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Early Detection and Treatment of Acute Clinical Decline in Hospitalized Patients: An Observational Study of ICU Transfers and an Assessment of the Effectiveness of a Rapid Response Program: A Dissertation

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EARLY DETECTION AND TREATMENT OF ACUTE CLINICAL DECLINE IN HOSPITALIZED PATIENTS: AN OBSERVATIONAL STUDY OF ICU TRANSFERS AND AN ASSESSMENT OF THE EFFECTIVENESS OF A RAPID RESPONSE PROGRAM

A Dissertation Presented

By

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EARLY DETECTION AND TREATMENT OF ACUTE CLINICAL DECLINE IN HOSPITALIZED PATIENTS: AN OBSERVATIONAL STUDY OF ICU TRANSFERS AND AN ASSESSMENT OF THE EFFECTIVENESS OF A RAPID RESPONSE PROGRAM: A DISSERTATION

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Clinical and Population Health Research

August 31, 2011

DEDICATIONS

To my son **Noah Thomas Emory Lord** (1/25/1995-6/14/1999) whose life birth and death from medical error changed the course of my personal and professional life. He is forever loved and forever missed.

To my Mother, **Gretchen (Kleppinger) Walsh** (1/22/1942-6/11/2007) who was always my biggest fan, constant support and always ready with a sympathetic and supportive ear. She has been a part of all my milestones and though she did not live to see this accomplishment she has still been part of it.

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ABSTRACT

The Institute for Healthcare Improvement (IHI) has promoted implementing a RRS to provide safer care for hospitalized patients. Additionally, the Joint Commission made implementing a RRS a 2008 National Patient Safety Goal. Although mandated, the evidence to support the effectiveness of a RRS to reduce cardiac arrests on hospital medical or surgical floors and un-anticipated ICU transfers remains inconclusive, partly because of weak study designs and partly due to a failure of published studies to report all critical aspects of their intervention. This study attempted to evaluate the effectiveness and the implementation of a RRS on the two campuses of the UMass Memorial Medical Center (UMMMC).

The first study presented was an attempt to identify the preventability and timeliness of floor to ICU transfers. This was done using 3 chief residents who reviewed 100 randomly selected medical records. Using Cohen's kappa to assess the inter-rater reliability it was determined that 13% of the cases could have possibly been preventable with earlier intervention.

The second study was an evaluation of the effectiveness of the Rapid Response System. Outcomes were cardiac arrests, code calls and floor to ICU admissions. There were two study periods 24 months before the intervention and 24 months after. A Spline regression model was used to compare the two time periods. Though there was a consistent downward trend over all 4 years there

were no statistically significant changes in the cardiac arrests and ICU transfers when comparing the before and after periods. There was a significant reduction in code calls to the floors on the University campus.

The third study was a modified process evaluation of the Rapid Response intervention that will assess fidelity of RRS implementation, the proportion of the intended patient population that is reached by the RRS, the overall number of RRS calls implemented (dose delivered) and the perceptions of the hospital staff affected by the RRS with respect to acceptability and satisfaction with the RRS and barriers to utilization. The process evaluation showed that that the Rapid Response System was for the most part being used as it was designed, though the nurses were not using the specific triggers as a deciding factor in making the call. Staff satisfaction with the intervention was very high.

Overall these studies demonstrated the difficulty in clearly defining outcomes and data collection in a large hospital system. Additionally the importance of different study designs and analysis methods are discussed.

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CHAPTER I
Introduction

Medical errors were the cause of an estimated 98,000 deaths in United States hospitals in 1999,[1] highlighting the urgent need to maximize patient safety and to improve the quality of inpatient care. Even in the over ten years since that first report there has been limited movement in terms of improving patient safety. Patients admitted to general medical or surgical floors are not always in monitored beds, meaning that heart and respiratory rates are not being automatically measured, recorded and evaluated by machines designed for this purpose. Because of the potential for un-witnessed cardiac arrests and other adverse clinical events, hospital inpatient medical-surgical floors have become a target for patient safety improvements.

Several studies have shown that there are some signs of patients' worsening condition hours before patients suffer cardiac arrest[2, 3] and that delays in adequate care, may be a factor in lower rates of survival.[4] These delays in care may be explained by inadequate staff training to recognize and deal with an urgent situation, inefficient systems for contacting a more experienced clinician; poor supervision of clinicians, inappropriate staffing and/or a culture that does not always support seeking help.[3]

ICU admissions are considered unanticipated if they originate from the general hospital floors rather than an operating room or emergency room. Only a few studies have assessed the frequency of potentially preventable ICU

admissions. A study done in England used two clinician assessors to determine the preventability of unanticipated ICU admissions based on a review of information in the medical records concerning the recognition, investigation, monitoring and management of abnormal cardiac or respiratory findings preceding an ICU transfer.[5] On average the two assessors considered 4.5% of the ICU admissions to be definitely avoidable, 4% probably avoidable and 36% possibly avoidable. Both assessors also agreed that 39% of the patients were admitted later in their clinical course than they should have been. The patients were divided into groups based on the assessment of suboptimal care. Group 1 included patients that had been well managed. The 2nd group included patients that the assessors agreed had received suboptimal care. The 3rd group consisted of cases about which there was disagreement between the assessors regarding the quality of care provided. Though these groups were similar in case mix, there were higher rates of mortality and late ICU admissions in the 2nd group. The assessors decided that the suboptimal care could be attributed, at least in part, to 1) failures of organizational systems, 2) staff inexperience or deficits in knowledge, 3) failure of staff to appreciate the urgency of the clinical situation, 4) lack of supervision. and 5) failure to seek advice.[3] In another study, relevant symptoms and/or significantly abnormal vital signs were observed up to eight hours earlier in 60% of the patients that were eventually transferred to the ICU from the floor.[2]

Another concern regarding ICU admissions is the timing of the transfers. Delays in transfers to the ICU, defined as having occurred over four hours after the first recognition of specific relevant physical signs, were associated with an increased mortality when compared to transfers that occurred within four hours of the documentation of the relevant signs.[6] An intervention that facilitates identification of patients early in their clinical decline could either prevent an ICU admission or facilitate a more timely admission to the ICU.

In response to this recognized threat to safer, higher quality care, Australian physicians in 1990 developed the concept of the Rapid Response System (RRS),[7] an intervention that would improve early identification of antecedents of cardiac arrest and other adverse events and provide early intervention to reverse the clinical decline associated with these signs. The term Rapid Response Team or System (RRT or RRS) is primarily used in the United States, whereas Medical Emergency Team (MET) or Critical Care Outreach Team (CCOT) is used in Europe and Australia.[8] In this Thesis the term Rapid Response System (RRS) will be used.

A RRS typically includes an individual or a team of clinicians called to the bedside when a patient's condition meets one or more criteria from a pre-determined set of physical signs and symptoms, (e.g. abnormally low or abnormally high blood pressure, heart rate, respiratory rate). A RRS can also be activated when a nurse, other hospital staff, patient or visitor has a serious concern about the patient even if physical signs are normal. When a patient's

clinical status begins to deteriorate, a chain of six decisions and events must occur to produce the optimal response to the change in condition (Figure 1.1):

1) Hospital staff must identify the change in vital signs or relevant new sign or symptom,

2) The staff must appreciate that the finding requires an urgent evaluation

3) The staff must notify the appropriate clinician/s of the urgency of the situation

4) The clinical evaluator/s must respond to the request and complete the evaluation

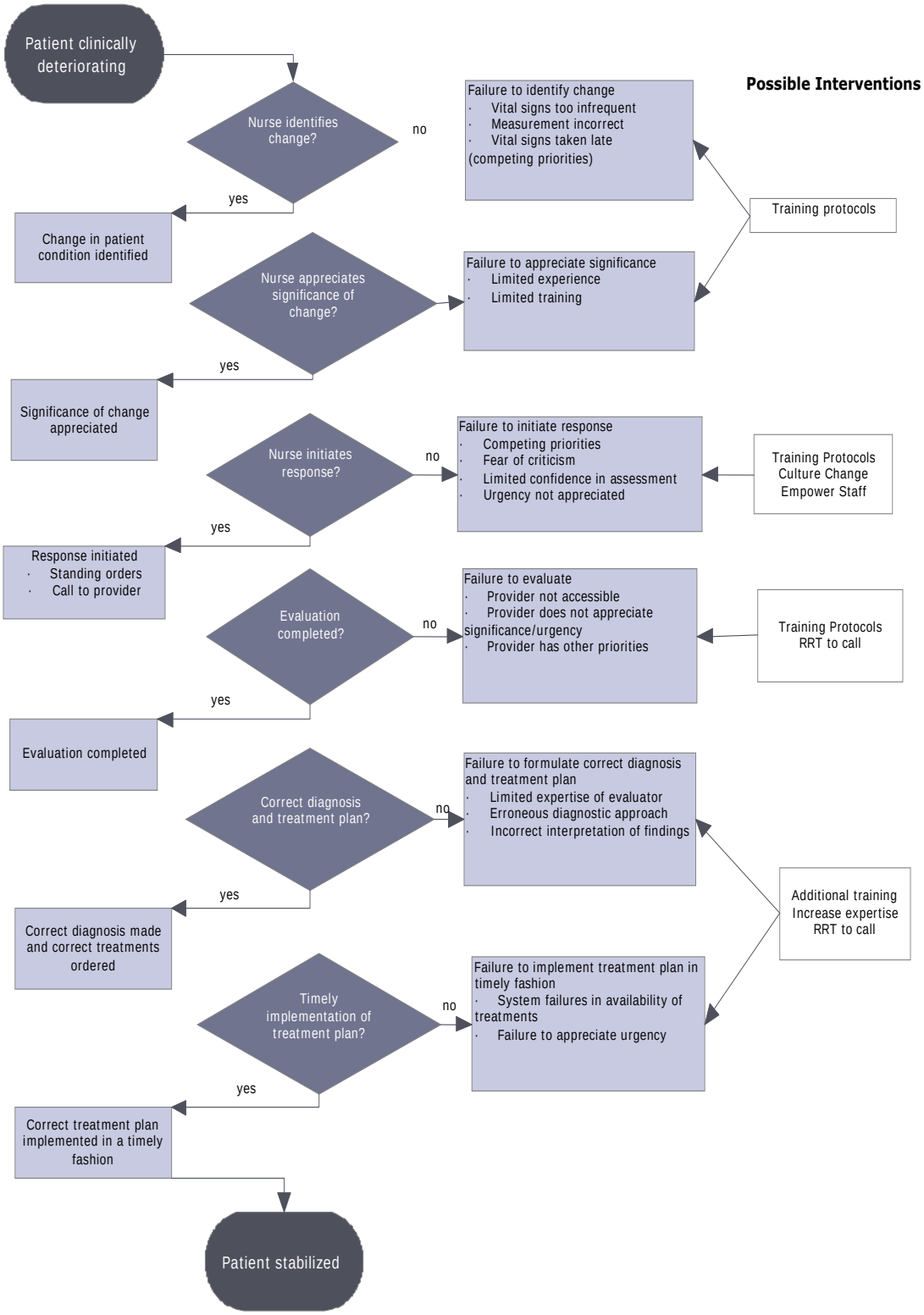
5) The evaluators must reach the correct diagnosis in a timely manner

6) The optimal treatment must be initiated in a timely manner.

RRSs are designed to prevent failures at each of the six steps in the process by:

1) Educating bedside nurses and other staff about the early signs of clinical decline
2) Empowering nurses to seek help in these situations
3) Providing a process to easily and quickly activate a team of responders
4) Assuring that the team includes the appropriate expertise and is accountable to senior clinicians
5) Educating clinicians about the appropriate diagnosis and treatment of early clinical decline, and facilitating urgent initiation of treatment
6) Providing a mechanism for the responding team to develop and implement a treatment plan

FIGURE 1.1: **Rapid Response System Conceptual Model**



RRS of various designs have increasingly been deployed by hospitals in Australia, Europe and the United States.[9] The Joint Commission on Accreditation of Healthcare Organizations made implementing a RRS a 2008 National Patient Safety Goal,[10] so there has been an interest in identifying the features of a RRS that are required to effectively and efficiently identify and treat patients in clinical decline and to determine the effect of RRS on patient outcomes

Studies of RRS interventions have been done in a variety of settings, using a variety of methods to determine the extent to which an RRS can provide safer, more efficient care. The RRS studies to date have varied widely in the methods used, analyses done and the outcomes measured. Primary outcomes for most RRS studies include unanticipated cardiac arrests; hospital wide mortality and unanticipated intensive care unit (ICU) transfers. Each of these outcomes have been studied and thought to be preventable with earlier recognition and intervention.

Anecdotal clinical and case reports indicate that hospitals with a RRS reduce cardiac arrests outside of the ICU and improve staff and patient satisfaction;[11] however, empirical evidence is somewhat limited. The only large randomized trial showed no difference between the intervention and the control hospitals, indicating that the implementation of the RRS may not have had any effect.[12] The use and effectiveness of individual RRS have been evaluated in several systematic reviews.[13-17] A Cochrane review included two published randomized

controlled trials, but excluded all of the other studies because they lacked a post-intervention control arm, which limited their ability to reach any conclusion about effectiveness.[16] Three of the reviews concluded that evidence on the effectiveness of a RRS is mixed at best and provides only moderate support for claims that RRS's improve measurable clinical outcomes.[13, 15, 17] The final review concluded that though the evidence is not strongly supportive of RRS effectiveness, there are still compelling reasons to implement a RRS.[14] All the reviewers recognized that poor quality and heterogeneity of the studies and interventions made it difficult to determine effectiveness.

Primary outcomes that have been evaluated by RRS studies include; cardiac arrest, [12, 18-37] hospital mortality rates,[19-21, 23, 24, 29, 33, 35, 36, 38] and unanticipated ICU admissions.[20, 22, 23, 33, 37] In addition to these primary outcomes, studies have evaluated the number of code calls outside of the ICU,[37, 39] changes in staffing,[23] length of stay,[19, 40] RRS calls compared to code calls,[19] and total ICU admissions.[33] There were variations in how the outcomes were defined and measured. For example cardiac arrest as an outcome was defined in four studies by specific, objective criteria, including no palpable pulse or the commencement of life support.[19, 23, 24, 33] Six other studies reported using either code calls or rates of cardiac arrest in the hospitals without further description of how these were measured.[26, 27, 29, 30, 32, 36] All the studies differed in how or if cardiac arrests were validated. The studies also varied in whether patients with do not resuscitate (DNR) orders were included and what areas of the hospitals were included in the

analysis. Similar differences in definitions and measures occurred in the other outcomes. The variability in outcomes, study design, implementation and reported components make it difficult for the studies to be compared to each other and for results to be combined in a meta-analysis.

Evaluating the effectiveness of a RRS is difficult given the differences in team memberships, the complexity and existing culture of the organizations and the many barriers to designing and implementing a strong evaluation. Primary among these barriers is the difficulty in deciding on standard definitions for the study outcomes and verifying when these definitions have been met. Currently most methods to do this are faulty and can under or over estimate the outcomes in question. For example to effectively evaluate the impact of a RRS on the incidence of in-hospital cardiac arrests inside and outside of the ICU requires a standard definition of cardiac arrest that could be used in all RRS studies. Differences in both definition and the method for measuring outcomes may explain some of the variation in the findings of RRS research.

In November the 2007 *Circulation*, the Journal of the American Heart Association, published guidelines for monitoring, reporting and conducting research on RRS.[41] The article emphasized the need for a uniform set of core and supplemental data elements to be collected and reported in RRS studies that can then be compared and combined to determine best practices and the effectiveness of RRS interventions. They provided definitions for a variety of

outcomes but still did not provide a standard method for measuring and verifying the outcomes.

There is a need for comprehensive, unbiased assessment of RRS that include the recommended measures and methodologies proposed by The First Consensus Conference on Medical Emergency Teams.[3] Ideally, well designed randomized trials would be conducted to build the RRS evidence base that is needed. However, the mandate of the Joint Commission that all accredited hospitals in the U.S. implement an RRS by January 2009 made it unacceptable in the U.S. to assign control hospitals to a non-RRS status because failure to implement an RRS would be a violation of this Joint Commission standard. Though not as strong a study design as a randomized controlled trial, before and after single site studies are the most feasible, acceptable alternative for evaluating the effectiveness of an RRS intervention in the U.S. Accounting for the change in patient case mix over time and for changes in quality improvement programs, in staffing, patient care policies and protocols, and diagnostic and treatment technologies are serious challenges inherent in this study design that few of the published RRS effectiveness studies have effectively addressed. Changes in any one of these factors from the pre to post-intervention period could have an independent effect on the outcomes being measured in an RRS study.

Patient safety initiatives such as a RRS, like other medical treatment, should be evidence-based. However, even with ambiguous evidence, experts at the

Institute for Healthcare Improvement (IHI) and the Joint Commission believe that RRS is an important factor in patient safety.[10, 11] When choosing the components of a RRS, clinicians and administrators can only rely on published research results to determine the best methods for the implementation and evaluation of the intervention.

Rapid Response Intervention at UMass Memorial Health Care (UMMMC)

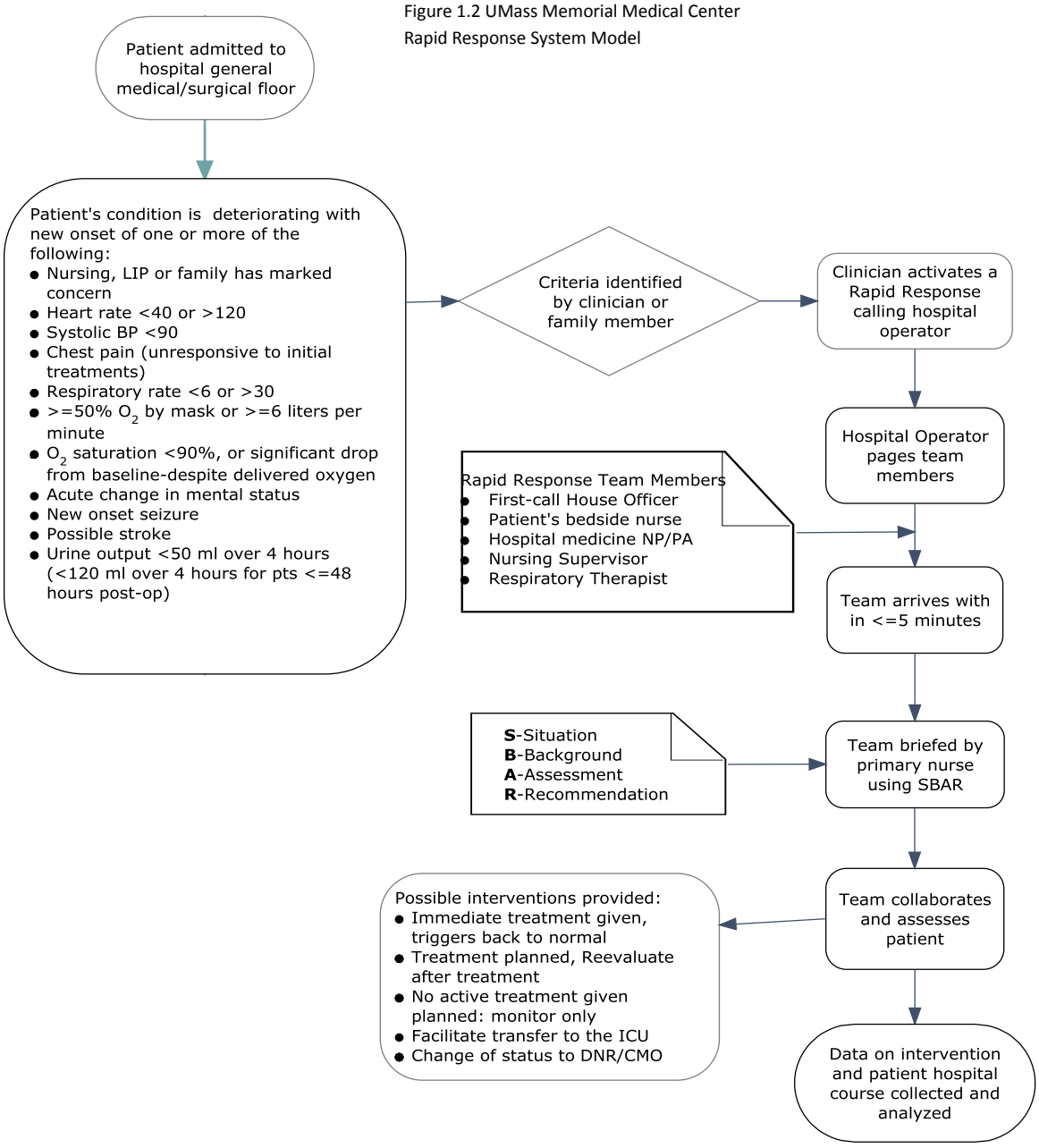
A RRS was fully implemented in January of 2009 at two UMMMC hospitals following a brief education and pilot period. The rapid response team (RRT) consists of the first call house officer for patients with house staff coverage, the patient's primary nurse, a hospital medicine clinician who could be a nurse practitioner (NP) or physicians' assistant (PA) or a hospitalist; a nursing supervisor and a respiratory therapist. The team is activated by any clinical staff, patient or visitor, when trigger signs (Table 1.1) are observed, suggesting a clinical decline in a patient's condition, or when there is a concern about a patient's condition even if a trigger criterion is not observed. Patient and visitor activation was added to the intervention in early 2011. The clinical leader of the team is a house officer when one is covering the patient and

Table 1.1: UMMMC Rapid Response System Triggers
Heart rate <40
Heart rate >120
Systolic BP <90
Chest pain
Respiratory rate <6
Acute drop in O_2sat to <90%
Significant drop in O_2sat from baseline
Fi O_2 >50% or O_2 > 6 lpm
Decreased level of consciousness
Agitation, delirium
Possible stroke
Seizure
Marked Concern by Clinical, Staff, Patient or Visitor

is available; otherwise, the hospital medicine clinician is the clinical lead. The hospital medicine clinician assists in the assessment of the patient, facilitates communication between the primary nurse and other clinicians, and facilitates transfer to the ICU when necessary. The nursing manager or supervisor supports the team in any transfers and the respiratory therapist aids in any necessary respiratory support. The patient's primary nurse has the responsibility of having all the necessary patient information available and communicating it by stating the Situation, Background, Assessment and his/her Recommendation (SBAR). This provides a consistent method for disseminating information effectively to the RRT. When the hospital operators receive a call for the RRT, they immediately activate the team using dedicated pagers, and the team is expected to arrive within 5 minutes of the page. Figure 1.2 shows the RRS model that was implemented at UMMMC.

