ANALYSIS OF PATIENT FALL DATA

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Submitted to the Graduate Faculty of

Swanson School of Engineering in partial fulfillment

of the requirements for the degree of

Master of Science in Industrial Engineering

University of Pittsburgh

2008

UNIVERSITY OF PITTSBURGH

SWANSON SCHOOL OF ENGINEERING

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Patient falls are common adverse events that occur in all healthcare environments. Patient falls are a common cause of morbidity (“disability caused by accident”) and the leading cause of nonfatal injuries producing trauma-related hospitalizations in the United States. Patient falls result in longer hospital stays, attendant increases in medical costs and reduced quality of life for the patients who experience these events.

The purpose of this thesis was to examine the patient fall data collected by a community based acute teaching hospital. These data were then analyzed by a variety of analytical methods to determine if there are correlations related to location and timing of the falls, as well as the characteristics of the patients who fell. Conclusions were then made as to possible improvements in methods to monitor patients to reduce patient fall rate.

The major results of this analysis were: (1) statistical methods were found to be useful in providing an improved understanding of the characteristics of the patient fall data and thus allow hospital staff to rely on quantitative metrics to make decisions of how to try and reduce patient fall rates, (2) the time intervals between consecutive fall events were found to be distributed exponentially, (3) the hospital-wide hospital monthly fall rate goals, as well as the individual hospital unit patient fall rate goals were shown to be regularly exceeded by the measured data, and (5) review of the fall score screen values used to assess the risk for patient falls, while overall a predictor of patient who did and did not fall, was not a good predictor for determining if individual patients would fall.

As a result of this study, a number of specific recommendations will proposed to the hospital as a means to potentially improve the methods for addressing patient falls. A hospital-

wide cultural change had been commenced in June 2007 to attempt to reduce the rate of patient falls. The effect of implementing this program will be followed by observing whether the over-all hospital and unit monthly fall rates are reduced.

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PREFACE

First, I want to thank my wife Martha without whose encouragement, support and love, this thesis would never have occurred. Next I want to thank all of the members of the hospital staff who have supported this effort and have cheerfully responded to my never-ending data requests with as much information as they could, and much more than had originally been offered. The time, effort and concern with which the hospital staff provides patient care and attempts to improve that care is a testament to their professional attitude and concern for the safety of all the patients under their care.

I wish to thank Dr. Brady Hunsaker as my thesis advisor who accepted my questions, and concerns with good grace and helpful comments. Also, I want to thank Dr. Kim Needy who also participated in directing the course of this thesis as well as helping me to decide to attend the University of Pittsburgh in the Industrial Engineering Department.

Finally, I wish to thank all the other researchers who provided valuable insight and a path to follow in this study.

Any flaws and errors contained in this thesis are mine alone.

INTRODUCTION

"Every system is perfectly designed to
achieve the results it does"

(David Beckwith, MD)

Hospitals are complex systems which endeavor to both return patients to optimal health as well as to provide a safe environment for patients while in the hospital. The effectiveness of the hospital personnel to perform those functions has been questioned in recent years. The Institute of Medicine (2004) states *"…the American health care delivery system is in need of fundamental change. Many patients, doctors, nurses, and health care leaders are concerned that the care delivered is not, essentially, the care we should receive. The frustration levels of both patients and clinicians have probably never been higher. Yet the problems remain. Health care today harms too frequently and routinely fails to deliver its potential benefits." (Donelan et al, 1999, Reed and St. Peter, 1997; Shindul-Rothschild et al, 1996; Taylor, 2001)* One crucial aspect to ensure that medical care systems improve is to modify the process of reporting adverse events (such as patient falls or medication errors) that occur within hospitals and seek to understand why these events occur, so as to minimize patient risk. Consideration has been given to modifying medical care system event reporting to be more like that used in aviation event reporting systems (see Billings [(1998]).

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has created a series of requirements that must be met in order for healthcare organizations to be accredited for receiving Medicare and Medicaid funding. JCAHO began to develop these requirements in 2000. One of the areas that are covered by these requirements includes programs to monitor and reduce patient falls. JCAHO does not specify a value to which the fall rate must be reduced, only that a program must be in place and must monitor the patient falls which occur.

The hospital, which was the source of the data analyzed in this thesis, is a member of a multi-hospital system, has had a fall prevention program for more than ten years. This program was established well before requirements by JCAHO were promulgated. This program originally included screening each patient for the risk of falling and then implementing a "careful watch" for those patients. Over time this screening evolved to become a more detailed policy with formalized procedures and during the program's period of operation has expanded the data collected for these adverse events. In 2005 the hospital established a patient fall task force that has been examining the patient falls which occur at their hospital and has been attempting to develop more effective procedures to prevent such falls.

We have had the opportunity to learn of the initiatives commenced at the hospital since we have been a member of the hospital's Patient Safety Committee for over four years. The function of the Patient Safety Committee is to oversee the Hospital Patient Safety Program and make recommendations that will increase patient safety. This thesis is the result of collaboration between us and members of the hospital staff. This analysis was partially driven by the desire on the part of the hospital staff to have a person who was not part of the official hospital system to independently and rigorously examine patient fall data and provide an assessment as to whether there may be trends within the data that would aid the hospital staff to modify behavior and potentially reduce the number of patient falls.

The primary quantitative conclusions and non-quantitative observations resulting from this study are presented below:

Conclusions:

1. The hospital patient monthly fall rate goals (or targets), assigned both hospital-wide, as well as for individual units were shown to be regularly exceeded over the period of available data. For both hospital-wide and individual units, the month-to-month fall rate variation was large, with the individual hospital unit standard deviations being larger than the hospital-wide values. Using a four month moving average provides an improved perspective of the time-dependent behavior of the patient fall data and appeared to reveal patterns in the fall rate data not apparent when observing the month-to-month data.

2. Linear regression analysis of hospital-wide and hospital unit monthly patient fall rates showed (with one exception) no statistically significant decrease (at the 99% confidence level) in the fall rate over the five year hospital-wide and four year unit data.

3. The average age of the patients who fell during the first data collection period was 70.14, while for the second data collection period it was 72.11. The median age of the patients who fell was 75 for the first data collection period and 73 for the second data collection period. For both data collection periods it was found that over 35% of the falls occurred for patients who were 80 or older. It was noted that about 20% of all falls occurred for patients who were 60 or younger.

4. The fall scores for the patients who fell (only obtained during the second data collection period) were plotted and a well-behaved distribution, with a mean value of approximately 22 was observed. When fall scores were obtained from a sample of patients who had not fallen, it was shown that the distribution of fall scores, for those patients, was much lower. The fraction of the fall scores that were less than 10 (indicating patients at low risk for falls) for the patients who fell was 0.12, while for the patients who did not fall was 0.30.

5. In comparing fall scores from two samples of patients (one sample that experienced a fall and the other which did not), it was found that for the sample that experienced falls, the range of fall scores appeared independent with age. For the sample of patients who did not fall, there was a trend of increasing fall scores with increasing age. Another observation is that for the sample of patients who did not fall who were less than 60 years old, few had fall scores greater than 20, while for the sample of patients who did fall there were a number of patients younger than 60 who had fall scores significantly larger than 20. As the patient age increases, the spread of the fall scores for the two figures become similar. In the range of ages between 70 and 80 the spread of the fall scores became very similar. These results indicate that although the fall screen used by the hospital may have some deficiencies, it does provide, on a general basis, the means for identifying those patients at higher risk of falls. In particular, it appears that for patients who are younger, if they have fall scores greater than 20, the fall screen may be a very good predictor of the likelihood of falling.

6. Severe falls, those falls causing significant harm to the patient, accounted for only about five percent of the total number of falls. These results were obtained only for the second data collection period.

7. Repeat falls (patients who fell more than once during the data collection period) were experienced by about 15% of the patients who fell, and those repeat falls accounted for 28% of the total number of falls. It was also concluded that the distribution of the patients who experienced repeat falls was consistent with a Poisson distribution. These results were obtained from the second data collection period.

8. The gender distribution of patients who experienced falls was consistent with the fraction of males and females for the population cohort above 65 years of age based on the 2000 U.S. Census results. While no data was available to ascertain whether a male patient having a high (>10) fall risk score had a greater or lesser risk of falling than a

female patient of the same age and fall risk score, the information presented for severe harm resulting from falls indicated that those patients who experienced most harm from falls were predominantly female (seven out of eight severe fall events were suffered by females). This harm score information was obtained from the second data collection period.

9. In analyzing the time interval between consecutive fall events for the two data collection periods for the hospital-wide data, using a Chi-square test, it was determined that both data collection periods were found to have a statistically significant result for having an exponential distribution. The statistical significance was stronger for the second data collection period than for the first data collection period. These results appear to be consistent with reliability theory.

Observations

1. Based on the review of literature (see Section 4.0), it appears that few studies were able to demonstrate measurable, long-term reductions in patient fall rates. The only study that was able to demonstrate a procedure that produced reductions in fall rate over a long time period (about a year) was Meade (2006). It was also noted that few studies performed quantifiable assessments of patient population characteristics.

2. Based on a review performed with the hospital personnel following the first data collection period (in August 2006), a number of changes to the way patient fall data was collected, as well as additions to the data collected were made. These actions included: (1) providing fall data to all the hospital units on a monthly basis, (2) the collection of additional data for the second data collection period enabled examination of different factors affecting patient falls (e.g., number of patient falls when temporary nurses were on duty). Examination of these data has led the hospital staff to discontinue collecting certain data since they have concluded that data does not make a significant contribution to the overall fall rate.

3. There was no statistically significant change in the trend of the available monthly patient fall rate for a number of years (about five years for the hospital-wide data and about four years for most unit fall data). It appears that making a statistically significant change to the average monthly patient fall rate would require significant changes to the existing hospital method of operation. In other words, a significant "cultural change" in the hospital staff and the methods used to address patient falls would need to be conducted to potentially reduce the existing patient fall rate. Such a cultural change is now being instituted by the hospital (see Section 2.2 and Appendix C).

4. Local environments (or subcultures), resulting from a variety of causes, exist in the different hospital units. These local environments probably influence patient fall rates. The hospital-wide procedures and protocols to prevent patient falls can be applied somewhat differently due to the experience of the supervisors and hospital staff, the unit's patient load, the patient characteristics on the particular unit and the physical design of the unit itself. Because of the multiple pathways by which patient falls may occur, achieving a reduction and maintaining a reduction in patient fall rate is difficult to accomplish.

5. The issue of effecting a cultural change in a complex organization such as a hospital is a difficult process to successfully implement. Competing effects can often cause the most well-prepared and organized effort at change to "drift" from its original intent as well as produce unexpected or unintended consequences (see Appendices F and G).

6. Statistical methods were found to be useful in displaying many of the characteristics of the patient fall data, as well as determining whether any of these characteristics produced statistically significant trends or results. For example, assessments were performed to determine whether there were statistically significant trends in patient falls during different shifts and hours of the day or over the days of the week, as well as assessing trends in the fall rate for both hospital-wide and individual hospital units.

Assessment of these data indicated there were no statistically significant trends at the 99% confidence level (see Sections 6.1.1 and 6.1.2). Allowing hospital staff to review these results can provide a more rigorous assessment of the data and reduce the likelihood of concluding that a trend exists where data did not warrant such a conclusion.

This study concludes that the use of statistical analysis of adverse medical event data, together with the opportunity for a person who has engineering experience, but is not part of the medical system, to examine the data, observe operations, ask questions of the hospital staff, and engage in discussions of specific issues confronting the hospital staff, may produce additional opportunities for the hospital staff to attack problems, better understand the trends and behavior of adverse events, and potentially improve patient outcomes.

1.0 OVERVIEW OF HOSPITAL AND OVERSIGHT AGENCIES

1.1 DESCRIPTION OF THE HOSPITAL

The hospital from which the data for this thesis was obtained is a community based acute care teaching hospital that serves 200,000 residents in southwestern Pennsylvania. The Hospital offers 216 beds for acute care patients and 56 beds for patients who need skilled nursing care. The hospital operates a separate Intensive Care Unit and Cardiac Care Unit. The hospital also offers ongoing rehabilitation and educational programs to patients with cardiac, neurologic, and orthopaedic diagnoses. The hospital is part of a multi-hospital system. An important aspect of this hospital's operation is that it services an area in Pennsylvania that has a significant fraction of people who are over 65. From the 2000 census (see U.S. Census) the Pennsylvania state average percentage of people over 65 was 15.2%, while for the area served by the hospital the fraction of people over 65 is 20.9%. From the 2000 census for all of the United States, the fraction of the population that was 65 or older was 12.4% (see Census 2000). The fact that the population served by this hospital has a significant fraction of patients older than 65 became evident during the analysis of the patient fall data collected.

1.2 A BRIEF HISTORY OF JCAHO

The development of the JCAHO (Joint Commission on Accreditation of Health Organizations) originated from earlier hospital inspection organizations (See Franko 2002). As described by Franko, *"The first hospital inspections were performed by the American College of Surgeons (ACS) in 1918, based on ACS Minimum Standard for Hospitals. In 1951, the ACS joined with the American College of Physicians, the American Hospital Association, the American Medical Association, and the Canadian Medical Association to form the Joint Commission on Accreditation of Hospitals (JCAH) – an independent, not-for-profit organization whose primary purpose was to provide voluntary accreditation. In 1952, JCAH took over the hospital standardization program from ACS, and in 1952, it published the JCAH Standards for Hospital Accreditation."*

Although originally a private organization, following the Medicare Act of 1965, hospitals would be considered eligible to participate in this program only if they were accredited by JCAH. While originally only to be used in hospitals, in 1975 JCAH expanded its accreditation extent by considering ambulatory health care facilities. In 1987 JCAH changed its designation to JCAHO to reflect its expansion into organizations other than hospitals. JCAHO is also referred to as the "Joint Commission," and throughout this thesis will be referred to as such.

The Joint Commission does not establish explicit requirements for organizations, rather it specifies that general plans or programs should be in place to reduce the likelihood or occurrence of specific adverse events, such as patient falls, medication errors, wrong site surgery events, etc. The standards promulgated by the Joint Commission are not supposed to be considered as punitive or restrictive, but rather as a means to have organizations meet the needs of their patients.

Joint Commission Guidelines for Patient Falls

JCAHO has developed specific guidelines for reducing patient falls. In 2005 the two specific guidelines were: (1) Reduce the risk of patient harm resulting from falls, and (2) implement a fall reduction program and evaluate the effectiveness of the program. The mechanism by which the hospital implements these guidelines is up to the individual institution. However, the records that are collected to support this system must be available for JCAHO review. In 2006, these guidelines were changed to require the facility to have a falls prevention program in place. Appendix D presents the 2008 National Patient Safety Goals, Hospital Program created by the Joint Commission. This information is presented in order to provide context for the number of specific initiatives and efforts hospitals are now being called upon to improve and address.

1.3 NATIONAL QUALITY FOUNDATION ENDORSED "SET OF SAFE PRACTICES"

In additional to the Joint Commission, the National Quality Foundation (NQF) also provides to hospitals a set of safe practices which it believes all hospitals should adhere to. These safe practices are promulgated by insurance companies and other agencies that have a vested interest in trying to ensure that the best patient safety is provided to insured patients. Appendix E provides the 2006 National Quality Foundation set of safe practices to which hospitals should adhere. These requirements and practices were presented to provide an appreciation for the challenge of managing the hospital environment. It is noted that in the effort to contain medical costs, Medicare is preparing in the near future to make decisions concerning which types of adverse medical events they will stop making payments for. The type of adverse events being considered include wrong site surgery, drug-resistant staph infection, surgical site infection, bed sores and falls (Lee 2007). Therefore, hospitals now have a greater incentive to find techniques to reduce the numbers of adverse events.

There are other regulatory bodies that can review a hospital's operation. These regulatory bodies are not provided within this thesis.

1.4 HOSPITAL PATIENT SAFETY COMMITTEE

The Patient Safety Committee at the hospital oversees the Patient Safety Program. The makeup of the committee is to include two residents of the community served by the hospital who are not members of the medical facility. Some of the major functions of the Safety Committee are to receive, review and evaluate serious event and incident reports, reports from the Patient Safety officer, and reports from any data collection agency appointed by the Pennsylvania Patient Safety Authority that may reduce serious events and make recommendations to reduce or eliminate future serious events and incidents. The committee also serves as a forum for discussion of recent events or trends that might be detrimental for patient care, as well as a sounding board for new ideas of how to modify existing safety programs. These ideas are then disseminated to the hospital department of interest where they can be evaluated.

We had been a member of the safety committee for the past four years. The analysis in this thesis represents collaboration with a number of medical personnel at the hospital to attempt to better understand and characterize patient falls and to potentially develop methods to potentially reduce their frequency.

1.5 HOSPITAL PATIENT SAFETY INITATIVES

The hospital has developed a large number of initiatives to try and improve overall patient safety. These initiatives include the patient fall task force, efforts to reduce problems with items such as central line infections and medication errors, as well as ensuring that all patients are rapidly treated to avoid infections. Each initiative is assigned a “Champion” who oversees the initiative and follows its progress, as well as interacting with other medical professionals to try and improve the performance of the initiative. Often these initiatives bring together a number of people from various units to brainstorm and consider changes to the current process.

As an example of this type of initiative, the hospital formed a patient fall committee in 2005. This committee included members of the nursing staff from different hospital units, and representatives from administration, doctor staff, physical therapy, central supply, as well as a representative from the facilities department of the hospital. The purpose of this committee was to examine data and facilitate communication between the various units and staff at the hospital and explore methods to reduce patient falls as well as to reduce the severity of patient falls. The people who were members of this committee were encouraged to bring ideas for improving patient fall safety. One result produced by this committee was the development of a spreadsheet that contained detailed information for each patient fall that is transmitted to all units to allow review of the data. The collection of a number of fall parameters and their transmission to different units allow for a rapid assessment of fall performance by each department and the possibility of observing trends in the data.

2.0 STUDY OVERVIEW

2.1 PROBLEM DESCRIPTION, METHOD AND THESIS GOAL

The purpose of this thesis was to examine the patient fall data collected by the subject hospital from December 1, 2005 through May 31, 2006 and December 1, 2006, through May 31, 2007 and also the long-term hospital-wide (from July 2002 through May 2007) and unit based (from July 2003 through May 2007) monthly falls rates. These data were then analyzed by a variety of analytical methods to determine if there were correlations related to location and timing of the falls, as well as the characteristics of the patients who fell. Factors such as age, gender, magnitude of the patient's fall score prior to the fall, the time of day and the day of the week at which the fall occurred were examined to determine if there were definitive indicators as to the cause of patient falls. Conclusions were then made as to possible improvements in methods to monitor patients and to reduce fall rates. In addition, this thesis discusses the difficulties that have been experienced by other healthcare organizations in attempting to reduce patient fall rates and sustain that reduction over time. The difficulties in reducing fall rates have been examined based on a number of previous studies. One of the goals of the hospital's fall prevention program was to constantly reevaluate the program's structure, its method of implementation, and review of data to determine if any change in fall rate has been observed.

The sequence of events performed in this analysis consisted of:

(1). Collecting and analyzing an initial set of patient fall data (collected from December 2005 through May 2006, together with hospital-wide and unit based fall rate for several previous years through May 2006),

(2) A summary of the collected data was prepared and presented to members of the hospital patient fall community in July 2006, with suggestions as to how to potentially improve data collection and presentation,

(3) Based on suggestions resulting from step (2), the hospital staff selected specific suggestions that would be implemented and used to modify the system,

(4) Following implementation of these changes, a second set of fall data was collected from the modified system (for the period December 2006 through May 2007, together with the hospital-wide and unit based fall rate from several previous years through May 2007),

(5) A comparison was performed between the two sets of data, and assessments made as to how different and similar the data was. Certain data collected during the second data period was unique and was analyzed separately, and

(6) Finally, from the data analyzed, a number of specific conclusions were drawn. Based on these conclusions, a number of suggestions as to how to potentially reduce patient falls rates were assembled.

The assessment of the collected patient fall data will include unit location, the date and time the fall occurred, the age and gender distribution of the patients who fell, and the number and severity of the falls. Because of the need to satisfy the Joint Commission's requirements, the hospital has been collecting, on a monthly basis, hospital-wide, as well the per unit patient fall rate data for a number of years. Therefore, the monthly fall data for the hospital-wide, as well as the unit fall data was available. These data were presented, analyzed and discussed in this thesis. However, this data only provides the monthly patient fall rate in terms of falls per 1000 patient days[1]. As will be described later in more detail, the total number of fall reports for

[1] For example, if the entire hospital experienced 30 falls in a month, and in that month had a total of 3000 patient days, the monthly fall rate would be [30falls]/[3000patient days/1000] = 10 falls per 1000 patient days. The division by 1000 patient days provides a normalizing factor that places the monthly total of

these two six month data collection periods is approximately 180 for the first and approximately 150 for the second data period.

2.2 DESCRIPTION OF THE HOSPITAL'S PROCEDURE FOR HANDLING PATIENTS WITH REGARD TO POTENTIAL FOR FALLS

The following section describes the procedure used by the hospital to identify and quantitatively assess the fall risk faced by patients. This assessment is provided to and acted on by the hospital staff.

If a patient arrives at the hospital through normal admission, or in the emergency department (ED), an assessment is performed to determine whether the patient is or is not a fall risk. This assessment is performed by application of a fall screen which produces a patient fall score. The application of the fall screen (see Appendix A) is performed by the nursing staff. The fall score system used at the hospital had three numeric ranges: less than 10 - no fall risk or low fall risk, 10 to 14 - moderate fall risk, 15 or greater - high fall risk.[2] This fall screen produces only whole integer scores. Once the patient arrives on the unit, whether they have arrived from the ED or normal patient admission the nurse will decide what type of precautions are necessary to reduce the risk of the patient falling based on the fall score. These precautions may include providing the patient with a low bed, a bed alarm (or both), or other more focused observation. Patient restraints are generally avoided. All patients, whether at-risk or not, have their fall scores reassessed each day. The procedure followed is incorporated in the hospital fall policy.

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patient falls in the context of the number of patient days the entire hospital or an individual hospital unit experienced.

[2] While this patient fall ranking was in place at the start of the study, it was changed in early 2006. At that time, the ranking was changed to include only two categories, (1) <10 - low fall risk, and >10 - high fall risk. The intermediate category was eliminated.

If a patient experiences a fall during the stay in the hospital, a patient fall form, presented in Appendix B, is filled out by the nursing staff. Subsets of this information were provided by the hospital to us. During the first data collection period, a physical copy of the fall form was provided. For the second data collection, spreadsheets for each month were provided with the information from the patient fall reports included.

The nurse rounding procedure that was in effect during most of the data collection period covered by this thesis was a reactive type. If the patient used the call button in their room, nursing would respond. Also, certain actions were performed by the nursing staff that observed the patients periodically during the day (delivering meals, taking temperatures and blood or administering medication), the existing procedures did not require the nursing staff to periodically examine patients for fall potential. A modified rounding procedure that is discussed at some length in this thesis was being developed and implemented on one unit (5M) during the later portion of the second data collection period (December 2006 through May 2007). This modified rounding procedure is proactive. It required the nursing staff (nurses and nurses' aides) to perform rounding for all patients at hourly intervals and observe patients, request if they had any immediate needs and determine whether there were environmental issues related to the patient's room where items may have to be moved or modified to reduce the likelihood of falls. Information describing this rounding procedure and the specific actions the nurses and nurses' aides were to follow is presented in Appendix C.

2.3 OPPORTUNITIES PROVIDED BY THE HOSPITAL TO UNDERSTAND ITS SYSTEM AND PROCEDURES FOR ADDRESSING PATIENT FALLS

In order to gain a perspective of the interactions that exist between the various groups within the hospital staff, as well as to better appreciate the required procedures that are followed by the various hospital staff groups, and particularly to understand the effort directed to patient safety, the hospital provided us a number of opportunities to observe hospital operations, talk to hospital staff as well as become more familiar with the system that is used to collect the patient fall information. These opportunities were invaluable in allowing us to understand the constraints under which the hospital staff operated, as well as to understand the potential for changing the system, thus creating a greater opportunity to make worthwhile suggestions at the end of the study. These opportunities included:

1. **Patient Safety Committee Member -** As a member of the Patient Safety committee, for over four years, we had the opportunity to observe and participate in discussions of how data is linked between different organizations in the hospital (for example, how easily the information that is obtained at the time of patient admission can be accessed by the nursing staff on the unit for a particular patient). Further, the patient safety meetings enabled us to appreciate the constraints that medical personnel operate under, as well as the opportunities they have to make changes to the methods used to collect and analyze information. Finally, these meetings allowed us a better understanding and appreciation for how the health care professionals weighed the effort required to pursue various initiatives, against the constraint to ensure their patients had high quality care provided while in the hospital. Observing the constant tensions that existed between ensuring that the immediate healthcare needs of the patient were met, ensuring that existing procedures and regulations were followed and attempting to make improvements within a system that has multiple bureaucratic, procedural, and financial constraints was recognized to be a difficult process with the potential for producing a

large amount of frustration on the part of the hospital staff. It was noted that the patient safety committee meetings were used as an opportunity for hospital staff from various disciplines to listen to problems experienced during the previous month, as well as to consider potential new or modified methods to improve patient care.

2. **Visits to Medical Units –** We were also provided the opportunity to participate in several tours of the hospital medical units to observe unit operations. These tours included observing nurses and nurse's aides performing their duties, as well as observing the interactions between the nursing and doctor staffs, the nursing staff and nursing aides, as well as interactions between the hospital staff and patients. These visits allowed us to begin to understand the logic of many of the interactions between the medical professionals, as well as developing an appreciation for the time constraints under which the hospital staff operated. One of the most important impressions made in these observation trips, was the large amount of time that the nursing staff was occupied by accessing, reading, and filling out various required medical forms. After observing operations we thought it would be interesting to try and determine the approximate time spent on a shift by a nurse in filling out various required medical forms and determine what fraction of that time resulted in direct benefit for patient care and safety and what fraction was directed simply to satisfying regulatory requirements that were not directly related to patient safety.

3. **Discussions with nursing staff -** Over the time spent on the patient safety committee, we also had the opportunity to discuss at length with a number of the nursing staff the efforts they have been pursuing to reduce patient fall rates. These discussions were useful in allowing us to appreciate the constraints hospital staff operated under, as well as to understand that significant variability exists between different units in attempting to reduce adverse events. It was discovered in these discussions that the nursing staff from different units had attempted to perform analyses or trending for the occurrence of

patient fall rates and for the particular aspects of when falls occurred (e.g., on a particular shift). These efforts, while sometimes producing positive outcomes, could have been made more effective if there had been resources available to provide statistical help in considering the planning, sampling, collecting and analyzing of the data. Also, it was noted that up to the time of the formation of the patient fall committee, whatever positive results that had been produced from these studies may not have had an effective method to be communicated to the nursing staff on other hospital units.

4. **Patient Fall Committee-** We had the opportunity to attend a number of meetings of the patient fall committee. The composition of this committee was described in Section 1.5. These meetings were focused on efforts to collect information that could potentially lead to reductions in the patient fall rate, and ensuring that information was disseminated to representatives from other units. These meetings included presentations and suggestions from nurses, nurse's aides, as well as doctors and nursing supervisory personnel concerning particular efforts directed to reducing patient fall rates. Finally, these meetings also included the demonstration of specialized patient equipment which contained new technological features that would provide the hospital staff with information for identifying at-risk patients. One demonstration featured a specialized patient bed. Technological features on these beds could be modified to provide alarm signals to the nursing staff if the patient were to get too close to leaving the bed[3]. These meetings were judged to be effective at allowing hospital staff, especially nurses and nurses aides to give free expression to different ideas of how best to modify or not modify existing procedures. Even more important however, these meetings provided a forum to exchange information between personnel from different units, and discuss whether implemented changes were working as expected, and what specific problems

[3] This particular demonstration was related to the Stryker beds. Ten of these beds were obtained for unit 3M and placed in service in March 2007.

had occurred since a particular process had been implemented, or piece of equipment had been obtained.

5. **Presentation to Nursing and Risk Manager of Results of Analysis of First Set of Data (July 27, 2006) –** Following the analysis of the first set of data analyzed (December 2005 through May 2006), we were provided the opportunity to present and discuss the results obtained from the first set of data analyzed. This presentation was made to a number of the nursing staff and risk management staff. The presentation provided a number of ideas that the nursing staff used to make changes to the existing system. Some of these changes were instituted prior to the commencement of the collection of the second data set (December 2006 through May 2007). These changes are discussed in Section 5.3.
6. **Root Cause Analysis -** The hospital provided us the opportunity to attend a Root Cause Analysis (RCA). These analyses are important for the hospital to examine, analyze and determine the root cause of an adverse event, and then apply the lessons learned from the RCA to improve the system to avoid similar events in the future. The root cause analysis observed provided insight into the questioning culture that exists in the hospital, the freedom of individuals within the system to voice concerns about trends in behavior, and the form of communication that exists between the different groups of the health care providers. The use of the RCA method has grown over the years within the hospital and is used to investigate a number of events every month.

2.4 LIMITATIONS OF STUDY

This section describes the limitations associated with this study, particularly in terms of the data provided by the hospital. While the personnel at the hospital were very supportive of this study and were extremely helpful in terms of the time they allowed for questions and the opportunities to discuss with personnel the issues that impacted the ability to collect, monitor, and assess patient fall data, there were constraints on how much time and effort the hospital staff could spend to satisfy our requests for information. The hospital staff had a large number of other important requirements that had to be met to satisfy both the patient care demands, as well as the normal requirements of a highly rule-based system (e.g., filling out a variety of forms). These requirements were often in tension with the desire on part of both the researcher and the medical personnel to collect additional information. While the type of information collected for patient falls was modified between the first and second data collection period it was recognized that collecting additional information and linking information from different databases would be highly desirable.

A list of important limitations to the data collection of this study follows:

1. More complete interfacing between the medical databases on the patient units and the admissions department are needed. At the present time it is not possible to have admission personnel recognize whether patients who are entering the hospital and had been patients at the hospital previously had experienced falls in their previous stays.
2. While a scoring system has been developed to identify patients who are at-risk for falls, the scoring system has limited granularity, thus a large fraction of all patients have scores in excess of 10, and are thus considered at high risk for falls. Development of another fall score scale might be advantageous, but making effective changes to the system would require a significant large amount of time and effort to implement.

3. While there were two specific periods where data was collected, it is recognized that having a longer time interval between the two intervals would have been advantageous. A set of 10 new Stryker beds that had been expected to be installed in unit 3M at the start of the second data collection period (December 31, 2006 through May 31, 2007), were not put in place until March 2007. Therefore, the effect of these beds on the patient fall rate for 3M for the second data collection period was limited. These beds provided the hospital staff with an improved ability to better care for patients who were at risk for falls by allowing the staff to immediately address an at-risk patient's need for a bed that could be lowered closer to the floor (and thus reduce the risk for harm if the patient did fall out of the bed), as well as having built-in alarms that allowed the nursing staff to know if an at-risk patient were attempting to get out of their bed.
4. Finally, while it was expected that the data collected provided a reasonable reflection of the actual performance of the system being measured, it was unknown how much variance from the actual performance of the system there was. For example, it was believed that the time, age, units, etc. for the fall events are accurately reported, but some error was expected[4], so the conclusions drawn from the collected data may be biased by those errors. It is concluded, from the observation of the system, that the data obtained was a reasonably good reflection of the actual system. However, it should always be understood that no matter what sort of trend was observed in the data presented, the data collected cannot be believed to be the response for the entire system. Paraphrasing Weick (1987) "the chart is not the patient," in this case, "the trend or behavior is not the hospital system."

[4] It will be noted in future sections that there were errors in some of the fall data collected, particularly in the first data collection period.

3.0 THE HOSPITAL AS A COMPLEX SYSTEM AND CULTURE

While patient falls within a hospital are events that have to be addressed and managed as part of the requirement of the hospital's work, the way the hospital deals with such events (designated as 'adverse events') indicates the type of culture which has developed and come to operate within the hospital itself. This thesis asserts that a fraction of patient falls that occur within the hospital are events that cannot be reasonably prevented. However, some other large fraction of these adverse events can potentially be avoided by the application of an aggressive falls identification and prevention policy, based on the best assessment of important metrics that indicate which patients have a large risk of falling and attempt to focus limited medical health resources to those patients at greatest risk. This focus includes not only the patient's actual medical condition, but also the environment of the particular unit the patient is on, the individual room environment in which the patient stays, as well as the clothes the patient wears. Further, it is argued that the level of prevention for patient falls and other adverse events varies over time due to the competing nature of various requirements that exist in the hospital environment.

This cultural aspect of hospital operation in large part determines whether or not an organization is successful in achieving its stated goal. While the study of the various subcultures that exist within the hospital was not specifically part of this study, consideration of how such a culture forms and operates is important in understanding how such an organization may change itself to improve patient safety.

In Section 4.0 a number of studies are discussed which attempted to determine the source of, or reduce fall rates (Meade et al (2006)), which failed to achieve any reduction

(Semin-Goossens et al (2003)), or eventually lost whatever reduction had initially been produced (Hitcho et al (2004)). It is suspected that the culture of those organizations contributed to those successes and failures.

Appendix F and G presents further information concerning the theoretical background of organizations and the difficultly that exists in effecting positive change in them.

4.0 PREVIOUS STUDIES

4.1 OVERVIEW OF PREVIOUS STUDIES

The issue of patient fall prevention has an extensive literature background. The cost and visibility that these events have on a medical system, besides the guidelines established by Joint Commission to monitor these events (see Section 1.2), have resulted in numerous studies to try and identify the primary causes for patient falls, as well as to attempt to reduce both the number and severity of patient falls. A discussion of these events is presented below.

4.2 IMPACT OF PATIENT FALLS ON HEALTHCARE SYSTEMS

Patient falls are common adverse events that occur in all healthcare environments. From Baker et al (1992) falling is a common cause of morbidity[5] and the leading cause of nonfatal injuries and trauma-related hospitalizations in the United States. Research by Hopkins et al (2005) has shown that major factors contributing to falls include: (1) previous falls, (2) disorientation at admission, (3) need for assistance and (4) lack of control of bowels. The preeminent factor determined by Hopkins et al (2005) was previous falls. A review of published reports on risk factors indicated a similar list of factors affecting falls – (1) gait instability, (2) agitated confusion, (3) urinary incontinence/frequency, (4) falls history, and (5) prescription of culprit drug (see Oliver et al (2004)).

[5] In this usage morbidity means “disability caused by an accident.”

Various studies have indicated that the frequency of fall rates vary considerably. Rubenstein et al (1988) estimates that there are 0.6 to 2.9 falls annually per bed in hospitalized patients and 0.6 to 3.6 falls annually per bed in long-term care institutions. The total cost of falls injuries in 1994 for adults aged 65 years and older was estimated at $20.2 billion, see Englander et al (1996). Based on the expected increase in the United States fraction of the population above 65, from 12.8% in 1995 to 18.5% in 2025 (see PPL-47 (October 1996)), the costs associated with patient falls will increase significantly unless the number of patient falls and their associated effects are reduced.

Following a fall event, the patient, especially if elderly, may experience reduced activity due to fear of future falls. The incremental cost for caring for an individual in the year after a fracture, resulting from a fall, were estimated to be between $16,300 and $18,700, see Brainsky et al (1997). All medical care centers are interested in trying to find if their available fall data contain important metrics that might enable personnel to identify either the patients that have a large fall risk (intrinsic factors), or conditions within the medical care facility that may tend to result in greater fall rate – such as events occurring during particular times of the day, or days of the week (extrinsic effects). Differences in nursing staffing or varying work requirements may contribute to these extrinsic factors.

It is apparent that the need to address patient fall issues is growing as the population of elderly patients increase, together with the increasing cost to care for patients who experience fall events. Therefore, studies that may aid in understanding the causes of patient falls, as well as the methods to mitigate their effects are needed.

4.3 REVIEW OF PREVIOUS PATIENT FALL STUDIES

The following section contains a description of a number of reports which investigated various aspects of patient falls. This following list and description of articles is not meant to be exhaustive, and the numbering of the list does not have meaning, other than linking the articles to the numbers listed in Table 1. The list is intended to provide the reader a perspective of the variety of different types of investigations performed and factors considered in patient fall investigations.

1. Haines et al (2004) performed a targeted multiple intervention fall program which included risk alert cards with an information brochure, exercise program education program and hip protectors. The participants in the targeted program experienced 30% fewer falls than the untargeted patient population. There was no information provided concerning whether the reduction in fall rate remained at this reduced level.

2. Chang et al (2004) examined a large number of fall reduction programs as well as patient exercise programs which had previously been performed (a total of 40). This study was a systematic review and meta-analysis of these previous studies. Interventions to prevent falls in older adults are effective in reducing both the risk of falling and the monthly rate of falling. The most effective intervention was a multifactorial fall risk assessment and managerial program. Exercise programs were also effective in reducing the risk of falling. No evidence was found for the effectiveness of environmental modifications or educational programs. This report provided no evidence that the factors which were claimed to reduce fall rate had a long-term impact on reducing the fall rate.

3. Mayo et al (1994) indicated that the use of an identification bracelet among high risk patients who are undergoing in-patient physical rehabilitation was not of any benefit in preventing falls among high-risk patients.

4. American Geriatrics Society et al (2001) argue that there are a number of specific risk factors that cause an increase in the likelihood of a patient to fall (including muscle weakness, history of falls, gait deficit). Further, they conclude that when there are multiple risk factors present in a single patient, the risk of falling increases significantly. They conclude that while single interventions may have some limited benefit (such as environment modification), most single interventions have limited benefit. This report distinguished between what are called intrinsic factors affecting falls, such as blindness and muscle weakness, and extrinsic factors, such as the type of footwear worn and design of the hospital room in which the patient resides. Some of these factors can be modified, such as muscle weakness (through exercise), or improved footwear. They conclude that the most effective method of reducing patient falls was to have a comprehensive assessment, hospital staff education, assistance devices and reduction of medications.

5. Schwendimann et al (2005) performed a study to investigate if patient falls were correlated with days of the week, months, seasons and lunar cycles. This study was conducted in Zurich Switzerland. Based on their analysis of collected data, they concluded that there was no correlation with days of the week, seasons, or lunar cycles.

