THE IMPACT OF WORK UNIT AND ORGANIZATION SUPPORT ON

HOSPITAL PATIENT SAFETY

By

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HOSPITAL PATIENT SAFETY

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ABSTRACT

Based on the construct of a *culture of safety,* the study purpose was to discern

the relationships between Organization Support (OS) and Work Unit Support (WS)

on Hospital Patient Safety. OS and WS were operationalized using the National

Database for Nursing Quality Indicators® (NDNQI®) RN Survey with Job

Satisfaction Scales. Patient Safety was operationalized using four Agency for

Healthcare Research and Quality (AHRQ) Patient Safety Indicators: Decubitus

Ulcer, Selected Infections due to Medical Care, Failure to Rescue (FTR), and Deep

Vein Thrombosis. A structural equation model was developed with adequate fit

indices (χ^2 = 40.811, df= 27, p= 0.234; CFI= 0.930; RMSEA= 0.065; SRMR=

0.074). Unexpectedly, increased OS was associated significantly (p= .030) with

increase Patient Safety events. A promising, though non-significant finding, was

increased WS and OS were associated with decreased FTR rates. Teamwork, a

component of WS was associated with decreased rates of FTR and Patient Safety

events.

Acknowledgements

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CHAPTER I

Health care providers, payers, policy leaders, and consumers increasingly are aware of the impact of adverse outcomes related to health care. The literature is rife with references to the Institute of Medicine (IOM) reports that highlighted the issue beginning with *To Err is Human* (IOM, 1999) and followed by *Crossing the Quality Chasm* (IOM, 2001), *Patient Safety: Achieving a New Standard of Care* (IOM, 2003) and *Preventing Medication Errors* (IOM, 2006). Although the interest in improving patient safety is evident, now nine years after the publication of *To Err is Human* (IOM, 1999), there is no evidence that overall errors have decreased (Leape & Berwick, 2005).   Still, little is known about designing safe health care systems. Much of the work done points to a *culture of safety* as the answer to decreasing complications and errors associated with health care. Hospital leaders are advised to develop a culture of safety within their institutions (IOM, 2006), yet the relationships between the work environment characteristics thought to describe a culture of safety and the occurrence of adverse patient outcomes is not entirely clear. A greater understanding of these relationships is needed to inform health care leaders and guide the development of safe health care systems.

In addition to the challenge of identifying organization characteristics associated with a culture of safety, there is the difficulty of developing quantitative measures that are indicative of quality patient care. The IOM (1999) recommended mandatory reporting of standardized measures representing adverse events that cause patient harm. However, the lack of uniform methods by which care processes and

outcomes are captured and reported, the highly variable manner in which patient care is documented, and the difficulties in developing methods to conduct risk adjustment have made the development of measures used to compare quality of care across institutions challenging. In response, a number of federal and private agencies developed measures to inform key stakeholders on the quality of care within health care institutions. Such indicators are used by health care leaders to drive improvement efforts within organizations, by consumers to make health care decisions, and by policy leaders to focus public policy initiatives.

Nurse researchers also have contributed to the development of quality measures, particularly measures purported to reflect the quality of nursing care provided within hospital settings. The measures are thought to be sensitive to the level, amount, and processes of nursing care. Others have studied the relationships between organization characteristics such as the number of nursing hours of care per patient day, nurse educational preparation, and perceptions of the work environment with outcome measures sensitive to nursing care (Aiken, Clarke, Cheung, Sloane, Silber, 2003; Aiken, Clarke, Sloane, 2002; Aiken, Clarke, Sloane, Sochalski, & Silber, 2002; Aiken, Sochalski, & Anderson, 1996). Reflecting the importance of the patient safety effort, national and regional databases such as the National Database for Nursing Quality Indicators® (NDNQI®) and the California Nursing Outcomes Coalition Database Project (CalNoc) are capturing nurse sensitive indicators.

Statement of the Problem

The recent emphasis on patient safety has generated interest in defining the relationships between organization characteristics and patient outcomes. Although the term culture of safety often is used in the literature, identification of the characteristics that support positive patient outcomes is needed to describe a *health care* culture of safety adequately. A better understanding of the relationships between work environment characteristics with nurse sensitive outcomes is important for nursing leaders and other health care administrators. Understanding these relationships is necessary so that informed decisions can be made regarding health care system design and the allocation of resources that support the work of nurses that result in positive outcomes for patients.

Study Purpose

The study purpose was to describe the impact of registered nurses' perceptions of work environment characteristics conceptualized as Work Unit Support and Organization Support on Patient Safety within hospitals. Instruments used were the:

(a)   National Database of Nursing Quality Indicators (NDNQI) RN Survey, Job Satisfaction with various work characteristics (e.g. Professional Development, Nursing Administration, Nurse-Nurse Interaction and Nurse-MD Interaction [Teamwork], Autonomy, Task, Decision Making, Supportive Nursing Management, Unit Quality of Care scales) and

(b)   Patient Safety Indicators (PSIs) developed by the Agency for

Healthcare Research and Quality (AHRQ). The selected

indicators (e.g. Decubitus Ulcer, Failure to Rescue, Infection

Resulting from Medical Care, and Postoperative Pulmonary

Embolus/Deep Vein Thrombosis) represent conditions often cited

as outcomes sensitive to nursing care (Clarke, & Aiken, 2003;

Hugonnet, Chevrolet, & Pettet, 2007; Morrison, 2006; Needleman,

Buerhaus, Mattke, Stewart, & Zelevinsky, 2002; Seago,

Williamson, & Atwood, 2006).

Background and Significance

The publication of *To Err is Human* (IOM, 1999) focused national attention

on the impact of medical errors with an error defined as "the failure of a planned

action to be completed as intended (e.g., error of execution) or the use of a wrong

plan to achieve an aim (e.g., error of planning)" (IOM, 1999, p. 54). In addition,

health care associated errors were identified as representing either "an act of

commission or an act of omission" (IOM, 1999, p. 28). Numerous references to the

report were seen in the health care literature and the popular press. The often quoted

statistic of 44,000 to 98,000 deaths each year resulting from medical errors was

staggering and changed the conversation at many levels regarding patient safety.

Although health care providers had some knowledge regarding the occurrence of

medical errors, prior to the initial IOM publication, the full impact of medical errors

had not been reported widely. Since the release of *To Err is Human* (1999) much

work has been done to reduce adverse events associated with health care. However, the results of these efforts have fallen short of the goal established by the IOM (1999) to reduce medical errors by 50% in five years.

With the publication of the IOM reports, the focus turned to the cause of errors, which was attributed to faulty processes (Reason, 1990). The complexity of health care systems and the inability of humans to manage and oversee such processes were cited as the cause of errors (Reason, 1990; VanCott, 1994). Individual practitioners were no longer viewed as the source of most health care associated errors, but instead, the processes used to provide care were seen as the most common root cause. Health care leaders called for action at the local and national level and suggested that the currently flawed health care system could be made safer through the use of system improvement strategies (IOM, 1999; 2001). Patient safety experts suggested that by developing processes that were inherently safe, rather than relying on individuals to work around faulty processes, errors could be reduced (IOM, 1999). However, the steps necessary to achieve a safe health care system, not just individual processes, were not understood clearly.

Many in health care turned to research conducted in other high risk systems for answers. Organization researchers have sought to explain the workings of high risk systems and why some systems remain relatively error free despite their complexity and propensity for catastrophe. This work resulted in the description of High Reliability Organization Theory (HROT). Based on studies conducted within non-health care systems identified as both high risk and highly reliable, concepts of

HROT were described. However, there is still much to learn regarding the relationships among these concepts within health care settings. The complexity of health care systems is significant and possibly unique compared to other complex systems. James Reason, as reported by Leape and Berwick (2005, p. 2387), "observed that health care is more complex than any other industry…in terms of relationships".

Research in the area of patient safety has increased tremendously since the publication of *To Err is Human* (1999) due in large part to government support for the patient safety research agenda. Also, a great deal has been learned from quality improvement projects and across-institution collaboratives such as the Institute for Healthcare Improvement (IHI) *100k Lives Campaign* and *5 Million Lives Campaign*. The lessons learned from these efforts are disseminated by agencies such as the IHI and AHRQ's Center for Quality Improvement and Safety among others. However, even with the strides made in selected areas, the sweeping improvements called for in the IOM reports have not been realized. This has led some to express disappointment at the limited progress in improving patient safety and in the inability of the health care system to reach the five year goal of 50% error reduction as set in *To Err is Human* (Leape & Berwick, 2005). Based on these mixed results, some speculate that we are only at the end of the beginning (Wachter, 2004).

Development of indicators to inform stakeholders regarding the quality of care also has progressed in recent years. Based on work conducted by researchers at the University of California and funded by AHRQ, a set of Patient Safety Indicators

(PSIs) drawn from administrative data was developed (Miller, Elixhauser, Zhan & Meyer, 2001; Romano, et al., 2003). A four phase process was used to develop the indicators using existing International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes that might be indicative of health care associated complications and to develop algorithms with specific inclusion and exclusion criteria. The PSIs, meant to be used as screening indicators, were described as a case finding tool rather than a comparative tool. The developers of the PSIs indicated that by conducting further analysis on the PSI cases, trends could be discovered and improvements initiated. However, since their initial development PSIs have been used for comparison purposes. PSI rates have been included in healthcare public reporting initiatives and used to suggest hospitals with low PSI rates provide superior quality of care (Healthgrades, 2007).

<div align="center">Conceptual Framework</div>

The study framework was High Reliability Organization Theory (HROT), which originated from critical analyses of the concepts of Normal Accident Theory (NAT) described by sociologist, Charles Perrow (Roberts, 1990a; 2003). Perrow (1984) described high risk systems as complex, meaning they contain highly interactive subsystems that respond nonlinearly to system failures, and as possessing *tight coupling*, referring to processes that contain time dependent, invariant steps. Based on observation of disasters associated with high risk systems such as nuclear power plants, chemical plants, and the space programs, Perrow suggested technology had progressed beyond humans' ability to manage it safely and recommended

abandonment of some of these systems due to the inevitability of large scale accidents. Although Perrow's work resonated with many at the time, others (e.g. Roberts, 1990a, 1990b; Roberts & Bea, 2001; Roberts, Stout & Hapern, 1994) felt it contained gaps and some inaccuracies. The researchers questioned what made some high risk systems highly reliable and set out to explain the reasons these organizations performed differently from the predictions of NAT (Roberts, 1990b; Weick, Sutcliffe, & Obsfeldt, 2005). Qualitative studies were conducted in high risk systems that had few errors, and from this work concepts that seemed to contribute to high reliability were described. It is important to note that the original work done in this area was in non-health care settings. Research was conducted within systems such as aircraft carriers, nuclear submarines, and the aviation industry.

Culture of Safety as a HROT Construct

A construct within high reliability organization theory is a culture of reliability or culture of safety. The term culture of safety has gained popularity and is used commonly in the patient safety literature. Organizations are encouraged to "adopt" a culture of safety (IOM, 2006). However, what is meant by a culture of safety is not always defined clearly by quality improvement leaders and patient safety researchers. One definition of a culture of safety developed by the Advisory Committee on the Safety of Nuclear Installations and adopted by AHRQ is:

> The safety culture of an organization is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of an

organization's health and safety management. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures (ACSNI, 1993; AHRQ, 2004, November).

Culture of Safety Concepts

Although researchers have identified various concepts associated with HROT, these concepts can be included within the construct of a culture of safety. The concepts described in the initial research studies include redundancy, early identification of problems (vigilance), simultaneous centralization and decentralization of decision making, and organization knowledge/learning. (Bierly & Spender, 1995; Bigely & Roberts, 2001; Roberts, 1990a; 1990b; Weick & Sutcliffe, 2001) Others described the concepts of preoccupation with failure, reluctance to simplify interpretation, sensitivity to operations, commitment to resilience, and deference to expertise (Weick & Sutcliffe 2001). Some of these concepts are similar but the language to describe them varies across researchers. See Table 1 (page 10) for HROT concept definitions.

Redundancy refers to a back up system or ability to conduct multiple checks of a process either by people or through equipment. *Vigilance, sensitivity to operations*, and *preoccupation with failure* can be described as a process of auditing or watching the system for expected or unexpected safety problems. Having team members recognize failures in the system before an error occurs gives the team an

Table 1
High Reliability Theory Concept Definitions

Concept	Definition
Redundancy	Multiple checks using varying methods are built into processes for early detection of system failures
Centralized Decision Making	Organization leaders establish core values, standards, and priorities upon which all decisions are based
Decentralized Decision Making	Organization leaders support front-line staff decision making based on individual and group knowledge and training. Decisions are made at the level of greatest expertise
Teamwork/Group Mind	The work group values safe processes over individual interests and uses communication strategies to increase group knowledge particularly related to the detection of possible system failures
Trust	Expectation held by individuals regarding their team members, leaders, and organizational processes and belief in the effectiveness of established processes
Organizational Learning	Continual training to achieve a high degree of specialization and integration among team members.

opportunity to address the problem before it is out of control. *Organization learning and training* is a key concept in HROT. Team members receive extensive training in formal processes and procedures, as well as, in the shared values of the organization. Therefore, when the unexpected occurs, those at the front lines are capable and ready to make good decisions. Also, managers have knowledge of the big picture but trust staff to do their work, knowing that staff has been well trained. Individuals and groups within HROs place a high value on teamwork and nurture relationships to build trust and effective communication patterns.

Centralized and decentralized decision making seems contradictory, however, this concept refers to the context of decision making and includes several components. The centralized aspect of decision making refers to the values, expectations, and standards as set by the organization's leaders. The decentralized component of decision making, sometimes referred to as a *deference to expertise*, refers to the organization support for decision making by individuals with the greatest knowledge or expertise (Weick & Sutcliffe, 2001; Weick, Sutcliffe, & Obstfeld, 2005). Expertise occurs at varying levels in an organization and often front line workers are best prepared to make a decision due to their unique knowledge and on the centralized values upon which their decisions are based. Complex issues or problems are brought to the experts, those individual(s) with the greatest knowledge. Rather than using a chain of command approach regardless of the problem, decisions are moved to the area of expertise. *Reluctance to simplify* also refers to the decision

making process used in HROs. In high reliability systems team members and/or disciplines are valued for their unique perspective. Even though it may be easier and faster to develop a process or handle a problem without system-wide involvement, this approach is thought to lead to oversimplification and increased risk of error.

Although there are many consistencies between the different researchers in their description of high reliability concepts, the relationships between the concepts have not been discerned fully. Also, it is not clear if some of the concepts are more critically important, if the concepts translate to health care organizations, and how to create a highly reliable environment. Even more challenging has been the measurement of high reliability concepts within an organization. Researchers have begun to develop tools to measure a culture of safety within health care settings. However, it is unclear if the scores on these measures are associated with the incidence of negative patient outcomes.

Empirical Indicators

The empirical indicators for HROT can be drawn from the original qualitative studies conducted in systems demonstrating low incidence of errors. Evidence of staff's ability to recognize potential errors in the system, use decision making appropriate for the situation, demonstrate commitment to using known safety practices, and support of team members in their use of safety practices was described in the early work done in HROs (Bierly & Spender, 1995; Bigely & Roberts, 2001; Roberts, 1990b; Weick & Sutcliffe, 2001). The presence of these characteristics could be obtained using observation and self reports from health care staff about the

processes used to provide care to patients. The NDNQI RN Survey with Job
Satisfaction scales measure concepts consistent with some of the concepts describing
a culture of safety, and the scales were used in this study. Measuring the
consequences of a culture of safety could include evaluation of the occurrence of
negative patient outcomes such as the incidence of specific clinical complications,
for example, PSIs.

Strengths and Weaknesses of HROT

The strength of HROT is in its relevance and perceived usefulness to health
care providers. The concepts seem applicable to what many health care providers
experience when practicing within a highly complex system. The numbers of
publications, which reference high reliability or a culture of safety, attest to the
connection health care providers feel to the theory. Although originally developed to
describe non-health care systems, the concepts do apply to other high risk systems
including health care. Another strength of the theory is that it can be used to make
basic predictions. It has been hypothesized that systems demonstrating high
reliability concepts will have fewer health care associated errors. However, within
health care settings there is limited research to evaluate this relationship.

Although HROT has garnered considerable attention among patient safety
experts, there are some aspects of the theory that could be considered weaknesses.
The language used to describe the concepts is not uniform: therefore, there seems to
be overlap among the concepts when described by different researchers. For
example, Weick and Sutcliffe (2001) described *deference to expertise* as a concept

within HROT. Rather than using the same chain of command approach regardless of the problem, decisions are moved to the area of expertise. Everyone working in the system has access to information on the functioning of the system and is ready to call in resources if a problem is detected. Others described a process where problems *migrate* through the system until the individuals with the unique knowledge of the problem are located to solve it (Roberts, 1990b). Also, the operational definitions of the concepts have not been established clearly. For example, *redundancy* has been identified as a concept of HROT, yet within the literature redundancy is used to describe multiple checks of a high risk process and also has been used to describe the availability of adequate staffing (Roberts, 1990b; IOM, 2004). In addition, further study is needed to define the relationships between the concepts. The theory can be diagrammed although diagrams have not been found in the literature. A diagram was developed by this researcher to illustrate the concepts and construct included in HROT (Figure 1, page 15). Even though additional research is needed to further theory development, HROT resonates with many in the health care community and holds promise as a framework to increase our understanding of health care organizational culture and the occurrence of health care related adverse events.

Theoretical Levels of HROT Concepts

Although the original studies describing HROT do not frame clearly the levels (individual, work group, organization) at which each of the concepts applies, it is implicit that the concepts occur at more than one level. In these original studies some concepts were ascribed to individuals but within the context of the work group.

Organization level concepts also were described both in the manner in which work groups function in concert, and how leaders set priorities so that the concepts used to mitigate risk were valued and adhered to throughout the organization.

Figure 1

High Reliability Organization Theory
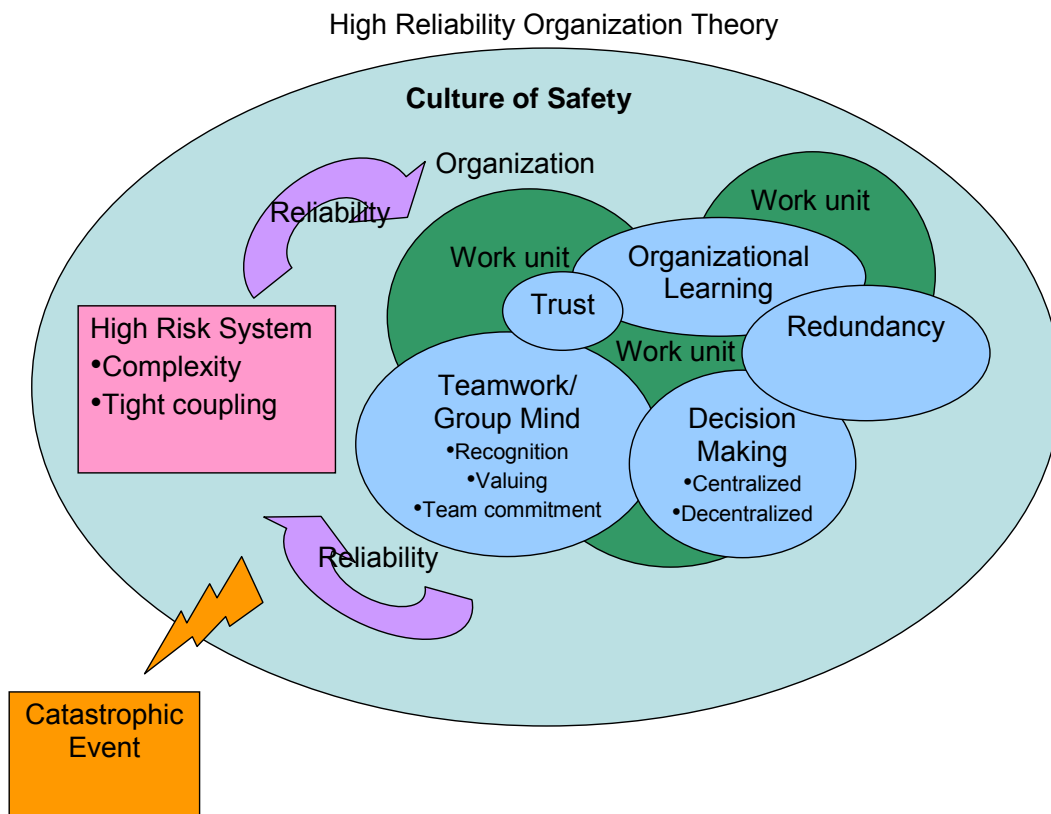
In her original study conducted over a three year period on two West Coast based aircraft carriers and one East Coast carrier, Roberts (1990a; 1990b) described the concepts used to reduce the impact of complexity and tight coupling. Roberts (1990a) described work group concepts when identifying these highly reliable organizations as having an extreme level of interdependence among individuals. Grabowski and Roberts (1997) further describe this interdependence by using the example of nuclear power plants in which the system is "only as strong as its weakest link" (Grabowski & Roberts, 1997, p.154).

Redundancy.

Redundancy is one concept frequently cited as present in High Reliability Organizations (HROs). Redundancy could be described as either an individual, a work group, or an organization level concept. Redundancy was used by organization leaders through system design and by individuals working in teams or via automation. Multiple checks of critical steps were incorporated in the process of HROs to reduce the occurrence of an error (Roberts, 1990b). Task components were broken down and checked by individual team members. Team members worked together to evaluate the entire process or task components as a group (Roberts, 1990a). The team interaction is reflective of individual knowledge and action but also of individuals working effectively within the team to maintain the redundancy.

Centralized and Decentralized Decision Making.

Weick (1987) described decision making in a way that identified it as an individual and group level phenomenon. He stated that decentralized decision making

begins with strong centralization where individuals are socialized on a set of core values. Once this occurs individuals can improvise and act autonomously basing their decisions on the underlying values of the organization (Weick, 1987). Grabowski and Roberts (1997) also describe this phenomenon in their discussions of autonomy and interdependence. Decision making in HROs is often time compressed and therefore individuals work together to move a complex problem to the level with the greatest expertise. If a routine problem is encountered, it is handled at the lowest level of the organization. However unusual problems migrate through the organization to find the most knowledgeable individual to make the decision. These descriptions reflect individual, work group, and organizational phenomena with the organization level phenomena being established through leadership prioritization and value setting.

Trust/Communication/Teamwork/Group Mind.

Several researchers describe a group of HRO concepts that appear to be related. Weick (1987) described the unique knowledge and qualities of individual team members, and how this diversity within the team improved the team's functioning. With increased team complexity, the ability to increase the complexity of decision making was observed, thereby increasing reliability. In addition, he described trust between team members as an essential component for the group level phenomenon (Weick, 1987). Jeffcott, Pidgeion, Weymand, and Walls (2006) describe trust as expectations about other people but also about the organizational systems. Roberts (1990b) described the constant watchfulness that occurred among team

members within HROs. Although individuals learn specialized skills they are applied

within the context of the team performance.

In addition, the constant communication among team members to keep the

group informed of potential errors in the system is described by HROT developers

(Roberts, 1990a; Weick & Roberts, 1993). Weick and Roberts (1993) described the

concept of *group mind* or *mindfulness* as a group level phenomena resulting from the

product of individual actions.

Organizational Learning/Training.

Roberts (1990a) described the individual roles and continuous training of

nuclear power plant operators, air traffic controllers and Navy aircraft operators. The

high degree of individual accountability and responsibility placed on low level

employees in these organizations also was emphasized (Grabowski & Roberts, 1987).

Roberts (1990a; 1990b) described the role of leaders within the organization. During

her study using crew interviews on Navy aircraft carriers, she identified the continuity

of the management team as an important component of a culture of reliability

(Roberts, 1990b). Roberts (1990b) also suggested that management staff prioritized

the constant learning and training of staff in HROs. Organization learning seems to be

observed at the work group and organization level with the organization level

representing management commitment and support. Overall mitigation of complexity

and tight coupling were accomplished by individual training, a high degree of

specialization and integration among team members, and a stable management team

that ensured an organization with a foundation of continuous training and use of strategies to decrease risk.

Although the concepts described from the original research conducted within HROs seem to occur at multiple levels, the relationship between these levels is not explained. It is unclear if the organization level concepts or work group concepts are of greater importance or if they must occur simultaneously for a culture of safety to be evident.

Research Questions

The study purpose was to describe the impact of registered nurses' perceptions of work environment characteristics conceptualized as Work Unit Support and Organization Support on Patient Safety.

1. What are the direct effects of Work Unit Support and Organization Support on Patient Safety?

2. What effect does the indirect relationship of Organization Support on Work Unit Support have on Patient Safety?

Definition of Research Terms - Organization and Work Unit Support

A culture of safety is conceptualized by the current researcher as including organization level and work unit level characteristics. The purpose of the study is to discern the relationships between Organization Support and Work Unit Support on Patient Safety. Organization Support is measured by three scales including two (*Professional Development* and *Nursing Administration*) from the NDNQI adapted Nursing Work Index and one (*Autonomy*) derived from the NDNQI adapted Index of

Work Satisfaction. Work Unit Support is measured by four scales (*Task, Teamwork [Nurse-Nurse Interaction, Nurse-MD Interaction], Decision Making*) from the NDNQI adapted Index of Work Satisfaction, one scale (*Supportive Nursing Management*) from the NDNQI adapted Nursing Work Index, and one scale from the Work Contextual items (*Unit Quality of Care*) used in the NDNQI RN Survey and Job Satisfaction scales. Nurse sensitive outcomes are evaluated using four of the AHRQ Patient Safety Indicators (PSIs) including Decubitus Ulcer, Failure to Rescue, Infection Resulting from Medical Care, and Postoperative Pulmonary Embolism or Deep Vein Thrombosis (AHRQ, 2007, March).

<div align="center">Assumptions</div>

There were several basic assumptions related to the data used in the study. One assumption was that the NDNQI RN Survey data were collected as defined by the established standardized NDNQI processes. Consistency in the manner in which the data were collected across participating hospital sites reduces the risk of bias or introduction of systematic error. The PSI data were assumed to be collected using uniform coding methods from individual patient medical records. The PSIs were assumed to be reliable measures with the ability to make valid inferences from the reported incidence.

<div align="center">Summary</div>

The publication of *To Err is Human* (IOM, 1999), generated a sense of urgency among the health care community to improve the system and reduce adverse events associated with care. Although progress has been made since the original IOM

reports were released, some have expressed dismay at the continued occurrence of medical errors (Leape & Berwick, 2005). Clearly, the problem has not been an easy one to resolve.

HROT has been used as a framework to understand the workings of a complex system such as health care and the possible concepts that might mitigate risk and reduce errors. However, the research conducted to determine the concepts of HROT were done in non-health care settings. Therefore, additional study is needed to determine the translation of these concepts to health care settings and to determine the concepts associated with a health care culture of safety. A few instruments purported to measure a culture of safety have been developed. However, a large sample data set inclusive of these measures is not readily available, and research to compare the instrument scores with patient safety outcomes by institution has not been thoroughly evaluated. In this study, established measures of organization and work unit characteristics consistent with HROT and standard indicators developed to identify the incidence of health care related complications were used to examine the relationships between hospital characteristics and patient outcomes. Understanding hospital work unit and organization characteristics and their relationship with possibly preventable complications of care is important to achieve a significant improvement in patient safety. As health care systems become more complex, it is essential that health care leaders and policy makers understand where to allocate limited resources and what initiatives are important to reduce health care related errors and poor patient outcomes. Armed with a greater understanding of the relationships between a healthcare culture

of safety and the occurrence of preventable complications, leaders will be better

prepared to support the development of hospitals that are safer for patients.

Chapter II

Although overall awareness regarding medical errors and patient safety has

increased, there is still much to learn regarding the characteristics that reflect a health

care culture of safety and the development of safe clinical systems. The review of the

literature covers several areas beginning with what is known about adverse health care

related events and patient safety science. In addition, work done to develop measures

and indicators that accurately describe the functioning of a health care system is

discussed. Third, the relationships between organization level characteristics that

describe the culture of an institution and the measures used to describe health care

outcomes are reviewed. The gaps in our current understanding of these relationships

will be presented.

Adverse Events Associated with Health Care and Patient Safety Science

In 1999 the Institute of Medicine's (IOM) landmark report, titled *To Err is*

Human, opened the discussion regarding medical errors. The reported estimates of

44,000 but possibly as many as 98,000 deaths each year as a result of medical errors

were a significant wake up call to health care providers and the public they serve.

These estimates were extrapolated from two studies, one based on the percentage of

medical errors at a Utah hospital and the other in a New York hospital (IOM, 1999).

To Err is Human (1999) sent shock waves through the health care system that are still

reverberating and influencing how health care providers view and address medical

errors, also called adverse health events or health care related errors. The IOM has

continued its work in this area with the follow up reports *Crossing the Quality Chasm:*

A New Health System For The 21st Century (IOM, 2001), *Keeping Patient's Safe:*

Transforming The Work Environment Of Nurses (IOM, 2004), and most recently

Preventing Medication Errors (IOM, 2006).

Medical errors reported in the popular press also drew the public's attention to

the severity of the issue. In 1994, at the Dana Farber Institute in Boston, one patient

died and another suffered permanent injury after receiving an overdose of

chemotherapy (Allen, 2004).   In 2001, Josie King, an 18 month old recovering from a

burn injury, died as a result of a medical error at the Johns Hopkins Hospital in

Baltimore, Maryland (Ayd, 2004). These highly publicized cases led to a sense of

urgency among health care leaders to prevent such devastating consequences of

medical care. Since then a multitude of local and national quality based initiatives

have been launched. However, recent cases, such as the September 2006 event when

three infants cared for in an Indiana neonatal intensive care nursery died after

receiving the incorrect concentration of heparin, and a strikingly similar event in

California one year later led many to question the seeming lack of progress made in

preventing errors (Davies, 2006; ISMP, 2007).

Factors Thought to Contribute to Adverse Health Care Related Events

The IOM reports and the resulting public discussions of adverse events spurred

interest in defining what constitutes a medical error and the contributory factors.

Errors are defined as "the failure of a planned action to be completed as intended (e.g.,

error of execution) or the use of a wrong plan to achieve an aim (e.g., error of

planning)" (IOM, 1999, p. 54). In this definition there is a distinction made between

the error and the intention. Reason (1990) suggested errors were not the results of

unintentional behaviors but rather result from actions that are inaccurately

implemented or do not lead to the intended outcome (Reason, 1990). Errors also have

been categorized in two ways: latent and active errors (IOM, 1999). Active errors

refer to those that occur at the front-line of care also called the *sharp end*. Active

errors focus on the actions of individuals where latent errors are those that occur due

to design flaws, faulty management, or poorly structured organizations (IOM, 1999).

