



VCU

Virginia Commonwealth University
VCU Scholars Compass

Theses and Dissertations


Graduate School

2014

Factors That Predict Incident Reporting Behavior in Certified Registered Nurse Anesthetists

Nicole K. Damico
Virginia Commonwealth University

Follow this and additional works at: <https://scholarscompass.vcu.edu/etd>

 Part of the [Anesthesia and Analgesia Commons](#), [Applied Behavior Analysis Commons](#), and the [Social Psychology Commons](#)

© The Author

Downloaded from

<https://scholarscompass.vcu.edu/etd/3614>

This Dissertation is brought to you for free and open access by the Graduate School at VCU Scholars Compass. It has been accepted for inclusion in Theses and Dissertations by an authorized administrator of VCU Scholars Compass. For more information, please contact libcompass@vcu.edu.

Factors That Predict Incident Reporting Behavior in Certified Registered Nurse Anesthetists

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of
Philosophy at Virginia Commonwealth University

by

Nicole Kemp Damico
Master of Science in Nurse Anesthesia, 1999
Bachelor of Science in Nursing, 1997

Director: Suzanne M. Wright, PhD
Vice Chair for Academic Affairs, Department of Nurse Anesthesia

Virginia Commonwealth University
Richmond, Virginia
December 2014

Acknowledgements

To the members of my dissertation committee, I extend my heartfelt thanks for their expert guidance and support throughout this process. Dr. Suzanne Wright shared her expertise in patient safety and insight into how to break this complex process into manageable steps. Without her timely advice, I might still be buried under a virtual pile of rough drafts. Dr. Corey Davis shared his expertise in informatics and talked me “off the ledge” more than once. Dr. Brian Hacker shared his quality improvement experience and constant reminders to keep this project practically relevant. Among the many things Dr. Diane Dodd-McCue has taught me, perhaps the most important was to embrace limitations and constraints.

There is a long list of others who have provided me invaluable support throughout this journey. I would especially like to thank Dr. Michael Fallacaro, my department chair, for his constant support and encouragement and the AANA Foundation for providing financial assistance for this project. I have been absolutely blessed to have caring friends and colleagues willing to offer just the right kind words or a sympathetic ear when I needed it most. I would like to extend a big thank you to Mr. Jerry Clarke, Mr. Michael Kammerman, Dr. Debbie Blizman, Dr. Mario Grasso, Dr. Amanda Faircloth, Dr. Jamie Furstein, and (soon to be) Dr. Joanne Fallon for helping me through.

Finally, I would like to thank my family. My husband Kevin has selflessly given his unwavering support throughout all three degrees I’ve now earned since we met. It is finally

enough. I look forward to the next phase of our lives together. My children, Maggie, Rachel and Alex, have offered their enthusiastic participation to 'Team Damico' even when it wasn't so obvious why or what we signed up to play. I hope that one day they will understand why it was important to me to do this and will each get to experience the feeling of achieving a lifelong goal, whatever that may be.

I have waited a long time for the opportunity to make the following proclamation, so without further adieu...

I, Nicole Kemp Damico, do hereby solemnly swear that I will never (ever, ever) enroll in another course at a university or other institution of higher education with the intent to earn a degree. I also swear that I will never stop learning.

Table of Contents

Table of Contents	iii
List of Tables	iv
List of Figures	v
Abstract	vi
Chapter One: Introduction	1
Background	2
Problem and Study Significance	5
Theoretical Framework	7
Purpose of the Study	8
Research questions	8
Conclusion	9
Chapter Two: Literature Review	10
Incident Reporting System Characteristics	11
Incident Reporting Systems and Patient Safety	13
Incident Reporting Systems in Aviation	15
Incident Reporting Systems in Health Care	20
Internal incident reporting systems	20

External incident reporting systems	22
Patient safety organizations	27
<i>Federally designated patient safety organizations</i>	27
<i>Non-federally designated patient safety organizations</i>	31
Use of Incident Reporting Systems by Health Care Providers	32
Underutilization of incident reporting systems	33
Underutilization by provider group	33
Determinants of use of incident reporting systems	35
Barriers to use of incident reporting systems	39
Theory of Planned Behavior	43
Hypotheses	50
Chapter Summary	51
Chapter Three: Methodology	53
Research Design	54
Population, Recruitment and Sampling Methods	56
Data Collection	58
Variables	59
Measurement	62
Data Analysis	70
Objective one	71

Objective two	71
Objective three	71
Objective four	74
Limitations	74
Human Subjects	76
Chapter Summary	76
Chapter Four: Results	78
Data	78
Review of Data Collection	79
Data Preparation and Cleaning	80
Data Analysis	83
Objective one	90
Objective two	100
Objective three	104
<i>Hypothesis one (H₁)</i>	106
<i>Hypothesis two (H₂)</i>	106
<i>Hypothesis three (H₃)</i>	106
<i>Hypothesis four (H₄)</i>	107
Objective four	110
<i>Hypothesis five (H₅)</i>	110
Chapter Summary	112

Chapter Five: Discussion	113
Summary of Study Findings	114
Objective one	114
Objective two	115
Objective three	116
Objective four	117
Theoretical Implications	118
Practical Implications	120
Limitations	123
Threats to internal validity	123
Threats to Statistical Conclusion Validity	124
Threats to External Validity	126
Concluding Remarks	126
References	129
Appendix A: Initial Survey Questionnaire	148
Appendix B: Survey Invitation Letter	152
Vita	153

List of Tables

Table	Page
1. Studies of Incident Reporting in Health Care Providers in the U.S. Published Since 1999....	37
2. Studies in ‘Multiple Facilities Subset’ That Identified Each Group of Barriers in the Review by Pfeiffer et al.	41
3. Study Objectives and Research Hypotheses.....	55
4. Overview of TPB Constructs, Definitions, Study Variables, and Operational Definitions	60
5. Demographic Items in the Study Questionnaire.....	64
6. Summary of Pilot Study Results and Survey Revisions.....	70
7. Initial Subscale Reliability Analysis.....	82
8. YRSEXP Variable Transformation to YRSEXPC	85
9. Observed Frequencies and Percentages for Demographic Variables	85
10. Contingency Table for Crosstabulation Between NONE and EMPLC	92
11. Contingency Table for Crosstabulation Between NONE and YRSEXPC	93
12. Contingency Table for Crosstabulation Between YRSEXPC and EMPLZ	94
13. Possible Values and Value Labels for the Variables PRB and REPORTER	97
14. Contingency Table for Crosstabulation Between GENDER and REPORTER.....	98

15. Descriptive Statistics for Survey Items in the INR Subscale	99
16. Response Frequencies for Items in the INR Subscale	99
17. Distribution of Scores for the Variable INR.....	100
18. Descriptive Statistics of Survey Item Scores	101
19. Summary of Responses to Survey Items in ATR, SPR, and PCR Subscales	102
20. Descriptive Statistics for the Variables ATR, SPR, PCR.....	104
21. Score Frequency Distributions for the Variables ATR, SPR, PCR	105
22. Tests of Normality for Main Study Variables.....	105
23. Descriptive Statistics for Variables in the Logistic Regression.....	108
24. Variables in the Equation Table for Logistic Regression of ATR, SPR, PCR on INR2	110

List of Figures

Figure	Page
1. International Classification for Patient Safety (ICPS)	14
2. The Theory of Planned Behavior	47
3. Hypothesized Relationships Among Study Variables	62
4. Sample and Population Frequency Distributions for AGE	86
5. Sample and Population Frequency Distributions for GENDER	87
6. Sample and Population Frequency Distributions for GEOREG	87
7. Sample and Population Frequency Distributions for EMPL	89
8. Sample and Population Frequency Distributions for YRSEXPC	90
9. Frequency Distribution in Percentage for PRB	96
10. The Theory of Reasoned Action	119

Abstract

FACTORS THAT PREDICT INCIDENT REPORTING BEHAVIOR IN CERTIFIED REGISTERED NURSE ANESTHETISTS

By Nicole Kemp Damico, PhD

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University.

Virginia Commonwealth University, 2014

Major Director: Suzanne M. Wright, PhD

Associate Professor and Vice Chair for Academic Affairs, Department of Nurse Anesthesia

The Institute of Medicine (IOM) Report “To Err is Human: Building a Safer Health System” highlighted the alarming rate and impact of medical errors (Kohn, 1999). Over a decade later, improving patient safety through reduction of medical errors continues to be a national priority. One of the strategies widely utilized to address this issue is the use of incident reporting systems. Prior research in medical and non-medical domains indicates that the success of this strategy is dependent upon widespread acceptance and use of reporting systems by frontline workers. Although certified registered nurse anesthetists (CRNAs) comprise over one-half of the anesthesia workforce and administer millions of anesthetics to patients in the United States each year, no studies have examined incident reporting behavior in this provider group.

The purpose of this study was to describe factors that predict the likelihood that CRNAs will use incident reporting systems, guided by the theory of planned behavior (Ajzen, 1991). A non-experimental, correlational design was utilized to address the study objectives and test the research hypotheses. Following IRB approval, a cross-sectional survey was administered electronically to a random sample of practicing CRNAs. The subjects reported their use of incident reporting systems within the past 12 months and completed the novel Incident Reporting Scale (IRS). Responses in the IRS were used to create the composite study variables. Correlation analyses and a standard logistic regression were utilized to determine the relationship between cognitive factors and the likelihood that CRNAs will use incident reporting systems.

Two hundred and eighty-three practicing CRNAs participated in the study. These CRNAs indicated that they value incident reporting, perceive social pressure to report, and feel in control over reporting, yet had not consistently used existing incident reporting systems in the past 12 months. A CRNA's attitude toward reporting and the degree to which he or she perceived social pressure to report, but not the degree to which he or she perceived having control over reporting, were determined to be significant predictors of the likelihood that a CRNA would use an incident reporting system. Social pressure to report was the most important factor in the prediction of this behavior.

The results of this study revealed that there are missed opportunities for learning from patient safety incidents in anesthesia practice. The information gained in this study has the potential to assist organizations in the design of strategies to promote incident reporting by practicing CRNAs.

Chapter One: Introduction

Robust mechanisms for collecting and sharing information about adverse events in health care in order to help prevent future events are recognized as essential to patient safety efforts across the globe. Such mechanisms are generally referred to as ‘incident reporting systems’, which comprise both the formalized processes and technology utilized to collect, organize, analyze and store reports about patient safety incidents from providers (World Health Organization [WHO], 2005). Patient safety incidents include all events that occur during the delivery of care that resulted, or could have resulted, in patient harm (Sherman, Castro, & Fletcher, 2009).

The fundamental purpose of incident reporting is to promote learning from these failures (Leape, 2002; WHO, 2005). Incident reporting systems can aid in learning in a variety of ways. Incident reporting systems can serve as useful, albeit not standalone, mechanisms for detection of patient safety incidents (Levtzion-Korach et al., 2010). They can serve as a powerful tool for raising awareness about hazards in the work environment (Anderson, Kodate, Walters, & Dodds, 2013; Billings, Cheaney, & Hardy, 1986). The nature of the data collected through incident reporting systems, which typically includes a narrative component (WHO, 2005), enables sophisticated analysis of patient safety incidents (Sherman et al., 2009). Analysis of aggregate data from incident reporting systems facilitates identification of trends, which can assist with goal prioritization, allocation of resources, and monitoring progress over time (Sherman et al.,

2009). Pooling aggregate data from multiple incident reporting can assist with formulating best practice recommendations (Leape, 2002). Incident reporting systems can also serve as a communication tool (Billings et al., 1986). An excerpt from the foreword to the World Health Organization (WHO) Draft Guidelines for Reporting and Learning Systems reflects the potential vision of incident reporting systems in health care (WHO, 2005):

...one day it may be possible for the bad experience suffered by a patient in one part of the world to be a source of transmitted learning that benefits future patients in many countries...

Background

For nearly 25 years, patient safety efforts have been focused on reducing medical errors and patient harm using a ‘systems thinking’ approach. Systems thinking is a cognitive framework based on the assumption that human beings are fallible and, consequently, safety is dependent upon creating systems that anticipate errors and either prevent or catch them before they cause harm (Wachter, 2012). Prior to the 1990s, the predominant approach to addressing medical errors was to blame and punish the providers involved (Leape, 1994; Vincent, 2010; Wachter, 2012). The impetus for the paradigm shift in patient safety was a compounding series of events, including the publication of a number of tragic cases of medical error in the lay press, a sharp increase in medical malpractice cases, release of sentinel articles about the application of human factors principles in medical domains, and pioneering research about patient safety in anesthesiology (Vincent, 2010).

Another significant influence in this paradigm shift was the release of the report “To Err is Human: Building a Safer Health System” by the Institute of Medicine (IOM) (Kohn, Corrigan,

& Donaldson, 1999), which brought national and international attention to the issue of preventable patient harm in the United States (Vincent, 2010). The report estimated that 44,000 – 98,000 patients die each year as a result of medical errors and many more are injured. In the context of that time, these figures placed preventable adverse events as one of the top ten leading causes of death in the U.S. The national cost of these events was estimated to be over \$17 billion dollars per year. The IOM report served as an urgent call to action, establishing medical errors and adverse events as a priority in patient safety efforts worldwide (Vincent, 2010).

Adoption of a systems thinking approach to patient safety was inspired by the effectiveness of this approach in non-medical industries (Kohn et al., 1999; Vincent, 2010, Wachter, 2012). Despite a high degree of complexity and risk, some organizations in fields such as nuclear power and commercial aviation are consistently able to avoid catastrophic events. These organizations are often referred to as high reliability organizations (HROs) (Hines, et al., 2008). HROs embrace the systems thinking approach to occupational safety (Wachter, 2012). One of the fundamental ways that HROs achieve safety is through utilization of operational processes that enhance system resilience (Weick & Sutcliffe, 2001), defined as the ability to detect, mitigate, or ameliorate hazards, then quickly recover the ability to perform core functions (Sherman et al., 2009). Incident reporting systems facilitate many of the fundamental activities required to enhance system resilience (Sherman et al., 2009).

Extensive utilization of incident reporting systems is a hallmark of HROs (Kohn et al., 1999; Weick, Sutcliffe, & Obstfeld, 2008). Barach and Small (2000) identified and reviewed 25 well-established incident reporting systems in such industries as nuclear power, petrochemical processing, steel manufacturing, and commercial aviation. Data collection methods included

interviews with reporting system designers and administrators that revealed incident reporting as a vital component of safety improvement efforts in their respective industries. Barach and Small (2000) asserted these reporting systems were widely utilized and very effective mechanisms for gathering information that would otherwise have not been available through other means.

The transition to a systems thinking approach in health care has led to an emphasis on incident reporting systems as a component of the overall strategy for improving patient safety. Expansion of both mandatory and voluntary incident reporting efforts was strongly advocated in the “To Err is Human” report (Kohn et al., 1999). In the years immediately following the release of the IOM report, there was a particular interest in developing new voluntary reporting systems, yet concerns about disclosure and medical liability were perceived to be a major barrier to these efforts (Leape, 2002).

Specifically to address these concerns, the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) was enacted (U.S. Government Accountability Office [GAO], 2010). This groundbreaking legislation promotes voluntary reporting by health care providers through the establishment of protected and formalized patient safety organizations (PSOs) (GAO, 2010). Incident reporting systems operated by PSOs are considered ‘external incident reporting systems’ because the data collected is ultimately shared outside the reporter’s particular facility or institution (WHO, 2005). A discussion of the various types of incident reporting systems will be provided in Chapter Two. Many of the nearly 100 PSOs that have been formed since passage of the Patient Safety Act (Agency for Healthcare Research and Quality [AHRQ], 2014; Kohn, 2010) represent focused initiatives to address patient safety in a particular area or health care specialty. Given the history of groundbreaking work in the area of patient safety in

the field of anesthesiology (Kohn et al., 1999; Vincent, 2010) it is not surprising that this includes several new organizations devoted to collecting incident reports from anesthesia providers (AHRQ, 2014). One example is the Anesthesia Quality Institute (Dutton, 2011).

Problem and Study Significance

Successful implementation of new incident reporting systems in the specialty of anesthesia in the U.S. is dependent upon the participation of Certified Registered Nurse Anesthetists (CRNAs). Certified registered nurse anesthetists and physician anesthesiologists are the primary providers of anesthesia care in the U.S. (Daugherty, Fonseca, Kumar, & Michaud, 2010). There are approximately 47,000 CRNAs in the U.S. who provide more than 34 million anesthetics per year (AANA, 2014). They practice in all areas of the country and provide all types of anesthesia care. In rural areas, CRNAs are the primary providers of anesthesia care (AANA, 2014). Without effectively capturing the first hand information that only CRNAs can provide, the overall picture of safety in anesthesia will not be complete.

Even with careful attention to the design and implementation of incident reporting systems there is no guarantee that health care providers will use them, as decades of experience has shown (Kohn et al., 1999; Department of Health and Human Services [DHHS], 2012). Existing incident reporting systems in health care are sorely underutilized (Cullen, et al., 1995; DHHS, 2012; Nuckols, Bell, Liu, Paddock, & Hilborne, 2007), and no interventions have been shown to be effective in addressing this problem. In a systematic review of the effectiveness of interventions to improve rates of incident reporting in health care, Parmelli et al. (2012) initially identified more than 2,000 published articles. Only four studies met methodological based criteria for inclusion in the analysis; and all were deemed highly susceptible to bias. Due to the

heterogeneity and complexity of the interventions studied, Parmelli et al. (2012) were unable to make meaningful comparisons among them. They concluded there is not enough evidence to draw conclusions about the effectiveness of the interventions. It was suggested that any organization introducing an incident reporting system should consider “conducting an evaluation using a robust design” (Parmelli et al., 2012, p. 9).

Asking CRNAs to use a novel type of incident reporting system is, fundamentally, asking them to adopt a new behavior. Changing the behavior of clinicians is recognized as a complex task (Grol & Grimshaw, 2003) likely to require a multi-faceted intervention (Campbell et al., 2000). Interventions comprised of multiple parts that act independently and inter-dependently have been coined ‘complex interventions’ (Campbell et al., 2000; Wakefield, McLaws, Whitby, & Patton, 2010). A theory-based approach to design and evaluation of such complex interventions is recommended (Campbell et al., 2000; Michie, Johnston, Francis, Hardeman, & Eccles, 2008). The first step in this process is to gain a better understanding of the factors that determine the behavior of interest (Michie et al., 2008). With this foundational information, a complex intervention that addresses each determinant of the behavior of interest can be developed.

There are no studies of incident reporting behavior in CRNAs in the published literature. A review of the literature on use of incident reporting systems in other health care provider groups will be presented in Chapter Two. There is wide variation in the methodological approaches used in prior studies so it is difficult to make meaningful conclusions from this body of work. These studies of incident reporting in other health care provider groups suggest that, while there are likely many institutional and individual level factors that influence this behavior,

cognitive factors are particularly influential. The findings of this study provide insight into use of incident reporting systems by CRNAs and determined that certain cognitive factors are associated with use of incident reporting systems by CRNAs. This study will serve as a foundational step in the development and evaluation of complex interventions to promote use of incident reporting systems by this important group of anesthesia providers.

Theoretical Framework

The theory of planned behavior (TPB) provided the theoretical framework for the study (Ajzen, 1986). The TPB is a psychological model for understanding and predicting human behavior that has been successfully applied in studies of a variety of clinical behaviors in health care providers (Beatty & Beatty, 2004; Bonetti et al., 2005; Limbert & Lamb, 2002; Puffer & Rashidian, 2004; Rashidian & Russell, 2012). The TPB has also been found to be a valid predictive model of use of incident reporting systems in pharmacists (Gavaza et al., 2011; Gavaza et al., 2012). It has been recommended as an appropriate theory upon which to base the development of complex interventions (Bonetti et al., 2005; Hardeman et al., 2002; Michie et al., 2008).

According to the TPB (Ajzen, 1985), prior to engaging in a behavior over which a person has some degree of free will, human beings formulate a cognitive intention. This intention is a state of readiness to perform that behavior, and is primarily determined by whether the person values performing that behavior, how much the person perceives social pressure to do it and whether he or she feels in control of the action in question (Francis et al., 2004). These cognitive factors correspond respectively to ‘attitude toward the behavior’, ‘subjective norm’, and

‘perceived behavioral control’ in the TPB. Further elaboration of the TPB is included in Chapter Two.

Purpose of the Study

The purpose of this study was to gain a better understanding of use of incident reporting systems by CRNAs. To achieve this aim, recent use of incident reporting systems and the attitudes and beliefs of practicing CRNAs toward incident reporting were described. The association between cognitive factors and use of incident reporting systems in CRNAs was explored. The specific cognitive factors explored as possible determinants of CRNAs’ use of incident reporting systems represented those reported frequently in previous studies of incident reporting behavior in other health care provider groups. These factors were operationalized using the framework of the TPB. Accordingly, intent to report served as the criterion variable, as a proxy measure of use of an incident reporting system. The predictor variables were attitude toward reporting, social pressure to report, and perceived control over reporting. This study sought to determine if there was a relationship between cognitive factors and intent to report to an incident reporting system in CRNAs.

Research Questions. This study aimed to answer the following research questions: a) Do CRNAs currently use incident reporting systems? b) Do CRNAs value incident reporting? c) Do CRNAs perceive social pressure to use incident reporting systems? d) Do CRNAs feel in control of using incident reporting systems? e) Is there a relationship between cognitive factors and the likelihood that a CRNA will use an incident reporting system?

Conclusion

A systems thinking approach to patient safety is now widely embraced in health care. A vital part of this approach is the use of incident reporting systems in order to learn from mistakes and prevent future harm. There is a current emphasis in the U.S. to create incident reporting systems under the direction of PSOs. This chapter began with a brief overview of factors that led to this shift in focus. New PSOs face a daunting challenge, namely to get health care providers to use their incident reporting systems. A critical barrier to the successful implementation of novel incident reporting systems in anesthesia was identified. The findings of this study have the potential to help to overcome this barrier by adding insight into factors that associated with use of incident reporting systems by CRNAs. Determining the influence of cognitive factors on use of incident reporting systems by CRNAs will assist with the development and evaluation of complex interventions to promote use of these systems in this population of health care providers.

This remainder of this paper is divided into four chapters. Chapter Two provides a more in depth presentation of design features of incident reporting systems, their role in the overall strategy and existing incident reporting systems in the U.S. A review of the literature on barriers to incident reporting in health care workers is followed by discussion of the TPB model and presentation of study hypotheses. Chapter Three provides an overview of the study methods and statistical analyses utilized to address the research questions and test hypotheses. Chapter Four presents an overview of the study results. Chapter Five provides a discussion and interpretation of the study findings.

Chapter Two: Literature Review

The groundbreaking report released by the Institute of Medicine (IOM) entitled “To Err is Human: Building a Safer Health System” estimated that 44,000 – 98,000 patients die each year as a result of medical errors; and many more are injured (Kohn et al., 1999). Over a decade later, the incidence of patient harm in U.S. hospitals has not declined significantly (Landrigan et al., 2010). Addressing this serious patient safety issue remains a national priority.

Preventing adverse events is one of the primary goals of patient safety improvement efforts in health care. As in other high-risk industries, a systems thinking approach is now utilized in health care to assess the nature of hazards, identify system failures, and plan improvement efforts (Wachter, 2012; Vincent, 2010). Due to the complex nature of the health care environment, a multifaceted approach is required to achieve these ends. Incident reporting systems are recognized as fundamental components of the overall strategy to improve safety in health care and non-medical domains (Kohn et al., 1999; Vincent, 2003).

A plethora of incident reporting systems have been implemented in the last several decades in health care. In this chapter, the role of incident reporting systems in the overall strategy to improve patient safety and a brief historical background of the use of these systems in the U.S. are presented. Despite widespread implementation of incident reporting systems, the potentially positive impact of this method for reducing the rate of adverse events is hindered by underutilization (DHHS, 2012; Staender, 2011).

In the United States, the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) was enacted to encourage the development of new incident reporting systems by federally designated patient safety organizations (PSOs). Many new PSOs have been formed in the past several years, including several devoted to improving anesthesia patient safety. The effectiveness of these novel incident reporting systems in improving patient safety is dependent upon their acceptance and use by CRNAs. Studies of incident reporting behavior in health care providers are reviewed in this chapter. The theory of planned behavior (TPB) (Ajzen, 1986) is proposed as a model for understanding use of incident reporting systems by CRNAs.

Incident Reporting System Characteristics

Incident reporting systems are defined as “processes and technology involved in the standardization, formatting, communication, feedback, analysis, learning, response, and dissemination of lessons learned from reported events” (WHO, 2005, p. 8). Incident reporting systems are embraced as integral to a culture of safety in many high reliability organizations (HROs). As a foundation for understanding the specific contributions incident reporting systems make in improving patient safety and the systems in use in the U.S. today, an overview of incident reporting system characteristics is provided.

One of the fundamental distinctions among incident reporting systems is the disposition of the data collected. Systems can be classified accordingly as ‘internal’ or ‘external’ systems. Internal incident reporting systems facilitate reporting by individuals within an organization or entity and original data stays within and is used primarily by that organization or entity. Conversely, external incident reporting systems communicate reported information to a regulatory agency, accrediting body, or regional or national safety organization (Leape, 2002).

Reports can be submitted to external systems by institutions or by individuals. When submitted by an institution, data is often in the form of aggregate or summary reports (WHO, 2005). When submitted by an individual, reports refer to a discrete occurrence or patient safety incident.

Reporting to incident reporting systems may be considered either mandatory or voluntary. The former describes a situation in which a policy or regulation requires a report to be submitted in the case of an adverse or unintended event. The latter, logically, solicits reports from individuals or groups based on their own free will. Ultimately, all systems are to some degree voluntary regardless of the stated intent (Kohn et al., 1999) to the extent that they are largely dependent upon the willingness of the reporter to accept and use the mechanism.

Incident reporting system administrators generally explicitly state the nature of reportable events for entry into the system. In “focused initiatives” (Kohn et al., 1999, p. 95), reportable events are limited to a subset or subsets of patient safety incidents, such as select incident types, patient outcome categories, patient care settings, or any combination of the above. An example of such a focused initiative is a reporting system designed for reporting of medication-related events only. In comprehensive reporting systems, reportable events include a far wider range of events.

Incident reporting systems can also be described as learning or accountability systems (WHO, 2005), although this distinction is often not explicitly stated. Likely, this is because many incident reporting systems are intended to achieve both aims. Learning systems tend to be voluntary efforts (WHO, 2005). Accountability systems typically collect reports about a narrow range of incident categories, such as events that result in injury or death. Reporting to accountability systems is often mandated by law or policy and followed by a root cause analysis

or other event investigation (Kohn et al., 1999). Punitive actions may be imposed against an institution or an individual as a result of the analysis.

The process for submitting incident reports also varies considerably among institutions that employ reporting systems. Possible methods for submitting incident reports include e-mail, the Internet, mail, facsimile, phone calls or combinations of the above. Data collection forms may be highly structured, with a series of discrete options to select, or mostly free-text fields. In most every case, there is a section of the incident reporting form reserved for a narrative description of the patient safety event (WHO, 2005). Many of these design features are referenced in the following discussion of incident reporting systems.

Incident Reporting Systems and Patient Safety

The International Classification for Patient Safety (ICPS) developed by the WHO World Alliance for Patient Safety (Sherman et al., 2009) provides a conceptual framework for understanding the specific role of incident reporting systems in improving patient safety. This framework was created to define and organize the myriad of concepts that have emerged in this area in recent decades (Sherman et al., 2009).

According to the ICPS, patient safety incidents are defined as circumstances that resulted, or could have resulted, in patient harm (Sherman et al., 2009). There are three major groups of constructs in the framework, as shown in Figure 1, which include: descriptive information about incidents (ovals), categorization of incidents (triangles), and system resilience (rectangles). Each category of constructs has multiple subgroups. The ‘descriptive information’ group includes the subgroups contributing factors/hazards, patient characteristics, incident characteristics, and organizational outcomes; all of which represent important contextual details about patient safety

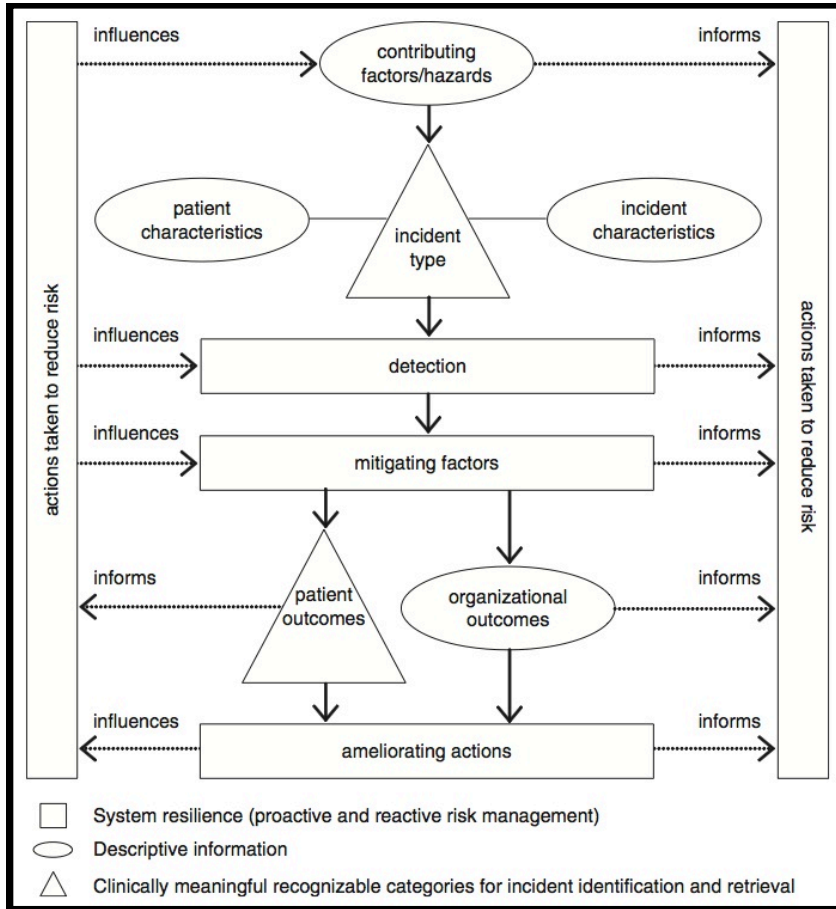


Figure 1. International Classification for Patient Safety (ICPS)

Source: Sherman, H., Castro, G., & Fletcher, M. (2009). Towards an International Classification for Patient Safety: the conceptual framework. *International Journal for Quality in Health Care*, 21(1), 2–8.

incidents. The ‘categorization of incidents’ group includes the subgroups incident type and patient outcome. The final group ‘system resilience’ refers to “the degree to which a system continuously prevents, detects, mitigates, or ameliorates hazards or incidents so that an organization can bounce back to its original ability to provide core function” (Sherman et al., 2009, p. 5). Proposed relationships among subgroups of constructs in the ICPS are complex.

