 seconds • Aspiration • Coughing • Desaturation: O2 saturation below baseline for greater than 30 seconds • Laryngospasm • Secretions requiring treatment • Stridor • Wheezing 4. Other Events • Hypothermia • Unplanned admission to hospital or increase in level of care • Vomiting (non-GI procedure) • IV related complication • Unexpected change in HR, BP RR > or < 30% • Other
Any Unanticipated Adverse Event	1=Case with any adverse event	0=Case with no adverse event

Table 3. Pediatric Sedation Research Consortium Institutions Ethnic Composition % (Social Science Data Analysis Network, 2001)

City by Region	Beds	Hispanic	Black	White	Asian
North East					
Philadelphia	381	5.07%	19.76%	70.24%	3.36%
*New Hampshire	336	1.6%	.68%	95%	1.28%
Bangor	329	.6%	.4%	96%	.69%
New York	731	25.12%	22.75%	39.6%	9%
*Massachusetts	726	6.7%	5%	81%	3.73%
*Connecticut	830	9.4%	8.6%	77.5%	2.4%
South					
Wilmington	180	4.7%	17.5%	73%	2.29%
Gainesville	602	5.7%	19%	69.6%	3.5%
Columbia	633	2.4%	31.8%	62.9%	2.36%
Knoxville	122	12.5%	12%	69%	.98%
Memphis	225	2.4%	43.2%	51.8%	1.38%
Atlanta (2 sites)	412	6.5%	28.6%	59.8%	3.28%
Miami	1,764	57.3%	18.9%	20.6%	1.36%
Fayetteville	581	6.9%	34.3%	52.58%	1.44%
Ft. Lauderdale	567	16.7%	20%	58%	2.2%
Louisville	253	1.6%	13.8%	82%	1.07%
Charlottesville	556	2.2%	13.8%	79.3%	2.9%
Savannah	530	2.1%	35%	60%	1.48%
Charleston	590	2.3%	31%	64%	1.3%
Mid West					
Sioux Falls	651	1.9%	1.3%	92.8%	.92%
Kansas City	241	5.2%	12.6%	78.3%	1.6%
Grand Rapids	179	6.3%	7%	83%	1.5%
La Crosse	325	.8%	.8%	94%	2.8%
Minneapolis	126	3.3%	5.24%	84.7%	4.11%
Columbus	371	1.83%	13.28%	80.4%	2.36%
Cleveland	244	12.5%	12%	69%	1.35%
Youngstown	95	1.8%	10%	86%	.41%
Omaha	142	5.5%	8.2%	82.8%	1.49%
West					
Denver	250	18.8%	5.3%	70.3%	2.93%
Total		**7.7%**	**15.1%**	**69.4%**	**2.2%**

*Ethnic background by State

References

Aday, L. A. (2001). Establishment of a conceptual base for health services research. *Journal of Health Services Research, 6*(3), 183-185.

Agrawal, D., Feldman, H. A., Krauss, B., & Waltzman, M. L. (2004). Bispectral index monitoring quantifies depth of sedation during emergency department procedural sedation and analgesia in children. *Annals of Emergency Medicine 43*(2), 247-255

American Academy of Pediatrics. (2002). Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures:addendum. *Pediatrics, 110*(4), 836-837.

American Association of Nurse Anesthetists. (2010). Considerations for Policy Development Number 4.2 Registered Nurses Engaged in the Administration of Sedation and Analgesia. Retrieved February 23, 2013, from http://www.aana.com/resources2/professionalpractice/Documents/PPM%20Consid%204.2%20RNs%20Engaged%20in%20Sedation%20Analgesia.pdf

American Society for Gastrointestinal Endoscopy, Society for Gastroenterology Nurses and Associates, & The American College of Gastroenterology. (2009). Sedationfacts. Retrieved August, 15, 2009, from http://www.sedationfacts.org/sedation-standards/nursing-sedation-regulations

American Society of Anesthesia House of Delegates. (2005). Standards for Basic Anesthetic Monitoring. Retrieved November 4, 2006, from www.asahq.org/publicationsandservices/standards/02.pdf

American Society of Anesthesiologists. (1996). Practice guidelines for sedation and analgesia by non-anesthesiologists. A report by the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. *Anesthesiology, 84*(2), 459-471.

American Society of Anesthesiologists. (2002). Practice guidelines for sedation and analgesia by non-anesthesiologists. *Anesthesiology, 96*(4), 1004-1017.

Amundsen, L. B., Artru, A. A., Dager, S. R., Shaw, D. W. W., Friedman, S., Sparks, B., & Dawson, G. (2005). Propofol sedation for longitudinal pediatric neuroimaging research. *Journal of Neurosurgical Anesthesiology, 17*(4), 180-192.

Arepally, A., Oechsle, D., Kirkwood, S., & Savader, S. J. (2001). Safety of conscious sedation in interventional radiology. *Cardiovascular and interventional Radiology, 24*, 185-190.

Barbi, E., Gerarduzzi, T., Marchetti, F., Neri, E., Verucci, E., Bruno, I., . . . Ventura, A. (2003). Deep sedation with propofol by nonanesthesiologists: a prospective pediatric experience. *Archives of Pediatrics & Adolescent Medicine, 157*(11), 1097-1103.

Bates, D. W., Vanderveen, T., Seger, D., Yamaga, C., & Rothschild, J. (2005). Variability in intravenous medication practices: implications for medication safety. *Joint Commission Journal on Quality & Patient Safety, 31*(4), 203-210.

Baxter, A., Mallory, M., Sujit, S., Frellich, S., & Spandorfer, P. (2006). *Etomidate versus pentobarbital for CT sedation.* Paper presented at the 2006 Pediatric Academic Societies Meeting, San Francisco, CA.

Beach, M., Blike, G., Cravero, J., Gallagher, S., & Weiss, J. (2005). *Provider specific differences in complications: results from the Pediatric Sedation Research Consortium*. Paper presented at the American Academy of Pediatrics National Confrence and Exhibition, Washington, DC.

Beach, M., Cravero, J., Blike, G. T., & Gelman, B. (2005). *Effect of age and emergency status on the risk of pulmonary complications during sedation: results from the pediatric sedation research consortium.* Paper presented at the 34th annual critical care congress, Phoenix, AZ.

Beach, M. L., Cravero, J., Blike, G. T., Gallagher, S. M., & Weiss, J. (2005, February 23). *Provider specific differences in complications: Results from the Pediatric Sedation Research Consortium.* Paper presented at the Proceedings of the American Society of Anesthesiologists Annual Meeting, New Orleans, LA.

Beal, A., Co, J. P. T., Dougherty, D., Jorsling, T., Kam, J., Perrin, J., & Palmer, H. (2004). Quality measures for children's health care. *Pediatrics, 113*(1 Pt 2), 199-209.

Beebe, S. D. (2000). Anesthesia and sedation for pediatric patients undergoing procedures outside of the operating room. *Current Reviews for Perianesthesia Nurses, 22*(21), 233-244.

Bennett, M. (2003). Guidelines for sedation of the critically ill child. *Paediatric Nursing, 15*(9), 14-18.

Berkenbosch, J., Lubisch, N., Gallagher, S., & Cravero, J. (2006). *Dexmedetomidine for pediatric procedural sedation results from the Pediatric Sedation Research Consortium.* Paper presented at the American Academy of Pediatrics 2006 National Conference and Exibition, Atlanta, GA.

Bland, C., & Mark, B. (2005). The intersection of nursing and health services research: An agenda to guide future research. *Nursing Outlook, 53*, 324-332.

Blegen, M. A. (2006). Patient safety in hospital acute care units. In J. J. Fitzpatrick, P. W. Stone & P. Hinton-Walker (Eds.), *Annual Review of Nursing Research* (Vol. 24, pp. 103-125).

Blike, G. T., & Cravero, J. (2001). Pride, Prejuidice, and Pediatric Sedation: A Multispecialty Evaluation of the State of the Art (pp. 44). Lebanon, NH: Dartmouth Summit on Pediatric Sedation.

Blike, G. T., Cravero, J., Beach, M., Hertzog, J., Havidich, J., Gelman, B., & Gallagher, S. (2006). *The nature of adverse events associated with pediatric procedural sedation: preliminary findings from the Pediatric Sedation Research Consortium*. Paper presented at the 8th annual National patient Safety Foundation Patient Safety Congress, San Francisco, CA.

Bluemke, D. A., & Breiter, S. N. (2000). Sedation procedures in MR imaging: safety, effectiveness, and nursing effect on examinations. *Radiology, 216*(3), 645-652.

Brennan, T. A., Leape, L. L., Laird, N. M., Hebert, L., Localio, A. R., Lawthers, A. G., . . . Hiatt, H. H. (1991). Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *New England Journal of Medicine, 324*(6), 370-376.

Carayon, P., Schoofs Hundt, A., Karsh, B. T., Gurses, A. P., Alvarado, C. J., Smith, M., & Flatley Brennan, P. (2006). Work system design for patient safety: the SEIPS model. . *Quality and Safety in Health Care, 15*(suppl 1), i50-58. doi: 10.1136/qshc.2005.015842

Castellano, P., & Lopez-Escamez, J. A. (2003). American Society of Anesthesiology classification may predict severe post-tonsillectomy haemorrhage in children. *Journal of Otolaryngology, 32*(5), 302-307.

Catalano, K. (2002). What is in a name--sedation or anesthesia. *AORN Journal 75*(3), 550-553.

Chai, K. (2005). *Patient safety goals and the impact on the JCAHO survey*. Glendale, CA: CINAHL Information Systems.

Clark, R., Flick, R., & Litman, R. (2005). Hot Topics in Pediatric Anesthesiology. *ASA Newsletter, 69*(March), 6. www.asahq.org/newsletters/2005/03-05/hottopic03_05.html

Cook, R., Woods, D., & Miller, C. (1998). A tale of two stories: contrasting views of patient safety *Workshop on Assembling the Scientific Basis for progress on Patient Safety* (Vol. 13, pp. 77). Chicago, IL: National Healthcare Safety Council of the National Patient Safety Foundation.

Coté, C. (2002). Sedation disasters in pediatrics and concerns for office based practice. *Canadian Journal of Anesthesia, 49*(6), R1-R4.

Coté, C., Karl, H. W., Notterman, D. A., Weinberg, J. A., & McCloskey, C. (2000). Adverse sedation events in pediatrics: analysis of medications used for sedation. *Pediatrics, 106*(4), 633-644.

Coté, C., Notterman, D. A., Karl, H. W., Weinberg, J. A., & McCloskey, C. (2000). Adverse sedation events in pediatrics: a critical incident analysis of contributing factors. *Pediatrics 105*(4 part 1), 805-814.

Coté, C. J., & Wilson, S. (2006). Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures: An update. *Pediatrics, 118*(6), 2587-2602. doi: 10.1542/peds.2006-2780

Cravero, J., Blike, G. T., Beach, M., Gallagher, S., & Weiss, J. (2005). *The creation and inital results of the Pediatric Sedation Research Consortium* Paper presented at the American Society of Anesthesia Annual Meeting, New Orleans, LA.

Cravero, J. P. (2009). Risk and safety of pediatric sedation/anesthesia for procedures outside the operating room. *Current Opinion in Anaesthesiololgy, 22*(4), 509-513. doi: 10.1097/ACO.0b013e32832dba6e

Cravero, J. P., Beach, M. L., Blike, G. T., Gallagher, S. M., Hertzog, J. H., & Pediatric Sedation Research Consortium. (2009). The incidence and nature of adverse events during pediatric sedation/anesthesia with propofol for procedures outside the operating room: a report from the Pediatric Sedation Research Consortium. *Anesthesia & Analgesia, 108*(3), 795-804.

Cravero, J. P., & Blike, G. T. (2004). Review of pediatric sedation. *Anesthesia & Analgesia, 99*(5), 1355-1364.

Davidson, J. E., Bloomberg, D., & Burnell, L. (2007). Scope creep: when nursing practice moves beyond traditional boundaries: an evidence-based example using procedural sedation. *Critical Care Nursing Quarterly, 30*(3), 219-232.

De Jong, K. J., & Abraham-Inpijn, L. (1994). A risk-related patient-administered medical questionnaire for dental practice. *International Dental Journal, 44*(5), 471-479.

Devers, K. J., Pham, H. H., & Liu, G. (2004). What is driving hospitals' patient-safety efforts? *Health Affairs, 23*(2), 103-115.

Donabedian, A. (1966). Evaluating the quality of medical care. *Milbank Memorial Fund Quarterly, 44*, 166-206.

Donabedian, A. (1978). The quality of medical care. *Science, 200*(4344), 856-864. doi: 10.1126/science.417400

Dresser, S., & Melnyk, B. M. (2003). Evidence-based practice. The effectiveness of conscious sedation on anxiety, pain, and procedural complications in young children. *Pediatric Nursing 29*(4), 320-323.

Duckett, S. J. (1983). Changing hospitals: the role of hospital accreditation. *Social Science & Medicine, 17*(20), 1573-1579.

Emergency Nurses Association. (2005). Emergency Nurses Association Position Statement procedural sedation and analgesia in the emergency department. Retrieved November 3, 2006, from www.ena.org

Ferguson, S. L. (2001). To err is human: strategies for ensuring patient safety and quality when caring for children. *Journal of Pediatric Nursing, 16*(6), 438-440.

Fernandez, C., & Gillis-Ring, J. (2003). Strategies for the prevention of medical error in pediatrics. *Journal of Pediatrics, 143*(2), 155-162.

Garcia Herrero, S., Mariscal Saldana, M. A., Manzanedo del Campo, M. A., & Ritzel, D. O. (2002). From the traditional concept of safety management to safety integrated with quality. *Journal of Safety Research, 33*(1), 1-20.

Gibson, E. J., Scherer, T. W., & Gibson, F. W. (2007). *How To Do Systems Analysis*. Hoboken, NJ: John Wiley & Sons.

Green, S. M., Kuppermann, N., Rothrock, S. G., Hummel, C. B., & Ho, M. (2000). Predictors of adverse events with intramuscular ketamine sedation in children. *Annals of Emergency Medicine, 35*(1), 35-42.

Hasan, R. A., Shayevitz, J. R., & Patel, V. (2003). Deep sedation with propofol for children undergoing ambulatory magnetic resonance imaging of the brain: experience from a pediatric intensive care unit. *Pediatric Critical Care Medicine, 4*(4), 454-458.

Havens, D., & Boroughs, L. (2000). "To err is human": a report from the Institute of Medicine. *Journal of Pediatric Health Care, 14*(2), 77-80.

Heistein, L. C., Ramaciotti, C., Scott, W. A., Coursey, M., Sheeran, P. W., & Lemler, M. S. (2006). Chloral hydrate sedation for pediatric echocardiography: physiologic responses, adverse events, and risk factors. *Pediatrics, 117*(3), e434-441.

Helmreich, R. L. (2000). On error management: lessons from aviation. *BMJ, 320*(7237), 781-785. doi: 10.1136/bmj.320.7237.781

Hoffman, G. M., Nowakowski, R., Troshynski, T. J., Berens, R. J., & Weisman, S. J. (2002). Risk reduction in pediatric procedural sedation by application of an American Academy of Pediatrics/American Society of Anesthesiologists process model. *Pediatrics, 109*(2 part 1), 236-243.

Iezzoni, L. I. (1997). Assessing quality using administrative data. *Annals of Internal Medicine, 127*(8), 666-674.

Institute of Medicine. (2001a). *Crossing the Quality Chasm: A New Health System for the 21st Century.* Washington DC: National Academy of Sciences.

Institute of Medicine. (2001b). To err is human. *Frontiers of Health Services Management, 18*(1), 1-2.

Institute of Medicine. (2004). *Keeping Patients Safe Transforming the Work Environment of Nurses*. Washington DC: National Academies Press.

Jackson, D. L., & Johnson, B. S. (2002). Conscious sedation for dentistry: risk management and patient selection. *Dental Clinics of North America, 46*(4), 767-780.

Keats, A. S. (1978). The ASA classification of physical status--a recapitulation. *Anesthesiology, 49*(4), 233-236.

Kingston, F. (2000). Pediatric sedation: contributing to evidence-based practice. *Journal of Pediatric Nursing, 15*(2), 127-130.

Kohn, L., Corrigan, J., & Donaldson, M. (1999). *Institute of Medicine (IOM) Report-To Err is Human: Building A Safer Health System.* Washington DC: National Academy of Sciences.

Lalwani, K., & Michel, M. (2005). Pediatric sedation in North American children's hospitals: A survey of anesthesia providers. *Paediatric Anaesthesia, 15*(3), 209-213.

Landrum, L. (1997). A nursing guide to conscious sedation. Clarification of current practice issues. *Critical Care Nursing Clinics of North America, 9*(3), 411-422.

Leape, L., Brennan, T. A., Laird, N., Lawthers, A. G., Localio, A. R., Barnes, B. A., . . . Hiatt, H. (1991). The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *New England Journal of Medicine, 324*(6), 377-384.

Leape, L. L., Berwick, D. M., & Bates, D. W. (2002). What practices will most improve safety? Evidence-based medicine meets patient safety.[see comment]. *JAMA, 288*(4), 501-507.

Lininger, R. A. (2004). Pediatric nurse practitioner sedation specialty role. *Journal of Pediatric Health Care, 18*(3), 158-160.

Lowrie, L., Weiss, A. H., & Lacombe, C. (1998). The pediatric sedation unit: a mechanism for pediatric sedation. *Pediatrics, 102*(3), E30.

Mace, S. E., Barata, I. A., Cravero, J. P., Dalsey, W. C., Godwin, S. A., Kennedy, R. M., . . . Emergency Nurses Association. (2004). Clinical policy: evidence-based approach to pharmacologic agents used in pediatric sedation and analgesia in the emergency department. *Journal of Pediatric Surgery, 39*(10), 1472-1484.

Malviya, S., Voepel-Lewis, T., Prochaska, G., & Tait, A. R. (2000). Prolonged recovery and delayed side effects of sedation for diagnostic imaging studies in children. *Pediatrics, 105*(3), E42.

Malviya, S., Voepel-Lewis, T., & Tait, A. R. (1997). Adverse events and risk factors associated with the sedation of children by nonanesthesiologists.[erratum appears in Anesth Analg 1998 Feb;86(2):227]. *Anesthesia & Analgesia, 85*(6), 1207-1213.

Maryland Board of Nursing. (2002). Registered Nurse Administration of Medications Classified As Anesthetic Agents (Vol. 2002-1): Maryland Board of Nursing.

Mason, K. P., Sanborn, P., Zurakowski, D., Karian, V. E., Connor, L., Fontaine, P. J., & Burrows, P. E. (2004). Superiority of pentobarbital versus chloral hydrate for sedation in infants during imaging. *Radiology, 230*(2), 537-542.

McDonald, K., Romano, P., Davies, S., Haberland, C., Geppert, J., Ku, A., & Choudhry, K. (2006). *Measures of Pediatric Health Care Quality Based on Hospital Administrative Data*. Bethesda, MD: Agency for Health Care Research and Quality.

Menke, H., Klein, A., John, K. D., & Junginger, T. (1993). Predictive value of ASA classification for the assessment of the perioperative risk. *International Surgery, 78*(3), 266-270.

Mertler, C., & Vannatta, R. (2005). *Advanced and Multivariate Statistical Methods* (Third ed.). Glendale, CA: Pyrczak Publishing.

Merwin, E., & Thornlow, D. (2006). Methodologies used in nursing research designed to improve patient safety. In J. J. Fitzpatrick, P. W. Stone & P. Hinton-Walker (Eds.), *Annual Review of Nursing Research* (Vol. 24, pp. 273-292).

Miller, M. A., Levy, P., & Patel, M. M. (2005). Procedural sedation and analgesia in the emergency department: what are the risks? *Emergency Medicine Clinics of North America, 23*(2), 551-572.

Mohr, J. J., Barach, P., Cravero, J. P., Blike, G. T., Godfrey, M. M., Batalden, P. B., & Nelson, E. C. (2003). Microsystems in health care: Part 6. Designing patient safety into the microsystem. *Joint Commission Journal on Quality & Safety, 29*(8), 401-408.

Molloy, G. J., & O'Boyle, C. A. (2005). The SHEL model: a useful tool for analyzing and teaching the contribution of Human Factors to medical error. *Academic Medicine, 80*(2), 152-155.

Nemeth , C., Nunnally, M., O'Connor, M., Klock, P., & Cook, R. (2005). Getting to the Point: developing IT for the sharp end healthcare. *Journal of Biomedical Informatics, 38*, 18-25.

Patterson, C. H. (2002). JCAHO solutions. Sedation, anesthesia update. *Nursing Management, 33*(1), 22.

Percy, L. (2006). Opposition to Board of Nursing's proposed conscious sedation rules. *ASA Newsletter, 70*(4).

Pettinicchi, T. (2005). Meeting the JCAHO patient-safety goals. *Nursing 2005, 35*(8 Suppl), 24-26.

Pitetti, R., Davis, P. J., Redlinger, R., White, J., Wiener, E., & Calhoun, K. H. (2006). Effect on hospital-wide sedation practices after implementation of the 2001 JCAHO procedural sedation and analgesia guidelines. . *Archives of Pediatric and Adolescent Medicine, 160*(2), 211-216.

Polaner, D. M., Houck, C. S., Rockoff, M. A., Mancuso, T. J., Finley, G. A., Maxwell, L. G., . . . Davis, P. J. (2001). Sedation, risk, and safety: do we really have data at last? *Pediatrics, 108*(4), 1006-1008.

Pronovost, P., Holzmueller, C. G., Needham, D. M., Sexton, J. B., Miller, M., Berenholtz, S., . . . Morlock, L. (2006). How will we know patients are safer? An organization-wide approach to measuring and improving safety. *Critical Care Medicine, 34*(7), 1988-1995.

Pronovost, P., Miller, M., & Wachter, R. (2006). Tracking progress in patient safety: an elusive target. *JAMA, 296*(6), 696-699. doi: 10.1001/jama.296.6.696

Reason, J. (2000). Human error: models and management. *BMJ, 320*(7237), 768-770. doi: 10.1136/bmj.320.7237.768

Roback, M. G., Wathen, J. E., Bajaj, L., & Bothner, J. P. (2005). Adverse events associated with procedural sedation and analgesia in a pediatric emergency department: a comparison of common parenteral drugs. *Academic Emergency Medicine: Official Journal of the Society for Academic Emergency Medicine, 12*(6), 508-513.

Sanborn, P. A., Michna, E., Zurakowski, D., Burrows, P. E., Fontaine, P. J., Connor, L., & Mason, K. P. (2005). Adverse cardiovascular and respiratory events during sedation of pediatric patients for imaging examinations. *Radiology, 237*(1), 288-294.

Sedman, A., Harris, J. M., Schulz, K., Schwalenstocker, E., Remus, D., Scanlon, M., & Bahl, V. (2005). Relevance of the Agency for Healthcare Research and Quality Patient Safety Indicators for children's hospitals. *Pediatrics, 115*(1), 135-145.

Shojania, K. G., Duncan, B. W., McDonald, K. M., & Wachter, R. M. (2002). Controversies. Safe but sound: patient safety meets evidence-based medicine. *JAMA, 288*(4), 508-513.

Simmons, D. (2005). Sedation and patient safety. *Critical Care Nursing Clinics of North America, 17*(3), 279-285.

Sloane, T. (2004). Opinions. Editorials: a commission out of joint: another report adds to evidence that JCAHO needs a total overhaul. *Modern Healthcare, 34*(31), 20.

Slonim, A. D., LaFleur, B. J., Ahmed, W., & Joseph, J. G. (2003). Hospital-reported medical errors in children. *Pediatrics, 111*(3), 617-621.

Slonim, A. D., Marcin, J. P., Turenne, W., Hall, M., & Joseph, J. G. (2007). Pediatric patient safety events during hospitalization: approaches to accounting for institution-level effects. *Health Services Research, 42*(6 Pt 1), 2275-2293.

Smallman, B. (2003). Pediatric sedation in satellite locations. *International Anesthesiology Clinics, 41*(2), 17-27.

Social Science Data Analysis Network. (2001). CensusScope. Retrieved November 20, 2006, from http://www.censusscope.org/about.html

Stucky, E. R., American Academy of Pediatrics Committee on Drugs, & American Academy of Pediatrics Committee on Hospital Care. (2003). Prevention of medication errors in the pediatric inpatient setting. *Pediatrics, 112*(2), 431-436.

Tabachnick, B., & Fidell, S. (2007). *Using Multivariate Statistics* (5th ed.). Boston, MA: Pearson Education.

Texas Board of Nursing. (2009). The Role of the Nurse in Moderate Sedation. *Position Statement.* Retrieved August, 15, 2009, from http://www.bon.state.tx.us/practice/position.html#15.8

Thomas, E. J., Orav, E. J., & Brennan, T. A. (2000). Hospital ownership and preventable adverse events. *International Journal of Health Services, 30*(4), 745-761.

Thornlow, D. K., & Stukenborg, G. J. (2006). The association between hospital characteristics and rates of preventable complications and adverse events. *Medical Care, 44*(3), 265-269.

Tohda, G., Higashi, S., Sakumoto, H., Sumiyoshi, K., & Kane, T. (2006). Efficacy and Safety of nurse-administered propofol sedation during emergency upper endoscopy for gastrointestial bleeding: a prospective study. *Endoscopy, 38*(7), 684-689.

Wachter, R. M. (2008). *Understanding Patient Safety*. New York, NY: McGraw Hill.

Walshe, K., & Boaden, R. (2005). *Patient Safety: Research into Practice*. Columbus, OH: McGraw Hill Education.

Wolters, U., Wolf, T., Stutzer, H., & Schroder, T. (1996). ASA classification and perioperative variables as predictors of postoperative outcome. *British Journal of Anaesthesia, 77*(2), 217-222.

Woods, D., Thomas, E., Holl, J., Altman, S., & Brennan, T. (2005). Adverse events and preventable adverse events in children. *Pediatrics, 115*(1), 155-160.

Woodthorpe, C., Trigg, A., Gurney, A., & Sury, M. (2007). Nurse led sedation for paediatric MRI: progress and issues. *Paediatric Nursing, 19*(2), 14-18.

Zeigler, V. L., & Brown, L. E. (1997). Conscious sedation in the pediatric population. Special considerations. *Critical Care Nursing Clinics of North America, 9*(3), 381-394.

CHAPTER THREE

Procedural Sedation in the United States: A Review of Nursing Regulations

Abstract

Although administration of procedural sedation is a common practice among nurses, at present a unified consensus statement on Registered Nurse (RN) sedation core competencies or a consistent way in which RN sedation practice is regulated in the United States is lacking. In this article, the topic of RN sedation is discussed and includes current sedation standards by the American Society of Anesthesiologists and the Joint Commission. Examples of current regulations from State Boards of Nursing throughout the United States are also reviewed. Three major controversies related to RN sedation practice exist: variation in Board of Nursing regulation, lack of research on RN sedation practice, and lack of a national standard for RN sedation. Recommendations to address each of these areas are provided to inform regulators and nurse educators about current standards and knowledge gaps in sedation care. Strategies to improve sedation research in order to advance practice in this area are also discussed.

Procedural Sedation in the United States: A Review of Nursing Regulations

Over the last three decades, the administration of sedation for diagnostic and therapeutic procedures has increased dramatically; at the same time, these procedures have been recognized as an area fraught with potential risk for patients. Sedatives are often used to provide analgesia, allay anxiety, and increase comfort in patients that require procedures such as endoscopy and Magnetic Resonance Imaging (MRI). Sedation is used in a variety of patient populations and in various settings such as radiology, ambulatory care, and the emergency department. Anesthesia providers (APs) such as anesthesiologists and certified registered nurse anesthetists usually provide sedation, but the non-anesthesia providers, including non-AP physicians, nurse practitioners, and RNs also perform the procedure.

The demand for RNs to provide sedation has increased in recent years. A 2006 survey of United States gastroenterologists found the number of endoscopic procedures in adults increased exponentially (200% to 400%) over the fifteen years prior to the study and RNs are often called on to provide sedation care in this care setting (Cohen et al., 2006). RNs also provide sedation for patients in critical care in order to maintain treatments, provide analgesia, and to minimize discomfort for therapies such as endotracheal intubation (Mason, 2012).

Sedation care protocols are often derived from standards of anesthesia care, developed by physician specialty organizations such as the American Society of Anesthesiologists (ASA). These guidelines have become the basis for sedation standards by accrediting agencies, specialty organizations and regulating agencies that influence sedation practice in the U.S.

Although the administration of procedural sedation, sometimes referred to, as “conscious” or “moderate” sedation, is a common RN practice there is no unified consensus statement on RN sedation core competencies or a consistent way in which RN sedation practice

is regulated in the U.S. Several subspecialty nursing organizations such as the American Society of Perianesthesia Nurses (ASPN) and the Society of Gastroenterology Nurses and Associates (SGNA) have developed their own sedation-related standards and have published jointly with medical sub-specialty groups. Multiple contradictory standards published by various medical and nursing specialty organizations and different sedation regulations by Boards of Nursing exist. Table 1 is provided to assist the reader in navigating the various terms associated with sedation care that are referenced in this article, however it is not an exhaustive list of all organizations or terms associated with sedation care in the United States. The purpose of this paper is to describe the current state of RN sedation regulation in the United States and to identify RN related sedation practice controversies. The topic of RN sedation will be explored, focusing on three major components. The first component is to define sedation practice, describe qualifications of sedation providers and risks associated with sedation. Secondly, sedation standards and regulations by accreditors, professional organizations and Boards Of Nursing that impact RN sedation care will be presented. Lastly, major controversies in RN sedation practice and recommendations will be discussed.