If a nurse fails to check a patient's allergy status and as a result administers a

medication to which that the patient is allergic, the error is an active error. Whereas if

a hospital uses different computer systems, one in the Emergency Department (ED)

and another on the medical-surgical units with no transfer of information between

systems the allergy information identified in the ED may not be accessible to the

medical/surgical clinician. If the lack of information results in the administration of a

contraindicated medication, the error is a latent error. Active errors tend to receive the

greatest attention but latent errors pose the greatest threat because they often remain in

the system even after active errors have been addressed (IOM, 1999).

Adverse Events Viewed as a Personal Failing

The perspective with which we have viewed adverse health events has evolved

over the last few decades as more is learned about patient safety science. Factors

related to the individual, the system, the work environment, and the culture of an

organization have all been used to explain and frame our understanding of why

medical errors occur.   Viewing an error as a personal failing or resulting from an

individual's poor performance is a long standing, though widely acknowledged ineffectual, way to view medical errors (Benner, 2001; IOM, 1999; Marx, 2003; Ottewill, 2003; Simpson, 2000). The *name, shame, and blame* approach focused on individual failings such as negligence, carelessness, forgetfulness, or recklessness. This framework implicated the individual as personally responsible for medical errors. Some described an expectation that health care providers make no mistakes and a failure to meet this standard was seen as a character flaw (Simpson, 2000). Unfortunately, this approach may have contributed to provider reluctance to report errors or *near misses*, defined as errors that do not reach the patient, and served to hide the problem rather than provide opportunities to improve (Benner, 2001).

Nursing, consistent with other disciplines, focused on the individual as the source of errors. For example, during the early 1980's, the journal *Nursing* had a regular monthly column addressing the issue of medication errors. The articles included strategies to prevent errors, some of which might be interpreted as warnings or admonishments to nurses of their personal responsibility when administering medications (Cohen, 1979; Cohen, 1980). Implicit in these writings was a message consistent with the beliefs of the time: good nurses do not make errors. Although some authors identified system or processes, such as unclear orders and miscommunication, as contributing to errors, the overall message tended to emphasize the need for caregiver diligence to prevent errors.

Provider education was the strategy often used to prevent errors. By learning key facts associated with care, it was believed mistakes could be prevented. For

example, learning to calculate medication doses accurately and memorizing specific information about medications were cited as strategies to prevent errors (Cohen, 1980). It seemed only memory and extreme care could ensure patient safety. A problem with these strategies was their narrow focus on active errors without consideration of the latent errors that remained in the system (IOM, 1999).

Consistent with the attention on the individual practitioner as responsible for errors, the response to error events generally was aimed at the individual. The removal of *bad* practitioners was believed to be a way in which to eliminate errors, therefore, it was not uncommon for health care providers involved in an error to be fired from their jobs. In the Dana Farber chemotherapy errors, which occurred in 1994, two of the involved physicians were dismissed, and at least 15 nurses received reprimands from the Massachusetts Board of Registration in Nursing (Watson, 2003). Even with the movement away from a culture of blame many, and particularly the public, may still frame errors as an individual failing. An article published 10 years after the Dana Farber event highlighted the improvements made in patient safety since the devastating chemotherapy errors. Allen (2004) wrote, "10 years ago, one patient died and another suffered irreversible heart damage at the Dana-Farber because the staff wasn't cautious enough…..none of the roughly 25 medical staff involved in their care noticed until weeks later. 'It was a pretty public humiliation,' recalled Dana-Farber nurse Judith Prisby, expressing a view held by many staff members at the time." (Allen, 2004). These statements reflect an ongoing blame mentality.

Possibly the tendency to assign blame for the negative consequences of health care errors is rooted in Western philosophy (Benner 2001; Reason, 1990). Reason (1990) suggested the manner in which we frame medical errors was based on our practice tradition in healthcare and Benner further described our history of *competitive individualism* as contributing to the blame culture. Benner proposed that competitive individualism is consistent with Kantian philosophy. Immanuel Kant linked moral agency to the intent of the individual and emphasized decisions and choices rather than action, communication, and relationships. This competitive individualistic approach, Benner maintained, is not consistent with a culture of safety and ignores the importance of shared learning that fosters continual improvement in a practice community. Benner suggested an Aristotelian philosophical approach that emphasized cooperation and ongoing experiential learning of the practice community as a preferred way to view adverse health care events. This approach encourages system improvement and prevention of repeated errors rather than correction of an individual's alleged character flaw (Benner; Simpson, 2000).

Recently, some nursing leaders have suggested that although a culture of blame is undesirable, an environment without accountability is not beneficial either. (Beyea, 2004; Marx, 2003;Yates, Hochman, Sayles, & Stockmeier, 2004) As an alternative a "just culture" has been suggested where the actions of the individual are evaluated based on specific criteria. If policies or known safety practices are violated, the practitioner is held accountable and may be reprimanded or disciplined for the action. However, some may argue this approach still fails to take into account other

factors that might have contributed to a health care practitioner's non-adherence to known safety protocols.

Adverse Events Viewed as a System or Process Failure

More recently, the study of human factors, systems, processes and organizational culture have been identified as influencing the incidence of health care related errors. Beginning in the late 1980's and into the 1990's systems analysis has surfaced as an important component of error evaluation. Although framing errors within a systems perspective has been described in different ways and by differing terms and theories, each approach has its roots in General Systems Theory (GST) as originally described by Ludwig von Bertalanffy (1968). Normal Accident Theory, Complex Adaptive Systems Theory, and High Reliability Organization Theory are all drawn from GST and have been used to evaluate medical errors. Total Quality Management (TQM), another framework based on systems theory, has been used to explain and reduce the risk of errors. W. Edwards Deming first developed and introduced TQM to Japanese industry (The W. Edwards Deming Institute[®], n.d.). The model is based on a systems approach with the intent of decreasing defects in manufacturing. TQM focused on eliminating latent errors in a system and the approach was adopted by some American high-risk industries such as aviation before it was suggested as a method to improve health care processes (Deming, 1986). These industries used a non-punitive approach and focused on understanding the built-in weakness within systems that lead to errors.

The framework used to describe adverse health care related events in *To Err is Human* (1999) was based on the work of James Reason who studied accidents to determine the role systems and human actions have in contributing to errors (IOM,1999).   Reason purported that humans make errors for a variety of reasons and inadequate systems can compound the error (Reason, 1990). Health care and high technology industries both of which are extremely complex are thought to be more prone to error (Perrow, 1984). Complex systems are described as having tightly tied components where there is little slack or room for error (Perrow, 1984). Complex systems also are characterized by their unpredictable response to error. In such systems a failure in one part of the system is thought to affect other parts of the system in unanticipated ways (IOM, 1999). These concepts are congruent with Complex Adaptive Systems theory where small changes are described as having the ability to lead to large, non-linear, unpredictable outcomes (Ebright, Patterson & Render, 2002; Plesk, 2001). The strategies used to reduce errors in other high risk systems and adopted for use in health care systems include: encouragement of open and non-punitive error reporting, intense evaluation of near misses, analysis of processes, and continual improvement of high risk or new processes. System based frameworks each focuses on analyses of processes to identify the weak points in the system where an error is more likely to occur.

Adverse Events and the Work Environment

Other factors cited as contributing to medical errors are associated with the work environment. Although these factors might be categorized as systems issues,

they differ somewhat from the discussions above because work environment factors focus on management and leadership decisions rather than specific processes that contribute to error. Many latent factors associated with the work environment have been linked to an increase in adverse health care events (IOM, 2004). Inadequate staffing, staff turnover, redesigned work, health care worker fatigue, increased patient acuity, and rapid turnover of patients all have been suggested as factors contributing to adverse health events (Gaba & Howard, 2002; IOM, 2004). Nursing leaders particularly have been interested in the work environment and its impact on patient outcomes. During the 1990's, changes in healthcare reimbursement such as prospective payment by Diagnostic Related Group (DRG) increased the financial pressure on many health care institutions. As a result, a number of organizations restructured their nursing care models with the goal of reducing costs (Buerhaus, 1994a). These efforts often led to reductions in nurse staffing and particularly in registered nurse staffing (Buerhaus, 1994b, 1995; Reardon & Reardon, 1995). Nursing administrators were not prepared to argue against such changes because little research had been done to evaluate the impact of nurse staffing on patient outcomes.

Concerns also were raised that the changes made in staffing and the results of restructuring efforts contributed to a growing dissatisfaction among nurses and an overall deterioration in the work climate. Aiken et al. (2001) evaluated the reported satisfaction of 43,000 nurses from over 700 hospitals across five countries. The researchers found that fewer than half of the nurses in each country agreed that management was responsive to their concerns, provided opportunity for nurses to

participate in decision making, or recognized their contribution to inpatient care. Only

30 to 40% of nurses reported adequate staffing to provide high quality care (Aiken et

al.). Over 40 % of U.S. nurses reported dissatisfaction with their job and had high

scores compared to norms on a measure of burnout (Aiken et al.). Although the

researchers did not evaluate the relationship between these variables and rates of

adverse patient outcomes, they did include survey questions related to the occurrence

of outcomes thought to be linked to poor quality care. U.S. nurses reported the

following indicators were "not infrequent": medication errors (15.7%), nosocomial

infections (34.7%), and patient falls with injury (20.4%) (Aiken et al.).

Interest in discerning the relationships between the work environment and

patient outcomes has led to an increasing number of studies with this focus conducted

by nurse researchers. Often these studies included work environment factors such as

staffing, perceived satisfaction, and nursing's control over practice and linked these

variables with patient outcomes identified through publicly available discharge data.

Kovner and Gergen (1998) studied the association between nurse staffing and adverse

events after major surgery. They found an inverse relationship between registered

nurse hours per patient day (RNHPPD) and the occurrence of urinary tract infection

(UTI), pneumonia, thrombosis, and pulmonary compromise (Kovner & Gergen,

1998). Consistent findings were reported in two other studies that evaluated hours of

care provided by registered nurses and other nursing care providers with adverse

outcomes such as UTI and *failure to rescue* defined as a death from upper

gastrointestinal bleeding, cardiac arrest, deep venous thrombosis, pneumonia, or sepsis

(Kovner, Jones, Zhan, Gergen, & Basu, 2002; Needleman, Buerhaus, Mattke, Stewart, & Zelevinsky, 2002). The researchers reported an inverse relationship between RNHPPD and the rate of these complications (Kovner et al., 2002; Needleman et al., 2002). Aiken, Sloane, Lake, Sochalski, and Weber (1999) evaluated work environment factors such as staffing, nurse perceptions of control over practice, and organizational support with mortality of hospitalized AIDS patients. They found that higher nurse to patient ratios reduced the odds of dying by one-half. In another study conducted by Aiken, Clark, Sloane, Sochalski, and Silber (2002) nurse staffing was linked with the quality of patient care. The results of the study suggested that patients in hospitals with the highest patient to nurse ratio (eight patients per nurse) had a 31% greater chance of dying than those in hospitals with four patients per nurse. On a national scale staffing differences of this magnitude could result in as many as 20,000 unnecessary deaths each year (Aiken et al., 2002).

Unruh (2003) conducted a study in Pennsylvania hospitals to compare nurse staffing and the incidence of specific patient outcomes. She found that those hospitals staffed with a greater proportion of licensed nurses had significantly lower rates of decubitus ulcers and pneumonia. Also, hospitals with higher numbers of licensed nurses per patient had significantly lower incidences of atelectasis, decubitus ulcers, falls and UTI (Unruh). Conversely, she found that those hospitals with more licensed nurses per patient had significantly higher rates of pneumonia (Unruh). In a study conducted by Cho, Ketefian, Barkauskas, and Smith (2003) mixed results were reported when comparing nurse staffing with adverse patient outcomes. Cho et al.

(2003) found an increase in RNHHPD and an increased RN proportion of total nursing care hours were related inversely to the rate of pneumonia. However, they reported an increase in nursing hours per patient day was associated with a higher probability of a decubitus ulcer. In 2003 an evidence report was published that synthesized results from a total of 26 studies on the relationship between nurse staffing and adverse outcomes (Hickam et al., 2003). From this work the researchers concluded that lower nurse staffing levels were associated with higher incidence of negative outcomes (Hickam et al.).

Adverse Events and Organizational Culture

The culture of an organization also has been identified as a factor that contributes to the occurrence of errors. Recently many patient safety initiatives have been aimed at creating a *culture of safety*. Many of the concepts associated with a culture of safety have been included in the discussion above. For example, patient safety established as a priority by senior leadership, a non-punitive environment with open reporting of errors, open communication, organization learning, vigilance for system failures, and use of systematic problem solving are commonly identified components of a culture of safety (Beyea, 2004; Paine, Baker, Rosenstein, & Pronovost, 2004; Weingart, Farbstein, Davis, & Phillips, 2004).

The IOM report, *Keeping Patient Safe* (IOM, 2004) also addressed the importance of a culture of safety for nursing practice and suggested High Reliability Organization Theory (HROT) be used to frame this cultural transformation. Consistent with HROT, the IOM report authors suggested that a culture of safety

stems from leadership's commitment to an empowered workforce where active

vigilance is rewarded. Open communication and non-hierarchical decision making

were identified as important factors in the development of a system where constant

watchfulness for potential failures is valued (IOM). Errors are more likely to occur in

systems where individuals are criticized or ignored when they speak up (IOM).

Kerfoot (2004) suggested that organizations often work to silence individuals and it is

a challenge for leaders to attend to *weak signals* and ensure important safety concerns

are not ignored. Recently The Joint Commission released a *Sentinel Event Alert*

related to intimidating and disruptive behaviors in healthcare organizations citing

these behaviors as contributing to medical errors (The Joint Commission, 2008). This

publication outlined organization requirements for addressing disruptive and

inappropriate behaviors as well as recommended actions that should be taken to

eliminate such behaviors and promote a culture of safety.

The use of *constrained improvisation* also was identified as inherent in a

culture of safety. Constrained improvisation refers to the practice of bending the rules,

based on knowledge of organization values and safety practices, in the interest of

patient safety (IOM, 2004). This concept also suggests a high degree of collaboration

among coworkers to develop solutions as issues arise. The development of a learning

organization is another concept consistent with a culture of safety (IOM). Continual

learning focused on the skills required to detect failures before they occur was a key

component of this concept. Leadership support for this type of learning organization

includes support for in-depth analysis used to identify the root causes of errors and

near misses (IOM). Non-punitive error reporting with responses to errors that are fair

and just also was identified as part of a culture of safety. Others have described

similar components as essential to a culture of safety (Callahan & Ruchlin, 2003;

Jeffs, Law, & Baker, 2007; Luria, Muething, Schoettker, & Kotagal, 2006; McKeon,

Oswaks, Cunningham, 2006; Patterson, 2007; Singer et al., 2003).

Although the patient safety experts seem to agree that a culture of safety leads

to better patient outcomes and a reduction of errors, this relationship has been difficult

to quantify. Instruments purported to measure a culture of safety have been developed

but only a few studies have examined the link between these measures and patient

outcomes. Vogus and Sutcliffe (2007) developed a safety culture scale and reported

higher scores were related inversely to medication errors and patient falls reported via

an incident report system. Zhohar, Livne, Tenne-Gazit, Admi, and Donchin (2007)

evaluated a nursing climate scale and the adherence to specific patient safety practices.

Patient safety practices were defined as documentation of appropriate medication

storage and maintenance of resuscitation equipment. They concluded that the scores

on the climate scale predicted scores on patient safety practices and suggested these

findings identify units where adverse events are more likely to occur (Zohar, et al.,

2007)

There are many ways that adverse health events can be framed. Although

viewing errors as the responsibility of an individual is clearly ineffectual many of the

more recent perspectives do not address all of the concepts included in a culture of

safety model. General Systems Theory gives a more inclusive view of adverse health

care events, when compared to the individual perspective, through its inclusion of concepts such as latent errors and its analysis of weaknesses in the system that contribute to adverse health events. However, the Systems Theory models do not predict errors or identify how errors might be prevented. High Reliability Organization Theory seems to be the most useful framework as described in Chapter I. HROT includes concepts associated with the individual, system, work environment and organizational culture thereby offers a comprehensive perspective of adverse health events. The construct of a culture of safety is complex and contains many concepts. The relationships between the concepts and the impact of individual concepts within the construct are still unclear. Further research is needed to evaluate the health care culture of safety construct and the occurrence of adverse health events.

Measurement of Adverse Health Events

Hospital System Quality Measures

Although the manner in which adverse events are viewed continues to evolve, the development of meaningful measures that inform health care leaders, consumers, and policy makers regarding quality of care has been equally challenging. Many professional and independent groups have developed measures thought to be indicative of the quality and safety of an organization. The Centers for Medicare and Medicaid Services (CMS) developed a set of hospital quality measures that also were adopted as core measures by The Joint Commission (CMS, n.d.; The Joint Commission, n.d.). Institutions caring for Medicare patients and those organizations that are Joint Commission accredited are required to submit data on these measures

with the organization's performance publicly available through CMS's web-based

Hospital Compare program (CMS, n.d.). The Institute for Healthcare Improvement

(IHI) developed a set of voluntary evidenced based bundles to prevent specific adverse

complications through their *100k Lives* and *5 Million Lives from Harm* campaigns

(IHI, n.d.). The National Quality Forum published a set of 30 voluntary consensus

standards called *safe practices* in 2003 (NQF, n.d.). These measures have been

adopted by the employer driven initiative, the Leapfrog Group. Leapfrog, also a

voluntary program, established a set of four *leaps* that include the 30 NQF endorsed

safety practices. Comparative information and institution specific progress in

achieving the safety practices are available on their website (Leapfrog Group, n.d.).

Nursing Care Quality Measures - National Database of Nursing Quality Indicators®

Nurse leaders also have participated in efforts to develop meaningful measures,

often referred to as nurse sensitive measures. The American Nurses Association

(ANA) embarked on the development of a Nursing Care Report Card project in 1994

(Gallagher & Rowell, 2003). Indicators were selected because of their sensitivity to

nursing care, as well as, their accessibility (Gallagher & Rowell, 2003). In 1998, the

National Database of Nursing Quality Indicators® (NDNQI®) was established with

indicators conceptually based on the structure, process, and outcome model proposed

by Avedis Donabedian (Dunton, Gajewski, Taunton, & Moore, 2004; Gallagher &

Rowell, 2003; Jennings, Loan, DePaul, Brosch & Hildreth, 2001). Organizations can

choose from a list of indicators available for data submission. The indicators include:

Patient Falls, Patient Falls with Injury, Pressure Ulcers (Total rate, Hospital acquired

rate, Unit acquired rate), Nursing Staff Skill Mix, Nursing Hours per Patient Day, RN

Surveys (Job satisfaction, Practice environment scale), RN Education and

Certification, Pediatric Pain Assessment Cycle, Pediatric Peripheral IV Infiltration,

Psychiatric Assault rate, Psychiatric Assault Injury rate, Restraint prevalence, Nursing

Turnover, and Nosocomial Infections (Ventilator Associated Pneumonia (VAP),

Catheter related Urinary Tract Infection (CAUTI), Catheter related Blood Stream

Infection (CLABSI) (NDNQI, 2006). In addition, Patient Days are collected to

identify nurse staffing demand and the time period over which outcomes occur.

Standardization of Language Describing Adverse Events

The work done to establish quality measures also served to standardize

reporting across institutions. Further efforts were made to standardize the language

and classifications of all adverse health care events. Taxonomies and classification

systems were developed for medication events, as well as, other adverse events or

errors to facilitate comparison across institutions. The National Coordinating Council

for Medication Error Reporting (NCC-MERP), in collaboration with the Food and

Drug Administration (FDA), established a uniform definition of a medication error

and developed taxonomy to classify medication related events. The FDA also adopted

the NCC-MERP taxonomy as their method of classifying and reporting post-

marketing medication error events (NCC-MERP, 2005). For non-medication event

reporting the National Quality Forum (NQF) has endorsed The Joint Commission's

Patient Safety Event Taxonomy (NQF, 2006).

Barriers to Data Collection and Reporting

The development of indicators that can be used to describe the safety of care

within an institution has been challenging and mandated reporting has met resistance.

Certainly the variable manner in which care is documented and adverse events are

reported has made the process more difficult. Many organizations do not have the

resources or information systems to extract data efficiently for reporting. Of particular

concern is the growing number of entities interested in receiving data. Many

organizations must prioritize their participation in quality initiatives due to the

resource requirements of data reporting.   Collection of event data often requires

medical record review, a time intensive and burdensome process. Further, reporting of

adverse events is known to be low compared to the actual incidence (Olsen et al.,

2007). Rozich, Haraden and Resar (2003) conducted a study using trigger tool

methodology to identify adverse drug events. Of the 274 events identified using the

trigger tool only 1.8% were reported as incidents (Rozich, 2003).

Quality measures that focus on processes of care can be particularly difficult to

capture. Often the contextual workings of a process are not available in medical

records or other documents. Time consuming methods often are required to obtain

detailed process information and therefore result in the need for additional resources to

perform these analyses.

Even though a recommendation from the IOM report *To Err is Human*

specified the need for standardized mandatory reporting of health care related errors,

progress on this initiative has been slow. Some of the reluctance stems from concerns

associated with the comparability of the data across institutions (e.g. accuracy of administrative data and ability to account for case mix differences). Other concerns are related to how the data will be used. Although the emphasis within the patient safety literature has moved toward system analysis rather than a focus on individual clinicians, public reporting can be used to make judgments about providers or institutions. Some have suggested open reporting will make health care providers and institutions more vulnerable to litigation and others have suggested that the shame of disclosure prevents open reporting of adverse health events (Leape, 1994). In states where quality improvement data are discoverable and can be admissible as evidence in legal proceedings, the fear of reporting is significant.

Fear associated with the consequences of reporting performance on quality of care measures and the use of data to compare organizations is still a concern for many health care leaders. Although legislation meant to offer protection to reporting agencies was signed into law, the rules and regulations are not finalized making it difficult for many institutions to proceed with transparent sharing of information (Liang, Rutherford, & Hamman, 2007). In July, 2005 President Bush signed into law the Patient Safety and Quality Improvement Act (PSQIA) of 2005, PL 109-41. The PSQIA is meant to provide legal protection for those reporting patient safety data and was designed to encourage voluntary reporting of medical errors. The act allows health care providers to report data to Patient Safety Organizations (PSOs) certified through the Agency for Healthcare Research and Quality (AHRQ). The data, called patient safety work product (PSWP), are defined as non-discoverable by those

involved in civil lawsuits and in most administrative or criminal proceedings. The Office for Civil Rights and Health Care Privacy (OCR) will develop and operate the enforcement program for the PSQIA. AHRQ gathered information to determine implementation rules and regulations for development of the PSOs (Feder, 2006). The proposed rule was released in February, 2008 with a comment period ending April 14, 2008 (Patient Safety and Quality Improvement Proposed Rule, 2008). In November, 2008 the final rule was published and will become effective January 19, 2009 (Patient Safety and Quality Improvement Final Rule, 2008).

State Legislated Initiatives

Legislators also have become involved in selecting quality indicators for public reporting. Many states have passed legislation mandating reporting of specific adverse outcomes or events. As of 2005, 24 states had instituted reporting of adverse events (23 mandatory systems and one voluntary system) with some states also including near misses as part of their reporting requirements (Rosenthal & Booth, 2005). For example, Minnesota, mandated reporting of significant adverse health events and published their error reports including organization specific performance (MDH, 2008).

Administrative Data as a Source of Quality Measures

Because clinical care is not documented in a uniform manner and data are often difficult to retrieve, some health care researchers have turned to alternate data sources when developing quality and safety measures. Administrative data, or claims data, are one source used to develop standardized quality measures. Administrative

data are based on standardized codes with the data generated for purpose of health care service reimbursement. Using administrative data to identify possible adverse patient outcomes increased during the 1990's although previously these data have been used to identify variations in clinical practice and in outcomes research (Zhan & Miller, 2003a). Advantages of using administrative data are its accessibility, electronic format, low cost, and large population base (Zhan & Miller, 2003a). The data are reported as International Classification of Diseases, 9th revision, Clinical Modification (ICD-9-CM) codes, procedure codes, and some demographic information. These data are submitted by provider organizations to third party payers as claims for payment and often to state and federal agencies. AHRQ Healthcare Cost and Utilization Project (HCUP) includes discharge abstract data from over 30 participating states and compiles the data into a research database (Zhan & Miller, 2003a).

Administrative data are not without limitations. When used for quality or patient safety research it is important to recognize that only events for which there are corresponding ICD-9-CM codes will be available to the researcher. The ICD-9-CM codes include a set of complication codes, as well as E codes that are used specifically to record an injury. However, these codes do not cover all possible complications nor are the E codes used uniformly. Also, errors can occur in coding. An IOM study found 65.2% agreement on the principal diagnosis between the hospital report and secondary review conducted by the researchers (IOM, 1977). In addition there are

limited fields to document secondary diagnoses and in the past there was not an ability to document the timing or onset of a complication.

Some states have used a *present on admission* (POA) code in an attempt to clarify the onset of a diagnosis but the POA code has not been uniformly adopted. A recent study conducted by Houchens, Elixhauser and Romano (2008) suggested the validity of certain quality indicators is impacted without the use of a POA code. In October, 2007 CMS as part of their Hospital Acquired Conditions project required providers to begin using a code for *present on admission* on Medicare claims (CMS, 2007). The code is expected to assist in clarifying the onset of secondary diagnoses and will impact reimbursement (CMS, 2007). Costs resulting from the treatment of defined preventable complications during an inpatient stay will not be reimbursed beginning in fiscal year 2009 (CMS Regulation 1533-FC, 2007). Some of the preventable complications targeted by CMS are consistent with the AHRQ PSIs. CMS has identified Catheter Associated Urinary Tract Infection, Pressure Ulcer, Serious Preventable Events (Blood Incompatibility, Object Left in During Surgery, Air Embolus), Surgical Site Infection, and Hospital Acquired Injuries (Fractures, Dislocations, Intracranial Injury, Crushing Injuries, Burns) as no longer reimbursable when occurring during a hospital stay. Additional conditions under consideration for inclusion in the fiscal year 2009 list include Vascular Catheter Associated Infections, Pulmonary Embolus/Deep Vein Thrombosis, Ventilator Associated Pneumonia, Staphlococcus Aureus Septicemia, Closdridium Difficile Associated Disease, Methicillin Resistant Staphlococcus Aureus, and Wrong Site/Wrong Person Surgery.

The early work using administrative data to screen for potentially preventable complications resulted in the development of the Complication Screening Program (CSP) (Iezzoni, 1997; Iezzonni, Daley, Heeren, Foley, Fisher, et al., 1994; Iezzonni, Daley, Heeren, Foley, Hughes, et al., 1994). The CSP, a computerized method of identifying potentially preventable complications using ICD-9-CM codes contained within discharge abstracts, was developed to determine if administrative data could provide useful information on quality of care within hospitals (Lawthers et al., 2000; Weingart et al., 2000). During the development of the CSP, algorithms using specific inclusion and exclusion criteria were established to focus the screen on cases more likely to represent adverse patient outcomes related to quality of care issues (Lawthers et al; Weingart et al.). Lawthers et al. conducted a validation study of the CSP and evaluated the positive predictive value (PPV) of each indicator, defined as the probability that a medical record review supported the coding of the complication flagged by the CSP system. They found that the PPV varied across complication type and the specific complication with the surgical complications having the highest PPV. Postoperative infection (97%) had the highest PPV among surgical cases. A total of ten surgical case screens had a PPV of at least 88%. However, only one medical screen, post-procedural hemorrhage or hematoma, appeared useful with a PPV of 90.6% (Lawthers et al.). These findings led Lawthers et al. to conclude that selected CSP screens could be used as a screening or case finding tool to conduct further quality review.

AHRQ Patient Safety Indicators

With the publication of the IOM reports the interest in developing a system to identify complications related to medical care accelerated. AHRQ researchers used CSP as well as other sources to identify complications believed to be related to health care quality. From this work 13 measures were identified. AHRQ then contracted with the University of California San Francisco and Stanford to continue the safety indicator development process. AHRQ Patient Safety Indicators (PSIs) were first published in 2002 based on the work done by these researchers (Miller, Elixhauser, Zhan, & Meyer, 2001).

Since the initial studies conducted to develop and evaluate the use of the AHRQ PSIs a number of researchers have used the indicators to examine relationships between hospital level characteristics and PSI rates. Zhan & Miller (2003b) studied the length of stay, charges, and mortality associated with PSIs using over 7 million hospital discharge abstracts. They reported postoperative sepsis as having the greatest impact on length of stay, charges and mortality. Zhan, Smith, and Stryer (2006) evaluated the PSI *Accidental Iatrogenic Pneumothorax* and identified the patient level characteristics associated with the highest incidence. The researchers suggested the PSI could assist with determining patients at greatest risk for this complication. Thornlow and Stukenborg (2006) evaluated five categories of PSIs using three methods of risk adjustment. The researchers found an inconsistent relationship between hospital ownership and teaching status with PSI rates. More recently, Vartak, Ward, and Vaughn (2008) compared PSI rates between teaching and non-teaching

hospitals and evaluated the relation of hospital and patient factors on PSI rates. They reported an inconsistent relationship between hospital teaching status and PSI rates and concluded that patient characteristics associated with hospital teaching status mediate the relationship between teaching status and PSI rates. Li, Glance, Cai and Mukamel (2008) studied the relationship between specific PSI postoperative complications for patients with and without mental disorders undergoing coronary artery bypass graft. They found a statistically significant increase in Decubitus Ulcer, Postoperative Hip Fracture and anesthesia complications for the patients with mental disorders.

Grobman, Feinglass and Murthy (2006) evaluated the obstetric PSI in over 175,000 deliveries in 142 Illinois hospitals. The researchers concluded that the frequency of obstetric trauma was associated with patient-specific and hospital level factors and that ICD-9-CM coding was inadequate to find preventable obstetric complications. Simonson, Ahern, and Hendryx (2007) used the obstetric PSIs to evaluate the complication rates for patients cared for by Certified Registered Nurse Anesthetist or anesthesiologist or a combination of the two providers. They found no difference if the rates of complications between the staffing models (Simonson, 2007).

Polancich and Prosser (2006) studied the flagged cases of the PSI *Decubitus Ulcer* and compared these to findings from a medical record review. They found that some exclusion criteria, such as admission from a nursing home, were difficult to capture since these patients often entered the system through the emergency department. The researchers concluded that the *Decubitus Ulcer* PSI should not be

used to measure the "true rate" of hospital acquired decubitus ulcers. Another concern

regarding the Decubitus Ulcer PSI is related to those cases that are present on

admission. Without accurate use of a filter such as the present on admission (POS)

code there is the possibility of an inflated rate being attributed to the hospital.

Houchens, Elixhauser and Romano (2008) evaluated PSI rates in two states that have

used the POA code for over a decade although neither state has performed validation

studies to determine if the code is used accurately. The researchers reported that for

most PSIs the impact of the POA code was moderate and over half of the safety events

remained after deleting POA diagnoses. However, weaknesses were reported in the

Decubitus Ulcer, Deep Vein Thrombosis, and Hip Fracture indicators. When POA

cases were dropped from the analysis fewer than half of the cases were still considered

potential safety problems attributable to the patient's hospital stay.