Incident reporting systems enable various activities in the overall strategy for improving patient safety represented by the ICPS framework. First, incident reporting systems are an important strategy for event detection. Event detection is an important precursor to determination of mitigation strategies, which are defined as “actions or circumstances that prevent or moderate the progression of an incident toward harming the patient” (Sherman et al., 2009, p. 6). By virtue of the nature of the data solicited, incident reporting systems also enable sophisticated event analysis to discover descriptive information that can be used to inform the development of action plans to reduce risk, such as system redesign or policy implementation. Finally, incident reporting systems enable organization of patient safety incidents into meaningful categories to assist with goal prioritization, allocation of resources, and monitoring progress toward goals over time.

Incident Reporting Systems in Aviation

Incident reporting systems are widely used in both medical and non-medical domains today. The inspiration for the development of modern systems is often attributed to research using the “critical incident technique” in the field of aviation during World War II. As the experience with incident reporting in aviation has undoubtedly influenced reporting efforts in health care (Barach & Small, 2000), the history and development of the Aviation Safety Reporting System (ASRS) is presented here.

Flanagan (1954) and a team of researchers in the Aviation Psychology Program of the United States Army Air Forces developed the critical incident technique during World War II. In a sentinel publication, Flanagan summarized over a decade of research using this technique, which was described as “a set of procedures for collecting direct observations of human

behavior” (Flanagan, 1954, p. 327). Data collected using the technique consisted of narrative reports by observers, who may or may not have been involved in the activity of interest.

On the basis of studies from 1941 – 1946, Flanagan and his team were able to recommend a number of safety interventions for the military aviation program. Notable recommendations included the revision of military pilot and crew selection criteria, generation of a list of behavioral requirements for combat leaders, changes in training procedures, and the redesign of cockpit and instrument panels (Flanagan, 1954) . The team’s later work led to the development of recommendations for commercial aviation such as development of critical requirements for pilots, a flight checklist for use in pilot performance assessment, selection criteria for air traffic controllers (ATCs), and procedures for evaluating the proficiency of ATCs (Flanagan, 1954).

The collection of critical incident reports from workers in the commercial aviation industry commenced soon after the publication of Flanagan’s work. Calls for a national aviation incident reporting system were made during hearings for the Federal Aviation Act of 1958 (Reynard, Billings, Cheaney & Hardy, 1986), although no such system was developed at that time. Instead, individual airline carriers developed internal incident reporting systems throughout the 1950s and 1960s. There is very little documentation of this practice in publicly available records. Multiple references to such systems are found in a report published on behalf of the National Aeronautics and Space Administration (NASA) (Reynard et al., 1986). The report includes several quotes by leaders in the aviation industry referencing the existence of databases of safety information held by individual airline companies, including incident reports from airline workers. Fear of litigation or punitive consequences prohibited organized efforts to

share and disseminate internal data (Reynard et al., 1986). As a result, early incident reporting systems did not play a significant role in aviation safety improvement efforts.

The role of incident reporting in commercial aviation increased dramatically in the 1970s. While there were undoubtedly many contributing factors, the crash of Trans World Airlines (TWA) Flight 514 on December 1, 1974 has been recognized as a major trigger for this change (Reynard et al., 1986). There were 85 passengers and 7 crew members on board the Boeing 727 headed to Dulles International Airport in Washington D.C. Approximately 40 miles from its destination, under cloudy and turbulent conditions, the aircraft descended in preparation for landing. Within a matter of minutes, it crashed into a Virginia mountaintop killing everyone on board (Reynard et al., 1986).

The real tragedy of TWA Flight 514 was that the crash could have been prevented. Only six weeks prior, a United Airlines flight in its final approach to Dulles had encountered virtually identical circumstances. The United Airlines crew descended to a similar altitude at approximately the same distance from their destination per the charted approach. Realizing there were mistakes in the approach and that the pilots and air traffic controllers had interpreted the landing procedure in different ways, the crew was able to take corrective actions and land the plane safely. The United Airlines crew reported the incident to their internal reporting system, including an assessment of the causative factors and successful corrective actions (Reynard et al. 1986). Officials with United Airlines, in turn, reported this information to the Federal Aviation Administration (FAA). There was no mechanism at the time to further disseminate this vital information, so the crew of TWA Flight 514 was never alerted to the hazardous conditions or possible solutions to the ensuing problem. The National Transportation Safety Board (NTSB)

later confirmed, after an extensive investigation, that the same causative factors cited by the United Airlines crew were the root causes of the TWA crash (FAA, 2013).

Within just months of the crash of Flight 514, the FAA convened a task force to evaluate the overall safety of the industry. One of the recommendations of the task force was to create an Aviation Safety Reporting System (ASRS) as a mechanism to disseminate information about safety incidents among all airlines (Reynard et al., 1986). The first iteration of this system was released in May 1975. Response to the program was underwhelming due to sustained, widespread fear of the punitive consequences of reporting (Reynard et al., 1986). To address this concern, it was decided that a third-party should collect, process, and analyze incident reports; and that reporters should be guaranteed immunity from disciplinary actions. NASA was chosen as the appropriate agency to serve in this capacity. A formal agreement between the FAA and NASA was reached in August 1975 and the ASRS began collecting incident reports just under a year later.

The ASRS was designed to collect reports from all types of workers in the commercial airline industry, including pilots, air traffic controllers, dispatchers, cabin crew, and maintenance staff. To incentivize workers to report incidents, the system was and remains voluntary and confidential and offers legal protection to reporters with limited exceptions, such as cases in which a violation is deliberate or involves a criminal act. In order to qualify for this protection, the report must be submitted within 10 days of the incident or when the person became aware of the incident.

ASRS reports are utilized for a variety of purposes. Original submissions are now screened within an impressive three days of submission. A safety alert message is sent out

immediately to “individuals in a position of authority” in order to initiate immediate corrective actions to address hazards, if applicable (NASA, 2014, p. 20). For other issues with immediate implications, the FAA or NTSB is notified with a “Quick Response” request (NASA, 2014, p. 20). The ASRS staff compiles and distributes a monthly newsletter, named CALLBACK, to all workers in the industry and publishes articles about significant reports to all operators and flight crews in the *ASRS Directline* periodical (NASA, 2014). Once processed, the ASRS reports are entered into an online database that is publicly available on the ASRS website. The ASRS staff makes database report sets available to interested parties upon request and also undertakes its own research projects in collaboration with aviation organizations. As of June 2013, reports submitted to the ASRS have served as the basis for 5,880 safety alert messages, 141 quick response requests, 407 CALLBACK issues, 10 *ASRS Directline* issues and 64 research studies (NASA, 2014).

Arguably, the ASRS is one of the most successful external incident reporting systems in the world. While comprising only one component of the comprehensive safety program in commercial aviation, the ASRS has been recognized worldwide for its vital contribution to safety improvements in the field (Connell, 2004). Over the last thirty-eight years of operation, ASRS staff has processed over one million reports in all, with a current average of 1,600 incoming reports each week (NASA, 2014). As the volume of reports has steadily increased in recent decades (Connell, 2004; NASA, 2014), the fatality risk for commercial aviation has plummeted. According to the FAA, this risk dropped by 83% from 1998 to 2008 alone (FAA, 2010).

Many other industries have utilized the ASRS model for implementing similar incident reporting systems in the hope of achieving the same level of success (NASA, 2014). Incident

reporting now plays a fundamental role in industries such as nuclear power, petrochemical processing, steel production, and military operations (Barach & Small, 2000). Success of the ASRS has undoubtedly been a factor in the persistent trend toward increased use of reporting systems in other high-risk industries worldwide (Kohn et al., 1999).

Incident Reporting Systems in Health Care

The use of incident reporting systems in health care predates Flanagan's work in aviation, yet early systems were predominantly utilized for accountability purposes not learning. The IOM report "To Err is Human" (Kohn et al., 1999) provided a comprehensive overview and evaluation of medical incident reporting systems in use at that time. One of the main recommendations of the report, which has been very influential, was to expand the development and utilization of both mandatory and voluntary incident reporting systems. A brief review of health care incident reporting systems, organized by type of system and year of implementation, is provided here. As a comprehensive review of all systems worldwide is beyond the scope of this paper, the focus is on incident reporting systems implemented in the U.S. for individual level reporting.

Internal Incident Reporting Systems. Internal incident reporting systems were first implemented in the hospital setting as a method for holding nurses accountable for their clinical performance, as described in an article in the American Journal of Nursing from 1939 (Faddis). In the report, a number of interventions for decreasing the rate of medication errors in the hospital setting were suggested. One recommendation was to require a report by the nurse involved in order to reinforce the lessons learned from the event for the nurse and capture salient details for the medical record. Commission of repeated errors was noted to be evidence of

carelessness and grounds for dismissal. It was stressed that reporting was “not a means of punishment” (Faddis, 1939, p. 1223), which suggests that it might have been perceived as such by the nursing staff.

Use of internal incident reporting systems for other accountability aims was common in hospitals in the 1950s (Francis, 1953; Ludlam, 1955). Lawsuits against hospitals and nurses increased as the risk of iatrogenic harm was recognized. At the time, events that caused harm to patients most often included falls, patient misidentification and medication errors (Mills & von Bolschwing, 1995). Nurses were asked to submit narrative reports of all unusual events that occurred during patient care to hospital administration. These reports were considered analogous to claims reports in the eyes of medical malpractice insurance carriers, and as such, were utilized to track hospital performance and determine insurance rates (Ludlam, 1998).

Internal incident reporting systems were the predominant type of incident reporting system used in health care for decades. As clinical risk management programs were implemented in hospitals across the U.S. during the 1950s and 1960s, internal incident reporting systems became ubiquitous (Mills & von Bolschwing, 1995; Secker-Walker & Taylor-Adams, 2001). Incident reports, almost always submitted by nurses, served as an early warning system of potential lawsuits and a documentation tool on behalf of the hospital’s defense. These reports also continued to be advocated as a strategy for self-evaluation for nurses (Germaine & Rinneard, 1976). Information collected was certainly used for quality improvement purposes in hospitals, however it was predominantly used in the areas of risk management and liability protection until well into the 1970s (Duran, 1980).

Nearly all hospitals in the U.S. have an incident reporting system in place today. A series of studies commissioned by the Agency for Healthcare Research and Quality (AHRQ), the RAND Corporation, and The Joint Commission provides a snapshot of these systems. The first study was undertaken to gather baseline information about the use of incident reporting systems in U.S. hospitals (Farley et al., 2008). Using a stratified random sampling strategy, 1652 risk managers at non-federal hospitals across the U.S. were surveyed in the last quarter of 2005. The study sample was representative of all hospitals in the U.S. according to size, accreditation status, ownership, and type (critical access versus non-critical access). At baseline, 97.6% of the hospitals had an incident reporting system in place, although characteristics and use of the systems varied among hospitals. Nurses submitted all or most of the reports in all hospitals. Slightly more than 98% of hospitals had an incident reporting system in place in a follow-up survey in 2009 (Farley et al., 2012).

External Incident Reporting Systems. External incident reporting systems have also been in use in health care for decades. The Food and Drug Administration (FDA) was the first national health care organization to implement both mandatory and voluntary external incident reporting systems. In collaboration with the American Society of Hospital Pharmacists and the American Association of Medical Record Librarians, the FDA released a voluntary system for reporting adverse drug reactions in 1952 (FDA, 2014). Very little information about this system is available in published literature. Exactly one decade later, the FDA began to require mandatory reporting of adverse drug events from the pharmaceutical industry, or post-marketing surveillance (FDA, 2014). The Spontaneous Reporting System (SRS), designed by the FDA to capture voluntary reports of drug-related events, followed in 1969 (Rossi & Knapp, 1984).

Close to 18,000 reports were submitted in the first year of operation, predominantly by drug manufacturers and hospitals (Rossi & Knapp, 1984).

Government requirements for reporting of certain types of patient safety incidents were first introduced in the 1970s. States began to enact requirements for reporting certain types of incidents that occurred in hospitals and developed reporting systems intended for use by facilities for this purpose (DHHS, 2008). The first state reporting system was introduced in California in 1972, followed by South Carolina in 1976 (Kohn et al., 1999; DHHS, 2008). Of note, federal requirements for reporting adverse events related to blood transfusions to the FDA were also passed into law in 1975 (21 CFR 606.170(b)).

There has been a slow but steady increase in the number of states with adverse event reporting systems in the past several decades. As of January 2008, 25 states and the District Columbia had mandatory systems in place; and one state had a voluntary system (Rosenthal & Takach, 2007). These efforts tend to focus on relatively serious or unusual events only and are almost always used, at least in part, to hold facilities responsible for their patient care performance (DHHS, 2008; Rosenthal & Takach, 2007). State adverse event reporting systems generally collect reports only at the institution level.

The Joint Commission on Accreditation of Healthcare Organization (now “The Joint Commission” [TJC]) manages another well-known external incident reporting system. The Sentinel Event Reporting Program was introduced in 1996 to provide a mechanism for hospitals to report certain events called ‘sentinel events’ (Kohn et al., 1999). A sentinel event is defined as “an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof” (TJC, 2013). While technically designated as a voluntary system, hospitals that fail

to have a procedure in place for identifying and responding to sentinel events risk losing their accreditation status with TJC. Sentinel events are generally reported to TJC by institutions, not individual health care providers.

Beginning in the 1990s, focused initiatives for capturing medication-related events have been the most widely utilized external incident reporting systems in the U.S. The Institute for Safe Medication Practices (ISMP), United States Pharmacopeia (USP), and the FDA have each spearheaded the implementation of a new medication incident reporting system. These efforts were intended to be complimentary (Kohn et al., 1999), with each making a unique contribution to the overall picture of medication safety in this country.

The ISMP and USP collaborated to design the medication error reporting (MER) program, which was introduced in 1991 (Santell, Hicks, McMeekin, & Cousins, 2003). Consistent with the missions of the two organizations involved, the MER program was initially intended to capture only events in which a “product’s labeling, packaging, or nomenclature precipitated, contributed to, or propagated a medication error” (Santell et al., 2003, p. 760). Both confidential and anonymous reports were accepted from individuals or institutions and all data was directly shared with the FDA. The initial response to the program was quite poor, with only approximately 500 total reports submitted in the first two years (Edgar, Lee & Cousins, 1994). After just over a decade of operation, the rate of reports had increased to approximately 1,500 per year (Crawford, Cohen & Tafesse, 2003; Kohn et al., 1999). The ISMP assumed sole control of the MER program in 2008 (ISMP, 2014).

Consistent with its more comprehensive mission, the FDA introduced the MedWatch incident reporting system in 1993 to collect spontaneous reports about all types of problems with

medications, as well as other medical products, from healthcare providers (Kessler, 1993). Reportable events include adverse events related to any medication, medical device, human cells or tissues, special nutritional products, cosmetics or food; or medical product problems, such as suspected contamination or poor packaging. MedWatch was initially implemented as a paper-based system, and then transitioned to an Internet-based program in 1998 (Getz, Stergiopoulos, & Kaitin, 2012), enabling health care workers to submit confidential reports to the FDA through multiple mechanisms. These methods included the FDA website; facsimile or mail using a paper form; or telephone. The FDA also introduced the Adverse Event Reporting System (AERS) in 1998 as a comprehensive database for all safety information about products marketed in the U.S., inclusive of mandatory safety reports, post-marketing surveillance data, adverse event reports submitted by hospitals or manufacturers, MedWatch reports and ISMP MER program reports.

The number of reports per year submitted to the FDA and ISMP has increased over the past decade (FDA, 2013). In 2011, the most recent complete year for which data is available, health care professionals submitted 524,260 adverse event reports (FDA, 2013). Of these, physicians submitted 53.1%, pharmacists 9.2%, and all other healthcare professional groups 37.7%. For the first six months of 2012, there were 299,583 reports, indicating the rate of reporting is still on the rise (FDA, 2013).

USP began a unique medication reporting initiative in 1998 called the MedMARx program. The goal of the MedMARx program was to create a national network of hospitals that agreed to collect and share information about medication-related errors in a standardized format (Cousins, 1998; Santell, Hicks, McMeekin, & Cousins, 2003). A proprietary, Internet-based incident reporting system was one of several methods of medication error identification

advocated by the MedMARx program. Other methods included chart review, computer triggers and direct observation. The MedMARx incident reporting system enabled anonymous reporting of medication-related incidents by health care providers at member institutions. The MedMARx program did not include a mechanism for sharing data directly with the FDA. As of 2005, there were over two million medication adverse event reports in the database from just over 1,000 facilities (Grissinger, Hicks, Keroak, Marella, & Vaida, 2010) representing approximately 20% of the 4,936 hospitals in the U.S. at that time (Kaiser Family Foundation, 2012). The program was transferred to the private corporation Quantros in 2008, which now claims to have “the largest comparative repository of adverse drug event data in the world” (Quantros, 2014).

While no studies have been undertaken to evaluate the independent effectiveness of these national incident reporting systems for improving patient outcomes, there is some evidence of the positive impact of these efforts. Wysowski and Swartz (2005) found that the FDA AERS database was an effective mechanism for identifying serious medication safety issues and to devise strategies for risk mitigation. In a review of reports of medication-related events submitted to the FDA from 1969 to 2002, they determined that 2.3 million reports were submitted in all, with 60% originating from health care workers. Based on evidence in these reports, 52 drugs were removed from the market for safety reasons from 1964 - 1993, 25 additional drugs were removed from the market from 1978 – 2003, and 11 drugs were assigned special requirements for prescription or restricted distribution programs as of 2005 (Wysowski & Swartz, 2005). The reports had also served to inform the design of product labeling, patient package inserts and patient medication guides for a number of drugs (Wysowski & Swartz, 2005).

Patient Safety Organizations. A new subset of external incident reporting systems has emerged in the U.S. in the last several years. One of the recommendations in the IOM “To Err is Human” report was the enactment of federal legislation to protect reporters from legal discoverability (Kohn, et al., 1999). None of the medical external incident reporting systems detailed so far in this chapter offer such protection. The IOM report also suggested that developing “mini systems” for reporting subsets of patient safety incidents was a viable option to enhance voluntary reporting in lieu of a single national system (Kohn et al., p. 105). The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) addresses both recommendations.

Final guidelines for implementing the regulations of the Patient Safety Act were published in the Federal Register in November 2008 (Patient Safety and Quality Improvement, Final Rule, 2008). The Patient Safety Act enabled the Department of Health and Human Services to create a list of organizations, to be known as patient safety organizations (PSOs). The role of PSOs was to receive information about patient safety events in order to analyze the data, provide feedback to providers, and develop and disseminate strategies for improving patient safety.

Federally Designated Patient Safety Organizations. To gain initial federal designation as a PSO in accordance with the Patient Safety Act, an organization is required to attest to meeting specific criteria. These criteria include the following: a) its primary mission must be to improve patient safety and the quality of health care delivery, b) information about patient safety events must be used to provide direct feedback and assistance to providers to minimize patient

risk, c) all PSO staff must be qualified to perform analyses on patient safety data, and d) adequate policies and procedures to ensure the confidentiality of patient safety data must be in place. Many types of organizations may apply to AHRQ to be federally designated as a PSO, including public and private entities; for-profit and not-for-profit organizations; and entities that are a component of another organization, such as a hospital association or health system. Component organizations are required to submit additional attestations and disclosure statements that describe in detail the full nature of the relationship with the parent organization.

The Patient Safety Act further outlined specific activities that federally designated PSOs are required to undertake within each 3-year listing period. First, PSOs must certify they will collect and analyze data regarding patient safety events from providers; provide feedback to the providers; and develop and disseminate recommendations to improve patient safety. It was the intent that federally designated PSOs would aggregate data from multiple providers in order to maximize learning. The Patient Safety Act further directed the Department of Health and Human Services to create a network of national patient safety databases (NPSD) to collect and aggregate data from multiple PSOs in order to identify patterns and trends, generate regional and national statistics, and develop generalizable strategies to improve patient safety. Responsibility for overseeing PSOs and the NPSD is assigned to the Agency for Healthcare Research and Quality (AHRQ).

The Patient Safety Act outlines legal protection for providers who voluntarily submit reports of patient safety events to federally designated PSOs. Data received by PSOs is considered privileged and confidential, if collected according to the guidelines outlined in detail in the regulation; and unauthorized disclosure strictly prohibited. Patient safety data is

specifically protected from discovery in civil suits, such as malpractice claims, or in disciplinary actions against a provider. The Patient Safety Act is intended to provide a minimum level of protection, in the absence of state laws that provide more comprehensive levels of protection for privilege and confidentiality of patient safety event reports. Under certain circumstances, such as criminal proceedings, disclosure of patient safety data is permitted as detailed in the regulations. The Office of Civil Rights (OCR) was charged with interpreting, implementing, and enforcing the confidentiality protections of the Patient Safety Act, analogous to their responsibilities in implementing the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule.

To enhance the ability to make comparisons in patient safety data among providers and facilities, the Patient Safety Act charged the AHRQ with developing standardized formatting and process guidelines for data entry, referred to as the Common Formats. Use of the AHRQ Common Formats is required by all PSOs that submit data to the NPSD. For PSOs not planning to send data to the NPSD, use of the common formats is not required. Instead, the Patient Safety Act outlines specific requirements for PSOs about the use of another “standardized format that permits valid comparisons of similar cases among similar providers, to the extent to which these measures are practical and appropriate” (Patient Safety and Quality Improvement Act, Final Rule, 2008).

The AHRQ is required to submit periodic progress reports to Congress on implementation of the Patient Safety Act. As of the time of publication of the first report in January 2010, (Government Accountability Office [GAO], 2010), there had been limited progress in implementing the act. Sixty-five PSOs were listed by AHRQ but only three had

begun to collect patient safety data. In interviews with staff from a random sample of listed PSOs, three reasons were commonly offered for the delay in becoming fully operational: additional time was needed to finalize business organizational policies and procedures, awaiting further development of the AHRQ Common Formats, and communicating the complex data privilege and confidentiality regulations to providers was a challenge (GAO, 2010). By March 2014, 77 PSOs were listed by the AHRQ, but 54 had been delisted (AHRQ, 2014b). No additional progress reports by the AHRQ have been released.

Federally designated PSOs can operationalize the requirements of the Patient Safety Act in a variety of ways. They can collect reports of patient safety events directly from health care workers without a pre-existing contractual relationship. Or, they may require that reporters be a member of a particular organization, work at a particular facility, or have a pre-established individual contractual agreement. The focus in the current discussion is the former, or PSOs that collect reports directly from providers that do not have a pre-established contractual relationship. There is virtually no information in the published literature about the utilization of PSOs or the effectiveness of these efforts given the relative novelty of these organizations. Many federally designated PSOs focus their efforts on a particular subset of patient safety incidents or specific specialty areas. An example of each is provided here.

The ISMP now operates a PSO that targets medication-related events. It was one of the first organizations to become listed as a PSO under the Patient Safety Act, a logical step given that the ISMP had decades of experience operating the aforementioned MER program. The ISMP PSO has continued to accept reports from health care workers, consumers and patients on a confidential basis using an electronic form available on their website (ISMP, 2014b).

Reportable events include any medication-related error, adverse reaction, close call, or hazardous conditions. Any health care provider can access the online form to report incidents to the ISMP MER program. All reports submitted to ISMP MER are subsequently entered into the FDA MedWatch system and no independently published reports indicate the level of participation by health care provider type in the ISMP MER program since the formation of the ISMP PSO.

The Anesthesia Quality Institute (AQI) is an example of a federally designated PSO that focuses their efforts on anesthesia related incidents. The AQI was initially listed as a PSO in 2010, as a component organization of the American Society of Anesthesiologists (ASA) (AHRQ, 2014a). The Anesthesia Incident Reporting System (AIRS) was released in 2011 as a mechanism for anesthesia providers to anonymously or confidentially report “any unintended event related to anesthesia or pain management with the significant potential for patient harm” (Dutton, 2011). In the first three years of operation, approximately 1,100 reports were submitted to AQI (AQI, 2014a). No breakdown of reporters by provider group, for example anesthesiologists or CRNAs, has been published. Based on the reports submitted to AQI, 32 case reports have been published in the ASA newsletter and the AQI public website since the inception of the AIRS (AQI, 2014b).

Non-Federally Designated Patient Safety Organizations. Anesthesia e-Nonymous (Ae) is an example of a non-federally designated patient safety organization. Formed in the fall of 2013, the organization is comprised of faculty and staff in the Department of Nurse Anesthesia at Virginia Commonwealth University (VCU). Their mission is to provide a mechanism for anesthesia providers across the nation to share anonymous narrative reports about anesthesia patient safety incidents in a timely manner. Only anonymous reports are solicited and no attempt

is made to identify the source of the report or identifiable information about the reporter, eliminating the need for federal protections under the Patient Safety Act. The reporting form instructions include a list of potentially identifiable data fields to remind the user not to include information that would render the patient, facility, or reporter identifiable. In addition, all original reports are carefully screened and de-identified using the 'Safe Harbor Method' for de-identification of Protected Health Information in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (Department of Health and Human Services, 2012) within one-week after submission.

Ae utilizes the narrative reports as the basis for case presentations on their website. Only registered users who have been authenticated as bona fide anesthesia providers may access these presentations, which are prepared by Ae faculty. The case presentations remain on the Ae website indefinitely and are searchable by keyword, posting date, and event type. To date, the group has presented 11 case presentations. A summary of all reported events and Ae website activities is planned at the end of the first year of operation.

Patient safety organizations, whether federally designated or not, have only very recently been introduced in the U.S. The success of external incident reporting systems managed by patient safety organizations as a strategy for improving patient safety depends on widespread use of these systems by workers in the field. There are no published reports to indicate the level of acceptance and use of these systems at this point and it therefore remains to be seen if they will make a valuable contribution to improving patient safety.

Use of Incident Reporting Systems by Health Care Providers

Incident reporting systems are now omnipresent in health care. Decades of experience with implementing and using these systems have revealed a number of limitations, which have been described extensively in the literature. The most significant limitation of incident reporting systems is underutilization. Low overall utilization of incident reporting systems and variable incident reporting system use by different provider groups result in misrepresentation of actual threats to patient safety and hinder the ability to derive benefits from this strategy.

Underutilization has plagued reporting efforts in health care for decades. Every incident reporting system mentioned in the IOM report “To Err is Human” was adversely affected by inconsistent and low overall reporting rates (Kohn et al., 1999). Little progress in this area has been made to date.

Underutilization of Incident Reporting Systems. In a series of studies by the Office of the Inspector General, it was determined that health care workers do not reliably utilize hospital or internal incident reporting systems (DHHS, 2012). In the first study, a random sample of Medicare beneficiaries was selected from all Medicare patients discharged in two undisclosed counties over a one-week period in 2008 (DHHS, 2010; DHHS, 2012). Of 278 total patients in the study sample, 41 patients suffered at least one adverse event that met study criteria. This amounted to an incidence of adverse events of 15%. An additional 15.2% of the patients suffered an event that caused temporary harm. The study findings precipitated a more broad study aimed at determining an estimate of the rate of adverse events in Medicare beneficiaries nationwide.

In the second study, a random sample of 780 Medicare beneficiaries was selected from all Medicare patients discharged nationally over a one-month period in 2008 (DHHS, 2012). In

this sample, 13.5% experienced at least one adverse event during their hospitalization and an additional 13% suffered an event that caused temporary harm. Extrapolating to the entire population of Medicare patients over the study period, it was estimated that 134,000 Medicare beneficiaries suffered harm associated with medical care (DHHS, 2012).

To determine if hospital incident reporting systems had effectively captured the adverse events in the national sample, a third and final study was undertaken (DHHS, 2012). A total of 195 different hospitals were noted to be associated with the adverse events captured in the 2010 study. Although 98% of these hospitals had an internal reporting system in place, only 14% of the adverse events were reported (DHHS, 2012). Poor utilization of hospital incident reporting systems is one of many reasons for the current emphasis on external reporting systems.

Existing external reporting systems, or those not associated with a particular institution, facility, or health system, are also underutilized. One of the most widely known external reporting systems is The Joint Commission's Sentinel Event Database. As previously noted, all facilities accredited by The Joint Commission must have a policy for identifying and responding to all sentinel events, defined as an unexpected event that leads to death or serious injury (The Joint Commission, 2013a). Reporting events to The Joint Commission's Sentinel Event Database is encouraged but not required. There were 3,300 hospitals in the U.S. accredited by The Joint Commission as of 2013 (TJC, 2013b), yet a mere 9,981 total sentinel events have been reported to the database in the 18 years it has existed (TJC, 2014). The Joint Commission acknowledges that "only a small proportion of actual events" are captured (The Joint Commission, 2013c).