The three studies presented in this dissertation thesis were reviewed and approved by the University of Massachusetts Institutional Review Board. These studies as a whole look at the different elements of developing, implementing and evaluating a RRS. The first study is an evaluation and identification of preventability and timeliness of floor to ICU admissions. This study demonstrates the difficulty in measuring and

Figure 1.2 UMass Memorial Medical Center
Rapid Response System Model



identifying these parameters while presenting a unique method for doing so. This contributes to the second study which is an evaluation of the effectiveness of the RRS to reduce cardiac arrests outside of the ICU and hospital wide, code calls and unanticipated ICU transfers from the general floors. The final study assesses how well the RRS has been implemented, and if it is being used as it was designed to, using a modified process evaluation. This method of analysis has not been previously done in RRS literature. The results of these studies, especially when combined with results from other single site studies, will provide additional evidence regarding the effectiveness of RRS and aid in a better understanding of the factors that make a RRS successful.

CHAPTER II
Preventability And Timeliness Of Floor to ICU Transfer

Introduction/Background

It has been suggested that a RRS can aid in early identification of hospitalized patients with emerging critical illness and intervention to stabilize the patient's condition and possibly prevent an ICU transfer. A RRS includes a Rapid Response Team (RRT) which is a group called by the primary nurse, other staff, patient or their visitors, to the bedside of any patient whose condition is deteriorating. In order to measure the impact that an RRT may have on in-hospital ICU transfers it is first important to understand the scope and nature of the problem.

Only a few studies have assessed in-hospital ICU transfers. A study done in England used two clinician assessors to determine the preventability of in-hospital ICU transfers.[5] On average, the two assessors considered 4.5% of the ICU transfers to be definitely avoidable, 4% probably avoidable and 36% possibly avoidable. Both assessors agreed that 39% of the patients who were admitted to the ICU later in their clinical course than they should have been. Failure to appreciate clinical urgency, lack of experienced staff, lack of supervision and failure to seek advice were all considered possible reasons why preventable transfers may have occurred. Another study showed that there were symptoms and abnormal vital signs, observed up to 8 hours earlier in 60% of the patients that were eventually transferred to the ICU from the floor.[2] Ideally, a patient's

declining condition should be identified as soon as possible to insure that opportunities are not missed to prevent the development of critical illness. Early intervention may prevent an ICU transfer or facilitate an optimally timed transfer to the ICU. Delays in transfers from the floors have been associated with poorer patient outcomes.[6] The RRT has been proposed as an intervention that may reduce preventable in hospital ICU transfers.

Studies that have evaluated RRT's effectiveness in reducing floor to ICU transfer have used different definitions of unanticipated transfers. These included any unscheduled transfer to the ICU from the general ward,[12] transfers that did not originate in the emergency department or the operating rooms, [23, 42] and when the patients met the criteria for a RR call but one was not called.[33] Two studies did not define unanticipated ICU transfers.[21, 36]

The results of the previous studies have been mixed. Two studies evaluating the impact of RRTs have reported a decrease in the rate of floor to ICU transfers;[21, 23] two did not find a change[12, 33] and two found an increase in transfers.[33, 42] The differences in findings of these studies raise the question of how many floor to ICU transfers can realistically be considered preventable and therefore be an appropriate outcome of the RRT. Understanding the extent that transfers from the floor to the ICU are preventable is an important first step in evaluating the effect that an RRT can have on reducing preventable transfers. The objective of this study was to use a standardized medical record review to determine the rate of preventable and untimely floor to ICU transfers.

Methods

This was a retrospective cohort study taking place at two hospitals (University and Memorial Campus) in the same academic medical center in central Massachusetts. All floor to ICU transfers (N=738) from 1/1/2007-12/31/2007 were identified from ICU records. Transfers that occurred within 24 hours of hospital admission were excluded (N=291) to avoid evaluating cases that may have been more appropriate for direct ICU admission. Of the 447 remaining transfers 100 were randomly selected to be evaluated by 3 chief residents who each reviewed 40 cases with 10 being reviewed by all three. For each patient transferred, nursing progress notes, nursing flow sheets from the 24 hours prior to the transfer and the ICU admission note were copied directly from paper charts and electronic medical databases. All materials were de-identified and presented to 3 physician reviewers who were chief residents at the two institutions. The physician reviewers were asked to determine the preventability and timeliness of the transfer based on their own understanding of the disease process and the patients' response to treatment in context of the patients' other characteristics and decisions of clinicians.

Analysis

Kappa analysis is an analytic method used to measure the proportion of agreement between reviewers that is beyond what would expected by chance. This was done using STATA to compute a kappa coefficient. There is no universally agreed upon standard to determine or test the significance of the

kappa co-efficient. However, table 2.1 shows the interpretation of the kappa co-efficient that is has generally accepted. In order to have a sample size large enough to detect a kappa statistic of .5 using two reviewers for each patient it was necessary for each pair of reviewers to evaluate at least 35 cases.

Table 2.1: Interpreting Kappa Co-efficient[43]	
Kappa Co-efficient	Level of Agreement
<=0	Poor
0.01-.20	Slight
0.21-0.40	Fair
0.41-0.60	Moderate
0.61-0.80	Substantial
0.81-1	Almost Perfect

Outcome definitions

A preventable transfer was defined in this study as the transfer from hospital floor to the ICU of a patient who had observable symptoms, signs, or diagnostic test results, in the 24 hours prior to an ICU transfer that, if they had they been noticed and intervened upon earlier, could have prevented further clinical decline and the need for an ICU transfer. An untimely transfer was considered one where, given the symptoms, the decision to transfer was delayed and care continued on the floor past the optimum time.

Review Process

Three reviewers, in three pairs, were asked to score 40 cases per pair using a 4 point Likert scale with ratings of definitely preventable, probably preventable, possibly preventable and definitely not preventable. They were also asked to indicate which factors in the case or treatment most influenced their decision based on the adequacy of the information provided.

The first 10 cases were presented to all three reviewers. After independently scoring each case the reviewers met together with a researcher to determine how to handle factors that could complicate reviewers' efforts to classify transfers according to the outcome definition. These included identified medical errors that lead to a patient's initial clinical decline, patients being sent to the ICU too early or unnecessarily, records with too little information or poor documentation, and assumptions that might be required to interpret some cases. When consensus was reached on approaches to each of these issues, each of the remaining cases was assigned to two reviewers, 10 at a time. After each set were scored the reviewers met in pairs to discuss any disagreements and where possible a consensus rating was reached.

Statistical Analysis

Frequencies of all variables were compared between the two campuses and statistically significant differences were identified using either a chi square or Fisher's exact test. Consensus ratings were used for all calculations. For preventability and timeliness, raw agreement between each member of a pair as

well as among all three reviewers was calculated. A Kappa statistic was used to determine if the degree of agreement between reviewers varied from chance and the Intraclass Correlation Coefficient, an evaluation of agreement between and across reviewers, was calculated as a comparison to the Kappa statistic. The consensus ratings were collapsed from the four original categories to two, combining definitely not and probably not preventable/timely, and definitely and probably preventable/timely. Raw agreement and kappa were then calculated for these new categories.

Results

Characteristics of the patients reviewed in this study are presented in Table 2.2. Table 2.3 displays the difference if any in patient characteristics when stratified by campus or agreement. No differences were detected in any category except age where patients at the Memorial campus were, on average, older than patients at the University campus. There was a higher mortality rate among the cases that the reviewers agreed were preventable. This did not reach conventional statistical significance ($p<0.05$).

Table 2.2 Study Population Demographics by Campus			
	University n (%)	**Memorial n (%)**	**p-value**
Total number of pts	**54**	**46**	
Sex			0.896
Male	31 (57)	27 (59)	
Female	23 (43)	19 (41)	
Age (Mean)	62.24	71.22	0.058
40 and under	4 (7)	2 (4)	
41-50	7 (13)	4 (9)	
51-60	13 (24)	7 (15)	
61-70	12 (22)	5 (11)	
71-80	12 (22)	11(24)	
81-90	5 (9)	16 (35)	
over 90	1 (2)	1 (2)	
Days on Floor			0.138
4 and under	29 (54)	29(63)	
5-10	14 (26)	14 (30)	
Over 10	11 (20)	3 (7)	
Hospital Admitting Diagnosis			0.581
CHF	8 (15)	5 (11)	
Other heart disease	2 (4)	1(2)	
Renal	2 (4)	3(6)	
Pneumonia	3 (6)	5(11)	
Other respiratory	3 (6)	3 (7)	
Liver disease	7 (13)	1 (2)	
Infection	6 (11)	5(11)	
Cancer	8(15)	6 (13)	
GI	2 (4)	5 (11)	
Stroke	2 (4)	6(130	
Ortho	3(6)	8(17)	
Hemotologic	1 (2)	1(2)	
Sepsis	2 (4)	2(4)	
Other	5 (9)	4(9)	
Disposition			0.465
Home self care	5(9)	1 (2)	
Home health care	9(17)	12 (26)	
Acute rehab facility	6 (11)	6 (13)	
Expired	17 (3)	12 (26)	
Hospice Medical Facility	2 (4)	1 (2)	
Long term care hospital	6 (11)	2 (4)	
Skilled nursing facility	9 (17)	11 (24)	
Against Medical Advice	0	1 (2)	

Table 2.3 Patient Demographics by Study Outcome				
	Agree not-preventable	**Agree preventable**	**Disagree**	**P-Value**
	n (%)	n (%)	n (%)	
Total number of pts	74 (100)	13 (100)	13 (100)	
Sex				0.663
Male	45 (78)	8 (14)	5 (9)	
Female	31 (74)	5 (12)	6 (14)	
Age (Mean)	69.3	66.70	61.53	0.555
40 and under	5(83)	0 (0)	1(17)	
41-50	7 (64)	2 (18)	2 (18)	
51-60	14 (70)	2 (10)	4 (20)	
61-70	14 (82)	2 (12)	1 (6)	
71-80	16 (70)	5 (22)	2 (9)	
81-90	19 (91)	1 (5)	1 (5)	
over 90	1 (50)	1 (50)	0 (0)	
Total	76 (76)	13 (13)	11 (11)	
Days on Floor				0.559
4 and under	43 (74)	8 (14)	7 (12)	
5-10	21 (75)	5 (18)	2 (7)	
Over 10	12 (86)	0 (0)	2 (14)	
Admitting Diagnosis				0.528
CHF	11 (86)	1 (7)	1 (7)	
Other heart disease	2 (67)	0 (0)	1 (33)	
Renal	5 (100)	0 (0)	0 (0)	
Pneumonia	5 (62)	3 (38)	0 (0)	
Other respiratory	4 (66)	1(17)	1(17)	
Liver disease	7 (88)	0 (0)	1(12)	
Infection	8 (73)	2 (18)	1(9)	
Cancer	10 (13)	2(15)	2(15)	
GI	9 (90)	1 (10)	0 (0)	
Stroke	3 (100)	0 (0)	0 (0)	
Ortho	4 (100)	0 (0)	0 (0)	
Hemotologic	2 (100)	0 (0)	0 (0)	
Sepsis	3 (75)	1 (25)	0 (0)	
Other	3 (33)	2 (22)	4 (45)	
Disposition				0.845
Home self care	5 (83)	0 (0)	1 (17)	
Home health care	13 (71)	2 (10)	6 (19)	
Acute rehab facility	10 (83)	2 (17)	0 (0)	
Expired	21(72)	6 (21)	2 (7)	
Hospice Medical Facility	2 (67)	0 (0)	1 (33)	
Long term care hospital	6 (75)	1 (12.5)	1 (12.5)	
Skilled nursing facility	16(80)	2 (10)	2 (10)	
Against Medical Advice	1 (100)	0(0)	0(0)	

Overall, raw agreement on preventability when the categories were collapsed was 87%, In 13 cases, even with discussion; the reviewers were not able to come to a consensus. (Table 2.4) Collapsing the 4 categories of preventability into 2 resulted in a higher Kappa statistic though in both cases the Kappa demonstrates agreement beyond the level of chance. The collapsed Kappa statistic showed moderate agreement among reviewers A/C, and B /C. There was substantial agreement between reviewers A/B. The Interclass Correlation was calculated as a comparison to the Kappa statistic and was low among all the reviewers.

Raw agreement on timeliness was similar to the preventability raw agreement, however when a Kappa statistic was calculated the scores were very low. Collapsing the categories improved the scores but not enough to show much more than agreement above chance.

Table 2.4 Preventability and Timeliness of Floor to ICU Transfers				
	Reviewers A and B	**Reviewers B and C**	**Reviewers A and C**	**All three Reviewers**
Raw agreement (4)	63%	63%	64%	63%
Kappa Preventability (4)	0.37	0.35	0.41	0.47
Raw agreement Collapsed(2)	89%	85%	87%	87%
Kappa Preventability Collapsed (2)	0.73	0.60	0.60	0.60
ICC Preventability	N/A	N/A	N/A	0.48
Raw agreement Timeliness	69%	63%	56%	N/A
Kappa Timeliness (4)	0	0.14	0.35	N/A
Kappa Timeliness (2)	-0.02	0.15	0.29	N/A

The 13 cases in which the reviewers were not able to come to a consensus are described in table 2.5. Two of these cases had poor documentation and both reviewers felt that making a determination was not possible. Of the other cases, there was disagreement on type and appropriateness of treatment in 7 and a disagreement in diagnosis in one. In the final case, there was disagreement in whether the patient needed the ICU or if they were stable on the floor.

Table 2.5: Reasons for Disagreement by Hospital Reviewers of ICU Transfers			
Study ID	**Disagreement**		
	Reason: Not Preventable	**Reason: Preventable**	**Category**
19	Poor prognosis	better treatment on floor	Treatment
45	Closer supervision necessary	Delay in getting imaging	Treatment
55	Pulmonary embolus	Remove mucus plug, Chest Physical Therapy	Treatment
110	History of heart disease, post-op	Patient stable on the floor	Transfer decision
132	Pleural effusion, resp. distress, multiple co-morbidities	Question of appropriate antibiotic on floor	Treatment
349	Underwent large volume paracentesis, closer monitoring necessary	Patient was stable on floor	Treatment
409	Poor documentation		
459	Poor documentation		
468	Ablation abnormal cardiac tissue would not have worked	Ablation would have prevented the transfer	Treatment
581	Lower GI bleed with significant HCT drop	Decision to go to CCU made by present of blood not instability	
642	Seizure	Narcotics	Diagnosis
692	High FiO2 requirements	Post op patient	
699	Worsening hypoxemia 2nd to pleural effusions	Pleural effusions could have been drained sooner	Treatment

There were 13 transfers that the reviewers agreed were either probably or definitely preventable. The reason for preventability and the suggestions for what could have been done differently to prevent the transfer are reported in Table 2.6. Of the preventable cases, 8 were deemed preventable because of poor medication management. Of these, 4 were thought to have needed broad antibiotic coverage to prevent the transfer. Two of the cases were determined to be preventable because a full resuscitation was done on patients with DNR orders and transfers were required once they had been resuscitated. The reviewers disagreed in two cases as to the primary factor that could have prevented the transfer.

Table 2.6: What Could Have Been Done to Prevent Transfer?

Study ID	**Physician Reviewer Comments**
10	Earlier recognition of CHF and diuretic use / K+ repletion
11	More aggressive pain and BP control
103	Attention to code status
190	Broad spectrum antibiotics
210	Early labs and CT
222	Broad spectrum antibiotics
272	Better opiod management
313	Broad spectrum antibiotics
369	Broad spectrum antibiotics
374	Better management on floor; not a necessary transfer
417	Better blood sugar control
436	Attention to code status
515	Earlier antiseizure medication

Discussion

This study demonstrated that possibly 13% of floor to ICU transfers could have been prevented with faster higher level treatment. Eight were deemed to be preventable because of poor medical management. The implications of poor medical management is something that would need to be investigated further to determine how many patients are being transferred to the ICU because of either not the correct or poorly timed antibiotic. In this study, there were three residents giving their opinion based on what they think they would have done in similar circumstances. Though they did their best to put themselves into the shoes of the treating clinicians, knowing the outcome specifically that the course of treatment did not work, may have made their decisions different then if they had been there.

In order to verify the occurrence of a preventable transfer due to poor medication management, it would be necessary to have pre-determined criteria as to what the proper medication procedure would be and then evaluate how many patients received this intervention. This would still be a complicated study to do because there is nothing that predicts how a patient is going to respond to medication. A medication regime that would be effective for one patient may not be the same for another.

Preventing unnecessary transfers not only provides a higher quality care for patients but also uses hospital resources more efficiently. For clinicians, the intensive care unit provides the highest level of monitoring and support for

patients in critical condition. Thibault and colleagues found that the perceived need for noninvasive monitoring rather than a need for immediate major interventions was the major reason for admission to a medical intensive care unit.[44] Their study showed that three out of four patients were admitted to the intensive care unit because of concerns about possible complications that would necessitate major diagnostic or therapeutic interventions, however, only ten percent subsequently required such interventions.

The decision to transfer patients to the intensive care unit is complex. In addition to the diagnosis, clinicians have to account for the wishes of the patient for further aggressive care in addition to clinical factors such as hemodynamic stability, prognosis, frequency of checks, blood draws, pulmonary toilet, medication usage, and the type and number of organs failing. The decision to transfer is often further complicated by the lack of clinical information. The patients' preferred code status is frequently unclear, undocumented, inaccurate or undecided for patients who cannot express themselves such as elderly patients with dementia, altered mental status, or acute distress. Many do-not-resuscitate orders are written only shortly before death, further suggesting that the decision may be biased by the patient's process of dying.[45] The sheer distress of the dying patient, family members at the bedside, and involved health care staff is often enormous and stressful and, may impact the clinician's ability to discern preventable critical from non-critical events.

The health care staff closest to the point of care may have cues that result in earlier recognition of a change in clinical status. Strategies to deploy resources at this point, such as the implementation of rapid response teams, may have multiple benefits for patient care and safety. Since December 2008, the Joint Commission's National Patient Safety Goals have required hospitals to develop rapid response teams. Although intuitively sensible, the effectiveness of, the optimal composition of, and the best triggers for activating rapid response teams have been questioned.[13, 46, 47]

Rapid response teams may act as a mechanism to direct patients to the appropriate care unit if the optimal triggers for activation and clinical parameters are identified. To identify these factors, it is first important to understand the rate of preventable ICU transfers. This study attempted to measure the rate of preventability and timeliness using a simple, easily replicated method. Given the results of this study, it is possible that earlier, higher level interventions in the form of an RR could reduce floor to ICU transfers by 13%. Excluded from this study were 291 transfers (39%) that occurred within 24 hours of initial admissions. It is likely that in most of these cases the patients were initially triaged to the wrong unit. Though not assessed in this study the RRT may have the greatest effect on these patients in providing a more rapid assessment and transfer to the ICU from the floor.[46] A portion of the patients who are admitted to the floor and within 24 hours are transferred to the ICU are likely to have been incorrectly triaged. Thirty-nine percent of all ICU admissions fall into this

category. Of those a certain percentage are going to be patients where a clinical decline is quick and unpredictable. The RRS could have an effect on the patients who have been triaged incorrectly to the floor in two ways. First, would be the direct care that the RRS would provide. Second, the RRS could serve as an educational tool to improve the triage process.

There were many issues that may have impacted the results of this study: variations in physicians' method of evaluation of cases, limited information available for some cases, limited time for reviewers to study the cases, the approach to medical errors and other variations in the cases. The three physician reviewers were chief residents at the same academic medical center. Though all three had similar training, there were differences in the way they initially evaluated the cases. There was much discussion on whether patients who had a poor prognosis would have received better care in the ICU or on the floor and what level of monitoring and interventions the patients may have preferred. In this study transfers for patients with a poor prognosis were considered not preventable. All three agreed that the RRT could play an important role in these cases by initiating end of life conversations with the patient and the family. Surprisingly, there were a few cases where the reviewers did not think that the transfers should have happened at all. With limited ICU beds available, only appropriate patients should be transferred to the ICU. In these cases, a RRT may play an important role in helping to stabilize a patient on the floor and preventing the transfer.

Doing a retrospective review of medical charts raised the question, whether having more information and the time to consider all possible interventions would give the reviewers an insight that the treating physicians may not have had. The physicians made every effort to put themselves in the shoes of the treating physician and judge the treatment as if they themselves were making the decision at the time.

This study was not trying to identify errors in diagnosis or treatment that led to the initial clinical decline of the patient the reviewers were to determine whether once symptoms of the decline were present, within the 24 hours prior to the transfer could the ICU transfer been prevented. There were several cases where the reviewers identified medical errors that ultimately led to a transfer. RRS may be effective in identifying and mitigating the impact of medical error. The cases where sepsis was a concern presented differences in the reviewers' approach to treatment of a person with sepsis. Specifically, a reviewer would rate the case as preventable if they thought that the patient should be treated on the floor with antibiotics but not-preventable if it was felt that all patients with any sepsis type symptoms should immediately go to the ICU.

The instrument to measure timeliness proved to be an ineffective tool. Even after multiple conversations there was still confusion over the definition of this measure, which was to be based on the time from identification of the symptom/s and signs of the condition that required a transfer to the time of the decision to transfer the patient to the ICU, not the time of the actual transfer.

