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THE IMPACT OF A NURSE-DRIVEN EVIDENCE-BASED DISCHARGE PLANNING
PROTOCOL ON ORGANIZATIONAL EFFICIENCY AND PATIENT SATISFACTION IN
PATIENTS WITH CARDIAC IMPLANTS

by

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A dissertation submitted in partial fulfillment of the requirements
for the degree of Doctor of Philosophy
in the College of Nursing
at the University of Central Florida
Orlando, Florida

Summer Term
2008

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ABSTRACT

Purpose: Healthcare organizations are mandated to improve quality and safety for patients while stressed with shorter lengths of stay, communication lapses between disciplines, and patient throughput issues that impede timely delivery of patient care. Nurses play a prominent role in the safe transition of patients from admission to discharge. Although nurses participate in discharge planning, limited research has addressed the role and outcomes of the registered nurse as a leader in the process. The aim of this study was determine if implementation of a nurse-driven discharge planning protocol for patients undergoing cardiac implant would result in improved organizational efficiencies, higher medication reconciliation rates, and higher patient satisfaction scores.

Methods: A two-group posttest experimental design was used to conduct the study. Informed consent was obtained from 53 individuals scheduled for a cardiac implant procedure. Subjects were randomly assigned to either a nurse-driven discharge planning intervention group or a control group. Post procedure, 46 subjects met inclusion criteria with half (n=23) assigned to each group. All subjects received traditional discharge planning services. The morning after the cardiac implant procedure, a specially trained registered nurse assessed subjects in the intervention for discharge readiness. Subjects in the intervention groups were then discharged under protocol orders by the intervention nurse after targeted physical assessment, review of the post procedure chest radiograph, and examination of the cardiac implant device function. The intervention nurse also provided patient education, discharge instructions, and conducted medication reconciliation. The day after discharge the principal

investigator conducted a scripted follow-up phone call to answer questions and monitor for post procedure complications. A Hospital Discharge Survey was administered during the subject's follow-up appointment.

Results: The majority of subjects were men, Caucasian, insured, and educated at the high school level or higher. Their average age was 73.5 ± 9.8 years. No significant differences between groups were noted for gender, type of insurance, education, or type of cardiac implant (chi-square); or age (t-test). A Mann-Whitney U test (one-tailed) found no significant difference in variable cost per case ($p=.437$) and actual charges ($p=.403$) between the intervention and control groups. Significant differences were found between groups for discharge satisfaction ($p=.05$) and the discharge perception of overall health ($p=.02$), with those in the intervention group reporting higher scores. Chi square analysis found no significant difference in 30-day readmission rates ($p=.520$). Using an independent samples t-test, those in the intervention group were discharged earlier ($p=.000$), had a lower length of stay ($p=.005$), and had higher rates of reconciled medications ($p=.000$). The odds of having all medications reconciled were significantly higher in the intervention group (odds ratio, 50.27; 95% CI, 5.62-450.2; $p=.000$).

Discussion/Implications: This is the first study to evaluate the role of the nurse as a clinical leader in patient throughput, discharge planning, and patient safety initiatives. A nurse driven discharge planning protocol resulted in earlier discharge times which can have a dramatic impact on patient throughput. The nurse driven protocol significantly reduced the likelihood of unreconciled medications at discharge and significantly increased patient satisfaction. Follow-up research is needed to determine if a registered

nurse can impact organizational efficiency and discharge safety in other patient populations.

ACKNOWLEDGMENTS

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LIST OF ACRONYMS/ABBREVIATIONS

AHRQ	Agency for Healthcare Research and Quality
BiV ICD	Biventricular Implantable Cardioverter Defibrillator
EBP	Evidence-Based Practice
EMAR	Electronic Medication Administration Record
EMR	Electronic Medical Record
ICD	Implantable Cardioverter Defibrillator
IHI	Institute for Healthcare Improvement
IOM	Institute of Medicine
IRN	Intervention Registered Nurse
LOS	Length of Stay
PI	Principal Investigator
PPM	Permanent Pacemaker
RN	Registered Nurse

CHAPTER ONE: THE PROBLEM

Introduction

Many healthcare organizations do not have processes in place derived from scientific evidence; therefore, nurse leaders are actively considering how they might best support evidence-based nursing practice from an organizational perspective. Organized efforts to promote evidence-based nursing practice are crucial if the benefits of research utilization are to become widespread within the health services arena (Foxcroft & Cole, 2005). With increasing demands to improve quality and patient safety in healthcare, organizations must develop policies and procedures that are based upon evidence and best practices. Nurse leaders, with the responsibility for the organization's largest number of employees, are challenged to improve patient safety and to create an organizational culture where positive patient outcomes and quality-centered patient care are priorities (King & Byers, 2007).

Nursing professionals play a critical role in patient safety and quality. The safe transition and hand off of care for patients before, during, and after hospitalization is a dangerous time (Anthony et al. 2005; Joint Commission, 2006). Healthcare organizations continue to struggle with shorter lengths of stay, communication lapses between disciplines, and patient flow issues that impede timely delivery of patient care. Nurses, with 24-hour responsibility for patient care and monitoring, play a prominent role in the safe transition of patients throughout the continuum of care. The aim of this study was to determine if an evidence-based nurse-driven discharge planning protocol

for patients status post cardiac implant placement can improve organizational efficiency, patient safety, and patient satisfaction.

Background

The issue of patient safety is one of the most significant challenges facing the American health care system (Agency for Healthcare Research and Quality [AHRQ], 2000). The 1999 Institute of Medicine report *To Error is Human: Building a Safer Healthcare System* estimates that as many as 44,000 to 98,000 people die in hospitals as a result of medical errors. More individuals die each year from adverse events in the delivery of health care than automobile accidents, workplace injuries, breast cancer, and acquired immunodeficiency syndrome (Institute of Medicine [IOM], 1999). Errors in healthcare are estimated to cost as much as \$37.6 billion per year, with \$17 billion of those costs associated with preventable errors (IOM, 1999). In 2001, the IOM released another report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, that describes a fragmented, inefficient system of care resulting in medical errors and unnecessary treatment and wasted resources. The IOM makes an urgent call for fundamental change to close the quality gap.