Current Sedation Practice

Sedation Principles

Sedation defined. The American College of Emergency Physicians (ACEP) defines procedural sedation as

> a technique of administering sedative or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate unpleasant procedures while maintaining cardiorespiratory function. Procedural sedation and analgesia (PSA) is intended to result in a depressed level of consciousness that

> allows the patient to maintain oxygenation and airway control independently (American College of Emergency Physicians, 2005, p. 178).

There are four levels of sedation defined by the ASA (see table 2); sedation occurs on a continuum that ranges from minimal to full anesthesia. Sedation level classification depends on the patient's assessed response to verbal commands, actual or potential impairment of the patient's ability to maintain his/her own airway, spontaneous ventilation, and cardiovascular function after drug administration (American Society of Anesthesiologist [ASA] Taskforce on Sedation and Analgesia by Non-Anesthesiologists, 2002).

Sedation levels. Sedation begins with "minimal sedation" also referred to as anxiolysis, in contrast to "general anesthesia" which is considered the end point of the sedation-analgesia continuum and occurs when patients are unarousable with painful stimulation. There are two levels of sedation between minimal and general anesthesia: moderate and deep; they are the focus of this paper. Distinguishing between the two is difficult, but important, because regulations and standards of care differ depending on the patient's sedation level.

Determining sedation level. The level of sedation patients achieve is not solely predictable based on the medication administered or the dose used (ASA, 2002). The assessed level of sedation-analgesia may change throughout the procedure (Green & Mason, 2010). Sedation provider qualifications for each sedation level are set by the Joint Commission, and are presented in table 2 (Joint Commission International, 2011). Qualifications required for the sedation provider range from no specific qualifications for minimal sedation, to the ability to manage and rescue patients from whatever level of sedation or anesthesia is achieved when moderate and deep sedation levels are planned (Joint Commission International, 2011). The ability of RN sedation providers to be able to manage and rescue patients from a deep sedation

level or anesthesia is widely debated. Conversely, some patients that receive sedative medications are exempt from meeting sedation monitoring requirements. Examples include patients receiving sedative medications for treatment of insomnia, anxiety or pain control. Patients who are not undergoing a diagnostic or therapeutic procedure, such as intubated and ventilated patients receiving continuous infusions of sedative agents, and patients at the "minimal" sedation level are also exempted from meeting sedation monitoring and provider guidelines (ASA, 2002).

Risks Associated with Sedation

Sedation Mortality and Adverse Event Surveillance

There is no national surveillance system to monitor sedation mortality or complications in the U.S. (Li, Warner, Lang, Huang, & Sun, 2009). Rather, numerous studies simply report patient-level data on sedation adverse events in one institution based on medications used, the health care setting in which sedation was provided, or the patient population being treated. Mortality and morbidity for moderate and deep sedation is unknown. Sedation mortality should theoretically be lower than anesthesia mortality rate, which was 1.1 per million population and 8.2 per million of hospital surgical discharges between 1999-2005 (Li et al., 2009).

Sedation Adverse Events

Sedation adverse event rates vary depending on the population being studied, the medication used, and how a sedation adverse event is defined. Most studies report on either adult or pediatric populations thus it is difficult to determine what the overall adverse event rate is; this is further complicated by the fact that adverse event results are often not comparable because they are defined differently. For example, there is no consistent definition for a common sedation adverse event, oxygen desaturation, leading to a range of reported rates for this complication

depending on the population or circumstance (Cravero et al., 2006). Pino et al. (2007) reported 31 episodes (0.12%) of oxygen saturation less than 90% as an adverse event in a sample of 25,774 sedation cases including adults and children. Cravero et al. (2006) defined desaturation adverse events as an oxygen saturation less than 90% for greater than 30 seconds, reporting 470 episodes (1.6%) in a pediatric sample of 30,037 sedation cases. Miner et al. (2009) reported on 150 adult patients undergoing sedation for painful procedures with propofol in the emergency department. In this study 74 patients received propofol alone and 71 patients received propofol in combination with alfentanil, an opioid analgesic (Miner, Gray, Stephens, & Biros, 2009). Miner et al. (2009) reported oxygen saturation less than 92% at any time during the procedure as an adverse event; this was found in 9.5% of the propofol cases and 15.5% of the propofol with alfentanil cases. None of these studies presented any data related to RN sedation administration., although, Cravero et al. (2006) noted that sedation is sometimes performed by nurses and Pino and colleagues (2005) indicated that both physicians and RNs are formally credentialed to provide sedation (Cravero et al., 2006; Pino, Bryan, & Alfille, 2005).

Adverse events for RN administered sedation have generally been reported in cases with small sample sizes and specific patient populations. For example, a study of RN administered sedation for burn care procedures analyzed the results of 1,293 procedural sedations for wound care on 328 patients in a 12 month period (Thompson, Andrews, & Christ-Libertin, 2012). RNs administered fentanyl and midazolam using a procedural sedation order set without direct physician supervision during the wound care procedure (Thompson et al., 2012). A total of ten adverse events, all consisting of decreased oxygen saturation of less than 90% on eight patients were reported, yielding an overall adverse event rate of 0.77% (Thompson et al., 2012).

Managing Sedation Risk

Risks associated with sedation have led to the implementation of sedation standards by accrediting agencies such as the Joint Commission and several practice standards by professional organizations such as the ASA that guide the administration of sedation by all non-APs including RNs (Metzner & Domino, 2010). Despite the efforts of many professional organizations to define sedation practice in their specialty, the ASA has achieved an influential role in the development of standards of non-AP practice used by accrediting and regulatory agencies such as the Joint Commission, the Centers for Medicare and Medicaid Service and state boards of nursing. Following a discussion of regulations for Non-APs the article will focus on standards and regulation of sedation administered by RNs.

Sedation Standards and Regulations

American Society of Anesthesia Sedation Guidelines

The ASA has published several guideline documents defining the levels of sedation, practice standards for non-APs, statements for granting non-APs privileges to perform moderate sedation analgesia and an advisory document on deep sedation analgesia by non-APs (American Society of Anesthesiologists, 2009, 2010, 2011; American Society of Anesthesiologists [ASA] Task Force on Sedation and Analgesia by Non-Anesthesiologists, 2002). The ASA guidance document for Sedation and Analgesia by Non-Anesthesiologists (ASA, 2002) was developed by a ten-member taskforce using a systematic review of 357 articles with direct evidence related to sedation by non-anesthesiologist physicians (ASA, 2002). The guidance document does not address sedation by RNs, however, regulatory agencies including some state Boards of Nursing and specialty nursing organizations have used it to develop RN sedation standards. Sedation standards by the Joint Commission were developed using many of the recommendations set forth in the ASA guidance document.

Joint Commission Sedation Regulation

Sedation standards. The Joint Commission sedation standards have been greatly influenced by the ASA guidance document for Sedation and Analgesia by Non-Anesthesiologists, (2002). The Joint Commission Comprehensive Accreditation Manual for Hospitals (CAMH) includes multiple standards in the Provisions of Care, Treatment and Services chapter (PC.03.01.01 to PC.03.01.07) that specifically address moderate and deep sedation with or without analgesia (Joint Commission International, 2011). These same standards apply to patients in any setting that receive general, spine or other regional anesthesia including ambulatory care settings (Joint Commission International, 2011).

The Joint Commission standards for sedation providers are detailed in table 2. These standards require perioperative patient assessment and development or concurrence with a plan of care by a licensed independent practitioner (Joint Commission International, 2011). Pre-procedural education is required and continuous physiologic monitoring during and after the procedure is required depending on the possible effects of the sedative administered is also required (Joint Commission International, 2011).

Joint Commission sedation regulation gaps. The Joint Commission sedation standards do not address all sedation situations, such as non-verbal patients, procedures such as bronchoscopy that make it difficult to communicate with the patient, or circumstances in which monitoring the patient during sedation could interfere with completion of the procedure such as MRI. The Joint Commission does not state whether or not RNs can meet the qualifications for rescuing patients that slip from a moderate to deep level of sedation or from a deep level of sedation into general anesthesia. They also do not specify the manner in which RNs may be qualified or credentialed to provide sedation; instead the document references standards for

medical staff credentialing. The Joint Commission also does not address or differentiate analgesia from sedation in their standards. Specialty nursing organizations, such as the Emergency Nurses Association, the American Association of Nurse Anesthetists (AANA) and boards of nursing have also developed RN sedation practice standards that offer conflicting guidance on the role, competencies, and scope of practice for RNs providing sedation.

Professional Organizations

Procedural Sedation Consensus Statement. Several professional nursing organizations have published or collaborated on RN guidelines for the administration of sedation. The "Procedural Sedation Consensus Statement," was last revised in 2008 and is endorsed by several medical and nursing professional organizations. The statement promotes that interventions by RNs including administration of medications such as etomidate, propofol, ketamine, fentanyl and midazolam are used to manage a range of painful conditions including moderate to deep sedation (American Nurses Association, 2008). In contrast the ASA and AANA published a joint statement that propofol should only be administered by APs and that induction agents such as thiopental, methohexital, etomidate should be similarly restricted (American Association of Nurse Anesthetists, 2004).

RN sedation training and competency. There is currently no uniformly accepted training for a sedation nurse (Centers for Medicare and Medicaid Services, 2012). The "Procedural Sedation Consensus Statement" supports that RNs can administer medications for procedural sedation in collaboration with any health care provider with privileges and credentials to administer sedation; the RN must be trained and competent in this role (American Nurses Association, 2008). Training and competencies such as demonstration of competence in airway management, ability to initiate CPR, demonstrated knowledge of pharmacology and the ability to

recognize complications and intervene appropriately are recommended (American Nurses Association, 2008). Although this consensus statement is often cited in regulatory standards and is supported by several nursing organizations, it does not specify the standard of sedation practice outside of emergency settings. The majority of references cited to support the consensus statement come from the emergency medicine literature.

Gastroenterology RN Sedation Practice

The SGNA has two positions statements associated with procedural sedation. The first is on the use of sedation and analgesia in the gastrointestinal endoscopy setting. This statement recognizes the sedation levels developed by the ASA, supports the RN role of administering medication to provide moderate sedation and describes the RN role during deep sedation by APs as supportive to the endoscopy team (Society of Gastroenterology Nurses and Associates, 2010). It does not provide any further guidance related to the issue of deep sedation (Society of Gastroenterology Nurses and Associates, 2010).

The SGNA also published a joint statement with the American Society for Gastrointestinal Endoscopy (ASGE) describing the role of the RN during endoscopy procedures including monitoring, preparing and administering medications under the direct supervision of the physician, and expected RN training and competency (American Society for Gastrointestinal Endoscopy & Society of Gastroenterology Nurses and Associates, 2004). The ASGE and SGNA, (2004) joint position statement identifies the need for RNs to function within the limitation of their state licensure and practice act and organizational policies. The statement references prior guidelines from the ASGE regarding monitoring for moderate and deep sedation and the difference in monitoring by the RN during moderate versus deep sedation. It does not address

whether the RN should administer medications leading to deep sedation (American Society for Gastrointestinal Endoscopy & Society of Gastroenterology Nurses and Associates, 2004).

Nurse administered propofol sedation in endoscopy

A statement on the use of RN-administered propofol sedation (NAPS) for endoscopy was issued jointly by the American Association for the Study of Liver Diseases, American College of Gastroenterology, American Gastroenterological Association, and American Society for Gastrointestinal Endoscopy, proposing that administration of propofol for deep sedation during endoscopies could be safely delivered by sedation trained nurses, under the supervision of a non-AP sedation credentialed gastroenterologists (Vargo, Cohen, Rex, & Kwo, 2009). Twenty-eight studies with 460,651 cases were evaluated and found to have a similar safety profile to standard sedation for upper endoscopy and colonoscopy (Vargo et al., 2009). A four-pronged training approach for NAPS providers was described including didactic, airway workshop, simulation training, and a preceptorship (Vargo et al., 2009). NAPS for endoscopy has not been endorsed by the SGNA and the administration of propofol by the RN remains controversial with many boards of nursing opposing this activity (Vargo et al., 2009).

Regulators

Board of nursing regulation of sedation

State boards of nursing regulate nursing practice, including defining RN practice, determining scope of practice, taking disciplinary actions against licensees, and providing guidance on RN practice in their state. However, there is great variation in how boards of nursing regulate RN sedation practice and it is difficult to obtain information to determine requirements and restrictions in RN sedation practice depending on the state. The SGNA in cooperation with gastroenterology physician and nurse organizations have developed a web site called

SedationFacts (*sgna.org/issues/sedationfactsorg.aspx),* which was intended to provide an up-to-date and evidence- based resource for gastroenterology specialists to determine sedation regulations by states.

Determining Board of Nursing sedation regulations. The SedationFacts site provides summaries of sedation regulations in each state including guidelines and links to the original state resource, however most of the information was last updated in 2011. Despite its shortcomings, this site is perhaps the most readily available resource to obtain information on board of nursing sedation regulations in the United States. However, all resources listed on the site must be verified to determine if it remains current. Variation in how some boards of nursing regulate RN sedation practice can be seen in table 3 which summarizes RN sedation regulations in non-intubated patients from one state from each of United States Census Bureau regional divisions (U.S. Department of Commerce Economics and Statistics Administration & U.S. Census Bureau, 2000).

Controversies in Nurse Sedation Care and Recommendations for Improvement

Variation in Board of Nursing Sedation Regulations. Sedation regulations from nine boards of nursing are listed on table 3; these are presented as examples of the variation in how RN sedation is regulated. Note from the table that the boards of nursing in Wisconsin and Missouri do not provide any specific guidance on RN moderate or deep sedation practice. In Massachusetts, the board of nursing requires organizational policies for moderate and deep sedation and details areas the policies must address. In contrast the board of nursing in Texas requires the use of professional guidelines to determine appropriate care for moderate sedation, while in Idaho a decision making model requires the RN to use national specialty organization standards to determine RN scope of sedation practice. In New York and Texas the administration

of propofol, methohexital, etomidate and ketamine by RNs for sedation is restricted which is in line with the AANA-ASA joint position statement on propofol administration (American Association of Nurse Anesthetists, 2004). However, current literature concerning sedation is rife with reports of RNs administering and monitoring propofol, ketamine and nitrous oxide, but little evidence on the skills and competence required to perform deep sedation safely is presented (Leroy, Schipper, & Knape, 2010; Metzner & Domino, 2010). Descriptions of organizational policies, institution specific training and outcomes such as patient satisfaction and adverse events concerning RN administered propofol generally consist of small sample sizes from individual institutions that provide little RN specific data (Ellett, 2010).

The AANA-ASA position statement conflicts with the "Procedural Sedation Consensus Statement" on the role of the registered nurse during sedation and the consensus statement on Nurse Administered Propofol Sedation (NAPS) for endoscopy (American Association of Nurse Anesthetists, 2004; American Nurses Association, 2008; Vargo et al., 2009). However, several physician specialty groups (Vargo et al., 2009) are promoting NAPS as safe and effective for use in endoscopy. The controversy related to the administration of propofol by nurses is emblematic of the difficulty in regulating RN sedation practice due to a lack of evidence about current sedation practice, lack of consistency in recommendations amongst nursing professional organizations, and the inconsistent or lack of board of nursing regulation about propofol administration (Ellett, 2010).

Recommendations

The National Council of State Boards of Nursing (NCSBN) is the organizing body of boards of nursing in the U.S. and provides a forum for the member boards to consult on matters of common interest (National Council of State Boards of Nursing, 2013). Part of the work of the

NCSBN is to promote the uniformity of regulations and nursing practice. RNs are providing sedation services including deep sedation to many patients in a variety of specialties and settings and are seeking guidance on their role in this evolving area. Questions regarding scope of practice of RNs related to sedation have appeared in various publications such as newsletters (see table 3). In the past the NCSBN has developed guidelines to educate and inform RNs about practice matters that may be controversial or new, for example, the use of social media.

The NCSBN authored a white paper on social media to provide guidance to nurses on this topic (National Council of State Boards of Nursing, 2011). Recently the NCSBN also developed a uniform licensure requirement that sets a national standard for licensure in the U.S. (McDougal et al., 2011). It is recommended that similar steps be taken by the NCSBN to provide guidance on RN sedation practice including propofol administration. The first step in the process would be for NCSBN to work collaboratively with boards of nursing, professional organizations and experts in sedation care to develop a guidance document for RNs about sedation practice including the practice of deep sedation and administration of propofol. Secondly, recognizing that the need for sedation care continues to increase, a process similar to that used to develop uniform licensure requirements could be used to develop minimal requirements for RN sedation care (McDougal et al., 2011; Metzner & Domino, 2010).

Lack of Research on Nurse Sedation Practice

Research in the area of sedation is limited, due to the large sample sizes required to detect complications, the variety of settings, and procedures in which sedation is administered. In order to improve sedation research, collaboratives such as the Pediatric Sedation Research Consortium (PSRC) have been established. The PSRC consists of a group of more than 30 institutions that collect pediatric sedation data using a standard web based data collection instrument (Cravero et

al., 2006). The PSRC database contains data on monitoring and medication practices, outcomes, and information on RNs as sedation providers (Cravero et al., 2006). While the PSRC has reported on many aspects of sedation care, including a focus on physician non-anesthesiologists, data on RN sedation providers has not been reported. The data collection methodologies and definitions of adverse events vary so results are not comparable. The practice of sedation will continue to evolve as newer sedative medications become available and technology advances. However, the effectiveness of these advances in decreasing complications associated with RN delivered sedation will be difficult to evaluate given the current knowledge about the specific practices and risks of RN delivered sedation.

Recommendations

Collaboratives similar to the PSRC are necessary in order to develop samples of adequate size to research adult sedation care. In addition, the development of standard data collection methods and instruments for sedation care is necessary to determine possible differences between sedation providers and patient populations. Available data on RN sedation care must be studied to determine current RN sedation practice and outcomes that can inform sedation providers and regulators, in order to implement evidence based safety practices and regulations.

Lack of Unified RN Sedation National Standards

The myriad guidelines and statements from many sources make it difficult to develop national standards of practice including the scope, specific training requirements, and competencies necessary for RNs to safely provide sedation. The lack of national standards also make it difficult for RNs and consumers to make informed decisions as to the standard of care that should be provided for sedation with a variety of procedures. There are many reports of

training requirements for RN providers, but current studies offer little information as to content, educational methods, competencies and outcomes of sedation training (Jest & Tonge, 2011).

In a recent systematic review investigating competence and skills necessary to provide sedation safely, only one study of nurse administered nitrous oxide was reviewed (Leroy et al., 2010). The authors were unable to find any well-designed prospective studies on sedation safety and the level of skill and competence of any non-anesthesia sedation providers (Leroy et al., 2010). Jest and Tonge (2011) used a learning-needs assessment in a sample of 55 RNs to find the knowledge gaps related to sedation practice of RNs already providing sedation in two different settings within an institution. RN responses to this assessment revealed that learning needs differed depending on the RNs specialty area (Jest & Tonge, 2011).

Recommendations

Most sedation national standards have been developed using a consensus method including a systematic review of evidence and expert panels to formulate recommendations for practice. The ANA has already started the process by endorsing the "Procedural Sedation Consensus Statement"(American Nurses Association, 2008). This consensus methodology should be applied to expand the scope of the "Procedural Sedation Consensus Statement" to other specialty areas or by patient population. Developing national standards addressing sedation competence will require further research, possibly using qualitative methods to determine competencies required by specialty, rather than attempting to apply a single level of training and competence across all specialties.

Conclusion

Sedation is a multispecialty discipline that will continue to evolve. Current RN sedation regulation in the U.S. remains fragmented and poorly documented. There are three major

controversies related to RN sedation practice: variation in board of nursing regulation, lack of research on RN sedation practice, and a lack of RN sedation national standards. Collaboratives between researchers, sedation clinicians, professional organizations and regulators will be necessary to develop a unified strategy that will guide RN practice in the field of sedation. Improving sedation care will require developing evidence on sedation practices and outcomes in various populations that can inform educators, policymakers and clinicians.

Table 1

Terms and abbreviations associated with sedation care and referenced in article

Term	Abbreviation	Description
American Association of Anesthesiologists[1]	ASA	Professional organization of anesthesia physicians, that have developed most of the standards regarding sedation in the United States
American Association of Nurse Anesthetists	AANA	Professional organization of Certified Registered Nurse Anesthetists
American College of Emergency Physicians[2]	ACEP	Professional organization representing emergency physicians, that have developed sedation standards for emergency medicine
American Nurses Association	ANA	Professional organization representing registered nurses in the United States
Anesthesia Provider(s)	AP(s)	Providers that are considered anesthesia providers Anesthesiologist and Certified Registered Nurse Anesthetists
Board of Nursing	BON	State boards that regulate nursing practice
Non-anesthesia provider(s) also called Non-anesthesiologists[1]	Non-AP(s)	Healthcare practitioners that are not specialists in anesthesiology for example radiologists, nurses, dentists, pediatricians, intensivists
Nurse Administered Propofol sedation[3]	NAPS	Practice of administration of propofol for deep sedation by nurses under the guidance of a physician not trained in anesthesia
The Joint Commission	TJC	An organization that establishes standards to accredit healthcare organizations

1 (American Society of Anesthesiologists [ASA] Task Force on Sedation and Analgesia by Non-Anesthesiologists, 2002)

2 (American College of Emergency Physicians, 2005)

3 (Vargo, et al. 2009)

Table 2

American Society of Anesthesia Sedation Level Definitions and Joint Commission Sedation Provider Qualifications

Level	[1]American Society of Anesthesia Definition	[2]Joint Commission Provider Qualifications
Minimal Sedation (anxiolysis)	A drug induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired ventilator and cardiovascular function is usually maintained.	None Specified
Moderate Sedation (formerly conscious sedation)	A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain the patient's airway, and spontaneous ventilation is adequate. Cardiovascular function usually is maintained.	Individual administering moderate sedation are qualified and have credentials to manage and rescue patients at whatever level of sedation or anesthesia is achieved, either intentionally or unintentionally.
Deep Sedation	A drug-induced depression of consciousness during which patients cannot be aroused easily; but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function usually is maintained.	Individual administering deep sedation are qualified and have credentials to manage and rescue patients at whatever level of sedation or anesthesia is achieved, either intentionally or unintentionally.
Anesthesia	General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilator function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.	Anesthesiologist, Doctor of medicine or osteopathy other than a anesthesiologist, Doctor of dental surgery or dental medicine, Doctor of podiatric medicine, Certified Registered Nurse Anesthetist with supervision, Anesthesiologist assistant supervised by an anesthesiologist

1 (American Society of Anesthesiologists [ASA] Task Force on Sedation and Analgesia by Non-Anesthesiologists, 2002)

2 (Joint Commission International, 2011)

Table 3
Board of Nursing Guidance in Nine Census Bureau Divisions for Registered Nurse Administration of Moderate or Deep Sedation and Propofol in Non-Intubated Patients

U.S. Census Bureau Divisions	**Conscious/Moderate Sedation**	**Deep Sedation**	**Propofol**
New England			
Massachusetts[1]	Advisory Ruling RN may administer if meets competency requirements. Organizational policies dictate acceptable meds, purpose, goals, techniques, doses/kg	April 2010 board meeting statement that RN may administer deep sedation in non-intubated requires organizational policies and anesthesia or airway expert present monitoring airway.	RN may administer following the deep sedation guidelines
Mid-Atlantic			
New York[2]	RN competent may administer	IV anesthetics agents such as propofol, ketamine, etomidate, methohexital and thiopental are reserved for anesthesia providers	RN may not administer
East North Central			
Wisconsin[3]	No specific guidance	No specific guidance	Specific policies by institutions are required. As in other IV meds RN must have appropriate education, skill level or monitoring and medical personnel available in the event of an emergency
West North Central			
Missouri[4]	No specific guidance	No specific guidance	No specific guidance
South Atlantic			
Delaware[5]	Position statement RN may	No specific guidance	No specific guidance

	administer, but must meet training requirements		
East South Central			
Kentucky[6]	Advisory opinion RN has right and obligation to administer meds in amount not to induce anesthesia or loss of consciousness	May not administer medications producing general anesthesia or for purpose of general anesthesia. Nitrous oxide may be given for sedation by competent nurse	No specific guidance
West South Central			
Texas[7]	Position statement RN may provide moderate sedation using evidence based practice guidelines by professional organizations and as long as nurse is competent	Position statement administration of anesthetic agents is outside the RN scope of practice. The RN may only administer anesthetics such as propofol, methohexital, ketamine and etomidate when assisting in presence of CRNA or anesthesiologist, when assisting individual competent in advanced airway management including emergency intubation, when patient is intubated and mechanically ventilated in critical care, when in an advanced education program in preparation for licensure as nurse anesthetist.	Must meet the criteria in the deep sedation position statement
Mountain			
Idaho[8]	Refers licensees to decision making model IDAPA 23.01.01.400 to consider scope of practice: 1. Does practice act prohibit	No Specific Guidance	No Specific Guidance

	2. Possessing current knowledge and competency 3. Consistent with national specialty organization standards 4. Authorized through organizational policies and procedures 5. Would the same standard be provided by reasonable and prudent nurse		
Pacific			
Oregon[9]	Within scope of practice for RN under direction of LIP, meeting specific patient risk, RN knowledge and skill, practice setting, personnel and equipment or special circumstance criteria	Within scope of practice for RN under direction of LIP, meeting specific patient, knowledge and skill, practice setting, personnel and equipment or special circumstance criteria	Within scope of practice if meets deep sedation requirements

1. Advisory Ruling
http://www.mass.gov/eohhs/provider/licensing/occupational/nursing/nursing-practice/advisory-rulings/sedation-mild-to-moderate-sedationanalgesia.html
Newsletter July 2010
http://www.mass.gov/eohhs/provider/licensing/occupational/nursing/newsletters.html
2. http://www.op.nysed.gov/prof/nurse/nurse-ivsedation.htm
3. http://www.drl.state.wi.us/prof_practice_faq_detail.asp?prfaqid=1243&profid=46&locid=0
4. http://pr.mo.gov/nursing.asp
5. http://www.sgna.org/Issues/SedationFactsorg/StandardsRegulations/StateRegulations/Delaware.aspx
6. Advisory Opinion #32 http://kbn.ky.gov/practice/AOS/aosindex.htm
7. http://www.bon.state.tx.us/practice/position.html#15.8
8. RN FAQ 2011-2013 http://ibn.idaho.gov/IBNPortal/BoardAdditional.aspx?Board=IBON&BureauLinkID=150
9. Nursing Practice Policies Use of Sedation and Anesthetic Agents http://www.oregon.gov/OSBN/pages/position_papers.aspx

References

American Association of Nurse Anesthetists. (2004). AANA-ASA Joint Position Statement Regarding Propofol Administration Retrieved June 29, 2012, from http://www.aana.com/resources2/professionalpractice/Pages/AANA-Position-Statements,-Advisory-Opinions,-and-Considerations.aspx

American College of Emergency Physicians. (2005). Clinical Policy: Procedural Sedation and Analgesia in the Emergency Department. *Annals of Emergency Medicine, 45*(2), 177-196.

American Nurses Association. (2008). Procedural Sedation Consensus Statement Retrieved June 28, 2012, from http://www.nursingworld.org/MainMenuCategories/Policy-Advocacy/Positions-and-Resolutions/ANAPositionStatements/Position-Statements-Alphabetically/Procedural-Sedation-Consensus-Statement.html

American Society for Gastrointestinal Endoscopy, & Society of Gastroenterology Nurses and Associates. (2004). Role of GI Registered Nurses in the Management of Patients Undergoing Sedated Procedures Retrieved August 27, 2012, from http://www.sgna.org/Education/PositionStatements.aspx

American Society of Anesthesiologists. (2009, October 21). Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia Retrieved August 25, 2012, from http://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx

American Society of Anesthesiologists. (2010, October 20). Advisory on Granting Priveleges for Deep Sedation to Non-Anesthesiologist Sedation Practitioners Retrieved August 25,

2012, from http://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx

American Society of Anesthesiologists. (2011, October 19). Statement on Granting Priveleges for Administration of Moderate Sedation to Practitioners Who Are Not Anesthesia Professionals Retrieved August 25, 2012, from http://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx

American Society of Anesthesiologists [ASA] Task Force on Sedation and Analgesia by Non-Anesthesiologists. (2002). Practice guidelines for sedation and analgesia by non-anesthesiologists. *Anesthesiology, 96*(4), 1004-1017.

Centers for Medicare and Medicaid Services. (2012, May 11). Conditions for Coverage and Conditions of Participation Retrieved August 26, 2012, from http://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/index.html

Cohen, L. B., Wecsler, J. S., Gaetano, J. N., Benson, A. A., Miller, K. M., Durkalski, V., & Aisenberg, J. (2006). Endoscopic sedation in the United States: results from a nationwide survey. *American Journal of Gastroenterology, 101*(5), 967-974. doi: 10.1111/j.1572-0241.2006.00500.x

Cravero, J. P., Blike, G. T., Beach, M., Gallagher, S. M., Hertzog, J. H., Havidich, J. E., & Gelman, B. (2006). Incidence and nature of adverse events during pediatric sedation/anesthesia for procedures outside the operating room: report from the Pediatric Sedation Research Consortium. *Pediatrics, 118*(3), 1087-1096. doi: 10.1542/peds.2006-0313

Ellett, M. L. (2010). A Literature Review of the Safety and Efficacy of Using Propofol for Sedation in Endoscopy. *Gastroenterology Nursing, 33*(2), 111-117.

Green, S. M., & Mason, K. P. (2010). Reformulation of the sedation continuum. *Journal of the American Medical Association, 303*(9), 876-877. doi: 10.1001/jama.2010.217

Jest, A. D., & Tonge, A. (2011). Using a learnng needs assessment to identify knowledge deficits regarding procedural sedation for pediatric patients. *Association of Operating Room Nurses Journal, 94*(6), 567-574.

