EXPLORATORY ANALYSIS OF THE RELATIONSHIP BETWEEN PRESENT-ON-ADMISSION FACTORS OF ADULT INPATIENTS AND RISK FOR NEEDING A RAPID RESPONSE TEAM INTERVENTION DURING HOSPITALIZATION

by

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ABSTRACT

EXPLORATORY ANALYSIS OF THE RELATIONSHIP BETWEEN PRESENT-ON-ADMISSION FACTORS OF ADULT INPATIENTS AND RISK FOR NEEDING A RAPID RESPONSE TEAM INTERVENTION DURING HOSPITALIZATION

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Knowledge of how intrinsic present-on-admission patient factors such as age, gender, and pre-existing comorbid conditions contribute to patient risk during hospitalization is an important aspect for clinicians to consider when developing individualized plans of care based on patient needs. Health care providers could use such knowledge to screen and identify higher risk patients upon admission to the hospital. For those patients, the health care team could provide greater surveillance and vigilance in observation and monitoring. Such proactive interventions may reduce or avoid the occurrence of patient deterioration or need for a Rapid Response Team (RRT) intervention during hospitalization and thus, in turn, avoid patient harm, Failure To Rescue, and mortality. The significance and influence of intrinsic present-on-admission patient factors with patient risk for adverse outcomes has been established. The purpose of this exploratory study was to examine selected intrinsic present-on-admission patient factors among RRT and non-RRT patients and the associations of these factors with the risk for an RRT intervention while hospitalized. Based on studies done to date, there is a gap in

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the literature regarding patient present-on-admission factors, their association with needing an RRT intervention while hospitalized, and the level of influence on that risk.

This study was a secondary analysis of existing data from a single medical center. Descriptive statistics and logistic regression were computed. Present-on-admission patient factors significantly associated with risk for an RRT intervention during hospitalization were identified. Results from this study need to be considered within the context of the limitations and unexpected findings need additional review and study. This study may represent an initial step forward in creating a possible predictive model in the future; however, at this time it is too early for healthcare practitioners to use this study's findings as further exploration, examination, development, testing, and validation are needed. Such a program of research carries the possibility of a present-on-admission risk prediction tool that could guide care decisions related to the magnitude of surveillance and vigilance a patient requires at the point of admission to the hospital and, in turn, may proactively prevent the need for an RRT event. This study's results have made an initial contribution to an existing gap in knowledge about intrinsic present-on-admission patient factors and their relationship to RRT risk.

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CHAPTER 1

INTRODUCTION

1.1 Background and Significance

A landmark study in 1992 by Silber, Williams, Krakauer, and Schwartz introduced a new quality indicator, Failure To Rescue (FTR) (Silber, Williams, Krakauer, & Schwartz, 1992). This measure provided another dimension to the traditional measures of complication and mortality rates. Failure To Rescue (FTR) is defined as death of a hospitalized patient following a specific complication of care (U.S. Department of Health and Human Services, 2003), when the health care team was unable to "rescue" the patient.

Health care providers and hospitals share a goal to minimize and prevent an outcome like FTR or mortality. Early on, hospitals created specialized resuscitation teams with a goal to prevent patient death by specifically addressing the emergent need of patients experiencing cardiopulmonary arrest. In more recent years, a new type of specialized team has been developed and deployed, known as a medical emergency team (MET) or rapid response team (RRT). A MET or RRT intervenes early with a goal to prevent an outcome like FTR or mortality. This newer team represents an earlier intervention from a timeliness aspect as compared with the traditional resuscitation team. The anticipated benefit is that effective use of a MET/RRT will preclude the need for a resuscitation team intervention which is a late intervention. Both resuscitation teams and MET/RRT share a common approach—the patient develops a certain set of trigger criteria that result in staff summoning the team which responds and provides needed interventions to avert patient harm or death. Researchers have published studies with mixed results on outcomes of patients receiving a MET/RRT intervention; however, most document some type of positive impact on the incidence of patient arrests and deaths (Chan et al., 2008; Hillman et al., 2005). Confounding findings have led some authors to question if these

teams are the most appropriate intervention given the limitations of data published to date and if other interventions may be of greater value (Spader, 2007; Winters, Pham, & Pronovost, 2006). Researchers are looking for significant relationships with various factors and patient outcomes associated with MET/RRT or FTR to further advance practitioner understanding and in turn responsiveness to these events. Even without a definitive evidence base, rapid response systems are a recommended intervention by the Institute of Healthcare Improvement (IHI) and Michael Devita, a well-published MET/RRT researcher, to address the issue of FTR (Aleccia, 2008; Institute for Healthcare Improvement, n.d.-a)

The American Heart Association established a national MET/RRT database in February 2006 (American Heart Association, n.d.). The AHA data collection tool includes such intrinsic patient characteristics as age, gender, and race, but the majority of data elements focus on the pre-event period, including the event itself, activation triggers, interventions used, patient outcome, and review of how well the program worked. In 2006, a group of Australian authors published guidelines for consistent MET data collection (Cretikos et al., 2006). Similarly, only a couple of intrinsic patient characteristics were included--age and gender. Again the majority of data elements focused on the event itself, interventions used, and outcomes. Neither tool addresses pre-existing patient comorbid conditions nor other patient factors present upon hospital admission that might be antecedents to MET/RRT.

Key to avoiding or minimizing Failure To Rescue is timeliness. Earlier recognition and intervention increases the likelihood of avoiding or minimizing harm and subsequent negative patient outcomes (Chen et al., 2009). The resuscitation team is a traditional means to address such a patient problem albeit a late intervention as the patient has already deteriorated to the point of cardiopulmonary arrest. MET/RRT can address patient deterioration earlier if recognized by health care providers and the team is summoned. Bobay, Fiorelli, and Anderson identified statistically significant patient-level factors that were indicators of a patient developing FTR (Bobay, Fiorelli, & Anderson, 2008) These signs were in-hospital changes for five

physiologic measures--pulse, respiratory rate, temperature, blood sodium levels, and urinary output. Earlier recognition of such patient changes can minimize or avoid FTR and mortality. Other factors have been identified as contributors to the development of FTR and mortality and include such things as nurse staffing and the degree of coordination among the health care team (Knaus, Draper, Wagner, & Zimmerman, 1986; Needleman, Buerhaus, Mattke, Stewart, & Zelevinsky, 2002). A review of relevant literature related to MET/RRT and FTR did not identify studies focusing on intrinsic patient factors present-on-admission to the hospital and their association with risk for needing a rapid response intervention during the hospital stay.

In a FTR literature review, Schmid, Hoffman, Happ, Wolf, and DeVita described areas that can influence recognition of patient deterioration, timeliness of intervention, and subsequent patient outcomes related to FTR (Schmid, Hoffman, Happ, Wolf, & DeVita, 2007). These areas are the patient, staff, staffing, and environment. Patient characteristics demonstrated association with mortality. The level of education, expertise, and skill level of staff may impact early and timely recognition. Environmental factors such as prompt availability of needed resources and a culture that supports open communication and collaboration can also impact the patient's course of care. While extrinsic factors such as staff and the environment of care are amenable to modification, intrinsic patient characteristics such as comorbidities and admission from the Emergency Department are not. What is typically missing from these bodies of work is how these intrinsic present-on-admission patient factors are associated with risk for MET/RRT, a recommended intervention to address FTR following in-hospital clinical deterioration. As such, a gap in the knowledge regarding these particular patient factors exists and served as the reason for this study.

In its 2009 National Healthcare Quality Report, the Agency for Healthcare Research and Quality found that between 2004 and 2006, FTR deaths per 1,000 adult discharges had decreased overall from 128.9 to 114.0 (U.S. Department of Health and Human Services, 2009). Another significant finding in the report was the disparity between insured and uninsured

patients. While uninsured patients also experienced similar trends and a decrease in FTR events, their FTR rates per 1,000 were much higher overall as compared to the insured populations.

HealthGrades, an independent organization that provides healthcare ratings, reported on Failure To Rescue in its Seventh Annual Patient Safety in American Hospitals Study (HealthGrades, 2010). The study looked at Medicare beneficiaries who were surgical inpatients and had serious treatable complications. From 2006 to 2008, the HealthGrades report found FTR was one of four patient safety indicators with the highest incidence rate and was the only one of the four that decreased. There were 14,418 FTR deaths during the study period with a decrease from 95.433 deaths per 1,000 at-risk hospitalizations to 92.714 accounting for a 6.9% improvement. While both these reports demonstrated improvement in the FTR statistics, the rate of occurrence remained very high.

Present-on-admission factors for adult inpatients have been associated with adverse outcomes; however, a review of the literature found no study of which intrinsic patient factors are most likely to be predictive of need for RRT intervention. A pilot study of RRT calls by this researcher revealed that most patients were admitted from the Emergency Department and that eight present-on-admission conditions as defined by ICD-9-CM present-on-admission diagnosis codes had high frequency of occurrence.

The RRT calls studied were based on typical RRT activation (Table 1.1) and occurred between October 1, 2008 and December 31, 2008. The reason for selecting these dates was that effective October 1, 2008, the Centers for Medicare and Medicaid Services changed the hospital International Classification of Diseases 9th Edition, Clinical Modification (ICD-9-CM) reporting requirements for diagnosis codes to require a present-on-admission qualifier (Centers for Medicare and Medicaid Services, n.d.). As a result, diagnoses present upon admission to the hospital were differentiated in the administrative database from those acquired/developed during hospitalization.

Table 1.1 RRT Activation Criteria

	respiratory distress/progressive dyspnea					
	respiratory rate less than or equal to 8 breaths per minute or more					
Respiratory	than or equal to 28 breaths per minute					
Compromise	oxygen saturation less than 90 percent on oxygen					
	threatened airway					
	systolic blood pressure less than 90					
	heart rate greater than or equal to 120					
Circulatory	new onset bradycardia, heart rate less than 60					
Compromise	symptomatic bradycardia (with decreased systolic blood pressure)					
	less than 90 and/or diaphoresis and/or chest pain)					
	excessive bleeding					
Navvalasiaal	decreased responsiveness or level of consciousness (new or					
Neurological	persistent)					
Compromise	agitation or delirium (new or persistent)					
	uncontrolled pain despite treatment					
Other	need to obtain more rapid assistance					
	if you are concerned and need a second opinion about your patient					

The resulting sample consisted of 263 adult inpatients with 2,514 secondary diagnosis codes flagged as present-on-admission. The majority of these patients were Caucasian and 60 years of age or older, 62.4% and 63.9% respectively. Race and ethnicity were combined in the administrative dataset with multiple field entry options. Gender was almost evenly divided with 49% men and 51% women. Most, 54.8% of the sample, were admitted from the Emergency Department. A frequency analysis of the 2,514 present-on-admission diagnosis codes revealed eight conditions accounted for 20% of all those recorded. These eight conditions were present

in 16.4% to 36.1% of the 263 RRT patients. These eight conditions and their ICD-9-CM codes appear in Table 1.2 along with the individual percent of the 2,514 secondary present-on-admission codes, the running cumulative percent, and the number and percent of patients in the sample of 263 RRT cases who had the code.

Table 1.2 Top Twenty Percent of Present-On-Admission Conditions in the RRT Sample

Present-On- Admission (POA) Conditions	ICD-9-CM Code and Title	Individual Percent of 2,514 Codes	Running Cumulative Percent for Codes	Number of 263 Patients with Condition	Percent of 263 Patients with Condition 36.12%
Hypertension	Essential Hypertension	3.76%	3.76%	93	30.1276
Diabetes Mellitus	250.x Diabetes Mellitus	3.26%	7.04%	82	31.18%
Coronary Atherosclerosis	414.0x Coronary Atherosclerosis	2.47%	9.51%	62	23.57%
Chronic Kidney Disease	585.x Chronic Kidney Disease	2.43%	11.94%	61	23.19%
Hyperlipidemia	272.0 Hypercholesterolemia 272.4 Other/Unspecified Hyperlipidemia	2.35%	14.29%	59	22.43%
Heart Failure	428.x Heart Failure	2.07%	16.36%	52	19.77%
Hypertensive Chronic Kidney Disease	403.x Hypertensive Chronic Kidney Disease	1.95%	18.31%	49	18.63%

Table 1.2 - Continued

Tobacco Use	305.1	1.71%	20.02%	43	16.35%
	Tobacco Use Disorder				

1.2 Framework

If clinicians knew which present-on-admission factors created higher significant risk for need of an RRT intervention during hospitalization, they could identify at-risk patients earlier and proactively address the individual patient need. The plan of care could be adjusted to implement higher levels of surveillance for these particular patients as opposed to all patients receiving a uniform level of surveillance and vigilance. In turn, a proactive response could avoid or minimize risk as evidenced by a reduction in or elimination of patient deterioration, need for RRT while hospitalized, or FTR. The ability to identify patients at higher risk at the time of admission provides an even earlier opportunity to intervene as compared to RRT and resuscitation teams and possibly prior to the patient presenting with any signs of deterioration.

The model in Figure 1.1 served as the framework for this study. The model depicts a timeline approach to patient intervention and patient outcome in response to adverse patient changes. When recognition and response are earlier in the timeline, a more positive patient outcome can be anticipated. As time progresses without recognition and response, the magnitude of risk for the patient to suffer a negative outcome increases. As such, timeliness is an important concept to patient outcomes. By identifying significant intrinsic present-on-admission patient factors that place the patient at higher risk for an RRT intervention while hospitalized (e.g., age, gender, pre-existing comorbidities), earlier proactive actions can be taken by the health care team to avoid or minimize patient harm or mortality.