Public policy groups have responded to the IOM report with recommendations to reduce medical errors. The Joint Commission requires organizations seeking accreditation to meet a patient safety program set of standards. The Joint Commission continues to require that organizations seeking accreditation meet patient safety requirements and have published National Safety Goals (The Joint Commission, 2008). These goals include proper patient identification, communication among caregivers,

safety of using medications, reduce harm associated with healthcare associated infections, medication reconciliation, reduce the risk of patient harm from falls, reduce risk of surgical fires, prevent hospital acquired pressure ulcers, and improve the recognition and response to changes in a patient condition.

The National Quality Forum has published recommendations for key evidence-based safe practices. Healthcare organizations are required to report on these evidence-based practices to maintain accreditation and receive reimbursement from the Centers for Medicare and Medicaid Services. Additionally, several pay for performance movements are underway in the United States which provides incentives for safe care and adherence to evidence-based standards (Leape & Berwick, 2005).

Healthcare organizations are faced with the fact that patients suffer harm not only from their underlying disease or illness, but from adverse events arising from medical mismanagement (Basanta, 2003). State and public policy makers are responding to the IOM reports and are instituting new health care policies and regulatory requirements for organizations. In order to meet increased pressures to improve patient safety and quality, nurse leaders are challenged to create a culture whereby quality patient care is ubiquitous. Organizations must change to adapt to the evolution of ever-changing and evolving healthcare policies and regulatory requirements.

Health care institutions are mandated to improve quality and integrate technology to prevent medical errors. Payers are also required to implement patient safety and medical error reduction programs to improve quality. The current health care system is outmoded and incapable of providing consistent, quality care (Ortiz, Meyer, & Burstin, 2002). Technologic advances are costly to an already struggling health care system.

The average cost to a health care facility to install a computerized system is \$7.9 million and although the investment can generate significant savings, hospitals are hesitant to incur the cost (Nursing Executive Center, 2004).

Health care providers have an enormous investment in medical error reduction and promoting patient safety. Providers must move from a “blame-shame” mentality to a systems approach that views medical errors as a system failure rather than human error. All care decisions must be evidence-based, and many health care institutions struggle with practices buried in tradition and not based upon current research.

The transfer of patient care from an acute care facility to home is a high-risk process that involves many patient safety issues (Anthony et al. 2005). Numerous studies have evaluated the discharge planning process from an organizational and patient perspective (Preen et al., 2005; Dukkers, Ros, & Berns, 1999; Naylor & McCauley, 1999; Bowles, 2000; Lappe et al. 2004; Anthony et al. 2005). Despite the statement that “discharge planning starts on admission,” organizations continue to struggle with a discharge process that is fragmented, non-standardized, and lacks a multidisciplinary focus. While the discharge planning process is multidisciplinary by nature, the nurse plays a prominent role with 24-hour responsibility for care and monitoring of patients (Watts & Gardner, 2005).

The purpose of this study was to test the outcomes of a discharge planning protocol after cardiac implantation. The independent variable was a nurse-driven evidence-based discharge planning protocol. The dependent variables were medication reconciliation rates, 30-day readmission rates, discharge time, length of stay, variable

cost per case, and patient satisfaction scores. Conceptual and operational definitions of study variables are summarized in Table 1.

Table 1: Conceptual and Operational Definitions

Variable	Conceptual Definition	Operational Definition
Nurse-driven discharge planning protocol	A process involving the early assessment of anticipated patient care needs with the immediate goal of anticipating changes in patient care needs and a long term goal of insuring continuity of health care.	A process whereby an intervention registered nurse (IRN) provides patient education, medication reconciliation, and discharge instructions for patients status post cardiac implant placement.
Length of stay	A term used to measure the duration of a single episode of hospitalization.	Total time in hours and minutes from the time the research participant has completed the cardiac implant procedure to the time of discharge.
Variable cost per case	A cost associated that fluctuates directly with output charges	The variable cost per case associated with cardiac implant placement obtained from the healthcare organizations cost accounting system for each study participant.
Medication reconciliation	The process of identifying the most accurate list of all medications a patient is taking, including name, dosage, frequency, and route, and using this list to provide correct medications for patients in the healthcare system.	Percent of unreconciled medications at discharge.
Patient satisfaction	A patient's overall satisfaction with care provided at a healthcare organization.	The degree of patient satisfaction with the hospital discharge process as measured by the Hospital Discharge Survey.
30-day Readmission Rate	Patients who return to the hospital within 30 days of discharge.	Research participants readmitted to the healthcare organization post cardiac implant placement. Measured as the number of cardiac implant patients who returned to the hospital with 30 days of discharge.

Cardiac Implant

A cardiac implant is a surgically implanted device that helps to regulate a slow or erratic heartbeat (Vesty, Rasmusson, Hall, Schmitz & Brush, 2004; Allen, 2006). The three major types of implants include cardiac resynchronization therapy (CRT) pacemakers, implantable cardioverter defibrillators (ICDs), and standard pacemakers. CRT pacemakers are used to treat patients with heart failure. These devices send out electrical impulses that promote a normal heart rhythm and coordinate the contractions of the heart. ICDs are implanted to treat abnormal heart rhythms such as ventricular tachycardia and ventricular fibrillation. ICDs are helpful to patients at risk for sudden cardiac death which occurs when the heart suddenly goes into ventricular fibrillation. ICDs provide a shock to the heart that can prevent sudden cardiac death by jolting the hearts rhythm back to normal. Standard pacemakers are used to treat patients with heartbeats that are too slow. All of the above-described devices are not distinct devices. Many CRT pacemakers also function as ICDs or standard pacemakers (Vesty, Rasmusson, Hall, Schmitz & Brush, 2004). All three types of devices are categorized as cardiac implant devices.

