2014

Rapid response systems : evaluation of program context, mechanism, and outcome factors

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RAPID RESPONSE SYSTEMS: EVALUATION OF PROGRAM CONTEXT, MECHANISM, AND OUTCOME FACTORS

by

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A thesis submitted in partial fulfillment
of the requirements for the Doctor of
Philosophy degree in Nursing
in the Graduate College of
The University of Iowa

May 2014

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PH.D. THESIS

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No one, prophet, intellectual or evaluator, can claim to be in possession of the universal standpoint, that secret scientific key to truth.

Ray Pawson & Nick Tilley
Realistic Evaluation

ACKNOWLEDGMENTS

During my doctoral studies I have received inspiration, encouragement, and support from many people.

I would not have begun this journey without the love, support and patience of my family and friends. Thank you for believing in me.

The University of Iowa College of Nursing faculty challenged me to expand my thinking. I have learned more than I believed was possible. Thank you.

A doctoral journey is not completed in isolation. My peers and colleagues in the PhD program have been there every step of the way. Thank you for your friendship, laughter, and insights.

My dissertation committee has graciously shared their wisdom and guided me through the most challenging stages of the PhD program. Thank you for helping me to grow as a scholar.

Finally, thank you to the hospital leadership, Rapid Response team members, and staff nurses for sharing their quality improvement data and providing excellent patient care every single day.

ABSTRACT

Prevention of in-hospital cardiac arrest (IHCA) is critical to reducing morbidity and mortality as both the rates of return to pre-hospital functional status and overall survival after IHCAs are low. Early identification of patients at risk and prompt clinical intervention are vital patient safety strategies to reduce IHCA. One widespread strategy is the Rapid Response System (RRS), which incorporates early risk identification, expert consultation, and key clinical interventions to bedside nurses caring for patients in clinical deterioration. However, evidence of RRS effectiveness has been equivocal in the patient safety literature.

This study utilized a holistic Realistic Evaluation (RE) framework to identify important clinical environment (*context*) and system triggers (*mechanisms*) to refine our understanding of an RRS to improve local patient *outcomes* and develop a foundation for building the next level of evidence within RE research. The specific aims of the study are to describe a RRS through *context*, *mechanism*, and *outcome* variables; explore differences in RRS outcomes between medical and surgical settings, and identify relationships between RRS *context* and *mechanism* variables for patient *outcomes*.

Study RRS data was collected retrospectively from a 397-bed community hospital in the Midwest; including all adult inpatient RRS events from May 2006 (2 weeks post-RRS implementation) through November 2013. RRS events were analyzed through descriptive, comparative, and proportional odds (ordinal) logistic regression analyses.

The study found the majority of adult inpatient RRS events occurred in medical settings and most were activated by staff nurses. Significant differences were noted between RRS events in medical and surgical settings; including patient status changes in the preceding 12 hours, event trigger patterns, and immediate clinical *outcomes*. Finally, proportional odds logistic regression revealed significant relationships between *context* and *mechanism* factors with changes in the risk of increased clinical severity immediately

following at RRS event. RE was utilized to structure a preliminary study to explore the complex variables and relationships surrounding RRSs and patient *outcomes*. Further exploration of settings, changes in clinical status, staffing and resource access, and the ways nurses use RRSs is necessary to promote the early identification of vulnerable patients and strengthen hospital patient safety strategies.

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CHAPTER 1

INTRODUCTION TO THE STUDY

Background

In 2000, the Institute of Medicine published findings describing the silent epidemic of systemic errors plaguing healthcare (Kohn, Corrigan, & Donaldson). This work included an estimate of between 44,000 and 98,000 patient deaths each year from preventable medical errors. Despite a heightened awareness and multiple patient safety initiatives, the impact of healthcare errors on patient morbidity and mortality continues in the United States. Using data collected from 2008 healthcare insurance claims, researchers estimated 1.5 million errors resulted in injury and over 2,500 deaths in that year alone (Shreve et al., 2010).

One preventable medical error that can impact hospitalized patients is failure to rescue (FTR), the loss of a patient's life after the development of an unexpected complication (Silber, Rosenbaum, & Ross, 1995). The need to rescue a hospitalized patient does not typically occur without early warning signs and symptoms of clinical deterioration. One pivotal study determined that 84% of subjects with cardiac arrest experienced acute clinical deterioration symptoms six to eight hours preceding the arrest (Schein, Hazday, Pena, Ruben, & Sprung, 1990). According to Ashcraft (2004), the underlying causes of FTR are varied and include: (a) missed signs and symptoms of pending cardiac arrest, (b) delayed or ineffective treatment measures, (c) uninformed providers who did not possess the knowledge to determine the best treatment course, and/or (d) inadequate evidence concerning the best treatment. In addition to cardiac arrest and/or mortality, missed or delayed responses to clinical warning signals also result in other costly interventions and complications such as emergency surgeries, longer hospital stays, increased pain and suffering, and additional injuries (Bucknall, Jones, Bellomo,

Staples, & The RESCUE Investigators, 2012; Ludikhuize, Smorenburg, de Rooij, & de Jonge, 2012; Massey, Aitken, & Chaboyer, 2008; Subbe, 2006; Quach et al., 2008).

Prevention of in-hospital cardiac arrest is critical to preventing mortality during hospitalization because survival rates after in-hospital cardiac arrest are low: 6.6% at discharge, 5.2% at one year, and 3% at three years (Bloom et al., 2007). In addition, prevention of in-hospital cardiac arrest is essential to avoid in-hospital morbidity; one study demonstrated only 75% of adults who survived in-hospital cardiac arrest possessed good short-term neurological outcomes at time of discharge (Nadkarni et al., 2006). Thus, early intervention is critical for patients with symptoms of clinical deterioration due to poor overall in-hospital cardiac arrest survival and decreased probability of return to full pre-arrest health status (Bellomo et al., 2004).

Early intervention strategies to prevent patient death from in-hospital cardiac arrest and decrease preventable complications led Australian healthcare providers to develop the Rapid Response System (RRS), also referred to as a rapid response team or RRT. RRSs were designed to reduce unexpected cardiac arrests and deaths outside intensive care units (Berwick, Calkins, McCannon, & Hackbarth, 2006; Devita et al., 2006). A RRS incorporates the strategies of early risk identification, expert consultation, and prompt and appropriate clinical interventions to support bedside healthcare providers caring for patients in clinical decline. Based on associations among early identification, early interventions, and improved patient outcomes, early positive reports of RSS impact quickly spread internationally. In the United States, the Institute for Healthcare Improvement (IHI) recommended RRS implementation as one of the six key evidence-based strategies comprising their “100,000 Lives” campaign and again in their more recent “5 Million Lives” campaign (Berwick et al., 2006; McCannon, Hackbarth & Griffin, 2007). While it is difficult to accurately estimate the lives saved in the 100,000 Lives and 5 Million Lives campaigns from RSSs alone, RSSs were believed to

significantly reduce mortality (Hackbarth, McCannon, Martin, Loyd, & Calkins, 2006; McCannon et al., 2007).

As the use of RRSs continues to expand, localized adaptations of the program and implementation variation have increased. Although these local RRS alterations have allowed healthcare providers to accommodate the individual needs and structures of existing hospital systems, benchmarking and global evaluation of RRS impact on patient outcomes have been significantly hampered (Hillman et al., 2005; Winters, Pham, & Pronovost, 2006). International consensus conferences began in 2005 (Devita et al., 2006) to mitigate some of these challenges. These scientific meetings focused on one aspect of RRSs and the current evidence each year, beginning with core definitions, program barriers, and the efficacy of RRS implementation. The first consensus conference expanded on the IHI's recommendations, stating that a RSS should have four key elements for success: (a) established crisis and response triggers, (b) predetermined team to provide clinical support, (c) administrative support, and (d) processes to evaluate and promote improvement in care to minimize future events (Devita et al., 2006).

Despite general agreement regarding core RRS components, additional program inconsistencies across multiple settings with locally unique outcome measurements continue to limit attempts to fully understand the mechanisms and impact of RRSs upon patient morbidity and mortality. Rather than continually seeking to prove or disprove the global effectiveness of the RRS as an early intervention program, revealing how the RRS (a) changes clinician behaviors, (b) provides clinical support for bedside providers, and (c) improves the safety culture creates an opportunity to improve RRSs.

Conceptual Underpinnings for the Study

In general, theories are used to describe, explain, or predict human and scientific phenomena (Burns & Groves, 2009). While grand nursing theories are sometimes abstract and of little value in practice, middle-range theories focused on a specific area

can provide guidance for practice and research. Middle-range theories also can be used to build theoretical frameworks to guide the development of rigorous research designs and interpretation strategies (Burns & Groves, 2009; Locke, Spirduso, & Silverman, 2007). Theoretical frameworks may draw upon one or more theories within nursing or from diverse specialties to provide a rich foundation for research development (Burns & Groves, 2009).

When beginning new research, it is important to have a solid theoretical framework congruent with the research specific aims (Burns & Groves, 2009). Frameworks which draw heavily on scientific theories are best suited to research where one can measure and test concepts and relationships. However, frameworks derived from substantive theories provide a basis for researchers who seek to explore phenomena and processes. Once a suitable framework is selected, the researcher is able to design a solid research plan that is aligned with both the current science and research objectives (Burns & Groves, 2009; Locke et al., 2007).

Although the science of patient safety has continued to advance, the discussion of theoretical frameworks in patient safety research remains limited (Lawton et al. 2012; Pronovost et al., 2009; Waterson, 2009). Hoff, Jameson, Hanna, and Flink (2004) reviewed 42 studies evaluating the impact of organizational factors on medication errors and patient safety. Surprisingly, the authors reported that more than 60% of the included studies provided no theoretical rationale linking study variables to measured outcomes. Of the studies which included a theoretical rationale, 27% utilized the IHI breakthrough series collaborative and/or quality improvement approach and 12% utilized a combination of approaches, such as group decision making and human factors design principles. The absence and variability of guiding frameworks in patient safety research creates challenges in interpreting and comparing research findings across studies.

Evaluation of patient safety programs launched within existing healthcare systems requires both a theoretical framework and additional considerations to determine the

effects of organizational complexity, interpersonal and organizational relationships, and culture on patient outcomes (Berwick, 2008). A search of patient safety literature led to Realistic Evaluation (RE) as a viable evaluation framework to address crucial components of healthcare program evaluation through non-experimental designs (Pawson, 2013; Pawson & Tilley, 1997).

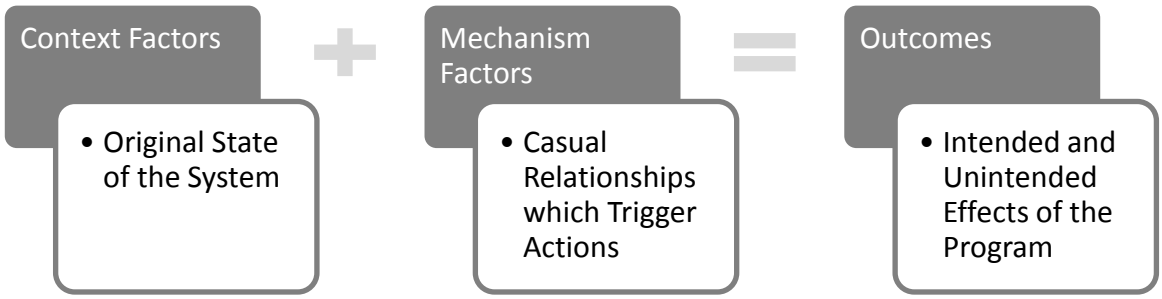
Realistic Evaluation

Realistic Evaluation (RE) was first described by Pawson and Tilley in 1997 as an evaluation framework for social and public programs. RE's value in patient safety research was recognized by patient safety leaders because interventions designed to improve patient safety within healthcare systems are largely social programs (Berwick, 2008). In fact, the RE framework is based upon the realist premise that the world is comprised of numerous individual *social systems* (Pawson & Tilley, 1997). These social systems are unique, complex, responsive, and unpredictable due to human and organizational interactions. Within hospitals, these systems include nursing units, ancillary departments, healthcare providers, and administration. The functionality of these systems depends highly on interactions among factors such as staffing, culture, relationships, policies, resources, patterns of behavior, and program components (Rycroft-Malone, Fontenia, Bick, & Seers, 2010). These factors present significant challenges for traditional research designs, which rely on generalizability, replication of findings, bias prevention, and control of confounding variables. However, users of the RE framework consider those interactive factors vital to understanding how programs drive change through impacting individual behaviors. RE thus provides an evaluation framework for understanding what makes a program effective within a specific setting for a specific population.

CMO Model

RE researchers understand and describe the operation of a social program through a CMO Model: Context + Mechanisms = Outcome (see Figure 1-1). Because program interventions are introduced into an existing social system, it is essential to understand the system in its original state. This original state, or *context*, includes the environment, history, relationships, organizational structure, and resources of the system (Pawson & Tilley, 1997; Porter & O'Halloran, 2011). The *mechanisms* within the model are descriptions of the causal relationships within the system that trigger actions (Pawson & Tilley, 1997; Wand, White, & Patching, 2001). They illustrate the powers, choices, decisions, and reactions that result in changes or outcomes. The *outcomes* within the model are both the intended and unintended effects of the program within a specific pattern of context and mechanism factors (Pawson & Tilley, 1997).

Figure 1-1. CMO Model in Realistic Evaluation



Identification of the mechanisms driving the program outcomes and distinguishing between context, mechanisms and program outcomes is subject to interpretation and may change depending on the level of analysis, data collection

strategies, and initial social system assessment (Pawson, 2013; Pawson & Tilley, 1997; Rycroft-Malone et al., 2010). However, the researcher's ability to evaluate the program impact is strengthened through clear descriptions of the social system, precise definitions of the program, and early identification of desired outcomes. (Pawson 2013; Pawson & Tilley, 1997).

Generative CMO Theories

Because context, mechanisms, and outcomes are highly interrelated in social systems research, RE researchers focus on explicating relationships among these variables to develop theories that are used to maximize program efficiency and effectiveness (Pawson & Tilley, 1997; Rycroft-Malone et al., 2010; Wand, White, & Patchling, 2011). The identification of potential context and mechanisms affecting program outcomes are used to develop tentative CMO configurations. The fit of the CMO configuration is compared to observed program operation and outcomes within the system through mixed methods of investigation. The collected observations are used to revise the CMO configurations and begin to develop a generative theory of program change. A generative theory builds on existing knowledge of relationships between context, mechanism, and outcome variables to explain the origins and working of these associations (Pawson & Tilley, 1997).

As this realistic evaluation process is repeated over time, the researcher refines the initial CMO configurations to create generative theories of program operations with outcomes. At this stage of RE it is common for researchers to include participants in theory refinement as they are uniquely suited to clarify, validate, and challenge the researchers' interpretations of the program operation. Finally, the ultimate RE goal is to cumulate existing generative CMO theories across many settings and program variations to develop broad middle-range theories that will guide the healthcare community in determining which program components will result in reliable outcome patterns for

specific settings and populations (Pawson & Tilley, 1997; Porter & O'Halloran, 2011; Wand et al., 2011).

Realistic Evaluation Assumptions

A key RE assumption is that not all of the decisions, choices, and reactions occurring within the system are the result of program interventions (Pawson & Tilley, 1997; Porter & O'Halloran, 2011; Wand et al., 2001). Healthcare systems are complex, dynamic social systems and are simultaneously influenced by mechanisms inside and outside the program. RE researchers include both internal and external factors in an iterative process of discovery and theory refinement. This iterative process allows for program optimization to foster more positive outcomes. In addition, researchers are able to consider alternative mechanisms that may mitigate or eliminate the impact of negative mechanisms on program outcomes (Pawson & Tilley, 1997; Porter & O'Halloran, 2011).

Another RE assumption is that the success of a program intervention will vary based on existing context and mechanism patterns of the social system (Keller, Gäre, Edenius, & Lindblad, 2009; Pawson & Tilley, 1997; Rycroft-Malone et al., 2010). The potential of programs to improve patient outcomes varies greatly due to the context and mechanism factors of the social system. Understanding the role these factors play in the implementation, maturation, and sustainability of a patient safety program is crucial for the future of patient safety research (Berwick, 2008; Bradley et al., 2009; Woodward et al., 2010). In summary, RE is an evaluation framework used by researchers to discover patterns and interactions among context, mechanisms, and outcomes that explain how social programs create change (Pawson & Tilley, 1997).

Realistic Evaluation and Rapid Response Systems

Limitations of Existing RRS Research Approaches

Early researchers attempted to assess RRS effectiveness by comparing the number of RRS events with cardiac arrests and overall mortality within single hospitals. Two Australian studies introduced RSS to the healthcare community (Bristow et al., 2000; Buist et al., 2002). Bristow et al. utilized a non-randomized cohort comparison study design while Buist et al. followed a non-randomized pre/post-intervention design. Bristow et al. (2000) noted fewer unexpected ICU admissions in the hospital with the introduction of a RRS into a specific hospital, while Buist et al. (2002) reported statistically significant decreases in cardiac arrests outside of the ICU and deaths from unexpected cardiac arrests in the hospital two years post-RRS implementation. These and other early studies utilized a variety of approaches, designs, definitions, and measurements contributing to differences in results; the findings were not generalizable across populations or settings for many methodological reasons (Winters et al., 2006). Despite the lack of generalizable findings, early RRS evaluation studies along with positive practice anecdotes encouraged RRS spread from Australia into the United States (Berwick, 2008). While RRS programs were promoted through the 100,000 Lives and 5 Million Lives campaigns, patient safety researchers sought to discern the impact on patient outcomes.

In 2005, researchers described the findings of a study that used a cluster randomized controlled trial (RCT) design in an attempt to identify causal relationships between RRS and decreases in cardiac arrests and mortality (MERIT Study Investigators, 2005). Despite earlier research that supported RRS effectiveness, this study initially found no benefits. However, the IHI, led by Berwick, challenged the design and interpretations of the MERIT findings. The IHI emphasized repeated positive results seen

by hospitals and smaller studies. The debate fueled the need for more RRS research (Berwick, 2008; IHI, n.d.).

Since 2006, the amount of RRS research has grown at a dramatic pace (Sarani & Scott, 2010). Due to concerns related to evidence strength and the lack of positive findings from RCTs, some researchers recommended the healthcare community proceed with caution in RRS adoption (Berwick, 2008; Winters et al., 2006). However, despite ambiguous evidence, RRS programs continued to spread quickly (McCannon et al., 2007).