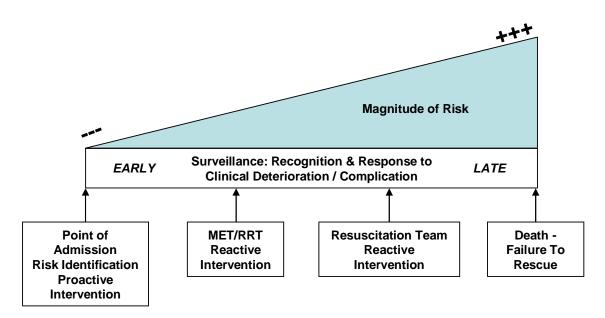


Figure 1.1 Framework for Study

1.3 Purpose

Knowledge of how intrinsic present-on-admission patient factors such as age, gender, and pre-existing comorbid conditions contribute to patient risk during hospitalization is an important aspect for clinicians to consider when developing individualized plans of care based on patient needs. The purpose of this exploratory study was to examine selected intrinsic present-on-admission patient factors among RRT and non-RRT patients and the associations of these factors with the risk for an RRT intervention while hospitalized. If results revealed significant associations, health care providers could use such knowledge to screen and identify higher risk patients as early as upon admission to the hospital. For those patients, the health care team could provide greater surveillance and vigilance in observation and monitoring. Such proactive interventions may reduce or avoid the occurrence of patient deterioration or need for RRT during hospitalization and thus in turn avoid FTR and mortality.

1.4 Research Questions

This study addressed the following research questions:

- 1. What are the commonalities and differences of selected demographic and present-onadmission patient factors for RRT and non-RRT patients?
- 2. What selected demographic and present-on-admission patient factors are significantly associated with risk for RRT during hospitalization?
- 3. How do selected demographic and present-on-admission patient factors influence the risk for RRT during hospitalization?

1.5 Assumptions

This study assumed that intrinsic patient factors present-on-admission to the hospital were significantly associated with increased patient risk for MET/RRT intervention during hospitalization due to clinical deterioration. The significant increased risk may result from one or a combination of intrinsic patient factors present-on-admission. Knowledge of significant present-on-admission patient factors could result in decreased risk during hospitalization through early proactive interventions in response to the assessed risk. Magnitude of risk for the patient increases as timeliness of recognition and response decreases. Late recognition and response to patient clinical deterioration or complication can result in negative outcomes even with an intervention.

1.6 Summary

FTR and mortality are unwanted patient outcomes. Many hospitals have implemented measures to minimize or prevent these negative consequences. The search for better or complementary methods continues. Even with these efforts, data from national studies demonstrate FTR and mortality continue to be a prevalent problem in spite of recent gains. Traditionally, resuscitation teams addressed the need of patients experiencing cardiopulmonary arrest and more recently hospitals have developed and deployed MET/RRT to intervene with patients who present with early indications of deterioration. Researchers are exploring key

factors associated with these negative patient outcomes. In particular, studies have focused on staff and environmental factors and less so on intrinsic patient factors present-on-admission to the hospital resulting in a gap in the literature. The former two are modifiable in that health care providers can respond differently; however, the latter, patient factors, is not. As a result, it is important for health care providers to know and understand which present-on-admission patient factors may hold a significant association with the need for RRT during hospitalization. Given such knowledge, health care providers could modify their responses to such patients and the plans of care to address the specific needs of higher risk patients through increased surveillance and vigilance. Identification of patients at higher risk upon hospital admission represents a proactive earlier intervention as compared to RRT. This study explored the relationship between present-on-admission factors of adult inpatients and risk for needing a Rapid Response Team intervention during hospitalization. Based on a critical review of relevant literature, such a focus has not been evaluated previously to this researcher's knowledge.

CHAPTER 2

CRTITICAL REVIEW OF RELEVANT LITERATURE

Failure To Rescue (FTR) results when a patient develops a specific complication and then dies. The healthcare team was not able to "rescue" the patient. Timely recognition that the patient is experiencing the complication and prompt treatment decrease the risk the patient will experience harm, FTR, or mortality. Studies have examined various factors associated with FTR. Rapid Response Systems (RRS) such as medical emergency, rapid response, and critical care outreach teams have been advocated as the method to address early recognition of and response to patient deterioration and thus avoid FTR. Major initiatives and efforts recommending and endorsing rapid response systems have developed over the years. These efforts show the degree to which these programs have spread as a means for early patient rescue not only for FTR but for other patient deterioration events as well. A noteworthy finding is the lack of studies focusing on intrinsic present-on-admission patient factors and their relationship to risk for a rapid response intervention while hospitalized. Intrinsic patient factors like comorbidities have been significantly linked to adverse patient outcomes such as in-hospital complications and mortality and thus play a role as potential predictors of patient risk.

2.1 Failure to Rescue (FTR)

2.1.1. Development of FTR

The concept of Failure To Rescue was introduced by Silber and colleagues in 1992 (Silber et al., 1992). It was defined as "death after an adverse occurrence [complication]" (p. 615) and "rescuing patients" was "preventing death after a complication" (p. 616). Silber noted the focus on a hospital's quality of care had usually been evaluated based primarily on its mortality rate. And as hospitals were compared to each other, the mortality rate was being used as a differentiating quality indicator. This situation created an impetus for Silber to examine

patient and hospital factors and their relationship with not only death rates, but with complication and Failure To Rescue rates as well. In particular, the researchers were seeking to discover if these factors were similar or varied for each of the rates. Silber and his colleagues conducted their study to explore how well a hospital could "rescue" a patient after the patient experienced a post-operative complication while hospitalized.

Silber's sample consisted of almost 6,000 Medicare patients 65 years of age or older electively admitted for one of two routine surgical procedures, cholecystectomy or transurethral prostatectomy. Data from the mid 1980's were obtained from chart abstractions and existing datasets. The setting included just over 500 hospitals in seven states. The total number of patients served as the denominator for both death and complication rates. FTR was the number of deaths of patients with complications divided by the total number of patients with complications. The complications list was developed by the research team and was based on the expected post-operative course of these two routinely performed surgical procedures. Most facilities performed these two common surgeries, and thus care was expected to be consistent across settings. As a result, it was thought that variation in the complications rate may be more related to patient characteristics and less so to hospital characteristics. Also some facilities may be better at rescuing patients once patients develop a complication.

Univariate analyses of hospital and patient characteristics were computed for three outcome rates--death, complications, and FTR. Of the hospital characteristics, only low hospital technology and 0 to 33% board certification of anesthesia staff were significantly associated with the death rate. No hospital characteristics were significantly associated with FTR or complication rates. A number of patient characteristics such as age 65 to 70 years, male gender, cholecystectomy, and absence of certain comorbid conditions like congestive heart failure and diabetes were significantly associated with one or more of the three rates-complications, mortality, and FTR. Only age 65 to 70 years and absence of metastasis were significantly associated with FTR. The hospital and patient characteristics were then analyzed

using multiple logistic regression for the same three outcome rates. Multiple patient characteristics showed significant associations with one or more of the three rates-complications, mortality, and FTR--as compared to the hospital characteristics. For FTR, the percent of board certified anesthesiologists decreased risk whereas the presence of surgical housestaff increased risk. Only two patient characteristics, age and prior history of metastasis, were significant for FTR and both of these patient factors increased FTR risk. Silber et al. concluded that evaluating FTR and complication rates in addition to the mortality rate may provide greater understanding of mortality rate variation in hospitals and lead to quality improvements.

Silber's study was a first step in exploring the new concept, Failure To Rescue. The researchers noted a number of limitations with their pilot study such as the sample had a small number of patients per facility, the complications list may not be usable with other surgical procedures or medical patients, patients admitted from the Emergency Department were excluded, and the surgical procedures were elective non-emergent. Also, the researchers noted that because their model didn't explain more variation, other factors, not yet identified, may be influencing the associations. Because the factors associated with each of the three outcomes were varied, these authors recommended further work and study, so that the full impact of their pilot study's findings could be understood and explored.

In a 2007 publication, Silber and colleagues addressed the evolution of FTR over the decade since its original inception in 1992 (Silber *et al.*, 2007). They wrote about how FTR had increased in popularity as a measurement indicator for the quality of care provided by hospitals. They also noted how across this time period modifications had been made to the original definitions used for measurement and analysis. For example, one researcher made a major change to the basic concept by applying FTR to medication errors and decubitus ulcers (Seago, Williamson, & Atwood, 2006). Instead of using deaths in the numerator, she used the number of medication error injuries and moderate or severe decubitus ulcers.

In the 2007 publication, Silber and his colleagues reported the results of their evaluations of subsequent versions of FTR that had emerged since its original conceptualization (Silber et al., 2007). The study's sample consisted of just over 400,000 surgical Medicare patient records from almost 1,600 hospitals. The data used were from years 1999 to 2000. The research team evaluated patient data using three versions of FTR. The first analysis was the original FTR conceptualization which evaluated all deaths and used the original 15 categories of complications. The second analysis was the FTR-N used as a nursing sensitive quality indicator; however, FTR-N included only six complications (pneumonia, shock, gastrointestinal bleeding, cardiac arrest, sepsis, and deep vein thrombosis) and associated deaths. The third analysis was the FTR-A and represented the version created by the Agency for Healthcare Research and Quality and added renal failure to the FTR-N list resulting in a total of seven specific complications. Based on the results of the study, the authors recommended use of the original FTR conceptualization for analysis and reporting given its better reliability.

2.1.2. Other Work Related to FTR

The impact of nurse staffing levels and the relationship to hospital quality of care measures were studied by Needleman and colleagues (Needleman et al., 2002). Fourteen patient outcomes were evaluated, and one of those was Failure To Rescue. For FTR, a specific set of six complications was evaluated, and these were limited to pneumonia, shock, cardiac arrest, upper gastrointestinal bleed, sepsis, and deep vein thrombosis. Administrative data from 1997 were used and represented 799 hospitals in 11 states. Just over 1.5 million patient records from nonfederal hospitals made up the sample with approximately two-thirds surgical patients and one-third medical patients. The study sample represented 26% of hospital discharges in the United States in 1997. The use of the large administrative dataset resulted in the research team having to develop coding guidelines and exclusion rules since the diagnosis codes did not indicate whether the conditions were present-on-admission or developed during the hospitalization.

The key nurse staffing levels evaluated in Needleman's study were the amount of care provided by hospital registered nurses (RN) as the proportion of RN care hours per day and the absolute number of RN care hours per day. Findings for medical patients differed from those for surgical patients. Lower rates of FTR were found for medical patients when the proportion of RN care hours per day was higher. For surgical patients, the FTR rates were lower when the absolute number of RN care hours was higher. While significant results were found for several medical and surgical patient outcomes, the researchers acknowledged that other factors might be influencing the findings such as the nurse's skills and education, the work environment, and communication.

In another major study, Aiken and colleagues evaluated the impact of the patient-tonurse ratio on mortality, Failure To Rescue, and nurse retention variables (Aiken, Clarke,
Sloane, Sochalski, & Silber, 2002). RN data were collected from surveys and patient data were
obtained from an administrative dataset across years 1998 and 1999. Just over 232,000 patient
records from 168 nonfederal Pennsylvania hospitals were used for Aiken's study. The patient
population included only general, orthopedic, and vascular surgery patients. Similar to the
Needleman study, these researchers had to use guidelines and rules since the diagnosis codes
did not differentiate whether a condition was present-on-admission or developed later as a
complication. Results demonstrated that when there were higher patient-to-nurse ratios, the risk
for FTR increased. For each additional patient assigned to an RN, there was a 7% increase in
the odds of an FTR. Aiken and colleagues noted that on-going surveillance of patients by
registered nurses is a safety net that allows for "early detection and prompt intervention when
patients' conditions deteriorate" (p. 1992). As a result, the success of such a safety net is
influenced by how many nurses are on hand to provide surveillance--more nurses equals
increased surveillance.

In contrast to the Aiken et al. results, Halm found staffing was not a significant predictor for Failure To Rescue (Halm et al., 2005). Halm's study design closely followed Aiken's study,

but on a much smaller scale. The data were taken from one institution and the sample consisted of 2,709 general, orthopedic, and vascular surgery patients discharged in 2002. Complication codes were determined from an administrative dataset using a methodology that was similar to the one used by Aiken et al. No significant associations were found between the staffing ratios and FTR. The researchers felt the findings reflected the facility's well established nurse-to-patient ratios that were consistently followed. Based on these results, one suggestion for practice was "screening patients for comorbidities on admission to the hospital, as well as in the ED, may help to identify interventions to support these groups of patients" (p. 250), but no specific methods or interventions on how to accomplish the screening were offered.

In a subsequent publication focusing on Failure To Rescue, Clarke and Aiken wrote more about nursing surveillance and how such vigilance contributes to early recognition and timely response to clinical deterioration of the patient (Clarke & Aiken, 2003). They noted surveillance involves "assessing patients frequently, attending to cues, and recognizing complications" (p. 44). Other factors such as patient load, experience level of the nurse, and clear communication were cited as considerations as well. Clarke and Aiken also noted that the process of rescuing the patient includes the RN being able to bring needed hospital resources readily to the patient and that "saving the patient is a team effort" (p. 45). In addition to a timely and appropriate response to a crisis, they stated "the nurse should anticipate possible complications and assemble the necessary supplies and equipment at the bedside" (p. 44). In the same publication, these authors discussed the challenge of applying the FTR measure to non-surgical patients in future research. Again, the issue was determining from the administrative dataset whether a condition was present-on-admission or developed during hospitalization. Also it was noted medical patients may be admitted to the hospital, and death may be an expected outcome for some of them whereas for surgical patients death is not typically thought of as the anticipated outcome.