6. Hitcho et al (2004) studied the characteristics of patient falls in a large (1,300 bed) urban hospital (St. Louis). They found that the average age of the patients who fell were 63.4 years[6] with about 85% of falls occurring in the patient's room, during the evening overnight period (59%), and during time when they were walking (19%). Since they also determined that 50% of the falls were related to elimination, which was a more common problem for

[6] This average age was compared to the average observed from the two data collection periods for this study (see Section 6.2.2). These averages are about 70 years for the first data collection period and about 72 for the second data collection period. This information indicates that the demographics of the area where the hospital is located can significantly affect the characteristics of the patients who experience falls. It would be expected that the older the patient population the larger the number of complications, and the greater the possibility of patient falls.

elderly patients, it was believed that increased hospital staff assistance to patients might reduce fall rates. One of the authors of the Hitcho study, MJ Krauss, was contacted (per personal communication) concerning the results of this study and she provided additional perspective that indicated the difficulty in constructing and sustaining a successful fall prevention program. She indicated that a nine month intervention program was initiated on two units of the hospital at the hospital stressing the use of toileting/safety rounds. A drop in the fall rate was observed in the first six months, but the rate subsequently increased after six months. The reason for the subsequent increase was concluded to be due to the various requirements that nursing personnel need to attend to in their care giving function. In particular it was noted that the patient's need for autonomy and lack of understanding of their limitations contributed to the difficulty in maintaining the reduced fall rate over time.

7. Semin-Goossens et al (2003) described a multifaceted intervention program that was implemented between 1999 and 2001 in Amsterdam. The aim of this program was to reduce patient falls by 30%. However, the result of this program did not produce any observable decrease in the monthly fall rates. They conclude that the reason for the failure of the program was that not enough effort was expended to change the attitude of the nurses who would have to implement the program. Portions of the nursing population apparently believed that falls were an inevitable result of the type of hospital patient population with which they had to care for. This result occurred even though the units on which the program was implemented resulted from nurses volunteering to be part of the program. This report indicates the need for an organization to carefully prepare for a planned cultural change. The need to have a buy-in for the proposed change is important from both supervisory personnel and the nursing staff.

8. Shorr et al (2002) assessed the relationship between physical restraints and patient falls. Although there were concerns about whether actual orders for restraint are used at the time of patient falls, they conclude that use of restraints do not protect hospitalized patients from falling. This study was performed in Memphis, Tennessee.

9. McInnes et al (2004) focused on the views of older people relative to their perspective and experiences of fall prevention programs. This study indicated that the older patients preferred strategies not involving behavior change among some groups, the need to promote the social value of falls prevention programs, and the importance of identifying and addressing factors associated with activity avoidance. They conclude that it is important to consult with the at-risk patient population to ensure that programs designed to prevent falls are consistent with the activities the patient is willing to do.

10. Yauk et al (2005) described a process that resulted in the development of a simple risk screener using routine admission and daily in-hospital stay data. This study found that four variables were identified as the most important predictors of falls: history of falls, ambulation assistance, disorientation, and bowel control problems. These factors were used in developing a fall screening tool. They emphasize that patients who have fallen in the past are likely to fall again, particularly when they are in a strange environment and require help in walking. This study was performed in Texas.

11. Oliver et al (2004) conducted a review of patient fall risk factors and risk assessment tools. The study concluded that, despite the variety of medical settings in which the various studies were conducted, only a small set of risk factors consistently emerged. These factors included gait instability, agitated confusion, urinary incontinence/frequency, falls history and prescription of certain drugs, in particular sedatives and hypnotics. The study

claimed that risk assessment tools have shown to predict falls with a high degree of accuracy.

12. Ganz et al (2007) attempted to identify prognostic value of risk factors for future falls among older patients. Eighteen previous studies were analyzed with regard to risk factors considered to contribute to the likelihood of patient falls. The conclusions from this study were that the pretest probability of falling per year for people 65 years and older was 27% (95% confidence interval, 19-36%). Patients who had fallen previously, are much more likely to fall again [likelihood ratio range 2.3-2.8]. And the most consistent predictor of future falls are clinically detected abnormalities of gait or balance [likelihood ratio range, 1.7-2.4]. Other factors such as visual impairment, medication variables, decreased activities of daily living, and impaired cognition did not consistently predict falls across studies.

13. Meade et al (2006) examined the effects of redesigned nursing rounding procedures on the patient fall rate and patient call light use. This revised rounding procedure was implemented in 46 units at 22 hospitals. The revised nursing rounding procedure required specific actions to be taken by the nursing staff. These actions included: (a) assessing patient pain levels, (b) offer toileting assistance, (c) assessing the patient's position comfort, (d) making sure the telephone and call light is within the patient's reach, (e) ensuring that the bedside table is next to the patient's bed, and (f) prior to the nurse or nurses' aide leaving the room inform the patient someone would be back within a given timeframe (either one or two hours). The results of the study indicated that patient falls were significantly reduced for the one-hour rounding group. This study indicates that even after a year following the initial study (for the one-hour nursing rounding procedure) the results of patient fall reduction were still significant (60% reduction from the baseline data).

14. Carrick et al (2007) examined whether listening to music might cause changes in human stability and be useful in fall prevention and rehabilitation. Stability scores were obtained through the use of computer dynamic posturography (CDP) and were measured for a group of subjects who had not had a history of falls or vertigo. The non-control group were given a daily specific music listening task and additional CDP scores were obtained at 10 minute, 1 week, and 1 one month after the subject's treatment in a blinded fashion. The results of this testing showed that there were positive changes in the subjects stability who underwent a variety of music listening tasks including the music of the French singer, Nolwenn Leroy. Nolween Leroy was found to be significantly superior to other types of music tested.

Table 1 provides a summary from a subset of the articles previously discussed concerning which risk factors were considered to be the most important contributor to patient falls.

Table 1. Summary of Patient Fall Articles Reviewed and Factors Affecting Patient Fall Rate

	Document Number (See Section 4.3)						
Risk Factor	**4**	**6**	**10**	**11**	**12**	**13**	**14**
Muscle Weakness	X						
History of Falls	X		X	X	X		
Gait deficit (Instability)	X			X	X		
Elimination		X	X	X			
Disoriented (confusion)			X	X			
Ambulation Assistance			X				
Medication (Sedatives)				X			
Excessive time between nursing rounds						X	
Failure to control patient's room environment						X	
Music as a method to reduce risk of falling							X

The data in the table demonstrates that the most frequent factor from the selected documents was “history of previous falls,” which was a factor in four of the seven reports. This factor was also considered to be very important for the fall screening test developed at the hospital from which data for this thesis was obtained.

4.4 COMMENTS ON PATIENT FALL STUDIES REVIEWED

It was six men of Indostan
To learning much inclined,
Who went to see the Elephant
(Though all of them were blind),
That each by observation
Might satisfy his mind.
John Godfrey Saxa, “Six Blind Men from Indostan”

The survey of the studies listed in Section 4.3 and the data presented in Table 1 provide a perspective about the variety of factors that have been studied by various researchers. It is noted here that the reports described in Section 4.3 were performed in a number of different geographic areas, with a number performed outside the United States. Some studies were focused on restraint use, while others focus on describing specific aspects of patient falls (such as age, location, reason for falls, etc.), and others describe specific fall intervention programs. The wide variety of causes postulated to be the primary driver of patient falls may be rooted in the various environments within which these studies were performed. As a group of investigators study their source of falls, they are burdened with their expectations and their personal direct experiences with previous patient falls. Those expectations and previous experiences could bias researchers to investigate particular causes that are not primary causes, but are considered important by the local hospital staff. The potential for this effect is made all the more probable due to the complex interactions which exist within the hospital system in which medical care is provided. Although each researcher attempts to discern the primary cause for the patient fall, it is difficult to uncover primary causes in a complex environment where multiple sets of factors contribute to patient falls. We are also susceptible to this research bias in this thesis.

Although a number of these studies indicated that some reduction in the existing fall rate had occurred, it was not certain, with the exception of Meade et al (2006) that there had been any long term reduction to the fall rate. In fact, from the Semin-Goossens (2003) report the investigators described the failure of the program to reduce patient falls at all, due apparently to disbelief on the part of nurses, who had agreed to participate in the proposed study, that patient falls could actually be reduced. The communication with MJ Krauss, one of the researchers from the Hitcho study (see Hitcho (2004)) indicated that over time, the fall reduction rate, which had initially been achieved eventually returned to its original higher level. While the exact reason for the return to the fall rates which had existed prior to the study is uncertain, it is probable that the demands exerted by the system on the hospital staff resulted in the effort required for sustaining the program to be degraded over time. Observing Figure 3 in Section 6.1.1.3 provides an indication that while there was some reduction in the hospital-wide monthly patient fall rate during the early portion of the data presented (July 2001 through about July 2004), there did not appear to be any continuing fall rate reduction following that date. The monthly hospital-wide fall rate appears to have remained approximately constant from about July 2004 to the present. From these data and discussions with the hospital staff it appears that the effort to reduce and maintain a lowered monthly patient fall rate, or to continue the reduction of fall rates over a long period of time is a very difficult process.

Although no specific data is available to determine what the source for being unable to further reduce the monthly fall rate, it is hypothesized that periodic requirements to address the many other caregiver requirements in the hospital can reduce the effort expended on being observant for patient fall danger signals. Further, if there are no large increases in the recent patient fall rates, there may be a psychological effect within the healthcare community to suppress large expenditures of effort to further reduce patient falls. However, if there were a sudden increase in the number of patient falls (as in May 2006 – see Figure 20), there may be an increased effort and pressure on the community to reduce the fall rate until it reaches a more acceptable level.

From the review of the previous studies performed, it is also concluded that usually a single fall prevention procedure or method (for example an identification bracelet in the Mayo

(1994) study), is not effective in reducing fall rates. A more varied and multidimensional method and extensive program including detailed risk assessment and more individual treatment of patients at-risk of falls may be required to reduce fall rates. And if this is the case, then such programs will require both significant effort as well as significant buy-in from management, administration as well as the nursing staff to have any possibility of success (see Semin-Goossens et al (2003)). Such an effort was described in the Meade (2006) report, which indicated that a significant cultural change was required to implement the revised rounding procedure. The hospital is currently going through a similar cultural change in trying to implement its modified rounding procedure that is based on the Meade (2006) report. This initiative will be discussed later in the report.

Primary Differences Between this Study and Other Studies Reviewed

The primary difference that we observe between many of the studies described in Section 4.3 and the analysis presented within this thesis is that this thesis made a significant effort to attempt to quantify and use statistical tools in assessing the data that was collected. This included a number of assessments as to whether there might be tendencies in falls occurring at specific times of the day, week or year, as well as trying to investigate the effectiveness of the existing fall screen. Also, a detailed breakdown of the age of the patients who fell is provided, as well as an assessment of the number and type of severe falls experienced. Further, assessments were performed regarding the method the hospital used to determine if it was succeeding in meeting its stated fall goals. As will be shown later the use of c-charts and moving averages aided in placing the month-to-month variation in the fall rate into better perspective.

An improvement that can be made to future studies of this type is to obtain hospital data that enables a more complete comparison between the population of patients who fell and those who did not. More data of the non-falling patient population would be useful in demonstrating whether or not there were measurable differences between those two populations. If so, examining the non-fall population may allow the development of more effective metrics to determine what to look for in the population of patients with a large fall risk.

5.0 STUDY METHODOLOGY

The following section describes the data collected for the patient fall events. It also provides an overview of the statistical methods used to analyze the data obtained from the hospital. Details of the process followed by the hospital in its handling of patient fall data are presented in Section 2.0.

5.1 DATA COLLECTED FROM DECEMBER 1, 2005 THROUGH MAY 31, 2006

For the first six month time period for this study (December 1, 2005 through May 31, 2006) the hospital provided an INITIAL INCIDENT/EVENT REPORT for every fall event that occurred during this period. The information provided by the hospital for this data collection period was from paper report sheets for each patient fall. The primary data extracted from these reports and analyzed subsequently is presented in Table 2.

Table 2.
Information Collected During the First Data Collection Period, December 1, 2005 through May 31, 2006

Item Description
Medical record number
Date of event
Time of event
Patient's date of birth
Patient's gender
Hospital unit in which the patient fall occurred

In addition to the individual fall information obtained for this period the hospital-wide monthly patient fall rate was provided from July 2002 through May 2006. Finally, the hospital also provided the monthly fall data for each hospital unit from July 2003 through May 2006. A target monthly fall value was established for the hospital-wide and each individual unit performance. Thus, the monthly measured fall rate could be readily compared against the target fall rate established by the hospital. The hospital-wide monthly fall rate is discussed in Section 6.1.1 while the individual unit data is presented in Section 6.1.2.

In addition to the data discussed above, we requested and the hospital provided all the ages of the patients admitted from 12/01/05 through 04/30/06. This information is used in Section 6.2.2 when comparisons are made between the ages of patients who fell and those who did not.

5.2 DISCUSSION OF DATA COLLECTED DECEMBER 1, 2005 THROUGH MAY 31, 2006 WITH HOSPITAL STAFF, JULY/AUGUST 2006

Following the collection and analysis of the first set of patient fall data, and following discussion of these data with the thesis advisors, a presentation was prepared and made to members of the hospital staff. This presentation on July 27, 2006 provided a synopsis of the data assessment performed, together with a number of suggestions that were developed on the basis of the data collected and analyzed. Following this presentation another discussion about possible changes in the existing patient fall data collection process was held with a number of nursing staff supervisors in August 2006 to consider implementation of suggestions made by us and hospital staff members for implementation for the second data collection period.

5.3 CHANGES IN THE FALL DATA COLLECTED FOR THE SECOND DATA COLLECTION PERIOD (DECEMBER 1, 2006 THROUGH MAY 31, 2007)

Following assessment of the first dataset, the hospital made the following changes in their patient fall data:

1. First, the Patient Fall task force developed a spreadsheet that summarized the monthly fall data as well as to include a wider range of information than had previously been collected. This information was disseminated to all the nursing supervisors, so they could monitor the patient fall data of the other units during the month. This form included the information presented on Table 3 below:

Table 3. Information Collected During the Second Data Collection Period, December 1, 2006 through May 31, 2007

(This information was disseminated to all hospital units)	
A	The number of patient falls per unit
B	The breakdown of when the falls occurred (day, swing or midnight shift)
C	The number of repeat falls during the month
D	Whether or not restraints were in use at the time of the fall
E	The Harm score, which describes the extent of the injury experienced by the patient as the result of the fall
F	The number of patient days for each unit
G	Average fall score prior to fall (where a fall score of 10 or greater indicates a high risk for falls)

In addition the same information as from the first data collection period was also collected. This additional information allows a more detailed and extensive assessment of the monthly fall data than had been available previously. Further, if a particular unit had reduced fall rates, the data, and any changes made by the unit should be available to be reviewed by other units, thus increasing the possibility for incorporating changes in procedures that could help to reduce their monthly fall rates. The information on the patient falls for the second data collection period was provided to us on spreadsheets, so data was more easily extracted and analyzed.

2. Ten special beds (Stryker) that improved the ability of nurses to monitor patients with a higher risk of falling were obtained. These beds were placed in one unit (3M) during March 2007. These beds provided the hospital staff with an improved ability to address patients at-risk for falls by allowing the staff to immediately address an at-risk patient's need for a bed that could be lowered closer to the floor (and thus reduce the risk for harm if the patient did fall out of the bed), as well as having built-in alarms that allowed the nursing staff to know if an at-risk patient was attempting to get out of the bed.

3. Unit based fall reduction supplies were obtained. The term unit based supplies means that fall prevention materials, such as bed alarms are located on the units, so once they are needed, they are readily accessible by the staff on that unit, and do not have to be searched for and thus avoid having limited staff expend effort obtaining fall prevention materials, when that effort could be expended to direct patient care.

4. From about February 2007 until the end of the second data collection period, a new method of rounding by the nursing staff was being prepared and implemented on unit 5M. This new rounding procedure was designed to ensure that each patient on the unit knew that every hour during the shift either a nurse or a nurse's aide would check each patient and room. This check would assess the patient's pain level, offer toileting assistance, ensure necessary items (such as telephones and water cups) were within reach for the patient, check fall alarms, and inspect the room for safety and clear pathways. The implementation of this new rounding procedure for the entire hospital did not occur until June 15, 2007. This revised rounding procedure is discussed in more detail in Appendix C.

The change in rounding procedure was based on a study performed by Meade et al (2006). The implementation of this new rounding process was viewed by the staff as a major hospital cultural change. It was recognized that in order for it to make a significant impact on improving patient care that both the nursing staff and administration would have to agree to a "buy-in" to the effort of changing the existing culture. Special training was provided to the nursing staff prior to the implementation of this procedure to ensure that the requirements associated with the hourly rounding procedure were understood.

The potential impact of this change in nursing rounding, although not able to be fully addressed by this thesis will be discussed in the conclusion section (See Section 7.0).

5.4 DESCRIPTION OF ANALYSIS METHODS

5.4.1 C-Chart

A c-chart (Hogg and Ledolter (1992), pg. 195) was created for the hospital-wide and unit monthly fall data to assess whether the observed variation in the patient fall data is within "control", or exhibits excessive variation. The c-chart deals with the number of defectives or adverse events over a certain unit. In this case the adverse events are the number of patient falls that occur over 1000 patient days. For this type of chart, an upper control limit (UCL) can be established that represents a value of patient falls that is unlikely to be reached. Therefore, if values greater than the UCL are obtained this represents an unlikely occurrence.[7] The UCL for the c-chart is based on taking the average of the patient fall data (c-bar) over the measured period and adding 3*SQRT (c-bar). The UCL approximates the three sigma limit for a Poisson

[7] A Lower control limit (LCL) for this case is not needed to be determined, since lower patient falls is a desired outcome.

distribution.[8] It is assumed that the 3-sigma band of the Poisson distribution approximates the 3-sigma bound for the normal distribution. Therefore, is would be expected that the UCL would bound 99.7% of all monthly patient fall rate data. Therefore, if the monthly patient fall rate values exceed the UCL, for the period of data available (~five years, 60 data points, for the hospital-wide data and ~4 years, 48 data points, for the individual unit data) it will be argued to be unexpected behavior. The c-chart was used to assess the stability of the hospital and individual unit data. It is expected that individual hospital units might have greater data variability than the entire hospital, since the hospital-wide values have much more data associated with it than a single hospital unit. Generally the hospital experiences about one fall a day, while individual units may experience only several falls per month. Further, it is expected that the individual unit may have greater variability in its behavior since having several high risk patients on a unit, or patients that experiences multiple falls per month would increase an individual unit's fall rate. Such individual unit results, when combined with all the other units (not all of which would have this adverse combination of events) would be expected to produce a hospital-wide response that would have less likelihood of exceeding the UCL.

5.4.2 Linear Regression and ANOVA Table

Linear regression (Montgomery Peck and Vinning (2006) Chapter 2), was used to assess whether there was a statistically significant trend in the patient fall data hospital-wide as well as the individual hospital unit data. Regressions were performed using the SPSS program (see SPSS v15 [2006]). Analysis of variance (ANOVA) information was extracted from the program output and included in tables in this thesis. For these regressions, the dependent variable (y-axis) was the fall rate data, while the independent variable was the time (month) (x-axis). This information included regression coefficients, fitted regression parameters, and F_0

[8] ($\lambda \pm 3\sqrt{\lambda}$ where λ is an approximation of the distribution of the number of defectives, in this case patient falls.

values. The null hypothesis (H_0), is defined as; there is no statistical significance to the fitted regression parameter that is the slope (μ) determined in the regression, and thus the patient fall trend is neither increasing nor decreasing. The alternate hypothesis (H_a) is defined as there is a statistical significance to the slope determined in the regression and thus there is an increasing or decreasing fall rate trend. This test is designated as: H_0 ; $\mu = 0$, H_a: $\mu \neq 0$.

The use of the linear regression model requires the assumption that the model errors are normally and independently distributed with a mean 0 and variance σ^2. Based on the observation of the results from the regression analysis performed on the various hospital-wide and unit data it was concluded that the hospital data approximated a normal distribution. This conclusion was generally supported by the analysis of the normality and residual plots from the SPSS output.

A sample table showing the representative regression data that is extracted from the SPSS program is presented in Table 4.

Table 4. Sample Table of Linear Regression Information

Model	**Sum of Squares**	**Degrees of Freedom**	**Mean Square**	**F_0**	**Sig**
Regression	7.873	1	7.873	4.855	0.032
Residual	92.430	57	1.622		
Total	100.303	58			
	Unstandardized Coefficient				
	B	**Std. Error**			
Constant	113.468	49.312			
Monthly Fall rate	-8.16E-09	0.000			
	R	R^2	Adjusted R^2		
	0.280	0.078	0.062		

The following provides description for the various parameters that are presented in Table 4:

Model Regression Sum of Squares (SS_R) – this value represents the sum of squares which is accounted by the regression performed.

Model Residual Sum of Squares (SS_{Res}) – this value represents the sum of squares which is not accounted for by the regression.

Model Total Sum of Squares (SS_T) – this value is simply the sum of the Regression and Residual sum of squares **(SS_R + SS_R).**

Degrees of Freedom (df)– the total, regression and residual degrees of freedom are related by the following; $df_{Tl} = df_R + df_{Res}$

Mean Square of Regression (MS_R) = Sum of Squares of Regression / $df_{Regression}$

Mean Square of Residual (MS_{Res}) = Sum of Squares of Residual/ $df_{Residual}$

F_0 = MS_R / MS_{Res} and follows the $F_{1,\ n-2}$ distribution. This value is also designated as the test value since it provides the method for testing the trending hypothesis.

The Constant and Monthly Fall Rate are related through the regression as follows:

y = Constant + (Monthly Fall Rate) * x, where y is the monthly fall rate and x is the time (in months)

Standard Error for Constant = SQRT (MS_R (1/n + (x-bar)^2/S_{xx})

S_{xx} = Σ (x_i - (x-bar))^2 and x-bar is the average of the x values.

Standard Error for Monthly Fall Rate = SQRT (MS_{Res} / S_{xx})

R^2 is the coefficient of determination = SS_R / SS_T – a “perfect” regression would produce a value of 1 (there would be no residual sum of squares). R is simply the square root of R^2.

The adjusted R^2 = 1 – (SS_{Res} / (n-2))/ (SS_T/(n-1))

Sig (also known as the p-value) = The smaller this value the more probable the alternate hypothesis (that there is a trend in the data) has statistical significance and cannot be rejected.

5.4.3 Chi-Square Exponential Test

In order to test whether the distribution of time intervals between consecutive patient falls is an exponential, a Chi-square test was used. The method used for this test is described below (see START[internet]):

1. Establish the Null Hypothesis H_o: Distribution is assumed to be exponential, the Alternate Hypothesis H_a: The distribution is not exponential
2. Estimate the mean of the observed data (exponential parameter)
3. The Chi-square test statistic is defined to be:

   $\chi^2 = \Sigma^k_{i=1} [(e_i - o_i)^2/e_i]$

   Where e_i is the expected number of events within subinterval i, and
   Where o_i is the observed number of events within subinterval i
4. Establish K = 5 subintervals for the observed data distribution. These subintervals were designed to be approximately equal for both data collection periods.
5. Obtain the Probability for the K = 5 subintervals. This probability is calculated using the following formulation:

   $Prob_{(mean)}$ (Subinterval I end value)=1.0–EXP(- [subinterval end value]/mean)
6. Determine test statistic for the Chi-square test. The degrees of freedom equal the number of subintervals (5), decremented by one for performing the test, and decremented for one due to the fact that the mean was determined from the data distribution. Therefore the total number of degrees of freedom = 3.
7. Establish the test significance level: α – 0.05
8. Obtain the Chi-square critical value ($\chi^2_{0.95, 3}$ = 7.815)
9. Compare the calculated Chi-square test statistic to the critical value. If the test value is less than critical value, do not reject H_o at the stated level of significance. If the test value is greater than the critical value, then reject H_o at the stated level of significance.

In examining this method, it was determined that instead of creating equal subintervals from the data (see steps 4 and 5), equal probability cells should be constructed. The reason for adjusting this procedure is to avoid the possibility of inadvertently biasing the boundaries of the data cells. While moving a cell boundary slightly over an observed data point affects the probabilities only a small amount, it may change the observed cell counts significantly. To avoid this potential methodology deficiency, equal probable intervals were created.

5.4.4 Chi-Square Uniform Distribution Test

A Chi-square goodness of fit test (Hogg and Ledolter (1992) pg. 254) was performed on a variety of the data presented in this thesis. This test provides a means to ascertain whether there is statistical significance to a particular conjecture about the distribution of the data. As an example, the goodness of fit test was used to assess whether there was a significant deviation from a uniform distribution of the patient falls over the days of the week, the time period encompassing the three shifts for the day and the individual hours of the day. In other words the test was conducted to determine whether there was a significant difference between the observed data, for a particular day of the week, shift of the day, or hour of the day, and the average value for each of these timeframes. The null hypothesis assumed that the number of falls over the interval being examined would be equally probable (for example, for the days of the weeks, the null hypothesis was that the expected distribution would be that each day of the week would have about 1/7 of all the falls). A Chi-square test is performed to determine whether the null hypothesis should be rejected. The value to be determined for this assessment is: $Q_{k-1} = \Sigma$ (Observation – Expected)^2 / Expected – the summation is performed from 1 to k. For the example of the days of the week k is 7. The Q_{k-1} value is compared against the value from the Chi-square distribution, X^2 (0.01, 6) (or 16.81) for the assessment of the days of the week example.

In order to use the goodness of fit tests, the assumption of normality must be met. It was concluded that the hospital data for which the goodness of fit test was used was approximated by a normal distribution.

5.4.5 MOVING AVERAGE

When data is obtained over a long time period it is expected that some amount of random variation will occur. This random variation may mask a trend, if present, in the data. Stock markets, which experience significant variation in the price over time, often use moving averages to discern a trend in data (see Moving Averages). The smoothing technique used for the data collected in this thesis was a simple averaging technique. What was performed in the hospital-wide and unit fall rate data was to average the data for the first four months, use that as the first data point, then construct the second data point by using the second to fifth data points. This process continued until all data values had been processed. When the resulting moving average was calculated and plotted the month-to-month variation was significantly reduced, and a number of distinctive trends were observed from the data.

A four month average period was used based on judgment following assessment of the observed variation using other averaging periods.

5.4.6 Chi-Square Normality Test

In order to test several distributions of data for normality a Chi-square test was used. The method used for this test is described below (see START [internet]):

1. Establish the Null Hypothesis H_o: Distribution is assumed to be normal, the Alternate Hypothesis H_a: the distribution is not normal.
2. Estimate the mean and standard deviation of the distribution from the observed data.
3. The Chi-square test statistic is defined to be:

   $\chi^2 = \Sigma^k_{i=1} [(e_i - o_i)^2/e_i]$

Where e_i is the expected number of events within subinterval i, and
Where o_i is the observed number of events within subinterval i

4. Establish K = 5 subintervals for the observed data distribution. These subintervals were designed to be approximately equal for both data collection periods.
5. Obtain the Probability for the K = 5 subintervals. This probability is calculated using the following formulation:

   $Prob_{(mean,\ standarddeviation)}$ (Subinterval I end value) = Normal ((subinterval end value – mean/standard deviation)

   The cumulative probability for the distribution is then inferred from this value.
6. Determine test statistic for the Chi-square test. The degrees of freedom equal the number of subintervals (5), decremented by one for performing the test, and by two further degrees of freedom for having inferred the mean and the standard deviation from the observed data. Therefore the total number of degrees of freedom = 2.
7. Establish the test significance level: α – 0.05
8. Obtain the Chi-square critical value ($\chi^2_{0.95,\ 2} = 5.99$)
9. Compare Chi-square test statistic to critical value. If the calculated test value is less than the critical value, do not reject H_o at the stated level of significance. If the test value is greater than the critical value, then reject H_o at the stated level of significance.

Consistent with what was done in Section 5.4.3, it was determined that instead of creating equal subintervals from the data (see steps 4 and 5), equal probability cells should be constructed. The reason for adjusting this procedure is to avoid the possibility of inadvertently biasing the boundaries of the data cells. While moving a cell boundary slightly over an observed data point affects the probabilities only a small amount, it may change the observed cell counts significantly. To avoid this potential deficiency equal probable intervals were created.

6.0 ANALAYSIS OF DATA COLLECTED

6.1 HOSPITAL-WIDE AND UNIT PATIENT FALL DATA

6.1.1 Hospital-Wide Patient Fall Date From July 2002 Through May 2007

The hospital-wide patient fall data provides an overview of the behavior of the total number of patient falls that occurred in all the units of the hospital from the period of July 2002 through May 2007.

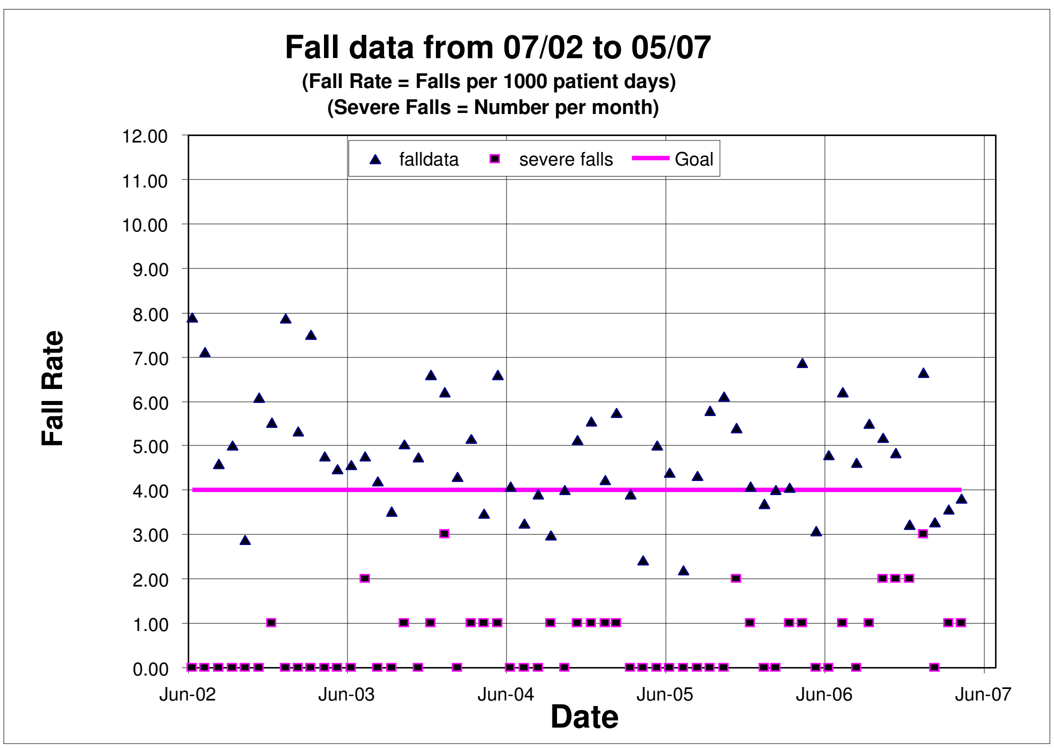


Figure 1. Hospital-Wide Monthly Patient Fall Data for July 2002 through May 2007

The data on Figure 1 shows the month-to-month patient fall rate in terms of falls per 1000 patient days and the goal (or target) the hospital had set for itself in keeping the fall rate below a certain value, in this case 4 patient falls per 1000 patient days per month. This monthly goal (4.0 patient falls/1000 patient days) was selected using the best evidence reported in the literature and the multi-hospital system's own experience. Based on review of the available data the total number of patient days for all the units of the hospital generally varied between 4000 and 6000 patient days per month (see Section 6.1.1.5).

6.1.1.1 Monthly Patient Fall Rate Date The monthly patient data fall rate on Figure 1 varies from a low of about 2 to a maximum of 8 (patient falls per 1000 patient days). The average value is 4.81 and the standard deviation is 1.32. Fifty two of the 59 monthly values are greater than the hospital goal of 4.0 patient falls/1000 patient days per month. A visual observation of the monthly patient fall data indicates that over the time period presented there does not appear to be any strong trend in the data. The month-to-month variation in the data appears to be about the same at the end of the period as is it at the beginning.

To provide perspective as to the raw number of patient falls that occurred over the period shown in Figure 1, Figure 2 presents the monthly total number of patient falls (not monthly patient fall rate) over the same period as Figure 1. The average number of monthly falls was 28.8, the median was 28, the standard deviation was 6.5, the minimum value was 17 and the maximum value was 45. Observing the figure it appears that most of the values fall between 20 and 40, centered close to 30 (consistent with the calculated average of 28.8). Basically, the figure indicates that there is a large month-to-month variation of the number of patient falls, but the calculation of the average indicates that over a number of months, the average number of falls works out to about 1 patient fall per day. The total number of falls for this period was 1699.

If a bound is established based on twice the standard deviation, the upper bound is then 41.8 and the lower bound is 15.8. Therefore, there are only two points that exceed the upper band and none that fall below the lower band. If the monthly fall data were normally distributed, this band should bound about 95% of all the data points. There are 59 data points, two of which fall outside this bound, indicating there are not an excessive number of outliers relative to the two times standard deviation bound.

Figure 2 also presents the number of monthly severe patient falls (see Section 6.1.1.2 for the definition of a severe fall). This average monthly value was 0.58, and the maximum monthly value was 3. For 34 of the 59 months in this period there were no severe falls. The total number of severe falls for this period was 34, making the fraction of severe falls relative to the total number of falls equal to (34/1699) = 0.02.

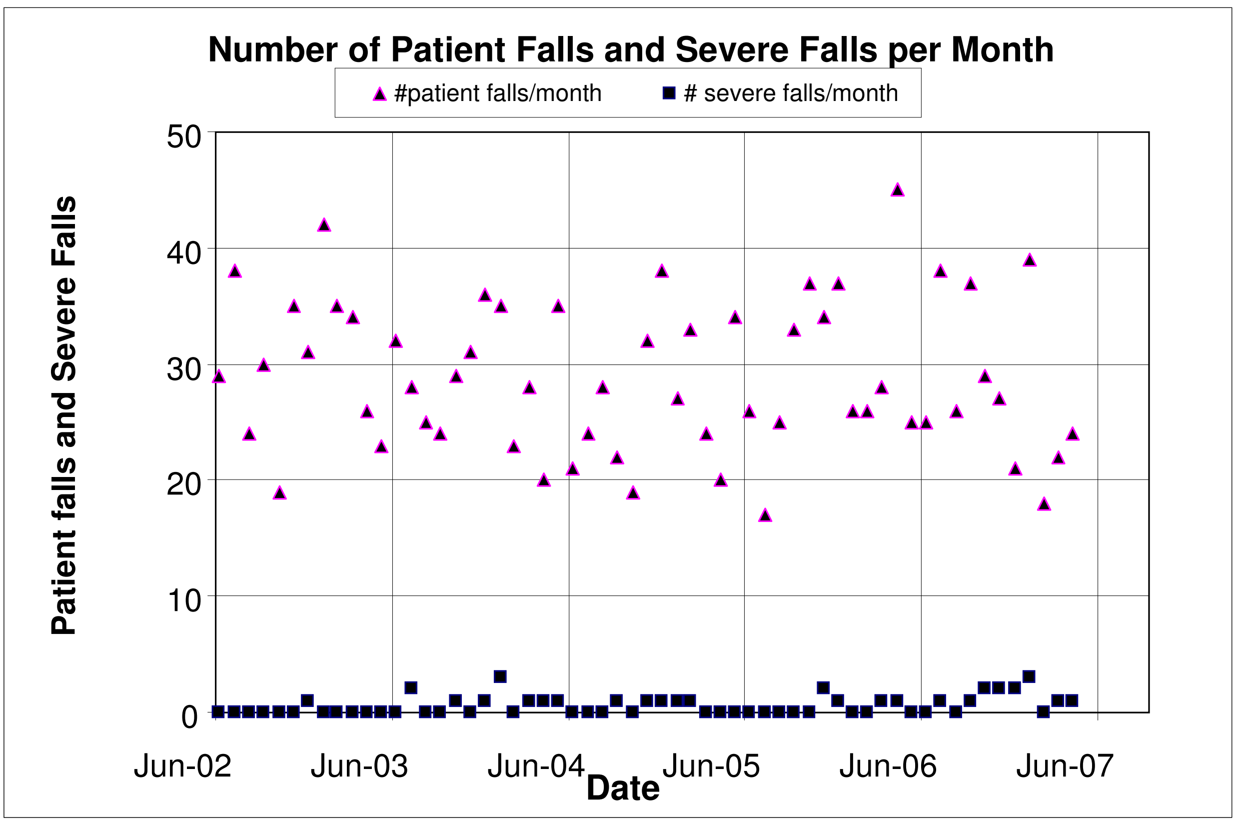


Figure 2. Number of Hospital Patient Falls per Month for July 2002 through May 2007

6.1.1.2 Monthly Severe Patient Fall Data In addition to the monthly patient fall data on Figure 1, the hospital also collects data on the patients whose falls resulted in what is defined to be severe harm to the patient. The number per month of these falls is shown on Figure 1. These values represent the number of patients who experienced a specific level of injury resulting from their falls. Table 5 provides a definition for the harm which results from such a patient fall event:

Table 5. Definitions of the Categories of Harm that Result from a Patient Fall

Designation	Impact/Affect on Patient	Severe Harm
D	Fall resulting in scrapes, abrasions, small lacerations without sutures	No
E	Fall resulting in injury requiring interventions, laceration requiring sutures, fracture with no extension of hospitalization	Yes
F	Fall resulting in fracture with prolonged hospitalization, head injury, condition requiring medical intervention and prolonged hospitalization (temporary) harm	Yes
G	Fall that contributed to or resulted in permanent harm	Yes
H	Fall that resulted in near death event (required ICU or other intervention to sustain life	Yes
I	Fall resulting in or contributing to death	Yes

Any patient that has experienced greater than a designation D (scrapes, abrasions, small laceration with sutures) is added to the severe injury tally. Detailed information was obtained for the harm score data was obtained during the December 1, 2006 through May 31, 2007 period. These types of falls will be discussed further in Section 6.2.6.2. While severe fall events are relatively rare, they have large implications on the hospital and its staff, and so all possible efforts are made to protect patients from such events. Table 6 lists the number of severe fall events from the period July 2002 to May 2007.