Although RRS researchers attempted to explicate the patient impact through experimental and quasi-experimental designs, Berwick noted significant concerns with the use of the RCT to evaluate RRS outcomes (2008). The purpose of the RCT is to look for cause and effect relationships. Researchers look for direct associations between the intervention and the outcome by using random assignment to intervention and control groups, double-blinding researchers and participants, and controlling for confounding variables within a specific research design (Burns & Grove, 2009). The very definition of the RCT design limits its use in RRS evaluation because patients cannot be randomized into a control group, as some evidence exists to suggest this would be substandard and even dangerous care (Calzavacca et al., 2010a; Santamaria, Tobin, & Holmes, 2010; Winters et al., 2013).

RRSs are complex programs designed to impact the social interactions and processes within existing healthcare systems to prevent unexpected inpatient morbidity and mortality. The evaluation of programs within complex healthcare systems presents researchers with unique challenges when designing studies with traditional experimental methods such as randomization, blinding, and controls; thus, a more holistic research approach is required (Berwick, 2008; Pawson & Tilley, 1997). Knowledge of the specific RRS, including contextual variables, is essential for healthcare providers to successfully design studies of RSS effectiveness, and to interpret the results. In addition, researchers

must take advantage of opportunities to explore the impact of these cultural and social factors (context) on the mechanisms and outcomes of the RRS.

Strengths of the Realistic Evaluation Framework for RRS Research

The RRS is essentially a social program, made up of interwoven processes, implemented by humans, residing inside a complex healthcare environment that results in observable and latent outcomes (Berwick, 2008). As Pawson and Tilley (1997) assert in *Realistic Evaluation*, efforts to prove whether or not a program works is destined to fail without understanding *how* it works and *in what situations* it works. An RRS cannot be measured outside of its context, defined by Pawson and Tilley (1997) as "social and cultural conditions" (p. 57), and no two contexts will ever be exactly the same. Researchers who seek to evaluate RRSs must consider differences between individual systems and unique local contexts to illuminate the RRS's full potential to decrease unexpected cardiac arrests and hospital mortality.

The value of evaluating the RRS within its context can clearly be seen in research published by Shah et al. in 2011. The study utilized a retrospective cohort design covering nine months prior to RRS implementation and 27 months after implementation. Researchers noted a "modest but non-sustained improvement" (p. 1363) in hospital mortality rates as well as an initial increase in rates of in-hospital cardiac arrest that returned to the pre-intervention level. While the researchers focused on analysis at the hospital level, additional insights could have been gained by breaking the data down to look at specific contextual factors. Differences in unit cultures, unit acceptance of the RRS concept, individual positive and negative rapid response event experiences, patient demographics, and even administrative support for different units and at different times in implementation, all of which were not included in the study design, may have contributed to variability in observed outcomes. Understanding the impact of these

potential differences can lead to a greater appreciation of how RRSs can be most effective in each implementation area (Berwick, 2008; Pawson & Tilley, 1997).

RE provides an evaluation framework to incorporate essential information about the social system with existing evidence from diverse research methodologies, settings, and programs. The holistic approach of RE to social program evaluation allows researchers to build upon existing knowledge to provide theoretical guidance for the relationships among RRS context, mechanism, and outcome variables within unique social systems. RE researchers use a wide array of scientific methodologies to develop practical theories designed to improve program outcomes (Pawson, 2013; Pawson & Tilley, 1997). As Pawson (2006) explains, the purpose of evaluation research is "not to judge but to explain, and is driven by the question `What works for whom in what circumstances and in what respects?'" (p. 178).

Statement of the Problem

The goal of RRS implementation is to combine early identification of clinically deteriorating patients and prompt access to clinical experts and resources to prevent inpatient complications or unexpected mortality. Despite the successful implementation of RRSs throughout many hospitals in the United States, hospitalized patients continue to experience preventable clinical set-backs and deaths. While many researchers have attempted to evaluate the overall effectiveness of RRSs, interpretations have been hampered by differences in RRS implementation, structures, processes, and outcome measurements. The resulting scientific literature has ranged from inconclusive to positive findings, with little opportunity to build on existing evidence. A problem evident in current RRS research is that researchers cannot use traditional research methods to comprehensively evaluate the impact of these complex patient safety programs on in-hospital morbidity and mortality.

Purpose of the Study

Rather than searching for unquestionable proof that a RRS reduces hospital morbidity and mortality, a realistic research strategy is to build upon existing evidence to determine what aspects of a RRS works in different settings, for particular types of patients, cared for by nurses with selected characteristics. Through this approach, a *long term research goal* is to enhance RRSs for maximum effectiveness within its particular context, as well as provide a foundation of evidence for patient safety research through RE.

The first step toward this goal and the *purpose* of this study was to identify important clinical environment (context) and system triggers (mechanisms) to refine our understanding of an RRS in order to improve local patient outcomes and develop a foundation for subsequent research in discrete settings. To achieve this purpose, the following specific aims were pursued:

Aim 1: Determine the frequency of selected RRS context, mechanism, and outcome variables within a Midwest acute care hospital over 7.5 years.

Aim 2: Explore differences in selected outcome variables between adult medical and surgical RRS events.

Aim 3: Identify relationships among selected RRS context and mechanism variables for RRS patient outcomes between in-hospital adult medical and surgical populations.

Summary

The incorporation of RE in RRS research utilizes existing evidence and unique local program research to identify patterns of context and mechanism factors, which may lead to successful outcomes in unique settings. The *rationale* for the current study as a first step in RE evaluation of a RRS is to determine the feasibility of this approach as well as to provide a broad understanding of possible context and mechanism factors

affecting clinical outcomes at a community based hospital with a mature RRS. The expected impact of the current study will provide insights into specific program refinements at the local level and establish groundwork for the next steps of full RE of RRSs within multiple settings.

Definition of Key Terms

CMO configurations: Tentative descriptions of how fundamental mechanisms within a specific context create observed outcomes. While this hypothesis can be tested, there will be multiple variations of the hypothesis that will be refined through subsequent investigations (Pawson & Tilley, 1997; Pawson, 2013).

Context (C): The original state of a system prior to the introduction of a social program; it includes physical environment, history, interpersonal and organizational relationships, organizational structure, and resources (Pawson & Tilley, 1997; Pawson, 2013).

Failure to Rescue (FTR): An unexpected inpatient death that occurs after adverse event or complication that was not present on admission (Silber et al., 1995).

Generative Theory: A working explanation of the source and function of associations between context, mechanism, and outcome variables based upon observed variable relationships (Pawson & Tilley, 1997).

Mechanism (M): Descriptions of causal relationships within the system that trigger actions or changes in behavior (Pawson & Tilley, 1997; Pawson, 2013).

Medical Emergency Team (MET): A RRS response team led by a physician to provide expert clinical care and resources to support staff caring for clinical deteriorating patients (DeVita et al., 2006).

Outcome (O): Measurements of progress toward a desired change in performance (Pawson & Tilley, 1997; Pawson, 2013).

Rapid Response System (RRS): A program designed for bedside healthcare providers to identify patients in early stages of clinical deterioration (efferent limb) and request experienced healthcare providers and resources for support (afferent limb). In addition to these direct care limbs, RRSs include administrative support along with processes for the collection and analysis of rapid response events (DeVita et al., 2006; DeVita et al., 2010).

Rapid Response Team (RRT): A RRS response team led by a critical care nurse to provide expert clinical care and resources to support staff caring for clinical deteriorating patients (DeVita et al., 2006).

Realistic Evaluation (RE): A framework for program evaluation which focuses on repeatedly identifying which program elements work in specific settings for unique community members in order to build a practical theory for program refinement and spread (Pawson & Tilley, 1997; Pawson, 2013).

Serious Harm: A change in a patient's clinical condition resulting in (a) additional hospital days, (b) life-sustaining treatments, (c) permanent injury, or (d) death. (DHHS, 2010).

Social Programs: An intervention of complex processes implemented by humans within an existing social system designed to change specified outcomes (Berwick, 2008; Pawson & Tilley, 1997)

Social Systems: An organizational system influenced largely by relationships, interactions, and learning. The system consists of distinct, yet interlinked entities which include patients and family members, staff, independent physicians, administration, ancillary departments, and nursing units within a hospital. Each hospital system is unique, complex, responsive, and unpredictable due to factors such as staffing, culture, internal and external relationships, policies, resources, and patterns of behavior (Rycroft-Malone et al., 2010).

CHAPTER 2

REVIEW OF THE LITERATURE

Introduction

Researchers have sought to determine the extent of preventable in-hospital mortality as well as relationships between in-hospital safety strategies such as Rapid Response Systems (RRS) and patient outcomes after national attention was drawn to the epidemic of preventable in-hospital deaths in the 2000 IOM report, *To Err is Human* (Kohn et al.). The authors determined an estimated 44,000 to 98,000 hospital patients die each year in the United States due to preventable medical errors. Based on this renowned report, the federal government, regulatory agencies, and accrediting bodies have called for substantial improvements in the delivery of healthcare and definitive research toward effective patient safety strategies (CMS, 2013; DHHS, 2012; IHI, 2011; NPP, 2011; TJC, 2013). This review of recent RRS literature will provide an overview of existing evidence, identify gaps in current scientific knowledge, and provide a foundation for the current study in order to understand the feasibility of RE in RRS research and to identify possible context and mechanism factors affecting patient outcomes.

In-Hospital Patient Mortality

Hospital mortality rates have been used within patient safety research as a measurement of quality health care (Classen et al., 2011). Mortality rates have limited usefulness as they compare the most extreme negative outcome, death, against all other possible outcomes. Despite this limitation, mortality rates can provide a starting point for patient safety initiatives. The Department of Health and Human Services (DHHS) released a report in 2010 noting the incidence of adverse events among Medicare patients discharged in October of 2008. The report showed 13.1% of patients discharged within the sample month had *serious harm* from adverse events with 18% of those patients experiencing more than one adverse event during their hospitalization. Researchers

defined serious harm as the need for additional hospital days and/or life-sustaining treatments, permanent injury, or death. Additionally, 9% of observed adverse events resulted in death, which translated to an estimated 1.5% or 15,000 Medicare patient deaths from adverse events out of an estimated 1 million Medicare discharges in October 2008. Most recently, James (2013) synthesized data from four studies to describe deaths from preventable adverse events (PAEs) and estimate their prevalence within the United States. Focusing on data published between 2008 and 2011, he reports an annual estimate of unexpected in-hospital deaths at more than 400,000 from adverse events; much higher than the often quoted estimate of 98,000 unexpected in-hospital deaths in 2000 (Kohn et al.). While PAEs and their causes may be difficult to detect within medical records, tools such as the Global Trigger Tool (GTT) are providing a systematic method for trained medical experts to locate adverse events and determine their preventability as described in this study.

James (2013) systematically combined data from studies using the GTT to estimate an in-hospital mortality rate of 0.89% from preventable adverse events. This rate was then applied to the estimated 34.4 million annual hospital discharges in the United States to arrive at an estimate of 210,000 deaths each year related to documented PAEs. However, James cautioned this was likely a significant underestimate due to lethal PAEs that could not be detected through medical records. He revised his estimate after taking into account estimates of errors missed by the GTT, missing or biased documentation, and missed diagnoses, resulting in a final estimate of 440,000 in-hospital deaths each year from PAEs. An annual mortality rate of 440,000 in-hospital deaths from PAEs would represent approximately one-sixth of all deaths in the United States.

Clearly the impact of PAEs within the United States (U.S.) healthcare system has not diminished since the IOM report, *To Err is Human* in 2000 (Kohn et al.). In fact, given advances in clinical interventions and wide-spread implementation of patient safety initiatives over the past thirteen years, these preventable deaths seem more tragic. While

errors cannot be totally eliminated due to the complexity of healthcare, the development of effective interventions to reduce preventable in-hospital deaths must be a top priority for patient safety researchers.

In-Hospital Cardiac and Cardiopulmonary Arrests

A challenge of using mortality rates to measure patient safety programs is mortality rates do not represent patients in clinical crisis whose deaths were prevented due to life-saving measures. In addition, overall measurements of in-hospital mortality are unable to provide the event- or program- specific details necessary for focused interventions (Classen et al., 2011). Consideration of patients with unanticipated cardiac arrests in addition to patients who ultimately died during a hospital admission can provide a broader look at the problem of keeping patients safe from *unexpected* complications and death.

Throughout the scientific literature, variations in the terminology and measurements of cardiac arrests are common despite early recommendations from a symposium of leaders in resuscitation science (Cummins et al. 1997). The published consensus statement from this group of experts defined complete cardiac arrest as (a) "absence of a palpable pulse;" (b) "unresponsiveness due to any cause;" and (c) "apnea, agonal respiratory attempts, or artificial ventilation" (p. 166). This definition will be used throughout the review of the literature as it includes both cardiac and cardiopulmonary arrests.

In 2013, leading clinical experts developed the AHA Consensus Statement describing key strategies to improve in-hospital cardiac arrest (IHCA) survival (Morrison et al.). This task force identified a lack of research designed to understand ICHA, despite earlier initiatives to reduce hospital morbidity and mortality rates (Morrison et al., 2013). The panel of experts additionally described substantial variations in clinical definitions, measurements, and reporting mechanism across hospitals, geographic regions, and

nations, leading to difficulties interpreting variable research findings. However, the prevalence of IHCA was estimated by researchers in a 2011 study using the American Heart Association's (AHA) Get with the Guidelines-Resuscitation (GTWG-R) program data (Merchant et al.). The researchers identified IHCA rates of 0.92 per 1,000 hospital admissions during 2003 through 2007; approximately 200,000 IHCAs occurred annually during this period. Furthermore, the report illustrated an annual increase in IHCAs despite early intervention and treatment strategies.

The GTWG-R repository is one attempt to standardize the collection, interpretation and reporting of IHCA events and outcomes (Merchant et al., 2011). As noted above, according to this data, every year approximately 200,000 American adults experience an IHCA. In contrast, Ehlenbach et al. (2009) estimated a substantially higher IHCA incidence rate of 2.73 per 1,000 by utilizing fee-for-service Medicare claims. While the incidence rates differ, an increasing IHCA incidence over time was noted in both studies. Ehlenbach et al. noted an increase greater than 37% from 3.78 events per 1,000 admissions in 1992 to 5.19 events per 1,000 admissions in 2005. Additionally, the study reported in 4.21% of *all* hospital deaths the patient had previously experienced an IHCA.

While the incidence of IHCA provides a broad look at in-hospital morbidity, additional information is required to assess the relationship between these cardiac arrests and hospital mortality rates. In a key study at Yale University (Larkin, Copes, Nathanson, & Kaye, 2010), researchers completed an in-depth analysis of IHCA mortality rates from 2000 to 2004 GWTG-R data. The research team found 54.4% of patients experiencing IHCA did not respond to resuscitation efforts and died at the event, while an additional 29.7% died later during the same hospitalization. Through an analysis of administrative data, researchers found only 18.3% of patients aged 65 and older who experienced an IHCA survived to discharge, with no statistically significant changes in that rate between 1992 and 2005 (Ehlenbach et al., 2009). Ehlenbach et al. also noted that patients who

survived IHCA were more frequently discharged to another hospital, skilled nursing center, or similar setting, which may indicate related decreases in cognitive or functional status.

Girotra et al. (2012) discovered the immediate survival rate of patients experiencing IHCA increased from 42.7% in 2000 to 54.1% in 2009 in 553 hospitals participating in a national quality-improvement registry. Similarly, risk-adjusted rates of IHCA survival to discharge increased from 13.7% to 22.4%, for an overall survival to discharge rate of 17.0%. An additional finding of note was a decrease in the rate of overall neurological disability after ICHA from 32.9% to 28.1%. Despite the desired trend in IHCA survival rates, the researchers noted their inability to distinguish between improvements in clinical care versus concurrent hospital trends such as early identification of clinical deterioration, increased acceptability of do-not-resuscitate orders for patients with a terminal illness, and critical care outreach strategies.

Preventable Adverse Events

While in-hospital mortality and IHCA rates provide a general means to evaluate patient safety, patient safety researchers should also assess rates of serious PAEs (Classen et al., 2011; DHSS, 2010; James, 2013; Landrigan et al., 2010). James (2013) defines PAEs as harm resulting from identifiable (a) "errors of commission," (b) "errors of omission," (c) "errors of communication," (e) "errors of context," and (f) "errors in diagnosis" (p. 123). While all errors do not lead to PAEs, their presence signals the *potential* for temporary, permanent, or even serious harm to have occurred (James, 2013; Van Den Bos et al., 2011). Identification and incidence of PAEs can assist in the identification of relationships between contributing factors and patient outcomes. This information can be used to strengthen in-hospital patient safety strategies.

To determine the impact of adverse events on morbidity and mortality, it is essential to measure frequency, as well as the likelihood for serious harm. Researchers

reviewed in-patient admissions at three large U.S. hospitals during October 2004 using the GTT in order to determine the incidence of adverse events (Classen et al., 2011). While the researchers did not attempt to determine preventability, expert reviews revealed 33.2% (91 per 1,000 hospital days) of adult admissions experienced adverse events. Out of the 393 documented adverse events, 2.7% resulted in permanent harm, 3.5% resulted in life-threatening conditions, and 2.0% resulted in death. Classen and colleagues noted statistically significant differences in hospital mortality rates between patients with documented adverse events (2.36%) compared to patients without documented adverse events (0.56%). Additionally, patients who experienced adverse events were more likely to (a) be older, (b) have a higher clinical acuity, (c) have a longer hospital length of stay, and (d) die during their admission.

Based on the high incidence of adverse events and subsequent harm, the assessment of preventability is necessary to focus patient safety strategies for maximum benefits. The retrospective review of ten hospitals in North Carolina utilized the GTT to uncover adverse events and physician review to determine preventability (Landrigan et al., 2010). The rate of adverse events for all adult admissions, excluding behavioral health and rehabilitation admissions was 56.5 events per 1,000 hospital days. As a limited number of patients experienced more than one adverse event during the same admission, the incidence of adverse events was also reported as 25.1 events per 100 admissions. An in-depth review of these adverse events revealed that 63.1% of the adverse events were preventable; 3.5% of preventable adverse events resulted in permanent harm, 9.6% were life-threatening, and 2.4% ended in death. In addition to these alarming rates of harm and adverse events, multivariate analysis revealed no statistically significant changes decreases over six years despite adjustments for patient demographics, hospital characteristics, and patient acuity.

Financial Impact

Not only do adverse events often lead to serious harm or death, they are also a financial burden on individuals and society. A 2010 DHHS report describing the incidence of adverse effects in the U.S. estimated Medicare costs from adverse events to be $324 million for October of 2008, and $4.4 billion for fiscal year 2009. A second estimate of costs associated with adverse events utilized data from commercial and retirement insurance claims (Van Den Bos et al., 2011). The research team focused on identification of errors of commission coded as adverse events. Based on documented adverse events and 2008 census data, the estimated medical costs resulting from medical errors was $17.1 billion nationwide. The financial impact of adverse events paired with potentials for serious harm or death strengthens the argument for effective patient safety research strategies.