In an invited commentary, Clarke again addressed nursing surveillance (Clarke, 2004). Drawing from community and mental health settings, he noted "close surveillance tailored to the client needs . . . can avert a variety of crises" (p. 68). He also called upon nurses to move from a "deterministic" to "probabilistic" view of patient outcomes allowing for an approach where "if we know the circumstances under which a patient enters treatment and a number of their clinical characteristics, we can intelligently speak of probabilities of them experiencing a good or poor outcome" (p. 69).

Based on these comments, it seems that in addition to timely recognition and response there is also an anticipatory or probabilistic antecedent to the development of a complication or FTR. Such that if patient factors and associated risk were better understood at the point of admission, levels of surveillance might be adjusted to specifically address a patient's needs and that risk. Such a patient-centric plan of care may contribute to more positive outcomes and possibly avoidance of complications and FTR. The level of expertise and education of the nursing staff has also been explored as a possible influential variable in relation to Failure To Rescue. Using datasets from her major study on patient-to-nurse ratio, mortality, Failure To Rescue, and nurse retention variables, Aiken and her co-researchers examined the relationship between the proportion of RNs prepared at the baccalaureate or higher level and mortality and Failure To Rescue (Aiken, Clarke, Cheung, Sloane, & Silber, 2003). The study sample was confined to general, orthopedic, and vascular surgery patients from 168 nonfederal Pennsylvania hospitals. The sample size was just over 250,000 patients discharged between 1998 and 1999. The study went beyond ratios and raised the question if other hospital RN characteristics might be contributing to positive patient outcomes. Again, the issue of distinguishing complications from preexisting comorbidities was addressed using a set of coding guidelines and rules.

In both models, before and after controlling for hospital and patient characteristics, the proportion of baccalaureate and master's prepared direct care nurses was significantly

associated with mortality and FTR. A 10% increase in the proportion of higher degree nurses demonstrated a 5% reduction in both mortality and FTR. However, years of experience were not significantly associated with these two outcomes in the full model. These results implied that higher proportions of higher degree nurses could have a significant impact on mortality and FTR for surgical patients. To enhance generalizability, the researchers recommended longitudinal datasets from hospitals in other states. These results spurred dialogue that influential factors may be more than just ratios and numbers of nurses (Long, Bernier, & Aiken, 2004). It may be that RNs with a baccalaureate degree "are more likely to demonstrate professional behaviors important to patient safety such as problem solving, performance of complex functions, and effective communication" (p. 1618).

Organizational nursing unit characteristics as measured with the Nursing Work Index Revised-B (NWI-R) instrument were explored in relation to adverse patient outcomes (Boyle, 2004). Failure To Rescue was one of those outcome variables. The study was conducted in a hospital with almost 1,000 beds and involved 21 medical and surgical units. Data for the study were collected from 390 RNs who completed the NWI-R survey and 11,496 patient discharges in 2001. The survey's sub-scale of Autonomy/Collaboration was found to have a significant inverse correlation with FTR. The researcher felt the finding lent support to the study's research question--are adverse patient outcomes associated with unit characteristics. The authors posited that increased levels of Autonomy/Collaboration supported open communication, nurse surveillance, and early recognition and response.

2.1.3. Major FTR Initiatives and Programs

Failure to Rescue has grown in its use as an indicator of hospital performance both from a quality and patient safety aspect. The Agency for Healthcare Research and Quality (AHRQ), part of the United States Department of Health and Human Services, includes it in their glossary as:

'Failure to rescue' is shorthand for failure to rescue (i.e., prevent a clinically important deterioration, such as death or permanent disability) from a complication of an underlying illness (e.g., cardiac arrest in a patient with acute myocardial infarction) or a complication of medical care (e.g., major hemorrhage after thrombolysis for acute myocardial infarction). Failure to rescue thus provides a measure of the degree to which providers responded to adverse occurrences (e.g., hospital-acquired infections, cardiac arrest or shock) that developed on their watch. It may reflect quality of monitoring, the effectiveness of actions taken once early complications are recognized, or both.

and cites it as a means to evaluate quality of care beyond mere complication rates (Agency for Healthcare Research and Quality, n.d.). In the AHRQ publication Guide to Patient Safety Indicators, FTR is Patient Safety Indicator 4 and is reported as "deaths per 1,000 patients having developed specified complications of care during hospitalization" (p. 30) (U.S. Department of Health and Human Services, 2003). As noted, FTR is not typical as compared to the other listed patient safety indicators. Whereas others focus on prevention, FTR focuses on reaction--the timeliness of how well hospitals recognize such complications and promptly and aggressively respond to them. Inclusion and exclusion criteria narrow application of the measurement to specific patients and use a defined set of complications--pneumonia, deep vein thrombosis/pulmonary embolus, sepsis, acute renal failure, shock/cardiac arrest, and gastrointestinal hemorrhage/acute ulcer. In its 2009 National Healthcare Quality Report, AHRQ reported that from 2004 to 2006, the FTR rate decreased from 128.9 to 114.0 per 1,000 patients, aged 18 to 74 years of age (U.S. Department of Health and Human Services, 2009). A breakdown of these patients by payer (e.g., Medicare, private insurance) showed the uninsured had a higher rate of death as compared to insured groups.

The National Quality Forum (NQF), http://www.qualityforum.org/, is a non-governmental non-profit organization that focuses on improving healthcare quality for Americans through a three-part mission:

Setting national priorities and goals for performance improvement; Endorsing national consensus standards for measuring and publicly reporting on performance; and Promoting the attainment of national goals through education and outreach programs.

In the 2004 publication, National Voluntary Consensus Standards for Nursing-Sensitive Care: An Initial Performance Measure Set, NQF endorsed 15 standards, one of which was Failure To Rescue for surgical inpatients (National Quality Forum, 2004). NQF's hospital-acquired complications list matched AHRQ except NQF did not include acute renal failure. Also, NQF evaluated only surgical patients whereas AHRQ included both medical and surgical patients. In identifying priorities for research, the NQF report noted opportunities to examine application of FTR for inpatient medical populations. In 2008, the National Quality Forum endorsed FTR as a performance measure for both in-hospital and 30-day mortality.(National Quality Forum, 2008a, 2008b).

With a grant from the Robert Wood Johnson Foundation (RWJF), The Joint Commission in 2005 worked on standardizing the technical specifications of the NQF endorsed nursing-sensitive performance measures (The Joint Commission, 2010). The Commission's work resulted in its publication, The Implementation Guide for the National Quality Forum (NQF) Endorsed Nursing-Sensitive Care Performance Measures (The Joint Commission, 2009). The FTR standard was titled "NSC-1 Death among surgical inpatients with treatable serious complications" and followed the NQF parameters. The list of serious complications did not include acute renal failure as was found in the AHRQ set. A follow-up grant from RWJF allowed The Joint Commission to pilot test the indicator in 55 hospitals across the United States in 2007

and 2008. The project summary did not report on findings or outcomes, but rather detailed the procedures and processes used to roll out and conduct the pilot.

HealthGrades, www.HealthGrades.com, is an organization that publishes ratings of health care performance. These reviews include not only facilities, but practitioners as well and are intended for a variety of audiences such as consumers, business, and those in the health care field. Additionally, HealthGrades compiles annual studies on various aspects of quality based on analyses of hospital patient records. Since 2004, HealthGrades has been publishing an annual report on patient safety in American hospitals. From the report's inception, Failure To Rescue has been included. In the seventh edition published in 2010, HealthGrades reported that FTR for surgical inpatients showed a 6.9% improvement, but also noted FTR had the highest incidence rate at 92.71 events per 1,000 at-risk hospitalizations (HealthGrades, 2010). Across the same study time period, the next closest patient safety indicator was decubitus ulcer at 36.05 and its findings had worsened. Of the top four patient safety indicators with the highest incidence rates. FTR was number one.

2.2 Rapid Response Systems (RRS) – An Early Intervention to Address Patient Deterioration

In 1995, Lee, Bishop, Hillman, and Daffurn introduced the concept of the Medical Emergency Team (Lee, Bishop, Hillman, & Daffurn, 1995). They described their one-year experience with the new intervention to manage "seriously ill patients at risk of cardiopulmonary arrest and other high-risk conditions" (p. 183). Subsequent studies on rapid response systems followed and shared a similar focus of evaluating and reporting on experiences with such teams and associated outcomes (Bellomo et al., 2003; Bristow et al., 2000; Buist et al., 2002; Chan et al., 2008; Chen et al., 2009; Dacey et al., 2007; DeVita et al., 2004; Hillman et al., 2005; Kenward, Castle, Hodgetts, & Shaikh, 2004; Pittard, 2003; Priestley et al., 2004). These reports came from a variety of hospital types in various countries and many were before-and-after designs. Various endpoints were measured and the most common ones were incidence of cardiopulmonary arrest, mortality rate, and unplanned transfer to an intensive care unit. While

the RRT may have had a positive impact on the endpoints, not all results were statistically significant and findings were not consistent across studies.

In 2007, Ranji, Auerbach, Hurd, O'Rouke, and Shojania reported their meta-analysis of rapid response systems (RRS) studies (Ranji, Auerbach, Hurd, O'Rourke, & Shojania, 2007). They found there had not been "consistent improvement in clinical outcomes" and published studies have been of "poor methodological quality" and concluded that "effectiveness of the RRS concept remains unproven" (p. 422). In another systematic review published the same year by another team of authors, findings were comparable (Winters et al., 2007). Winters et al. noted "weak evidence" and study limitations (p. 1238). For RRS to become a standard of care, the authors stated "large randomized controlled trials are needed to clarify the efficacy of rapid response systems" (p. 1238). Authors of a systematic review on critical care outreach services arrived at a similar conclusion. They noted while there were reports of improved patient outcomes, conclusive evidence was deficient. (Esmonde et al., 2006) Other authors did not share these opinions. Tee and colleagues recognized that FTR was a hospital performance problem and implementing MET was a logical intervention to respond to overt physiologic signs and symptoms of patient deterioration (Tee, Calzavacca, Licari, Goldsmith, & Bellomo, 2008). They noted that "implementing a complex intervention like RRS poses enormous logistic, political, cultural, and financial challenges" (p.205). As far as studying such a phenomenon, they pointed out effectiveness studies are difficult to conduct and double-blinded randomized controlled trials are not possible. They envisioned that continued evidence from a variety of sources will "increase the rationale and logic of RRS" (p. 205).

Chan et al., in a 2010 systematic review and meta-analysis of rapid response teams, found that while the use of RRTs has "broad appeal, robust evidence to support their effectiveness in reducing hospital mortality is lacking" (p. 18) (Chan, Jain, Nallmothu, Berg, & Sasson, 2010). Jones et al., in a 2011 review article on rapid response teams, noted the widespread adoption of RRT despite solid evidence validating its effectiveness (Jones, DeVita,

& Bellomo, 2011). They concluded the primary impetus for such adoption is a "belief that they make hospitals safer and prevent serious adverse events after sudden alterations in vital signs" (p. 145) and "the rationale that early intervention is beneficial in almost all medical emergencies" (p. 145). What is missing from these many reports is a focused examination of the patient at the point of admission to the hospital. None of these studies specifically evaluated if any intrinsic patient present-on-admission factors were significantly associated with increased risk for needing a rapid response intervention while hospitalized.

Consistent with the intent of rapid response systems, studies have focused on early recognition of the patient who develops distress and prompt response by a specialized team that can address the patient's needs. The timeliness of the intervention favored improved patient outcomes and thus contributed support to early recognition and response before the patient reached a point beyond rescue. Manojlovich and Talsma identified rapid response teams as a process of care that can help to avoid further patient deterioration and FTR (Manojlovich & Talsma, 2007). Likewise, Schmid and colleagues in a published FTR literature review noted RRT as a means to prevent FTR events and suggested that changes in the practice environment might even reduce the need for RRT (Schmid et al., 2007). And in some facilities, a rapid response system has been implemented specifically to improve FTR performance (Jones, Bleyer, & Petree, 2010).

Regardless of the availability of supporting evidence since the introduction of the rapid response system concept, efforts to create and deploy such teams have increased. These early response teams are known by various titles such as medical emergency, rapid response, or critical care outreach. They have been increasingly recommended and endorsed as an early intervention for patients experiencing clinical deterioration as a means to prevent further harm, FTR, and death. The MET/RRT concept has become more organized at the international level with the establishment of the Rapid Response Systems organization, http://www.rapidresponsesystems.org/. Its sixth annual international symposium was held in May 2010 and provided for a variety of educational activities. Its target audience is individuals with some type of connection to rapid response programs. The development of such organized efforts at the international level is evidence of the widening interest, dissemination, and adoption of such teams in health care settings.