Table 6. Number of Severe Patient Falls from July 2002 to May 2007

Time Period	Number of Severe Falls
July 1, 2002 – June 30, 2003	1
July 1, 2003 – June 30, 2004	10
July 1, 2004 – June 30, 2005	5
July 1, 2005 – June 30, 2006	5
July 1, 2006 – May 31, 2007	13
Total Number of Severe Falls	34

Examination of the severe fall rate in Table 6 and the plotted data in Figure 1 indicate that there has not been any significant reduction in these types of falls over the five year period that is covered by the data. In fact, for November 2006, there were three severe patient falls, only the second time this has occurred in the approximate five year period presented. Further, the total number of severe falls in the period July 1, 2006 to May 31, 2007 was larger than any other previous yearly period. The behavior of this data again indicates that reducing or eliminating severe patient falls is an extremely difficult undertaking, even on the part of an organization that is committed to pursuing such a reduction.

To provide a perspective on the fraction of patient falls that result in severe falls, the total number of patient falls over the period July 2002 to May 2007 is 1699, while the total number of severe falls was 34. Thus, severe falls account for about 2% of the total falls that occur.

6.1.1.3 C-Chart Assessment of Hospital-Wide Patient Fall Data A C-Chart formulation (see Section 5.4.1) for the hospital-wide monthly patient fall rate data was performed and is presented below on Figure 3. The average monthly patient fall rate (4.81) and UCL value (11.4) is also presented on Figure 3. If there were a number of monthly patient fall values that exceed the UCL, it could be argued that the hospital method of addressing patient falls was not in control, that is, it periodically produced fall rates that exceeded a roughly three sigma limit which is associated with the UCL. Since all the individual monthly data points are less than the UCL, it is concluded that the system (the entire hospital) does not exhibit any unstable behavior. This is consistent with the information presented in Section 5.4.1. As noted previously the standard deviation for all the individual monthly values equals 1.32.

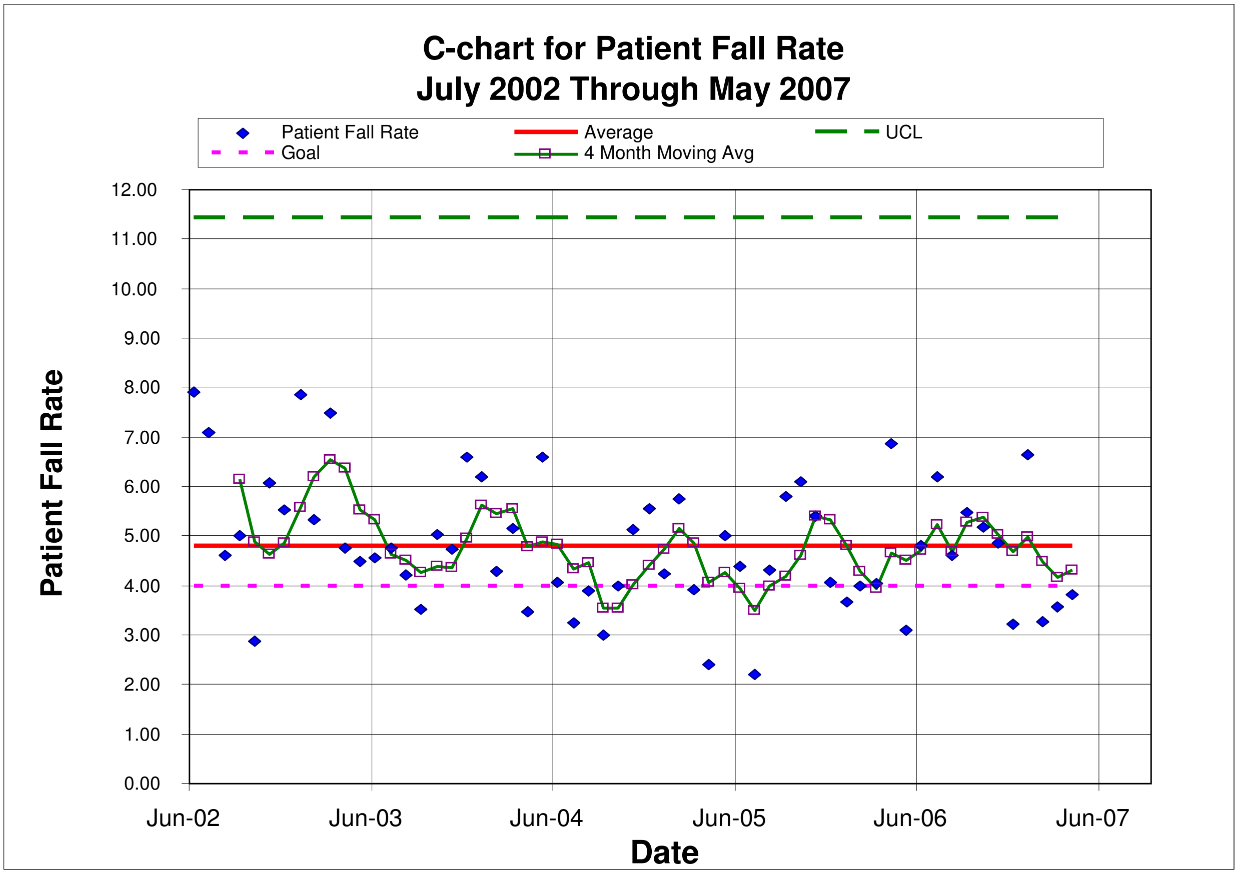


Figure 3. Hospital-Wide Patient Fall Data, Including C-Chart UCL and 4 Month Moving Average Values for July 2002 through May 2007

As noted previously the hospital-wide goal for monthly patient fall rate is to not exceed 4.0. This value is less than the average produced from all the monthly fall data, thus it is concluded that while there are months when the fall rate is below the desired goal, it appeared for most of the time period the actual monthly data exceeded the desired goal.

The four month moving average (see Section 5.4.5) is shown on Figure 3. Although most of its values exceed the hospital goal, its plot gives an indication that there may be a decreasing trend in the patient fall data over the time period from approximately July 2002 through July 2004. From about 2005 on, the moving average appears to have no increasing or decreasing trend. At the end of the data period the moving average value is close to the value of the goal (4.0). However, the moving average also displays a cyclic trend that tends to have a period of a little less than a year. The peaks of these cycles for the moving data tend to be later in the year, while the minimums tend to be in the summer. The higher values of the moving average may indicate that during periods later in the year, more elderly patients are admitted in the hospital and suffer seasonal illnesses that may cause an increase in fall rate. The behavior in the last year of the moving average has little if any pronounced peak, as was observed in the earlier periods.

6.1.1.4 Results from Linear Regression Analysis of Hospital-Wide Patient Fall Data The following table presents the results for the linear regression performed for the hospital-wide monthly patient fall data shown on Figure 3. The null hypothesis tested is that the slope of the regression is equal to zero. See Section 5.4.2 for details for linear regression in this application.

Table 7. Linear Regression Results of the Monthly Hospital-Wide Patient Fall Data

Model	Sum of Squares	Degrees of Freedom	Mean Square	F_0	Sig
Regression	7.873	1	7.873	4.855	0.032
Residual	92.430	57	1.622		
Total	100.303	58			
	Unstandardized Coefficient				
	B	Std. Error			
Constant	113.468	49.312			
Monthly Fall rate	-8.16E-09	0.000			
	R	R^2	Adjusted R^2		
	0.280	0.078	0.062		

The results from the information in Table 7 indicate that; (1) the amount of information explained by the linear regression performed is quite small (see R^2 =0.078), and (2) the F_0 is such that it does not exceed the critical value[9], $F_{\alpha, 1, n-2}$. (For $\alpha = 0.01$, $F_{\alpha, 1, n-2} = 7.08$ [assuming n-2 = 60, which is virtually the same as the actual number of datapoints (59)]). Since F_0 (4.855) is less than $F_{\alpha, 1, n-2}$ (7.08) it is concluded that the null hypothesis, that the slope of the regression is equal to zero is accepted. Thus the regression provides no statistically significant evidence (at the 0.01 level) that a discernable slope in the data exists. While a visual observation of the data appears to indicate a decreasing trend of the moving average data, the variation in the month-to-month fall rate does not allow a statistically supportable conclusion that the patient monthly fall rate is decreasing over any portion of the July 2002 to May 2007 time period.

Check for Normality for Hospital-Wide Patient Fall Rates

As discussed in Section 5.4.2, the use of linear regression makes the assumption that the model errors are normally and independently distributed with a mean 0 and variance σ^2. In order to ascertain whether these data were normally distributed, these monthly patient fall rates that were presented on Figure 3 were reformatted and presented on Figure 4 below. This reformatting was to assemble the patient fall rates from the smallest to the largest, and then plot them in ascending order, creating a cumulative density function for the data.

[9] $F_{\alpha, 1, n-2}$ is designated as the critical value, since it is the value which is compared against the test value, F_0 produced from the regression. Depending on the value of the test value compared to the critical value will determine whether the null hypothesis is accepted or rejected.

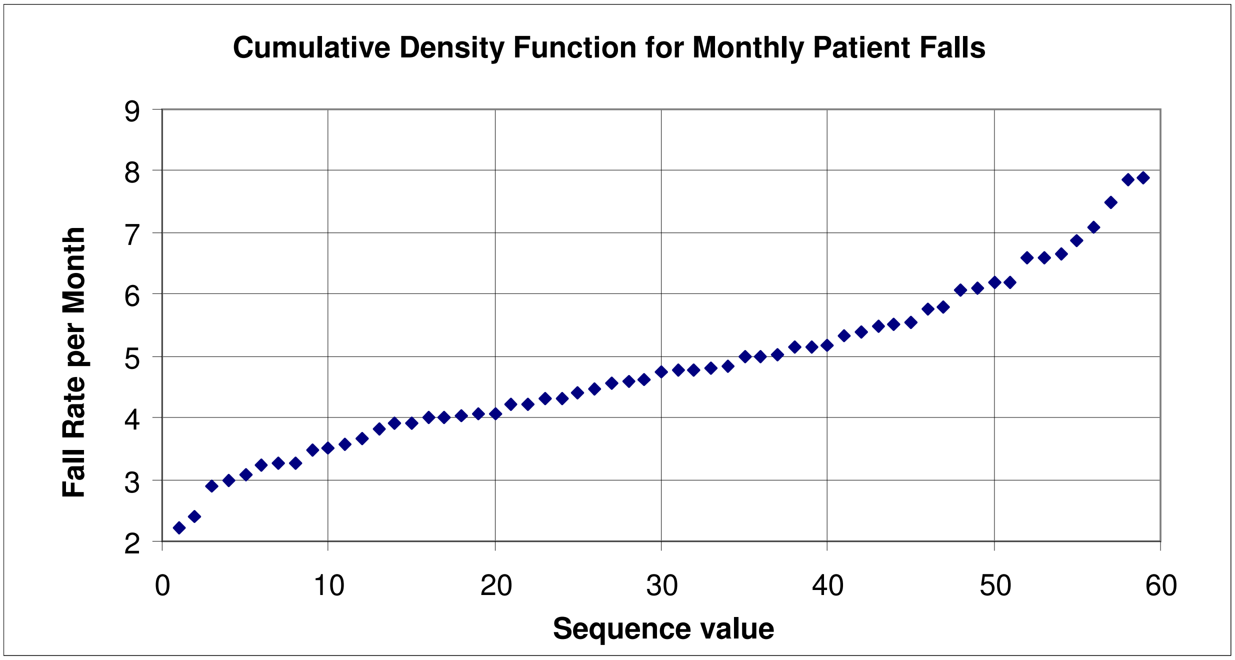


Figure 4. Cumulative Density Function for Monthly Hospital-Wide Patient Fall Data for July 2002 through May 2007

The Chi-square methodology that was described in Section 5.4.6 was applied to this data. The data in Table 8 below presents the results of the analysis performed to determine if this distribution of data was normally distributed.

Table 8. Information Used to Perform Chi-square Normality Test for the Hospital Monthly Fall Rates, July 2002 through May 2007

Null hypothesis H_o is that the overall patient fall rates follow a normal distribution (Chi-square critical value ($\chi^2_{0.95,\,2}$ = 5.99)						
Characteristics of distribution: mean = 4.81 patient falls per month, std dev = 1.32 patient falls per month, number of values = 59						
Interval	End value for Observed Data Interval (Patient Falls per Month)	Cumulative Probability*	Interval Probability	Number of items Observed (O) in Interval	Number of items Expected (E) in Interval	(E-O)^2/E
1	Infinity	1.00000	0.20000	12	11.8	0.003
2	5.9209	0.80000	0.20000	9	11.8	0.664
3	5.1444	0.60000	0.20000	13	11.8	0.122
4	4.4756	0.40000	0.20000	13	11.8	0.122
5	3.6991	0.20000	0.20000	12	11.8	0.003
		Totals	**1**	**59**	**59**	**0.914**

* The end value for the equal probability intervals were determined by using the invNorm(area[,μ,σ]) distribution function on the TI-83 calculator, Texas Instruments (2003)[10]. The end value for the interval was determined by providing; (1) the cumulative probability, the distribution mean and the distribution standard deviation

The Chi-square test statistic value for this test (0.914) is less than the Chi-square 95% critical value ($\chi^2_{0.95,\,2}$ = 5.99), so the null hypothesis cannot be rejected at the 95% confidence interval. Therefore, it is concluded that the distribution of monthly fall rates is distributed normally at the 95% confidence level. A test for normality was not performed for the individual hospital unit data.

6.1.1.5 Checks for Correlation of Hospital-Wide Patient Days and Number of Patient Falls

Is there a correlation between having a larger number of patient falls when there are a larger number of patients at the hospital? A simple argument could be made that the larger the number of patient days per month, a greater stress would be placed on the hospital staff and it would be more probable that a larger number of patient falls would result. This could be

[10] The InvNorm function for the TI-83 calculator computes the inverse cumulative normal distribution function for a given area under the normal distribution curve specified by mean μ and standard deviation σ. Thus, knowing the mean and standard deviation, you can determine the point on the normal distribution curve that is associated with a specific area for the entire distribution. From Table 8, the end point for the interval associated with 0.20 of the normal distribution is 3.6991.

mitigated by having additional staff to handle the higher system stress. However, it would be true that the larger the number of patient days, the greater the requirements placed on the hospital staff to minimize patient falls. A simple assessment of this hypothesis follows.

Analysis - Method 1 – Simple Month-to-Month Correlation

Figure 5 presents the total number of patient days, on a monthly basis, cross plotted with the total number of patient falls, also on a monthly basis. Note that this figure contains data that extends from January 2000 through May 2007.

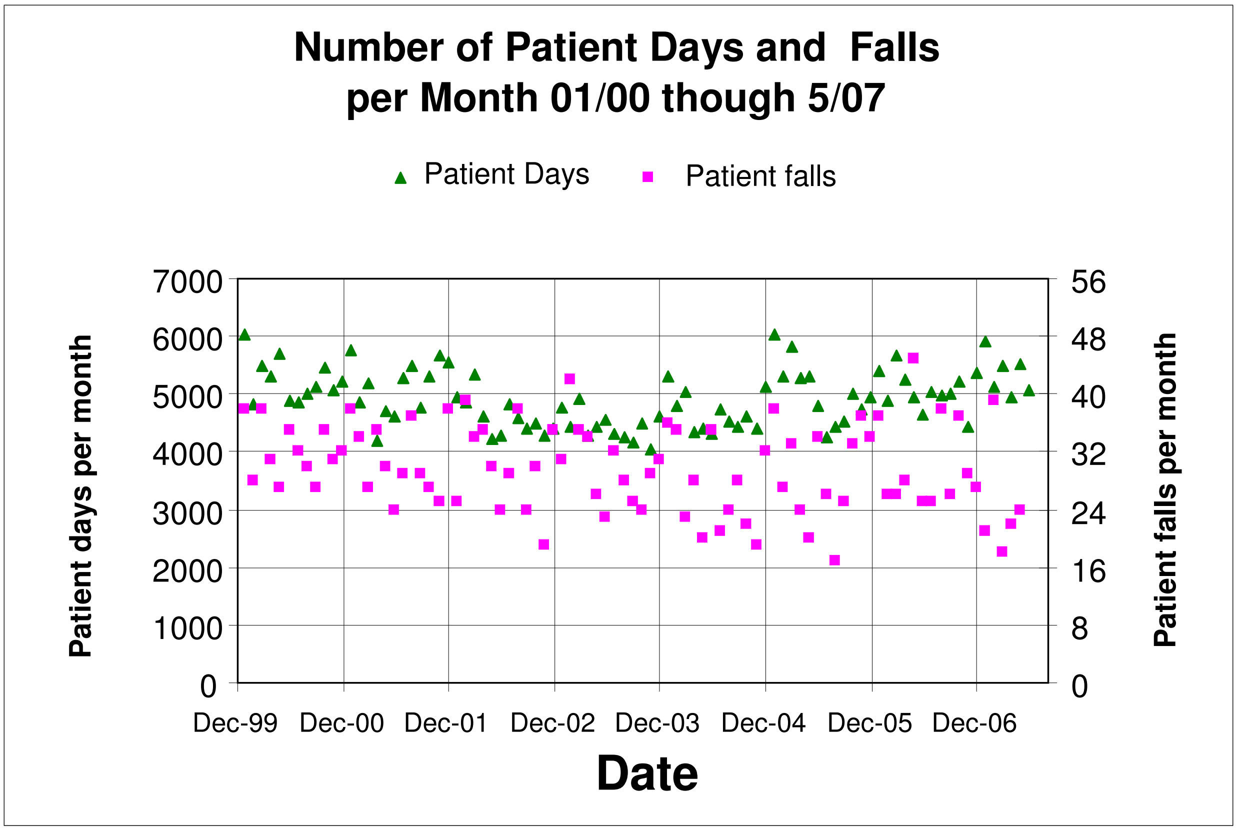


Figure 5. Cross Plot of Patient Days and Patient Falls on a Monthly Basis

The data presented on Figure 5 demonstrates that the number of patient days per month varies within a range of about 4000 to 6000, while the total number of monthly patient falls varies between about 16 and 45.

In order to assess whether or not there is a correlation between changes in the patient days and patient falls, a percent change in both parameters was calculated. This percent change was calculated between consecutive months. An assessment was performed to determine if there was a correlation for each month. A correlation meant that both the number of patient days and patient falls increased or decreased for the month being assessed compared to the previous month. If one parameter increased and another decreased, then there was no correlation. A tabulation of all the data produced 45 months with no correlation (a condition where patient falls increased and patient days decreased, or vice versa), while 41 months did have correlations[11] (a condition where patients falls and patient days both increased or both decreased). Based on these results it is concluded that there was not any correlation between these two parameters on a hospital-wide basis.

Analysis - Method 2 – Linear Regression of Derived Parameters

An alternative method can be employed to determine whether there is a correlation between these two parameters. A parameter that divides the number of patient falls by the number of patient days per month is determined. Then by dividing the number of patient days per month by the number of days per month produces a parameter that can act as a "virtual" estimate for the average number of patients in a month.

By making these transformations, we can make the supposition that the months that had the largest number of average patients per day may produce the largest number of falls per patient day, if the hospital is "over stressed" by handling a larger number of patients per day.

These transformations were performed on the data shown on Figure 5. The resulting correlation between the two parameters is presented in Figure 6.

[11] There were a total of 86 month, the first month was not used since it served as the basis, and there were two data points were there zero percent change, and thus those months could not be placed into either the correlated or uncorrelated columns.

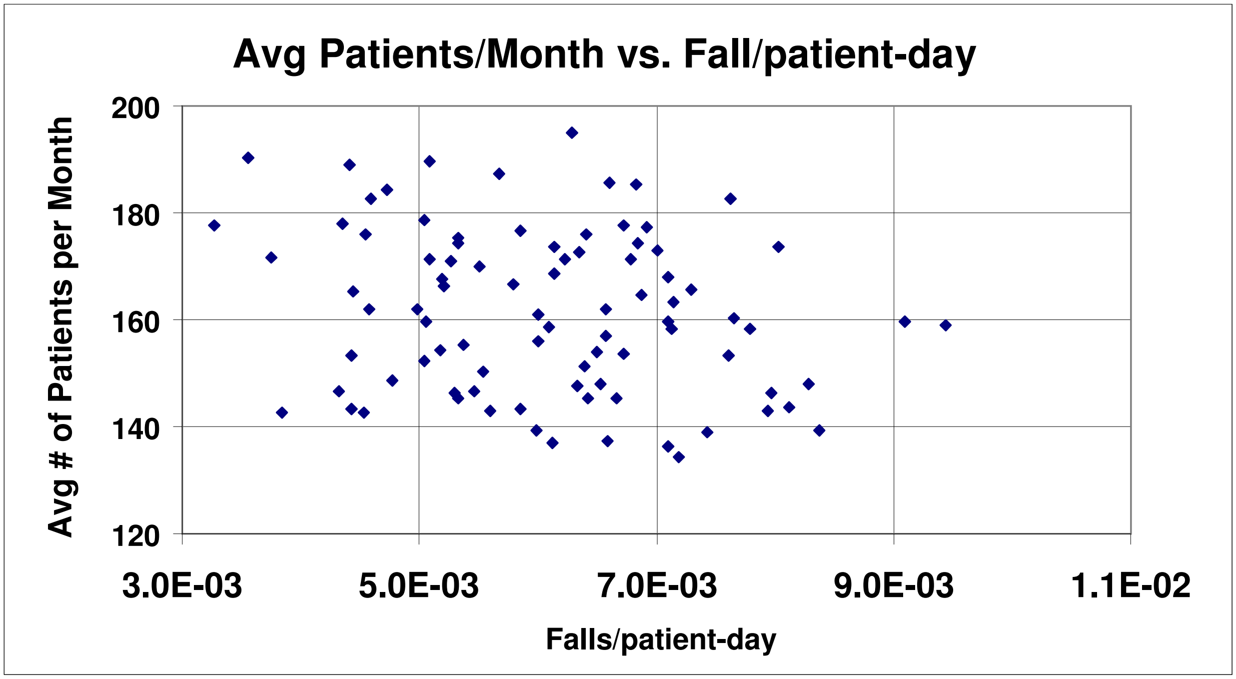


Figure 6. Cross Plot of Average Number of Patients per Month versus Falls/Patient Day

A linear regression was performed to determine if there was any statistical correlation. The results from this regression are presented on Table 9.

Table 9. Linear Regression Results of Patients per Month versus Falls per Patient Day

Model	Sum of Squares	Degrees of Freedom	Mean Square	F_0	Sig
Regression	0.000	1	0.000	4.033	0.048
Residual	0.000	87	0.000		
Total	0.000	88			
	Unstandardized Coefficient		Standardized Coefficients		
	B	Std. Error	Beta		
Constant	0.009	0.001			
Monthly Fall rate	-1.71E-005	0.000	-0.210		
	R	R^2	Adjusted R^2		
	0.210	0.044	0.033		

The results of this regression indicate that, as can be seen from Figure 6, there does not appear to be any trend in the data. The amount of information explained by the linear regression performed is quite small (see $R^2 = 0.044$), and (2) the F_0 (4.033) does not exceed the estimated value of $F_{\alpha, 1, n-2}$. (For $\alpha = 0.01$, $F_{\alpha, 1, n-2} = 6.965$ [assuming n-2 = 87] . This value is the split between the difference of 7.08 for n = 60 ,and 6.85, n=120. This result means that the null hypothesis that the slope of the regression is equal to zero cannot be rejected, and thus the regression provides no statistically significant information to suppose a trend exists.

From Figure 6, the two points that appear to be outliers and have the largest falls/patient day, occurred in February 2003 (with a total of 42 falls), and May 2006 (with a total of 45 falls). If the larger number of patients per day were to stress the system and cause a larger number of falls per patient-day, then the expected trend in this data would be to have an increase from the lower left to the upper right. This trend is not observed in this data. The two outliers discussed are associated with a lower number of average patients per day (~160).

This conclusion can also be argued to make sense. Observing Figure 5, the total number of patient days remains in a rather tight band of about 4000 to 6000 patient days per month, with annual peaks occurring in the later months of one year and early months of the next year. It is likely that the hospital staff recognizes these variations and prepares for the seasonal changes in patient load.[12] Another way to describe the situation is that the hospital staff has adapted to handling large month-to-month variations within this band. Another possible factor that may explain this behavior (that is, having a larger number of falls in a month that does not contain the largest number of patient days) is the mix of patients and their medication conditions, rather the just the raw number of patients.

[12] While detailed discussions with the nursing staff was not conducted concerning these issues, we were present at a meeting where the chief nurse was called to the phone and had to respond to the issue of having a larger than expected hospital census (a larger than expected number of patients) for that day. It was clear from this conversation that well thought out contingencies existed in the hospital to handle conditions when the hospital census increased unexpectedly. Additional staff and beds were made available and the additional patients were distributed as needed in the different units. It is noted however, that in a sudden influx of patients, the possibility of not being able to deal effectively with new at-risk patient conditions may occur. So even if the system is able to respond to a sudden increase in patients, how effectively this response is in terms of not creating additional risk for patients is another issue.

6.1.2 Unit Patient Fall Data From July 2003 Through May 2007

In addition to the hospital-wide monthly fall reports analyzed, there was also monthly data concerning the fall performance for the various units of the hospital. The description of the various hospital units from which data was obtained, is presented in Table 10:

Table 10. Description of the Hospital Patient Units

Unit Designator	Unit	Number of beds On Unit	Description of Unit and Type of Patients Treated	Average Age of Patients Who Fell in Units During the 12/06 through 05/07 Period The number of falls are listed as ()
2MR	2 Mansfield Rehabilitation	16	Patients with acute rehabilitation needs	66.50 (22)
TCU	2 Mansfield TCU	19	Patients who need short (<15 days) of skilled nursing care	82.07 (14)
2CR	2 Crawford Rehabilitation	18	Patients with primary surgical needs	78.88 (8)
3CR	3 Crawford Rehabilitation	27	Patients with primary surgical needs	74.74 (19)
3M	3 Mansfield	24	Patients with primary medical needs (can double 6 rooms for a total of 30)	77.26 (19)
4M	4 Mansfield	24	Patients with primary medical needs or orthopedic surgical needs (can double 6 rooms for a total of 30)	77.74 (38)
5M	5 Mansfield	24	Patients with acute cardiac needs	72.67 (12)
CVU	Cardio Vascular Unit	12	Patients with intensive cardiovascular needs	40.00 (1)
ICU	Intensive Care Unit	11	Patients with intensive medical or surgical needs	65.00 (1)
Health (5CR)	Behavioral Health	32	Patients with primary behavioral health needs	48.59 (17)

Table 10 data indicate that based on this data collection period there is some variation in the average age of the patients who fell in the different hospital units. In particular the behavioral health unit had a significantly lower average age for the patients who fell than most of the other units. This is an indication that the causes of the falls on this unit are not due specifically with health issues, but more with drug and behavioral issues[13]. A number of the units had average patient fall ages which were similar (TCU [82.07], 2CR [78.88], 3CR [74.74], 3M [77.26], 4M [77.74], and 5M 72.676]). However, because general unit age information is not available, it is not possible to draw conclusions regarding the similarities or differences in age for non-falling populations for these units.

This fall performance data shows what the patient fall rate was on a monthly basis. The interval over which this data was presented was from July 2003 to May 2007 (shorter than the hospital-wide fall data – July 2003 through May 2007). As for the hospital-wide data each unit had a fall rate goal that was not to be exceeded. This performance measure is designated as the targeted fall rate.

As an illustration, to provide a perspective for the breakdown of the number of patient days per unit, the data for March 2007, which was randomly selected, is provided in Table 11.

Table 11. Number of Patient Days per Unit for March 2007

Unit	Number of Patient Days	Unit	Number of Patient Days
2MR	408	5M	671
TCU	498	CVU	236
3CR	717	ICU	261
3M	754	Behavioral Health	714
4M	781	2CR	463

The data from each of the hospital units was analyzed and the average fall rate and the standard deviation of the fall rate were calculated. Table 12 below presents the results of this analysis.

[13] This was confirmed by discussions with the hospital nursing staff.

Table 12. Summary of Information for Unit Fall Data from July 2003 through May 2007

	Patient falls/1000 patient days per month		
Unit	**Target Fall Rate (Falls/100 Patient Days)**	**Average Fall Rate**	**Standard Deviation**
2MR	7	5.78	4.15
TCU	3	**5.64**	3.90
3CR	4	**4.96**	3.30
3M	4	**4.90**	3.06
4M	4	**5.89**	3.31
5M	4	**5.45**	3.04
CVU	1.25	1.73	2.92
ICU	1.25	1.46	2.35
Behavioral Health	4	2.50	1.92
2CR	4	3.81	2.79
For all Hospital Units	4	4.81	1.32

As described previously, the target fall rate was established based on the best evidence reported in the literature and the health care system's own experience. Those target values varied as a result of the layout of the units, as well as the patients that were being cared for on the unit. The **bold** average fall rate values in the table above show that the average values of the measured data exceed the target values. Another value presented in this table is the standard deviation. The standard deviation values are generally quite large, approximating (and sometimes exceeding) the value of the average value for the unit. This indicates that the monthly patient fall data has a large amount of variation associated with it. For a significant number of hospital units the standard deviation is close to or larger than 2, the only unit having a standard deviation smaller than 2 is the Behavioral Health unit. For comparison purposes the data for all the hospital units are presented in Table 12. The standard deviation for this data is only 1.32. This result is expected if the data from the individual units is independent from the activity on other hospital units. The standard deviation for the entire hospital, made up of the individual unit values should be smaller than the hospital-wide value. The assumption of independence of the units is concluded to be reasonable since there are differences in patient type, unit staff personnel and there are differences in how patient falls were addressed or attempted to be prevented on a unit basis (see Section 2.2).

It is also noted that there are a variety of target fall rate for different units. The CVU and ICU units (1.25) have much smaller targets fall rates than other units (7, 4, or 3). The primary reason for this is due to the design of the CVU and ICU units, where the nursing station is located in a central location allowing the nursing staff to observe all the patient rooms in the unit. In addition, the patient to nursing ratio is much smaller than for other units. In the CVU and ICU the ratio is closer to 2 while for other units it may be as high as 8.

Figures 7 through Figure 16 present the individual unit patient fall information together with the unit target, the four month moving average, and the c-chart UCL. Following the figures are the results from the linear regression performed for each of the medical units, Tables 13 through 22. Particular items that are observed on the figures are noted following the figure. Discussion of the linear regression data are presented after Table 22.

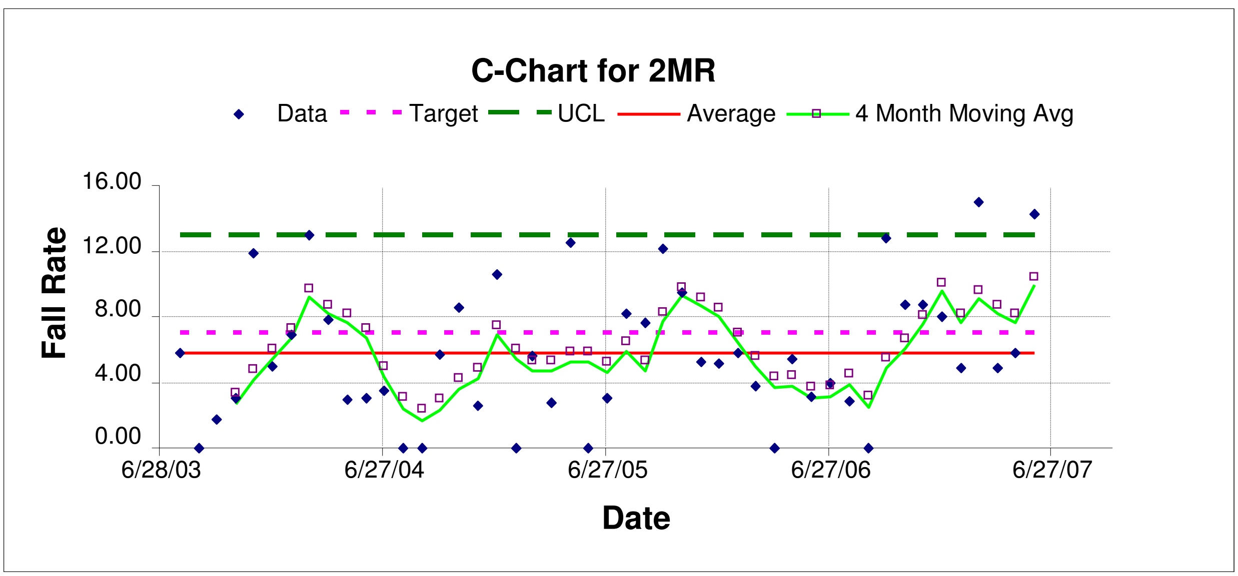


Figure 7. Unit 2MR Patient Fall Date for July 2003 through May 2007

There are several monthly values that are close to or exceed the UCL, however, the average monthly patient fall rate is less than the target value of 7. The two values which exceed the UCL occurred during the last data collection period. There appears to be no pattern associated with the moving average data.

Table 13. Linear Regression Results for Unit 2MR Patient Fall Data

Model	Sum of Squares	Degrees of Freedom	Mean Square	F_0	Sig
Regression	3.2E+15	1	3.165E+15	2.516	0.120
Residual	5.7E+15	45	1.258E+15		
Total	6.0E+16	46			
	Unstandardized Coefficient				
	B	Std. Error			
Constant	1.3E+10	8939890.7			
2MR Monthly Fall rate	2000211.9	1261096.0			
	R	R^2	Adjusted R^2		
	0.230	0.053	0.032		

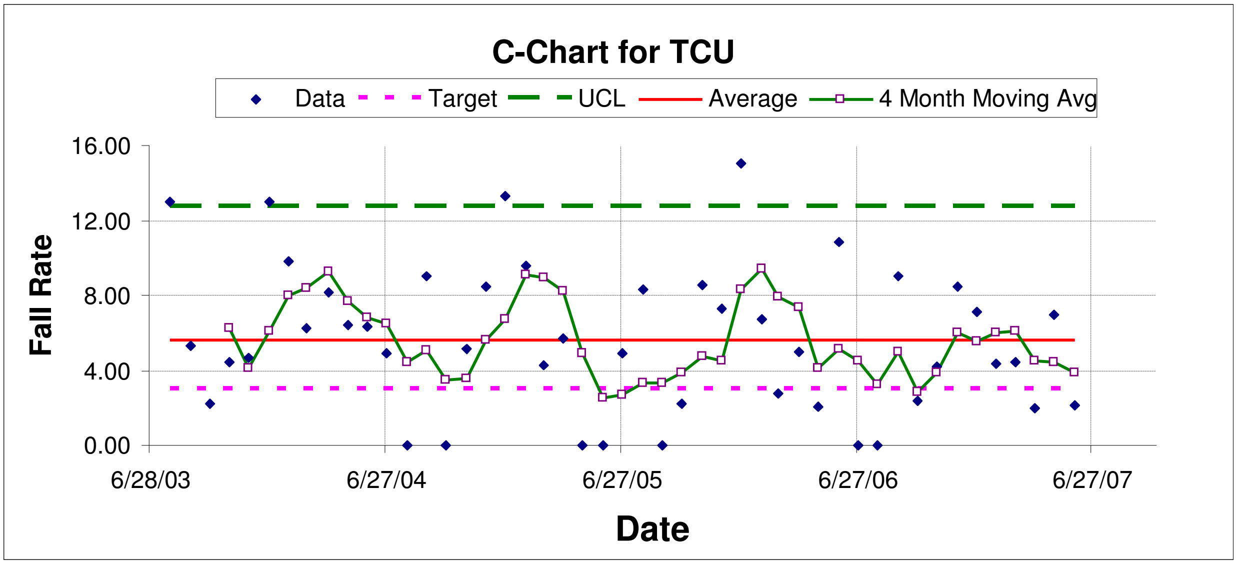


Figure 8. Unit TCU Patient Fall Data for July 2003 through May 2007

There are four monthly values that exceed the UCL. The average fall value exceeds the goal of 3. The moving average appears to indicate a cyclic pattern for several of the years with peaks in the early part of 2004, 2005 and 2006. The average monthly patient fall rate (>5) value significantly exceeds the target value (3).

Table 14. Linear Regression Results for Unit TCU Patient Fall Data

Model	Sum of Squares	Degrees of Freedom	Mean Square	F_0	Sig
Regression	2.4E+015	1	2.439E+15	1.914	0.173
Residual	5.6E+16	45	1.274E+15		
Total	6.0E+16	46			
	Unstandardized Coefficient		Standardized Coefficients		
	B	Std. Error	Beta		
Constant	1.3E+10	9216076.5			
Monthly Fall rate	-1865801	1348798.8	-0.202		
	R	R^2	Adjusted R^2		
	0.202	0.041	0.019		

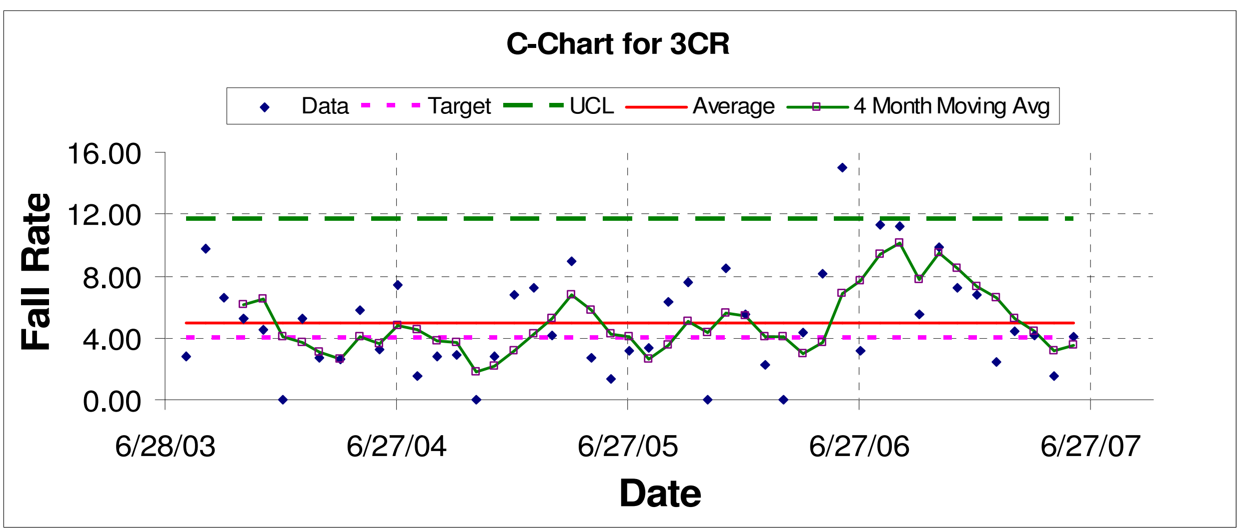


Figure 9. Unit 3CR Patient Fall Data for July 2003 through May 2007

There is only one monthly value that exceeds the UCL, although two other points are close to the value. All three of these points occurred from May to August of 2006. The moving average has little variation except for the second half of 2006 when it reaches its highest level. The average monthly patient fall rate value is only slightly larger than the target value (4).