Joint Commission International. (2011). *Comprehensive Accrediation Manual for Hospitals*. Oak Brook: Joint Commission Resources.

Leroy, P. L., Schipper, D. M., & Knape, H. J. (2010). Professional skills and competence for safe and effective procedural sedation in children: recommendations based on a systematic review of the literature. *International Journal of Pediatrics, 2010*, 934298. doi: 10.1155/2010/934298

Li, G., Warner, M., Lang, B. H., Huang, L., & Sun, L. S. (2009). Epidemiology of Anesthesia-related Mortality in the United States, 1999–2005. *Anesthesiology, 110*(4), 759-765 doi: 10.1097/ALN.0b013e31819b5bdc

Mason, K. P. (2012). *Pediatric Sedation Outside of the Operating Room*. New York: Springer.

McDougal, B., Bitz, K., Derouen, S., Nagel, J., Thomas, K., Newman, B., . . . Filippone, J. L. (2011). The 2011 Uniform Licensure Requirements for Adoption. *Journal of Nursing Regulation, 2*(3), 19-22.

Metzner, J., & Domino, K. B. (2010). Risks of anesthesia or sedation outside the operating room: the role of the anesthesia care provider. *Current Opinion in Anaesthesiology, 23*(4), 523-531. doi: 10.1097/ACO.0b013e32833b7d7c

Miner, J. R., Gray, R. O., Stephens, D., & Biros, M. H. (2009). Randomized clinical trial of propofol with and without alfentanil for deep procedural sedation in the emergency

department. *Academic Emergency Medicine, 16*(9), 825-834. doi: 10.1111/j.1553-2712.2009.00487.x

National Council of State Boards of Nursing. (2011). White Paper: A Nurse's Guide to the use of Social Media Retrieved March 6, 2013, from https://http://www.ncsbn.org/2930.htm

National Council of State Boards of Nursing. (2013). About NCSBN Retrieved March 6, 2013, from https://http://www.ncsbn.org/about.htm

Pino, R. M., Bryan, R., & Alfille, P. (2005). Procedural Sedation in a Large Teaching Hospital. *Anesthesiology, 103*(A615).

Society of Gastroenterology Nurses and Associates. (2010). Statement on the Use of Sedation and Analgesia in the Gastrointestinal Endoscopy Setting Retrieved August 27, 2012, from http://www.sgna.org/Education/PositionStatements.aspx

Thompson, E., Andrews, D., & Christ-Libertin, C. (2012). Efficacy and Safety of Procedural Sedation and Analgesia for Burn Wound Care. *Journal of Burn Care and Research, 33*(4), 504-509.

U.S. Department of Commerce Economics and Statistics Administration, & U.S. Census Bureau. (2000). Census Regions and Divisions of the United States Retrieved September 28, 2012, from https://http://www.census.gov/geo/www/us_regdiv.pdf

Vargo, J. J., Cohen, L. B., Rex, D. K., & Kwo, P. Y. (2009). Position statement: Nonanesthesiologist administration of propofol for GI endoscopy. *American Journal of Gastroenterology, 104*(12), 2886-2892. doi: 10.1038/ajg.2009.607

CHAPTER FOUR

Pediatric Sedation: A Descriptive Study of Registered Nurse Practice

Abstract

Children, especially those under age six require sedation for procedures due to their developmental level and difficulty complying with positioning. There are few studies that describe nurse sedation practices or adverse events. Studies of pediatric sedation care have small sample sizes that are inadequate to detect adverse events. This study reports practices and outcomes of sedation delivered and monitored only by RNs during diagnostic radiology procedures drawn from a sample of 12,564 cases from the Pediatric Sedation Research Consortium (PSRC) database. There were 726 adverse events (5.78%). However, no deaths, cardiac arrests, intubations or aspirations were reported in this sample. The most common adverse event was inadequate sedation/agitation/delirium 196 (1.56%) and desaturation below baseline for greater than 30 seconds 173 (1.38%). Further research comparing sedation practices and outcomes by type of providers, including nurses, are necessary to improve practice.

Pediatric Sedation: A Descriptive Study of Registered Nurse Practice

The growing demand for diagnostic procedures such as Magnetic Resonance Imaging (MRI) and Computerized Tomography (CT) scans for children of all ages has led to an increased demand for procedural sedation services (Havidich & Cravero, 2012). Procedural sedation is "a technique of administering sedative or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate unpleasant procedures while maintaining cardiorespiratory function. Procedural sedation and analgesia (PSA) is intended to result in a depressed level of consciousness that allows the patient to maintain oxygenation and airway control independently" (Godwin et al., 2005, p. 178). In order to meet the need for sedation services in this population, numerous specialties such as radiologists and Registered Nurses (RNs) with varying education and experience provide sedation (Havidich, & Cravero, 2012).

Sedation In Pediatrics

The goals of sedation in children are to maintain safety, minimize discomfort, decrease anxiety, minimize psychological trauma, increase cooperation with exam requirements such as immobilization in order to complete the procedure, and to return the child to their pre-procedural physical and cognitive state (Coté & Wilson, 2006). Children under six years of age often require deep levels of sedation in order to gain the cooperation necessary to complete diagnostic procedures (Coté & Wilson, 2006). Sedated children are at risk for serious adverse events such as apnea, airway obstruction and hypotension (Coté & Wilson, 2006). Adverse responses to sedation cannot be eliminated, but can be mitigated by assuring that appropriate screening, medications, equipment, monitoring and personnel are in place to provide sedation (Coté & Wilson, 2006).

Sedation Outside the Operating Room

Until the 1980s, the practice of sedation was completed in the operating room by anesthesiologists (Krauss & Green, 2007). In the last 20 years, the demand for sedation outside the operating room, in locations such as radiology, has led to the expansion of sedation services by many non-anesthesia provider specialties such as staff RNs, advanced practice nurses, and physician specialists such as intensivists and radiologists (Krauss & Green, 2007). This study focused only on staff RN sedation providers; advanced practice nurses such as nurse practitioners and Certified Registered Nurse Anesthetists (CRNAs) were excluded. Although RNs often provide sedation care directly to patients, institutional oversight of sedation generally remains with physician specialists, such as anesthesiologists, who provide expertise in the development of sedation protocols and assuring sedation quality (Krauss & Green, 2007). The current model of varying institution level sedation practice and administrative responsibility means that sedation systems differ depending on location. This inherent variation in sedation care has made research difficult. Many studies about sedation analyze practices and outcomes of physician sedation providers but research on RNs is limited (Couloures, Beach, Cravero, Monroe, & Hertzog, 2011).

Studies of RN pediatric sedation care are similarly limited and involve small sample sizes, describe implementation of RN sedation services, only include data on one location, or compare sedative medication regimes (Srinivasan, Turmelle, DePalma, Mao, & Carlson, 2009; Gozal & Gozal, 2008; Shah et al., 2011; Sury, Hach, Deeley, Dicks-Mireaux, & Chong 1999; Lavoie, Vezina, Paul-Savoie, Cyr, & Lafrenaye, 2012; Blumke & Breiter, 2000; Beebe et al., 2000; Woodthorpe, Trigg, Gurney, & Surry, 2007; Sterni, Beck, Cole, Carlson, & Turmelle, 2008). This study was undertaken to describe practices and outcomes of pediatric sedation by RNs in radiology to determine the patient characteristics, medications delivered, monitoring

practices and outcomes of sedation by RNs in children during diagnostic MRI, CT scan, and ultrasound procedures.

Pediatric Sedation Guidelines

In 2006, the American Academy of Pediatrics (AAP) updated guidelines for the monitoring and management of pediatric patients during and after procedural sedation (Coté & Wilson, 2006). The updated document was modified to incorporate similar language, definitions of sedation and monitoring guidelines found in sedation regulations such as the Joint Commission sedation standards (Joint Commission International, 2011). The AAP does not include any information regarding the RN role in providing or assisting with sedation or data regarding RN sedation practice (Coté & Wilson, 2006). The AAP guidelines also utilize the American Society of Anesthesiologists (ASA) (American Society of Anesthesiologists, 2002) guidance document for Sedation and Analgesia by Non-Anesthesiologists in describing safe pediatric sedation practice.

American Society of Anesthesiologists

The ASA has published several advisories, statements, and guidelines concerning sedation by non-anesthesiologists, which have set the standard for sedation care in the United States.

There are four levels of sedation described by the ASA, ranging from minimal to general anesthesia, occurring on a continuum (see Table 1). In the pediatric population a deep level of sedation is often required in order to complete diagnostic procedures (Coté & Wilson, 2006; Gozal & Gozal, 2008). The ASA also established standards for the care of the sedated patient and an anesthesia risk score (see Table 2). Several studies on pediatric sedation have demonstrated that children, especially those under age six, are at risk of unintentionally moving

from the intended level of sedation to a deeper than intended level of sedation (Coté & Wilson, 2006). Therefore, providers are required to have the skills necessary to rescue patients from a deep level of sedation during the procedure (Coté & Wilson, 2006).

Sedation provider qualifications. The ability to rescue patients is a qualification described in all standards and regulations associated with sedation. However, the RN role during sedation, the qualifications to administer sedation or rescue a sedated patient are not addressed in the AAP standards (Coté & Wilson, 2006). In contrast, the most recent ASA statements on granting privileges for moderate sedation defines nonanesthesiologist sedation practitioners as "licensed physicians, dentists, or podiatrists who have not completed postgraduate training in anesthesiology but are specifically trained to personally administer or supervise the administration of moderate sedation" and supervised sedation practitioners as "a licensed registered nurse, advanced practice nurse or physician's assistant who is trained to administer medications and monitor patients during moderate sedation under the direct supervision of a nonanesthesiologist sedation practitioner or an anesthesiologist" (ASA, 2010, p. 3). In the latest ASA advisory statement on granting privileges for deep sedation, only non-anesthesiologist sedation practitioners and anesthesia professionals such as anesthesiologists and CRNAs are qualified to administer deep sedation (American Society of Anesthesiologists, 2010). The ASA advisory statements do not provide any information on current RN sedation practice, whether or not RNs are providing sedation care under direct supervision, the level of sedation, types of medications RNs deliver or the outcomes of RN sedation.

Sedation in Radiology

Children often receive sedation for procedures in radiology such as CT scans and MRI, which may require moderate to deep levels of sedation (Coté & Wilson, 2006). The radiology

environment presents many challenges to sedation providers such as difficulty in visualizing the patient during the procedure because the patient is placed inside an enclosed area and must remain still (American Society of Anesthesiologist Task Force on Anesthetic Care for Magnetic Resonance Imaging, 2009). Assessing level of responsiveness would also interfere with successful completion of the exam for which the patient was sedated (Coté & Wilson, 2006). Monitoring pulse and respiratory rate may be impeded during MRI procedures because of the incompatibility of equipment such as standard electrocardiogram machinery and leads in the presence of static and dynamic magnetic fields and radiofrequency energy emissions that pose safety hazards to the patient (American Society of Anesthesiologists Task Force on Anesthetic Care for Magnetic Resonance Imaging, 2009). The radiology environment presents several challenges to RN sedation providers. Prior studies have provided data from single locations, using sample sizes that are underpowered to detect adverse events. Samples in the tens of thousands are required to estimate adverse sedation events (Cravero et al., 2006).

RN Sedation Outcomes in Radiology

Bluemke and Breiter (2000) measured the effect of RNs on safety and effectiveness on sedation for MRI. The study sample of 4,761 sedated patients was obtained from a sedation database at Johns Hopkins Hospital from an eight-year period of data collection (Bluemke & Breiter, 2000). RNs followed a sedation protocol that included a pre-sedation history and review of systems conducted by a radiologist (Bluemke & Breiter, 2000). Patients were eligible for RN sedation if they were ASA I or II and met fasting guidelines (Bluemke & Breiter, 2000). Patients received sedative medications based on age and weight to induce conscious/moderate to deep sedation with monitoring during the procedure and recovery completed by the sedation RN with physician oversight (Bluemke & Breiter, 2000).

There were only 20 (0.42%) complications observed and no deaths reported (Bluemke & Breiter, 2000). Sedation failure rates were reported for each medication on the sedation protocol and ranged from a low of 4.8% for chloral hydrate to 13.1% for oral diazepam (Bluemke & Breiter, 2000). In this study the mean time to onset of sedation and the variability in the time to onset of sedation were measured to determine the predictability of sedation (Bluemke & Breiter, 2000). Comparisons of sedation times were made between a group of four sedation radiology RNs, radiology RNs who did not routinely perform sedation, and inpatient floor nurses who rarely provided sedation in radiology (Bluemke & Breiter, 2000). The group of four sedation radiology RNs had significantly shorter mean time to onset of sedation and demonstrated the least variability in sedation times when compared to the other RNs in the study (Bluemke & Breiter, 2000).

Lavoie, Vezina, Paul-Savoy, Cyr, and Lafrenaye (2012) described outcomes of a pediatric intensivist supervised RN led sedation program for painful and painless procedures using a retrospective review of records for a one-year period. Sedation RNs followed stringent patient selection criteria including: "ASA that had to be less than 3, no active upper respiratory tract infection, no acute neurologic condition, no high fever, and no snoring or sleep apnea" (Lavoie et al, 2012 p. 2). The RNs in this sedation program were expected to provide sedation and monitor patients during many types of procedures such as imaging, endoscopy, and bone marrow aspiration (Lavoie et al., 2012). In this study 555 procedures were performed on 448 children ranging in age from 3 weeks to 18 years; MRI was the most frequent (24%) followed by CT scan (10%) (Lavoie et al., 2012).

There were no deaths, aspirations, unexpected admissions or resuscitations reported. There was a 22% complication rate with 8% of these consisting of oxygen saturation less than

90%, bradycardia or hypotension more than 2 standard deviations below the normal for the age of the child, and a 5% rate of sedation failure due to patient agitation, inadequate sedation and failure to perform the procedure (Lavoie et al., 2012). The authors found that outcomes of this nurse led sedation program were similar to other programs reported in the literature (Lavoie et al., 2012).

RN Sedation Training

Reports of RN led sedation services provide general descriptions of "sedationist" responsibilities such as screening patients using predetermined criteria and monitoring the patient during the procedure (Sterni, Beck, Cole, Carlson, & Turmelle, 2008; Woodthorpe, Trigg, Gurney, & Sury, 2007). The qualifications and training of a nurse sedationist varies, as there are no standard certifications or qualifications that have been developed for RNs in this role. Woodthorpe, Trigg, Gurney and Sury, (2007) describe the use of tutorials by a pediatric anesthesiologist along with training including principles and hazards of sedation, identification of common sedation contraindications, and a preference for RNs with experience in the intensive care unit, emergency department, or post-operative recovery. The RNs in this sedation service also demonstrated airway management skills on anesthetized children in the operating room with reassessment of skills every three months (Woodthorpe et al., 2007).

There were 926 children scheduled for MRI with sedation: 5.5% were denied sedation due to various contraindications and 780 required sedation with a 95% success rate (Woodthorpe et al., 2007). Seven children experienced incidents described as "clinically significant" but none required admission to the hospital and four of them successfully completed the procedure (Woodthorpe et al., 2007). The study authors did not describe if RNs performed airway or other interventions during sedation, however they did opine that the skill and judgment

of the RN to refer children that would not be effectively sedated or were at risk for complications was a factor in making this RN sedation service successful and safe (Woodthorpe et al., 2007).

Sterni, Beck, Cole, Carlson and Turmelle, (2008), described a sedation team model overseen by anesthesiologists in which the sedation qualified RN completed the same training as sedation qualified non-anesthesia physicians. All sedation providers completed a 60 to 80 hour lecture based anesthesia airway management course and also completed mentored skills training; credentialing was approved at the discretion of the chief of anesthesia (Sterni et al., 2008). RN sedation providers were limited to using only oral or rectal chloral hydrate or midazolam and could administer pentobarbital for sedation via the intravenous or intramuscular route (Sterni et al., 2008). The RN sedation protocol limited RNs to sedate children with an ASA I score and no history of sedation or problems related to sedation (Sterni et al., 2008). There were no outcome data reported on the sedation team.

Limitations of RN Sedation Studies

While several studies have reported RN sedation outcomes such as adverse events, the sample sizes for most of these studies are inadequate to detect the low frequency of mortality and morbidity associated with sedation, which is one in many thousands (Cravero et al, 2006). Multicenter data on sedation and large sample sizes are necessary in order to estimate the incidence of rare sedation events (Cravero et al, 2006). Recently, studies completed by the PSRC, have used data from their large multi-center database to describe many aspects of pediatric sedation by non-anesthesia providers. A study using a total of 30,037 records from the PSRC found that 1,601 recorded some type of complication, which is a 5.3% incidence rate. Complications included one incident of aspiration and one cardiopulmonary resuscitation; both

ended with discharge of the patient in good condition after brief hospitalization (Cravero et al, 2006).

Although the PSRC collects data on sedation by many types of non-anesthesia providers including RNs, the results that have been reported for RNs have been aggregated with other providers. For example in a study by Couloures, Beach, Cravero, Monroe and Hertzog, (2011) complication rates depending on provider specialty were described but RN provider data were included in the "other" category that also included radiologists, dentists, surgeons, and pediatric resident/fellows, among others (Couloures et al., 2011). The present study will provide a description of practices by RNs that deliver and monitor sedation to children for diagnostic MRI, CT scan, and ultrasound, performed in the radiology department using data from the PSRC database.

Research Design and Methods

Research Question

What are the patient characteristics, medications delivered, monitoring practices and outcomes of sedation by RNs in children during diagnostic MRI, CT scan, and ultrasound procedures?

Methods

A descriptive research design using secondary data from the PSRC database was used to examine patient characteristics and sedation practices and outcomes by RNs on children in diagnostic radiology. Descriptive data on physician sedation providers has been previously reported using the PSRC database. These data are presented to provide a means for comparison. The PSRC has reported on several aspects of sedation care including adverse event rates, outcomes associated with sedative medications, and physiologic monitoring practices during

procedural sedation (Cravero et al., 2006; Cravero, Beach, Bilke, Gallagher, Hertzog, 2009; Couloures et al., 2011; Langhan et al., 2012). Data collected prospectively by member institutions is submitted to the database using a web based data collection tool (Cravero et al., 2006).

Data Collection

The PSRC consists of 35 member institutions that use a standard method of collecting pediatric sedation data and assures the integrity of data collection procedures through individual member institution primary investigators (Cravero et al., 2006). Sites are located in the Northeast, South, Mid-West and Western United States and there are sites in Israel, Canada and the Netherlands (Cravero et al., 2006). The institutions include children's hospitals, community hospitals and academic centers. Participating institutions obtain institutional review board approval to prospectively collect data on pediatric sedation and designate a primary investigator (Cravero et al., 2006). Each PSRC site selects a location of their choice within their institution to collect data via a web based data collection tool (Cravero et al., 2006). Data are entered via a Sybase database management system that presents one question per screen; subsequent questions are generated based on prior responses and are entered on standard answer sets using a series of check boxes with the ability to add free text if necessary (Cravero et al., 2006). The software validates the input as it is entered in order to decrease errors (Cravero et al., 2006). The study web site and data entry portal are secure and require authentication in order to input data (Cravero et al., 2006). All participating institutions and primary investigators are blinded to data submitted by other individual institutions (Cravero et al., 2006). Study authors are blinded to individual institution data in order to decrease the possibility that member institutions would

withhold adverse event data due to concerns related to their standing in the consortium or the institution's reputation (Cravero et al., 2006).

Primary investigators are required to perform periodic inventories of data submissions. More than 90% of cases must be reported and primary investigators must submit a separate count of sedations performed in the study location and compare it to the actual cases submitted to the PSRC database. This assures that data are not selectively submitted. Audits are performed on 5% of the submitted cases to ensure data integrity (Couloures et al., 2011). Each site selects the locations within their institution that contribute to the database.

Protection of Human Subjects

This study was submitted to the University of Virginia institutional review board and was exempt under Health and Human Services regulation 4(45 CFR 46.101(b)(4)). PSRC data are de-identified to meet the Health Insurance Portability and Accountability Act and encrypted when transferred from the member institution to assure data security (Cravero et al., 2006).

Data Management

An encrypted data file was obtained from the PSRC consisting of one record for each case meeting the study inclusion criteria as listed in Table 3. The data file was downloaded into a password-protected directory on a University of Virginia UNIX system. Data were examined, checked, and cleaned of errors. A data set for analysis was prepared using Statistical Analysis System (SAS, Inc., Cary, NC, USA), to translate data into a file for analysis. Data file cases and variables were screened and evaluated for patterns of missing data. There were two variables with greater than 5% missing data, however these variables were not considered in this study because they were added to the PSRC web based data collection tool after data collection started, so the cases were retained.

Sample

A detailed description of the study sample size and selection criteria is provided Table 3. Inclusion criteria were: children up to and including the age of 14 years and sedated for diagnostic MRI, CT scan, or ultrasound from January 2005 to September 2007. Cases in which only RNs monitored patients and delivered medications were included. Study exclusion criteria were children over the age of 14 years and 1 month; children that were either monitored or received medications by an RN and any other sedation provider; cases in which the ASA score was missing and cases in which interventional radiologic studies were completed and children receiving local anesthetics.

Data Elements

The data elements collected by the PSRC were established by the consortium using AAP, ASA and American College of Emergency Physician guidelines that have been previously outlined; a review of the literature and the consensus of the consortium membership (Cravero et al., 2006). Data collection elements consist of three major categories: 1) sample characteristics, 2) role of sedation provider, and 3) procedure characteristics. Examples of the variables associated with each of these are listed below and further details are provided on Tables 4 and 5. An exhaustive list of the PSRC study variables is available at http://an.hitchcock.org/PediatricSedationRC/.

Sample characteristics. The data collected for this study included age, weight, sex, ASA status, primary diagnosis (that is, the primary indication for the procedure being performed) and coexisting diagnosis (see Table 4) (Cravero et al., 2006).

Sedation provider information. Data collected on cases with RNs delivering and monitoring sedation are listed in Table 5 and includes the provider responsible for oversight of the sedation.

The provider responsible for oversight of sedation category only includes providers responsible for the sedation case but does not mean the provider had contact with the patient (Cravero et al., 2006). The role of sedation providers is not mutually exclusive. For example it is possible for different providers to monitor the same sedation case. However, this study sample only included cases in which an RN was the only provider delivering and monitoring sedation.

Diagnostic radiology procedure characteristics. Data collected about the procedure includes the procedure performed, medications and monitoring equipment used, planned and actual depth of sedation achieved, and complications (see Table 5) (Cravero et al., 2006).

Results

The sample of 42,392 radiology procedures for MRI, CT scan and ultrasound had 12,564 (29.64%) cases where patients received medications and were monitored only by RNs during sedation. Deep sedation was planned for 1,738 (13.83%) of the cases and achieved in 1,721 (13.70%). Moderate sedation was achieved by RNs in 10,455 cases (82.84%). ASA scores, which represent anesthesia risk, were compared to a sample of 30,037 sedation cases from the PSRC database, reported by Cravero et.al, (2006) in which physicians were the providers responsible for sedation. ASA scores for the RN alone sample were ASA I (37.82%) and ASA II (50.80%); these were similar to the physician provider group. ASA scores are presented in Figure 1. The ASA III scores for the RN group were 10.92% and 11.60% for the physician group. The similarity in ASA III scores is notable, as sedation guidelines recommend anesthesia or other subspecialty consultation due to increasing sedation risk for these patients (Coté & Wilson, 2006).

Sedation Monitoring Equipment Use

Monitors used by RN providers during diagnostic radiology procedures are presented in Figure 2. Langhan et al. (2012) reported monitor use in 17,033 radiology cases and 50,094 MRI cases; the results from both samples are presented on Figure 2 for comparison. Langhan et al. (2012) reported electrocardiogram use of 67.00% for MRI, 55.00% for radiology procedures but it was 14.62% in the RN provider sample. RN sedation providers also used capnography (Etco2) monitoring in 26.00% of cases, while the MRI sample reported by Langhan et al., (2012) used Etco2 monitoring in MRI for 77.00% of cases.

Adverse Events

In the sample reported here, there were no deaths, cardiac arrests, intubations or aspirations reported. Cases with only RN sedation providers had 726 (5.78%) adverse events with the adverse event category respiratory complications being the most common (n = 297; 2.36%) (see Table 5). However, the lack of published descriptive statistical data on RN sedation adverse events in a large sample of pediatric patients makes it problematic to evaluate the results of this study. Thus, comparison data on adverse events from a sample of 30,037 children published by Cravero et al. (2006) using PSRC data are reported per 10,000 cases in Figures 3 and 4.

The data from Cravero et al. (2006) included physician and advance practice sedation providers; patients underwent 12 categories of procedures including radiologic. When adverse events were examined in the RN alone provider sample, the most common type of adverse event requiring intervention was prolonged sedation with a rate of 42.2/10,000; Cravero et al. (2006) reported a 22.3/10,000 rate of prolonged sedation. In the Cravero et al. (2006) physician provider sample, the most common adverse event type was incomplete procedure, with an 88/10,000 rate while in the RN alone sample the rate was 0.7/10,000. Adverse event types that may not require

intervention such as desaturation (defined as an oxygen saturation below baseline for greater than 30 seconds) was the most common type of adverse event in both samples. Vomiting in a non-gastrointestinal procedure was more common in the RN sample than in the comparison group; and was the second most common type of adverse event that may not require intervention these results are presented per 10,000 (see Figure 4).

Medication Use

In the present study, 13.70% of the sample was deeply sedated. RNs administered only one medication 6,865 times (54.64%) of the sample. Medication use by RNs (see Figure 5) illustrates the wide variety of medications used for sedation. Fentanyl, an opioid analgesic, was administered in 9.22% of RN sedation cases in comparison to 8.00% reported by Cravero et al., (2006). Fentanyl was used by the RN provider sample in combination with midazolam and in combination with pentobarbital and midazolam. Ketamine and propofol were administered in the RN sedation sample 188 (1.50%) and 23 (0.18%) times respectively. In comparison, both these medications were administered more often 13.60% (n = 4,075) of cases and 50.10% (n = 15,059) of cases respectively in the sample reported by Cravero et al. (2006). The two most common medications administered by RNs were pentobarbital (48.24%) and Chloral hydrate (43. 36%) of the RN sample. More than one medication was delivered during 45.36% of cases sedated by RNs.

Discussion

Anesthesia Sedation Risk

Patients sedated by RNs had similar ASA risk scores as another large sample of patients sedated by physician and advanced practice providers (Cravero et al., 2006). ASA risk score has been used by some organizations as a method to identify patients at a higher risk for sedation

complications and to restrict RN sedation practice to patients with ASA scores of I or II (Lavoie et al., 2012). However, ASA III scores for this sample were similar to the physician provided sedation group reported by Cravero et al., (2006). This finding is important because it is unclear if RNs credentialed to provide sedation are completing training that prepares them to care for a patients with an ASA III risk score.

However, pediatric critical care experienced RNs do have the training and experience to care for patients who are severely ill. Pediatric Intensive Care Unit (PICU) RNs are required to have skills in drug administration, resuscitation, respiratory care, and the recognition and interpretation of various physiologic measures (Committee on Hospital Care, 1993). Thus, the PICU RN might be better equipped with the skills and experience to deliver sedation to children up to and including ASA III than a general pediatric or radiology nurse that receives training and demonstrates competency only in sedation care but may not have the other skills and experience to manage underlying coexisting conditions.

Adverse Events

There are two types of adverse sedation events noted in this study: adverse events that may not require intervention such as desaturations that may be transient and not require treatment. The second type are unexpected adverse events that may require the RN to intervene, such as suctioning in order to manage patient secretions or prolonged sedation requiring the RN to extend the recovery period. It is notable that in this sample the most common unanticipated adverse event for the RN provider was prolonged sedation, which is often associated with the medications used for the procedure. However, it is not clear from these data how prolonged the sedation was.

Prolonged sedation in children after a radiologic procedure has been previously reported by Malviya, Voepel-Lewis, Prochaska and Tait (2000) in their study of 376 children sedated by RNs for MRI and CT scan. They found that despite using the recommended sedation discharge criteria of returning to baseline vital signs, level of consciousness close to their baseline, and the ability to maintain a patent airway, 53% of children were asleep during their trip home from the hospital and 31% were asleep for at least six hours after discharge from sedation for diagnostic MRI or CT scan (Malviva et al., 2000). Furthermore, motor imbalance was the most frequently reported side effect reported by parents, in one case persisting up to the day after sedation. In the study, 66% of infants less than 12 months old that had gross motor imbalance with the effect lasting for more than 6 hours (Malviya et al., 2000). Thus, it is possible that prolonged sedation may not be wholly evaluated at discharge and may require follow-up the day after sedation to obtain an accurate measure of the frequency of this adverse event. This may be accomplished by including a follow-up call the day after the procedure. Some sedation services may already have this process in place as part of their performance improvement system. However, it is unknown if the questions asked are eliciting information from parents regarding adverse events after discharge that do not require treatment. Similarly, Malviya and colleagues (2000) reported nausea and vomiting in 13% of children after discharge from procedural sedation that resolved without treatment within six hours.

In this study sample, vomiting was the second most common sedation adverse event that may not require intervention by the RN, and was almost two times more frequent than in the physician sedation provider comparison group (Cravero et al., 2006). The increased frequency of vomiting with sedation by the RN alone group is likely related to the medications used by

RNs. The most common medications administered either alone or in combination were pentobarbital, chloralhydrate and midazolam in this study sample.