National and international initiatives have been developed and formalized around the implementation and adoption of rapid response systems and programs. The Safer Systems-Saving Lives program was created by the Australian Commission for Safety and Quality in Health Care (Victorian State Government Department of Health Australia, n.d.-b) with the intent to "engage hospitals throughout Australia in a commitment to improve patient care and prevent avoidable deaths." Resources and references for setting up a rapid response system are available through the Australian website (Victorian State Government Department of Health Australia, n.d.-a). In the United Kingdom, the National Institute for Health and Clinical Excellence (National Institute for Health and Clinical Excellence, n.d.) also addresses the issue of worsening patient condition while hospitalized and provides a downloadable clinical guideline, Acutely III Patients in Hospital: Recognition and Response to Acute Illness in Adults in Hospital, providing information and recommendations on dealing with this patient need (National Institute for Health and Clinical Excellence, 2007, July). The World Health Organization Collaborating Centre for Patient Safety Solutions (WHO Collaborating Centre for Patient Safety Solutions, 2007) also provides references and resources for its list of nine patient safety solutions. These nine patient safety solutions were developed by and vetted with an international panel of patients, health care providers, experts, organizations, and agencies; however, it is interesting to note that MET/RRT was not included as one of the nine.

In the United States, the Institute for Healthcare Improvement (IHI) has actively promoted the establishment of rapid response teams as a means to address basic care quality and patient safety problems in addition to those that can lead to Failure To Rescue (Institute for Healthcare Improvement, n.d.-a). Through the IHI website, resources and references are

provided on how to establish RRT. In its 100,000 Lives Campaign that ran from January 2005 through June 2006, IHI included the use of RRT as one of its six key strategies (Institute for Healthcare Improvement, n.d.-b). The Protecting 5 Million Lives from Harm campaign followed from December 2006 through December 2008 (Institute for Healthcare Improvement, n.d.-c) and also included RRT as an essential tactic.

The Joint Commission addressed patient deterioration in its 2008 National Patient Safety Goals (NPSGs) by adding Goal 16 directing hospitals to "improve recognition and response to changes in a patient's condition" (The Joint Commission, 2007, May 31). The goal does not specify that a MET or RRT must be implemented but that the hospital must select "a suitable method that enables health care staff members to directly request additional assistance from a specially trained individual(s) when the patient's condition appears to be worsening." The goal was carried forward in the 2009 NPSGs (The Joint Commission, 2008). Effective January 1, 2010, the goal was deleted from the National Patient Safety Goals list. It was not eliminated, but became a required element of performance in the hospital accreditation standards program (The Joint Commission, 2009, October). Despite the on-going critique of studies on the effectiveness and impact of RRT/MET as a means to prevent patient harm, FTR, and death, organizations and agencies continue to actively acknowledge, promote, recommend, and endorse the intervention.

2.3 Intrinsic Patient Characteristics

2.3.1. Influence and Contribution of Intrinsic Patient Characteristics to Risk

Intrinsic patient characteristics are variables that cannot be modified such as age, gender, race/ethnicity, admission source, or payer source. Additional characteristics such as pre-existing comorbidities may be effectively controlled or managed through various on-going therapeutic interventions. Admission to the hospital for an acute event or electively for a planned procedure does not change the fact that these intrinsic patient factors are part of the patient's baseline health status. Thus, these characteristics are present upon admission

regardless of the cause of that admission. These intrinsic patient characteristics then can have an influence on and contribute to the patient's trajectory while hospitalized since they can impact risk. Studies have identified significant associations for comorbidities with adverse patient outcomes in various patient populations such as acute burn injuries, hip fractures, and intensive care unit stays (French, Bass, Bradham, Campbell, & Rubenstein, 2008; Johnston et al., 2002; Thombs, Singh, Halonen, Diallo, & Milner, 2007).

Silber and his research teams explored some of these intrinsic patient characteristics in their FTR studies. In the 1992 landmark study that introduced the concept of FTR, Silber et al. evaluated patient characteristics such as age, gender, and certain comorbid conditions in relation to three outcome measures--death within 30 days from admission, complication, and FTR (Silber et al., 1992). The study population was comprised of almost 6,000 surgical patients undergoing cholecystectomy or transurethral prostatectomy. Patients younger than 65 years of age and patients admitted from the Emergency Department were excluded from the study sample. Univariate analyses demonstrated significant associations with age, male gender, and absence of comorbid conditions for one or more of the three outcome measures. The analysis of the patient characteristics using multiple logistic regression demonstrated significant increased risk for one or more of the three outcome measures. Age was associated with significant increased risk for death, complication, and FTR, but male gender was only associated with increased risk for complication. A prior history of diabetes, stroke, congestive heart failure, or chronic obstructive pulmonary disease was only associated with an increased risk for complication whereas a metastasis history was associated with increased risk for both death and FTR. Patient race was a key focus of another study published by Silber and colleagues in 2009 (Silber et al., 2009). They found "better survival and failure to rescue at teaching-intensive hospitals is seen for white patients, but not for black patients" (p. 113).

Two major studies published in 1994 by lezzoni et al. examined the relationship of 13 chronic conditions with complications and death during hospitalization (lezzoni et al., 1994a;

lezzoni et al., 1994b). The research team thought these conditions were present upon admission, had not developed during a patient's hospitalization, and contributed to patient risk. The analyses were done on secondary diagnosis codes from administrative data. The sample was made up of almost two million medical and surgical discharges from California hospitals. Since the administrative dataset at that time did not differentiate secondary diagnosis codes as present upon admission or acquired/developed during the hospitalization, the research team developed methodologies to make such a determination. Thirteen chronic conditions were used by the researchers as underlying present-on-admission factors (lezzoni et al., 1994a; lezzoni et al., 1994b).

lezzoni and her research teams used multivariable logistic regression models to examine the influence of the 13 chronic conditions on the outcomes of hospitalized adult patients (lezzoni et al., 1994a; lezzoni et al., 1994b). The 13 chronic conditions were: cancer (primary) with poor prognosis, metastatic cancer, acquired immunodeficiency syndrome (AIDS), chronic pulmonary disease, coronary artery disease, congestive heart failure, peripheral vascular disease, severe chronic liver disease, diabetes mellitus with end organ damage, chronic renal failure, nutritional deficiencies, dementia, and functional impairment. In the first study, the relationship of these conditions to death was evaluated (lezzoni et al., 1994b). All the chronic conditions were associated with a significant increased risk for death except for coronary artery disease which reduced risk and dementia which was not significant. Based on the findings, the authors recommended the influence of chronic conditions needed to be considered when evaluating death rates. In the second study, the relationship of these conditions to complications developed during hospitalization was evaluated (lezzoni et al., 1994a). All the chronic conditions were associated with a significant increased risk for inhospital complications except for primary cancer and AIDS which reduced risk and chronic renal failure, dementia, and functional impairment which were not significant. The researchers also found patient age and an admission source as a transfer were associated with a significant

increased risk for complications whereas male gender, black or Hispanic race, and emergent or urgent admission type significantly decreased risk.

In 1998, Elixhauser et al. published a list of 30 comorbidity measures for use with administrative data for predicting outcomes (Elixhauser, Steiner, Harris, & Coffey, 1998). Because administrative datasets at the time did not differentiate diagnosis codes in administrative datasets as present-on-admission, these researchers developed a methodology to do so. Using data from over 400 acute care California hospitals, the team analyzed almost two million records. Outcome measures were ones common at the time of the study--length of stay, death during hospitalization, and charges. Of the 30 comorbidity measures, 18 significantly increased the risk for in-hospital mortality and included: congestive heart failure, cardiac arrhythmias, pulmonary circulation disorders, peripheral vascular disorders, paralysis, other neurological disorders, chronic pulmonary disease, diabetes-complicated, renal failure, liver disease, acquired immune deficiency syndrome (AIDS), lymphoma, metastatic cancer, coagulopathy, weight loss, fluid and electrolyte disorders, alcohol abuse, and psychoses. Seven of the comorbidity measures were significantly associated with a decreased risk of in-hospital death and included: valvular disease, hypertension, peptic ulcer disease excluding bleeding, obesity, blood loss anemia, and depression. The remaining five--uncomplicated diabetes, solid tumor with metastasis, rheumatoid arthritis/collagen vascular disease, deficiency anemias, and drug abuse--were not significant. Elixhauser's comorbidity predictors for significant increased risk of in-hospital mortality were similar to many of the chronic conditions lezzoni et al. found to be predictors for significant increased risk of in-hospital death (lezzoni et al., 1994b).

lezzoni and her research team presented several arguments for considering chronic conditions when examining patient outcomes (lezzoni et al., 1994b). When evaluating an outcome such as in-hospital death, they observed efforts often "concentrate on acute clinical conditions or physiologic abnormalities" (p. 436). lezzoni et al. noted that focusing on acute events is warranted, but "there are compelling arguments for considering the impact of chronic

illnesses, conditions that are pre-existing, often long-term, and generally palliated, not cured" (p. 436). First of the arguments these authors put forth was that the presence of pre-existing conditions can be found in association with acute events and more so in older populations. The second focused on the greater challenge to the patient to deal with an acute event in the presence of pre-existing chronic conditions. Lastly, in order to better understand patient risk and prediction, the authors stated that differentiation of present-on-admission risk conditions versus conditions that develop during hospitalization was needed. They concluded "while acute physiologic derangements are clinically obvious predictors of poor patient outcomes, chronic conditions also play an important role" (p. 454).

2.3.2. Identifying Present-On-Admission Conditions in Administrative Data

Prior to October 2008, researchers using secondary diagnosis codes in administrative data had not been able to distinguish whether a condition was present upon admission to the hospital or acquired during hospitalization based on the code alone. The issue resulted in development of decision algorithms that attempted to perform such assignment. Different researchers have used various methodologies with identified limitations (Baldwin, Klabunde, Green, Barlow, & Wright., 2006; Lawthers et al., 2000; Southern, Quan, & Ghali, 2004; Yan, Birman-Deych, Radford, Nilasena, & Gage, 2005). Failure To Rescue has been calculated using similar algorithms of inclusion and exclusion codes applied to administrative datasets. As reported by Needleman et al., the use of exclusion conditions increases when clearly identified present-on-admission codes are not present and results in decreased identification of valid cases (Needleman & Buerhaus, 2007). The lack of precision for these processes has been a limitation to researchers and some published studies have attempted to quantify the magnitude of the issue.

Horwitz, Cuny, Cerese, and Krumholz evaluated the accuracy of the AHRQ FTR algorithm in a study of 2,354 FTR cases from 40 hospitals (Horwitz, Cuny, Cerese, & Krumholz., 2007). From the administrative data of these patients, 3,073 complications were identified that

matched the definitions by AHRQ to qualify for FTR. The charts were reviewed for accuracy to compare to the FTR coding algorithm determination. Findings revealed that the algorithm correctly identified only 1,193 cases, 50.7% of the sample. Of the 3,073 complications identified by the algorithm, it was determined that 29.5% of those were actually present upon admission to the hospital. Based on the limitations identified by these results, the researchers concluded FTR may be of use as an internal measure but is lacking for comparing facilities, and improvements in coding are needed.

Talsma, Bahl, and Campbell conducted a similar study to evaluate the precision of the AHRQ algorithm to identify FTR cases (Talsma, Bahl, & Campbell, 2008). From their sample, they randomly selected cases for review to validate the findings. Out of the 45 randomly selected cases for review, 31.1% had questionable documentation to validate the algorithm's identification of the case as FTR. In an internal evaluation at the study hospital, the Talsma research team also found that up to 43% of FTR cases had complications identified as occurring during hospitalization but were actually present upon admission. These researchers concluded from their findings that multiple variables, especially current health problems and comorbidities, influenced FTR status and survival.

In a subsequent study, Talsma and colleagues took a random sample of FTR cases from six hospitals across a three year time span (Talsma, Jones, Liu, & Campbell, 2010). Using chart review, they verified the identified FTR complications in 75.5% of the sample of 461 records. In 228 of these records, 49.5% of the FTR complications were identified as being present upon admission. The research team felt that the finding "will assist clinical leadership in determining targeted intervention to early identify and treat complications that are POA [present on admission]" (p. 421). These researchers recommended that more investigation is needed "to better understand the clinical trajectory of specific cases upon admission to the hospital" (p. 422).

Moriarty and colleagues analyzed discharges using administrative data and the AHRQ and NQF algorithms (Moriarty, Finnie, Johnson, Huddleston, & Naessens, 2010). Like others, these researchers found the algorithm identified cases as FTR and complication acquired during hospitalization, but the condition was actually present upon admission. These authors concluded that existing FTR definitions identify present-on-admission conditions as complications of care during hospitalization and reviewing charts may be necessary to substantiate findings. Flagging complications as present-on-admission versus hospital-acquired enhances clarity and helps to focus process improvement efforts (Naessens, Scott, Huschka, & Schutt, 2004). As studies have demonstrated, algorithms may identify cases where the condition was actually present upon admission to the hospital, and thus the accuracy of these algorithms is not assured.

Effective October 1, 2008, the Centers for Medicare and Medicaid Services changed hospital International Classification of Diseases 9th Edition, Clinical Modification (ICD-9-CM) reporting requirements for diagnosis codes. A qualifier now has to be added to the diagnosis code to indicate if the condition was present-on-admission (Centers for Medicare and Medicaid Services, n.d.). As a result, diagnoses present upon admission to the hospital can now be easily differentiated in administrative data from those acquired during hospitalization. The change in coding methodology eliminates the need to use algorithms for identifying present-on-admission conditions from other diagnosis codes.