No published studies have described the use of a nurse-driven discharge protocol and its effects on organizational efficiency, patient safety, and patient satisfaction for patients who receive cardiac implants. The purposes of this research study were to determine if a nurse-driven discharge planning protocol for short-stay cardiac patients status post cardiac implant placement reduces length of stay, reduces 30-day readmission rates, reduces variable cost per case, improves the process of discharge medication reconciliation, and increases patient satisfaction. Findings of this

research will assist in addressing gaps in knowledge that exist regarding discharge planning for a specific patient population from an organizational and patient perspective.

Assumptions

The underlying assumptions of this study were:

1. The study sample is representative of the general population of cardiac patients.
2. Specially trained registered nurse with expertise in cardiovascular care will be able to successfully assess, educate, and discharge patients after a cardiac implant procedure.
3. Specially trained registered nurses will follow the discharge protocol as outlined by the Principal Investigator.

Hypotheses

This study tested the following hypotheses:

Hypothesis 1: The implementation of a nurse-driven discharge planning protocol for patients undergoing a cardiac implant will result in reduced length of stay when compared to patients receiving traditional discharge planning services.

Hypothesis 2: The implementation of a nurse-driven discharge planning protocol for patients undergoing a cardiac implant will result in an earlier discharge time when compared to patients receiving traditional discharge planning services.

Hypothesis 3: The implementation of a nurse-driven discharge planning protocol for patients undergoing a cardiac implant will result in decreased variable cost per case when compared to patients receiving traditional discharge planning services.

Hypothesis 4: The implementation of a nurse-driven discharge planning protocol for patients undergoing a cardiac implant placement will result in reduced 30-day readmission rates when compared to patients receiving traditional discharge planning services.

Hypothesis 5: Patients who receive a nurse-driven discharge planning protocol will have lower rates of unreconciled medications at the time of discharge when compared to patients who receive traditional discharge planning services.

Hypothesis 6: The implementation of a nurse-driven discharge planning protocol for patients undergoing a cardiac implant will result in greater patient satisfaction scores related to discharge planning when compared to patient receiving traditional discharge planning services.

Summary

The results of this research may provide evidence to empower nurses to lead the way as a team leader in the discharge planning process. The use of an evidence-based nurse-driven discharge protocol has the potential to improve organizational efficiency, prevent adverse events, and improve patient satisfaction.

The research study is further described in the remainder of this document. Chapter 2 provides a review of the relevant literature and outlines the framework that guided the research study. Chapter 3 outlines the research methodology. Chapter 4 reports the results from the research study. Chapter 5 provides a discussion of the findings of the study as related to each research hypothesis.

CHAPTER TWO: REVIEW OF RELEVANT LITERATURE/Framework

This research examined the use of a nurse-driven evidence-based discharge protocol for patients status post-cardiac implant placement and its impact on organizational efficiency, patient safety, and patient satisfaction. There is a dearth of nursing research studies describing the implementation of a nurse-driven discharge protocol and its effects on these outcomes. This literature review summarizes relevant research related to patient safety, organizational efficiency, evidence-based practice, and discharge planning. The theoretical framework that guided the research is explained.

A search of relevant databases was conducted to identify research studies involving organizational effectiveness, patient throughput, patient safety, quality improvement, and discharge planning. Databases searched included Academic Search Premier, CINAHL, Health Source: Medline, Nursing/Academic Edition, PsycINFO, Proquest, EBM Reviews, Blackwell Synergy, and PubMed. Attempts were made to access unpublished material, and journal indices were checked for studies where the title and abstract met inclusion criteria. The databases were searched for the keywords- *evidence-based practice, patient safety, patient throughput, quality improvement, medication reconciliation, and discharge planning*. Studies must have been published in English between 1990 and 2007.

Patient Safety

The quality and safety of health care in the United States has become a major public health concern and the focus of significant research (Robinson et al., 2002).

Medical and medication errors and their resulting adverse consequences have impacted health care organizations for many years. The 1999 Institute of Medicine's (IOM) report on medical errors thrust the awareness of patient safety and medical errors to the forefront.

The IOM (1999) defines a medical error as a failure of a planned act to be completed as intended, or the use of a wrong design to achieve an aim. An adverse event is an injury caused by medical management rather than the patient's underlying condition. The types of medical errors include delivery of the wrong medication, diagnostic errors, equipment failure, hospital-acquired infections, blood transfusion-related injuries, and the misinterpretation of medical orders (AHRQ, 2000).

The issue of medical errors has been discussed in the literature long before the IOM's report. A growing body of research addressing the problem of medical errors emerged in the early 1990's with the work of Lucian Leape, M.D. and David Bates, M.D. (AHRQ, 2000). The Harvard Medical Practice Study (1991) reported the results of a population-based study of iatrogenic injury in hospitalized patients in the state of New York in 1984. Nearly 4% of patients suffered an injury that increased their length of stay or resulted in disability. Approximately 14% of the injuries were fatal, 69% of the injuries were due to avoidable errors (Leape et al., 1991; Brennan, 1991).

Leape (1994) postulated that high medical error rates are related to the culture of medicine. Practitioners strive for error-free practice and view errors as a failure of character. Error prevention strategies tend to focus on the individual rather than the system. Leape recommended that successful error prevention efforts must focus on root causes and system errors in design and performance. Errors are more often a function

of the systems in which people work. Poor system design makes errors difficult to detect (Leape, 1996).

Kim, An, Kim, and Yoon (2007) conducted an descriptive correlational study with 866 nurses at eight hospitals in Korea to describe nurses' perceptions of error reporting and patient safety culture in their hospitals. The Agency for Healthcare Research and Quality questionnaire on patient safety was used for the study. The authors concluded that a majority of nurses were uncomfortable reporting errors and patient safety issues in their working units. Nurses at the bedside expressed more concerns regarding patient safety than nurses who were older ($p < .01$) and those who work in management positions ($p < .01$). The authors concluded that a culture of patient safety and error reporting was not emphasized enough at Korean teaching hospitals and recommended the implementation of a non-punitive culture whereby individuals can openly discuss medical errors and potential hazards.