Level of Analysis

Organization phenomena often are conceptualized at multiple levels.

Kozlowski and Klein (2000) described multilevel models as providing an integrated

concept of organizations that is more relevant than the single level models used in the

past. Chao (2000) identified cultural research as requiring multilevel analysis because

it describes individual and group level phenomena. Because organizations are

comprised of hierarchical nested systems, it would be difficult to find a single level

phenomena that is unaffected by other levels. The conceptual underpinnings of

multilevel research are based on General Systems Theory as described by von

Bertalanffy (1968) and are consistent with a world view in which the whole cannot be

reduced into its individual parts. Kozlowski and Klein suggested this multi-level perspective provides a greater understanding of the phenomena that occur across levels within organizations.

The research model for this study used multilevel concepts aggregated to the hospital level. This model was consistent with a mixed-determinant model described by Kozlowski and Klein (2000). A mixed-determinant model is defined as one in which multilevel determinants are used to evaluate a single level outcome. Measures of hospital level nurses' perceptions of the work environment were aggregated at the work unit level and organization level and evaluated for impact on occurrence of hospital level patient outcomes. A model was developed to illustrate the proposed relationship between the variables (Figure 2, page 51). Kozlowski and Klein (2000) also described the emergence of phenomena within organizations as either a *composition* or *compilation* processes. The current research was consistent with a composition model in which the phenomena are isomorphic or remain consistent as they move upward through an organization. In contrast, a compilation model describes a process where phenomena are distinctly different at varying levels of the organization. Therefore, for example, in the composition model autonomy, measured using individual data, is conceptualized as the same phenomena across levels of the organization. When evaluating a composition model the level at which concepts are measured must be taken into consideration and are used to evaluate the model. The model includes tenets regarding the variation in emergence. For example in the current research, individual data were conceptualized as representative of an emerging

shared property within a work group and organization. Kozlowski and Klein described shared unit properties as emerging from individuals shared perceptions. Also, Chao (2000) suggested that the effects of culture on organization performance generally are measured by using individual responses aggregated at a higher level (Chao, 2000).

When developing instruments intended to measure concepts at a particular group level, it is important to use the appropriate level referent during item generation. Verran, Mark and Lamb (1992) suggested creating items with group level referents rather than individual referents if the data will be aggregated at the group level. As noted previously the NDNQI RN Survey with Job Satisfaction scales was adapted to include such item revisions.

Recommendations for Further Study

The characteristics of organizations, work groups, and individuals are purported to have an impact on patient outcomes yet these relationships have not been elucidated clearly. Although a culture of safety has been viewed as essential to successful reduction of adverse patient care events, this relationship has not been established. Further analysis of the relationships between the culture of safety concepts and adverse patient outcomes is needed to improve our understanding of the nature of a health care culture of safety.

Preliminary studies evaluating such hospital level characteristics as teaching status and ownership on PSI rates have not found significant differences. However, other relationships may exist that have not been discerned. Evaluation of work

environment characteristics impacting nursing care and the rate of those PSIs conceptualized as sensitive to nursing care should be explored. Such research could lead to a better understanding of the concepts that comprise a health care culture of safety and the manner in which these concepts contribute to patient outcomes. In addition, knowledge gained from further study of the relationships between concepts of a culture of safety and patient outcomes could be used to inform health care leaders as they design systems where patients receive care.

Figure 2

Hypothesized relationship between variables
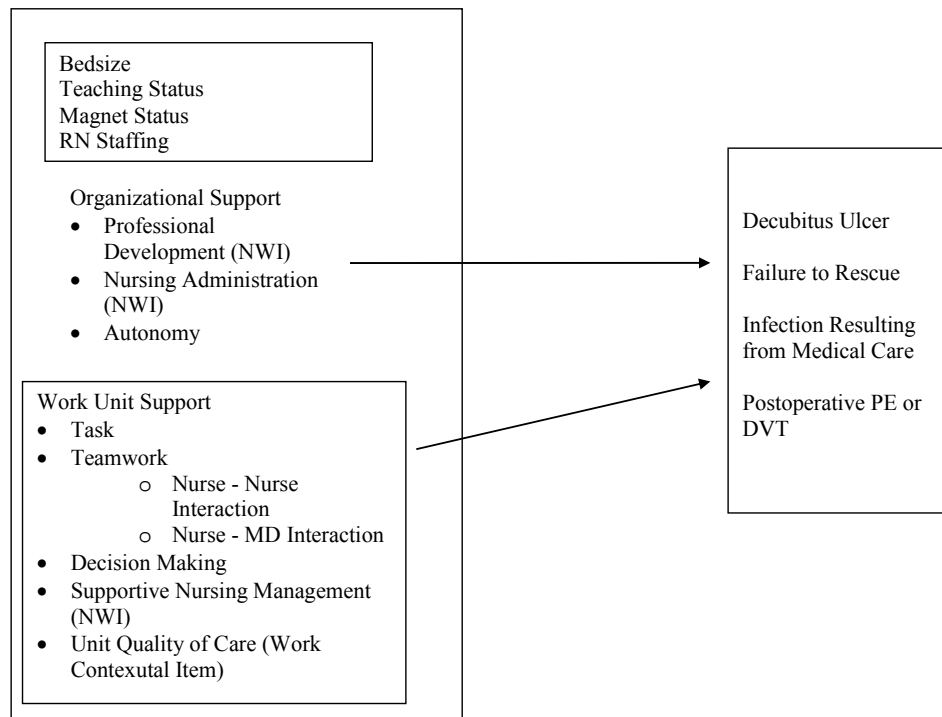
Chapter III

Chapter III describes the study design, research sample, setting, measures, description of the data procedures, as well as the manner in which the data were analyzed to explore the relationships specified in the research questions. Ethical considerations of the study are discussed.

Overview of Research Design

A secondary data analysis of cross-sectional data was conducted for this exploratory study using three existing data sets. A hypothesized multilevel causal model was used to guide the examination of relationships between Work Unit Support and Organization Support on hospital level Patient Safety. Work Unit Support and Organization Support were operationalized using the 2005 National Database for Nursing Quality Indicators® (NDNQI®) RN Survey with Job Satisfaction scales, and Patient Safety was operationalized using the 2005 National Inpatient Sample (NIS) and State Inpatient Databases (SID). Both the NIS and SID contain data needed to calculate the incidence of selected Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicators (PSIs).

Sample and Setting

A convenience sample of 97 hospitals that participated in the NDNQI® RN Survey with Job Satisfaction scales during 2005 were matched by a hospital specific identifier number with data from either the 2005 National Inpatient Sample (NIS), or State Inpatient Databases (SID). These 97 hospitals represented the final sample used in the study with individual hospitals as the unit of analysis. Databases were merged

using a unique hospital identifier, the American Hospital Association (AHA)

identification number, present in each of the data sets. The ability to match the

NDNQI hospitals was based on several factors but was dependent primarily on the

hospital including their AHA number when reporting administrative data. Some states

do not submit data to either NIS or SID and some do not include hospital identifiers.

Therefore, hospitals were excluded from the study if it was not possible to link the

institution with their NDNQI data using the AHA number. Also, the Patient Safety

Indicators (PSIs) are specific to adult medical/surgical practice so pediatric institutions

and psychiatric hospitals were eliminated. Federal hospitals do not submit data to the

NIS or SID. Therefore, hospitals from this category also were excluded.

The NIS data resulted in a match of 44 hospitals with the NDNQI data set.

Subsequently SID data were obtained to increase the sample size used in the study.

Like NIS data, the SID data include discharge abstract information. However, the data

are inclusive of all hospital discharges from the state, not a limited sample.

Hospital characteristics

The participant hospital's locations by state are listed in Table 2 (page 54)

and other defining hospital characteristics are summarized in Table 3 (page 54).

Hospitals located in 20 states were represented with the highest percentage of

hospitals located in New York (19.6%), California (12.4%), New Jersey (12.4%), and

Florida (9.3%).   Hospital Bedsize was categorized into one of six groups defined by

the number of licensed beds reported by the NDNQI participating hospitals.

Table 2
Hospital Location by State

State	n	% of total
Arkansas	1	1.0
Arizona	6	6.2
California	12	12.4
Colorado	3	3.1
Connecticut	1	1.0
Florida	9	9.3
Iowa	1	1.0
Illinois	3	3.1
Massachusetts	2	2.1
Maryland	8	8.2
Minnesota	2	2.1
Missouri	2	2.1
North Carolina	3	3.1
New Hampshire	1	1.0
New Jersey	12	12.4
New York	19	19.6
Rhode Island	1	1.0
Utah	9	9.3
Vermont	1	1.0
Wisconsin	1	1.0
Total N	97	100

Table 3
Hospital Characteristics

Characteristics		
Hospital Bed Size	n	% of total
0-99	14	14.5
100-199	21	21.6
200-299	18	18.6
300-399	17	17.5
400-499	10	10.3
>500	17	17.5
Magnet Status	n	%
Not Magnet	70	72.2
Designated magnet	27	27.8
Teaching Status	n	%
Academic	24	24.7
Teaching	28	28.9
Non-teaching	45	46.4

Sample hospitals ranged in size from the lowest category of 0-99 beds (14.5%) to the highest greater than 500 beds (17.5%) with the majority of hospitals (85.5%) having greater than 100 beds. Most hospitals were identified as non-teaching (48%), although academic (24.7%) and teaching (28.9%) hospitals were similar in number. The majority of hospitals had not received Magnet designation (72.2%).

Unit Types

NDNQI RN Survey data are derived from individual RN responses within hospitals. Only units with a 50% response rate or greater were included in the study based on Elliott's (2006) psychometric analysis of the NDNQI RN Survey Data aggregation. Elliott concluded this level of participation was representative of the work group. RN responses from seven different unit types were included: Medical, Surgical, Medical/Surgical, ICU, Stepdown, Rehabilitation, and Surgical Services. These specific unit types were used because the four AHRQ PSIs included in the study represent potential quality of care issues experienced by hospitalized medical and surgical patients. The unit types were chosen because the patient populations cared for on these units were consistent with the types of patients that may experience the selected PSIs. Other unit types such as pediatrics, psychiatric, and outpatient clinic areas were excluded.

Sample size

Kline (2005) suggests several methods that may be used with structural equation modeling to conduct a power analysis. A power analysis is used to determine the probability that the statistical results of the study will lead to a rejection of the null

hypothesis if the hypothesis is false (Rosenthal & Rosnow, 1991). One approach

discussed by Kline (2005) involves a model level analysis first developed by

MacCallum, Browne and Sugawara (1996). The researcher specifies the alpha,

degrees of freedom, desired power, and RMSEA. Using these parameters, an

adequate sample size is calculated based on the RMSEA and noncentral chi square.

Publicly available software was used to conduct these calculations (Preacher, &

Coffman, 2006) under the following specifications: power 80%, degrees of freedom

101, null RMSEA 0.01, and alternate RMSEA 0.08. The degrees of freedom were

determined by subtracting the degrees of freedom in the saturated model (136) from

the degrees of freedom in the hypothesized model (35). The parameters identified for

the null RMSEA (0.01) and alternate RMSEA (0.08) were chosen to specify a close fit

in the population (Kline, 2005). Based on these specifications a minimum sample size

of 67 was identified. Therefore, the final sample of 97 was considered adequate to

conduct the analysis of the data based on the hypothesized model.

Data Sources

NDNQI Data

The NDNQI resulted from the American Nurses Association's (ANA) Nursing

Report Card project and represents the only national U.S. nurse-sensitive database. In

1998, the NDNQI was established with indicators conceptually based on the structure,

process, and outcome model proposed by Avedis Donabedian (Dunton, Gajewski,

Taunton, & Moore, 2004; Gallagher & Rowell, 2003; Jennings, Loan, DePaul, Brosch

& Hildreth, 2001). Through the development of the NDNQI, the ANA intended to

meet two goals. The first goal was to provide data that could be used within institutions in quality improvement activities. The second goal was to establish a data resource for researchers studying specific relationships between nursing and patient outcomes.

The NDNQI RN Survey with Job Satisfaction Scales includes several instruments measuring perception of the work environment, quality of care, and other work contextual items. The scales include an NDNQI adaptation of selected items of the Nursing Work Index (Aiken & Patrician, 2000), the Index of Work Satisfaction (Stamps, 1997; Taunton et al., 2004), the NDNQI-adapted Job Enjoyment Scale (Brayfield, & Roth, 1951), and work contextual items, for example, situations on the last shift worked, unit quality of care, breaks (Rogers, Hwang, & Scott, 2004), and shift rotation.

NDNQI participation is voluntary and may be supported by nursing leaders for a variety of reasons such as comparison of performance on nursing care indicators with other institutions, preparation for or meeting benchmarking requirements set by the American Nurses Credentialing Center's (ANCC) Magnet Recognition Program[®], and evaluation of internal organizational trends and performance. An institution may participate in the entire survey including the NDNQI-Adapted Index of Work Satisfaction, NDNQI-Adapted Nursing Work Index, and the NDNQI-Adapted Job Enjoyment Scale or a short form of the survey.

NDNQI data quality is enhanced through the use of automated tools available to hospital site coordinators and NDNQI staff. Data are entered into a specific data

entry portion of the NDNQI web site by individuals that have demonstrated

knowledge regarding the specific NDNQI protocol. During data entry immediate

automated feedback identifies missing or anomalous data. In addition, automated data

reports are employed for error checking and data proofing.

NIS and SID Data

The NIS and SID are two of the databases included in the Healthcare Cost and

Utilization Project (HCUP) and were developed through a coordinated federal, state,

and industry effort sponsored by AHRQ.   HCUP databases are intended to inform

healthcare decision makers and to provide data for research. HCUP includes five

databases with the NIS and SID databases representing inpatient encounter

information. NIS and SID data include discharge abstract information from inpatient

hospital stays. Data submission is coordinated through individual state data

organizations that have partnered with AHRQ.   The NIS data set approximates a 20%

stratified sample of community hospitals.   The 2005 NIS data are supplied from 1054

hospitals across 37 states (AHRQ, 2007, June). The 2005 SID represents all inpatient

hospitalizations from 38 participating states and includes over 90 percent of U.S.

community hospital discharges. Twenty-six of the participating states allow inclusion

of hospital level identifiers. The NIS stratified sample is drawn from the SID. HCUP

data undergo basic quality data checks such as determining diagnosis code validity

and gender checks to evaluate diagnoses or procedures that are gender specific.

NIS or SID data sets were used in the AHRQ sponsored development of the

Patient Safety Indicators. PSI rates for individual hospitals are determined by using

statistical analyses that apply PSI algorithms including specific inclusion and exclusion criteria to the data. The PSIs were derived from billing codes and represent a set of potentially preventable complications associated with inpatient care. Four PSIs (Decubitus Ulcer, Failure to Rescue, Infection Resulting from Medical Care, Postoperative Pulmonary Embolus or Deep Vein Thrombosis) purported as sensitive to nursing care (Clarke, & Aiken, 2003; Hugonnet, Chevrolet, & Pettet, 2007; Morrison, 2006; Needleman, Buerhaus, Mattke, Stewart, & Zelevinsky, 2002; Seago, Williamson, & Atwood, 2006) were used in the study.

<div align="center">Measures</div>

<div align="center">*Exogenous Variables*</div>

The exogenous variables included in the research analysis model were derived from the NDNQI RN Survey with Job Satisfaction Scales data set. NDNQI first offered the annual RN Survey with Job Satisfaction Scales in 2002 after extensive psychometric evaluation. Taunton et al. (2004) reported the results of a pilot study and two additional studies conducted to evaluate the psychometric properties of the NDNQI adaptation of the Index of Work Satisfaction (IWS). The IWS, developed by Stamps (1997), included scales measuring various components associated with satisfaction or dissatisfaction in the work environment. With Dr. Stamps permission, NDNQI staff adapted the instrument to include group level rather than individual level referents, separated questions containing multiple concepts, and refined item wording. The pilot study to evaluate the adapted survey was conducted with 431 RNs from 10 NDNQI participating hospitals. Using exploratory principal components factor

analysis a six factor solution was identified as the most interpretable and each scale had an acceptable internal consistency with Cronbach's alpha scores ranging 0.71 to 0.87 (Taunton et al., 2004).

Following the initial pilot, Study I using the adapted IWS tool was conducted to re-evaluate the instrument's subscale structure and assess concurrent validity (Taunton et al., 2004). Ten NDNQI participating urban hospitals volunteered with 918 RNs responding to the survey. A marker item was added to each subscale and served as a representative of the items specific to the focus of the subscale. In addition, selected items from the Index on Job Satisfaction (Brayfield & Roth, 1951) were added to the survey to evaluate concurrent validity. Truncated principal components analysis with Varimax rotation was used to evaluate the underlying structure of the survey. A seven factor solution was determined to be the most interpretable and explained 53% of the variance for the IWS. Cronbach's alpha scores were identified as acceptable (> 0.7) for the scales of Task (0.77), Nurse-Physician Interaction (0.85), Decision Making (0.81), Autonomy (0.71), but not for Nurse-Nurse Interaction (0.66) and Professional Status (0.49). The reliability of the composite was reported as 0.9 using theta. Concurrent validity was supported using Brayfield and Roth's (1951) job enjoyment items which explained 58% of the variance of the NDNQI IWS.

Study II was conducted to confirm the dimensionality of the NDNQI-Adapted IWS, reexamine concurrent validity using the scores on the Index and Job Enjoyment, to evaluate scores on items with a group and an individual referent, and to determine

the feasibility of internet data collection (Taunton et al., 2004). Eleven NDNQI hospitals volunteered to participate in Study II and 2277 RNs completed the survey. Internal consistency reliability was acceptable except for the Professional Status subscale (0.63). Structural equation modeling (SEM) was used to reevaluate the factor structure. The statistical analyses supported the seven factor model of the IWS and the unidimensional structure for Job Enjoyment. Concurrent validity was also supported with the IWS subscales explaining 56% of the variance in Job Enjoyment.

The NDNQI adapted Nursing Work Index scales also have demonstrated internal consistency reliability. Cronbach's alpha scores were identified as acceptable (> 0.7) based on evaluation of the 2005 NDNQI RN Survey data for the Professional Development (0.876), Supportive Nursing Management (0.916), and Nursing Administration (0.874) scales.

The NDNQI Job Satisfaction scales were used to operationalize Organization Support and Work Unit Support. The response options for each item were represented by a six point Likert scale except for Quality of Care where a four point scale was used. Higher scores represent positive responses. Negatively worded items are reverse scored so that higher scores remain indicative of a positive response. The scales to define Organization Support and Work Unit Support were chosen based on their consistency with HROT concepts at the work group level or the organization leadership level.

Organization Support

Organization Support was measured using three scales including two (*Professional Development* and *Nursing Administration*) from the NDNQI adapted Nursing Work Index and one (*Autonomy*) derived from the NDNQI adapted Index of Work Satisfaction.

The *Professional Development* scale contains items consistent with the culture of safety concepts of *organization learning*, as well as, the concept of *deference to expertise* described by Weick and Sutcliffe (2001). The individual items reflect leadership and organization level support for these concepts. Organization learning was identified in the original research conducted in high reliability systems and refers to the support for training and continual learning of all team members (Roberts, 1990b). A complementary concept to organizational learning was described by Weick and Sutcliffe (2001) as deference to expertise and refers to a system where problems are not handled in a hierarchical manner but rather migrate through the system to the individual(s) with the greatest expertise.

The *Nursing Administration* scale is consistent with the concepts of *centralized decision making* with items reflective of hospital leadership support of these concepts. Centralized decision making was identified in the original studies of highly reliable systems as a strategy used by system leaders to set values and goals (Grabowski & Roberts, 1997; Weick, 1987).

The *Autonomy* scale describes the level of control nurses have over their work and is consistent with the culture of safety concepts of *autonomy* (Grabowski &

Roberts, 1997) and *decentralized decision making* (Weick, 1987). The items

contained within the scale reflect leadership's support of nurses' control over day-to-

day practice. Decentralized decision making is linked with centralized decision

making in that leaders determine the underlying values and goals for the system but

then support front line staff to make decentralized decisions based on their knowledge

of the overall goals and specialized training (Weick, 1987). These three scales were

suggested to be representative of the Organization Support for a culture of safety.

Work Unit Support

Work Unit Support was measured using four scales (*Task, Nurse-Nurse*

Interaction, Nurse-MD Interaction, Decision Making) from the NDNQI adapted Index

of Work Satisfaction, and one scale (*Supportive Nursing Management*) from the

NDNQI adapted Nursing Work Index. Additionally, and one Work Contextual item

specific to the quality of nursing care on the last shift worked (*Unit Quality of Care*)

also was used from the NDNQI RN Survey.

The *Task* scale is consistent with the concepts of *redundancy, deference to*

expertise (Weick & Sutcliffe, 2001) and *decentralized decision making*. The items

reflect work unit practices related to patient care. Deference to expertise and

decentralized decision making were described earlier. Redundancy refers to the use of

more than one method to check the accuracy of critical steps in high risk processes

(Roberts, 1990b).

Teamwork is a concept often cited as important to a culture of safety (Jeffcott,

Pidgeion, Weymand, & Walls, 2006; Roberts, 1990a; Roberts, 1990b; Weick &

Roberts, 1993). In the study, teamwork was measured using a composite of the *Nurse-Nurse Interaction* and *Nurse-MD Interaction* scales. Both scales include items reflective of the work group interactions and effectiveness. To create the variable a series of steps were taken. First a factor analysis was conducted using the Nurse-Nurse Interaction, Nurse-Physician Interaction, and cross-products of the Nurse-Nurse Interaction and Nurse Physician Interaction standardized scores for each hospital. Initial factor analysis using principal components analysis with Varimax rotation and extraction of items with eigenvalue ≥ 1.0 resulted in a one factor solution. By conducting a factor analysis using the three variables, an interpretation could be made regarding how well the hospital level scores group together and if the scores could be combined to reflect a composite hospital variable representing teamwork. The one factor solution explained 85.7% of the variance and was further supported by evaluating the Scree plot. Based on the factor analysis results it was determined the crossproducts of the Nurse-Nurse and Nurse-Physician Interaction scores would be used as the variable for Teamwork.

The *Decision Making* scale is consistent with the concepts of *reluctance to simplify* (Weick & Sutcliffe, 2001) and *trust*. Individual items reflect nurses' ability to impact important policy decisions on the work unit. Reluctance to simplify refers to the commitment of leaders and front line staff to obtain all the information needed to make accurate decisions (Weick & Sutcliffe). This approach may not offer the most expedient resolution but is thought to contribute to safer more efficacious decision making (Weick & Sutcliffe, 2001). Trust refers to individuals' expectations of others

but also of their trust in organizational systems (Jeffcott, Pidgeion, Weymand, & Walls, 2006).

The *Supportive Nursing Management* scale is consistent with the concepts of *centralized and decentralized decision making* and a *reluctance to simplify*. The items in this scale refer to the unit manager or work group leader characteristics.

One item identified as a work contextual item was included in the measure of work unit support for a culture of safety. The item addresses the *Unit Quality of Work* and was conceptualized for this research as a global composite of the culture of safety construct.

Other organization support variables were included in the model analysis including, Hospital Size, RN Staffing, Teaching Status, and Magnet Designation. These variables were derived from the NDNQI data set.

Endogenous Variables

The outcome of interest is hospital Patient Safety as manifested by four of the AHRQ PSIs including: *Decubitus Ulcer, Failure to Rescue, Selected Infections Due to Medical Care*, and *Postoperative Pulmonary Embolism or Deep Vein Thrombosis*. AHRQ PSIs were first published in 2002 based on the work done by Miller, Elixhauser, Zhan, and Meyer (2001) and are purported to represent potentially preventable iatrogenic events or complications associated with health care. A four phase process was used in the development of the PSI's. Initially, an evaluation of existing measures and a literature review related to International Classification of Diseases, 9th revision, Clinical Modification (ICD-9-CM) codes was conducted (Miller

et al.). Phase Two included a hand search of the ICD-9-CM codes identified in phase one as potentially suitable patient safety indicators. A subset of codes then was identified. During Phase three inclusion and exclusion criteria were developed for each ICD-9-CM code in the subset. Inclusion criteria were used to identify the type of discharge so that the appropriate risk pool of patients was included in the indicator. Exclusion criteria were used to remove PSI events deemed non-preventable or unrelated to a medical error (Miller et al.). In the development of the inclusion criteria the researchers also decided if the ICD-9-CM code was only to be included in the indicator algorithm if it was listed as a secondary diagnosis. Because secondary diagnoses generally represent a condition that has occurred during the hospital stay, the researchers took this conservative approach and excluded primary diagnoses that are most often present on admission.

Phase Four involved testing of the PSI algorithms using HCUP data from the State of New York (Miller et al., 2001). The researchers reported higher length of stay and greater mortality rates for discharges with PSI events. Also, PSI events were associated with increasing age, male gender, white ethnicity, Medicare and private pay insurance, not-for profit hospital, major teaching status, higher nurse expertise, urban location, higher number of hospital beds, and institutions using a higher number of diagnosis codes (Miller et al.). However, based on multivariate regression analysis they did not find a substantial predictive ability of these variables, which the researchers attributed to the many individual and hospital level factors not included in the administrative data set that may better predict the occurrence of PSIs.

Romano et al. (2003) refined the PSIs by adding codes to improve the identification of potential safety events. Content validity of the indicators was evaluated using multi-disciplinary panels of reviewers. PSIs were maintained if the reviewers could confirm the diagnosis in at least 75 % of the reported cases and physician reviewers more often identified flagged cases rather than controls as *process of care* failures (Romano et al.). Face validity was evaluated using an expert coding consultant with consensual validation by eleven panels consisting of seven to nine clinicians nominated through their professional organizations. After revision of the PSIs based on these findings, the 1995-2000 HCUP data were used to evaluate their performance. Based on this analysis the researchers reported the individual PSI rates by hospital geographic location, owner status, and teaching status. A higher incidence of many of the PSIs was found in urban teaching hospitals although the researchers noted that the limited ability to risk adjust administrative data was a limitation. The researchers concluded that the AHRQ PSIs are appropriate as screening tools and would provide useful information on the epidemiology of patient safety (Romano et al.).

Subsequently, researchers have expanded their studies to examine the relationships between specific variables and the PSIs . As described in Chapter 2, studies have evaluated the relationship between PSIs and inpatient length of stay, mortality, and hospital charges (Zhan & Miller, 2003b), the patient or hospital characteristics associated with PSIs (Grobman, Feinglass, & Murthy, 2006; Thornlow & Stukenborg 2006; Zhan, Smith, & Stryer 2006), the care delivery model and PSI

rates (Simonson, Ahern, & Hendryx, 2007), and the comparison between PSI

Decubitus Ulcer rates and rates identified using medical record review (Polancich, &

Prosser, 2006).

Four PSIs were used in this study to evaluate the quality of care at the hospital

level including: Decubitus Ulcer, Failure to Rescue, Deep Vein Thrombosis, and

Selected Infections due to Medical Care. Each PSI has specific inclusion and

exclusion algorithms based on ICD-9-CDM codes as part of the indicator. These

algorithms are included in publicly available AHRQ software and were used to

calculate hospital rates for each indicator.

The *Decubitus Ulcer* PSI is defined as hospital discharges with ICD-9-CM

code of decubitus ulcer in any secondary diagnosis field among cases meeting the

inclusion and exclusion rules for the denominator. All medical and surgical

discharges for patients 18 years of age and older are included in the denominator.

Exclusions are characteristics such as a hospital stay of less than five days, admission

from a long term care facility, and specific neurologic diagnoses. The incidence of

Decubitus Ulcer reported by AHRQ for 2004 equaled 26.051 cases per 1000

discharges (AHRQ HCUPnet Decubitus Ulcer, n.d.). However, in this report all age

groups were included in the denominator. A recently published HealthGrades (2007)

report of the incidence of PSIs in U.S. hospitals using 2004 Medicare data identified

decubitus ulcer rates as 31.994 cases per 1000 discharges.

Failure to Rescue, now identified as *Death Among Surgical Inpatients with*

Serious Treatable Complications, is defined as all discharges with a disposition of

"deceased" among cases meeting the inclusion and exclusion rules. All discharges 18 years and older with potential complications of care are identified as failure to rescue cases. Specific complications such as the following diagnoses: nosocomial pneumonia, deep vein thrombosis/pulmonary embolus, sepsis, acute renal failure, shock/cardiac arrest, or gastrointestinal hemorrhage/acute ulcer are included in the indicator (AHRQ, 2007, March). Exclusion criteria include cases over age 75 years, transfers from a long-term care or another acute care facility, as well as, specific exclusion criteria for each diagnosis included in the failure to rescue definition. AHRQ reported the overall incidence of Failure to Rescue based on 2004 data as 119.00 cases per 1000 population at risk with the age criteria applied as noted (AHRQ HCUPnet: Failure to Rescue, n.d.). The Failure to Rescue incidence reported by HealthGrades (2007) using 2004 Medicare data was 131.903 cases per 1000 discharges.

Selected Infections due to Medical Care includes all discharges with the ICD-9-CM code of 999.3 (other infection after infusion, injection, transfusion, vaccination) or 996.62 (infection and inflammatory reaction due to other vascular device, implant, and graft) in any secondary diagnosis field among cases meeting the inclusion and exclusion rules for the denominator. Included in the denominator are all surgical and medical discharges 18 years of age or older or Major Diagnostic Category (MDC) 14 (pregnancy, childbirth, and puerperium) (AHRQ, 2007, March). Exclusions include length of stay less than two days, and any ICD-9-CM code indicating an immunocompromised state or cancer. AHRQ reported the 2004 incidence of this PSI

as 1.565 cases per 1000 discharges (AHRQ HCUPnet Selected Infections Due to Medical Care, n.d.). However the age exclusion was not applied in the report. HealthGrades (2007) reported the incidence of *Selected Infections Due to Medical Care* as 2.241 cases per 1000 discharges using 2004 Medicare data.

Postoperative Pulmonary Embolism or Deep Vein Thrombosis is defined as discharges among cases meeting the inclusion and exclusion criteria for the denominator with ICD-9-CM codes for deep vein thrombosis or pulmonary embolism in any secondary diagnosis field. All surgical discharges age 18 or older are included in the denominator. Excluded cases are those with a procedure code indicative of interruption of the vena cava and those with MDC 14 (pregnancy, childbirth, and puerperium). AHRQ reported the incidence of this PSI as 8.947 cases per 1000 discharges based on 2004 data, however as noted previously the age criteria were not applied to the data (AHRQ HCUPnet Postoperative Pulmonary Embolism, n.d.). The HealthGrades (2007) report identified the incidence of Postoperative Pulmonary Embolism or Deep Vein Thrombosis as 11.998 cases per 1000 discharges using 2004 Medicare data.