2.4 Summary

There has been much research activity related to FTR since the 1992 publication by Silber et al. (Silber et al., 1992) and the 1995 MET publication by Lee et al. (Lee et al., 1995). Since its original inception in 1992 as a comparative quality measure, Failure To Rescue has evolved with changes in defining criteria and measurement methodologies. The original focus, the failure of hospital-delivered care to rescue a patient experiencing a complication, remains a consistent thread in spite of these variations. Although early work primarily concentrated on

post-surgical patients, the FTR phenomenon has also been applied to the medical patient population. Early recognition and timely response are regarded as cornerstone interventions to address FTR and thus avoid patient harm and death. The development and deployment of rapid response systems like medical emergency, rapid response, and critical care outreach teams provided resources that answered that need for early response and recognition in patients experiencing clinical deterioration. Subsequent studies and publications have provided additional information, experiences, and findings on both topics. Findings however have not always been consistent across publications. Rapid response systems have grown nationally and internationally and have been advocated by various agencies and organizations as a key patient safety initiative. All these efforts contribute to the overall goal to minimize or prevent adverse patient outcomes by recognizing and responding sooner to avoid patient harm, FTR, and death.

Prevention of FTR focuses on early recognition and timely response to variations in the patient's physiologic status. RRT/MET is recommended as an intervention for responding to those physiologic deviations. The general activation criteria for RRT/MET primarily focus on acute physiologic derangements such as vital signs. Consideration of intrinsic patient characteristics is not included. The significance and influence of intrinsic present-on-admission patient factors with patient risk for adverse outcomes has been established. As such, these variables need to be explored to determine their role and contribution to patient risk for needing a RRT intervention during hospitalization.

A review of relevant literature did not identify any major works focusing on intrinsic present-on-admission patient factors and their relationship to the risk for RRT during hospitalization. Based on studies done to date, there is a gap in the literature regarding patient present-on-admission factors, their association with needing a rapid response team intervention while hospitalized, and the level of influence on that risk. Publications have focused primarily on staff variables, the environment, and MET/RRT experience and outcomes. What remains

unanswered is why some patients on a given unit or in a particular hospital experience MET/RRT whereas others do not. Assuming that staff variables, the environment, and the availability of MET/RRT are similar or uniform on a nursing unit or within a particular facility, then what is the missing differentiating factor? It may possibly be intrinsic present-on-admission factors unique to the patient that create risk. Knowing if such significant factors exist could provide health care providers with additional insight and guidance in planning patient care and surveillance. Consequently, the approach for patients at higher risk for MET/RRT while hospitalized would move away from reactive to preventive and thus contribute to the avoidance or minimization of patient harm, FTR, and death.

CHAPTER 3

METHODS AND PROCEDURES

The purpose of this study was to describe and explore the commonalities, differences, and associations of selected intrinsic present-on-admission patient factors among RRT and non-RRT patients. Additionally, the influence of these factors on the risk for RRT during hospitalization was investigated. Analytic methods included descriptive statistics and logistic regression.

3.1 Research Design

This study was a secondary analysis of existing administrative hospital data. To address the questions of the study, descriptive statistics (counts, percents, means, and standard deviations) and univariable and multivariable logistic regression were computed using SPSS. The study variables for discharged adult inpatients were acquired from the medical center's administrative database. Variables obtained from that source included demographic data, situational data such as admit source (e.g., via Emergency Department), and ICD-9-CM present-on-admission (POA) diagnosis codes. RRT events for the study were obtained from the medical center's RRT spreadsheet along with RRT activation reasons and number of calls per patient.

3.2 Sample

The sample for this study was composed of adult inpatients, 18 years of age and older.

All the patients were discharged over three consecutive months. Subjects were further subdivided based on whether or not an RRT intervention was needed during hospitalization.

The medical center also uses the RRT program to address some additional specialized situations identified by the facility such as hyperkalemia, possible septic patient in the Emergency Department, and family activated calls. These unique situations were not included

in the study because they do not represent typical activation criteria found in most hospitals. If such facility-specific RRT calling criteria were included, these data could confound results and be a threat to external validity. The inclusion and exclusion criteria for this study are summarized in Table 3.1.

Table 3.1 Inclusion and Exclusion Criteria

Inclusion	Adult inpatients, 18 years of age or older, and discharged between October
Criteria	1, 2008 and December 31, 2008
	Unique facility-specific developed RRT calling criteria caseshyperkalemia,
Exclusion Criteria	possible septic patient in Emergency Department, family activated calls
	RRT false calls

3.3 Setting

The setting for this study was a major urban medical center in the southwest United States that has approximately 1,000 licensed beds. It has additional attributes such as Magnet hospital status by the American Nurses Credentialing Center, Level I Trauma Center designation by the American College of Surgeons, and certifications from the Joint Commission for Disease-Specific Care. Average inpatient discharges per month are approximately 3,000 and provide for a diverse patient population. Sources for admission include elective, unplanned from the emergency department, or planned transfers from other hospitals and facilities. Additionally, the medical center is an academic setting for medical students, interns, residents, fellows and nursing students, both undergraduate and graduate.

The medical center's RRT program was initiated in May 2005 and consists of an adult critical care unit registered nurse and a respiratory therapist who follow defined care protocols based on assessed patient need. Table 3.2 lists key trigger criteria the facility uses as a guideline for when health care providers need to summon RRT and is consistent with rapid response programs in general.

Table 3.2 Medical Center's RRT Activation Criteria

	- requiredery distress/progressive dyennes
	respiratory distress/progressive dyspnea
	respiratory rate less than or equal to 8 breaths per minute or more than
Respiratory	or equal to 28 breaths per minute
Compromise	
	oxygen saturation less than 90 percent on oxygen
	threatened airway
	systolic blood pressure less than 90
	heart rate greater than or equal to 120
Circulatory	a new anget bradygardia beart rate loss than 60
Circulatory	new onset bradycardia, heart rate less than 60
Compromise	symptomatic bradycardia (with decreased systolic blood pressure less
	than 90 and/or diaphoresis and/or chest pain)
	excessive bleeding
	Ŭ
Neurological	decreased responsiveness or level of consciousness (new or
	persistent)
Compromise	agitation or delirium (new or persistent)
	uncontrolled pain despite treatment
Other	need to obtain more rapid assistance
	if you are concerned and need a second opinion about your patient
	· , , , , ,

3.4 Data Obtained from Medical Center Resources

Data from adult inpatients discharged between October 1, 2008 and December 31, 2008 were obtained from the medical center's administrative database. The administrative database receives information electronically from other systems such as the patient admissions system and the health information management department's coding system. The requested study variables were: age, gender, race/ethnicity, admit source, payer source, ICD-9-CM

Present-On-Admission diagnosis codes with description, length of stay, and discharge disposition. The patient list was examined for subject inclusion criteria.

A list of RRT calls occurring for the adult inpatients discharged between October 1, 2008 and December 31, 2008 was obtained from the medical center's RRT patient list. The medical center's RRT list is maintained in a separate stand alone electronic spreadsheet and also includes the reasons for and incidence of RRT activation. The RRT list was examined for exclusion criteria--unique facility-specific RRT called cases and false calls. In addition to the administrative database study variables, two additional data elements were obtained from the RRT patient list for the RRT subjects. First was the reason the RRT was activated and second was the number of RRT calls per patient during a single inpatient hospitalization. Table 3.3 lists all the study variables and associated data sources.

Table 3.3 List of Data Sources and Associated Study Variables

RRT Patient List	Number of RRT Calls per RRT Subject
	Reasons for RRT Activation
	Age
	Gender
	Race/Ethnicity
Administrative Database	Admit Source
	Payer Source
	ICD-9-CM Present-On-Admission Diagnosis Codes
	Length of Stay
	Discharge Disposition

3.5 Procedure

Institutional Review Board (IRB) approval was granted and data were then requested and obtained from the identified sources. A secondary analysis of these existing data was performed.

3.5.1. Data Acquisition

A list of all adult inpatients discharged between October 1, 2008 and December 31, 2008 along with the study variables (Table 3.3) for each subject was obtained from the medical center's administrative database. A separate list of RRT calls along with reasons for and incidence of RRT activation was obtained from the medical center's RRT patient list.

3.5.2. Data Processing

Data spreadsheets were imported into a database program built specifically for the study by this researcher. Data integrity was evaluated by randomly selecting records in the database for comparison back to the spreadsheets to verify accuracy of data import. Additionally, the database was evaluated for blank fields, unusual values, and duplicate entries through a series of queries. After data import integrity was verified, the spreadsheets were deleted. The subject list was reviewed for inclusion and exclusion criteria. All subjects met the inclusion criteria. Only one data issue was identified. Just over 100 subjects had "Unknown" listed for race/ethnicity and, as a result, did not allow for coding as Race/Ethnicity Non-White Yes (1) or No (0). These cases were removed from the research dataset because race/ethnicity was a predictor variable in the regression model.

The RRT list was reviewed for any unique facility-specific calling criteria cases. Some were found and deleted. The resulting RRT list was then compared and crosschecked against the subject list using the patient account number, a unique assigned billing number and identifier for a single patient admission. RRT cases identified from the subject list were retained and the remaining RRT cases were deleted from the RRT listing. Each subject who experienced any RRT events while hospitalized per the RRT list were coded as RRT Yes (1) and all the

other subjects were coded as RRT No (0) in the subject list. The creation of RRT Yes/No as the dependent dichotomous outcome variable in the adult discharged inpatient list with the study variables allowed for computation of the descriptive statistics and univariable and multivariable logistic regression.

The resulting subject list met inclusion and exclusion criteria and differentiated those subjects who required RRT while hospitalized (RRT) from those who did not (non-RRT). Each record in the subject list along with the study variables was unique. There were no multiple entries for the same patient record thus the assumption of independent observations was met. The resulting RRT list included only those cases that matched a patient account number in the subject list and were not triggered by unique facility-specific calling criteria nor were a false call and also included the reasons for RRT activation.

3.5.3. Private Health Information

Patient Account Number. The patient account number was needed as a unique record identifier in working with the administrative database. For the study, a code sheet was created assigning each subject a uniquely generated code to serve in place of the account number. The researcher replaced the account number in the database with a new unique subject code. A code sheet listing the patient account number and corresponding newly assigned subject code was printed and kept separate from the electronic database in a secured file. The account numbers were deleted from the database with just the subject codes remaining. The code sheet allowed the researcher to cross reference back to the source record if any questions arose during the data analyses or issues were identified. Once all data analyses had been computed and verified, the printed code sheet was destroyed at the close of the study.

3.6 Ethical Considerations

Because this study was a secondary analysis of existing data, the Institutional Review Board was petitioned to exempt this study from full board review since the involvement of

human subjects as described by Category 4 in the Code of Federal Regulations Title 45 Part 46.101(b)(1)(4), can qualify this study for exempt status.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects (p. 3) (Department of Health and Human Services, 2009, July 14).

Additionally a petition for waiver of consent and authorization was submitted to the IRB as is allowed per the Code of Federal Regulations Title 45 Part 46.116(d)(1)-(4). This study fulfilled those criteria as follows:

(1) The research involves no more than minimal risk to the subjects; (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) The research could not practicably be carried out without the waiver or alteration; and (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation (p. 8) (Department of Health and Human Services, 2009, July 14).

Exemption status and waiver of consent were granted by the Institutional Review Boards of the university and the medical center.

3.7 Data Analyses

Data were received from the researcher-built database into SPSS for analysis. Statistics were computed to describe the study population as a whole and the two sub-sets, RRT and non-RRT subjects. These descriptive statistics included counts, percents, means, and standard deviations based on the data types, nominal and interval. Univariable and multivariable logistic regression were computed. Results were examined to determine if any of the study variables were significantly associated with risk for RRT during hospitalization and the degree of that risk. Results for predictors were reported and included unadjusted and adjusted

p-values, odds ratios, and 95% confidence intervals. Statistical methods used to answer each of the three research questions are reported in Table 3.4.

Table 3.4 Research Questions and Statistical Methods Used

Research Question	Statistical Methods
1. What are the commonalities and	Counts, Percents, Means, Standard
differences of selected demographic and	Deviations
present-on-admission patient factors for RRT	
and non-RRT patients?	
2. What selected demographic and present-	Univariable and Multivariable Logistic
on-admission factors are significantly	Regression using Predictors/Covariates
associated with risk for RRT during	and RRT Yes/No as the Dependent
hospitalization?	Dichotomous Outcome Variable
3. How do selected demographics and	
present-on-admission factors influence the	
risk for RRT during hospitalization?	

For the regression analysis, the outcome of RRT, Yes (1) or No (0), was the dependent dichotomous outcome variable. There were thirteen predictors/covariates in the regression equation. Nominal data variables were re-coded into a dichotomous format, 0 = No/Absent and 1 = Yes/Present, to allow for regression analyses. For example, gender reported in the administrative dataset as male and female was recoded to male gender as 0 for No and 1 for Yes. For Self-Pay Payer Status, subjects were coded as 1 = Yes/Present if the patient's care was not funded/covered by insurance nor any other source of third party payment (J. Whitfield, personal communication, March 1, 2012). In these instances, the patient assumed financial responsibility for all charges. These predictors are listed in Table 3.5 along with their regression equation data format.