Table 15. Linear Regression Results for Unit 3CR Patient Fall Data

Model	Sum of Squares	Degrees of Freedom	Mean Square	F_0	Sig
Regression	2.0E+15	1	2.021E+15	1.575	0.216
Residual	5.8E+16	45	1.284E+15		
Total	6.0E+16	46			
	Unstandardized Coefficient				
	B	Std. Error			
Constant	1.3E+10	9508138.3			
Monthly Fall rate	2010269	1601918.2			
	R	R^2	Adjusted R^2		
	0.184	0.034	0.012		

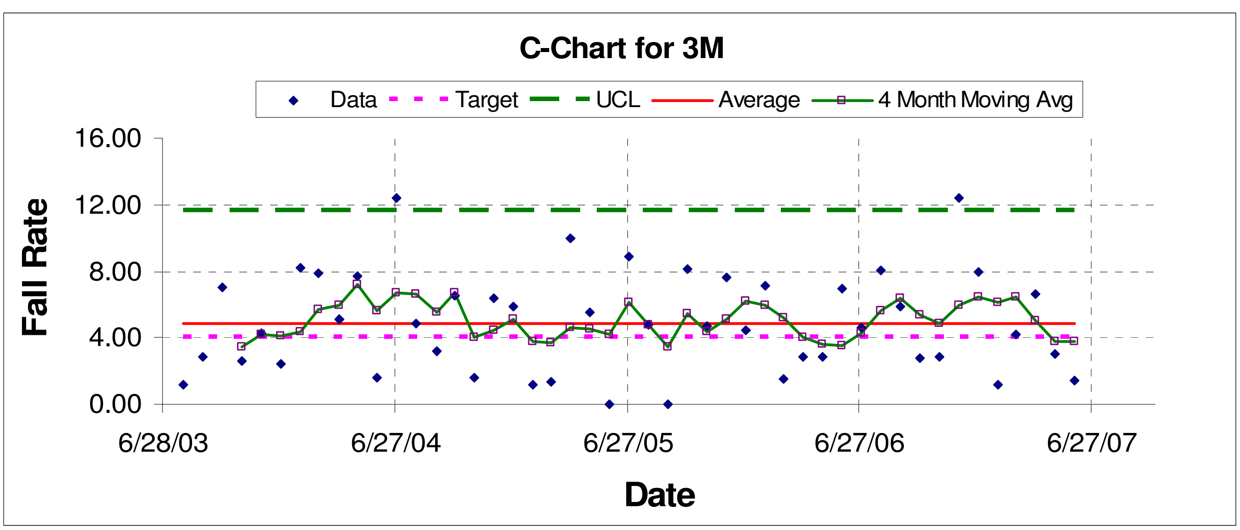


Figure 10. Unit 3M Patient Fall Data for July 2003 through May 2007

There are two monthly values that exceed the UCL. The rolling average shows little variation over the entire data period. The average monthly patient fall data is only slightly larger than the target value. Ten Stryker beds were placed on this unit in March 2006. Stryker beds allow the staff on the unit to immediately provide patients who are at-risk for falls an improved method for monitoring and reducing fall risk. From the limited data obtained since March 2007 it is not possible to draw a conclusion about the ability of the Stryker beds to reduce patient falls on this unit.

Table 16. Linear Regression Results for Unit 3M Patient Fall Data

Model	Sum of Squares	Degrees of Freedom	Mean Square	F_0	Sig
Regression	1.3E+12	1	1.255E+12	0.001	0.976
Residual	6.0E+16	45	1.329E+15		
Total	6.0E+16	46			
	Unstandardized Coefficient				
	B	Std. Error			
Constant	1.3E+10	10124892			
Monthly Fall rate	54046.341	1758349.6			
	R	R^2	Adjusted R^2		
	0.005	0.000	-0.022		

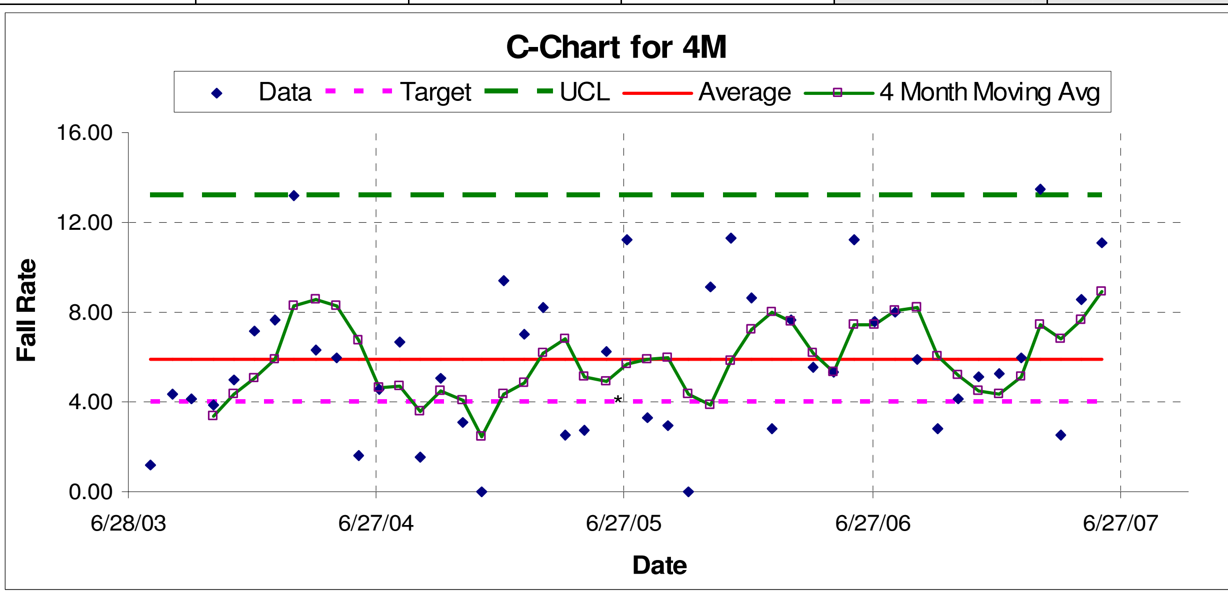


Figure 11. Unit 4M Patient Fall Data for July 2003 through May 2007

There are two monthly values that exceed the UCL. While the moving average indicates some cyclic behavior, it is not as well pronounced as the TCU data (see Figure 8). The average monthly patient fall rate (~6) is significantly larger than the target fall rate (4). The last five months of data for 2007 appears to indicate an upward trend that may (or may not be linked) to a nerve block protocol which has been instituted on the unit during this timeframe. This issue is being investigated by the nursing staff at the current time.

Table 17. Linear Regression Results for Unit 4M Patient Fall Data

Model	Sum of Squares	Degrees of Freedom	Mean Square	F_0	Sig
Regression	3.4E+15	1	3.430E+15	2.739	0.105
Residual	5.6E+16	46	1.252E+15		
Total	6.0E+16	45			
	Unstandardized Coefficient				
	B	Std. Error			
Constant	1.3E+10	10630754			
Monthly Fall rate	2609959.8	1576975.8			
	R	R^2	Adjusted R^2		
	0.240	0.057	0.036		

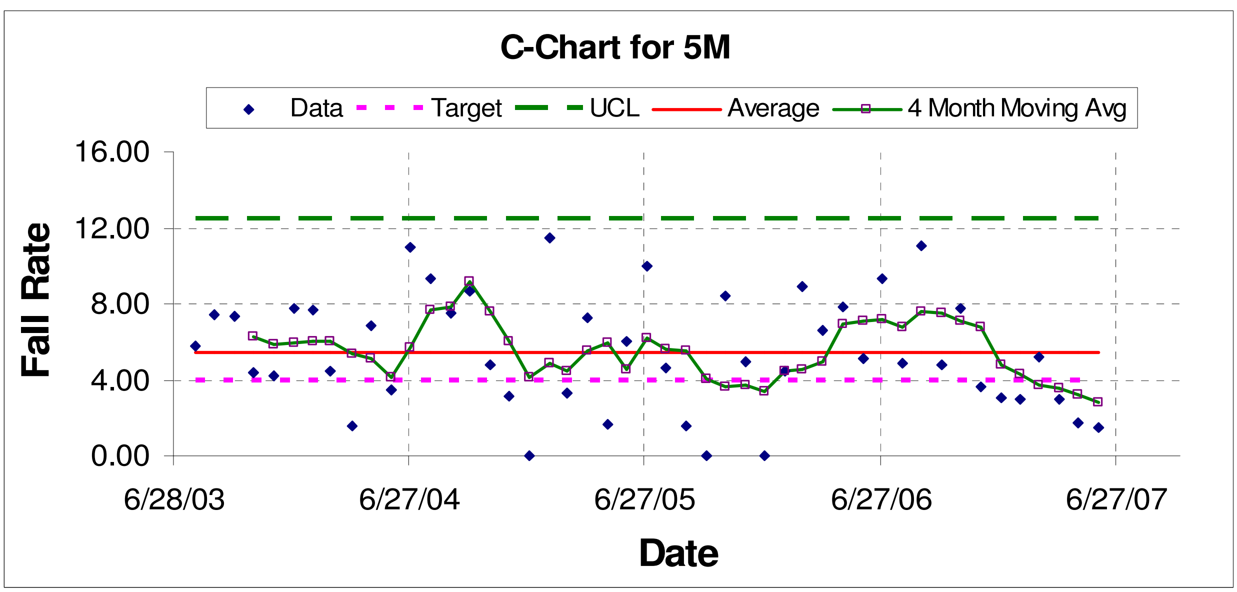


Figure 12. Unit 5M Patient Fall Data for July 2003 through May 2007

There were no monthly values which exceeded the UCL, although there were several values that approached to limit. The moving average values did not display a cyclic pattern. The average monthly patient fall rate (~5) was a little larger than the target fall rate (4). The trend in the last several months of the collected data indicated a downtrend for the moving average that was lower than any other moving average value. This may be linked to the fact it was on this unit that the revised rounding procedure (see Section 4.4) was initially implemented early in 2007. Monitoring of this fall rate in the future may be an indication of whether or not this rounding procedure would be effective in reducing the fall rate.

Table 18. Linear Regression Results for Unit 5M Patient Fall Data

Model	Sum of Squares	Degrees of Freedom	Mean Square	F_0	Sig
Regression	2.3E+15	1	2.314E+15	1.812	0.185
Residual	5.7E+16	45	1.277E+15		
Total	6.0E+16	46			
	Unstandardized Coefficient				
	B	Std. Error			
Constant	1.3E+10	10776244			
Monthly Fall rate	-2329892	1730832.7			
	R	R^2	Adjusted R^2		
	0.197	0.039	0.017		

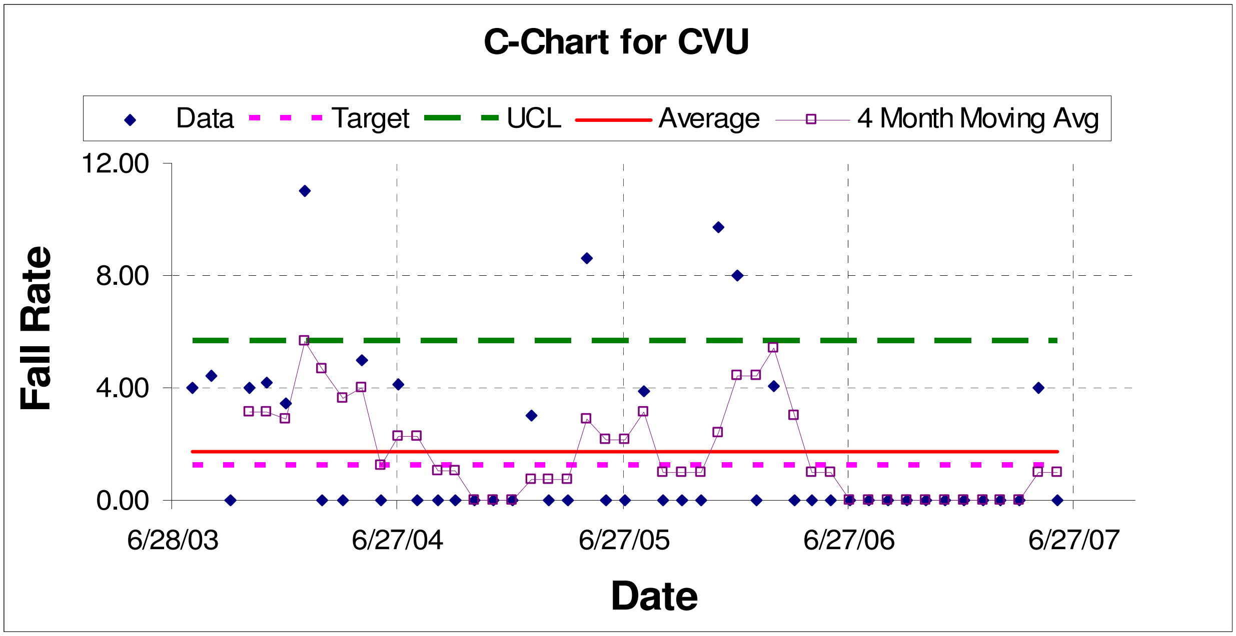


Figure 13. Unit CVU Patient Fall Data for July 2003 through May 2007

There are four monthly values that exceed the UCL. There are also two moving average values that have almost the same value as the UCL. The moving average data has a large variation over time. There are a large number of months where the fall data was zero. The average monthly patient fall rate is slightly greater than the target value of 1.25. Finally, it is noted that over the period from May 2006 through May 2007 there was only one month where there had been any falls. This is the most consistent pattern of no patient falls over the period of the data collection. This pattern was discussed with nursing personnel, however they can provide no explanation for this behavior. As had been mentioned previously (See Section 6.1.2) the CVU unit is one in which the nurses station is centrally located allowing nurses to easily observe the rooms and patients in the unit and thus potentially observe and address at-risk patients more effectively than nurses on other units. Also, the patient to nurse ratio on this unit is much smaller than on other units. These two facts are part of the reason for why the target value for this unit is 1.25 instead of the larger target values assigned to other units. The large variation in the moving average may be due to the fact that there is generally a much smaller number of patients in this unit and therefore a single or a couple patient falls a month may distort the fall rate (see Section 6.1.2, Table 11).

Table 19. Linear Regression Results for Unit CVU Patient Fall Data

Model	Sum of Squares	Degrees of Freedom	Mean Square	F_0	Sig
Regression	4.9E+15	1	4.944E+15	4.061	0.050
Residual	5.5E+16	45	1.219E+15		
Total	6.0E+16	46			
	Unstandardized Coefficient				
	B	Std. Error			
Constant	1.3E+10	5938891.4			
Monthly Fall rate	-3553487	1763369.2			
	R	R^2	Adjusted R^2		
	0.288	0.083	0.062		

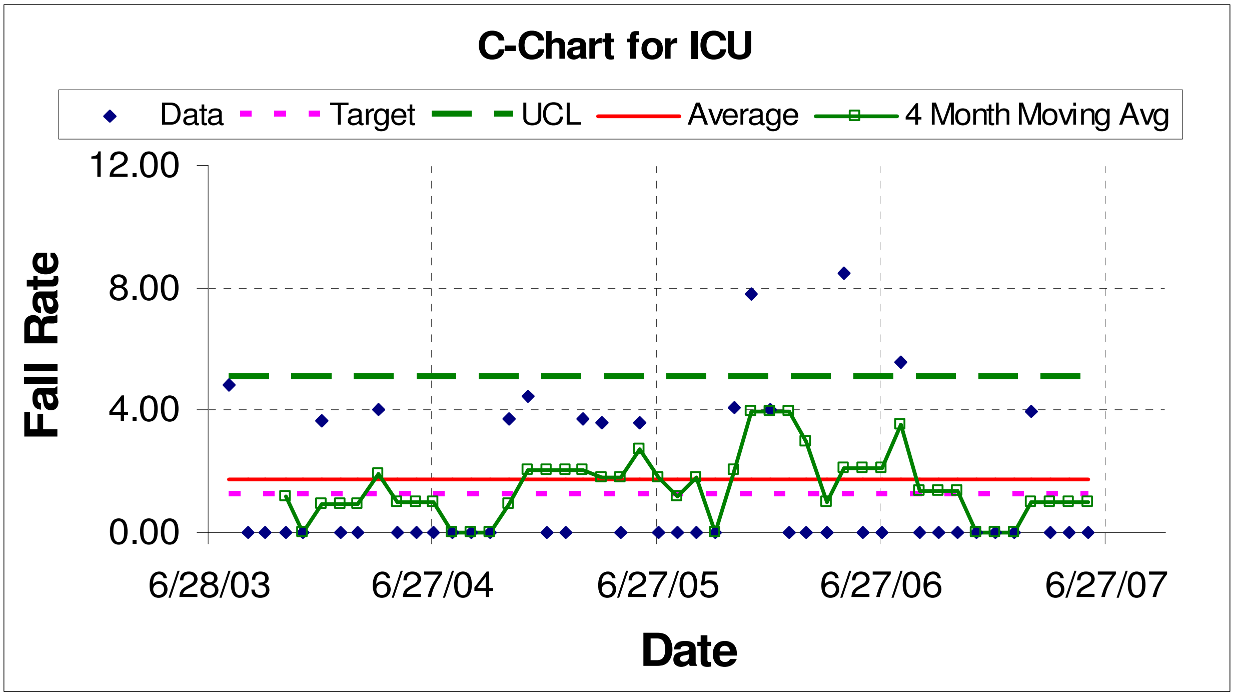


Figure 14. Unit ICU Patient Fall Data for July 2003 through May 2007

There are three monthly values that exceed the UCL and a number of other values approach this limit. None of the moving average values exceed the UCL. The monthly fall values for the last year of the data (May 2005 to May 2006) had only two non-zero values. This behavior is similar to that displayed for the CVU data. The average patient fall data (less than 2) is slightly larger than the target value (1.25). It is noted that over the period from May 2006 through May 2007 there was only one month where there had been any falls. This is the most consistent pattern of no patient falls over the period of the data collection. This pattern was discussed with nursing personnel, however they can provide no explanation for this behavior. As had been mentioned previously (See Section 6.1.2) the ICU unit is one in which the nurses station is centrally located such that nurses can easily observe the rooms and patients in the unit, and thus potentially observe and address at-risk patients more effectively than nurses on other units. Also, the patient to nurse ratio on this unit is much smaller than on other units. These two facts are part of the reason why the target value for this unit is 1.25 instead of the larger target values assigned to other units. The large variation in the moving average may be due to the fact that there is generally a much smaller number of patients in this units and therefore a single or a couple patient falls a month may distort the fall rate. The behavior for the ICU is similar to that observed for the CVU (see Section 6.1.2, Table 11).

Table 20. Linear Regression Results for Unit ICU Patient Fall Data

Model	Sum of Squares	Degrees of Freedom	Mean Square	F_0	Sig
Regression	1.3E+12	1	1.343E+12	0.001	0.975
Residual	6.0E+16	45	1.389E+15		
Total	6.0E+16	46			
	Unstandardized Coefficient				
	B	Std. Error			
Constant	1.3E+10	6556644.6			
Monthly Fall rate	-74325.49	2390317.5			
	R	R^2	Adjusted R^2		
	0.005	0.000	-0.023		

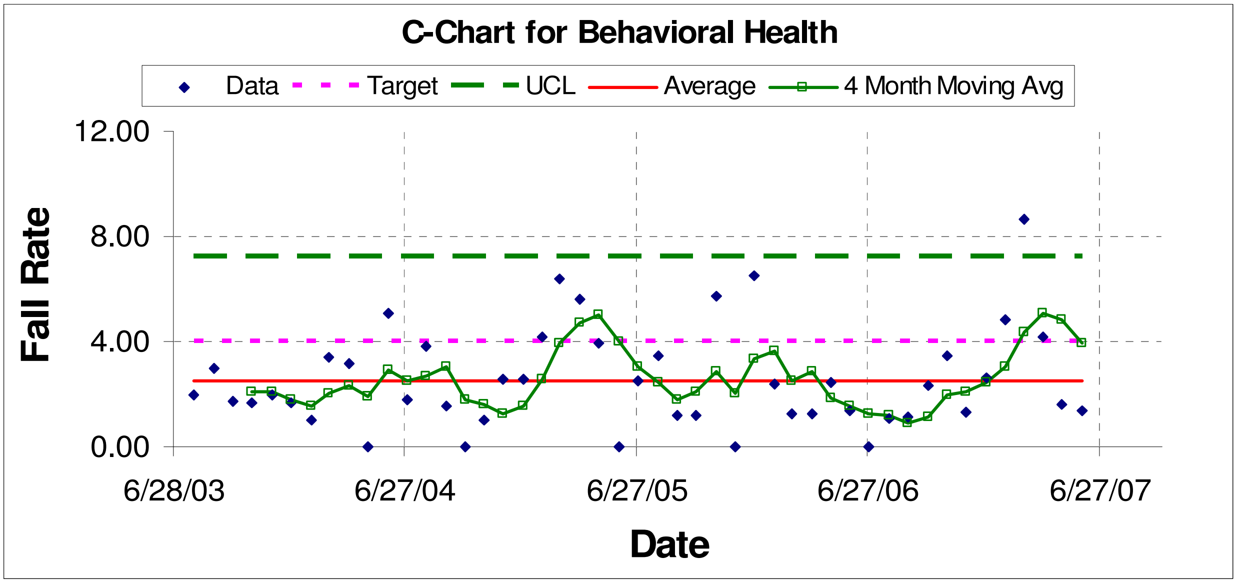


Figure 15. Unit Behavioral Health Patient Fall Data for July 2003 through May 2007

There is only one data point that exceeds the UCL, although several other data points approach the limit. The moving average for this data shows a generally flat behavior with only two large peaks, one at about April 2005 and one at about March 2007. The average monthly fall rate (~3) is less than the target fall rate (4).

Table 21. Linear Regression Results for Unit Behavioral Health Patient Fall Data

Model	Sum of Squares	Degrees of Freedom	Mean Square	F_0	Sig
Regression	7.2E+14	1	7.181E+14	0.547	0.463
Residual	5.8E+16	45	1.318E+15		
Total	6.0E+15	46			
	Unstandardized Coefficient				
	B	Std. Error			
Constant	1.3E+10	8853704.3			
Monthly Fall rate	2058238.3	2782687.6			
	R	R^2	Adjusted R^2		
	0.110	0.012	-0.010		

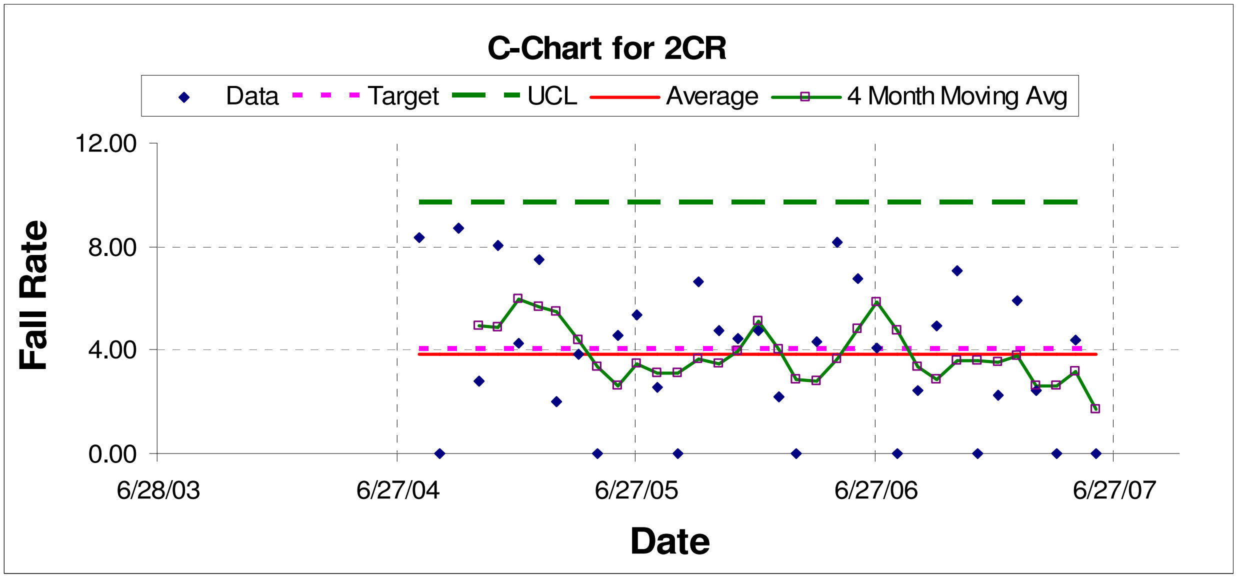


Figure 16. Unit 2CR Patient Fall Data for July 2003 through May 2007

There are no monthly patient fall rate values that exceed the UCL. The moving average shows some variation, but not much cyclic behavior. However, observing the trend of the moving average it could be argued that there is an observed decreasing trend in the fall rate over time. The average monthly fall rate (3.81) almost equals the target value (4). This unit did not begin until July 2004.

Table 22. Linear Regression Results for Unit 2CR Patient Fall Data

Model	Sum of Squares	Degrees of Freedom	Mean Square	F_0	Sig
Regression	1.9E+15	1	1.805E+15	2.679	0.111
Residual	2.3E+16	33	6.908E+14		
Total	2.5E+16	34			
	Unstandardized Coefficient				
	B	Std. Error			
Constant	1.3E+10	7601382.1			
Monthly Fall rate	-2648004	1617930.0			
	R	R^2	Adjusted R^2		
	0.274	0.075	0.047		

Discussion of Data on Figure 7 through 16

The results of the information in Figures 7 through 16 shows that few of the monthly data points exceed their respective UCL value. Recall that the UCL represents the approximate 3-sigma limit of a Poisson distribution (in other words, a 3-sigma bound should capture 99.7% of all data). Therefore, when this limit is exceeded, it does represent an unlikely event. However, also recall the discussion from Section 5.4.1 where it is expected that individual hospital units might have greater data variability than the entire hospital, since the hospital-wide values have much more data associated with it than a single hospital unit. On average the hospital experiences about one fall a day, while individual units may experience only several falls per month. Further, it is expected that the individual unit may have greater variability in its behavior since having several high risk patients on a unit, or a patient that experiences multiple falls per month would increase an individual unit's fall rate. When comparing the hospital-wide and unit response with regard to the UCL this variability was observed. The data on these figures also indicate that for a number of the units the average measured fall rate exceeds the unit goal. The data in Table 12 also show that the variation (standard deviation) over time is large (generally larger than half the average) for all units. This indicates that there exists significant month-to-month variability in the unit fall rate data.

It is concluded from the data presented on Figures 7 through 16, the process of controlling patient falls within these units (based on the UCL) is achieved in most cases. In addition, from the data presented on these plots it appears that there are generally not any major trends in the patient fall rates over the available data.

Discussion of the Regression Tables 13 through 22 and Other Observations

In order to try and quantitatively assess whether there may be any trend in unit patient fall rate, linear regression analysis is performed for all the hospital units. The null hypothesis tested was that the slope from the regression is equal to zero (no quantifiable trend in the data).

Various observations, including those for Tables 13 through Tables 22, are discussed below:

(1) The amount of information explained by the linear regression performed for all of the hospital units is quite small (see R^2 values).

(2) The F_0 (test value) is such that it does not exceed the $F_{\alpha, 1, n-2}$ (critical value). (For $\alpha = 0.01$, $F_{\alpha, 1, n-2} = 7.08$ [assuming n-2 = 60 rather than the 45 it actually is]. The value 7.08 applies for all units except for 2CR which has an n = 35. The value for $F_{\alpha, 1, n-2}$, for this unit is 7.31 [assuming n-2 = 40]. This result means that the null hypothesis that the slope of the regression is equal to zero cannot be rejected, and thus the regression provides no discernable trend for the monthly patient fall rate. The only exception to this result is for unit 2CR for which there is a statistically significant indication of a decreasing trend, at the 99% confidence level.

(3) When the four month moving average is examined, it appears that several of the units experience cyclic patterns. These units include 2MR (Figure 7), TCU (Figure 8) and 4M (Figure 11). It is not clear why these units should exhibit a moving average behavior different from other units.

(4) The last observation is that for unit 5M, which began the modified nursing rounding procedure (see Section 2.2) in March 2007, appears to be experiencing a discernable decline in fall rate over the past several months. Further observation of this unit through the remainder of 2007 may indicate how successful this modified rounding procedure will be.

An important point to be made about the unit data is that these data combine to produce the hospital-wide data presented in Figure 3. The variability in the unit data indicate that it is important to understand local conditions on the individual units to be able to understand why the hospital-wide data behaves as it does. As mentioned before it is not known what the causes are for the observed differences between the units, although different staff, supervisory personnel and patient loads are considered possibilities.

6.2 PATIENT FALL DATA ASSESSMENT FROM THE TWO SIX MONTH DATA COLLECTION PERIODS

6.2.1 Distribution of Patient Fall Data by Hospital Unit

Table 23 presents the distribution of the number of patient falls by hospital unit for the two data collection periods.

Table 23. Patient Falls by Hospital Unit for the Two Data Collection Periods

Unit (First designation is for the first data period, the second designation is for the second data collection period)	**December 2005 through May 2006**	**December 2006 through May 2007**
3M/3MS - 3M	19	19
4M/4MT - 4M	36	38
5MSD – 5M	19	12
2C - 2CR	13	8
3C - 3CR	33	19
2MR/2MT – 2MR	21	22
5CM - Behavioral Health	26	17
2MTCU – TCU	6	14
ICU – ICU	3	1
5MCCU – CVU	2	1
ED – ED	1	0
Total	179	151

The total number of patient falls for the first data collection period does not match the total for the period (183) due to some reports not including the unit designation. There is general consistency between the two sets of patient falls for these two data collection periods except for: (1) the number of falls for 3C/3CR decreased significantly (33 to 19), (2) the number of patient falls for behavioral health decreased (26 to 17), and (3) the TCU falls increased (6 to 14) from the first to second data collection period.

6.2.2 Patient Age Data Assessment

An assessment was performed for the age of the patients for those that fell and for the total patient population (both patients who fell and those that did not fall) for the first data collection period. Table 24 provides a breakdown of the age of the patients who fell compared to the entire hospital population for the first data collection period. The age data obtained for the entire hospital patient population was discussed in Section 5.1.

Table 24. Assessment of Age for Patients who fell, and for the Total Hospital Population for December 2005 through May 2006*

Age Range	Patients who fell		Total Population*		
	# of Patients	Fraction of Total	# of Patients	Fraction of Total	Fraction of Patients Who Fell Compared to Total Population
0-50	26	0.146	641	0.187	0.041
51-60	16	0.090	395	0.115	0.041
61-70	31	0.174	513	0.150	0.060
71-80	38	0.213	848	0.247	0.045
>80	67	0.376	1030	0.301	0.065
Total	178[14]	0.999	3427	1.000	-

* The age data for the total population was obtained from 12/01/05 through 04/30/06. It is assumed that the comparisons presented in the table are applicable over the entire six month period.

The fractions in this table are generally consistent between those who fell and the total population with the exception of the >80 population. Here the fraction of the patients who fell was significantly larger than the general population fraction of those >80 (0.376 vs. 0.301). This may indicate that patients >80 years old have other risk factors (incontinence, confusion, etc.) that would make that population much more at risk for falls. Also in this table the fraction of the patients who fell compared to the entire patient population for that age grouping is presented. Surprisingly, the 0-50 (0.146), 61-70 (0.174) and 71-80 (0.213) age population have similar

[14] Note that the number of falls in this table differs slightly from the number previously cited (183). This difference is due to several patient fall reports not having the patient age listed during this data report period.

fractions. The largest fraction is that for the >80 population (0.376). The behavior for the two lowest age groups may be partially explained by the fact that a large fraction of the falls for patients below 60 are probably due to falls in the Behavioral Health unit. In examining the data from which Table 10 was derived, it was found that for the second data collection period, of the 17 falls that occurred in the Behavioral Health unit, only 3 were for patients that were 60 or older. The result for patients >80 appears to imply that for that population of patients, it should be expected to have a larger fraction of patients that are at-risk for falls.

Table 25 provides a comparison between the quartile breakdown between the population of patients who fell and the total hospital population (those who fell and those who did not).

Table 25. Quartile Breakdown for Populations of Patients who fell and the Total Population, December 2005 through May 2006*

Quartile Breakdown	Age Breakpoints for Patients (Who Fell)	Age Breakpoints for Patients (Total Population)
Min	21	13
Q1 (<=25%)	61	56
Q2(<= 50%)	75	73
Q3 (<=75%)	84	82
Max	98	102

* The age data for the total population was obtained from 12/01/05 through 04/30/06. It is assumed that the comparisons presented in the table are applicable over the entire six month period.

The data presented in Table 25 indicates that there is little difference in the age distributions of the patients who fell and the total hospital population in the first data collection period. Q2 represents the median age, meaning that there are many patients whose age exceeds that the Q2 value, as have ages which are less than the Q2 value. The average age of the patients who fell was 70.14. The Hitcho et al (2004) analysis of the ages of patients who fell from a St. Louis hospital study showed that the average age of the patients who fell was 63.4 years. This difference is at least partially explainable due to the fact the fraction of the total population who were aged greater than 65, served by the two different hospitals (see U.S.

Census) was significantly larger in the city served by the hospital which provided data for this thesis (20.9%), versus the city of St. Louis (13.7%). Because of the similarity in the information for this data collection period, a similar study was not performed for the December 2006 through May 31, 2007 data collection period.

Figures 17 and 18 present the distribution of the patients that fell during the two data collection periods.

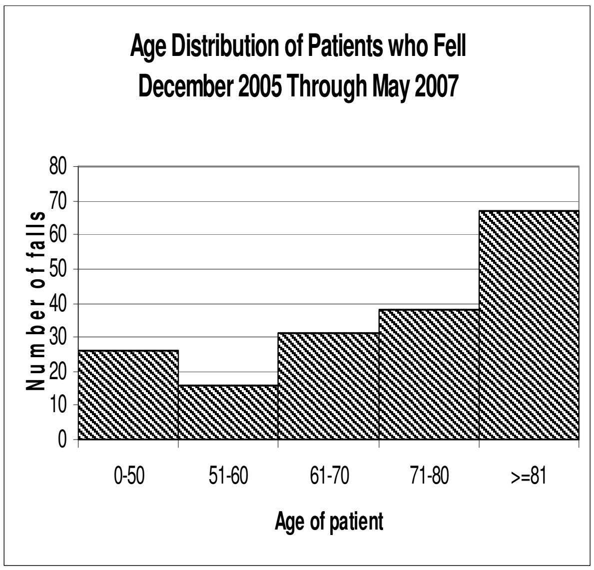


Figure 17. Age Distribution of Patients who fell for December 2005 through May 2006

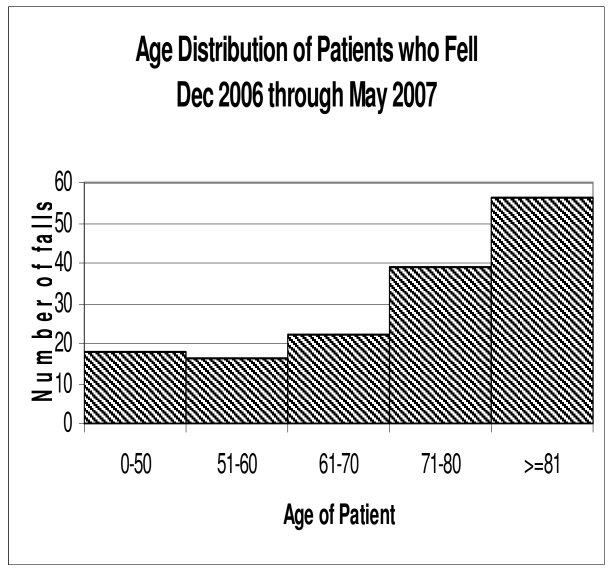


Figure 18. Age Distribution of Patients who fell for December 2006 through May 2007

These two figures indicate a similar distribution in the age of the patients who fell for the two data collection periods. These two figures also indicate that for both data collection intervals about 20 percent of the falls occur to patients who are younger than 60. Table 26 presents further details of the age of the patient population that experienced falls for the two data collection periods.

Table 26. Analysis of the Age for the Patients who fell for both Data Collection Periods

	December 1, 2005 through May 31, 2006	**December 1, 2006 through May 31, 2007**
Average Age	70.14	72.11
Minimum Age	25	26
Quartile 1 (25th percentile)	61	64
Quartile 2 (50tth percentile) (Median)	75	77
Quartile 3 (75th percentile)	84	84
Maximum Age	98	92

The data in Table 26 indicates that there is little difference in the age distribution between the first and second data collection periods. The average age of the patient who fell in the second data collection period was about 2 years older than in the first data collection period. The maximum age for the patients who fell was 92 in the second data collection period, while it is 98 for the first data collection period.