Table 2.7: Physician Review Comments on Cases Agreed to be Preventable

	Reviewer 1		Reviewer 2	
Study ID	**Predominant Factor**	**What could have been done**	**Predominant Factor**	**What could have been done**
10	The past medical history suggested a CHF history that is consistent with SX. No CXR was ordered on the first day that SX presented (1/4/07 @ 3am) Increased HR 140-160 @ 1 am 1/5/07	Earlier recognition if CHF and diuretic use may have been helpful. This DX should have been priority to make over anxiety. COPD component is being treated already	The patient had a low potassium (3.6) and depressed EF which may have led to her coding	K+ Repletion
11	The patient was transferred to the ICU for pain control and hypertension. There is no documentation as to how the patient was managed on the floor but usually pain and ?MTN can be managed on a regular floor	More aggressive pain and BP control	Originally disagreed but changed mind after discussion	
103	The patient was transferred to the CCU because they were coded. Pts code status was DNR/DNI but it was improperly documented. If the code status was known she wouldn't have been coded and would have likely died on the floor and not been transferred to the ICU	attention to code status	Pt was DNR/DNI but a code was called. Both agreed that she should not have been coded and transferred. They scored it differently but meant the same thing. Pt should not have been transferred but once she coded and was recuscitated she had to be transferred.	
190	The patient developed resp. failure 2nd to PNA. She may not have deteriorated if she had broader antibiotic coverage	She was slowly declining for >12 hours before ICU transfer. Initial antibiotic choice may have prevented transfer or	Earlier treatment of aspiration PNA/Hospital acquired pneumonia with broad coverage antibiotics	Early treatment with antibiotics Instead of treatment for community acquired pneumonia

		broadening antibiotic coverage may have been preventative.		
210	Patient was admitted with a COPD exacerbation but subsequently develops AMS and abdominal distention with elevated HR 100	There were no labs in the 24hr period prior to transfer/code blue. Patient needed CT abdomen, ABG, Chemistries, prior to the ICU admit. His ph was 7.14 by the time he arrived in the ICU Rx bicarb, Bipap, look for necrosis, dialysis. Full abd exam needed parenthesis (large volume)	The patient developed v-fib and coded, while the precipitating event is unclear. The patient had electrolyte abnormalities that may have contributed	There were electrolyte abnormalities upon arrival to the ICU and it doesn't appear electrolytes were checked in the 24 hours prior to transfer
222	Inadequate antibiotics coverage initially when infection is pleural fluid suspected. Patient was only covered with levaquin (with no coverage of MRSA in patient with pigtail catheter in the pleural space)	Starting broad antibiotic coverage earlier	This patient had turbid fluid drained from his therapeutic thoraccentesis. This patient needed an emergent chest tube.	The patient could have had his heart rate better controlled.
272	Unresponsive. On opioids for pain mgt of mets rectal ca.	Closer look of opioids not to be given in excess resulting in mental status change, unresponsiveness. Closer look at pt's insulin pump, pt has a basal rate at 0.50/h and at 1:30 given himself 3.7 u bolus of insulin on ambalt to ICU, blood glc is 28	Pt likely could have been managed on the floor he was transferred for an unresponsive episode in the setting of low blood sugar while he was wearing an insulin pump	Insulin pum while in hospital with altered mental status
313	Patient was transferred to ICU for hyperemia presumed 2nd to PNA. The patient came from a group home but was only started on ?? Upon admission	Earlier broad spectrum antibiotics	They used the wrong IVR Should have used 1/2 NS instead of DSW	needed to use 1/2 NS

369	The patient was transferred for hypertension/sepsis. At admission the hypotension was thought to be hypo?? Not septic	Earlier broad spectrum antibiotics	Found by VNA @ home with hypotension and weakness on 6/25. Pt was hypotensive, exhibit early signs of SIRS, Rx for cellulites with clindamycin as pts PCN-allergic. On 6/26 pm, increased O2 requirement, continue to be hypotensive given by NF overnight broad ABX coverage	Early broad coverage ABX administration for SIRS/sepsis
374	Both were unclear what precipitated the transfer. Both thought it was not a necessary transfer			
417	Transfer to ICU seems to be due to only poorly controlled hyperglycemia	Tighter blood g/c control with the ??? Dose of long lasting insulin pre-op, during op, and post op with giving insulin with meals and not relying only on insulin sliding scale. Obtaining endocrinology general medicine consult early if needed for tighter blood glucose control	The patient was transferred to the ICU for on insulin drip because of hyperglycemia that could have been avoided with more aggressive management on the floor. The patient also missed a dose of insulin post-op that contributed	Insulin could have been restarted pot-op. When the sugar was difficult to control endocrine could have over constructed
436	End stage disease with directives not to transfer to ICU	Attention to documented wishes of pt and family	Patient was DNR/DNI and should not have gone to the ICU. Both reviewers agreed with this but scored it differently. Decided to score as preventable, because it should not have happened.	

515	Left sided neglect (9/17/07), lethargic decreased mental status) post neurosurgery. Reasonable to consider active seizures plus no response to narcan	Early loading doses of antiseizure medications vs early EEG	It was thought the pt may have had a seizure leading to unresponsiveness and ICU transfer. His dilantin level was low which may have precipitated the seizure.	Therapeutic dilantin

There are two levels of timeliness that are important to consider in terms of the quality of care provided to a patient prior a floor to ICU transfer; 1) the amount of time it took a care team to identify the need for an ICU transfer based on presenting symptoms and 2) the time that the transfer actually occurred once the decision was made. Though both are equally important, the former involves clinical judgment and the latter situations that are mainly out of the providers' hands because of issues such as number of ICU beds or availability of patient transport personnel. In this study, it was difficult to determine the timing from the point that symptoms were recognized to the time the decision to transfer was made using the information available. Future research is needed in order to determine the timeliness of clinician decisions about the need for an ICU transfer. This would be best done as a prospective study with the ability to debrief physician and nurses at the time of the transfer or shortly after.

A limitation of this study was that it was retrospective. Of the 13 cases where there was agreement regarding preventability, it is still unclear if these reviewers would have made any different choices than the providers had they

been there at the time. A 13 percent preventability rate in floor to ICU transfers suggests an important area for further research, both for better quality of care and management of resources.

Conclusion

This study did show some success with the methods used to determine a preventability rate. The methods used in this study were unique in that the reviewers were given standardized information about each patient. About half of the cases were thought to have enough information to make a determination of preventability. With a few modifications this method allowed portability of the information to be reviewed so that the reviewers were able to do the work when convenient, did not require reviewers to access or review entire charts for each patient, and all the reviewers made their determination based on the same information. The Kappa scores showed that the level of agreement reached was higher than what would have happened by chance.

The measurement for timeliness was not an effective measurement. Future studies should focus on measuring the time from when symptoms are first observed and documented to the time that a decision to transfer a patient to the ICU. This is important to better understand the differences that a more timely transfer might make on a patients ultimate outcome. In order to effectively and accurately measure timeliness it is first necessary to determine a set of symptoms to be identified as being a signal that a ICU transfer may be necessary. The system used in this study did not define specific symptoms and

the information given was not extensive enough to establish a clear idea of the timing. Future studies that look at what antecedents were in the available medical record before a decision to transfer was made would contribute to the existing literature and help to understand what an intervention like the RRS might impact.

The best method for measuring timeliness might be to evaluate the actual time from the first documented symptom that would indicate a need to transfer. This could be done by documenting the time and date of when the decision to transfer took place and a medical chart review would provide the time of the first symptom. The amount of time between the two might indicate that there was something that could be improved.

CHAPTER III
Rapid Response System's Impact on Code Calls, Cardiac Arrests, and Floor to ICU Transfers

Introduction

A rapid response system (RRS) is a hospital program that provides the means for bringing qualified clinicians immediately to the bedsides of patients who are experiencing significant clinical decline outside of the intensive care unit (ICU) setting. These declines are usually manifest by the occurrence of one or more "trigger" signs such as low blood pressure or increased heart or respiratory rate. The objective of a RRS is early identification of a clinical decline with effective early intervention to prevent further decline, cardiac arrest and death.

The Institute for Healthcare Improvement (IHI) has promoted implementing RRS's to provide safer care for hospitalized patients [11] and the Joint Commission made implementing a RRS a 2008 National Patient Safety Goal.[10] Although RRSs are now mandated for all hospitals in the United Sates, the evidence to support the effectiveness of any RRS to reduce cardiac arrests on hospital medical or surgical floors, un-anticipated ICU transfers and over-all hospital mortality rates remains inconclusive. This is partly because of weak study designs and partly due to a failure of published studies to report all critical aspects of their intervention. Recently, two published reports have proposed guidelines for the methodological components that should be included in published RRS studies.[41, 48] This study will evaluate the effectiveness of a RRS in

hospitals on the two campuses of the UMass Memorial Medical Center (UMMMC).

Background

Cardiac arrests that occur outside of the ICU, emergency room (ER) and operating room (OR) are considered unanticipated, meaning that a patient was presumed to have a very low probability of such an event and thus could safely be cared for on a general hospital floor with limited or no cardiac monitoring. A few studies to date have examined the occurrence of unanticipated cardiac arrests and how often they may be preventable. A study done in the United Kingdom used a panel of clinicians to evaluate in-hospital cardiac arrests. This study suggested that 68% of the cardiac arrests were potentially avoidable.[49] This study further concluded that 100% of these patients had not received adequate care in the 24 hours before the arrest, even though there were signs suggesting deterioration in their condition. Similarly, a study in Italy found that 89% of the patients who had an in-hospital cardiac arrest outside the ICU had observable signs of deterioration before the arrest. Of these patients, depending on the type of antecedent sign, 23-81% of patients did not receive appropriate care in response to antecedent signs, in the judgment of the authors.[50] A study done in the United States found similar outcomes, with 84% of patients outside the ICU showing signs of deterioration or a significant, relevant new complaint within eight hours before the arrest.[51] These initial studies suggest that an intervention that identifies these antecedents early and effectively treats the

condition/s underlying the antecedent signs may reduce the rate of cardiac arrests on general hospital floors.

The code team in a hospital is designed to be activated when a patient is in cardiac or respiratory arrest or other life threatening condition. Some hospitals have replaced their code teams with a rapid response team or have the code team also act as the rapid response team. At UMMMC when a patient is arresting outside of an ICU, the entire code team is activated, and they bring with them the equipment needed to perform advanced life saving procedures. All code blue calls at both UMMMC campuses are made through the telecommunications office, which documents time, location, and nature of the calls and pages the code team members. The objective of this study was to evaluate the effectiveness of a newly implemented Rapid Response System in reducing cardiac arrests in and out of the ICU and hospital wide, and to evaluate the changes in the rates and use of code calls. Admissions to the ICU are considered unanticipated if they originate from general medical/surgical care units as opposed to the operating rooms or the emergency departments.

Setting

This study was conducted in the 2 hospitals on the main campuses of the UMMMC, located in Worcester, Massachusetts. The hospitals provide care for patients from the city of Worcester and from elsewhere in Worcester County. With more than 700 acute care beds, UMMMC is the largest acute care provider

in central Massachusetts. UMMMC hospitals are level 1 tertiary care, teaching institutions with an average admission rate of 3600 patients per month.

Intervention

A RRS was fully implemented in January of 2009 at both UMMMC hospitals following a brief education and pilot period. The rapid response team (RRT) consists of the first call house officer, hospital medicine clinician, a nursing supervisor and a respiratory therapist. The team can be activated by any clinical staff when one or more trigger signs are observed, suggesting a clinical decline in a patient's condition. Clinical staff also has the option to activate the RRT when they are concerned about a patient's condition even if a trigger criterion is not observed.

Methods

This was a before/after study design to evaluate the effectiveness of the RRS intervention. The 2 years before the intervention 01/01/2007 to 12/31/2008 and the 2 years after, 1/01/2009 to 12/31/2010, were compared. A pilot RRS model was performed during the last two weeks of 2008 on two floors at each hospital. This time period was included in the before period because of the limited number of floors and calls received.

Code calls are recorded by UMMMC telecommunications. This log includes date and time of call and floor but no other identifying information. The code team does not keep record of all calls but does fill out a code sheet when the code cart is used. Discharge codes of cardiac arrest are assigned to any patient who experiences a cardiac arrest during his or her hospital stay. In order

to verify that a cardiac arrest, as defined for this study, had occurred, all code calls, code sheets and discharge codes were cross referenced with each other. Additionally all discharge codes were reviewed in an electronic data base (Meditech) to identify the occurrence and location of the arrest. The rate of code calls and cardiac arrests were calculated patient days in the hospital units included.

All floor to ICU transfers were identified using Meditech. Each transfer was considered unique so one patient may have had more than one transfer to the ICU. Excluded were any transfers to the ICU from the emergency department or the operating rooms.

Data on RRS events was collected using a Rapid Response Event Record developed specifically for this study, which was filled out by the responding hospital medicine clinician during and immediately after the event. This record includes information regarding the Rapid Response (RR) trigger, treatment during the call, and outcome of the patient. Also included are several questions regarding the RR responding clinician opinion of how the call went and an evaluation of the team. Additional information regarding the RR calls (time of call, event

location) and all code calls were collected from Telecommunications. Only adult in-patients were included in the study. Table 3.1 describes the outcome definitions and measures.

Table 3.1: Rapid Response Outcome Definitions and Measures						
	RR Calls	**Cardiac Arrests (Med-Surg Only)**	**Cardiac Arrests Hospital Wide**	**Cardiac Arrest ICU Only**	**Code Calls (Floors Only)**	**Floor to ICU Transfers**
Measure description	Rate of Rapid Response calls	Cardiac or Respiratory arrests that occur outside of the ED, OR, ICU or diagnostic areas.	All Cardiac arrests that occur anywhere in the hospital	Rate of Cardiac Arrests in the ICU	Code calls received by telecommunications that originate from the floors	All transfers from the floor to the ICU
Operational Definition	The number of calls received telecommunications	Any Cardiac or respiratory which required CPR, ACLS was considered as well as all asystole or PEA.	All cardiac/respiratory arrests, which required CPR, ACLS was considered as well as asystole or PEA. Includes OR, ED and ICU.	All Cardiac Arrest that occurred in the ICU only and required CPR, ACLS was considered as well as asystole or PEA	All code calls per month by unit	Transfers that do not originate from the ER or OR
Denominator	1000 patient days	1000 patient days	1000 patient days	1000 patient days	1000 patient days	1000 patient days
Data collection Method	Rapid Response Event forms and telecommunication records	Arrests identified by ICD9 discharge code and verified by Medical Record Review	Arrests identified by ICD9 discharge code and verified by Medical Record Review	Arrests identified by ICD9 discharge code and verified by Medical Record Review	Telecommunications records of calls outside of the ICU, ED and OR.	Meditech

Statistical Analysis

There were two study periods, for evaluation of cardiac arrests and code calls, 1/01/2007 to 12/31/2008 (before the intervention) and 1/01/2009 to 12/31/2010 (after the intervention). Floor to ICU transfers included the 12 months before the intervention and the 24 months following the intervention. The incidence rates of cardiac and respiratory arrest, of unanticipated transfers from the general floor to an ICU, and of code calls before and after the intervention, were analyzed separately. Each outcome rate was graphed with a locally weighted scatterplot smoothing (LOWESS) curve. There were three statistical tests to determine any change in the rates of the outcomes. Initially a t-test compared the means to determine if the mean rates changed before and after. A linear regression was done to evaluate the trend of the outcome over the entire 4 year study period. Then a test of significance for the Spline knot at 1/1/2009 was done. If that test was significant, a Spline regression model was used to evaluate differences in the slopes before and after the intervention, using rates of cardiac arrests, code calls and ICU transfers by month as the dependent variable and study months since 1/01/2007 as the major independent variable. The beginning of full implementation, 1/01/2009 was used in the Spine analysis as the knot so that the core model was $Y= \beta_0 + \beta_1 T_1 + \beta_2 T_2$ where T_1 is the months since 1/01/2007, $T_2 = T_1 - 24$ if $T_1 > 24$, otherwise $T_2 = 0$. β_1 is the slope to reflect the trend during the period before intervention, β_2 is the change in the slope in going from the first period to the after period. This analysis will show if there is any

trend over time and if the trends are different between two study periods. STATA software was used to do the analysis. Frequency tables were developed for triggers, bedside interventions and patient disposition following a RRS intervention.

According to data collected before the study period, the estimated incidence of cardiac arrests on the general hospital floors was 1/1000 discharges, in-hospital mortality was 10/1000 discharges, and the ICU transfer rate was 20/1000 discharges. Some studies have shown that a RRS could decrease cardiac and respiratory arrest rates by as much as 50%, decrease in-hospital mortality by 30% to 40%, and decrease ICU transfers by 15%. To calculate the power necessary for this study, we assumed that the RRS would decrease the rate of cardiac and respiratory arrests by 50%, mortality rates by 30% and ICU transfer rate by 15%. To detect these differences in the rates before and after RRS with 80% power using a two-sided alpha level, the numbers of patients required per period are listed in the table below. Assuming the average number of patients admitted in UMMMC is approximately 3600 per month, we had 80% power to detect the expected change in outcomes. Power calculations were done using only university campus data.

Table 3.2: Sample size and power estimation (University Campus)						
Outcome	Incidence Before RRS	Incidence After RRS	Two-sided alpha level	Power	# of patients required in before period (12 mths)	# of patients required in after period (24 mths)
Cardiac arrests	0.1%	0.04%	0.05	80%	33752	67504
In-hospital deaths	2.3%	1.7%	0.05	80%	35994	71988
ICU transfer	2%	1.7%	0.05	80%	32333	64666

Results

Rapid Response Calls

There were a total of 683 calls, 449 at the University Campus and 234 at Memorial over the two years of hospital wide implementation. The triggers were collected on the Event form and are included in Table 3.3. The majority of the calls were made because of an acute drop in oxygen saturation or “staff concern”. Very few calls were for possible stroke, possibly in part because a separate acute stroke team became available shortly after the RRS. Increasing oxygen delivery and providing medications were the most common interventions instituted by the responding team. Transfer to the ICU continued to be the most common outcome of a call followed by stabilization of the patient on the floor. There were only a few changes of DNR/CMO status.

The characteristics of patients were aggregated and evaluated for differences in the populations before and after the evaluation and displayed in Table 3.4. This data was provided in aggregate form and no statistical testing done.

Table 3.3: Rapid Response Triggers, Interventions, and Disposition

	Campus		
Rapid Response Triggers (Some patients had more than 1 trigger)	**Memorial (n=97)**	**University (n=201)**	**Total**
Acute drop in O2sat to 90%	30 (31)	82 (41)	112
Marked nursing housestaff or family	25(26)	63(31)	88
LOC Decreased level of consciousness	22(23)	56(28)	78
Heart rate> 120	17(18)	32(16)	49
Significant drop in O2sat from base	12(13)	26(13)	38
Systolic BP < 90	12(13)	20(10)	32
Seizure	11(12)	19(9)	30
Heart rate <40	5(6)	13(6)	18
Chest Pain	9(10)	13(6)	22
RR rate le 6	6(7)	8(4)	14
Agitation/ delirium	1(2)	7(3)	8
Fi O2 50% or O2 6 lpm	4(5)	6(3)	10
Trigger Unknown	2(3)	4(2)	6
Possible stroke	1(2)	2(1)	3
Urine output low	3(4)	2(1)	5
Interventions (Some patients had more than 1 intervention)			
Increase Oxygen	37 (38)	101 (50)	138
Meds	37(38)	82(41)	119
Start Oxygen	23(24)	57(28)	80
IV Fluid Bolus	15(16)	37(18)	52
Nebulizer TX	12(13)	20(10)	32
Tracheal Suction	10(11)	12(6)	22
None	4(5)	19(9)	23
Other	26(27)	40(20)	66
Disposition			
Transfer to ICU	42(43)	89 (44)	131
Immediate treatment given Trigger/s back to normal	32(33)	59(29)	91
Treatment planned; reevaluate following treatment	18(19)	54(27)	72
No active treatment given or planned	1(2)	10(5)	11
Change of status to DNR CMO	1(2)	3(1)	4
Other	6(7)	28(14)	34

Table 3.4: Patient Demographics				
	Memorial		University	
	Pre-intervention	Post-interventi	Pre-intervention	Post-intervention
Male	12940 (40)	11281(39)	18791 (56)	19322 (55)
Female	19770 (60)	17676 (61)	15399 (45)	16135 (45)
<25	722 (2)	729 (3)	1656 (5)	1608 (5)
25-34	1,582 (5)	1,685 (6)	2,397 (7)	2319 (7)
35-44	3,478 (11)	3,021 (10)	4158 (12)	4,022 (11)
45-54	5,341 (16)	5,032 (17)	6704 (20)	6591 (19)
55-64	5,946 (18)	5,360 (19)	6729 (20)	7249 (20)
65-74	5,426 (17)	4,795 (17)	5279 (15)	5700 (16)
75-84	6,211 (19)	4,995 (17)	4792 (14)	5144 (14)
85-94	3,635 (11)	3,048 (11)	2330 (7)	2619 (7)
95-104	368 (1)	293 (1)	145 (0.4)	207 (0.6)
105-114	1 (.003)	1 (.003)	0	4 (0.01)
White	28,41 (86)	25158 (87)	29142 (85)	30,618 (86)
Other Race	1879 (6)	2111 (7)	2616 (8)	2,665 (7.5)
Black	1,256 (4)	1278 (4)	1213 (3.5)	1,354 (4)
Asian	1,009 (3)	69 (0.2)	537 (1.5)	455 (1.2)
LAB ONLY	274 (0.8)	245 (0.8)	373 (1)	69 (0.2)
Unknown	110 (0.33)	58 (0.2)	141 (0.4)	202 (0.6)
Refused	61 (0.10)	7 (0.2)	58 (0.1)	69 (0.2)
Native Hawaiian/Pacific Island	33 (0.1)	15 (0.05)	37 (0.1)	11 (0.03)
American Indian/Alaskan Native	14 (0.04)	18 (0.06)	26 (0.07)	18 (0.05)
Hispanic	25 (0.07	0 (0)	31 (0.09)	0
Blank	8 (0.02)	0 (0)	16 (0.04)	0
Number of Patients	32,710	28,959	34190	35461
LOS (Mean)	3.8	3.8	5	5
LOS Total days	122,734	108,464	172119	179416

Results for the Spline Regression are presented in the following graphs and tables. Hospital wide includes all events occurring on the hospital floors, in the ICUs and in diagnostic area; Floors only include medical surgical and psychiatric units but no diagnostic areas.