Table 3.5 Thirteen Predictor Variables/Covariates and Data Format

Predictor Variables/Covariates			Regression Equation
Age (years)			interval
Male Gende	er	dichotomous 0 = No / 1 = Yes	
Non-White I	Race/Ethnicity		dichotomous 0 = No / 1 = Yes
Emergency	Department Admi	ssion Source	dichotomous 0 = No / 1 = Yes
Self-Pay Pa	yer Status		dichotomous 0 = No / 1 = Yes
		401.x Essential	dichotomous
	Hypertension	Hypertension	0 = Not Present / 1 = Present
	Diabetes	250.x Diabetes Mellitus	dichotomous
	Mellitus		0 = Not Present / 1 = Present
	Coronary Atherosclerosis	414.0x Coronary	dichotomous
Present-		Atherosclerosis	0 = Not Present / 1 = Present
On- Admission	Chronic Kidney	585.x Chronic Kidney	dichotomous
(POA)	Disease	Disease	0 = Not Present / 1 = Present
Conditions		272.0	dichotomous
and ICD-9-CM	Hyperlipidemia	Hypercholesterolemia 272.4 Other/Unspecified	0 = Not Present / 1 = Present
Medical		Hyperlipidemia	
Diagnosis	Heart Failure	428.x Heart Failure	dichotomous
Codes			0 = Not Present / 1 = Present
	Hypertensive	403.x Hypertensive	dichotomous
	Chronic Kidney Disease	Chronic Kidney Disease	0 = Not Present / 1 = Present
		305.1 Tobacco Use	dichotomous
	Tobacco Use	Disorder	0 = Not Present / 1 = Present

The number of covariates in regression analysis was addressed by Hosmer and Lemeshow (Hosmer & Lemeshow, 2000). They recommended a minimum of ten events for each covariate to avoid variance estimation issues. Given their ratio of ten events per covariate and the thirteen covariates for this study, 130 events were needed. The medical center experiences about 100 RRT events per month. This study evaluated three consecutive months of data which contained 242 patients experiencing an RRT while hospitalized. Thus, the expectation as put forth by Hosmer & Lemeshow was fulfilled.

3.8 Summary

The purpose of this study was to explore a selected set of intrinsic patient factors present at the time of admission for those patients who had an RRT intervention during hospitalization and those who did not. This study also described the characteristics of both groups. By computing these analyses, present-on-admission patient factors significantly associated with risk for an RRT intervention during hospitalization were identified. By conducting this study, knowledge about present-on-admission patient factors and their association with risk for RRT was increased. These initial analyses may serve as a foundation, laying the groundwork for future studies that could further increase knowledge of intrinsic present-on-admission patient factors that increase risk for RRT during hospitalization.

CHAPTER 4

RESULTS

Descriptive statistics were computed for the research sample as a whole and the RRT and non-RRT subsets. RRT events were analyzed by examining reasons for activating the team. Univariable logistic regression was computed to obtain unadjusted odds ratios for the thirteen predictor/covariate study variables. Two multivariable logistic regression models were computed, Model 1 and Model 2. Model 1 included all thirteen predictors/covariates. From Model 1, five of the thirteen variables were retained and multivariable logistic regression was recomputed to produce Model 2.

4.1 Research Sample

The original sample consisted of 9,328 patients. All were adult inpatients, 18 years of age or older, and consecutively discharged between October 1 and December 31, 2008, inclusive. Of the 9,328 patients, 103 had "Unknown" listed for race/ethnicity. Because the information was not available and the variable was a predictor/covariate in the regression model, those patients were removed from the sample. The final research sample consisted of 9,225 patients with 64,428 present-on-admission diagnosis codes. There were 8,983 patients (97.4%) who had no RRT during hospitalization and 242 (2.6%) who experienced RRT while hospitalized.

Descriptive statistics for this study's predictor/covariate study variables for the total research sample are listed in Table 4.1. Ages ranged from 18 to 107 years with a mean of 54.1 ± 19.3. Male gender (40.2%), non-white race/ethnicity (38.3%), and self-pay payer status (9.2%) were each in the minority. The composition of race/ethnicity for the total research sample is detailed in Table 4.2. Over half of the research sample's race/ethnicity was white. Among non-whites, Black Non-Hispanic/Non-Latino was the largest group. For insured patients, almost 80%

of the sample was comprised of two primary payer categories--managed care and Medicare. Almost half the sample, 46.5%, was admitted from the Emergency Department. The primary source for all other admissions was physician referral. Of the eight present-on-admission conditions, three were present in over one-fifth of the sample--hypertension (37.9%), diabetes mellitus (21.4%), and hyperlipidemia (21.2%).

Table 4.1 Thirteen Predictor/Covariate Study Variables for Total Research Sample

Predictor/Covariate Study Variables			Research Sample	
	<i>N</i> = 9,225 Patients			
Age (years)	X□		54.1 (<i>SD</i> 19.3)	
Male			3705 (40.2%)	
Non-White F	Race/Ethnicity		3536 (38.3%)	
Emergency	Department Admission So	urce	4290 (46.5%)	
Self-Pay Pa	yer Status		846 (9.2%)	
Present-	Hypertension	401.x Essential Hypertension	3498 (37.9%)	
on-	Diabetes Mellitus	250.x Diabetes Mellitus	1972 (21.4%)	
Admission	Coronary	414.0x Coronary	1410 (15.3%)	
Conditions	Atherosclerosis	Atherosclerosis		
and	Chronic Kidney Disease	585.x Chronic Kidney	1132 (12.3%)	
ICD-9-CM		Disease		
Medical	Hyperlipidemia	272.0 Hypercholesterolemia	1959 (21.2%)	
		272.4 Other/Unspecified		
Diagnosis		Hyperlipidemia		
Codes	Heart Failure	428.x Heart Failure	1140 (12.4%)	
	Hypertensive Chronic	403.x Hypertensive Chronic	954 (10.3%)	
	Kidney Disease	Kidney Disease		
	Tobacco Use	305.1 Tobacco Use Disorder	1375 (14.9%)	

x□ Mean SD Standard Deviation

Table 4.2 Race/Ethnicity for Total Research Sample

Race/Ethnicity Category	Research Sample
	N = 9,225 Patients
American Indian/Alaskan Hispanic/Latino	6 (.1%)
American Indian/Alaskan Non-Hispanic	7 (.1%)
Asian Hispanic/Latino	29 (.3%)
Asian Non-Hispanic/ Non-Latino	77 (.8%)
Black Hispanic/Latino	1 (.0%)
Black Non-Hispanic/Non-Latino	2253 (24.4%)
Hawaiian/Pacific Islander Hispanic/Latino	4 (.0%)
Hawaiian/Pacific Islander Non-Hispanic	1 (.0%)
Hispanic	6 (.1%)
Hispanic/Latino Other	77 (.8%)
Hispanic/Latino White	901 (9.8%)
Other Non-Hispanic/Non-Latino	174 (1.9%)
Caucasian	8 (.1%)
White Non-Hispanic/Non-Latino	5681 (61.6%)

4.2 Rapid Response Team (RRT) Events

There were 242 patients, representing 2.6% of the patients in the total research sample, who experienced 274 RRT events while hospitalized. There was a total of 373 activation reasons cited for the 274 RRT events. Of these RRT patients, 211 (87.2%) experienced only one RRT event during hospitalization. Thirty RRT patients (12.4%) had two RRT events during their hospitalization and one (.4%) had three. For each RRT event, one or more activation reasons were cited and included staff worried, chest pain, other, or a change in heart rate, blood pressure, respiratory status, oxygen saturation, or level of consciousness. For the 274 RRT

events, a total of 373 activation reasons were cited and are listed in Table 4.3. Staff worried and change in respiratory status were the most frequent activation reasons at 21.2% each. Respiratory issues, change in respiratory status and oxygen saturation, accounted for 36.5% of all activation reasons cited. The numbers of activation reasons per RRT event are listed in Table 4.4. The majority of RRT events, 195 (71.2%), had only one activation reason cited. For RRT events that had only one activation reason cited, change in respiratory status was the most frequent occurrence at 23.1%. Respiratory issues--change in respiratory status and oxygen saturation--accounted for 39% of all the single activation reasons. An analysis of the RRT events with only one activation reason is listed in Table 4.5.

Table 4.3 All RRT Activation Reasons

RRT Activation Reasons	Frequency	Individual Percent	Cumulative Percent
		of 373 Activation	of 373 Activation
		Reasons	Reasons
Staff Worried	79	21.2%	21.2%
Change in Respiratory Status	79	21.2%	42.4%
Change in Oxygen Saturation	57	15.3%	57.6%
Change in Level of Consciousness	57	15.3%	72.9%
Change in Blood Pressure	35	9.4%	82.3%
Change in Heart Rate	28	7.5%	89.8%
Other	25	6.7%	96.5%
Chest Pain	13	3.5%	100.0%

Table 4.4 Numbers of RRT Activation Reasons per RRT Event

RRT Activation Reasons	Frequency of 274 RRT Events
1	195 (71.2%)

Table 4.4 - Continued

2	60 (21.9%)
3	18 (6.6%)
4	1 (0.4%)

Table 4.5 RRT Activation Reasons for 195 RRT Events with Only One RRT Activation Reason

RRT Activation Reasons	Frequency
Change in Respiratory Status	45 (23.1%)
Staff Worried	38 (19.5%)
Change in Oxygen Saturation	31 (15.9%)
Change in Level of Consciousness	30 (15.4%)
Change in Blood Pressure	18 (9.2%)
Change in Heart Rate	16 (8.2%)
Other	14 (7.2%)
Chest Pain	3 (1.5%)

4.3 Descriptive Statistics for RRT and non-RRT Study Variables

The total research sample was divided into two subsets--patients who experienced an RRT event while hospitalized and those who did not. There were 8,983 non-RRT patients representing 97.4% of the total research sample. RRT patients numbered 242 and comprised 2.6% of the total research sample. Descriptive statistics for each subset are listed in Table 4.6.

The mean age for non-RRT patients was 53.9 ± 19.3 years with a range from 18 to 107. Male gender and non-white race/ethnicity were each less than half of the non-RRT subset. The number admitted from the Emergency Department approached half at 46.3%. Just less than 10% were self-pay payer status. Of the eight present-on-admission conditions, three were each present in over one-fifth of the sample--hypertension, diabetes mellitus, and hyperlipidemia. The

remaining five--hypertensive chronic kidney disease, chronic kidney disease, heart failure, tobacco use, and coronary atherosclerosis--ranged from 10.2% to 15.1% in the non-RRT subset.

RRT patients had a mean age of 63.1 ± 17.4 years and ranged from 18 to 96. Male gender and non-white race/ethnicity were each less than half for the RRT subset. Over half of RRT patients, 52.9%, were admitted from the Emergency Department. The prevalence of self-pay payer status was low for the RRT subset at 3.7%. Six of the eight present-on-admission conditions were each present in over one-fifth of the RRT patients--hypertension, diabetes mellitus, coronary atherosclerosis, chronic kidney disease, hyperlipidemia, and heart failure. The remaining two--hypertensive chronic kidney disease and tobacco use--approached 20% each.

Table 4.6 Thirteen Predictor/Covariate Study Variables for Non-RRT and RRT Patients

Predictor/Cova	ariate Study Variable	s	Non-RRT	RRT
			Patients	Patients
				n = 242
			(97.4%)	(2.6%)
Age (years) x			53.9	63.1
			(19.3 SD)	(17.4 SD)
Male		3595 (40.0%)	110 (45.5%)	
Non-White Race/Ethnicity		3448 (38.4%)	88 (36.4%)	
Emergency Department Admission Source		4162 (46.3%)	128 (52.9%)	
Self-Pay Payer Status		837 (9.3%)	9 (3.7%)	
Present-on-	Hypertension	401.x Essential	3404 (37.9%)	94 (38.8%)
Admission		Hypertension		
Conditions	Diabetes Mellitus	250.x Diabetes Mellitus	1901 (21.2%)	71 (29.3%)

Table 4.6 - Continued

and	Coronary	414.0x Coronary	1352 (15.1%)	58 (24.0%)	
ICD-9-CM	Atherosclerosis	Atherosclerosis			
Medical	Chronic Kidney	585.x Chronic	1079 (12.0%)	53 (21.9%)	
Diagnosis	Disease	Kidney Disease			
Codes	Hyperlipidemia	272.0	1905 (21.2%)	54 (22.3%)	
		Hypercholesterolemia			
		272.4			
		Other/Unspecified			
		Hyperlipidemia			
	Heart Failure	428.x Heart Failure	1091 (12.1%)	49 (20.2%)	
	Hypertensive	403.x Hypertensive	913 (10.2%)	41 (16.9%)	
	Chronic Kidney	Chronic Kidney			
		Disease			
	Disease				
	Tobacco Use	305.1 Tobacco Use	1332 (14.8%)	43 (17.8%)	
		Disorder			

x ☐ Mean SD Standard Deviation

4.4 Logistic Regression

All of the 13 predictors/covariates used in the regression computations were nominal measures except for age which was an interval measure. The nominal measures were coded dichotomously as 1 for Yes or 0 for No to indicate presence of the variable. Logistic regression was computed with RRT as the dependent dichotomous outcome where 1 was RRT and 0 was no RRT.