<div align="center">Level of Analysis</div>

<div align="center">*Data Aggregation - Indices of Reliability and Validity*</div>

Aggregated data should meet certain criteria to insure shared property representation. Aggregated item means are used to calculate reliability indices such as Cronbach's alpha. Inter-item correlations generally recommended between 0.30 to 0.70 at the individual level should exceed 0.60 when evaluating aggregated data

because aggregated correlations are usually higher than those generated using individual responses (Verran, Mark, & Lamb, 1994). Analysis of variance procedures are used to further evaluate reliability and validity. For data aggregated at the group or organization level, less variation within the work unit compared to between units is expected. A significant F ratio with a probability level of less than or equal to 0.05 is indicative of greater between-group than within-group variability. A significant F ratio supports validity of the measure as a group phenomenon and suggests the mean can be used to represent group opinion (Forbes, & Taunton, 1994). Glick (1985) identified an intraclass correlation (ICC[1,k]) greater than 0.60 as necessary to support aggregation of data to the group level. Glick also suggested the ICC (1,k) measures aggregated reliability by giving an estimate of mean rater reliability rather than individual rater reliability (Glick, 1985). The ICC (1,1), indicative of individual rater reliability, and the eta squared coefficient, an estimate of effect size, also are used to evaluate perceptual agreement (Hughes, & Anderson, 1994). Scores for both ICC (1,1) and eta-squared range between 0 to 1 with 1 representing perfect perceptual agreement. A recommended ICC (1,1) and eta-squared have not been established but lower scores are indicative of high variability within groups or low variability between groups (Hughes, & Anderson, 1994). Omega-squared also has been identified as an indicator of effect size of an independent variable and is thought to be less likely to overestimate effect sizes as the number of groups increases (Forbes, & Taunton, 1994).

NDNQI RN Survey Data Aggregation – Hospital Level

In a recent study (Elliott, 2006) NDNQI RN Survey and Job Satisfaction 2004 data were evaluated to determine the appropriateness of data aggregation at the work unit and hospital level. These results were compared with the conceptualized level in the hypothesized model to evaluate consistency with the reported findings. Professional Development, Nursing Administration, and Autonomy are hypothesized as hospital level variables in the current research. Indices of reliability and validity were assessed to determine the appropriateness of aggregating data at the hypothesized level (Elliott, 2006). The data evaluated were based on 50 percent group participation in the survey. Reliability was evaluated based on reported Cronbach's alpha, interitem correlations, and percent of interitem correlations greater than 0.60. Cronbach's alpha was greater than 0.90 for all three scales indicating internal consistency reliability within the group, in this case, organization or hospital level. Interitem correlations aggregated at the hospital level also were evaluated. Nurse Administration interitem correlation ranged from 0.73 to 0.89, Professional Development 0.25 to 0.90 and Autonomy ranged from 0.50 to 0.82. The percent of interitem correlations above 0.60 was greater than 60 percent for both the Autonomy and Nurse Administrator scales. However, the Professional Development scale had 51 percent of the interitem correlations greater than 0.60.

Indices of validity at the hospital level were also evaluated. ICC (1,k) were greater than 0.60 for each scale (Autonomy (0.82), Professional Development (0.84),

and Nurse Administrator (0.89)), indicating stability across groups drawn from the same population. ICC (1,1) were evaluated to determine hospital level perceptual agreement with all representing medium (0.12) to large ($\geq$ 0.30) correlations thereby indicating perceptual agreement: Autonomy (0.29), Professional Development (0.32), and Nurse Administrator (0.43). Eta squared and Omega-squared also were evaluated for the three scales at the hospital level and all showed a medium ($\eta^2 = 0.25$, $\omega^2 = 0.25$) to large ($\eta^2 = 0.40$, $\omega^2 = 0.40$) effect size indicating perceptual agreement: Autonomy ($\eta^2 = 0.3$, $\omega^2 = 0.29$), Professional Development ($\eta^2 = 0.32$, $\omega^2 = 0.32$), and Nurse Administrator ($\eta^2 = 0.42$, $\omega^2 = 0.41$). F ratios for each scale were significant at the 0.05 level of probability.

NDNQI RN Survey Data Aggregation – Work Unit Level

Task, Nurse-Nurse Interaction, Nurse-MD Interaction, Decision Making, Supportive Nurse Management are conceptualized in the current research as work unit level indicators. As with the conceptualized hospital level indicators, these were evaluated based on previous research finding to determine consistency with the proposed model (Elliott, 2006). The data evaluated were based on 50 percent group participation in the survey. Cronbach's alpha was greater than 0.90 for all five scales indicating internal consistency within the group, in this case work unit level. Interitem correlations aggregated at the work unit level also were evaluated. Task interitem correlations ranged from 0.61 to 0.85, Nurse-Nurse Interaction 0.54 to 0.87, Nurse-MD Interaction 0.74 to 0.92, Decision Making 0.55 to 0.80 and Supportive Nurse

Management 0.70 to 0.94. All of the scales had interitem correlation of 0.60 for greater than 60 percent of items.

Indices of validity at the work unit level also were evaluated. ICC (1,k) were greater than 0.60 for each scale with Task (0.87), Nurse-Nurse Interaction (0.83), Nurse-MD Interaction (0.83), Decision Making (0.85), and Supportive Nurse Management (0.88) indicating stability across groups drawn from the same population. ICC (1,1) were evaluated to determine hospital level perceptual agreement with all representing medium (0.12) to large (≥ 0.30) correlations, thereby indicating perceptual agreement: Task (0.30), Nurse-Nurse Interaction (0.28), Nurse-MD Interaction (0.27), Decision Making (0.24), and Supportive Nurse Management (0.27). Eta squared and Omega-squared also were evaluated for the five scales at the work unit level and all showed a medium ($\eta^2 = 0.25$, $\omega^2 = 0.25$) effect size indicating perceptual agreement: Task ($\eta^2 = 0.29$ $\omega^2 = 0.29$), Nurse-Nurse Interaction ($\eta^2 = 0.24$, $\omega^2 = 0.24$), Nurse-MD Interaction ($\eta^2 = 0.24$, $\omega^2 = 0.24$), Decision Making ($\eta^2 = 0.26$, $\omega^2 = 0.26$), and Supportive Nurse Management ($\eta^2 = 0.32$, $\omega^2 = 0.32$). F ratios for each of the scales were statistically significant at the 0.05 level of probability. Based on the evaluation of these indices data aggregation at the hypothesized level is supported.

<div align="center">Procedures</div>

The NIS and SID data sets were obtained from AHRQ after submission of an HCUP application. Included in the application process is a requirement that all researchers involved in data analysis complete the AHRQ HCUP data use agreement training. The on-line training emphasizes data protection, describes the individual

researcher's responsibility in using the data, and is meant to reduce the risk of violations (AHRQ, HCUP Data Use Agreement Training, n.d.). The data use agreement training was completed by the researcher and those identified to support the data analysis process. The data were provided for the selected year in compact discs with compressed files in ASCII format. Permission to use NDNQI data for the study was obtained after submission of a Student Research Scientist agreement outlining the study proposal. The research proposal was submitted to the Health Subjects Committee of the University of Kansas Medical Center and approval obtained.

<div align="center">Data Preparation</div>

The NDNQI RN Survey and Staffing data sets were prepared for analysis using SPSS 15.0. Variables were aggregated to the unit, unit type, and then hospital level. The Teamwork variable was created as described earlier. RN Hours Per Patient Day (HPPD) were calculated by unit and aggregated by unit type and then by hospital using the NDNQI Staffing data set. The RN Staffing variable was created as described in the next section of this chapter. After completion of the initial data preparation, the two NDNQI datasets were merged using the unique AHA hospital number.

The NIS and SID datasets were used to calculate the AHRQ PSIs. SAS v9.1 was used with the AHRQ QI SAS modules (v 3.21a) to calculate the observed and risk adjusted rates for each of the four PSI indicators used in the study. The software includes specifications to calculate risk-adjusted rates that adjust for case mix differences and expected rates that adjust for performance differences (AHRQ, 2007,

March 12). These data were exported to a Microsoft® Office Excel 2003 file and then
imported into a SPSS 15.0 file. The two SPSS datasets (NDNQI RN Survey and
Staffing dataset and AHRQ PSI dataset) were compared to identify matching
hospitals. A final sample of 97 hospitals was included in the study. Upon completion
of data preparation the merged data set was converted to an ASCII file to allow
structural equation modeling analysis using MPlus 5.1.

Missing data

The data were evaluated for missing values. NDNQI RN Survey scores are
calculated only if a given respondent has four or more items on a scale with a
response. These scales then were aggregated to the unit and then hospital level.
Therefore, there were no missing survey data in this data set. However, decisions were
required related to the creation of the RN Staffing variable. Some hospitals had not
submitted staffing data on each of the eligible unit types with staffing data (Medical,
Surgical, Medical/Surgical, ICU, Stepdown, and Rehabilitation) within their
institution.   Missing data were less than 6% for the eligible unit types present in the
hospital except for Rehabilitation Units where the missing data figure equaled 30%.
In addition, some institutions did not have each unit type within their institution.
Therefore, these hospitals did not, nor could they have, reported staffing data for those
unit types. To address both of these issues, a composite RN Staffing variable was
developed using the following approach. A standardized z-score was created using the
mean and standard deviation for each unit type. The scores were aggregated to the
hospital level thereby giving a summary of RN staffing adjusted for each unit type.

This became the RN Staffing variable for each hospital and eliminated the need to impute data to address these situations.

Although the strategy described above addressed issues related to differences between hospitals' reporting of staffing data for eligible unit types, it did not resolve an issue of missing staffing data for five hospitals. Three hospitals had not submitted staffing data during the third quarter of 2005 but had submitted staffing data earlier in the year, and two had not reported any staffing data. Third quarter data were used in the study because collection occurred in close proximity (the quarter prior) to participants' completion of the NDNQI RN Survey. Three of the hospitals had reported staffing data for the second quarter of 2005 but third quarter data were not submitted. A decision was made to use second quarter staffing data for these institutions as a proxy measure for the third quarter data. Two hospitals had not reported any staffing data during 2005. Imputed values were entered for these institutions using the following strategy. A regression analysis was conducted using the 95 hospitals in the sample with staffing data. Hospital size, Hospital teaching status, and Magnet status were regressed on the RN Staffing variable. A RN Staffing value was calculated for the two hospitals based on their hospital characteristics. The calculated value was imputed for these two institutions.

<div align="center">Data Analysis</div>

Structural equation modeling (SEM) was used to model the proposed relationships and to answer the research questions.

1. What are the direct effects of Work Unit Support and Organization Support on Patient Safety?

2. What effect does the indirect relationship of Organization Support on Work Unit Support have on Patient Safety?

The hypothesized model was tested using Mplus, a SEM package. The SEM included an evaluation of the fit between the correlation matrix from the hypothesized model and the data as well as the strength of the saturated correlation matrix. SEM also was used to test the indirect effects specified within the research model. The results of the initial analysis led to an exploration of alternate models and the development of a final alternate model that provided a reasonable fit with the data.

Assumptions

Multivariate normality is a common assumption of SEM (Kline, 2005). Kline (2005) recommends evaluating the impact of outliers as nonnormality can result in an underestimation of the model fit and standard errors. The final dataset was evaluated for normality and interpretability. To evaluate multivariate normality, probability plots were developed and skewness and kurtosis values were evaluated for each variable (See Tables 4 and 5, page 79). Decubitus Ulcer (1.216) and DVT (1.433) were skewed positively but were still below an extremely skewed value of 3.0 (Kline, 2005). Decubitus Ulcer (2.114) and DVT (3.395) also had kurtosis values indicative of a positive kurtosis but were less than an extreme value defined by Kline (2005) as an absolute kurtosis above 8.0 (Kline, 2005). Histograms were created for each variable to further evaluate data distribution. No significant problems were identified

with data normality, therefore the basic assumptions of a structural equation analysis were supported.

Structural Equation Model

Figure 3 (page 80) depicts the hypothesized causal model and the relationships to be tested. The model is recursive, reflecting unidirectional causation. Three latent varaibles, depicted as circles, include Work Unit Support, Organization Support, and Patient Safety. Each of the latent variables has identified empirical indicators that are the operational indicators for the factor. Work Unit Support was defined using five of the NDNQI RN Survey with Job Satisfaction scales (Task, Teamwork, Decision

Table 4
Exogenous Variables: Survey Statistics by Dimension

Variables	Mean	SD	Variance	Skewness	Kurtosis
Quality of Care	3.29	0.1745	0.03	-0.324	0.887
Task	3.17	0.2642	0.07	-0.025	0.242
Teamwork	4.08	0.2009	0.04	0.087	0.205
Decision Making	3.20	0.2548	0.07	-0.123	0.267
Supportive Nursing Management	4.04	0.3235	0.11	-0.207	0.153
Professional Development	4.14	0.2618	0.07	-0.504	1.202
Nurse Administration	3.68	0.3543	0.12	-0.143	-0.538
Autonomy	3.45	0.1944	0.04	0.101	-0.152

Note. SD= standard deviation

Table 5
Endogenous Variables:Risk Adjusted PSI Rates

Variables	Mean	SD	Variance	Skewness	Kurtosis
Decubitus Ulcer	0.0243	0.0128	0.0001635	1.216	2.114
Failure to Rescue	0.0914	0.0635	0.0040299	-0.164	-0.893
Infections due to Medical Care	0.0024	0.0014	0.00000019	0.336	-0.346
Postoperative Pulmonary Embolus or Deep Vein Thrombosis	0.0113	0.0061	0.0000037	1.433	3.695

Note. SD= standard deviation

Making, Supportive Nurse Management, and Unit Quality of Work). Organization

Support, the second latent variable was operationalized using three scales

(Professional Development, Nursing Administration, and Autonomy). Patient Safety

was operationalized by the selected AHRQ PSIs. Each of the scales used as indicators

Figure 3
Hypothesized Model
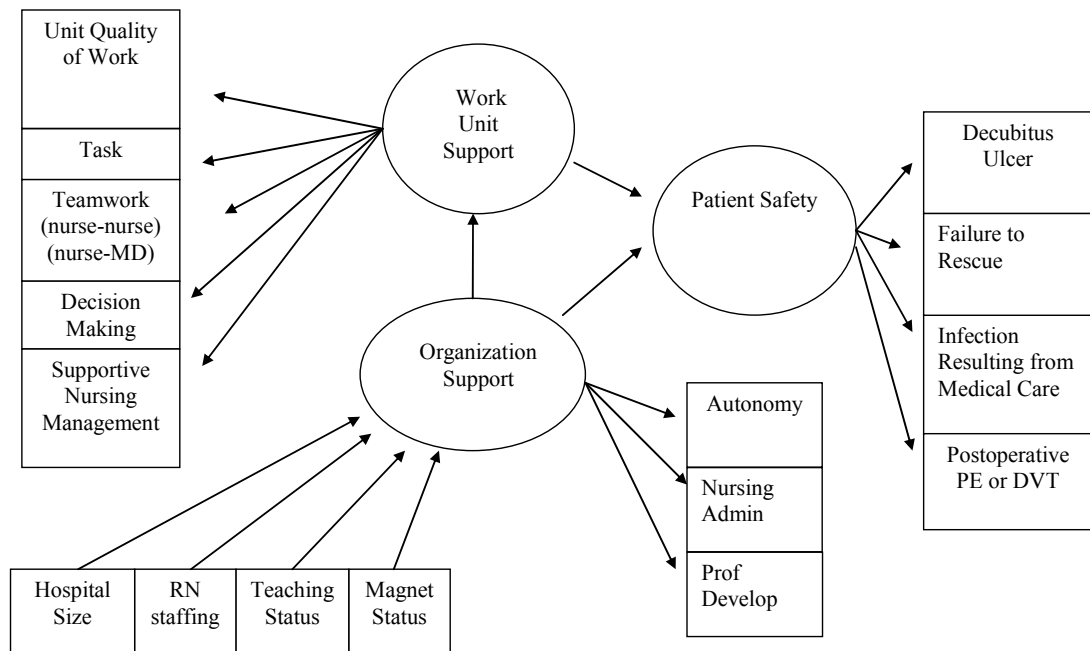
has an error term associated with it to designate the unexplained variance for observed

variables. The latent variables have an associated disturbance term used to designate

unexplained variance in the latent variables. Four manifest or observed variables are

represented by boxes and include: Hospital Bedsize, Teaching Status, RN Staffing,

and Magnet Status. The RN Staffing variable was created using RN Hours Per Patient

Day (HPPD) data reported for the quarter prior to the administration of the NDNQI

RN Survey. RN HPPD were aggregated by unit type by hospital so that each hospital

had the potential of six RN staffing variables.   The six unit types included Medical,

Surgical, Medical-Surgical, ICU, Rehabilitation, and Stepdown. An assumption of

perfect measurement is made with these variables because there is not a mechanism to

evaluate their reliability. The latent variables of Organization Support and Work Unit

Support directly affect Patient Safety. In addition, it is hypothesized that Organization

Support indirectly affects Patient Safety through Work Unit Support.

Statistical Analysis

To evaluate the extent that the data are consistent with the hypothesized model,

specific goodness of fit indexes were used including chi-square, Comparative Fit

Index (CFI) and Root Mean Square Error Approximation (RMSEA). The criterion for

each index was established to determine adequacy of model fit to the data. A small

nonsignificant maximum likelihood chi square statistic was established as a criterion

representative of good fit. A non significant chi square suggests there is no statistical

difference between the hypothesized model and the data. In addition, a CFI of 0.90 or

higher was used to indicate a reasonably good fit of the proposed model (Kline, 2005).

The CFI evaluates the data fit to the hypothesized model compared to an independence

model. Often a null model is used as the independence model with the null model

representing no relationship between the variables. The RMSEA was also used with a

value below 0.05 indicative of a close approximate fit (Kline, 2005). The RMSEA

evaluates the degree of falseness of the null hypothesis by approximating a non-central

chi-square distribution. If the null hypothesis is not supported by the data, the

RMSEA value increases as the non-central chi-square distribution is shifted to the right compared to the central chi-square distribution. Higher values indicate a poorer fit, while low values, less than 0.05, indicate a close approximate fit (Kline, 2005).

Assessment of the structural model also was accomplished by examining the regression aspects of the model. By using structural equation modeling in the data analysis all of the hypothesized relationships represented by equations were solved simultaneously rather than serially as in regression analysis. The strength of the causal paths, direct and indirect, will be assessed by the path coefficient (β). Beta weights will be evaluated to determine the contribution of exogenous variables to the model.

Ethical Considerations

The ethical considerations in this study are consistent with those in any study using hospital level administrative data and primarily center on confidentiality. Three unique hospital numbers are included in HCUP data and were used to link with other data sets. These hospital identifiers included "the HCUP Partner's own number scheme for identifying hospitals and facilities, the hospital identifier used by the American Hospital Association (AHA) and, a unique HCUP hospital identifier" (AHRQ, 2007, June). As required by the HCUP Data Use Agreement, these data were not used to report or identify individual hospital performance. In addition, the NIS and SID data sets contain encrypted patient identifiers so that multiple admissions within and across hospitals can be linked without the ability to access unique patient identifying information. However, the NIS and SID excludes data elements that could

identify individual patients. Data were not analyzed at an individual patient level

within the study. The study was reviewed approved by the Health Subjects

Committee of the University of Kansas Medical Center as an exempt study.

Summary

The purpose of the study was to evaluate the relationships between variables

associated with a culture of safety and specific adverse patient outcomes sensitive to

the care provided by nurses. A secondary analysis using cross-sectional data was used

in this exploratory study to evaluate the relationships between independent variables

consistent with the concepts of HROT and the culture of safety construct and outcome

variables which describe the occurrence of complications and adverse events

associated with the provision of health care. Three existing data sets were used

including selected scales from the NDNQI full RN Survey and Job Satisfaction scales

and the AHRQ HCUP NIS and SID data sets. The NIS and SID represent inpatient

encounter data and were used to determine the occurrence of four AHRQ PSIs. The

selected NDNQI scales measure nurses' perceptions of the work environment and are

consistent with concepts associated with a culture of safety. The AHRQ PSIs

represent potentially preventable adverse patient outcomes which the nurse researchers

have suggested are sensitive to nursing care.

Data were prepared and the data sets merged prior to analysis. Multivariate

analyses were performed to test the research questions. The unit of analysis was

individual hospitals and a model of the proposed relationship between the variables

was developed (Figure 3, page 80). Although there is an interest in developing a

culture of safety within health care settings, little is known about the relationships

between the culture of safety concepts and outcomes associated with patient care.

CHAPTER IV

Chapter IV presents the results of analyses of the hypothesized and alternative

models. The analyses were conducted to evaluate the research questions:

1. What are the direct effects of Work Unit Support and Organization Support on

    Patient Safety?

2. What effect does the indirect relationship of Organization Support on Work

    Unit Support have on Patient Safety?

Work Unit Support and Organization Support were derived from the 2005 NDNQI®

RN Survey with Job Satisfaction Scales data set. Patient Safety was operationalized

using the Agency for Healthcare Research and Quality (AHRQ) Patient Safety

Indicators (PSIs) of *Decubitus Ulcer, Failure to Rescue* (identified as *Death Among*

Surgical Inpatients with Serious Treatable Complications beginning in 2008), *Selected*

Infections due to Medical Care, and Pulmonary Embolus/Deep Vein Thrombosis. The

study purpose was to describe the impact of registered nurses' perception of work

environment characteristics conceptualized as Work Unit Support and Organization

Support on Patient Safety.

Description of Variables

Variables included in the study were based on the proposed model depicted in

Figure 3 (page 80). The exogenous and manifest variables included in the research

analysis model are derived from the NDNQI RN Survey with Job Satisfaction Scales

data set.

Exogenous Variables

In the hypothesized model (Figure 2, page 51) Quality of Care, Task, Teamwork, Decision Making, and Supportive Nurse Management scales defined the latent variable Work Unit Support. The Nursing Administration, Professional Development, and Autonomy scales defined the latent variable Organization Support. Descriptive statistics for each scale are included in Table 4 (page 79). Mean scores for each variable were aggregated to the unit and then hospital level. Items within each scale were scored using a six point Likert scale except for Quality of Care where a four point scale was used. Higher scores represent a higher amount of the respective variable.

Endogenous Variables

The outcome of interest is hospital Patient Safety as operationalized by four of the AHRQ PSIs including: *Decubitus Ulcer, Failure to Rescue, Selected Infections Due to Medical Care*, and *Postoperative Pulmonary Embolism or Deep Vein Thrombosis*. Risk adjusted PSI rates were calculated for each hospital. Descriptive statistics for the PSIs are listed in Table 5 (page 79). These events represent relatively rare occurrences and have a small variance. Muthén & Muthén (2007) recommend that when using MPlus the variables are kept on a scale where their variances are between 1 and 10 to reduce the risk of computational difficulties. Therefore, following calculation of the risk adjusted rates for each of the PSIs by hospital, standardized z scores were calculated. The use of standardized scores allowed for convergence when conducting the structural equation modeling analysis.

Manifest variables

Four manifest variables were used in the analyses and describe the hospital characteristics of interest for the sample. These variables included: Hospital Bedsize, Hospital Teaching Status, RN Staffing, and Magnet Status. Each of these variables was derived from the NDNQI RN Survey with Job Satisfaction Scales or Quarterly Staffing data.

Analysis of Original Hypothesized Model

The hypothesized model proposed in Chapter 3 (Figure 3, page 80) was used to evaluate the relationships between Work Unit Support and Organization Support on Patient Safety. The model, as originally specified, was entered into the structural equation software and the results were analyzed. Covariance and correlation indices were evaluated. There were significant moderate and strong correlations among the scales used to operationalize the latent variables of Work Unit Support and Organization Support. The strongest correlations were noted in the latent variable, Work Unit Support, between Decision Making and Supportive Nursing Management (0.73), Decision Making and Task (0.70), and Task and Quality of Care (0.66) (See Table 6, page 89). In addition, correlations across the three latent variables, Work Unit Support, Organization Support, and Patient Safety, were evaluated and significant moderate to strong correlations were noted between Autonomy and Task (0.84), Autonomy and Decision Making (0.82), Autonomy and Teamwork (0.78), Autonomy and Supportive Nursing Management (0.63), Autonomy and Quality of Care (0.67), Professional Development and Decision Making (0.73), Professional Development

and Supportive Nursing Management (0.73), and Decision Making and Nursing

Administration (0.66). Correlations of this magnitude suggest multicolinearity and

resulted in an error message during the computation of the model indicating the model

was *not positive definite*. Kline (2005) suggests correlations of 0.85 or higher are

indicative of extreme multicollinearity. Although none of the correlations between

variables reached this magnitude, an analysis of the latent variable correlation matrix

indicated the correlation between Work Unit Support and Organization Support to be

greater than 1.0 (r= 1.09). Therefore, the parameter estimates could not be computed.

To address this issue a revision to the hypothesized model such as removal of collinear

variables was necessary (Brown, 2006) (Table 6, page 89 and Table 7, page 90).

<div align="center">*Evaluation of Original Model Fit*</div>

The goodness of fit indices indicated the model did not fit the data adequately

(χ^2 = 394.868, df = 95, p <0.001; CFI = 0.636, RMSEA = 0.180, 90% confidence

interval [CI] = 0.162-0.199, p [RMSEA ≤ 0.05] < 0.001). See Table 8 (page 90) for

the fit indices for both the original and final alternate model. The nonstandardized

parameters were reviewed and Organization Support (r= 5.113, p= 0.029) and Work

Unit Support (r= -7.465, p= 0.036) had a significant direct impact on Patient Safety.

However the model results could not be used because the covariance matrix was *not*

positive definite as described earlier. Also a negative residual variance for the latent

variable Work Unit Support was noted in the hypothesized model. The findings of a

Table 6

Hypothesized Model Correlations Within and Across Latent Variables

Variable	Work Unit Support				Organization Support					Patient Safety		
	QOC	Task	Team	Decision Makg	Supp. Nurse Manag	Prof Develop	Nsg Admin	Auton	DU	FTR	IMC	DVT
QOC	1.000											
Task	0.660	1.000										
Team	0.539	0.559	1.000									
Decision Makg	0.496	0.704	0.567	1.000								
Supp. Nurse Manag	0.459	0.462	0.487	0.734	1.000							
Prof Develop	0.232	0.412	0.354	0.726	0.550	1.000						
Nsg Admin	0.143	0.354	0.275	0.664	0.342	0.494	1.000					
Auton	0.670	0.840	0.778	0.820	0.625	0.507	0.421	1.000				
DU	-0.163	-0.013	-0.136	0.011	-0.069	0.050	0.039	-0.228	1.000			
FTR	-0.021	-0.271	-0.135	-0.220	-0.166	-0.092	-0.013	0.113	-0.116	1.000		
IMC	0.072	0.096	-0.003	0.157	0.096	0.165	-0.038	-0.032	0.118	-0.128	1.000	
DVT	-0.052	0.097	-0.104	0.215	0.128	0.298	0.228	-0.251	0.230	-0.221	0.233	1.000

Note. QOC= Quality of Care, Team= Teamwork Decision Mkg= Decision Making, Supp Ns Manag= Supportive Nursing Management, Prof Develop= Professional Development, Nsg Admin= Nursing Administration, Auton= Autonomy, DU= Decubitus Ulcer, FTR= Failure to Rescue, IMC= Infectious due to Medical Care, DVT= Pulmonary Embolus or Deep Vein Thrombosis

Table 7
Hypothesized Model Correlations Between Manifest Variables and All Other Variables

Variable	Hospital Bed size	Hospital Teaching Status	Magnet Status	RN Staffing
Hospital Bed size	1.000			
Hospital Teaching Status	-0.571	1.000		
Magnet Status	0.181	-0.221	1.000	
RN Staffing	0.007	-0.270	0.084	1.000
QOC	-0.316	0.680	0.246	0.267
Task	-0.253	-0.049	0.136	0.471
Team	-0.236	0.118	0.007	0.092
Decision Making	-0.014	0.007	0.129	0.137
Supportive Nursing Management	-0.005	0.092	0.065	0.130
Professional Development	0.316	-0.220	0.185	0.111
Nursing Administration	-0.034	0.049	0.024	-0.209
Autonomy	-0.251	0.099	0.118	0.319
DU	0.219	-0.280	0.098	-0.101
FTR	0.188	-0.045	0.059	-0.309
IMC	0.488	-0.344	0.193	0.242
DVT	0.392	-0.394	0.256	0.069

Note. QOC= Quality of Care, Team= Teamwork, DU= Decubitus Ulcer, IMC= Infections due to Medical Care, DVT= Pulmonary Embolus or Deep Vein Thrombosis

Table 8
Fit Indices for Original and Final Alternate Models

Indices	Original Model	Final Alternate Model
χ^2	394.868*	40.811**
CFI	0.636	0.930
RMSEA	0.18	0.065
Confidence Interval	0.162 - 0.199	0.000-0.108
p [RMSEA $\leq$ 0.05]	$\leq$ 0.001	0.282
SRMR	0.137	0.074

Note. *p$\leq$ 0.001; **p= 0.072

not positive definite covariance matrix and negative residual variances indicated a

problem with fit of the model to data (Muthén & Muthén, 2007). As a result, alternate

models were considered based on High Reliability Organization Theory (HROT) and

the theoretical constructs of a *culture of safety*.

Development of the Final Alternate Model

Data analysis using structural equation modeling includes model

respecification if the hypothesized model does not represent an adequate fit (Hoyle,

1995; Kline, 2005).   In this study the original hypothesized model represented a poor

fit with the data and the number of high correlations between variables suggested

redundancies. In addition, when structural equation computations were attempted, the

resulting output indicated there were linear relationships preventing statistical

evaluation of the defined model. Alternate models were explored with the goal of

developing a parsimonious theory driven model. Development of the final alternate

model was pursued using HROT to guide the process followed by the consideration

and introduction of modifications suggested from the Structural Equation Modeling

(SEM) output. Modification indices give information regarding the expected change

in $\chi2$ when the identified modifications are made to the model. Changes to the model

based on modification indices were introduced only after determining their

consistency with HROT and the construct of a culture of safety. Alternate models

were explored and the results evaluated.

The process used to identify a final alternate model was iterative. Different

models were run using SEM and evaluated for their fit with the data. Of the many

models explored, some were separate models where individual PSIs, such as Failure to

Rescue were included as observed variables. Also models with respecified Patient

Safety latent variables were tested by using different combinations of PSIs. Although

some of these models seemed promising from a theoretical perspective none resulted

in an improved fit with the data when compared with the final alternate model.

Models in which the Decision Making and Autonomy scales were included in either

Work Unit Support or Organization Support and models in which one of these scales

was eliminated were tested. Inclusion of either of these scales individually or together

resulted in a not positive definite error message or nonconvergence. The researcher

also considered a model that did not include work unit support and organization

support as two separate variables, each with unique impact on patient safety. The

correlation between the latent variables Work Unit Support and Organization Support

was evaluated, and a high/moderate correlation was noted (r= 0.696). Consideration

was given to the possibility that one variable may reflect hospital or institution level

support better. A single variable called Institutional Support was developed by

combining the scales used to operationalize Work Unit Support and Organization

Support. The model was tested but resulted in a poorer fit than when the two level

latent variables were used suggesting that the single institutional support variable did

not explain the relationships between hospital level characteristics and patient safety

outcomes adequately. See Table 9 (pages 93 and 94) for a sample of the models tested

and results.