6.2.3 Time Distribution of Patient Falls

Because of the number of patient falls that were collected for both data periods (183 in the first data period and 151 in the second data period), the question of whether there was any discernable behavior in the time between the consecutive falls is addressed. The attempt to understand whether there was any pattern in the time interval between patient falls was driven by the desire to investigate whether, on a hospital basis, there was a recognizable pattern for these intervals. The possibility of observing patterns regarding days of the week, shifts in the day or hours of the day was considered plausible since the tempo of hospital operations varies significantly throughout the day and the week. Further, during the week and the day different hospital personnel are working, and differences in operating characteristics between these work groups might be reflected in patient fall rates.

6.2.3.1 Time Intervals Between Consecutive Patient Falls The first step in analyzing the time distribution of patient falls was to observe the frequency of the fall reports, and to assess the interval of time between sequential falls. These time sequences were determined on the basis of the entire hospital and not individual units. It was concluded that the individual units did not produce a large enough number of falls to allow a successful analysis. Therefore, the time intervals discussed below are derived from patient fall reports based solely on the time they occurred and not where they occurred within the hospital. Doing this would provide a set of times between consecutive patient fall reports over the entire data collection period. Figures 19 and 20 below show the time sequence of fall reports for the two data collection periods. The number of falls represented on the y-axis is the cumulative falls over the period.

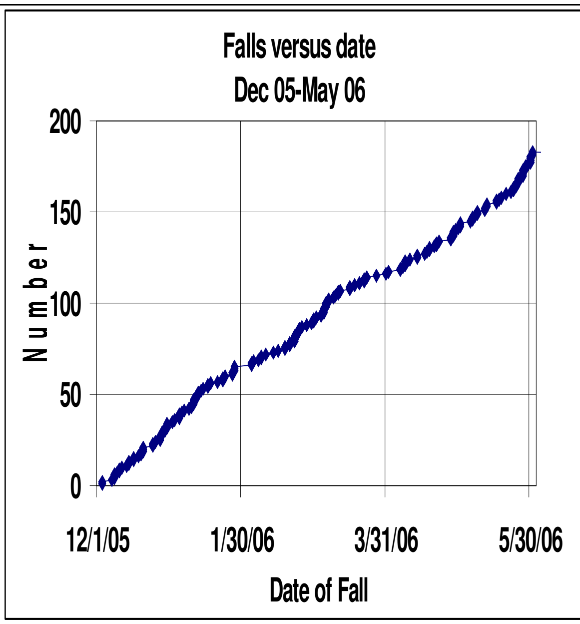


Figure 19. Cumulative Patient Falls for December 2005 through May 2006

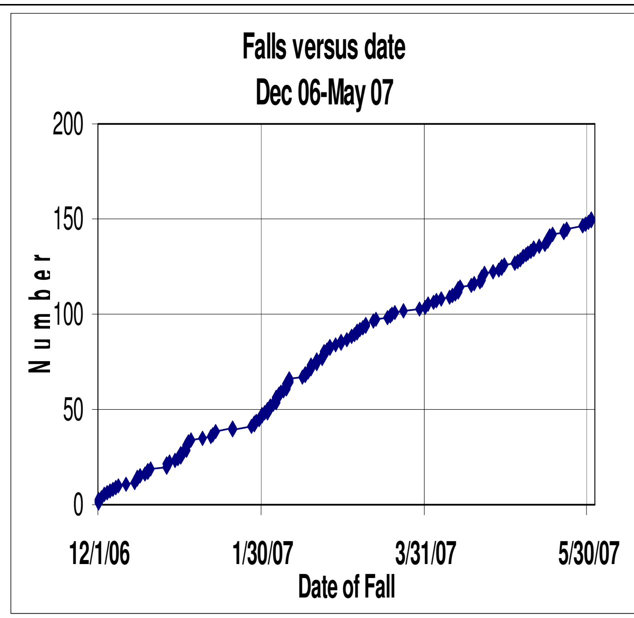


Figure 20. Cumulative Patient Falls for December 2006 through May 2007

The slope of the lines in these figures provides an assessment of how many patient falls occur over the period. The steeper the slope at any part of the line indicates a greater number of falls over that time period, while the flatter the slope at any part of the line, the fewer number of falls over that time period. As can be seen, there are periods of few patient falls (for example January 2007 on Figure 20, as well as periods of many patient falls (for example, May 2006, Figure 19). Table 27 provides details of the characteristics of the time intervals between consecutive falls for these two data collection periods.

Table 27. Information about Time Intervals between Consecutive Patient Falls for both Data Collection Periods

	December 1, 2005 to May 31, 2006	**December 1, 2006 to May 31, 2007**
Mean time between Falls (hours)	23.4	28.4
Standard deviation for the interval data (hours)	26.4	32.7
Maximum time between falls (hours)	157.2	172.8
Median time between patient falls (hours)	13.9	18.9
Monthly fall information	Number of Falls per Month and Falls per Day ()	Number of Falls per Month and Falls per Day ()
December	34 (1.10)	27 (0.87)
January	31 (1.00)	21 (0.68)
February	24 (0.86)	39 (1.40)
March	27 (0.87)	18 (0.58
April	25 (0.83)	22 (0.73)
May	42 (1.36)	24 (0.77)
Total number of falls	183	151
Average falls/day for the entire data collection period	1.00	0.83

The mean time between falls increased between the two data collection periods. There is significant variation from one month to another in terms of the fall rate, varying from 0.83 to 1.36 falls per day for the first data collection period and from 0.73 to 1.40 falls per day for the second data collection period.

To provide a perspective of the how these time intervals between consecutive falls are distributed over the data collection periods, these data are presented on Figures 21 and 22 below.

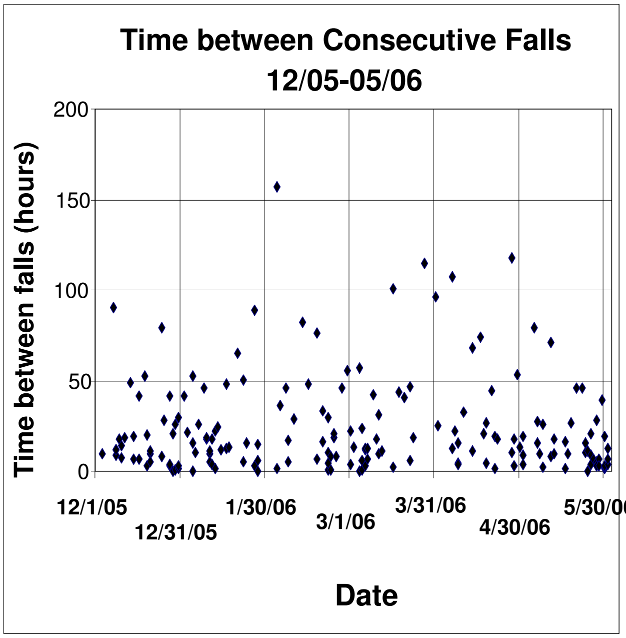


Figure 21. Distribution of Times Between Consecutive Patient Falls for December 2005 through May 2006

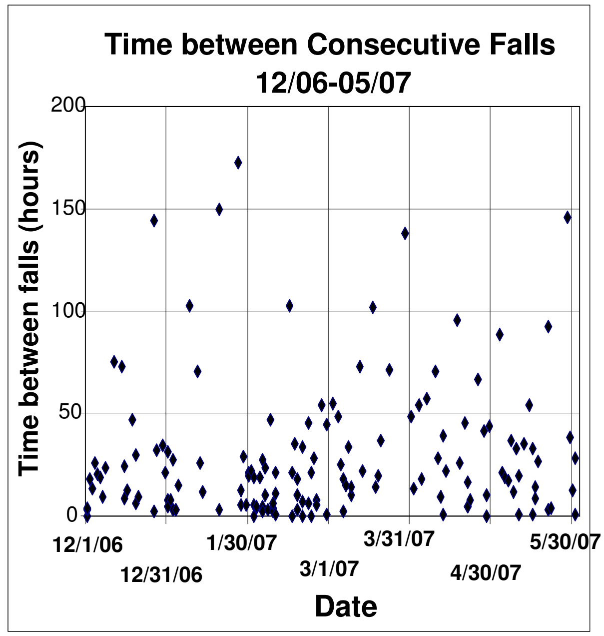


Figure 22. Distribution of Times Between Consecutive Patient Falls for December 2006 through May 2007

From these figures it is observed that a significant fraction of all the time intervals between consecutive falls are less than 50 hours for both data collection periods and that as the time intervals become larger, the number of datapoints becomes smaller. In order to see whether there is any discernable pattern in these fall intervals, the time intervals in Figures 21 and 22 were rearranged in descending in order and then replotted against a sequence number. Figures 23 and 24 below present these rearranged data.

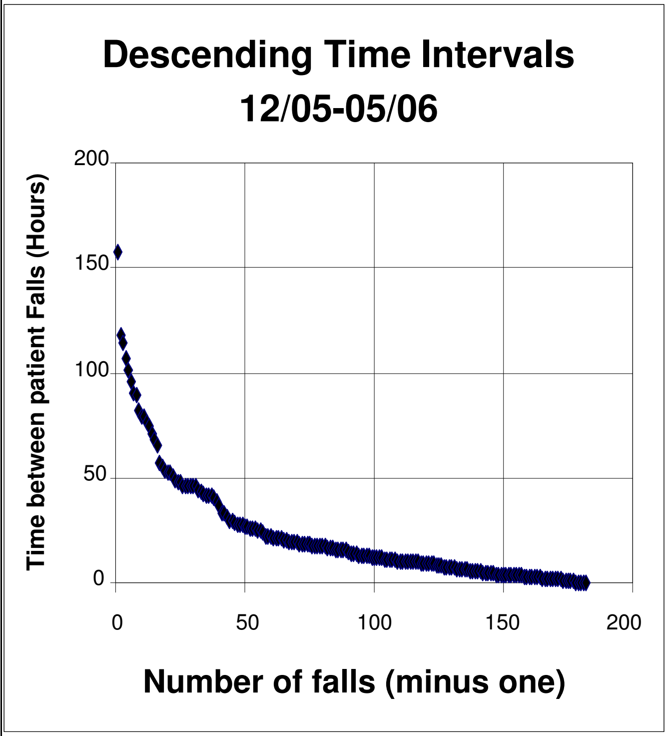


Figure 23. Period (Hours) Between Consecutive Patient Falls, from Largest to Smallest for December 2005 through May 2006

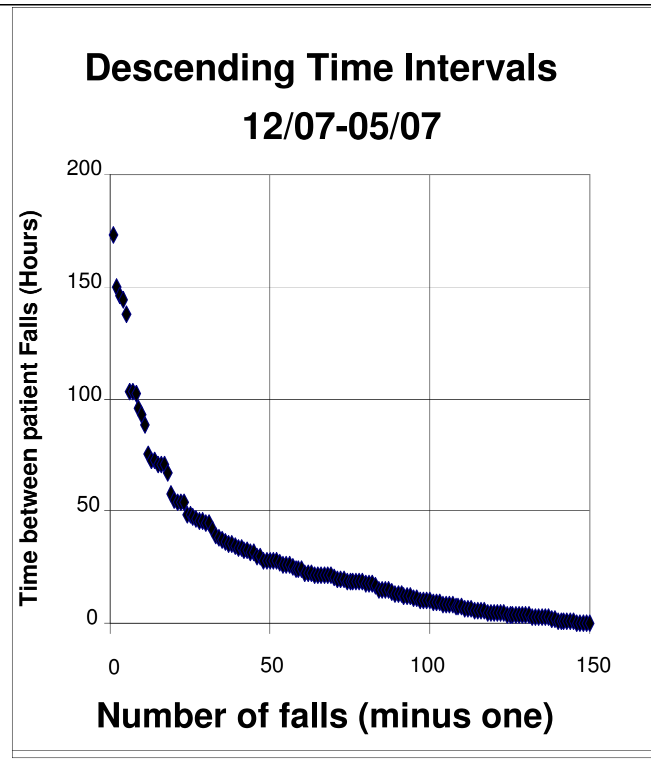


Figure 24. Period (Hours) Between Consecutive Patient Falls, from Largest to Smallest for December 2006 through May 2007

The data on Figures 23 and 24 appear to indicate an exponential shape for the time intervals between patient falls. In order to test whether these data have an exponential distribution a Chi-square test will be performed. The method applied for this test is described in Section 5.4.3. Tables 28 and 29 below present the results of applying this methodology for the two data collection periods.

Table 28. Information Used to Perform the Chi-square Exponential Test for the First Data Collection Period (12/05 – 05/06)

Null hypothesis H_o is that the time intervals between consecutive patient falls follows an exponential distribution (Chi-square critical value ($\chi^2_{0.95, 3} = 7.815$)						
Characteristics of distribution: mean = 23.386 hours, std dev = 26.409 hours, Median = 13.875 hours, number of intervals = 182						
Interval	End value for interval (Hour between consecutive falls)	Cumulative Probability	Interval Probability	Number of items Observed (O) in Interval	Number of items Expected (E) in Interval	(E-O)^2/E
1	Infinity	1.00000	0.20000	39	36.4	0.186
2	37.638	0.80000	0.20000	19	36.4	8.318
3	21.429	0.60000	0.20000	42	36.4	0.862
4	11.946	0.40000	0.20000	40	36.4	0.356
5	5.2184	0.20000	0.20000	42	36.4	0.862
		Totals	**1**	**182**	**182**	**10.584**

* The End value for the equal probability intervals were determined by:
Ln (P(cumulative Probability)) = ln [1.0-EXP(-(end value/mean of distribution))

The cumulative probability values are 0.2, 0.4, 0.6, 0.8 and 1.0. The end value for the interval is then solved for.

Table 29. Information Used to Perform the Chi-square Exponential Test for the Second Data collection Period (12/06 – 05/07)

Null hypothesis H_o is that the time intervals between consecutive patient falls follows an exponential distribution (Chi-square critical value ($\chi^2_{0.95, 3} = 7.815$)						
Characteristics of distribution: mean = 28.357 hours, std dev = 32.735 hours, Median = 18.905 hours, number of intervals = 150						
Interval	End value for interval (Hours between consecutive falls)	Cumulative Probability	Interval Probability	Number of items Observed (O) in Interval	Number of items Expected (E) in Interval	(E-O)^2/E
1	Infinity	1.00000	0.20000	27	30	0.300
2	45.639	0.80000	0.20000	27	30	0.300
3	25.983	0.60000	0.20000	32	30	0.133
4	14.485	0.40000	0.20000	25	30	0.833
5	6.328	0.20000	0.20000	39	30	2.700
		Totals	**1.0**	**150**	**150**	**4.266**

The Chi-square test statistic value for the first data collection period (10.584) exceeds the Chi-square 95% value ($\chi^2_{0.95,\ 3}$ = 7.815), so at this significance level the null hypothesis is rejected. However at the Chi-square 99% level ($\chi^2_{0.99,\ 3}$ = 11.345) it is not exceeded, and therefore at this level the null hypothesis is not rejected.

For the second data collection period the Chi-square test value (4.065) is less than the Chi-square critical value ($\chi^2_{0.95,\ 3}$ = 7.815), and therefore the null Hypothesis (H_o) cannot be rejected at the 95% confidence interval.

Therefore, it is concluded that the distribution of time between patient falls appears to distributed exponentially for both data collection periods, however, the conclusion is statistically weaker for the first dataset than the second.

6.2.3.2 Discussion of the Exponential Character of the Distribution of Time Intervals Between Consecutive Patient Falls What does the fact that the time between consecutive patient falls for the entire hospital appears to follow an exponential function actually mean? The conclusion drawn from this observation is that the occurrence of patient falls replicates the stable failure period in the "Bathtub Curve," shown in Figure 25.

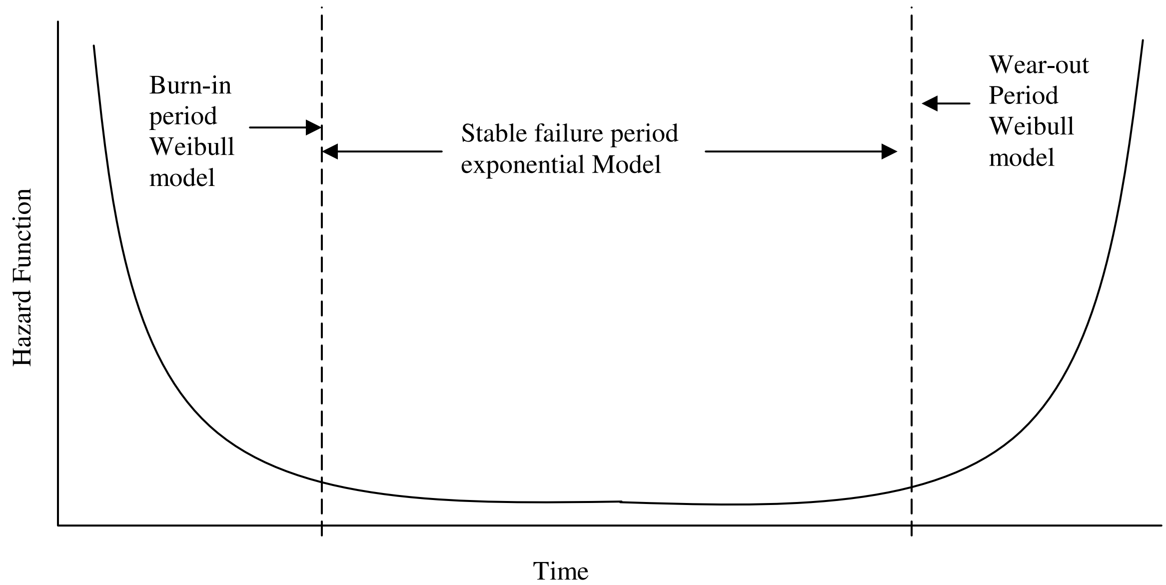


Figure 25. The Bathtub Curve

This curve represents the type of failure behavior experienced by an operating system (See Speaks S. (internet)). During the burn-in period as the system operates it has a decreasing number of failures as the system reduces the number of defective components and operations. During the wear-out period the system experiences component failure and consequent increasing failure rates. During the stable failure period the system operates at optimal efficiency and the failure rates are at their lowest. It is during the stable failure period when random failures[15] occur at a constant rate independent of how long the units have been operating. It is during this period that errors follow an exponential form.

From Empirical System Reliability (Internet) it was stated that "…the most common assumption about the statistical characteristics of failures is that they form a Poisson Process, which implies two properties: exponentially distributed time between failures and independence of failures. The plot of the time intervals between consecutive patient falls (see Figures 23 and 24), and the results of the Chi-square test (see Tables 28 and 29) indicates these distributions

[15] In this context, failures represent patient falls. These are events that hospitals want to reduce and avoid.

do have an exponential behavior. It is conjectured that most falls are independent, that is, that one fall in one unit of the hospital does not influence another fall in other units. However, for a small subset of falls, there may be some dependence. Certain patients who experience repeat falls may not fall into this category. These repeat fall patients, and possibly individual unit factors may degrade the assumption of independence. However, it is believed that a large fraction of falls are independent. Section 6.2.6.4 discusses the examination of the second data collection information that indicates about 70% of patient falls are non-repeat falls.

Although no information is available from the hospital concerning the burn-in or wear-out periods, the conjecture that the failure rates observed in the collected data are from a stable failure period is supported by the behavior of the patient fall data shown in Figure 3 which shows the monthly fall rate for the hospital. This figure indicates that the monthly patient fall rate is well behaved. Although there are significant month-to-month variations, there was no statistically significant trend in the fall rate observed. It is conjectured that even if the hospital were to undergo significant modifications in procedures and experience a significant reduction in patient fall rates, the time between consecutive falls would continue to follow an exponential behavior. It is also conjectured that if other adverse hospital events, for which accurate timing of when the events occurred were available, the time period between these events would also display an exponential pattern.

Based on the data presented and the results of the regression performed, it is concluded that these data are generally consistent with the stable period shown in the bathtub curve (Figure 25) above.

6.2.3.3 Distribution of Falls by Day of the Week The fractional breakdown for the falls per day of the week for both data collection periods is shown in Table 30.

Table 30. Results from Patient Fall Distribution over Days of the Week for both Data Collection Periods

Day of the Week	December 1, 2005 through May 31, 2006		December 1, 2006 through May 31, 2007	
Day of the Week	Number of falls	Fraction of Total	Number of Falls	Fraction of Total
Sunday	20	0.11	14	0.09
Monday	23	0.13	20	0.13
Tuesday	31	0.17	22	0.15
Wednesday	22	0.12	23	0.15
Thursday	31	0.17	23	0.15
Friday	30	0.16	28	0.18
Saturday	26	0.14	21	0.14
Total	183	1.00	151	0.99
Average number of falls per day of week	26.1	n/a	21.6	n/a

Figures 26 and 27 present bar charts showing the variation of the number of patient falls over the days of the week. The average values for the number of falls per week, from Table 30, are also shown on the following figures.

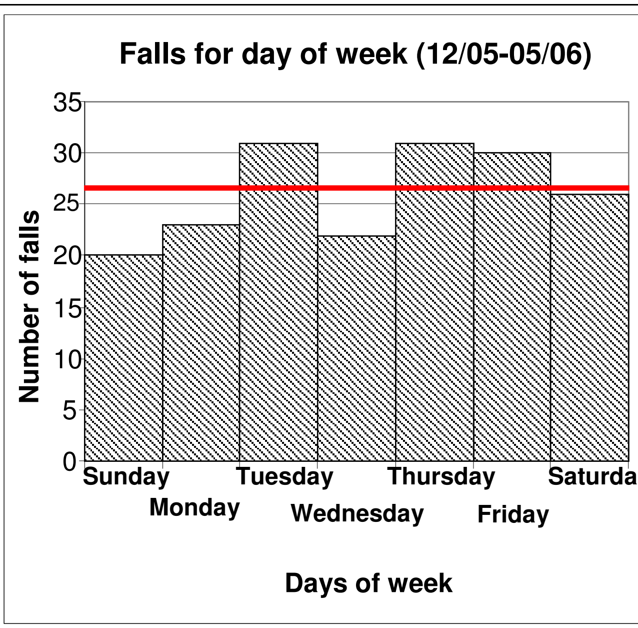


Figure 26. Bar Chart for Patient Falls over the Days of the Week for December 2005 through May 2006

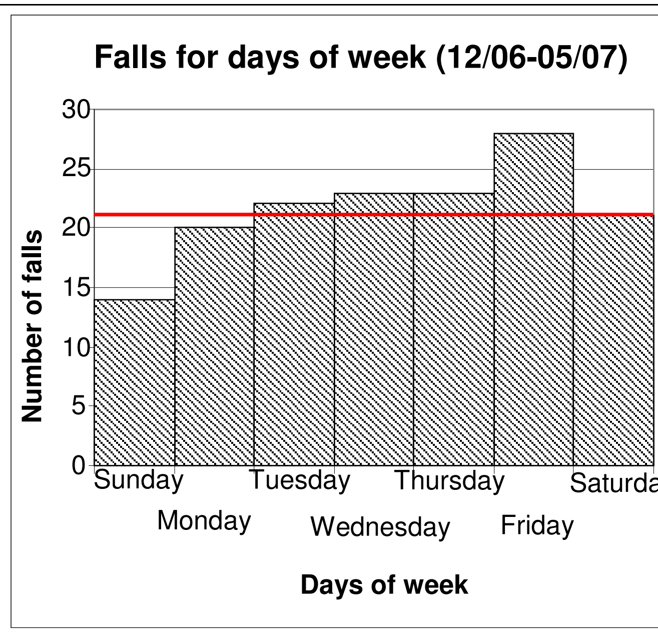


Figure 27. Bar Chart for Patient Falls over the Days of the Week for December 2006 through May 2007

The data from these two figures appear consistent for the two data collection periods. A Chi-square goodness of fit test (see Section 5.4.4) was performed on these data. The null hypothesis (H_0) for this test assumed that the number of falls for each day of the week would be equally probable (that is, the probability of a fall occurring on any particular day of the week is 1/7), was applied. The results of the test are presented in Table 31.

Table 31. Goodness of Fit Results for Patient Falls Over Days of the Week for both Data Collection Periods

	December 1, 2005 through May 31, 2006	**December 1, 2006 through May 31, 2007**
Degrees of Freedom	6	6
Q_6[16] (calculated)	4.37	4.901
Critical Value χ^2 (0.01, 6)[17] (table value)	16.812	16.812

Since the Q_6 values are smaller than the critical value, the null hypothesis (that the number of falls per day is equally probable) cannot be rejected. Therefore, this information provides no statistically significant evidence (at the 99% confidence level) that patient falls over the days of the weeks are distributed other than in a uniform manner. This result cannot exclude the possibility that there are statistically significant falls during the days of the week for the individual units of the hospital. However, since the sample sizes of these falls would be much smaller than the number of falls for the entire hospital, such an assessment was not performed.

[16] Q_6 represents the square of the difference between the number of falls per day and the average number of falls per day divided by the average of the number of falls. The average number of falls can be observed in Table 28.
[17] χ^2 (0.01, 6) represents the chi-square value for a statistical level of confidence of 0.01, with six degrees of freedom.

6.2.3.4 Distribution of Falls by Shift An assessment was performed to determine if there was any preference to when the falls occurred over the eight hour time period. Table 32 presents the breakdown of this data for the two data collection periods.

Table 32. Results from Patient Fall Distribution over Shifts of the Day for both Data Collection Periods

	December 1, 2005 through May 31, 2006		**December 1, 2006 through May 31, 2007**	
Time of Shift	Number of Falls	Fraction of total	Number of Falls	Fraction of total
0700-1459	71	0.39	51	0.34
1500-2259	53	0.29	59	0.39
2300-0659	59	0.32	41	0.27
Total	183	1.00	151	1.00
Average number of falls per shift	61	n/a	50.4	n/a

The figures presenting the eight hour shift data are shown on Figures 28 and 29 below. The average values for the number of falls per shift, from Table 32, are also shown on the following figures.

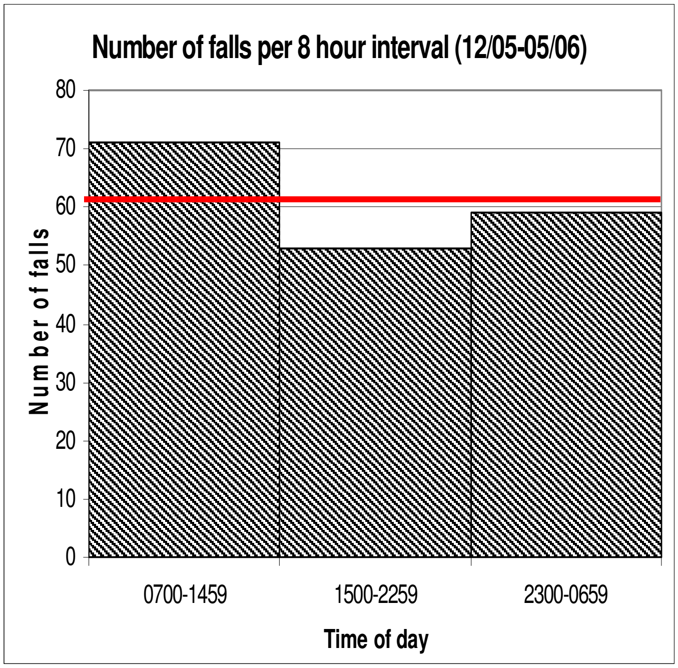


Figure 28. Bar Chart for Patient Falls over Shifts of the Day for December 2005 through May 2006

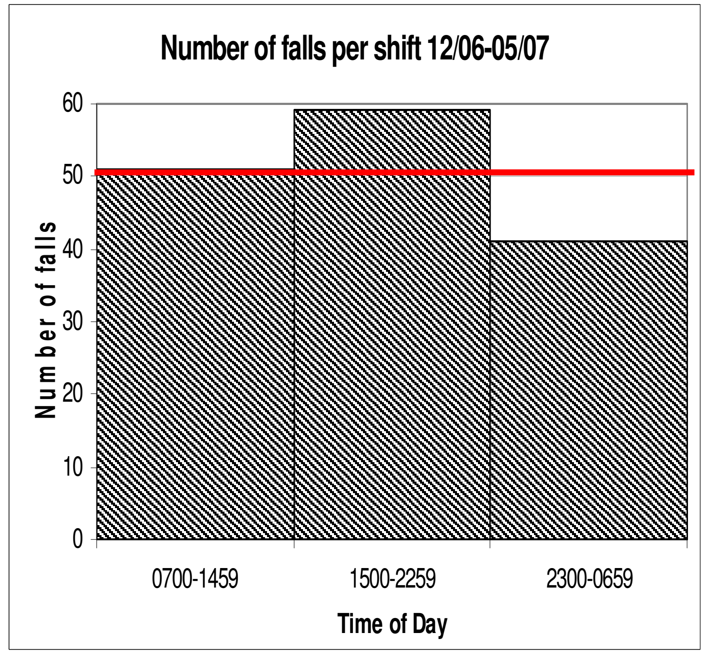


Figure 29. Bar Chart for Patient Falls over Shifts of the Day for December 2006 through May 2007

A Chi-square goodness of fit test (see Section 5.4.4) was performed on these data. The null hypothesis assumed that the number of falls per each shift of the day would be equally probable (that is, the probability of a fall occurring on any shift of the day is 1/3), was applied. The results of the test are presented in Table 33.

Table 33. Goodness of Fit Results for Patient Falls and Shifts of the Day for both Data Collection Periods

	December 1, 2005 through May 31, 2006	December 1, 2006 through May 31, 2007
Degrees of Freedom	2	6
Q_2 (calculated)	3.10	3.23
Critical Value χ^2 (0.01, 2) (table value)	9.21	9.21

Since the Q_2 values are smaller than the critical value, the null hypothesis (the number of falls per shift are equally probable) cannot be rejected at the 99% confidence level. Therefore, this information provides no statistically significant evidence that patient falls over the shift period are distributed other than in a uniform manner (that is, no shift appears to produce a statistically significant larger or smaller number of falls than any other shift).

Again this result cannot exclude the possibility that there are statistically significant falls during the days of the week for individual units of the hospital. Personal communications with the 3M unit nursing supervisor indicated that there had been long intervals where no patient falls were reported during the midnight (2300-0659) shift for unit 3M. This information again provides an indication that individual units, as well as the personnel who work on individual shifts on a unit may develop methods and protocols that are effective at reducing patient fall rates in their local environment and on the particular shift they are assigned. The potential that these individual unit or shift effects are "washed out" when looking at overall hospital data is possible.

6.2.3.5 Distribution of Falls by Hour of the Day An assessment was performed to determine if there was any preference to when the falls occurred over the individual hours of the day. Table 34 presents the breakdown of this data for the two data collection periods.

Table 34. Results from Distribution over Hours of the Day for both Data Collection Periods

	December 1, 2005 through May 31, 2006		December 1, 2006 through May 31, 2007	
Hour of the day	Number of falls	Fraction of Total	Number of falls	Fraction of Total
0000-0100	13	0.07	8	0.05
0101-0200	6	0.03	2	0.01
0201-0300	5	0.03	7	0.05
0301-0400	9	0.05	5	0.03
0401-0500	6	0.03	5	0.03
0501-0600	7	0.04	6	0.04
0601-0700	10	0.05	3	0.02
0701-0800	4	0.02	5	0.03
0801-0900	13	0.07	6	0.04
0901-1000	9	0.05	4	0.03
1001-1100	12	0.07	12	0.08
1101-1200	7	0.04	4	0.03
1201-1300	12	0.07	5	0.03
1301-1400	8	0.04	9	0.06
1401-1500	7	0.04	8	0.05
1501-1600	5	0.03	8	0.05
1601-1700	5	0.03	4	0.03
1701-1800	3	0.02	13	0.09
1801-1900	8	0.04	8	0.05
1901-2000	11	0.06	6	0.04
2001-2100	7	0.04	11	0.07
2101-2200	8	0.04	5	0.03
2201-2300	6	0.03	3	0.02
2301-2359	2	0.01	4	0.03
Total =	183	1.00	151	1.00
Average number of falls per hour	7.63	n/a	6.29	n/a

Figures 30 and 31 below present the shift data. The average values for the number of falls per hour, from Table 34, are also shown on the following figures.

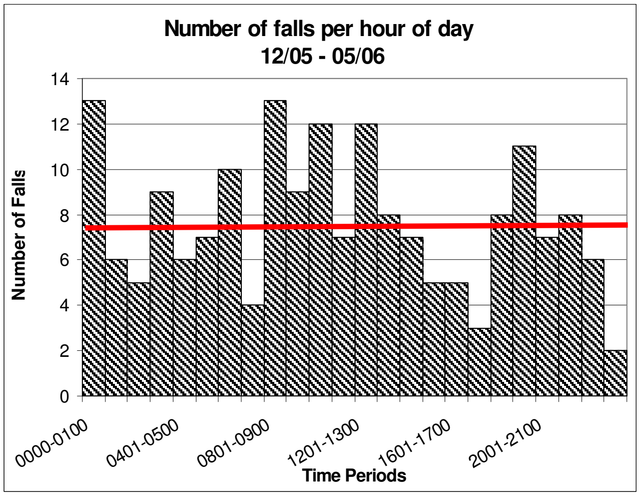


Figure 30. Bar Chart for Patient Falls over Hours of the Day for December 2005 through May 2006

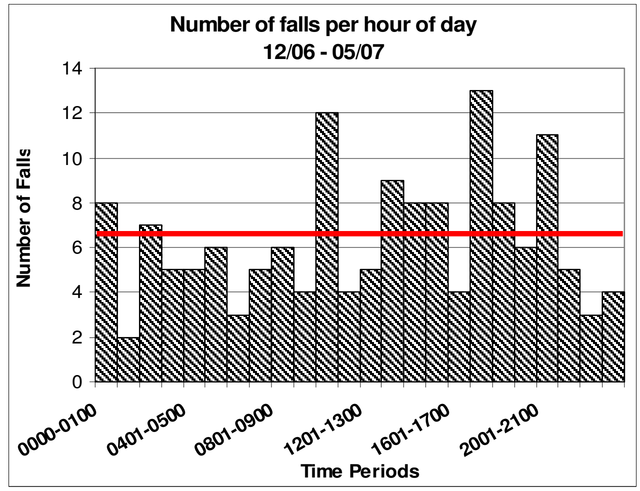


Figure 31. Bar Chart for Patient Falls over Hours of the Day for December 2006 through May 2007

From a visual inspection of these figures, the one major difference is that the for the second data collection period there appears to be more hours of the day that have numbers of falls that are smaller than the data from the first collection period. The supposition that the nursing staff from the 3M unit had that the late swing shift and midnight shift may produce fewer falls does not appear to be supported form the first data collection period, but might be supported from the second data collection period.

A Chi-square goodness of fit test (see section 5.4.4) was performed. The null hypothesis assumed that the number of falls for each hour of the day would be equally probable (that is, the probability of a fall occurring on any particular hour of the day is 1/24), was applied. The results of the test are presented in Table 35.

Table 35. Goodness of Fit Results for Patient Falls over Hours of the Day for both Data Collection Periods

	December 1, 2005 through May 31, 2006	**December 1, 2006 through May 31, 2007**
Degrees of Freedom	23	23
Q_{23} (calculated)	28.016	30.033
Critical Value χ^2 (0.01, 23) (table value)	41.638	41.638

Since the Q_{23} values are smaller than the critical value, the null hypothesis (that the number of falls per hour are equally probable) cannot be rejected. Therefore, the Chi-square test provides no statistically significant evidence (at the 99% significance level) that patient falls over the hours of the day are distributed other than in a uniform manner.

6.2.3.6 Distribution of Falls by Hour of the Day (on a Shift Basis) Having the patient falls per hour of the day over the two data periods also permits the assessment of whether there are any statistical conclusions that can be drawn by analyzing the distribution of falls per hour over each of the shift periods. These shift periods were 2301 to 0700, 0701 to 1500, and 1501 to 2300 hours. The null hypothesis being tested in this assessment was that the number of falls that occurred over the hours of each shift is equally probable, that is within the shift 2301 to 0700, there will not be a statistically significant difference between hours 2301-0000, 0001-0100, 0101-0200, etc. The data for the following analysis was obtained from Table 34 and analyzed through the use of the goodness of fit test (see Section 5.4.4). The results for these assessments for each shift are presented in Table 36 below.

Table 36. Goodness of Fit Results for Patient Falls and the Hours of the Day over the Shift Periods for both Data Collection Periods

	December 1, 2005 through May 31, 2006	December 1, 2006 through May 31, 2007
Degrees of Freedom	**7**	**7**
(2301-0700) Q_7 (calculated)	10.964	5.6
Critical Value X^2 (0.01, 7) (table value)	18.475	18.575
(0701-1500) Q_7 (calculated)	7.57	8.434
Critical Value X^2 (0.01, 7) (table value)	18.475	18.575
(1501-2300) Q_7 (calculated)	6.32	11.568
Critical Value X^2 (0.01, 7) (table value)	18.475	18.575

Since the Q_7 values are smaller than the critical values, the null hypothesis (that the number of falls per hour for the particular shift are equally probable) cannot be rejected. Therefore, this information provides no statistically significant evidence (at the 99% significance level) that patient falls over the hours of a particular shift are distributed other than in a uniform manner.

6.2.4 Gender Distribution of Patients who Fell

An assessment of the fractional split between male and female patients who fell during the two data collection was performed. The data of this breakdown is provided in Table 37.

Table 37. Gender Distribution of Patients who Fell for both Data Collection Periods

Gender	December 2005, May 2006	December 2006, May 2007
Male	0.44	0.39
Female	0.56	0.61

This data indicates that for both data collection periods there were more females than males who fell. There was not hospital data readily available to compare the breakdown in sexes for the population of patients who did not fall. However, since the average age of the patients who fell were ~70 years, it was concluded that using the information from the 2000 Census (see U.S. census) would provide usable information about the male/female fraction for the general population and that this information could be used to assess whether the observed gender fraction for the fall population was unexpected. This information is presented in Table 38 below.

Table 38. Fraction of Males and Females above 65 years, from 2000 Census

Age range (years)	Fraction of females	Fraction of males
65 to 74	54.8	45.2
75 to 84	60.5	39.5
>85	71.1	28.9

These results indicate that the distribution between males and females who experienced patient falls in the hospital, presented in Table 38, is consistent with the distribution between males and females of this age cohort in the general population.