Figure 3.1 Rate of Code Calls (Floor Only) University Campus

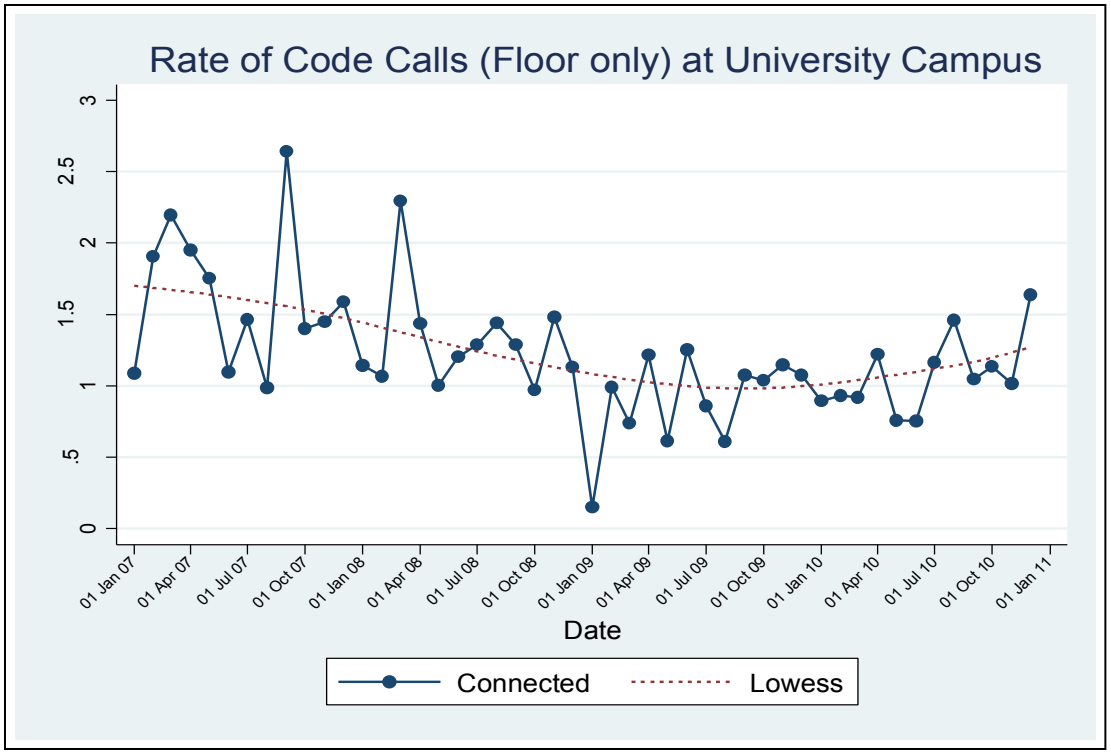


Table 3.5: Rate of Code Calls (Floor Only) at University Campus						
Campus	**Mean rate**		**p-value**	**Co-efficient Spline Regression**		**P-value**
	Before	After		Before	After	
University	1.47	0.99	<0.0001	-0.012	0.00029	0.33

Initially a t-test comparing the mean rates of code calls before and after the Rapid Response Intervention showed a statistically significant decrease in the average rate of code calls. However, when a Spline Regression model was used to compare the slopes before and after the intervention, it showed that though there was a decline during the period before the intervention, after the slope was almost straight meaning that there was no longer a decline in code calls. It appears that before the intervention there was a slight decrease overtime in the rate of code calls and after it began to even out and become more stable.

Figure 3.2: Rate of Cardiac Arrests (Hospital Wide) at University Campus

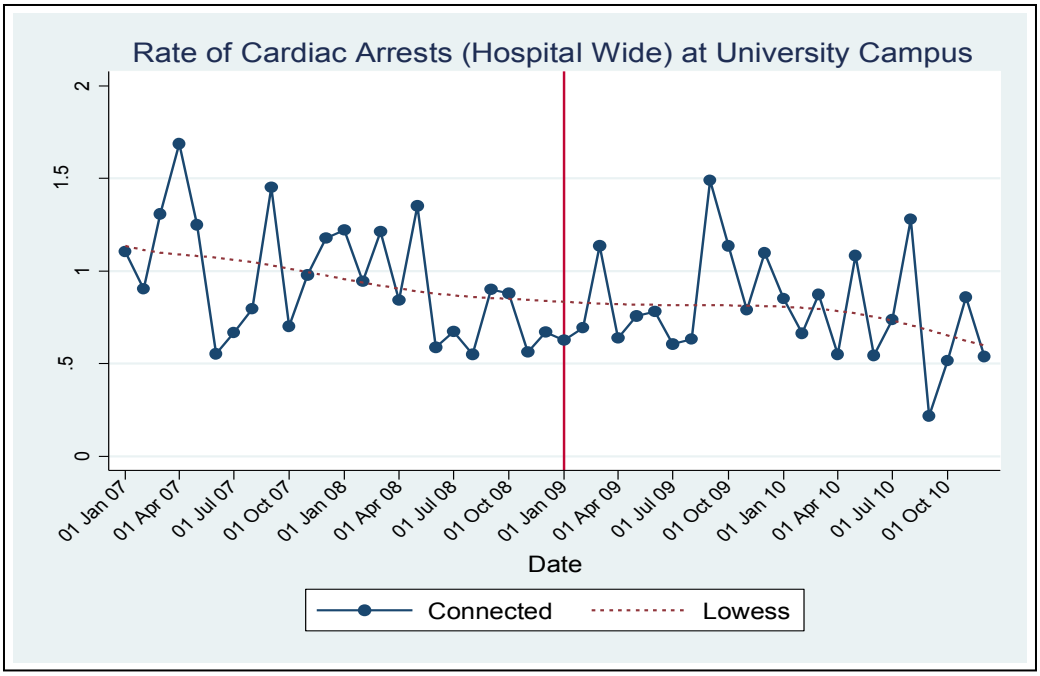


Table 3.6: Rate of Code Calls (Hospital Wide) University Campus

Campus	**Mean rate/ 1000 patient days**		**p-value**	**Difference between slopes before and after the knot (1.1.2009)**	
	Before	After		Difference in slope	p-value
University	0.957	0.796	0.071	.0004107	0.307

The initial t-test comparing the mean rates of cardiac arrests before and after the intervention showed no statistically significant change. A standard linear regression showed with each month cardiac arrests decreased by 0.00027/1000 patient days, demonstrating an overall decline in cardiac arrests throughout the study period. The test for significance of the knot showed that there was no significant difference so there was no need to continue testing the slopes before and after the intervention.

Figure 3.3: Rate of Cardiac Arrests (Medical Surgical Floors Only) University Campus

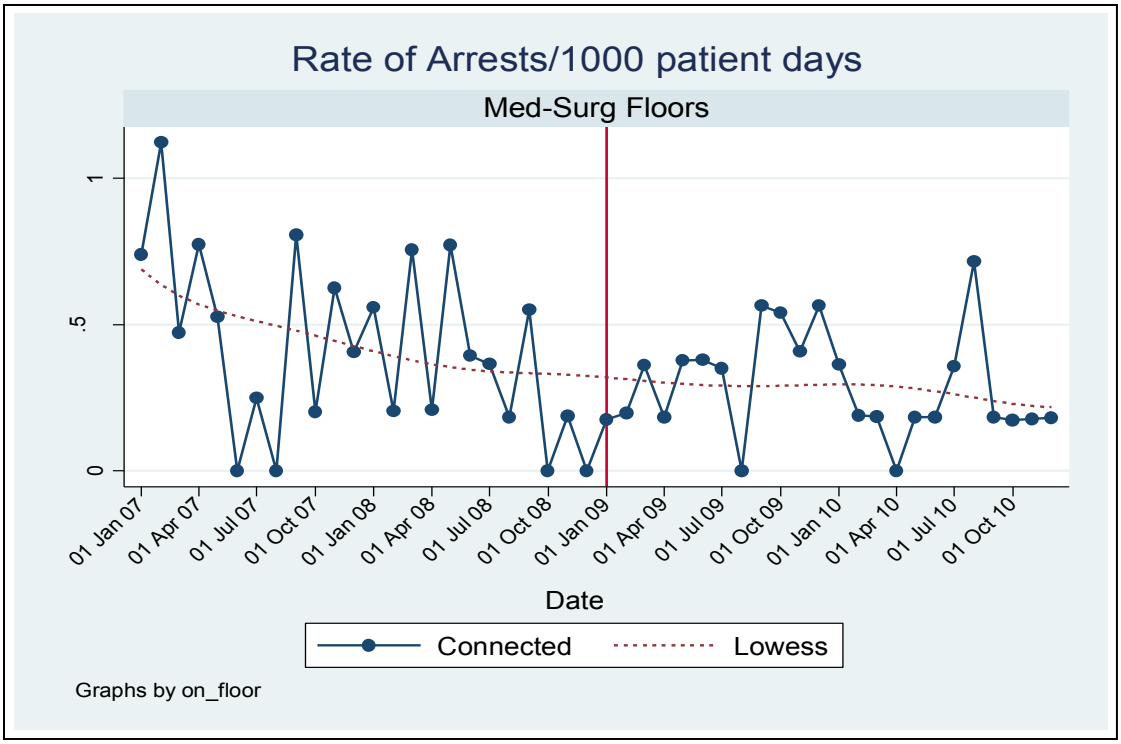


Table 3.7: Rate of Cardiac Arrests (Medical/Surgical Floors Only) University Campus					
Campus	**Mean rate/ 1000 patient days**		**p-value**	**Difference between slopes before and after the knot (1.1.2009)**	
	Before	After		Difference in slope	p-value
University	0.421	0.291	0.08	0.0005289	0.112

The initial t-test showed that there was no statistically significant difference in the mean rate before and after the beginning of the intervention. The linear regression showed that for every increase in month the rate of cardiac arrests overall decreased by 0.0002/1000 patient days over the entire study period. The test for significance of the knot at 1/1/2009 showed that that the knot was not significant and no other testing was done.

Figure 3.4: Rate of Cardiac Arrests (ICU only) at University Campus

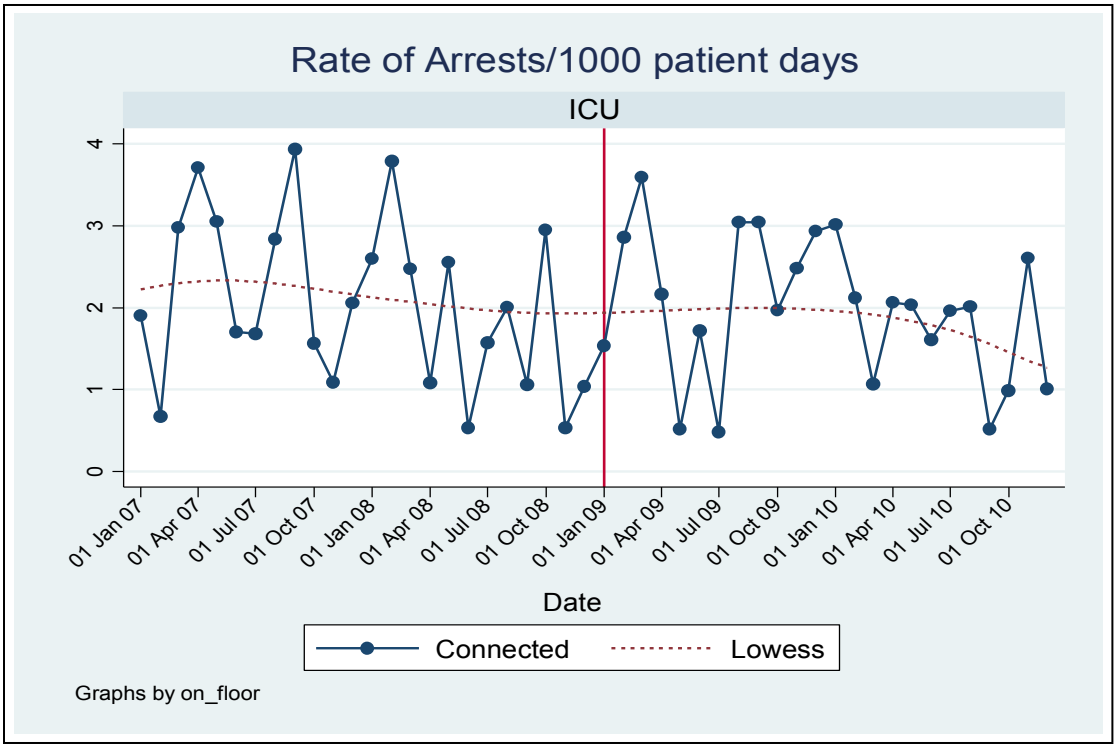


Table 3.8: Rate of Cardiac Arrests (ICU Only) at University Campus

Mean rate/ 1000 patient days		Difference of Mean rates	p-value	Difference between slopes before and after the knot (1.1.2009)	
Before	After			Difference in slope	p-value
2.057	1.972		0.7605	0.0003469	0.792

The initial t-test showed that there was no statistically significant change in the mean rate before and after the beginning of the intervention. The linear regression showed that there was not a significant decrease in the rate of cardiac arrests over the entire study period. The test for significance of the knot at 1/1/2009 showed that that the knot was not significant and no other testing was done.

Figure 3.5: Rate of Code Calls (Floor Only) at Memorial Campus

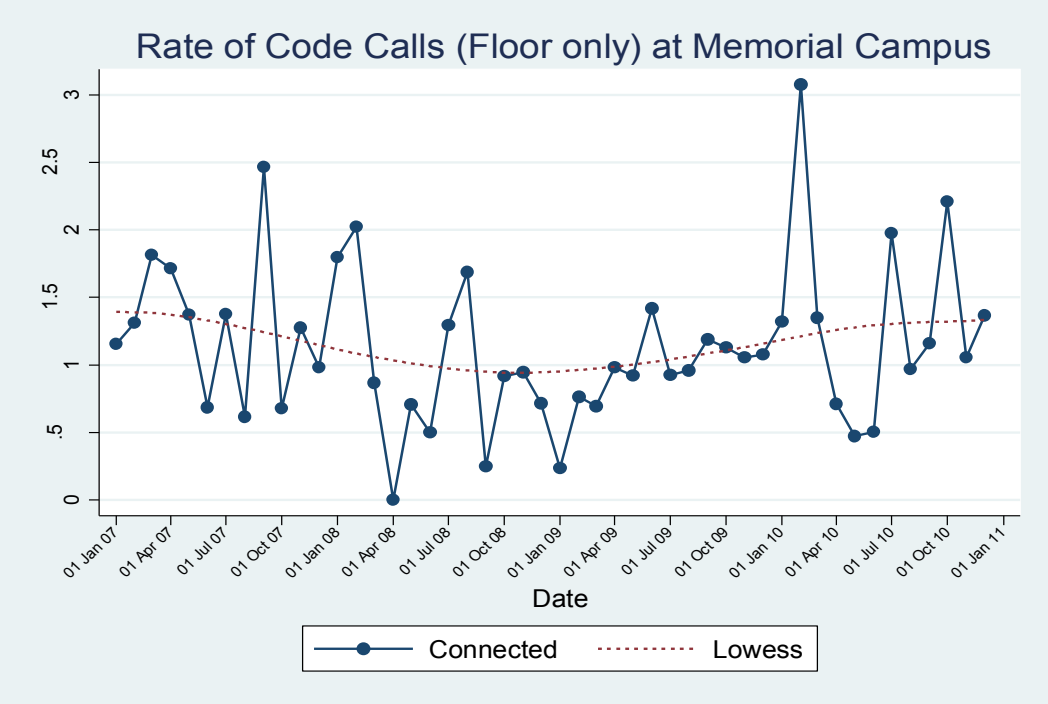
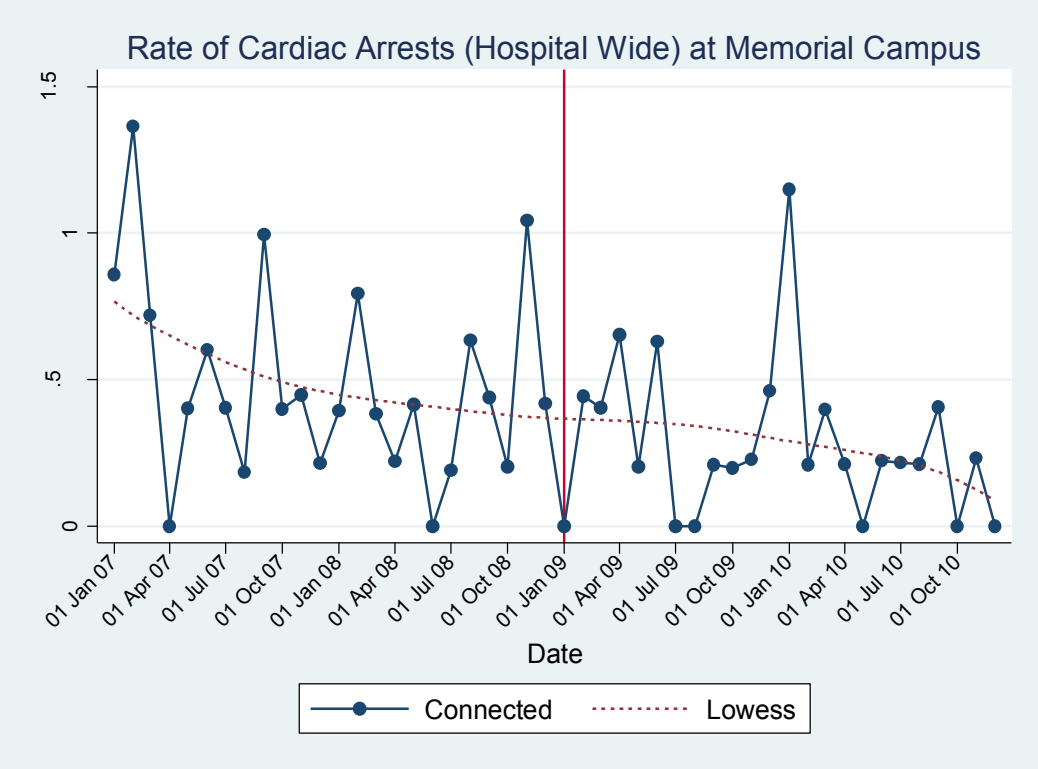


Table 3.9: Rate of Code Calls (Floor Only) at Memorial Campus						
Campus	**Mean rate**		**p-value**	**Co-efficient Spline Regression**		**P-value**
	Before	After		Before	After	
University	1.132	1.147	0.9273	-0.0009249	0.0010159	0.026

The initial t-test showed that there was no statistically significant difference in the mean rate before and after the beginning of the intervention. The linear regression showed that there was a slight increase of .0000125 code calls/1000 patient days per month over the study period. The test for significance of the knot at 1/1/2009 showed that that the knot was significant (p-value= 0.15) so the Spline regression was used with the knot at 1/1/2009. The Spline regression showed that there was a significant difference in the rate of code calls to the floor by 0.0010/1000 patient days.

Figure 3.6 : Rate of Cardiac Arrests (Hospital Wide) Memorial Campus



The rate of cardiac arrests for Memorial was not normally distributed so instead of a t-test, a Mann-Whitney test of the median rates was done. This showed a significant difference in the median of cardiac arrests before and after the intervention.(p=0.092). Again because of not being normally distributed the data was transformed showing that there was a significant decrease of 0.000196 (p=0.024) in the rate of cardiac arrests over the whole study period. Testing for the knot did not show a difference between the two slopes so no more testing was necessary.

Figure 3.7: Rate of Cardiac Arrests (Medical/Surgical Floors) Memorial Campus

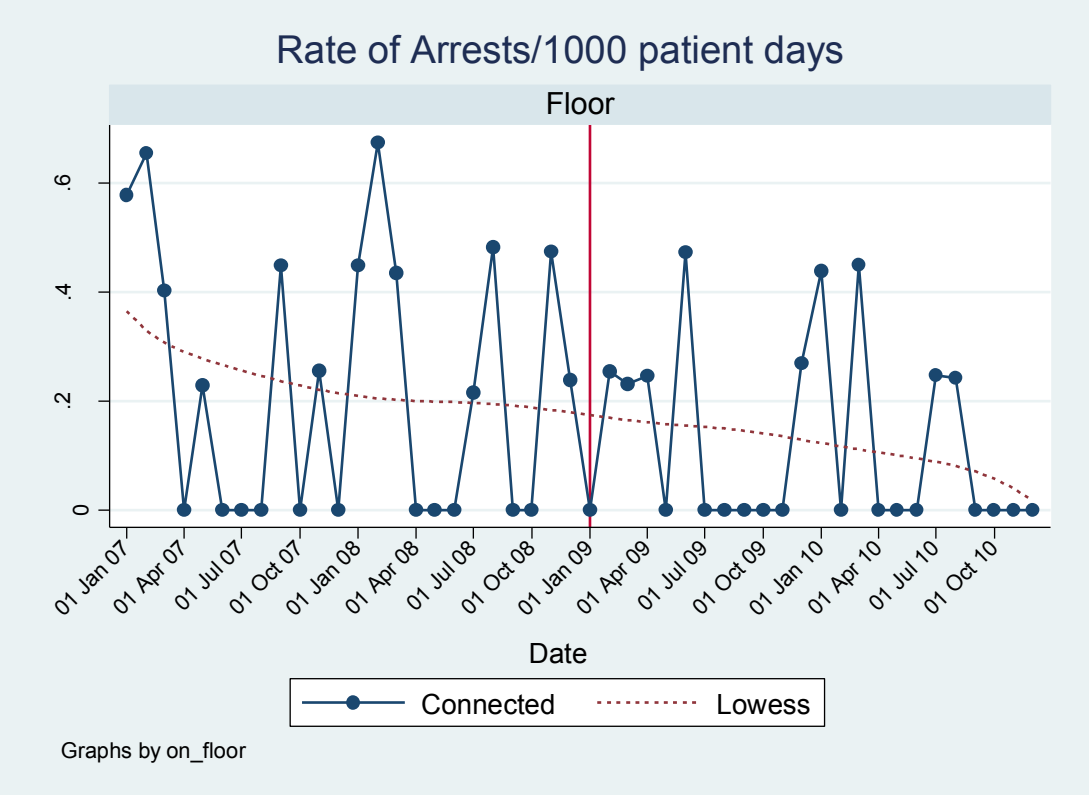


Table 3.10: Rate of Cardiac Arrest (Medical/Surgical Floors Only) Memorial Campus

Campus	Mean rate		p-value	Difference between slopes before and after the knot (1.1.2009)	P-value
	Before	After		0.001367	0.553
University	0.2307	0.1188	0.07		

The initial t-test showed that there was no statistical significant difference in the mean rate before and after the beginning of the intervention. The linear regression showed that there was a slight decrease of .0001552 code calls/1000 patient days per month over the study period. The test for significance of the knot at 1/1/2009 showed that that the knot was not significant so no more testing was necessary.