Early Warning Signs of Clinical Deterioration

Health care providers must be able to identify patients at risk for clinical deterioration to reduce the incidence of hospital mortality and ICHA. In a seminal effort to highlight the ability of early intervention strategies to reduce IHCA, Schein et al. (1990) published research uncovering a pattern of IHCA antecedents. This report noted 84% of patients experiencing IHCA displayed symptoms of clinical distress within an eight-hour period preceding arrest. In addition, as many as 70% of the patients displaying clinical signs of deterioration prior to IHCA were noted to have an observed decline in respiratory or mental status. Schein et al. grouped the clinical distress symptoms into six major categories: (a) respiratory, (b) metabolic, (c) cardiac, (d) neurologic, (e) unclassified, or (f) multiple symptoms. These findings highlighted an important window of opportunity to prevent IHCA and ultimately prevent in-hospital mortality through early intervention strategies.

Identification of the antecedents to clinical deterioration and unexpected deaths is essential for early identification and interventions for patients at risk. Hillman et al. (2001) reported half of unexpected deaths (excluding cardiac arrest) on medical-surgical units had documented serious clinical abnormalities within 48 hours prior to death. Additionally, almost one-third of patients who demonstrated serious clinical signs in the 48 hours prior to their death were noted to have displayed those signs for the entire 48-hour period. Hillman et al. noted the most common documented symptoms of clinical deterioration in these patients were decreased systolic blood pressure and increased heart rate, with nursing or junior medical staff documenting their worry in 25% of unexpected deaths within the eight hours preceding death.

A focus on clinical symptom presentations prior to serious deterioration provides another approach beyond general mortality rates. Hillman led such an investigation exploring the relationship of symptoms with clinical deterioration requiring critical care within an ICU (Hillman et al., 2002). Over 60% of patients unexpectedly transferred to the ICU from medical-surgical units had displayed clinical symptoms within the preceding eight hours. The most commonly documented signs were decreased systolic blood pressures, increased heart rates, increased respiration rates, and decreases in consciousness. In addition to these clinical signs, nursing and junior medical staff also documented worry regarding the patient's clinical condition during the eight hours prior to transfer in 70% of patients from medical-surgical units. The researchers also found that patients transferred to the ICU from medical-surgical units were more critical than patients transferred from the operating room and more likely to die (47.6%) than patients transferred to the ICU from the operating room (19.3%) or emergency room (31.5%).

Further research built upon these early findings is needed to (a) identify patients most at risk of clinical deterioration leading to death and (b) design early intervention strategies to decrease mortality risk in those patients. In 2004, a prospective study reviewed all non-ICU admission charts each day to identify patients with symptoms of

clinical deterioration. This information was then compared to actual deaths to evaluate possible relationships between in-hospital clinical status and mortality (Buist, Bernard, Vguyen, More, & Anderson, 2004). Researchers discovered that 8.9% of all patients admitted to the medical or surgical units experienced one or more key signs of clinical deterioration. Out of those patients who displayed symptoms of clinical deterioration, 26% died before discharge. The most common signs of clinical deterioration were noted to be decreases in oxygen saturation (present in 51% observations) and low systolic blood pressure (present in 17.3% of observations). The most common pattern of abnormal clinical symptoms was increased heart rate, respirations, and blood pressure, present in 23% of all abnormal observations. The clinical deterioration symptoms significantly associated with increased mortality risks were decreased level of consciousness, systolic blood pressure, respirations, oxygen saturation, and pulse rate. In addition, the presence of more than one sign of clinical deterioration also increased the risk of mortality.

Despite evidence of associations between clinical and vital sign abnormalities with morbidity and mortality, the prevalence of these warning signs in patients who do not ultimately experience life-threatening conditions complicates their use as predictors of mortality (Harrison, Jacques, McLaws, & Kilborn, 2006). This lack of specificity of clinical abnormalities has led to the search for clinical patterns, which may better predict a patient's individual risk of mortality. Harrison et al. uncovered four patterns of clinical symptoms strongly associated with unexpected mortality prior to discharge from the hospital: (a) cardiac and respiratory symptoms with decreased urine output; (b) cardiac and respiratory symptoms with decreased consciousness; (c) respiratory symptoms with decreased urine output; and (d) cardiac and respiratory symptoms alone.

Massey et al. (2009) investigated additional factors leading to negative patient outcomes, to build upon existing knowledge of the presence and relationships between early warning signs of clinical deterioration and hospital mortality. These researchers argued that the presence of specific setting and practice characteristics in the presence of

clinical symptoms of deterioration led to increases in both hospital morbidity and mortality. While the presence of clinical symptoms signaled a risk for continued clinical deterioration, the practice context and subsequent staff reactions could either mitigate or potentiate this risk (Massey et al., 2009). Factors which increased a hospitalized patient's risk of morbidity or mortality included: (a) failure of bedside staff to recognize the critical nature of the patient's status, (b) reluctance or avoidance of nursing and junior medical staff to ask for help or advice, (c) a deficit in clinical assessment or treatment knowledge by health care providers, (d) lack of essential organizational resources and support for bedside care, and (e) inadequate clinical supervision to promote and reinforce optimal care. In further support of the importance of non-clinical factors, researchers noted early warning sign factors associated with PAEs included inadequate monitoring and assessment of hospitalized patients resulting in treatment delays and further clinical deterioration (DHHS, 2010). These findings established the need to understand the relationships between those non-clinical and non-patient factors, which mitigated the progression of clinical deterioration to morbidity, and mortality.

Rapid Response Systems

Overview

In response to the need to provide early interventions to patients in clinical deterioration, a hospital in Sydney Australia developed an in-hospital emergency team to aid in the early identification and intervention for clinically unstable patients prior to cardiorespiratory arrest (Hourihan, Bishop, Hillman, & Daffurn, 1995). The Medical Emergency Team (MET) responded to 294 events over a six-month period. The research team noted a decrease in mortality for patients with IHCA prior to MET intervention (84%) compared to patients receiving early intervention care by the MET (27%). Rapid Response Systems (RRSs), such as the MET, began to receive international interest after two large studies conducted by Australian research teams also reported positive patient

outcomes following MET implementation (Bristow et al., 2000, Buist et al., 2002). Both research teams described the MET as a method of providing early clinical care to "at-risk" patients in lieu of a code blue team. The MET membership included an intensivist, medical hospitalist, and critical care or senior nurse who responded to predetermined signs of clinical deterioration. Bristow et al. recommended further exploration of RRS programs after documenting reductions in unexpected ICU admissions and decreases in Do-Not-Resuscitate (DNR) deaths following introduction of the MET. Additionally, Buist et al. reported a 50% decrease in unexpected IHCA rates (3.77 per 1,000 admissions pre-implementation, 2.05 per 1,000 admissions post-implementation) and subsequent mortality (77%, 55%) following MET implementation. After case-mix adjustments for patient acuity, Buist et al. discovered a 50% reduction in unexpected IHCA after MET implementation. These promising findings sparked the widespread implementation and subsequent adaptations of RRS programs throughout the healthcare community (Berwick, 2008).

Significant variations exist in RRS terminology, program designs, and outcome measurements despite repeated recommendations for standardization. In 2006, a panel of patient safety experts developed a consensus statement to provide a common understanding of RRSs (DeVita et al.). The panel began by acknowledging the lack of a uniform label for RRSs (e.g., MET). RRS was described as the overarching structure within a hospital for providing critical care to patients in clinical deterioration. The RRS consists of four essential components: (a) a method to identify patients in clinical crisis (b) a mechanism to trigger a clinical intervention; (c) a response by a team of critical care specialists; and (d) administrative support in the form of policies, procedures, and quality improvement evaluations. The panel noted the use of two common names for the teams responding to RRS events in the literature required clarification within the healthcare community. The panel recommended MET be used to describe critical care response teams led by a physician, with Rapid Response Team (RRT) reserved for teams led by an

experienced nurse. Finally, the panel provided general recommendations for event documentation along with primary and secondary outcome measures to be utilized for research and quality improvement projects. Subsequent international RRS conferences, literature reviews, and research recommendations have acknowledged challenges largely resulting from lack of standardized definitions and outcome measurements (Butner, 2011; Chan et al., 2010; Laurens & Dwyer, 2010; Sarani & Scott, 2010; Winters et al., 2013).

The Impact of RRSs on Patient Outcomes

Evaluation of research on the impact RRSs have on patient outcomes has been complicated by continued variability in program implementations, sample selections, independent variables, and outcome measurements (Winters et al., 2013). Additionally, the lack of consistent consideration of context and mechanism factors limits the usability of many findings (Berwick, 2008). However, existing RRS evidence provides valuable guidance in the identification of evidence gaps and the development of new research approaches.

RRS Effects on Hospital Mortality

The ultimate goal of RRSs is to facilitate early identification of patients at risk to bring experts and critical resources to the bedside to realize a substantial reduction in unexpected deaths and injury. However, changes in mortality rates associated with RRSs continue to be inconsistently reported in the literature. In 2008, Chan et al. evaluated the effectiveness of a RRT consisting of two ICU nurses and a respiratory therapist (RT) through a prospective cohort study of adult inpatients. The impact on hospital mortality rates was compared between pre-implementation rates in 2004 and 2005 and post-implementation rates in 2006 and 2007. Observed total hospital mortality rates had a non-statistically significant decrease from 3.22 deaths per 100 admissions to 3.09 deaths per 100 admissions, with an adjusted odds ratio of 0.95 ($p = 0.52$). Additionally, the team found 4.3% deaths occurred during the RRT event, 61.4% deaths occurred after transfer

to the ICU, and the remaining deaths occurred less than (17.1%) and greater than (17.7%) 7 days prior to discharge. Researchers noted incidences of under-treatment of critical patients and underutilization of the RRS may have affected mortality rates.

In the search for patterns in RRS outcomes, a study compared the characteristics of adult patients who responded to RRT interventions against those who did not respond to RRT interventions; 24% of RRT patients died after transfer to the ICU and 14% died on their medical-surgical unit (Kolluru, Singh, Kanwar, Szpunar, & Saravolatz, 2010). The research team defined *responders* as patients whose clinical condition stabilized after a RRT intervention, allowing them to remain on their medical-surgical unit, where *non-responders* required a higher level of care or experienced a cardiac arrest after a RRT intervention. The reasons for RRT *activation*, or RRT triggers, were explored for potential associations with patient outcomes. RRT activation for a respiratory diagnosis or an observed decrease in oxygen saturation increased the odds of non-response (OR 1.8 and OR 2.6, respectively). However, RRTs activated due to a staff members' concern about their clinical status was associated with increased likelihood of a patient's response to the RRT intervention (OR 0.23). Overall hospital mortality rates or RRT activation rates were not reported. In that same year, a prospective evaluation of a MET implementation reported a 10% reduction in total hospital mortality (OR 0.90), 12% reduction in hospital mortality for medical patients (OR 0.88), and a 28% reduction in hospital mortality for patients admitted to surgical units who were determined to not require surgical intervention (Konrad et al., 2010). Konrad et al. did not find a statistically significant decrease in hospital mortality rates for patients receiving surgical interventions despite adjustments for patient demographics and acuity levels. In addition to statistically significant reductions in total hospital mortality rates after RRT implementation, 30-day mortality rates decreased from 25% to 7.9% and 180-day mortality rates decreased from 37.5% to 15.8% for patients receiving RRT interventions

compared to patients with documented RRT activation criteria prior to the program implementation.

However, the evidence of RRS impacts on patient outcomes has revealed inconsistent findings of significance and sustainability. Beitler and colleagues (2011) conducted a research study in 2011 which compared 6 years of overall hospital mortality rates before and after RRS implementation. The researchers found a statistically significant decrease in hospital mortality rates after RRS implementation from 15.50 deaths per 1,000 discharges to 13.74 deaths per 1,000 hospital discharges (RR 0.887), which retained significance after adjustment for temporal mortality trends (RR 0.825). Additional non-ICU mortality rates decreased from 7.08 deaths per 1,000 discharges to 4.61 deaths per 1,000 discharges (RR 0.651). Laurens and Dwyer (2011) also found reductions in hospital mortality rates after implementation of a MET from 9.9 deaths per 1,000 admissions to 7.5 deaths per 1,000 admissions (RRR 21.4%) despite underuse by bedside clinical staff. However, assessment of a RRT program on adult non-obstetric mortality rates at an academic medical center showed only a slight, nonsustained decrease in hospital mortality rates during the first 27 months of the program (Shah, Cardenas, Kuo, & Sharma, 2011). Howell et al. (2012) evaluated a RRS utilizing a novel RRT consisting of the patient's health care providers within an academic medical center (2012). While there were no statistically significant differences in both unadjusted and adjusted hospital mortality rates, the researchers observed a 72% decrease in unadjusted unexpected hospital mortality an 80% decrease in the adjusted odds of unexpected death.

Because the widespread implementation of RRSs throughout the United States, Europe, and Australia limits the ability for new pre- post-RRS implementation research designs, findings from countries with limited healthcare resources can provide unique perspectives. Evaluation of a RRS in Brazil revealed a statistically significant decrease in hospital mortality rates from 16.27 deaths per 1,000 discharges to 1.69 deaths per 1,000 discharges after RRS implementation (Gonçales et al., 2012). This reduction of in-

hospital mortality was estimated to have resulted in 67 fewer deaths from RRT interventions. These findings were supported by the evaluation of the implementation of a RRT led by an intensivist in a large Saudi Arabian academic medical center (Al-Qahtain et al., 2013). Mortality rates were compared between a two-year pre-implementation period and a three-year post-implementation period. Total hospital mortality rates decreased from 22.5 deaths per 1,000 admissions to 20.2 deaths per 1,000 hospital admissions (RR 0.90) after RRT intervention and mandatory RRT follow up for 48-hours. Patients who had received ICU care were also noted to have an additional decrease in mortality rates from 18.2 deaths per 1,000 admissions to 14.8 deaths per 1,000 admissions.

RRS Effects on Hospital Cardiac Arrests

While mortality rates establish a general evaluation of patient safety, IHCA rates focus the evaluation on the impact of RRS on a potentially non-lethal outcome. A research team headed by Buist (2002) provided one of the foundational reports of RRS effectiveness; subsequent research by another team led by Buist (2007) detailed the impact of a MET on IHCAs over six years. The researchers explained that IHCAs are typically seen as a failure of the health care team to provide "optimal clinical care" (Buist, Harrison, Abaloz, & Van Dyke, 2007, p. 335). A statistically significant 24% decrease in IHCAs was observed over six years following RRS implementation within an academic medical center, from 2.4 per 1,000 admissions to 0.66 per 1,000 admissions.

Although Chan et al. (2008) did not find a statistically significant decrease in hospital mortality rates, statistically significant decreases were seen in hospital code rates, from 11.20 codes per 1,000 admissions to 7.53 codes per 1,000 admissions ($p < 0.001$), and in non-ICU code rates, from 6.08 per 1,000 admissions to 3.08 per 1,000 admissions ($p < 0.001$) following RRS implementation. However, improvement was not

seen in IHCA mortality rates, as there were no statistically significant differences observed pre-RRS implementation (77.9%) and post-RRS implementation (76.1%).

In contrast to these findings, RRSs were noted to have statistically significant effects on IHCA in subsequent research studies. Konrad et al. (2010) reported a statistically significant decrease in IHCA rates from 1.12 arrests per 1,000 admissions to 0.83 arrests per 1,000 admissions (OR 0.74) after RRS implementation. Beitler et al. (2011) also found a decrease in IHCA after MET intervention (RRR 45.5%) and a comparison of RRS rates compared to historical controls by Laurens et al. (2011) showed a decrease in non-ICU cardiac arrests from 3.23 per 1,000 discharges to 1.62 per 1,000 discharges (RRR 0.493).

A positive impact of RRSs on IHCA rates pre- and post-implementation has been found internationally. In Brazil, a statistically significant decrease from 3.54 arrests per 1,000 discharges to 1.69 arrests per 1,000 discharges was found (Gonçales et al., 2012). Al-Qahtani et al. (2013) also observed a statistically significant decrease in non-ICU arrests from 1.4 per 1,000 hospital admissions to 0.9 per 1,000 admissions in Saudi Arabia.

RRS Effects on Unexpected Transfers to ICU or Higher Level of Care

The success of RRSs can also be evaluated through the rates of immediate patient disposition (i.e., patients who require transfer to ICUs or other specialized care areas vs. stabilized patients who are able to remain in medical-surgical units). Evaluation of the immediate disposition of patients receiving RRS interventions can shed light onto both the timely activation and prompt interventions of the response team. While Chan et al. (2008) did not find strong support of the effectiveness of a RRS through mortality rates; the immediate disposition of patients after an RRT event patient showed 51.6% clinically stabilized, 3.7% transferred to a telemetry unit, 0.3% required emergency surgery, and 0.3% required cardioversion. Kolluru et al. (2010) noted 51.5% of patients were

stabilized after RRT interventions, while 48.5% were transferred to the ICU. Out of those patients who did not respond to the RRT interventions, 62% responded to the higher level of care in the ICU, 24% died despite ICU care, and 14% died on the floor. The potential benefits of RRSs were further demonstrated in the decline of patients in clinical crisis requiring levels of care beyond those available in the medical or surgical units. Laurens and Dwyer (2011) reported an overall decrease in unexpected adult and pediatric transfers to the ICU from 22.4 per 1,000 admissions to 17.6 per 1,000 admissions ($p < 0.001$) after implementation of a RSS. While Beitler et al. (2011) provided no comparisons to pre-RRS ICU transfer rates; researchers noted 55.3% of RRT events resulted in a different or higher level of care, 41.2% stabilized the patient to remain at the same level of care, and 2.8% events resulted in death, with the remaining events leading to a specialized emergency intervention. A two-year RRS evaluation within an academic medical center revealed 50% of RRT interventions led to ICU transfers and 41% RRTs stabilized the patient to remain on the medical-surgical unit, with the remaining events resulting in transfers to specialty areas such as telemetry, cardiac catheterization lab, and operating room (Shah et al., 2011).

Finally, a research team headed by Schneider (2013) analyzed patients stabilized after RRT interventions to estimate the effectiveness of RRS triage process. Out of the patients remaining on the floor after stabilization by the RRT, only 12.7% patients required a repeat RRT intervention and 0.3% experienced an IHCA on the medical-surgical unit within 24 hours. Based on these findings, the research team determined the RRS triage process was effective.