Revision of Latent Variables

The original model using HROT as a framework was developed to reflect

factors that describe work unit and organization level influences on specific outcomes

of patient care. Individual work units were conceptualized as having a local culture

that impacts patient safety. The latent variable of Work Unit Support was developed

Table 9
Sample of Alternate Models Explored with Fit Indices

Model	Work Unit Support Scales	Organization Support Scales	Institutional Support	Manifest Variables	Patient Safety Indicators	Observed Variables	Model Results		
							χ^2	CFI	RMSEA
Original	QOC, TK, TM, DM, SNM	PD, NA, A	None	HBS, Mag, RNStfg, HT	DU, FTR, DVT, IMC	None	Not Positive Definite 394.86*	0.64	0.18
Alternate 1	QOC, TK, TM, DM, SNM	PD, NA, A	None	None	DU, FTR, DVT, IMC	None	Not Positive Definite		
Alternate 2	QOC, TK, TM, SNM, A	DM, PD, NA	None	HBS, Mag, RNStfg, HT	DU, FTR, DVT, IMC	None	Not Positive Definite		
Alternate 3	QOC, TK, TM, SNM	DM, PD, NA, A	None	HBS, Mag, RNStfg, HT	DU, FTR, DVT, IMC	None	Not Positive Definite		
Alternate 4	QOC, TM, DM	PD, NA, SNM	None	HBS, Mag, RNStfg, HT	DU, FTR, DVT, IMC	None	Not Positive Definite		
Alternate 5	QOC, TK, TM	PD, NA, SNM, A	None	HBS, Mag, RNStfg, HT	DU, FTR, DVT, IMC	None	No Convergence		
Alternate 6	None	None	QOC, TM, SNM, PD, NA	HBS, Mag, RNStfg, HT	DU, FTR, DVT, IMC	None	No Convergence		
Alternate 7	None	None	QOC, TM, SNM, PD, NA	Mag, RNStfg	DU, DVT, IMC	None	65.44*	0.79	0.11

Note. QOC= Quality of Care, TM = Teamwork, TK= Task, DM = Decision Making, SNM = Supportive Nursing Management, PD= Professional Development, NA = Nursing Administration, A = Autonomy, DU= Decubitus Ulcer, FTR= Failure to Rescue,
IMC= Infections due to Medical Care, DVT= Pulmonary Embolus or Deep Vein Thrombosis; Mag= Magnet Status, HBS= Bedsize; HT= Hospital Teaching Status; RNStfg= RN Staffing
*= $p < 0.05$

Table 9 (continued)
Sample of Alternate Models Explored with Fit Indices

Model	Work Unit Support Scales	Organization Support Scales	Institutional Support	Manifest Variables	Patient Safety Indicators	Observed Variables	Model Results		
							χ^2	CFI	RMSEA
Alternate 8	None	None	QOC, TM, SNM, PD, NA	Mag, RNStfg	FTR	None	38.60*	0.85	0.12
Alternate 9	QOC, TK, TM	SNM, PD, NA	None	HBS, Mag, RNStfg, HT	DU, FTR, DVT, IMC	None	241.52*	0.54	0.16
Alternate 10	QOC, TM	SNM, PD, NA	None	Mag, RNStfg	DU, DVT, IMC	None	44.32*	0.90	0.08
Alternate 11	QOC, TM	SNM, PD, NA	None	Mag, RNStfg	None	FTR	30.41*	0.89	0.11
Alternate 12	QOC, TM	SNM, PD, NA	None	None	None	DU, FTR, DVT, IMC	22.28	0.96	0.064
Alternate 13	QOC, TM	SNM, PD, NA	None	None	DU, DVT, IMC	FTR	24.73	0.98	0.036
Alternate 14	QOC, TM, RNStfg	SNM, PD, NA, DM	None	None	DU, DVT, IMC	FTR	Not Positive Definite		
Alternate 15	QOC, TM, RNStfg, DM	SNM, PD, NA	None	None	DU, DVT, IMC	FTR	No Convergence		
Alternate 16	QOC, TM, RNStfg	SNM, PD, NA, A	None	None	DU, DVT, IMC	FTR	No Convergence		
Alternate 17	QOC, TM, RNStfg, A	SNM, PD, NA	None	None	DU, DVT, IMC	FTR	Not Positive Definite		
Alternate 18	QOC, TM, RNStfg	SNM, PD, NA, DM	None	HT, HBS	DU, DVT, IMC	FTR	80.77*	0.83	0.095
Final	QOC, TM, RNStfg	SNM, PD, NA	None	None	DU, DVT, IMC	FTR	31.93	0.97	0.043

Note. QOC= Quality of Care, TM = Teamwork, TK= Task, DM = Decision Making, SNM = Supportive Nursing Management, PD= Professional Development, NA = Nursing Administration, A = Autonomy, DU= Decubitus Ulcer, FTR= Failure to Rescue, IMC= Infections due to Medical Care, DVT= Pulmonary Embolus or Deep Vein Thrombosis; Mag= Magnet Status, HBS= Bedsize; HT= Hospital Teaching Status; RNStfg= RN Staffing
*= p <0.05

to represent the manner in which a group of people interact and coordinate their efforts to provide care to patients. Organization support was conceptualized as the manner in which hospital leaders develop a work environment based on HROT concepts so that care can be provided in a safe manner. The Work Unit Support and Organization Support variables were used to describe the level at which a hospital's work units and the overall organization possess key characteristics consistent with HROT and the relationship between the level of support and adverse patient outcomes. This conceptualization was used throughout the development and evaluation of alternate models to describe the relationships between variables.

To develop a final alternate model, the first step was to evaluate the variables used to describe the latent variable Work Unit Support. Strong correlations (> 0.60) were found among the job satisfaction scales used to define Work Unit Support. Scales with high correlations were evaluated by reviewing the items comprised within each scale to identify similar concepts across scales. For example, the Decision Making and Task scales were highly correlated. The items in both scales were compared and on initial review did not appear similar in concept. Task items reflect staff perceptions on having adequate time to provide care to patients. The items that comprise the Decision Making scale are focused on independent decision making and the opportunity to participate in decision making. However, nurses' perceptions regarding having adequate time to provide patient care may be predicated on their perceptions of management's provision of work related resources and having a voice in decision making. Decision Making also was correlated highly with the Supportive

Nurse Management variable. After review of the items contained in these two scales it was noted that Decision Making and Supportive Nurse Management had potential redundancy. Both scales include items evaluating nurses' perception of the support they receive from mangers regarding the decisions they make and management's inclusion of staff in decision making. Task also had a strong correlation with the Quality of Care item. Similarities between Task scale items and the Quality of Care item were considered. Task and Quality of Care may be strongly correlated in that staff's perception of having adequate time to provide care could be tied to their perception of the ability to provide quality care.

Next, the variables with strong correlations across the latent variables of Work Unit Support and Organization Support were evaluated. The Autonomy variable was strongly correlated with the Task, Decision Making, Teamwork, and Supportive Nurse Management variables. The Autonomy scale items reflect staff nurses' perceived authority to make independent decisions and have control over practice. The Autonomy scale items were considered similar to those in the Decision Making scale that reflect support by nurse managers and administrators of nurses' decisions and Task scale items that could reflect control over practice based on adequacy of time to provide patient care. The strong correlation between the Autonomy and Teamwork variable was unanticipated because these concepts seem dissimilar. However, the items within the Autonomy scale focus on having control over practice and input into care decisions. This may be consistent with nursing's role being recognized as an essential component of the healthcare team.

The Professional Development variable was strongly correlated with the Decision Making and Supportive Nursing Management variables. The items within the Professional Development scale focus on continual learning and support for these endeavors within the organization. The ability to participate in educational activities is typically dependent on support from hospital management as reflected in the Supportive Nursing Management Scale. Professional Development and Decision Making items could be considered to have similarities in that both require a degree of support from managers and administrators. Overall the variables with the highest correlations were Decision Making, Autonomy, and Task. When these variables were included in the SEM computations, an error message of nonconvergence or *not positive definite* resulted.

Based on the comparison of items across highly correlated scales, revisions to the Work Unit Support and Organization Support latent variables were made. Work Unit Support was redefined to include three variables: Teamwork, Quality of Care, and RN Staffing. Teamwork was retained because it is consistent with HROT and had fewer redundancies to other scales. Teamwork has been identified by safety experts as a key component to reliable and accurate execution of high risk processes and is a concept within HROT (Dixon & Shoffer, 2006; Frankel, Leonard, & Denham, 2006). Some have suggested teamwork is the most essential element to providing safe patient care and includes a number of subcomponents including the ability to communicate effectively, manage conflict, demonstrate mutual respect among members, and identify shared values (Baker, Day, & Salas, 2006; Leonard, Graham, & Bonacum,

2004). The Quality of Care item "In general how would you describe the quality of nursing care delivered to patients on your unit?" with response options of excellent, good, fair, and poor was considered a reflection of several scales and was retained as a component of Work Unit Support. This item had fewer strong correlations with the other scales and may represent a composite of factors that influence nurses' perception regarding their ability to provide quality care. RN Staffing, originally included in the model as a control variable, was reevaluated and included as a component of Work Unit Support. This is consistent with the HROT concept of redundancy. In the IOM report *Keeping Patients Safe: Transforming the Work Environment for Nurses* (2004) adequate staffing is suggested as an example of redundancy. Checks within the system often are done by more than one staff member watching for potential failures in a system. Also, increased staffing may allow nurses to be more vigilant and thereby support early recognition of subtle changes in patient status or the development of patient complications. This activity is applied at the work unit level, therefore seemed to fit conceptually with Work Unit Support. Based on this interpretation, RN Staffing was included within the latent variable of Work Unit Support.

The latent variable of Organization Support also was revised after evaluation of those variables with high correlations. Organization Support was modified to include Professional Development, Supportive Nursing Management, and Nurse Administration. Based on the concepts of HROT, leaders support front-line staff and set the expectation that safety strategies will be used to prevent errors and system failures. Leaders also encourage reporting of potential problems in the system. These

HROT concepts were considered as revisions were made to the latent variable Organization Support. Autonomy was removed based on the redundancy with other Work Unit Support variables. Supportive Nursing Management was determined to have a better fit both conceptually and based on SEM model fit indices when included within the Organization Support latent variable. Supportive nurse management may be more reflective of organization level influences rather than work unit. Nurse managers are often responsible for one or several clinical work units. Therefore their impact on patient safety may be more consistent with organization factors. The factors that influence staff nurses' perception of nurse manager support may be more reflective of the organization level rather than unit level influences. Nurse Managers are in a unique position often called middle or lower level management where they are accountable to staff and administrative levels within the organization. To be successful in the role, a nurse manager must have the ability to meet expectations of both groups. Possibly the manner in which this is demonstrated is more consistent with organization level influences. Nurse Administration was retained as a variable within Organization Support.

As noted above, the RN Staffing variable was included in the latent variable Work Unit Support but the other control variables included in the original model also were reconsidered. Hospital Bedsize and Hospital Teaching Status were removed from the model because they did not offer any additional information or explanation to the model. Neither represented significant findings and inclusion of these variables represented a poorer fit with the data. The findings for Hospital Teaching status were

consistent with previous research where teaching status and PSI rates associations

were inconsistent (Thornlow & Stukenborg, 2006; Vartak, Ward, & Vaughn, 2008).

The researcher decided to remove the Magnet Status variable also. It was recognized

during data analysis that the variable did not clearly differentiate hospitals that had

achieved a Magnet status from those that had not and were not pursuing Magnet

status. This was determined to be problematic. NDNQI hospitals report if they have

or have not achieved Magnet designation. However, it was recognized that some

hospitals identified as not having Magnet status were likely "Magnet aspiring". The

inability to cleanly differentiate hospitals using this variable was concerning and

therefore it was decided to remove it from the model.

The latent variable of Patient Safety also was evaluated based on SEM results

and conceptual congruence between the variables. As alternate models were

considered, it was noted that the latent variable Patient Safety had a better fit with the

data when Failure to Rescue was removed. Models with varying combinations of the

four PSIs describing Patient Safety were evaluated and Failure to Rescue continued to

represent a poorer fit. The researcher considered the differences between the four

variables used to operationalize Patient Safety. Failure to Rescue was determined to

be different than the other PSIs in several ways. Failure to Rescue was developed to

flag potentially preventable deaths (Clarke, 2004). The other indicators represent

complications but do not all result in death as defined by AHRQ. In addition the PSIs

Decubitus Ulcer, Infections due to Medical Care, and Deep Vein Thrombosis all

represent complications or conditions that have been found to be preventable when

evidenced based interventions are used. Certain patient populations are recognized as at risk for these complications and the ability to determine which patients are at risk is established. Protocols have been developed based on scientific evidence to prevent these three complications and nurses are typically familiar with such practice interventions and when to implement them. However, preventive strategies are not so clearly established with Failure to Rescue which incorporates several complications that may be experienced by patients postoperatively. These conditions may be more difficult to anticipate and an established protocol may not be available to prevent their occurrence. Rather, their identification requires a constant watchfulness or vigilance by the nurse so that early detection and treatment can be implemented. For example, the complications included within this PSI are pneumonia, gastric hemorrhage, sepsis, and shock (AHRQ, 2007, March).   These complications may develop quickly or subtly over time but require the constant watchfulness or vigilance of skilled care providers (Bobay, Fiorelli, & Anderson, 2008; Clarke, 2004; Manojlovich & Talsma, 2007; Meyer & Lavin, 2005; Meyer, Lavin, & Perry, 2007).

A model was developed that retained the latent variables of Work Unit Support and Organization Support as described above but modified the Patient Safety variable to include Decubitus Ulcer, Infections due to Medical Care, and DVT. Failure to Rescue was included in the model as an observed variable. The decision to remove Failure to Rescue from the latent variable of Patient Safety is consistent with recent work done by AHRQ in the development of a composite patient safety indicator. In March, 2008, AHRQ published a paper describing the efforts to use a group of PSIs as

a composite to evaluate patient safety (AHRQ, 2008, March). The authors suggest the composite indicator may be useful to consumers, providers, policy makers, and purchasers of health care services as they make healthcare choices and prioritize quality initiatives and programs. The PSIs included in the AHRQ composite indicator are Decubitus Ulcer, Postoperative Respiratory Failure, Iatrogenic Pneumothorax, Postoperative Pulmonary Embolus or Deep Vein Thrombosis, Selected Infection Due to Medical Care, Postoperative Sepsis, Postoperative Hip Fracture, Postoperative Wound Dehiscence, Postoperative Hemorrhage or Hematoma, and, Accidental Puncture or Laceration. Failure to Rescue (PSI 4), now identified as Death Among Surgical Inpatients with Serious Treatable Complications, was not included in the composite.

After evaluation of model variations the final alternate model was identified (Figure 4, page 103). The model includes respecified latent variables of Work Unit Support, Organization Support, and Patient Safety. Failure to Rescue is included as an observed variable.

<p align="center">Results of the Final Alternate Model</p>

The final alternate model included 10 variables with 3 continuous latent variables. The variance for all three latent variables was constrained to 1.0 which was done to allow better interpretation of the associations among the latent variables. By fixing each latent variable to 1.0 the latent variables are standardized which allows interpretation of relationships based on an established scale (Hoyle, 1995).

Figure 4
Final Alternate Model: Unstandardized and (Standardized) Direct Effects for Model

0.169**
(0.846)

Teamwork

-0.084
(-0.084)

Failure to
Rescue

0.111**
(0.638)

Unit Quality of
Care

Work
Unit
Support

-0.935*
(-0.689)

-0.087
(-0.113)

-0.082
(-0.378)

RN Staffing

0.194**
(0.252)

0.819*
(0.633)

0.229**
(0.312)

Decubitus
Ulcer

0.156**
(0.569)

Nursing
Administration

Patient
Safety

0.157**
(0.781)

Professional
Development

Organization
Support

0.892**
(0.851)

0.226**
(0.308)

Infection
Resulting
from Medical
Care

0.176**
(0.708)

Supportive
Nursing
Management

0.553**
(0.754)

Postoperative
Pulmonary
Embolus or
DVT

Statistical significance reported for unstandardized effects only
*p≤ 0.1
**p ≤ 0.05

Model Fit and Direct Effects

Correlation and covariance matrices were evaluated. Moderate correlations

still were present in the revised model. The highest correlation within the Work Unit

Support variable was between Teamwork and Quality of Care (r= 0.539). Correlations

between indicators of Organization Support were highest for Supportive Nursing

Management and Professional Development (r= 0.550) and lowest for Supportive

Nurse Management and Nursing Administration (r= 0.342). Correlations across latent

variables were all below 0.5 with the highest between Teamwork and Supportive

Nurse Management (r= 0.487). Patient Safety correlations were highest for DVT and

Infection due to Medical Care (r= 0.233) lowest for Decubitus Ulcer and Infections

due to Medical Care (r= 0.118). See Table 6 (page 89) for correlation matrix and

Appendix A (page 135) for the covariance matrix

The goodness of fit indices suggested the model reasonably fit the data (χ^2=

40.811, df = 29, p= 0.234; CFI = 0.930; RMSEA = 0.065, 90% confidence interval

[CI] = 0.000-0.108, p [RMSEA < .05] = 0.282; SRMR= 0.074). See Table 8 (page 90)

for the fit indices for both the original and final alternate model. The apriori criteria,

CFI > 0.90; RMSEA < 0.08, established to evaluate the model fit were met. The

confidence intervals for RMSEA reflect the amount of uncertainty associated with

RMSEA as a point estimate at the 90% level of statistical confidence. The lower

bound confidence interval is at 0.00 therefore the null hypothesis of close fit could not

be rejected. However, the upper bound confidence interval is slightly greater than

0.10. Therefore the hypothesis of poor approximate fit cannot be rejected. This

indicates that the RMSEA is subject to some sampling error and may be reflective of

the small sample size (Kline, 2005).

Table 10 (page 105) presents the unstandardized model parameters and the

standardized effect, *StdYX,* which depicts the amount of standardized change in an

outcome variable per standard deviation unit of a predictor variable. See Figure 4

(page103) for both the unstandardized and standardized direct effects for the final

alternate model variables. All model inferences were derived from the unstandardized

effects, therefore statistical significance is reported using the unstandarized

coefficients only.

Table 10

Final Alternate Model Parameters

Variable	Unstandardized				Standardized
	Est	S.E.	Est/S.E.	Two-tailed p-Value	StdYX
Work Unit Support by indicators					
QOC	0.111	0.022	7.765	<.001	0.638
Teamwork	0.169	0.019	5.960	<.001	0.846
RN Staffing	0.194	0.086	2.250	0.024	0.252
Organization Support by indicators					
Supp. Nurse Manage	0.176	0.028	6.344	<0.001	0.708
Prof Develop	0.157	0.030	5.266	<0.001	0.781
Nsg Admin	0.156	0.035	4.512	<0.001	0.569
Patient Safety by indicators					
DU	0.229	0.099	2.308	0.021	0.312
INMC	0.226	0.100	2.255	0.024	0.308
DVT	0.553	0.202	2.745	0.006	0.754
Organization Support On Work Unit Support	0.819	0.246	3.334	0.001	0.633
Pt Safety On Work Unit Support	-0.935	0.524	-1.783	0.075	-0.689
Pt Safety On Organization Support	0.892	0.412	2.167	0.030	0.851
Failure to Rescue On Work Unit Support	-0.084	0.173	-0.486	0.627	-0.084
Failure to Rescue on Organization Support	-0.087	0.134	-0.646	0.518	-0.113

Note. Est = estimate; SE = standard error of the estimate; QOC= Quality of Care, Team= Teamwork Supp Ns Manag= Supportive Nursing Management, Prof Develop= Professional Development, Nsg Admin= Nursing Administration, Auton= Autonomy, DU= Decubitus Ulcer, IMC= Infections due to Medical Care, DVT= Pulmonary Embolus or Deep Vein Thrombosis

The effect of Organization Support on Patient Safety was significant (p= 0.030), but the effect of Organization Support on Failure to Rescue was not (p= 0.518). However the findings were contradictory. As Organizational Support increased Patient Safety Events increased. In contrast increased Organization Support was associated with a decreased, though not statistically significant, decrease in Failure to Rescue.

Work Unit Support did not have a statistically significant direct effect on Patient Safety (p= 0.075) or Failure to Rescue (p= 0.627). However, the direct effect of Work Unit Support on Patient Safety at a statistical significance below p< 0.100 could be interpreted as a promising finding. The relationship between increased Work Unit Support and decreased Patient Safety was fairly strong (see Table 10). Though not statistically relevant, the findings are consistent with those anticipated based on HROT. This finding warrants further exploration.

The association between Work Unit Support variables and Patient Safety variables were evaluated using the correlation matrix to discern the relationships. Increased scores on Teamwork, Quality of Care, and RN Staffing resulted in lower rates of Decubitus Ulcer, Infections due to Medical Care, DVT, and Failure to Rescue with a few exceptions. As Quality of Care scores increased so did the rate of Infections due to Medical Care. Increased RN Staffing was associated with increased rates of Infections due to Medical Care and DVT. The indicators of Organization Support had mixed relationships with Failure to Rescue and the indicators used to describe Patient Safety. Increased rates of Supportive Nursing Management were associated with decreased rates of Decubitus Ulcer, and Failure to Rescue but with increased rates of Infections due to Medical care and DVT. Increasing rates of Professional Development were associated with decreasing rates of Failure to Rescue but increasing rates of all three Patient Safety indicators. As Nurse Administration scores increased rates of Infections due to Medical Care and Failure to Rescue

decreased but DVT and Decubitus Ulcer rates increased. See Table 11 (page 107) for

estimated covariance and correlation matrices for the latent variables.

Indirect Effects

The final alternate model also contained one hypothesized indirect effect as defined in

the second research question "What does the indirect relationship of Organization

Support on Work Unit Support have on Patient Safety?" The indirect effect (-0.7657)

for this path indicated increased Organization Support through Work Unit Support was

Table 11
*Final Alternate Model: Estimated Covariance and Correlations for the Latent
Variables*

Latent Variable	Work Unit Support	Organization Support	Patient Safety	Failure to Rescue
Covariance Matrix				
Work Unit Support	1.000			
Organization Support	0.819	1.670		
Patient Safety	-0.204	0.725	1.838	
Failure to Rescue	-0.155	-0.213	-0.413	0.990
Correlation Matrix				
Work Unit Support	1.000			
Organization Support	0.633	1.000		
Patient Safety	-0.151	0.414	1.000	
Failure to Rescue	-0.156	-0.166	-0.306	1.000

associated with a decreased rate of Patient Safety adverse events. Therefore, even

though the direct relationship between Organization Support and Patient Safety

indicated both increase together, once Work Unit Support was included, the effect of

Work Unit Support resulted in a decrease in Patient Safety events.

To determine if Work Unit Support acted as a mediator, several criteria were evaluated (Baron & Kenny, 1986; Judd & Kenny, 1981). First, a correlation between Organization Support and Patient Safety was established. Second Organization Support must be correlated with the hypothesized mediator, in this case Work Unit Support, and Work Unit Support also must affect Patient Safety. These criteria were met. The Sobel test determines whether the impact of the independent variable, in this case Organization Support, is significantly reduced in the presence of the mediator, Work Unit Support. The unstandardized coefficients and standard errors for each of the following relationships were entered into an interactive calculation tool: Organization Support on Work Unit Support (0.819), Work Unit Support on Patient Safety (-0.935), standard error of Organization Support on Work Unit Support (0.246) and standard error of Work Unit Support on Patient Safety (0.524). Sobel = -1.5727096; p= 0.11578608 indicating a mediator effect was not present (Preacher & Leonardelli, 2006). A Sobel test also was conducted to evaluate the relationship of Work Unit Support as a possible mediator of Organization Support on Failure to Rescue. As described above the unstandardized coefficients and standard errors of the following relationships were entered into an interactive calculation tool: Organization Support on Work Unit Support (0.819), Work Unit Support on Failure to Rescue (-0.084), standard error of Organization Support on Work Unit Support (0.246) and standard error of Work Unit Support on Failure to Rescue (0.173). Sobel = -0.48046625; p= 0.6308959 indicating a mediator effect was not present (Preacher & Leonardelli, 2006). Based on this analysis it was determined Work Unit Support did

not act as a mediator of Organization Support on Patient Safety nor of Organization Support on Failure to Rescue.

Summary

The analysis of the relationships between Work Unit Support and Organization Support on Patient Safety resulted in the identification of a final alternate model that provided a reasonable fit with the data. The final alternate model was developed using the framework of HROT to guide evaluation of alternate models. The only statistically significant effect was that of Organization Support on Patient Safety with increasing levels of Organization Support co varying with increased rates of negative Patient Safety events. Although this relationship was unanticipated, the direction of Work Unit Support suggested some promising considerations for future exploration. As Work Unit Support increased Patient Safety events decreased and when the impact of Organization Support on Patient Safety was evaluated through Work Unit Support the directional relationship changed to decreased Patient Safety events. This relationship was not statistically significant but supports further study to determine the impact of a Work Unit culture and an Organization level culture on Patient Safety. The final chapter incorporates these findings into a discussion of the significance and contribution of the final alternate model.

Chapter V

This chapter presents a discussion of the research findings based on the study

questions. The contribution of an final alternate model depicting the relationships

between hospital level characteristics suggested as descriptors of High Reliability

Organization Theory (HROT) concepts and the incidence of patient safety events is

also presented. Two research questions were posed in the study. The first related to

the direct effect of Work Unit Support and Organization Support on Patient Safety

whereas the second related to the indirect effect of Organization Support through

Work Unit Support on Patient Safety. The limitations of the study and

recommendations for further research also are presented.

Previous studies have focused on measurement of the individual or group level

characteristics associated with the provision of safe care and others have reported the

incidence of specific patient safety events. However, very little work has been done to

evaluate organization level characteristics consistent with HROT concepts compared

with the occurrence of specific patient safety events (Vogus & Sutcliffe, 2007;

Zhohar, Livne, Tenne-Gazit, Admi, & Donchin, 2007). An understanding of these

relationships is essential to the development of hospital systems and work

environments that mitigate the risk of poor outcomes and support safe patient care.

Significance of the Study

Although a focus on the quality of care provided within hospitals has increased

over the last decade, there is still a lack of understanding regarding the characteristics

of work environments that promote safe care. A *culture of safety,* a construct of HROT, has been suggested as the type of work environment where errors are less likely to occur. Health care leaders have suggested that HROT, although originally derived from non-healthcare settings, can be used to guide our understanding of complex high-risk environments considered characteristic of healthcare facilities. However, the concepts associated with a health care culture of safety and the mechanisms to develop or promote such a culture still contain knowledge gaps. In addition, the relationships between the concepts describing HROT have not been discerned fully. As errors continue to plague healthcare institutions almost a decade after the publication of the IOM (1999) report *To Err is Human*, it is evident that there remains much to learn regarding the development of safe health care systems.

The goal of the study was to evaluate the relationships between HROT concepts as identified during the theory's development and the occurrence of patient safety events that describe potential quality of care concerns. The findings of the study add to the body of knowledge regarding these relationships and can be used to guide further work on the topic.

<center>Interpretation of the Results</center>

A hypothesized model depicting the relationships between Work Unit Support, Organization Support, and Patient Safety was developed (Figure 3, page 80). Structural equation modeling was used to examine these relationships. The hypothesized model had a poor fit with the data therefore alternate models were tested. Based on the analysis of the data and guided by the theoretical constructs of a culture

of safety and HROT, a final alternate model with reasonable fit indices was developed. The interpretation of the results addresses the research questions individually.

Direct Effects of Work Unit Support and Organization Support

on Patient Safety and Failure to Rescue

Organization Support had a statistically significant direct effect on Patient Safety. However, the findings were unanticipated because Patient Safety events increased with increased levels of Organization Support. It was expected that higher scores on the scales used to depict Organization Support would be associated with lower Patient Safety events. The NDNQI® RN Survey and Job Enjoyment scales used to operationalize Organization Support were Supportive Nursing Management, Nurse Administration, and Professional Development. The correlations between the individual Organization Support scales and the Patient Safety events were evaluated to determine particular patterns. Mixed results were noted in the directional correlation between the scales used to operationalize Organization Support and Patient Safety events. As Supportive Nursing Management scores increased Decubitus Ulcer rates decreased. Increasing Nursing Administration scores were associated with lower rates of Infections due to Medical Care. All other correlations between the variables used to describe Organization Support and the Patient Safety increased together, meaning as the individual Organization Support scale scores increased so did the incidence of Patient Safety events.

There was no statistically significant relationship between Organization Support and Failure to Rescue (p= 0.518), however the correlations between the

Organization Support scales and Failure to Rescue were consistent.   With increasing Supportive Nursing Management, Nursing Administration, and Professional Development scores, the rates of Failure to Rescue decreased. This inverse relationship was anticipated but as noted failed to reach statistical significance.

Based on HROT concepts leaders must support front-line staff by establishing systems where known safety practices are implemented and staff are held accountable for their use. In high reliability systems, leaders encourage reporting and early recognition of potential problems in the system. Leaders also discourage silence and reward staff for detecting and reporting system failures regardless of the rank or position of the staff member. In such systems, safety is more highly valued than maintaining hierarchical relationships within the group. It could be that the scales used to define Organization Support measure concepts other than those associated with the HROT concepts.

The individual scale questions were reexamined and considered in light of the unexpected study findings. Supportive Nursing Management scores increased with increased Infections due to Medical Care and DVT. Nurse Administration scores increased along with increased DVT. Increased Professional Development scores were associated with higher rates of Decubitus Ulcer, Infections due to Medical Care, and DVT. These NDNQI RN Survey and Job Enjoyment scales are comprised of items measuring characteristics of professional nursing practice environments and relate to nurses' relationship with the nurse manager or nurse administrators within their hospital and work unit. Though aspects of the work environment should be

important to a culture of safety, the items were not developed with the intent of measuring a culture of safety or HROT. Possibly the scale items are not reflective of how well leaders establish expectations and processes that support a culture of safety. The items as developed may measure more specifically the approachability or responsiveness of management to staff needs. Therefore, the items may measure the quality of the relationship between clinical staff and management or administration. A positive relationship with management and management's development of systems that support the concepts consistent with HROT may be very different. The Professional Development scale questions are related to ability of nurses to advance within the organization and to avail themselves of educational opportunities. This researcher suggested that the scale was consistent with the concept of a *learning organization* as described in HROT. Weick and Sutciffe (2001) also describe a concept of *preoccupation with failure* that is similar to a learning organization. Both concepts related to support for staff to learn continually from error and for the lessons learned to be used to improve processes within the system. The specificity of this type of learning may not be captured with the Professional Development scale. Therefore scales used to operationalize Organization Support may not measure the concepts as described in the study design.