Figure 3.8: Rate of Cardiac Arrests (ICU Only) Memorial Campus

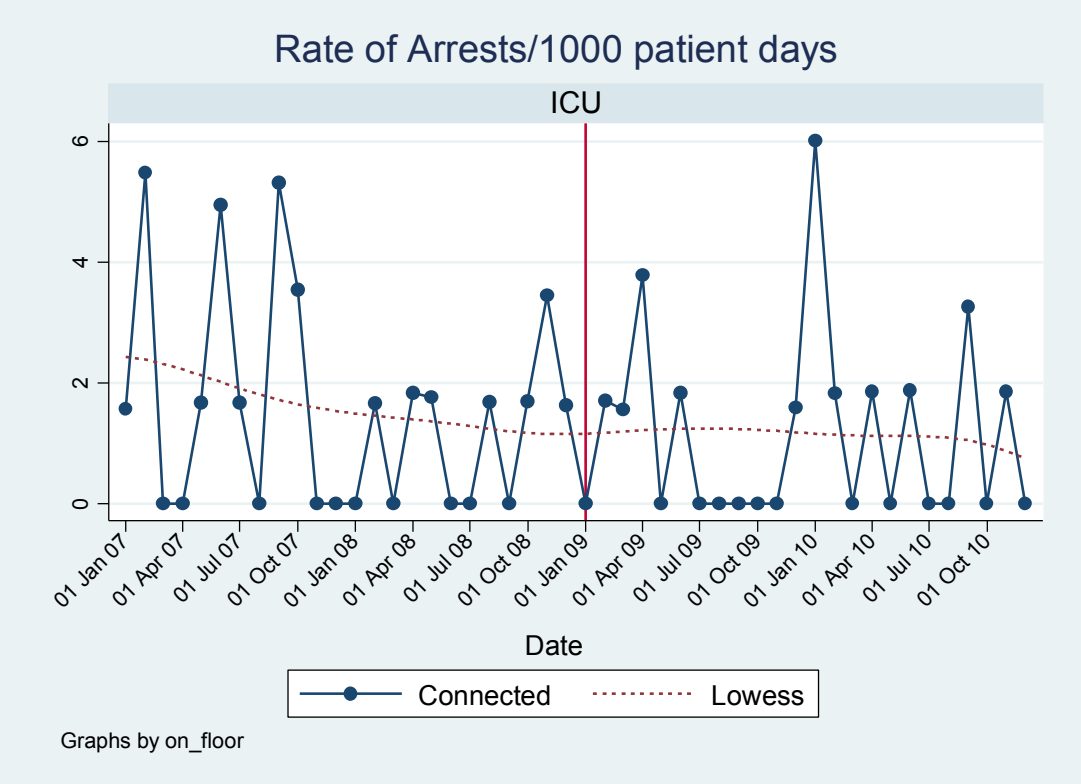


Table 3.11: Rate of Cardiac Arrest (ICU Only) Memorial Campus					
Campus	**Mean rate**		**p-value**	**Difference in slopes before and after the knot (1/1/2009)**	**P-value**
	Before	After		Difference	
University	1.581	1.132	0.357	0.0013677	0.0553

The initial t-test showed that there was no statistically significant difference in the mean rate before and after the beginning of the intervention. The linear regression showed that there were no significant differences over the study period. The test for significance of the knot at 1/1/2009 showed that that the knot was not significant so no more testing was necessary.

Figure 3.9: Rate of Floor to ICU Transfers

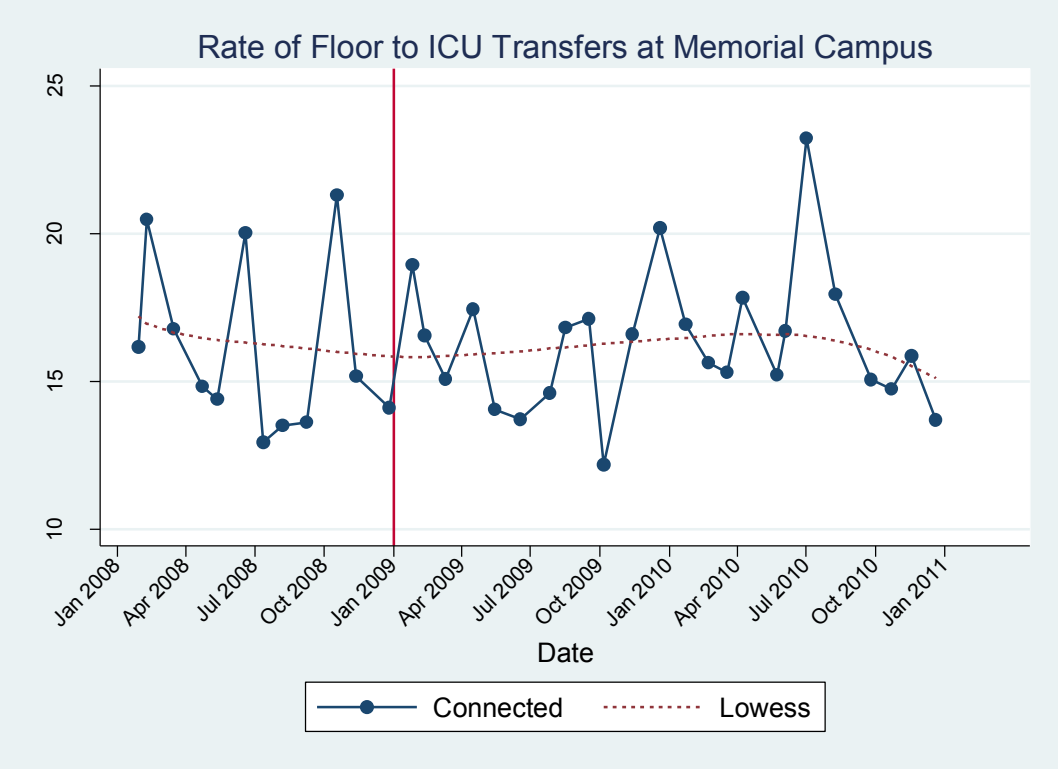


Table 3.12: Rate of ICU Transfers from Medical/Surgical Floors Memorial Campus					
Campus	**Mean rate**		**p-value**	**Difference between slopes before and after the knot (1.1.2009)**	**P-value**
	Before	After		0.0029	0.640
Memorial	16.1	16.3	0.822		

The initial t-test showed that there was no statistically significant difference in the mean rate before and after the beginning of the intervention. The linear regression showed that there were no significant differences over the study period. The test for significance of the knot at 1/1/2009 showed that that the knot was not significant so no more testing was necessary.

Figure 3.10: Rate of Floor to ICU Transfers

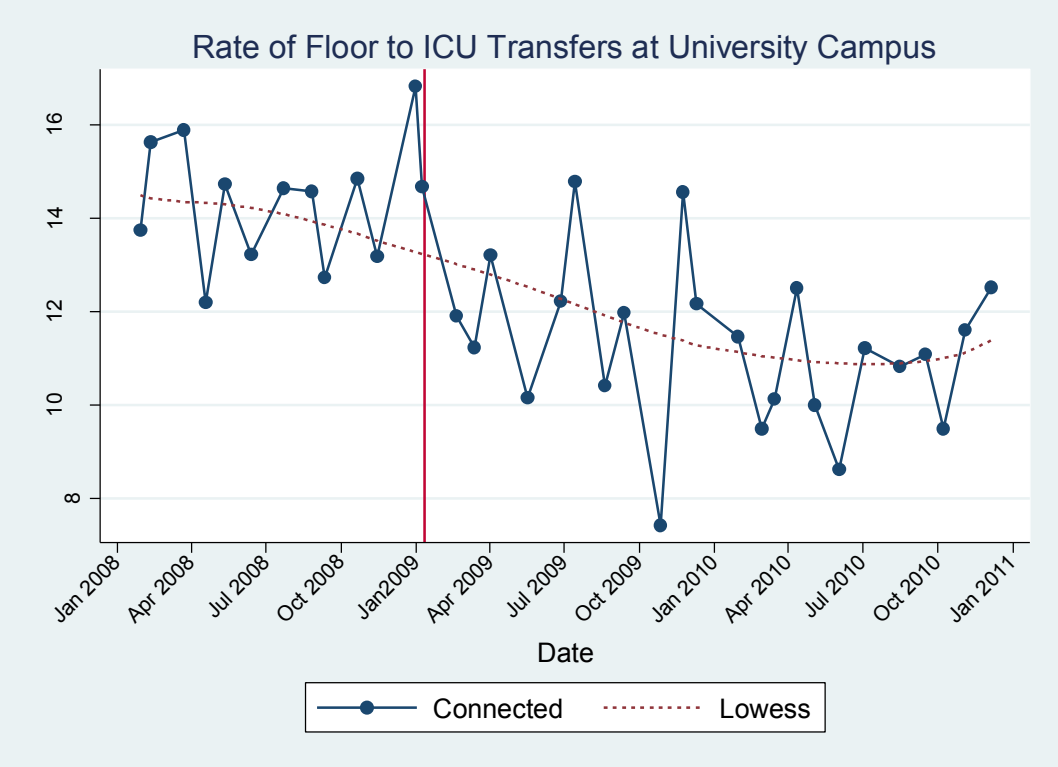


Table 3.13: Rate of ICU Transfers from Medical/Surgical Floors Memorial Campus

Campus	Mean rate		p-value	Difference between slopes before and after the knot (1.1.2009)	P-value
	Before	After		0.00082	0.846
University	14.35	11.40	<0.000		

Initially a t-test comparing the mean rates of ICU transfers before and after the RRS showed a statistically significant decrease in the average rate of code calls. A linear regression showed that there was a decrease of 0.004388 over the entire 3 year study period. However, when a Spline Regression model was used to compare the slopes before and after the intervention there were no significant differences in the slopes.

Table 3.14: Mean Rates/ 1000 Patient Days Before and After the RRS Intervention				
	University		Memorial	
Outcome	Before	After	Before	After
Code Calls on Floor	1.47	0.99	1.132	1.147
Cardiac Arrests Hospital Wide	0.957	0.796	0.484	0.278
Cardiac Arrests Med/Surg Floors Only	0.421	0.291	0.231	0.119
Cardiac Arrests ICU Only	2.057	1.972	1.58	1.13
Floor to ICU Transfer	14.35	11.40	16.1	16.3

Discussion

This before and after study found some changes when comparing the outcomes before and after the RRS intervention. The most notable were the code calls on the University and Memorial campuses. University campus showed a significant difference between the mean rates of code calls from the two study periods as well as an overall decrease over the entire 4 years. However, the Spline regression showed that the slope after the intervention did not differ significantly from 0 meaning that it became almost flat. This could mean that there was a decrease in the time period before and the intervention stopped the decline. A more logical explanation is that around 1 call per 1000 patient days is the lowest that could be expected on the floor and having the RRS in place helped to stabilize the rate of code calls at this low level. A similar finding was found at the Memorial campus, though there was a slight increase over the 4 years and the trend seems to be climbing. The RRS is likely responding to calls

that in the past would have gone to the code team even when they were not life threatening events. However, there was not a corresponding decrease in cardiac arrests. This is still an important and relevant finding. Code teams are traditionally triggered for life threatening situations that require the highest level of care possible. In our hospitals, the code team members are critical care clinicians who leave the ICU's to respond. Though difficult to measure, this may leave the ICU patients without adequate coverage for the amount of time needed for the code call. If the call is indeed for a life threatening emergency, then the team's activation and absence from the ICU is the appropriate response. However, if the code team is being summoned for less urgent cases then the team is not being effectively used and may be using important resources unnecessarily. In this study, the reduction of code calls, without a reduction in cardiac arrest would indicate that the code team was not being activated properly and was responding to situations that are now being handled with the RRT.

The cardiac arrest data hospital wide did not show a significant change from the before period although, there was a significant decline that began before the intervention and continued throughout the study period. Preventing cardiac arrests hospital wide is an ongoing improvement process for most hospitals. The RRS may or may not have contributed to this decline. Even though this study looked at two years post-implementation it may not have been sufficient time to find a difference.

The results on the medical surgical floors were similar to those hospital wide. Cardiac arrests declined over the entire 4 years without a significant difference in rate after the intervention. The RRS is a change not only in protocols and procedures but also a cultural change. Currently, based on the reason for calls and the descriptions of the patients given on the Event Record, the calls are coming in for patients who are well into a decline. The nurses may not be using the trigger criteria as their primary factor when deciding to activate the RRS. With more education and perhaps more effective trigger criteria there may be changes in the activation process that could impact the arrests on the floors. Additionally, though not part of this study, patients and visitors are now able to directly activate the RRS. Further evaluation would be necessary to determine if having patients and families call will change the number of calls, the conditions for which they call and the impact these calls have on preventing cardiac arrests on the floors.

Finally, there was not a significant change in the rate of cardiac arrests in the ICU. The RRS would not be expected to reduce these arrests, but does clarify that the RRS was not just shifting patient who were going to arrest into the ICU. The majority of patients with a RRS call were transferred to the ICU; it is not clear from the data if some of these could have been prevented with an earlier RRS activation. Another evaluation of floor to ICU transfers could identify if patient being transferred earlier in the disease process might contribute to a shorter length of stay and mortality rates.

The average rates of code calls and cardiac arrests are displayed in Table 3.12. There were very low rates of arrests especially on the medical surgical floors. Compared to other RRS literature (Table 3.13) the rates of cardiac arrests at UMMMC were low. This could be demonstrating a floor effect with only a small amount of room for improvement. Perhaps evaluating the current med/surg cardiac arrests and determining where improvement is needed would be useful before initiating other improvement interventions. Additionally, because of the rarity of the events, it might be helpful to evaluate the individual characteristics of each event rather than changes in rates.

Table 3.15: **A Sampling of Cardiac Arrest Rates in the RRS Literature**

Study	Rates of Cardiac Arrests before intervention	Rate of Cardiac arrests after intervention
Bellomo	63 (count)	22 (count)
Brilli	0.10/ hospital day	0.04/ hospital day
Buist	3.77/1000 pts days	2.05 /1000 pts days
Dacey	7.6/1000 discharges	3.0/1000 discharges
DeVita	6.5/1000 admissions	5.4/1000 admissions
Gould	1.90/1000 discharges	1.01/1000 discharges
Jones	4.06/1000 discharges	1.90/1000 discharges
Kenward	2.6/1000 admissions	2.4/1000 admissions
Mailey	2.8%	2.4%
Offner	4.4/1000 pt days	1.4/1000 pt days

Rates of floor to ICU transfers on the University campus showed a decline over the entire study period (3 years) but no significant difference when comparing the slopes before and after the intervention. Memorial campus showed did not show a decline in ICU transfers at all during the study period. Reducing floor to ICU admissions may not be the best measure of the effectiveness of a RRS. Though it was not shown in this study it is possible that a RRS may actually increase floor to ICU transfers. If patients are being assessed and triaged earlier in their disease process they may have a better outcome even if sent to the ICU. Evaluating the severity of illness at admission to the ICU, ICU length of stay, and discharge status may be better measures than the rate of transfers from the floors.

Another area where the RRS may be improving quality in care is when end of life decision are necessary. The RRS is in a unique situation to help facilitate discussions and support patients and families during the decision process. Changes in DNR/CMO status was only recorded for 4 patients across both campuses, however given the limited return of the Event Records it is possible that this was happening more often.

Evidence shows that July is one of the most dangerous months to be in a teaching hospital because this is the month when the interns and residents advance and less experienced house staff become responsible for patient care. Because the RRS at UMMMC includes a hospital clinician and house staff are able to activate the system it essentially served as a bridge during this time

period. Future studies could look at the difference that the RRS has made during multiple years. Additionally the RRS also serves as another method to provide teachable moments to the brand new house staff.

Study Limitations

There were several limitations to this study. The most prominent is the difficulty in obtaining the required hospital data over a period of several years. The methods and quality of documentation changed during the study period with implementation of a new billing and medical record software as well as multiple staff changes. For example, the Event Record was changed to an electronic billing system from which information was difficult to obtain. The verification of cardiac arrests required cross-referencing ICD 9 discharge codes with electronic progress notes to determine the actual occurrence of an arrest and the location and outcome of the arrest. The clinician documentation for a arrest, ICU transfer and activation of the RRS was minimal in terms of the detail of the cardiac events, the clinicians thoughts about the patient's condition and the treatment plan which made abstracting information for analysis difficult.

Though not as strong a study design as a randomized controlled trial, before and after, single site studies are the most feasible and acceptable alternative for evaluating the effectiveness of a RRS intervention. Accounting for the change in patient case mix over time and for changes in quality improvement programs, staffing, patient care policies and protocols, and diagnostic and treatment technologies are serious challenges inherent in this study design that

few if any published RRS effectiveness studies have effectively addressed. These were also challenges for this study. There was limited patient level data available and the information provided was already in aggregate form and was not able to be included in the statistical model. There were no known other interventions that could have impacted the changes, but not all interventions or initiatives were known to the investigators. Changes in any one of these factors from the pre to post-intervention period could have an independent effect on the outcomes being measured in an RRS study.

Conclusion

Similar to other studies in the literature the results of this study were inconclusive in terms of outcome related to the RRS implementation. This serves as further evidence that the methods and outcomes used to study RRS may not be the most effective. This study attempted to establish standard definitions and measures in the evaluation of the RRS. This was not always possible given that much of the needed data were not available. Further research should explore not only better methods for studying RRS but better overall methods for evaluating hospital based quality improvement interventions.

Proposed Ideal Study of the Effectiveness of a Rapid Response System

Introduction

The study of the effectiveness of a Rapid Response System that is reported on in this dissertation demonstrated some of the many difficulties in implementing and

evaluating hospital quality improvement interventions. Two primary problems negatively impacted the evaluation at UMass Memorial Medical Center: the lack of identification of problems that the RRS was being designed to improve and the availability of data that accurately depicted these problems. The directive by the Joint Commission to implement a RRS by January 2008 and a lack of resources to do a series of quick, retrospective studies made this impossible to accomplish. The following is a description of how to ideally develop and evaluate an RRS intervention using Statistical Process Control as an analytic tool and a process evaluation.

Background: Statistical Process Control (SPC)

W. Edwards Deming in 1975 described two types of statistics based on the reason for doing a study.[52] The first and most commonly used in research is enumerative statistics. According to Deming the focus of an enumerative study is the action that will be taken on the sampled population. The second, an analytic study is one in which the action to be taken is on the process that created the results with the goal to improve outcomes. The purpose of a statistical study whether to improve a process or to judge an outcome determines the type of analysis that should be done.

Statistical Process Control is an analytic tool originally designed for use in manufacturing settings to reduce defects, increase productivity and reduce costs in the manufacturing process. The objective of SPC is to improve the process that is producing the outcomes. SPC use in healthcare is growing in popularity

due in part to its relative ease of use and interpretability. The primary tool used in SPC is the Control Chart or Shewhart Charts. This method based in statistical theory, plots data points on a chart that includes a center line (drawn at the mean) upper and lower control limits. These control limits define the central tendency and the range of natural variation of plotted values assuming that the process that produced those values has remained unchanged. The upper and lower control limits are statistically computed based on the probability of the distribution i.e., normal, binomial or Poisson. Control chart software will compute the control limits that coincide with plus or minus 3 standard deviations from the mean of the distribution.[53] Though they may appear similar it is important to understand that the upper and lower control limits are not the same as Confidence Interval limits.

The type of control chart that is used is based on the type of data that is being plotted. (Table 3.16)

3.16 **Criteria for Choosing the Correct Control Chart**[53]			
Xbar-R	Continuous data	More than 1 observation per subgroup	Less than 10 observations per subgroup*
Xbar-S	Continuous data	More than 1 observation per subgroup	Not less than 10 observation per subgroup
XmR	Continuous data	Not More than 1 observation per subgroup	N/A
C Chart	Discrete Data	Both occurrences and non occurrences **cannot** be counted	Equal areas of opportunities exist
u-chart	Discrete Data	Both occurrences and non occurrences **cannot** be counted	Equal areas of opportunities do not exist
p-chart	Discrete Data	Both occurrences and non occurrences **can** be counted	Subgroups are not equal size
Np-chart	Discrete Data	Both occurrences and non occurrences **can** be counted	Subgroups are equal size

* Subgroup is a sample of data pulled from a larger group
** For example: counting the number of cardiac arrests that did occur one cannot count the number of cardiac arrests that did not occur

The variation in a process can be used to predict the amount of improvement possible. A stable process implies that the variation and central tendency in outcomes will remain predictable within statistically controlled limits unless a fundamental change is made to the factors that control the process. A process that is stable does not mean that there is no need for improvement; it means the process is consistently producing the outcome.[53] For example, within a hospital system, the current process may be producing a consistent number of cardiac arrests outside of the ICU but that number may be able to be improved by changes in the process.

Healthcare quality improvement studies typically occur in settings that do not lend themselves to strong experimental study designs. Patients and hospitals cannot always be randomized into receiving or not receiving the RRS intervention ethically or practically. Traditional before and after study designs either compare aggregated data during two time points or require many months or years of data collection to determine changes that may be associated with the RRS intervention. The Plan, Do, Study, Act (PDSA) is a method used to implement, review and revise quality improvement interventions often using SPC as the “study” part of the cycle. (Figure 3.11)

Figure 3.11 PDSA Cycle[54]

Source: Langley *et al.* (1996)

The goal of SPC in the PDSA cycle is not just to determine if a change occurred but if that change was an improvement and what changes in the process were responsible for those changes, or what areas need to be revised to produce more change. This would be in the study part of the cycle; areas of necessary changes would be identified by using SPC (Act). Those changes would be put into action (Plan and Do), and once again SPC would be used to evaluate if the change was an improvement. This cycle would continue until the process is producing the desired outcomes.

SPC is considered a time series analysis; although it does not aggregate data to compare whether there was a statistically significant difference from one period of time to another. Other time series analyses like Spline Regression compare changes in the slopes between two time periods before and after the intervention. The Spline Regression Model does not take into account the different types of variation and therefore does not contribute to understanding what areas of the process need improving.

Proposed Study Design

There are several steps that need to happen before designing an RRS intervention. The first step would be to identify areas that are in need of improvement. To decide which areas the RRS should address, representatives of each department associated with inpatient adult care would be brought together,

either in focus groups or individual meetings, to target outcomes for improvement. For the RRS, the following departments and groups would be important hospital medicine, nursing, nurses' aides and assistants, hospital residents, ICU clinical staff and members of the code team.

Collecting data in a hospital system is complicated by the use of clinical systems that were not originally designed for aggregate population level data. However, when data collection is considered a priority with the burden and the benefits being shared among departments, accurate and useful information can be gathered. Discussions with interested parties will have the best chance of identifying accurate and useful measures, as those described in table 3.17.