West and Reeves (2005) conducted a survey of nurses working at 20 London hospitals based on a prototype employee questionnaire developed in the United States. The aim was to investigate whether nurses experienced barriers to the delivery of care to address important patient concerns (physical comfort, emotional support, and coordination of care), and to describe which aspects of care was most affected when nurses lacked the required resources of time, tools, and training. Surveys from 2,880 nurses (47% response rate) were returned. The results indicated that nurses were aware of deficits in standards of care that are important to patients. The survey revealed that 64% of the nurses felt overworked and reported that they did not have time to perform essential nursing tasks, such as responding to patient's fears and anxieties,

and giving patients and relatives information. The authors concluded that the reporting of problems with quality and safety of care must go beyond the basics. The authors reported that nurses lacked the time, tools and training to deliver high quality care in London hospitals and recommended some low cost interventions such as training in social and interpersonal aspects of care to remove the barriers to patient-centered care.

Armstrong and Laschinger (2006) conducted an exploratory study using a predictive, non-experimental design to link the quality of nursing practice environments to a culture of patient safety. Kantor's theory of structural empowerment was used as a guiding framework. The Conditions of Work Effectiveness Questionnaire was used to survey nurses at a small community hospital. The authors utilized characteristics of the Magnet Recognition Program™ recognizing that nurses who worked at Magnet hospitals reported a higher level of empowerment and were more satisfied and reported higher quality nursing care. Magnet designation specifically recognizes nursing excellence and is the highest level of recognition a health care organization can receive for nursing professional practice (Lundmark & Hickey, 2007). Overall empowerment was found to be significantly positively related to all Magnet professional practice characteristics ($r = 0.316 - 0.612$), perceptions of patient safety culture ($r = 0.50$). The combination of structural empowerment and Magnet hospital characteristics was a significant predictor of staff nurses' perceptions of a patient safety climate in the organization. The authors concluded that nurse leaders have the ability to improve the level of patient safety in their organizational by creating an empowering professional practice environment for nurses.

Evidence-Based Practice

Putting research evidence into practice improves nursing and patient care outcomes (Valente, 2003). Conduct of research is a systematic approach to generate knowledge to ensure the highest possible quality of care. Research is crucial to the implementation of evidence-based practice. Nurses are expected to integrate the best clinical evidence when making decisions about an individual's care (Rogers, 2004).

Evidence-based practice (EBP) was initially derived from evidence-based medicine which was developed in Canada as a mechanism to teach medical students (Pape, 2003). Evidence-based practice is a more universal term intending to cover all disciplines within the healthcare arena. Ervin (2002) defines evidence-based nursing practice as practice in which nurses make clinical decisions using the best available research and other evidence that is reflected in approved policies, procedures, and clinical guidelines.

Professional nurses are responsible for working together with all members of the healthcare team to promote positive patient outcomes. Grossman and Bautista (2002) recommend collaboration to help healthcare organizations carry out quality improvement initiatives. Characteristics necessary for collaborative relationships include: equal knowledge and leadership, clear communication, accountability, flexibility, and ability to share recognition (Grossman & Bautista, 2002). Collaboration within the health care team is necessary to facilitate EBP.

Scott-Findley and Golden-Biddle (2005) argue that research must be focused from an organizational perspective rather than an individual perspective. They posit that a majority of individuals work in very complex organizational structures and that

organizational culture is an important determinant in research use and evidence-based practice. Healthcare professionals implicitly draw upon organizational culture and how it works to shape their work patterns and actions.

Regulatory agencies within the United States support efforts to improve quality and efficiency within the healthcare system by the use of evidence-based research in clinical practice settings (Pape, 2003). The focus on EBP has forced healthcare providers to steer away from intelligent guesswork and individual patient observations to determine the best possible actions required to care for patients. With increasing demands to improve quality and efficiency in healthcare, traditional procedures and practices must now be based upon evidence. Traditions can be difficult to change and barriers exist with the implementation and overall adherence to evidence-based guidelines.

Many nurses have difficulty modifying their nursing interventions to accommodate current nursing research evidence (Klassen, Karshmer, & Lile, 2002). McKenna, Ashton, and Keeney (2004) conducted a study to identify barriers to research utilization. As part of the study, they developed an instrument to measure barriers to evidence-based practice. A group of healthcare professionals including 356 general practitioners and 356 community nurses were randomly selected to take part in the study. The overall response rate was 65% (n = 462). They identified several barriers: limited relevance of research to practice, keeping up with the current changes in primary care , poor computer facilities, and difficulties influencing changes in primary care The study concluded that the need for continued support from nursing educators and clinical leaders is of paramount importance to primary care professionals and that education is

not effective without such support. Identification of barriers was a first step to changing the management of evidence-based practice.

Hicks et al. (1996) conducted a pilot survey to develop a diagnostic instrument to identify research-training needs within primary health care groups. Semi-structured interviews of six members of four primary health care teams were conducted along with the use of indirect data collection (repertory grid) to uncover deep-seated and unacknowledged views on the topic. The authors concluded that despite efforts to create a research based system there has been little success or wholehearted adoption of evidence-based care. An accurate tool for measurement of baseline attitudes and subsequent changes towards EBP is imperative.

Olade (2003) conducted a descriptive correlational study to identify the attitudes of nurses (n = 106) in rural practice settings towards nursing research, and assess relationships between their attitudes and other factors. Fewer than one-quarter of the nurses had a favorable attitude toward research. Isolation from nurse researchers created a barrier to research utilization. Olade (2003) concluded that the development of a favorable attitude among nurses to integrate evidence into practice must involve educators and administrators. Leaders in organizations must create collaborative strategies that emphasize the importance of EBP in the clinical setting.