Univariable logistic regression was computed for each of the 13 predictors/covariates to produce unadjusted odds ratios and *p*-values. These results are listed in Table 4.7. Eight of the predictors/covariates were each significant at the .05 level and included age, admission from the Emergency Department, self-pay payer status, diabetes mellitus, coronary atherosclerosis, chronic kidney disease, heart failure, and hypertensive chronic kidney disease. The unadjusted

odds ratio for these eight indicated that all increased risk except for self-pay payer status which indicated a reduction in risk. Hosmer and Lemeshow propose using a p-value of < .25 to select variables from the univariable results for use in the multivariable model "along with all variables of known clinical importance" (p. 95) (Hosmer & Lemeshow, 2000). Using p < .25, male gender and tobacco use were added to the eight predictors/covariates significant at the .05 level. Three variables--non-white race/ethnicity, hypertension, and hyperlipidemia--exceeded .25. Because this analysis was an initial exploratory study and used results from the pilot RRT study by this researcher, all 13 predictors/covariates were selected for entry in the multivariable logistic regression model. Model 1 was computed to produce adjusted odds ratios and p-values. Results for Model 1 are listed in Table 4.7.

Three predictors/covariates in multivariable Model 1 were significant at the .05 level and included age, self-pay payer status, and tobacco use. Following variable selection of Bursac et al., significance was evaluated for Model 1 at the .10 level (Bursac, Gauss, Williams, & Hosmer, 2008). Using this alpha level resulted in selection of five predictors/covariates for multivariable logistic regression for Model 2. The retained five variables included age, self-pay payer status, tobacco use, chronic kidney disease, and hyperlipidemia. Multivariable Model 2 was computed using these five predictors/covariates. Adjusted odds ratios and *p*-values for Model 2 are listed in Table 4.8. Three predictors/covariates in Model 2 were significant at the .05 level--age, chronic kidney disease, and tobacco use. Adjusted odds ratios indicated that each of these variables significantly increased patients' risk for RRT during hospitalization.

Table 4.7 Unadjusted and Adjusted (MODEL1) Odds Ratios for Thirteen Study Predictors/Covariates

Predictors/Covariates		Unadjusted	р	Adjusted	р
		Odds Ratio		(MODEL 1)	
		(95.0% CI)		Odds Ratio	
				(95.0% CI)	
Age (years)		1.026 (1.019-1.033)	< .001	1.025 (1.016-1.034)	< .001
Male		1.249 (.966-1.614)	.089	1.116 (.856-1.453)	.417
Non-White Race/Ethnicity		.917 (.704-1.196)	.524	1.020 (.760-1.368)	.897
Emergency Department		1.301 (1.007-1.680)	.044	1.029 (.772-1.371)	.845
Admission Source					
Self-Pay Payer Status		.376 (.192734)	.004	.488 (.241990)	.047
Present-	Hypertension	1.041 (.801-1.353)	.764	.801 (.581-1.106)	.178
on-	Diabetes	1.547 (1.168-2.049)	.002	1.238 (.914-1.678)	.167
Admission	Mellitus				
Conditions	Coronary	1.779 (1.317-2.403)	< .001	1.170 (.835-1.640)	.361
	Atherosclerosis				
	Chronic Kidney	2.054 (1.505-2.804)	< .001	1.767 (.945-3.306)	.075
	Disease				
	Hyperlipidemia	1.067 (.785-1.450)	.678	.727 (.524-1.009)	.057
	Heart Failure	1.837 (1.334-2.529)	< .001	1.109 (.776-1.586)	.569
	Hypertensive	1.803 (1.280-2.540)	.001	.664 (.349-1.265)	.213
	Chronic				
	Kidney Disease				
	Tobacco Use	1.241 (.888-1.735)	.206	1.475 (1.040-2.090)	.029

CI Confidence Interval

Table 4.8 MODEL 2 - Multivariable Logistic Regression

Predictors/Covariates	Adjusted Odds Ratio (95.0% CI)	р
Age	1.025 (1.017-1.033)	< .001
Self-Pay Payer Status	.506 (.254-1.010)	.053
Chronic Kidney Disease	1.636 (1.190-2.247)	.002
Hyperlipidemia	.749 (.547-1.026)	.072
Tobacco Use	1.528 (1.084-2.153)	.015

CI Confidence Interval

4.5 Summary

The first research question focused on describing commonalities and differences of the selected 13 study variables for RRT and non-RRT patients. The research sample was comprised of 9,225 adult inpatients of which 8,983 (97.4%) had no RRT event during hospitalization and 242 (2.6%) did. The 242 RRT patients had a total of 274 RRT events. The majority of the RRT patients, 87.2%, had only one RRT event during hospitalization. The overall most common activation reasons for RRT were staff worried and change in respiratory status. The majority of RRT events, 71.2%, had only one activation reason and the most common one was change in respiratory status.

Non-RRT patients were on average 53.9 years old. The majority of these patients were female, of white non-Hispanic/non-Latino race/ethnicity, and not admitted through the Emergency Department. The majority had some type of health insurance coverage. Of the eight present-on-admission conditions, only three--hypertension, diabetes mellitus, and hyperlipidemia--were each present in more than 20% of these patients. Hypertensive chronic kidney disease, chronic kidney disease, heart failure, tobacco use, and coronary atherosclerosis were present in these non-RRT patients from 10.2% to 15.1%. RRT patients were on average 63.1 years old. The majority of these patients were female and of white non-Hispanic/non-Latino race/ethnicity. Just over half were admitted through the Emergency Department. The majority

had some type of health insurance coverage. Six out of the eight present-on-admission conditions were each present in more than 20% of these patients--hypertension, diabetes mellitus, coronary atherosclerosis, chronic kidney disease, hyperlipidemia, and heart failure. The remaining two, hypertensive chronic kidney disease and tobacco use, were almost at 20% each.

The second and third research questions focused on exploring if any of the 13 study variables were significantly associated with patient risk for an RRT during hospitalization and, if so, what was the degree of influence on that risk. Using the 13 predictor/covariate study variables, univariable and multivariable logistic regression were computed with RRT as the dependent dichotomous outcome variable. After univariable logistic regression, multivariable logistic regression was computed using the 13 predictors to yield Model 1. From Model 1, five of the original 13 predictors/covariates were selected for Model 2. Multivariable logistic regression was recomputed with these five predictors/covariates to produce Model 2.

In Model 2, three of the predictors/covariates were significant at the .05 level--age, chronic kidney disease, and tobacco use. The adjusted odds ratio for age was 1.025 (95% CI = 1.017-1.033) indicating that for every one year increase in age, patients were 1.025 times as likely (2.5% more likely) to have an RRT event during hospitalization. The adjusted odds ratios for present-on-admission chronic kidney disease was 1.636 (95% CI = 1.190-2.247) and tobacco use 1.528 (95% CI = 1.084-2.153). These results indicated that patients with chronic kidney disease present-on-admission were 1.636 times as likely (63.6% more likely) to have an RRT event during hospitalization than those without the condition. Patients using tobacco at the time of admission were 1.528 times as likely (52.8% more likely) to have an RRT event during hospitalization than those not using tobacco. These results indicated that significant intrinsic patient factors present-on-admission existed that increased patients' risk for an RRT event during hospitalization.

CHAPTER 5

CONCLUSIONS AND IMPLICATIONS

5.1 Conclusions

Findings of this study indicated that intrinsic present-on-admission patient factors existed that significantly increased the risk for RRT during hospitalization. Three of the predictors/covariates--age, chronic kidney disease, and tobacco use--from Model 2 were significant at the p < .05 level. The multivariable logistic regression results indicated that for each one year increase in age, patients were 2.5% more likely to experience an RRT event while hospitalized. For patients with chronic kidney disease and tobacco use present upon admission to the hospital, multivariable logistic regression results indicated increased risk for an RRT event while hospitalized by 63.6% and 52.8% respectively. These significant findings were not unexpected as age and comorbid conditions have been associated with adverse patient outcomes such as death, complications, and Failure To Rescue. The association of such intrinsic present-on-admission patient factors with risk for an RRT event during hospitalization has not been previously studied based on a critical review of relevant literature.

Age is a long-standing, well-known, non-modifiable risk factor. The finding in this study that age was a significant predictor for increased risk was not unexpected. In the adjusted odds ratios for both Model 1 and Model 2, age was significant at the p < .001 level. In the landmark study that introduced Failure To Rescue, Silber et al. also had a similar finding (Silber et al., 1992). In a study of elective surgical patients, Silber and his research team computed multiple logistic regression for a set of patient characteristics. Their results indicated that age significantly increased the risk for death, complications, and Failure To Rescue. lezzoni et al. also found that age increased the risk for in-hospital complications (lezzoni et al., 1994a). Another research team noted in their sample that patients over 70 years of age accounted for

most FTR events (Bobay et al., 2008). When the age limit was changed to 50 or greater, the broader group of patients comprised just over 90% of the FTR events.

As a present-on-admission comorbid condition, chronic kidney disease was not an unexpected finding as a significant predictor for increased RRT risk during hospitalization. In Model 1, chronic kidney disease had a p-value of .075 and was selected for Model 2 using an alpha of < .10. In Model 2, the p-value for chronic kidney disease was .002. Silber et al. studied five specific comorbid conditions in relation to death, complications, and FTR (Silber et al., 1992). Results from the study indicated that diabetes mellitus, stroke, congestive heart failure, and chronic obstructive pulmonary disease significantly increased risk for complications, but not for death or FTR. While Silber did not specifically study kidney disease, his results demonstrated the significant association of comorbid conditions with a patient's in-hospital trajectory. lezzoni et al. studied thirteen chronic conditions that included renal failure in relation to in-hospital complications and death (lezzoni et al., 1994a; lezzoni et al., 1994b). They found metastatic cancer, chronic pulmonary disease, congestive heart failure, severe chronic liver disease, diabetes with end organ damage, and nutritional deficiencies all significantly increased the risk for both in-hospital complications and death. Cancer with poor prognosis, acquired immunodeficiency syndrome (AIDS), chronic renal failure, and functional impairment increased risk for death, and coronary artery disease increased risk for complications.

Elixhauser et al. studied a set of 30 comorbid conditions that included renal failure in relation to length of stay, hospital charges, and in-hospital mortality (Elixhauser et al., 1998) and found 18 comorbid conditions that significantly increased risk for in-hospital mortality-congestive heart failure, cardiac arrhythmias, pulmonary circulation disorders, peripheral vascular disorders, chronic pulmonary disease, diabetes-complicated, renal failure, liver disease, acquired immune deficiency syndrome (AIDS), lymphoma, metastatic cancer, coagulopathy, weight loss, fluid and electrolyte disorders, alcohol abuse, and psychoses. With the population of the United States aging and living longer, there is a greater possibility that

older individuals living with chronic conditions over a longer life span will require hospitalization. The Centers for Disease Control and Prevention have reported that the aged population, 65 years and older, will double to about 71 million by 2030 and estimate that 80% have one and 50% have two or more chronic conditions (Centers for Disease Control and Prevention, 2011). Thus, there is an increased possibility of chronic comorbid conditions to be present upon admission to the hospital and to possibly add risk to the patient while hospitalized. Talsma et al. concluded from their study that comorbidities influenced FTR and mortality (Talsma et al., 2008). As noted by lezzoni et al., chronic conditions add to the vulnerability of patients in the presence of an acute illness and why such conditions need to be considered in risk prediction (lezzoni et al., 1994b).

Tobacco use has long been recognized as a health risk. This study's finding that it increased risk for RRT is not unexpected. Present upon admission tobacco use significantly increased risk for an RRT event while hospitalized in both Models 1 and 2 at *p*-value < .05,. The health risks of tobacco use have been communicated to the public over many years by the Surgeon General of the United States (Centers for Disease Control and Prevention, 2010). A frequency analysis of the most common activation reasons for RRT events in this study revealed respiratory issues to be the most prevalent reason. For all the 373 activation reasons cited, change in respiratory status and change in oxygen saturation accounted for 36.5% of all the reasons given. The majority of RRT events, 71.2%, had only one activation reason cited. For these events, change in respiratory status accounted for almost one-quarter of all the reasons cited. The primary prevalence of these respiratory activation reasons may have some possible link to the significant finding of increased RRT risk associated with tobacco use. Additionally, pulmonary comorbid conditions like chronic obstructive pulmonary disease, not a variable in this study, may also play a role as well.

There were some unexpected findings for this study. In Model 1, male gender, nonwhite race/ethnicity, admission from the Emergency Department, and seven out of the eight present-on-admission conditions were not significant predictors at the .05 level. Male gender has been significantly associated with increased risk for in-hospital complications (Silber et al., 1992). Survival and FTR were found to be worse for black patients compared to white patients in teaching hospitals (Silber et al., 2009). Admission from the Emergency Department may be viewed as a factor that could add to patient risk, but was not a significant predictor in the present study despite the fact that 52.9% of the RRT patients in this study were admitted from the Emergency Department. Results from prior studies (Elixhauser et al., 1998; lezzoni et al., 1994a; lezzoni et al., 1994b; Silber et al., 1992) indicated a significant association with certain cormorbid conditions and in-hospital death, complications, and FTR. Given results from these prior published studies, it was unexpected that only one out of the eight present-on-admission conditions identified in the pilot study was found to be a significant predictor in Model 1; however, other published studies did not examine risk associated with RRT events.

Self-pay payer status was significant at p < .05 in Model 1, but the adjusted odds ratio indicated that it reduced risk for an RRT event while hospitalized. In Model 2, it approached significance with p = .053, but again its adjusted odds ratio indicated a reduction in risk. The finding that self-pay payer status had mixed significance and its adjusted odds ratios indicated a reduction in risk was an unexpected finding, especially given reported statistics showing poorer outcomes related to FTR for the uninsured (U.S. Department of Health and Human Services, 2009).