As seen in the review of the literature, the notable differences in RRS teams, settings, mortality measurements, and evaluation periods across research studies present challenges in the aggregation and interpretation of the potential effects of this early intervention strategy on hospital deaths, cardiac arrests, and unexpected transfers to ICUs. In addition, the inconsistent reporting of context and mechanism RRS factors

within the study hospitals limits the ability of patient safety researchers to evaluate their impact on patient outcomes.

The Impact of RRSs on Staff Behaviors

While limited evidence exists regarding the effects of RRS implementation on hospital culture and staff behaviors, potential benefits, and costs must be considered in the evaluation of RRSs. Shapiro, Donaldson, and Scott (2010) evaluated the impact of a RRS on attitudes and behaviors of nursing staff in thirteen states using semi-structured interviews and thematic analysis. Nurses described the RRS as: (a) efficiently bringing resources and experts to the bedside, (b) facilitating ICU transfers, and (c) essential when considering employment possibilities. Additionally, the researchers noted that nurses felt RRSs were most effective when they felt they could activate the team without hesitation. Mixed messages about appropriate RRS activation and concerns regarding who would care for patients assigned to nurses on the team when the RRS was activated were reported as barriers to effectiveness.

These findings were supported by a study conducted by Benin et al. (2012) within a large academic medical center. During open-ended interviews, nursing staff and junior medical staff described complex advantages and disadvantages to RRS implementation. The benefits were described as increased nurse morale and empowerment, equalization of workloads for both nurses and junior medical staff, increased access to experts and ICU care, increased learning opportunities, as well as increases in nurse retention rates. Potential concerns associated with RRSs were increased tensions between nursing and medical staff over perceptions of errors or missed care, increased workload for RRT members, decreases in autonomy for junior medical staff, and challenges in maintaining continuity of medical care providers. Consideration of these context and mechanism factors in RRS research designs may lead to further understanding of optimal research and RRS program designs.

Factors Influencing RRS Activation and Effectiveness

In addition to measuring the ability of RRSs to improve patient outcomes, researchers have recognized a need to identify elements of the individual systems and settings which may influence the RRS effectiveness. These factors are used to assist in the comparison of RRS outcome measurements across settings and studies; however, inconsistent reporting and definitions limit their usefulness. In addition, understanding the operation of RRSs can aid in the development of recommendations for improved efficiency, utilization, and outcomes.

RRS Activation Triggers

Identification of relationships between patient outcomes and RRS activation triggers can provide guidance in understanding risk factors and the potential ability to save patients based on clinical symptoms. Several studies have provided data to describe the reasons, or triggers, for RRS activation. Despite substantial differences in the triggers evaluated within each study and the proportions identified, broad utilization patterns can be seen. Five objective symptoms of clinical deterioration and worry of clinical deterioration are the most prevalent RRS activation triggers reported in recent studies (Beitler et al., 2011; Chan et al., 2008; Jäederling et al., 2011; Kolluru et al., 2010; Schneider et al., 2013; Shah et al., 2011; Shearer et al., 2012). The most commonly utilized triggers for RRS activation are: (a) decreased oxygen saturation (O_2Sat), (b) changes in heart rate (HR), (c) changes in respiratory rate (RR), (d) decreased systolic blood pressure (hypotension), (e) decreased level of consciousness (LOC) or changes in mental status (MS), and (f) worry or concern about the patient's clinical status (See Table 2-3).

In addition to patterns of use, researchers have also recognized the importance of the identification and understanding of associations between triggers and patient outcomes in order to strengthen RRSs (see Table 2-1 for reported percentages of RRS

triggers). Kolluru et al. uncovered statistically significant relationships between specific RRS triggers and patient outcomes in 2010. Patients receiving RRS interventions triggered by decreased oxygen saturation had a decreased probability of clinical stabilization (OR 2.6), while patients receiving RRS interventions for staff worry (OR 0.23) had an increased probability of clinical stabilization at the same level of care. The increased odds of survival related to concerns about a patient's clinical condition were believed to result from bedside nurses' early identification of warning signs before significant clinical deterioration by bedside staff. These findings were supported by another study comparing RRS events triggered by staff worry to events triggered by objective clinical symptoms across six hospitals (Santiano et al., 2009). A greater percentage of patients receiving RRS interventions triggered by staff worry (75%) were stabilized and able to remain on the medical-surgical unit compared to those receiving RRS interventions triggered by deteriorating clinical symptoms (70%). In addition, a statistically significantly smaller proportion of patients with RRS events triggered by staff worry (1.1% triggered by worry vs. 7.6% all other triggers) experienced in-hospital cardiac arrest, supporting the hypothesis that early interventions decrease hospital mortality.

Table 2-1. Reported Percentages of Top 6 RRS Activation Triggers

Study	Low O_2 Sat	HR	RR	Low SBP	LOC-MS	Healthcare Provider Worry
Beitler et al., 2011	33.3%	16.7%	13.7%	19.3%	43.0%	46.8%
Chan et al., 2008	8.0%	23.4%*	13.3%**	11.7%	27.4%	6.9%
Jäederling et al., 2011 (Sweden)	-	13.3%*	55.8%	33.5%	15.6%	17.2%
Jäederling et al., 2011 (Australia)	-	19.9%*	37.5%	24.3%	20.6%	14.4%
Kolluru et al., 2010	31.9%	17.9%	10.6%	7.1%	20.1%	6.6%
Schneider et al., 2013	16.3%	19.5%*	-	21.7%	17.3%	15.0%
Shah et al., 2011	25%	20%*	24%**	14%	25%	19%
Shearer et al., 2012	80.0%	-	-	73.3%	-	-

Notes: More than one trigger can activate a RRS event resulting in percentages totaling greater than 100% per study.

* Tachycardia: Heart rate greater than 130 beats per minute.

** Tachypnea: Respiratory rate greater than 30 breaths per minute.

RRS Maturity

Two studies have suggested that the effectiveness of a RRS in improving patient outcomes increases as the program matures. Decreases in hospital mortality rates were noted in mature RRSs compared to RSSs in early stages of program implementation (Calzavacca et al., 2010a; Santamaria et al., 2010). While the decreases in hospital mortality were not statistically significant in the study conducted by Calzavacca et al. (2010a), decreases in delayed RRS activations (from 40.3% to 22%) and unexpected ICU transfers (from 31.3% to 17.5%) did reach significance. Santamaria et al. (2010) noted statistically significant decreases in hospital mortality (0.58 to 0.30 deaths per 1,000 hospital days) and in-hospital cardiac arrests (IHCA) (0.78 to 0.25 arrests per 1,000 hospital days) attributed to RRS maturity. Researchers noted the evaluation of these findings over the duration of the program suggested a RRS requires two years to achieve statistically significant decreases in IHCAs and four years for statistically significant

decreases in hospital mortality rates. These studies provide insight into potential reasons for limited evidence of RRS effectiveness for young programs.

Multiple RRS Events

Given the tendency for RRS researchers to analyze data collected over time or at multiple points in time, the potential inclusion of multiple RRS events for one patient is great. Researchers may choose to include either index RRS events, final RRS events, or a random RRS event in final research designs. However, the exclusion of these RRS events may limit generalizability by changing the study population in unpredictable ways. While researchers may utilize statistical tools designed to incorporate a subject specific random effect to account for potential correlations between measurements, researchers may also choose to report frequencies and statistically significant differences between populations with single and multiple RRS events (Calzavacca, 2010b; Jäederling et al., 2011; Konrad et al., 2010).

Jäederling et al. compared differences in RRSs and patient outcomes between a Swedish and Australian hospital (2011). The researchers reported 80.5% of patients who received RRS interventions received only one RRS activation in the Swedish hospital compared to 72.2% of patients in the Australian hospital. However, no information was provided regarding the significance of the difference or effects on additional findings. In the pre-post-implementation study by Konrad et al. (2010), no statistically significant differences were found between survival rates for patients who received one MET team activation compared to patients who received more MET activations. These findings differed from those by Calzavacca et al. (2010b), who explored differences between patients receiving single and multiple MET interventions. Multiple MET responses were noted more frequently for surgical patients and patients with arrhythmias. Patients with multiple MET interventions had a statistically significant 34% increase in hospital mortality rates over patients with single MET interventions. Given the limited evidence regarding differences between patients receiving multiple RRS and single RRS

interventions and the potential impacts on patient outcomes, it is essential for researchers to address potential variable dependence as well as increasing the evidence base.

Summary

Researchers must explore factors influencing the effectiveness of RRSs to decrease the high numbers of unexpected hospital deaths. While the evidence of RRS effectiveness has grown substantially since the Buist (2002) and Bristow (2000) studies, the ability to synthesize and utilize the evidence in practice settings remains challenging. Researchers must build upon existing knowledge to design studies that incorporate context and mechanism factors from local programs. Through the inclusion of these factors, researchers can begin to understand how RRSs can be most effective within specific settings and populations (Berwick, 2008; Pawson & Tilley, 1997). This research study is designed to utilize a new RRS research approach to identify significant context and mechanism factors to strengthen our understanding of the RRS to improve patient outcomes within the local setting, contribute to current RRS evidence, and support future research within discrete settings.

CHAPTER 3

RESEARCH DESIGN AND METHODOLOGY

Introduction

In 2001, The Institute of Medicine (IOM) chronicled the struggles of healthcare organizations and professionals to provide effective, efficient, and safe care in the United States (Kohn et al.). In the IOM's report *To Err is Human* the health care community was encouraged to utilize strategies from systems and organizational sciences to improve the delivery of healthcare. This challenge sparked numerous healthcare improvement strategies designed to streamline care, manage chronic illnesses, and protect patients from harm (Berwick, 2008). However, despite these processes and interventions, the health care community continues to struggle to implement, evaluate, and enhance patient safety strategies within existing complex systems (Berwick, 2008; Pawson, 2013).

The Rapid Response System (RRS) was designed as a hospital patient safety program to reduce unexpected cardiac arrests and deaths outside intensive care units (Berwick et al., 2006). The aim of a RRS is to quickly bring critical care resources and experts to bedside providers when patients are in clinical decline in order to prevent unexpected in-hospital deaths. In 2004, a sentinel study noted up to 84% of patients experiencing cardiac arrest in the hospital experience symptoms of acute clinical deterioration in the six to eight hours preceding their arrest; the survival rate after witnessed in-hospital cardiac arrest is as low as 25% (Bellomo et al., 2004). A recent study of 204 patients experiencing a severe adverse event during hospitalization, such as cardiopulmonary arrest, unexpected transfer to the ICU, emergency surgery, and death, found 81% of the patients demonstrated clinical symptoms prior to the event, with half of those demonstrating symptoms as long as 25 hours prior to the event (Ludikhuize et al., 2012). The opportunity to save lives through the early intervention of RRSs remains great (Berwick, 2008).

Based on the promise of decreasing morbidity and mortality, the Institute for Healthcare Improvement (IHI) and The Joint Commission (TJC) have promoted the RRS as a key patient safety strategy (Berwick et al., 2006; McCannon et al., 2007). The effect of context and mechanism factors on RRS processes must be evaluated to understand its true impact on patient outcomes (Pawson, 2013; Winters et al., 2006). However, as the RRS initiative spread and evolved within existing healthcare systems, the challenge of rigorous and consistent evaluation grew. Researchers began to explore the effectiveness of RRSs, collecting both definite and equivocal evidence of improved patient outcomes using a variety of settings, methods, and measurements (IHI, n.d.). These ambiguous findings contributed to mounting questions by patient safety researchers about the true ability of the RRS to positively influence patient outcomes (Winters et al., 2006).

While researchers continued to examine the impact of RRSs on patient outcomes through primarily experimental designs, Berwick noted significant concerns with the use of the randomized controlled trial (RCT) to evaluate RRS outcomes (2008). The RRS is essentially a social program; it is made up of interwoven processes, implemented by humans, and resides inside a complex healthcare environment that results in observable and latent outcomes (Berwick, 2008). As Pawson and Tilley (1997) assert in *Realistic Evaluation*, efforts to prove whether or not a program works without understanding *how it works* and *in what situations it works* are destined to fail. However, the RCT design attempts to remove or control all extraneous variables that could potentially influence the measured outcomes. When this is successful, cause and effect relationships between the independent variable and dependent variable can be examined in greater detail. However, RRSs exist within highly complex environments where these additional variables directly impact the success or failure of the system. Thus, the RRS cannot be measured outside of its context, defined by Pawson and Tilley (1997) as "social and cultural conditions" (p. 57), and no two contexts will ever be exactly the same. Researchers seeking to understand RRS outcomes must look to the observed differences between individual

systems and their unique contexts to illuminate the RRS's full potential to decrease unexpected cardiac arrests, morbidity, and mortality.

Study Purpose

The purpose of this study is to identify important clinical environment (context) and system triggers (mechanisms) to refine our understanding of an RRS in order to improve local patient outcomes and develop a foundation for subsequent research in discrete settings. Through a realistic evaluation lens, selected RRS context and mechanism factors were explored to identify relationships with patient outcomes through descriptive statistics and logistical regression (Pawson & Tilley, 1997). Using this approach, selected context and mechanism variables with (a) a patient's need for a higher level of care, (b) cardiac or respiratory arrest, and (c) the patient's immediate survival were examined. Bringing to light RRS factors associated with patient outcomes may provide a foundation for future research to understand how context and mechanism patterns can improve patient outcomes.

Research Aims

1. Determine the frequency of selected RRS context, mechanism, and outcome variables within a Midwest acute care hospital over 7.5 years.
2. Explore differences in selected outcome variables between medical and surgical RRS events.
3. Identify relationships among selected RRS context and RRS mechanism variables for RRS patient outcomes between in-hospital medical and surgical populations.

Population

The study will evaluate 7.5 years of data from an existing RRS within a 397-bed full-service referral hospital serving 25 counties within the Midwest. The hospital provides inpatient and outpatient care, as well as emergency services and community health promotion activities. The RRS was implemented in late April of 2006 as a means

for bedside nurses to receive urgent assistance and increased access to interventions and resources when patients deteriorate clinically. While the RRS has evolved through quality improvement efforts since 2006, core elements have remained consistent.

In the current study facility, the RRS is activated when a patient's clinical status meets defined criteria or in response to subjective concerns or worry. The RRS can be activated by nursing staff or any healthcare provider, as well as the patient or family member. The RRS is activated when a call is placed to the hospital operator to request the assistance of the RRT. The hospital operator then pages the RRT team members "right away" to the patient's location and notifies the Patient Care Liaison or House Supervisor of the RRS event. The RRS team consults with the person activating the team and/or the staff nurse to assist in clinical assessments, possible treatments, and any need for transfer to a higher level of care, as well as provides staff support or follow-up on barriers.

Inpatient RRS events from May 2006 (2 weeks post-program implementation) through November 2013 were included in the data analysis. RRS events associated with patients under the age of eighteen, patients admitted for childbirth, patients in the intensive care unit, and patients in outpatient service areas were excluded. Each RRS event was the unit of analysis in this study.

Data Collection and Instrumentation

Since implementation, RRS events have been documented within the patient's medical record and a separate standardized data collection tool titled "Rapid Response Team Record" (B-RRT) for quality improvement (see Appendix A, Appendix B). A B-RRT is completed by the Patient Care Liaison or House Supervisor after each RRS event. A copy of the form is left with the Unit Manager for immediate follow up of any concerns, with a second copy given to the Director of Patient Care Administration for further review, aggregation, and reporting to hospital quality committees. The Patient Care Liaison and House Supervisors are Registered Nurses who have critical care

experience, are ACLS certified, have RRS response training, and receive feedback on RRS events as well as data collection from the Director of Patient Care Administration. The limited number of data collectors, along with standardized training and monitoring, increase the reliability of data collection processes and completeness of recorded data.

The Director of Patient Care Administration facilitates and oversees the entry of the collected data into a secure data file. RRS event records do not contain any identifying information for the staff activating the RRS beyond their role (nurse, respiratory therapist, house supervisor, or other). Therefore looking for activation patterns by individual staff members is not possible within this data set. The event records contain a unique identifier of the patient for whom the RSS was activated. However, no patient names, social security numbers, or other identifying information was transmitted with the RRS data file. Research files were stored securely on the University of Iowa nursing research server and protected by password and individual file access. A HIPPA waiver and final approval for the study was obtained through the local hospital Institutional Review Board and provided to the University of Iowa Institutional Review Board (IRB-02 Behavioral/Social Science).

Selection of Study Context, Mechanism and Outcome Factors

Variables within the RRS data set were evaluated for inclusion within the study design based on existing RRS evidence, current research design, limited frequency of individual factors, completeness of the data fields, and the ability to consistently measure a factor from RRS implementation to present (see Figure 3-1).

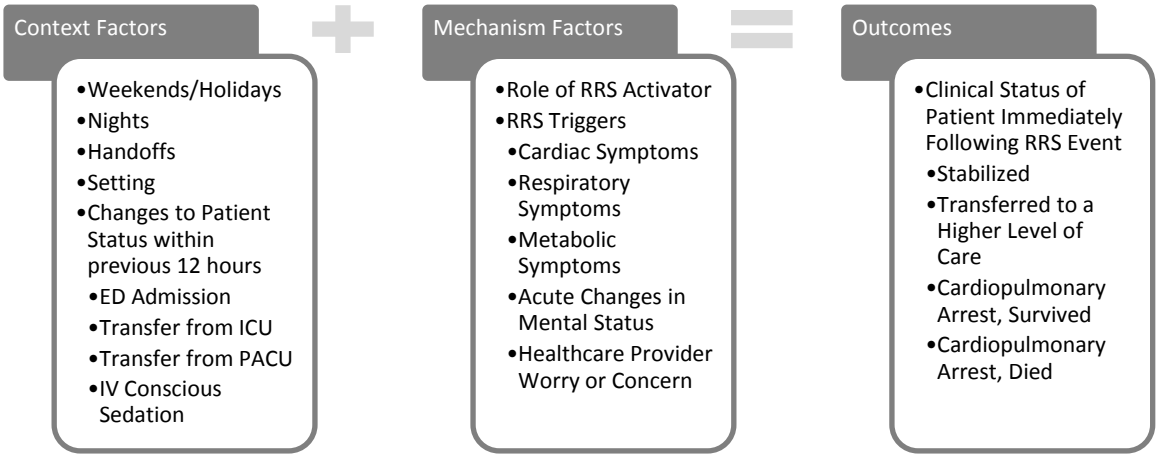
Context factors were defined as variables which describe the original state of the system and existed prior to or at the time of RRS activation. Temporal context factors included day and time of the event, which were used to explore the event to explore potential differences in resource availability, nursing practices, and staffing levels.