Cowling, Newman, and Leigh (1999) conducted a qualitative study of 54 health care professionals to identify the individual and institutional obstacles to the adoption and practice evidence-based medicine and to develop a competency framework of the knowledge, skills and attitudes required for adoption to take place. They used a triangular approach of a review and synthesis of relevant literature, exploratory in-depth

interviews, fieldwork, and self-administered questionnaires. A competency framework was derived from the analysis of data. The authors identified the need for training in technical skills and research competencies to foster a change in practice and adoption of EBP. Five clusters of competencies along with behavioral outcomes were recommended: personal attributes, interpersonal skills, self-management skills, information management skills, and technical knowledge and ability. Recognition of information needs, literature-searching skills, critical appraisal, translation of research evidence, and implementation of research evidence were the behavioral outcomes desired in EBP.

Organizational Efficiency

A key issue facing health care organizations is how to maximize existing capacity to meet increasing patient volumes while maintaining operational efficiency and cost-effectiveness (Kobis & Kennedy, 2006). As of January 2008, the Joint Commission conducts system tracers to identify problems with patient flow. The rationale behind the new tracer is patient safety. Treatment delays, medical errors, and unsafe practices exist during times of patient congestion and can contribute to sentinel events (Joint Commission, 2008).

Emergency department overcrowding is closely related to patient throughput problems and creates a cascade of systemic problems caused by operational inefficiencies, inefficient processes, underutilized information technology systems and poor communication throughout the healthcare system (Scalise, 2006). Inpatient measures that affect patient throughput include length of stay for medical-surgical

patients, average patient admission and discharge time by nursing unit, avoidable days, percentage of patients that are outliers, inpatient bed utilization by hospital and nursing unit, and average bed turnaround time (Scalise, 2006).

Marathe, Wan, Zhang, and Sherin (2007) examined factors affecting the variation in technical and cost efficiency of community health centers (CHCs). The study was a non-experimental panel study of 493 CHCs with repeated measures of efficiency indicators for five years (n = 2,465 observations). The context-design-performance framework was used for the study. The framework looked at interrelationships among a health center's environment (context), organizational structure (design), and performance. The context variables included Medicare, poverty, physicians, minority, region, and rurality. The design variables included size of staff, staff mix, integration, financial resources, federal grants, and total revenue. The performance indicators included cost efficiency and technical efficiency. The researchers found that regardless of efficiency measures, efficiency was influenced more by contextual factors than organizational structure factors.

Vera and Kuntz (2007) analyzed cost and performance data from a database of 92 hospitals. They also obtained survey data from 43 chief executive officers (CEOs) of hospitals in a Germany to obtain information on organizational design. The hypothesis was that hospitals who exhibit a high degree of process orientation in their organization are more efficient than hospitals with a low degree of process orientation. The authors found that organizations with a high degree of process orientation had a moderate but significant effect on the efficiencies of hospitals. Practice implications outlined included

the importance of implementation rules and physician participation to create an adequate organizational culture.

Liu, Hobgood, and Brice (2007) conducted a retrospective study comparing emergency department (ED) flow for patients treated in a tertiary care facility during periods of ED overcrowding, defined as critical bed status and during times of normal patient volume. Charts of 118 patients were reviewed (61 critical bed status, 57 normal patient volume). During time of significant ED overcrowding, patients experienced their most significant delay in waiting for an inpatient bed. The authors recommended simple improvements in disposition, such as changes in hospital policy to provide accelerated admissions to inpatient units.

Welch, Jones, and Allen (2007) conducted a study in an effort to improve patient throughput. A retrospective analysis of real time data was collected on individual ED encounters captured by various hospital information systems. An integrated tracking system provided information on several data elements: available beds staffing, registration status, laboratory, radiology, orders, patient acuity, chief complaint, discharge cueing, consultations, waiting for room, and housekeeping. Outcome measures included census by hour of day, arrival by hour of day, average acuity by hour of day, radiology operations by hour of day, laboratory operations by hour of day, turnaround time by hour of day, and admission rate by hour of day. Data were analyzed for 39,704 ED encounters. The researchers identified patterns of ED census, acuity, operations, and throughput that varied with the time of day. The authors conclude that ED cycle data can help facilities anticipate resources needed and the services for efficient patient flow.

Discharge Planning

Due to changing reimbursement patterns and a shift from inpatient to outpatient care, lengths of stay are shortened and healthcare organizations are challenged to increase throughput to ensure a timely discharge. The transition of a patient from a healthcare organization to home is characterized as a high-risk process that can result in medical errors (Anthony et al. 2005). Traditionally, when patients are admitted to a healthcare facility, their primary care physician is responsible for all aspects of their hospital care. Healthcare organizations now deal with a changing model of patient care management in which patients are managed by a hospitalist service during their hospitalization. A hospitalist is a physician whose primary focus is the general medical care of hospitalized patients. Upon discharge from the hospital, care is transferred back to the primary care physician. Gaps in communication result and many primary care physicians do not receive information regarding their patients' hospitalization. Personal health information often times does not accompany patients as they transition to home or a clinic setting.

Anthony et al. (2005) conducted an in-depth process evaluation study to identify and address the sources of error at discharge. A battery of epidemiologic and quality control methods were used to provide a detailed process analysis. Methods used were probabilistic risk assessment, process mapping, qualitative analyses, failure mode and effects analysis, and root cause analysis. Taxonomy of errors at the time of discharge and several principles of a newly re-engineered hospital discharge process was created. Errors identified from a healthcare organization perspective included lapses in communication, inadequate patient education, medication error, lack of timely follow-up,

and a lapse in community services. Errors from a patient perspective included early post-discharge, drug/alcohol use, language/cultural barriers, medication non-adherence, and failure to keep the follow-up appointment. Errors from the clinician perspective included lab/test error, inappropriate discharge, inappropriate medication, and inadequate use of community resources (Anthony et al., 2005).