Underutilization by Provider Group. Use of incident reporting systems varies by provider group. Nurses and physicians constitute the two largest groups of providers of inpatient hospital care in the U.S. (Shi & Singh, 2008). Not surprisingly, studies of healthcare workers' use of incident reporting systems often focus on these two provider groups. Nuckols et al. (2007) found a large disparity in the volume of incident reports by provider type. After analysis of a total of 2,228 paper incident reports submitted at two hospitals, the authors found that 88% were reported by nurses, 1.9% by physicians, 8.9 % by "other providers" and 1.3% by "unknown providers". These findings were quite similar to those reported by Evans et al. (2006) in a study conducted at multiple facilities in Australia. They found that, of 1275 total incident reports, 84% were submitted by nurses, 5% by physicians and 11% by other allied health providers. The vast majority of the reports were submitted on a paper incident reporting form.

Studies to compare reporting rates among providers using electronic incident reporting systems show slightly different results. It is notable that computerized incident reporting systems enable analyses of dramatically larger number of reports across a larger number of hospital facilities. Milch et al. (2006) completed a descriptive analysis of 92,547 events collected with electronic incident reporting systems in place at 26 nonfederal hospitals in the U.S. The group subsequently reported a follow-up analysis of an even larger set of incident reports (n = 266,224) drawn from the same convenience sample of hospital facilities (Rowin et al., 2008). The breakdown of incidents by reporter type was cited: nurses 45.3%, physicians 1.4%, and all other hospital employees 53.6%.

Determinants of Use of Incident Reporting Systems. Factors at both the individual and institutional levels play a role in determining use of incident reporting systems in health care

providers (Holden & Karsh, 2007; Naveh & Katz-Navon, 2013). As an initial foray into understanding incident reporting behavior in CRNAs, the focus in this study is on individual level factors that influence incident reporting behavior. Most of the studies on health care providers' use of incident reporting systems involved internal reporting systems. One likely reason for this is that there are far more internal, hospital-based systems than external systems, as presented in the previous section. In addition, some external incident reporting systems are designed for submission of aggregate reports from institutions or hospital facilities only, such as the Joint Commission Sentinel Event Reporting system.

In a review of the literature for this study, 54 published research reports concerning individual level influences on health care providers' use of incident reporting systems were identified. The review was limited to studies published since 1999 because older studies may no longer reflect factors that are relevant to modern practice. The specific year was an arbitrary decision based on the year of publication of the aforementioned IOM report "To Err is Human" (Kohn et al., 1999), which has been very influential in modern incident reporting efforts in the U.S. Another particular focus of this review is on studies done in the U.S. because they are most likely to reflect the cultural milieu in which CRNAs practice. This subset of the studies identified is shown in Table 1. None of these studies describe use of external reporting systems. There is considerable variability in the methodological approaches taken in the studies shown in Table 1. The majority of the studies, or ten of the 15 studies shown, used a survey questionnaire for data collection, although none of these were the same questionnaire. The three most recent studies involving survey methods based their questionnaire design on a particular theoretical framework (Gavaza et al., 2011; Gavaza et al., 2012; Uribe & Scheikhart, 2002). In two studies

the questionnaires were based on the TPB (Gavaza et al., 2011, Gavaza et al., 2012). In the third study (Wagner, Castle, & Handler, 2012), the questionnaire was based on the Donabedian Quality of Care Conceptual Framework (Donabedian, 1988). Interestingly, the subjects in the

Table 1

Studies of Incident Reporting in Health Care Providers in the U.S. Published Since 1999

Study Citation	Method of Data Collection	Subjects' Discipline (Specialty)	Study Setting
Blegen et al., 2004	Survey	RN, n=1105	National sample from 159 adult care units; 25 hospitals
Elder, Graham, Brandt, & Hickner, 2007	Focus Groups	MD, PA, NP, n=45 RN, n=21 Others (administrative staff), n=73	Family practice physicians' offices
Elder, Brungs, Nagy, Kudel, & Render, 2008	Focus Groups	RN (ICU), n=33	Four community hospitals
Garbutt et al., 2007	Survey	Attending MD (pediatrics), n=439 Resident MD (pediatrics), n=118	Two university affiliated hospitals
Garbutt, Waterman, & Kapp, 2008	Survey	MD (medicine), n=742 MD (surgery), n=309	Academic & community hospitals in Washington and Missouri
Gavaza et al., 2011	Survey	Pharmacist, n=337	Community & hospital pharmacies in Texas
Gavaza et al., 2012	Survey	Pharmacist, n=377	Community and hospital pharmacies in Texas
Handler et al., 2007	Mixed Methods	MD, n=6 RN, n=7 Pharmacists, n=6 PA/NP, n=9	Urban and suburban nonprofit nursing homes
Jeffe et al., 2004	Focus Groups	MD, n=30 RN, n=49 Nurse Manager, n=10	Academic & community hospitals in St. Louis metropolitan area

Note. RN = registered nurse; MD = medical doctor; PA = physician's assistant; nurse practitioner = NP; intensive care unit = ICU

Table 1 continued

Study Citation	Method of Data Collection	Subjects' Discipline (Specialty)	Study Setting
Kaldjian et al., 2008	Survey	Attending MD, n=138 Resident MD, n=200	Three medical centers (mid-west, mid-Atlantic, northeast regions)
Schechtman & Plews-Ogan, 2006	Survey	Attending & resident MD, n=120	One academic medical center, mid-atlantic
Stratton, Blegen, Pepper & Vaughn, 2004	Survey	RN (pediatric), n=57	Six pediatric units in four hospitals (Midwestern rural consortium, n=2; urban areas in Rocky Mountain Region, n=4)
Taylor et al., 2004	Survey	MD, n=74 RN, n=66	Large academic children's medical center in Seattle, WA
Uribe & Schweikhart, 2002	Mixed Methods	MD, n=56 RN, n=66	Large Midwest academic medical center
Wagner, Castle, & Handler, 2012	Survey	Administrators, n= 399	Nursing homes across the U.S.

Note: RN = registered nurse; MD = medical doctor; PA = physician's assistant; nurse practitioner = NP; intensive care unit = ICU

study by Wagner et al. (2012) were nursing home administrators. In the remaining seven studies that utilized a survey questionnaire, the content was described simply as being based on a review of the literature. This variability in measurement makes it extremely difficult to make meaningful comparisons across the studies. It is equally difficult to make meaningful comparisons across the qualitative studies shown in Table 1 because of methodological variations in those studies.

The study by Elder, Brungs, Nagy, Kudel, and Render (2008) is of particular interest here because of the similarity between the study subjects and CRNAs. Elder et al. (2008) sampled 33 ICU nurses for a qualitative study intended to gain an understanding of their experiences with

incident reporting in their facilities. In that all CRNAs must have experience in a high acuity patient care setting such as an ICU prior to matriculation in a nurse anesthesia program, this study may have particular relevance to the study proposed in this paper. The researchers met with 33 nurses in a total of eight focus groups in order gain a better understanding of their experiences with incident reporting. In these interviews, the researchers asked the participants to describe the reasons why they did or did not report patient safety incidents. The participants in four or more of the focus groups reported that when there was little or no harm to the patient they were less inclined to report; and that lack of time was a barrier to reporting. The researchers organized the comments from the participants in three major themes of reasons to report/barriers to reporting: amount of effort, properties of the error, and perceived benefits and detriments.

Barriers to Use of Incident Reporting Systems. Factors that influence use, or non-use, of incident reporting systems by health care providers are often described in the literature as barriers to reporting. Pfeiffer, Manser, and Wehner (2010) reported a systematic review of the literature of barriers to incident reporting in hospitals. In their report, Pfeiffer et al. provided a detailed descriptive analysis of 19 studies on barriers to incident reporting in the literature through 2008, including 13 cross-sectional surveys and six qualitative studies. They did not limit the studies to the U.S. Their findings are presented here because they provide useful information for devising study hypotheses.

Pfeiffer et al. (2010) reported that they identified one hundred and ninety six individual barriers that were mentioned across all studies in their review. Pfeiffer et al. (2010) organized all of these barriers in 25 thematic groups. The collective sample included 2,208 physicians; 5,204

nurses; and 424 other health care workers. Accordingly, the results of the studies in the review most accurately describe barriers to incident reporting in physicians and nurses.

Studies of barriers to reporting in a single institution or specialty area may reflect only local conditions or nuances of a particular reporting system. Accordingly, the studies of particular interest in the article by Pfeiffer et al. (2010) review are those with a sample drawn from multiple sites or hospital units. This distinction limits the studies to a subset of seven survey studies, called the 'multiple facilities subset' here (Braithwaite, Westbrook, & Travaglia, 2008; Evans et al., 2006; Garbutt et al., 2008; Jeffe et al., 2004; Wakefield et al., 1999; Wakefield et al., 2001). In this subset, only 20 of the original 25 thematic groups were represented. The thematic groups identified in more than one of the seven studies are shown in Table 2. These barriers represent those most commonly cited by nurses and physicians across multiple facilities, specialties, and areas of care using a variety of different reporting systems. As previously noted, incident reporting behavior varies by provider group. Accordingly, perceived barriers to incident reporting have also been found to vary by provider group. In a convenience sample of 773 doctors and nurses from a wide variety of clinical settings, Evans et al. (2006) found that 89.2% of the nurses had completed an incident report in the past, but only 64.6% of the physicians had done so. This was a statistically significant finding ($p < .001$). The barriers to reporting identified by each provider group were different as well. The study survey provided participants a list of 19 possible barriers to incident reporting for which they were asked to rate the degree to which each acted as a deterrent to reporting on a 5-point Likert scale. The barriers most commonly identified by the nurses were lack of feedback (61.8%), a belief that there was no point in reporting near misses (49%), and forgetting to make a report when busy

Table 2.

Studies in 'Multiple Facilities Subset' That Identified Each Group of Barriers in the Review by Pfeiffer et al. (2010)

Thematic group of barriers	Number of studies that identified group
Fear of blame/disciplinary action	5
Reporting is time-consuming	5
Lack of trust in the anonymity/confidentiality of the system	4
No (appropriate) feedback is given on reported incidents	4
Not knowing what to report/no clear definition of incident	3
Belief that incident reporting systems are not effective at enhancing patient safety	3
Outcome (incident characteristics)	3
Fear of legal consequences	2
Fear that own competence may be questioned	2
Not knowing how to report an incident	2
Under-recognition	2

(48.1%). In the physician group, the most commonly cited barriers were lack of feedback (57.7%), the form took too long to complete (54.2%), and the belief that the incident was too trivial (51.2%). A significantly higher proportion of physicians reported the following barriers: the form took too long to complete ($p = .022$), the incident was too trivial ($p = .027$), and not knowing whose responsibility it was to submit the report ($p < 0.001$). Significantly more nurses than doctors reported not seeing any point in reporting near misses ($p = .003$). Barriers to external

incident reporting in physician anesthesia providers have also been explored. In a descriptive survey sent to anesthesiologists across New Zealand approximately 10 years after the introduction of the Australian Incident Monitoring Study (AIMS) (Runciman et al., 1993), Yong and Kluger (2003) asked the participants to estimate how many incident reports he or she had completed within the year prior and how many incident reports he or she had ever submitted. Those who stated they did not use the AIMS were asked to list all the reasons why this was so. Fifty percent of the 136 respondents reported having not completed an incident report in the year prior to the survey, and 15% had never completed a report. The three most commonly listed reasons for not reporting were medicolegal implications, inadequate feedback, and that the forms were unavailable or hard to locate (Yong & Kluger, 2003). These barriers, and several others identified less often in the study, are consistent with findings by Pfeiffer et al. (2010) in other physician and nursing groups.

Another survey of anesthesiologists in Australia by Heard, Sanderson, and Thomas (2012) showed different results. The study participants were asked to rate the degree to which barriers to reporting previously identified in the literature influenced their decision to report adverse events. The 13 barriers included in their survey are consistent with those identified by Pfeiffer et al. (2010). There was only one survey item for which more study participants agreed than disagreed, namely “Doctors who make errors are blamed by their colleagues”. The authors concluded that, while comparison with previous work was difficult, the education and culture in anesthesiology could be more favorable to reporting than in other areas. There are no studies in the published literature of perceived barriers to incident reporting in CRNAs.

The large body of exploratory studies examining barriers to incident reporting has provided a foundation for descriptive correlational studies of reporting behavior in health care workers. There is an emerging trend in the literature toward application of theory-based approaches to this issue. Incident reporting, regardless of the specific system involved, is a voluntary behavior that health care providers must choose to engage in, or not. In recognition of this, a variety of behavioral theories have been applied.

Theory of Planned Behavior

Use of an incident reporting system is, fundamentally, an activity in which each health care provider has the option to engage or not engage. In order to design and implement interventions that will encourage use of any type of incident reporting system, it is important to understand factors that determine health care providers' decision to report or not report. A great deal of research has been undertaken to understand clinician behavior, using a variety of theoretical approaches (Godin, G., Bélanger-Gravel, A., Eccles, M., & Grimshaw, J., 2008). The theory of planned behavior (TPB) is one of the most commonly utilized models for understanding a wide variety of behaviors in non-medical domains (Armitage & Connor, 2001) and health-related behaviors in patients (Godin & Kok, 1996; Perkins et al., 2007). It has also recently been applied as a model for understanding and predicting clinical practice decisions (Perkins et al.) and incident reporting in health care providers (Gavaza et al., 2011; Gavaza et al., 2012; Holden & Karsh, 2009).

The TPB was designed to understand and predict human behavior in specific situations in which a person has at least some degree of free will (Ajzen, 1991). It is an extension of the theory of reasoned action (TRA; Ajzen, 1991), a model that predicts that, in circumstances over

which a person has complete control, behavior is determined by a person's attitude toward the behavior as well as social influences (Fishbein & Ajzen, 1975). Examples of circumstances in which the TRA can accurately predict behavior include choosing among candidates in an election, smoking marijuana, or attending lectures of a given class on a regular basis (Ajzen, 1985). Performance of many activities is, in fact, not 100% within a person's control and instead is dependent upon the presence of appropriate opportunities, skills, and resources (Ajzen, 1985). In situations of this nature, the TRA was found to have limited predictive accuracy (Ajzen, 1985).

The theory of planned behavior extended the theory of reasoned action. The TPB was developed to predict behavior in situations in which a person may not have all of the requisite knowledge, resources and capabilities (Ajzen, 1985). Ajzen proposed that, while a person's actual degree of control over a situation influenced behavior, it was generally neither feasible nor necessary to measure this construct (Ajzen, 1985). Instead a person's *perception* of degree of control over performing a behavior was proposed as a reasonable proxy measure; and a more important determinant of behavior (Ajzen, 1985). The idea that perceived degree of control may play a role in behavior was largely based on Bandura's work on the construct of self-efficacy, or a person's beliefs about his or her capabilities to exercise control over his or her own level of functioning and over events that affect his or her life (Bandura, 1993).

A basic assumption of the TPB is that human beings engage in many activities in a goal-directed manner and it is therefore possible to predict whether or not a person will engage in those specific activities (Ajzen, 1985). The TPB ultimately posits that human behavior is determined by a person's underlying beliefs about that behavior (Ajzen, 1985). As shown in

Figure 1, there are a number of intervening steps that characterize the relationship between beliefs and behavior.

According to TPB, a person might possess many beliefs about a particular behavior or activity, yet only a relatively small number of salient beliefs can influence the decision to engage in that behavior at a given moment (Ajzen, 1991). Ajzen refers to this subset of beliefs as ‘accessible’ beliefs (Ajzen, 2005). Accessible beliefs can be subdivided into three categories: behavioral, normative, and control (Ajzen, 2005). Behavioral beliefs are a person’s subjective assessments of the attributes of a behavior and the consequences of performing that behavior (Ajzen, 2006). Normative beliefs constitute a person’s assessments of whether or not other individuals or groups of individuals expect one to engage in a particular activity. The specific individuals or groups that influence decision-making varies according to the population and behavioral context studied (Ajzen, 2006). Control beliefs concern a person’s perception of factors that will enable or deter performance (Ajzen, 2005). It is important to note that a person’s beliefs influence his or her decision-making, but these beliefs may not necessarily be consistent with reality. By their very nature, personal beliefs are biased and may potentially be irrational (Ajzen, 2005).

The TPB proposes that behavioral beliefs, normative beliefs, and control beliefs, respectively activate the formation of attitudes toward a behavior, subjective norm, and perceived behavioral control (Ajzen, 2005). Attitude toward a behavior (ATT) is the extent to which a person positively or negatively values performing that behavior (Ajzen, 2006). Subjective norm (SN) is the degree to which a person perceives social pressure to perform or not perform a behavior (Ajzen, 1985). SN can be derived from a person’s beliefs about whether or

not others that are important to them also engage or do not engage in a specific activity (Ajzen, 2004). Or, SN can be derived from a person's beliefs about whether others approve or disapprove of engaging in that activity (Ajzen, 2004). Perceived behavioral control (PBC) is the degree to which a person feels in control of performing the behavior (Francis et al., 2004). The TPB further proposes that ATT, SN, and PBC are independent determinants of intention, which represents a person's readiness to perform that behavior (Ajzen, 2006). Intentions, as a primary construct in the TPB, are assumed to be "indications of how hard people are willing to try, of how much of an effort they are planning to exert, in order to perform the behavior" (Ajzen, 1991, p. 181). There is a positive correlation between the strength of an intention and the likelihood that a person will perform a given behavior (Ajzen & Madden, 1986). Attitude towards a behavior, subjective norm, and perceived behavioral control have a variable impact on intentions dependent upon the particular behavior, context, and population studied (Ajzen, 1991; Ajzen, 2005). In some situations, perceived behavioral control can also exert a moderating influence on behavior, depicted as a dotted line in Figure 2, in that a strong intention will only result in action when the person is confident that he or she can perform an activity (Ajzen, 2005). While the TPB describes a linear cognitive process in which the formation of beliefs leads to the development of intentions that, in turn, guide behavior, this is not to say that a person explicitly reviews each step in order to decide to undertake a particular activity (Ajzen, 2005). The performance of many activities is in fact quite spontaneous, while still consistently based on a person's underlying beliefs and intentions (Ajzen & Fishbein, 2000).

Many previous studies have utilized the TPB in order to understand and predict the behavior of health care providers (Godin, G., Bélanger-Gravel, A., Eccles, M., & Grimshaw, J.,

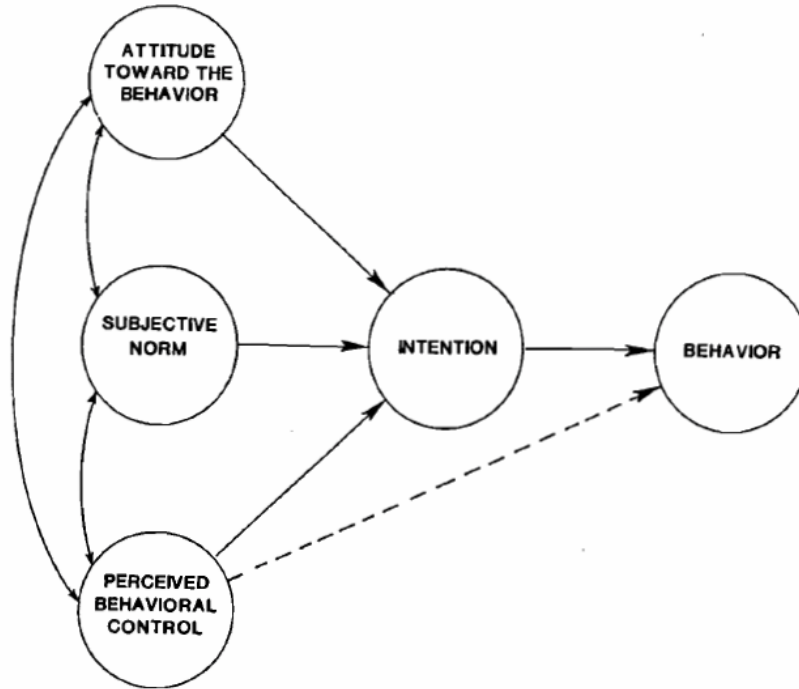


Figure 2. The Theory of Planned Behavior

Source: Ajzen, I. & Madden, T. (1985). Prediction of Goal-Directed Behavior Relation: Reasoned and Automatic Processes. *European Review of Social Psychology*, 11(1), 1-33.

2008; Perkins, et al., 2007). In a systematic review of the literature from 1966 – 2006, Perkins et al. (2007) identified 13 studies that utilized the TPB to predict a wide variety of clinician behaviors. Seven studies involved only physicians, three only nurses, two only pharmacists, and the remaining study involved a variety of health care workers. Perkins et al. concluded that use of the TPB was supported as a model for understanding clinician behavior (2007). The systematic review of the literature from 1960 – 2007 by Godin et al. included studies that applied a wide variety of theoretical models to understand and predict clinicians' intentions and behaviors (Godin et al., 2008). The researchers did not distinguish the TRA from the TPB, due to the similarity between the theoretical models. By far, the TPB and the TRA were the most

commonly utilized models for understanding and predicting intention and behavior. Fifty-six studies using the TPB or TRA to study intention were identified versus eight studies that used other models. Similarly, 14 studies using the TPB or TRA to study behavior were identified versus one study that used another model. None of the studies in this review specifically examined reporting system behaviors of health care workers.

A recent study by Gavaza et al. (2011) suggests the TPB is a valid model for understanding use of reporting systems in pharmacists. The study was undertaken to explore the utility of the TPB for understanding pharmacists' intent to report adverse drug events (ADEs) to the FDA. The researchers utilized a modified TPB model that proposed five constructs as the primary determinants of intention: attitude towards ADE reporting, subjective norm regarding ADE reporting, perceived behavioral control over reporting ADEs, as well as perceived moral obligation to report ADEs (PMO), and past reporting behavior (PRB; Gavaza et al., 2011). The results of the study showed a combination of attitude, subjective norm, and perceived behavioral control explained 34% of the variance in the pharmacists' intent to report, $p < .001$. Based on the standardized regression coefficient (β) values for each predictor variable, (ATT: $\beta = .221$, $p < .001$; SN: $\beta=0.438$, $p < .001$; PBC: $\beta = .028$, $p = .526$), they determined that SN was the strongest independent predictor of INT. Perceived behavior control was not a significant predictor of intent to report after controlling for other variables. The addition of PRB explained 1% of the variance ($P = .021$), while PMO explained 2.6% of the variance ($P < .001$).

Hypotheses

The findings of the study by Gavaza et al. (2011) and the aforementioned body of work on barriers to incident reporting in health care providers are the foundation for the hypotheses in

this proposed study. The study by Gavaza et al. (2011) is particularly relevant because it is recent and explores the influence of cognitive factors on use of incident reporting systems. Application of the TPB to incident reporting behavior in health care providers is a relatively novel undertaking. This study included only the three direct predictors in intent from the original TPB, in the interest of parsimony and in light of the sensitivity of multiple regression analysis to the number of independent variables in the model (Tabachnick & Fidell, 2007). These constructs were operationalized as the study variables 'attitude toward reporting' (ATR), 'social pressure to report' (SPR), 'perceived control over reporting' (PCR). A single criterion variable 'intent to report' (INR) served as a proxy measure of CRNAs' use of incident reporting systems.

Nearly all of the thematic groups of barriers identified in the review by Pfeiffer et al. (2010) can be aligned with the constructs ATT, SN, and PBC in the TPB. For example, the thematic groups fear of blame/disciplinary action, lack of trust in the anonymity/confidentiality of the system, lack of feedback is given on reported incidents, belief that incident reporting systems are not effective in improving patient safety, and fear that own competence may be questioned would all align with the construct ATR. Similarly, the thematic groups 'reporting is time consuming', 'not knowing what to report' and 'not knowing how to report an incident' align with the PCR construct. The thematic group fear that own competence may be questioned aligns with the construct SPR. That the most frequently cited barriers in the literature aligned with the constructs of the TPB suggested that these particular cognitive factors would be associated with use of incident reporting systems by CRNAs.

The number of studies identified in the review by Pfeiffer et al. (2010) that mentioned a thematic group might cautiously be interpreted as a very rough indication of the relative impact

of a group of barriers on reporting behavior. As such, the relative importance of the TPB constructs was predicted to be ATR, PCR, then SPR. This prediction differed from the observed relative importance of these variables for pharmacists reported by Gavaza et al. (2011). The studies reviewed by Pfeiffer et al. (2010) predominantly reflected the views of nurses and physicians. The contextual and cultural factors associated with CRNA practice were predicted as likely to be more similar to that of nurses and physicians than of pharmacists. In addition, none of the focus group participants in the study by Elder et al. (2008) highlighted social pressure as a major factor in their use of incident reporting systems. In contrast, many of the focus group participants in the study by Elder et al. (2008) reported factors related to their assessment of the value and consequences of incident reporting, and perceived time constraints affected their use of incident reporting systems. Consequently, these studies formed the basis for a hypothesis related to the relative significance of the variables in this study.

- *Hypothesis one (H₁):* There is a direct positive linear relationship between attitude toward reporting and the likelihood that a CRNA will use an incident reporting system.
- *Hypothesis two (H₂):* There is a direct positive linear relationship between social pressure to report and the likelihood that a CRNA will use an incident reporting system.
- *Hypothesis three (H₃):* There is a direct positive linear relationship between perceived control over reporting and the likelihood that a CRNA will use an incident reporting system.
- *Hypothesis four (H₄):* Together, the combination of attitude toward reporting, social pressure to report, and perceived control over reporting will best predict the likelihood that a CRNA will use an incident reporting system.
- *Hypothesis five (H₅):* A CRNA's attitude toward reporting will be the strongest predictor of the likelihood that he or she will use an incident reporting system.

Chapter Summary

Incident reporting systems provide high reliability organizations the opportunity to learn about system failures and to subsequently design strategies for addressing areas of weakness. Although incident reporting systems have been widely implemented in health care, workers in this industry do not reliably embrace and utilize these systems for unknown reasons. An overview of the basic characteristics of incident reporting systems designed for individual level reporting and a brief chronological history of the development of incident reporting systems in aviation and medicine in the U.S. was provided in this chapter. Use of incident reporting systems by health care providers in the U.S. and a review of the literature on barriers to incident reporting was presented.

Current emphasis in the area of incident reporting in health care is on the implementation of patient safety organizations following the enactment of the Patient Safety Act of 2005. In lieu of one national, comprehensive reporting system for all health care workers, patient safety organizations represent an opportunity for the creation of a national network of mini-reporting systems to pool data from multiple sources representing subsets of patient safety incidents. In addition, patient safety organizations offer providers protection from medical legal liability, which has long been sought and embraced as desirable. As in many other health care professions, the reporting of adverse events in anesthesiology has recently been introduced through the advent of PSOs, as described in this chapter. Such patient safety organizations provide anesthesia providers across the U.S. the opportunity to directly participate in national patient safety efforts. Success of these reporting efforts will only be achieved through widespread adoption and utilization of these novel incident reporting systems.

Understanding reporting behavior in health care providers is essential to the development of a robust reporting system. No study of use of incident reporting systems by CRNAs has been undertaken, yet this group of providers comprises one-half of the anesthesia work force in the U.S. As such, successful establishment of patient safety organizations in the specialty of anesthesia is dependent on the participation of CRNAs.

The theory of planned behavior is a widely accepted behavioral model that has been used in a variety of applications. A detailed description of this model was provided in this chapter. The theory has been shown to be a useful model for understanding clinical practice in health care providers. Recent application of the theory of planned behavior to use of an incident reporting system in pharmacists suggested potential utility of this model for describing cognitive factors that influence CRNAs' use of incident reporting systems.

This study is the first to examine incident reporting behavior in CRNAs. The general aim of this study was to gain insight into factors that influence use of incident reporting systems by CRNAs. This study also assessed the validity of the TPB as a model for understanding CRNAs' use of incident reporting systems. Information about CRNAs use of incident reporting systems will be useful for designing and evaluating strategies to encourage incident reporting in this population. Chapter Three describes research methods and statistical analyses utilized to address the research questions and test study hypotheses.

Chapter Three: Methodology

The creation of a single, national incident reporting system capable of capturing adverse patient safety events of all types in all settings is neither feasible nor desirable (Kohn, 1999). National, focused initiatives for collecting incident reports of subtypes of patient safety incidents, or mini-systems, are a more viable option for collecting the valuable information about adverse events that only frontline health care workers can provide ((Kohn, 1999; Leape, 2002). Patient safety organizations (PSOs) devoted to collecting reports about particular subtypes of patient safety incidents, such as anesthesia-related incidents, offer such mini-systems. As one of the primary providers of anesthesia care in the U.S. (Daugherty et al., 2007), Certified Registered Nurse Anesthetists (CRNAs) have a vital role in successful implementation of PSOs in the specialty of anesthesia.

The purpose of this study was to gain insight into factors that influence use of incident reporting systems by CRNAs. The theory of planned behavior (TPB) has been found to be a useful model for understanding use of clinical practice guidelines by health care providers and use of an incident reporting system in pharmacists. No prior studies have applied the TPB to the behavior of CRNAs. In order to assess the validity of the TPB for understanding CRNAs' use of incident reporting systems, this study examined the relationship between the predictor variables attitude toward reporting (ATR), social pressure to report (SPR), and perceived control over reporting (PCR) and the criterion variable intent to report (INR).

Findings from this study will assist organizations in formulating customized strategies for successful development and evaluation of new incident reporting systems in anesthesiology. In order to develop evidence-based, complex interventions to promote incident reporting by CRNAs, it is necessary to first gain an understanding of the most important factors that determine this behavior in this group.

This chapter describes the research methods and statistical analyses utilized to address the research questions: a) Do CRNAs currently use incident reporting systems? b) Do CRNAs value incident reporting? c) Do CRNAs perceive social pressure to use incident reporting systems? d) Do CRNAs feel in control of using incident reporting systems? e) Is there a relationship between cognitive factors and the likelihood that a CRNA will use an incident reporting system? The study objectives and hypotheses are shown in Table 3. The study design, population, recruitment and sampling strategies, predictor and criterion variables, instrument design, data collection and analysis, and limitations are presented in the following pages.