Having an assessed patient risk level at the point of admission could contribute to better informed planning of care. Levels of care could be adjusted specific to the identified level of patient risk instead of defaulting to a uniform standard level of surveillance and vigilance for all. Having studies that establish which intrinsic present-on-admission factors contribute to risk would allow for evidence-based decision making versus a best guess or gut feel. Given current and proposed changes in healthcare reimbursement, having additional information so best choices can be made for resource utilization might contribute to cost effectiveness and

efficiency as well. Also, proactive interventions based on a risk assessment done at the point of admission might possibly avoid an RRT intervention during hospitalization and may result in enhanced patient outcomes. Consistent with the framework for this study, magnitude of risk is less when intervention is earlier. RRT serves a role as a timelier and earlier intervention as compared to the traditional resuscitation team and shares the overall goal to minimize or prevent adverse patient outcomes such as complications, FTR, or death. Assessment of patient risk at the point of admission is even earlier than waiting until an RRT intervention is needed. The RRT subjects in this study had a mean length of stay of 13.4 ± 13.9 days and 16.5% of them had a discharge status of expired. Such final discharge outcomes lend support to the need for continued study and exploration of methods for earlier identification of patients at risk so that timelier proactive interventions can be implemented.

This study examined selected intrinsic present-on-admission patient factors for non-RRT and RRT patients and the associations of those factors with the risk for an RRT intervention while hospitalized. Based on a critical review of relevant literature conducted by this researcher, this study was the first to specifically conduct such an exploration. As such, this study's results have made an initial contribution to an existing gap in knowledge about intrinsic present-on-admission patient factors and their relationship to RRT risk.

5.2 Limitations

There were several limitations for this study. Results from this study need to be considered within the context of these limitations.

Source Data. This study was a retrospective analysis of existing data. A retrospective design does not give the researcher control over the collection of the study variables. Data previously collected by other individuals may possibly lack accuracy or completeness. The medical center has processes in place to help insure data integrity. For the RRT Patient Listing, an RRT taskforce reviews these data on an on-going basis. For the administrative data, quality control mechanisms help to insure coding data quality. Monthly internal audits are conducted on

coders and all record types. Additionally, an external vendor also conducts an audit every three months (J. Kimery, personal communication, May 7, 2010). Despite the administrative data limitations, these datasets are used by researchers due to their ready availability, low cost to acquire, computer readiness, and inclusion of information on large populations (lezzoni, 1997; Miller, Elixhauser, Zhan, & Meyer, 2001; Zhan & Miller, 2003).

Setting. The setting for this study was a single medical center. The findings of the study may be unique to the study facility and not generalizable to other settings. The specific location, patient referral patterns, and patient mix of the study facility may not be typical of others; however, these attributes also provide for a broad and diverse mix of many patient types and diagnoses treated at the medical center. The sample for this study consisted of patients discharged from the medical center in the last quarter of the calendar year. If the medical center experiences seasonal trend patterns in patients then such seasonality could have had an influence on the make-up of the sample population. The effect could skew the distributions of patient factors such as present-on-admission demographics and conditions. A Canadian research team studied 52 of the most common hospital admission diagnoses in Ontario and found that 33 of these had significant moderate or strong seasonal occurrence (Upshur, Moineddin, Crighton, Kiefer, & Mamdani, 2005).

RRT Subjects. There were 242 RRT subjects representing 2.6% of the total research sample. The low percentage is a limitation. Hosmer and Lemeshow recommended a minimum of ten events for each covariate to avoid variance estimation issues (Hosmer & Lemeshow, 2000). Given their expectation, this study with 13 covariates needed a minimum of 130 events. Since there were 242 RRT subjects, that recommendation was fulfilled. False calls were excluded in this study.

Non-RRT Subjects. Some non-RRT subjects may have qualified for an RRT intervention based on established activation criteria, but such a need was not recognized and thus no RRT intervention was implemented and documented. Such a possibility could result in

not capturing the true total number of RRT patients. The time period for this study was three and one-half years after implementation of the RRT program at the medical center. Since the inception of the team, there has been active on-going education and emphasis on early recognition and response to patient deterioration and to summon the RRT. The facility's ongoing advocacy to use RRT and feedback on the program's results to end-users should have helped to minimize the impact of such a limitation.

<u>Patient Factors</u>. This exploratory study focused on selected intrinsic patient factors identified in a pilot study previously conducted by this researcher. The prior descriptive study examined and analyzed intrinsic present-on-admission factors for discharged adult inpatients who required an RRT intervention while hospitalized. There may be other intrinsic present-on-admission patient factors, not yet identified, that may influence patient risk for an RRT intervention during hospitalization.

5.3 Recommendations

This study's results identified a few intrinsic present-on-admission patient factors significantly related to increased RRT risk during hospitalization. As such, these findings may represent an initial step forward in creating a possible predictive model in the future; however, at this time it is too early for healthcare practitioners to use this study's findings as further exploration, examination, development, testing, and validation are needed. Unexpected findings from this study need additional review and study. The unusual findings related to non-white race/ethnicity and self-pay payer status definitely need further study given the known disparities in healthcare for diverse and vulnerable populations such as these.

Additional intrinsic present-on-admission patient factors, not yet identified, may also play a significant role in contributing to risk of RRT during hospitalization. Given published studies that have demonstrated a significant association between comorbid conditions and inhospital death, complications, and FTR, other comorbid conditions beyond those identified in the pilot study need to be explored. In particular, the finding in this study that the primary

activation reason for RRT was pulmonary related indicates a need to look at present-onadmission comorbid conditions of pulmonary origin. Such comorbid conditions should not be exclusively physiologic, but also include psychiatric as well. Other intrinsic present-onadmission patient factors to investigate include: actual chronologic age versus a calculated adjusted age, other admission sources (e.g., transfer from another hospital), primary reason for the hospital admission (e.g., medical issue, elective surgical procedure, emergency surgical procedure), status of comorbid condition (e.g., long-standing well-controlled, newly diagnosed erratic), readmission within 30 days of a prior hospital discharge or Emergency Department visit, nutritional status, drug use (e.g., number of medications taken; types of medicationsprescription, over-the-counter, illegal), height and weight to derive body mass index, ability to communicate with and convey needs to the healthcare team (e.g., aphasic, English as a secondary language, non-English speaker), highest level of formal education, home living conditions, occupational exposures, use of complementary/alternative therapies, and, as genetic testing continues to become more commonplace, known genetic pre-dispositions. These other intrinsic present-on-admission patient factors to explore in future studies represent recommendations from this researcher and suggestions from practitioners from the setting of this study (S. Houston, M. Leveille, K. Shuey, & A. Veenstra, personal communication, March 1 & 5, 2012).

Future studies need to include larger samples and a diverse collection of facilities and locations as a means to contribute to generalizability and develop specificity. Given the low incidence of RRT cases as compared to the total sample, other research designs such as case-control that address phenomena that are not commonplace should be considered. This study used administrative codes as the primary source for conditions. Limitations of the administrative dataset have been described, yet these large datasets have been a key source for numerous published studies across many years for large populations. With the rapid growth of the electronic health record, many intrinsic present-on-admission patient factors will be readily

available and provide ease of access to a wider variety of variables. Currently many of the data elements suggested for future study are rarely available, if at all, in administrative datasets, but the electronic health record may be the solution to this existing issue. Having such data already in electronic format will facilitate collection and analysis of large numbers of records as compared to manual individual chart review and data collection. Future studies should capitalize on this new data source and the greater number of present-on-admission data variables which will be available. Such a program of research carries the possibility of a present-on-admission risk prediction tool that could guide care decisions related to the magnitude of surveillance and vigilance a patient requires at the point of admission to the hospital and, in turn, may proactively prevent the need for an RRT event.

APPENDIX A UNIVERSITY INSTITUTIONAL REVIEW BOARD APPROVAL LETTER

July 05, 2011



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Expertise at UT Arlington

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Protocol Title: Exploratory Analysis of the Relationship between Present-

On-Admission Factors of Adult Inpatients and Risk for Needing a Rapid Response Team Intervention during

Hospitalization

RE: Exempt Approval Letter

IRB No.: 2011-0351e

The UT Arlington Institutional Review Board (UTA IRB) Chair (or designee) has reviewed the above-referenced study and found that it qualified as exempt from coverage under the federal guidelines for the protection of human subjects as referenced at Title 45 Part 46.101(b)(4). You are therefore authorized to begin the research as of <u>June 16, 2011</u>.

Please be advised that as the principal investigator, you are required to report local adverse (unanticipated) events to this office within 24 hours. In addition, pursuant to Title 45 CFR 46.103(b)(4)(iii), investigators are required to, "promptly report to the IRB <u>any</u> proposed changes in the research activity, and to ensure that such changes in approved research, during the period for which IRB approval has already been given, are **not initiated without IRB review and approval** except when necessary to eliminate apparent immediate hazards to the subject."

Be A Maverick 14

All investigators and key personnel identified in the protocol must have documented Human Subject Protection (HSP) training or CITI Training on file with this office. The UT Arlington Office of Research Administration Regulatory Services appreciates your continuing commitment to the protection of human research subjects. Should you have questions or require further assistance, please contact Robin Dickey at robind@uta.edu or you may contact the Office of Regulatory Services at 817-272-3723.

Sincerely,

Patricia Turpin
DN: postalCode=76019, o=The University of Texas at Arlington, street=701 South Nedderman Drive, st=TX, I=Arlington, c=US, cn=Patricia Turpin, email=pturpin@uta.edu
Date: 2011.07.08 17:36:31-05'00'

Patricia G. Turpin, PhD, RN, NEA-BC Clinical Associate Professor UT Arlington IRB Chair

APPENDIX B

MEDICAL CENTER INSTITUTIONAL REVIEW BOARD APPROVAL LETTER



IRB Approval - Expedited Review of New Study

To:

John F. Dixon, MSN, RN, NE-BC

Copy to:

John F. Dixon, MSN, RN, NE-BC

Date:

September 07, 2011

Re:

011-152

Exploratory Analysis of the Relationship between Present-On-Admission Factors of Adult Inpatients and Risk for Needing a Rapid

Response Team Intervention during Hospitalization

Your new proposal was reviewed by a designated member of Baylor IRB Red via expedited review.

This study was determined to be eligible for expedited review as it involves no greater than minimal risk to the subjects and fits into the following category(ies) from the 1998 approved list:

Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis)

This review included the following components:

 Study Application 		Approved as Presented
 Project Summary 	Version 1.0	09/02/2011
• Form 15	Version 1.0	09/02/2011
• Form 18	Version 1.0	08/29/2011
 Administrative Signature 	Version 1.0	08/29/2011
 Data Collection Form 	Version 1.0	08/27/2011

Your submission has been approved. The approval period begins on 09/07/2011 and expires on 09/06/2012. Your next continuing review is scheduled for 08/06/2012.

This study is approved to be conducted at the following locations: Baylor University Medical Center, Main, BUMC-Other

The following individuals are approved as members of the research team: Dixon, John F., MSN, RN, NE-BC; Houston, Susan, RN, PhD, NEA-BC; Leveille, Marygrace, PhD, RN, ACNP-BC; Marsh, Fred; Wilder, Claudia, PhD; Williams, Madaline

Based on the information provided in your submission, the IRB has determined that this study qualifies for a waiver of informed consent in accordance with 45 CFR 46.116 (d) and a waiver of HIPAA Authorization 45 CFR 160 and 164.

All events that occur on this study including protocol deviations, serious adverse events, and unanticipated problems involving risks to subjects /others, subject complaints or other similar events must be reported to the IRB in accordance with the respective policies.

Remember that this study is approved to be conducted as presented. Any revisions to this proposal and/or any of the referenced documents must be approved by the IRB prior to being implemented. Additionally, if you wish to begin using any new documents, these must receive IRB approval prior to implementation of them in the study.

IRB approval may not be the final approval needed to begin the study. All contractual, financial or other administrative issues must be resolved through Baylor Research Institute prior to beginning your study.

If you need additional assistance, please contact the IRB Coordinator at 214-820-9989.

Sincerely,

Signature applied by Lawrence R. Schiller on 09/07/2011 04:54:06 PM CDT

favience R. Schillers

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BIOGRAPHICAL INFORMATION

Dr. Dixon received his Bachelor of Arts degree in biology from Jacksonville University (Jacksonville, Florida) in 1976 and was chosen for membership in the Green Key Leadership Society of Jacksonville University and the Beta Beta Beta Biological Honor Society. In 1981, he received his Bachelor of Science in Nursing degree cum laude from Florida State University (Tallahassee, Florida) and served as president of the School of Nursing's graduating class. Also while there, he was selected for membership in Sigma Theta Tau, the International Nursing Honor Society, and the Mortar Board Honor Society and was presented with the Sigma Theta Tau Beta Pi Chapter Award of Distinction. He earned his Master's Degree in Nursing in 1990 from the University of Texas at Arlington (Arlington, Texas), functional area in nursing administration and role area in nursing administration and nursing education. While in the PhD in Nursing program at the University of Texas at Arlington, Dr. Dixon was named a University Scholar and was inducted into the Phi Kappa Phi Honor Society. With the completion of this PhD and his transition to nurse scientist, Dr. Dixon is looking forward to continuing his professional nursing career for many years to come and to be actively engaged in research.