These are the recommended outcomes and measures based on observations of the RRS at UMass. Please note that there is currently no Code Team log at UMass and information from the EICU records is limited.

For RR calls, cardiac arrests, code calls and floor to ICU transfers rates would be determined and plotted on a control chart on a monthly basis to insure that enough data points are available. Hospital and ICU length of stay and APACHE scores would be plotted as a monthly average. The other outcomes, reasons for code RRS calls and ICU transfers would necessitate a more qualitative analysis. Data would be separated by themes and changes in those themes would be documented overtime. Staff satisfaction scores would be calculated annually and compared to previous years.

Table 3.17 Proposed Outcomes for the Evaluation of a Rapid Response System

Outcome	Definition	Measure	Data source (analysis)
RR Calls	Rate of Rapid Response (rates by month	The number of calls received telecommunications	Rapid Response Event forms and telecommunication records (SPC)
Cardiac Arrests (floors only, ICU only, Hospital wide	Any Cardiac or respiratory which required CPR, ACLS was considered as well as all asystole or PEA (rate by month)	Cardiac or Respiratory arrests that occur outside of the ED, OR, ICU or diagnostic areas.	Code team log and form cross referenced with medical record review (SPC)
Code Calls	Number of code calls to floors only (rate by month)	Code calls received by telecommunications that originate from the floors	Code team log and telecommunications records (SPC)
Reason for code call	Reason for code calls (categorized)	The documented reason for code calls (cardiac, non-cardiac)	Code team log (qualitative analysis)
Floor to ICU transfers	Transfers to the ICU that do not originate in the OR, ED (rate per month)	Rate of floor to ICU transfers	EICU data (SPC)
Reason for ICU transfers	Reason for transfers that do not originate from OR or Ed (categorized)	Reasons for ICU categorized	EICU admission record (qualitative analysis)
LOS Hospital/ICU	Number of days in the ICU(rate by month)	Average number of days in the ICU by month	EICU records, medical records (SPC)
ICU APACHE Scores	Severity score assigned to patients at ICU admission (average score by month)	Average score by month	EICU records (SPC)
Clinical Staff Satisfaction	Clinical staff satisfaction with the intervention and overall satisfaction (quantifiable change in satisfaction scores)	Changes in survey results	Individual surveys given to staff before and after the intervention (SPC and qualitative)

Analysis: Statistical Process Control

Individual control charts will be used to plot the rates of all the outcomes. Data will be prospectively collected on patients who are admitted to the hospital and are over the age of 18, the study should begin with months before the intervention and continue through the months and years after the intervention with continuous monitoring and changes in the process made as necessary. Most of the data collected will likely be rates with a Poisson distribution so a U-Chart will be used. Statistical control will be determined using the retrospective data to determine a baseline for the process.

A process that does not show baseline stability may be demonstrating special causes that are influencing the outcome of the process. These special causes may need to be addressed within the current process before changes are made to the overall process. For example, if cardiac arrests are happening on the floor at a higher rate (outside of the control limits) in one particular month indicating a special cause it would be important to determine the cause before going forward with a different intervention.[55]

Figure 3.12: Sample of the Control Chart Using Partial Data from the Previous Study

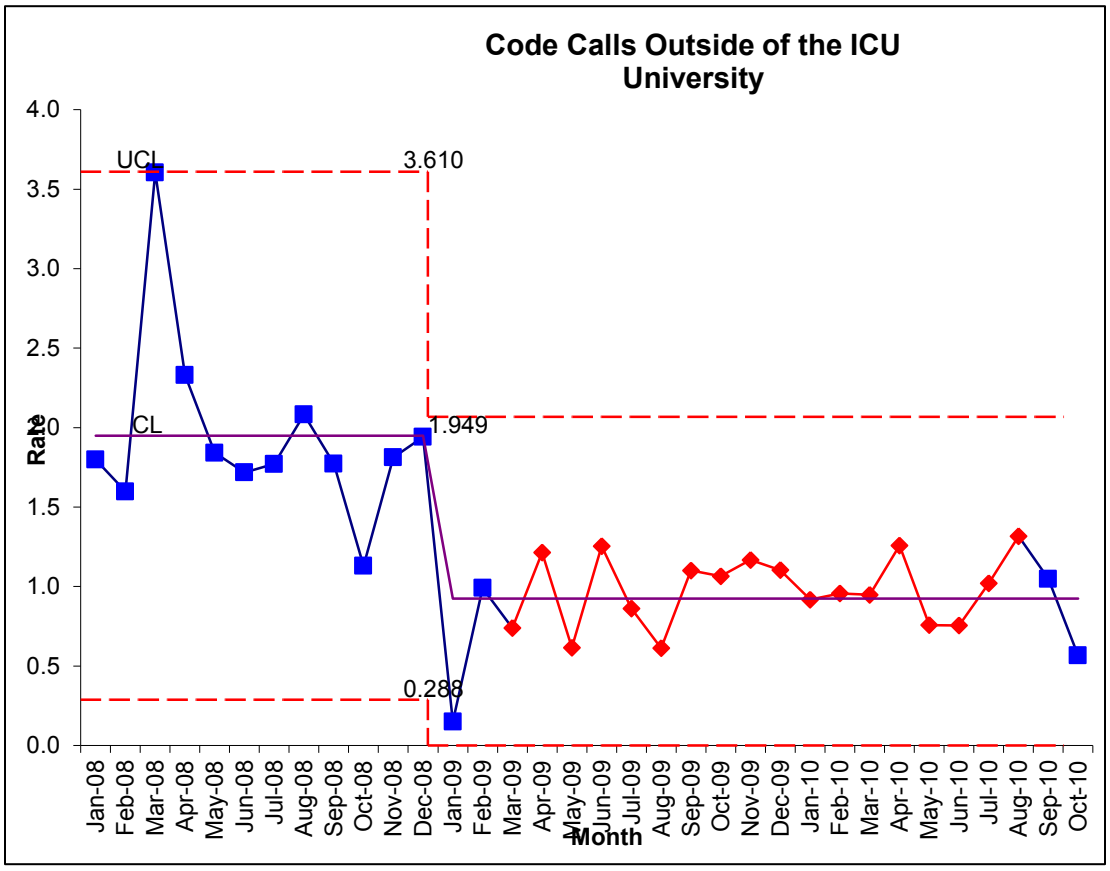


Figure 3.12 shows a sample control chart using partial data from the thesis study and was created using QI Macros. The software set the control limits. The data from the time before the intervention suggests that the process was within control limits and although there was one point right on the upper control limit line, it was still considered in control. January 2009 was the month of the full implementation of the intervention. At that time the rates of code calls fell to 0; which was probably due to a brief confusion about when to call the RRS as opposed to the

code team. Following that month there was an obvious drop in the rate of code calls. The center line (mean rate) actually shifts dramatically following the intervention. This implies that the intervention actually changed the code call process with a resulting significant drop in the overall rate of calls. If used as part of the PDSA cycle, this chart would show that not only that there was a shift in the mean but the amount of variation in the process appears to also have been reduced. When additional information relating to any changes of the reasons for code calls is combined with these results, it could suggest that the RRS has reduced the number of code calls that were not life threatening.

Discussion of Strengths and Weaknesses of SPC

When the goal of the study is to improve the process of delivering healthcare, SPC allows for fast interpretation that can be used to revise and improve the intervention. SPC can be used to estimate the outcome of the process by using a sample of the population or when possible the entire population can be used. SPC is not designed to be a onetime analysis of an intervention. Ideally it is used as an ongoing evaluation of the process which is modified when special cause variation occurs. When this is consistently being tracked during real time the intervention becomes a dynamic process as opposed to a one time intervention with effectiveness being determined months or years later. However, for this to work properly, data has to be easily available on a regular basis. This was not possible during the evaluation period of the RRS at UMass. When systems are set up to track and document data in an SPC format

then more frequent monitoring can occur with timely changes to the process being made. This approach does not allow a more typical before and after or time series analysis to be done since the intervention or process is being changed as time goes by.

In the beginning, there might be some confusion in the use of SPC to evaluate and improve a process. A process “in control” does not necessarily mean that the outcome is the desired outcome. An in control process implies that the process is producing what it is designed to produce. If that is not a desired outcome, the process still needs to be improved. With consistent monitoring, SPC can quickly identify when a process becomes out of control and can pinpoint a specific time when this happens, so that users can analyze the cause of the variation and change the process. SPC is easily interpretable with minimal education of staff so that it can be used by clinical staff in real time with only minimal statistician support. Therefore, more quality improvement projects can be conducted quickly and accurately.

A systematic review of published studies done in the healthcare field that used SPC in their analysis found that SPC:[56]

1. helped people to assess the impact of changes to the process
2. contributed to improvement of healthcare processes
3. helped people identify areas for improvement
4. helped people distinguish special from common cause
5. enabled valuable prediction of future process performance

6. helped describe and quantify process variability
7. improved communication between process actors
8. enabled better informed decision making
9. empowered process stakeholders
10. helped stakeholders learn about their processes

Additionally the studies reported some negatives with the use of SPC which included:

1. sharing the performance data in control chart format did not automatically lead to improvement in healthcare organizations
2. statistical control did not necessarily equal clinical control or desired performance
3. cause and effect relationships are not always obvious, even if a change is identified with statistical confidence
4. Stakeholders have differences in their ability to apply SPC correctly

Perhaps one of the most important items that came from the systematic reviews was documented limitations regarding data for use in control charts. These included factors about the data that makes using SPC less effective. The most common types of control charts are not well suited to analysis of infrequent or rare events. Other data concerns relate to the collection of the data itself, including:

a. difficulties in collecting data that could not be automated (paper medical records)

b. long sampling periods delayed use of the charts to continuously improve processes
c. control chart interpretation was difficult if charts were not annotated with interventions or other influences on process performance

Traditional practices and system culture may also create difficulties in introducing and using SPC effectively. The following difficulties were reported in terms of changing how interventions and other processes were evaluated:

1. limited knowledge on how to apply SPC correctly, extensive education of staff required
2. SPC not seen as helpful or an improvement over other evaluation systems in place
3. finding the right level of aggregation of data for SPC application can be difficult and require trade-offs
4. data collection can be time consuming and costly
5. determining the probability distribution is difficult for staff not familiar with the concept
6. lack of access to reliable data in a timely fashion can be a barrier to real-time SPC application
7. lack of computer power was a barrier to real time SPC application

Another downside of using SPC is that it does not lend itself to cross-institutional summaries. Because of SPC's dependence on the variation within a specific process, hospitals with different processes produce differing variation.

Recommendations for future studies of quality improvement projects

Studies done in hospitals are difficult to combine in meta analyses because of the differences in settings, patient populations and interventions. There is value in replicating and combining research from single sites in order to determine best practices; however, published studies in healthcare quality improvement might be more useful if the focus is on implementation strategies and methods of evaluating of the intervention. Improving processes in healthcare serves a different function than finding the most effective clinical treatment or even understanding the epidemiology of specific disease processes. Each hospital is going to have different strengths and weaknesses depending on their clinicians, other staff and patient populations. SPC and the PDSA cycle provide tools to evaluate the process in a way that is easy to use and interpret allowing for faster improvements to the process. Publicizing of the use of these tools will provide important information to guide other organizations in their use. The goal of this type of research is to evaluate and record the impact that the different iterations of an intervention have on the outcomes.

Cardiac arrests on the floor sometimes have antecedents before the arrest but sometimes do not. This is an essential part in determining if the RRS actually reduced the number of preventable cardiac arrests on the floor as well as the number of preventable ICU admissions. A better outcome measure would be the number of preventable cardiac arrests and ICU admissions. Both these measures would need to be defined by a set of pre-determined antecedents that

would be documented in the medical records. This could be complemented by interviewing the patient's care team soon after the event.

Process Evaluation

It is important in quality improvement research to not only understand if the intervention improved outcomes but whether it worked as it was designed and how the process improved outcomes. The process evaluation of the RRS should have started with a survey of clinical staff and patients about the methods being used to contact and get help at a patient's bedside. This would not only have provided a baseline to evaluate the intervention but the identified gaps would also have guided the development of the RRS. Anecdotally, there were many official and unofficial ways for bedside nurses to get help. These depended largely on the ability of the bedside nurse to understand and communicate the urgency of the situation to the house officers.

A process evaluation can also determine if the intervention responded to all the patients who needed a RRS and did not receive it; but it is necessary to identify those patients. Transfer from the floor to the ICU and cardiac arrests on the floor are two strong indicators that a patient's condition has had an acute clinical decline while on a general floor. Identifying these patients and evaluating each medical record for triggers that would have activated the system could give an approximate number of patients who were missed by the RRS. Sometimes improving one area can create unexpected negative outcomes in other areas. It is important to evaluate unintended outcomes of the RRS which might include:

- delay in activating the code team
- bedside nurse spending too much time with the RRS patient and less time with other patients
- patients being treated on the floor longer than optimal.
- too many unnecessary calls
- increase in ICU transfers without an adequate number of beds available

The high time cost, energy and money of quality improvement projects makes it important to understand where an intervention is needed, what needs to be changed and how the improvement team will determine that a change has produced improvements. The first step in doing both a quantitative and qualitative study is to identify the areas that need improving by involving all stakeholders. Once a baseline is established an intervention is designed with continuous tracking of outcomes. Monitoring of the data being collected allows adjustments and changes as needed. Following these steps with a process evaluation provides the best use of resources to improve the quality of healthcare being provided.

CHAPTER IV
Modified Process Evaluation of a Rapid Response Team

Introduction

Rapid Response Systems (RRS) have been implemented in many hospitals in the United States and other countries with the goal of bringing a higher level of care to the bedside of a patient experiencing a clinical decline outside of the Intensive Care Unit (ICU). The thought is that bringing a care team with critical care skills to the patient will improve certain outcomes such as cardiac arrests outside of the ICUs and reduce the frequency of transfers to the ICU from the floor. Systematic reviews have shown that the evidence for the effectiveness for RRS is mixed.[13-17] The authors of reviews and meta analyses have cited poor study design, flawed data analysis, and heterogeneity in implementation, team members and outcome measures as reasons for the lack of clear evidence to support the intervention. The Institute for Healthcare Improvement encourages systems thinking to facilitate performance improvement by stating that “Every system is perfectly designed to achieve exactly the results it gets”.[57] If the outcomes of RRS implementation are not what was hoped for or expected, it becomes important to look at the RRS from a different prospective, to evaluate the process in addition to the final outcomes. While studies aimed at evaluating intervention effectiveness focus on outcomes, process evaluation determines if the intervention was implemented and used as it was designed to be used.[58]

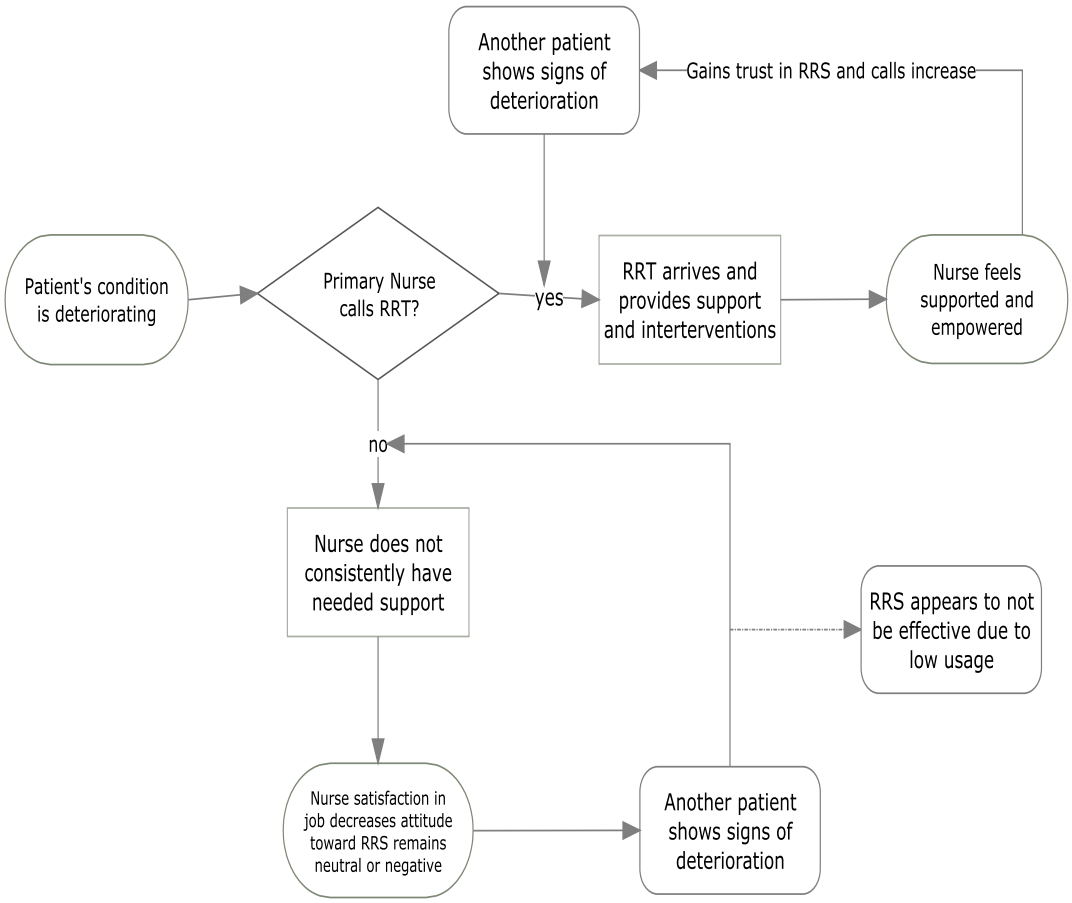
There have been some studies that attempted to look beyond the clinical outcomes of a RRS. They assessed the attitudes and experiences of bedside nurses who are the most frequent users of the RRS. Three studies, report the results of surveys of hospital staff aimed at assessing usage and perceptions of a RRS.[60,61,62] A study from Australia, with a sample size of 73 nurses, found that the more experienced the nurse the more likely he/she was to use the RRS.[59] The nurses' suggested that improvements of the RRS should focus on additional education for nurses and team members and on working with team members to help them be more positive and supportive when responding to a call. In another Australian study investigators developed a survey and administered it to a sample of 351 nurses.[60] They found that nurses were more likely to call the covering provider before calling the RRT even though the protocol was to call the RRT first. The authors also found that nurses may be underestimating the significance of the trigger signs and often opting not to call the RRT when trigger signs are present. The nurses in the study felt that the RRS prevented cardiac arrest and helped them to manage unwell patients. However, some of the nurses were hesitant to call fearing criticism of their ability to care for their patients. Nineteen percent of the responders felt that RRS calls were required because medical management by the doctors, especially junior doctors, was thought to be inadequate. Eighty-one percent of the nurses indicated that they would call if they were unable to contact the covering physician and 56% said they would call if

they were concerned about their patient even if the vital signs were normal. Investigators in Canada using the same survey (n=275) found similar results.[62]

A study that used 50 semi-structured individual interviews of nurses in 6 California hospitals found that the nurses use a combination of the specified triggers and their own knowledge to decide when to activate the RRS for patients who did not meet the criteria.[62] The authors also found that newer nurses were more likely to consult with a more experienced nurse before calling even when this was not part of the protocol.

Two other studies observed that the number and rate of calls to the RRS team increase over time.[39,63] This may explain some of the differences in outcomes across published studies. As the primary nurses become more comfortable and confident in the system, the number of calls to the team may increase, this may have an effect on the outcomes. Additionally, the reaction of the responding clinicians, whether positive or negative, is will impact RRS usage. (Figure 4.1)

Figure 4.1: Conceptual Model of Nurses' Usage of the RRS



An evaluation of the effectiveness of an intervention is not enough. A process evaluation will determine the extent to which the intervention functioned as it was designed. There are several domains in a process evaluation: context, reach, dose delivered, dose received, fidelity, implementation and recruitment.[58] The objective of this chapter is to explain the development and implementation of a RRS at two academic hospitals as well as a modified process evaluation looking at the following domains: reach, dose delivered and fidelity. Also included is an evaluation of nursing and other staff perspectives of and attitudes towards the RRS.

Implementing a Rapid Response System

The UMMMC Office of Quality and Patient Safety convened a working group with representation from medical and surgical subspecialties, nursing, respiratory therapy, hospital medicine, and critical care. After a thorough review of the literature and discussion of several models for the RRS, this group reached agreement on objectives, a model and eleven clinical triggers to guide activation.

The objectives for the Rapid Response System were:

- To identify, diagnose and immediately treat hospitalized patients outside of the ICU at the first sign of serious clinical decline
- To prevent code calls and urgent, unexpected transfers to the ICU and to reduce overall hospital mortality

The initial RRS model included a dedicated critical care nurse as the key RRS responder. This person could be called for informal consults without activation of the system. A hospital medicine staff physician was the clinical lead and the first-call house officer for the patient was included on the team. A 2 week pilot study on two floors at each hospital revealed that nurses rarely formally activated the system, but frequently sought the advice of the critical care nurse in managing acute problems. This model was well received by the floor nurses and staff, but the limited resources of the institution made it impossible to support the expansion of the critical care nursing staff. The work group also received input from hospital medicine that their staff physicians were reluctant to commit to serve as clinical lead because of competing time and service demands. Some residency program directors also advocated for house officers to be designated as clinical leaders of the Rapid Response team as they would have specific case knowledge of the patient and would also benefit educationally from the experience. As a result, the work group identified an alternative model that was financially feasible and responsive to the concerns expressed about the first model.

Revised Model

The hospital medicine service had recently begun a program of hiring nurse practitioners (NP) and physician assistants (PA) trained in acute care medicine to support the work of staff hospitalists. After discussion on a variety of models, the work group decided that the NPs and PAs had the skills to respond to the acute clinical issues faced by a Rapid Response team and that their collective enthusiasm for the program made them good candidates to take on the role that the critical care nurses had in the original model. The NPs and PAs also have access to supervision and back-up by the in-house hospital medicine physicians (hospitalists). Rapid Response Team members and roles and protocols for the revised model are described in Table 4.1.