Research Design

This study employed a non-experimental, descriptive, correlational design to explore the relationship between attitude toward reporting, social pressure to report, and perceived control over reporting; and intent to report to an incident reporting system in CRNAs. A non-experimental design was selected due to the nature of the research questions and phenomenon of interest. An extensive review of the literature revealed that incident reporting behavior in CRNAs has not been previously described, although studies of incident reporting behavior in other health care provider groups have been reported. Use of a quantitative design enabled testing of hypotheses about the relationships among variables that were developed based on the

Table 3

Study Objectives and Research Hypotheses

Objectives	Research Hypotheses
1. To describe current use of incident reporting systems by CRNAs in the U.S.	N/A
2. To describe the extent to which CRNAs <ol style="list-style-type: none"> a. value incident reporting b. perceive social pressure to use incident reporting systems c. feel in control of using incident reporting systems 	N/A
3. To determine if there is a relationship between attitude toward reporting, perceived social pressure to report, and perceived control over reporting and the likelihood that a CRNA will use an incident reporting system	<p>H₁: There is a direct positive linear relationship between attitude toward reporting and the likelihood that a CRNA will use an incident reporting system.</p> <p>H₂: There is a direct positive linear relationship between social pressure to report and the likelihood that a CRNA will use an incident reporting system.</p> <p>H₃: There is a direct positive linear relationship between perceived control over reporting and the likelihood that a CRNA will use an incident reporting system.</p> <p>H₄: Together, the combination of attitude toward reporting, social pressure to report, and perceived control over reporting will best predict the likelihood that a CRNA will use an incident reporting system.</p>
4. To determine the relative influence of attitude toward reporting, perceived social pressure to report, and perceived control over reporting on the likelihood that a CRNA will use an incident reporting system.	H ₅ : A CRNA's attitude toward reporting will be the strongest predictor of the likelihood that he or she will use an incident reporting system.

literature review (Polit & Beck, 2009). The information gained by using this descriptive, correlational design may be used to develop interventions in future quasi-experimental studies in this area (Polit & Beck).

Population, Recruitment and Sampling Methods

The target population in this study was CRNAs in the U.S. actively practicing in the field at the time of the study. This subset of CRNAs was assumed to be most likely to experience, and therefore to submit incident reports about, patient safety incidents. The accessible population was actively practicing CRNAs in the U.S. who were members of the American Association of Nurse Anesthetists (AANA) in good standing at the time of data collection.

There are currently over 47,000 CRNAs in the U.S. (AANA, 2014), however not all are actively engaged in clinical practice in the specialty. Approximately 90% of all CRNAs are currently members of the AANA. In the most recent AANA Annual Membership Survey (AANA, 2013a), 96% of AANA members reported being employed as a CRNA and, of these, 96% indicated their primary work position was in the area of clinical practice. Other possible primary position categories include education, administration, research, and other. If extrapolated to the entire population of CRNAs in the U.S., this amounts to 43,315 CRNAs employed in practice positions. There are six classes of membership in the AANA (AANA, 2013b). Only one class, active membership, includes CRNAs who are actively practicing in the specialty. Active members are further divided into five categories, of which only two include CRNAs who are actively practicing in the specialty: active certified and active recertified. Approximately 36,800 CRNAs currently hold active certified or active recertification status in the AANA (AANA, 2014b).

Following Institutional Review Board (IRB) approval of the study protocol as exempt from full review, a random sample of CRNAs was selected from the AANA database. The AANA does not release the contact information of its membership, however, upon written

request, the AANA Research Division staff will randomly select a sample of CRNAs and deploy an electronic survey instrument on a researcher's behalf (AANA, 2014b). Sample inclusion criteria included certified and recertified CRNAs who reported spending 51% or more of their professional time in the area of clinical practice in their AANA member profile. Only CRNAs that self-report being employed full or part-time are presented the option of designating the area of their primary employment on the AANA member profile; hence there was no need to designate employment status as a separate inclusion criterion. Demographic questions in this study survey mirrored those in the AANA Annual Membership survey to permit post hoc comparison between the study sample and the population (Polit & Beck, 2011).

In order to decrease the risk of a Type II error and enhance the statistical conclusion validity of the study, power analysis was performed to determine sample size (Polit & Beck, 2011). By convention, a significance criterion of 0.05 and power of 0.80 were set (Cohen, 1992b; Polit & Beck, 2011; Tabachnick & Fidell, 2007). Estimation of effect size was based on the review of the literature (Polit & Beck, 2011). Meta-analyses of prior studies using the TPB have found a moderate to strong relationship between the combination of ATT, SN, PBC and INT; and a moderate relationship between each individual predictor and INT (Armitage & Connor, 2001; McEachan, Connor, Taylor, & Lawton, 2011). Frances et al. (2004) also recommend a medium effect size for determination of sample size using power analysis in studies using the TPB. Given these estimates of power, significance and effect size; and three predictors, the minimum sample size was 77 subjects (Polit & Beck, 2011). A more conservative 'rule of thumb' estimation method indicated that greater than or equal to 107 subjects were

required for the proposed analyses (Tabachnick & Fidell, 2007). This was the target number of subjects for the study.

Data Collection

The study questionnaire was formatted as an electronic survey managed and delivered with the web application Research and Electronic Data Capture (REDCap™). REDCap™ is a secure, web-based application housed on VCU servers (Harris et al., 2009). Researchers can deploy surveys in REDCap™ by using either a participant list or a public survey link. While either method can be configured to protect the anonymity of survey participants, the public link feature is more robust in this regard and was therefore utilized in this study.

For the main study, participants were recruited in an electronic survey invitation from the AANA Research Division. The invitation letter included the title and purpose of the research; a statement of consent; an estimate of the time commitment required to participate in the study; the primary investigator's contact information; and the public link to the electronic survey. A copy of the invitation letter is provided in Appendix A.

A subject's 'click' on the public survey link served as the consent to participate in the survey. Upon selecting the link, participants were redirected to the REDCap™ software application to complete the study questionnaire, which was presented in the form of three web pages. The first page presented to prospective subjects included a welcome message, brief reiteration of the study purpose and definitions of key terms. A 'Next Page' link redirected the participants to the instructions for completing the survey. Another 'next page' link presented the items that comprised the body of the questionnaire. A final link, 'Submit' closed the survey and displayed a message to thank the participant and the primary researcher's contact information.

The survey was configured such that a response for each item was not required in order to submit or close the survey. Whenever the participant inadvertently or purposefully closed the survey prior to completing all items, the record was marked as incomplete in the database.

To increase the probability of attaining the target sample size, the application to the AANA requested that the electronic survey invitation was sent to 3000 CRNAs. Historically, an average of 3% of recipients have elected to opt-out of participation upon initial receipt of survey invitations delivered by email from the AANA and approximately 10% of the remaining recipients subsequently completed the surveys (AANA, 2014b). The request to the AANA therefore specified that 3000 invitations were sent in case of a response rate of less than 10% or a higher opt out rate. One email reminder was sent to all recipients of the original survey invitation after three weeks per AANA policy (AANA, 2014b).

The electronic survey link was active for four weeks. The number of CRNAs that opted out of participation upon receipt of the invitation email is unknown. Three hundred and eighty seven subjects accessed the survey link in the email, although three subsequently closed the link without answering any survey items. Ninety of the remaining subjects completed the demographic section but not the remainder of the survey and were excluded from the analysis. The final survey response rate for the study was 9.8%.

Variables

Study variables were derived from the constructs of the TPB. There are five primary constructs in the TPB, which were adapted and defined for the current study as shown in Table 4. A single criterion variable, 'intent to report' (INR), was the primary outcome of interest in hypothesis testing. Intent to report served as a proxy measure of use of incident reporting systems for two

Table 4

Overview of TPB Constructs, Definitions, Study Variables, and Operational Definitions

TPB Construct	Definition (Ajzen, 2006)	Study Variable	Operational Definition
Attitude	The extent to which a person positively or negatively values performing that behavior	Attitude toward reporting (ATR)	The extent to which a CRNA positively or negatively values submitting reports of patient safety incidents to an incident reporting system
Subjective norm	The degree to which a person perceives social pressure to perform or not perform a behavior	Social pressure to report (SPR)	The degree to which a CRNA perceives social pressure to submit reports of patient safety incidents to an incident reporting system
Perceived behavioral control	The degree to which a person feels in control of performing the behavior	Perceived control over reporting (PCR)	The degree to which a CRNA feels in control of submitting reports of patient safety incidents to an incident reporting system
Intention	An indication of a person's readiness to perform a behavior	Intent to report (INR)	The degree of likelihood that a CRNA will submit reports of patient safety incidents to an incident reporting system
Behavior	The manifest, observable response in a given situation with respect to a given target	Use of an incident reporting system	Submission of an incident report to an incident reporting system when a CRNA encounters a patient safety incident

reasons. The first relates to the accuracy of variable measurement. Study participants could only be expected to report his or her current attitude and beliefs toward use of incident reporting systems, not the state of mind he or she was in at the time he or she last used an incident reporting system. That is, the predictor variables could only be measured accurately in present tense. The TPB proposes that cognitive factors are determinants of behavior that occurs within a reasonably short time period after (McEachen et al., 2011). Because the predictor variables could only be measured in present tense, it follows that the outcome variable could only refer to behavior that would occur in the near future. It was not feasible to measure actual use of incident reporting systems in the study subjects. Thus, intent to report was selected as a proxy measure of the behavior of interest.

The second reason for the use of a proxy measure for incident reporting behavior was that it was not necessary to measure both constructs in order to achieve the study aims. Intention has been found to be a strong predictor of behavior in prior studies (Godin & Kok, 1996). A recent systematic review of TPB studies of the clinical practice of health care providers identified ten studies that specifically addressed the relationship between intention and behavior (Eccles et al., 2006). While Eccles et al. identified a number of methodological issues; they asserted that intention was a reasonable proxy measure for behavior. Using intent to report as the outcome variable was consistent with two recent studies of reporting behavior in pharmacists (Gavaza et al., 2011; Gavaza et al., 2012).

The direct correlation between perceived behavioral control and behavior proposed in the TPB could not be evaluated because the TPB construct 'behavior' was not measured. The predictor variables 'attitude toward reporting', 'social pressure to report', and 'perceived control

over reporting' represented the direct determinants of intention according to the TPB. While many researchers have attempted to enhance the predictive accuracy of the TPB by adding additional constructs to explain intention, it is recommended that this be undertaken with great caution and on the basis of strong empirical evidence (Ajzen, 2011). As the current study was the first test of the TPB in the population of CRNAs and a relatively novel application of the model to incident reporting behavior in health care providers in general, additional constructs were not included. The study variables and hypothesized relationships that were assessed to achieve the study objectives are shown in Figure 3.

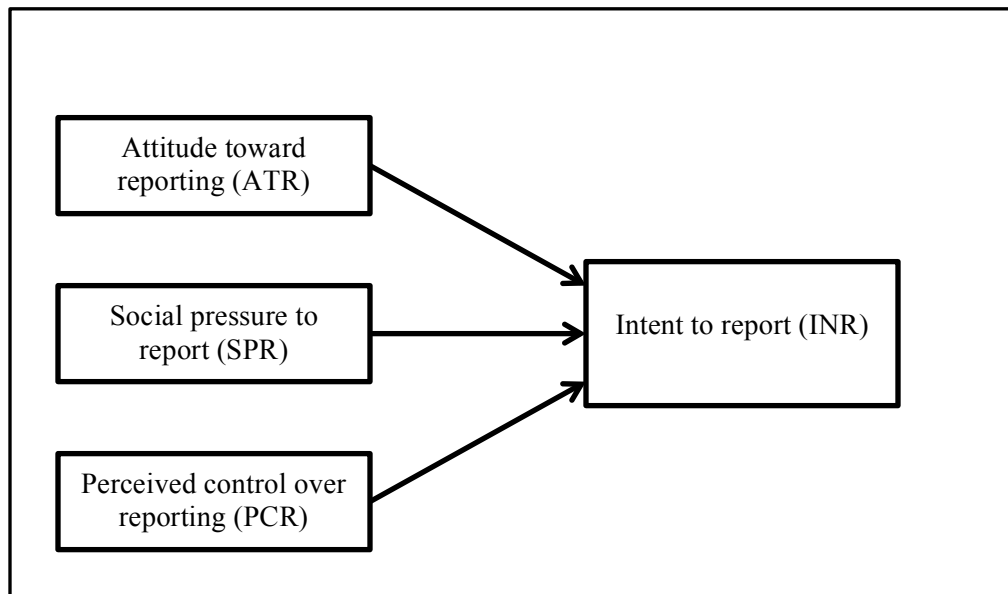


Figure 3: Hypothesized Relationships Among Study Variables

Measurement

The recommended method for measuring the variables based on the TPB is a self-administered questionnaire (Ajzen, 2006; Francis et al., 2004; Young et al., 1991). No standard questionnaire exists that has been validated for use in all contexts (Ajzen, 2006). It is

recommended that a customized questionnaire be developed that is appropriate for the specific population and behavior of interest (Ajzen, 2006). Step-by-step instructions for undertaking questionnaire development in the published literature were incorporated into the design of the initial questionnaire (Francis et al., 2004; Young et al., 1991).

The initial questionnaire was comprised of three parts. Part I included introductory information, demographic items, and two items related to past reporting behavior. Introductory information included contextual information about the study, definitions of key concepts and directions for completing the survey to increase the likelihood that participants clearly understood the behavior of interest and how to use the instrument in order to improve its accuracy (Polit & Beck, 2011). Five demographic items were included to facilitate post hoc assessment of the sample representativeness (Polit & Beck, 2011). The wording and possible choices for those items were identical to that on the AANA Annual Membership survey, with one exception. Possible choices for the item ‘primary employment arrangement’ were collapsed from 25 to six to reflect the most commonly selected categories in the AANA Annual Membership survey (AANA, 2013a). Items in the demographic section are shown in Table 5.

Part II, the ‘Incident Reporting Scale’, was comprised of 16 items organized into four ‘subscales’ corresponding to the study variables. A self-administered questionnaire based on the TPB can include items that directly measure predictor variables, items that indirectly measure predictor variables, or both (Ajzen, 2006; Francis et al., 2004). Items that directly measure predictor variables simply ask participants about their attitude toward a behavior, subjective norm and perceived behavioral control outright (Francis et al., 2004). Items that indirectly measure predictor variables must be devised through a lengthy process, which involves

Table 5

Demographic Items in the Study Questionnaire

Variable	Questionnaire item/wording	Response choices
Age	What is your age?	Under 30 years 30 – 34 years 35 – 39 years 40 – 44 years 45 – 49 years 50 – 54 years 55 – 59 years 60 – 64 years 65 + years
Gender	Please indicate your gender:	Male Female
AANA geographic region	In what AANA geographic region do you practice in your primary position?	Region 1 Region 2 Region 3 Region 4 Region 5 Region 6 Region 7
Primary practice arrangement/source of income	Please indicate your primary practice arrangement (provides the greatest proportion of your income):	Employee of a hospital Employee of a group Independent contractor Owner/partner Military/Govt./VA Employee in other setting
Years of experience as a CRNA	For how many years have you practiced as a CRNA?	Less than 2 years 2 – 5 years 6 – 10 years 11 – 15 years 16 – 20 years Greater than 20 years

qualitative and quantitative research methods in order to elicit all of the beliefs associated with the predictor variables in the study population.

Only items that directly measure the predictor variables were used in this study for several reasons. Survey questionnaires based on the TPB that include items to indirectly

measure predictor variables tend to be rather lengthy. In a study of nurses' use of clinical practice guidelines based on the TPB, Puffer and Rashidian (2002) utilized a survey that included indirect measurement of three predictor variables. Their questionnaire included a total of 38 items related to the variables attitude toward the behavior, subjective norm, and perceived behavioral control. The aforementioned guidelines for designing a survey based on the TPB by Frances et al. (2004) provide a sample questionnaire using indirect measurement of attitude toward a behavior, subjective norm, and perceived behavioral control. Again, a total of 38 items on the sample questionnaire related to the three predictors. With the addition of items to assess other study variables and demographics, the final survey questionnaire in the study by Puffer and Rashidian (2002) contained 52 items; and the sample questionnaire by Frances et al. (2004) 48 items. In order to encourage busy health care providers to participate in survey research, it is advisable to keep questionnaire length as short as is reasonably possible (McPeake, Bateson, & O'Neill, 2014; VanGeest, Johnson, & Welch, 2007). Utilizing only items that directly measure the predictor variables helped limit the overall length of the survey questionnaire in this study.

The second reason for the decision to include only items that directly measure the predictor variables was the precedent in the literature. In a study of the use of incident reporting systems in pharmacists based on the TPB, Gavaza et al. (2011) opted to utilize only items to directly measure the predictor variables attitude toward reporting, subjective norm, and perceived behavioral control. They found that 34% of the variance in pharmacists' intent to report to the FDA was explained by ATT, SN, and PBC, $p < .001$. Based on the standardized regression coefficient (β) values for each predictor variable, (ATT: $\beta = .221$, $p < .001$; SN: $\beta = 0.438$, $p < .001$; PBC: $\beta = .028$, $p = .526$), they determined that SN was the strongest

independent predictor of INT. They concluded that the TPB is a valid model for predicting pharmacists' use of incident reporting systems. Similarly, the current study will utilize only items that directly measure the predictor variables.

Published guidelines for direct measurement of predictor variables in studies based on the TPB were incorporated into the design of the questionnaire for this study (Ajzen, 2006; Francis et al., 2004). The initial questionnaire included four to five items for each predictor variable and three items for the criterion variable. Wording of survey items was based on the questionnaire utilized in the study by Gavaza et al. (2011), with the permission of the primary author. Except in the case of demographics, items were mixed up throughout the survey, rather than presented in sections organized by variable (2006).

Items in the 'attitude toward reporting' (ATR) subscale presented a statement and a pair of opposite adjectives, or bipolar adjectives (Francis et al., 2004). The participants were instructed to select a number on a seven-point scale that best described his or her opinion about the statement. Items in the 'social pressure to report' (SPR) subscale concerned the CRNA's perception of the opinions of people important to him or her. Items in the 'perceived control over reporting' (PCR) subscale referred to the degree of confidence the CRNA had in his or her capability to submit an incident report. In order to fully capture this construct, the items related to the variable PCR were designed to address both CRNAs' self-efficacy and his or her beliefs about the controllability of reporting. Sample items provided by Ajzen (2006) and Francis et al. (2004) served as the model for these items in the initial questionnaire.

According to Francis et al., several methods are acceptable for operationalizing 'intention' in a questionnaire based on the TPB (2004). The most commonly utilized method,

called the 'generalized intention' method (Francis et al., 2004), was used in this study. This was also the method selected for the study by Gavaza et al. (2011). This method for operationalizing 'intention' resulted in the creation of three survey items for the 'intent to report' (INR) subscale. Item wording was selected largely based on a review of the items in the study by Gavaza et al. (2011).

Part III of the initial questionnaire was comprised of several evaluative questions to solicit feedback about the clarity of the instrument and instructions in a pilot study (Polit & Beck, 2011). Francis et al. (2004) suggest a list of such evaluative statements, which was utilized in its entirety. One example was the item "Were there any annoying features of the wording or formatting?" Pilot study participants were also asked to estimate the time required to complete the survey. This information was utilized provide the main study participants with a more accurate estimate of the time required to complete the survey in the invitation email. This is a recommended strategy for improving participation in electronic survey research (McPeake, Bateson, & O'Neill, 2012). The evaluation questions and time estimate request were deleted prior to distribution of the final questionnaire in the main study. The initial questionnaire is shown in its entirety in Appendix B.

Upon approval of the study proposal and receipt of formal notification of exempt status from the IRB, a pilot study to evaluate the face validity, clarity, and reliability of the survey content was undertaken. While face validity is a relatively weak method for establishing the overall validity of the tool, it can help to improve participation in the study by ensuring the items are rational from the perspective of members of the population of interest (Polit & Beck, 2011).

A convenience sample of five CRNAs who practice at a variety of clinical sites was selected for the pilot study. Francis et al. (2004) suggest a sample size of five is sufficient for the purpose of evaluating survey questionnaire clarity and this recommendation is supported in the literature (Hertzog, 2008). Recruitment of the pilot study participants was through referrals from CRNAs personally known to the researcher. Each participant received an invitation to participate in the survey by email, which included the title and purpose of the research; a statement of consent; an estimate of the time commitment required; the primary investigator's contact information; and the public link to redirect the participant to the electronic survey. Data collection ended when five complete responses were obtained for analysis.

All narrative comments to the evaluative and estimated time of completion questions in the initial pilot study were exported from the survey web application into Microsoft® Word for review. Remaining data was exported from the survey web application into IBM® SPSS® version 22. The pilot study participants reported that the survey required 5 – 10 minutes to complete. Analysis of the qualitative data revealed that two participants felt the questionnaire was repetitive. One participant offered the following comment: “The question that begins, ‘It is expected...’ could be a little ambiguous. I wasn't quite sure if it meant expected as a requirement of my employment, or expected as a matter of my own personal ethics or beliefs, or by my peers.”

The quantitative items in the survey were then analyzed. The survey items were rearranged to align with the study variables and negatively worded items were recoded using the SPSS 'TRANSFORM' command. The internal consistency of the items related to each study variable was assessed. This method for assessment of internal consistency is the most commonly

utilized technique for establishing the reliability of summed item scores such as those proposed for this study (Polit & Beck, 2011). It is the recommended technique for evaluation of instrument internal consistency in TPB questionnaires (Ajzen, 2006; Francis et al., 2004).

The Cronbach's alpha was calculated using the COMPUTE command in SPSS. An alpha value of 0.60 is the suggested minimum value for retaining a question in the final analysis in a TPB study (Francis et al., 2004). Wherever the alpha value for the items related to a particular variable was less than 0.6, further analysis was undertaken to determine an appropriate course of action. Cronbach's alpha for the variables ATR, SPR, and PCR was below 0.6 in the initial analysis of the pilot study data when all items were included in the analysis. For the variables ATR and PCR, reducing the number of items to three for each variable improved the reliability to an acceptable level. For the items related to the variable SPR, reliability approached 0.6 after reducing the number of items to three. Review of qualitative data indicated slightly awkward wording for one item related to this variable. The item was reworded and a second pilot study in a new convenience sample of 14 CRNAs was undertaken.

Table 6 summarizes the results of the two pilot studies and revisions to the questionnaire. Reliability of the items related to the variable PCR, interestingly, was significantly lower in the second pilot study sample yet the wording of the items was unchanged from the first pilot. There were no comments in the qualitative section of the survey to give insight into this finding. A fourth item for the variable PCR, which was identical to one of the two items utilized by Gavaza et al. (2011) was added to the final questionnaire. Part III of the initial questionnaire was deleted and the REDCap™ project was made available for data collection.

Table 6

Summary of Pilot Study Results and Survey Revisions

Subscale	First Pilot	Analysis	Cronbach's Alpha First Pilot	Second Pilot	Cronbach's Alpha Second Pilot	Final Questionnaire
ATR	5 items	Optimal reliability with 3 items	0.816	3 items	0.875	No changes
SPR	4 items	Optimal reliability with 3 items	0.589	3 items, minor rewording of 1 item	0.840	No changes
PCR	4 items	Optimal reliability with 3 items	0.733	3 items	0.385	1 new item added
INR	3 items	All items retained	0.963	3 items	0.673	No changes

Data Analysis

At the end of the data collection period, all study data was exported from REDCap™ into IBM® SPSS® version 22 and cleaned in preparation for analysis. The negatively worded items in the body of the survey questionnaire were recoded. To review the data for accuracy, univariate descriptive statistics were generated. Reliability analysis was performed to evaluate the items in the Incident Reporting Scale. Based on the reliability analysis, the number of items in the scale was reduced from 13 to 11 for all statistical analyses.

Objective one. In order to describe current use of incident reporting systems by CRNAs in the U.S., study participants were asked to indicate whether he or she had experienced a patient safety incident in the past 12 months. Naturally, only these participants would have been expected to have used an incident reporting system. Whenever a study participant indicated having encountered a patient safety incident in the past 12 months, a follow-up item asked if he or she had submitted an incident report about the incident. The CRNAs that encountered a patient safety incident and also submitted an incident report were categorized as ‘always’, ‘sometimes’, ‘rarely’, or ‘never’. The demographic profile of the CRNAs that submitted incident reports (i.e. selected always, sometimes, rarely in the questionnaire) was compared to the demographic profile of the CRNAs that did not report (i.e. selected never) in contingency tables, with calculation of Chi-squared statistics. To describe the likelihood that CRNAs will use incident reporting systems in the near future, summing the scores of all items in the INR subscale created a composite variable.

Objective two. Objective two was to describe the extent to which CRNAs value incident reporting; perceive social pressure to use incident reporting systems; and feel in control of using incident reporting systems. This objective was addressed through descriptive analyses of the summed scores for the items in the ATR, SPR and PCR subscales.

Objective three. Objective three was to determine if there is a relationship between attitude toward reporting, perceived social pressure to report, and perceived control over reporting; and the likelihood that a CRNA will use an incident reporting system. Prior to the analyses related to objective three, all data in the Incident Reporting Scale were screened to determine if statistical assumptions were met. The distributions of the data for all main study

variables were significantly negatively skewed. Multiple attempts to transform the data were unsuccessful. Non-parametric statistical analyses were therefore selected to test the first three of four research hypotheses related to this objective:

- H₁: There is a direct positive linear relationship between attitude toward reporting and the likelihood that a CRNA will use an incident reporting system.
- H₂: There is a direct positive linear relationship between social pressure to report and the likelihood that a CRNA will use an incident reporting system.
- H₃: There is a direct positive linear relationship between perceived control over reporting and the likelihood that a CRNA will use an incident reporting system.

Calculation of the Spearman's correlation coefficient was utilized to determine if there was a bivariate correlation between each predictor and the dependent variable because it was suited to the level of variable measurement and robust to violations of normality (Field, 2009). The test statistic generated in the analysis was the Spearman's rho (r_s), with a possible range of values of 0 to 1. An r_s value between 0 and 0.29 was interpreted as a small effect; a value between 0.3 and 0.49 as a medium effect; and between 0.5 and 1 as a strong effect (Field, 2009; Gray & Kinnear, 2012)

The final research hypothesis related to study objective three was as follows:

- H₄: There is a relationship between attitude toward reporting, social pressure to report, and perceived control over reporting and the likelihood that a CRNA will use an incident reporting system.

While there are no studies of incident reporting behavior by CRNAs in the published literature, a review of studies in other health care provider groups suggests that cognitive factors exert a strong influence on incident reporting behavior. The literature also suggests that the specific cognitive factors in the TPB model are particularly relevant to use of incident reporting

systems by health care providers. Multiple regression analysis was the most commonly utilized technique for studies based on the TPB in the literature (Ajzen, 2005; Armitage & Conner, 2001; Francis et al., 2004).

Multiple regression analysis was the planned statistical procedure to test Hypothesis Four. Due to violations of the assumption of normality, an analogous non-parametric analysis was undertaken instead. Logistic regression was selected because it was suitable for the level of variable measurement. This is a commonly utilized statistical technique in health sciences research (Tabachnick & Fidell, 2007), which is robust to violations of assumptions of normality. In order to run the analysis, the original dependent variable was transformed to a dichotomous variable to determine if there was a relationship between the two outcomes and the set of predictor variables.

The Model Summary table in SPSS was utilized to determine if the combination of the three predictors improved the likelihood of predicting whether CRNAs were likely to report or not report; and to what degree prediction success was improved. The significance value for this portion of the analysis was set at $p < .01$. The logistic regression output also included the value of Nagelkerke's R^2 , a method for reporting the amount of variance in the dependent variable that is explained by a set of predictors (Tabachnick & Fidell, 2009). Calculation of the Wald statistic was utilized to determine if each of the independent variables contributed significantly to the prediction. The significance value for this component of the analysis was set at $p < .05$. Hypothesis Four was supported if a) the test of the full model was statistically significant; and b) the Wald statistics for all three predictor variables were significant.

Objective Four. The relative importance of the three predictors in the TPB has been found to vary widely by the context, behavior and population under study (Godin & Kok, 1996). The relative importance of the individual predictors in the TPB model has not been assessed in the current population and context. Prior studies of barriers to use of incident reporting systems and qualitative study of incident reporting by ICU nurses (Elder et al., 2008), suggested that a CRNAs assessment of the value and consequences of submitting an incident report would be the most important determinant of the CRNAs' use of an incident reporting system. Accordingly, the following hypothesis was tested using standard logistic regression:

- H₅: A CRNA's attitude toward reporting will be the strongest predictor of the likelihood that he or she will use an incident reporting system.

The logistic regression analysis also included calculation of the value of the exponential function of B, or Exp(B). This statistic is the equivalent of the beta weight in a standard multiple regression analysis, in that it helps to determine the relative importance of each independent variable in the prediction of the dependent variable. Hypothesis Five was supported by the finding that attitude toward reporting was both significant, $p < .05$, and had the highest value for Exp(B).

Limitations

One of the most significant limitations of this study was the use of self-reported data for measurement of study variables. The nature of the phenomena of interest limited the possible types of measures that could be utilized. It is virtually impossible to gather information about human beliefs and feelings by other methods, however it is also impossible to verify the accuracy of these self-reports (Polit & Beck, 2012).

One possible source of systematic bias that posed a threat to construct validity in this study was researcher expectancy (Polit & Beck, 2012). The study participants were informed in the survey invitation that the purpose of the study was to gain a better understanding of incident reporting behavior in CRNAs. It was implied that the researcher placed a positive value on incident reporting and the study participants may have felt inclined to also assign a positive value to this behavior, which could have affected the study findings. One possible way to address this is to observe the participants during data collection to attempt to detect signals of expectations (Polit & Beck, 2012). This was not possible in this case. Presumably, researcher's expectations would also have affected the results of similar studies in other populations (Gavaza et al., 2010; Gavaza et al., 2012). Comparison of the study findings to those studies, in effect, helped to control for this confounder. Reassuring the study participants that their responses would remain anonymous also helped to minimize this effect (Polit & Beck, 2012).