Hospital information was not available to make a determination as to whether a male patient of a certain age having a high risk of falling, had a larger or smaller chance of falling than a female patient of the same age and who had a high risk of falling. However, see Section 6.2.6.2 for further information about the split between male and female patients who experienced severe harm from the falls they experienced.

6.2.5 Number of Falls for the two Data Collection Periods, Review of two Standard Deviation Bound

Table 39 presents the total number of recorded patient falls for the two data collection periods on a month by month basis. The results again indicate that the monthly average number of falls was smaller for the second data collection period than for the first. It is also observed that both data periods include one month that contains a significantly larger number of patient falls than the average. May 2006 had 42 patient falls, while February 2007 had 39 patient falls.

Table 39. Number of Patient Falls for the two Data Collection Periods

First Data Collection Period		Second Data Collection Period	
Month	**Number of Falls**	**Month**	**Number of Falls**
12/05	34	12/06	27
01/06	31	01/07	21
02/06	24	02/07	39
03/06	27	03/07	18
04/06	25	04/07	22
05/06	42	05/07	24
Total Number of Falls	183	Total Number of Falls	151
Average/Month	30.50	Average/Month	25.17
Standard Deviation	6.77	Standard Deviation	7.41
2 Standard Deviation Band	16.96 – 47.46	2 Standard Deviation Band	10.35 - 39.99

A simple assessment of whether there are extreme outliers in the monthly fall in Table 39 can be performed by taking the standard deviation for each data period, multiple by two and add and subtract from the respective average. Performing this calculation demonstrates that for both data periods this bound, also presented Table 39, captures all the monthly data. Two standard deviations about the mean, if data were normally distributed, would capture about 95.4% of all data.

6.2.6 Other Results from Data Collected from December 1, 2006 through May 31, 2007

As discussed in Section 5.3 additional information was collected and assessed during the second data collection period. The following sections discuss and analyze these data.

6.2.6.1 Fall Score Data The patient fall score is a method the hospital nursing staff uses to determine the risk a patient has for experiencing a fall. A score of 10 and larger indicates a large risk for falls. Values below 10 indicate a low fall risk. Appendix A describes the factors that are used to determine a patient's fall score at hospital. This scoring is performed by nurses. The fall score is reassessed on a daily basis. Figure 32 presents the distribution for the fall scores from the second data collection interval for the patients who fell.

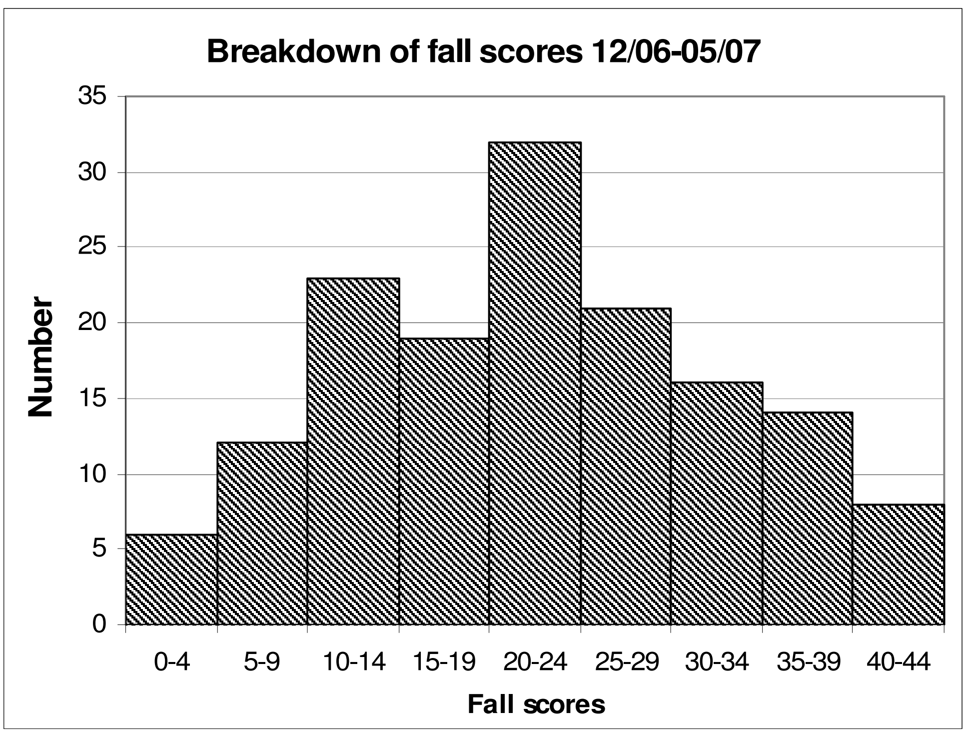


Figure 32. Distribution of Fall Scores for Patients who Fell For December 2006 through May 2007

As can be observed in this figure the vast majority of the fall scores exceed the critical value of 10. However, about 10% of the falls occurred for patients who scored under 10.

Personnel at the hospital are concerned that the fall score tool may not be the most robust method for ensuring that the most at-risk patients are identified. This fall screen is currently being examined to determine whether it should be modified. The shape of this distribution appears to be normal, and this will be examined in Section 6.2.6.1.

Figure 32 is for a population of patients who fell. In order to compare the set of fall scores from Figure 32, a set of fall scores from patients who did not fall were obtained. This set of data included 128 patients from a variety of hospital units. This data were obtained from records of patients from late July to early August 2007. This population of patients also had an age distribution similar to that of the population of patients who fell. The age distribution of these patients is presented on Figure 33.

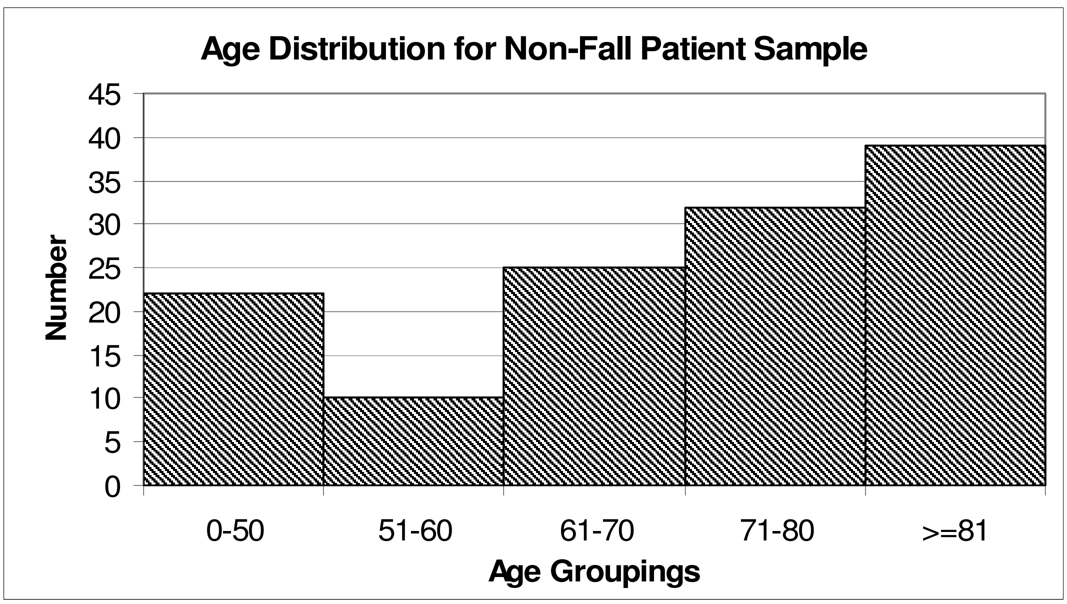


Figure 33. Distribution of the Ages for a Sample of Patients who did not Fall from late July to early August 2007

The distribution of ages in this figure is similar to the age distribution that is presented on Figures 17 and 18. To provide more detailed comparison of the similarity between the ages of the different patient populations, Table 40 presents the fractions of the ages of different patient groups for the two data collection periods as well as the non-fall patient population presented in Figure 33 above.

Table 40. Fractional Breakdown of the Ages of Fall and Non-Fall Patient Groups

Age Breakdown (Years)	Fall Patients 12/05-05/06	Fall Patients 12/06-05/07	Non-Fall Patients July-August 2007
0-50	0.15	0.12	0.17
51-60	0.09	0.11	0.08
61-70	0.17	0.15	0.20
71-80	0.21	0.26	0.25
>80	0.38	0.37	0.30

The comparison in Table 40 indicates that the ages for the sample of non-fall patients is similar to the general age population of those that did fall in the two data collection periods. The biggest difference in this comparison was the fact that the non-fall patient population had a significantly smaller fraction of patients who were greater than 80. This finding is similar to that observed in Section 6.2.2. Figure 34 below presents the fall scores for the non-fall patient population.

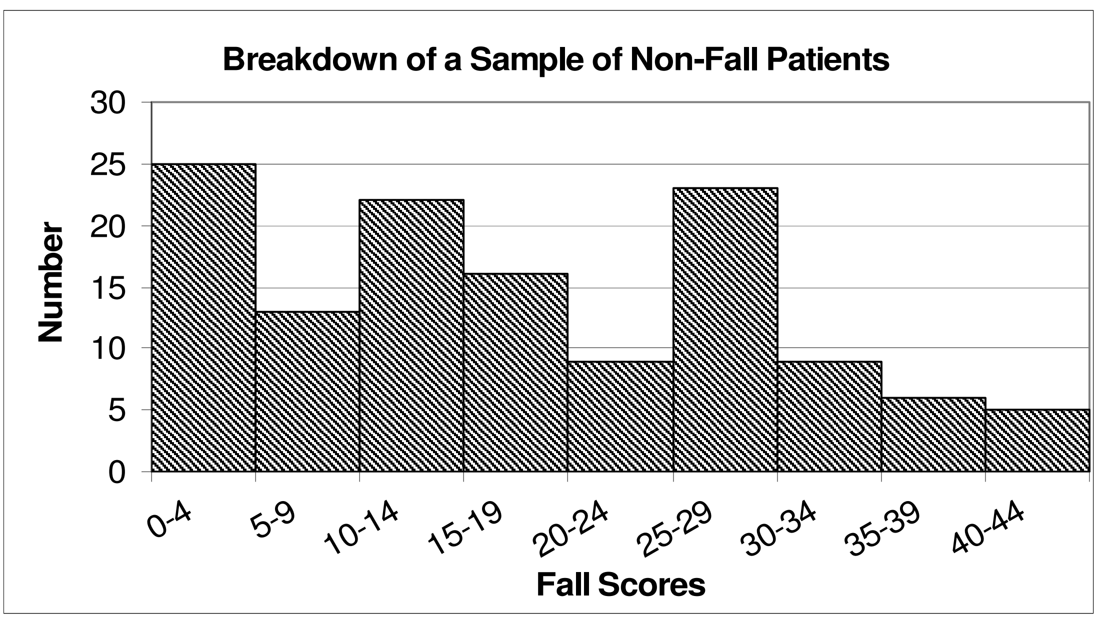


Figure 34. Distribution of the Fall Scores for a Sample of Patients who did not Fall from late July to early August 2007

The fall scores on Figures 32 and 34 appear to indicate the presence of two different distributions. Table 41 presents the fraction of the population in the different fall score bins.

Table 41. Fractional Breakdown of Fall Scores for Two Patient Samples (Fall and Non-Fall)

Fall Score Category	12/06-05/07 Population (Falling Patients)	Data from Late July and Early August 2007 (Non-Falling Patients)
0-4	0.04	0.20
5-9	0.08	0.10
10-14	0.15	0.17
15-19	0.13	0.13
20-24	0.21	0.07
25-29	0.14	0.18
30-34	0.11	0.07
35-39	0.09	0.05
40-44	0.05	0.04

It is apparent from the data in the Table 41 and the data in Figures 32 and 34 that the non-fall patient population has a much larger fraction of lower fall scores (for scores <10, the non-falling population's fraction was 0.30, while for the falling population it was 0.12). Surprisingly, the fraction of patients who had fall scores ranging from 10-19 was similar for the two groups (0.28 for patients who fell and 0.30 for patients who didn't). The largest difference was in the fall score range of 20-24 (for patients who fell the fraction were 0.21 while for the patients who did not the fraction was 0.07). Finally, it was observed that for those patients with the largest fall scores, 35-44, the fractions were 0.14 for patients who fell and 0.09 for patients who did not. It would be expected that patients with this large of a fall score are at extreme risk of falling. However, it may also be the case that many of these patients are so medicated or ill that they may not be able to even attempt to get out of their beds.

The final comparison presented for these two sets of data are to produce figures showing the relationship between fall scores and patient ages. Figures 35 and 36 are presented below.

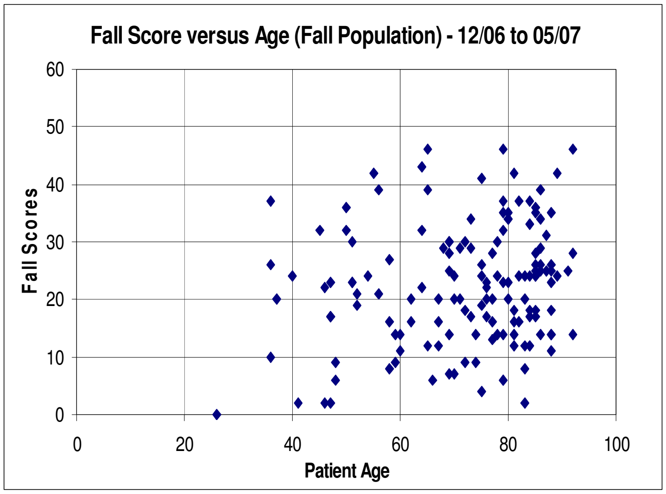


Figure 35. Fall Scores versus Patient Age (for Patients who fell) for December 2006 through May 2007

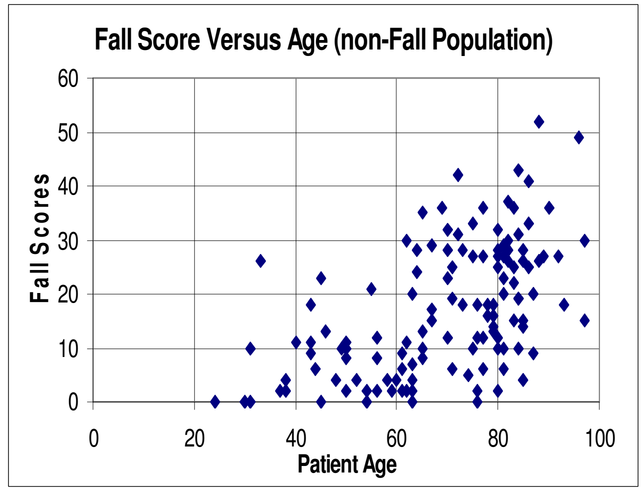


Figure 36. Fall Scores versus Patient Age (for a Sample of Patients who did not fall) from late July to early August 2007

The data on Figure 35 indicates that for the sample of patients who fell, the distribution of the fall scores has a large range, for both young (<=60) and old (>60 patients). Also, the data on Figure 35 indicates that there are significantly more elderly patients than younger patients. However, for the sample of patients who did not fall on Figure 36, the fall score appears to be dependent on patient age. For the sample of patients who did not fall, as patient age increases, so does the fall score. This observation may be inferred to indicate that the fall screening tool does have some specificity, since it is apparent that as patient's age increases, the fall score, and with it the risk of the patient falling will also increase. Another observation is that on Figure 36, patients who are less than about 60, have few fall scores greater than 20, while Figure 35 indicates that there are numerous patients, aged less than 60, who have fall scores significantly larger than 20. As the patient age increases, the spread of the fall scores for the two figures become more alike.

In order to better quantify the differences in the fall scores on Figures 35 and 36, a detailed assessment of the average, standard deviation and median fall score values was performed for the patients who were: (1) less than or equal to 60, (2) greater than 60, (3) greater than 70, and (4) greater than 80. This data is presented in Table 42 below.

Table 42. Comparisons of Fall Score Characteristics of Fall and Non-Fall Patient Samples (December 2006 through May 2007, and Late July through early August 2007)

	Fall Score Characteristics (Fall Sample) – 12/06-05/07	**Fall Score Characteristics (non-Fall Sample) – late July to early August 2007**
Description	Value	Value
Average fall score for patients <=60 years	**19.35**	**7.47**
Standard deviation of fall score for patients <=60 years	11.22	6.98
Median of fall score for patients <=60 years	20.50	5.00
# patients in sample	34	32
Average fall score for patients >60 years	**23.21**	**20.52**
Standard deviation of fall score for patients >60 years	10.11	11.61
Median of fall score for patients >60 years	24.00	20.00
# patients in sample	117	96
Average fall score for patients >70 years	**23.34**	**22.07**
Standard deviation of fall score for patients >70 years	9.88	11.33
Median of fall score for patients >70 years	24.00	23.00
# patients in sample	95	67
Average fall score for patients >80 years	**23.61**	**25.10**
Standard deviation of fall score for patients >80 years	9.82	10.99
Median of fall score for patients >80 years	24.00	26.00
# patients in sample	56	39

The observations from the data of this table include:

1. For the patients who were less than or equal to 60, the fall scores for the sample of patients who fell (19.25) was much larger than for the sample of patients who did not (7.47).

2. The standard deviation (the spread in the sample of fall scores) is much larger for the sample of patients who fell (for patients less than or equal to 60). This is consistent with what is seen on Figures 35 and 36.

3. The average fall scores and standard deviations for both the fall and non-fall samples, for the greater than 60, greater than 70 and greater than 80 groups are similar. Again, this is consistent with the data on Figure 35, since these data have a large spread in fall scores regardless of age.

4. The median fall score for the sample of patients who fell is the same for the greater than 60, greater than 70 and greater than 80 groups (24.00), while it increases somewhat for the sample of patients who did not fall, for greater than 60 group (23.00), greater than 70 group (23.00), and greater than 80 group (26.00). The fact that the median fall score is the same of the fall population is a result of the fact that the fall score is basically independent of age, once greater than 60.

From this data is concluded that for the patient sample which experienced falls, the fall score and the spread of the fall score is independent of age once the patient is above 60 years of age. For the patients who do not experience falls it appears that while there is a small increase in fall score with age (for greater than 60), that increase is small. However, for the non-fall patient sample, the average fall score for the less than or equal 60 group is quite small (7.47), which is below the high-risk fall score (10).

These results indicate that although the fall screen used by the hospital may have some deficiencies, it does provide on a general basis the means for identifying those patients at higher risk of falls. In particular, for patients who are younger than 60, if they have fall scores greater than 20, the existing fall screen may be a good predictor of the risk of falling.

Normality Test for Fall Score Data

For Population of Patients who Fell

In inspecting Figure 32, the distribution of fall scores for the population of patients who fell appears to be normally distributed. A test is performed below to determine if there is a statistical significance to the appearance of normality in Figure 32.

The individual patient fall values were analyzed using the Chi-square normality test (see Section 5.4.6). The results of applying that methodology are presented in Table 43 below.

Table 43. Information Used to Perform the Chi-square Normality Test for the Patient Fall Scores for December 2006 through May 2007 (Patient Falls)

Null hypothesis H_o is that the overall patient fall rates follow a normal distribution (Chi-square critical value ($\chi^2_{0.95,\,2} = 5.99$)						
Characteristics of distribution: mean = 22.338, std dev = 10.483, Number of values = 151						
Interval	End value for interval (Patient fall score)*	Cumulative Probability	Interval Probability	Number of items Observed (O) in Interval	Number of items Expected (E) in Interval	(E-O)^2/E
1	Infinity	1.00000	0.20000	32	30.2	0.107
2	31.161	0.80000	0.20000	27	30.2	0.339
3	24.993	0.60000	0.20000	32	30.2	0.107
4	19.582	0.40000	0.20000	31	30.2	0.021
5	13.515	0.20000	0.20000	29	30.2	0.048
		Totals	**1**	**151**	**151**	**0.622**

* The End value for the equal probability intervals were determined by using the invNorm distribution function on the TI-83 calculator, Texas Instrument (2003). The end value for the interval was determined by providing; (1) the cumulative probability, the distribution mean and the distribution standard deviation

The Chi-square test statistic value for this test (0.622) is less than the Chi-square 95% value ($\chi^2_{0.95,\,2} = 5.99$), so the null hypothesis cannot be rejected. Therefore, it is concluded that this distribution of patient fall scores is distributed normally at the 95% level of significance.

For Population of Patients who did not Fall

In inspecting Figure 34, the distribution of fall scores for the population of patients who did not fall does not appear to be normally distributed. A Chi-square test for normality was performed for this data.

The individual patient fall values were analyzed using the Chi-square normality test (see Section 5.4.6). The results of applying that methodology are presented in Table 43 below.

Table 44. Information Used to Perform the Chi-square Normality Test for the Patient Fall Scores for late July and Early August 2007 (no Patient Falls)

Null hypothesis H_o is that the overall patient fall rates follow a normal distribution (Chi-square critical value ($\chi^2_{0.95, 2}$ = 5.99)						
Characteristics of distribution: mean = 17.258, std dev = 12.041, number of values = 128						
Interval	End value for interval (Patient Fall Score)*	Cumulative Probability	Interval Probability	Number of items Observed (O) in Interval	Number of items Expected (E) in Interval	(E-O)^2/E
1	Infinity	1.00000	0.20000	29	25.6	0.452
2	27.392	0.80000	0.20000	20	25.6	1.225
3	20.309	0.60000	0.20000	19	25.6	1.702
4	14.207	0.40000	0.20000	28	25.6	0.225
5	7. 124	0.20000	0.20000	32	25.6	1.600
		Totals	**1**	**128**	**128**	**5.204**

* The End value for the equal probability intervals were determined by using the invNorm distribution function on the TI-83 calculator (Texas Instrument 2003). The end value for the interval was determined by providing; (1) the cumulative probability, the distribution mean and the distribution standard deviation

The Chi-square test statistic value for this test (5.204) is less than the Chi-square 95% value ($\chi^2_{0.95, 2}$ = 5.99), so the null hypothesis cannot be rejected. Therefore, it is concluded that this distribution of patient fall scores is distributed normally.

6.2.6.2 HARM SCORE DATA Once a patient experiences a fall, the injury experienced as a result of the fall is assessed and a score is given to the resulting harm or injury. These harm designations were presented in Table 5.

The harm scores for the 151 falls occurring during the December 2006 through May 2007 periods were collected. Table 45 provides a tally of the scores.

Table 45. Tally of Harm Scores for December 2006 through May 2007

Harm Score	Number of Fall	Fraction of Total
X – No Harm	108	0.71
D	35	0.23
E	4	0.03
F	4	0.03
G	0	0.00
H	0	0.00
I	0	0.00
Total	151	1.00

Figure 37 presents the distribution of the data from Table 45.

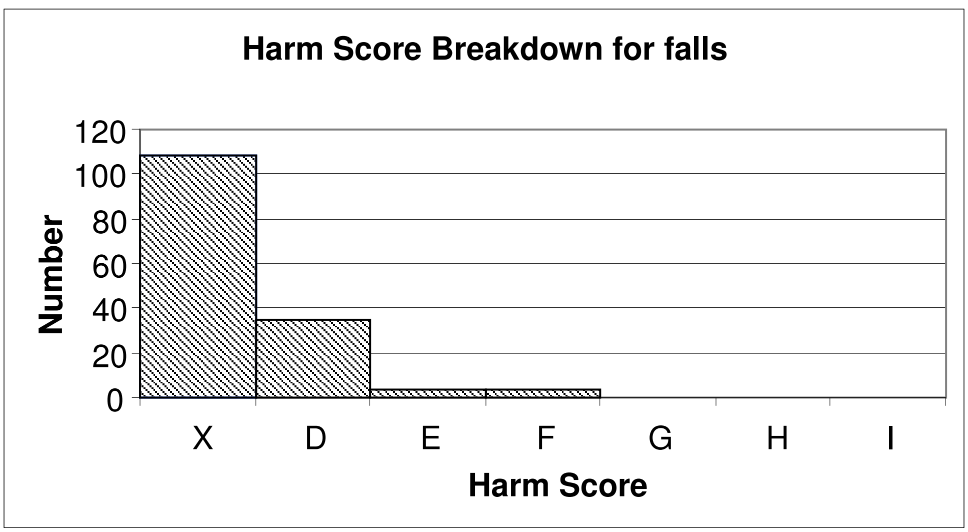


Figure 37. Harm Score Distribution for December 2006 through May 2007

The form of this data appears to follow a classically shaped Pareto Chart. Over 70 percent of all falls resulted in no injury to the patient and less than a quarter of the total resulted in only minor injury. Only six percent of the falls produced serious harm for those patients who fell.

This figure appears to provide a clear application of Pareto's law, which in one form states - 80% of problems or difficulties are caused by 20% of the problems. In this application, the falls that produce the greatest injury (types E and F), and which therefore cause the greatest cost to the hospital are caused by only 6% of the total number of falls for this period.

A further analysis of the eight severe fall data events for this data period was performed. In Table 46 specific information about the severe fall events are listed.

Table 46. Severe Fall Data for December 2006 through May 2007

Date	Time	Day of the Week	Unit	Age of Patient	Fall Score	Gender	Harm Score
12/07/07	545	Thursday	2CR	75	4	Female	E
12/18/07	650	Monday	4M	83	8	Female	F
1/01/07	715	Monday	4M	79	35	Female	E
1/27/07	1751	Saturday	BH	47	17	Female	E
2/02/07	520	Friday	3M	79	14	Female	E
2/19/07	1345	Monday	3M	70	7	Male	F
4/28/07	0005	Saturday	3CR	86	34	Female	F
5/10/07	1540	Thursday	4M	59	9	Female	F

Of the eight severe falls for this period, four of the patients had fall scores less than 10 (the critical value designating low and high fall risk). Also, five of the eight falls occurred during the midnight shift. The eight falls were distributed over five different units, but three of them occurred on 4M. All the falls occurred either on the weekend (3), Monday (3), or Thursday (2). Finally, all but one severe fall patient was female. It may be useful to perform a more extensive assessment of the severe fall data from earlier timeframes to see if there are trends in this data over longer timeframes.

There were several unexpected results from these data. First, about half of the patients who experienced a severe fall injury had fall scores less than a 10. It would have been expected that those patients who experienced the most severe injury from their falls should have had higher fall scores. As indicated by the data in Figure 32, for all the fall events for this data collection period, only about ten percent of the patients who fell had fall scores less than 10. This may be an indication that the fall score tool used may not be as robust as desired in identifying those patients at-risk to falling. It may also indicate that the conditions that lead to patient falls resulting in harm may be different than non-severe patient falls. As indicated previously the hospital staff is considering replacing the existing fall screen. Second, the age of the patients who experienced these falls were younger than expected. One of the patients was only 47 was a patient in the Behavioral Health unit who had been assigned a fall score of 17. Another patient was only 59, and was assigned a fall score of 9 (just under the high fall risk category) on unit 4M. The fact that there were only two of the eight patients who suffered severe harm were older than 80 was also somewhat unexpected, particularly when you consider the data that was presented in Figures 17 and 18, where the largest number of patients who suffered falls were greater than 80. Finally, all but one of the patients who experienced severe harm was a female. From Table 37 the split between male and female patients who fell was approximately 40 to 60% (see Section 6.2.4). Having all but one patient who experienced severe harm being female may indicate that females may be more at-risk to suffer severe harm when they fall.

Harm Score Data and Similarity to a Poisson Distribution

In Sections, 6.2.3.3 through 6.2.3.6 goodness of fit assessments were performed to determine whether or not there was a statistically significant variation as to when patient falls occurred, during the week or the day, compared to assuming that there was simply an average (or flat) distribution, that is, that falls would occur as frequently on any day of the week or hour of the day as any other. However, goodness of fit tests can be performed to determine if data follow other types of distributions, such as Poisson. Hogg and Ledolter (1992), page 254 provides such an example. The method used in this reference was applied to the harm score data that was presented in Table 45 and Figure 37. The one additional piece of information that is needed is to assign a numeric score for the harm score types. In the following analysis the Harm score X category is given a score of 0, D is assigned 1, E is assigned 2 and F is assigned 3.

The null hypothesis is that the distribution displayed on Figure 37 is a Poisson distribution. The first step is to determine the estimate of the mean (λ) of the assumed Poisson distribution. This is performed by using the observed data in Table 45, with assigned numeric values, and the total number of falls that occurred over the second data collection period (n = 151).

$$\lambda = [(108)(0) + (35)(1) + (4)(2) + (4)(3)]/151 = 0.364$$

Using the estimated λ of 0.364, an expected number of patients who would experience harm at the various harm levels if this distribution were Poisson was developed and presented in Table 47 below. The values used to determine the goodness of fit data are also presented in this table.

Table 47. Expected Poisson Frequencies and Harm Score Categories

Value of Harm Score	0 (X)	1 (D)	2 (E)	3 (F)
Fraction of Poisson Distribution having this Harm Score with a λ = 0.364	0.695	0.253	0.046	0.006
Expected (E) Number of Patients having this harm score assuming 151 experiencing Falls (Assuming Poisson Distribution)	104.945	38.203	6.946	0.906
Observed (O) number of patients having these harm scores (from Table 45)	108	35	4	4
The values resulting from the goodness of fit test $(O-E)^2/E$	0.089	0.268	1.249	10.566

This assessment produces a summed value of 12.172 (Q_3). Since the mean for the Poisson Distribution had to be estimated from the data, a critical Chi-square value for $\chi^2_{0.01,\,2}$ is used. This critical value is 9.210. Since the critical value is less than 12.172, the hypothesis (that this distribution is Poisson) cannot be supported. It is observed that the greatest contribution for the Q_3 value comes from the F values. If this value had been 2 instead of 4, the hypothesis that this distribution was Poisson would have been supported.

A weakness of this method for testing for a Poisson distribution is that the harm score categories being tested, may not be appropriate variables. It is not certain that the harm of score "E" is a integer multiple of harm score "D."

6.2.6.3 Assigned Agency Nurses During the second data collection period, an assessment was made of whether or not temporary nursing staff was on duty at the time of patient falls. It was believed that the presence of temporary nurses may be a factor that contributed to the occurrence of patient falls since these nurses may not have been as familiar with hospital protocols and requirements as the regular nursing staff. One of the changes that had been included in the modified patient fall procedure was to collect information on this effect.

During the Months of January 2007 through May 2007, patient falls that were related to the presence of an assigned nurse on staff were recorded. The results from this assessment are presented in Table 48.

Table 48. Assigned Nursing Staff Results for January 2007 through May 2007

Month/Year	Number of Patient Falls	Number of Patient Falls Associated with Assigned Nursing Staff
January/2007	21	2
February/2007	39	3
March/2007	18	1
April/2007	22	2
May/2007	24	3
Total	124	11

Therefore the total fraction of patient falls that had temporary nursing involved was 0.09. The Sr. Director of Patient Services at the hospital was contacted (by personal communication) and provided an estimate that about three percent of the total nursing hours were worked by temporary nurses in the time period of about a year ago (during the period when this data was being collected). Currently that percentage is now only about one percent. It is concluded that although the percentage of falls associated with assigned nursing staff (nine percent) is larger that this estimate, it is considered a weak factor affecting patient falls. The collection of this type of data was one of the decisions made after the first data collection period.

6.2.6.4 Repeat Patient Falls and Percent of Patients who Fell An analysis was performed assessing the patients who fell repeatedly during the December 2006 through May 2007 period. Analyzing the 151 falls that occurred during this period it was determined that 108 patients fell only once, 15 patients fell twice, 3 fell three times and 1 fell four times. Figure 38 presents the distribution of these falls in terms of the number of times individual patients fell.

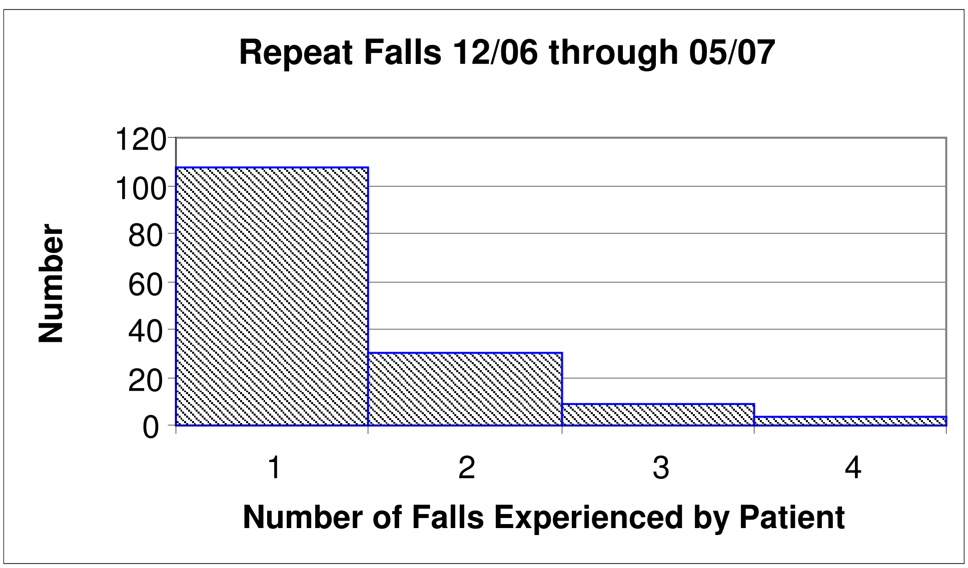


Figure 38. Repeat Fall Distribution for December 2006 through May 2007

The form of Figure 38 is similar to the Pareto chart behavior of Figure 37 for the harm score.

An analysis of these repeat fall scores resulted in showing that for the total of 151 falls reported for this period, 43 resulted from repeat falls from 19 patients, meaning that 108 patients fell only one time. Therefore, (43/151) = 28% of all falls were due to (19/127) = 15% of all patients who fell.

Finally, because the fall scores had been collected for each patient fall, a distribution of the patient fall scores who had experienced repeat falls could be obtained. This distribution is presented in Figure 39.

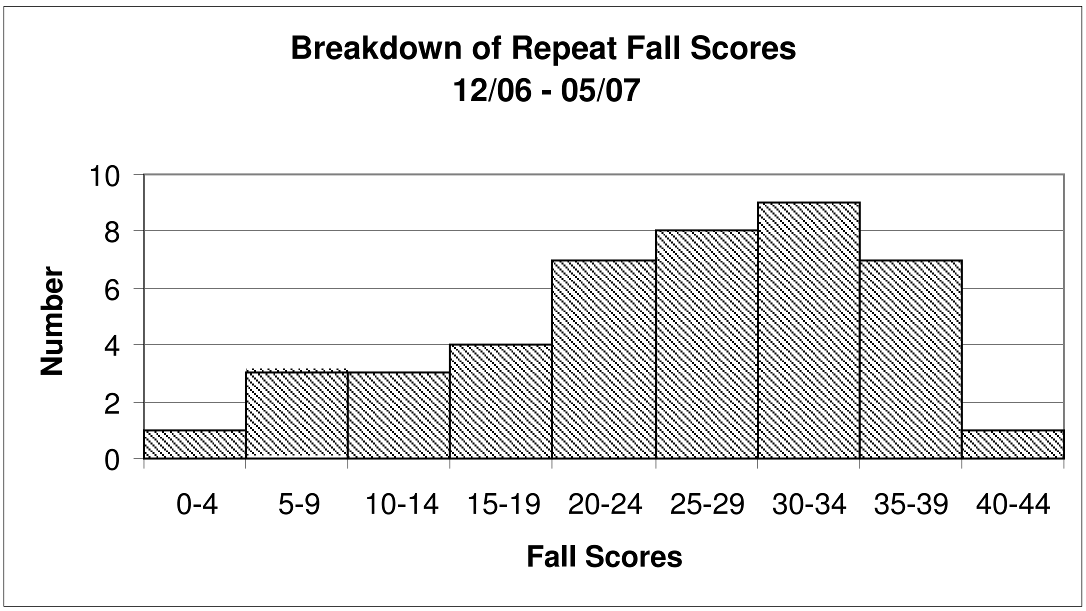


Figure 39. Distribution of Repeat Patient Fall Scores for December 2006 through May 2007

Comparing the distribution of the fall scores in Figure 39 to that for all patient fall scores from Figure 32, it appears Figure 32 has a much more symmetrical distribution, while Figure 39 is much more skewed to the right (a greater proportion of the patient falls have larger fall scores). This result makes sense if it is presumed that patients who have repeat falls would have more physical factors that produce a larger fall score. Further, as this population experienced repeated falls, a reassessment of the patient's fall score was performed. It would be expected that the fall scores associated with these repeat fall patients would increase, as the hospital staff sought to reduce their risk of falling. This would be particularly true for the patients who experienced three and fours falls. It is noted however, that even for this population of patients, there are four patients who had fall scores less than 10.

Percent of Patients who Fell

The total number of patients who were admitted to the hospital during the period December 1, 2006 through May 31, 2007 was obtained. The total number of patients admitted was 5418. The falls per patient is then 151/5418 = 0.028 for the average of all hospital units.

Repeat Fall Data and Similarity to a Poisson Distribution

In previous sections, 6.2.3.3 through 6.2.3.6, goodness of fit assessments were performed to determine whether or not there was a statistical significance as to when patient falls occurred, during the days of the week as well as the hours of the day, compared to assuming that there was simply an average (or flat) distribution, or, that falls would occur as frequently on any day of the week or hour of the day as any other. However, goodness of fit tests can be performed to determine if data follow other types of distributions, such as Poisson. Hogg and Ledolter (1992), page 254 provides such an example. The method used in this reference was applied to the repeat falls data that was presented in Section 6.2.6.4 and Figure 38. For the 151 falls which occurred in the December 2006 through May 2007 period, there were 108 patients who experienced a single fall, 15 patients who fell twice, 3 patients who fell three times and one patient who fell four times. This produces a total of 127 repeat falls. For purposes of this analysis the patients who fell only once were designated as having zero repeat falls, those who experienced two falls as having one repeat fall, those with three falls as having two repeat falls, and those with four falls as having three repeat falls. The null hypothesis is that the distribution displayed on Figure 38 is a Poisson distribution.

The first step in this process is to determine the estimate of the mean (λ) of the assumed Poisson distribution. This is performed by using the observed data (repeat falls) as described above. The estimate of the mean is presented below.

$$\lambda = [(108)(0) + (15)(1) + (3)(2) + (1)(3)]/127 = 0.18897$$

Using the estimated mean of λ (0.18897), an expected number of patients who would experience repeat falls if this distribution were Poisson was developed and presented in Table 49 below. The values used to determine the goodness of fit data are also presented in this table.