RN Sedation Practices

Sedative Medication Use. Sedative medications are ordered by physicians or advance practice nurses. RNs often use preexisting protocols that delineate the drugs, routes, frequency, dosing, and indications for use by the sedating RN (Lavoie et al., 2012; Gozal, Drenger, Levin, Kadari & Gozal, 2004). For example Chloral hydrate can be given orally or rectally and is frequently used for MRI and CT scans because of its effectiveness and safety profile (Mason, Sanborn, Zurakowski, Carian, Connor, Fontaine & Burrows, 2004). However, it has a bitter taste that children may refuse to swallow or regurgitate, it has no reversal agent, can cause respiratory depression and prolonged sedation in some patients (Mason et al., 2004). In this study, chloral hydrate was the second most commonly administered medication by an RN. In the case of chloral hydrate, its use by RNs has persisted, despite evidence that other medications such as pentobarbital may be as effective and have fewer side effects. Pentobarbital was the most common sedative administered by RNs in this study sample, but it is not clear how or if RNs had a choice as to the sedative medication they administered.

Chloral hydrate alone or in combination with other medications such as diphenhydramine and meperidine has been compared with other sedatives such as oral midazolam and oral pentobarbital in small studies (Costa, Costa, Brasileiro, Bendo, Viegas & Paiva; 2012; Mason et al., 2004). Most studies concerning chloral hydrate include samples of fewer than 1,000 patients with dosing variations (Costa et al., 2012). Chloral hydrate has been associated with adverse events ranging from deaths to vomiting (Costa et al., 2012). Adverse events were examined by Malviya et al. (2000) after discharge from procedural sedation. Chloral hydrate was the most

common drug associated with motor imbalance and agitation; plus there were three reported episodes of prolonged sedation requiring an emergency department visit.

In this study RN use of fentanyl (9.22%), an opioid with analgesic properties, is of note because this study only included diagnostic procedures (MRI, CT scan and ultrasound) that are usually considered painless. Fentanyl use by RNs was higher compared to other providers performing 12 possible categories of procedures (8%) (Cravero et al., 2006). Conversely propofol was the most common medication delivered by other providers and was more common than RN use of propofol (Cravero, 2006). The medication administration patterns in this RN diagnostic radiology sample indicate that there is variation in RN sedation practices for diagnostic radiology when compared to practices by other sedation providers. Current training strategies emphasize a generalized approach at the organizational level rather than determining specific sedation practices by specialty and using that data to develop specialty specific training. However a generalized approach may fail to consider specialty specific sedation practices and the associated education needs of sedation providers. It is also unclear how prescribing decisions are made either by individual physicians or sedation committees that develop medication protocols. Additionally, many times, RNs administered combinations of medications that make each medication's effects less predictable.

The use of more than one medication is a risk factor for adverse events that has been identified in multiple studies (Lavoie et al., 2012; Coté et al., 2000). Numerous sedative and analgesic medications are available for use in procedural sedation and these can be administered in various combinations. However, it is difficult to study adverse events of combined sedative medications. One barrier is that a large sample of patients is necessary to collect enough data to

determine which medication combinations provide the desired sedative effects with the fewest adverse events.

Sedation Level Due to the risks associated with sedation, the Joint Commission and the ASA have established sedation standards including credentialing requirements all sedation providers must meet (Joint Commission International, 2011; ASA, 2002). These sedation standards have focused on physician and advanced practice providers and offered limited guidance to RNs and their role in delivering sedation. Nursing professional standards and boards of nursing offer conflicting guidance on RN sedation practice. An in depth review of nursing sedation regulations in the United States is reported in a different manuscript (Crego, 2013)**.** This descriptive study provides data on actual RN sedation practice that illustrates the disparity between RN sedation practice and RN sedation regulation.

Most sedation standards address RNs providing minimal to moderate sedation but in this sample RNs often planned and provided deep sedation to children undergoing diagnostic radiological procedures. For example, the ASA published a statement that only nonanesthesia physicians may be credentialed to provide deep sedation and may not delegate or supervise the administration or monitoring of deep sedation (ASA, 2012). Few boards of nursing and professional standards address deep sedation by RNs or have incorporated standards from organizations such as the ASA that restrict RNs from administering propofol and other anesthetic medications into their position statements. However, this study found that 13.7% of RNs in the sample provided deep sedation, demonstrating that RNs are already providing care that conflicts with recommendations by the ASA and exceeds the scope of practice set by some state boards of nursing (Davidson, Bloomberg, & Burnell, 2007).

Limitations

The study sample was obtained using data collected by PSRC member institutions that self select and may represent organizations with highly organized sedation systems, with more experienced providers and sedation expertise than non-member institutions. Sedation outcomes in PSRC institutions may represent best practices rather than usual pediatric sedation outcomes. Although the PSRC includes data on provider types, characteristics of the provider are unknown, such as education level of RNs, clinical experience of the provider, or any specific sedation training requirements.

Conclusions

Sedation care is part of a complex system involving individual patient risk factors, sedation provider competency, medication choice and monitoring of the patient throughout and after the procedure is completed. This descriptive study indicates that there are several gaps in knowledge of sedation care by RNs in diagnostic radiology. Patients sedated by RNs had similar anesthesia risk scores to those sedated by physician and advanced practice providers, including ASA III patients. However, most credentialing for RN sedation care providers assume the patient is at a low anesthesia risk. Sedation standards do not require RN sedation providers with training and experience in caring for severely ill patients, instead they must be competent to rescue the patient from deep sedation or general anesthesia. However, the specific skills necessary for RNs to meet the rescue qualifications are not currently delineated and may also be dependent on the procedure length and location.

This study includes descriptions of current practices by RNs delivering and monitoring sedation. RNs in this study provided a deep level of sedation, despite restrictions on this practice by some professional organizations and regulatory bodies including state boards of nursing. The PSRC database excludes information on the location where sedation occurred so it is not possible

to determine if RNs performing deep sedation were doing so outside their scope of practice, however this result may indicate that RN provided deep sedation may be a frequent occurrence in the pediatric population, despite the lack of uniform deep sedation standards. Adverse events in sedation may be closely related to the medications used, the type of procedure the child was sedated for and the monitoring completed throughout and after discharge. However, research on RN provided sedation has been done in single sites with small sample sizes that are insufficiently powered to provide adequate information on adverse events or to compare outcomes of RN sedation to other providers.

Future Research

Although only cases in which sedation was monitored or delivered by RNs were included in this study, sedation involves other providers such as anesthesiologists who maintain responsibility for sedation cases even if they do not directly involve contact with the patient or involve more than one type of sedation provider during the procedure. Further research comparing sedation practices and outcomes by different types of providers is necessary to understand the significance of differences in patient risk factors, sedation practices, and the type of sedation provider on sedation outcomes. Differences in how sedation services are managed at the organizational level is also an area in which research is needed to determine how system level factors affect sedation outcomes. In addition, research is needed to determine outcomes of evidence based sedation education programs that considers the particulars of sedation by the type of procedure, location or specialty.

Table 1
American Society of Anesthesiologists Sedation Level Definitions, sedation equipment and monitoring standards and Monitoring Parameters

Sedation Level Definition[1]	Equipment and Monitoring Standards
Minimal Sedation (anxiolysis) Level A drug induced state in which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired ventilation and cardiovascular function are usually maintained.	▪ Pulse oximetry ▪ Continuous heart rate measurement ▪ Blood pressure measurement at regular intervals Continuous monitoring of respiratory frequency and pulmonary ventilation
	Monitoring Parameters
Moderate Sedation Level A drug-induced depression of consciousness in which patients respond purposefully to verbal commands alone or when accompanied by light tactile stimulation. The patient maintains their airway without intervention and spontaneous ventilation is adequate. Cardiovascular function usually is maintained.	**Pre-procedure** ▪ Assessment with a history and physical, ▪ Pre-sedation assessment (usually including the ASA risk score) and an anesthesia plan. ▪ Reassessment immediately prior to administration of sedation
Deep Sedation Level A drug-induced depression of consciousness in which patients cannot be aroused easily; respond purposefully following repeated or painful stimulation. The patient maintains independent ventilatory function that may be impaired. Patients may require assistance to maintain airway patency, spontaneous ventilation may be inadequate. Cardiovascular function usually is maintained.	**Intra-Procedure** ▪ Measurement and assessment of the patient's physiologic status from administration of the sedative until recovery ▪ Vital signs monitored continuously recorded every 5-15 minutes ▪ Continuous assessment of patient's level of sedation ▪ Persons monitoring the patient must have no other responsibility during this time frame
General Anesthesia Level A drug-induced loss of consciousness in which patients are not arousable, even by painful stimulation. Ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, positive pressure ventilation may be required due to depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.	**Post-procedure** ▪ Continuous reassessment until patient reaches baseline parameters ▪ Patient returns to baseline physiologic and status assessed by using standardized score. ▪ Patient is discharged when criteria such as ability to tolerate liquids and physiologic measures return to baseline

[1]Adapted from American Society of Anesthesiologist Task Force on Sedation and Analgesia by Non-Anesthesiologists. (2002). Practice guidelines for sedation and analgesia by non-anesthesiologists. *Anesthesiology,* 96(4), 1004-1017.

Table 2
American Society of Anesthesiologists physical status classification

Physical Status Classification
Class I - Normally healthy patient
Class II – Patient with mild systemic disease
Class III – Patient with severe systemic disease
Class IV – Patient with a severe systemic disease that is a constant threat to life
Class V – A moribund patient who is not expected to survive without the operation
Class IE, IIE, IIIE, IVE – An "E" Suffix can be added to each ASA class to indicate an emergency surgery /procedure

[1]Adapted from American Society of Anesthesiologist Task Force on Sedation and Analgesia by Non-Anesthesiologists. (2002). Practice guidelines for sedation and analgesia by non-anesthesiologists. *Anesthesiology,* 96(4), 1004-1017.

Table 3
Sample Inclusion criteria, number of excluded case and sample size

Sample Inclusion	Excluded Cases	Sample Size
PSRC Data file • January 2005 to September 2007 • Children up to and including 14 years • Sedated by any provider • Diagnostic MRI, CT or Ultrasound	None	42,392
Only cases with RNs delivering & monitoring sedation	29,656	12,736
Only cases with an ASA score	130	12,606
Only cases in which one or more of the following medications was used Non-Opioids: • Ativan, chloralhydrate, dexmedetomidine, DPT, midazolam, pentobarbital, thiopental, valium Anesthetic Agents: • etomidate, ketamine, methohexital, propofol Opioids: • alfentanil, fentanyl, meperidine, morphine, nalbuphine, remifentanil Reversal Agents: • caffeine, flumazenil, nalbuphine, nalmefene, naloxone Anticholinergics: • Atropine and glycoprrolate Inhaled medications: • Albuterol and racemic epinephrine	42	12,564
Study Sample	29,828	12,564

Table 4
Characteristics of pediatric patient cases that were monitored and received medications for sedation by an RN in diagnostic radiology

Variable	*N*	Descriptive Statistics
Sample Characteristics		
Weight in kilograms	12,564	Mean 15.08 Standard Deviation 9.5 Range 0.5 - 236
Age in months	12,564	Mean 34.9 Standard Deviation 32.2 Range 0 - 168
	N	*Percent*
Age in Categories		
Infant (0-12 month)	3,687	29.35
Toddler (12- 24 month)	2,562	20.39
Early Childhood (2-5 years)	4,410	35.10
Middle Childhood (6-11 years)	1,690	13.45
Teen (12-14 years)	215	1.71
Sex		
Male	6,966	55.44
Female	5,584	44.44
Missing	14	0.11
Primary Diagnosis		
Cardiovascular	168	1.34
Craniofacial Abnormalities	465	3.7
Gastrointestinal	213	1.7
Metabolic/Genetics (includes obesity)	359	2.86
Neurological	7,369	58.65
Prematurity Related	56	0.45
Respiratory – lower airway	127	1.01
Respiratory- Upper airway	140	1.11
Coexisting Diagnosis		
Cardiovascular	518	4.12
Craniofacial Abnormalities	79	0.63
Gastrointestinal	1003	7.98
Metabolic/Genetics (includes obesity)	425	3.38
Neurological	1,843	14.67
Prematurity Related	333	2.65
Respiratory – lower airway	1,195	9.51
Respiratory- Upper airway	2,491	19.83
Number of Coexisting Conditions/Case		
None	7,086	56.40
One	3,791	30.17
Greater than 1 coexisting condition	1,687	13.43

Table 5
Description of providers responsible for sedation and characteristics of diagnostic radiology procedures in a sample of cases of sedation monitored and delivered by an RN

Variable	*N*	Percent
Sedation Provider Information		
[1] Provider Ultimately Responsible for Sedation		
Anesthesiologists	4,339	34.54
Pediatrician	2,909	23.15
APRN/PNP/PA	2,299	18.3
Intensivist	1,404	11.17
Emergency Medicine Physician	1,264	10.06
Radiologist	190	1.51
Other	108	0.86
Fellowship Level	28	0.22
RN	18	0.14
House Staff	3	0.02
Missing Data	2	0.02
CRNA	0	0
RN alone Monitoring and delivering sedation	12,564	100
Diagnostic Radiology Procedure Characteristics		
[2]Diagnostic Radiologic Procedures		
MRI Scan	8,802	70.06
CT Scan	3,861	30.73
Ultrasound	61	0.49
Depth of Sedation Planned		
Minimal	364	2.9
Moderate	10,455	83.21
Deep	1,738	13.83
General Anesthesia	7	0.06
Depth of Sedation Achieved		
Minimal	429	3.41
Moderate	10,408	82.84
Deep	1,721	13.7
General Anesthesia	6	0.05
[3]Total Adverse Events	726	5.78
[4]Adverse Events by Category		
Respiratory Complications	297	2.36
Neurological Complications	261	2.08
Other Complications	221	2.36
Cardiovascular Complications	34	0.27
Emergent Complications	19	0.15
Non-Sedative Medication Used		
Glycopyrrolate	279	2.22
Albuterol	146	1.167

Atropine	109	0.87
Flumazenil	1	0.008
Naloxone	1	0.008
Number of Medications per Case		
1 medication	6,865	54.64
2 medications	5,209	41.46
3 medications	484	3.85
4 medications	6	0.05
Most Common Combination of Medications		
Midazolam and pentobarbital		
Pentobarbital and fentanyl	3,572	62.68
Dexmedetomidine and midazolam	716	12.56
Midazolam, pentobarbital, fentanyl	478	8.39
Chloralhydrate and Midazolam	401	7.04
Midazolam and ketamine	232	4.07
	149	2.61

[1] The provider responsible reflects the provider responsible for the sedation case but does not mean the provider had contact with the patient
[2] Cases may have more than one diagnostic radiology procedure
[3] Adverse Events are defined as any case with reported complication
[4] Cases may contain more than one category of adverse events

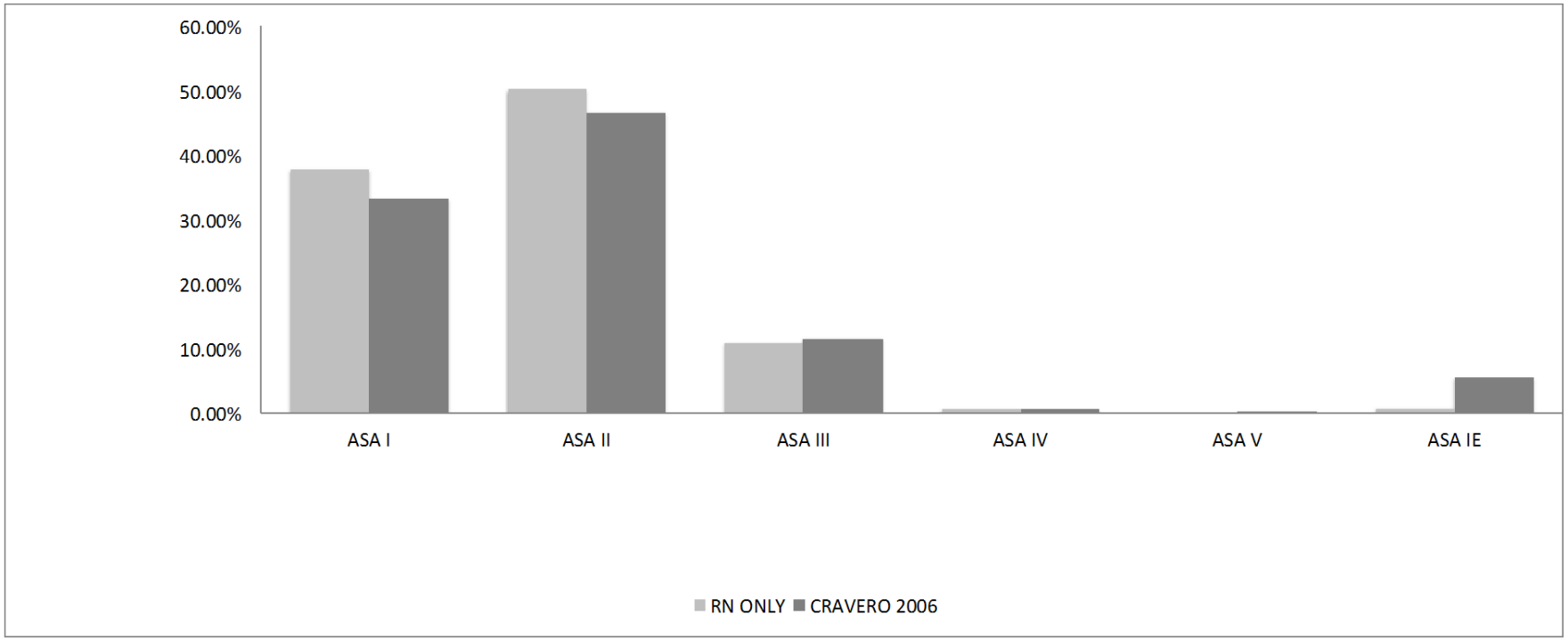

Figure 1 Comparison between nurse and other sedation providers ASA scores
[1]ASA scores for sedation delivered and monitored by nurses were obtained from a sample of 12,564 cases. Comparison data were obtained from the Pediatric Sedation Research Consortium sample of physicians and advanced practice nurses on 30,037 sedation cases reported by Cravero et al.,(2006).

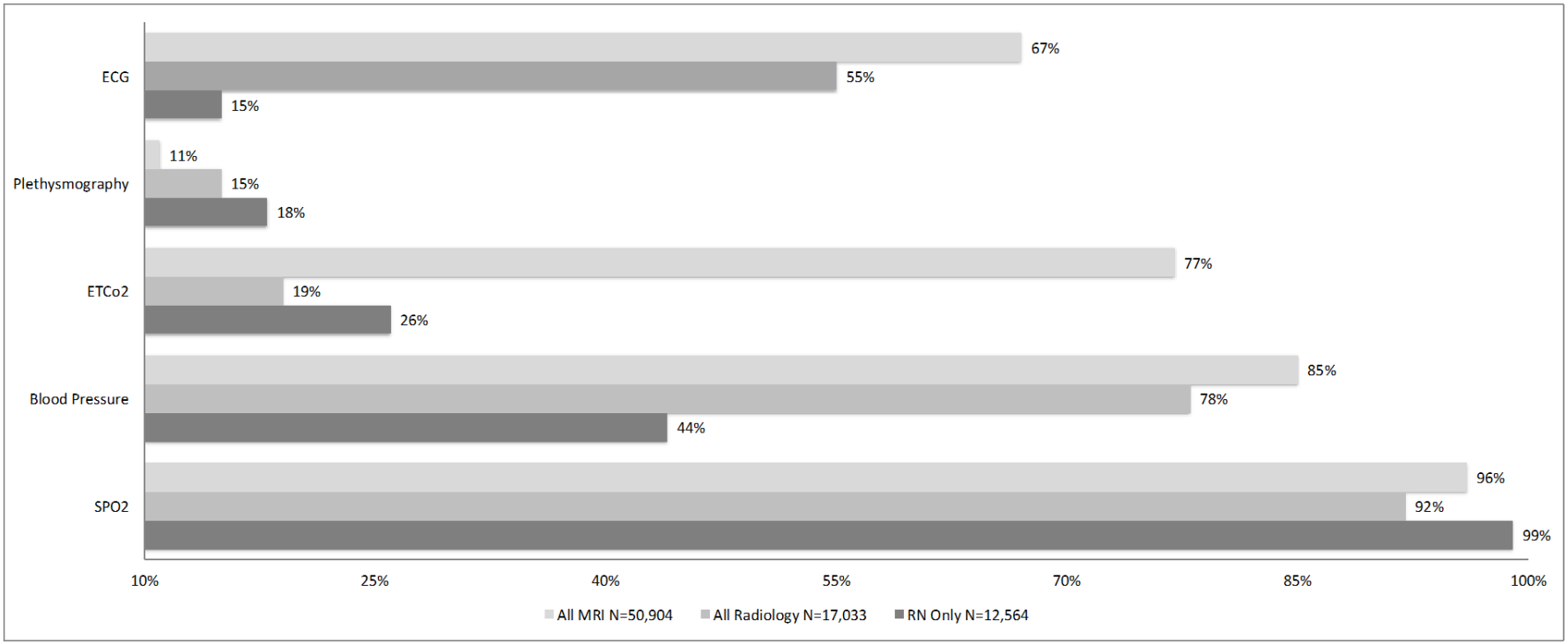

Figure 2 Comparison of monitoring equipment use for sedation cases by physician and nurse providers in diagnostic radiology
[1]Monitoring data for nurse delivered sedation includes MRI, CT scan and ultrasound in a sample of 12,564 cases. Comparison physician monitoring data was obtained from the Pediatric Sedation Research Consortium sample of 50,904 sedation cases in MRI and other radiology procedures reported by Langhan et al., (2012).

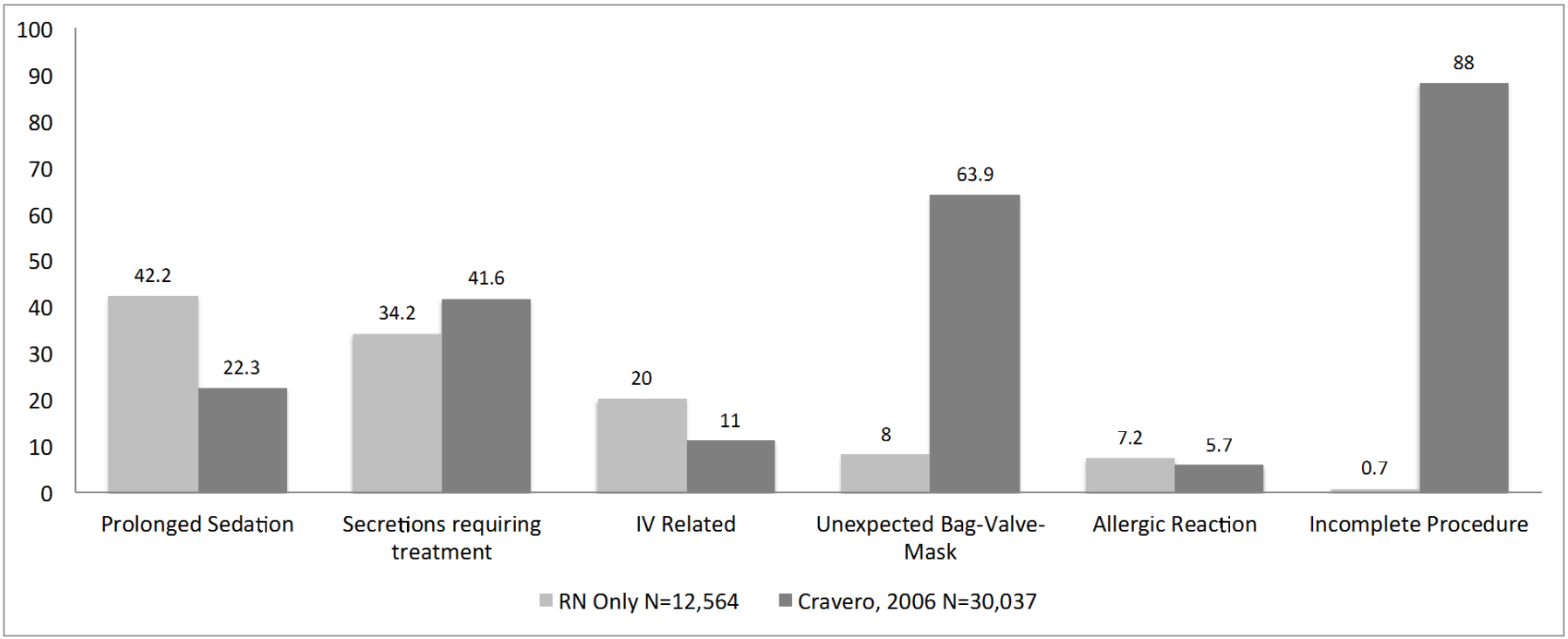

Figure 3 Comparison of unexpected adverse events per 10, 000 between nurse and other sedation providers
[1] Incomplete procedures are due to inadequate sedation. Unexpected adverse events for sedation delivered and monitored by nurses were obtained from a sample of 12,564 cases. Comparison data of unexpected events was obtained from the Pediatric Sedation Research Consortium sample of physicians and advanced practice nurses on 30,037 sedation cases reported by Cravero et al.,(2006).

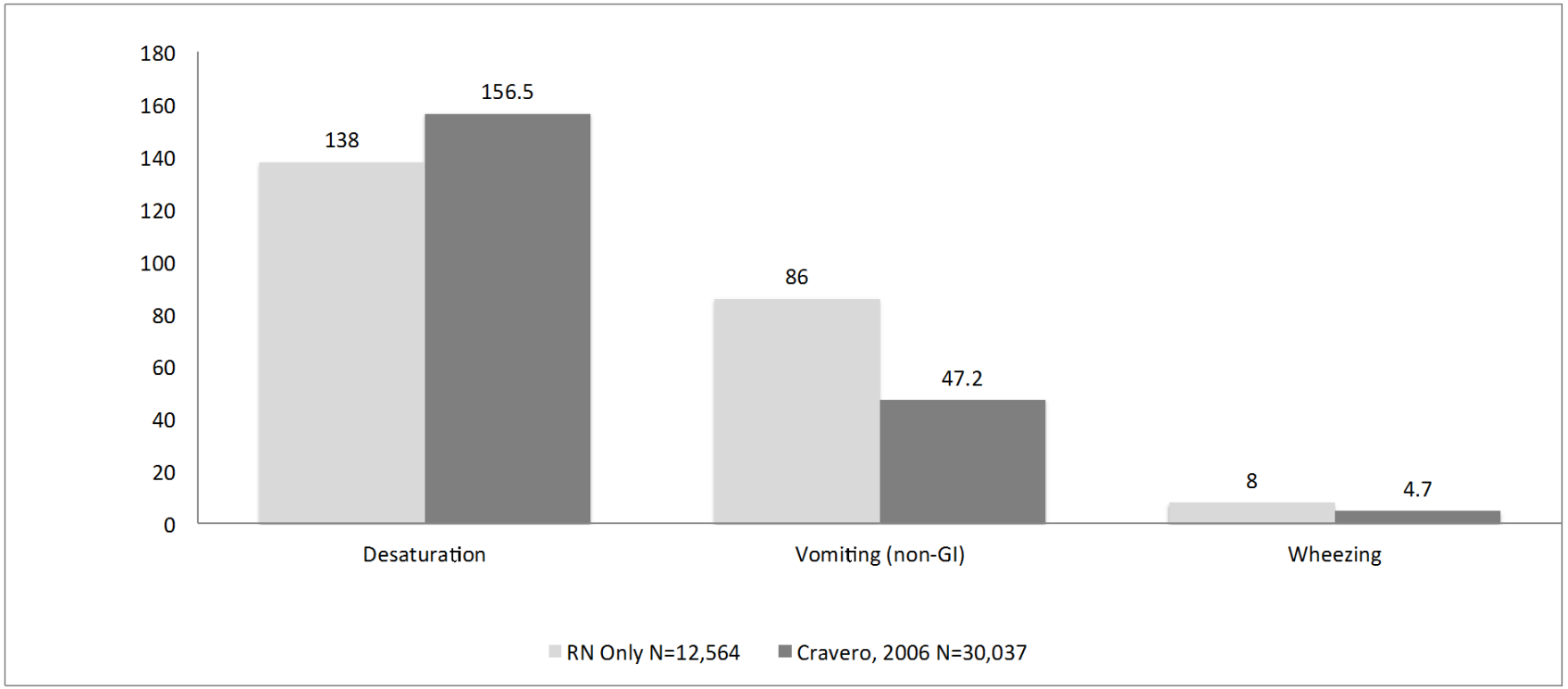

Figure 4 Frequency of nurse and other sedation provider adverse events that may not require intervention
[1] Adverse events for sedation delivered and monitored by nurses were obtained from a sample of 12,564 cases. Comparison data of adverse events was obtained from the Pediatric Sedation Research Consortium sample of physicians and advanced practice nurses on 30,037 sedation cases reported by Cravero et al., (2006).