Table 4.1: **Established Roles and Protocols for Rapid Response Team**

Team Member	Role	Protocol
Bedside Nurse	To activate the RRS and to have all necessary patient information ready for team	To use pre-determined criteria to activate team; use SBAR to communicate with team
Hospital Medicine NP/PA or Hospitalist	To offer clinical support; responsible for all documentation associated with RRS	Arrive within 5 minutes of call Complete Rapid Response Record
House Officer	Clinical Lead	Arrive within 5 minutes of call
Nursing Supervisor	Nursing support and resource management	Arrive within 5 minutes of call (nights and weekends only)
Respiratory Therapist	Maintain Airway	Arrive within 5 minutes of call

When the primary nurse calls the Rapid Response number (a dedicated line) the operator activates a system that simultaneously alpha pages required team members. The covering house officer receives a page and is required to call telecommunications to acknowledge receipt, and to receive the location of the patient.

Educational and promotional efforts

Nursing brochures, pocket cards and pens developed in-house were distributed during educational sessions that were conducted on every unit, every shift, targeting floor nurses, medical assistants, patient care assistants, and ward secretaries. Posters were developed that included activation triggers and the RRS process and were left at each nursing station after they were used in training sessions. This was an efficient way to reach the most nurses with the least amount of disruption of their duties. All of the educational materials included the trigger criteria and specific situations when the RRS would not be appropriate to activate.

Hospital medicine clinicians and house staff received role-specific training. Other staff members including attending medical staff and respiratory therapists were informed of the intervention by a combination of in-person trainings, emails, messages on screen savers and paychecks, and information in an organizational newsletter. These were venues already developed for the dissemination of new information and did not require additional funds. The implementation group was responsible for the education during the pilot and nursing educators provided

"Just in Time" education before full implementation. The educational sessions occurred over a 2 week period, 20 minutes per session at minimal cost.

Methods

A modified process evaluation was conducted evaluating fidelity, reach, dose delivered, and staff perspectives of the RRS.[58] Table 4.2 describes in detail the domains being assessed, the questions answered for each domain, the targeted populations and the measures and data sources.

Table 4.2: Modified Process Evaluation Domains[58]

Domain	Research Question	Target of Evaluation	Measures/Data Source
Fidelity/ Nurse and staff performance: Nurse and RRT member performance	Are the RRS protocols being followed? % of staff that arrived in 5-10 minutes % use of SBAR of the nurses	Primary Nurse Rapid Response Team	Rapid Response Event Forms
Reach: The proportion of the intended target that is reached by the Rapid Response Team.	What % of patients who are eligible for RRS receive it? Does this differ by patient characteristics (age, gender, and acuity), shift, floor or unit, or Hospital?	Patients	Medical records Meditech Visicu
Dose delivered: The number of calls that are made to and responded to by the Rapid Response System.	How many calls were made? Does this differ overtime, by shift or hospital?	Primary nurses	Rapid Response Event Forms Tele-communications Record
Perspective of Staff affected	What is the acceptability/satisfaction? What are the barriers to RRS use?	Primary nurses	Focus groups Surveys (individuals)

Fidelity

The fidelity of the intervention was assessed based on the extent that the staff, primary nurses and team members followed the protocols established for them. The protocols for the primary nurse and other clinical staff included identifying an established trigger and activating the Rapid Response Team (RRT). Triggers and four situations which should not trigger a RRS are described in Table 4.3. Additionally, they were to communicate the Situation, Background, Assessment and Recommendations using the SBAR format shown in Table 4.4.

Table 4.3 **Rapid Response Triggers** **All Triggers refer to NEW ONSET of the Condition**	**There are 4 situations in which a Trigger usually does *not* require action:**
• Nursing, LIP or family has a marked concern about the patient	1. **Baseline condition**: The patient has the Trigger as a baseline condition ***normal for the patient*** (e.g. a patient with CHF on multiple medications with systolic BP of 88 and no symptoms)
• Heart rate < 40 or >120	
• Systolic BP < 90	
• Chest pain unresponsive to initial treatments and NTG	2. **Treatment underway:** The Trigger has been documented on previous recent assessments AND the responsible ***clinicians have already addressed the Trigger***
• Respiratory rate <6 or >30	
• O_2 saturation <90% or significant drop from baseline - despite delivered oxygen	
• >= 50% O_2 by mask or >= 6 liters per min	3. **Expected finding:** The Trigger has been documented on recent assessments and is an EXPECTED finding for the clinical circumstances (e.g. expected drowsiness while recovering from conscious sedation)
• Acute change in mental status	
• New onset seizure	
• Possible stroke	
• Urine output <50 ml. over 4 hours (<120 ml over 4 hours for patients 48 hrs or less post-op)	4. **Patient not a candidate for Rapid Response:** ***patients who are CMO*** will usually not benefit from Rapid Response because life-saving treatments are not indicated. (Most DNR patients ARE candidates for Rapid Response)

Table 4.4 SBAR	
1. **Situation** • "I called a Rapid response because: " • "I am concerned about:" • "The current VS and mental status are:"	**2.** **Background** • Important medical/surgical history: • Recent procedure(s): • Recent significant labs: • Pertinent allergies/meds
2. **Assessment** • *"*Some possible problems that concern me are:"	**4.** **Recommendation** • **"**I would like the patient evaluated for:"

The protocols for the Rapid Response Team include, arriving within 5 minutes of the call, evaluating the patient, initiating a treatment plan and when able to transfer care back to the care team or to the ICU. A Rapid Response Event form was filled out by the responding Rapid Response Hospital Medicine Clinician and includes information about the event that triggered the call as well as the interventions that followed the calls. This information was compared to the written protocols developed for this intervention to assess how often the process varied from those protocols.

Reach

The RRS is designed with the intention of reaching all medical/surgical patients whose conditions are acutely deteriorating. All patients who have a cardiopulmonary arrest on the medical/surgical floors or who were transferred from the floor to the ICU without an RRS intervention were identified using

telecommunication records, ICD 9 discharge codes, an electronic database and the Rapid Response Event Record. These patients represent those who may have met the RRS criteria but did not receive a team intervention. The frequency of these occurrences was recorded monthly to assess changes over time.

Dose Delivered

Using the Rapid Response Event Records and tele-communication Records we determined the incidence of calls per 1000 patient days by month, and assessed whether those calls increased or decreased over time. These results were compared other published reports to determine if the usage of the RRS is what would have been expected.

Staff Perspective

The attitudes, knowledge and behaviors of primary nurses are key to the frequency and appropriateness of RRS calls. Nursing behavior is the most important proximal factor related to reach and dose delivered because nurses initiate almost all rapid response calls. Figure 4.1 shows how the attitudes and perspectives of the nurses can be impacted by the response they receive from the responding RRT and the patients care team. This could impact the usage of the RRS. To evaluate nurses' satisfaction and barriers to using the RRS, a focus group and a survey were developed. The information provided during the focus group was transcribed and analyzed for reoccurring themes. The outcomes of the focus groups also informed the development of additional questions for a survey based on one used in two prior studies.[60,61] The survey was administered

by the nursing supervisors under the direction of the Office of Quality to all nurses who work in the hospital areas covered by the RRS. This survey measured satisfaction, perceived barriers and perceived usefulness of the RRS. Both nurses who have activated the RRS and those who have not were included. Excluded were any per-diem nurses, and those who worked exclusively in areas not covered by the RRS.

Results

Fidelity

Fidelity of the intervention was primarily evaluated using the Rapid Response Event Records that collected information regarding the response time of the team, the reporting of the event by the bedside nurse and the appropriateness of the call. The responding hospital medicine Clinicians were responsible for filling out the Event Form. Out of a total of 683, only 338 Event Records were completed: 202 from University (return rate of 45 %) and 98 from Memorial (a return rate of 42%). The remaining 38 had campus or location missing so it is unclear where these were from and they could not be used in any analysis that required separation by campus. There are several reasons that may explain the low return of the event forms. First, they were hard copies only so that it required that they be available when needed, and that once filled out they be returned to the pickup location. Second, the importance of the forms may not have been clear to the staff filling them out. If the call resulted in no formal intervention, it was not seen as a priority, or when the event occurred during a

busy day, the forms may have been forgotten. There were no obvious differences based on the time, date or day of the call. During the second year of the intervention, there was a change on the University campus in that NPs and PAs were no longer covering during the day time shifts. The RRS pager was then given to the hospitalist. This resulted in a lower than average return of the forms. The following tables summarize the information reported in the forms that were returned.

Table 4.5: Response Time of the Rapid Response Team (University)

Team Member	<=5 min	5-10 min	10-15	>15	No show	Not sure	Missing
House Officer	122 (60)	23 (11)	3 (2)	6 (3)	7 (3)	4 (2)	37 (18)
Hospital Medicine Clinician	169 (84)	9 (4.5)	1 (.5)	0(.5)	1(.5)	0	21 (10)
Respiratory Therapist	147 (73)	9 (4.5)	1(.5)	1(.5)	1(.5)	5 (2)	38 (19)
Bedside Nurse	172 (85)	1(.5)	0	0	1(.5)	1(.5)	27(13.5)
Nursing Supervisor	101 (50)	12 (6)	3 (1.5)	3 (1.5)	12 (6)	10 (5)	61(30)

Table 4.6: Response Time of the Rapid Response Team (Memorial)

Team Member	<=5 min (%)	5-10 min	10-15	>15	No show	Not sure	Missing
House Officer	55(56)	6 (6)	3(3)	2 (2)	3(3)	0	29 (30)
Hospital Medicine Clinician	74 (76)	9 (10)	0	0	0	0	15 (15)
Respiratory Therapist	77 (79)	3 (3)	0	0	1 (1)	0	17 (18)
Bedside Nurse	79 (81)	0	0	0	0	1(1)	18 (18)
Nursing Supervisor	58 (59)	5 (5)	1(1)	1(1)	0	4 (4)	29 (30)

The responding HO was considered the clinical lead for the Rapid Response Team. Table 4.7 includes the response given by the hospital medicine clinicians as to the effectiveness of the HO interaction. This was not specified in any of the educational material and was collected to be able to determine if the interaction with HO might have an impact on the usage of the RRS.

Table 4.7: Effectiveness of the House Officer Response

	Not Effective 1	2	Somewhat Effective 3	4	Very Effective 5	Missing
University	6 (3)	11 (5.5)	17 (8.5)	37 (18)	84 (42)	47 (23)
Memorial	0	1(1)	8 (8)	15 (15)	43 (44)	30 (32)

Table 4.8: Nurses use of SBAR

	University			Memorial		
	Incomplete	Somewhat complete	Complete	Incomplete	Somewhat complete	Complete
Situation	17	68	101	3	38	41
Background	21	77	77	5	36	39
Assessment	14	62	101	7	32	40
	Yes	No			Yes	No
Recommendation	119	63			60	22
Missing	234			449		

The beside nurses' protocol included providing information to the other team members using the SBAR format. This format was designed to encourage more effective communication during hand-offs. The components in SBAR include: describing the situation, giving adequate and necessary background about the situation and patient, providing an assessment, and giving their recommendation. This format was familiar to many nurses and was reintroduced during the education process and provided on pocket cards and all RRS literature. The responding hospital medicine clinician was asked to rate the bedside nurses on how well they used SBAR to give the information. The results are described in Table 4.8.

All responders were asked via the Event Record to comment on whether the call to the Rapid Response Team was the appropriate or if another type of intervention would have been more appropriate. (Table 4.9) The most concerning of these responses are the cases where the team felt that a code call would have been most appropriate for the patient. The education of the nurses stressed that a life threatening condition should lead to a code call and that if there was any doubt then the code team should be called.

Table 4.9: Was a Rapid Response Call Appropriate for This Patient?	University (%)	Memorial (%)
Yes	141(70)	61 (62)
If not what would have been a more appropriate response?		
Code Call	15 (7)	6 (6)
Routine Page to LIP	22 (11)	7 (7)
Routine page to Respiratory Therapy	1 (.5)	1(1)
Could have been handled by nursing alone	1(.5)	0 (0)
Missing	22 (11)	23 (23)
Total	202	98

Reach

It was difficult to determine if the RRS reached all the patients who were eligible for the intervention. The first attempt was to look at all cardiac arrests and determine which ones did not have a RRS call within the 24 hours preceding the cardiac arrest. There were a total of 193 code calls on the University campus, 40 of them had corresponding RRS calls. (Table 4.11) On the Memorial campus there were 121 code calls with 17 corresponding RRS calls. There were a total of 129 cardiac arrests on the floor at University and 29 arrests on the floor at Memorial after the RRS intervention. Of the arrests after the intervention only 3 were associated with a RR within 24 hours before the arrest. All of these were at University campus. Without doing a paper chart review it was not possible to determine if any antecedents were present 24 hours before the arrest. Code calls at UMMMC are not recorded with patient identifiers, so when a code sheet is not filled out, which happens when the call did not require a code cart, it was

impossible to determine what the other code calls were for. Both before and after the intervention less than 50% of all code calls had corresponding codes sheets (Table 4.11).

Table 4.10: **Code calls with RRS Call**		
	Total Code Calls	Corresponding RR Call
University	193	40
Memorial	121	17

Table 4.11:
Code calls (Med/Surg Floors Only) with Corresponding Code Sheet

Campus	1/1/2007-12/31-2007			1/1/2008-12/31/2008			1/1/2009-12/31/2009			1/1/2010-10/31/2010		
	Code Calls	Code Sheets	%	Code Calls	Code Sheets	%	Code Calls	Code Sheets	%	Code Calls	Code Sheets	%
Memorial	72	26	36	51	24	47	47	16	34	58	30	52
University	91	16	18	95	29	31	70	29	41	69	31	45

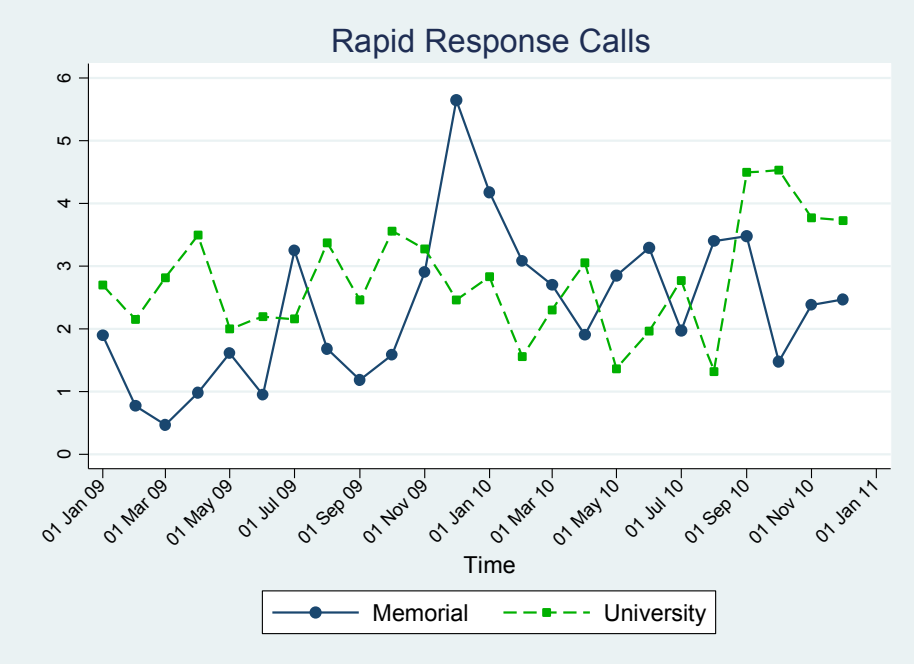
Dose delivered

There were a total of 683 Rapid Response calls 449 at the University Campus and 234 at Memorial. The University campus averaged 18 calls per month with a range from 9 to 32 and an average rate of 2.8 calls per 1000 patient days. The Memorial campus averaged 10 calls per month with a range from 2 to 21 and an average rate of 2.3 calls per 1000 pt days. There was no statistically significant increase or decrease over the 24 month study period.

Collected from the Event Record were the Rapid Response triggers, the bedside interventions and the disposition of the patient following the RR

intervention. The most common outcome of the rapid response was a transfer to the ICU, followed by the RRT being able to treat and stabilize the patient on the floor. On the University campus there were some calls that did not require any treatment at all. Rarely did the RR call prompt a change in DNR/CMO status.

Figure 4.2: Rate of RRS Calls/1000 Patient Days



Staff Perspective

A focus group of 7 medical/surgical bedside nurses resulted in responses to five different areas described in Table 4.12.

Table 4.12: Focus Group Themes
When the bedside nurse decided to call
• Things were going bad but it was not a code • When the covering physician was not responding • When there seemed like there were no other options • When there was uncertainty about a situation
Usage of the Triggers Criteria
• Do not refer to the list often • Didn't know there were trigger criteria • Rely on a "gut" feeling • Some of the trigger criteria are normal for surgical and other patients
Reasons that the bedside nurses waited to call or did not call at all
• Called the resident first and finally insisted that they deal with it or a RR would be called • Borderline cases waited to see if they would turn with standard interventions • Newer nurses tend to ask the more experienced nurses before calling themselves
Concerns from the Bedside Nurses
• When first implemented there was a slow response time • The House Officer is not always an effective part of the team • Sometimes the covering physician is not happy that the RR was called; even if they were not responding to the bedside nurse's concerns
Benefits of the Rapid Response Team
• Covering MD is quicker to respond if they know a RR has been called • The RR is a fallback or a safety net when the bedside nurse is out of options • The RR is able to facilitate faster ICU transfers • Someone to call when the covering physician is unavailable or it is unclear who is covering the patient • Provides clinical support to a new Intern • Very good interactions with the responding Hospital Medicine Clinicians • It has made the bedside nurse's job easier • Probably prevented codes and saved lives • RRT will show up when called • Newer nurses are being taught by the responding team • Other nurses will take over the patients of a nurse who has called for a RR

Twenty nursing survey were distributed to 10 nurse managers with a return of 27 surveys. Of those who responded the majority felt that the hospitals treated complex patients and that the RRT prevents cardiac arrests and transfers to the ICU as well as being able to help manage sicker patients outside of the ICU. Most nurses called for a RRT when their patients were sick and they could not reach a covering physician, though they will try to contact a physician first. Overall there was no concern about being criticized or that the intervention was being over used. Prior to the RRS, the nurses needed to contact the HO, the HO would triage their patient over the phone and determine the priority with which they would come to see the patient. According to the nurses involved in the focus group the RRS has improved the method of getting the HO to focus on their patients.

Table 4.13: **Rapid Response Nursing Survey Results**					
Questions					
1. Number of years nursing?	**1-5**	**6-10**	**11-15**	**16-20**	**Over 20**
	14	4	1	1	7
2. Approximately how many hours a week, on average, do you work?	<20	21-30	31-40	>40	
	1	5	20	1	
3. Approximate number of RRS calls you have made?	0	1-3	4-6	7-10	>10
	1	8	12	6	
Rapid Response Questions	**Strongly disagree**	**Disagree**	**Uncertain**	**Agree**	**Strongly Agree**
4. Patients in the hospital have complex problems	0	2	0	10	14
5. The RRT prevents unwell patients from having a cardiac or respiratory arrest	1	1	3	14	8
6. The RRT prevents ICU admissions from the floors	3	6	15	2	1
7. The RRT allows me to seek help for my patients when I am worried about them	0	2	1	18	6
8. The RRT is not helpful in managing sick patients outside of the ICU	7	16	3	1	0
9. When one of my patients is sick I call the covering doctor before calling a RRT	1	1	1	17	7
10. If I cannot contact the covering doctor about my sick patient I call a RRT	0	2	4	16	5
11. I am reluctant to call a RRT on my patients because I will be criticized if they are not that unwell	8	15	3	1	0
12. RRT calls are required because the management of the patient by the doctors has been inadequate	9	11	3	4	0
13. RRT calls are required because the management of the patients by the nurses has been inadequate	12	9	3	3	0
14. I would call a RRT on a patient I am worried about even if their vital signs are normal	1	9	7	9	1
15. I think that the RRT is overused in the management of hospital patients	7	15	4	0	0
16. I don't like calling RRT because I will be criticized for not looking after my patient well enough	10	15	2	0	0

17. RRT calls reduce my skills in managing sick patients	10	17	0	0	0
18. Using RRT system increases my work load when caring for a sick patient	11	11	3	2	0
19. The RRT can be used to prevent a minor problem from becoming major	0	4	0	16	0
20. If my patient fulfills the listed RRT criteria but does not look unwell I would not make a RRT call	6	17	3	1	0
21. RRT calls teach me how to better manage sick patients on my floor	1	5	9	10	0
22. The RRT has improved care for patients at UMMMC	1	0	6	15	5

Responding hospital medicine clinician's response to the Rapid Response Calls were collected from the Event Records and were classified into different themes Table 4.13. There were a few areas of improvement identified including RRS activation for a patient with a DNR/DNI order, non-med/surg floors being poorly equipped for the situation, and a few situations where the RRS was not needed.

Table 4.14: Comments from the Rapid Response Event Record **Not all comments are included most duplicate comments were not repeated; comments summarized and shortened when appropriate**
Barriers (Negatives)
Pt DNR/DNI no need for RR
Primary team did not feel comfortable calling ICU
Floor poorly equipped for the situation
HO and nurse supervisor were no show
HO was looking for us to take over care of pt
Needed code call
Could have been dealt with by attending
Didn't have the right equipment in CT to assess patient
Spent 3 hours with patient
Full report not given
Night float was engaged in situation prior to eventual event
Family medicine was well aware of the situation
Night float did not show up
Nurse supervisor showed up after pt was sent to radiology
Service of the RR not needed
MDs not showing up
Confusion over calling a code or an RR
Encouragement (Positives)
All parties involved very cooperative and informative; staff knew the patient well
All team members arrived promptly
Appreciated RT and bedside nurse quick response
Nursing staff great team work
Bedside RN and floor staff very responsive; able to gather necessary info
CT staff helpful and prepared
ED very gracious and helpful
Excellent bedside nurse and floor staff Cardiac fellow present very helpful
Excellent response and input by all present
Excellent team effort
Good team communication/effort /work/smooth process
Great team work by all members
Nurse very helpful
Suggestions for improvement
Better HO response (or different system)
Floors better prepared for Emergencies or RRT carry necessary equipment

Discussion

Improvement interventions in healthcare require standardized methods to evaluate the outcomes but they also require an understanding of how the intervention has changed the process of healthcare delivery, and if the intervention is working as designed. Rapid Response Systems make intuitive sense. Hospitals must be giving better care to patients if they receive faster, higher level care at their bedside when they need it, no matter where they are in the hospital. The expectation is that RRS studies would show this. However, this is not the case. Single site studies continue to show ambiguous results. In these situations process evaluations, even modified ones, become necessary for researchers and hospital leadership to better understand how the intervention was implemented and used.