Table 49. Expected Poisson Frequencies and Repeat Fall Values

Number of Repeat Falls	0	1	2	3	Sum of (O-E)^2/E (Q_3)
Fraction of Poisson Distribution having this number of repeat falls with a mean of λ = 0.18897	0.827811	0.156431	0.014780	0.000931	
Expected (E) Number of Patients having this number of repeat falls, assuming 127 repeat falls occurring	105.132	19. 867	1.877	0.118	
Observed (O) number of patients having these number of repeat falls	108	15	3	1	
The values resulting from the goodness of fit test $(O-E)^2/E$	0.078	1.192	0.672	6.593	8.535

This assessment produces a summed value of 8.535 (Q_3). Since the mean for the Poisson distribution had to be estimated from the data, a critical Chi-square value for χ^2 (0.01, 2) is used to test the null hypothesis. This critical value at this level is 9.210. Since this value is greater than 8.535, the null hypothesis (that this distribution is Poisson) cannot be rejected.

While this result may not occur for every data period, it is of interest that it is reproduced for a parameter that clearly does have the characteristics of a Poisson random variable (number of repeat falls experienced by a population of patients who fell during this period). This result is also consistent with the reasonable expectation that the number of patients who experience an increasing number of repeated falls over a specific period will decrease rapidly.

6.2.6.5 Fraction of patient falls per patient admission- per hospital unit The hospital was able to provide the total number of admissions for this data collection period and this data also included a breakdown, by unit, of the patient admissions. Table 50 provides the total admissions for the entire period, and compares this to the total number of falls that occurred during this period.

Table 50. Fraction of Patient Falls Relative to Total Patient Admissions for December 2006 through May 2007

Unit	Total Patient Falls	Total Patient Admissions	Falls/ Patient Admission
2C	8	552	0.0145
2MR	22	183	0.1202
TCU	14	269	0.0520
3C	19	718	0.0265
3M	19	769	0.0247
4M	38	831	0.0457
BH	17	653	0.0260
5M	12	686	0.0175
CVU	1	397	0.0025
ICU	1	360	0.0028

The data in Table 50 indicates that there is a significant variation in falls per patient admission for the different units. The minimum value is 0.0025 for CVU and the maximum is 0.1202 for 2MR. This variation must be a partial reflection of the different type of patients that the different units receive and care for. 2MR is a rehabilitation unit and therefore may have many more patients who are attempting to regain mobility and thus face a larger risk of falling. The cardio vascular unit on the other hand is a unit that has much greater and more effective nursing observation, as well as a higher nursing to patient ratio and therefore a much smaller likelihood of patients being unattended or unobserved.

6.5.6.6 Variation in patient admission by unit The data in Table 51 presents the total admissions, by unit over the December 2006 through May 2007 period. This data provides a perspective of how patients admissions vary over time, as well as by unit.

Table 51. Patient Admissions by Unit for December 2006 through May 2007

Unit	12/06	01/07	02/07	03/07	04/07	05/07	Total (ranking)
2C	82	102	83	91	99	95	552 (6)
2MR	25	28	28	33	35	34	183 (10)
TCU	45	50	41	47	46	40	269 (9)
3C	130	130	114	131	109	104	718 (3)
3M	129	158	111	129	121	121	769 (2)
4M	134	158	137	146	126	130	831 (1)
BH	117	109	94	112	113	108	653 (5)
5M	130	112	112	105	99	128	686 (4)
CVU	68	71	75	69	58	56	397 (7)
ICU	54	70	49	54	67	66	360 (8)
Total	914	988	844	917	873	882	5418

This table also includes the ranking, from the highest number of patients, to the lowest number of patients. This data shows that the largest patient admission month for the period is January (with 988) while the lowest was February (with 844). This table also shows that the unit that had the largest number of admission was 4M with 831. While this data is useful in providing some perspective of how patients get distributed within the hospital it does not provide information concerning what type of patients they are, or whether a particular unit has a much greater work load due to its patient population. It also does not indicate how the hospital responses to the varying unit load by providing nursing staff to the different units.

This data also supports several things that had been mentioned earlier. First, the number of patient's admissions for the CYU and ICU are much smaller than the other units. This had been discussed related to the behavior of the hospital unit fall data over time (see Section 6.1.2). Also the Behavioral Health unit which has medical issues that differ significantly from other units, while not having the largest number of admissions, did have a significant number (ranked fourth highest out of the ten units).

7.0 CONCLUSIONS, OBSERVATIONS AND STAFF EXPECTATIONS

The important quantitative conclusions and non-quantitative observations resulting from this study are presented below:

Conclusions:

1. The hospital patient monthly fall rate goals (targets), assigned both hospital-wide, as well as for individual units, were shown to be regularly exceeded over the period of the examined data (see Sections 6.1.1 and 6.1.2). For both hospital-wide and individual units, the month-to-month fall rate variation was large, with the individual unit standard deviations being larger than the hospital-wide values (see Table 12). However, use of the four month moving average provided an improved perspective of the time-dependent behavior of the patient fall data, and at times appeared to reveal patterns in the fall rate data not apparent when observing the monthly data. In particular, the four month moving average revealed a cyclic behavior for the hospital-wide data as well as for several of the individual hospital units (see Figures 3, 7, 8, and 11). Generally, the peak of these cycles occurred near the end of the year or early in the following year, which would likely correspond to periods when the hospital probably had a large population of elderly patients who suffered from influenza or other cold weather illnesses. The greater the population of elderly patients, the greater then likelihood of patients falling (see Tables 24 and 25). The monthly fall rate data produced few points that exceeded the UCL value developed using the c-chart formulation. Only individual unit data occasionally exceeded the UCL values (see Figures 7 through 16). Since the UCL

approximates the 3-sigma limit for a Poisson distribution, any values above the UCL likely indicate unexpected behavior on the unit, such as a repeat fall or a population of patients which have a higher than normal risk of falling.

2. Linear regression analysis of hospital-wide and unit monthly patient fall rates showed (with one exception) no statistically significant decrease (at the 99% confidence level) in fall rate over the five year hospital-wide and four year unit data. The one exception was unit 2CR which did show a statistically significant decreasing trend at the 99% confidence level (see Section 6.1.1.2, Figure 16 and Table 22).

3. The average age of the patients who fell during the first data collection period was 70.14, while for the second data collection period it was 72.11 (see Section 6.2.2, Table 26). The median age of the patients who fell was 75 for the first data collection period and 73 for the second data collection period. For both data collection periods it was found that over 35% of the falls occurred for patients who were 80 or older. The average age of the patients who fell at the hospital compared to an average age of 63.4 from Hitcho et al (2004). The higher average patient age for the hospital population was consistent with the differences in census information which showed that the area where the Hitcho study was performed (city of St. Louis) had a much smaller fraction of people above 65 (13.7%) as compared to one of the cities served by the hospital which provided the data for this thesis (20.9%). Finally, it was noted that about 20 percent of all falls occurred to patients who were 60 or younger.

4. The fall scores for the patients who fell (only obtained during the second data collection period) were plotted and a well-behaved distribution, with a mean value of approximately 22 was observed (see Section 6.2.6.1, Figure 32 and Table 41). When fall scores were obtained from a sample of patients who had not fallen, it was shown that the values of the fall scores for those patients were smaller (Figure 34 and Table 41). The fraction of

the fall scores that were less than 10 (indicating patients at low risk for falls) for the patients who fell was 0.12, while the fraction for the patients who did not fall was 0.30.

5. The comparison of fall scores from two populations of patients (one population that experienced a fall and the other which did not) was performed (Section 6.2.6.1, Table 42, and Figures 35 and 36). For the population that experienced falls, the range of fall scores appeared independent with age. For the population that did not fall, there was a trend of increasing fall scores with increasing age, with the lowest scores being associated with patients less than 60 years old. For patients who are less than 60 years old, there were few fall scores greater than 20, while for the patients who fell, there were numerous patients less than 60 years old who had fall scores significantly larger than 20. As the patient age increases beyond 60 years old, the spread of the fall scores for the two figures become similar. These results indicate that although the fall screen used by the hospital may have some deficiencies, it provided, on a general basis, the means for identifying those patients at higher risk of falls. In particular, it appeared that for patients who are less than 60 years of age, if they have fall scores greater than 20, the fall screen may be a good indicator they were at a high risk for falls.

6. Severe falls, or those falls causing significant harm to the patient, accounted for only about five percent of the total number of falls (see Section 6.2.6.2, Table 46). These results were obtained only for the second data collection period.

7. Repeat falls (see Section 6.2.6.4, Table 49), patients who fell more than once during a particular period, were experienced by about 15% of the patients who fell, and those repeat falls accounted for 28% of the total number of falls. It was also concluded that the distribution of the patients who experienced repeat falls was consistent with a Poisson distribution. These results were obtained from the second data collection period.

8. The distribution of patient falls between males and females was consistent with the fraction of males and females for the population cohort above 65 years of age based on the 2000 U.S. Census results (see Section 6.2.4, Table 37). While no data was available to ascertain whether a male patient having a high (>10) fall risk score had a greater or lesser risk of falling than a female patient of the same age and fall risk score, the information presented for severe harm resulting from falls (see Section 6.2.6.2) indicated that those patients who experienced most harm from falls were predominantly female (seven out of eight severe fall events were suffered by females). This harm score information was obtained from the second data collection period.

9. In analyzing the time interval between consecutive patient fall events for the two data collection periods analyzed for the hospital-wide data, it was determined that the distribution of these time intervals had an approximate exponential form (Section 6.2.3.1, Figures 23 and 24 and Tables 28 and 29). This assessment was performed using a Chi-square test. The 99% critical value was 11.345 for the first data collection period and the test value was 10.584. The 95% critical value was 7.815 and the test value was 4.266 for the second data collection period. Therefore, the statistical significance was stronger in the second data collection period than in the first data collection period. This result appears to be consistent with reliability theory (see Section 6.2.3.2).

Observations

1. Based on the review of literature (see Section 4.0), it appears that few studies were able to demonstrate measurable, long-term reductions in patient fall rates. The only study that was able to demonstrate a procedure that produced reductions in fall rate over a long time period (about a year) was Meade (2006). It was also observed that few studies performed quantifiable assessments of patient population characteristics.

2. Based on a review performed with the hospital personnel following the first data collection period, a number of changes were made to the data that was collected for the second data set. These changes included collecting additional data from that collected during the first data period (See 5.3). The additional data were provided to all the hospital units on a monthly basis. The collection of additional data for the second data collection period enabled examination of different factors affecting patient falls (e.g., number of patient falls when temporary nurses were on duty). Examination of these data has led the hospital staff to discontinue collecting certain data since they have concluded that data does not make a significant contribution to the overall fall rate.

3. Based on being unable to demonstrate that there was no statistically significant change in the trend of the monthly patient fall rate for a number of years (about five years for the hospital-wide data and about four years for most hospital unit fall data), it was concluded that making a statistically significant change to the average monthly patient fall rate would require major changes to the existing hospital method of operation. In other words, a significant "cultural change" in the hospital staff and the methods used to address patient falls would need to be conducted to potentially reduce the existing patient fall rate. Such a cultural change is now being instituted by the hospital. This cultural change will result in a new method of performing patient rounding (i.e., performing more frequent checks of all patients on a unit – see Appendix C) by the nurses and the nurse's aides. The effect of this new nursing rounding procedure (instituted throughout the hospital in mid-June 2007) should be able to be assessed at the end of 2007, by which time about six months of data under the new method of rounding should be available. In examining the unit on which this modified rounding procedure was tested prior to being implemented hospital-wide in June 2007 (unit 5M) it appears from the four month moving average to have potentially reduced this unit's fall

rate (See Section 6.1.2, Figure 12). This new rounding procedure had been commenced in this unit in mid-March 2007.

4. Local environments (or subcultures), resulting from a variety of causes, exist in the different hospital units. These local environments probably produce different outcomes in patient fall rates (see Section 6.1.2). The hospital-wide procedures and protocols to prevent patient falls can be applied somewhat differently due to the experience of the supervisors and hospital staff, the unit's patient load, the patient characteristics on the particular unit and the physical design of the hospital unit itself. Because of the multiple pathways by which patient falls may occur, achieving a reduction and maintaining a reduction in patient fall rate is difficult to accomplish. The process of achieving goals and maintaining desired levels of performance is discussed in more detail in Appendix G.

5. The issue of effecting a cultural change in a complex organization such as a hospital is a difficult process to successfully implement. Competing effects can often cause the most well-prepared and organized effort to change a system to "drift" from its original intent as well as produce unexpected or unintended consequences[18]. This process of attempted change and competing effects of drift are discussed in Appendices F and G.

6. Statistical methods were found to be useful in displaying many of the characteristics of the patient fall data, as well as determining whether any of these characteristics produced statistically significant trends or results. For example, assessments were performed as to whether there were statistically significant trends when falls occurred during different shifts and hours of the day or over the days of the week, as well as assessing trends in the fall rate for both hospital-wide and individual units. Assessment

[18] An example of an unintended consequence was provided by the nursing staff shortly after the hospital-wide implementation of the new rounding procedure. A patient provided feedback which indicated that he was "bothered" by the hourly period which was being used by the nursing staff to create a lower risk environment. This type of patient response was not anticipated by the nursing staff when the new rounding procedure was considered.

of these data indicated there was no statistically significant trends at the 99% confidence level. Allowing hospital staff to review these results can provide a more rigorous assessment of the data and reduce the likelihood of concluding that a trend exists where data did not warrant such a conclusion (See Section 6.2). The use of simple methods to check for outliers in the hospital-wide and unit data, such as multiplying the standard deviation by 2 and observing if any monthly values exceeded the bound of the average plus and minus this value, showed that few if any monthly values exceeded this bound such results supported the conclusion that the data was normally distributed (see Section 6.1.1).

Staff Expectations

Expectation can serve as both positive and negative metric in organizations. If expectation and reality is not aligned, actions can be taken that can result in making performance worse. It was considered appropriate to understand what some of the expectations of the hospital staff were in terms of patient falls prior to the performance of this thesis. In discussions with the staff members, these were what could be considered “folklore” regarding what conditions would have produced larger fall rates. It was noted in discussion with a senior staff member that many of these “folklore” beliefs were not challenged until the patient fall committee had been organized, data had been collected, and reliable data had been collected for a number of months. This indicated that once expectations about what conditions caused higher faults were embedded in the staff members it was difficult to change those expectations without an analysis being performed on a set of reliably collected data.

1. It was expected that more falls would occur on the midnight shift, since there was less staff. Analysis showed there was no statistically significant trend in when the falls occurred (see Section 6.2.3).

2. There had been an expectation that the more temporary presence of agency nurses would result in a larger number of patient falls. However, examination of available data indicated there is not such a correlation (see Section 6.2.6.3).
3. While the hospital staff recognized that patient falls were generally related to older patients, they was not an appreciation that younger patients also had a non-trivial risk for falling (see Section 6.2.2).
4. The distribution of fall scores for the patients who fell – the distribution having a mean at about 22, peak values of about 44, and with a little more than 10% of the patients who fell having scores less than 10. The hospital staff has had a concern for some time that the fall screen currently in use may not have the ability to identify as well as they would like, patients at risk of falling. As shown in Section 6.2.6.1, it was shown that the fall screen was able to, on a general basis of overall patient populations to identify those more likely to fall.
5. The high age of the population of patients who fell (~70 and 72 for the two data collection periods) was not a surprise to the staff.

8.0 SUGGESTIONS FOR IMPROVING DATA COLLECTION AND ASSESSMENT

Following an assessment of the data collected by the hospital, and realizing that the assessment produces questions about the behavior of the system, as well as providing a better understanding of how the system behaves and reacts, it seems logical to conclude that the behavior of the system and the patient fall process can be better understood by modifying procedures and collecting additional information. The following list provides a number of suggestions for adjusting procedures and collecting additional information that may be of value to better understand the processes that produces patient falls. Some of these suggestions have applicability beyond patient fall rates.

1. <u>Create an interdisciplinary committee</u> to study the potential applications of statistical process control for selected data collected by the hospital. This committee would include administration, doctors, residents, nurses, nurse's aides, and computer programmers from the hospital. The specific charter for the committee would be to examine how the data that is currently collected can best be processed and assessed, as well as to consider whether there are other data that can be collected so as to improve the care of patients and the statistical knowledge of the hospital staff. Suggestions for providing more data that is directly accessible by the hospital staff should be collected, examined and prioritized to determine which suggestions have the greatest likelihood of making a positive impact on patient care.

   A few specific suggestions of what this committee could examine include:

- Determine what type of data collected could make use of statistical treatments such as c-chart, moving averages, Chi-square tests, and linear regression techniques.
- Based on the statistical data which was concluded to be useful to collect and disseminate to the hospital staff, consider rudimentary statistical training for nursing, doctor and administrative staff to allow more consistent assessment of the data collected, particularly in the area of protecting against concluding that a trend is present when it is not.
- Consider the most effective methods to collect the additional data that will not impact current work practices.
- Consider methods to provide unit hospital staff with information from previous admissions for the same patient (such as previous falls). Currently, such linkage across computer systems is not available.
- Examine existing nursing forms to determine if they can be redesigned to allow staff to more efficiently process the forms, as well as reduce the likelihood of error in filling them out. For example, align columns that require numeric tabulation, as well as placing the most important information first.
- Perform a survey to request what information hospital staff would find most useful to have ready access to. The responders to this survey should provide information as to why the staff needs this information.

2. <u>Allow collection and assessment of fall scores for a sample of patients who did not fall in order to compare these scores between the two samples</u> (those patients who fell and those who did not). While this assessment was performed in Section 6.2.6.1, this should be done on periodic basis to observe whether there is any change over time. Also, if the current fall screen is modified in the future performing this comparison may be useful in determining its effectiveness.

3. <u>Allow easier collection of age information</u> for patients so the age distribution of those who fall and those who do not can be more easily compared.

4. Add to the assessment of patient falls a method of recording and visualizing where the patient fell on a unit and within a room. Adding a floor map to the Patient Fall Form (see Appendix B) may be useful in this regard. Monitoring the location of the falls may provide a more complete assessment of whether there is a location or environmental component affecting the fall rate. This assessment can also include whether the fall was due to an extrinsic factor (those things that are not associated with the patient's medical condition, such as a slippery floor, tangled wires, items not within easy reach of the patient and the type of clothes and footwear the patient was or was not wearing).

5. Examine more closely the severe fall incidents for commonalities of gender, age, condition, location and time. The severe fall events, although only a small fraction of the total fall population, may have different characteristics than the non-severe fall events and their small number may require much greater examination in order to discern those characteristics. Section 6.2.6.2 results indicate that females may be at greater risk of experiencing severe harm from a fall than males.

6. For hospital units, closely monitor any changes in unit procedures or protocols that could affect outcomes. Individual unit environments (staff, application of hospital wide protocols and procedures, differences in unit layout or patient characteristics) may greatly impact unit performance characteristics.

7. Consider collecting and analyzing data from other adverse events and assess their characteristics. Determine the similarities and differences between patient fall data and other adverse events. Are there actions that can be taken that can potentially reduce both types of events? This database should allow hospital staff to input information from adverse events as well as near-miss events. This database would be designed to allow similar events to be accessed and trends for those events could be visualized.

8. Perform a series of System-wide assessments for certain fall parameters, age, occurrence, etc. Observing fall characteristics between different hospitals within the system may identify important hospital-specific factors that are predictors of patient falls. These characteristics may not be discernable by observing data from a single hospital.
9. Linked to the previous suggestion, periodic meetings (by means of a videoconferencing) between different hospitals within the multi-hospital system could be held. The purpose of these meeting would be to present hospital "best practices," where quantifiable data from studies would be presented to demonstrate the successful application of a particular hospital initiative. These meetings could also be used to discuss important lessons learned from adverse events that occurred at different hospitals.
10. Observe the impact of instituting the revised rounding procedure that is now being put into place hospital-wide. Produce periodic reports that present trends showing the effect of this new rounding procedure.
11. Attempt to determine the fraction of time on a shift in which the nursing staff works directly with patients and the time spent in working with medical or regulatory forms. It may be possible to better coordinate the location of material on a unit, or the methods of filling out forms so as to reduce time spent in repetitive or less important tasks, compared to patient care.
12. For individual hospital units, perform assessment of the characteristics of the patients who reside on the unit. Attempt too understand how the age, medical condition, gender, or other patient factors may contribute to unit-based factors that increase or decrease the likelihood of patient falls or other adverse events. This assessment would include examining both the fall and non-fall patients on the unit.

Plans for Continuing Work

We intend to continue as members of the patient safety committee, and to also continue to work with members of the hospital staff to investigate patient falls, as well as other adverse events. Our hope is to provide information that will aid staff members to improve patient safety.

Concluding Statement

This study concludes that the application of statistical analysis techniques to adverse medical event data, together with the opportunity for a person who has engineering experience, but is not part of the medical system, to examine the data, observe operations, ask questions of the hospital staff and engage in discussions of specific issues confronting the hospital staff, may produce additional opportunities for the hospital staff to attack problems, better understand the trends and behavior of adverse events, and potentially improve patient outcomes.

APPENDIX A

PATIENT FALL SAFETY ASSESSMENT SCALE

FALL SAFETY ASSESSMENT USED AT HOSPITAL

The following is the scale that is currently in use at the hospital to determine the fall risk for patients. This screening measurement is administered by nurses on a daily basis for each patient under their charge.

The number in () represents the score assigned if the patient has the particular aspect

Table A-1. Patient Fall Score Factors

Mental Status/Cognitive Perception
- □ Confusion/Disorientation (intermittent or continuous) (5)
- □ Agitation/severe restlessness (5)
- □ Minimum understanding (2)
- □ No understanding (2)
- □ Implusiveness/Impaired decision making (3)

Total ________

Mobility
- □ Assistance devices (Canes, walkers, prosthesis, etc.) (2)
- □ Unsteady gait or dizziness (4)
- □ Limited mobility (3)
  (2)
- □ Decrease mobility for > 3 days (3)

Total ________

Vision/Speech/Hearing
- □ Difficulty with sight (2)
- □ Difficulty speaking (aphasia, language barrier, etc.) (2)
- □ Hard of hearing (2)

Total ____

History of Falls
- □ Admission diagnosis related to fall (15)
- □ During hospitalization(s) (15)
- □ Anywhere other than hospital (10)

Total ______

Medications
- □ Antihistamines (2)
- □ Cathartics or diuretics (2)
- □ Anti-hypertensives (2)
- □ Narcotics (2)
- □ Benzodiazepines/Sedatives/Hypnotics
- □ Hypoglycemics (2)

Total ______

Elimination
- □ Nocturia (2)
- □ Incontinence (2)
- □ Urgency of frequency (2)

Total ______

PLEASE TOTAL ALL SECTION SCORES ________
PLEASE CIRCLE LEVEL OF RISK BASED ON TOTAL SCORE: 0 to 9 (No risk to Low Risk)

10 to 14 (Moderate Risk) 15 or greater (High Risk)

Initiate appropriate fall Protocol

APPENDIX B

PATIENT FALL FORM

The following table is used at the time that a fall occurs to collect information regarding the event.

Table B-1. Patient Fall Follow-up Form

Confidential Peer Review Patient Safety Information – PLEASE **DO NOT** PLACE ON PATIENT'S MEDICAL RECORD

Date of Fall:______________________________ MR#: _____________________ Gender:↑Male↑Female

Time of Fall:______________________ Day of Week of Fall:_______________________________________

Fall Score:_____________________ ☐ Assisted fall ☐ Unassisted fall Age: __________

Last Risk Assessment Code: (Circle)
1. 0-12 hours **2**. >12-24 hours **3**. >24-48 hours **4**. >48-72 hours **5**. >72 hours – 1 week
6. >1 week

Harm Score Code:
- ☐ **D**=Scrapes, bruises, abrasions, small lacerations without sutures
- ☐ **E**=Injury requiring treatment or intervention, laceration requiring sutures, fracture with no extension of hospitalization
- ☐ **F**=Fracture with prolonged hospitalization, head injury, condition requiring medical intervention and prolonged hospitalization (temporary harm)
- ☐ **G**=Fall that contributed to or resulted in permanent harm
- ☐ **H**=Fall that resulted in near death event (required ICU or other intervention to sustain life)
- ☐ **I**=Death

Type of injury:

____

***Harm Score $\geq$ E, immediately notify and send copy to Risk Management.**

If patient score $\geq$ 10, was CAFS implemented? ☐ Yes ☐ No

Mental Status:

- ☐ Alert and oriented x 3
- ☐ Confused on admission
- ☐ Confused after admission but before fall
- ☐ New confusion at time of fall

Sleeping agent, narcotic or hypnotic given within the last 8 hours? ☐ Yes ☐ No

Drug:____________________ Date/Time:___________/_______

Why did the patient state they fell? ____

What was the root cause of the fall? ____

New fall prevention measures/action steps implemented to prevent future fall? ____
____

*Is fall documented on the Kardex?	↑Yes ↑No	If not completed, reeducate nurse
*Was SBAR Physician Notification Form completed?	☐ Yes ☐ No	
*Was addendum concerning fall added to Voicecare?	↑Yes ↑No	

Patient assigned to agency nurse? ↑Yes ↑No

Unit census ______ # of Nursing Assistants on duty ________

Signature: _____________________________________ Date: ________________________

Revised: 1-07

APPENDIX C

REVISED PATIENT ROUNDING PROCEDURE

SUBJECT: Patient Rounding

DATE: MARCH 2007

POLICY: In order to promote patient safety and comfort, nursing will conduct proactive rounds at regular intervals. Enhancing patient comfort and pain control, preventing patient falls, promoting satisfaction and providing safe patient environment s are primary goals of the rounding process.

PROCEDURE:

1. Nursing rounds will be conducted at regular intervals on all inpatient units.
   a. Rounds will be conducted every one hour.

2. The RN/LPN will conduct rounds on the even hours and the nursing assistant will conduct rounds on the odd hours.

3. The Unit Director/RN/designees will be responsible for assigning a team/group of patients whom the nursing assistant will be responsible to round on. The RN/LPN will round on their assigned patients.

4. During the first round of the shift, the NA and RN/LPN will place their name and spectralink phone number on the white board and instruct the patient to call the spectralink phone directly with needs, as appropriate.

5. During the rounding process, the nursing staff will follow a protocol that provides directions for patient care.

   This includes:
   a. Introducing self.
   b. Assessing pain level. If a patient is in pain and a person other than a nurse is competing the rounds, the nurse is to be notified immediately.
   c. Offering toileting assistance.
   d. Repositioning patients for comfort, as needed. Repositioning patients for pressure relief will be done on odd hours.

e. Ensuring that items are within patient reach (call bell, telephone, tissue, bedside table, light switch).
f. Placing wastebasket can next to bed.
g. Assuring that fall alarms are turned on and other fall prevention measures (i.e. low beds are in the low position) are in place, as appropriate.
h. Surveying the room for safety and clear pathways.
i. Asking the patient, "Is there anything else you need before I leave?"
j. Telling the patient, "someone will be back in about an hour."

6. The nursing staff will round as close to the hour as possible.

7. The nursing staff will secure the assistance of other staff members as needed.

8. A patient should not be disturbed if they are sleeping.

9. If a person rounding other than the nurse recognizes that a patient has an emergency need, the nurse is to be notified immediately.

10. The Unit Director/designee will conduct validation rounding on a weekly basis to ensure that regularly scheduled rounds are being conducted.

11. Metrics will be monitored to evaluate effectiveness of the rounding process and these will include:
    a. Fall rate
    b. Pain management effectiveness
    c. Patient satisfaction

These metrics will be regularly shared with the staff.

THE FOLLOWING ARE THE SPECIFIC INSTRUCTIONS NURSES ARE TO FOLLOW WHEN IMPLEMENTING THE NEW ROUNDING PROCEDURE

1. Tell patient, “I’m rounding” and ask “Do you need anything?”

2. Assess patient pain level. If nonnurse (nurse’s aide) is rounding and patient is in pain, notify the nurse immediately.

3. Offer toileting assistance and/or check for incontinence.

4. Assess patient’s position and comfort; assist in positioning. Reposition those patients unable to reposition self (odd hours).

5. Ensure call light is within reach.

6. Ensure telephone is within reach.

7. Ensure TV remote control and light switch are within reach.

8. Place the bedside table next to the bed.

9. Ensure tissues and water pitcher are within reach.

10. place the waste can next to the bed

11. Prior to leaving the room, ask, “Is there anything I can do for you before I leave?”

12. Tell the patient that someone will be back to round in about an hour.

13. The nurse is to also provide the patient with the nurse’s SPECTRALINK phone extension. This is a phone extension for the hospital phone system that would enable the patient to contact the nurse immediately.

APPENDIX D

JOINT COMMISSION 2008 NATIONAL PATIENT SAFETY GOALS, HOSPITAL PROGRAM

Table D-1. Joint Commission 2008 National Patient Safety Goals, Hospital Program

This year's new requirements (3E and 16A) have a one-year phase-in period that includes defined expectations for planning, development and testing ("milestones") at 3, 6 and 9 months in 2008, with the expectation of full implementation by January 2009. See the Implementation Expectations for milestones.

Goal 1	Improve the accuracy of patient identification.
1A	Use at least two patient identifiers when providing care, treatment or services.
Goal 2	Improve the effectiveness of communication among caregivers.
2A	For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person receiving the information record and "read-back" the complete order or test result.
2B	Standardize a list of abbreviations, acronyms, symbols, and dose designations that are not to be used throughout the organization.
2C	Measure and assess, and if appropriate, take action to improve the timeliness of reporting, and the timeliness of receipt by the responsible licensed caregiver, of critical test results and values.
2E	Implement a standardized approach to "hand off" communications, including an opportunity to ask and respond to questions.
Goal 3	Improve the safety of using medications.
3C	Identify and, at a minimum, annually review a list of look-alike/sound-alike drugs used by the organization, and take action to prevent errors involving the interchange of these drugs.
3D	Label all medications, medication containers (for example, syringes, medicine cups, basins), or other solutions on and off the sterile field.
3E	**Reduce the likelihood of patient harm associated with the use of anticoagulation therapy.**
Goal 7	Reduce the risk of health care-associated infections.
7A	Comply with current **World Health Organization (WHO) Hand Hygiene Guidelines** or Centers for Disease Control and Prevention (CDC) hand hygiene guidelines.
7B	Manage as sentinel events all identified cases of unanticipated death or major permanent

loss of function associated with a health care-associated infection.

Goal 8	Accurately and completely reconcile medications across the continuum of care.
8A	There is a process for comparing the patient’s current medications with those ordered for the patient while under the care of the organization.
8B	A complete list of the patient’s medications is communicated to the next provider of service when a patient is referred or transferred to another setting, service, practitioner or level of care within or outside the organization. The complete list of medications is also provided to the patient on discharge from the facility.
Goal 9	Reduce the risk of patient harm resulting from falls.
9B	Implement a fall reduction program including an evaluation of the effectiveness of the program.
Goal 13	Encourage patients’ active involvement in their own care as a patient safety strategy.
13A	Define and communicate the means for patients and their families to report concerns about safety and encourage them to do so.
Goal 16	**Improve recognition and response to changes in a patient’s condition.**
16A	**The organization selects a suitable method that enables health care staff members to directly request additional assistance from a specially trained individual(s) when the patient’s condition appears to be worsening.**

APPENDIX E

NATIONAL QUALITY FOUNDATION SET OF SAFE PRACTICES - 2006

NQF-Endorsed™ Set of Safe Practices* - 2006

1. Create and sustain a healthcare culture of safety.

    Element 1: Leadership structures and systems must be established to ensure that there is organization-wide awareness of patient safety performance gaps, that there is direct accountability of leaders for those gaps, that an adequate investment is made in performance improvement abilities, and that actions are taken to assure the safe care of every patient served.
    Element 2: Healthcare organizations must measure their culture, provide feedback to the leadership and staff, and undertake interventions that will reduce patient safety risk.
    Element 3: Healthcare organizations must establish a proactive, systematic, and organization-wide approach to developing team-based care through teamwork training, skill building, and team led performance improvement interventions that reduce preventable harm to patients.
    Element 4: Healthcare organizations must systematically identify and mitigate patient safety risks and hazards with an integrated approach in order to continuously drive down preventable patient harm.

2. Ask each patient or legal surrogate to "teach back" in his or her own words key information about the proposed treatments or procedures for which he or she is being asked to provide informed consent.
3. Ensure that written documentation of the patient's preferences for life-sustaining treatments is prominently displayed in his or her chart.
4. Following serious unanticipated outcomes, including those that are clearly caused by systems failures, the patient and, as appropriate, the family should receive timely, transparent, and clear communication concerning what is known about the event.

5. Implement critical components of a well-designed nursing workforce that mutually reinforce patient safeguards, including the following:
    - a nurse staffing plan with evidence that it is adequately resourced and actively managed and that its effectiveness is regularly evaluated with respect to patient safety;
    - senior administrative nursing leaders, such as a chief nursing officer, as part of the hospital senior management team;
    - governance boards and senior administrative leaders that take accountability for reducing patient safety risks related to nurse staffing decisions and the provision of financial resources for nursing services; and
    - the provision of budget resources to support nursing staff in the ongoing acquisition and maintenance of professional knowledge and skills.
6. Ensure that non-nursing, direct care staffing levels are adequate, that the staff is competent, and that they have had adequate orientation, training, and education to perform their assigned direct care duties.
7. All patients in general intensive care units (ICUs) (both adult and pediatric) should be managed by physicians who have specific training and certification in critical care medicine ("critical care certified").
8. Ensure that care information is transmitted and appropriately documented in a timely manner and in a clearly understandable form to patients and to all of the patient's healthcare providers/ professionals, within and between care settings, who need that information in order to provide continued care.
9. For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person who is receiving the information record and read back the complete order or test result.
10. Implement standardized policies, processes, and systems to ensure the accurate labeling of radiographs, laboratory specimens, or other diagnostic studies so that the right study is labeled for the right patient at the right time.
11. A "discharge plan" must be prepared for each patient at the time of hospital discharge, and a concise discharge summary must be prepared for and relayed to the clinical caregiver accepting responsibility for postdischarge care in a timely manner. Organizations must ensure that there is confirmation of the receipt of the discharge information by the independent licensed practitioner who will assume responsibility for care after discharge.
12. Implement a computerized prescriber order entry (CPOE) system built upon the requisite foundation of re-engineered evidence-based care, an assurance of healthcare organization staff and independent practitioner readiness, and an integrated information technology infrastructure.
13. Standardize a list of "do not use" abbreviations, acronyms, symbols, and dose designations that cannot be used throughout the organization.
14. The healthcare organization must develop, reconcile, and communicate an accurate medication list throughout the continuum of care.

15. Pharmacists should actively participate in medication management systems by, at a minimum, working with other health professionals to select and maintain a formulary of medications chosen for safety and effectiveness, being available for consultation with prescribers on medication ordering, interpretation and review of medication orders, preparation of medications, assurance of the safe storage and availability of medications, dispensing of medications, and administration and monitoring of medications.

16. Standardize methods for the labeling and packaging of medications.
17. Identify all high alert drugs, and establish policies and processes to minimize the risks associated with the use of these drugs. At a minimum, such drugs should include intravenous adrenergic agonists and antagonists, chemotherapy agents, anticoagulants and anti-thrombotics, concentrated parenteral electrolytes, general anesthetics, neuromuscular blockers, insulin and oral hypoglycemics, and opiates.
18. Healthcare organizations should dispense medications, including parenterals, in unit-dose, or, when appropriate, in unit-of-use form, whenever possible.
19. Action should be taken to prevent ventilator-associated pneumonia by implementing ventilator bundle intervention practices.
20. Adhere to effective methods of preventing central venous catheter-associated bloodstream infections, and specify the requirements in explicit policies and procedures.
21. Prevent surgical site infections (SSIs) by implementing four components of care:
    - appropriate use of antibiotics;
    - appropriate hair removal;
    - maintenance of postoperative glucose control for patients undergoing major cardiac surgery; and
    - establishment of postoperative normothermia for patients undergoing colorectal surgery.
22. Comply with current Centers for Disease Control and Prevention (CDC) Hand Hygiene guidelines.
23. Annually, immunize healthcare workers and patients who should be immunized against influenza.
24. For high-risk elective cardiac procedures or other specified care, patients should be clearly informed of the likely reduced risk of an adverse outcome at treatment facilities that participate in clinical outcomes registries and that minimize the number of surgeons performing those procedures with the strongest volume-outcomes relationship.
25. Implement the Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery for all invasive procedures.
26. Evaluate each patient undergoing elective surgery for his or her risk of an acute ischemic perioperative cardiac event, and consider prophylactic treatment with beta blockers for patients who either:
    - 1. have required beta blockers to control symptoms of angina or have symptomatic arrhythmias or hypertension, or
    - 2. are at high cardiac risk owing to the finding of ischemia on preoperative testing and are undergoing vascular surgery.

27. Evaluate each patient upon admission, and regularly thereafter, for the risk of developing pressure ulcers. This evaluation should be repeated at regular intervals during care. Clinically appropriate preventive methods should be implemented consequent to this evaluation.
28. Evaluate each patient upon admission, and regularly thereafter, for the risk of developing venous thromboembolism/deep vein thrombosis (VTE/DVT). Utilize clinically appropriate, evidence-based methods of thromboprophylaxis.
29. Every patient on long-term oral anticoagulants should be monitored by a qualified health professional using a careful strategy to ensure the appropriate intensity of supervision.
30. Utilize validated protocols to evaluate patients who are at-risk for contrast media-induced renal failure, and utilize a clinically appropriate method for reducing the risk of renal injury based on the patient's kidney function evaluation.

APPENDIX F

THE HOSPITAL AS A COMPLEX SYSTEM AND CULTURE

"After having thus successively taken each member of the community in its powerful grasp, and fashioned them at will, the supreme power then extends its arm over the whole community. It covers the surface of society with a network of small complicated rules, minute and uniform, through which the most original minds and the most energetic characters cannot penetrate, to rise above the crowd. The will of man is not shattered, but softened, bent, and guided: men are seldom forced by it to act, but they are constantly restrained from acting: such a power does not destroy, but it prevents existence; it does not tyrannize, but it compresses, enervates, extinguishes, and stupefies a people, till each nation is reduced to nothing better than a flock of timid and industrious animals, of which the government is the shepherd."