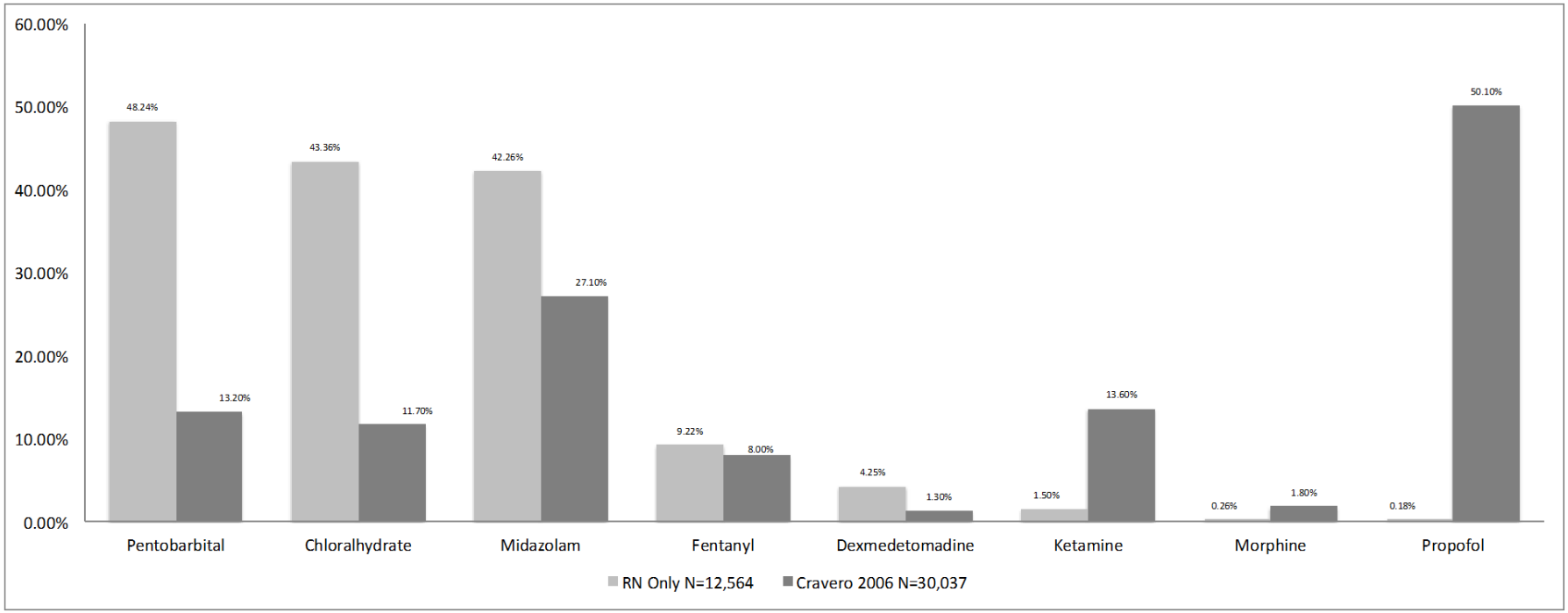

Figure 5 Medication use by nurses and other sedation providers.
[1]Medication use for sedation delivered and monitored by nurses was obtained from a sample of 12,564 cases. Comparison data was obtained from the Pediatric Sedation Research Consortium, a sample of physicians and advanced practice nurses on 30,037 sedation cases reported by Cravero et.al, (2006).

References

American Association of Nurse Anesthetists. (2010). Considerations for Policy Development Number 42 Registered Nurses Engaged in the Administration of Sedation and Analgesia. Retrieved February 23, 2013, from http://www.aana.com/aboutus/Pages/default.aspx

American Nurses Association. (2008). Procedural Sedation Consensus Statement. Retrieved June 28, 2012, from http://www.nursingworld.org/MainMenuCategories/Policy-Advocacy/Positions-and-Resolutions/ANAPositionStatements/Position-Statements-Alphabetically/Procedural-Sedation-Consensus-Statement.html

American Society of Anesthesiologists. (2010). Advisory on Granting Privileges for Deep Sedation to Non-Anesthesiologist Sedation Practitioners. Retrieved August 25, 2012, from http://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx

American Society of Anesthesiologists. (2011). Statement on Granting Privileges for Administration of Moderate Sedation to Practitioners Who are not Anesthesia Professionals. Retrieved August 25, 2012, from http://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx

American Society of Anesthesiologists. (2012). Statement on Granting Privileges to Nonanesthesiologists Physicians for Personally Administering or Supervising Deep Sedation. Retrieved February 1, 2013, from http://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx

American Society of Anesthesiologists Task Force on Anesthetic Care for Magnetic Resonance Imaging. (2009). Practice advisory on anesthetic care for magnetic resonance imaging: a report by the Society of Anesthesiologists Task Force on Anesthetic Care for Magnetic Resonance Imaging. *Anesthesiology*, *110*(3), 459-479. doi: 10.1097/ALN.0b013e31818f9206

American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. (2002). Practice guidelines for sedation and analgesia by non-anesthesiologists. *Anesthesiology*, *96*(4), 1004-1017.

Beebe, D. S., Tran, P., Bragg, M., Stillman, A., Truwitt, C., & Belani, K. G. (2000). Trained nurses can provide safe and effective sedation for MRI in pediatric patients. *Canadian Journal of Anesthesia*, *47*(3), 205 - 210.

Bluemke, D. A., & Breiter, S. N. (2000). Sedation procedures in MR imaging: safety, effectiveness, and nursing effect on examinations. *Radiology, 216*(3), 645-652.

Committee on Hospital Care, & Pediatric Section of the Society of Critical Care Medicine. (1993). Guidelines and Levels of Care for Pediatric Intensive Care Units. *Pediatrics, 92*(1), 166-175.

Costa, L. R., Costa, P. S., Brasileiro, S. V., Bendo, C. B., Viegas, C. M., & Paiva, S. M. (2012). Post-discharge adverse events following pediatric sedation with high doses of oral medication. *Journal of Pediatrics, 160*(5), 807-813. doi: 10.1016/j.jpeds.2011.10.025

Coté, C., & Wilson, S. (2006). Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures: an update. [Practice Guideline]. *Pediatrics, 118*(6), 2587-2602. doi: 10.1542/peds.2006-2780

Couloures, K. G., Beach, M., Cravero, J. P., Monroe, K. K., & Hertzog, J. H. (2011). Impact of provider specialty on pediatric procedural sedation complication rates. *Pediatrics, 127*(5), e1154-1160. doi: 10.1542/peds.2010-2960

Cravero, J. P., Beach, M. L., Blike, G. T., Gallagher, S. M., & Hertzog, J. H. (2009). The incidence and nature of adverse events during pediatric sedation/anesthesia with propofol for procedures outside the operating room: a report from the Pediatric Sedation Research Consortium. *Anesthesia and Analgesia, 108*(3), 795-804. doi: 10.1213/ane.0b013e31818fc334

Cravero, J. P., Blike, G. T., Beach, M., Gallagher, S. M., Hertzog, J. H., Havidich, J. E., & Gelman, B. (2006). Incidence and nature of adverse events during pediatric sedation/anesthesia for procedures outside the operating room: report from the Pediatric Sedation Research Consortium. *Pediatrics, 118*(3), 1087-1096. doi: 10.1542/peds.2006-0313

Crego, N. (2013). Procedural Sedation in the United States: A Review of Nursing Regulation. Unpublished manuscript.

Godwin, S. A., Caro, D. A., Wolf, S. J., Jagoda, A. S., Charles, R., Marett, B. E., & Moore, J. (2005). Clinical policy: procedural sedation and analgesia in the emergency department. *Annals of Emergency Medicine*, 45(2), 177-196. doi: 10.1016/j.annemergmed.2004.11.002

Gozal, D., Drenger, B., Levin, P. D., Kadari, A., & Gozal, Y. (2004). A pediatric sedation/anesthesia program with dedicated care by anesthesiologists and nurses for procedures outside the operating room. *Journal of Pediatrics, 145*(1), 47-52. doi: 10.1016/j.jpeds.2004.01.044

Gozal, D., & Gozal, Y. (2008). Pediatric sedation/anesthesia outside the operating room. Current *Opinion in Anaesthesiology, 21*(4), 494-498. doi: 10.1097/ACO.0b013e3283079b6c

Havidich, J. E., & Cravero, J. P. (2012). The current status of procedural sedation for pediatric patients in out-of-operating room locations. *Current Opinion in Anaesthesiology, 25*(4), 453-460. doi: 10.1097/ACO.0b013e32835562d8

Jest, A. D., & Tonge, A. (2011). Using a learning needs assessment to identify knowledge deficits regarding procedural sedation for pediatric patients. *AORN Journal*, *94*(6), 567-574.

Joint Commission International. (2011). Comprehensive Accreditation Manual for Hospitals. Oak Brook: Joint Commission Resources.

Krauss, B., & Green, S. M. (2008). Training and credentialing in procedural sedation and analgesia in children: lessons from the United States model. *Paediatric Anaesthesia, 18*(1), 30-35. doi: 10.1111/j.1460-9592.2007.02406.x

Langhan, M. L., Mallory, M., Hertzog, J., Lowrie, L., & Cravero, J. (2012). Physiologic monitoring practices during pediatric procedural sedation: a report from the Pediatric Sedation Research Consortium. *Archives of Pediatric and Adolescent Medicine, 166*(11), 990-998. doi: 10.1001/archpediatrics.2012.1023

Lavoie, L., Vezina, C., Paul-Savoie, E., Cyr, C., & Lafrenaye, S. (2012). Procedural pediatric sedation by nurses: available, competent, and safe. *International Journal of Pediatrics*, 2012, 1-5. doi: 10.1155/2012/820209

Lightdale, J. R., Mahoney, L. B., Fredette, M. E., Valim, C., Wong, S., & DiNardo, J. A. (2009). Nurse Reports of Adverse Events During Sedation Procedures as a Pediatric Hospital. *Journal of Perianesthesia Nursing, 24*(5), 300-306. doi: 10.1016/j.jopan.2009.07.004

Malviya, S., Voepel-Lewis, T., Prochaska, G., & Tait, A. R. (2000). Prolonged recovery and delayed side effects of sedation for diagnostic imaging studies in children. *Pediatrics, 105*(3), E42.

Mason, K. P., Sanborn, P., Zurakowski, D., Karian, V. E., Connor, L., Fontaine, P. J., & Burrows, P. E. (2004). Superiority of pentobarbital versus chloral hydrate for sedation in infants during imaging. *Radiology, 230*(2), 537-542. doi: 10.1148/radiol.2302030107

Polaner, D. M., Houck, C. S., Rockoff, M. A., Mancuso, T. J., Finley, G. A., Maxwell, L. G., . . . Davis, P. J. (2001). Sedation, risk, and safety: do we really have data at last? *Pediatrics, 108*(4), 1006-1008.

Schulte-Uentrop, L., & Goepfert, M. S. (2010). Anaesthesia or sedation for MRI in children. *Current Opinion in Anaesthesiology, 23*(4), 513-517. doi: 10.1097/ACO.0b013e32833bb524

Shah, A., Mosdossy, G., McLeod, S., Lehnhardt, K., Peddle, M., & Rieder, M. (2011). A blinded, randomized controlled trial to evaluate ketamine/propofol versus ketamine alone for procedural sedation in children. *Annals of Emergency Medicine, 57*(5), 425-433 e422. doi: 10.1016/j.annemergmed.2010.08.032

Shavit, I., Keidan, I., Hoffmann, Y., Mishuk, L., Rubin, O., Ziv, A., & Steiner, I. P. (2007). Enhancing patient safety during pediatric sedation: the impact of simulation-based training of nonanesthesiologists. *Archives of Pediatric and Adolescent Medicine, 161*(8), 740-743. doi: 10.1001/archpedi.161.8.740

Srinivasan, M., Turmelle, M., Depalma, L. M., Mao, J., & Carlson, D. W. (2012). Procedural sedation for diagnostic imaging in children by pediatric hospitalists using propofol: analysis of the nature, frequency, and predictors of adverse events and interventions. *Journal of Pediatrics, 160*(5), 801-806 e801. doi: 10.1016/j.jpeds.2011.11.003

Sterni, L., Beck, S., Cole, J., Carlson, D., & Turmelle, M. (2008). A model for pediatric sedation centers using pharmacologic sedation for successful completion of radiologic and procedural studies. *Journal of Radiology Nursing, 27*(2), 46 - 60. doi: 10.1016/j.jradnu.2008.01.004

Sury, M. R., Hatch, D. J., Deeley, T., Dicks-Mireaux, C., & Chong, W. K. (1999). Development of a nurse-led sedation service for paediatric magnetic resonance imaging. *Lancet, 353*(9165), 1667-1671.

Thompson, E., Andrews, D., & Christ-Libertin, C. (2012). Efficacy and Safety of Procedural Sedation and Analgesia for Burn Wound Care 4. Retrieved 101262774, 33, from http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=yrovftm&NEWS=N&AN=01253092-201207000-00008

Wachtel, R. E., Dexter, F., & Dow, A. J. (2009). Growth rates in pediatric diagnostic imaging and sedation. *Anesthesia & Analgesia, 108*(5), 1616-1621. doi: 10.1213/ane.0b013e3181981f96

Woodthorpe, C., Trigg, A., Gurney, A., & Sury, M. (2007). Nurse led sedation for paediatric MRI: progress and issues. *Paediatric Nursing, 19*(2), 14-18.

CHAPTER FIVE

Registered Nurse and Physician Procedural Sedation Practices and Adverse Events in Pediatric Diagnostic Radiology

Abstract

Objective: Many children require sedation in order to complete diagnostic radiology procedures. The objective of this study is to examine differences in sedation-related adverse events depending on the type of provider monitoring and delivering sedation (nurse alone, physician alone or nurse-physician team).

Hypothesis: Patient characteristics (age, weight, American Society of Anesthesiologists sedation risk score, coexisting medical conditions), the type of radiologic procedure (Magnetic Resonance Imaging [MRI]), number of medications administered for sedation, monitoring equipment used, and the provider monitoring and delivering sedation (nurse alone, physician alone or nurse-physician team) will predict any adverse event or adverse event type (neurologic, respiratory, emergent, and other) in children sedated for diagnostic radiologic procedures.

Methods: Secondary data from the Pediatric Sedation Research Consortium database was used to obtain a sample of cases sedated for diagnostic radiology procedures by three different types of providers (nurses alone, physicians alone or nurse-physician sedation teams). Five hierarchical models were used to determine the effect of the type of sedation provider, on any adverse event, and on four specific adverse event types (neurologic, respiratory, emergent, and other).

Results: Several factors such as having an MRI and administration of more than two medications during sedation increased the risk of adverse event occurrences. Cases in which sedation was monitored and delivered by nurses alone or physicians alone had lower odds of any adverse event, and neurologic or emergent adverse event types, compared to nurse-physician teams.

Conclusion: Future studies that examine how nurse-physician sedation teams differ from other sedation providers are needed to understand why these cases were at an increased risk for adverse events.

Registered Nurse and Physician Procedural Sedation Practices and Adverse Events in Pediatric Diagnostic Radiology

Children require sedation more frequently and for different reasons than adults (Coté & Wilson, 2006). The pediatric population has the highest risk for sedation complications, requires sedation for procedures more often than adults, and requires deeper levels of sedation in order to gain cooperation during procedures. At the same time, this population has the least tolerance for complications, due to their anatomical and physiological differences in areas such as the respiratory system (Cravero et al., 2006). Traditionally, anesthesia providers administered sedation in the operating room. A dramatic increase in procedures outside the operating room, such as endoscopy, has increased the demand for sedation care by non-anesthesiologist providers (Cohen et al., 2006). Subsequently, a growing number of specialists, including registered nurses (RNs) are providing sedation care for many procedures in various settings (Couloures, Beach, Cravero, Monroe, & Hertzog, 2011; Cravero et al., 2006).

Current research on RN-provided sedation is limited, primarily consisting of single-site studies describing the implementation and outcomes of RN-led sedation services, or outcomes of RN-administered medication protocols in a single setting such as a radiology or endoscopy unit. Outcomes of RN-provided sedation have not been compared to physician non-anesthesiologist sedation providers (MD), or to MD and RN teams that monitor and deliver sedation.

The specific aims of this study were to:

1. Describe the influence of type of sedation providers (RN, MD, RN and MD) on safety (the occurrence of any unanticipated adverse events) in children, when the influence of patient risk factors (age, weight, anesthesia risk using ASA class [ASA score], co-existing medical conditions), radiologic procedure type (computerized axial tomography [CT], magnetic

resonance imaging [MRI], or ultrasound) and sedation care processes (medication type and monitoring type) are considered.

2. Describe the influence of type of sedation providers (RN, MD, RN and MD) on specific safety events (neurologic, respiratory, emergent, and other adverse events) in children when the influence of patient risk factors (age, weight, ASA score, co-existing medical conditions), radiologic procedure type (CT, MRI, Ultrasound), and sedation care processes (medication type and monitoring type) are considered.

Background

Although the actual number of sedations performed by RNs is unknown, several studies document that RNs provide sedation as part of sedation teams and for procedures such as MRI, CT, and endoscopy (Beebe et al., 2000; Lavoie, Vezina, Paul-Savoie, Cyr, & Lafrenaye, 2012; Woodthorpe, Trigg, Gurney, & Sury, 2007). A survey of endoscopists in the United States found that 89.5% included RNs as part of the endoscopy and sedation team (Cohen et al., 2006). However, there has been little research on the role, practices, or outcomes of sedation administered only by RNs; similarly, few comparisons have been conducted of patient outcomes from sedation provided by RNs, non-anesthesiologist physicians (MDs), or RN and MD teams.

Descriptive practice data have been reported for RNs who act as the sole providers monitoring and delivering sedation (Crego, 2013). In this study, 35% of cases received sedation and were monitored by only an RN during non-interventional diagnostic radiology procedures (Crego, 2013). However, sedation standards are focused on physician sedation providers and practices. The American Academy of Pediatrics (AAP) sedation guidelines describe the role of personnel such as RNs in an assistive capacity, to provide monitoring and support in the event resuscitation is required, rather than as a primary sedation provider (Coté & Wilson, 2006).

Little specific guidance is provided to RNs regarding roles or appropriate scope of practice in providing sedation care; RN practice is regulated by state-based Boards of Nursing that oversee licensure and scope of practice, and there is a lack of consistency regarding RN-provided sedation (Pate & Steelman, 2007). Crego (2013) conducted a detailed review of RN-provided sedation standards and regulation in the United States, and noted a gap in knowledge regarding both actual sedation practices by RNs and patient outcomes. Evidence-based regulation and standards for RN-provided sedation are lacking.

Several studies on pediatric sedation care using the Pediatric Sedation Research Consortium (PSRC) database, containing multisite data on pediatric sedation, have reported adverse event rates and physiologic monitoring practices for non-anesthesiologist sedation providers, but have not specifically examined data for RN sedation providers (Cravero et al., 2006; Langhan, Mallory, Hertzog, Lowrie, & Cravero, 2012). The impact of provider specialty on major complications during procedural sedation was reported by Couloures, et al. (2011). Rates of major complications during procedures in which sedation was provided by non-anesthesiologists were compared with anesthesia sedation providers (Couloures et al., 2011), and RN sedation providers were included in the same category with residents, fellows, radiologists, surgeons, dentists, advanced practice nurses, and certified registered nurse anesthetists, so that specific rates of complications for RN sedation providers cannot be determined.

Patients and Methods

A retrospective, cross-sectional, correlational design was used to determine differences in adverse events by provider type (RN alone, MD alone, and RN and MD) depending on sedation risk factors (age, weight, ASA score above two, number of co-morbid conditions), any MRI procedures, the number of medications provided to patients, type of monitoring, and the

occurrence of adverse events. The same variables and block configurations were used to examine any adverse events and specific categories of adverse events, such as neurologic, respiratory, other, and emergent adverse events. A complete list of the events included in each category is provided in Table 1. The primary data source used to conduct this study was the PSRC database (Cravero, Blike, Beach, Gallagher, & Weiss, 2005; Cravero et al., 2006).

Pediatric Sedation Research Consortium Database

The PSRC database contains data from multiple sites on pediatric sedation. It was created to collect data from a large sample of patients, providers, and procedures, to better ascertain the incidence of and factors associated with adverse events in this population (Cravero et al., 2006). A large data pool is necessary to accurately assess sedation-related adverse events because of the low rate of occurrence, which has been estimated to be between less than1 per 10,000 and 5.3% (Cravero et al., 2006; Polaner et al., 2001).

The PSRC is an organization of more than 30 sites, including free-standing children's hospitals, general hospitals, and children's hospitals within hospitals, that prospectively collect data on pediatric sedation in at least one area or specialty within their organizations (Cravero et al., 2006). PSRC member institutions obtain institutional review board approval at the data collection site, select the location (e.g., endoscopy) or group (e.g., sedation service) for data collection. PSRC sites use a standard web-based data collection tool, and share de-identified information on pediatric sedation with the rest of the consortium members. The data collection methods used by the PSRC have been detailed in several studies; a brief summary is provided here (Couloures et al., 2011; Cravero et al., 2006).

Data collection is overseen at each PSRC member institution by a primary investigator who assures that more than 90% of cases are reported to the database (Couloures et al., 2011).

Procedures in place to minimize selection bias include submission of an independent sedation case count and audits of at least 5% of cases (Couloures et al., 2011). Data are entered via a secure web-based tool, and includes patient age, weight, ASA score, primary diagnosis, comorbid conditions, medications administered, the procedure completed, and outcome of the sedation procedure. The database includes information on sedation providers, including RNs, and physician providers by specialty. Data elements for sedation procedures include the provider who monitored and administered sedation, and outcomes of the sedation, including adverse events, listed by system (Cravero et al., 2006). For this study, variables were directly obtained or derived from existing variables in the PSRC database.

Variables from the PSRC database have a significant association with adverse sedation-related events. Variables were included in the PSRC database after an extensive literature review and consensus by an expert panel of pediatric sedation specialists highlighted the importance of these variables in understanding pediatric sedation practices. The PSRC also provides access to a large number of cases, thereby leading to many significant variables ($p < .01$), reported in italics on Tables 2 and 3. However, factors that have the greatest effect ($p < .0001$) on sedation-related adverse events were the main focus of this study, and are discussed and reported in bold in Tables 2 and 3.

Study Variables

A description of the variables and definitions used for this study are presented in Table 1. Study variables have been categorized into work-system, care process, and safety, following the Systems Engineering Initiative for Patient Safety (SEIPS) model (Figure 1) to conceptualize safety in pediatric sedation delivery systems (Carayon et al., 2006). The model components were

used to guide the development of variables to examine sedation-related adverse events associated with provider type.

Work System Variables. The work system includes elements that interact, such as people (patients/providers), technology and tools (CT scan, MRI, and ultrasound), environment, and organization. Two people are at the center of the work system: the sedation provider (MD or RN), and the patient. Sedation providers were categorized as the provider who monitored sedation and delivered medications during the procedure, instead of the provider who has responsibility for the sedation, a criterion used to determine the sedation provider in previous studies using PSRC data (Couloures et al., 2011). Individual patient characteristics that influence the occurrence of adverse events include patient age, weight, ASA class, and co-existing medical conditions (Cravero et al., 2006), and influence the sedation care process (Carayon et al., 2006; Pronovost, Miller, & Wachter, 2006). Different facets of procedures, for example the decreased visibility of patients inside an MRI scanner, and the requirement for MRI-compatible monitoring equipment, affect care processes ("Practice advisory on anesthetic care for magnetic resonance imaging: a report by the Society of Anesthesiologists Task Force on Anesthetic Care for Magnetic Resonance Imaging," 2009).

Care Process Variables. Care processes are the tasks performed by sedation providers, for example choosing a sedative medication or a type of technology, such as pulse oximetry, to aid patient monitoring. Care processes differ depending on the interaction among work system components. Thus, medications selected for sedation vary widely due to provider experience with certain medications, length of the procedure, the patient's ability to comply with demands of the procedure, preference for route of administration, or restrictions due to provider credentialing. In addition, medication combinations, such as analgesics and sedatives, may be

administered for one case. Therefore, it is difficult to categorize cases into groups based on the medications administered. A critical incident analysis of medications used in 95 cases of pediatric sedation deaths or permanent neurologic injury (Coté, Karl, Notterman, Weinberg, & McCloskey, 2000) found a strong relationship to adverse events when combinations of three or more sedating medications were used. Thus, the number of medications used during cases was included in all models, rather than the class or type of medication administered.

Monitoring practices also vary depending on an organization's policies regarding pediatric sedation, provider preference, and the availability of equipment for use with certain procedures such as MRI. Langhan et al. (2012) described eight monitoring device combinations used in pediatric sedation; these combinations formed the basis for the monitoring variables used in this study. A combination of pulse oximetry and blood pressure monitoring was used as the referent variable. It represents the minimum required sedation monitoring, a standard set by the AAP (Coté & Wilson, 2006).

Outcome Variables. The way care is delivered to patients by providers directly affects the organizational outcomes detailed in the SEIPS model, quality and patient safety (Carayon et al., 2006). The outcome variables tested in the current study were any unanticipated adverse event, neurologic, emergent, respiratory, and other complications, as reported in the PSRC database.

Study Sample

A data file containing a sample of 41,392 cases was obtained from the PSRC. The study inclusion criteria were: children up to and including 14 years of age; patient sedated for diagnostic MRI, CT, or ultrasound; and cases from January 2005 to September 2007, in which only RNs, only MDs, or an MD and RN team monitored patients and delivered medications. Cases involving any advanced practice nurses, such as Certified Registered Nurse Anesthetists,

were excluded. Physician specialists included in this study were emergency medicine physicians, house staff, intensivists, oral surgeons, pediatricians, radiologists, and surgeons. MD and RN teams were defined as any case in which RN or MD specialists already meeting study inclusion criteria delivered or monitored sedation in any combination; cases in which anesthesiologists, dentists, or fellows monitored or delivered sedation were excluded.

Additional study exclusion criteria were children over the age of 14 years, cases in which the ASA score was missing, and cases in which any radiological exam other than diagnostic CT scan, ultrasound, or MRI was completed. A total of 5,040 cases were excluded from the study sample: 799 cases were missing ASA status, an advanced registered nurse practitioner monitored or delivered sedation in 2,327 cases, and a fellow, medical technician, other provider monitored or delivered sedation in 1,914 cases. The resulting sample of 36,352 sedation cases was used for this study.

Analysis

All statistical analysis was completed using SAS version 9.1 (SAS Institute, Inc., Cary, NC, USA). North Carolina). Assumptions that were tested included multicollinearity testing. The procedure type variables (CT scan and ultrasound) were removed from the model due to the high negative correlation between CT scan and MRI cases, leaving ultrasound cases that composed only 0.31% of the sample cases. A new variable (any MRI) was created and included in the model for procedure type. Residuals for outliers were also examined (Tabachnick & Fidell, 2007).

Hierarchical logistic regression models were used to explain the presence of any unanticipated adverse event, neurologic, emergent, respiratory, and other complications, depending on provider type (RN, MD, RN and MD). Each of the regression models (any

unanticipated adverse events, neurologic, emergent, respiratory, and other complications) was completed in the following manner: block 1, work system (age, weight, ASA score greater than 2, and number of co-existing medical conditions); block 2, any MRI procedure; block 3, care process (number of medications administered); block 4, care processes (monitoring equipment in use); and block 5, provider types (RN alone, MD alone, and MD and RN), in which the referent category was the MD and RN team. Overall model fit of each model was evaluated by examination of -2 log likelihood and chi-square. Odds ratios and confidence intervals for each variable in all the models are presented on Tables 2 and 3.

Results

Descriptive statistics for the study variables are provided in Table 1. In the study sample, 78% of the cases were 5 years of age or younger; there were no deaths or cases of cardiac arrest. The majority (87%) of the study sample had an ASA score of 1 or 2. ASA scores for sample cases are provided in Figure 2; these were similar by provider types. There was at least one comorbid condition in 35% of the sample. The most common comorbidities were upper respiratory (13%) and neurologic conditions (12%). The most common type of sedation provider was RN and MD teams (61%). Most cases (75%) received only one medication. The most common type of medication administered was anesthetics (63%); propofol was administered in 57% of the cases. The total number of unanticipated adverse events was 2,164 (6%); the most common adverse events were respiratory (3%), followed by neurologic (2%).

Results of the models for any unanticipated adverse events are presented on Table 2. All other model results are listed on Table 3. Cases in model 5 having any MRI had a 2.76 ($p <$ .0001) odds ratio (OR) of experiencing any adverse event compared to patients that did not have an MRI. Cases in the RN alone and MD alone provider groups had lower odds ($p <$ .0001) of

unanticipated adverse events (0.46 and 0.53 OR, respectively), compared to MD and RN provider teams, after controlling for age, weight, ASA score greater than 2, number of comorbidities, any MRI, number of medications administered, and monitoring combinations. Cases receiving more than two medications had the highest odds (6.33 OR, $p < .0001$) of experiencing any adverse event, and constituted 4% of the study sample.

An additional model of any adverse events, in which sedation with propofol was controlled, yielded similar results for the RN alone and MD alone providers. In this study sample, propofol was administered 1,568 times in the MD alone group, 19,245 times by MD and RN teams, and 23 times by RN alone providers, but was delivered by an RN in 896 (3%) of the sample cases. Propofol was administered in combination with more than two medications in only 1% of sample cases. In 50% of the study sample, propofol was administered as a single agent. The single-medication variable was used as the referent category in all of the study models. In order to control for the possible effect of propofol use in the single-medication group, propofol was added to the any adverse event model (model 6), and the results were included in Table 2. In model 6, after controlling for propofol, cases in which more than two medications were administered had higher odds of experiencing any adverse event (6.39 OR, $p < .0001$) compared to model 5, that did not control for propofol (more than two medications, 6.33 OR, $p < .0001$).

The current AAP-recommended combination of pulse oximetry and blood pressure monitoring were the only monitors used was used as the reference variable in the model. Cases with pulse oximetry, blood pressure, electrocardiogram, and end tidal CO_2 had lower odds (0.83 OR) of adverse events compared to the combination of only pulse oximetry and blood pressure in the any adverse event model, but this result was not statistically significant.

A comparison of the full models for neurologic, respiratory, emergent, and other events is provided on Table 3. All adverse event type models controlled for propofol administration. Cases with any MRI procedures had higher odds of adverse event types ($p < .0001$) in all models except the emergent events; the highest odds were in the neurologic event model (3.09 OR). Cases in which more than two medications were administered had higher odds of experiencing the type of adverse event being tested (neurologic 6.86 OR, respiratory 5.34 OR, emergent 8.91 OR, and other 4.73 OR; $p < .0001$), and were the highest across all the models. The RN alone group had lower odds of experiencing neurologic (0.32 OR, $p < .0001$) and emergent (0.28 OR, $p < .0001$) events. Cases with MD alone providers had lower odds of neurologic (0.44 OR, $p < .01$) and emergent (0.52 OR, $p < .01$) events than RN and MD sedation teams. The monitoring combination of pulse oximetry, blood pressure, electrocardiogram, and end tidal CO_2 had lower odds (0.62OR, $p < .0001$) in the neurologic adverse event model than monitoring only with pulse oximetry and blood pressure. In the emergent adverse event model, monitoring with only pulse oximetry, blood pressure, electrocardiogram, and end tidal CO_2 had higher odds (1.38 OR, $p < .01$) of an emergent adverse event than monitoring only with pulse oximetry and blood pressure.