Recent changes in the patient's clinical status prior to the RRS, including admission to the unit from the ED or physician's office, transfer to the unit from the ICU or PACU, or IV conscious sedation within the previous 12 hours, were included as a context variable to explore potential differences related to patient acuity. The final context factor included within the study design was the type of unit where the RRS event occurred to account for the culture, training, and focus of the unit.

Mechanism factors were defined as variables which directly led to the activation of the RRS and included the person activating the RRS and the triggers for the RRS. RRS activators included staff nurses and non-staff nurses to explore the impact of the role on the RRS outcome. RRS triggers included one or more indicators of changes (objective or subjective) in the patient's clinical status, which were collapsed into trigger categories as described in current RRS guidelines (AHRQ, n.d.) to evaluate differences in warning signs.

Finally, an outcome factor was defined as the effect of the program and measured by the clinical disposition of the patient immediately at the end of RRS event. The single RRS outcome factor was separated into four mutually exclusive levels of clinical severity. The best clinical outcome resulted when the patient was stabilized and able to remain on the medical or surgical unit. An increase in clinical severity following the RRS event resulted when the patient required a transfer to a higher level of care for increased monitoring or clinical interventions. An additional increase in clinical severity following the RRS event resulted when the patient experienced cardiopulmonary arrest with successful resuscitation. Finally, the most severe clinical outcome occurred when the patient experienced cardiopulmonary arrest with unsuccessful resuscitation attempts, resulting in death.

Figure 2-1. Tentative Model of RRS CMO Factors



Procedures to Achieve Specific Aim 1

The first specific aim was to describe a local RRS within a Midwest acute care hospital by determining the frequency of selected RRS context, mechanism, and outcome variables over 7.5 years. This aim was accomplished by assessing actual numbers and percentages of selected categorical context, mechanism, and outcome variables to describe the activity and patterns of the local RRS for adult inpatient units (see Table 3-1, Table 3-2, & Table 3-3

Table 3-1. Categorical Context Variables

Context Variable	Context Label	Definition	Coding
Day of Week	Weekday	Mondays, Tuesdays, Wednesdays, Thursdays and Fridays from 2400 to 2359.	0
	Weekend and Holiday	Sunday, Saturday, New Year's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Days, Christmas Eves, Christmas Day, New Year's Eve from 2400 to 2359.	1
Nursing Shift	Day Shift	Nursing shifts beginning at 0700 and ending at 1859.	0
	Night Shift	Nursing shifts beginning at 1900 and ending at 0659.	1
Shift Handoff	Regular Shift	Shift time not affected by nursing handoff, from 0800 to 1859 and 2000 to 0659.	0
	1-Hour Post-Handoff	Shift time where nursing handoff occurs, from 0700 to 0859 and 1900 to 1959.	1
Setting	Surgical Units	Cardiac Surgery, Joint Replacement Center, Spine Center, Surgical Specialties, and Surgical Stepdown.	0
	Medical Units	Cardiology, General Medicine, Neurology, Oncology, and Rehabilitation.	1

Table 3-1. continued

Context Variable	Context Label	Definition	Coding
Recent Arrival to Unit	No ED Admission < 12 Hours	Patient not admitted to unit from ED in the previous 12 hours.	0
	ED Admission < 12 Hours	Patient admitted to unit from ED in the previous 12 hours.	1
	No Direct Admission < 12 Hours	Patient was not admitted to the unit directly from a physician's office in the previous 12 hours	0
	Direct Admission < 12 Hours	Patient admitted to unit directly from physician's office in the previous 12 hours.	1
	No ICU Transfer < 12 Hours	Patient not transferred to unit from ICU in the previous 12 hours.	0
	ICU Transfer < 12 Hours	Patient transferred to unit from ICU in the previous 12 hours.	1
	No PACU Transfer < 12 Hours	Patient not transferred to the unit from PACU in the previous 12 hours.	0
	PACU Transfer < 12 Hours	Patient transferred to unit from PACU in the previous 12 hours.	1
Post-IV Conscious Sedation	No IV Conscious Sedation < 12 Hours	Patient had not received IV Conscious Sedation in the previous 12 hours.	0
	IV Conscious Sedation < 12 Hours	Patient had received IV Conscious Sedation in the previous 12 hours.	1

Table 3-2. Categorical Mechanism Variables

Mechanism Variable	Mechanism Label	Definition	Coding
Event Activator	Non-Nurse Activation	Events not activated by staff nurse, may include respiratory therapy, house supervisor, patients, and family members.	0
	Nurse Activation	Events activated by staff nurse.	1
Event Triggers	Cardiac	Events activated in response to cardiac concerns (acute change in heart rate to less than 40 or greater than 130, acute change in systolic BP to less than 90, acute change in diastolic BP to less than 40).	1
	Respiratory	Events activated in response to respiratory concerns (acute change in respiratory rate to less than 10 or greater than 28, acute change in saturation to less than 92% despite oxygen use).	1
	Mental Status	Events activated in response to acute change in mental status or level of consciousness	1
	Metabolic	Events activated in response to metabolic concerns (acute change in urine output to less than 50 ml in 4 hours, acute significant bleeding).	1
	Worry	Events activated in response to staff concerns (worried or concerned about the patient, i.e., chest pain, acute shortness of breath).	1
	Multiple	Events activated in response to more than more than one category of RRS triggers	1

Table 3-3. Categorical Outcome Variable

Outcome Variable	Outcome Label	Definition	Coding
Clinical Disposition	Stabilized	Events where the patient was clinically stabilized and able to remain on the unit at the end of the RRS event.	0
	Transferred to Higher Level of Care	Events where patient required a higher level of care (intensive care unit) at the end of the RRS event.	1
	Cardiopulmonary Arrest – Survived	Events where the patient experienced cardiopulmonary arrest and was successfully resuscitated at the end of the RRS event.	2
	Cardiopulmonary Arrest - Died	Events where the patient experienced cardiopulmonary arrest and were not successfully resuscitated at the end of the RRS event.	3

Procedures to Achieve Specific Aim 2

The second study aim was to explore observed differences between selected context mechanism variables with outcomes of independent RRS events. The comparisons are based on frequencies, percentages, and chi-square significance testing to identify important differences between RRS events by unit setting and event activators.

Procedures to Achieve Specific Aim 3

The third specific aim is to identify relationships and interactions among selected RRS context and RRS mechanism variables for RRS patient outcomes within inpatient hospital medical and surgical populations. Proportional odds, or ordinal logistic regression was used to determine context and mechanism factors with significant relationships to RRS outcomes by unit type (medical versus surgical). Proportional odds ordinal logistic regression is a generalization of the traditional logistic regression process, which can address more than one outcome. As with logistic regression, ordinal logistic models relate a linear predictor to the odds of an outcome. Unlike logistic regression, the estimated odds is for an increase (or decrease) in the outcome variable (i.e., from a 1 to 2, or 2 to 3), rather than just a change in the odds of a 1 vs. a 0 outcome. The method is called proportional because the change in odds is the same for all adjacent categories (there is only one regression coefficient for each explanatory variable). Differences in the marginal frequencies of the various outcomes are accounted for by the introduction of separate intercepts. These models will identify the CMO configuration of context and mechanism factors, which supports optimized patient outcomes for patients overall and within different primary populations. In other words, what works best for whom and in what circumstances (Pawson, 2013; Pawson & Tilley, 1997)?

Summary

In summary, the purpose of this study is to identify important context and mechanism factors as well as significant differences and relationships through RRS outcomes. The findings from this preliminary study, described in Chapter 5, will be used to guide local RRS refinements as well as establish an evidence base for the next steps of a RE program of RRS research.

CHAPTER 4

ANALYSIS OF DATA

The RRS event variables were selected a priori for study inclusion based on research aims, RE framework, relevant literature, RRS structure, and local expert feedback (Berwick, 2008; Pawson, 2013; Pawson & Tilley, 1997; Winters et al., 2013). Multiple statistical approaches at the RRS event level were used to explore the study aims. The first specific aim sought to describe RRS events by determining frequencies and associated percentages of selected context, mechanism, and outcome variables (CMOs). The second specific aim focused on a comparison of RRS events to explore differences in RRS outcomes by unit setting (medical versus surgical) and event activators through frequencies, percentages, and significance testing. Finally, the third aim was explored using proportional odds or ordinal logistic regression to identify CMO relationships between unit settings. Descriptive and chi-square analyses were performed with R Version 3.0.2, proportional odds ordinal logistic regression analyses were performed with polr function from the MASS Library for R, Version 7.3-29 (Ripley, Bates, Hornik, & Giebhardt, 2013), and McFadden's pseudo R^2 was calculated using the pscl Library for R (Jackman, Tahk, Zeileis, Maimone, & Fearon, 2012).

RSS Event Population

The initial dataset included 2,293 RSS events, which included all reported events between May 1, 2006 and November 30, 2013. Review of the 2,293 RRS resulted in exclusions related to completeness of records (96% complete) and site of the RSS events (85% were on adult medical or surgical areas) as shown in Table 4-1.

Preliminary analyses began with the assessment of a potential violation of the independence between medical and surgical RRS events. While the majority of RRS events were activated for unique patients, 217 events (11.19%) were patients who experienced more than one RRS event (including one patient who experienced six RRS

events). All patients with a single RRS event were retained for further analyses. For each patient who had more than one RRS event, one event was randomly selected per patient to ensure the validity of the assumption that the records were independent. The resulting final dataset included 1,721 RRS events associated with unique patient identifiers.

Table 4-1. RSS Event Selection

All RRS Events		2293	
	Missing Medical Record Number	44	
	Missing/Unclear Event Location	6	
	Missing Event Time	12	
	Missing Event Activator	24	
	Missing Event Reason	0	
	Missing Event Outcome	4	
All Hospital RRS Events with Complete Data		2203	96.08%
	Outpatient, Diagnostic or Treatment Areas Events	127	
	Non-Patient Care Area Events	3	
	Labor and Delivery Events	14	
	Postpartum Events	5	
	Intensive Care Nursery Events	1	
	Pediatric Events	2	
	Intensive Care Unit Events	49	
	Psychiatric Unit Events	13	
	Skilled Nursing Unit Events	14	
	Events for Fall Assessment	36	
All Adult Medical-Surgical RRS Events		1939	84.56%
Unique Adult Medical Surgical RRS Events		1721	75.05%

Description of RRS Events

Exploration of Context Factors

As noted earlier, RRS context factors are defined as existing clinical climate and environment attributes present prior to the RRS event. Context factors reviewed for this

study included temporal factors to evaluate resources and practice patterns, as well as recent changes in the patient's clinical status or clinical acuity. Differences in staffing patterns on weekends, holidays, and night shifts are important context variables due to potential differences in resource allocations and staffing patterns during these shifts (Table 4-2). While an event could occur in more than one resource limited time, individual analyses of these factors revealed approximately one-third of all RRS events occurred on weekends and holidays (28.18%), while night shift events (7:00 p.m. to 6:59 a.m.) accounted for 43.17% of all RRS events. Only a small percentage of RRS events (8.09%) occurred in the first hour following shift change (7:00 a.m. to 7:59 a.m. and 7:00 p.m. to 7:59 p.m.) where staff nurses are typically involved in handoff report and shift planning activities.

Table 4-2. RRS Events by Context Factors (N=1721)

Context Factors	Yes		No	
Limited Resource Times				
Holiday and Weekend Shifts	28.18%	(485)	71.82%	(1236)
Night Shifts	43.17%	(743)	56.83%	(978)
Handoff	8.08%	(139)	91.92%	(1582)
Antecedents to RRS Events				
ED Admission <12 Hours	8.02%	(138)	91.98%	(1583)
Direct Admission <12 Hours	3.72%	(64)	96.28%	(1657)
ICU Transfer <12 Hours	2.67%	(46)	97.33%	(1675)
PACU Transfer < 12 Hours	5.81%	(100)	94.19%	(1621)
IV Conscious Sedation < 12 Hours	7.21%	(124)	92.80%	(1597)

Note: Single RRS events may occur within more than one limited resource time period.

Exploration of Mechanism Factors

In the study, mechanisms are factors which preceded and were documented as associated with the RRS event activation (Pawson & Tilley, 1997). The mechanism factors were documented by the House Supervisor and included the role activating the

RRS and the clinical reason for the RRS event. RRS activators included the staff nurse caring for the patient, other healthcare providers, any hospital staff member, a patient, a patient's family member, or a patient's friend.

A comparison of RRS events by activator indicates staff nurses activated the majority of RRS events (93.90%) (see Table 4-4). RRS event triggers were objective findings and/or subjective concerns related to patient risk for clinical deterioration as described earlier in Table 3-2. While a single RRS event could be triggered for multiple reasons (76.99%), healthcare provider worry (98.66%) was noted as the most frequently occurring trigger, followed by respiratory symptoms (38.58%), cardiac symptoms (28.82%), and acute changes in mental status (28.24%).

Table 4-3. RRS Events by Mechanism Factors (N=1721)

Mechanism Factors	Yes		No	
Nurse Activation	93.90%	(1616)	6.10%	(105)
RRS Triggers				
Cardiac Symptoms	28.82%	(496)	71.18%	(1225)
Respiratory Symptoms	38.58%	(664)	61.42%	(1057)
Mental Status Symptoms	28.24%	(486)	71.76%	(1235)
Metabolic Symptoms	3.43%	(59)	96.57%	(1662)
Healthcare Provider Worry	98.66%	(1698)	1.34%	(23)
Multiple Triggers	76.99%	(1325)	23.01%	(396)

Note: RRS events may be activated for symptoms from more than one trigger category.

Exploration of Outcomes

The RSS event outcome factor was organized into four mutually exclusive outcome levels based on increasing clinical severity: clinical stabilization, transfer to a higher level of care, cardiac arrest with resuscitation, and death (Table 4-4.). A broad overview reveals the majority of RRS events resulted in clinical stabilization (59.04%). Among the remaining RRS events, most were transferred to a higher level of care

(38.87%), followed by cardiopulmonary arrest with survival (1.34%) and cardiopulmonary arrest with death (0.76%).

Table 4-4. RRS Events by Four Outcome Levels (N=1721)

Outcome	Yes		No	
Stabilized	59.04%	(1016)	40.97%	(705)
Transferred to Higher Level of Care	38.87%	(669)	61.13%	(1052)
Cardiopulmonary Arrest – Survived	1.34%	(23)	98.66%	(1698)
Cardiopulmonary Arrest – Died	0.76%	(13)	99.25%	(1708)

Differences in RRS Events by Setting

The second aim of the study was to identify differences in RRS events by setting. The primary patient setting for each nursing unit (medical or surgical) provides the organizational strategy for comparative analyses, while understanding occasional mixing of patient types occurred due to bed availability, co-morbidities, and individual preferences. More than 63% (1086) of RRS events occurred on medical units with more than one-half of all medical RRS events occurring on the General Medicine Unit (51.93%) and the smallest percentage occurring on the Rehabilitation unit (2.67%). The remaining medical RRS events were distributed among Cardiology (15.75%), Neurology (12.06%), and Oncology (17.59%). More than 60% of surgical RRS events occurred in two units, the Joint Replacement Center (31.97%) and Surgical Specialties (32.91%) (Table 4-5).

Table 4-5. Clinical Settings of RRS Events (N=1721)

Unit	Yes		No	
Medical	63.10%	(1086)	36.90%	(635)
Cardiology	15.75%	(171)	84.25%	(915)
General Medicine	51.93%	(564)	48.07%	(522)
Neurology	12.06%	(131)	87.94%	(955)
Oncology	17.59%	(191)	82.41%	(895)
Rehabilitation	2.67%	(29)	97.33%	(1057)
Surgical	36.90%	(635)	63.10%	(1086)
Cardiac Surgery	21.89%	(139)	78.11%	(496)
Joint Replacement Center	31.97%	(203)	68.03%	(432)
Spine Center	11.18%	(71)	88.82%	(564)
Surgical Specialties	32.91%	(209)	67.09%	(426)
Surgical Stepdown	2.05%	(13)	97.95%	(622)

Differences between Context Factors by Setting

Chis-square analysis revealed significantly more medical RRS events occurred within 12 hours of admission from the ED (medical 9.85%, surgical 4.88%; $p<.001$) and physician's offices (medical 4.05%, surgical 3.15%; $p=.0411$), while more surgical RRS events occurred within 12 hours of transfer from PACU (surgical 14.65%, medical 0.65%; $p<.001$) (see Table 4-5).

Table 4-6. RRS Event Context Differences between Clinical Settings (N=1721)

Context	Medical Yes	Medical No	Surgical Yes	Surgical No	$\chi 2$	ϕ	p
Limited Resource Times							
Holiday Weekend	29.65% (322)	70.35% (764)	25.67% (163)	74.33% (472)	2.94	.04	.0862
Night Shift	44.66% (458)	55.34% (601)	40.63% (258)	59.37% (377)	2.49	.04	.1146
Handoff	8.20% (89)	91.81% (997)	7.87% (50)	92.13% (585)	0.02	.01	.8853
ED Admit	9.85% (107)	90.15% (979)	4.88% (31)	95.12% (604)	12.76	.09	<.001
Direct Admit	4.05% (44)	95.95% (1042)	3.15% (20)	96.85% (615)	0.68	.02	.0411
ICU Transfer	2.49% (27)	97.51% (1059)	2.99% (19)	97.01% (616)	0.22	.01	.6362
PACU Transfer	0.65% (7)	99.36% (1079)	14.65% (93)	85.35% (542)	140.98	.29	<.001
IV Conscious Sedation	7.83% (85)	92.17% (1001)	6.14% (39)	93.86% (596)	1.46	.03	.2271

Note: Single RRS events may be occur within more than one limited resource time period. Effect sizes are designated as small (.10), medium (.30), and large (.50) ϕ values.

Differences between Mechanism Factors by Setting

While a healthcare provider's worry or concern about a patient's clinical status was the most prevalent RRS trigger for both medical and surgical settings, significant differences were seen between settings for the second and third triggers (Table 4-7). The percentage of RRS events triggered for respiratory symptoms was significantly higher for medical events than surgical events (medical 42.27%, surgical 32.28%; $p<.001$), followed by cardiac symptoms (medical 23.76%). A reverse pattern is seen for cardiac symptoms with a significantly higher percent of surgical events than medical events (surgical 37.48%, medical 23.76%; $p<.001$). No statistically significant differences were seen between settings for mental status changes, metabolic symptoms, or multiple triggers.