Although the relationships between the Organization Support scales and Patient Safety events were mixed, this was not the case with Failure to Rescue. Failure to Rescue rates uniformly decreased with increased Organization Support scale scores. The relationship was not statistically significant but the consistency of the

relationships was of interest. Failure to Rescue has generated a great deal of attention

in recent years. It has been used as a nurse sensitive measure and as an outcome

measure in studies evaluating the impact of work environment and staffing patterns.

Possibly Failure to Rescue is more sensitive to the relationships staff have with

managers and administrators than those indicators used to describe the latent variable

Patient Safety.

Failure to Rescue seems to be a more complex concept and may require a

higher functioning organization as defined by diverse measures of the work

environment including staff's perception of leaders.   Failure to Rescue does not have

a set of evidenced based prevention strategies. Rather, Failure to Rescue prevention

seems influenced by vigilance of clinicians with the knowledge and skill to recognize

clinical patterns indicative of an impending complication. Prevention of Decubitus

Ulcer, DVT, and Infections due to Medical Care requires clinical staff to identify

patients at risk, implement established prevention strategies, and periodically reassess.

These three preventable complications have been the focus of recent national quality

initiatives such as the Institute of Healthcare Improvement (IHI) *5 Million Lives

Campaign* and were targeted recently by the Centers for Medicare and Medicaid

Services (CMS) as Hospital Acquired Conditions (CMS, 2007). With each of these

conditions, Decubitus Ulcer, DVT (within Ventilator Associated Pneumonia

prevention), and Infections due to Medical Care, the IHI published a bundle or set of

interventions to prevent their occurrence. The bundles are evidenced based and

include interventions often established in clinical care plans or protocols used by

nursing staff. Unlike Failure to Rescue, these complications generally do not require constant watchfulness for onset of subtle signs that can quickly escalate to serious clinical deterioration and death. Failure to Rescue seems to represent a more complex complication and likely requires highly skilled or expert staff along with adequate staffing to ensure early recognition and intervention. The organization support to establish an environment that supports staff attaining this level of functioning may be more complex as well. Additional indicators representative of management's ability to establish a work environment that promotes strong clinical skills, effective communication, and the availability of specialized experts when needed could be important components to include in the model. Further exploration of alternate models is needed.

Work Unit Support had no statistically significant effect on Patient Safety (p= 0.075) or Failure to Rescue (p= 0.627), however, as Work Unit Support scores increased the incidence of the Patient Safety events and Failure to Rescue decreased. Although the overall inverse relationship was expected, there were mixed relationships between the individual scales within Work Unit Support and Patient Safety events. The scales used to operationalize the revised Work Unit Support latent variable were Teamwork, the Quality of Care item, and RN Staffing. As Teamwork scores increased all three Patient Safety events decreased as well as Failure to Rescue. These inverse relationships between Teamwork and the outcomes of interest were expected. Teamwork reflects the ability of a group to coordinate efforts at the location of care delivery also called the *sharp end* of the process.   Effective teamwork is used to

describe high reliability organizations. The Teamwork variable was developed as a composite of the NDNQI RN Survey Nurse-Nurse Interaction and Nurse-MD Interaction scales. Teamwork, as a study variable, was developed as a composite of the two scales because effective working relationships within the discipline and across disciplines was conceptualized as important to the functioning of an effective team. The finding regarding teamwork is consistent with a considerable body of research conducted to evaluate the relationships between nurse-physician collaboration and negative patient outcomes. Decreased mortality (Knaus, Draper, Wagner & Zimmerman, 1986; Mitchell, Armstrong, Simpson, & Lentz, 1989), fewer ICU readmissions (Baggs, Ryan, Phelps, Richeson, Johnson, 1992; Baggs et al., 1999), and shorter risk adjusted length of stay (Shortell et al., 1994) have all been associated with increased levels of collaboration, or concepts similar to collaboration such as communication and coordination.

Review of the items within the Nurse-Nurse Interaction and Nurse-MD Interaction scales suggested these questions were aligned closely with the concept of teamwork described in the theory. The items focus on the respect physicians have for nurses and their unique knowledge, the ability of team members to work together when the workload increases, and the ability of the group to support new team members. These questions are consistent with those concepts describing a culture of safety. Also, some have suggested that teamwork describes a local level or work unit culture that is consistent with the use of this variable to describe work unit support (Frankel, Leonard, & Denham, 2006).

Although teamwork could be considered a unique concept of HROT, many

other HROT concepts could be linked to the effectiveness of team functioning. For

example, the concepts of Trust, Organization Learning, and Decision Making

(Decentralized and Centralized) all have connections to the ability of team members to

cooperate and coordinate their efforts to prevent errors. Weick and Sutcliffe (2001)

use the concepts *reluctance to simplify, sensitivity to operations, preoccupation with*

failure, and deference to expertise as concepts associated with high reliability

organizations. These concepts could be predicated on how effectively teams work

together. The team members must move key decisions to the members with the

highest knowledge regardless of hierarchy (deference to expertise and sensitivity to

operations), report and address errors cooperatively (preoccupation with failure), and

have respect for individual level knowledge (reluctance to simplify). Systems such as

the airline industry have considered the concept of teamwork as an important

contributor to air travel safety and have described a flattened hierarchy where anyone

within the system has the authority to stop a process if a safety concern is identified

(Nash, 2008). Healthcare leaders and regulators have suggested this concept is

important to a healthcare culture of safety (Baker, Day, & Salas, 2006). Many of the

safety processes prescribed by the Joint Commission through their National Patient

Safety Goals are dependent on team cooperation for implementation. For example,

development of a program, such as a Rapid Response Team, whereby a deteriorating

patient's condition can be escalated to the attention of experts by any health care

worker is a 2009 National Patient Safety Goal. Implementation of such a goal requires

effective team functioning. This concept may be one of the most important when considering a healthcare culture of safety and therefore have a greater association with patient safety.

Increased Quality of Care scores were correlated with decreased Decubitus Ulcer and DVT rates as well as Failure to Rescue but were correlated with increased rates of Infections due to Medical Care. An inverse relationship between the Quality of Care item and the Patient Safety variables was expected. It may be that nurses involved in direct care of patients are uniquely qualified to evaluate the quality of care provided and the level at which patient complications are prevented. The underlying determinants of the assessment are not identified through this global question. Therefore, it would be of value to analyze the contributing factors associated with nurses' perception of quality of care further. The positive correlation between Quality of Care and the rate of Infections due to Medical Care was unexpected. Possibly Infections due to Medical Care, which is primarily indicative of central line catheter bacteremia, is an outcome more greatly influenced by group level care rather than individual nursing care provided in a particular work unit. If so, nursing's perception of quality of care may not capture the care provided by multiple disciplines to prevent central line catheter bacteremia. The bundles of care used in recent patient safety campaigns such as the Institute of Healthcare Improvement (IHI) *100k Lives campaign* and *5 Million Lives Campaign* describe interventions that are required of multiple providers. Therefore, this outcome may be less sensitive to the Quality of Care item. The question directs the respondent to describe the quality of *nursing* care delivered

on the work unit and therefore would not necessarily reflect quality of care provided by other groups.

RN staffing has been suggested to be an important factor in prevention of patient complications and early recognition of problems arising during the course of hospitalization. Although staffing is not defined explicitly as a concept of HROT it is implied in the concept of redundancy. Some have considered staffing levels to act as a type of redundancy suggesting that the staffing pattern must be able to support the level of assessment and monitoring needed to identify changes in patient status (IOM, 2004). In this study increased levels of RN Staffing were associated with decreased rates of Decubitus Ulcer and Failure to Rescue but conversely increased RN Staffing was correlated with slightly increased rates of Infections due to Medical Care and DVT.

Previous studies have evaluated the relationship with nurse staffing and the occurrence of negative patient outcomes. Hickam et al. (2003) synthesized results from a total of 26 studies on the relationship between nurse staffing and adverse outcomes. These researchers concluded that lower nurse staffing levels were associated with higher incidence of negative outcomes (Hickam et al.). Increased staffing also has been associated with decreased rates of various complications such as urinary tract infection, pneumonia, pulmonary compromise, mortality, and *Failure to Rescue,* defined as a death from upper gastrointestinal bleeding, cardiac arrest, deep venous thrombosis, pneumonia, or sepsis (Aiken, Clark, Sloane, Sochalski, & Silber, 2002; Aiken, Sloane, Lake, Sochalski, 1999; Kovner & Gergen, 1998 Kovner, Jones,

Zhan, Gergen, & Basu, 2002; Needleman, Buerhaus, Mattke, Stewart, & Zelevinsky, 2002). However, some researchers have reported mixed results when comparing nurse staffing and patient outcomes. Unruh (2003) reported hospitals staffed with a greater proportion of licensed nurses had significantly lower rates of decubitus ulcers and pneumonia. Conversely, she found that those hospitals with more licensed nurses per patient had significantly higher rates of pneumonia (Unruh). Cho et al. (2003) found increased RN staffing to be related inversely to the rate of pneumonia. However, they reported an increase in nursing hours per patient day was associated with a higher probability of a decubitus ulcer.

The relationship between nurse staffing and Failure to Rescue found in this study is consistent with other research findings. Previous studies have reported increased mortality, sometimes defined as Failure to Rescue, with lower staffing levels (Aiken, Sloane, Lake, Sochalski, & Weber,1999; Aiken, Clark, Sloane, Sochalski, & Silber, 2002; Needleman, Buerhaus, Mattke, Stewart, & Zelevinsky, 2002). Recently, a study conducted by Friese, Lake, Aiken, Silber and Sochalski (2008) found a significant reduction in Failure to Rescue for surgical oncology patients based on higher levels of nurse staffing, educational preparation, and the practice environment. Failure to Rescue requires a degree of vigilance and monitoring that may require more robust staffing models. Overall Failure to Rescue may be more sensitive to staffing levels than other adverse outcomes.

It was disappointing that neither Decision Making nor Autonomy scales were able to be included in the model. Although there were problems with the model being

not positive definite with these scales included, the concepts remain of interest and need further exploration. The HROT concept related to decision making is focused on decisions being made at the level of expert knowledge regardless of individual rank. The theoretical concept is descriptive of decision making guided by the values and standards set by leadership. The items within the Decision Making scale focus on nurses' opportunity to participate in decision making and managers' seeking staff input prior to making decisions. One item specifically relates to nursing administrators backing up staff. This item is aligned with the HROT concept that leadership staff supports decision making of front line staff. However, the other items are more general and not specifically related to the expectation that staff members either have the expert knowledge or access to those that do and leadership supports decision making at this level. Autonomy is closely aligned to decision making in HROT. Leaders support the decision making done by front-line staff members because they recognize in high risk environments conditions may change rapidly requiring immediate action based on system level values, training, and expert knowledge. The Autonomy scale items focus on the control staff nurses have over their work and the input they have in the care for patients. There seem to be some redundancies with the Autonomy scale and Decision Making scale and as noted above the concepts are closely aligned in HROT as well. Possibly items specifically related to HROT would include both the knowledge and authority to make decisions under the concept of decision making.

In summary, although the relationships between the scores for the individual scales used to operationalize Organization Support and Work Unit Support and the rate of Patient Safety events were mixed, this was not the case for Failure to Rescue. Failure to Rescue rates decreased with each of the scales used to describe Organization Support and Work Unit Support. Although this did not represent a statistically significant relationship, it is interesting that the directional relationships were consistent with each of the scales. As noted, consistent relationships between the scales and the Patient Safety indicators were not demonstrated possibly related to the use of measures representative of satisfaction with the professional work environment rather than HROT concepts. In contrast, decreased Failure to Rescue rates may be associated with the presence of HROT concepts within a system and other components reflected within the work environment scales. As suggested previously, Failure to Rescue may represent a more complex concept than the Patient Safety indicators and be associated with many work environment factors. Also the model may not include key factors associated with mortality as reported by other researchers such as nurses' level of education, certification, or years of experience.

Indirect Effects of Organization Support through Work Unit Support

on Patient Safety and Failure to Rescue

The second research question was related to the relationship of Organization Support through Work Unit Support on Patient Safety and Failure to Rescue. The indirect effect (-0.7657) for this path indicated increased Organization Support through Work Unit Support was associated with a decreased rate of Patient Safety

adverse events and Failure to Rescue (-0.0687). Therefore, even though the direct

relationship between Organization Support and Patient Safety events indicated both

increase together, once Work Unit Support was included, the effect of Work Unit

Support resulted in a decrease in Patient Safety events. With Failure to Rescue the

indirect relationship was consistent with the direct relationship. Increased

Organization Support through Work Unit Support resulted in a lower rate of Failure to

Rescue. However, a mediating effect was not found. A test was conducted to

evaluate the relationship and a mediating effect was not supported. The coefficients

and methods used to conduct the Sobel test are described on page 108. These results

could be related to the measures used to operationalize Organization Support and

Work Unit Support. As suggested earlier the scales used to define Organization

Support may be more representative of the perception staff have of their relationship

with managers and administrators rather than the support those leaders give to HROT

concepts. The scales used to define Work Unit Support may be more consistent with

HROT concepts and thereby result in a decrease in Patient Safety events and Failure to

Rescue when the effect of Organization Support is evaluated through Work Unit

Support. Although leadership influences are considered an important aspect of a

culture of safety, possibly the ability of the work unit to function as an effective team

is the most significant factor in how well preventive practices are carried out. These

findings suggest the development of effective work groups could be an important

component to development of a culture of safety.

Limitations

Several study limitations were identified. Limitations were related to the

variables used to operationalize Patient Safety, Failure to Rescue, Work Unit Support

and Organization Support. Also, limitations were identified with the final sample size

when evaluated using the parameters of the final alternate model. Generalizability of

the study also is limited based on the sample used.

Variable Limitations

Limitations of the study included the use of administrative data to determine

the incidence of specific health care related complications as defined by the PSIs.

Administrative data are collected primarily for the purpose of billing for health care

services and were not developed for use as a quality improvement or patient safety

tools. Although hospital staff members involved in coding of healthcare services

receive specialized training and use standard codes, there is a risk of variability in

coding methods within and across institutions. Variance in coding can introduce

random error, systematic error, or both. An early study reported 65.2% agreement on

the principal diagnosis between the hospital report and secondary review conducted by

the researchers therefore it is recognized that coding variability within and across

institutions is likely (IOM, 1977). In addition, administrative data are coded based on

medical record documentation. Inadequate documentation of patient care and

condition during hospitalization can impact coding and inaccurately represent the

occurrence of PSIs within an organization. AHRQ has begun additional validity

testing of the PSIs. In the first phases of this study both Selected Infections due to

Medical Care and DVT underwent further study. Flagged cased were evaluated via

medical record abstraction to validate if the case actually had the event. Based on this

work the positive predictive value (PPV) for Selected Infections due to Medical Care

= 61%, PPV for DVT = 83% (AHRQ, 2008, September).

Another limitation associated with administrative data is the ability to identify

complications that occur during a patient's hospital stay rather than those that are

present on admission. The algorithms developed by AHRQ attempted to identify and

remove these present on admission cases. Prior to 2008, the PSI algorithms addressed

this issue by using secondary diagnoses and other parameters to make it more likely

the complication was one that had occurred during hospitalization, rather than one the

patient experienced prior to hospital admission. For example, patients admitted from

certain locations were excluded from some of the PSIs. Patients admitted from

nursing homes were excluded from the denominator of cases used to determine the

Decubitus Ulcer rate for a hospital. During the development of the indicator, it was

considered that these patients may be more likely to have a Decubitus Ulcer present on

admission; therefore they were excluded from the indicator.   However, beginning in

October, 2008 hospitals were required to submit a *Present on Admission* code for

those conditions that occurred prior to the patient's admission to the hospital. Recent

studies have suggested that without the use of a present on admission code the

accuracy of some PSIs such as Decubitus Ulcer is compromised (2008). Therefore it

is likely that error has been introduced without the use of the present on admission

code. However, because the code was not included in the algorithms the error was

present across all institutions. In the future the use of the present on admission code

should improve the accuracy of the cases flagged by the PSI algorithms. However, as

noted with all administrative data, the adequacy of clinical documentation will

continue to be a factor. The ability to identify a condition as present on admission is

dependent on the clinical documentation reflecting the time of onset of complications.

The present on admission code will not be applied by coders if the documentation

does not reflect clearly that the patient had the condition on admission to the hospital.

Another limitation is that the NDNQI RN Survey and Job Satisfaction scales

were developed to measure nurse satisfaction and perception of the work environment.

These measures are not direct measures of a culture of safety. Instruments purported

to measure a culture of safety have been developed. However, a large sample of

hospitals where culture of safety survey results from one of these instruments could be

matched with patient outcomes data was not readily accessible. Therefore the scales

included in the survey were evaluated for congruence with the concepts of a culture of

safety and used as a proxy for these concepts. Also, although a standardized process is

used to collect NDNQI RN Survey data, if variance in data collection procedures

occurred bias may be introduced and threaten validity of the inferences drawn from

the measures.

Limitation of Sample Size

The sample size was another study limitation. Because the level of analysis

was at an institution or hospital level, the availability of a large sample size was

difficult to obtain. An inadequate sample size could limit the ability to detect

statistically significant relationships between the exogenous and endogenous variables.

Although there was no statistically significant direct effect of Work Unit Support on

Patient Safety (p= 0.075) the relationship could be interpreted as a promising finding.

Sample size could have contributed to the lack of significance, but also further study

with additional components representative of HROT should be considered.

During the development of the study design and the hypothesized model, an

evaluation was conducted to determine the minimum sample required to evaluate the

model under the following specifications: power 80%, degrees of freedom 101, null

RMSEA 0.01, and alternate RMSEA 0.08. Publicly available software was used to

conduct these calculations (Preacher, & Coffman, 2006). A sample size of 67 was

determined based on these criteria. Once the model was respecified a power analysis

of the final alternate model was conducted under the following specifications: power

80%, degrees of freedom 29, null RMSEA 0.01, and alternate RMSEA 0.08. The

same software as noted above was used to conduct the calculations and resulted in 135

as the minimum sample. Therefore the sample size for the final alternate model was

inadequate making it less likely that significant relationships could be detected in the

statistical analysis.

Study Generalizabiltiy

The generalizability of the study is limited by the self selected sample of

hospitals participating in the NDNQI. The NDNQI hospitals may have inherent

characteristics not uniformly represented in hospitals throughout the United States.

By nature of their participation, it might be concluded they have an increased

commitment to quality improvement and self assessment. Hospitals that submit data to the NDNQI may possess unique work environment and organization factors as compared with hospitals that do not participate in the NDNQI.

<div align="center">Implications</div>

The study has implications for health care leaders as they strive to create a culture of safety within their organizations. Although a statistically significant relationship was not found between Work Unit Support and Patient Safety or Failure to Rescue, the relationships between the measures used to define the latent variables does lead to some further considerations. The consistent relationship between an increase in Teamwork and a reduced rate of each of the indicators used to define Patient Safety, as well as Failure to Rescue was an interesting finding. The development of effective work teams has been cited by researchers as a key component to reduction of errors and patient harm. These correlations support the suggestions of patient safety experts that teamwork is an important HROT concept. Many healthcare providers were educated and socialized to act independently rather than work cooperatively in teams. Hospitals are complex systems where patients are cared for by multiple providers often in various geographic locations within an institution. The need for groups to communicate effectively and coordinate their unique knowledge and skills may be of particular importance in a healthcare culture of safety. Possibly health care leaders could best develop a culture of safety by establishing programs focused on the development of effective team skills. Helping team members use processes that support clear communication, effective conflict

management, and encourage all team members to speak up if an impending error is recognized would be the most successful strategy to reduce poor outcomes of care.

The relationship between increased scores for the Quality of Care item and decreased rates of two Patient Safety indicators (Decubitus Ulcer and DVT) and decreased rate of Failure to Rescue suggest that seeking feedback from front line staff on quality of care could be helpful to leaders. Staff's assessment of the quality of care provided on the unit may be associated with patient outcomes. The Quality of Care item may act as a proxy measure for various factors that contribute to patient care processes within a given work unit.

Although there were mixed relationships between RN Staffing and the indicators used to define Patient Safety, the correlation between staffing and Failure to Rescue was consistent with other studies. Increased RN Staffing levels were correlated with decreased rates of Failure to Rescue. Failure to Rescue represents cases of mortality and the factors contributing to this indicator may be particularly sensitive to staffing levels. Failure to Rescue requires a constant vigilance so that early recognition and intervention can occur when complications arise. The ability to be vigilant may be more sensitive to staffing and therefore the provision of adequate staffing levels is an important implication for health care leaders in their efforts to reduce patient mortality. Administrators should continue to prioritize the need for effective RN staffing models to reduce the risk of hospital mortality and Failure to Rescue.

Recommendations

The research findings can be used to guide further study of the culture of safety construct and its relationship to negative patient outcomes. Three areas for further exploration are proposed.

First, further study is needed to determine the relationship between the organization level and work unit level factors on patient safety outcomes. During the data analysis using SEM, an alternate single level model in which the scales used to operationalize Work Unit Support and Organization Support were combined into one Institutional Support latent variable was explored but did not result in an improved fit with the data. System level influences and local work area influences are consistent with HROT and the impact of these levels should be evaluated further in healthcare settings.

The strength of the relationship between increased Work Unit Support and decreased Patient Safety events warrants further study. The relationship is consistent with HROT and the culture of safety construct. The low sample size might have contributed to the lack of a statistically significant finding. The direct relationship between Work Unit Support and Patient Safety events coupled with the indirect relationship of Organization Support through Work Unit Support on Patient Safety reinforced the impact the local culture or work group has on patient safety. Although HROT concepts require leadership support, the location of care delivery could be the most significant aspect to the model. The relationships between work unit and

organization level factors that contribute to a healthcare culture of safety need further exploration.

Second research using measures that are aligned more closely to the HROT concepts, particularly those attributed to leadership influence in supporting a culture of safety is needed. Instruments purported to measure a culture of safety are available, however the data across multiple organizations has not been available readily. The instruments currently available have some similarities in their dimensions, but are not identical. It would be valuable to evaluate the most commonly used instruments and organization level outcomes across a large number of institutions. Joint Commission (2008) and others have suggested using instruments to evaluate the culture of safety within an organization and use the findings to guide development of a stronger culture of safety. However, only with further evaluation of the relationship between the instrument scores and patient outcomes will leaders be able to determine what factors are most significant in contributing to positive patient outcomes. Also, the instruments most commonly used to measure a culture of safety do not specify if the survey dimensions reflect a particular level of functioning with the organization. As suggested earlier, evaluation of the organization level at which culture of safety concepts occur requires further exploration. Possibly using these established instruments with consideration of the levels they may represent would be meaningful.

Third, further study is needed of the relationships between the construct of a culture of safety and specific patient outcomes. The associations between the indicators used to define Organization Support and Work Unit Support with the

indicators defining Patient Safety varied. The relationship between the Organization

Support and Work Unit Support indicators with the outcome of Failure to Rescue was

particularly interesting in that Failure to Rescue rates decreased as each of the

Organization Support and Work Unit Support indicators increased. Although this

researcher has suggested the indicators defining Organization Support may not have

adequately operationalized the HRO concepts associated with leadership support of a

culture of safety, they may measure organization level factors associated with Failure

to Rescue. Possibly some concepts have a greater impact on particular outcomes and

one model may not adequately represent those factors associated with all negative

patient outcomes. Further evaluation of models that include additional latent variables

should be considered.

Conclusions

The descriptive correlational study using secondary data analysis made several

contributions to the area of patient safety outcomes research. Few studies have used

measures purported to describe concepts associated with HROT and compare these

with preventable complications of care. An alternate model that provided adequate fit

of the data added to the understanding of the relationships of these variables and the

impact on patient safety. The Organization Support variable had an unanticipated

relationship with Patient Safety events. Increased levels of Organization Support and

increased Patient Safety events were correlated at a statistically significant level.

Upon further evaluation the indicators used to define Organization Support may have

reflected staff nurses' satisfaction with leaders rather than the leaders' support of

HROT concepts. However, a promising finding, although not statistically significant, was noted with increased Work Unit Support being associated with decreased rates of Patient Safety events and Failure to Rescue. Also Organization Support through Work Unit Support resulted in a reduced rate of Patient Safety events and Failure to Rescue but also was not statistically significant. The association between the indicators used to describe the latent variables of Organization Support and Work Unit Support with those used to describe patient outcomes also suggested some interesting patterns. Increased Teamwork scores were consistently correlated with reduced Patient Safety and Failure to Rescue rates.

The findings of this study can be used to guide further exploration of the relationships at a work unit and organization level on patient safety outcomes. The ability to develop systems that support positive patient outcomes and reduce the rate of error continues to be a high priority for healthcare consumers, providers, leaders, and policy makers. Development of a culture of safety is purported to be associated with positive patient outcomes. Continued exploration of the relationships between the concepts of HROT and specific patient outcomes will assist healthcare leaders as they determine what organization characteristics are of greatest importance in promoting patient safety. Informed by this knowledge healthcare leaders will be able to make better decisions that support the work of nurses and all healthcare providers and lead to systems that are safer for patients.

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Appendix A
Covariances Within and Across Latent Variables

Variable	Work Unit Support					Organization Support				Patient Safety		
	QOC	Task	Team	Decision Makg	Supp Nurse Manag	Prof Devel	Nsg Admin	Auton	DU	FTR	IMC	DVT
QOC	0.30											
Task	0.30	0.069										
Team	0.019	0.029	0.040									
Decision	0.022	0.047	0.029	0.064								
Nurse Manage	0.026	0.039	0.031	0.060	0.104							
PD	0.010	0.028	0.018	0.048	0.046	0.068						
NA	0.009	0.033	0.019	0.059	0.039	0.045	0.124					
Auton	0.022	0.043	0.030	0.040	0.039	0.025	0.029	0.037				
DU	-0.022	-0.003	-0.027	0.003	-0.022	0.013	0.014	-0.041	0.990			
FTR	-0.004	-0.071	-0.027	-0.055	-0.053	-0.024	-0.005	-0.041	-0.115	0.990		
IMC	0.012	0.025	-0.001	0.040	0.031	0.043	-0.013	-0.044	0.117	-0.127	0.990	
DVT	-0.009	0.025	-0.086	0.054	0.041	0.077	0.080	0.022	0.227	-0.218	0.231	0.990

Note. QOC= Quality of Care, Team= Teamwork Decision Mkg= Decision Making, Supp Ns Manag= Supportive Nursing Management, Prof Develop= Professional Development, Nsg Admin= Nursing Administration, Auton= Autonomy, DU= Decubitus Ulcer, FTR= Failure to Rescue, IMC= Infections due to Medical Care, DVT= Pulmonary Embolus or Deep Vein Thrombosis

APPENDIX B

NDNQI

NATIONAL DATABASE OF NURSING QUALITY INDICATORS

2005 NDNQI RN Satisfaction Survey-Revised

The 2005 survey is presented in five sections. **Part I** contains items selected to represent the subscales of the NDNQI-Adapted Index of Work Satisfaction, Nursing Work Index, and Job Enjoyment Scale. These items, phrased at the individual level, were added in response to participants' concern that their individual feelings were not being considered. **Parts II and III** are measured at the work group, or unit level, just as other indicators included in the NDNQI are measured at the patient care unit level. **Part II** is the NDNQI adaptation of Stamps' (1997) *Index of Work Satisfaction* (adapted with permission of Dr. Paula Stamps) and the NDNQI adaptation of selected subscales of the Aiken and Patrician (2000) *Nursing Work Index* (adapted with permission from Dr. Aiken). Part II contains eleven subscales: *Task, Nurse-Nurse Interactions, Nurse-Physician Interactions, Decision-Making, Autonomy, Professional Status, Pay, Supportive Nurse Management, Nursing Administration, and Professional Development*. **Part III** is the *Job Enjoyment Scale*, which is comprised of 7 items extracted from the Brayfield and Rothe (1951) questionnaire. **Part IV** contains demographic and work contextual items relating to quality of care, floating and overtime, RN characteristics, preparation, and job plans. **Part V** contains 13 items added by ANA to collect information for the Nurse Competence in Aging Initiative. The items are posted on the RN Satisfaction Home Page (www.nursingquality.org) under the Instrument link. The data collected from these items will not be included in the NDNQI RN Satisfaction Report. Go to www.GeroNurseOnline.org for contact and other information on this initiative.

Part II: NDNQI-Adapted Index of Work Satisfaction

Nurses with whom I work would say that:
Response options: strongly agree, agree, tend to agree, tend to disagree, disagree, strongly disagree.
Task:
1. They are satisfied with the nursing care they provide to patients.
2. They could do a better job if they did not have so much to do all the time.

3. They have plenty of time to discuss patient care problems with other nursing service personnel.
4. They have sufficient time for direct patient care.
5. They have plenty of opportunity to discuss patient-care problems with other nursing service personnel.
6. They could deliver much better patient care if they had more time with each patient.

Nurse-Nurse Interaction:
1. Nursing personnel pitch in and help each other when things get in a rush.
2. It is hard for new nurses to feel "at home" on the unit.
3. There is a good deal of teamwork among nursing personnel.
4. They are satisfied with the interactions among the nursing staff.
5. Nursing personnel are not as friendly and outgoing as they would like.
6. The nurses on our unit support each other.

Nurse-Physician Interaction:
1. Physicians in general cooperate with nursing staff.
2. They are not satisfied with their interactions with hospital physicians.
3. There is a lot of teamwork between nurses and doctors on our unit.
4. Physicians at this hospital look down too much on the nursing staff.
5. Physicians respect the skill and knowledge of the nursing staff.
6. Physicians at this hospital generally appreciate what the nursing staff do.

Decision-Making:
1. There is ample opportunity for nursing staff to participate in administrative decision-making processes.
2. Administrative decisions at this hospital interfere too much with patient care.
3. They are not satisfied with their participation in decision-making for the unit.
4. They have all the voice they want in planning policies and procedures for the unit.
5. Nursing administrators generally consult with the staff on daily problems.
6. They have the freedom in their work to make important decisions.
7. They can count on nursing administrators to back them up.

Autonomy:
1. They have sufficient input into the program of care for each of their patients.
2. They have too much responsibility and not enough authority.
3. Nurses have a good deal of control over their own work.
4. They are frustrated sometimes because their activities seem programmed for them.
5. They are required sometimes to do things on the job that are against their better professional judgment.
6. Nurses need more autonomy in their daily practice.
7. They are free to adjust their daily practice to fit patient needs.

Part II: NDNQI-Adapted Nursing Work Index

Nurses with whom I work would say that:
Response options: strongly agree, agree, tend to agree, tend to disagree, disagree, strongly disagree.

Professional Development:
1. They have career development opportunities.
2. They have access to regional and national conferences.
3. They have access to active inservice programs for nurses.
4. They have support for pursuing degrees in nursing.
5. They have a preceptor program for newly hired RNs.
6. They have clinical nurse specialists who provide patient care consultations.
7. They have flexible work schedules.
8. They have access to continuing education programs for nurses.
9. They have opportunities for advancement.
10. They are not satisfied with opportunities for professional development.