In the neurologic event model, cases in which two medications were administered had a 3.18 OR ($p < .0001$) of having an adverse neurologic event; these were higher odds for this variable (administration of two medications) than in any of the other adverse event models. Additionally, cases that received more than two medications in the neurological category had the second highest odds (6.86 OR, $p < .0001$) of having a neurologic adverse event.

Cases with high ASA had higher odds of experiencing any adverse event, (Table 2 model six, 1.44 OR, $p < .0001$) and respiratory event model eight found on Table 3 (1.64 OR, $p < .0001$). Cases with one and two comorbid conditions had higher odds of respiratory adverse

events, (1.46 and 1.64 OR respectively, $p < .0001$). Cases in which more than two medications were administered had higher odds of adverse events ($p < .0001$) in all models, but had the highest OR (8.91) in the emergent event model. Because the model variable was the sum of medications and not the type of medication, it is unclear if more than two medications were administered after sedation had started in order to treat the emergent event. Cases with propofol had lower odds of neurologic (0.53 OR, $p < .0001$) and higher odds of respiratory (2.16 OR, $p < .0001$), and emergent events (2.08 OR, $p < .01$), than those cases not receiving propofol.

A preliminary analysis of the interactions between high ASA scores and provider type (RN alone, MD alone and RN and MD teams) was undertaken. A chi square comparison of cases with high ASA sedated by RNs alone and cases sedated by other sedation providers (MD alone and RN and MD sedation teams) found no difference between the groups. When the interaction variables (high ASA with RNs alone and high ASA with MDs alone) were added to the adverse event model, the RNs alone with high ASA cases had a negative relationship to adverse events that was significant ($p<.0001$) compared to RN and MD teams while the MD alone and high ASA interaction was not significant. The RN alone providers also had a significant negative relationship to adverse events compared to RN and MD sedation teams.

A subsequent preliminary analysis of the interaction between sedation providers (RN alone, MD alone and RN and MD teams) and the number of medications administered (one, two or greater than two) was also performed. When the number of medications administered (two or greater than two) were interacted with RN alone and MD alone and added to the adverse event models, MD alone cases continued to be significant although the interactions were not significant. RNs alone became non-significant, and all three interactions with RN only, high

ASA, two medications and greater than two medications all were significant and negatively related to any adverse event.

Discussion

Work System Factors

Sedation Providers. This study demonstrated that cases with only RNs and only MDs monitoring and delivering sedation had fewer adverse events than RN and MD sedation teams. A team consisting of an MD and RN either monitoring or delivering sedation is often discussed in regulations and standards of sedation practice; the emphasis is placed on interventional procedures in which the MD is performing a procedure, such as endoscopy (Coté & Wilson, 2006; Joint Commission International, 2011). Guidelines usually describe two provider roles during sedation. One provider performs an intervention or procedure, and can deliver or direct the delivery of sedative medications by another competent provider (Coté & Wilson, 2006; Joint Commission International, 2011). The second provider has the sole responsibility of continuously monitoring the patient throughout deep sedation procedures; if moderate sedation is performed, the second provider can only assist with interruptible tasks during the sedation procedure and monitors the patient (Coté & Wilson, 2006; Joint Commission International, 2011). Sedation guidelines are not as clear regarding provider roles in sedation teams when the procedure is diagnostic, and teams may operate differently during diagnostic versus interventional procedures. Differences may include the equipment providers choose to monitor patients during sedation. The current AAP monitoring standard of pulse oximetry and blood pressure was more effective than most other monitoring combinations in this study. Other differences include how teams decide to divide the medication delivery and monitoring responsibilities during sedation, and how providers communicate these decisions. For example,

the MD provider may be present only for induction of sedation, and the RN alone may then monitor the patient during the diagnostic procedure. In the event that the patient requires more sedation during the procedure, it is unclear how additional sedation is provided, if the physician is not present or the procedure occurs in a location where sedative medications are not readily available.

Sedation is provided in multiple locations and by different specialists, which often results in what are termed sedation microsystems, defined as subgroups of people who routinely provide care to subpopulations of patients within an institution (Blike, Cravero, & Nelson, 2001). Field observations of sedation microsystems using a human factors approach identified wide variations in sedation care among different sedation care microsystems within one hospital (Blike et al., 2001). There may also be differences in the way providers work in a sedation team environment depending on their training and experience. For example, emergency medicine physicians or pediatric intensivists may function differently within care teams, compared to radiologists who may have fewer opportunities to deliver care in a team environment.

The influence of team factors, such as the use of an organization-wide sedation team with consistent membership, or individuals who hold credentials in providing sedation and work in teams, may be important in comparing outcomes of sedation delivery systems. Preliminary studies by Blike, Cravero and Nelson (2001) identified team-training skills used by airline crews as essential components in developing quality sedation care systems. However, current sedation training and competency continues to highlight psychomotor skills such as airway management, knowledge of sedative medications, and monitoring procedures to assure safe sedation care, with little to no description of training or assessment of team behaviors.

ASA Sedation Risk. ASA score was included in the study models to adjust for risk so that differences in outcomes related to the provider rather than the severity of illness in each case could be examined. Higher ASA score has been associated with an increased incidence of adverse sedation events in the pediatric emergency department (Caperell & Pitetti, 2009). The ASA sedation risk scores for the study sedation provider groups (RN alone, MD alone, and MD and RN teams) were similar, indicating that the groups were of comparable risk for complications. This was further substantiated by the preliminary results on the adverse event models including interactions of high ASA and provider type which found that cases sedated by RNs alone achieved significantly fewer adverse events in cases at similar risk for complications as the MD and RN teams. However, risk adjustment in pediatrics is more difficult to determine than in adult populations due to factors such as varying developmental level, and environmental factors, such as parental influence, that could affect risk but are not readily measured (Kuhlthau, Ferris, & Iezzoni, 2004). ASA scores are assessed before sedation procedures are started to identify patients at risk of complications (American Society of Anesthesiologists, 2002). The association of ASA scores greater than 2 with an increased risk of complications during sedation has contributed to the use of this score by some organizations to determine whether an RN can be the primary sedation provider. This criterion has also been used by some boards of nursing to restrict the practice of RNs providing sedation (Alaska Board of Nursing, 2009; Metzner & Domino, 2010).

ASA scores did not have as much of an influence on sedation-related adverse events as other known factors. Children are generally sedated more deeply than adults because, depending on developmental levels, they are less likely to cooperate during diagnostic procedures; this necessitates the administration of multiple sedative medications or use of anesthetic agents. Age

may not fully account for developmental variations in children; the need for deeper sedation may be more related to the type of procedure and the amount of sedation needed in order to complete the procedure. Thus a procedure such as an MRI that is lengthy, noisy, and requires long periods of stillness may require a child at a particular developmental level to be more deeply sedated than for a CT scan. In this study, MRI procedures were an important factor associated with sedation-related adverse events, and may be an additional consideration when adjusting for sedation risk (Kuhlthau et al., 2004).

Care Processes

Medication Administration. This study indicates that the number of medications administered, regardless of the type of medication, was a consistently important factor in the occurrence of adverse events that had been previously reported by (Coté, Karl et al., 2000) in a smaller sample of cases with sedation critical incidents (cardiopulmunary resuscitation and permenant neurologic injury). Cases in which patients received more than two medications had the highest odds of adverse events, yet most sedation regulations affecting RNs have focused on the category of medication administered rather than the number of medications provided. In some cases RNs are administering anesthetics such as propofol for diagnostic radiology procedures, which may not be part of the RN scope of practice and is restricted in some states. RNs may also administer anesthetic agents such as ketamine for other procedures. The extent and effect of anesthetic administration by RNs for sedation, and the increased risk for adverse events posed by this practice, should be further investigated.

Furthermore, the administration of multiple sedation agents by RNs may require changes in RN sedation training, or sedation service policies developed by healthcare organizations. The inclusion of guidance on administration of multiple sedative medications in sedation competency

training, and referring cases requiring more than two medications to anesthesia providers, rather than simply relying on high ASA scores to determine appropriate referrals, must be considered. Nursing regulators and pre-licensure programs must be aware of this evolving area of practice, and ensure that RNs have the skills necessary to safely provide sedation care, which may include medications that were typically reserved for the anesthesia environment.

RN sedation provider education. There are specific knowledge, skills, and competency requirements for sedation providers that have been established by many organizations (Coté & Wilson, 2006). However, most sedation standards do not consider the baseline knowledge and skills RNs have in this area, for example familiarity in assigning or verifying ASA risk scoring, administration of medications for the purpose of sedation rather than analgesia, effects, and recognition of adverse events associated with administration of multiple sedative agents, use of anesthetic agents such as propofol for sedation in non-ventilated patients. Education about sedation is usually not part of undergraduate nursing programs. Sedation training for RNs occurs in different ways depending on the organization sedation credentialing process often including attendance at lectures, self-paced tutorials and/or experiences in simulation or perioperative care units. There is no standard training or certification for RN sedation. Organizations such as the Society for Pediatric Sedation (SPS) have developed both core competencies and a sedation provider course based on findings of the PSRC studies of MD-provided sedation. Core sedation competencies for nurses are published at the SPS website (www.pedsedation.org/sections/nurses_non_members.iphtml) and provide a general outline of areas of competency, but they lack specific information on how RNs might gain skills such as assessment of the airway using Mallampati scores and they do not address differences in competency for RNs that are providing deep versus moderate sedation. Data on RN-provided

sedation from the PSRC could be used to develop training that would specifically address the types of adverse events and medications that the RN provider would most likely use for sedation and provide evidence to support the current competencies endorsed by organizations such as the SPS.

The variations in sedation practice and the lack of uniform sedation standards and regulations make it difficult to develop standard training. One exception might be certification for RNs that deliver anesthetics such as ketamine and propofol. Currently nitrous oxide sedation can be administered by RNs after attending a credentialing program that meets state licensing requirements for dentists and dental hygienists and completing a skill based competency (Zier, Drake, McCormick, Clinch & Cornfield, 2007). This model of education and competency verification could be used similarly to address the concerns posed with agents such as ketamine and propofol.

Limitations

The availability of a large database on pediatric sedation will be important for an understanding of provider practices and adverse events in other sedation care areas. However, there are limitations to the data, such as a lack of information on the characteristics of the sedation providers. Level of experience, provider specialty, credentials, knowledge and training unique to MDs, RNs, and specialized anesthesia providers was not available from the PSRC. Variations in experience, background, and specific roles for members of sedation teams may vary not only depending on the organization, but also by specific MD and RN teams providing sedation within an organization. These factors were not accounted for in this study.

Another limitation is the lack of information on geographic locations where data were collected, and on organizational characteristics of the care setting. It was thus not possible to

compare RN sedation care practice according to location or the state board of nursing regulations in effect.

A further limitation is the lack of clinical data on individual patients in the database. One way to overcome this limitation would be expansion of the PSRC database so that researchers could gain access to clinical and organizational data from contributing organizations. The addition of clinical data would allow greater understanding of the person level factors that possibly contribute to adverse sedation outcomes.

A limitation of using logistic regression is that there is an assumption that responses of different cases are independent of each other (Tabachnick & Fidell, 2007). Lack of information regarding where the data were collected (which PSRC member organization), the number of providers represented in the sample, and if the sample includes a large number of patients that constitute multiple cases (many patients sedated numerous times) make it difficult to discern if this assumption is met. Last, data on sedation from PSRC member institutions may reflect best practices by organizations that are committed to provide quality sedation care rather than being representative of sedation care at the national level.

Conclusion

This study informs clinicians of the differences in outcomes when MD and RN teams provide sedation compared to RNs monitoring and delivering sedation alone and MDs monitoring and delivering sedation alone. As sedation care continues to develop into a multispecialty discipline, it is important to know what the contribution of each type of provider is to overall sedation outcome and how provider teams function to provide sedation care. Further evaluation of the interactions among the study variables also warrant further research. In order to gain a better understanding of the MD and RN sedation team dynamic, clinically based

investigations using quantitative and qualitative methods may be necessary, to develop sedation team training techniques, and examine current organizational sedation policies.

Data from this study provides evidence to inform managers, regulators, and policymakers about the factors that are most relevant in determining the occurrence of adverse events, and assist in the development of evidenced-based training to include consideration of the procedure being completed, team communication, and use of multiple sedative agents. The multispecialty nature of sedation care requires improved collaboration amongst the numerous specialist involved in the care of sedated patients. The PSRC provides the framework for collaboration amongst many organizations that provide sedation and could be further utilized to develop evidence on organizational and regulatory factors that affect sedation care delivery.

Figure 1. The Systems Engineering Initiative for Patient Safety Model used to conceptualize variables related to pediatric sedation safety. Reproduced from [Quality and Safety in Health Care, Carayon, Hundt, Karash, Gurses, Alvarado, Smith, Brennan, volume number 15, page i51 2006]with permission from BMJ Publishing Group LTD.

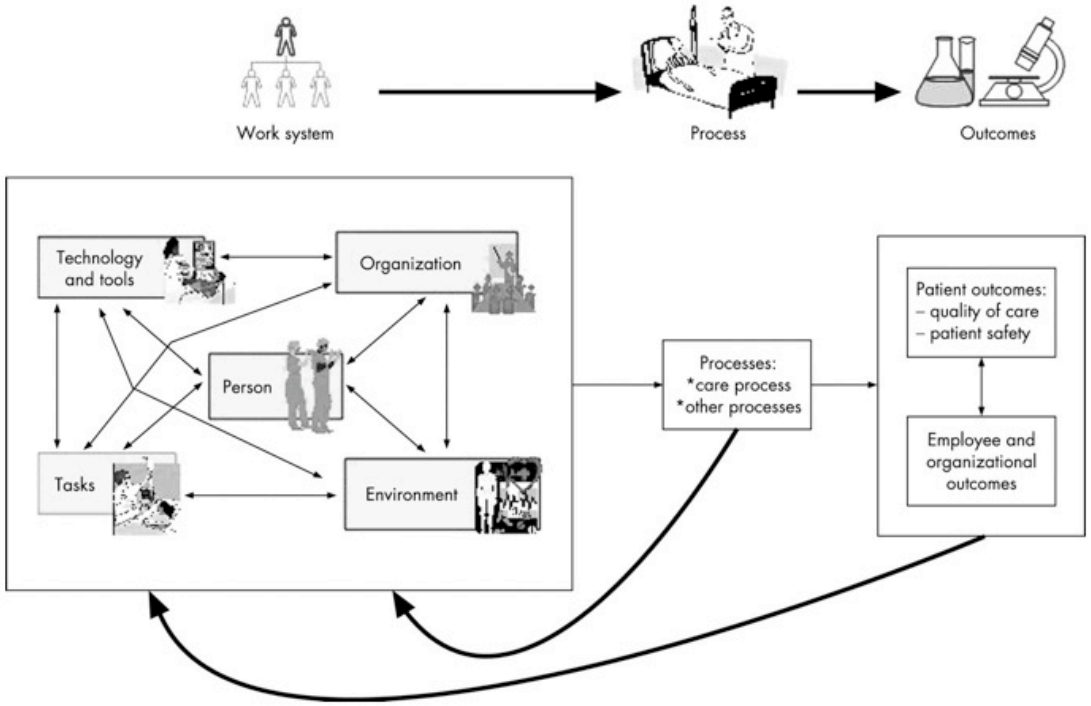

Figure 2. ASA Score by Provider

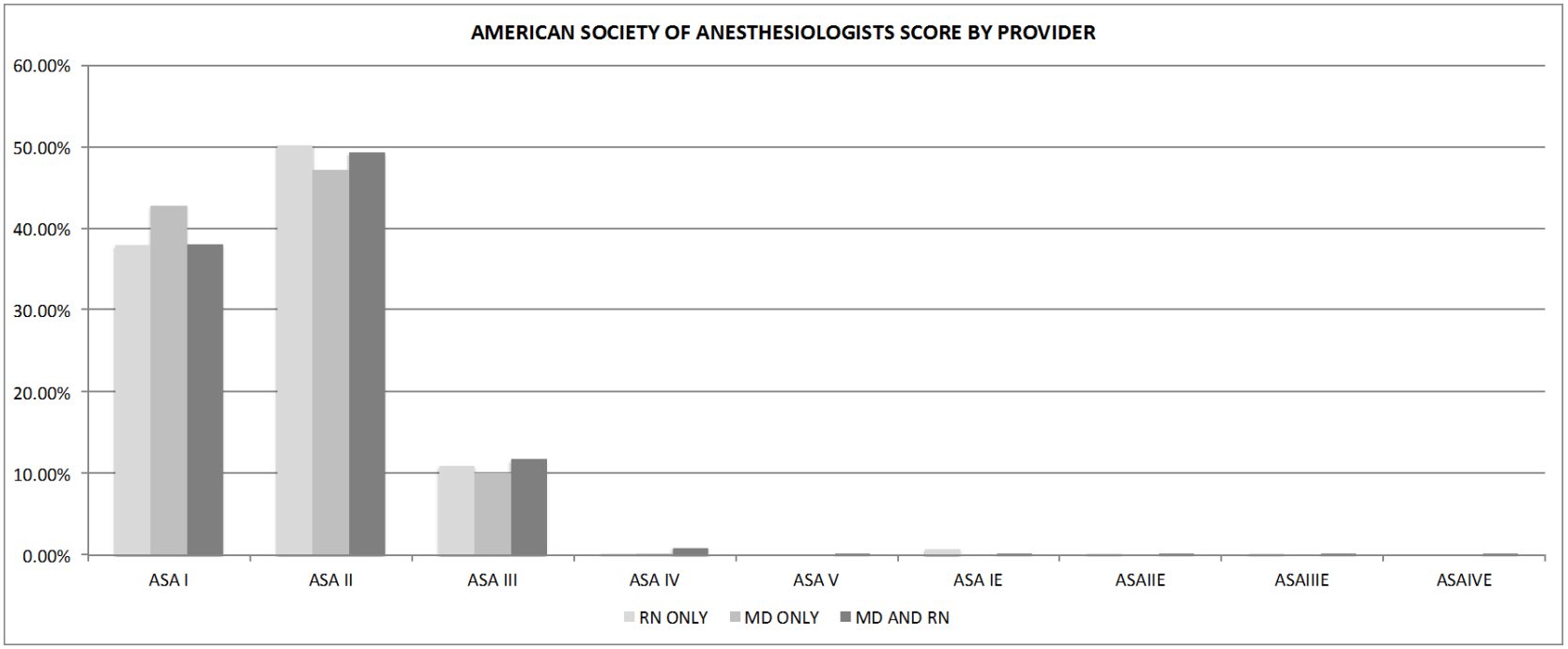

Table 1. Descriptions and definitions of study variables presented by conceptual model components

System Component Variable Name	**Model Component** Operational Descriptions			**Total Cases** 36,409	
Work System	**Person – Patient Risk Factors**	M	SD	N	%
Infant	0-12 months			8,068	22.1
Toddler	13-24 months			6,706	18.4
Early childhood	25 months- 60 months (5 years)			13,687	37.6
Middle childhood	61 months – 132 months (11 years)			6,912	19.0
Teen	133 months – 168 months (14 years)			979	2.6
Age In Months	Age in months range 0-168 months	42.28	36.35		
Weight	Weight in kilograms	16.88	10.97		
ASA risk score	American Society of Anesthesiologists Status/ASA Score				
	I. Normal, healthy patient, without organic, physiologic, or psychiatric disturbance			13,875	38.1
	II. A patient with controlled medical conditions without significant systemic effects			17,979	49.4
	III. A patient having medical conditions with significant systemic effects intermittently associated with significant functional compromise			4,121	11.3
	IV. A patient with a medical condition that is poorly controlled, associated with significant dysfunction and is a potential threat to life			224	0.6
	V. A patient with critical medical condition associated with little chance of survival with or without surgical procedure			2	0.01
	IE. Class I patient procedure performed as an emergency			95	0.2
	IIE Class II patient procedure performed as an emergency			29	0.08
	IIIE Class III patient procedure performed as an emergency			22	0.06
	IVE Class IV patient procedure performed as an emergency			5	0.01
	VE Class V patient procedure performed as an emergency				
High ASA	1= American Society of Anesthesiologists ASA Score greater than II			4,498	2.3
	0= American Society of Anesthesiologists ASA Score I or II			31,854	87.6
Coexisting Gastrointestinal	1=Coexisting GI condition			2,398	6.6
	0= No coexisting GI condition			33,954	93.4
Coexisting Neurologic	1=Coexisting Neurologic condition			4,231	11.6
	0= No coexisting Neurologic condition			32,121	88.3
Coexisting lower Respiratory	1=Coexisting Respiratory Lower Airway condition			33,377	8.2
	0= No coexisting Respiratory Lower Airway condition			2,975	91.8
Coexisting upper Respiratory	1=Coexisting Respiratory Upper Airway condition			4, 557	12.5
	0= No coexisting Respiratory upper Airway condition			31,795	87.5

Coexisting Cardiovascular	1=Coexisting Cardiovascular condition 0= No coexisting Cardiovascular condition		1, 251 35,101	3.4 96.5
Coexisting Craniofacial	1=Coexisting Craniofacial condition 0= No coexisting Craniofacial condition		183 36,169	0.5 99.5
Coexisting Metabolic	1=Coexisting Metabolic/genetic (includes obesity) condition 0= No coexisting Metabolic/genetic (includes obesity) condition		860 35,492	2.3 97.6
Coexisting Prematurity	1=Coexisting prematurity related condition 0= No coexisting prematurity related condition		575 35,777	1.5 98.4
No comorbidity	1=Cases without any coexisting condition 0= Cases with any coexisting condition		23,730 12,622	65.2 34.7
One comorbidity	1= Cases with 1 comorbid condition 0= Cases with >1 or <1 coexisting conditions		9,388 26,964	25.8 74.1
Two comorbidities	1= Cases with 2 comorbid conditions 0= Cases with >2 or < 2 coexisting conditions		2,345 34,007	6.4 93.5
Greater than two comorbidities	1= Cases with >2 comorbid conditions 0= Cases with <2 coexisting conditions		889 35,463	2.4 97.5
Work System	**Person – Provider Type**			
MDs alone	Only cases with non-anesthesia physician delivering medication and monitoring sedation.		1, 728	4.7
RN and MD team	Cases with non-anesthesia physician and nurse that deliver medication and/or monitor sedation.		22,060	60.6
RNs alone	Only cases with non-anesthesia nurses delivering medication and monitoring sedation.		12, 564	34.5
Work System	**Technology and tools –Procedure Type**			
CT Scan Only	1= Diagnostic computerized axial tomography performed 0= No diagnostic computerized axial tomography, no magnetic resonance imaging or ultrasound		8,343 28,066	22.9 77.1
MRI Only	1= Diagnostic Magnetic Resonance Imaging/MRA/MRV/MRS performed 0= No diagnostic Magnetic Resonance Imaging/MRA/MRV/MRS, no CT Scan or ultrasound		27,681 8,728	76.0 23.7
Ultrasound Only	1= Diagnostic ultrasound performed 0= No diagnostic ultrasound body, computerized axial tomography or magnetic resonance imaging		85 36,324	0.2 99.8
Any MRI	1= Cases with any diagnostic Magnetic Resonance Imaging/MRA/MRV/MRS performed 0= Cases with procedures other than Magnetic Resonance Imaging/MRA/MRV/MRS performed		27, 965 8,444	76.81 23.19
Care Process	**Medication Type**			
Non opioids	1=Used Ativan, chloral hydrate, dexmedetomidine, midazolam, pentobarbital, thiopental, valium 0= No non opioids		15,584 20,768	42.8 57.1

Opioids	1= Used fentanyl, meperidine, morphine nalbuphine, remifentanil, alfentnil 0= No Opioids		1,747 34,605	4.8 95.1
Anesthetics	1= Used etomidate, ketamine, methohexital, propofol 0= No Anesthetics		22,852 13, 500	62.8 37.1
Anticholinergics	1= Used atropine or glycopyrrolate 0=No Anticholinergics		1,184 35,168	3.2 96.7
Inhaled Medications	1= used albuterol, racemic epinephrine 0= No Inhaled Medications		195 36, 157	0.5 99.4
No medications	1=Cases without any medication administered 0= Cases with any medications administered		57 36,399	0.16 99.84
One medication	1= Cases with 1 medication administered 0= Cases with >1 or <1 medications administered		27,265 9,087	75 25
Two medications	1= Cases with 2 medications administered 0= Cases with >2 or < 2 medications administered		7,808 28,544	21.4 78.5
Greater than two medications	1= Cases with >2 medications administered 0= Cases with <2 medications administered		1,279 35,073	3.5 96.4
Propofol	1= Cases with propofol administered 0=Cases without propofol administration		20,836 15,573	57.2 42.7
Care Process	**Monitoring Type**			
No monitoring	1= No monitors 0= Any type of monitoring		66 36,386	0.2 99.8
Only ECG (electrocardiogram)	1= Only ECG monitoring 0=ECG and other monitoring		2 35,480	.01 99.9
Only etCO2 (end tidal CO2)	1= Only etCO2 monitoring 0=EtCO2 and other monitoring		3 36,349	.01 99.9
Only spo2 (pulse oximetry)	1= only spo2 monitoring 0=spo2 and other monitoring		1,662 34,690	4.5 95.4
Only bp (blood pressure)	1=Only BP monitoring 0= BP and other monitoring		3 36,349	.01 99.9

Only pulse oximetry, blood pressure, electrocardiogram end tidal CO2	1= only spo2, ECG, blood pressure and etCO2 monitoring 0= Monitoring does not include only spo2, ECG, blood pressure and etCO2		12,367 23,985	34.0 65.9
Only pulse oximetry, blood pressure, electrocardiogram	1= only spo2, ECG and blood pressure monitoring 0= Monitoring does not include only spo2, ECG and blood pressure		4,176 32,176	11.4 88.5
Only pulse oximetry, electrocardiogram	1= only spo2 and ECG monitoring 0= Monitoring does not include only spo2 and ECG		371 35,981	1.02 98.9
Only pulse oximetry, blood pressure	1= only spo2 and blood pressure monitoring 0= Monitoring does not include only spo2, and blood pressure		6,333 30,019	17.4 82.5
Only Pulse oximetry, end tidal CO2	1= only spo2 and etCO2 monitoring 0= Monitoring does not include only spo2 and etCO2		2,586 33,766	7.1 92.8
Impedence Plethysmography	0= No Pleth (Impedence Plethysmography) 1= Pleth (Impedence Plethysmography) monitoring		5,621 30,731	15.4 84.5
BIS (Bispectral Index) monitoring	1=BIS monitoring 0= No BIS monitoring		23 36,329	0.06 99.9
Inspired_o2 monitoring	1= Inspired o2 monitoring 0= No Inspired o2 monitoring		484 35,868	1.3 98.6

Outcome	Safety (Dependent Variable)		N	%
Neurologic adverse events	Unanticipated adverse events		35, 683	98.16
	5. Neurologic 0=No neurologic events		669	1.84
	1= Any of the listed neurologic events			
	• Agitation/delirium			
	• Prolonged recovery time			
	• Prolonged sedation *			
	• Unintended deep sedation			
	• Inadequate sedation*		35,894	98.74
Emergent adverse events	6. Emergent 0= No emergent events		458	1.26
	1=Any of the listed emergent events			
	• Cardiac Arrest			
	• Death			
	• Use of reversal agents			
	• Emergency anesthesia consultation			
	• Unexpected need for bag-valve mask ventilation *			
	• Unplanned intubation			
	• Allergic reaction			
	• Secretions requiring treatment			
	• Unplanned admission to hospital or increase in level of care		35,403	97.39
Respiratory adverse events	3. Respiratory 0= No respiratory events		949	2.61
	1= Any of the listed respiratory events			
	• Airway Obstruction			
	• Apnea>15 seconds			
	• Aspiration			
	• Coughing			
	• Desaturation: O2 saturation below baseline for greater than 30 seconds			
	• Laryngospasm			
	• Stridor			
	• Wheezing			
Other adverse events	4. Other Events 0= No other events			
	1=Any of the listed other events		35,732	98.29
	• Hypothermia		620	1.71
	• IV related complications			
	• Unexpected change in HR, BP RR > or < 30%			
	• Vomiting (non-GI procedure)			
	• Other			
Any Unanticipated adverse event	0= Case with no adverse event		34,188	94.05
	1= Any adverse event		2, 164	5 .95

Table 2. Model of the influence of person level variables, procedure type, medications administered, monitoring equipment used and provider type on occurrence of any adverse events