Due to the specificity of the measurement tool to the behavior and population of interest in this study, the external validity of the results was limited. Multiple statistical analyses were undertaken to confirm that the study sample was representative of the population of CRNAs in the U.S. in order to maximize the generalizability of the results. This does not ensure the generalizability of the results to other health care provider groups or to other behaviors in CRNAs.

It was not possible to assess for non-response bias due to the method of sampling that was employed. It is possible there are important differences between CRNAs who opted to participate in this study and those who did not. Ideally, a comparison between the two groups would be made. No information about the study participants who opted not to participate was

available. Use of the AANA database was an economical and efficient method for accessing the largest, most representative sample of CRNAs in the U.S. The benefits of using this method outweighed this limitation in this case.

Human Subjects

An application for exempt status was submitted to the Virginia Commonwealth University (VCU) Institutional Review Board (IRB). The study met all criteria for exempt status as outlined in the VCU IRB Written Policy & Procedure Manual, Part 2, Section VIII-2 (VCU, 2014). Data collection commenced upon written confirmation of exempt status was received from the VCU IRB.

Only anonymous survey responses were collected in this study. No attempt to identify or contact the participants was made. The REDCap™ application does not capture the IP addresses of the participant (Tran, personal communication). Study data collected in REDCap™ was stored on secure servers at Virginia Commonwealth University. Only the primary investigator was assigned user rights to access the study database. The logging feature in REDCap™ was enabled for this project, which created an audit trail for tracking data manipulation and export procedures (Harris et al., 2009).

Chapter Summary

In this chapter, the methods for this non-experimental descriptive correlational study were described, including the details of the study population, sampling methods, variables, data collection and data analysis procedures. The theory of planned behavior served as the theoretical framework for understanding and predicting the use of incident reporting systems by certified registered nurse anesthetists. The TPB model and the proposed relationships

among constructs were presented. This study aimed to describe use of incident reporting systems by CRNAs in the U.S. at the time of data collection. It also aimed to describe the extent to which CRNAs value incident reporting, perceive social pressure to use incident reporting systems, and feel in control of using incident reporting systems. Finally, the study aimed to determine if there is a relationship between cognitive factors and incident reporting behavior in CRNAs; and which specific cognitive factor is most important. Ultimately, the findings from this study will support efforts to implement new incident reporting systems in anesthesia practice by facilitating the development of interventions to promote use of incident reporting systems by CRNAs.

Chapter Four: Results

The collection of reports about patient safety incidents from frontline healthcare workers is a key component of modern patient safety efforts. The purpose of this research was to provide anesthesia patient safety organizations with a predictive model of use of incident reporting systems by CRNAs to assist with the design and implementation of strategies to maximize reporting by this provider group. The relationship between cognitive factors and use of incident reporting systems was explored.

This study utilized a descriptive, correlational research design to meet four objectives: a) to describe current use of incident reporting systems by CRNAs in the U.S.; b) to describe the extent to which CRNAs value incident reporting, perceive social pressure to use incident reporting systems, and feel in control of using incident reporting systems; c) to determine if there is a relationship between attitude toward reporting, perceived social pressure to report, and perceived control over reporting and the likelihood that a CRNA will use an incident reporting system; and d) to determine the relative influence of attitude toward reporting, perceived social pressure to report, and perceived control over reporting on the likelihood that a CRNA will use an incident reporting system.

This chapter describes the data preparation procedures and statistical analyses that were utilized to explore the relationship between cognitive factors and use of incident reporting systems in CRNAs. The chapter begins with a brief review of the data collection procedures and a description of the data cleaning process. The statistical procedures that were utilized to assess

representativeness of the study sample are then outlined. Finally, the results of the statistical analyses are presented as they relate to the study objectives and research hypotheses.

Data

Review of data collection. Approval of the study protocol as exempt from full review was obtained from the Virginia Commonwealth University Institutional Review Board. A novel questionnaire was developed and piloted for the study using the software application REDCap™. Upon written request, the AANA Research Division distributed the electronic link to the study survey questionnaire to a random sample of 3000 practicing CRNAs in the U.S. The email offered recipients an electronic link to ‘opt-out’ of receiving future emails regarding the research study. The AANA does not report the opt-out rate to researchers for individual studies. Historically, the average opt-out rate for surveys deployed by the AANA is approximately 3% (AANA, 2014b).

Approximately 20 hours after the initial email invitation was distributed by the AANA, interim inspection of the data in REDCap™ revealed there were no responses for one survey item related to past reporting behavior. The survey item was configured using the branching logic feature. A review of the survey configuration revealed an error in the logic syntax for the item, which was corrected. The survey link had been accessed 107 times prior to correction of the error. This subset of study participants did not have access to the question related to past reporting behavior as intended. Proper functionality of the branching logic feature was verified weekly during the remaining data collection period.

One reminder email was sent by the AANA approximately three weeks after the initial invitation. The link to the electronic study survey was active for four weeks. In that time, 306

complete responses were recorded for a survey response rate of 10.2%. This is consistent with the average response rate for surveys deployed using this method of recruitment (AANA, 2014b).

Data preparation and cleaning. All survey data were exported directly from REDCap™ into IBM SPSS 22. All survey items constituted categorical variables in the SPSS data file. Variable names and value labels were inspected and amended as needed. All data were manually inspected for accuracy. Part I of the survey included demographic and past reporting behavior items. Data for the demographic items consisted of the five categorical variables AGE, GENDER, GEOREG, EMPL, and YRSEXP.

The first past reporting behavior item, “To your knowledge, have you encountered any patient safety incidents in the past 12 months? (Check all that apply)”, was presented to all study participants. This item was formatted as a checklist in REDCap™. Exported data for this survey item constituted four dichotomous variables in SPSS, corresponding to the four possible answer choices (none, near-miss, no-harm, adverse event) on the survey. These variables were renamed NONE, NM, NH, and AE in SPSS. Possible values in the exported dataset were unchecked=0 and checked=1. Values for the variable NONE represented a double negative and were therefore relabeled for clarity as 0 = Experienced event, and 1 = No events.

After correction of the branching logic, survey respondents that selected the choices near miss, no-harm, or adverse event for the first past reporting behavior item were presented a second past reporting behavior item. This item stated “In the past 12 months, how often did you complete an incident report when you encountered a patient safety incident?”. Possible

responses were 'always', 'sometimes', 'rarely', or 'never'. Data for the item constituted the categorical variable past reporting behavior (PRB) in the data file.

Part II of the survey questionnaire, or the 'Incident Reporting Scale', contained 13 items that measured the main study variables attitude toward reporting (ATR), social pressure to report (SPR), perceived control over reporting (PCR), and intent to report (INR). The items were grouped into four subscales corresponding to the variable to which each item related, namely the 'ATR Subscale', 'SPR Subscale', 'PCR Subscale' and 'INR subscale'.

In the survey questionnaire, the items in Part II were purposefully not arranged by subscale. Respondents selected a score from 1-7 for each of the 13 items. The data for these items therefore constituted 13 categorical variables, each with seven possible values, in the data file. These variables were grouped by subscale in the data file and renamed with lowercase letters corresponding to the subscale to which they belonged (atr, spr, pcr, or inr). Twelve of the 13 items were positively worded such that lower scores (1 – 3) represented a negative response, the midpoint (4) a neutral response, and higher scores (5 – 7) a positive response. One item was negatively worded in the survey such that lower scores (1 – 3) represented a positive response and higher scores (5 – 7) a negative response. This item was recoded using the TRANSFORM command.

The FREQUENCIES command in SPSS was utilized to generate descriptive statistics and frequency histograms for all 13 variables. There were less than or equal to 3.9% missing values for each variable, however Missing Values Analysis (MVA) identified that the values were missing not at random (MNAR) (Little's MCAR test: $\chi^2 = 229.708$, DF = 166, Sig. = .001). The 23 cases with missing values were deleted, leaving 283 cases with complete data sets for all

13 variables. This number of cases exceeded the target sample size calculated with power analysis.

Reliability analysis was then performed to evaluate each subscale in order determine the desirability of deleting items prior to calculation of the main variable scores. Inter-item correlation is a measure of the strength of the relationship between individual items within a subscale (range 0 - 1). It is recommended that the inter-item correlations be at least .3 within a subscale (Polit & Beck, 2012). If the inter-item correlation is lower than .3, the item may not be congruent with the underlying construct. Item-scale correlation is a measure of the strength of the relationship between an individual item and the overall score for a scale or subscale. It is recommended that the item-scale correlations are at least .30 within a subscale (Polit & Beck, 2012). The Cronbach's alpha is another measure commonly utilized to assess the internal consistency of items within a multi-item scale (range 0 – 1). It is recommended that the Cronbach's alpha value is approximately .60 for all items in a subscale (Francis et al., 2004).

With all items in the analysis, the inter-item correlations and item-scale correlations were below .3 for the PCR Subscale, as shown in Table 7. The Cronbach's alpha value for the items

Table 7

Initial Subscale Reliability Analysis

	ATR Subscale	SPR Subscale	PCR Subscale	INR Subscale
Number of survey items	3	3	4	3
Inter-item correlation range	.55-.76	.56-.72	.00-.42	.66-.88
Item-scale correlation range	.61-.77	.70-.78	.09-.36	.69-.87
Cronbach's alpha	.84	.85	.44	.90

in the PCR Subscale was also below .60. Two items were deleted from the subscale, based on a

review of the detailed SPSS output, which showed that the lowest inter-item and item-scale correlations were related to the items 'pcr_2' and 'pcr_3'. Deletion of these items improved the inter-item and item-scale correlations to 0.41. The Cronbach's alpha for the two-item PCR Subscale was also improved to 0.59 by the deletion of the two items. The Cronbach's alpha has been criticized as inaccurate for two-item scales (Eisinga, Grotenhuis, & Pelzer, 2013).

Calculation of the Spearman's rho statistic (ρ) is an alternate method of assessing the strength of the relationship between items in a two-item scale (Eisinga et al., 2013). This analysis revealed a moderate correlation between the two items in the PCR Subscale that was significant at the $p < .01$ level ($\rho = 0.44$, $p = .000$).

The reliability of the Incident Reporting Scale with the 11 items remaining was assessed using the SCALE RELIABILITY procedure in SPSS. All item-scale correlations were greater than .3 in the analysis (range .49 - .86; mean .73). The Cronbach's alpha for the full scale was .94, which is well above the recommended value of .60 for multi-item scales (Polit & Beck, 2012).

The four main study variables were computed from the data for the 11 survey items remaining in the analysis. The variable ATR was computed as the sum of the scores for atr_1 - atr_3; SPR as the sum of scores for spr_1 - spr_3; and INR as the sum of scores for inr_1 - inr_3. The range of possible scores for the composite variables ATR, SPR and INR was 3 - 21. The variable PCR was computed as the sum of the scores for pcr_1 & pcr_4, with a possible range for the composite variable of 2 - 14.

Data Analysis

Five demographic items in the study survey questionnaire measured the categorical variables AGE, GENDER, GEOREG, EMPL, and YRSEXP in this study. Possible values for the variable YRSEXP were not identical to the age categories used in the data set available for the population of CRNAs in the U.S at the time of data analysis. Categories for YRSEXP were collapsed or amended to create the new variable YRSEXP, as shown in Table 8, for comparison of demographic data in the study sample with that of the population.

Table 8

YRSEXP Variable Transformation to YRSEXP

YRSEXP value	YRSEXP label	YRSEXP value	YRSEXP label
1	< 2 yrs	1	< 2 yrs
2	2 - 5 yrs	2	2 - 5 yrs
3	6 - 10 yrs	3	6 - 10 yrs
4	11 - 15 yrs	4	11 - 20 yrs
5	16 - 20 yrs	4	11 - 20 yrs
6	> 20yrs	5	> 20 yrs

Descriptive statistics for the six demographic variables were generated in SPSS. The observed frequencies for demographic variables in the study sample are summarized in Table 9. The observed frequencies of the demographic variables for the study sample were compared to demographics of the target population, CRNAs in the U.S., in order to assess representativeness of the sample. A summary of demographic data for the target population was obtained from the AANA Annual Membership Surveys (AANA, 2011; AANA, 2013a).

Paired frequency bar charts of the sample and population data were created for each variable for visual inspection. A Chi-squared goodness of fit test of the null hypothesis that there

Table 9

Observed Frequencies and Percentages for Demographic Variables

Variable	Number of missing values	Categories	Frequency	Percentage
AGE	1	< 30 yrs	1	.4
		30 – 34 yrs	12	4.3
		35 – 39 yrs	22	7.8
		40 – 44 yrs	29	10.3
		45 – 49 yrs	30	10.6
		50 – 54 yrs	40	14.2
		55 – 59 yrs	61	21.6
		60 – 64 yrs	55	19.5
		> 65 yrs	32	11.3
GENDER	6	Male	130	47
		Female	147	53
GEOREG	1	Region 1	22	7.8
		Region 2	57	20.2
		Region 3	25	8.9
		Region 4	38	13.5
		Region 5	49	17.4
		Region 6	47	16.7
		Region 7	44	15.6
EMPL	1	Hospital Group	127	45.0
		Independent Owner	84	29.8
		Military	45	16.0
		Other	15	5.3
			7	2.5
		4	1.4	
YRSEXP	2	< 2 yrs	3	1.1
		2 – 5 yrs	24	8.5
		6 – 10 yrs	44	15.7
		11 – 15 yrs	29	10.3
		16 – 20 yrs	29	10.3
		> 20 yrs	152	54.1
YRSEXP	2	< 2 yrs	3	1.1
		2 – 5 yrs	24	8.5
		6 – 10 yrs	44	15.7
		11 – 20 yrs	58	20.6
		> 20 yrs	152	54.1

was no difference between the sample frequencies (observed) and the population (hypothesized) frequencies was performed for each variable. The significance level was set at .05. Unless otherwise stated, there were no cells with an expected value of less than 5%. There were no obvious differences between the frequency distribution of the sample subjects and the population with respect to AGE, as shown in Figure 4. This finding was confirmed with a non-significant chi squared test ($\chi^2 = 13.603$, $df = 8$, $p = .093$).

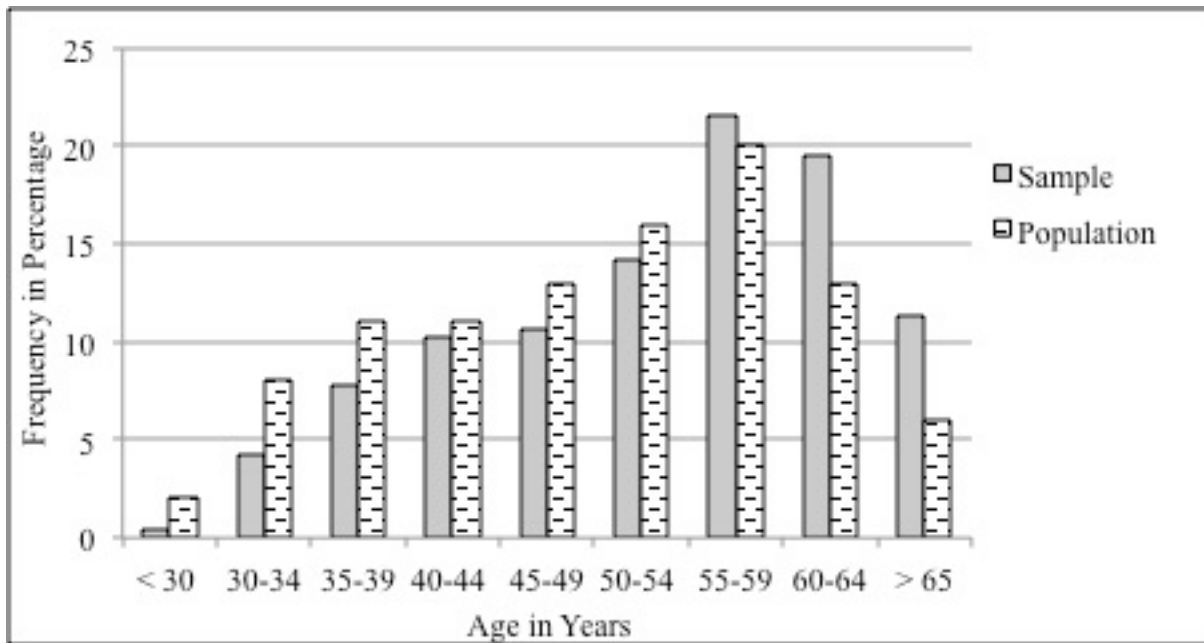


Figure 4: Sample and Population Frequency Distributions for AGE

The percentages of males and females in the sample and population were nearly identical, with 47% males and 53% females in the sample; and 46% males and 54% females in the population. The paired frequency distributions are shown in Figure 5. This was confirmed with, not surprisingly, a non-significant significant chi squared test ($\chi^2 = 0.035$, $df = 1$, $p = .852$).

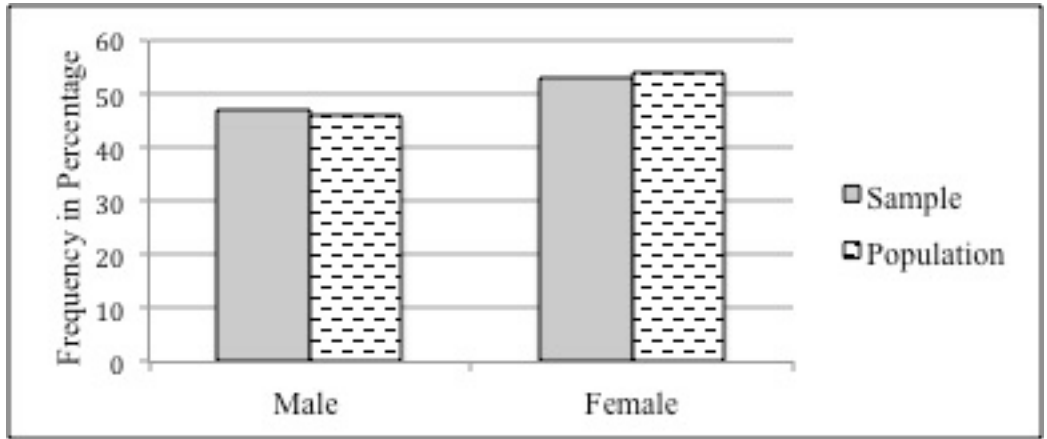


Figure 5: Sample and Population Frequency Distributions for GENDER

The designated geographic regions of the AANA serve the purpose of partitioning the membership into seven relatively equal groups to ensure equal representation of all CRNAs in the organization. The proportion of members in each geographic region was not included in the available population data file reported by the AANA, but was assumed to be approximately equal among the seven regions for the sake of comparison here. The paired frequency distributions for the sample and population shown in Figure 6 reflect that Region 2 was disproportionately represented in the study sample.

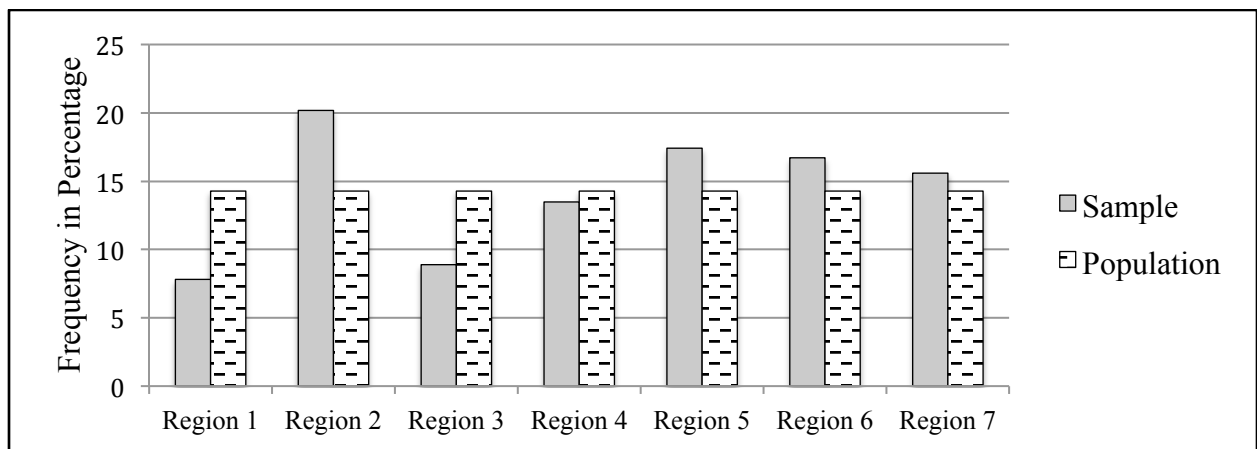


Figure 6: Sample and Population Frequency Distributions for GEOREG

This was not surprising in that Region 2 includes Virginia and the surrounding states. It is likely that CRNAs in Region 2 that received the survey invitation were familiar with the primary researcher's institution and were, therefore, more likely to participate in the study. The Chi-squared test was performed with the sample GEOREG data compared to hypothetical data for the population reflecting equal representation from all seven geographic regions. There was no evidence to reject the null hypothesis that the sample data represented all geographic regions equally ($\chi^2 = 8.360$, $df = 6$, $p = .213$).

The frequency distributions for employment practice setting for the sample and the population appeared to be quite similar, as shown in Figure 7. The Chi-squared test to confirm this finding was not reliable due to the finding that one half of the cells had an expected value of less than five cases (Field, 2009). In order to test the null hypothesis that there was no difference between the sample and the population with respect to employment practice setting, the six possible choices in the original survey were collapsed to three possible values to create the variable EMPLC. These values were labeled 'Hospital', 'Group', and 'Other' in the data file. The chi squared test of the null hypothesis that there was no difference between the sample and the population for the variable EMPLC was not significant ($\chi^2 = 3.409$, $df = 2$, $p = .182$), with no cells with expected values of less than five cases.

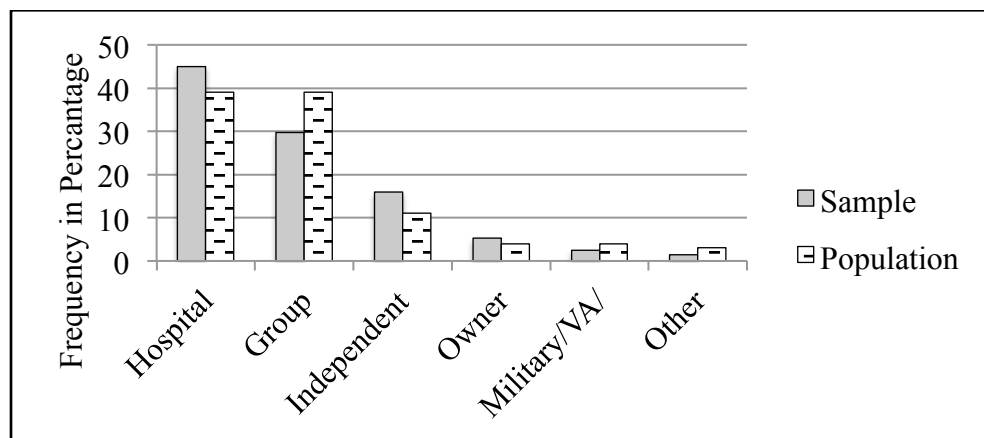


Figure 7: Sample and Population Frequency Distributions for EMPL

To compare the sample to the population with respect to years of experience as a CRNA, the variable YRSEXP was utilized. There were noticeably fewer CRNAs with five years or less experience and a greater percentage of CRNAs with more than twenty years of experience in the study sample upon review of the paired sample and population bar charts shown in Figure 8. This finding was confirmed with a significant chi squared test ($\chi^2 = 21.522$, $df = 4$, $p = .000$). Follow up analyses were performed to determine if the differences between the sample and population with respect to years of experience as a CRNA influenced the study results. The analyses were intended to determine if there was an effect of years of experience as a CRNA on the subjects' scores for the variables ATR, SPR, PCR, and INR. Exploratory analysis revealed that the scores for ATR, SPR, PCR and INR were non-normally distributed within YRSEXP groups. A non-parametric Levene's was performed to confirm equality of variances (homogeneity of variance) for each variable ($p > .05$) (Nordsokke & Zumbo, 2010).

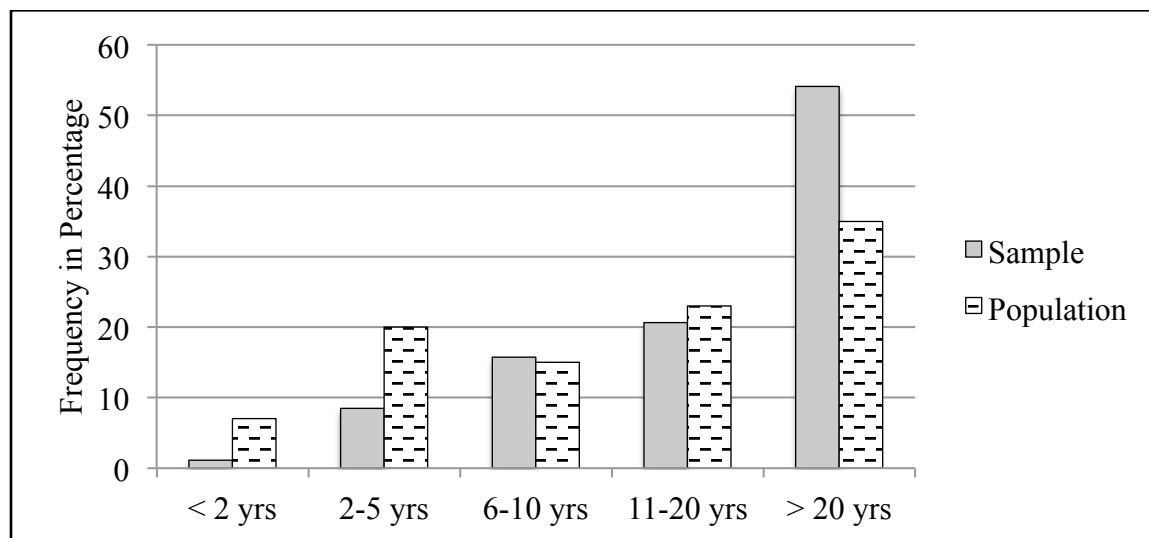


Figure 8: Sample and Population Frequency Distributions for YRSEXP

Kruskal-Wallis tests were then performed to determine if there was an effect of years of experience on each variable score. In each analysis, the dependent variable was the main study variable score and the independent variable was YRSEXP. The levels of the independent variable, or groups, were the categories of the variable YRSEXP. The null hypothesis for the Kruskal-Wallis test in each analysis was that there was no significant difference in the median variable scores between the years of experience groups. The null hypothesis was retained in all analyses, with no apparent effect of years of experience on the median scores at the .05 level for ATR ($H = 1.166, p = .884$), SPR ($H = 2.234, p = .693$), PCR ($H = 1.584, p = .812$), or INR ($H = 3.159, p = .532$). It is not likely that the differences between the sample and the population with respect to years of experience influenced the study findings.

Objective one. The first study objective was to describe current use of incident reporting systems by CRNAs in the U.S. Only CRNAs that have experienced a patient safety incident would be expected to submit incident reports. An initial survey item asked the study participants

to report if he or she had experienced patient safety incidents in the past 12 months. There were 147 subjects (52%) that reported having experienced at least one patient safety incident and 136 subjects (48%) that reported having experienced no patient safety incidents. Of the subset of subjects that reported having experienced at least one incident, 80 subjects (54%) reported having experienced a near-miss, 68 subjects (46%) experienced a no-harm event, and 29 subjects (20%) experienced an adverse event. Twenty-one subjects reported having experienced more than one type of incident and, of those, seven indicated having experienced all three types of incidents.

The crosstabs procedure in SPSS was utilized to generate contingency tables in order to determine if there was a relationship between events experienced and each of the five demographic variables. Only significant findings are presented. The first significant result was for the relationship between events experienced and the employment practice setting. The analysis consisted of crosstabulation of the variables NONE and EMPLC. The possible values for the variable NONE were 'checked' and 'not checked', which were labeled as 'No events' and 'Experienced events'. Due to the small number of subjects in some categories, the six possible primary employment arrangement choices in the original survey were collapsed to three possible values for the variable EMPLC. These values were labeled 'Hospital', 'Group', and 'Other' in the data file.

There were 282 complete data pairs for the variables NONE and EMPLC. The contingency table is shown in Table 9. Approximately equal proportions of subjects (n=282) experienced events (52%) and did not experience events (48%) in the analysis. A greater proportion of the subjects in the hospital setting (n=127) experienced events (58%) than did not

experience events (42%); and more subjects in group practice (n= 84) experienced events (54%) than did not experience events (46%). Of the subjects in the ‘other’ group for EMPLC (n= 71), a smaller proportion experienced events (39%) than did not experience events (61%). A chi-square test for an association between NONE and EMPL showed significance beyond the .05 level ($\chi^2= 6.093$, $df = 2$, $p = .048$). Subjects in the hospital and group practice settings were statistically significantly more likely to report having experienced events than subjects in other settings.

Review of the contingency table shown in Table 10 enables calculation of the Odds Ratio of experiencing incidents for CRNAs in a hospital or group setting. The value of 1.95 indicates that CRNAs that work in a hospital or group setting were nearly two times more likely to report having experienced at least one patient safety incident than CRNAs working in other settings.