Based on the findings of the study, a new discharge process was recommended. Principles of the newly engineered discharge process include explicit delineation of roles and responsibilities; patient education that occurs during all phases of hospitalization; and information that flows easily from the primary care provider to the hospital team, among the hospital team, and back to the primary care provider. All information should be captured throughout the hospital stay, not only at the time of discharge. A comprehensive written discharge plan that addresses medications, therapies, dietary and other lifestyle modifications, follow-up care, patient education, and information about what to do if symptoms worsen must be included. Other principles include organizing and delivering all information regarding hospitalization to the primary care provider within 24 hours of discharge, and providing the patient access to discharge information in the patient's primary language and at the appropriate educational level. Waiting until the discharge order is written before beginning the discharge process is likely to increase errors, and efficient and safe hospital discharge is less likely if the case management staff only works the day shift (Anthony et al., 2005).

Preen et al. (2005) conducted a prospective, randomized, controlled clinical trial to determine the impact of a hospital-coordinated discharge plan on hospital length of

stay, quality of life (patient and provider) and satisfaction with discharge procedures. The participants (n=189) were randomly assigned to two groups recruited from respiratory, cardiovascular and general medical surgical wards in Western Australia. Intervention group participants received a discharge care plan completed before discharge that was sent to the patient's primary care provider and other community service providers for review. The control group received standard discharge care. Significant improvements were seen in discharge planning involvement (p=0.02), health services access (p=0.038), confidence with discharge procedures, and opinion of discharge based on previous experience for patients (p=0.004) in the intervention group. Improved mental quality of life was significantly improved from pre-discharge to 7 days post-discharge (p=0.003). Hospital length of stay showed no difference. The extent and speed of primary care provider and hospital communication were significantly improved (p=0.02) with the intervention. Outcomes beyond 7 days were not evaluated.

Naylor and McCauley (1999) conducted a secondary analysis of data collected on 202 patients hospitalized with common medical and surgical cardiac diagnoses who completed a 24-week post-discharge follow up program that was part of a larger randomized, controlled trial. The intervention group received comprehensive discharge planning and home follow up by an advanced practice nurse for four weeks after discharge. The control group received usual care. Medical patients in the intervention group had fewer readmissions during the 24-week follow up and a reduced total number of days of re-hospitalization. There were fewer hospital readmissions in the surgical group when measured from discharge to six weeks. No differences in functional status were observed between the intervention and the control group. The findings suggested

high-risk elderly patients may benefit from a coordinated discharge planning and home follow-up by an advanced practice nurse.

Due to problems in transition from the hospital to home, a discharge liaison nurse role was created in the Netherlands. Forty-eight percent of the hospitals in the Netherlands employ a specialized discharge professional. Dukkers, Ros, and Berns (1999) conducted a nation-wide hospital survey in the Netherlands to explore the role and function of discharge professionals. The function differed between the hospitals and three profiles were identified: the organizational type, the advisory type, and the policy making type. The organizational type organized the discharge of the patient, assessed the need for community care, and planned the community care. The advisory type advised the hospital nurse on matters concerning discharge but did not organize the discharge itself. The policy-making type consulted with hospital, personnel, community care workers, and other health care professionals concerning the discharge process, formulated guidelines and provided information. Positive outcomes on the discharge preparation process were identified from the evaluation studies although the quality of the evaluation studies was poor. The authors recommended further substantial research to evaluate the discharge liaison role.

Lappe et al. (2004) conducted a nonrandomized, observational before-after study comparing patients before (1996-1998) and after (1999-2002) implementation of a discharge medication program at a multi-hospital system in Utah (total n=57,465). Patients were followed for up to one year. Measurement included prescription of indicated medications at hospital discharge, post-discharge death, or readmission. At one year, the prescription rate of indicated medications increased significantly to 90%

($p < 0.001$). At 1 year, unadjusted absolute event rates for readmission and death were 210 per 1000 person-years and 96 per 1000 person-years before the discharge medication program implementation, and 191 per 1000 person-years and 70 per 1000 person-years post implementation. The authors suggested that the implementation of a basic quality improvement program for cardiovascular patients was feasible and may be associated with decreased readmission rates and mortality.

Proctor, Wilcockson, Pearson, and Allgar (2001) conducted a combined mixed method study to identify factors leading to unsuccessful discharge. The study was retrospective and analyzed data from 1500 patient records. Unsuccessful discharge was defined as unplanned admission, readmission within 6 weeks of discharge or an extended length of stay. The authors explored the role of the patient/carer in negotiating relationships with health care professionals, patients, family members, friends, and neighbors and the differing assumptions about duty associated with caring roles in the hospital and community settings. Using prospective qualitative techniques, patients predicted to be at-risk of unsuccessful discharge and their formal and informal caregivers were followed through the discharge process to look at decision-making and outcomes related to discharge. The researchers found contradictions that confront practitioners, patient, and carers that arose from hospital policies designed to promote cost-effective and efficient use of resources. The findings suggested that for patients at risk for unsuccessful discharge, the underlying issues are related to the patient's informal caregiver's sense of self and their links to family and community.

Watts and Gardner (2005) conducted an exploratory descriptive study to investigate the beliefs of Australian critical care nurses with regard to the discharge

process. The aim was to gain insight into the discharge planning process for 218 critical care nurses who completed a questionnaire developed for the study. The authors found that discharge-planning processes were informal and influenced by patient acuity. Critical care nurses reported that workload issues, unplanned discharges and inadequate communications interfered with formalized discharge planning efforts.

McWilliam and Wong (1994) conducted an interpretive study of the process of discharging patients from the hospital to care at home. The sample consisted of 10 informal and 55 professional caregivers. The study led to a new understanding of the context-related work of nurses. Three components of context-related work were identified: working with the characteristics of the bureaucracy, compensating for bureaucracy of the health care team, and providing leadership which ensured effective care from others. The authors concluded that the professional nursing practice is both shaped and hidden by the bureaucratic context with which it occurs. By openly recognizing how the context shapes nurses hidden work in its health care context, the value of nurse will enhance professional recognition for nurses.