Alexis de Tocqueville

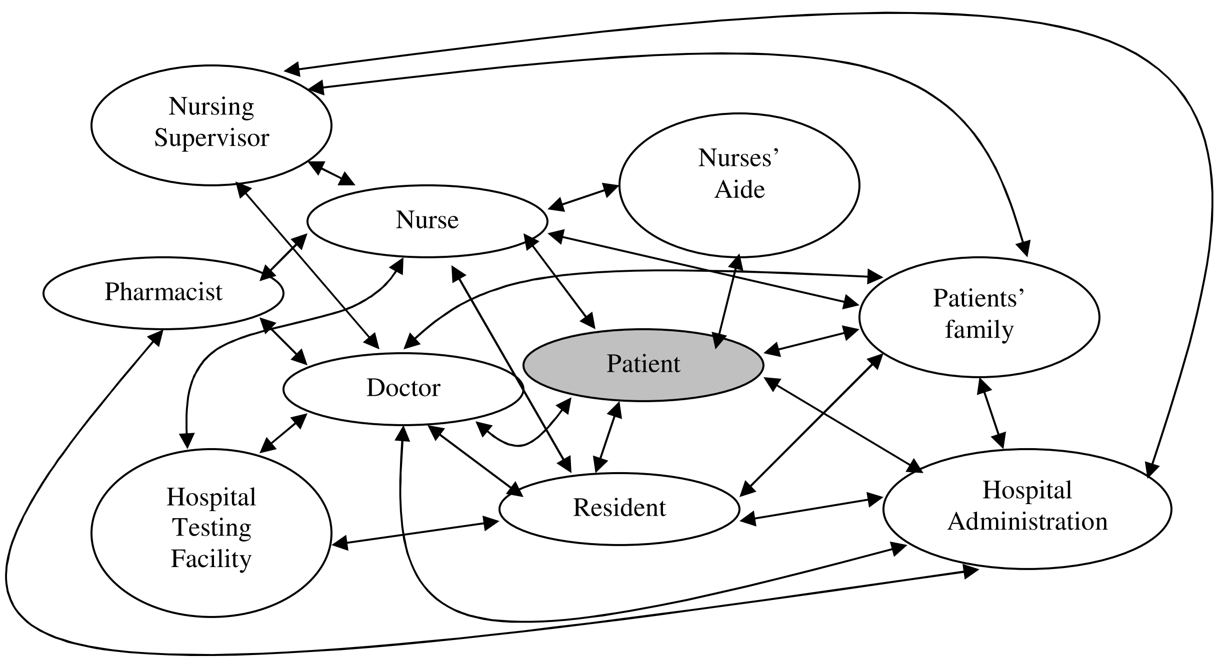
This appendix discusses aspects of changing organizations for purposes of improving performance. The appendix supplements several of the important issues discussed in this thesis, particularly in regard to the modified rounding procedure that has recently been implemented by the hospital (see Appendix C).

Because of the large number of subunits and individuals involved in a patient's care in the hospital, the multiple tasks which they must perform and requirements that those subunits and individuals must meet, the hospital can be considered a complex system. Perrow (1999) argues that when a complex system also has tight coupling (that is, when the effect of an action in one part of a system has an immediate, or almost immediate effect on another part of the system), certain classes of potential adverse events, called <u>normal accidents</u>, are inherent within the system[19]. Roberto (2002) provided a more detailed definition of coupling, which hw defined as: *"..one breakdown triggers a series of other problems. Tightly coupled systems have four characteristics: time-dependent processes, a fairly rigid sequence of activities, one dominant path to achieving the goal, and very little slack[20]."* This definition fits the nature of hospital operations and interactions. The hospital structure includes various nursing units and testing facilities having multiple communication links between doctors, nurses and patients who interface with numerous computer systems and highly sophisticated medical equipment while dealing with patients who have complicated and time varying medical needs. Further, the multiple interactions and communication paths that may form, breakdown and reform in rapid succession create a configuration where tight coupling between caregivers and patients exist. This structure provides the opportunity for various adverse events to occur, and because of the various connections and communication channels that exist between groups, makes it sometimes difficult to identify the optimum means to eliminate the risk of adverse events. Figure F-1 shows a representation of the complexity that exists in the communication networks between the various individuals and groups in the hospital. This figure provides a conceptual overview for how poor or inadequate communication between members of the hospital staff, or between the patient and hospital staff may lead to potentially increased risk for the patient. The requirement that effective and timely transmittal, receipt and understanding of communication between all these individuals and groups must occur indicates how important it is that all groups have a concise, reliable summary of the information relating to the patient. This information includes medical and fall history, sensitivities to drugs, test results, etc. In addition, there must be mechanisms and procedures to ensure that accurate communication occurs between

[19] Perrow (1999) provided the following definition of a normal accident, "If interactive complexity and tight coupling – system characteristics – inevitably will produce an accident, I believe we are justified in calling it a normal accident, or a system accident. The odd term normal accident is meant to signal that, given the system characteristics, multiple and unexpected interactions of failures are inevitable."

[20] The term slack means that there is: (1) limited time between an event that commences a system failure and the actual failure itself. The less slack, the less time an operator has to recognize, properly respond and correct a failing system condition.

personnel in different medical groups. Some of these communication pathways must be responded to rapidly (for example, a medication request from the patient to the staff nurse), while others (such as an administrative directive to the pharmacy department concerning how to ensure proper records are kept for medication requests) may be addressed over a long period of time. System personnel must have the ability to recognize which communication must be responded to rapidly while others may be delayed. This prioritization must be quickly understood, recognized and acted on.

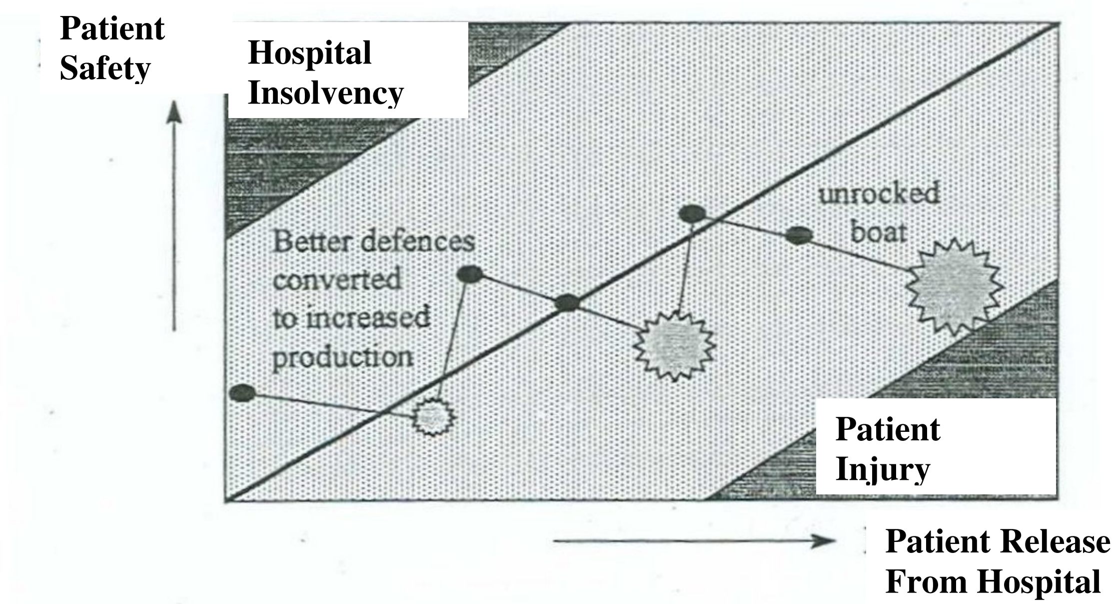


(Arrows represent communication links between groups and individuals)

Figure F-1. Example of Complexity and Communication Coupling in a Hospital Setting

Reason (2002) argues that complex systems constantly struggle to balance the conflicting demands of production and safety. In the hospital environment "production" can be defined as ensuring that all patients are provided a satisfactory level of care and oversight, without letting any patient or concern degrade the operation of the system. Reason points out that organizations tend to follow a path through what he called "safety space" shown in Figure F-2. Safety space defines that envelope of operations where (for the example of a hospital) the safety of all the patients is maximized, and yet excessive time and effort is not expended on either too much safety[21] (thereby potentially degrading the care for some patients due to providing excessive care and time to another set of patients), or on production (e.g., trying to end a patient's stay too early for purposes of reducing financial pressure on the hospital). The competing tensions between such operations create a time dependent variation in patient care and may make hospital care non-optimal. Without having developed sophisticated metrics that enable the system to be finely tuned to ensure that neither too much patient production or safety is emphasized, it is possible the system may fall into a situation of not caring sufficiently for all the patients they have, due to focusing too many resources on a subset of at-risk patients (thus increasing the risk of adverse events among the patient population which is not at-risk), or not providing sufficient resources to the patients due to competing financial pressures (thus also potentially increasing the number of adverse events). The consequence of failing to remain within this safety space, is to increase the risk of adverse events (such as patient falls, or medication errors) that can lead to and include the death of a patient.

[21] Although the concept of having too much patient safety may appear to be counterintuitive, it makes sense when the competing requirements for the care of a unit of patients are considered. With a limited number of caregivers on a unit, the more time and effort spent on one patient, means that the other patients will have a smaller amount of time and care provided. The optimum time provided between patients (who have different care requirements) on a unit is most likely determined based on the experience of the medical staff. The assessment of the staff on the unit is a constantly adapting and adjusting process that balances available resources against daily changing patient population and needs. The assignment of resources to a patient depends on the patient's condition, other patient demands, the experience of the unit supervisor and the staff. The successful assessment that worked one day may not be appropriate the next.



From Reason (2002). Managing the Risks of Organizational Accidents, Ashgate Publishing Limited, James Reason

Figure F-2. Progression through Safety Space

The greatest difficulty in Reason's formulation is that there are few metrics that can be used to identify when an organization is approaching an unacceptable boundary in its safety space. The defenses against an approach to the acceptable edge of safety space consists of items such as training, procedures, learning from past failures or previous "near misses" where the system did not fail, but might have if only one other error or mishap had occurred in a particular sequence of events. Another defense is to closely monitor trends in patient care and try and discern whether the system may be approaching a dangerous region, and if so, to adjust the system to avoid that potential problem (for example, if an increase in patient falls appears to be correlated with providing a certain narcotic early in the evening prior to the patient sleeping, then the action to be taken should be to reduce providing the narcotic or determine if the narcotic could be given later in the evening closer to the time the patient is scheduled to go to sleep).

An example of possible metrics presented in this thesis that provides some assessment of an impeding problem are the upper control limits (UCLs) and trends of the moving average that were presented for the unit fall rates (see Figures 7 through 16 in Section 6.1.2). By observing monthly data values and whether they are trending toward the UCL, as well as trends in the moving average may provide the hospital staff with a metric that may help identify potential problems that are occurring or developing in a particular unit (for example see Figure 11 for unit 4M in Section 6.1.2).

Creating a system that can effectively respond to changing conditions is a challenging effort. Tucker and Edmondson (2003) indicate it is difficult for hospital environments to create conditions to allow productive changes to be made to the environment, and therefore difficult to adjust and respond to these varying conditions. Specifically, they state, "*Our study shows that it is difficult for hospital workers to use problems as opportunities for improvements. The dynamic pattern described in this article is not unique to hospitals, although it may be exaggerated in health care by task variability, the extreme time pressure faced by workers, and the increasing cost pressures faced by hospitals….By reframing workers' perceptions of failures from sources of frustration to sources of learning, managers can engage employees in system improvement efforts that would otherwise not occur.*" An example of such a reframing of employee perceptions was the formation of the Patient Fall Committee at the hospital that is described in Section 1.4. This committee attempts to obtain input from a variety of health care groups and develop methods to reduce patient fall rates. More importantly, it brings together hospital staff from a number of different units to discuss what has been shown to be successful and what has not. This consideration of different ideas from different teams of hospital staff provides a greater variety of perspectives which increase the chances for determining improved methods of patient care. Further, with the inclusion of a number of staff personnel from a variety of different units, it would be expected that when the committee makes a decision to modify procedures, those decisions would have a greater buy-in on the part of the hospital staff.

An example of the effect described in the Tucker and Edmundson (2003) article is the issue of organizational focus and emphasis. While it would generally be argued that the primary overriding purpose of all organizations within a hospital should be directed to ensuring the best health care be provided for the patients, often subunits within the system have competing demands. These demands include, but are not limited to; satisfying administrative requirements, satisfying internal and external audit and review demands, addressing discipline problems (which can be related to patient care), dealing with intergroup or interpersonal conflicts and power struggles.[22] All complex organizations have to deal with these types of issues that are not considered part of their primary mission.[23] But in Figure F-3, the difference between the ideal system state and the actual system reality becomes apparent. It should be understood that the actual state of the system may vary significantly over time, such that competing demands to the primary goal may become greater or smaller.

[22] While some of these items may be actually a result of previous legal efforts to improve patient care, the processing of a large number of forms or complying with a myriad of federal and state regulations can become a process where the issue of patient safety can lose it primary focus, and the form or regulation dominates the thinking of the person working on it. In other words, the completion of a hospital form or satisfying a regulation becomes the focus of the medical personnel, instead of care for the patient. This process related to the quote from Alexis de Tocqueville at the start of this appendix.

[23] Sagan (1993) describes highly reliable systems as those that have four specific attributes: (1) a primary message that overrides all others that describes the purpose of the system, (2) appropriate system redundancy, (3) a reliability culture that is expressed by a centralized training process, and (4) effective organizational learning. However, normal accident theorists, such as Perrow (1999) have argued that each of those aspects of a system is weakened in an actual system. Any organization that states it has a primary message or purpose also has multiple secondary messages, which may at times override the primary message. For example, the FAA has as its primary message “passenger safety,” yet that message contends with issues such as timely transport of people and cargo and having an air transport system whose cost is not so exorbitant that no one would use it. These secondary messages impact the primary message whether admitted by the system or not. Similar constraints exist for each of the other system attributes.

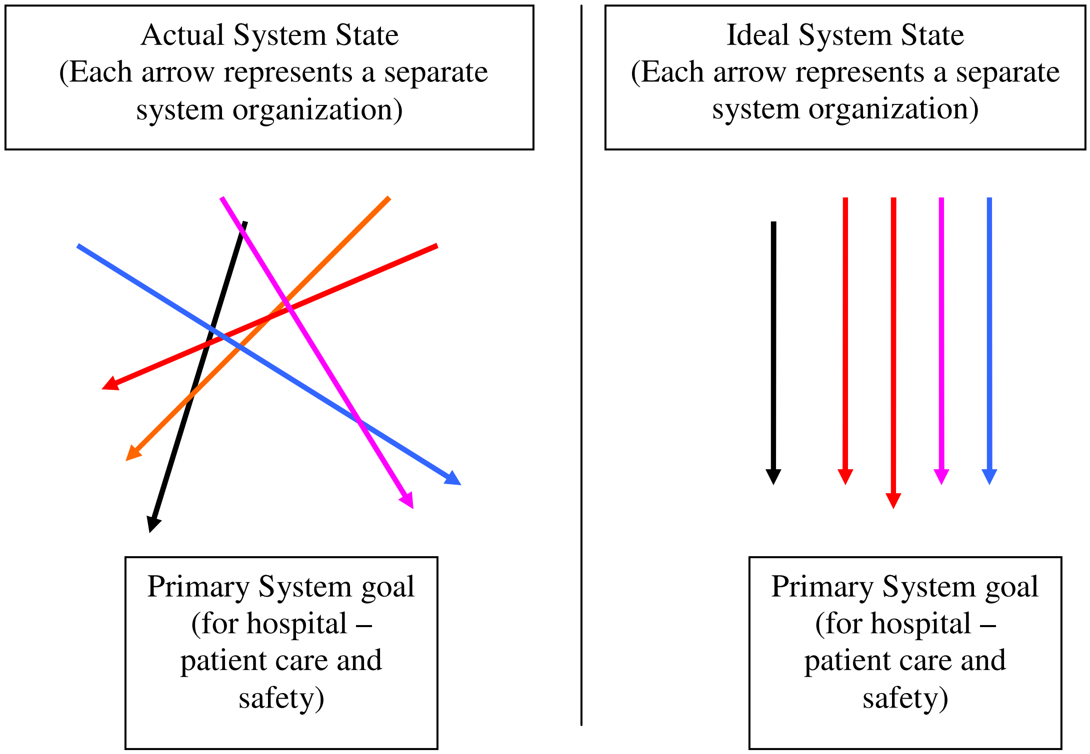


Figure F-3. Ideal versus Actual State of Complex System to Stated Primary Goal

Further, a hospital contains a culture that approaches issues using methods that are consistent with its history and outlook. A "medical" outlook may differ significantly from other types of cultures. Sexton et al (2000) describes a cross sectional survey and results from a questionnaire of how pilots and several types of doctors perceive that stress affects their performance and how teamwork is viewed in their professions. In response to the question, "Even when fatigued, I perform effectively during critical times," 60% of all medical respondents agreed, while only 26% of pilots agreed. In response to the statement, "Junior team members should not question the decision made by senior team members," 97% of all pilots disagreed with the statement, while only 58% of the surgical residents disagreed. Such differences in responses indicate significant cultural differences in outlook between aviation and medical personnel, which are shaped by the history of their professions, the view each profession has of the consequences of potential failure, and the ability of the profession to accept personal failures or errors. These particular cultural aspects of an organization can produce potential problems if the culture creates a climate where the individuals within it come to believe that taking action is to be avoided, even when dire consequences may result from not taking actions.

The concept of structurally induced inaction described by Snook and Connor, see Starbuck and Farjoun (2005) is an example of medical failure due to a highly trained medical team allowing its collective judgment to be overridden by its inability to take charge of the care of a patient whose primary caregiver was not physically present, but who was believed, by the members of the medical team present at the patient's bedside, to be controlling care through periodic phone calls. Even though the patient in the room where the team was working experienced continuous epileptic seizures and a dangerously deteriorating physical condition, not one of the medical personnel present took charge of the situation and overrode the perceived control of the primary caregiver who was not physically present. Systems that truncate or limit personal initiative through overly restrictive procedures can produce a much less effective and less safe system.

Finally, hospitals, as in other complex organizations, have to deal with coupling effects between units. The ability of a hospital to respond to a successful strategy or procedural change performed on one unit will indicate how successful the hospital will be in creating rapid and effective coupling between units. The ability to recognize and implement successful strategies, while discarding less successful strategies is a measure of how effective the hospital organization is at encouraging and sustaining improvement over time. Another way to describe this process is that in a poorly-run organization, subunits operate with little or no connection with other units, while well-run organizations operate attempting to improve operations continuously throughout the organization. The more tightly coupled the organization is the more likely it will be in selecting and implementing successful strategies if it has developed a reliable working culture.[24] As mentioned previously, the hospital has mechanisms for recognizing and implementing these successful strategies, such as the previously mentioned Patient Safety Committee and the Patient Fall Committee.

[24] If an organization has not developed a reliable working culture, the tight coupling between subunits can be the initiators of system-wide failures. See Snook (2000) concerning the discussion of the theory of Practical Drift, and the effect of tight coupling in a system that has failed to ensure an organization wide consistency between subunits. This effect is discussed in more detail in Appendix G.

APPENDIX G

CULTURAL CHANGE IN COMPLEX ORGANIZATIONS HAVING MULTIPLE SUBCULTURES AND THE EFFECT OF ORGANIZATIONAL DRIFT

And still the Weaver plies his loom, whose warp
and woof is wretched Man
Weaving th' unpattern'd dark design, so dark we
doubt is owns a plan.

-The Kasîdah of Hâjî Abdû al-Yazdi

As discussed in Section 3.0 and Appendix F a hospital is a complex system with is own primary culture and secondary subcultures that operates according to sets of procedures and protocols to achieve its primary goal (providing the best care for patients in their charge), while at the same time dealing with other conflicting (but important) requirements, such as financial constraints or personnel issues. As in any complex system the hospital by its very nature has multiple departments, such as pharmacy, radiology, serology, etc. In addition, the hospital has a number of different patient care units as shown in Table 10. This table showed that there were eight major units and two smaller ones (CVU and ICU). Each of these units can be considered a subculture within the hospital-wide culture. And because of the combination of these individual unit cultures and the various other organizations which interact with them (hospital administration, doctors, rehabilitation, the pharmacy department, hospital facilities, etc.) the ability to both understand the resulting organization and effect positive change in the hospital performance is a difficult process. While work in the hospital is to be performed following a standardized set of rules and protocols, it is probable that individual units, because of the particular requirements of patient load, supervisory and staffing experience, and equipment availability will operate somewhat differently from each other. Further, the hospital staff that works in these units will develop their own methods for achieving their primary goal.

So with these limitations understood, how can existing healthcare organizations act to significantly improve themselves?

Tucker and Edmondson (2003) examined how different units handled the problems which arose during the performance of patient care. The approaches were generally focused on the immediate requirement to obtain needed equipment or satisfy a deficiency that suddenly arose. The hospital staff found it difficult to try and address long term solutions for these types of problems because hospital staff and supervisory personnel were consumed with the attempt to address their primary task of patient care which, more often than not required an immediate response. They had no time to try and improve a process, they were in a position where they were running as fast as they could just to stay in place.

Committees like the existing patient safety committee and the patient fall committee formed at the hospital could be a mechanism by which the hospital would attempt to create solutions to systemic long-term problems. Input would come from the individual units and modified procedures would come form these committees that should include members from the various units.

Figure G-1 provides a figure showing the impact of unit performance on overarching hospital rules, with a feedback loop allowing problems in individual units to be addressed by performance and patient care improvement committees (such as the patient fall committee).

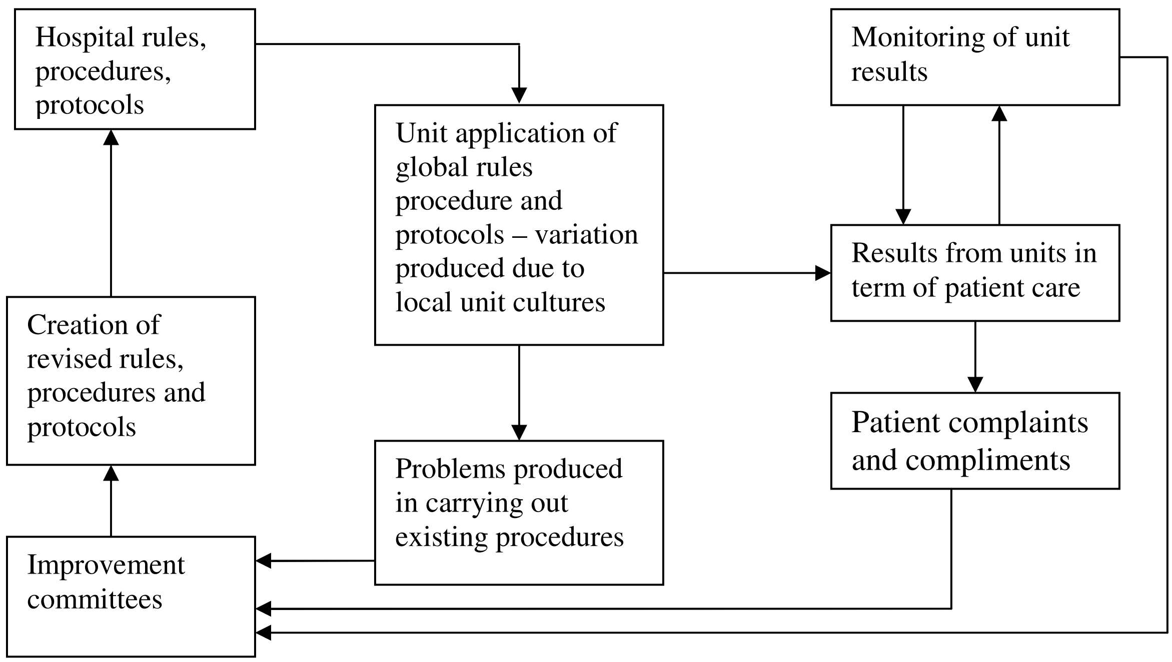


Figure G-1. Interplay of Global and Local Rules and Procedures in a Hospital

One way this figure can be viewed is that the feedback loop is simply a method to try and (1) improve the overall hospital patient care, and (2) make the individual unit cultures conform to the desired hospital culture. However, it is expected that the individual unit subcultures will continue to have their own character due to the insular nature that results from the formation of such cultures. The performance of these subcultures depend on the teams that are formed and how they operate.

Snook (2000) described a process by which military crews are formed by the application of "overlapping sheaths of information," that enables the individuals to perform their tasks. Figure G-2 displays this military example of "overlapping sheaths of information." The outermost sheath (or shell) in Figure G-2 includes basic military training (customs and fundamental authority). The next inner shell includes the specific rules and regulations associated with the specific organization (or unit) to which the crew is assigned (e.g., rules of engagement). The next inner shell describes the information required for effective crew formation and operation within the organization (e.g., mission briefings), while the center shell provides the information required by the crew to perform specific missions within the organization (e.g., oral orders).

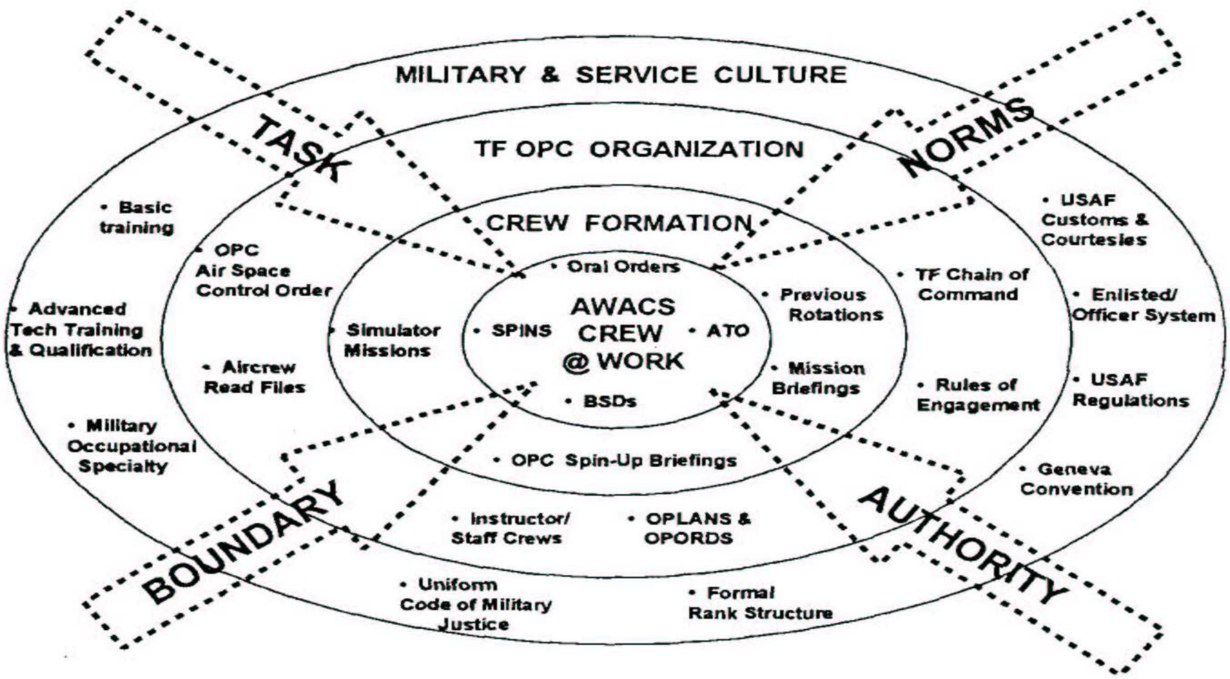


Figure G-2. Organizational Shells

This figure G-2 was adapted from Ginnett (1987). A similar structure could be developed for the formation of medical teams for specific units (or for that matter the training of engineers, lawyers, or other professions). As training for individuals to be part of a unit progress, each overlapping sheath of information carries them closer and closer towards the culture of the subunit, which is the group to which the individual belongs, and from which he or she receives their most immediate positive or negative signals on his or her performance. From these signals an individual leans how to operate effectively in their local environment. The important result from this figure is the consequence of how, as additional information is provided to the individual, they become prepared for their local environment task. However, it is possible that there exists a tension, in that the information provided in the inner shells override the information previously provided in the outer shells (such as the global rules and regulations of the hospital), thus weakening the information provided in the outer shells.

Snook (2000) also argued that individuals in different subunits in a complex organization may think and act differently because of the environments in which they must perform their tasks. These differences were described by Lawrence and Lorsch (1967) as “orientations.” Their model contained three specific orientations: (1) orientations to goals, (2) orientation to time, and (3) interpersonal orientations. These different orientations when considering subcultures within an organization may end up producing less effective integration between the different subunits. As one example, while important requests for medication must go through the pharmacy, the need to respond to those requests for the pharmacist cannot be the same as the hospital staff who are attempting to treat a patient who is experiencing a major medical complication. In Starbuck and Farjoun (2005) Chapter 10, a situation arose with a patient, a young boy, who was experiencing epileptic seizures while directions for treatment was being received from the primary doctor who was not physically present at the patient’s bedside, and thus was not able to observe the physical situation of her patient. In effect, the groups of medical personnel, one group at the patient’s bedside, and one on the phone with the first group, saw the medical condition of the patient completely differently.

The point of this discussion is that subcultures, while often being able to operate independently from other units for periods of time, eventually will become closely linked to other components of the larger organization. When that tighter coupling occurs, these differences in orientation may adversely affect their ability to operate effectively. For example, if one unit believes a primary cause of patient falls is due to one factor, while another subunit believes a primary cause is another factor their differing response to the cause may adversely affect performance in one or both units. This effect of subunit development and operation may explain some of the variation that is observed in Figures 7 through 16 (Section 6.1.2) which shows the individual unit fall rate. While some units appear to have similar yearly cyclic behavior based on the moving average data (e.g., 2MR, TCU and 4M), others (e.g., 3CR, 3M and 5M) have little or none of this behavior.

The operation and outcomes of complex systems such as hospitals may sometimes be made to appear understandable through the use of collecting and analyzing specific data (e.g., unit fall rates, or distribution of the age of patients who fall), however this understanding may be an illusion. Explaining the specific behavior of data, such as the fall information for specific units (compare the varying falls rates, at the end of the collected data in 2007 for units 4M (Figure 11) and 5M (Figure 12) requires perhaps more information than the system can collect or assess[25]. There are reasons for such behavior, but how successful a system may be in determining what the causes of those different behaviors is another matter. No matter how much data may be collected or what type of complex process may be instituted, there will always be some behavior and aspects of the system's operation that are hidden or almost impossible to undercover.

A method for producing reliable operation in such a complex and demanding system as a hospital is described by Weick (1987). He states, *"…accidents[26] occur because the humans who operate and manage complex systems are themselves not sufficiently complex to sense and anticipate the problems generated by those systems. This is a problem of "requisite variety," because the variety that exists in the system to be managed exceeds the variety in the people who must regulate it. When people have less variety than is requisite to cope with the system, they miss important information, their diagnoses are incomplete, and their remedies are short-sighted and can magnify rather than reduce a problem."* Roberto (2002) describes the

[25] The system here includes the people who operate within the system.
[26] In the context of this report, "accidents" can be equated to "adverse events."

failure of a mountain climbing expedition on Mt. Everest in 1996 that mirrors aspects of the complexity issued raised by Weick. As a result of a number of small interlocking problems and delays experienced by the groups climbing to the summit, the previously agreed time at which they were to descend to their camp was exceeded. The leaders of the group had been overstressed by the problems that occurred prior to the ascent, as well as being afflicted with overconfidence in their own abilities to take their group to the summit and safety return them to camp. Once the group members had exceeded they previously agreed turn back time, many members were caught in a storm, resulting in the death of five members, including the two leaders.

Weick's argues that this type of failure can be mitigated by inculcating the culture with a sense of intense, constant self-questioning on the part of the individuals in the system. That questioning, in effect searching for potential failure paths in the system, can aid in allowing the people in the system to more effectively see the complexity that exists in the systems in which they operate.

Snook (2000) also argues that within constant questioning and searching for potential failure modes, the best designed system can easily drift from its originally designed structure and operating characteristics and drift toward potential failure modes. He proposes a theory of behavior called "Practical Drift," explaining how all complex systems are subject to this type of failure. Snook defines practical drift as "A Slow, Steady, Uncoupling of Practice from Procedure." Figure G-3 presents a visual description of this process:

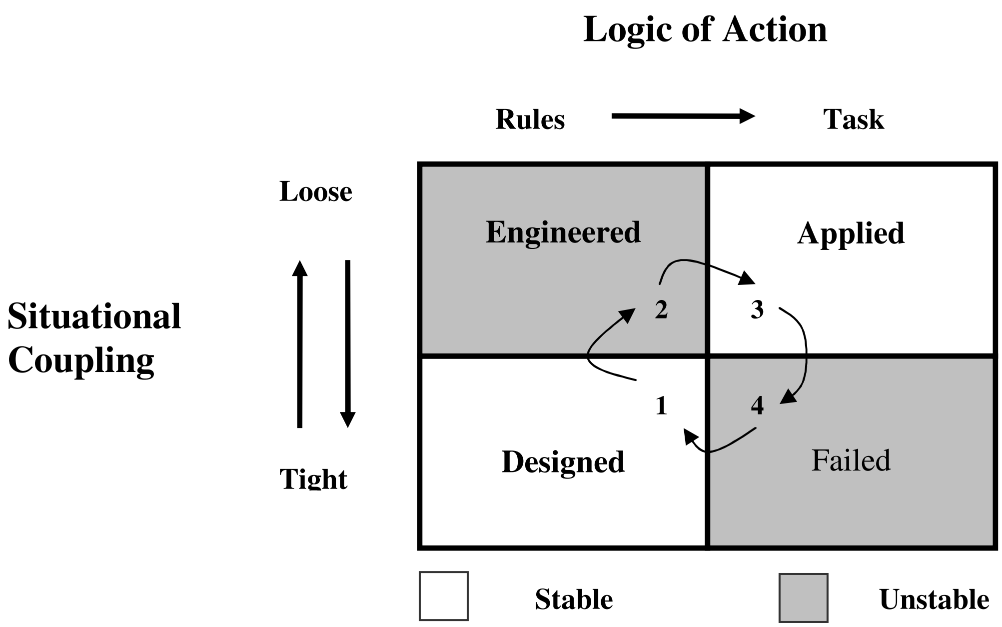


Figure G-3. Practical Drift

The left axis "Situational Coupling" is the indication of how strongly the subunits within the organization are connected to one another. The top axis "Logic of Action," represents whether the effort in the system are driven by previously developed and organization-wide rules or is driven by task-based constraints. In other words are the people in the system operating according to previously laid out rules to accomplish their task, or modifying or ignoring rules to accomplish their tasks. The description of the process proceeds from the lower left quadrant to the lower right quadrant. A description of the quadrants follow:

- Quadrant 1 represents the organization as designed - global rules are developed to accomplish tasks. The system is tightly coupled and because of the global rules everyone knows what is expected of them. There are no subcultures, and since the system has just been designed, there is no existing experience to substitute for the global rules.

- Quadrant 2 - An organization as initially operating - in most cases subunits operated in an uncoupled mode, because with the implementation of the system into the real world, physical separation of the system subunits occurs, causing a process toward loose coupling. However, the system continues to operate using globally based rules, because again it has no, or little, experience base to indicate that the global rules are deficient.
- Quadrant 3 - represents transformation to practical operation of the organization. Overtime local, efficient, task-based developed experience begins to replace the use of some of the originally designed global system rules. The system has now developed its own local experience, which has overridden, to some extent, the globally based rules developed at the time of the system design. These changes may or may not be reflected in modified global rules. The more subunits there are in the organization, the less likely that all these experienced-based changes will be reflected in a new set of global rules. The loose coupling remains, and overtime may increase as the subcultures in the system develop their own strategies to accomplish their tasks in a manner that is locally efficient.
- Quadrant 4 - The locally efficient, but loosely coupled rules don't match global demands of a situation in which subunits are now tightly coupled. Subunits which had little or no contact, may suddenly come into intimate contact, attempting to accomplish tasks in different manners. In this situation subunits may interact in ways that lead to failure of a portion or of the entire system.

Snook (2000) provides a visual description of a complex system and its aspects of operation:

"On a beautiful spring day the surface of Boston Harbor is dotted with dozens of sailboats. From the stern of each boat, from the perspective of each captain, progress is technically rational – there are desired destinations and captains maneuver their boats accordingly. However, from the perspective of an airline passenger on final approach to Logan Airport, the paths struck by hundreds of boats look chaotic and random; boats appear to be drifting in all directions. From the perspective of each captain, progress could be described as practical sailing – the result of continuous intelligent adjustments and adaptations to changing local conditions and goals. From the global perspective of 10,000 feet, it appears that no one is in charge and boat traffic seems to be drifting out of control."

A similar behavior can be argued to occur within hospitals. Even if those operations do not result in catastrophic failure resulting in patient harm or death, there is a constant shifting and movement of processes, procedures, operations and staff. However, the belief that administrators and supervisors have a more comprehensive understanding of the operations under their cognizance than they actually do is an illusion[27]. That illusion may not be an overwhelming one, or necessarily dangerous, but in certain situations it may become dangerous. And recognition that they lack that knowledge is needed to avoid that illusion growing to a dangerous level.

Recognition that this illusion exists, is both the start of wisdom and recognition that all complex organizations contain impenetrable aspects that may, at a crucial moment, defeat the best attempts of those trying to understand and make sense of a particular system response they are unsure of. No matter how much time and effort is spent in trying to understand or avoid failures, some aspects of the organization will always remain a dark design, even to those who participated in its formation and have the greatest understanding of its inner workings.

[27] See for example, Feynman (1986), who discusses the observed differences in the assessed probabilities of shuttle rocket failures between administrators and engineers. Overtime administrators came to believe that the likelihood of rocket failure was much smaller than did engineers.

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