Table 10

Contingency Table for Crosstabulation Between NONE and EMPLC

		EMPLC			Total
		Hospital	Group	Other	
NONE	Experienced events	73	45	28	146
	No events	54	39	43	136
Total		127	84	71	282

There was also a significant finding in the test for a relationship between the events experienced and years of experience as a CRNA. The analysis consisted of crosstabulation of the variables NONE and YRSEXPC. The possible values for NONE were labeled ‘Experienced events’ and ‘No events’ in the data file. The variable YRSEXPC, with five possible values, was

utilized in the analysis. The contingency table from the crosstabs procedure is shown in Table 11. Approximately equal proportions of subjects experienced events (52%) and did not experience events (48%) in the full set of data pairs (n=281). There were also approximately equal proportions of subjects with over 20 yrs of experience as a CRNA (n=152) that experienced events (51%) and did not experience events (49%). Of the subjects with 11 – 20 yrs experience (n=58), a smaller proportion experienced at least one type of event (38%) than did

Table 11

Contingency Table for Crosstabulation Between NONE and YRSEXPC

	YRSEXPC					Total
	< 2 yrs	2-5 yrs	6-10 yrs	11-20 yrs	> 20 yrs	
NONE Experienced events	3	15	29	22	77	146
No events	0	9	15	36	75	135
Total	3	24	44	58	152	281

not (62%). The opposite was true in the group of subjects with 6 - 10 yrs of experience (n=44), where 66% experienced at least one type of event and 34% did not. A chi-square test of the association between NONE and YRSEXPC showed significance beyond the .05 level ($\chi^2=11.948$, df = 4, p = .018).

Review of the contingency table for years of experience and reporting incidents shown in Table 11 enabled calculation of the Odds Ratio for experiencing patient safety events by years of experience groups. The Odds Ratio for experiencing an incident for CRNAs with ten years of experience or less was 2.2 compared to CRNAs with more than ten years of experience. This group of CRNAs was over twice as likely to report having experienced an incident than all other groups. In comparison, the Odds Ratio for experiencing a patient safety incident of 0.49 for CRNAs with 11-20 years of experience versus all other groups indicates these CRNAs reported

having encountered events approximately half as often as all other groups. CRNAs with 20 years of experience or more were equally likely to report having encountered an incident as to report having not experienced an incident. The Odds Ratio for experiencing a patient safety incident for CRNAs with 20 years or more versus all other years of experience groups was 0.93.

In order to determine if years of experience and employment practice setting had independent effects on experiencing a patient safety incident, a follow up analysis was performed. There were relatively small numbers of subjects with < 2 years and 2-5 years of experience. In the < 2yrs, 2-5 yrs and 6-10 yrs groups, a greater proportion of the subjects experienced incidents than did not. These categories were therefore collapsed to create a new variable, YRSEXP2, with the three possible values '10 yrs or less', '11-20 yrs', and '>20 yrs'. A crosstabulation between YRSEXP2 and EMPLZ was performed to create the contingency table, shown below in Table 12. There was a significant relationship at the $p < .05$ level between YRSEXP2 and EMPLZ ($\chi^2 = 14.262$, $df = 4$, $p = .007$).

Table 12

Contingency Table for Crosstabulation Between YRSEXP2 and EMPLZ

		EMPLZ			Total
		Hospital	Group	Other	
YRSEXP2	10 yrs or less	40	24	7	71
	11-20 yrs	26	19	13	58
	> 20 yrs	61	41	50	152
Total		127	84	70	281

The data in Table 12 was utilized to calculate the Odds Ratio of working in each practice setting for CRNAs according to years of experience. The Odds Ratios of a CRNA working in a

hospital or group setting versus other practice settings was 3.92 for subjects with 10 years of experience or less, 1.18 for subjects with 11-20 years of experience, and .37 for subjects with more than 20 years of experience. Respondents with 10 years of experience or less were nearly four times more likely to work in a hospital or group setting compared to subjects with more than 10 years of experience. Subjects with 11-20 years of experience were nearly equally likely to work in a hospital or group setting compared to other years of experience groups. When compared to the subjects in all other groups, subjects with greater than 20 years of experience were half as likely to work in a hospital or group setting.

It was intended that survey respondents that selected the choices near miss, no-harm, or adverse event were presented a follow up question: “In the past 12 months, how often did you complete an incident report when you encountered a patient safety incident?”. For unknown reasons, the survey branching logic feature did not function properly initially when the survey was deployed such that subjects were not presented the follow up question. The error was corrected immediately upon discovery. Responses to this survey item constituted the categorical variable past reporting behavior (PRB) in the final dataset. There were only 85 cases with valid data for PRB after deletion of cases with missing values on the main study variables.

Descriptive analysis of the subset of 85 cases was performed in order to determine if the population of CRNAs in the U.S. was adequately represented. A chi-squared goodness of fit test was performed for each demographic variable, with the significance level set at .05. The subset of cases was representative of the population with respect to age ($\chi^2= 11.427$, $df = 8$, $p = .179$), gender ($\chi^2= 1.445$, $df = 1$, $p = .229$), and geographic region ($\chi^2= 11.160$, $df = 6$, $p = .084$). The subset of cases was not representative of the population with respect to years of experience ($\chi^2=$

22.192, $df = 4$, $p = .000$). With a sample size of 85, more than 20% of the cells in the chi squared test for employment practice setting had expected values of less than five. This indicated that the analysis was not sufficiently powered to detect differences in the proportion of subjects in each category employment practice setting. The variable EMPLC, with several categories collapsed, was therefore utilized in the analysis. The subset of cases was not representative of the population with respect to employment setting ($\chi^2 = 9.73$, $df = 2$, $p = .008$). Significant differences between the subset of 85 cases and the population of CRNAs in the U.S. indicated that the results of analyses based on these cases might have limited generalizability.

Several analyses were, nonetheless, undertaken. Descriptive statistics were generated in SPSS and the frequency distribution for the variable PRB is shown in Figure 9.

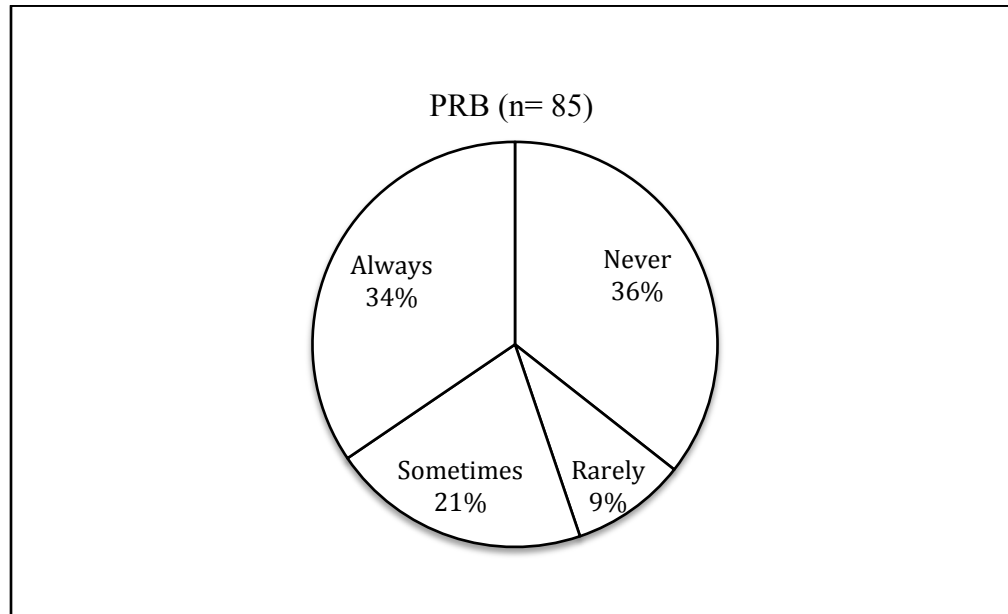


Figure 9: Frequency Distribution in Percentage for PRB

Due to the relatively small number of cases for this variable overall, the categories ‘always’, ‘sometimes’, and ‘rarely’ were collapsed to create the dichotomous variable, REPORTER, as shown in Table 13. Of the 85 cases for the variable, 36% were non-reporters and 64% were reporters, indicating that a higher proportion of CRNAs that experienced events claimed to have reported the incidents than did not.

Table 13

Possible Values and Value Labels for the Variables PRB and REPORTER

Survey Response	PRB value	PRB value label	REPORTER value	REPORTER value label
Always	1	Always	1	Reporter
Sometimes	2	Sometimes	1	Reporter
Rarely	3	Rarely	1	Reporter
Never	4	Never	0	Non-reporter

To determine if there were differences in reporting behavior among demographic groups, the crosstabs procedure in SPSS was utilized to create contingency tables and perform chi squared tests in the subset of subjects that replied to the question related to past reporting behavior. The dichotomous variable REPORTER was utilized in these analyses due to the small number of cases overall for the variable PRB. Six crosstabulations were performed; one for each of the demographic variables in the study.

The relationship between REPORTER and GENDER was analyzed in the first crosstabulation. The contingency table for the analysis is shown in Table 14. Of the subjects

Table 14

Contingency Table for Crosstabulation Between GENDER and REPORTER

		REPORTER		Total
		Non-reporter	Reporter	
GENDER	Male	19	16	35
	Female	12	38	50
Total		31	54	85

that reported events (n=54), a higher proportion were females (70%) compared to males (30%). A chi-square test of the association between REPORTER and GENDER showed significance beyond the .05 level ($\chi^2 = 8.150$, $df = 1$, $p = .004$). Because the analysis was a comparison of variables with two levels each (2 X 2), a 2-sided Fisher's Exact Test was included in the SPSS output, which confirmed a relationship between REPORTER and GENDER at a significance level of $< .05$ ($p = .006$). The Odds Ratio of reporting for females was 5.01, indicating that females in the sample were five times more likely to indicate they had reported incidents than males.

Five additional crosstabulations were performed between AGE, GEOREG, YRSEXP, EMPL, or YRSEXP; and REPORTER using procedures identical to that just described. There were no significant findings in any of the analyses, indicating there was no relationship between reporting behavior and age, geographic region, years of experience or employment practice setting. The detailed results of these analyses are not provided here.

The final analyses related to Objective One were performed to describe the proportion of CRNAs in the U.S. that are likely to report patient safety incidents in the future. The composite variable INR was utilized in the analyses, which was measured using three items in the INR

Subscale of the study survey. A summary of descriptive statistics for the three survey items in the INR Subscale (full sample, n=283) is shown in Table 15.

Table 15

Descriptive Statistics for Survey Items in the INR Subscale

Variable	Mean	Mode	Median	Standard deviation	Range	Minimum	Maximum
inr_1	5.92	7	6	1.45	6	1	7
inr_2	5.89	7	6	1.41	6	1	7
atr_3	5.81	7	6	1.35	6	1	7

Responses to the items in the INR Subscale were predominantly positive, which resulted in negatively skewed score distributions for the three items (not shown). Analysis of the proportion of subjects that selected negative, neutral, and positive scores for the items, shown in Table 16, provides a more meaningful breakdown. Approximately 85% or more of the study subjects responded positively to each survey item in the INR subscale.

Table 16

Response Frequencies for Items in the INR Subscale

Survey Item	% Responses		
	Negative	Neutral	Positive
inr_1: I plan to submit incident reports about patient safety incidents that I encounter [strongly disagree ↔ strongly agree].	6.7	6.7	86.5
inr_2: I intend to submit incident reports about patient safety incidents that I encounter [strongly disagree ↔ strongly agree].	6.4	7.1	86.6
inr_3: I want to submit incident reports about patient safety incidents that I encounter [strongly disagree ↔ strongly agree].	5.3	9.9	84.5

The composite variable INR, which was equal to the sum of the scores for the three items in the INR Subscale on the survey, was a measure of the likelihood that a CRNA would use an incident reporting system in the future. The range of possible scores for INR was 3 – 21, which was the range of observed scores in the sample (n=283). The distribution of INR scores was negatively skewed, so the best measure of centrality for the variable was the median score of 18. This was considerably higher than the midpoint or neutral score for the variable, reflecting that CRNAs indicated they were likely to use incident reporting systems. Interestingly, the mode of the scores for the INR subscale was the maximum score, or 21. Due to the overall high proportion of scores above the midpoint of the range, the scores were further categorized as mildly, moderately or strongly positive. Mildly positive was defined as scores from 13 – 15, moderately positive as scores from 16 – 18, and strongly positive as scores from 19 – 21. The frequency distribution of the scores, as so defined, is shown in Table 17. The majority of CRNAs (89.1%) in the sample claimed to be likely to report future patient safety incidents they encounter. Of these, the majority claimed to be strongly likely to report future safety incidents.

Table 17

Distribution of Scores for the Variable INR.

Variable	Score frequency (%)				
	Negative	Neutral	Mildly Positive	Moderately Positive	Strongly Positive
INR	21 (7.4)	10 (3.5)	33 (11.7)	83 (29.3)	136 (48.1)

Objective two. The second objective of the study was to describe the extent to which CRNAs value incident reporting, perceive social pressure to use incident reporting systems, and feel in control of using incident reporting systems. Objective Two was addressed through

descriptive analysis of the individual survey items and the composite variables ATR, SPR, and PCR. The items pcr_2 and pcr_3 were deleted from the Incident Reporting Scale due to low reliability and were also not included in the analyses related to Objective Two.

The scores for each survey item ranged from 1 – 7. One item that was negatively worded in the survey was recoded in the data file prior to analysis. Data for the eight survey items constituted eight categorical variables in the data file. After recoding, lower variable scores (1-3) represented a negative response, the midpoint (4) a neutral response, and higher scores (5 – 7) a positive response. The FREQUENCIES command in SPSS was utilized to generate the descriptive statistics, shown in Table 18, for the survey items utilized in this analysis.

Table 18

Descriptive Statistics of Survey Item Scores

Variable	Mean	Mode	Median	Standard deviation	Range	Minimum	Maximum
atr_1	5.79	7	6	1.34	6	1	7
atr_2	6.02	7	6	1.32	6	1	7
atr_3	5.77	7	6	1.43	6	1	7
spr_1	6.06	7	6	1.20	5	2	7
spr_2	5.84	7	6	1.35	6	1	7
spr_3	5.20	6	5	1.57	6	1	7
pcr_1	6.31	7	7	1.16	6	1	7
pcr_4	5.06	5	5	1.61	6	1	7

There were 283 complete sets of data for all eight variables. The distributions of the scores for the individual survey items were negatively skewed. To provide a more meaningful descriptive analysis of the results than statistics of centrality, the responses to each survey item were categorized by negative, neutral, and positive responses as shown in Table 19. The majority of the subjects' scores represented positive responses for all survey items. The lowest proportions

Table 19

Summary of Responses to Survey Items in ATR, SPR, and PCR Subscales

Survey Item	% Responses		
	Negative	Neutral	Positive
atr_1: Submitting incident reports about patient safety incidents that I encounter is [bad ↔ good].	6.4	7.8	85.9
atr_2: Submitting incident reports about patient safety incidents that I encounter is [harmful ↔ beneficial].	5.3	7.1	87.6
atr_3: Submitting incident reports about patient safety incidents that I encounter is [worthless ↔ valuable].	8.5	7.8	83.7
spr_1: The people in my life whose opinions I value would [not approve ↔ approve] of me submitting incident reports about patient safety incidents that I encounter.	4.9	7.8	87.3
spr_2: Most people important to me thing that I [should not ↔ should] submit incident reports about patient safety incidents that I encounter.	7.4	9.5	83.0
spr_3: The professional colleagues whose opinions I value [do not submit ↔ submit] incident reports about patient safety incidents they encounter.	12.0	17.3	70.7
pcr_1: I am confident that I could submit an incident report about I patient safety incident that I encountered if I wanted to [strongly disagree ↔ strongly agree].	4.9	2.1	92.9
pcr_4: Submitting incident reports about patient safety events that I encounter is [difficult for me ↔ easy for me].	17.7	13.1	69.3

of positive responses were for the items spr_3 and pcr_4.

The item spr_3 concerned the subject's opinion of whether or not his or her professional colleagues report incidents. Approximately 71% of the study subjects responded that his or her colleagues submit incident reports, 12% that professional colleagues do not report incidents, and 17% had no opinion about the statement. The item pcr_4 concerned the subject's perceived degree of difficulty in reporting incidents. Approximately 69% of the subjects rated incident

reporting as easy for him or her, 17% rated incident reporting as difficult, and 13% had no opinion.

The scores for the variables ATR, SPR and PCR were calculated by summing the scores for the survey items in each subscale. There were originally four items related to the variable PCR, however scale reliability analysis indicated that there was low internal consistency between the items. The two items with the lowest inter-item and item-scale correlations were deleted. The score for the variable PCR was calculated from the remaining two items.

ATR was calculated as the sum of the scores for the items atr_1, atr_2, and atr_3. The range of possible scores for ATR was 3 – 21. Lower scores (3 – 11) corresponded to a negative attitude toward reporting; the midpoint (12) a neutral attitude toward reporting; and higher scores (13 – 21) a positive attitude toward reporting. The variable SPR was calculated as the sum of the scores for the items spr_1, spr_2, and spr_3. The range of possible scores of scores for SPR 3 – 21. The variable PCR was calculated as the sum of the scores for the items pcr_1 and pcr_4. The range of possible scores for PCR was 2 – 14. Lower variable scores (2 – 7) indicated a perceived lack of control over reporting; the midpoint (8) a neutral opinion of the degree of control; and higher variable scores (9 - 14) perceived control over reporting. A summary of the descriptive statistics for ATR, SPR, and PCR are shown in Table 20.

A very high proportion of the scores for each variable were positive, when defined as all scores higher than the midpoint. The proportion of positive scores was highest for the variable ATR (91.5%), indicating that the CRNAs had a positive attitude toward reporting. The next highest proportion of positive scores was for the variable PCR (88.3), which indicated that CRNAs perceive that they have control over reporting. The lowest proportion of positive scores

Table 20

Descriptive Statistics for the Variables ATR, SPR, PCR

Variable	N	Range	Min	Max	Mean	Median	Std. Deviation	Variance
ATR	283	18	3	21	17.58	18	3.56	12.642
SPR	283	17	4	21	17.10	18	3.61	13.054
PCR	283	12	2	14	11.36	12	2.34	5.495

was for the variable SPR (86.7%). Although relatively low compared to the other variables, this was an overwhelmingly positive result that was interpreted to mean that CRNAs perceive social pressure to report.

To provide more descriptive precision, the positive scores for ATR, SPR, and PCR were further distinguished as mildly positive, moderately positive and strongly positive. For the variables ATR and SPR, mildly positive was defined as scores from 13 – 15; moderately positive as scores from 16 – 18; and strongly positive scores from 19 – 21. For the variable PCR, mildly positive was defined as scores from 8 - 10; moderately positive as scores from 11 – 12; and strongly positive scores from 13 – 14. The score frequencies, as so defined, are shown in Table 21. In each case, the highest proportions of responses represented strongly positive scores. This result confirms the interpretation that CRNAs have a positive attitude toward reporting, perceive social pressure to report, and perceive that they have control over incident reporting.

Objective three. Prior to the statistical analyses to address the third study objective, the distributions of the variables ATR, SPR, PCR, and INR were assessed with descriptive statistics and frequency histograms. All four variables were negatively skewed and kurtotic. Non-normality was confirmed through visual examination of p-plots and detrended p-plots. The

Table 21

Score Frequency Distributions for the Variables ATR, SPR, PCR

Variable	Score frequency (%)				
	Negative	Neutral	Mildly Positive	Moderately Positive	Strongly Positive
ATR	16 (5.7)	8 (2.8)	36 (12.7)	92 (32.5)	131 (46.3)
SPR	25 (8.8)	13 (4.6)	33 (11.7)	91 (32.2)	121 (42.8)
PCR	19 (6.7)	14 (4.9)	49 (17.3)	98 (34.6)	103 (36.4)

Kolmogorov-Smirnov (K-S) test was also performed on each variable, with a significance value set at .05. The results of the K-S were significant for all variables, which confirmed deviations from normal (Field, 2009). Table 22 presents a summary of normality tests.

Table 22

Tests of Normality for Main Study Variables

Variable	Skewness z-score	Kurtosis z-score	K-S Test (df = 283)
ATR	-10.83	10.48	D = .168 p = .000
SPR	-8.04	3.55	D = .153 p = .000
PCR	-7.59	4.56	D = .155 p = .000
INR	-10.00	6.98	D = .188 P = .000

Multiple attempts were made to transform each variable to correct for negative skewness as suggested by Tabachnick and Fidell (2007), including the reflected square root, reflected

logarithm, and reflected inverse. Descriptive statistics, frequency histograms, p-plots, detrended p-plots, and the K-S test were repeated on each transformed variable. All analyses indicated persistent non-normality for the transformed variables. Given these results, data exploration for outliers was not undertaken. The required assumptions for multiple regression analysis were not met. Non-parametric analyses were selected in place of the parametric analyses originally planned for testing the study hypotheses.

Hypothesis one (H_1). Hypothesis One posited that CRNAs with a positive attitude toward reporting would have an increased likelihood of using an incident reporting system:

- **H_1 : There is a direct positive linear relationship between attitude toward reporting and the likelihood that a CRNA will use an incident reporting system.**

The original analysis planned to test Hypothesis One was the Pearson Product Moment Correlation. The non-parametric equivalent, Spearman's rho, was performed instead due to violations of normality. The test statistic generated by the Spearman's test is the r_s . The bivariate correlation between ATR and INR was significant at the $p < .01$ level ($r_s = .81$, $p = .000$). A CRNA's attitude toward reporting was strongly positively correlated with the likelihood that he or she would report incidents.

Hypothesis two (H_2). Hypothesis Two posited that CRNAs that perceived positive social pressure to report will have an increased likelihood of using an incident reporting system:

- **H_2 : There is a direct positive linear relationship between social pressure to report and the likelihood that a CRNA will use an incident reporting system.**

The bivariate correlation between SPR and INR was significant at the $p < .01$ level ($r_s = .74$, $p = .000$), indicating that a CRNA's perceived social pressure to report was strongly

positively correlated with the likelihood of using an incident reporting system.

Hypothesis Three (H_3). Hypothesis Three posited that CRNAs that perceive having control over reporting will have an increased likelihood of using an incident reporting system:

- **H_3 : There is a direct positive linear relationship between perceived control over reporting and the likelihood that a CRNA will use an incident reporting system.**

The bivariate correlation between PCR and INR was significant at the $p < .01$ level ($r_s = .74$, $p = .000$), indicating that perceived control over reporting was strongly positively correlated with the likelihood of reporting incidents in CRNAs.

Hypothesis Four (H_4). Hypothesis Four posited that a combination of cognitive factors, versus a single factor alone, will best predict the likelihood that a CRNA will report patient safety incidents:

- **H_4 : Together, the combination of attitude toward reporting, social pressure to report, and perceived control over reporting will best predict the likelihood that a CRNA will use an incident reporting system.**

To test this hypothesis, a logistic regression was selected as an alternative to multiple regression. The intent of the analysis was to determine if there was a relationship between cognitive factors and the likelihood that a CRNA will use an incident reporting system. Logistic regression is a commonly utilized alternative to multiple regression in non-normally distributed data (Field, 2009; Tabchnick & Fidell, 2007).

In preparation for the analysis, a dichotomous dependent variable (INR2) was computed using the TRANSFORM command in SPSS. Values on the original variable (INR) in the range 3 – 12 were recoded as the value '0' for INR2. This group included the scores at the midpoint of

the range, or neutral scores, and was labeled ‘Not likely to report’. Values for INR in the range 13 – 21 were recoded as the value ‘1’ for INR2 with the value label ‘Likely to report’. Defined as such, descriptive analysis revealed that 89% of subjects were in the Likely to report group (n=252) and 11% were in the Not likely to report group (n=31) for the variable INR2. There were 283 complete data sets for the four variables in the analysis. Detailed descriptive statistics for these variables are shown in Table 23.

Table 23

Descriptive Statistics for Variables in the Logistic Regression

	ATR	SPR	PCR	INR2
Mean	17.58	17.10	11.36	.89
Median	18.00	18.00	12.00	1.00
Mode	21	21	14	1
Std. Deviation	3.556	3.613	2.344	.313
Minimum	3	4	2	0
Maximum	21	21	14	1

Assumptions tests for logistic regression were performed prior to the analysis. Logistic regression requires each predictor variable to be linearly related to the logit (Field, 2009). Detailed instructions by Field (2009) were utilized to test this assumption. Three new variables were created using the SPSS compute command. The variables LnATR, LnSPR, and LnPCR represented the logarithm of the values for the independent variables ATR, SPR, and PCR respectively. A binary logistic regression was then performed with ATR, SPR, PCR, ATR*LnATR, SPR*LnSPR, and PCR*LnPCR entered as covariates. The significance value for

all three interaction terms was greater than 0.05, indicating the assumption of linearity of the logit was met for ATR, SPR, and PCR (Field, 2009).

Logistic regression is sensitive to the biasing effect of multicollinearity, or strong correlations between predictor variables (Field, 2009). Collinearity diagnostics were performed for the predictors ATR, SPR, and PCR. Criteria for diagnosis of multicollinearity include a) tolerance values less than 0.2; b) variance inflation factor (VIF) value greater than 10; or c) condition index value greater than 30 coupled with variance proportions greater than 0.50 for at least two variables (Field, 2009; Tabachnick & Fidell, 2007). None of the criteria were met in the analysis of the predictor variables indicating multicollinearity was not a problem.

A logistic regression analysis was conducted to determine if a combination of cognitive factors was predictive of the likelihood that a CRNA will use an incident reporting system. A standard logistic regression procedure was performed with ATR, SPR, and PCR entered as the independent variables; and INR2 as the dependent variable. No prediction of the relative contribution of each independent variable to the model was made a priori, such that all independent variables were entered at once in the procedure.

The test of the full model against a constant only model was statistically significant at the .01 level, indicating that the predictors, as a set, reliably distinguished between CRNAs that were likely to report and CRNAs that were not ($\chi^2 = 106.789$, $df = 3$, $p = .000$). Prediction success was improved from 89% for the constant only model to 95% for the full model. The Nagelkerke's R^2 is the preferred method for reporting the amount of variance in the dependent variable that is explained by the predictors in a logistic regression model, analogous to the coefficient of determination (R^2) in a multiple regression (Tabachnick & Fidell, 2009). The Nagelkerke's R^2

value of .63 indicated that 63% of the variance in the likelihood that a CRNA will use an incident reporting system is explained by cognitive factors.

The Variables in the Equation table from the SPSS is shown in Table 24, which confirms that all three predictors were entered in the regression model as intended. The beta weight value (B) in the table is not useful as a standalone value for interpretation (Tabachnick & Fidell, 2009). The Wald statistic, calculated as the squared beta weight over the squared standard error of the beta weight, tests the regression coefficient of each variable. The Wald statistic has a chi square distribution with 1 degree of freedom. At a significance level of .05, assessment of the Wald statistics revealed that ATR and SPR each made a significant contribution to the regression model, but PCR did not. There was not enough evidence to support Hypothesis Four. The combination of the factors attitude toward reporting and social pressure to report best predicts the chance that a CRNA will be likely to use an incident reporting system. There is no value in adding perceived behavioral control to the predictive model.

Table 24

Variables in the Equation Table for Logistic Regression of ATR, SPR, PCR on INR2

	B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I. for EXP(B)	
							Lower	Upper
Step 1 ^a ATR	.291	.097	8.896	1	.003	1.337	1.105	1.619
SPR	.366	.103	12.668	1	.000	1.443	1.179	1.765
PCR	.102	.130	.619	1	.432	1.107	.859	1.428
Constant	-8.752	1.629	28.860	1	.000	.000		

a. Variable(s) entered on step 1: ATR, SPR, PCR.

Objective four. A logistic regression analysis was selected to address this objective because this technique does not require that the variables in the analysis are normally distributed. Hypothesis Five posited that attitude toward reporting would be the best single predictor of the likelihood that a CRNA will use an incident reporting system:

- ***H₅: A CRNA's attitude toward reporting best the strongest predictor of the likelihood that he or she will use an incident reporting system.***

A standard logistic regression analysis with ATR, SPR, and PCR as independent variables; and INR2 as the dichotomous dependent variable was utilized to address this objective. The assumptions of linearity of the logit and collinearity were met, as previously described. The test of the full model against a constant only model was statistically significant at the .01 level, indicating that the predictors, as a set, reliably distinguished between CRNAs that were likely to report and CRNAs that were not ($\chi^2 = 106.789$, $df = 3$, $p = .000$).

Review of the SPSS output for the logistic regression procedure revealed key information about the relative importance of the three independent variables in the prediction model. At the .05 level, the variables ATR (Wald = 8.896, $p = .003$) and SPR (Wald = 12.668, $p = .000$) each made a significant contribution to the model, however PCR (Wald = .619, $p = .432$) did not. The exponential function of B, or Exp(B), in a logistic regression analysis is the equivalent of the beta weight in a linear regression (Tabachnick & Fidell, 2009). The Exp(B) values indicated that the likelihood of a CRNA using an incident reporting system increased by 34% for every one point change in the attitude toward reporting score and 44% for every one point change in the social pressure to report score. In summary, a CRNA's attitude toward reporting and perceived social pressure to report have a significant but not substantial effect on the likelihood that he or

she will use an incident reporting system. Social pressure to report has a greater effect than attitude toward reporting on the likelihood that a CRNA will use an incident reporting system. Hypothesis Five was not supported.

Chapter Summary

In this chapter, the survey results and statistical analyses were presented in detail. This study aimed to describe use of incident reporting systems by CRNAs and to gain a better understanding of the factors that determine this behavior. Descriptive statistics were utilized to describe CRNAs' use of incident reporting systems in the past 12 months. Correlation analyses were undertaken to determine if there is a relationship between cognitive factors and use of incident reporting systems in CRNAs. A standard logistic regression analysis revealed that attitude toward reporting and perceived social pressure to report, but not perceived control over reporting are significant determinants of the likelihood that a CRNA will use an incident reporting system. Social pressure to report was most important determinant of incident reporting behavior in this group of health care providers. In Chapter Five, the theoretical and practical implications of the study results, the limitations of the study, and recommendations for further research are presented.

Chapter Five: Discussion

One of the primary goals of patient safety efforts is to reduce the rate of adverse events. A systems thinking approach to safety is now embraced in health care domains. One of the tenets of this approach is that in order to reliably avoid accidents and injuries despite a high degree of inherent complexity and risk in the environment, it is important to analyze and understand events that caused, or could have caused, patient harm after they occur. These events are often called patient safety incidents.