Variables	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6†
	Odds Ratios (95% Confidence Interval)					
Age in months	1.001 (1-1.003)	1.00 (1-1.003)	.999 (0.9-1.0)	.999 (0.99-1.001)	0.999 (0.9-1.0)	.999 (.99-1.00)
Weight	**1.012*** (1.006-1.018)	**1.012*** (1.006-1.018)	**1.011*** (1.006-1.01)	**1.013*** (1.007-1.02)	**1.013*** (1.007-1.02)	**1.013*** (1.007-1.02)
High ASA	**1.398*** (1.242-1.574)	**1.476*** (1.3-1.6)	**1.45*** (1.3-1.6)	**1.401*** (1.2-1.5)	**1.441*** (1.2-1.6)	**1.44*** (1.3-1.6)
One comorbidity	*1.163*** (1.053-1.286)	*1.173*** (1.06-1.3)	1.102 (.99-1.2)	1.175 (1.0-1.3)	*1.2*** (1.1-1.3)	*1.2*** (1.09-1.33)
Two comorbidities	*1.362*** (1.158-1.601)	**1.381*** (1.1-1.6)	1.173 (0.9-1.3)	*1.307*** (1.1-1.5)	*1.328*** (1.1-1.6)	*1.332*** (1.1-1.6)
Greater than 2 comorbidities	**1.621*** (1.283-2.048)	**1.67*** (1.3-2.1)	1.277 (1-1.6)	1.432 (1.1-1.8)	1.45 (1.1-1.8)	1.45 (1.1-1.8)
Any MRI		**1.915*** (1.7-2.2)	**1.871*** (1.64-2.13)	**2.68*** (2.3-3.1)	**2.76*** (2.4-3.2)	**2.72*** (2.3-3.17)
Two medications			**2.05*** (1.9-2.3)	**2.119*** (1.9-2.4)	**2.50*** (2.2-2.8)	**2.52*** (2.3-2.8)
Greater than 2 medications			**4.974*** (4.3-5.8)	**5.121*** (4.4-6.0)	**6.33*** (5.4-7.4)	**6.393*** (5.4-7.5)
Propofol						1.179 (0.98-1.4)
Only spo2				**2.293*** (1.9-2.8)	**3.32*** (2.7-4.2)	**3.387*** (2.7-4.2)
Inspired o2				**2.82*** (2.1-3.7)	**2.087*** (1.6-2.8)	**2.081*** (1.6-2.8)
Only pulse oximetry, electrocardiogram				**3.57*** (2.7-4.7)	**4.69*** (3.5-6.3)	**4.758*** (3.6-6.4)
Only pulse oximetry, end tidal CO2				0.98 (0.8-1.2)	*1.335*** (1.1-1.6)	*1.351*** (1.1-1.6)
Only pulse oximetry blood pressure electrocardiogram				**2.38*** (2-2.8)	**2.08*** (1.8-2.5)	**2.156*** (1.8-2.6)
Only pulse oximetry blood pressure electrocardiogram end tidal CO2				1.09 (.9-1.2)	0.841 (0.7-0.95)	0.833 (.74-.94)
RN alone					**0.456*** (0.4-0.5)	**0.519*** (0.4-0.6)
MD alone					**0.521*** (0.4-0.6)	**0.523*** (0.4-0.6)
Chi-Square -2Log Likelihood	**162.1701*** 16279.515	**273.7647*** 16167.921	**732.373*** 15709.312	**951.3172*** 15490.368	**1105.6623*** 15336.023	**1109.0150*** 15332.67

P-VALUE:* $p < 0.0001$; **$p < 0.01$ †This model of any adverse event includes propofol administration

Table 3. Models of the influence of person level variables, procedure type, medications administered, monitoring equipment used and provider type on the occurrence of neurologic, respiratory, emergent and other adverse events

Variables	Neurologic Model 7	Respiratory Model 8	Emergent Events Model 9	Other Events Model 10
ODDS RATIOS (95% Confidence Interval)				
Age in months	0.99 (0.9-1.0)	.998 (0.9-1)	1.001 (0.9-1)	1.002 (0.9-1)
Weight	1.010 (0.9-1.02)	**1.018*** (1.01-1.02)	1.005 (0.9-1)	1.008 (0.99-1.02)
High ASA	*1.419*** (1.1-1.8)	**1.637*** (1.3-1.9)	*1.481*** (1.2-1.9)	*1.224*** (.97-1.5)
One comorbidity	0.86 (0.7-1.0)	**1.456*** (1.2-1.7)	*1.296*** (1-1.6)	*1.168*** (.96-1.4)
Two comorbidities	0.956 (0.7-1.3)	**1.641*** (1.3-2)	*1.683*** (1.2-2.3)	*1.319*** (.98-1.77)
Greater than 2 comorbidities	1.206 (0.8-1.8)	*1.83*** (1.3-2.6)	1.749 (1.1-2.8)	1.139 (.72-1.8)
Any MRI	**3.093*** (2.4-4)	**2.572*** (2.03-3.3)	1.287 (0.9-1.8)	**2.706*** (2-3.6)
Two medications	**3.182*** (2.6-3.8)	**2.271*** (1.9-2.7)	**2.15*** (1.7-2.8)	**2.3*** (1.8-2.8)
Greater than 2 medications	**6.86*** (5.3-8.8)	**5.34*** (4.2-6.7)	**8.908*** (6.5-12.1)	**4.732*** (3.5-6.3)
Propofol	**0.526*** (0.4-0.7)	**2.160*** (1.6-3)	*2.082*** (1.4-3.1)	1.029 (.75-1.4)
Only spo2	**2.978*** (2.1-4.2)	**4.6*** (3.3-6.4)	1.744 (0.78-3.9)	**2.623*** (1.7-4)
Inspired o2	0.847 (0.4-1.7)	**3.39*** (2.4-4.8)	1.678 (0.9-3.2)	1.68 (0.9-3.1)
Only pulse oximetry, electrocardiogram	*1.923*** (1.1-3.3)	**5.658*** (3.7-8.6)	1.688 (0.5-5.4)	**6.083*** (3.9-9.3)
Only pule oximetry, end tidal CO2	0.948 (0.7-1.3)	*1.528*** (1.1-2)	**3.858*** (2.5-6)	*1.568*** (1.2-2.1)
Only pulse oximetry blood pressure electrocardiogram	*1.688*** (1.3-2.2)	**1.981*** (1.52-2.6)	*1.790*** (1.2-2.6)	**2.987*** (2.2-4)
Only pulse oximetry blood pressure electrocardiogram End tidal CO2	**0.613*** (0.5-0.8)	0.916 (0.7-1.1)	*1.381*** (1.1-1.8)	0.99 (.78-1.3)
RN alone	**0.321*** (0.2-0.4)	0.724 (0.5-1)	**0.283*** (0.17-0.5)	0.698 (0.5-0.98)
MD alone	*0.440*** (0.3-0.7)	0.740 (0.5-1.0)	*0.518*** (0.3-0.9)	0.658 (0.4-1.4)
Chi-Square	**467.5526***	**581.9097***	**346.4321***	**337.3091***
-2Log Likelihood	6213.735	8213.451	4571.925	5974.828

P-VALUE: *$p < 0.0001$; **$p < 0.01$

References

Alaska Board of Nursing. (2009). Alaska Board of Nursing Advisory Opinion Registered Nurse Administration of Sedating and Anesthetic Agents. Retrieved May 23, 2013, from http://www.dced.state.ak.us/occ/pub/nur1809.pdf

American Society of Anesthesiologists. (2002). Practice guidelines for sedation and analgesia by non-anesthesiologists. *Anesthesiology, 96*(4), 1004-1017.

Babl, F.E., Oakley, E., Seaman, C., Barnett, P., & Sharwood, L. (2008). High-Concentration Nitrous Oxide for Procedural Sedation in Children: Adverse Events and Depth of Sedation. *Pediatrics*, 121(3)., e528-e532. doi: 10.1542/peds.2007-1044

Beebe, D. S., Tran, P., Bragg, M., Stillman, A., Truwitt, C., & Belani, K. G. (2000). Trained nurses can provide safe and effective sedation for MRI in pediatric patients. *Canadian Journal of Anesthesia, 47*(3), 205 - 210. doi: 10.1007/BF03018913

Blike, G., Cravero, J., & Nelson, E. (2001). Same patients, same critical events--different systems of care, different outcomes: description of a human factors approach aimed at improving the efficacy and safety of sedation/analgesia care. *Quality Management in Health Care, 10*(1), 17-36.

Caperell, K., & Pitetti, R. (2009). Is higher ASA class associated with an increased incidence of adverse events during procedural sedation in a pediatric emergency department? *Pediatric Emergency Care, 25*(10), 661-664.

Carayon, P., Schoofs Hundt, A., Karsh, B. T., Gurses, A. P., Alvarado, C. J., Smith, M., & Flatley Brennan, P. (2006). Work system design for patient safety: the SEIPS model. . *Quality and Safety in Health Care, 15*(suppl 1), i50-58. doi: 10.1136/qshc.2005.015842

Cohen, L. B., Wecsler, J. S., Gaetano, J. N., Benson, A. A., Miller, K. M., Durkalski, V., & Aisenberg, J. (2006). Endoscopic sedation in the United States: results from a nationwide survey. *American Journal of Gastroenterology, 101*(5), 967-974. doi: 10.1111/j.1572-0241.2006.00500.x

Coté, C., Karl, H. W., Notterman, D. A., Weinberg, J. A., & McCloskey, C. (2000). Adverse sedation events in pediatrics: analysis of medications used for sedation. *Pediatrics, 106*(4), 633-644.

Coté, C. J., & Wilson, S. (2006). Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures: An update. *Pediatrics, 118*(6), 2587-2602. doi: 10.1542/peds.2006-2780

Couloures, K. G., Beach, M., Cravero, J. P., Monroe, K. K., & Hertzog, J. H. (2011). Impact of provider specialty on pediatric procedural sedation complication rates. *Pediatrics, 127*(5), e1154-1160. doi: 10.1542/peds.2010-2960

Cravero, J., Blike, G. T., Beach, M., Gallagher, S., & Weiss, J. (2005). *The creation and inital results of the Pediatric Sedation Research Consortium* Paper presented at the American Society of Anesthesia Annual Meeting, New Orleans, LA.

Cravero, J. P., Blike, G. T., Beach, M., Gallagher, S. M., Hertzog, J. H., Havidich, J. E., & Gelman, B. (2006). Incidence and nature of adverse events during pediatric sedation/anesthesia for procedures outside the operating room: report from the Pediatric Sedation Research Consortium. *Pediatrics, 118*(3), 1087-1096. doi: 10.1542/peds.2006-0313

Crego, N. (2013). Pediatric sedation: a descriptive study of registered nurse practice in radiology. *Unpublished Manuscript*

Joint Commission International. (2011). *Comprehensive Accreditatation Manual for Hospitals*. Oak Brook, IL: The Joint Commission.

Kuhlthau, K., Ferris, T. G., & Iezzoni, L. I. (2004). Risk adjustment for pediatric quality indicators. *Pediatrics, 113*(1 Pt 2), 210-216.

Langhan, M. L., Mallory, M., Hertzog, J., Lowrie, L., & Cravero, J. (2012). Physiologic monitoring practices during pediatric procedural sedation: a report from the Pediatric Sedation Research Consortium. *Archives of Pediatrics & Adolescent Medicine, 166*(11), 990-998. doi: 10.1001/archpediatrics.2012.1023

Lavoie, L., Vezina, C., Paul-Savoie, E., Cyr, C., & Lafrenaye, S. (2012). Procedural pediatric sedation by nurses: available, competent, and safe. *International Journal of Pediatrics, 2012*, 820209. doi: 10.1155/2012/820209

Metzner, J., & Domino, K. B. (2010). Risks of anesthesia or sedation outside the operating room: the role of the anesthesia care provider. *Current Opinion in Anaesthesiology, 23*(4), 523-531. doi: 10.1097/ACO.0b013e32833b7d7c

Pate, M. F., & Steelman, R. (2007). Questions unanswered: propofol use in the pediatric intensive care unit. *AACN Advanced Critical Care, 18*(3), 248-252.

Polaner, D. M., Houck, C. S., Rockoff, M. A., Mancuso, T. J., Finley, G. A., Maxwell, L. G., . . . Davis, P. J. (2001). Sedation, risk, and safety: do we really have data at last? *Pediatrics, 108*(4), 1006-1008.

Practice advisory on anesthetic care for magnetic resonance imaging: a report by the Society of Anesthesiologists Task Force on Anesthetic Care for Magnetic Resonance Imaging. (2009). *Anesthesiology, 110*(3), 459-479. doi: 10.1097/ALN.0b013e31818f9206

Pronovost, P., Miller, M., & Wachter, R. (2006). Tracking progress in patient safety: an elusive target. *JAMA, 296*(6), 696-699. doi: 10.1001/jama.296.6.696

Tabachnick, B., & Fidell, S. (2007). *Using Multivariate Statistics* (5th ed.). Boston, MA: Pearson Education.

Woodthorpe, C., Trigg, A., Gurney, A., & Sury, M. (2007). Nurse led sedation for paediatric MRI: progress and issues. *Paediatric Nursing, 19*(2), 14-18.

CHAPTER SIX

Conclusion

The purpose of this dissertation was to examine pediatric registered nurse (RN) sedation practices and outcomes that inform current regulation of and potentially impact pediatric sedation safety in the United States. A systems engineering conceptual framework (Systems Engineering Initiative for Patient Safety model) was used to identify the concepts influencing sedation safety and knowledge gaps pertaining to RN sedation safety. This work has described three issues relevant to RN sedation care: (1) inconsistencies in the regulation of RN sedation practice by Boards of Nursing in the U.S.; (2) RN pediatric sedation practice in diagnostic radiology; and (3) outcomes of RNs monitoring and delivering sedation alone as compared to physician (MD) monitoring and delivering sedation alone and teams of RN and MD sedation providers. However, there are considerable gaps in knowledge in each of these areas of sedation care that will require further research in order to improve sedation care and safety in the U.S.

RN Sedation Regulation

A comprehensive examination of the organizations and agencies that are currently involved in setting national sedation care standards as well as the methods and evidence used to develop the standards was presented as a foundation for understanding current RN sedation regulation. Many external forces shape how RN sedation is regulated in the U.S. The multispecialty, complex nature of procedural sedation care has created a discordant system characterized by disagreements amongst physician specialty groups and RN specialists about how to make sedation care safe; this is evident in the contradictory standards and regulations found in the sedation literature. The research used to support opposing opinions on controversial issues such as the use of anesthetics by non-anesthesiologist providers are often criticized by

experts with differing viewpoints. Evidence is lacking to guide the practice and regulation of sedation by RN providers. This dissertation provides information about sedation practices by RNs in the pediatric population and used an existing data source to expand knowledge about their sedation practices and outcomes in order to inform sedation regulatory policy.

Although RNs frequently sedate adult and pediatric patients, most sedation research has focused on the physician role in sedation safety. The lack of data on RN sedation practice has hindered the development of evidenced-based nursing regulations. Current state Boards of Nursing regulations of sedation do not take into account contemporary sedation practices, such as RNs providing deep sedation. Evidence-based standards of RN sedation care are needed to improve patient care and protect public safety. The National Council of State Boards of Nursing (NCSBN) has the capability to develop a research strategy to elucidate current RN sedation practices and outcomes, as well as to provide guidance on the competencies necessary to develop an evidence-based, uniform sedation regulatory strategy. The first step in this process is to examine data from currently available sources to identify current RN sedation practices to expand research in this area.

Current RN Sedation Practice

Secondary data from an established sedation database was used to examine current RN sedation practice. Descriptive data on RN sedation practice in diagnostic radiology was obtained using the Pediatric Sedation Research Consortium (PSRC) database (Cravero, Bilke, Beach, Gallagher, Hertzog, Havidich & Gelman, 2006; Langhan, Mallory, Hertzog, Lowrie, & Cravero, 2012). Several notable findings emerged about RN sedation practice, such as the frequency that RNs provide deep sedation in diagnostic radiology. In addition patients sedated by RNs alone had similar American Society of Anesthesiologist (ASA) risk scores when compared to prior

studies describing cases sedated by physician sedation providers (Cravero et al., 2006; Langhan et al., 2012). Trends in sedative medications administered by RNs, such as the types of medications (e.g. opioids, anesthetics) and medication combinations used were also a key finding.

There were a high number of cases in which RNs used two or more medications for sedation in diagnostic radiology. The extent to which RNs administer more than one medication has not been described in prior studies of RN sedation practice. RNs delivered combinations of different types of medications to induce sedation, for example a combination of opioid and non-opioid sedatives. Thus descriptive statistics on the types of medications RNs administered includes some overlapping data. The most common combinations of medications were also reported. It was unclear why certain types of medications were combined, such as fentanyl, an opioid analgesic being used for a painless diagnostic procedure administered with a barbiturate like pentobarbital. This combination was the second most common medication combination administered by RNs in diagnostic radiology. There were also a low number of cases with RNs administering propofol, an anesthetic agent that is often restricted by state Boards of Nursing for use by RNs performing sedation. However, examining outcomes of sedation practice is necessary to gain a better understanding of the practices that improve or threaten safety.

Sedation Outcomes

The PSRC database was used to examine sedation outcomes of RNs monitoring and delivering sedation alone, physicians monitoring and delivering sedation alone and of RN and physician sedation teams working together to monitor and deliver sedation. After controlling for ASA score, procedure type, medications administered, and number of comorbid conditions, cases in which RNs alone or physicians alone monitored and delivered sedation had fewer

adverse events than RN and MD teams. It is unclear why this difference was found. However, there were several factors that influenced this result.

Variables with overlapping data such as the type of medication administered, were problematic in modeling adverse events. Instead, the number of medications administered during sedation was included in the model and were found to be important factors in the adverse event and adverse event type models. Cases in which two or more medications were administered had higher odds of experiencing adverse events. Identifying patients receiving two or more medications for procedural sedation may be a better indicator of adverse event risk than other measures, such as ASA risk score.

Determining if additional precautions, such as heightening levels of vigilance by increasing the frequency of obtaining physiological measures (i.e., blood pressure) or adding capnography monitoring during procedures regardless of the intended level of sedation or the type of medication used is a necessary next step. A preliminary investigation of the interaction of provider type and number of medications administered was considered in the adverse event model. Analysis of interactions requires a more in depth analysis that is beyond the scope of this dissertation but that will be included in future work by the investigator.

Propofol use was added to the study adverse event models because it was used in more than half the study sample and was rarely administered with any other medication. Although the use of propofol did increase the odds of any adverse events, it was not statistically significant and propofol use had little effect on several types of adverse events. However, RN administration of propofol for sedation remains a controversial issue. Regulations restricting the use of particular drugs to sedate patients may have unintended consequences such as promoting the use of other medications that may result in more adverse events. The use of several medications at

once to achieve an adequate depth of sedation but that can increase the odds of adverse events may be an unintended consequence of restricting the use of specific medications.

The outcome of changing sedative medication administration patterns to improve sedation safety was recently reported in a presentation at the Pediatric Academic Societies May, 2013 meeting. The investigator reported that by changing to a combination of ketamine and propofol instead of ketamine and fentanyl, a 14% decrease in overall adverse events and a 35% decrease in desaturations requiring bag valve mask ventilation was achieved in a group of emergency departments (Bhatt et al., 2013). This finding could indicate that restricting RN use of a drug such as propofol could influence physician sedative medication ordering practices and cause RN providers to use other potent but non-restricted drugs such as fentanyl to achieve deep levels of sedation. In addition, as new sedative medications become available and evidence of the safety of using combinations of medications grows, regulations and standards of sedation care will require updating to incorporate new evidence on the affect of specific medications on adverse sedation events.

One strategy currently used to mitigate the risk of sedation adverse events is to consider the patient's risk of complications in order to assign the appropriate provider to manage their sedation. ASA greater than two was included in all of the adverse event and adverse event type models. There was no difference in the percentage of cases with ASA scores greater than two between RN alone cases and remaining cases, which include both the MD alone, and RN and MD teams. A preliminary investigation of the interaction of provider type and ASA greater than two was considered in the adverse event model. Analysis of interactions requires a more in depth analysis that is beyond the scope of this dissertation but that will be included in future work by the investigator. In this study sample the type of procedure (any MRI) and the use of more than

two medications were better predictors of adverse sedation events than high ASA. These findings indicate that perhaps the ASA score, which has been validated in patients receiving anesthesia in the operating room but has never been validated on patients receiving sedation outside the operating room, may lack specificity in identifying cases at higher risk for sedation complications.

Limitations

Limitations of this study include that the PSRC database used for this study does not contain more specific information about sedation providers and the organizations and regions in which they work. This level of information is important to determine other aspects of sedation provider qualifications and experience that may impact adverse events. For example, although the PSRC database consists of data on children, several of the consortium member institutions are general, not pediatric hospitals. Therefore, the amount of experience an RN or MD provider has sedating children could influence sedative administration choice, the route of medication administration and the response toward untoward sedation events. Patient level data is not included in the database, limiting the ability of investigators to evaluate the severity of adverse events and to identify delayed adverse events, and to conduct more extensive patient outcome studies.

Organizational sedation policies such as how sedation providers are trained or credentialed, how sedation performance is monitored and the mechanisms used to deliver sedation are also unavailable in the PSRC and could not be evaluated. Regional information is also limited in the PSRC so it was not possible to determine if the state RN sedation regulations had an affect on how RNs practiced sedation. The lack of an up to date source listing sedation regulation by states further limits the ability to evaluate regulation affects on sedation practice.

In addition there is no cost or reimbursement data that might further inform how sedation provider choices are made.

Contributions

This study has contributed to current knowledge of sedation regulation, practices and outcomes of RNs providing care to children in diagnostic radiology. This study has also provided a framework for using secondary data from the PSRC database to develop knowledge in this area. Using a systems engineering conceptual framework and drawing from existing data from a reliable source it was possible to obtain information on RN sedation practice from a large multisite sample and compare safety outcomes with other types of sedation providers. The same methods can be used to further expand knowledge of RN sedation practice in practice locations such as endoscopy and compare findings to other providers or practice areas. It is particularly important to use large sample sizes to accurately determine the frequency and types of adverse events that occur with RN sedation.

The first important finding was that the patients sedated by RNs alone had similar sedation risk scores as other sedation providers but that RN cases consistently had lower odds of adverse events than other sedation providers. This finding contradicts the assumption that RNs provide care to generally healthy and lower risk patients than physician providers do and has implications for how RNs are educated to provide sedation. In addition, the higher risk of adverse events when RN and physician teams provide sedation compared to other types of providers has not been reported previously. Current standards and guidelines addressing sedation practice focus on the skills and preparation of individual sedation providers and have not investigated how these teams function. However, findings from this study indicate that RN and

physician sedation teams may not be working in the same way as individual providers and that these differences can impact safety.

Findings on current RN sedation practices such as RN medication administration patterns can also inform clinicians and educators about the importance of discussing the administration of single and combinations of sedative agents. The best predictor of adverse sedation events in this study were the number of medications administered, this finding has not been noted in prior studies of RN sedation and could be used to identify patients particularly at risk for complications or lead to alterations in sedative medication ordering patterns. This study also supports the continued focus on airway competency for RN sedation providers based on the frequency with which respiratory adverse events occurred.

There were two areas in which this study contributed to the regulation of RN sedation practice. The first area is that reporting findings from a large multisite database can be used to begin to build evidence on current RN sedation practices so that regulations can address specific areas of contemporary sedation practice. In reviewing state Board of Nursing regulations, many appeared to be based on evidence that was over a decade old and based on studies of physician sedation practice that should be updated. The second way this study contributes to improving sedation regulation is by presenting a systematic review of the current regulatory strategies used by state Boards of Nursing by drawing attention to the contradictory aspects of sedation regulation and providing a strategy to improve how RN sedation is regulated in the U.S. Although this study has contributed to several areas of RN sedation care delivery and safety there are several research gaps that require investigation. Little is known about how RN and MD teams work together to provide sedation and whether or not team behaviors and communication differ depending on the type of procedure being performed or the complexity of the case.

Future Research

Research on sedation team dynamics may require primary data collection of quantitative and qualitative data to be collected and combined with data collected in the PSRC database. Other provider characteristics such as the experience and specialty training of RN sedation providers might also be factors that influence sedation safety, but would also need to be collected through primary data collection. Future research using the PSRC database should investigate outcomes of interventional procedures when RN and MD sedation teams deliver care, compared to the outcome of sedation provided by RN and MD teams for diagnostic procedures. Some of this data could be obtained using high fidelity simulations.

Although there has been some research exploring the use of simulation to improve sedation care delivery, the emphasis has been on the performance of the physician sedation provider or to test the ability of sedation safety systems to respond to adverse sedation events, rather than to identify the communication and other safety practices multidisciplinary teams use to provide sedation (Cravero & Havidich, 2011). The use of simulation to train sedation providers and improve skills in performing sedation has only recently been studied, but could be expanded to investigate how decision-making occurs immediately before the sedation procedure begins (Cravero & Havidich, 2011). Simulation may also be beneficial in the initial and re-credentialing process to assure that sedation providers such as RNs continue to maintain competency in the skills required to rescue the patient.

The effectiveness of credentialing methods for RN sedation practice remains largely underdeveloped and untested. Many methods have been reported in order to credential sedation providers (Havidich & Cravero, 2012). The processes used include self-study programs with written testing, with some organizations requiring experiences in the operating room or other

forms of skills demonstration to be completed by sedation providers. However, the information provided in the education process usually concerns minimal established standards and information on common adverse events, such as respiratory events.

Sedation education for RNs could be enhanced if data on the types of medications, medication combinations, and common adverse events RNs must manage during sedation were identified and included in the sedation education process. In addition, RNs often work with other sedation providers such as physicians, so communication methods and the roles of sedation team members may need to be identified and elucidated in organizational policies and procedures that are used for provider training. This method has been used in developing organizational policies in other areas, such as organizational resuscitation policies and the development of rapid response teams. Research on how sedation-care delivery systems, organizational policies including training methods impact the outcomes of sedation care has not been published. Information on the PSRC member organizations sedation care delivery systems, organizational policies and training methods could be a preliminary source of this type of data and could also advance research in the area of sedation regulation and policy.

As research on sedation continues, information at the regional and organizational level will be necessary to understand internal and external influences on sedation care delivery. Expansion of the PSRC database will allow researchers to access and compare organizational data such as the type of sedation delivery system used, organizational sedation policy characteristics, and how sedation provider credentialing occurs, to further increase knowledge about safe sedation practice. In addition, collecting the same type of data on sedation in organizations that are not members of the PSRC would provide important comparison data to determine if the PSRC reflects the standards sedation practice and outcomes or the gold standard

of sedation care. This will be an important determination, if results of the data from the PSRC are going to be used to change current sedation practices and policies.

Another gap in sedation research is determining what defines quality sedation. Current data on sedation has focused on some quality measures such as time for induction of sedation, recovery times and changes in physiologic measures such as vital signs to evaluate sedation safety. However, there is very little data on other common measures of quality concerning sedation. For example, there is paucity of research exploring the use of a common quality measure such as parent or patient satisfaction with sedation delivery systems. Also, although the frequency and type of delayed adverse events have been reported in a few studies, more data would be useful as these may be important in evaluating how sedation care is delivered (Malviya, Voepel-Lewis, Prochaska, & Tait, 2000). In addition, there is very little information on the effectiveness of methods to avoid sedation for diagnostic procedures all together, which would decrease the costs and potential for adverse sedation events. Finally, evidence about RN sedation practice with adults is also needed and could be obtained using a similar framework as the current PSRC database.

Conclusion

This study applied a systems engineering framework to identify concepts important to expand knowledge of sedation safety in pediatric diagnostic radiology. Research on sedation can be used to develop improved sedation care delivery systems that payors, regulators and the public can use to evaluate quality and to assure public safety. While this research has contributed to foundational knowledge concerning RN sedation regulation, practices and outcomes, it also reported differences in sedation practice and outcomes of physician providers. Several areas requiring further research were identified during the research process. The strategies and

methodology used to conduct this study can be employed in future studies to continue to build knowledge in this area.

References

Bhatt, M., Roback, M. G., Klassen, T. P., Farion, K. J., Ali, S., Beno, S. C., . . . Johnson, D. W. (2013). *Improving the quality of emergency department sedation*. Paper presented at the Pediatric Academic Societies Annual Meeting, Washington, DC.

Cravero, J. P., Blike, G. T., Beach, M., Gallagher, S. M., Hertzog, J. H., Havidich, J. E., & Gelman, B. (2006). Incidence and nature of adverse events during pediatric sedation/anesthesia for procedures outside the operating room: report from the Pediatric Sedation Research Consortium. *Pediatrics, 118*(3), 1087-1096. doi: 10.1542/peds.2006-0313

Cravero, J. P., & Havidich, J. E. (2011). Pediatric sedation--evolution and revolution. *Paediatric Anaesthesia, 21*(7), 800-809. doi: 10.1111/j.1460-9592.2011.03617.x

Havidich, J. E., & Cravero, J. P. (2012). The current status of procedural sedation for pediatric patients in out-of-operating room locations. *Current Opinion in Anaesthesiology, 25*(4), 453-460. doi: 10.1097/ACO.0b013e32835562d8

Langhan, M. L., Mallory, M., Hertzog, J., Lowrie, L., & Cravero, J. (2012). Physiologic monitoring practices during pediatric procedural sedation: a report from the Pediatric Sedation Research Consortium. *Archives of Pediatrics & Adolescent Medicine, 166*(11), 990-998. doi: 10.1001/archpediatrics.2012.1023

Malviya, S., Voepel-Lewis, T., Prochaska, G., & Tait, A. R. (2000). Prolonged recovery and delayed side effects of sedation for diagnostic imaging studies in children. *Pediatrics, 105*(3), E42.

APPENDICES

Appendix 1
JOURNAL of NURSING REGULATION

Author Guidelines

Content Preparing your manuscript
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Journal of Nursing Regulation (JNR), the official journal of the National Council of State Boards of Nursing (NCSBN ®), a quarterly, peer-reviewed, academic and professional journal. It publishes timely articles that advance the science of nursing regulation, promote the mission and vision of NCSBN, and enhance communication and collaboration among nurse regulators, educators, practitioners, and the scientific community. The journal supports evidence-based regulation, addresses issues related to patient safety, and highlights current nursing regulatory issues, programs, and projects in both the United States and the international community. In publishing *JNR,* NCSBN's goal is to develop and share knowledge related to nursing and other healthcare regulation across continents and to promote a greater awareness of regulatory issues among all nurses.