Table 4-7. RRS Event Mechanism Differences between Clinical Settings (N=1721)

Mechanism Factors	Medical Yes	Medical No	Surgical Yes	Surgical No	$\chi 2$	ϕ	p
Nurse Activations	93.98% (1019)	6.17% (67)	94.02% (597)	5.98% (38)	0.00	.00	.960
RRS Triggers							
Cardiac Symptoms	23.76% (258)	76.24% (828)	37.48% (238)	62.52% (397)	36.12	.14	<.001
Respiratory Symptoms	42.27% (459)	57.74% (627)	32.28% (205)	67.72% (430)	16.43	.10	<.001
Mental Status Symptoms	28.09% (305)	71.92% (781)	28.50%% (181)	71.50% (454)	0.01	.01	.896
Metabolic Symptoms	3.22% (35)	96.78% (1051)	3.78% (24)	96.22% (611)	0.22	.00	.635
Worry	98.71% (1702)	1.29% (14)	98.58% (626)	1.42% (9)	.00	.00	.995
Multiple Symptoms	76.43% (830)	23.57% (256)	77.95% (495)	22.05% (140)	0.44	.02	.505

Note: RRS events may be activated for symptoms within more than one trigger category.

Effect sizes are designated as small (.10), medium (.30), and large (.50) ϕ values.

Differences between Outcomes by Setting

Comparisons of RRS outcomes between medical and surgical events revealed a significantly higher percentage of stabilized outcomes for surgical units than medical units (62.68% versus 56.91%; $p = .0215$) and a greater percentage transferred to a higher level of care for medical events than surgical events (medical, 40.79%; surgical, 35.59%; $p = .0371$) (Table 4-8). There were no significant differences between the percentages of cardiopulmonary arrest with survival or death for medical and surgical RRS events.

Table 4-8. RRS Event Outcome Differences between Clinical Settings (N=1721)

Outcome	Medical Yes	Medical No	Surgical Yes	Surgical No	$\chi 2$	ϕ	*p*
Stabilized	56.91% (618)	43.09% (468)	62.68% (398)	37.32% (237)	5.28	.06	.0215
Transferred to Higher Level of Care	40.79% (443)	59.21% (643)	35.59% (226)	64.41% (409)	4.34	.05	.0317
Cardiopulmonary Arrest – Survived	1.473% (16)	98.53% (1070)	1.10% (7)	98.90% (628)	0.18	.01	.6678
Cardiopulmonary Arrests – Died	0.83% (9)	99.17% (1077)	0.63% (4)	99.37% (631)	0.03	.01	.7779*

Note: Effect sizes are designated as small (.10), medium (.30), and large (.50) ϕ values.

**p* value based on Fishers exact test due to small Ns.

Relationships among Context and Mechanism Factors with Clinical Outcomes

In this study, the outcome variable has been represented by four unique levels ranked by progression of clinical severity to evaluate the change in the odds of progressively worse outcomes as a function of the various context and mechanism factors. However, in order to avoid numerical problems, the most severe levels were combined due to the extremely small sample sizes thereby reducing the outcomes levels to three distinct levels.

A summary table is presented in Table 4.9 to provide representation of the CMO overall means and standard deviations of medical events, surgical events, and all RRS events.

Table 4-9. RRS Event Categorical Means and Standard Deviations

	Medical Events		Surgical Events		Total Events	
	Mean	SD	Mean	SD	Mean	SD
Levels of Clinical Outcome						
Stable	0.57	0.50	0.59	0.49	0.63	0.48
Transferred to Higher Level of Care	0.41	0.49	0.39	0.49	0.36	0.48
Cardiopulmonary Arrest	0.02	0.15	0.02	0.14	0.02	0.13
Outcome Ranking (Stable = 1, Transferred = 2, Cardiopulmonary Arrest =3)	1.454	0.542	1.391	0.523	1.431	0.536
Context Factors						
Holidays and Weekends	0.30	0.46	0.28	0.45	0.26	0.44
Nights	0.45	0.50	0.43	0.50	0.41	0.49
Handoff	0.08	0.27	0.08	0.27	0.08	0.27
ED Admission within 12 Hours	0.10	0.30	0.08	0.27	0.05	0.22
Direct Admission within 12 Hours	0.04	0.20	0.04	0.19	0.03	0.17
ICU Transfer within 12 Hours	0.02	0.16	0.03	0.16	0.03	0.17
PACU Transfer within 12 Hours	0.01	0.08	0.06	0.23	0.15	0.35
IV Conscious Sedation within 12 Hours	0.08	0.27	0.07	0.26	0.06	0.24
Mechanism Factors						
Nurse Activations	0.94	0.24	0.94	0.24	0.94	0.24
Cardiac Trigger	0.24	0.43	0.29	0.45	0.37	0.48
Respiratory Trigger	0.42	0.49	0.39	0.49	0.32	0.47
Mental Status Trigger	0.28	0.45	0.28	0.45	0.29	0.45
Metabolic Trigger	0.03	0.18	0.03	0.18	0.04	0.19
Worry Trigger	0.99	0.11	0.99	0.11	0.99	0.12
Multiple Triggers	0.76	0.42	0.77	0.42	0.78	0.41
Clinical Setting						
Medical	---	---	---	---	0.63	0.48
Surgical	---	---	---	---	0.37	0.48

Correlations among variables appear in Table 4-10. Rank biserial correlations between the dependent outcome variable and the explanatory context and mechanism independent variables ranged from |0.029| to |0.259| with a median value of |.0493| (Table 4-10). Nine independent variables, when considered alone, had statistically significant ($p < .05$, two-tailed) correlations with outcome: night shift (r = -.050), direct admission from a physician's office in the preceding 12 hours (r = .048), transfer from ICU in the preceding 12 hours (r = .062), transfer from PACU in the preceding 12 hours (r = -.051), medical setting (r = .057), nurse activation, (r = -.053), cardiac trigger (r = .073), respiratory trigger (r = .259), and multiple triggers (r = .153).

Collinearity among the independent variables was examined within context factors, within mechanism factors, and between context and mechanism factors. Out of 36 ϕ-correlation-coefficients among context factors shown in Table 4-10, 33 (91.7%) were less than .1 in absolute value, two (5.6%) were between .10 and .12 and one (2.8%; between setting and PACU transfer) equaled .289 (median ϕ among content factors =.042). Among the 21 ϕ-coefficients for mechanism factors 12 (57.1%) were less than .1 in absolute value, six (28.6%) fell between .10 and .17, and three (14.3%) fell between .34 and .43 (median ϕ among mechanism factors = .077). The three highest ϕ-coefficients were between multiple and specific triggers (ϕ = .34 for cardiac and mental status triggers and ϕ = .44 for respiratory triggers). Out of the 63 ϕ-coefficients between context and mechanism factors, 61 (96.8%) were less than .1 in absolute value. For the remaining two ϕ-coefficients, one (between cardiac triggers and transfer from PACU in the preceding 12 hours) equaled .133 and the other (between cardiac triggers and setting) equaled -.146 (median ϕ between context and mechanism factors = .022). Taken as a whole, these results reveal no serious problems with collinearity, with the possible exception of correlations between multiple triggers and several of the individual trigger variables. Due to the overlap between multiple and specific triggers, and that the multiple trigger is

partly a function of specific triggers, it was excluded as an independent variable in the regression analyses that follow.

Table 4-10. RRS Event CMO Correlation Matrix

	Clinical Outcome	Weekend/ Holiday	Night	Handoff	ED Admit	Direct Admit	ICU Transfer	PACU Transfer	IV CS	Medical	Nurse	Cardiac	Respiratory	Metabolic	Mental Status	Provider Worry	Multiple
Clinical Outcome	1																
Context Factors																	
Weekend/ Holiday	.029	1															
Night	-.050	.023	1														
Handoff	-.011	.009	-.004	1													
ED Admit	.046	.053	.080	.007	1												
Direct Admit	.048	-.041	.015	.032	-.058	1											
ICU Transfer	.062	.056	.037	-.023	-.049	-.033	1										
PACU Transfer	-.051	-.117	-.036	-.046	-.073	-.049	-.041	1									
IV CS	.045	-.060	.102	-.041	-.082	-.055	-.046	-.069	1								
Medical	.057	.043	.039	.006	.088	.023	-.015	-.289	.031	1							
Mechanism Factors																	
Nurse	-.053	.036	-.057	.040	-.005	.012	.027	-.009	-.023	-.004	1						
Cardiac	.073	-.014	.000	.019	-.008	.024	-.010	.133	-.043	-.146	.044	1					
Respiratory	.259	.061	.032	-.007	-.027	.021	.098	-.054	-.013	.099	.013	-.154	1				
Metabolic	.021	.010	.029	-.044	.003	.031	-.011	.022	.009	-.015	.008	.049	-.077	1			
Mental Status	-.027	-.003	-.049	-.006	.024	-.007	-.048	.021	-.095	-.005	.004	-.077	-.166	-.054	1		
Provider Worry	-.029	-.051	.040	.035	-.040	-.084	.019	.029	.013	.005	-.030	-.161	-.105	-.117	.039	1	
Multiple	.153	.011	.014	.010	.004	.020	.031	.059	-.099	-.018	.074	.342	.433	.103	.343	-.040	1

Proportional odds logistic regression, a generalization of logistic regression to ordinal data, was used to evaluate relationships between the outcome and explanatory variables. Explanatory variables were entered in three hierarchical blocks. The first block contained all context variables except setting; the second, all mechanism variables; and the third, the setting variable. Within each block, variables were ordered using a forward selection procedure with no variables excluded within a given block. Results were first interpreted at the block level using chi-square tests and McFadden's pseudo R^2 (UCLA, Statistical Consulting Group, 2011). McFadden's pseudo R^2 is similar to traditional R^2 but based on maximum likelihood rather than least squares estimation. The first two blocks yielded statistically significant results overall (context block χ^2 (8, N=1712) = 30.84, p <.000; mechanism block χ^2 (6, N = 1712) = 170.7, p <.000); however mechanism variables contributed more uniquely (pseudo R^2 difference = .077 -.012 = .065) to explaining variation in outcomes than did the context block by itself (pseudo R^2 = .012). The setting block did not account for any additional statistically significant variance in outcome after the all previous content and mechanism variables had been controlled (t to enter = -1.344; p to enter = .090) (see Table 4-11).

Contributions of individual variables within blocks were examined from three perspectives. The first perspective was the same one discussed previously using rank-biserial coefficients that reflect the contributions of given explanatory variables considered alone. The second perspective represents a simultaneous regression approach in which the unique contribution of a given explanatory variable is considered after controlling for the effects all other explanation variables. The third approach was based on variables that were statistically significant (p <.05) when entered using the forward selection procedure.

Content variables that yielded statistically significant results using either the simultaneous procedure or the forward selection (see Table 4-11) included Transfer from ICU, Night Shift, Ed Admission, Conscious Sedation, Direct Admission and Transfer

from PACU. All of these variables were associated with more positive outcomes except for Night Shift and Transfer from PACU.

After controlling for all context variables, four mechanism variables yielded statistically significant results using either the simultaneous procedure or the forward selection (see Table 4-11): Respiratory, Cardiac, and Metabolic Triggers, and Nurse Activation. All triggers were associated with more positive outcomes and Nurse Activation with more negative outcomes. Setting (Medical versus Surgical) was entered as a third block after controlling for all prior context and mechanism variables, and it did not account for any additional statistically significant variance in outcome.

Table 4-11. Proportional Odds Logistic Regression Analyses of Overall RRS Context, Mechanism, and Outcome Relationships (N=1721)

	Block 1 Context Factors					Block 2 Mechanism Factors					Block 3 Setting Factor							Zero-Order Correlation Values	
	t to Enter	*p* to Enter	Final $\hat{\beta}$	Final t	Final *p*	t to Enter	*p* to Enter	Final $\hat{\beta}$	Final t	Final *p*	t to Enter	*p* to Enter	Final β	Final t	Final *p*	OR	Δ OR	r_{rb}	*p*
Transfer from ICU	-2.639	.004	-0.854	-2.886	.002			-0.646	-2.095	.018			-0.660	-2.138	.016	0.517	48.3	.062	.010
Night Shift	2.153	.016	0.268	2.662	.004			0.349	3.307	.001			0.353	3.340	.000	1.423	42.3	-.050	.039
ED Admission	-2.237	.013	-0.428	-2.389	.009			-0.561	-2.998	.001			-0.543	-2.895	.002	0.581	41.9	.046	.057
Conscious Sedation	2.168	.015	-0.428	-2.242	.013			-0.576	-2.865	.002			-0.573	-2.849	.002	0.564	43.6	.045	.063
Direct Admission	-2.311	.011	-0.577	-2.254	.012			-0.553	-2.058	.019			-0.546	-2.030	.021	0.579	42.1	.048	.047
Transfer from PACU	1.664	.048	0.345	1.532	.063			0.423	1.807	.036			0.338	1.394	.082	1.402	40.2	-.051	.035
Weekend/Holiday	0.118	.118	-0.130	-1.187	.118			-0.084	-0.733	.232			-0.083	-0.724	.235	0.920	8.0	.029	.230
Handoff	0.238	.406	0.043	0.237	.406			0.027	0.145	.443			0.026	0.136	.446	1.026	2.56	-.011	.619
Respiratory						-11	<.000	-1.338	-11.953	<.000			-1.329	-11.848	<.000	0.265	73.5	.259	<.000
Cardiac						-5.459	<.000	-0.700	-5.865	<.000			-0.716	-5.965	<.000	0.489	51.1	.073	.003
Nurse Activation						3.008	.001	0.633	3.026	.001			0.633	3.026	.001	1.884	88.4	-.053	.028
Mental Status						-1.465	.072	-0.184	-1.551	.061			-0.185	-1.560	.059	0.831	16.9	-.027	.264
Metabolic						-1.532	.063	-0.489	-1.726	.042			-0.493	-1.741	.041	0.611	38.9	.021	.385
Provider Worry						-1.596	.055	-0.715	-1.596	.055			-0.707	-1.582	.058	0.493	50.7	-.029	.230
Setting											-1.344	.090	-0.152	-1.344	.090	0.859	14.1	.057	.018
McFadden's Pseudo R^2	.012					.077					.078								

Based on the pattern of statistically significant results for this hierarchical analysis, a final model was explored in which variables within the previous model that did not yield significant results for either forward on simultaneous entry were eliminated. This final model was based on the same procedures used in the previous analysis in which all variables were included. The final variables included in the trimmed down model appear in Table 4-12. Variables yielding significant results included Transfer from ICU, Night Shift, Ed Admission, Conscious Sedation, Direct Admission and Transfer from PACU, Respiratory Trigger, Cardiac Trigger, and Nurse Activation. These eight variables were also the ones that typically had the strongest rank-biserial correlations with outcome when considered alone. As in the prior regression analysis, mechanism variables had stronger associations with outcomes (pseudo R^2 difference = .074 -.011 = .063) than did context variables (pseudo R^2 = .011). Variables associated with lessor risk included: Transfer from ICU, Ed Admission, Conscious Sedation, Direct Admission, Respiratory Trigger, and Cardiac Trigger; those associated with greater risk included: Night Shift, Transfer from PACU and Nurse Activation.

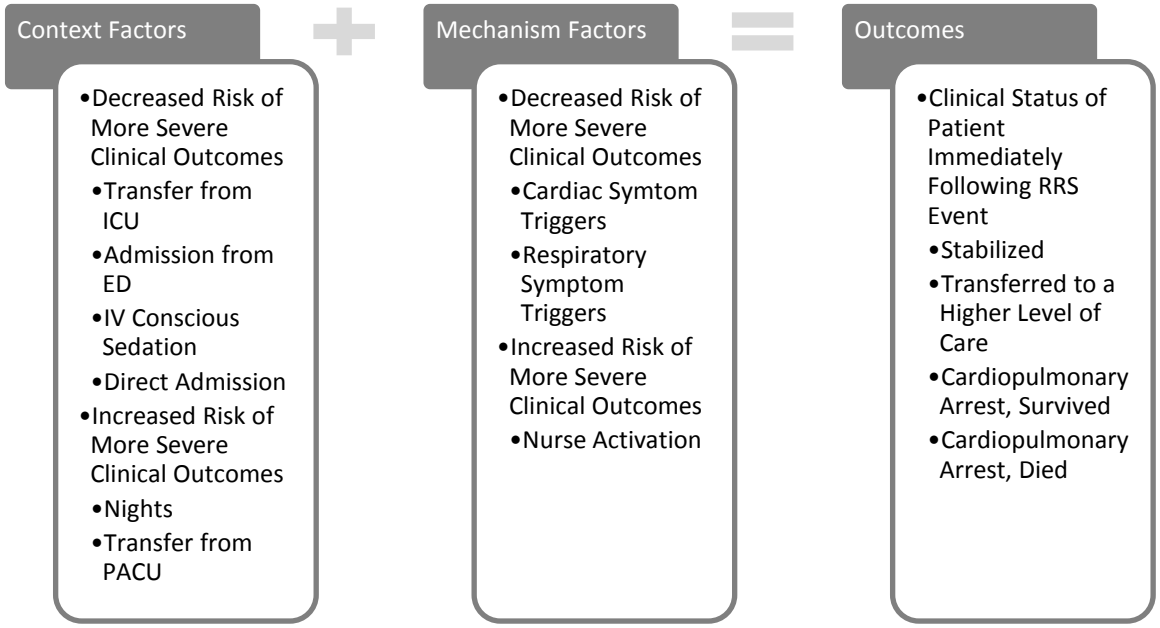
Table 4-12. Proportional Odds Logistic Regression Analyses of Final RRS Context, Mechanism, and Outcome Relationships (N=1721)

	Block 1 Context Factors					Block 2 Mechanism Factors							Zero-Order Correlation Values	
	t to Enter	p to Enter	Final $\hat{\beta}$	Final t	Final p	t to Enter	p to Enter	Final $\hat{\beta}$	Final t	Final p	OR	Δ OR	rrb	p
Transfer from ICU	-2.639	.004	-0.872	-2.950	.002			-0.648	-2.110	.018	0.523	47.7	.062	.010
Night Shift	2.153	.016	0.266	2.640	.004			0.341	3.240	.001	1.406	40.6	-.050	.039
ED Admission	-2.237	.013	-0.439	-2.450	.007			-0.557	-2.980	.001	0.573	42.7	.046	.057
Conscious Sedation	-2.168	.015	-0.417	-2.190	.014			-0.536	-2.690	.004	0.585	41.5	.045	.063
Direct Admission	-2.311	.010	-0.560	-2.190	.014			-0.523	-1.960	.025	0.592	40.8	.048	.047
Transfer from PACU	1.664	.048	0.372	1.660	.048			0.411	1.780	.038	1.509	50.9	-.051	.035
Respiratory						-11.040	<.000	-1.271	-11.800	<.000	0.281	71.9	.259	<.000
Cardiac						-5.462	<.000	-0.651	-5.620	<.000	0.521	47.9	.073	.003
Nurse Activation						2.999	.001	0.624	3.000	.001	1.866	86.6	-.053	.028
McFadden's Pseudo R2	.011					.074								

Summary

The study sought to explore RRS events and outcomes for adult medical-surgical inpatients within a community-based hospital to further knowledge regarding relationships among context, mechanism, and outcome factors (CMO). The first aim was to describe the dataset of RRS events; where almost two-thirds of all events occurred within medical units. Evaluation of mechanism factors revealed over 90% of all events were activated by staff nurses, with worry noted as an RRS trigger in over 98% of RRS activations. Finally, a majority of RRS events resulted in stabilization, followed by transfer to a higher level of care. The second research aim revealed differences between medical and surgical RRS events in patient status changes in the preceding 12 hours, patterns of event triggers, and events resulting in stabilization or transfer to higher levels of care, which will be explored further in Chapter 5. The final research aim identified nine key relationships between context and mechanism factors leading to significant increases or decreases in the likelihood of an RRS outcome moving from stabilization, to requiring a transfer to a higher level of care, to cardiopulmonary arrest with survival or death. Based on the identified relationships between the RRS context, mechanism, and outcome factors, the previous CMO Study model (see Figure 3-1) was revised in Figure 4-1. The interplay among the RRS context, mechanisms and outcomes has provided insight into potential areas of quality improvement and program revision to decrease morbidity and mortality, which will be discussed within Chapter 5.