Incident reporting systems are widely utilized for collecting information about patient safety incidents from health care workers. There are a plethora of existing incident reporting systems in health care, however these systems are sorely underutilized. The Patient Safety and Quality Improvement Act of 2005 was enacted to encourage the formation of patient safety organizations to promote voluntary reporting by health care workers. Patient safety organizations offer a novel approach to incident reporting.

The purpose of this study was to provide information that can be used by anesthesia patient safety organizations to foster voluntary reporting of patient safety incidents by practicing CRNAs. The study sought to describe current use of incident reporting systems by CRNAs and to explore the influence of cognitive factors on incident reporting behavior in this population of health care providers. Selection of the specific cognitive factors to investigate was guided by the theory of planned behavior (Ajzen, 1991).

Chapter Five presents a summary of the study results in the context of the research objectives and study hypotheses. Implications of the study findings, including directions for future research, and limitations of the study are then discussed.

Summary of Study Findings

Objective one. The first study objective was to describe current utilization of incident reporting systems by CRNAs in the U.S. Descriptive statistical analyses were performed to address this objective, with follow up analyses when indicated. Naturally, only CRNAs that have experienced a patient safety incident would be expected to use an incident reporting system. The first step in addressing the first objective was therefore to determine the proportion of CRNAs that experienced a patient safety incident in the past 12 months.

The proportion of CRNAs that reported having experienced patient safety incidents was alarmingly high. Fifty two percent of CRNAs experienced at least one type of patient safety incident in the 12 months prior to the survey. Of these, 54% experienced at least one near-miss and 46% experienced at least one incident that reached the patient but did not cause detectable harm. Twenty percent of CRNAs experienced an adverse event. It was notable that approximately 14% of CRNAs experienced multiple types of incidents and 5% experienced all three types of patient safety incidents in the past 12 months.

The group of CRNAs that reported having experienced at least one patient safety incident was congruent to the group of CRNAs that did not experience incidents with respect to age, geographic region and gender. CRNAs working for a hospital or an anesthesia group were more than twice as likely to report having experienced at least one patient incident than CRNAs in all other employment arrangements. CRNAs with ten years or less of experience were twice as

likely to experience a patient safety incident as CRNAs with more than ten years of experience. CRNAs with 11 – 20 years of experience were least likely to report having experienced a patient safety incident compared to all other groups. There was a statistically significant association between years of experience and employment setting, with CRNAs with ten years or less experience determined to be four times more likely to work in hospital or group practice settings.

The next step in addressing Objective One was to describe CRNAs' recent use of incident reporting systems. At the extremes, approximately thirty seven percent of CRNAs did not report any of the patient safety incidents they encountered in the past 12 months and 34% reported all of the incidents they encountered. The remaining 29% of CRNAs reported patient safety incidents inconsistently. The demographic characteristics of CRNAs that reported and CRNAs that did not report were similar except with respect to gender. Female CRNAs were five times more likely than male CRNAs to have reported patient safety incidents.

The final step in addressing Objective One was to describe the likelihood that CRNAs would report future patient safety incidents. Approximately 89% of CRNAs were likely to report, and nearly one half of all CRNAs were strongly likely to report, patient safety incidents. Recent reporting behavior was correlated with the likelihood that a CRNA would report future incidents.

Objective two. The second study objective was to describe the extent to which CRNAs a) value incident reporting, b) perceive social pressure to use incident reporting systems, and c) feel in control of using incident reporting systems. Descriptive analyses revealed that a large majority of CRNAs had positive attitudes toward reporting; perceived social pressure to report incidents and felt in control over using incident reporting systems. Greater than or equal to 36%

of CRNAs had strongly positive views in each of these areas. Less than or equal to 9% of CRNAs held negative views toward incident reporting in any of these areas. Less than or equal to 5% of CRNAs had neutral opinions.

Objective Three. The third study objective was to determine if there is a relationship between attitude toward reporting, perceived social pressure to report, and perceived control over reporting; and the likelihood that a CRNA will use an incident reporting system. This objective was addressed through testing of four study hypotheses. Calculation of Pearson Product Moment correlations and a multiple regression analysis were originally planned to address this objective. The Spearman's test and logistic regression analysis were utilized to test the hypotheses related to this objective instead because descriptive analysis revealed significantly negatively skewed distributions for the variables to be utilized in the analyses. Hypotheses one through three were supported. Hypothesis four was not supported.

- *Hypothesis one (H₁):* **There is a direct positive linear relationship between attitude toward reporting and the likelihood that a CRNA will use an incident reporting system.**

The Spearman's test ($r_s = .81$, $p = .000$) revealed a strongly positive relationship between attitude toward reporting and the likelihood that a CRNA will use an incident reporting system.

- *Hypothesis two (H₂):* **There is a direct positive linear relationship between social pressure to report and the likelihood that a CRNA will use an incident reporting system.**

The Spearman's test ($r_s = .74$, $p = .000$) revealed a strongly positive relationship between social pressure to report and the likelihood that a CRNA will use an incident reporting system.

- **Hypothesis three (H_3): There is a direct positive linear relationship between perceived control over reporting and the likelihood that a CRNA will use an incident reporting system.**

The Spearman's test ($r_s = .74$, $p = .000$) revealed a strongly positive relationship between perceived control over reporting and the likelihood that a CRNA will use an incident reporting system.

The fourth study hypothesis was tested using logistic regression analysis. This procedure was selected in place of the planned multiple regression analysis because descriptive analysis revealed that the scores for the dependent variable were substantially negatively skewed. Hypothesis four was not supported.

- **H_4 : Together, the combination of attitude toward reporting, social pressure to report, and perceived control over reporting will best predict the likelihood that a CRNA will use an incident reporting system.**

The results of the logistic regression analysis revealed that the combination of attitude toward reporting and social pressure to report best predict the likelihood that a CRNA will use an incident reporting system. There was no increase in the predictive value of the model with the addition of perceived control over reporting.

Objective four. The fourth study objective was to determine the relative influence of attitude toward reporting, perceived social pressure to report, and perceived control over reporting on the likelihood that a CRNA will use an incident reporting system. A logistic regression analysis was utilized to address this objective. The hypothesis related this objective was not supported.

- *Hypothesis five (H₅): A CRNA's attitude toward reporting will be the strongest predictor of the likelihood that he or she will use an incident reporting system.*

Attitude toward reporting and social pressure to report, but not perceived control over reporting, contributed significantly to the logistic regression model. The degree to which a CRNA perceived social pressure to report incidents had the largest effect on the likelihood that he or she would use an incident reporting system.

Theoretical Implications

Many aspects of the design of this study were guided by the theory of planned behavior. According to the theory, a person's decision to engage or not engage in a voluntary behavior is ultimately determined by the person's beliefs about the likelihood that doing so would result in a particular outcome (Ajzen, 1991). Actually engaging in a behavior is proposed to be the direct result of having formed a cognitive intention to perform that behavior. The most proximal antecedents of the intention to engage in a behavior are the person's attitude toward that behavior, the degree to which he or she perceives social pressure to engage in the behavior, and the degree to which he or she feels in control over performing the behavior. The theory of planned behavior has been found to be a valid model for prediction of a wide variety of clinical behaviors in health care providers (Godin & Kok, 1996).

With respect to incident reporting behavior, the validity of the theory of planned behavior was investigated in a prior study in pharmacists (Gavaza et al., 2011). The authors of the study concluded that the theory of planned behavior was a valid model for prediction of this behavior. The published study results, however, revealed that only attitude toward incident reporting and social pressure to report were statistically significant in the prediction model. There was no

predictive value in adding perceived control. Social pressure to report was the more important predictor of the two in the regression model. Findings in the current study are consistent with the findings of the study by Gavaza et al. (2011). The combination of attitude toward reporting and social pressure to report is predictive of the likelihood that a practicing CRNA will use an incident reporting system, with no value in adding perceived control over reporting. Of the two significant predictors, social pressure to report is more important.

The theory of planned behavior represents an extension of the theory of reasoned action (Madden, Ellen, & Ajzen, 1992). The theory of reasoned action, as represented graphically in Figure 10, proposes that intention is the immediate precursor to behavior; and that intention is determined by a person's attitude toward the behavior and perceived social pressure to perform the behavior. The major difference between the theory of reasoned action and the theory of planned behavior is the addition of the concept of perceived behavioral control in the latter.

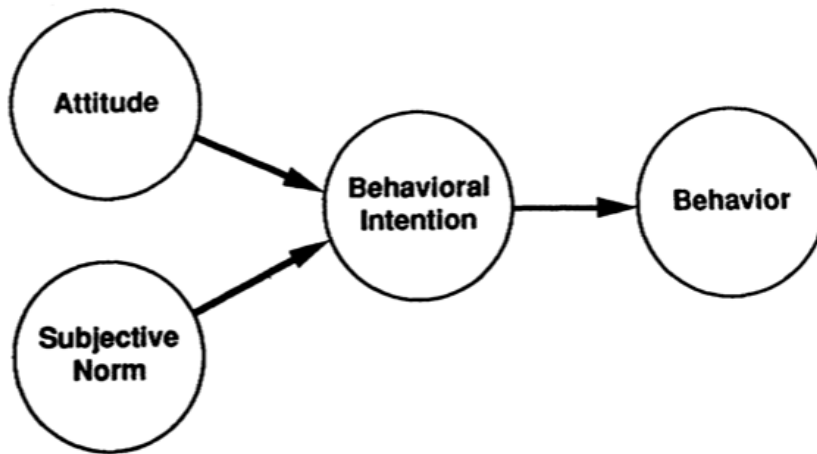


Figure 10: The Theory of Reasoned Action.

Reproduced from: Madden, T.J., Ellen, P.S., & Ajzen, I. (1992). A Comparison of the Theory of Planned Behavior and the Theory of Reasoned Action. *Pers Soc Psycho Bull*, 18(3), 3-9.

Perceived behavioral control refers to the degree to which a person believes he or she has the skills, resources, and opportunities required to perform that behavior (Ajzen, 1991). A systematic review of 56 prior studies using the theory of planned behavior for prediction of clinical practice behaviors in healthcare providers reveals that the relative impact of perceived behavioral control, versus other cognitive considerations, on behavioral intention is quite variable (Godin & Kok, 1996). The current study and the study by Gavaza et al. (2011) indicate that perceived behavior control might not have a significant impact on reporting behavior in CRNAs or pharmacists. The theory of reasoned action may be a more valid model for predicting incident reporting behavior in health care providers. Additional research is needed to test this hypothesis.

Practical Implications

This study represents the first attempt to describe incident reporting behavior in CRNAs in the U.S. One of the key findings was that practicing CRNAs encounter patient safety incidents often. Over half of all CRNAs experienced at least one patient safety incident in the past 12 months. Twenty percent of CRNAs experienced at least one adverse event, or an event that resulted in detectable patient harm, in the past 12 months. The actual yearly incidence of patient safety incidents related to anesthesia care in the U.S. is unknown (Eichorn, 2013). Although dramatic improvements in anesthesia patient safety have been made in the past several decades (Gaba, 2000; Eichorn, 2013; Li et al., 2009), findings from this study are consistent with evidence in the literature that adverse events during anesthesia care continue to occur at an unacceptably high rate (Metzner, Posner, Lam, & Domino, 2011). Ongoing efforts to improve anesthesia patient safety are indicated.

CRNAs employed by hospitals or in group practices were more likely to experience patient safety incidents than those employed in other practice arrangements. This finding was not surprising in that CRNAs employed by a hospital or in a group practice are more likely to provide services in the hospital setting. Patients of higher acuity levels would be expected to have surgery, and anesthesia, in the hospital setting versus outpatient or office-based settings. This suggests that, in order to capture the highest volume of reports about patient safety incidents, efforts should be focused on the hospital setting. It is worth noting however that employment arrangement does not necessarily indicate the setting in which a CRNA practices. Consideration should be given to including practice setting in place of, or in addition to, employment arrangement as a demographic variable in future studies of incident reporting behavior in CRNAs.

CRNAs with ten years or less of experience were twice as likely to experience patient safety incidents when compared to CRNAs with more than ten years of experience. This finding might, on the surface, seem to indicate that CRNAs with less experience were more likely to contribute to the occurrence of patient safety incidents or to make mistakes. This study finding should be interpreted with great caution in light of the finding that number of years of experience was also strongly related to the CRNA's employment arrangement. CRNAs with ten years or less of experience were four times more likely to be employed in a hospital or group practice. It is possible that CRNAs with ten years or less experience experienced more patient safety incidents as a result of the employment arrangement or practice setting in which they worked. It is also possible that CRNAs with ten years or less experience received better education in patient safety principles and were therefore more accurate in identifying patient safety incidents as such.

There are certainly other possible interpretations of this study finding. Further research is needed in order to make a valid conclusion about the relationship between years of experience as a CRNA and the number of patient safety incidents experienced.

That over one-third of CRNAs did not report any patient safety incidents they encountered, and another 27% of CRNAs reported inconsistently, was disturbing from the standpoint that every unreported incident represents a missed opportunity for learning. Compared to other provider groups in prior studies using similar research methods, CRNAs reported a slightly greater proportion of the patient safety incidents they encountered. In a survey of Australian physician anesthetists, the median number of incidents experienced in the 12 months prior was four, yet 50% of the anesthetists had not reported any incidents in that time (Yong & Kluger, 2003). In a survey study closely resembling the current study, only 7% of pharmacists had reported an adverse drug event to the FDA within the past 12 months (Gavaza et al., 2011). The proportion of pharmacists that had encountered events in that time was not stated in the published report.

There were, admittedly, important differences in the methodology utilized in the current study versus these prior studies. One example was that the definition of a reportable incident was not identical across the studies. Another confounder was that no distinction was made in the current study between incidents that directly involved the study participants versus those that did not. It is possible that some incidents did not directly involve the study participant or occurred at the CRNA's institution but were not anesthetic-related incidents. It is also possible that other providers involved in the incidents reported them. From a practical standpoint, the precise degree of underreporting is not important. The findings of this study suggest that CRNAs, like

other health care providers, do not reliably report patient safety incidents. Comprehensive strategies to maximize utilization of incident reporting systems by CRNAs are needed.

Limitations

The limitations of this study relate to the design, statistical analyses, and instrumentation. The impact of these limitations on the validity of the results is discussed in the following section.

Threats to internal validity. Internal validity in this study relates to the degree to which it can be asserted that variability in the likelihood that a CRNA will report incidents is related to cognitive factors versus other factors that were not controlled. The greatest threats to internal validity in this research were the study design and selection bias.

This study utilized a non-experimental, correlational design. Although this type of design is the most susceptible to threats to internal validity, it was well suited to the phenomena of interest and the exploratory nature of this study. As an initial effort to empirically examine incident reporting behavior in CRNAs, another possible option was to utilize a qualitative study design. A cross-sectional survey was selected in order to be consistent with prior studies of incident reporting in other health care provider groups and to efficiently capture data from a large cross-section of CRNAs across the U.S. The benefits of increased external validity and feasibility were weighed against the risk of weakened internal validity.

Selection bias was also a threat to the internal validity of this study. Potential study participants were randomly selected from the AANA membership roster by the AANA research division. Randomization is one of the most effective strategies to mitigate selection bias (Polit & Beck, 2012). Only approximately 10% of the subjects that were invited ultimately consented to participate in the study however. It is possible that inherent differences in the group of CRNAs

that were willing to participate in this survey study were responsible for the observed outcomes, not the independent variables in the study. CRNAs that were more willing to reply to a survey about incident reporting may be inherently more willing to report incidents than other CRNAs in the U.S. The demographic characteristics of the respondents were compared to the population of CRNAs in the U.S. in order to ensure that all major demographic groups were represented. There were no statistically significant differences in the variable scores among the demographic groups.

Threats to statistical conclusion validity. Statistical conclusion validity in the context of this study refers to whether the statistical analyses were sufficiently powered to detect relationships between cognitive factors and incident reporting that exist in reality. Many steps were taken to attenuate threats to statistical conclusion validity.

The target sample size for the statistical analyses that were originally planned was calculated a priori by power analysis and crosschecked with customary guidelines in the literature. The most conservative estimate of the target sample size was utilized (n=107 cases). The final number of complete survey responses after deletion of cases with missing values (n=283) far exceeded the target sample size. When alternate analyses were required, appropriate steps were taken to ensure recommendations for the minimum sample size for each test were met in each case. One example was in the logistic regression analysis. It is recommended that the ratio of the number of 'events' for each predictor variable (events per variable) is greater than or equal to 10:1 (Bagley, White & Golomb, 2001). The term 'events' refers to the number of cases representing each binary outcome of the dependent variable. There were three predictor

variables and at least 30 cases per event in this study. The recommended ratio of at least 10:1 events per variable was achieved.

It is possible that perceived control over reporting is important in the prediction of incident reporting behavior in CRNAs but this study did not detect this relationship. One possible reason for this is that non-parametric analyses were utilized throughout this study. The rationale for this was that the distributions of the study variables were markedly negatively skewed, even with transformations. This was a conservative decision in that some experts assert that when the sample size is greater than 50, violations of assumptions are acceptable for parametric tests (Polit & Beck, 2012). The nonparametric statistical analyses that were utilized may not have been sufficiently powered to detect relationships between study variables.

It is also plausible that perceived control over reporting was simply not effectively operationalized. A novel survey questionnaire was developed for this study because there was no existing instrument that could be utilized in its entirety. Two pilot studies were completed in order to evaluate the questionnaire wording and the reliability of the survey items, however only the face validity of the instrument was assessed. Face validity is helpful for encouraging participation in a survey study, but represents the weakest form of evidence that an instrument measures what it is supposed to measure (Polit & Beck, 2012).

The design and content of the questionnaire were based on a large body of prior empirical work using the theory of planned behavior. Published guidelines for creating a questionnaire based on the theory of planned behavior were consulted (Azjen, 2005; Francis, 2004). Whenever applicable, wording of survey items was identical to that in the survey questionnaire developed by Gavaza et al. (2011). Analyses following the pilot study and the main study revealed

relatively low internal consistency among the items in the perceived control over reporting subscale. Only two survey items were entered in the main study analyses for that variable compared three items per variable for the other two predictors. There was precedent for this decision in the literature (Gavaza et al., 2011). In future studies of incident reporting behavior it would be worthwhile to continue to include the variable in order to further assess the impact, or non-impact, of perceived control over reporting. More in-depth assessment of the content validity of survey items related to perceived control over reporting is indicated.

Threats to external validity. External validity in the context of this study relates to the degree to which it can be inferred that the relationships identified are true for all practicing CRNAs in the U.S. Descriptive analysis revealed that the study sample was representative of the population with respect to age, gender, geographic region, and employment arrangement. The study sample was not congruent to the population with respect to years of experience, however there were no significant differences in the subjects' scores among the age groups. Analyses were undertaken to test for a difference in the median scores, variance and distributions of the scores. None of these analyses revealed significant differences. It is theoretically possible that the relationships detected in the relatively experienced CRNAs in this study are not actually present in the population of all CRNAs in the U.S. Replication of this study in a sample that includes more subjects that have six years or less of experience would strengthen the external validity of the results.

Concluding Remarks

This study revealed that valuable information about patient safety incidents that occur during anesthesia care is not being effectively captured by existing incident reporting systems.

Strategies to increase the rate of incident reporting by CRNAs are needed. Novel incident reporting systems operated by patient safety organizations may be a worthwhile addition to existing systems. It is hoped that the findings in this study will assist with the development and evaluation of interventions to maximize CRNA reporting to existing incident reporting systems and facilitate successful implementation of new systems.

This study determined that a CRNAs' attitude toward reporting and the degree to which he or she perceives social pressure to report are the most important influences on incident reporting behavior. CRNAs with a positive attitude toward reporting and who perceived social pressure to report are more likely to report patient safety incidents. Of these factors, social pressure to report is more important. There is also more room for positive change in the degree of social pressure to report than in CRNAs' attitude toward reporting. The proportion of CRNAs with a strongly positive attitude toward reporting is higher than the proportion of CRNAs that perceive a high degree of social pressure to report. It was notable that in this study only 71% of CRNAs indicated that their professional colleagues submit incident reports. Increasing the degree to which CRNAs perceive other anesthesia providers accept and utilize incident reporting systems has potential to improve the rate of incident reporting.

Social pressure to engage in a behavior, according to the theory of planned behavior, may arise from any individual or group that is important to that person (Ajzen, 2011). Increased social pressure may be achieved either through assuring a person that others approve of the behavior or by increasing his or her motivation to comply with the wishes of others (Ajzen, 2011). One possible strategy for increasing the degree to which CRNAs perceive social pressure to report is to promote the positive benefits of incident reporting through individuals or groups

that are likely to be influential for practicing CRNAs. This study did not seek to identify the specific individuals or groups that are most important to CRNAs. In a study of pharmacists, the most important social influences to report patient safety incidents were, in order of importance, the FDA, patients, professional associations, supervisors, and hospital administrators. Social pressure to report patient safety incidents has also been found to arise from professional colleagues, supervisors, and subordinates (Wu et al., 2008).

Further empirical investigation is one option for determining the individuals or groups that are most likely to be important influences on CRNAs. Additionally, it may be important to engage individuals or groups that are intuitively likely to be influential to CRNAs in promotion of incident reporting systems. Empirical outcome evaluation of the effectiveness of strategies to increase the rate of reporting can be undertaken concurrently. As an example, organizations that operate incident reporting systems might consider utilizing local 'champions' or CRNAs in leadership positions to market incident reporting efforts. Regardless of the specific strategy employed, creating an environment in which CRNAs feel supported and encouraged to report patient safety incidents by those most important to them is the key to maximizing engagement in incident reporting efforts in the specialty.

References

- Agency for Healthcare Research and Quality (2014a, June 9). *Federally-Listed PSOs*. Retrieved from <http://www.pso.ahrq.gov/listed>
- Agency for Healthcare Research and Quality (2014b, March 23). *Directory of Delisted Patient Safety Organizations*. Retrieved from <http://www.pso.ahrq.gov/listed/delisted>
- Ajzen, I. (1985). From intentions to actions: A theory of planned behavior. In J. Kuhl & J. Beckman (Eds.), *Action Control: From Cognition to Behavior* (pp. 10–39). Heidelberg, Germany: Springer-Verlag.
- Ajzen, I. (1991). The theory of planned behavior. *Organizational Behavior and Human Decision Processes*, 50(2), 179–211.
- Ajzen, I. (2005). Explaining Intentions and Behavior. In *Attitudes, Personality and Behaviour* (2nd ed., pp. 117–141). McGraw-Hill Education.
- Ajzen, I. (2006). *The TPB Model*. Retrieved from <http://people.umass.edu/aizen/tpb.html>
- Ajzen, I. (2011). The theory of planned behaviour: reactions and reflections. *Psychology & Health*, 26(9), 1113–27.
- Ajzen, I., & Fishbein, M. (2000). Attitudes and the Attitude-Behavior Relation: Reasoned and Automatic Processes. *European Review of Social Psychology*, 11(1), 1–33.
- Ajzen, I., & Madden, T. (1986). Prediction of Goal-Directed Behavior: Attitudes, Intentions, and Perceived Behavioral Control. *Journal of Experimental Social Psychology*, 22, 453–474.

- Anderson, J.E., Kodate, N., Walters, R., & Dodds, A. (2013). Can incident reporting improve safety? Healthcare practitioners' views of the effectiveness of incident reporting. *International Journal for Quality in Health Care*, 25(2), 1 – 10.
- American Association of Nurse Anesthetists (2011, November). *AANA Member Survey Data 2011*. Retrieved from <http://www.aana.com/myaana/AANABusiness/aanasurveys/Pages/default.asp>
- American Association of Nurse Anesthetists. (2013a, August). *AANA Member Survey Data 2013*. Retrieved from <http://www.aana.com/myaana/AANABusiness/aanasurveys/Pages/default.asp>
- American Association of Nurse Anesthetists. (2013b, September). *Bylaws and Standing Rules of the American Association of Nurse Anesthetists*. Retrieved from <http://www.aana.com/myaana/AANABusiness/governance/Pages/Bylaws,-Standing-Rules-and-Resolutions.aspx>
- American Association of Nurse Anesthetists. (2014a, June 9). *About Us*. Retrieved from <http://www.aana.com/aboutus/Pages/default.aspx>
- American Association of Nurse Anesthetists. (2014b, May 21). *AANA Electronic Survey Policy and Order Form*. Retrieved from <http://www.aana.com/resources2/research/Pages/Research-Services.aspx>
- Anesthesia Quality Institute (2014a, June 26). *Anesthesia Incident Reporting System*. Retrieved from <http://www.ismp.org/orderforms/reporterrortoismv.asp>
- Anesthesia Quality Institute (2014b, June 20). *Anesthesia Incident Reporting System: Case Reports*. Retrieved from <http://www.aqihq.org/casereportsandcommittee.aspx>

- Armitage, C.J., & Conner, M. (2001). Efficacy of the Theory of Planned Behaviour: a meta-analytic review. *The British Journal of Social Psychology*, 40(Pt 4), 471–99.
- Bagley, S. C., White, H., & Golomb, B. A. (2001). Logistic regression in the medical literature: Standards for use and reporting, with particular attention to one medical domain. *Journal of clinical epidemiology*, 54(10), 979-985.
- Bandura, A. (1993). Perceived Self-Efficacy in Cognitive Development and Functioning. *Educational Psychologist*, 28(2), 117–148.
- Barach, P., & Small, S.D. (2000). Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems. *British Medical Journal*, 320(7237), 759–763.
- Beatty, P.C.W., & Beatty, S.F. (2004). Anaesthetists' intentions to violate safety guidelines. *Anaesthesia*, 59(6), 528–540.
- Blegen, M.A., Vaughn, T., Pepper, G., Vojir, C., Stratton, K., Boyd, M., & Armstrong, G. (2004). Patient and Staff Safety: Voluntary Reporting. *American Journal of Medical Quality*, 19(2), 67–74.
- Bonetti, D., Eccles, M., Johnston, M., Steen, N., Grimshaw, J., Baker, R., ... Pitts, N. (2005). Guiding the design and selection of interventions to influence the implementation of evidence-based practice: an experimental simulation of a complex intervention trial. *Social Science & Medicine (1982)*, 60(9), 2135–47.
- Braithwaite, J., Westbrook, M., & Travaglia, J. (2008). Attitudes toward the large-scale implementation of an incident reporting system. *International Journal for Quality in Health Care*, 20(3), 184–191.

- Campbell, M., Fitzpatrick, R., Haines, A., Kinmonth, A.L., Sandercock, P., Spiegelhalter, D., & Tyrer, P. (2000). Framework for design and evaluation of interventions to improve health. *British Medical Journal*. 321, 694–696.
- Campbell, N.C., Murray, E., Darbyshire, J., Emery, J., Farmer, A., Griffiths, F., ... Kinmonth, A. L. (2007). Designing and evaluating complex interventions to improve health care. *British Medical Journal (Clinical Research Ed.)*, 334(7591), 455–9.
- Cohen, J. (1992a). Statistical Power Analysis. *Current Directions in Psychological Science*, 1(3), 98–101.
- Cohen, J. (1992b). A Power Primer. *Psychological Bulletin*, 112(1), 155–159. Retrieved from <http://psycnet.apa.org/journals/bul/112/1/155/>
- Connell, L.J. (2004). *Cross-Industry Applications of a Confidential Reporting Model*. (NASA ASRS Pub. 62). Moffet Field, CA: National Aeronautics and Space Administration. Retrieved from <http://asrs.arc.nasa.gov/publications/research.html>
- Cousins, D.D. (1998). Developing a uniform reporting system for preventable adverse drug events. *Clinical Therapeutics*, 20 Suppl C, C45–58.
- Covell, C.L., & Ritchie, J.A. (2009). Nurses' responses to medication errors: suggestions for the development of organizational strategies to improve reporting. *Journal of Nursing Care Quality*, 24(4), 287–97.
- Crawford, S.Y., Cohen, M.R., & Tafesse, E. (2003). Systems factors in the reporting of serious medication errors in hospitals. *Journal of Medical Systems*, 27(6), 543–551.

Cullen, D., Bates, D., & Small, S. (1995). The incident reporting system does not detect adverse drug events: a problem for quality improvement. *The Joint Commission Journal on Quality Improvement*, 21(10), 541–548.

Daugherty, L., Fonseca, R., Kumar, K.B., & Michaud, P.C. (2010). *An Analysis of the Labor Markets for Anesthesiology* (Technical Report No. TR-688-EES). Rand Corporation. Retrieved from http://www.rand.org/pubs/technical_reports/TR688.html

Department of Health and Human Services. (2008). *Adverse Events in Hospitals: State Reporting Systems*. (OEI-06-07-00471). Retrieved from <https://oig.hhs.gov/oei/reports/oei-06-07-00471.pdf>

Department of Health and Human Services. (2010). *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*. (OEI-06-09-00090). Retrieved from <https://oig.hhs.gov/oei/reports/oei-06-09-00090.asp>

Department of Health and Human Services. (2012). *Hospital Incident Reporting Systems Do Not Capture Most Patient Harm* (OEI-06-09-00091). Retrieved from <https://oig.hhs.gov/oei/reports/oei-06-09-00091.asp>

Duran, G. (1980). On the Scene: Risk Management in Health Care. *Nursing Administration Quarterly*, 5(1), 19–36.