Supportive Nursing Management:
1. Their nurse manager is a good manager and leader.
2. Their nurse manager is supportive of nurses.
3. Their nurse manager backs up the nursing staff in decision making even in conflicts with physicians.
4. They are not satisfied with their nurse manager.
5. Their nurse manager consults with staff on daily problems.

Nursing Administration:
1. They are satisfied with the hospital chief nurse executive.
2. Their hospital chief nurse executive is equal in authority to other top-level hospital executives.
3. Their hospital chief nurse executive is visible to staff.
4. Their hospital chief nurse executive is equal in power to other top-level hospital executives.
5. Their hospital chief nurse executive is accessible to staff.

Part III: NDNQI-Adapted Job Enjoyment Scale

Part IV: Demographic and Contextual Item

<u>Quality of Care:</u>
In general, how would you describe the quality of nursing care delivered to patients on your   unit?

Response options: excellent, good, fair, poor

3. Over the past year, what has happened about the amount of overtime needed from RNs on your   unit?

Response options: increased, remained the same, decreased, don't know.

References

Aiken, L., & Patrician, P. A. (2000). Measuring organizational traits of hospitals:
   The Revised Nursing Work Index. *Nursing Research*, *49*, 146-153.
Brayfield, A., & Rothe, H. (1951). An index of job satisfaction. *Journal of Applied Psychology,*
      35, 307-311.
Stamps, P. (1997). *Nurses and work satisfaction: An index for measurement*. Chicago: Health
      Administration Press.

2-14-05

APPENDIX C

NIS
APPLICATION

August 15, 2008

CENTRAL DISTRIBUTOR

HCUP NIS APPLICATION The Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample (NIS) is available through the HCUP Central Distributor under the auspices of the Agency for Healthcare Research and Quality (AHRQ). The NIS database excludes data elements that could directly or indirectly identify individuals. Access to the files is open to users who sign a Data Use Agreement. Users must agree to use the database for research and statistical purposes only and to make no attempts to identify individuals.

For information on the NIS, see the "Overview of the Nationwide Inpatient Sample" at http:///www.hcup-us-ahrq.gov.

Directions to Complete the HCUP NIS Application:

1   Print or type all responses. An electronic copy is available on request.

2   Complete Part I: Organization and/or Individual Requesting Use of the HCUP NIS

3   Complete Part II: Selection of HCUP NIS (page 3).

4   Determine the Total Payment Due and Select Payment Method (Part III).

5   Read and sign the Indemnification Clause (Part IV).

6   Complete the online HCUP Data Use Agreement Training Course and provide your Certification Code (Part V).

7   Read and sign the Data Use Agreement for Nationwide Inpatient Sample.

8   Submit the completed application (pages 2 -11):
           HCUP Central Distributor
           Social & Scientific Systems, Inc.
           8757 Georgia Avenue, 12ᵗʰ Floor
           Silver Spring, MD 20910

Part I: Organization and/or Individual Requesting Use of the HCUP NIS General Information:

Applicant Name:

Position/Title:

Organization (include Branch, Division, Department):

Street Address:

City: State: Zip Code: Phone Number: Fax:

Internet Address:

Part II: Selection of HCUP NIS

The price of the NIS has been set to cover the full costs associated with disseminating it to data requesters. The price includes labor costs related to handling inquiries, preparing data files, and copying documentation; and the costs associated with materials and shipping.

Students in good standing may purchase any version of the NIS for $20. Students must demonstrate that they are in fact a student by providing: 1) a copy of a valid student ID, OR 2) a letter from the registrar's office indicating that they are student in good standing, OR 3) a note or letter from a professor or program director verifying that they are in fact a student in good standing.

If you have questions or want more information, please contact the HCUP Central Distributor by phone by e-mail at HCUPDistributor@AHRQ.gov.

Database	Media/structure	Price
NIS, 2006	1 year of data in 2-CD set, compressed files in ASCII format	$200 All Others $20 Students
NIS, 2005	1 year of data in 2-CD set, compressed files in ASCII format	$200 All Others $20 Students
NIS, 2004	1 year of data in 2-CD set, compressed files in ASCII format	$200 All Others $20 Students
NIS, 2003	1 year of data in 2-CD set, compressed files in ASCII format	$200 All Others $20 Students
NIS, 2002	1 year of data in 2-CD set, compressed files in ASCII format	$200 All Others $20 Students
NIS, 2001	1 year of data in 2-CD set, compressed files in ASCII format	$200 All Others $20 Students
NIS, 2000	1 year of data in 2-CD set, compressed files in ASCII format	$200 All Others $20 Students
NIS, 1999	1 year of data in 2-CD set, compressed files in ASCII format	$160 All Others $ 20 Students
NIS, 1998	1 year of data in 2-CD set, compressed files in ASCII format	$160 All Others $ 20 Students
NIS, Release 6, 1997	1 year of data in 2-CD set, compressed files in ASCII format	$160 All Others $ 20 Students
NIS, Release 5, 1996	1 year of data in 2-CD set, compressed files in ASCII format	$160 All Others $ 20 Students
NIS, Release 4, 1995	1 year of data in 2-CD set, compressed files in ASCII format	$160 All Others $ 20 Students
NIS, Release 3, 1994	1 year of data in 2-CD set, compressed files in ASCII format	$160 All Others $ 20 Students
NIS, Release 2, 1993	1 year of data in 2-CD set, compressed files in ASCII format	$160 All Others $ 20 Students
NIS, Release 1, 1988-1992	5 years of data in 6-CD set, compressed files in ASCII format	$322 All Others $20 Students

Part III: Determine the Total Payment Due and Select Payment Method

Total Payment Due

If you need help determining the payment due, submit the completed application (pages 2-11), without payment, to the *HCUP Central Distributor* and request an invoice. An itemized invoice will be faxed or e-mailed to you stating the total payment due, including taxes for applicants in Maryland. Note that the HCUP Central Distributor collects taxes only from applicants in Maryland. All other applicants are responsible for determining tax liability and remitting taxes directly to state and local taxing authorities.

TOTAL PAYMENT DUE	
NIS Data Cost From Part II:	$_____
Tax (MD applicants only):	$_____
Total Payment Due:	$_____

Orders will not be filled until the completed application and

full payment have been received. Payment Method

The HCUP Central Distributor accepts purchase orders, and payment may be made by major credit card, check, or electronic funds' transfer.

Paying by Credit Card

Visa, MasterCard, and American Express are accepted. Your credit card is not charged until the day your order is shipped. A credit card receipt for your purchase is included with the order.

Credit card information is accepted by mail or telephone. If you would like to mail the information, please complete items 1 – 10 of the Credit Card Payment form on the next page and mail it with your itemized invoice or completed application to the following address:

> *HCUP Central Distributo*r
> *Social & Scientific Systems, Inc.*
> *8757 Georgia Avenue, 12*th *Floor*
>   *Silver Spring, MD 20910*
>
> If you prefer to provide your credit card information by telephone, please call toll-free at (866) 556-4287 between 9 a.m. and 5 p.m. Eastern Time.

Paying by Check

Checks should be made payable to *Social & Scientific Systems, Inc.* Mail a check for the total payment due with your itemized invoice or completed application. The address is listed above.

Credit Card Payment Form

If you would like to pay by credit card, please complete items 1 – 10 of this form and enclose it with your application. If you prefer to provide your credit card information by telephone, please call toll-free at (866) 5564287 between 9 a.m. and 5 p.m. Eastern Time.

1. **Date**:
2. **Individual/Company Name:**
3. **Names On Credit Card:**

   a. *Please list the names on the credit card exactly as they are shown on the card.*

4. **Type Of Credit Card: MASTERCARD VISA AMERICAN EXPRESS**
5. **Amount:**
6. **Credit Card Number:**
7. **Expiration Date:**
8. **Credit Card Billing Address:**
9. **City, State & Zip Code:**
10. **Customer Signature:**

For Office Use Only

Verbal Authorization For Signature: *Yes*   *No*

Person Requesting Credit Card Processing:

_____

Requester's Phone Number And Extension:

_____

Project Code Number:

_____

Date Processed:

_____

Invoice

*Numbers:*_____

Paid: Input By:

_____

Part IV: Indemnification Clause

Recipient shall indemnify and hold Thomson Healthcare Inc. and its directors, officers, employees, agents, affiliates and subsidiaries harmless from any and all losses, claims, damages, liabilities, costs and expenses (including, without limitation, reasonable attorney's fees and costs) arising out of any claim arising from any third parties, including but not limited to any or some combination of the several States comprising the United States of America and/or the Government of the United States of America, concerning Recipient's use of the NIS data provided by Thomson Healthcare Inc. Further, Recipient agrees that Thomson Healthcare Inc. shall not be liable to Recipient for any reason whatsoever arising out of the NIS data or the Recipient's use of the NIS data.

Recipient certifies and warrants that it has made no representations to Thomson Healthcare Inc. concerning any uses it (Recipient) intends to make of the NIS data provided by Thomson Healthcare Inc. under the terms and conditions of Thomson Healthcare Inc. contract with the U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality. Further, Recipient agrees that no representation of Recipient as to the Recipient's intended use of the NIS data was used to determine whether the Recipient's request to use NIS data would be approved.

Recipient shall indemnify and hold Social & Scientific Systems, Inc. (SSS) and its directors, officers, employees, owners, and agents harmless from any and all losses, claims, damages, liabilities, costs and expenses (including, without limitation, reasonable attorney's fees and costs) arising out of any claim arising from any third parties, including but not limited to any or some combination of the several States comprising the United States of America and/or the Government of the United States of America, concerning Recipient's use of NIS data provided by SSS. Further, Recipient agrees that SSS shall not be liable to Recipient for any reason whatsoever arising out of the NIS data or the Recipient's use of the NIS data.

Recipient certifies and warrants that it has made no representations to SSS concerning any uses it (Recipient) intends to make of the NIS data provided by SSS under the terms and conditions of its contract with the U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality. Further, Recipient agrees that no representation of Recipient as to the Recipient's intended use of the NIS data was used to determine whether the Recipient's request to use NIS data would be approved.

Signed: Date:

New Requirement: HCUP Data Use Agreement Training

Because of the sensitive nature of the data contained in the Healthcare Cost and Utilization Project (HCUP) databases, there is a continued need to reinforce the safeguards and restrictions placed on use of the data. All data purchasers and users of HCUP data must complete the HCUP Data Use Agreement (DUA) Training Course. This course emphasizes the importance of data protection, helps to reduce the risk of inadvertent violations, and describes your individual responsibility when using HCUP data. The course will take approximately 15 minutes to complete and you will not be required to take it more than once.

If you have not previously completed the HCUP DUA Training Course, please go to the HCUP-US website at http://www.hcup-us.ahrq.gov/tech_assist/dua.jsp, complete the online HCUP DUA Training Course, and enter the certification number at the end of the course in the space provided below.

HCUP DUA Training Course Certification Code

_____

DATA USE AGREEMENT for the Nationwide Inpatient Sample from the Healthcare Cost and Utilization Project Agency for Healthcare Research and Quality

This Data Use Agreement ("Agreement") implements the data protections of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Public Law 104-191) and the Agency for Healthcare Research and Quality (AHRQ) confidentiality statute. Any individual ("data recipient") seeking to obtain or use data in the Nationwide Inpatient Sample (NIS) from the Healthcare Cost and Utilization Project (HCUP) maintained by the Center for Delivery, Organization, and Markets (CDOM) within AHRQ, must sign and submit this Agreement to AHRQ or its agent before access to the NIS may be granted.

In accordance with HIPAA, the NIS may only be used or disclosed in the form of a *limited data set*, as defined by the HIPAA Privacy Rule (45 CFR § 164.514(e)).

The AHRQ confidentiality statute, Section 924(c) of the Public Health Service Act (42 U.S.C. 299c-3(c)), requires that data collected by AHRQ that identify individuals or establishments be used only for the purpose for which they were supplied. Data supplied to AHRQ for HCUP and disclosed in limited data set form are identifiable under the HIPAA Privacy Rule and are provided by the data sources only for research, analysis, and aggregate statistical reporting. Therefore, data recipients may use HCUP data only for these purposes.

No Identification of Persons–Any effort to determine the identity of any person contained in HCUP databases (including but not limited to patients, physicians, and other health care providers), or to use the information for any purpose other than for research, analysis, and aggregate statistical reporting, would violate the AHRQ confidentiality statute, the conditions of this Agreement, and the HIPAA Privacy Rule. Recipients of the data set are prohibited under the AHRQ confidentiality statute and the terms of this Agreement from releasing, disclosing, publishing, or presenting any individually identifying information obtained under this Agreement. AHRQ omits from the data set all direct identifiers that are required to be excluded from limited data sets as defined by the HIPAA Privacy Rule. It may be possible in limited situations, through deliberate technical analysis, and with outside information, to ascertain from the limited data sets the identity of particular persons. Considerable harm could ensue if this were to occur. Therefore, any attempts to identify individuals are prohibited and information that could identify individuals directly or by inference must not be released or published. In addition, users of the data must not attempt to contact individuals for any purpose, including verifying information supplied in the data set. Any questions about the data must be referred exclusively to AHRQ.

Use of Establishment Identifiers–Section 924(c) of the Public Health Service Act (42 U.S.C. 299c-3(c)) also restricts the use of any information that permits the identification of establishments for purposes other than those for which the information was originally supplied. Permission is obtained from the HCUP data sources (state data organizations, hospital associations, and data consortia) to use the identification of hospitals (when such identification appears in the data sets) for research, analysis, and aggregate statistical reporting. This may include linking institutional information from outside data sets for these purposes. Such purpose does *not* include the use of information in the data sets concerning individual establishments for commercial or competitive purposes involving those individual establishments, or to determine the rights, benefits, or privileges of establishments. Users of the data must not identify establishments directly or by inference in disseminated material. In addition, users of the data must not contact establishments for the purpose of verifying information supplied in the data set. Any questions about the data must be referred exclusively to AHRQ. Misuse of identifiable HCUP data about hospitals would violate the AHRQ confidentiality statute and trigger its penalty provisions.

The undersigned gives the following assurances with respect to the NIS data set:

- I will not use and will prohibit others from using or disclosing the data set (or any part), except for research, analysis, and aggregate statistical reporting, and only as permitted by this Agreement.
- I will ensure that the data are kept in a secured environment and that only authorized users will have access to the data.
- I will not release or disclose, and will prohibit others from releasing or disclosing, any data that are individually identifiable under the HIPAA Privacy Rule, or any information that identifies persons, directly or indirectly, except as permitted under this Agreement and in accordance with the above-mentioned AHRQ confidentiality statute.
- I will not release or disclose information where the number of observations (i.e., individual discharge records) in any given cell of tabulated data is less than or equal to 10.
- I will not release or disclose, and will prohibit others from releasing or disclosing, the data set (or any part) to any person who is not a member, agent, or contractor of the organization (specified below), except with the approval of AHRQ.
- I will require others employed in my organization (specified below), and any agents or contractors of my organization, who will use or will have access to the data set, to sign a copy of this Agreement (specifically acknowledging their agreement to abide by its terms) and I will submit those signed Agreements to AHRQ or its agent before granting access.
- I will not attempt to link, and will prohibit others from attempting to link, the discharge records of persons in the data set with individually identifiable records from any other source.
- I will not attempt to use and will prohibit others from using the data set to learn the identity of any person included in the data set or to contact any such person for any purpose.
- In accordance with the AHRQ confidentiality statute, I will not use and will prohibit others from using the data set concerning individual establishments (1) for commercial or competitive purposes involving those individual establishments; (2) to determine the rights, benefits, or privileges of individual establishments; or (3) to report, through any medium, data that could identify, directly or by inference, individual establishments.
- When the identities of establishments are not provided in the data sets, I will not attempt to use and will prohibit others from using the data set to learn the identity of any establishment.

- I will not contact and will prohibit others from contacting establishments or persons in the data set to question, verify, or discuss data in the HCUP databases.
- I acknowledge that the NIS contains data elements from proprietary restricted computer software (3M APR-DRGs, HSS APS-DRGs, and Medstat Disease Staging) supplied by private vendors to AHRQ for the sole purpose of supporting research and analysis with the NIS. While I may freely use these data elements in my research work using the NIS, I agree that I will not use and will prohibit others from using these proprietary data elements for any commercial purpose. In addition, I will enter into a separate agreement with the appropriate organization or firm for the right to use such proprietary data elements for commercial purposes. In particular, I agree not to disassemble, decompile, or otherwise reverse-engineer the proprietary software, and I will prohibit others from doing so.
- I will indemnify, defend, and hold harmless AHRQ and the data organizations that provide data to AHRQ for HCUP from any or all claims and losses accruing to any person, organization, or other legal entity as a result of violation of this Agreement. This provision applies only to the extent permitted by Federal and State law.
- I will make no statement and will prohibit others from making statements indicating or suggesting that interpretations drawn are those of the data sources or AHRQ.
- I will acknowledge in all reports based on these data that the source of the data is the "Nationwide Inpatient Sample (NIS), Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality."

Safeguards. I agree to use appropriate safeguards to prevent use or disclosure of the data set other than as permitted by this Agreement.

Permitted Access to Limited Data Set. I shall limit the use or receipt of the data set to the individuals who require access in order to perform activities permitted by this Agreement. This Agreement must be signed by all such individuals and submitted to AHRQ or its agent before access to the data set may be granted.

Re-disclosure. I will not re-disclose (i.e., share) the data set (or any part), unless the individual who will receive the data has agreed in writing to be bound by the same restrictions and conditions that apply to me under this Agreement.

The HIPAA Privacy Rule. I agree not to use or disclose the data set in any manner that would violate the HIPAA Privacy Rule if I were a covered entity under the Privacy Rule.

Agents and Contractors. I shall ensure that any agents, including contractors and subcontractors to whom I provide the data set, agree in writing to be bound by the same restrictions and conditions that apply to me with respect to the limited data set.

Reporting Violations of this Agreement. I agree to report any violations to AHRQ within twenty-four (24) hours of becoming aware of any use or disclosure of the limited data set in violation of this Agreement or applicable law.

Term, Breach, and Termination of this Agreement. This Agreement shall continue in full effect until the data recipient has returned all copies of the data set to AHRQ. Any noncompliance by the data recipient with the terms of this Agreement will be grounds for immediate termination of the Agreement if, at the sole determination of AHRQ, the data recipient knew or should have known of such noncompliance and failed to immediately take reasonable steps to remedy the noncompliance.

Reporting to the United States Department of Health and Human Services. If the data recipient fails to remedy any breach or violation of this Agreement to the satisfaction of AHRQ, and if termination of the Agreement is not feasible, AHRQ shall report the recipient's breach or violation to the Secretary of the United States Department of Health and Human Services, and the recipient agrees that he or she shall not have or make any claims against AHRQ with respect to such report(s).

I understand that this Agreement is requested by the United States Agency for Healthcare Research and Quality to ensure compliance with its statutory confidentiality requirement. My signature indicates my Agreement to comply with the above-stated requirements with the knowledge that any violation of the AHRQ confidentiality statute is subject to a civil penalty of up to $10,000 under 42 U.S.C. 299c-3(d), and that deliberately making a false statement about this or any matter within the jurisdiction of any department or agency of the Federal Government violates 18 U.S.C. 1001 and is punishable by a fine of up to $10,000 or up to five years in prison. Violators of this Agreement may also be subject to penalties under state confidentiality statutes that apply to these data for particular states.

Signed:_____

Date:_____ Print or Type Name of Data Recipient:

_____

Title:_____

_____ Organization:

_____

Address:_____

_____ City: _____ State: _____ ZIP

Code: _____ Phone Number: _____ Fax:

_____ E-mail:

_____

_____ The information above is maintained by AHRQ for the purpose of enforcement of this

Agreement. This information may also be used by AHRQ to create an HCUP mailing list.

The mailing list allows AHRQ to send users information such as notices about the release of

new databases

APPENDIX D
SID APPLICATION

December 19, 2008

CENTRAL DISTRIBUTOR
UNIFORM STATE APPLICATION

Data Organizations participating in the Healthcare Cost and Utilization Project (HCUP) have agreed to release their State Inpatient Databases (SID), State Ambulatory Surgery Databases (SASD), and State Emergency Department Databases (SEDD) through a Central Distributor under the auspices of the Agency for Healthcare Research and Quality (AHRQ). This uniform application was designed by the participating Data Organizations to satisfy their requirements. As such, the information requested in this application is for the Data Organizations. The information is not for AHRQ or the HCUP Central Distributor. AHRQ and the HCUP Central Distributor are facilitating access to the SID, SASD and SEDD, which are owned and regulated by the individual Data Organizations participating in HCUP. The Data Organizations dictate which data elements may be released through the HCUP Central Distributor. However, data elements in the SID, SASD, and SEDD are in a uniform HCUP format that is consistent across all states and years of HCUP data.

Directions to Complete the Uniform State Application:
1. Print or type all responses.
2. Complete all applicable parts of this application.
> Part I Organization and/or Individual Requesting Use of the HCUP Databases (page 2)
> Part II Intended Use of Data and Project Activities
> Part III Selection of HCUP Databases
3. Determine the Total Payment Due and Select Payment Method (Part IV).
4. Read and sign the Indemnification Clause (Part V, page 17).
5. Complete the online HCUP Data Use Agreement Training Course and provide your Certification Code (Part VI, page 18).
6. If purchasing the SID, read and sign the Data Use Agreement for HCUP State Inpatient Databases (Part VII, page 19).
7. If purchasing the SASD, read and sign the Data Use Agreement for HCUP State Ambulatory Surgery Databases (Part VIII, page 23).
8. If purchasing the SEDD, read and sign the Data Use Agreement for HCUP State Emergency Department Databases (Part IX, page 27).
9. Submit the completed application (pages 2-31):
HCUP Central Distributor
Social & Scientific Systems, Inc.
8757 Georgia Avenue, 12th Floor Silver Spring, MD 20910

Part I: Organization and/or Individual Requesting Use of the HCUP Databases

General Information:

Applicant Name:
Position/Title:
Organization (include Branch, Division, Department):
Street Address:

City: State: ZIP Code: Phone Number: Fax:

Internet Address:

Type of Organization:

Check the *one* box that best describes your organization.

- o University/college/teaching institution

- o Government agency

- o Managed care, insurer

- o Healthcare provider

- o Pharmaceutical, biotechnology, medical product firm

- o Trade association, lobbying group, consortium

- o Research organization, consultant

- o Other (describe in space provided)

Check the one box that best characterizes the type of ownership of your organization.

- o Not-for-profit

- o For-profit

Part II: Intended Use of Data and Project Activities

Describe the intended use of the data requested. Attach additional pages if necessary. Include:

- Brief description of project(s) and intended use of the data (e.g., clinical research, health services research, analyses to address public policy issues, analyses to address private policy issues, creating products or tools such as quality measurements, severity adjustment software, etc.)

- Brief description of the subject area(s) that you plan to investigate (e.g., health outcomes, quality, cost, utilization, access, markets, etc.)

- Brief description of the potential uses of the final products that you may create using the data (e.g., papers, reports, tools, analyses for public domain and/or internal use, etc.)

Please refer to Part VI "Data Use Agreement for HCUP State Inpatient Databases" (page 19), Part VII "Data Use Agreement for HCUP State Ambulatory Surgery Databases" (page 23), and Part VIII "Data Use Agreement for HCUP State Emergency Department Databases" (page 27) for complete descriptions of the acceptable uses of the HCUP SID, SASD, and SEDD. In general, the HCUP SID, SASD, and SEDD are available for the purpose of research and aggregate statistical reporting. Attempts to identify individuals are strictly prohibited. Information that could identify individuals or establishments directly or by inference may not be released in disseminated materials. The data may not be re-released in any form without prior approval of the participating Data Organization(s).

HCUP Request:

Check *all* boxes that describe the reasons for requesting the HCUP databases.

- o Research requires specific state(s).
- o Research requires variables only available in the selected states (e.g., encrypted patient ZIP
- o Codes, encrypted physician identifiers). Indicate variables below.

Other (describe in space provided)

Part III: Selection of HCUP Databases

Section I. Select State Inpatient Databases (SID)

Mark boxes for the data you are requesting (see next page) and enter the total cost of requested data under the column titled "Total."

Please refer to the Databases section of the HCUP User Support Website (www.hcup-us.ahrq.gov) for detailed information about the SID. Not all HCUP data elements are available from every state.

The participating Data Organizations dictate the price of the data. Handling charges are already included. Some Data Organizations offer a price discount to AHRQ Grant recipients, and Arizona currently offers a discount to students.

If you are not sure if you qualify for the AHRQ Grantee discount, please refer to Section IV. AHRQ Grantee (page 14).

Students in good standing may purchase the 2005-2007 Arizona SID for $20. Students must demonstrate that they are in fact a student by providing: 1) a copy of a valid student ID, OR 2) a letter from the registrar's office indicating that they are student in good standing, OR 3) a note or letter from a professor or program director verifying that they are in fact a student in good standing.

If you have any questions or want information on other years of data or more

sensitive data elements for a state, please contact the HCUP Central

Distributor by phone at (866) 556-4287 (toll free), fax at (866) 792-5313 (toll free), or e-mail at HCUPDistributor@AHRQ.gov.

State	HCUP SID Price Structure	1990	1991	1992	1993	1994	1995 - 2007	Total
Arizona	All Applicants	$ 20	$ 20	$ 20	$ 20	$ 20	See next page	
Arkansas	All Applicants	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
California	All Applicants	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
Colorado	All Applicants	$ 240	$ 240	$ 240	$ 240	$ 240	See next page	
Florida	All Applicants	$ 120	$ 120	$ 120	$ 120	$ 120	See next page	
Hawaii	Not-for-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
	For-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
Iowa	All Applicants	$ 420	$ 420	$ 420	$ 420	$ 420	See next page	
Kentucky	All Applicants	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
Maine	Non-profit/Educational	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
	Commercial	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
Maryland	All Applicants	$ 20	$ 20	$ 20	$ 20	$ 20	See next page	
Massachusetts	All Applicants	$ 820	$ 820	$ 820	$ 820	$ 820	See next page	
Michigan	Not-for-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
	For-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
Nebraska	All Others	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
	AHRQ Grantee (Complete Section IV, page 14)	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
Nevada	Not-for-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
	For-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
New Jersey	All Applicants	$ 45	$ 45	$ 45	$ 45	$ 45	See next page	
New York	All Others	$ 670	$ 670	$ 670	$ 670	$ 670	See next page	
	AHRQ Grantee (Complete Section IV, page 14)	$ 345	$ 345	$ 345	$ 345	$ 345	See next page	
North Carolina	Not-for-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
	For-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
Oregon	Not-for-profit Affiliation	Not Available	Not Available	Not Available	$ 220	$ 220	See next page	
	For-profit Affiliation--SEE FOOTNOTE.	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
Rhode Island	All Applicants	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
South Carolina	All Applicants	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
Utah	Public, State/Federal Agency, Academic Organization	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
	Private Organization	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
Vermont	Not-for-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
	For-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
Washington	All Applicants	. $ 720	. $ 720	. $ 720	. $ 720	. $ 720	See next page	
West Virginia	All Applicants	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
Wisconsin	All Applicants	. $ 620	. $ 620	. $ 620	. $ 620	. $ 620	See next page	

**The Oregon Association of Hospitals and Health Systems does not disseminate data to for-profit organizations through the HCUP Central Distributor.