Medication Reconciliation

Medications harm at least 1.5 million people per year and hospitals report at least 400,000 adverse drug events per year (Bates, 2007). Due to this high incidence of errors, one of The Joint Commission's National Patient Safety Goals is to accurately and completely reconcile medications across the continuum of care (Joint Commission, 2008). The rationale for this safety goal centers around the inherent risks that exist at the time of hand-offs across settings, services, health care providers, and levels of care

(Beyea, 2007). Health care organizations are required to have processes in place to accurately obtain and document a complete medication history for all patients on admission, at transfer from one level of care to another, and at discharge (Joint Commission, 2006).

Medication reconciliation is the process of identifying the most accurate list of all medications a patient is taking including name, dosage, frequency, and route and using the list to provide correct medications for patients in the healthcare system (Institute for Healthcare Improvement [IHI], 2007). The IHI reports that 50% of all medication errors and 20% of adverse drug events in hospitals are due to poor communication among caregivers (IHI, 2007). Nurses play an instrumental role in reducing and patient's risk of adverse medication events.

Martens (1998) conducted an ethnographic study of medication discharge education from older persons with heart disease. The study collected interview, observational, and document data from 114 patients, family members, nurses, and medical records to describe the process of medication discharge education. The study found that older patients and family members valued medication discharge education and preferred personalized written and oral instructions. The education process was found to be both structured and unstructured, uncoordinated, and driven by regulatory standards.

Manning et al (2007) conducted an exploratory, randomized trial of patients at one of four participating medical units at a US hospital (n=138) to determine if a new tool of a Durable Display at Discharge Medication (3-D) Discharge Worksheet improved patient satisfaction, improved patient understanding, and reduced self-reported

medication errors compared to a standard Medication Discharge Worksheet. Trained survey personnel interviewed patients by telephone 7-14 days after discharge. Both methods of discharge instruction were found to have high patient satisfaction levels and few self-reported errors. Subjects that received the 3 D tool demonstrated greater understanding of their medications ($p < .0282$).

Boockar, LaCorte, Giambanco, Fridman, and Siu (2006) conducted a pre-intervention post-intervention study to examine the effect of medication reconciliation conducted by a pharmacist on the occurrence of discrepancy-related adverse drug events associated with medications ordered at the time of a patient's transfer from the hospital to a skilled nursing facility. As part of the intervention, a pharmacist conducted a reconciliation of drugs ordered at discharge with the pre-hospital medications and communicated any discrepancies to the physician. During the study period, 168 skilled nursing facility residents had 259 hospital admissions. The pharmacist reconciliation identified 696 total prescribing discrepancies with physicians responding to 598 (85.9%). The odds of having a discrepancy related adverse drug event were significantly lower in the post-intervention group compared to the pre-intervention group (odds ratio, 0.11; 95% CI, 0.01-1.0; $p = 0.05$). This medication reconciliation process and communication with the physician reduced discrepancy related adverse drug events. The most commonly identified discrepancy-related adverse drug event was pain from the omission of an analgesic and antibiotics.

Kramer et al. (2007) conducted a study to investigate the feasibility of implementing an electronic system for targeted pharmacist and nurse-conducted admission and discharge medication reconciliation and its effects on patient safety,

cost, and satisfaction among providers and nurses. The two-phase study involved a pre-implementation phase in which admission and medication histories followed standard processes. In the post-implementation phase, pharmacists and nurses collaborated to complete admission and discharge medication using electronic documentation. A total of 283 patients were included in the study. Patients were identified by a set of trigger questions that the nurse asked the patient during the admission process. The questions included the use of seven or more medications, a history of asthma, chronic obstructive pulmonary disease, diabetes, a cardiac condition, readmission for an adverse drug reaction, need for vaccination (pneumococcal or influenza), three or more medication allergies, and the need for medications to be identified. Patients who had the electronic medication reconciliation reported a greater understanding of the medications prescribed after discharge, including medication administration instructions and potential adverse events.

The review of the relevant literature has identified the importance of a culture of patient safety and the mandate from regulatory agencies for healthcare organizations to comply with patient safety standards. The research also identifies the challenges for healthcare organizations to improve organizational efficiencies and to implement evidence-based practice. The literature indicates that support and training from nurse leaders is crucial for nurses to implement evidence-based interventions. The research has identified patient safety concerns with medication reconciliation and the discharge planning process. Recommendations from the literature include interventions that target structured discharge planning processes and medication reconciliation education.

Several of the studies were conducted in countries other than the United States and

findings from those studies may not be relevant to health care professionals in the United States. Gaps in the literature exist surrounding the role of the registered nurse in medication reconciliation, patient throughput, and the discharge planning process.

Theoretical Framework

Rogers' Diffusion of Innovations guided the conduct of this study. Rogers' Theory views how new ideas, processes, and products diffuse and spread within and across organizations (Rogers, 2003). The four main elements that are intertwined to form the theory of diffusion of innovation include the innovation itself, communication, time, and the social system of the organization. An adaptation of Rogers' Diffusion of Innovations was selected to design and conduct the study (Figure 1). The nurse-driven discharge planning protocol was viewed as an innovation within the context of Rogers' framework and the study's findings on patient outcomes and overall organizational performance.