Dutton, R.P. (2011). Introducing the anesthesia incident reporting system (AIRS). *American Society of Anesthesiologists Newsletter*, 75(10), 30–33. Retrieved from <http://aqihq.org/airsIntro.aspx>

- Eccles, M.P., Hrisos, S., Francis, J., Kaner, E.F., Dickinson, H.O., Beyer, F., & Johnston, M. (2006). Do self-reported intentions predict clinicians' behaviour: a systematic review. *Implementation Science*, 1(1), 1-28. doi:10.1186/1748-5908-1-28
- Edgar, T.A., Lee, D.S., & Cousins, D.D. (1994). Experience with a national medication error reporting program. *American Journal of Health-System Pharmacy*, 51(10), 1335–1338.
- Eichhorn, J. H. (2013). Review article: Practical current issues in perioperative patient safety. *Canadian Journal of Anesthesia*, 60(2), 111–118.
- Eisinga, R., Grotenhuis, M. T., & Pelzer, B. (2013). The reliability of a two-item scale: Pearson, Cronbach, or Spearman-Brown? *International journal of public health*, 1-6.
- Elder, N.C., Graham, D., Brandt, E., & Hickner, J. (2007). Barriers and motivators for making error reports from family medicine offices: a report from the American Academy of Family Physicians National Research Network (AAFP NRN). *Journal of the American Board of Family Medicine*, 20(2), 115-123.
- Elder, N.C., Brungs, S.M., Nagy, M., Kudel, I., & Render, M.L. (2008). Nurses' Perceptions of Error Communication and Reporting in the Intensive Care Unit. *Journal of Patient Safety*, 4(3), 162–168.
- Evans, S.M., Berry, J.G., Smith, B.J., Esterman, A., Selim, P., O'Shaughnessy, J., & DeWit, M. (2006). Attitudes and barriers to incident reporting: a collaborative hospital study. *Quality and Safety in Health Care*, 15(1), 39–43.
- Faddis, M. (1939). Eliminating Errors in Medication. *AJN American Journal of Nursing*, 39(11), 1217–1223.

- Farley, D.O., Haviland, A., Champagne, S., Jain, A.K., Battles, J.B., Munier, W.B., & Loeb, J. M. (2008). Adverse-event-reporting practices by US hospitals: results of a national survey. *Quality and Safety in Health Care*, 17(6), 416–423.
- Farley, D.O., Haviland, A., Haas, A., Pham, C., Munier, W.B., & Battles, J. B. (2012). How event reporting by US hospitals has changed from 2005 to 2009. *BMJ Quality & Safety*, 21(1), 70–77.
- Federal Aviation Administration. (2010). *Commercial Aviation Safety Team: Working Together for Aviation Safety*. Retrieved from http://www.cast-safety.org/pdf/cast_06-10-10.pdf
- Federal Aviation Administration. (2013). *Lessons Learned From Transport Airplane Accidents: TWA Flight 514 Boeing 727-231, N54328*. Retrieved from http://lessonslearned.faa.gov/ll_main.cfm?TabID=3&LLID=47
- Field, A. (2009). *Discovering statistics using SPSS* (3rd ed.). Thousand Oaks, CA: Sage Publications Ltd.
- Fishbein, M., & Ajzen, I. (1975). *Belief, attitude, intention and behavior: An introduction to theory and research*. Reading, MA: Addison-Wesley. Retrieved from <http://people.umass.edu/aizen/f&a1975.html>
- Flanagan, J.C. (1954). The critical incident technique. *Psychological Bulletin*, 51(4), 327.
- Food and Drug Administration. (2013, June 11). *FAERS Reporting by Healthcare Providers and Consumers by Year*. Retrieved from <http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm128305.htm>

- Food and Drug Administration. (2014, March 25). *Significant Dates in U.S. Food and Drug Law History*. Retrieved from <http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm128305.htm>
- Francis, A.J.J., Eccles, M.P., Johnston, M., Walker, A., Grimshaw, J., Foy, R., ... Bonetti, D. (2004). *Constructing questionnaires based on the theory of planned behavior: A manual for health services researchers*. Newcastle, UK: Centre for Health Services Research.
- Francis, K. (1953). A new simplified accident record form. *Hospitals*, 27(3), 90–92.
- Gaba, D. M. (2000). Anaesthesiology as a model for patient safety in health care. *BMJ (Clinical Research Ed.)*, 320(7237), 785–8.
- Garbutt, J., Brownstein, D. R., Klein, E. J., Waterman, A., Krauss, M. J., Marcuse, E. K., ... Gallagher, T. H. (2007). Reporting and disclosing medical errors: pediatricians' attitudes and behaviors. *Archives of Pediatrics & Adolescent Medicine*, 161(2), 179.
- Garbutt, J., Waterman, A., & Kapp, J. (2008). Lost opportunities: how physicians communicate about medical errors. *Health Affairs*, 9(1), 53–6.
- Gavaza, P., Brown, C.M., Lawson, K.A., Rascati, K.L., Steinhardt, M., & Wilson, J. P. (2012). Effect of social influences on pharmacists' intention to report adverse drug events. *Journal of the American Pharmacists Association*, 52(5), 622–9.
- Gavaza, P., Brown, C.M., Lawson, K.A., Rascati, K.L., Wilson, J.P., & Steinhardt, M. (2011). Examination of pharmacists' intention to report serious adverse drug events (ADEs) to the FDA using the theory of planned behavior. *Research in Social & Administrative Pharmacy:RSAP*, 7(4), 369–382. doi:10.1016/j.sapharm.2010.09.001

- Germaine, A., & Rinneard, B. (1976). How effectively do you use your incident/accident report? *Hospital Administration in Canada*, 18(8), 24–26.
- Getz, K.A., Stergiopoulos, S., & Kaitin, K.I. (2012). Evaluating the Completeness and Accuracy of MedWatch Data. *American Journal of Therapeutics*.
doi:10.1097/MJT.0b013e318262316f
- Godin, G., Bélanger-Gravel, A., Eccles, M., & Grimshaw, J. (2008). Healthcare professionals' intentions and behaviours: A systematic review of studies based on social cognitive theories. *Implementation Science*, 3(36), 1–12.
- Godin, G., & Kok, G. (1996). The theory of planned behavior: a review of its applications to health-related behaviors. *American Journal of Health Promotion*, 11(2), 87–98.
- Grissinger, M.C., Hicks, R.W., Keroack, M.A., Marella, W.M., & Vaida, A.J. (2010). Harmful medication errors involving unfractionated and low-molecular-weight heparin in three patient safety reporting programs. *The Joint Commission Journal on Quality and Patient Safety*, 36(5), 195–202.
- Grol, R., & Grimshaw, J. (2003). From best evidence to best practice: effective implementation of change in patients' care. *Lancet*, 362(9391), 1225–30.
- Handler, S. M., Perera, S., Olshansky, E. F., Studenski, S. a, Nace, D. a, Fridsma, D. B., & Hanlon, J. T. (2007). Identifying modifiable barriers to medication error reporting in the nursing home setting. *Journal of the American Medical Directors Association*, 8(9), 568–74.

- Hardeman, W., Johnston, M., Johnston, D.W., Bonetti, D., Wareham, N., & Kinmonth, A.M. (2002). Application of the theory of planned behaviour in behaviour change interventions: a systematic review. *Psychology and Health, 17*(2), 123–158.
- Harris, P. A., Taylor, R., Thielke, R., Payne, J., Gonzalez, N., & Conde, J.G. (2009). Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics, 42*(2), 377–81.
- Heard, G.C., Sanderson, P.M., & Thomas, R.D. (2012). Barriers to Adverse Event and Error Reporting in Anesthesia. *Anesthesia & Analgesia, 114*(3), 604–614.
- Hertzog, M.A. (2008). Considerations in Determining Sample Size for Pilot Studies. *Research in Nursing & Health, 31*(January), 180–191.
- Hines, S., Luna, K., Lofthus, J., et al. (2008). *Becoming a High Reliability Organization: Operational Advice for Hospital Leaders*. (Prepared by the Lewin Group under Contract No. 290-04-0011.) AHRQ Publication No. 08-0022. Rockville, MD: Agency for Health Care Research and Quality.
- Holden, R.J., & Karsh, B.T. (2009). A theoretical model of health information technology usage behaviour with implications for patient safety. *Behaviour & Information Technology, 28*(1), 21–38.
- Institute for Safe Medication Practice (2014a). *Historical Timeline*. Retrieved from <https://www.ismp.org/about/timeline.asp>

- Institute for Safe Medication Practice (2014b). *The National Medication Errors Reporting Program (ISMP MERP)*. Retrieved from <https://www.ismp.org/orderforms/reporterrortoismmp.asp>
- Jeffe, D.B., Dunagan, W.C., Garbutt, J., Burroughs, T.E., Gallagher, T.H., Hill, P.R., ... Fraser. (2004). Using Focus Groups to Understand Physicians' and Nurses' Perspectives on Error Reporting in Hospitals. *Joint Commission Journal on Quality and Patient Safety*, 30(9), 9.
- Kaldjian, L. C., Jones, E. W., Wu, B. J., Forman-Hoffman, V. L., Levi, B. H., & Rosenthal, G. E. (2008). Reporting Medical Errors to Improve Patient Safety. *Archives of Internal Medicine*, 168(1), 40–46.
- Kaiser Family Foundation State Health Facts. (2012). Data Source: American Hospital Association Annual Survey: Health Forum LLC. Retrieved at <http://kff.org/other/state-indicator/total-hospitals/#notes>
- Kessler, D.A. (1993). Introducing MEDWAtch: A New Approach to Reporting Medication and Device Adverse Effects and Product Problems. *Journal of the American Medical Association*, 269(21), 2765–2768.
- Kohn, L.T., Corrigan, J.M., & Donaldson, M.S. (1999). *To err is human: building a safer health system* (p. 312). Washington, DC: Institute of Medicine.
- Landrigan, C.P., Parry, G.J., Bones, C.B., Hackbarth, A.D., Goldmann, D.A., & Sharek, P.J. (2010). Temporal trends in rates of patient harm resulting from medical care. *New England Journal of Medicine*, 363(22), 2124–34.

- Leape, L. (1994). Error in medicine. *Journal of the American Medical Association*, 272(23), 1851–1856.
- Leape, L.L. (2002). Reporting of adverse events. *New England Journal of Medicine*, 347(20), 1633–1638.
- Levtzion-Korach, O., Frankel, A., Alcalai, H., Keohane, C., Orav, J., Graydon-Baker, E., ... Bates, D. W. (2010). Integrating incident data from five reporting systems to assess patient safety: making sense of the elephant. *Joint Commission Journal on Quality and Patient Safety*, 36(9), 402–410.
- 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.
- Limbert, C., & Lamb, R. (2002). Doctors' use of clinical guidelines: Two applications of the Theory of Planned Behaviour. *Psychology, Health & Medicine*, 7(3), 301–310.
- Ludlam, J. (1998). *Health Policy-the Hard Way: An Anecdotal Personal History by One of the California Players*. Hope Publishing House.
- Ludlam, J.E. (1955). Guide to a planned safety program. *Hospitals*, 29(12), 68.
- Madden, T.J., Ellen, P.S., & Ajzen, I. (1992). A Comparison of the Theory of Planned Behavior and the Theory of Reasoned Action. *Pers Soc Psycho Bull*, 18(3), 3-9.
- McEachan, R.R.C., Conner, M., Taylor, N.J., & Lawton, R.J. (2011). Prospective prediction of health-related behaviours with the Theory of Planned Behaviour: a meta-analysis. *Health Psychology Review*, 5(2), 97–144.
- McPeake, J., Bateson, M., & O'Neill, A. (2014). Electronic surveys: how to maximise success. *Nurse Researcher*, 21(3), 24–6.

- Michie, S., Johnston, M., Francis, J., Hardeman, W., & Eccles, M. (2008). From Theory to Intervention: Mapping Theoretically Derived Behavioural Determinants to Behaviour Change Techniques. *Applied Psychology, 57*(4), 660–680.
- Milch, C.E., Salem, D.N., Pauker, S.G., Lundquist, T.G., Kumar, S., & Chen, J. (2006). Voluntary electronic reporting of medical errors and adverse events. *Journal of General Internal Medicine, 21*(2), 165–170.
- Mills, D.H., & von Bolschwing, G.E. (1995). Clinical risk management: experiences from the United States. *Quality in Health Care : QHC, 4*(2), 90–6.
- National Aeronautics and Space Administration. (2014). *Aviation Safety Reporting System Program Briefing 2013*. Retrieved at http://asrs.arc.nasa.gov/docs/ASRS_ProgramBriefing2013.pdf
- Naveh, E., & Katz-Navon, T. (2013). Antecedents of willingness to report medical treatment errors in health care organizations: A multilevel theoretical framework. *Health Care Management Review, 1*–10.
- Nordstokke, D. W., & Zumbo, B. D. (2010). A new nonparametric Levene test for equal variances. *Psicológica, 31*(2), 401-430.
- Nuckols, T.K., Bell, D.S., Liu, H., Paddock, S.M., & Hilborne, L.H. (2007). Rates and types of events reported to established incident reporting systems in two US hospitals. *Quality & Safety in Health Care, 16*(3), 164–8.
- Parmelli, E., Flodgren, G., Fraser, S.G., Williams, N., Rubin, G., Eccles, M.P. (2012). *Interventions to increase clinical incident reporting in health care*. Cochrane Database of Systematic Reviews, Issue 8. Art. No.: CD005609.

Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), Pub. L. 109-41, 42

U.S.C. 299b-21-b-26. Retrieved from <http://www.gpo.gov>

Perkins, M.B., Jensen, P.S., Jaccard, J., Gollwitzer, P., Oettingen, G., Pappadopulos, E., & Hoagwood, K.E. (2007). Applying theory-driven approaches to understanding and modifying clinicians' behavior: what do we know? *Psychiatric Services (Washington, D.C.)*, 58(3), 342–8.

Pfeiffer, Y., Briner, M., Wehner, T., & Manser, T. (2013). Motivational antecedents of incident reporting: evidence from a survey of nurses and physicians. *Swiss Medical Weekly*, 143(November), w13881.

Pfeiffer, Y., Manser, T., & Wehner, T. (2010). Conceptualising barriers to incident reporting: a psychological framework. *Quality and Safety in Health Care*, 19(6), 1–10.

Polit, D.F., & Beck, C.T. (Eds.). (2011). *Nursing Research: Generating and Assessing Evidence for Nursing Practice* (9th ed.). Philadelphia, PA: Lippincott Williams & Wilkins.

Puffer, S., & Rashidian, A. (2004). Practice nurses' intentions to use clinical guidelines. *Journal of Advanced Nursing*, 47(5), 500–9.

Quantros. (2014). MEDMARX ADE Data Repository. Retrieved from <http://quantros.com/our-products/safety-and-risk-management-srm/medmarx-medication-database>

Rashidian, A., & Russell, I. (2012). General practitioners' intentions and prescribing for asthma: using the theory of planned behavior to explain guideline implementation. *International Journal of Preventive Medicine*, 3(1), 17–28.

- Reynard, W.D., Billings, C.E., Cheaney, E.S., & Hardy, R. (1986). *The development of the NASA aviation safety reporting system* (Vol. 1114). Moffet Field, CA: National Aeronautics and Space Administration.
- Rosenthal, J., & Takach, M. . (2007). *2007 Guide to State Adverse Event Reporting Systems*. State Health Policy Survey Report, Vol. 1, No. 1. (Publication No. 2007-301) Portland, ME: National Academy for State Health Policy.
- Rossi, A.C., & Knapp, D. (1984). Discovery of New Adverse Drug Reactions: A Review of the Food and Drug Administration's Spontaneous Reporting System. *Journal of the American Medical Association*, 252(8), 1030–1033.
- Rowin, E.J., Lucier, D., Pauker, S.G., Kumar, S., Chen, J., & Salem, D.N. (2008). Does Error and Adverse Event Reporting by Physicians and. *The Joint Commission Journal on Quality and Patient Safety*, 34(9), 537–545.
- Runciman, W.B., Sellen, A., Webb, R.K., Williamson, A., Currie, M., Morgan, C., & Russell, W.J. (1993). Errors , Incidents and Accidents in Anaesthetic Practice. *Anaesthesia & Intensive Care*, 21(5), 506–519.
- Santell, J.P., Hicks, R.W., McMeekin, J., & Cousins, D.D. (2003). Medication Errors: Experience of the United States Pharmacopeia (USP) MEDMARX Reporting System. *The Journal of Clinical Pharmacology*, 43(7), 760–767.
- Secker-Walker, J., & Taylor-Adams, S. (2001). Clinical Incident Reporting. In C. Vincent (Ed.), *Clinical Risk Management : Enhancing Patient Safety (2nd Edition)*. London, GBR: BMJ Books.

- Schechtman, J. M., & Plews-Ogan, M. L. (2006). Physician perception of hospital safety and barriers to incident reporting. *Joint Commission Journal on Quality and Patient Safety*, 32(6), 337–343.
- Sherman, H., Castro, G., & Fletcher, M. (2009). Towards an International Classification for Patient Safety: the conceptual framework. *International Journal for Quality in Health Care*, 21(1), 2–8.
- Shi, L., Singh, D.A.(Eds.). (2009). *Delivering health care in America*. Jones & Bartlett Publishers.
- Staender, S. (2011). Incident reporting in anaesthesiology. *Best Practice & Research Clinical Anaesthesiology*, 25(2), 207–214.
- Stratton, K. M., Blegen, M. a, Pepper, G., & Vaughn, T. (2004). Reporting of medication errors by pediatric nurses. *Journal of Pediatric Nursing*, 19(6), 385–92.
doi:10.1016/j.pedn.2004.11.007
- Tabachnick, B.G., & Fidell, L.S. (Eds.). (2007). *Using multivariate statistics*. New York: Harper and Row (5th ed.). New York, NY: Pearson.
- Taylor, J.A., Brownstein, D., Christakis, D.A., Blackburn, S., Strandjord, T. P., Klein, E. J., & Shafii, J. (2004). Use of incident reports by physicians and nurses to document medical errors in pediatric patients. *Pediatrics*, 114(3), 729–35.
- The Joint Commission (2013a, June 10). *Sentinel Event Policy and Procedures*. Retrieved from http://www.jointcommission.org/sentinel_event.aspx

- The Joint Commission (2013b, October 29). *Improving America's Hospitals - The Joint Commission's Annual Report on Quality and Safety 2013*. Retrieved from <http://www.jointcommission.org/annualreport.aspx>
- The Joint Commission (2013c, September 20). *Sentinel Event Data - General Information*. Retrieved from http://www.jointcommission.org/sentinel_event_data_general/
- The Joint Commission (2014, April 15). *Sentinel Event Data - Event Type by Year*. Retrieved from http://www.jointcommission.org/se_data_event_type_by_year/
- Uribe, C., & Schweikhart, S. (2002). Perceived Barriers to Medical-Error Reporting: An Exploratory Investigation. *Journal of Healthcare Management, 47*(4), 263–280.
- VanGeest, J.B., Johnson, T.P., & Welch, V.L. (2007). Methodologies for improving response rates in surveys of physicians: a systematic review. *Evaluation & the Health Professions, 30*(4), 303–21.
- Vincent, C. (2003). Understanding and responding to adverse events. *New England Journal of Medicine, 348*(11), 1051–1056.
- Vincent, C. (2010). *Patient safety* (2nd ed.). West Sussex, UK: John Wiley & Sons.
- Wachter, R.M. (2012). *Understanding Patient Safety* (Vol. 2nd). New York, NY: McGraw-Hill.
- Wagner, L. M., Castle, N. G., & Handler, S. M. (2012). Use of HIT for adverse event reporting in nursing homes: barriers and facilitators. *Geriatric Nursing (New York, N.Y.), 34*(2), 112–115.
- Wakefield, B.J., Blegen, M.A., Uden-Holman, T., Vaughn, T., Chrischilles, E., & Wakefield, D. S. (2001). Organizational Culture, Continuous Quality Improvement, and Medication Administration Error Reporting. *American Journal of Medical Quality, 16*(4), 128–134.

- Wakefield, D.S., Wakefield, B.J., Borders, T., Uden-Holman, T., Blegen, M., & Vaughn, T. (1999). Understanding and Comparing Differences in Reported Medication Administration Error Rates. *American Journal of Medical Quality*, 14(2), 73–80.
- Wakefield, J.G., McLaws, M.L., Whitby, M., & Patton, L. (2010). Patient safety culture: factors that influence clinician involvement in patient safety behaviours. *Quality and Safety in Health Care*, 19(6), 585–91.
- Weick, K.E., & Sutcliffe, K.M. (2001). *Managing the unexpected: assuring high performance in an age of complexity*. San Francisco, CA: Jossey-Bass.
- Weick, K.E., Sutcliffe, K.M., & Obstfeld, D. (2005). Organizing and the process of sensemaking. *Organization Science*, 16(4), 409–421.
- World Health Organization. (2005). *WHO draft guidelines for adverse event reporting and learning systems*. Geneva, Switzerland. Retrieved from http://www.who.int/patientsafety/implementation/reporting_and_learning/en/
- World Health Organization. (2009). Conceptual Framework for the International Classification for Patient Safety Version 1.1 Technical Report. Retrieved from: <http://www.who.int/patientsafety/implementation/taxonomy/publications/en/>
- Wu, J. H., Shen, W. S., Lin, L. M., Greenes, R. A., & Bates, D. W. (2008). Testing the technology acceptance model for evaluating healthcare professionals' intention to use an adverse event reporting system. *International Journal for Quality in Health Care*, 20(2), 123–129.
- Wysowski, D.K., & Swartz, L. (2005). Adverse Drug Event Surveillance and Drug Withdrawals in the United States, 1969-2002. *Archives of Internal Medicine*, 165, 1363–1369.

Yong, H., & Kluger, M.T. (2003). Incident reporting in anaesthesia: a survey of practice in New Zealand. *Anaesthesia and Intensive Care*, 31(5), 555.

Young, H.M., Lierman, L., Powell-Cope, G., Kasprzyk, D., & Benoliel, J.Q. (1991). Operationalizing the theory of planned behavior. *Research in Nursing & Health*, 14(2), 137–44.

Appendix A

Initial Survey Questionnaire

Thank you for your interest in participating in the research study “Factors That Predict Incident Reporting Behavior in Certified Registered Nurse Anesthetists”. The purpose of this study is to describe CRNAs' attitudes and beliefs toward submitting incident reports of patient safety incidents. Your candid responses to the questions in this survey may benefit the profession of anesthesia in the future by helping to gain a better understanding of use of incident reporting systems by CRNAs.

Your participation in this study is voluntary and you are free to withdraw your participation from this study at any time. This survey should take only 10 minutes to complete.

This survey has been approved by the Institutional Review Board of Virginia Commonwealth University. There are no risks associated with participating in this study. The survey collects no identifying information of any respondent. All of the response in the survey will be recorded anonymously.

If you have any questions regarding the survey or this research project in general, please don't hesitate to contact Nicole Damico at damicosn@vcu.edu or her advisor Dr. Suzanne Wright at smwright@vcu.edu. If you have any questions concerning your rights as a research participant, please contact the IRB of Virginia Commonwealth University at 827-1735 or ORSP@vcu.edu.

By completing and submitting this survey, you are indicating your consent to participate in the study. Your participation is greatly appreciated!

Part I:

What is your age? Under 30 years
 30 - 34 years
 35 - 39 years
 40 - 44 years
 45 - 49 years
 50 - 54 years
 55 - 59 years
 60 - 64 years
 65 + years

Please indicate your gender: Male
 Female

In what AANA geographic region do you practice in your primary position?
 Region 1 (CT, ME, MA, NH, NJ, NY, Puerto Rico, RI, VT)
 Region 2 (GA, KY, NC, SC, TN, VA, WV)

- Region 3 (IL, IN, MI, WI)
- Region 4 (AR, IA, KS, MN, MO, NE, ND, OK, SD)
- Region 5 (AZ, CA, CO, HI, ID, MT, NV, NM, OR, UT, WA, WY)
- Region 6 (DE, DC, MD, OH, PA)
- Region 7 (AL, FL, LA, MS, TX)

Please indicate your primary practice arrangement (provides the greatest proportion of your income):

- Employee of a hospital
- Employee of a group
- Independent contractor
- Owner/partner Military/Govt./VA
- Employee in other setting

For how many years have you practiced as a CRNA?

- Less than 2 years
- 2 - 5 years
- 6 - 10 years
- 11 - 15 years
- 16 - 20 years
- Greater than 20 years

To your knowledge, have you encountered any patient safety incidents in the past 12 months? (Check all that apply)

- None
- Near miss
- No-harm event
- Adverse event

(The electronic survey was configured with branching logic such that the following item was displayed only to participants that selected 'Near-miss' OR 'No-harm event' OR 'Adverse event' on the previous item.)

In the past 12 months, how often did you complete an incident report when you encountered a patient safety incident? **This includes submitting an incident report to a hospital-based or local incident reporting system and/or submitting an incident report to an 'external organization'.

- Always
- Sometimes
- Rarely
- Never

In Part II of this survey you will be presented a series of statements with seven numbered response options. You are to select the response that corresponds to your opinion about the statement. A sample item is shown here.

The weather in Richmond, VA is: 1 2 3 4 5 6 7
Bad-----Good

Your response to this item would be interpreted as follows: 1 = extremely bad 2 = quite bad 3 = slightly bad 4 = neutral, neither good or bad 5 = slightly good 6 = quite good 7 = extremely good

**If you have no opinion about a statement, please select the response '4'.

Part II:

Please note that for the purposes of this study 'reporting a patient safety incident' refers to submitting an incident report about a patient safety incident using an incident reporting system. This can be either a hospital-based or local incident reporting system or an incident reporting system operated by an 'external organization'.

Definitions of key terms:

Patient safety incident - an event or circumstance that resulted, or could have resulted in patient harm. This includes all of the following incident types:

- Near miss - an incident that did not reach the patient
- No harm incident - reached the patient but caused no detectable harm
- Adverse event (harmful incident) - an incident that reached the patient and resulted in impairment of a structure or function of the body, injury, suffering, disability or death

External organization - a patient safety organization that is not affiliated with a single hospital, facility, or group. In this survey, this refers to any of the following:

- Federally designated patient safety organization (PSO) - organization listed by the Agency for Health Care Research and Quality. Provides federal protection from disclosure and discovery under the Patient Safety Act.
- Non-federally designated patient safety organization - an organization that collects anonymous reports of patient safety incidents from health care providers
- Food and Drug Administration - confidential reporting of patient safety incidents through the MedWatch program

Submitting incident reports about patient safety incidents that I encounter is:

___1___2___3___4___5___6___7
Bad-----Good

The people in my life whose opinions I value would _____ of me submitting incident reports about patient safety incidents that I encounter.

___1___2___3___4___5___6___7
Not approve-----Approve

I plan to submit incident reports about patient safety incidents that I encounter.

___1___2___3___4___5___6___7
Strongly disagree-----Strongly agree

I am confident that I could submit an incident report about a patient safety incident that I encountered if I wanted to.

___1___2___3___4___5___6___7
Strongly disagree-----Strongly agree

Submitting incident reports about patient safety incidents that I encounter is:

___1___2___3___4___5___6___7
Harmful-----Beneficial

Most people important to me think that I _____ submit incident reports about patient safety incidents that I encounter.

___1___2___3___4___5___6___7
Should not-----Should

I intend to submit incident reports about patient safety incidents that I encounter.

___1___2___3___4___5___6___7
Strongly disagree-----Strongly agree

The decision to submit an incident report about patient safety incidents that I encounter is beyond my control.

___1___2___3___4___5___6___7
Strongly disagree-----Strongly agree

Submitting incident reports about patient safety incidents that I encounter is:

___1___2___3___4___5___6___7
Worthless-----Valuable

The professional colleagues whose opinions I value _____ incident reports about patient safety incidents they encounter.

___1___2___3___4___5___6___7
Do not submit-----Submit

I want to submit incident reports about patient safety incidents that I encounter.

___1___2___3___4___5___6___7
Strongly disagree-----Strongly agree

Submitting incident reports about patient safety incidents that I encounter is:

___1___2___3___4___5___6___7
Difficult for me-----Easy for me

I feel under social pressure to submit incident reports about patient safety events that I encounter.

___1___2___3___4___5___6___7
Strongly disagree-----Strongly agree

Appendix B

Survey Invitation Letter

Subject: You are invited to a research survey – Factors Associated with Use of Incident Reporting Systems by CRNAs

Survey Questionnaire: Factors That Predict Incident Reporting Behavior in Certified Registered Nurse Anesthetists

Thank you for your interest in participating in the research study "Factors That Predict Incident Reporting Behavior in Certified Registered Nurse Anesthetists". The purpose of this study is to describe CRNAs' attitudes and beliefs toward submitting incident reports of patient safety incidents. Your candid responses to the questions in this survey may benefit the profession of anesthesia in the future by helping to gain a better understanding of use of incident reporting systems by CRNAs.

Your participation in this study is voluntary and you are free to withdraw your participation from this study at any time. This survey should take 10 minutes or less to complete. This survey has been approved by the Institutional Review Board of Virginia Commonwealth University. There are no risks associated with participating in this study. The survey collects no identifying information of any respondent. All of the responses in the survey will be recorded anonymously.

If you have any questions regarding the survey or this research project in general, please don't hesitate to contact Nicole Damico at damicosn@vcu.edu or her advisor Dr. Suzanne Wright at smwright@vcu.edu. If you have any questions concerning your rights as a research participant, please contact the IRB of Virginia Commonwealth University at 827-1735 or ORSP@vcu.edu.

By completing and submitting this survey, you are indicating your consent to participate in the study. Your participation is greatly appreciated! Note: This invitation does not imply any endorsement of the survey research and/or its findings by the AANA. The survey contents and findings are the sole responsibility of the individual conducting the survey.

To take the survey, please visit <https://redcap.vcu.edu/rc/surveys/?s=Z4JsypABL>

If you wish to unsubscribe from receiving survey invitations from the AANA, please email researchsurvey@aana.com. To unsubscribe from all emails from the AANA, please use the unsubscribe button below.

Vita

Nicole Kemp Damico was born at Patrick Air Force Base, Florida. She earned her Associate's in Applied Science Degree in Nursing at Tidewater Community College; and her Bachelor's of Science Degree in Nursing and Master's of Science in Nurse Anesthesia Degree at Virginia Commonwealth University. Nicole has practiced as a Certified Registered Nurse Anesthetist in the Richmond Metro Area since 2000. She is currently an Assistant Professor and the Director of Professional Practice in the Department of Nurse Anesthesia at Virginia Commonwealth University.