Figure 4-1. CMO Model of Significant RRS



CHAPTER 5

DISCUSSIONS, CHALLENGES, AND CONCLUSIONS

The goal of RRSs is the reduction of inpatient complications and unexpected hospital mortality through early identification of clinical instability and early mobilization of expert clinical resources. The rapid uptake, widespread implementation, and local adaptations of the RRS have impeded synthesis of the current evidence. This study utilizes the principles of RE to frame the variables based upon existing evidence to explore the interplay among context, mechanism and outcome variables. The study provides an exploration of 7.5 years of information from a medium sized Midwestern hospital to explicate the relationship among CMO variables to further understand key relationships that ultimately impact patient outcomes.

This chapter provides a discussion of the findings, challenges, and implications of the current study in light of existing RRS evidence. Key findings are discussed for each research aim, including a portrayal of the local RRS, differences between medical and surgical RRS events, and relationships between context, mechanism, and outcomes. The limitations and challenges of this study are next discussed to provide guidance for interpretation of findings, followed by recommendations for future research. Finally, the conclusion offers key implications for nursing practice and RRS evaluation.

Implications of RRS Event Characteristics

The first study aim was directed toward understanding RRSs by describing actual events through the RE framework of context, mechanism, and outcome (CMO) factors. The inclusion of context and mechanism factors within RRS research is essential for understanding the environment in which the RRS exists as well as how the RRS functions within the healthcare setting (Berwick, 2008; Pawson & Tilley, 1997). The original dataset of RRS events consisted of 2,293 events; application of exclusion criteria reduced the data population to 1,721 RRS events for study exploration. A discussion of the implications of

described event characteristics as they relate to context, mechanism, and outcome factors follows.

Context Factors

There is little evidence in the literature regarding the impact of resource-limited time frames on nursing units, critical patient events, and patients at risk for clinical deterioration; however, nurses rely on a variety of resources to successfully care for patients. One resource-limited time that has previously been explored in RRS evaluations are night shift events. Studies have reported between 43% (Sarani et al., 2011) and 56.7% (Jäderling et al., 2011) of RRS events occurred during 8-hour night shifts. An additional period of patient vulnerability due to resource limitations are handoff periods. Nursing handoffs require the off-going and on-coming nurse to focus on transmission of clinical information for continuity of care while still responsible for direct patient care. In fact, Jones et al. (2005) discovered a significant increase in the risk of clinical instability in the hour surrounding nurse handoffs (OR 1.25; $p = 0.001$) compared to all other periods. The current study found that 43% of RRS events occurred during 12-hour night shifts, 28% occurred on weekend or holiday shifts, and 9% of RRS events occurred within one hour of nursing handoffs. As these time periods are not mutually exclusive, the total percentage of RRS events which occurred within any resource-limited time is not clear. However, these findings do highlight the impact of limited resources during clinical deterioration. The occurrence of RSS events during these time frames is clinically significant, given research revealing that event times were significant variables in immediate, 24-hour, and neurologic survival following cardiopulmonary arrests (Peberdy et al, 2008). Peberdy et al. found that cardiopulmonary arrests that occurred during night shift had (a) poorer rates of response to emergency interventions immediately following the event (OR 1.15; $p < .001$) and 24 hours after the event (1.19; $p < .001$), (b) increased neurologic impairment (OR 1.17; $p < .001$), and (c) lower survival to discharge rates (1.18; $p < .001$) when compared to day and evening events.

In addition, survival odds for cardiopulmonary arrests on weekday day and evening shifts were higher than on weekends (OR1.15 [95% CI, 1.09-1.22]). These findings, in conjunction with the current study findings, relate the importance of staffing resources on patient survival rates.

Mechanism Factors

The role of the RRS activator is not readily discussed in the literature. However, a study by Beitler et al. (2011) reported 85% of RRS events were initiated by staff nurses in a five-year academic medical center cohort study. Therefore, it was not surprising that the current study found 94% of all RRS events were activated by staff nurses involved in direct patient care. Early activation of RRSs ultimately must rely on staff nurse activation by clinical judgment and experience, although guidelines have been established to highlight key assessment findings which may indicate a patient is at risk for clinical instability (AHRQ, n.d.; Cioffi et al., 2010; Genardi et al., 2008; Rattay et al., 2011).

The high rate of RRS activations by staff nurses in this study suggests that nurses were vigilant in detecting risk and requesting additional clinical support. Rattay et al. (2011) suggested that in addition to vital signs, assessment findings, and patient complaints, staff nurses utilize more subtle cues based on context, experience, and critical thinking to determine clinical severity, which drives their request for assistance. It is the awareness of clinical significance and/or the pattern of cues that trigger the nurse's worry. These subtle cues have been reported as noisy breathing, inability to talk in complete sentences, increased supplemental oxygen needs, restlessness, changes in orientation, and acute pain (Cioffi et al., 2010). In addition, the category of worry or clinical concern includes symptoms which may not readily fit within the four distinct RRS activation trigger categories (cardiac, respiratory, mental status, and metabolic). Investigators have found nurses were 35 times more likely to activate a RRS based on worry or concerns about a patient's clinical condition than objective symptoms (Genardi et al., 2008). Kolluru et al (2010) also reported

that when RRS events were activated for worry or concern about a patient's condition, those patients were more likely to respond favorably to the RRS intervention, likely due to early activation. Findings from the current study support the importance of worry and concern as a valid reason for RRS activation; worry about the patient's clinical stability was reported in 98.66% of all events, and was the most frequently reported trigger.

Outcome Factor

This study appraises the effectiveness of a long-standing RRS within a community referral hospital, rather than short-term clinical outcomes within academic medical centers commonly seen in the literature. Studies from two academic medical centers (Chan et al., 2008; Kolluru et al., 2010) found a majority of RRS events resulted in clinical stabilization on the original unit (52% and 51.5%, respectively), followed by transfers to a higher level or specialized care (41% and 42%). Two additional academic medical center RRS studies (Beitler et al., 2011; Shah et al., 2011) found higher percentages of RRS events resulted in transfers to higher levels of specialized care (56% and 59%, respectively), followed by clinical stabilization (41% and 41%). The percentages of stabilization and transfers after RRS in the four studies varied, but they were congruent in that the vast majority of all RRS interventions averted immediate cardiopulmonary arrest and death. The current study supports existing evidence in regards to RRS effectiveness. Over half of RRS events resulted in clinical stabilization on the medical-surgical unit, followed by 39% requiring transfers to a higher level of care for additional monitoring or specialized interventions, 1% experiencing cardiopulmonary arrest with survival, and less than 1% ending in cardiopulmonary arrest and death.

Implications of Comparisons of RRS Events

The second aim focused on comparisons of RRS event differences between medical and surgical settings. Sarani et al. first argued the need to understand differences between medical and surgical RRS events to impact patient mortality in 2011. Although Sarani et al.

separated RRS populations based on the attending physician's specialty rather than unit setting, the study still provides a reference point for the basic comparisons between RRS events in medical and surgical settings. The current study found that a larger percentage of RRS events occurred on medical units (63%) as compared to surgical units (37%). These findings can be compared to work by Jäderling et al. in 2011 (Sweden: 50.9% medical, 49.1% surgical; Australia: 51.1% medical, 48.8% surgical), Sarani et al. in 2011 (74% medical, 26% surgical), and Kolluru et al. in 2010 (89% medical, 7% surgical, 3% other). While the reasons for the observed differences in RRS activity between medical and surgical settings is unclear, Sarani et al. suggested that patients in medical settings were older with more chronic illnesses and co-morbidities, resulting in more severe symptoms of clinical deterioration, while patients in surgical settings tended to experience acute but reversible post-operative complications. While these characteristics are not included within the current study, the confirmation of clinical setting as a key context variable within RRS evaluations supports these theories.

Additional Differences between Medical and Surgical Events by Specialty Unit

There has been little exploration of RSS event distribution between specialty units; however, this level of analyses is necessary to provide guidance for identifying patients at risk for clinical deterioration. In this study more than half of all medical RRS events occurred on the General Medicine Unit (51.93%). General Medicine Unit nurses are typically challenged by patients with a wide variety of clinical conditions, including several chronic disease populations, in contrast to specialized medical units serving specific populations. Staff nurses' ability to care for this wide diversity of acutely ill patients with many chronic co-morbidities requires increased levels of observation, assessment, and critical thinking skills to pick up the subtle cues of clinical deterioration (Shapiro, 2010) which suggests additional resources may benefit these patients.

Surprisingly, the Joint Replacement Center was second only to the Surgical Specialties unit in the percentage of overall surgical RRS events that occurred during the data collection period (31.3% and 31.7%, respectively). The high percentage of surgical RRS events in the Joint Replacement Unit is unexpected as approximately 85% of admissions to this unit are post-operative elective hip and knee replacements (S. Marshall, personal correspondence, 2014). Elective surgeries are scheduled after patients are medically cleared for surgery, and thus the patients might be expected to be less acutely ill and less likely to require activation of the RRT than those undergoing other types of surgeries. Smaller percentages of unit admissions are post-operative hip replacements resulting from fractures and general post-surgical fracture care, thus further exploration will be required to account for the number of surgical RRS events occurring on this specialty unit. Another finding was also surprising, but in the converse: surgical RRS events occurred least often in the Surgical Stepdown Unit (2.06% of all surgical RRS events). The Surgical Stepdown Unit is a specialized unit that cares for post-operative patients with high acuity levels or complex nursing needs. The low number of RRS events within the Surgical Stepdown Unit may be due to increased staffing and monitoring resources that offsets the increased clinical instability of patients. These resources may provide staff very early indications of clinical deterioration and the ability to manage them independently of RRS resources. The observed differences between the settings of surgical RRS events suggest that patient acuity alone is not strong predictor of RRS events, as patient acuity may be mitigated by available resources.

Implications of Differences between Medical and Surgical Events by Additional Context Factors

There has been limited exploration in the RRS literature of RRS patient activity within the timeframe preceding the RRS event. Sarani and colleagues (2011) found the same rate of RRS events within 24 hours of either ED admission or ICU transfer for both medical

(8%) and surgical (8%) settings. However, as Sarani did not report the breakdown of patients admitted from the ED or ICU, comparisons to the current study are limited. In the current study, significant differences were found in the percentage of RRS events occurring on medical versus surgical floors within the first 12 hours following an admission from the ED (medical 9.85%, surgical 4.88%; $p < .001$) as well as with RRS events within the first 12 hours following direct admission from the physician's office (medical 4.05%, surgical 3.15%; $p = .0411$). Within medical settings, these increases in RRS activity in the initial hours following an admission from the ED and physician's offices may stem from increased acuity levels and a heightened awareness of clinical risk in these populations (Harm, Ummenhofer, Luethy, & Zuercher, 2012; Oldroyd et al., 2010). A significant difference was also noted in events occurring within 12 hours of transfer from the PACU for RRS events on surgical floors compared to medical floors (14.65%, 0.65%; $p < .001$). While it is expected that the vast majority of post-operative patients would transfer to a surgical unit versus a medical unit, the increased occurrence of surgical RRS events following transfer from the PACU may result from a heightened awareness of risks for post-operative clinical instability by surgical staff (Weingarten et al., 2012). However, the impact of factors not included in this study such as post-surgical acuity measures and transfer practices may also contribute to differences in post-operative activation settings. These findings provide a focal point to further evaluate RRS activations and effectiveness based on entry points in to the healthcare system and patient acuity levels.

Implications of Differences between Medical and Surgical Events by Mechanism Factors

Considering mechanism factors when analyzing RRSs allows description of the powers, choices, decisions, and reactions within the system that result in outcomes (Pawson & Tilley, 1997). The focus on RRS mechanisms within the literature to date has largely been on the triggers or reasons for RRS activation as well as possible relationships between

triggers and outcomes. Weingarten et al. (2012) suggested that surgical RRS events may be associated with more acute clinical conditions that can be reversed. Conditions such as hypovolemia, blood loss, over-sedation, and hypotension are frequently associated with cardiac symptoms. In contrast, medical RRS events may more commonly initiated for advanced or terminal clinical conditions seen as respiratory symptoms (Weingarten et al., 2012). Despite these clinical rationales, previous studies have provided little or no distinction for RRS triggers between medical and surgical populations (Sarani et al., 2011). Five studies published since 2010 reported respiratory symptoms as the most common medical and surgical RRS trigger (Beitler et al., 2011; Jäderling et al., 2011; Kolluro et al., 2010; Shah et al., 2011; Shearer et al., 2012). However, a single study by Sarani et al. (2011) comparing medical and surgical RRS events found a unique trigger pattern with higher percentages of medical and surgical RRS events triggered for cardiac symptoms (medical 65%; surgical 62%), followed by worry (medical 37%; surgical 4%), and respiratory symptoms (medical 32%; surgical 36%).

In the current study, worry was the most common trigger for RRS events regardless of setting; however, significant differences were found between the other medical and surgical RRS event triggers. Respiratory symptoms (42.27%) were the second most prevalent trigger in medical events and cardiac symptoms (37.48%) were the second most common trigger in surgical events. In addition to the differences in the second highest percentage of RRS triggers in each setting, this study found significantly higher percentage of medical RRS events were triggered for respiratory symptoms than surgical RRS events (medical 42.27%, surgical 32.28%; $p < .001$) and a significantly higher percentage of surgical RRS events were triggered by cardiac symptoms than medical RRS events (medical 23.76%, surgical 37.48%; $p < .001$). The identification of different trigger patterns between medical and surgical RRS events allows for nursing policy and program improvements based on the needs of each setting. By customizing nursing assessments and providing

specific feedback to nursing staff, RRSs may be able to further reduce in-hospital morbidity and mortality.

Implications of Differences between Medical and Surgical Events by Outcomes

One means of evaluating RRS effectiveness in reducing inpatient morbidity and mortality is the measurement of immediate clinical outcomes. These measures are utilized to provide insights into early awareness of clinical deterioration, prompt RRS activation, and effective interventions. Through this approach, a study by Schneider et al. (2013) supported this measure of RRS effectiveness as 87% of patients felt to be clinically stable after RRS interventions required no further RRS activations or emergency responses. Additionally, out of the 12.7% of patients who required a repeat RRS activation, 99% were alive after 24 hours (17% on unit, 83% in ICU). In the current study, a comparison of RRS outcomes between medical and surgical settings revealed a significantly larger percentage of surgical RRS events resulted in immediate clinical stabilization compared to medical events (surgical 63%, medical 57%; $p = .0195$). As noted above, the greater positive response to RRS interventions in surgical settings may be due to post-operative complications that respond quickly to standard treatments.

The literature reflects limited exploration of the differences in outcomes between medical and surgical patients. However, Sarani and his colleagues (2011) suggested that differences result from advanced patient ages, co-morbid conditions, and chronic illnesses in medical populations. Current findings revealed a significantly higher percentage of medical RRS events resulted in patients requiring a higher level of clinical care than surgical RRS events (41% versus 36%; $p=.0356$). This study's contributions toward understanding these differences provide a basis for refining system approaches based on unique settings and population needs.

Implications of Relationships between Context and Mechanism Factors with Clinical RRS Outcomes

Building on the findings of the first two study aims, relationships between context and mechanism factors with RRS outcomes were explored through proportional odds logistic regression. Significant ordinal relationships between context and mechanism factors with the likelihood of three increasing levels of clinical severity from stabilization to requiring a higher level of care to cardiopulmonary arrest are discussed with implications for nursing practice. While these findings are unique to the local RRS, in addition to providing local guidance they provide insights into RRSs and establish an evidence base which has not been explored in the literature.

Implications of Relationships between Context Factors and Clinical Outcomes

The final exploratory model detected significant relationships with four context factors where the likelihood of a worsening clinical outcome was reduced; RRS activation within 12 hours of patient arrival on the nursing unit from an ICU (OR 0.523, OR Δ 47.7%, $p = .0175$), ED (OR 0.573, OR Δ 42.7%, $p = .0014$.), and physician's office (OR 0.592, OR Δ 40.8%, $p = .0252$) or within 12 hours of receiving IV conscious sedation (OR 0.585, OR Δ 41.5%, $p = .0036$). While clinical acuity may be variable in these patients, overall they were more likely to be stabilized on the unit than transferred to a higher level of care, and more likely to be able to be managed through a higher level of care than experience cardiopulmonary arrest. Findings from this unique RRS evaluation suggest nursing staff in this organization may consider these types of patients to be at higher risk within the first 12 hours and are therefore more attentive to clinical deterioration. The awareness of risk may shift a nurses' interpretation of clinical or subjective findings toward initiating prompt action rather than waiting for additional confirmation from multiple early warning signs. Additionally, these patients may receive additional nurse-patient interaction through the

admission process or post-conscious sedation monitoring policies, which may allow earlier recognition of key clinical indicators of risk. Because RRS events for patients who had arrived in medical-surgical units from the ED or ICU within the previous 12 hours tended to have less risk of worse clinical outcomes, these patients may be have benefitted from an increase in clinical monitoring or a heightened perception of risk severity.