Fidelity

The RRS was designed to have each staff member perform a different role with different protocols for each role. The RRS implementation team was responsible for most of the education of all staff before it was implemented hospital wide. During the study period the RRS could be activated by any staff member using the standardized triggers or their clinical judgment. The nurses did not always use the criteria as a reason to call and most often relied on “gut” instinct that something was wrong and their patient needed additional help. This was not using the RRS triggers as they were designed to be used. However researchers at Virginia Mason Medical Center did a retrospective medical record review on patients that had not received RRS intervention and found that had all

patients with an observable trigger would have activated the RRS 2100 times in a month or 3 calls per hour. The trigger criteria at Virginia Mason were similar to the ones used at UMMMC. The trigger criteria may be a useful guideline but it is likely that some clinical judgment is required to interpret triggers and identify those that genuinely need the immediate attention of the RRS. Future research is needed to determine which triggers accurately predict the need for a RRS intervention.

The majority of the calls were thought to be appropriate calls to the RR with a total of 19% of the calls at University and 12% of the calls at Memorial that the responding team thought would have been better handled by someone else. The most concerning possible negative outcome of the RRS would be the delay of a call to a code team when the patient is in a life threatening situation. Bedside nurses were instructed to continue to call a code for any life threatening situation, however, there were a total of 21 RRS calls that the team felt should have been code calls. Though prior studies have not addressed any unexpected negative consequences to the RRS, this is one worth pursuing.

The RRS was designed to function as a team, with each member expected to arrive at the bedside within 5 minutes. All of the team needed to travel to the location of the floor except the bedside nurse. Not all members of the team arrived a hundred percent of the time within the five minute window and there were times that the bedside nurse was not available when the team arrived. Most of the calls were initiated for a patient who was in some type of acute

distress and the bedside nurse would know the most about the patient's condition. This negatively impacts the ability of the rest of the team to make quick, accurate decisions regarding care.

Though the RRS education was not the first time the nurses had been taught the SBAR techniques, it has not been a standard tool used hospital wide. The bedside nurses clearly differed in their usage of SBAR. The education of the bedside nurses included a quick summary of the use of SBAR and it was included in all the educational material. However, it was not the primary focus of the education process. Even though RRS eliminates, to a degree, the necessity for the calling nurse to have enough facts to convince a physician to evaluate a patient, it is still important that the nurse be able to communicate concerns when the team arrives. There was limited time and resources to develop and implement the RRS education. The focus of the education was on how to activate the team and how to identify patients who needed a RRS intervention. For better efficiency during a RRS call, as well as for increased communication among staff, staff should be more consistently and widely educated on the usage of SBAR and other protocols related to the RRS.

All of the information regarding the protocols of the RRT was recorded on the Event Records. Though these would ideally be completed at the bedside or shortly after this was not always the case. Many times the Event Records were filled out hours or even days later. Only about 50% of the forms were collected, and there was much missing data on these collected forms. Therefore, these

data are not a reliable measurement of what actually occurred. The limited documentation of the RRS calls most likely occurred for a variety of reasons including availability and usability of the form. The forms were copied and made available, but at times were difficult to find. The forms were long and took time to complete. Returning completed forms was a multi-step process that allowed for the possibility of completed forms being misplaced. It is also possible that when no intervention was needed, no form was filled out. Based on the available information there was no obvious differences in the calls that generated a form and those that didn't. It is important to have complete and accurate information to determine the strengths and weaknesses of an intervention, but this was hindered by the limited information that the forms provided.

Reach

In the absence of electronic medical records that allow for searches on particular symptoms or vital signs, identifying the patients who needed a RRS but did not receive it was the most difficult element of this process evaluation and could not be evaluated completely. Virginia Mason's study of patients with documented triggers but with no RRS intervention showed that not only was it not necessary to intervene for all those patients, it wouldn't be possible. This demonstrates the need to evaluate reach by looking at the outcomes of the patient and tracing backwards to determine if a RRS should have been called.

There may be some specific types of illnesses, signs or symptoms that should always trigger an RRS intervention. These situations could be used to

develop triggers that may be more effective in identifying patients who are in an early clinical decline. Clinical judgment will always be vital in determining the types of interventions needed for each individual patient. The Event Record was filled out by the responding team and therefore the reason for a call that is recorded may not be the reason why the RRS was activated. Further study of reasons for activation is needed.

A review of all the cardiac arrests and floor to ICU transfers during this study period showed very few of the cardiac arrests on the floors or transfers had a corresponding RRS. This is not, however, as accurate a measure as it should be. The dates and times in the different data sets did not usually line up exactly so it was impossible to determine which RRS call was associated with which arrests or transfers. Patient identifiers available in the arrest data and ICU transfer data but only on the information from the Event Records not the telecommunications logs, so it was not possible to identify patients in this way.

There are several options available to bedside nurses when their patients are in need of a higher level of care. The best assessment to determine if a patient should have had a RRT called would be in real time. Once the time has passed it becomes difficult to reconstruct all the variables and the clinical judgment that was involved.

Another way to measure the reach of the RRS is to look beyond this as a patient care intervention and consider it a nursing support intervention. Then the nurses become the target of the intervention and measurement focuses on

whether they received the help that they needed every time they needed it. This would include areas that are covered by the RRS as well as the training of the nurses to know when to activate it. Alternatively, reach can also be measured by the hospital areas that are covered by the RRS, the patient population and who has the ability to call. About a year after full implementation, the RRS was made available to the diagnostic areas of the hospital, and in the future patients and visitors will be able to activate the RRS.

Dose

Dose refers to the amount of the intervention that was provided to the target audience. Dose was measured in the process evaluation by the number of calls that the RRS received. There are no clear guidelines about the rate of calls that a hospital wide RRS should be receiving. A sampling of rates of calls by month from the RRS literature ranges from less than 2 to 111, and the calls do not correlate with the size of the hospitals. There are so many variables that could impact the number of calls that it becomes impossible to determine what the target number is. In order to determine if the dose of this intervention is correct, it would be necessary to evaluate how these patients were being helped before the RRS. Is this process continuing, was it successful and has it continued parallel to the RRS?

Table 4.15: **Calls per Month from RRS Literature**		
Study	Hospital Size (number of beds)	Average calls per month
Virginia Mason	336	90
Bellomo, 2004	400	25
Brilli, 2007	Not reported	13
Bristow, 2000	380-530	1.75
Dacey, 2007	350	13
DeVita, 2004	622	29
Jones, 2005	400	8
Kenward, 2003	136	11
McFarlane, 2007	472	111
Salamonson, 2001	200	8
Konrad	900	29
Lighthall	150	22
Hanson	136	4

Staff Perspective

In many patient safety interventions the burden of execution is on the nurses and the success depends on their ability and willingness to implement the interventions. Initially there were concerns about the RRS but these came mostly from the hospital medicine physicians who were concerned that the use of triggers would create more demands on their time. Much time was spent investigating and debating the model and triggers to use. As the RRS started the responding staff realized that the triggers were not going to be over used. There is still a concern about the calls (n=21) that the responding staff felt should have been a code call.

The nurses have embraced the RRS and for the most part have found it a very positive experience. They admit to not really using the triggers and relying more on their clinical experience and intuition. New nurses were more likely to consult with a senior nurse before calling the RRT. The RRS is intended to get help to the bedside quickly when needed. There is a possibility that having nurses double check before calling could have an unintended delay in getting help.

Conclusion

RRS studies do not consistently demonstrate the effectiveness of RRSs in reducing cardiac arrests out of ICUs, all cause hospital mortality and related outcomes. Hospital research, assessing health related outcomes and processes, is made difficult because of the wide variation in patient's primary diagnose and comorbidities. As well as the causes and treatment options of acute decline. Defining and measuring the features of an acute decline might involve retrospective reviews of paper medical records especially in the absence of an electronic medical record. Even with medical record reviews, there could be differences among reviewers as to what is considered an acute decline and who might have benefited from a RRS. Some outcome measures can be crude, and affected by differences in patient characteristics over time. Even with commonly used adjustments, it may be difficult to validate a positive or negative effect of an intervention like RRS. Because of the difficulty and wide variation of RRS a process evaluation is a tool that could begin to shed light on how a RRS works.

There have not been extensive process evaluations done to determine if a RRS is working as it was designed to. It is difficult to evaluate the process of implementation and usage and how it affects the outcomes. At UMMMC, the RRS was most often, used as it was designed. There were some cases where the nurses used it as a negotiating tool by telling the HO that they help was needed and if they did not come, the nurse would call the RRS, thereby changing the way care comes to the bedside apart from formally activating the RRS. It also appears that the responding team is seen as an educational source for bedside nurses, where they are able to ask questions and get information that make them more confident in their care of patients. These components were not designed into the system but provide insight into ways the RRS can, overtime, change the interaction among staff and the hospital culture for the better. This modified process evaluation showed that there are components in each area, fidelity, reach, dose and staff perspective that could have contributed to the outcomes of the study both positively and negatively. However, more importantly, it shows that this intervention has been well received by the staff, especially the bedside nurses, and has the possibility of increased usage over time which may show better clinical outcomes as well.

CHAPTER V
Conclusion and Final Discussion

primum non nocere: First do no harm

"Knowing is not enough; we must apply. Willing is not enough; we must do."
Johann Wolfgang von Goethe

RRS research has been widely published and accepted by healthcare improvement and hospital regulatory agencies. However, the evidence that RRSs are improving the care delivered to hospitalized patients is still inconclusive. There are multiple differences in study methodology, outcome definitions and statistical analysis in the published studies, and this makes it difficult to combine the studies meaningfully.

The goal of the research presented in this dissertation was to examine a Rapid Response System that was implemented in two UMMMC hospitals. This was done using three separate studies; an evaluation of unanticipated ICU transfers before the intervention, effectiveness of the RRS on specific outcomes and a modified process evaluation.

Unanticipated ICU Transfers

The first study was a retrospective look at unanticipated ICU transfers that would indicate one area where a RRS could improve patient care. Floor to ICU transfers have been evaluated in other RRS research as an outcome to determine the effectiveness of the intervention. Understanding the scope of a problem before planning an intervention would provide the best circumstances in

which to design the best intervention. Given the Joint Commission mandate, there was not time to identify specific outcomes at UMMMC prior to implementation of the RRS. Unanticipated ICU transfers were identified as an area of improvement in some of the earlier RRS published studies, but little was known about the actual extent of the problem and what ways a RRS would improve it. It was decided to evaluate the floor to ICU transfers in the year before there was discussion about implementing a RRS.

Using physician review of medical records, this study attempted to determine the preventability and timeliness of floor to ICU transfers. The results of the study demonstrated that reviewers agreed that 13% of the transfers were preventable. The study had several limitations including limited information provided to reviewers, differences in interpretation of the outcome measures among reviewers and different opinions about the constituents of ideal care among the reviewers. Even with these limitations this study provided some evidence that there may be transfers to the ICU that could be prevented by an RRS if the system were triggered early in the course of clinical deterioration of the patient.

This study brought to light some of the difficulties in measuring floor to ICU transfers as an outcome. Preventability, as defined in this study, still required some unavoidable clinical judgments. In order for the RRS to be successful in reducing the rate of ICU transfers, there has to be a method that would clearly identify cases that could have been prevented with earlier intervention. Additional

work is necessary to better understand the preventable cases and what type of similarities they have that could be translated into more accurate triggers for the RRS.

Effectiveness of a RRS

The second study was a before and after evaluation of the effectiveness of a RRS in decreasing the rates of cardiac arrests on the floors and hospital wide, unanticipated ICU transfers and code calls outside of the ICU. It showed that there was a statistically significant reduction in the number of code calls at the University campus before and after the intervention. The other outcomes for the most part consistently declined in frequency during both the before and after periods, suggesting that a secular trend was the most likely cause of the differences in outcomes between the before and after periods. Though the preventable transfers study showed that possibly 13% of floor to ICU transfers could have been prevented with the implementation of a RRS, the results of this effectiveness study did not demonstrate a reduction in floor to ICU transfers. This study illustrated the difficulties in identifying appropriate definitions and measurement of RRS outcomes and the most accurate method for analyzing the results. Different type of analyses could impact the results for certain outcomes. In this study factors such as differences in patient populations and other hospital interventions were not controlled for during the two study periods, and this may have impacted the results.

Modified Process Evaluation

Finally, the third study was a modified process evaluation of aspects of the implementation and use of the RRS that may have impacted outcomes in the second study. It showed that the RRS was not necessarily being activated using the agreed upon trigger criteria, was at times called when the code team was more appropriate and that the house officer did not always respond as expected. It was difficult to determine whether the RRS was being triggered for every patient that might benefit from it and this may have underestimated the changes in rates of cardiac arrests and ICU transfers in the previous study. The nurses were for the most part positive about the RRS, and their perception was that the intervention improved care.

The Process Improvement Model and a RRS

Quality improvement and patient safety in healthcare have lagged behind other quality improvement efforts in complex and potentially dangerous businesses such as aviation and in businesses producing products prone to defects such as manufacturing. Many different improvement theories have been redesigned for healthcare implementation. In addition to improvement theory redesign, epidemiologic and bio-statistical methods have been adapted to measure changes related to quality improvement interventions.

Figure 5.1:Process Improvement Model
Used with permission from IHI

Promoted by the Institute for Healthcare Improvement and originally developed by Langley et al. is the Model of Improvement. This model incorporates 3 questions and the Plan, Do, Study, Act action items.[54] Figure 5.1 displays the model. The model takes into account the fundamental difference between quality improvement intervention research and conventional scientific research as demonstrated in the first question, what are we trying to accomplish? Much of patient safety research in the past has had as a primary goal increasing

knowledge that may over time change healthcare processes. The Model of Improvement's goal is to effect change in a continuous more immediate time frame. The two approaches are not mutually exclusive, and the traditional research approach may be necessary in some cases to initially guide development of the improvement intervention. The Model of Improvement would then guide the continued evaluation and improvement of the interventions using a standardized method.

"What are we trying to accomplish?"

The RRS that we implemented had several goals, but the answer to the Model of Improvement's first question was: "To improve the care of patients outside of the ICU who were experiencing an acute clinical decline". It was anticipated that improved care would result in changes in the frequency of ICU transfers, Cardiac arrests and code calls.

"How will we know that a change is an improvement?"

This question addresses the importance of accurate measurement. Not only do we need to have accurate data we need to have practical and valid operational definitions of our outcomes and need to use validated methods of data collection. There are multitudes of methods to measure change in an outcome over time, but without careful consideration of exactly what we are measuring, we may fail to understand what an intervention is really doing. Some RRS studies have used code calls or other proxy measures for cardiac arrests. If we had done that in this study and only reported the change in code calls using

counts we would have shown a 50% decrease since the implementation. But in this study the reduction of code calls did not translate into a reduction in cardiac arrests.

Another outcome that some RRS studies have evaluated is hospital mortality. This is a rather crude outcome that is affected by many patient characteristics that change over time. Even with commonly used adjustments it may be difficult to validate a positive or negative effect on overall hospital mortality of an intervention like RRS, which would be expected to have only a small overall effect, because of the relatively small numbers that leave little room for improvement. A more sensitive analysis might focus on a few disease specific mortalities hypothesized to be more likely prevented by rapid response, such as sepsis related deaths among patients admitted to floor beds, death from COPD related to complications, or post operative deaths among those transferred to the floor after surgery.

Because of the difficulty in getting the Event Records returned and the missing data on the ones that were returned, the data collected did not necessarily accurately reflect the actual events that took place. However, based on what was collected either an acute or significant drop in oxygen saturation accounted for 44% and 54% of the reported triggers at Memorial and University respectively. This might be an intermediate outcome in the pathway to a more serious decline and death. As an example, if long duration hypoxemia is a risk factor for increased hospital mortality then maybe evaluating the RRS impact on

reducing the amount of time a patient spends with percent oxygen saturation less than 88 would be a more useful measure of RRS effectiveness.

Relevant outcomes for a RRS may depend on hospital specific factors, specifically those areas that are in need of improvement. In some hospitals with limited ICU beds a successful RRS may be one that is able to stabilize a patient on the floor or aid in monitoring and supporting that patient on the floor. For other hospitals it may be to be more efficient at getting the declining patient to the ICU earlier in the process to provide the highest level of care, quickly in the ICU. In a hospital with poor nurse morale the RRS may provide much needed support and improve working conditions for nurses and other clinicians or to help retain well trained, experienced staff. In a teaching hospital the RRS may serve as a resource for new, inexperienced house officers for both immediate support and ongoing education. Maybe the best overall measure would be an improvement in the overall hospital safety culture or patient satisfaction. All of these are important to safe, high quality care and all can be somewhat elusive to measure, especially in institutions that are in almost a constant state of flux.

“What changes can we make that will result in improvement?”

We made a change when we implemented a RRS. It was successfully implemented, was well accepted and used by the nurses, and the perception of the nurses and other staff was that the RRS improved care outside of the ICU. But the statistical analysis and evaluation of the outcomes showed little change in the primary outcomes that had been targeted. There was minimal if any statistically significant change in cardiac arrests, ICU transfers or code calls. So did the RRS improve what we were looking to improve or were the outcomes perhaps not the right ones to be measuring? Did we not completely understand what the implementation team wanted to accomplish?

The Model of Improvement is designed to evaluate and react to outcomes in a relatively short amount of time. The actual amount of time necessary to observe a change if one is happening will change based on the intervention and the outcomes being measured.

Future of RRS Research

A randomized controlled trial (RCT) is the most robust of any study design and would be the most appropriate design for evaluation of a RRS. However, because of the mandate by the Joint Commission that all hospitals must have a RRS and the ethical considerations of randomizing patients or hospitals to a RRS and a control, a RCT is not feasible. Another complication of using a RCT to evaluate a RRS is the ease with which cross contamination between trial and control arms might occur if randomization occurred within a hospital. Secular

trends unrelated to the intervention but affecting RRS outcomes could also reduce the power of a RCT to identify a statistically significant effect. This is what likely happened in the only RCT done in 12 hospitals implementing a RRS and 11 that did not.[12] In this study both intervention and control hospitals showed a decrease in the measured outcomes.

Don Berwick formally of IHI, suggests that we stop asking "Where is the RCT" but rather "What is everyone learning?".[64] What we learn from failed improvement efforts may be just as important as what we learn from successful efforts. Sharing lessons from both successful and unsuccessful interventions may support dissemination of effective strategies and prevent others from using resources attempting failed interventions.

It has been suggested that some specific challenges are involved when trying to effect change in large systems. A hospital may not always be a large, multi site system but many of the difficulties can still exist. These include delayed response, integration, staff behavior change and disruption to existing protocols.[54] In terms of implementing the RRS, to some degree; all four of these difficulties existed and may have impacted the results of these studies.

Delayed response is the time between implementing a change and being able to observe or measure the effects of that change. The amount of time that a RRS needs to be in place to effect measurable change in outcomes would likely be different depending on the different characteristics of the hospitals. The RRS at UMMMC was evaluated for two years after the full implementation. Because of

the difficulty in measuring whether the RRS reached every patient that needed it, and the rarity of some of the outcomes being measured, two years may not have been a long enough to fully evaluate all the changes that the RRS might have made. It is not clear how much time a RRS needs after implementation to be fully accepted and used to the fullest extent by all potential users. The number of calls did not change drastically over the study period indicating that there was no initial increase followed by a period of leveling off which would have been expected. With more education and modifications to the triggers there may be an increase in calls over time.

The impact of a RRS on the safety culture of the hospital and staff satisfaction would need to be assessed over a greater amount of time to assess that the changes occurred and were sustained over time. As the RRS becomes more ingrained in the culture of the hospital these and other changes may be observed.

Integration is the difficulty of implementing an intervention that spans multiple systems. The RRS intervention included multiple hospital systems including; two different hospitals, multiple nursing units, office of quality and patient safety, critical care, nursing, hospital medicine, diagnostic areas and residency training. There are differences in culture and priorities in all of these departments that needed to be taken into account with the roll out of the intervention in each of these systems. Continued evaluation of the differences in uses among these departments would provide valuable information. The amount of time it will take

the nursing units to change not only the way that they contact help for their patients but also the mindset of when it is appropriate to contact the RRS will impact not only the behavior of clinical staff but also the delayed response and the integration of the RRS.

Behavior change is perhaps the most challenging aspect of introducing a new intervention into a healthcare system. The acceptance and use of a RRS will depend on how it is perceived by the staff. The modified process evaluation indicated that the nurses felt positive about the intervention and were willing to use it; however, there was not a systematic use of the RRS based on the trigger criteria and there were several situations where the RRS was not the appropriate call for the situation. Some of the possible reasons that the nurses have not adopted the use of specific triggers may be due to the relatively limited training that they received, difficulty in determining when a trigger is new, and possible concerns of being seen as over reacting. More investigation is necessary to determine which signs and symptoms should always trigger a RRS call and those areas where clinical judgment should be used.

Finally the RRS is a disruption to the status quo. The nurses that participated in the surveys or focus groups were generally happy with the change to the status quo. They felt that they were better able to get additional help for their patients after the implementation of the RRS. This, like any new intervention will have positives and negatives. Though this study did not investigate any potential negative effects of the RRS, it is probable that there were some. In this study, the

RRS calls that were deemed inappropriate, because a code call would have been better, created a delay in care for potentially life threatening conditions. Other possible unanticipated consequences could be the effect on other patients when the RRT is being pulled away from other work and possible animosity towards nurses for making a RRS. Surveys of team members might be useful in determining some of these outcomes.

Conclusion

Because of the differences in institutions, team make up, patient population and differences in data sources and outcome collection methods, RRS studies are difficult to compare or combine in a meaningful way. Future studies that focus on some of the softer outcomes such as patient or staff satisfaction with the RRS, changes in hospital culture and enhanced learning opportunities as well as hospital specific outcomes may provide more support and guidance for RRS development and implementation.

RRS makes intuitive sense; it seems reasonable to think that getting a higher level of care to the bedside in a more timely fashion will improve patient outcomes. The confusion over seemingly conflicting results from studies is probably based more on the ability to accurately determine which outcomes to study and the best methods to measure those outcomes. This is will be accomplished in quality improvement by combining the strengths of multiple disciplines: clinical, system improvement theory, quality control, and research.

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