State	HCUP SID Price Structure	1995	1996	1997	1998	1999	2000 - 2007	TOTAL
Arizona	All Applicants	$ 20	$ 20	$ 20	$ 20	$ 20	See next page	
Arkansas	All Applicants	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
California	All Applicants	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
Colorado	All Applicants	$ 240	$ 240	$ 240	$ 240	$ 240	See next page	
Florida	All Applicants	$ 125	$ 125	$ 125	$ 120	$ 120	See next page	
Hawaii	Not-for-profit Affiliation	Not Available	Not Available	Not Available	$ 620	$ 620	See next page	
	For-profit Affiliation	Not Available	Not Available	Not Available	$ 820	$ 820	See next page	
Iowa	Not-for-profit Affiliation	$ 420	$ 420	$ 420	$ 420	$ 420	See next page	
	For-profit Affiliation	$ 420	$ 420	$ 420	$ 820	$ 820	See next page	
Kentucky	All Applicants	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
Maine	Non-profit/Educational	Not Available	Not Available	Not Available	Not Available	$ 420	See next page	
	Commercial	Not Available	Not Available	Not Available	Not Available	$ 420	See next page	
Maryland	All Applicants	$ 20	$ 20	$ 20	$ 20	$ 20	See next page	
Massachusetts	All Applicants	$ 830	$ 830	$ 830	$ 820	$ 820	See next page	
Michigan	Not-for-profit Affiliation	Not Available	Not Available	Not Available	Not Available	$ 545	See next page	
	For-profit Affiliation	Not Available	Not Available	Not Available	Not Available	$ 970	See next page	
Nebraska	All Others	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
	AHRQ Grantee (Complete Section IV, page 14)	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
Nevada	Not-for-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
	For-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
New Jersey	All Applicants	$ 55	$ 50	$ 50	$ 45	$ 45	See next page	
New York	All Others	$ 695	$ 695	$ 690	$ 670	$ 670	See next page	
	AHRQ Grantee (Complete Section IV, page 14)	$ 370	$ 370	$ 365	$ 345	$ 345	See next page	
North Carolina	Not-for-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
	For-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
Oregon	Not-for-profit Affiliation	$ 770	$ 770	$ 770	$ 770	$ 770	See next page	
	For-profit Affiliation—SEE FOOTNOTE.	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
Rhode Island	All Applicants	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
South Carolina	All Applicants	$ 470	$ 470	$ 470	$ 620	$ 620	See next page	
Utah	Public, State/Federal Agency, Academic Organization	Not Available	Not Available	$ 770	$ 770	$ 770	See next page	
	Private Organization	Not Available	Not Available	$ 1,520	$ 1,520	$ 1,520	See next page	
Vermont	Not-for-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
	For-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
Washington	All Applicants	$ 720	$ 720	$ 720	$ 70	$ 70	See next page	
West Virginia	All Applicants	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
Wisconsin	All Applicants	$ 620	$ 620	$ 620	$ 620	$ 620	See next page	

State	HCUP SID Price Structure	2000	2001	2002	2003	2004	2005-2007	TOTAL
Arizona	All Applicants	$ 20	$ 20	$ 20	$ 20	$ 20	See next page	
Arkansas	All Applicants	Not Available	Not Available	Not Available	Not Available	$ 470	See next page	
California	Government, Non-profit Research or Educational	Not Available	Not Available	Not Available	$ 220	$ 20	See next page	
	All Others	Not Available	Not Available	Not Available	$ 220	$ 220	See next page	
Colorado	All Applicants	$ 340	$ 340	$ 340	$ 440	$ 440	See next page	
Florida	All Applicants	$ 120	$ 120	$ 120	$ 120	$ 120	See next page	
Hawaii	Not-for-profit Affiliation	$ 820	$ 820	$ 820	$ 820	$ 820	See next page	
	For-profit Affiliation	$ 1,020	$ 1,020	$ 1,020	$ 1,020	$ 1,020	See next page	
Iowa	Not-for-profit Affiliation	$ 420	$ 420	$ 520	$ 520	$ 520	See next page	
	For-profit Affiliation	$ 820	$ 820	$ 1,020	$ 1,020	$ 1,020	See next page	
Kentucky	All Applicants	$ 1,520	$ 1,520	$ 1,520	$ 1,520	$ 1,520	See next page	
Maine	Non-profit/Educational	$ 420	$ 420	$ 420	$ 670	Not Available	See next page	
	Commercial	$ 420	$ 420	$ 420	$ 1,320	Not Available	See next page	
Maryland	All Applicants	$ 20	$ 20	$ 20	$ 20	$ 20	See next page	
Massachusetts	All Applicants	$ 820	$ 820	$ 820	$ 820	$ 820	See next page	
Michigan	Not-for-profit Affiliation	$ 545	$ 545	$ 545	$ 545	$ 570	See next page	
	For-profit Affiliation	$ 970	$ 970	$ 970	$ 1,520	$ 1,520	See next page	
Nebraska	All Others	Not Available	$ 1,020	$ 1,020	$ 1,020	$ 1,020	See next page	
	AHRQ Grantee (Complete Section IV, page 14)	Not Available	$ 520	$ 520	$ 520	$ 520	See next page	
Nevada	Not-for-profit Affiliation	Not Available	Not Available	$ 270	$ 270	$ 270	See next page	
	For-profit Affiliation	Not Available	Not Available	$ 520	$ 520	$ 520	See next page	
New Jersey	All Applicants	$ 45	$ 45	$ 45	$ 45	$ 45	See next page	
New York	All Others	$ 670	$ 670	$ 670	$ 670	$ 720	See next page	
	AHRQ Grantee (Complete Section IV, page 14)	$ 345	$ 345	$ 345	$ 345	$ 370	See next page	
North Carolina	Not-for-profit Affiliation	$ 520	$ 520	$ 520	$ 520	$ 520	See next page	
	For-profit Affiliation	$ 1,520	$ 1,520	$ 1,520	$ 1,520	$ 1,520	See next page	
Oregon	Not-for-profit Affiliation	$ 770	$ 770	$ 770	$ 770	$ 770	See next page	
	For-profit Affiliation—SEE FOOTNOTE.	Not Available	Not Available	Not Available	Not Available	Not Available	See next page	
Rhode Island	All Applicants	Not Available	Not Available	$ 120	$ 120	$ 120	See next page	
South Carolina	All Applicants	$ 620	$ 620	$ 620	$ 620	$ 620	See next page	
Utah	Public, State/Federal Agency, Academic Organization	$ 770	$ 807	$ 807	$ 807	$ 807	See next page	
	Private Organization	$ 1,520	$ 1,595	$ 1,595	$ 1,595	$ 1,595	See next page	
Vermont	Not-for-profit Affiliation	Not Available	$ 540	$ 540	$ 540	$ 540	See next page	
	For-profit Affiliation	Not Available	$ 1,040	$ 1,040	$ 1,040	$ 1,040	See next page	
Washington	All Applicants	$ 70	$ 70	$ 70	$ 70	$ 70	See next page	
West Virginia	All Applicants	$ 470	$ 470	$ 470	$ 495	$ 495	See next page	
Wisconsin	All Applicants	$ 620	$ 620	$ 720	$ 720	$ 720	See next page	

State	HCUP SID Price Structure	2005	2006	2007	TOTAL
	Students	$ 20	$ 20	$ 20	
Arizona	Non-profit/Educational	$ 120	$ 120	$ 120	
	For-profit Affiliation	$ 320	$ 320	$ 320	
Arkansas	All Applicants	$ 470	$ 470	$ 470	
California	Government, Non-profit Research or Educational Institution	$ 20	$ 20	$ 20	
	All Others	$ 220	$ 220	$ 220	
Colorado	All Applicants	$ 500	$ 500	$ 500	
Florida	All Applicants	$ 120	$ 120	Not Available	
Hawaii	Not-for-profit Affiliation	$ 820	$ 820	Not Available	
	For-profit Affiliation	$ 1,020	$ 1,020	Not Available	
Iowa	Not-for-profit Affiliation	$ 520	$ 570	$ 570	
	For-profit Affiliation	$ 1,020	$ 1,120	$ 1,120	
Kentucky	All Applicants	$ 1,520	$ 1,520	Not Available	
Maine	Non-profit/Educational /Commercial	Not Available	Not Available	Not Available	
Maryland	All Applicants	$ 20	$ 20	$ 20	
Massachusetts	All Applicants	$ 820	Not Available	Not Available	
Michigan	Not-for-profit Affiliation	$ 570	$ 570	Not Available	
	For-profit Affiliation	$ 1,520	$ 1,520	Not Available	
	All Others	$ 1,020	$ 1,020	Not Available	
Nebraska	AHRQ Grantee (Complete Section IV, page 14)	$ 520	$ 520	Not Available	
	Not-for-profit Affiliation	$ 420	$ 420	$ 420	
Nevada	For-profit Affiliation	$ 820	$ 820	$ 820	
New Jersey	All Applicants	$ 45	$ 45	$ 45	
	All Others	$ 720	$ 720	Not Available	
New York	AHRQ Grantee (Complete Section IV, page 14)	$ 370	$ 370	Not Available	
North Carolina	Not-for-profit Affiliation	$ 520	$ 520	Not Available	
	For-profit Affiliation	$ 1,520	$ 1,520	Not Available	
	All Others	$ 770	$ 770	$ 770	
Oregon	For-profit Affiliation—SEE FOOTNOTE	Not Available	Not Available	Not Available	
Rhode Island	All Applicants	$ 120	Not Available	Not Available	
South Carolina	All Applicants	$ 620	$ 620	Not Available	
Utah	Public, State/Federal Agency, Academic Organization	$ 807	$ 1,595	Not Available	
	Private Organization	$ 1,595	$ 3,170	Not Available	
Vermont	Not-for-profit Affiliation	$ 640	$ 640	Not Available	
	For-profit Affiliation	$ 1,240	$ 1,240	Not Available	
Washington	All Applicants	$ 70	$ 70	$ 70	
West Virginia	All Applicants	$ 495	$ 495	$ 495	
Wisconsin	All Applicants	$ 820	$ 820	Not Available	

Section II. Select State Ambulatory Surgery Databases (SASD)

Mark boxes for the data you are requesting. Please refer to the Databases section of the HCUP User Support Website (www.hcup-us.ahrq.gov) for detailed information about the SASD. Not all HCUP data elements are available from every state.

The participating Data Organizations dictate the price of the data. Handling charges are already included. Some Data Organizations offer a price discount to AHRQ Grant recipients. If you are not sure if you qualify for this discount, please refer to Section IV. AHRQ Grantee (page 14). Enter the total cost of requested data under the column titled "Total."

If you have questions or want information on other years of data or more sensitive data elements for a state, please contact the HCUP Central Distributor by phone at (866) 556-4287 (toll free), fax at (866) 792-5313 (toll free), or e-mail at HCUPDistributor@AHRQ.gov.

State	HCUP SASD Price Structure	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	TOTAL
California	Government, Non-profit Research or Educational Institution	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	$ 20	$ 20	$ 20	
	All Others	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	$ 220	$ 220	$ 220	
Colorado	All Applicants	$ 315	$ 315	$ 315	$ 315	$ 315	$ 340	$ 340	$ 340	$ 380	$ 380	$ 380	
Florida	All Applicants	$ 125	$ 120	$ 120	$ 120	$ 120	$ 120	$ 120	$ 120	$ 120	$ 120	Not Available	
Iowa	Not-for-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	$ 520	$ 520	$ 570	$ 570	
	For-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	$ 1,020	$ 1,020	$ 1,120	$ 1,120	
Kentucky	All Applicants	Not Available	Not Available	Not Available	$ 1,520	$ 1,520	$ 1,520	$ 1,520	$ 1,520	$ 1,520	$ 1,520	Not Available	
Maine	Non-profit/Educational	Not Available	Not Available	$ 420	$ 420	$ 420	$ 420	$ 420	Not Available	Not Available	Not Available	Not Available	
	Commercial	Not Available	Not Available	$ 1,020	$ 1,020	$ 1,020	$ 1,020	$ 1,020	Not Available	Not Available	Not Available	Not Available	
Maryland	All Applicants	$ 20	$ 20	$ 20	$ 20	$ 20	$ 20	$ 20	$ 20	$ 20	$ 20	$ 20	
Michigan	Not-for-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	$ 545	$ 570	$ 570	Not Available	
	For-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	$ 970	$ 1,020	$ 1,020	Not Available	
	All Others	Not Available	Not Available	Not Available	Not Available	$ 1,020	$ 1,020	$ 1,020	$ 1,020	$ 1,020	$ 1,020	Not Available	
Nebraska	AHRQ Grantee (Complete Section IV, page 14)	Not Available	Not Available	Not Available	Not Available	$ 520	$ 520	$ 520	$ 520	$ 520	$ 520	Not Available	
New Jersey	All Applicants	$ 45	$ 45	$ 45	$ 45	$ 45	$ 45	$ 45	$ 45	$ 45	$ 45	$ 45	
New York	All Others	$ 470	$ 470	$ 470	$ 470	$ 470	$ 470	$ 470	$ 520	$ 520	$ 520	Not Available	
	AHRQ Grantee (Complete Section IV, page 14)	$ 245	$ 245	$ 245	$ 245	$ 245	$ 245	$ 245	$ 270	$ 270	$ 270	Not Available	
North Carolina	Not-for-profit Affiliation	Not Available	Not Available	Not Available	$ 520	$ 520	$ 520	$ 520	$ 520	$ 520	$ 520	Not Available	
	For-profit Affiliation	Not Available	Not Available	Not Available	$ 1,520	$ 1,520	$ 1,520	$ 1,520	$ 1,520	$ 1,520	$ 1,520	Not Available	
South Carolina	All Applicants	Not Available	Not Available	Not Available	$ 732	$ 732	$ 732	$ 732	$ 732	$ 732	$ 732	Not Available	
Utah	Public, State/Federal Agency, Academic Organization	$ 770	$ 770	$ 770	$ 770	$ 807	$ 807	$ 807	$ 807	$ 807	$ 1,595	Not Available	
	Private Organization	$ 1,520	$ 1,520	$ 1,520	$ 1,520	$ 1,595	$ 1,595	$ 1,595	$ 1,595	$ 1,595	$ 3,170	Not Available	
Vermont	Not-for-profit Affiliation	Not Available	Not Available	Not Available	Not Available	$ 540	$ 540	$ 540	$ 540	$ 640	$ 640	Not Available	
	For-profit Affiliation	Not Available	Not Available	Not Available	Not Available	$ 1,040	$ 1,040	$ 1,040	$ 1,040	$ 1,240	$ 1,240	Not Available	
Wisconsin	All Applicants	Not Available	$ 520	$ 520	$ 520	$ 520	$ 620	$ 720	$ 720	$ 820	$ 820	Not Available	
TOTAL DATA COST: Calculate total cost for all data requested. See Part IV (page 15) for instructions on determining the total payment due:													

Section III. Select State Emergency Department Databases (SEDD)

Mark boxes for the data you are requesting (see next page) and enter the total cost of requested data under the column titled "Total".

Please refer to the Databases section of the HCUP User Support Website (www.hcup-us.ahrq.gov) for detailed information about the SEDD. Importantly, the SEDD contain only emergency department visits that do not result in hospitalizations. To complete an analysis on all emergency department visits, researchers should purchase the SEDD and the SID. Not all HCUP data elements are available from every state.

The participating Data Organizations dictate the price of the data. Handling charges are already included. Some Data Organizations offer a price discount to AHRQ Grant recipients, and Arizona currently offers a discount to students.

If you are not sure if you qualify for the AHRQ Grantee discount, please refer to Section IV. AHRQ Grantee (page 14).

Students in good standing may purchase the 2005-2007 Arizona SEDD for $20. Students must demonstrate that they are in fact a student by providing: 1) a copy of a valid student ID, OR 2) a letter from the registrar's office indicating that they are student in good standing, OR 3) a note or letter from a professor or program director verifying that they are in fact a student in good standing.

If you have any questions or want information on other years of data or more sensitive data elements for a state, please contact the HCUP Central Distributor by phone at (866) 556-4287 (toll-free), fax at (866) 792-5313 (toll free), or e-mail at HCUPDistributor@AHRQ.gov

State	HCUP SEDD Price Structure	1999	2000	2001	2002	2003	2004	2005	2006	2007	TOTAL
	Students	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	$ 20	$ 20	$ 20	
Arizona	Non-profit/Educational	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	$ 120	$ 120	$ 120	
	For-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	$ 320	$ 320	$ 320	
California	Government, Non-profit Research or Educational Institution	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	$ 20	$ 20	$ 20	
	All Others	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	$ 220	$ 220	$ 220	
Florida	All Applicants	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	$ 120	$ 120	Not Available	
Hawaii	Not-for-profit Affiliation	Not Available	Not Available	Not Available	Not Available	$ 820	$ 820	$ 820	$ 820	Not Available	
	For-profit Affiliation	Not Available	Not Available	Not Available	Not Available	$ 1,020	$ 1,020	$ 1,020	$ 1,020	Not Available	
Iowa	Not-for-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	$ 520	$ 520	$ 570	$ 570	
	For-profit Affiliation	Not Available	Not Available	Not Available	Not Available	Not Available	$ 1,020	$ 1,020	$ 1,120	$ 1,120	
Maine	Non-profit/Educational	$ 1,120	$ 1,120	$ 1,120	$ 1,120	$ 1,120	Not Available	Not Available	Not Available	Not Available	
	Commercial	$ 2,620	$ 2,620	$ 2,620	$ 2,620	$ 2,620	Not Available	Not Available	Not Available	Not Available	
Maryland	All Applicants	$ 20	$ 20	$ 20	$ 20	$ 20	$ 20	$ 20	$ 20	$ 20	
Massachusetts	All Applicants	Not Available	Not Available	Not Available	$ 820	$ 820	$ 820	$ 820	Not Available	Not Available	
Nebraska	All Others	Not Available	Not Available	$ 1,020	$ 1,020	$ 1,020	$ 1,020	$ 1,020	$ 1,020	Not Available	
	AHRQ Grantee (Complete Section IV, page 14)	Not Available	Not Available	$ 520	$ 520	$ 520	$ 520	$ 520	$ 520	Not Available	
New Jersey	All Applicants	Not Available	Not Available	Not Available	Not Available	Not Available	$ 45	$ 45	$ 45	$ 45	
South Carolina	All Applicants	Not Available	$ 1,874	$ 1,874	$ 1,874	$ 1,874	$ 1,874	$ 1,874	$ 1,874	Not Available	
Utah	Public, State/Federal Agency, Academic Organization	Not Available	$ 1,615	$ 1,615	$ 1,615	$ 1,615	$ 1,615	$ 1,615	$ 1,615	Not Available	
	Private Organization	Not Available	$ 3,190	$ 3,190	$ 3,190	$ 3,190	$ 3,190	$ 3,190	$ 3,190	Not Available	
Vermont	Not-for-profit Affiliation	Not Available	Not Available	Not Available	$ 540	$ 540	$ 540	$ 640	$ 640	Not Available	
	For-profit Affiliation	Not Available	Not Available	Not Available	$ 1,040	$ 1,040	$ 1,040	$ 1,240	$ 1,240	Not Available	
Wisconsin	All Applicants	Not Available	Not Available	Not Available	Not Available	Not Available	$ 720	$ 820	$ 820	Not Available	

TOTAL DATA COST: Calculate total cost for all data requested. See Part IV (page 15) for instructions on determining the total payment due:

Section IV. AHRQ Grantee

Some states offer a discounted price for AHRQ Grant Recipients. If you are an AHRQ Grantee and intend to use the data requested for a currently funded AHRQ project, you are entitled to the discounted price and should mark your data request accordingly. Include the name of the principal investigator, title, and the corresponding grant number in the space provided below. Other types of grants are non-applicable. The Uniform State Application in no way constitutes a grant application.

The Research Grant Application Form PHS 398 is to be used in applying for AHRQ grants. This form is available online from the National Institutes of Health Web site at the following URL:

   http://www.nih.gov/grants/funding/phs398/phs398.html

Copies of the PHS 398 Grant Application Form are also available from:

   AHRQ Publications Clearinghouse

   P.O. Box 8547
   Silver Spring, MD 20907-8547
   Telephone: (800) 358-9295

If you are requesting data at the AHRQ Grantee discounted price, please provide the following information:

Name of Principal Investigator / Title:

AHRQ Grant Number:

Part IV: Determine the Total Payment Due and Select Payment Method

Total Payment Due

If you need help determining the payment due, submit the completed application (pages 2-31), without payment, to the *HCUP Central Distributor* and request an invoice. An itemized invoice stating the total payment due, including taxes for applicants in Maryland, will be faxed or e-mailed to you. Note that the HCUP Central Distributor collects taxes only from applicants in Maryland. All other applicants are responsible for determining tax liability and remitting taxes directly to state and local taxing authorities.

TOTAL PAYMENT DUE	
Total SID Data Cost From Section I:	$_____
Total SASD Data Cost From Section II:	$_____
Total SEDD Data Cost From Section III:	$_____
Tax (MD applicants only):	$_____
Total Payment Due:	$_____

Orders will not be filled until the completed application and a purchase order or full payment have been received.

Payment Methods

The HCUP Central Distributor accepts purchase orders, and payment may be made by major credit card, check, or electronic funds' transfer.

Paying by Credit Card

Visa, MasterCard and American Express are accepted. Your credit card is not charged until the day your order is shipped. A credit card receipt for your purchase is included with the order.

Credit card information is accepted by mail or telephone. If you would like to mail the information, please complete items 1 – 10 of the Credit Card Payment form on the next page and mail it with your itemized invoice or completed application to the following address:

> *HCUP Central Distributor*
> *Social & Scientific Systems, Inc.*
> *8757 Georgia Avenue, 12*th *Floor*
> *Silver Spring, MD 20910*

If you prefer to provide your credit card information by telephone, please call toll-free at (866) 556-4287 between 9 a.m. and 5 p.m. Eastern Time.

Paying by Check

Checks should be made payable to *Social & Scientific Systems, Inc.* Mail a check for the total payment due with your itemized invoice or completed application. The address is listed above.

Credit Card Payment Form

If you would like to pay by credit card, please complete items 1 – 10 of this form and enclose it with your application. If you prefer to provide your credit card information by telephone, please call toll-free at (866) 556-4287 between 9 a.m. and 5 p.m. Eastern Time.

1. **Date**:
2. **Individual/Company Name:**
3. **Names On Credit Card:**
   Please list the names on the credit card exactly as they are shown on the card.

4. **Type Of Credit Card: MASTERCARD VISA AMERICAN EXPRESS**
5. **Amount:**
6. **Credit Card Number:**
7. **Expiration Date:**
8. **Credit Card Billing Address:**
9. **City, State & ZIP Code:**
10. **Customer Signature:**

For Office Use Only

Verbal Authorization For Signature: **Yes**   **N**o

Person Requesting Credit Card Processing: _____

Requestor's Phone Number And Extension: _____

Project Code Number: _____

Date Processed: _____ *Invoice Numbers Paid:* _____

Project Code: _____

Part V: Indemnification Clause

Recipient shall indemnify and hold Thomson Healthcare Inc. and its directors, officers, employees, agents, affiliates and subsidiaries harmless from any and all losses, claims, damages, liabilities, costs and expenses (including, without limitation, reasonable attorney's fees and costs) arising out of any claim arising from any third parties, including but not limited to any or some combination of the several States comprising the United States of America and/or the Government of the United States of America, concerning Recipient's use of SID, SASD, or SEDD data provided by Thomson Healthcare Inc. Further, Recipient agrees that Thomson Healthcare Inc. shall not be liable to Recipient for any reason whatsoever arising out of the SID, SASD, or SEDD data or the Recipient's use of the SID, SASD, or SEDD data.

Recipient certifies and warrants that it has made no representations to Thomson Healthcare Inc. concerning any uses it (Recipient) intends to make of the SID, SASD, or SEDD data provided by Thomson Healthcare Inc. under the terms and conditions of Thomson Healthcare Inc. contract with the U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality. Further, Recipient agrees that no representation of Recipient as to the Recipient's intended use of the SID, SASD, or SEDD data was used to determine whether the Recipient's request to use SID, SASD, or SEDD data would be approved.

Recipient shall indemnify and hold Social & Scientific Systems, Inc. (SSS) and its directors, officers, employees, owners, and agents harmless from any and all losses, claims, damages, liabilities, costs and expenses (including, without limitation, reasonable attorney's fees and costs) arising out of any claim arising from any third parties, including but not limited to any or some combination of the several States comprising the United States of America and/or the Government of the United States of America, concerning Recipient's use of SID, SASD, or SEDD data provided by SSS. Further, Recipient agrees that SSS shall not be liable to Recipient for any reason whatsoever arising out of the SID, SASD, or SEDD data or the Recipient's use of the SID, SASD, or SEDD data.

Recipient certifies and warrants that it has made no representations to SSS concerning any uses it (Recipient) intends to make of the SID, SASD, or SEDD data provided by SSS under the terms and conditions of its contract with the U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality. Further, Recipient agrees that no representation of Recipient as to the Recipient's intended use of the SID, SASD, or SEDD data was used to determine whether the Recipient's request to use SID, SASD, or SEDD data would be approved.

Signed: Date:

Part VI: HCUP Data Use Agreement Training

New Requirement: HCUP Data Use Agreement Training

Because of the sensitive nature of the data contained in the Healthcare Cost and Utilization Project (HCUP) databases, there is a continued need to reinforce the safeguards and restrictions placed on use of the data. All data purchasers and users of HCUP data must complete the HCUP Data Use Agreement (DUA) Training Course. This course emphasizes the importance of data protection, helps to reduce the risk of inadvertent violations, and describes your individual responsibility when using HCUP data. The course will take approximately 15 minutes to complete and you will not be required to take it more than once.

If you have not previously completed the HCUP DUA Training Course, please go to the HCUP-US website at http://www.hcup-us.ahrq.gov/tech_assist/dua.jsp, complete the online HCUP DUA Training Course, and enter the certification number at the end of the course in the space provided below.

HCUP DUA Training Course Certification Code

_____

DATA USE AGREEMENT for the State Inpatient Databases from the Healthcare Cost and Utilization Project Agency for Healthcare Research and Quality

This Data Use Agreement ("Agreement") implements the data protections of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Public Law 104-191) and the Agency for Healthcare Research and Quality (AHRQ) confidentiality statute. Any individual ("data recipient") seeking to obtain or use data in the State Inpatient Databases (SID) from the Healthcare Cost and Utilization Project (HCUP) maintained by the Center for Delivery, Organization, and Markets (CDOM) within AHRQ, must sign and submit this Agreement to AHRQ or its agent before access to the SID may be granted.

In accordance with HIPAA, the SID may only be used or disclosed in the form of a *limited data set*, as defined by the HIPAA Privacy Rule (45 CFR § 164.514(e)).

The AHRQ confidentiality statute, Section 924(c) of the Public Health Service Act (42 U.S.C. 299c-3(c)), requires that data collected by AHRQ that identify individuals or establishments be used only for the purpose for which they were supplied. Data supplied to AHRQ for HCUP and disclosed in limited data set form are identifiable under the HIPAA Privacy Rule and are provided by the data sources only for research, analysis, and aggregate statistical reporting. Therefore, data recipients may use HCUP data only for these purposes.

No Identification of Persons–Any effort to determine the identity of any person contained in HCUP databases (including but not limited to patients, physicians, and other health care providers), or to use the information for any purpose other than for research, analysis, and aggregate statistical reporting, would violate the AHRQ confidentiality statute, the conditions of this Agreement, and the HIPAA Privacy Rule. Recipients of the data set are prohibited under the AHRQ confidentiality statute and the terms of this Agreement from releasing, disclosing, publishing, or presenting any individually identifying information obtained under this Agreement. AHRQ omits from the data set all direct identifiers that are required to be excluded from limited data sets as defined by the HIPAA Privacy Rule. It may be possible in limited situations, through deliberate technical analysis, and with outside information, to ascertain from the limited data sets the identity of particular persons. Considerable harm could ensue if this were to occur. Therefore, any attempts to identify individuals are prohibited and information that could identify individuals directly or by inference must not be released or published. In addition, users of the data must not attempt to contact individuals for any purpose, including verifying information supplied in the data set. Any questions about the data must be referred exclusively to AHRQ.

Use of Establishment Identifiers–Section 924(c) of the Public Health Service Act (42 U.S.C. 299c-3(c)) also restricts the use of any information that permits the identification of establishments for purposes other than those for which the information was originally supplied. Permission is obtained from the HCUP data sources (state data organizations, hospital associations, and data consortia) to use the identification of hospitals (when such identification appears in the data sets) for research, analysis, and aggregate statistical reporting. This may include linking institutional information from outside data sets for these purposes. Such purpose does *not* include the use of information in the data sets concerning individual establishments for commercial or competitive purposes involving those individual establishments, or to determine the rights, benefits, or privileges of establishments. Users of the data must not identify establishments directly or by inference in disseminated material. In addition, users of the data must not contact establishments for the purpose of verifying information supplied in the data set.   Any questions about the data must be referred exclusively to AHRQ. Misuse of identifiable HCUP data about hospitals would violate the AHRQ confidentiality statute and trigger its penalty provisions.

The undersigned gives the following assurances with respect to the SID data set:

- I will not use and will prohibit others from using or disclosing the data set (or any part), except for research, analysis, and aggregate statistical reporting, and only as permitted by this Agreement.
- I will ensure that the data are kept in a secured environment and that only authorized users will have access to the data.
- I will not release or disclose, and will prohibit others from releasing or disclosing, any data that are individually identifiable under the HIPAA Privacy Rule, or any information that identifies persons, directly or indirectly, except as permitted under this Agreement and in accordance with the above-mentioned AHRQ confidentiality statute.
- I will not release or disclose information where the number of observations (i.e., individual discharge records) in any given cell of tabulated data is less than or equal to 10.
- I will not release or disclose, and will prohibit others from releasing or disclosing, the data set (or any part) to any person who is not a member, agent, or contractor of the organization (specified below), except with the approval of AHRQ.
- I will require others employed in my organization (specified below), and any agents or contractors of my organization, who will use or will have access to the data set, to sign a copy of this Agreement (specifically acknowledging their agreement to abide by its terms) and I will submit those signed Agreements to AHRQ or its agent before granting access.
- I will not attempt to link, and will prohibit others from attempting to link, the discharge records of persons in the data set with individually identifiable records from any other source.
- I will not attempt to use and will prohibit others from using the data set to learn the identity of any person included in the data set or to contact any such person for any purpose.
- In accordance with the AHRQ confidentiality statute, I will not use and will prohibit others from using the data set concerning individual establishments (1) for commercial or competitive purposes involving those individual establishments; (2) to determine the rights, benefits, or privileges of individual establishments; or (3) to report, through any medium, data that could identify, directly or by inference, individual establishments.
- When the identities of establishments are not provided in the data sets, I will not attempt to use and will prohibit others from using the data set to learn the identity of any

> establishment.

- I will not contact and will prohibit others from contacting establishments or persons in the data set to question, verify, or discuss data in the HCUP databases.
- I will indemnify, defend, and hold harmless AHRQ and the data organizations that provide data to AHRQ for HCUP from any or all claims and losses accruing to any person, organization, or other legal entity as a result of violation of this Agreement. This provision applies only to the extent permitted by Federal and State law.
- I will make no statement and will prohibit others from making statements indicating or suggesting that
- interpretations drawn are those of the data sources or AHRQ.
- I will provide an abstract and reference for any published research material resulting from the use of these HCUP State Inpatient Databases to the HCUP Central Distributor.
- I will acknowledge in all reports based on these data that the source of the data is the specific state(s) or data organization(s) that submitted data to the HCUP (e.g., "state name(s), State Inpatient Databases (SID), Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality."

Safeguards. I agree to use appropriate safeguards to prevent use or disclosure of the data set other than as permitted by this Agreement.

Permitted Access to Limited Data Set. I shall limit the use or receipt of the data set to the individuals who require access in order to perform activities permitted by this Agreement. This Agreement must be signed by all such individuals and submitted to AHRQ or its agent before access to the data set may be granted.

Re-disclosure. I will not re-disclose (i.e., share) the data set (or any part), unless the individual who will receive the data has agreed in writing to be bound by the same restrictions and conditions that apply to me under this Agreement.

The HIPAA Privacy Rule. I agree not to use or disclose the data set in any manner that would violate the HIPAA Privacy Rule if I were a covered entity under the Privacy Rule.

Agents and Contractors. I shall ensure that any agents, including contractors and subcontractors to whom I provide the data set, agree in writing to be bound by the same restrictions and conditions that apply to me with respect to the limited data set.

Reporting Violations of this Agreement. I agree to report any violations to AHRQ within twenty-four (24) hours of becoming aware of any use or disclosure of the limited data set in violation of this Agreement or applicable law.

Term, Breach, and Termination of this Agreement. This Agreement shall continue in full effect until the data recipient has returned all copies of the data set to AHRQ. Any noncompliance by the data recipient with the terms of this Agreement will be grounds for immediate termination of the Agreement if, at the sole determination of AHRQ, the data recipient knew or should have known of such noncompliance and failed to immediately take reasonable steps to remedy the noncompliance.

Reporting to the United States Department of Health and Human Services. If the data recipient fails to remedy any breach or violation of this Agreement to the satisfaction of AHRQ, and if termination of the Agreement is not feasible, AHRQ shall report the recipient's breach or violation to the Secretary of the United States Department of Health and Human

Services, and the recipient agrees that he or she shall not have or make any claims against AHRQ with respect to such report(s).

I understand that this Agreement is requested by the United States Agency for Healthcare Research and Quality to ensure compliance with its statutory confidentiality requirement. My signature indicates my Agreement to comply with the above-stated requirements with the knowledge that any violation of the AHRQ confidentiality statute is subject to a civil penalty of up to $10,000 under 42 U.S.C. 299c-3(d), and that deliberately making a false statement about this or any matter within the jurisdiction of any department or agency of the Federal Government violates 18 U.S.C. 1001 and is punishable by a fine of up to $10,000 or up to five years in prison. Violators of this Agreement may also be subject to penalties under state confidentiality statutes that apply to these data for particular states.

Signed:_____

Date:_____

Print or Type Name of Data Recipient:
_____

Title:_____
_____

Organization:
_____

Address:_____
_____

City: _____ State: _____ ZIP Code: _____

Phone Number: _____ Fax:_____

E-mail:
_____

The information above is maintained by AHRQ for the purpose of enforcement of this Agreement. This information may also be used by AHRQ to create an HCUP mailing list. The mailing list allows AHRQ to send users information such as notices about the release of new databases and errata when data errors are discovered.

Please include me on the HCUP mailing list.