RRS events which occurred on night shift or within 12 hours of transfer from PACU were the final significant context factors within the model; however, they were associated with additional risk of a worse clinical outcome with OR increases of 40.6% ($p = .0006$) for night shift events and 50.9% ($p = .0376$) for events following transfer from PACU. The nature of patient care on medical-surgical units at night may cluster nursing contact into small periods of time, limit overall nurse-patient interaction to promote restorative sleep (Bartick, Thai, Schmidt, Alta, & Solet, 2009), and yet may vary greatly by nurse, unit culture, and hospital policies. While nursing practices emphasize the importance of balancing rest and assessment needs for hospitalized patients, current findings suggest that the balance may not have been appropriate for patients who deteriorated during the night. The increased risk of more severe clinical outcomes within the 12 hours following transfer from PACU may reflect an increase in post-operative acuity levels or procedure specific risks which are not captured within the dataset.

Implications of Relationships among Mechanism Factors and Clinical Outcomes

Two mechanism factors were significantly associated with a decreased likelihood of a RRS outcome of higher clinical severity. RRS events activated due to respiratory (OR 0.281, OR Δ 71.9%, $p < .0000$) and respiratory (OR 0.521, OR Δ 47.9%, $p < .0000$) symptoms were significantly less likely to result in a more clinically severe outcome than other triggers.

Examination of cardiac and respiratory RRS triggers (heart rate, blood pressure respiratory rate, and oxygen saturation) suggests these are symptoms are more visible to the nurse, easily compared to RRS activation guidelines, and thus more quickly interpreted as risk. Rattray et al. (2011) found that changes in respiratory rates, oxygen saturation, and systolic blood pressures were significant contributors to staff nurse determinations of acuity and likelihood of seeking clinical advice or support. These indicators of clinical stability are routinely gathered through vital sign assessments for medical and surgical patients according to protocols and orders, at least once a shift and more frequently based on clinical concerns. This process provides a consistent means to evaluate clinical stability, as well historical values for comparison. Additionally, the cardiac and respiratory guidelines for RRSs provide clear thresholds for healthcare professionals to consider RRS activation as a valuable clinical intervention (AHRQ, n.d.). Other triggers for RRS activation such as increased bleeding, mental status changes, and decreased urine output (Ludikhuize et al., 2012) are less visible, more subject to interpretation, and may not be assessed as frequently, potentially resulting in delayed activation (Mackintosh, Rainey, & Sandall, 2011). The clarification of less specific or measurable RRS triggers for nursing staff may result in earlier activations, as well as provide guidance for evaluations of clinical risk within medical and surgical settings.

RRS activations by nursing staff (OR 1.866, OR Δ 86.6%, $p = .0014$) was the only mechanism factor related to an increased risk of requiring a transfer to a higher level of care and of cardiopulmonary arrest. While this finding may seem contradictory to previous findings, the presence of this relationship can likely be explained through the role of the staff nurse in caring for hospitalized patients. RRS nurse activations are based on clinical findings, subjective information, and assimilation of previous experiences which result in judgments of clinical severity (Cioffi et al., 2010; Genardi et al., 2008; Rattay et al., 2011). Thus, staff nurses activate RRSs in actual episodes of acute clinical deterioration, which may require additional care and monitoring in an ICU setting. Other members of the

healthcare team may not fully possess an accurate of full picture of the patient's clinical condition and activate the RRS based on limited information that is not associated with "real" clinical deterioration. Another potential explanation for the increased likelihood of escalation in clinical severity in nurse-activated events is delays in symptom identification or RRS activation. Delays in RRS activation by staff nurses have been discovered in several studies; however the reasons for these delays have remained largely speculative (Cioffi et al, 2010, Ludikhuize et al., 2012, Rattay et al, 2011, Shapiro, Donaldson, & Scott, 2010; Tirkkonen, et al, 2012; Winters et al, 2012). This finding provides new evidence of the substantial role nursing staff play in the monitoring and evaluation of clinical deterioration in medical-surgical settings, as well as the importance of early identification of risk and the value of an effective RRS.

Limitations and Challenges

Careful review of the study design and research aims reveals challenges and limitations. The utilization of pre-existing quality improvement data provided a substantial number of RRS events; however, there were limitations on the available context, mechanism, and outcome factor data. Despite limited CMO factors available for exploration, the data were similar to CMO factors included in previous RRS research, and. the quality improvement data were from a complete and reliable source. Key strategies by the local hospital to assure high quality data included immediate data collection post RRS event by a limited group of trained professionals and a secondary review for completeness. Through these efforts, less than 5% of the documented RRS events were excluded for missing or unclear information.

The sorting of RRS event components as CMO factors is challenging and should be an iterative process (Pawson, 2013). During RE analysis of social programs, the boundaries between these factors are initially based upon clinical experience, published evidence, theories, and consultation with content experts. As the evidence of contributory RE studies

is brought into a larger analysis of the RRS, the function and role of each factor within the RRS is explicated. These insights lead to the CMO configurations, which are able to provide the greatest contributions to the evaluation and refinement of RRSs. Given the small percentage of outcome variability accounted for in the final regression model, adaptations such as including additional CMO factors, collapsing of individual factors into larger categories, and utilizing new analysis strategies should be considered in future study designs.

Similarly, study findings are not representative of community hospital RRSs in the Midwest. In fact, the value of the RE framework is dependent on identifying differences in local system implementations, adaptations, and outcomes to identify the rich diversity of CMO patterns to guide further exploration and organization changes.

An additional challenge was present in classification of unit type related to the comparison of medical and surgical patients and their outcomes. The study explored the differences in patients in medical and surgical settings, but there was likely some population mixing. Although each unit has the potential for atypical patient placements at any time, the overall focus, culture, and polices of the unit remain stable. Therefore, it can be argued that the premise of context was maintained despite small variations in patients underlying clinical conditions.

Finally, while the final study model was only able to account for a limited variance in immediate RRS outcomes (7.42%); this study is only designed to explore the CM and O relationships. Current study findings should be used to refine CMO models, followed by the addition of clinical information such as patient diagnosis, procedures, timeliness of symptoms identification, and RRS interventions to provide a more complete explanatory model of what works well about the RRS in the current setting and for whom.

Recommendations for Future Research

This dissertation provides support for additional research to broaden the evidence related to the design, implementation, and evaluation of RRSs using a RE framework. RE provided theoretical guidance to the research design and factor selection often missing in published research. However, RE emphasizes the need for repeated studies within similar and dissimilar populations to develop practical knowledge of what RRS factors work best in specific settings to achieve the best outcomes (Pawson & Tilley, 1997; Pawson, 2013). Replication of this study within community hospitals, academic medical centers, Veteran's Administration (VA) hospitals, and small rural or critical access hospital (CAH) would enhance the ability to understand the complexities of RRS effectiveness.

Additional analyses within this study population and future replications have the potential to provide additional evidence. This overview of the RRS system masks any differences in utilization patterns and program acceptance over time. Furthermore, the temporal trends from the natural program lifecycle and local system adaptations were also masked and should be illuminated in future studies. Longitudinal RRS event analysis would provide information on the impact of program implementation strategies, system maturation, and performance sustainment. It is reasonable to speculate that the maturity of this RRS is contributes to the low number of cardiopulmonary arrests with survival and death (Calzavacca et al., 2010a; Santamaria et al., 2010); however there is not a time variable associated with their occurrence. Further analyses should explore key process change movements such as approval of standing orders for RRS teams, addition of hospitalists, and educational strategies.

Over 21 individual RRS triggers within this RRS were reduced to five mechanism factor categories based on hospital classification, clinical knowledge and published RRS literature. A focused exploration of individual triggers within each category and the pattern of multiple triggers has the potential to refine clinical RRS guidelines and identify clusters of triggers associated with specific outcomes.

A point for further review would be the differences in those events activated by nurses and those activated by all others. With the majority of RRS events activated by nurses, separate multivariate ordinal regression analysis comparing nurse-activated to non-nurse-activated RRS events may reveal differences in factor selections and impacts on outcomes. This approach would provide guidance to explore the triggers nurses considered in RRS activation, and triggers that nurses may have been overlooked, dismissed, or undervalued in RRS events triggered by a non-nurse.

Expansion of RRS research into new settings would allow for the refinement of study designs, data collection strategies, and research aims based on the findings of this study and published evidence. Inclusion of procedures for medical records and/or hospital billing data would allow for a more complete understanding of the patients' clinical condition at the time of the RRS event and the identification of additional context and mechanism factors. Determinations of admission type and new factor identification would be based on information from clinical sources such as admission histories, clinical documentation, ICD-9 billing codes, or procedure codes. The ability to include this level of classification and data abstraction within the research design would be dependent on hospital characteristics such as electronic medical records and billing databases. As classification between medical admissions and surgical admissions from diagnoses, as well as identification of factors of interest may be unclear, the use of clear definitions and consensus between clinical experts would be crucial in early research design efforts.

Finally, while the findings from this study provide insight into a local RRS, limited information was generated regarding use, value, and weaknesses of the RRS from the perspectives of nurses and patients. Identification of these limitations should guide the development of future studies to explore new aspects of RRS design, implementation, effectiveness, and sustainability. Qualitative research designs would be useful to explore why nurses do or do not activate the RRS for specific objective and subjective symptoms, positive and negative experiences of nurses using RRSs, barriers and facilitators of RRS

activation, perceived benefits of the RRS by patients, and their RRS event experiences. In addition to qualitative methods, quantitative research approaches should provide further exploration of RRS activation delays, effectiveness of RRS interventions, and missed RRS opportunities.

Conclusions

Since the 2001 IOM *To Err is Human* report, healthcare systems have made numerous improvements in the provision of patient care, yet the incidence of unexpected in-hospital morbidity and mortality remains a challenge. The RRS has been promoted by patient safety organizations as a strategy to reduce severe clinical deterioration and cardiopulmonary arrest through of early identification of clinical risk and prompt mobilization of experts and sources; however, the evidence of RRS effectiveness in reducing morbidity and mortality has been equivocal (Berwick et al., 2006; IHI, n.d.; McCannon et al., 2007; Winters et al., 2006).

In 2008, Berwick introduced the RE framework as an approach to evaluate patient safety programs, such as RRSs, due to their complexity and multi-faceted interactions. In the current study, the RE framework provided a structure to identify, select, and organize key CMO factors into the research design to determine within a local context what worked and for what patient groups (Pawson & Tilley, 1997). The current study utilizes RE as a framework to provide actionable guidance to improve local systems, such as evaluating staffing patterns during resource-limited times and exploring staff nurse barriers or concerns resulting in RRS activation delays. Additionally, the findings of this study will allow across settings to uncover CMO patterns generating more generalizable strategies as the research evolves.

The current study revealed significant differences in RRS events in medical settings versus RRS events in surgical settings within a community referral hospital. Similar findings within academic medical center RRSs (Sarani et al., 2011; Weingarten et al., 2012)

support the designation of unit setting as a significant context factor in RRS research. Further exploration of differences between medical and surgical units should guide actionable strategies to more readily identify vulnerable patients and maximize unit strengths to further reduce in-hospital morbidity and mortality. Additionally, the current study illuminated the importance of further exploration of the association between resource-limited times and poor clinical outcomes. Understanding how nurses care for medical and surgical patients at night, as well as potential differences in symptom identification during resource-limited times, should illuminate areas for refining local RRS refinements. These discoveries may guide new approaches to how nurses prioritize their actions and leadership staffing practices during resource-limited times. Finally, the current study illuminated a significant relationship between RRS events activated by staff nurses and an increased risk of worse clinical outcomes, which cannot be fully explained by existing research. Determining how staff nurses identify symptoms of clinical deterioration and make decisions to activate RRS within variable patterns of context and mechanism factors may guide local and large-scale RRS improvements.

Summary

The use of the RE framework proved to be a valuable framework for exploring the complexities surrounding RRSs and patient risk. This study provided an opportunity to identify significant CMO relationships within a unique community hospital setting to guide local program refinement and the design of future RRS research. Significant findings have highlighted the importance of including context and mechanism factors in RRS research, as well as the key role of the staff nurse in reducing in-hospital patient morbidity and mortality.

APPENDIX A. RAPID RESPONSE TEAM RECORD (B-RRT) - 2006

[redacted] [redacted]

Rapid Response Team (RRT) Record

Date:_____ Patient location:_____

Time RRT called:_____ Time RRT responded:_____ Time RRT finished:_____

Who called for the RRT? ☐ Nurse
☐ Resp. Care
☐ House Sup initiated
☐ _____

Reason for activating team: *(check all that apply)*
☐ Worried or concerned about the patient, i.e., chest pain, acute shortness of breath. Specify:
_____
_____
☐ Acute change in heart rate to less than 40 or greater than 130
☐ Acute change in systolic BP to less than 90
☐ Acute change in diastolic BP to less than 40
☐ Acute change in respiratory rate to less than 8 or greater than 28
☐ Acute change in saturation to less than 90% despite oxygen use
☐ Acute change in urine output to less than 50 ml in 4 hours
☐ Acute mental status changes
☐ Acute significant bleeding

Patient length of stay prior to RRT: *(check one)*
☐ ED admit less than 12 hours
☐ Direct admit less than 12 hours
☐ Transferred from ICU less than 12 hours
☐ Received from PACU less than 12 hours
☐ Other_____

Treatment measures taken: *(check all that apply)*
☐ Aerosol treatment ☐ Supplemental O_2
☐ Intubated ☐ BiPAP
☐ Oral airway ☐ Cardioversion
☐ Suctioning ☐ IV fluid bolus
☐ None
Medications:_____
_____

Diagnostic measures taken: *(check all that apply)*
☐ ABG ☐ Pulse ox ☐ CBC
☐ CXR ☐ CMP ☐ Coag profile
☐ EKG ☐ CT ☐ Cardiac monitor
☐ None
Other:_____

Patient Disposition: *(check all that apply)*
☐ RRT initiated interventions
☐ New treatment orders initiated
☐ Patient coded and survived
☐ Patient coded and expired
☐ Patient required transfer to a higher level of care:_____
☐ Other:_____

DNR status:
Was patient DNR prior to RRT? ☐ Yes ☐ No
Was patient DNR after RRT? ☐ Yes ☐ No

Notification: The following were notified
☐ Attending physician
☐ On-call physician
☐ Consult_____

Documentation:
☐ Documentation of the event in the Medical Record has been validated
☐ If Vital Sign monitor or telemetry is in use, the last 12-16 hours of information has been printed and stapled to this report. ☐ NA

Staff involved in Rapid Response Team:
☐ House Sup_____
☐ RT_____
☐ Nurse_____
☐ Other_____

Census____ # licensed staff____ # PCTs____
# of admissions in last 4 hours_____
# of discharges in last 4 hours_____

Patient Label

This form is not part of the permanent medical record

Rapid Response Team Record
B-RRT (4/06)
Make 2 copies: ☐ [redacted] ☐ Director
☐ Respiratory Care, [redacted]

APPENDIX B. RAPID RESPONSE TEAM RECORD (B-RRT) – 2011

[redacted] [redacted]

Rapid Response Team (RRT) Record

Date:_____ Patient location:_____

Time RRT called:_____ Time RRT responded:_____ Time RRT finished:_____

Who called for the RRT?
- ☐ Nurse
- ☐ Resp. Care
- ☐ House Sup initiated
- ☐ _____

Reason for activating team: *(check all that apply)*
- ☐ Worried or concerned about the patient, i.e., chest pain, acute shortness of breath. Specify: _____
- ☐ Acute change in heart rate to less than 40 or greater than 130
- ☐ Acute change in systolic BP to less than 90
- ☐ Acute change in diastolic BP to less than 40
- ☐ Acute change in respiratory rate to less than 8 or greater than 28
- ☐ Acute change in saturation to less than 90% despite oxygen use
- ☐ Acute change in urine output to less than 50 ml in 4 hours
- ☐ Acute mental status changes
- ☐ Acute significant bleeding
- ☐ Sudden numbness or weakness of face, arm or leg especially on one side of body
- ☐ Sudden confusion, trouble speaking or understanding
- ☐ Sudden trouble seeing in one or both eyes
- ☐ Sudden trouble walking, dizziness or loss of balance or coordination
- ☐ Sudden severe headache with no known cause

Patient length of stay prior to RRT: *(check all that apply)*
- ☐ ED admit less than 12 hours
- ☐ Direct admit less than 12 hours
- ☐ Transferred from ICU less than 12 hours
- ☐ Received from PACU less than 12 hours
- ☐ Conscious sedation within last 12 hours

Treatment measures taken: *(check all that apply)*
- ☐ Aerosol treatment
- ☐ Intubated
- ☐ Oral airway
- ☐ Suctioning
- ☐ Scoop
- ☐ None
- ☐ Supplemental O_2
- ☐ BiPAP
- ☐ Cardioversion
- ☐ IV fluid bolus

Medications:_____

Diagnostic measures taken: *(check all that apply)*
- ☐ ABG ☐ Pulse ox ☐ CBC
- ☐ CXR ☐ CMP ☐ Coag profile
- ☐ EKG ☐ CT ☐ Cardiac monitor
- ☐ Other X-ray_____ ☐ None

Other:_____

Patient Disposition: *(check all that apply)*
- ☐ Patient coded and survived
- ☐ Patient coded and expired
- ☐ Patient required transfer to a higher level of care:___
  - If transferred to ICU with CAP, re-assess antibiotics with DO676
- ☐ ED for trauma assessment

DNR status:
Was patient DNR prior to RRT? ☐ Yes ☐ No
Was patient DNR after RRT? ☐ Yes ☐ No

Notification: The following were notified
- ☐ Attending physician by: ☐HS ☐Nurse ☐Hospitalist
- ☐ On-call physician
- ☐ Consult_____:

Documentation:
- ☐ Documentation of the event in the Medical Record has been validated
- ☐ House Sup documentation of event completed.
- ☐ If Vital Sign monitor or telemetry is in use, the last 8 hours of information has been printed and stapled to this report. ☐ NA

Staff involved in Rapid Response Team:
- ☐ House Sup_____
- ☐ RT_____
- ☐ Nurse *(always indicate)*_____
- ☐ Hospitalist beeped stat @_____ arrived @_____
- ☐ Other_____

Did the physician respond timely? ☐ Yes ☐ No

Pushback from any physician for calling a RRT?
☐ No ☐ Yes, *name*_____

Did this patient have vascular (not CAB) surgery? ☐ Yes ☐ No
Was the nurse aware of "SBAR?" ☐ Yes ☐ No

Census____ # licensed staff____ # PCTs_____
# of admissions in last 4 hours____
# of discharges in last 4 hours____

Patient Label

This form is not part of the permanent medical record

Rapid Response Team Record
B-RRT (3/11)

[redacted]

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