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Unless otherwise requested, prepare your manuscript according to the *Publication Manual of The American Psychological Association,* 6th edition. Make sure the narrati
paragraphs.

As appropriate, break the manuscript into main sections by inserting subheads, which should be succinct, meaningful, and similar in sense and tone. Provide practical information supported by evidence and examples from your own experience and practice to illustrate certain points.

Include case histories when appropriate. Avoid excessive technic At first mention, p
complete terms for abbreviations and acronyms. For all subsequent uses of these terms, use the abbreviation or acronym only.

Format top Use flush left alignment only. Do not justify the right margin. Do not
footers. Do not insertru
any mechanism, including MS Word's Format < Borders & Shading functionality.

Length top Article length should be 2,500 to 4,500 words, including sidebars, tables, figures, and references. Book reviews should be 600 words. ***Sidebars, tables, and figures*** top You may wish to create sidebars to emphasize, clarify, or elaborate on special points. To do this, create a separate Word file for that copy. DO NOT box this copy using MS Word's text box functionality. Label the copy clearly; for example, "Points to remember about....". Keep in mind that during the editorial process, sidebars may be created from the text by the editorial team.

Number tables consecutively with Arabic numbers and provide a title for each one. Tables and figures must be cited in numerical order in the text. DO NOT embed tables in the text file. Please place all sidebars, tables, and figures at the end of the file, after the references.

Illustrations top If you wish to submit art electronically, you may send the images as a Tagged Image File Format (TIFF) or as an Encapsulated Postscript (EPS) file. Do not submit Word

Journal of Nursing Regulation - Author Guidelines http://jnr.metapress.com/home/authors.mpx

documents or PowerPoint slides for figures or photos. Do not embed illustrations or images in the article file; each should be sent as a separate file.

Combination art (line/tone) should have a minimum of 500 dpi. Color figures sho
the art that you supply, briefly describe what it shows and its source; for example, "Illustration #1: Obtaining a ____; Source: ____."

If you have suggestions for other visual elements but don't have access to the actual images, please let us know.

References top Make sure your references are from professionally reliable sources and are no more than 5 years old (unless it is a classic work on the topic). All citations in the manuscript must appear in the reference list, and vice versa. Provide sufficient references to support your research, but do not go overboard. Your reference list should be succinct, not exhaustive.

Include a maximum of 25 references. Verify in the manuscript, cite each author and year
Psychological Association (APA) style. For online references, inclu
information was posted (if available), and the date it was accessed. For citations and r
and include all important elements—author, title, location, publisher, and date. Arrange reference entrie
alphabetical order by the surname of the first author. Alphabetize entries w

out. Place the reference list at the end of the manuscript.

Submitting your manuscript top

Please submit your manuscript electronically by e-mailing the MS Word file. Be sure to send the file as an attachment to your cover e-mail; DO NOT embed the manuscript within your e-mail. Please attach any illustrations as separate files.

In your cover e-mail, include your name, address, home and work telephone numbers, cell phone number (if appropriate), e-mail address, and fax number (if appropriate). Be sure to include a separate list of all authors who wrote or contributed to the article, including their full names, degrees, credentials, titles, and affiliations.

Keep both an electronic copy and a hard copy for your files.

After we receive your manuscript... top

We will send you an e-mail confirming that we received your manuscript. If we decide we are interested in publishing it, we will send it out for blind peer review. After this review, we will let you know if your manuscript has been accepted, accepted pending revisions, or rejected.

Accepted manuscripts will go through an in-house editorial process to ensure consistency with our editorial style. You will be involved in this process and will have the opportunity to review and approve the edited version.

For additional author information, contact Cynthia Saver, RN, MS csaver@clsdevelopment.com. For a complimentary issue of the journal for review, contact Beth Radtke bradtke@ncsbn.org.

Thank you for your interest in writing for us!

Appendix 2

Pediatric Nursing

Writing for *Pediatric Nursing:* This journal's purpose is to reflect trends, policies, practice, and research in pediatric nursing. Topics should be timely, controversial, and currently unavailable in the literature. A query letter is requested, including an abstract of the manuscript and the anticipated submission date. Un- solicited manuscripts are welcome, provided that they are for the exclusive use of *Pediatric Nursing* and have not been previously published or accepted for publication, or are under consideration elsewhere. Authors are encouraged to use clear, concise, nondiscriminatory language.

Manuscript Form: Manuscripts should be typewritten, double-spaced, on one side of 8-1/2 x 11 inch white paper; maximum length 20 pages (5,000 words). A cover page should include the manuscript title (10-12 words); authors' names, credentials, and primary affiliations; and the address, telephone numbers, and fax number of the primary author. This page should be followed by a substantive abstract of approximately 125- 150 words. Manuscript title should be repeated on the first page of the text.

Photographs can be color or black and white glossy, 5" x 7" or 8" x 10" inches, and of crisp, clear quality. Authors must obtain all required per- mission to use tables or figures from other sources prior to publication.

References: References, photo- graphs, figures, tables, and all other details of style must conform with the *Publication Manual of the American Psychological Association* (APA, 6th ed., 2010). All references in text should be cited by author and date, for example, (Doe & Brown, 2010). List all references in alphabetical order. Only use references that are actually cited with- in the text. Authors are encouraged to provide the digital object identifier (DOI) number directly after all references when possible.

Citing multiple authors: In-text citations with six or more authors should include the first author followed by et al., even in the first citation.

Seven authors or less:

In the Reference section, list all seven authors. Sample: Doe, J.R., Brown, M.S., Trent, J.R.,

Michaels, M.S., Bradley, J.R., Willis, M.S., & Williams, J.R. (2010). *Pediatric nursing care.* New York: Academic Press. (Book)

Eight or more authors: In the Reference section, list the first six authors, then an ellipsis, then the last author. Sample:

Doe, J.R., Brown, M.S., Smith, J.R., Jones, M.S., Thomas, J.R., White, M.S., ... James, J.R. (2010). Coping with hospitalization. *Pediatric Nursing, 21(2),* 115-120. (Journal Article)

Manuscripts must NOT contain reference software codes, and the use of reference software is highly discouraged.

Review Process: Receipt of manuscript is acknowledged by the editorial coordinator. *Pediatric Nursing* is a refereed journal; therefore, each manuscript is reviewed by members of the Manuscript Review Panel as well as the editors. Because manuscripts are reviewed blind (authors anonymous), names of authors should appear **only** on the cover page. Decisions regarding acceptance for publication are based on the recommendations of the referees.

Editing: *Pediatric Nursing* reserves the right to edit all manuscripts according to its style and space requirements and to clarify content. Edited copy will be returned to the primary author for approval.

Publication: Authors will be notified of a manuscript's acceptance usually within 12 weeks of receipt, with publication in the next available issue. Manuscripts not accepted for publication will not be returned to the authors. Authors may purchase re- prints of their articles at the time of publication. All authors of published articles will receive 10 complimentary copies (to be distributed to any co- authors) in appreciation of their work.

Submission Procedure: Authors must submit two hard copies and one electronic copy (CD-ROM, flash drive, e-mail; MS Word format only) to be eligible for review. Electronic submission may be e-mailed to Editorial Coordinator Joe Tonzelli at joe@ajj.com. Send hard copies to address below. The Journal will accept both IBM and Macintosh format disks.

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Appendix 3

Pediatrics Author Guidelines

Introduction

Pediatrics is the official peer-reviewed journal of the American Academy of Pediatrics. *Pediatrics* publishes original research, clinical observations, and special feature articles in the field of pediatrics, as broadly defined. Contributions pertinent to pediatrics also include related fields such as nutrition, surgery, dentistry, public health, child health services, human genetics, basic sciences, psychology, psychiatry, education, sociology, and nursing. *Pediatrics* is the most-cited journal in the field of pediatrics, with a 2010 impact factor of 5.391, and a circulation of 66,000. It is translated in full or in part into four languages, Spanish, Polish, Chinese, and Portuguese.

Pediatrics considers unsolicited manuscripts in the following categories: reports of original research, particularly clinical research; review articles; special articles; and case reports. When preparing a manuscript for *Pediatrics,* authors must first determine the manuscript type and then prepare the manuscript according to the specific instructions below.

The electronic edition of *Pediatrics* is the journal of record. Some accepted articles may also be presented in full in the print version. The editors reserve the right to determine whether an accepted manuscript will be published in the print edition in addition to the electronic edition of *Pediatrics.*

Acceptance Criteria

Relevance to readers is of primary importance in manuscript selection. The readership includes general and specialist pediatricians, pediatric researchers and educators, and child health policy- makers. *Pediatrics* receives many more high quality manuscripts than can be accommodated based on our available space. The current acceptance rate is approximately 10%. An article that is thought by the editors to be not relevant to readers, outside of scope or very unlikely to be accepted may be rejected without review. All manuscripts considered for publication are peer reviewed. Peer reviewers are selected by the editors based on their expertise in the topic of the manuscript; generally at least 2 reviews are required before a decision is rendered. Authors may suggest appropriate reviewers and may also suggest reviewers who should not review the manuscript.

Authors should carefully follow instructions for manuscript preparation, and ensure that the manuscript is proofread before submission. Manuscripts that do not adhere to the author instructions will not be considered for review. Careless preparation of a manuscript suggests careless execution of the research and therefore makes acceptance unlikely. Manuscripts are scanned for plagiarism using the latest software; if potential plagiarism is detected, the editors will contact the authors for clarification, and may also contact the authors' institution.

Submissions of original research are judged on the importance and originality of the research, scientific strength, clinical relevance, the clarity of the manuscript, and the number of submissions on the same topic.

Pediatrics accepts review articles, with preference given to systematic reviews, which may include meta-analyses. State-of-the-Art Review Articles and Perspectives are generally solicited by the editors or the associate editors for their respective sections. Special Articles reflect topics or issues of relevance to pediatric health care that do not conform to a traditional study format. Case Reports must challenge an existing clinical or pathophysiologic paradigm; provide a starting point for novel hypothesis-testing clinical research; and/or offer a clinical lesson. Quality Reports provide a venue for manuscripts that describe the implementation and outcome of quality-improvement projects. Authors should review and follow the comprehensive reporting guidelines for a wide variety of study designs that are available at http://www.equator-network.org/home/.

Authors submitting manuscripts involving adverse drug or medical device events or product problems should also report these to the appropriate governmental agency.

Pediatrics does not publish manuscripts that involve animal research.

Unsolicited commentaries will be considered for publication; however, most commentaries are solicited by the editors. Responses to a published article should be submitted as eLetters (see this section); selected eLetters may be published in the journal as Letters to the Editor.

Incorrect grammar, language use, or syntax may distract readers from the science being communicated and may lead to less favorable reviews. To help reduce this possibility, we strongly encourage authors to have their manuscripts reviewed for clarity

by colleagues. If the authors' native language is not English, we strongly encourage review and editing by a colleague whose native language is English or the use of an English language editing service.

Peer reviewers are asked to assess each manuscript for originality; for interest to scientists, practitioners and policy makers; for quality of the analysis; and for quality of the presentation, and are asked to assess the priority of the paper for publication. After the reviews are received, the editors may take one of the following actions: *Accept; Accept with Revisions; Reject with option to Resubmit;* or *Reject.* A rejected manuscript may not be resubmitted. A manuscript may be rejected with an option to resubmit when additional data or analyses are requested by reviewers, or when extensive revision of the text is needed. The resubmitted manuscript receives an additional round of peer review (which may include new reviewers), and the manuscript may or may not be accepted. A decision of *Accept with Revision* indicates that the editors intend to accept the manuscript contingent on adequate response to reviewers. A decision of Accept (which is exceedingly rare on first submission) indicates that the manuscript is ready to place into production without further modification. Decisions by the editors are final.

Publication Ethics

Authorship. An "author" is someone who has made substantive intellectual contributions to a published study. Each author is required to meet ALL THREE of the following criteria:

1) Substantial contribution(s) to conception and design, acquisition of data, or analysis and interpretation of data; 2) Drafting the article or revising it critically for important intellectual content; and 3) Final approval of the version

NOTE: Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute a sufficient basis for authorship.

All persons listed as authors must meet these criteria, and all persons who meet these criteria must be listed as authors. Although *Pediatrics* does not specifically limit the number of authors (except for Case Reports), articles submitted with an unusual number of authors invite scrutiny by editors and reviewers for clear justification for the presence of each person on the authorship list. *Pediatrics* does not permit more than one author to claim any particular position in the author list (e.g., two first authors, or two senior authors). Decide authorship issues, including the order, before submission. **After submission, any authorship changes require the written approval of all authors.**

Conflict of Interest. When a paper is accepted by *Pediatrics,* all authors must submit a conflict of interest form. *Pediatrics* adheres to the policy and uses the standardized form of the International Committee of Medical Journal Editors (ICMJE). (http://www.icmje.org/coi_disclosure.pdf). The collection of this form is automated within the online submission system.

IRB Approval. All studies that involve human subjects must be approved or deemed exempt by an official institutional review board; this should be noted in the Methods section of the manuscript.

Industry sponsorship. *Pediatrics* generally does not accept reports of studies in which all authors are employed by a commercial entity with a financial interest in the results of the study.

Registration of Clinical Trials. All clinical trials must be registered in a World Health organization-approved Clinical Trial registry prior to enrollment of the first subject. The registry name and registration number should be included on the title page. Reports of unregistered trials will be returned to authors without review. Publication of the results of a trial that was initiated prior to the ICMJE requirement for trial registration will be considered by the editors on a case-by-case basis.

Journal Style

All aspects of the manuscript, including the formatting of tables, illustrations, and references and grammar, punctuation, usage, and scientific writing style, should be prepared according to the most

current *AMA Manual of Style* (http://www.amamanualofstyle.com). 1 **Author Listing.** All authors' names should be listed in their entirety, and should include

institutional/professional affiliations and degrees held.

Titles. *Pediatrics* generally follows the guidelines of the AMA Manual of Style for titles (http://www.amamanualofstyle.com). Titles should be concise and informative, containing the key topics of the work. Declarative sentences are discouraged as they tend to overemphasize a conclusion, as are questions, which are more appropriate for editorials and commentaries. Subtitles, if used, should expand on the title; however, the title should be able to stand on its own. It is appropriate to include the study design

("Randomized Controlled Trial"; "Prospective Cohort Study", etc.) in subtitles. The location of a study should be included only when the results are unique to that location and not generalizable. Abbreviations and acronyms should be avoided. The full title will appear on the article, the inside table of contents, and in MEDLINE. Full titles are limited to 97 characters, including spaces. Short titles must be provided as well and are limited to 55 characters, including spaces. Short titles may appear on the cover of the journal as space permits in any given issue.

Abbreviations. On the title page, authors should provide an alphabetically ordered list of abbreviations used in the manuscript and what they stand for. Unusual abbreviations should be avoided. All terms to be abbreviated in the text should be spelled out at first mention, followed by the abbreviation in parentheses. The abbreviation may appear in the text thereafter. Abbreviations may be used in the abstract if they occur 3 or more times in the abstract. Abbreviations should be avoided in tables and figures; if used they should be redefined in footnotes.

Key Words. Authors should provide key words on the title page, using Medical Subject Headings (MeSH) terms as a guide. Visit: *http://www.nlm.nih.gov/mesh/meshhome.html*

Units of Measure. Like many US-based journals, *Pediatrics* uses a combination of Système International (SI)2,3 and conventional units. Please see the *AMA Manual of Style* for details.

Proprietary Products. Authors should use nonproprietary names of drugs or devices unless mention of a trade name is pertinent to the discussion. If a proprietary product is cited, the name and location of the manufacturer must also be included.

References. Authors are responsible for the accuracy of references. Citations should be numbered in the order in which they appear in the text. Reference style should follow that of the *AMA Manual of Style,* current edition. Abbreviated journal names should reflect the style of Index Medicus. Visit: *http://www.nlm.nih.gov/tsd/serials/lji.html*

Authoring Groups: If you choose to include an organization, committee, team, or any other group as part of your author list, you must include the names of the individuals as part of the Acknowledgments section of your manuscript. This section should appear after the main text prior to your References section. The terms "for" or "on behalf of" must also be used when referencing the authoring group in the by-line.

Manuscript Preparation

All submissions must adhere to the following format: —Times New Roman font, size 12 —Title Page, Contributor's Statement Page, Abstract, Acknowledgments, and References should be **single-spaced** —Main Body Text should be **double-spaced** —Main Submission Document as Microsoft Word or RTF file (no PDFs) —Do **not** include page headers, footers, or line numbers

Refer to the "Article Types" section (below) for specific guidelines on preparing a manuscript in each specific category; note in particular the requirements regarding abstracts for different categories of article.

Title Page

The "title page" should be the first pages of your main document, and depending on the individual needs of a paper may encompass more than one page.

Title pages for all submissions **must** include the following:

1) Title (97 characters [including spaces] or fewer)

2) Full names for all authors, including degrees, and institutional/professional affiliations.

3) Contact information for the Corresponding Author (including: name, address, telephone, and e-mail).

4) A short title (55 characters [including spaces] or fewer). Please note: the short title may be used on the cover of the print edition.

5) Abbreviations in alphabetical order. 6) Key words.

7) Funding source. Research or project support, including internal funding, should be listed here; if the project was done with no

specific support, please note that here. Technical and other assistance should be identified in Acknowledgments

8) Financial Disclosure Statement (if there is nothing to disclose, please state so). 119) Conflict of Interest Stater
authors (if there are no conflicts, please state so). 10) If applicable, Clinical Trial registry name and registration number

11) For regular article submissions, include the "What's Known on This Subject; What This Study Adds" (see below under article type for description). This is not needed for any other article type.

If a title page does not include all of the above items, the submission may be returned to the authors for completion.

[Sample Title Page]

Title of Manuscript [97 characters maximum, including spaces]

Alice Author1, MD, Clarence CoAuthor1,2, MD, PhD, Ann Analyst, MPH, on behalf of Authoring Group A

Affiliations: 1Children's Hospital, Chicago, Il; 2University of Chicago, Chicago, Il **Address correspondence to:** Alice Author, Department of Pediatrics, Children's Hospital,

1234 Main Street, Chicago Il, 60641, [aauthor@example.com], 773-900-9000.

Short title: Short running title for Manuscript [55 characters maximum, including spaces]

Abbreviations: Hgb – hemoglobin; SES – socioeconomic status

Key Words: iron deficiency, anemia, infant, adult, developmental origins of health and disease

Funding Source: All phases of this study were supported by an NIH grant, ######. [or] No external funding was secured for this study.

Financial Disclosure: Clarence CoAuthor has example disclosure. The remaining authors have no financial relationships relevant to this article to disclose.

Conflict of Interest: Ann Analyst has example conflict. Clarence CoAuthor has other example conflict. The other authors have no conflicts of interest to disclose.

Clinical Trial Registration: (Registry name and registration number if any) **[for Regular Articles only:]**

What's Known on This Subject

Max 40 words; in paragraph style (not bulleted lists)

What This Study Adds

Max 40 words; in paragraph style (not bulleted lists)

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Clinical Trials

A study is considered a clinical trial if it prospectively assigns human subjects (whether randomized or not) to intervention or concurrent comparison or control groups to study the cause- and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like. If authors report the results of a clinical trial, they must affirm that the study has been registered at www.clinicaltrials.gov or another WHO-approved national or international registry prior to the enrollment of the first subject. Current information on requirements and appropriate registries is available at http://www.icmje.org/. The trial registration number must be listed on the title page of the manuscript, and at the end of the abstract. Authors are also required to complete the CONSORT Form and submit it along with the initial submission of their manuscript. In our submission system, this form is found under "Instructions and Forms." It can be reached directly at:

http://mc.manuscriptcentral.com/societyimages/pediatrics/Consort%20Form.pdf.

Contributors' Statement Page

All submissions must contain a Contributors' Statement Page, directly following the Title Page. Manuscripts lacking a complete contributors' statement page will be returned to the authors for correction.

All persons designated as authors should qualify for authorship (see above), and all those who qualify should be listed. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Contributors who do not meet the criteria for authorship (such as persons who helped recruit patients for the study, or professional editors) should be listed in an acknowledgments section. Because readers may infer their endorsement of the data and conclusions, these persons must give written permission to be acknowledged.

The Contributor's Statement Page should list the authors in order, and for each, specify the contribution(s) made by that individual. A sample Contributor's Statement Page is shown below. **Follow this required format** when creating your Contributors' Statement Page.

Contributor's Statement: George X. Smith: Dr. Smith conceptualized and designed the study, drafted the initial

manuscript, and approved the final manuscript as submitted.

Roseanne Z. Jones: Dr. Jones carried out the initial analyses, reviewed and revised the manuscript, and approved the final manuscript as submitted.

Tucker R. Green: Ms. Green designed the data collection instruments, and coordinated and supervised data collection at two of the four sites, critically reviewed the manuscript, and approved the final manuscript as submitted.

Regular Article

Article Types

Abstract length: 250 words or fewer (structured) Article length: 3,000 words or fewer

NOTE: Title Page, Contributor's Statement Page, Abstract, Acknowledgments, and References are not included in the article length limit.

Regular Articles are original research contributions that aim to inform clinical practice or the understanding of a disease process. Regular Articles include but are not limited to clinical trials, interventional studies, cohort studies, case-control studies, epidemiologic assessments, and surveys. Components of a Regular Article include:

What's Known on This Subject; What This Study Adds Brief summaries on the topic of "What's Known on This Subject" and "What This Study Adds" are each limited to 40 words. For this section, please use precise and accurate language in paragraph form (i.e., *not bullet points).* For manuscripts accepted as regular articles, these summaries will become a highly visible part of your published paper, with prominence on the first page. Moreover, these summaries will be highlighted and presented in other areas of the journal, namely *Pediatrics Digest.* It is therefore paramount that you use language of the same caliber as the rest of your paper.

Structured Abstract A structured abstract must include headings such as: **Objective (or Introduction), Methods** (or **Patients and Methods), Results,** and **Conclusions.** The objective should clearly state the hypothesis; patients and methods, inclusion criteria and study design; results, the outcome of the study; and conclusions, the outcome in relation to the hypothesis and possible directions of future study.

o **Introduction** A 1- to 2-paragraph introduction outlining the wider context that generated the study and the hypothesis.

o **Methods** A "Patients and Methods" or a "Methods" section detailing inclusion criteria and study design to ensure reproducibility of the research.

o **Results** This section should give specific answers to the aims or questions stated in the introduction. The order of presentation

of results should parallel the order of the methods section.

o **Discussion** The section should highlight antecedent literature on the topic and how the current study changes the understanding of a disease process or clinical situation, and should include a section on the limitations of the present study.

o **Conclusion** A brief concluding paragraph presenting the implications of the study results and possible new research directions on the subject.

Case Report

Abstract length: 250 words or less (unstructured) Article length: 1,600 words or less Author lim it: Sever
less

Case Reports highlight unique presentations or aspects of disease processes that may expand the differential diagnosis and improve patient care. In general, case reports will include 10 cases or fewer. For a manuscript to be considered a Case Report, it must meet at least one the following 3 criteria:

. 1) Challenge an existing clinical or pathophysiologic paradigm, and/or

. 2) Provide a starting point for novel hypothesis-testing clinical research, and/or

. 3) Offer a clinical "lesson" that may allow pediatric colleagues to provide improved care.

Case Reports should consist of an unstructured abstract that summarizes the case(s), a brief introduction (recommended length, 1-2 paragraphs), a section that details patient presentation, initial diagnosis and outcome, as well as a discussion that includes a brief review of the relevant literature and describes how this case brings new understanding to the disease process.

The general instructions regarding submission (including cover letter, title page requirements, contributor's statement page, journal style guidance, and conflict of interest statements) also apply to Case Reports.

Commentary

Abstract length: no abstract Article length: 400 to 800 words

Commentaries are opinion pieces consisting of a main point and supporting discussion. These contributions usually pertain to and are published concurrently with a specific article; the commentary serves to launch a broader discussion of a topic. Commentaries may address general issues or controversies in the field of pediatrics.

While the vast majority of commentaries are solicited, we do accept unsolicited commentaries. However, unsolicited commentaries will go through the same peer-review process as other papers, and acceptance rates are low. Responses to published articles should be submitted as eLetters (see below).

The general instructions regarding submission (including cover letter, title page requirements, contributor's statement page, journal style guidance, and conflict of interest statements, also apply to Commentaries).

Ethics Rounds

Ethics Rounds present discussions of cases that illustrate ethical dilemmas in patient care, research, or administration. Authors who have a case that raises ethical issues and who want to submit a paper for Ethics Rounds should email Assistant Editor John Lantos (jlantos@cmh.edu).

The general instructions regarding submission (including cover letter, title page requirements, contributor's statement page, journal style guidance, and conflict of interest statements, also apply to Ethics Rounds).

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Monthly Feature

Abstract length: no abstract Article length: 1,200 words or less

The "Monthly Feature" column offers an opportunity to gain insight into aspects of our field: past, present, and future. Alternating monthly, the column will provide ongoing updates from three standing groups: (1) Global Health; (2) the Council on Medical Student Education in Pediatrics (COMSEP); and (3) the Historical Archives Advisory Committee for the AAP.

While many of the Monthly Features are invited, any queries or proposals should be directed to the editors of their respective columns: Jay Berkelhamer, MD (jberkelhamer@aap.net) for Global Health; Susan Bannister, MD (Susan.Bannister@albertahealthservices.ca) for COMSEP; and Jeffrey Baker, MD (Baker009@mc.duke.edu) for the AAP Historical Archives Advisory Committee.

The general instructions regarding submission (including cover letter, title page requirements, contributor's statement page, journal style guidance, and conflict of interest statements) also apply to Monthly Features.

Pediatrics Perspectives

Abstract length: no abstract Article length: 1,200 words max Autho

Pediatrics Perspectives are unsolicited commentaries that focus on issues of policy, public health, or other research and clinical topics related to infant, child, and/or adolescent health. These articles should be 1200 words maximum, be written by no more than three authors and have no more than 7 references.

The general instructions regarding submission (including cover letter, title page requirements, contributor's statement page, journal style guidance, and conflict of interest statements) also apply to Pediatrics Perspectives.

Quality Report

Abstract: 250 words or less (structured; see Regular Articles) Article: 3,000 words or
appropriate for figures, tables, multimedia, measurement tools

Quality Reports are intended to add to our understanding of how to improve quality in clinical settings in which pediatrics is practiced. Reports should provide descriptions of the change process, whether successful or unsuccessful, and include insights regarding why planned interventions did or did not lead to improvement. Descriptions of clinical trials to assess whether an intervention is effective or the development and testing of improvement-related tools for validity and reliability would be better suited as a Regular Article. However, pilot projects of interventions to improve the quality of care may be acceptable if there are important lessons that will serve as the basis for future studies. If you are uncertain whether your manuscript is appropriate as a Quality Report, email Interim Deputy Editor Alex Kemper, MD, MPH, MS (alex.kemper@duke.edu).

Authors are expected to generally follow the Standards for Quality Improvement Reporting Excellence (SQUIRE) Guidelines for reporting their quality improvement projects. These guidelines are described in detail on the SQUIRE website at www.squire-statement.org. Authors should note that the basic structure of a quality report should mirror the rest of the journal, using the IMRaD (Introduction, Methods, Results, Discussion) format. The SQUIRE guidelines suggest specific areas that need to be addressed in each section, with recognition that every report will have different areas of emphasis.

The following list is a very brief description of the sections of a Quality Report; authors should refer to the full SQUIRE report at www.squire-statement.org.

Introduction: ***What did you start?*** Summarizes background, local problem and local setting, and specific aim(s) of project.

Methods: ***What did you do?*** Describes ethical aspects, contextual issues, the intervention itself, implementation and evaluation plan, analysis.

Results: ***What did you find?*** Describes the actual course of the intervention, changes in process and outcomes, degree of success, problems and failures, lessons learned.

Discussion: ***What do the findings mean?*** Summarizes findings and considers factors that may have affected the outcome; includes interpretation of findings, conclusions, and next steps. The general instructi
regarding submission (including cover letter, title page requirements, contributor's statement page, journal style guidance, and conflict of interest statements) also apply to Quality Reports. **Review Article Abstract length: 250 words or less (structured or unstructured depending on review type) Article length: 4,000 words or less**
Review Articles combine and/or summarize data from the knowledge base of a topic. Preference is given to

systematic reviews and meta-analyses of clearly stated questions over traditional narrative reviews of a topic. Both types of review require an abstract; the abstract of a narrative review may be unstructured. The general instructi
regarding submission (including cover letter, title page requirements, contributor's statement page, journal style guidance, and conflict of interest statements) also apply to Review Articles. **Systematic Reviews and Meta-Analyses** Reports of systematic reviews and meta-analyses should use the PRISMA statement (http://www.prisma-statement.org/) as a guide, and include a completed PRISMA checklist and flow diagram to accompany the main text. Blank templates of the checklist and flow diagram can be downloaded from the PRISMA Web site (http://www.prisma-statement.org/statement.htm). Structured abstracts for sy
include: Context, Objective, Data Sc
al1[pp22-23]).

Special Article

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Statistical methods for obtaining all P-values should be provided

Units of independent variables must be provided in tables and results sections if regression coefficients are provided

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References

1. Iverson C, Christiansen S, Flanagin A, et al. *AMA Manual of Style.* 10th ed. New York, NY: Oxford University Press; 2007.

2. Lundberg GD. SI unit implementation: the next step. *JAMA.* 1988;260:73-76.

3. Système International conversion factors for frequently used laboratory components. *JAMA.* 1991;266:45-47.

4. International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals. http://www.icmje.org.

5. Clarke M, Lucey J. From paper to web-based submission: the evolution of *Pediatrics'* manuscript submission and review. *Pediatrics.* 2003:112:1413-1414.