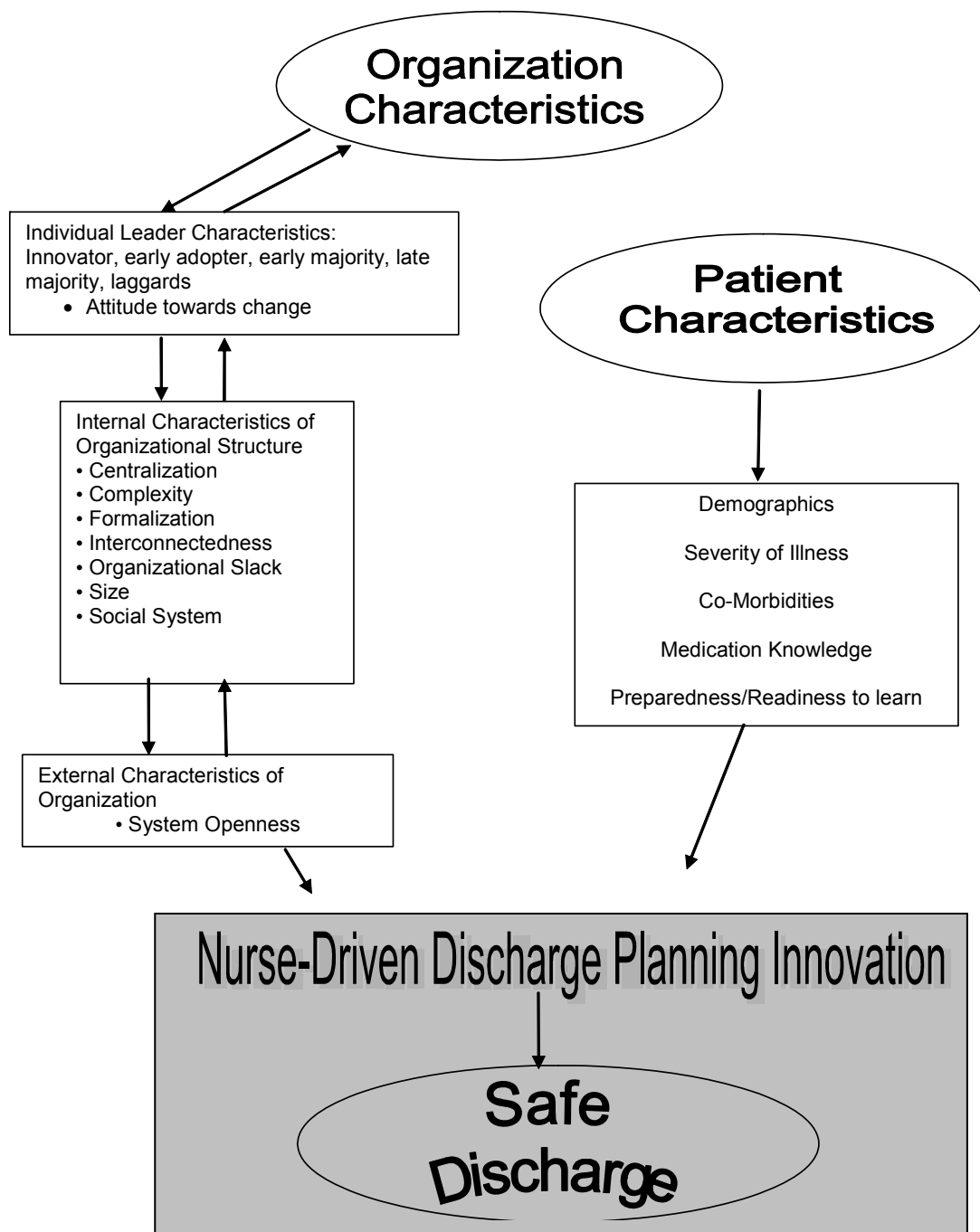


Figure 1: Adaptation of Rogers' Diffusion of Innovations

The Innovation

An *innovation* is a new idea, thing, procedure, or system that is perceived to be new by the person adopting the innovation. The characteristics of the innovation in relation to diffusion help to explain the rate of adoption by individuals or organizations. These characteristics are relative advantage, compatibility, complexity, trialability, and observability (Rogers, 2003).

Relative advantage is the perceived improvement over what currently exists that the innovation can enhance or improve within the organization (Rogers, 2003). For organizations, the return on investment (ROI) influences the rate of adoption. If the ROI is advantageous, the greater the relative advantage for the organization and therefore, the faster the rate of adoption.

Compatibility refers to how well the innovation aligns with the experiences, values, and beliefs of the adopter (Rogers, 2003). The more complex the innovation, the more time it takes to implement the innovation. If the innovation aligns with the mission and vision of the organization, the more likely the innovation will be adopted (Lundblad, 2003).

Complexity refers to the ease of understanding of the innovation. Simple ideas tend to be implemented faster than complex ideas. Ideas are classified on a complexity-simplicity continuum (Rogers, 2003). The complexity of an innovation, as perceived by the social system within an organization, is negatively related to its rate of adoption (Rogers, 2003).

Trialability is the level at which the adopter can test the innovation before a full-scale implementation and adoption of the innovation. New ideas can be tried on an

installment plan to limit the amount of uncertainty associated with the idea (Rogers, 2003).

Observability is the degree to which the results of the innovation are visible to others (Rogers, 2003). The observability of an innovation, as perceived by members of the organization, is positively related to its rate of adoption.

Communication

The second element of Rogers' theory of innovation diffusion is *communication*. Communication is defined as the process by which people develop and share information with each other to achieve understanding (Rogers, 2003). The communication process requires an innovation and a unit of adoption. The relationship between the innovation and the unit of adoption is extremely important in the diffusion of innovation theory. The person delivering the communication about the innovation is more important than the innovation itself. The more similar the source of information is to the potential adopter, the faster the adoption of the innovation (Rogers, 2003).

Time

The third element of Rogers' theory is *time*. The three components of the time element include the innovation-decision process, adopter categories, and the rate of adoption. Knowledge, persuasion, decision, implementation, and confirmation are part of the innovation decision process. Adopter categories include innovators, early adopters, early majority, late majority, and laggards. The rate of adoption is an S-

shaped curve which means that only a few individuals initially adopt the innovation but as time goes on, the rate of adoption increases (Lundblad, 2003).

The *innovation-decision* process within an organization occurs as a five-stage innovation process that includes agenda setting, matching, redefining/restructuring, clarifying, and routinizing (Lundblad, 2003). Agenda setting and matching comprise the initiation phase of an innovation within an organization and the last three stages comprise the implementation phase of adoption of the innovation into practice within the organization.

Adopter categories are a second part of the time element in Rogers' theory. These categories are a measure of how inclined an individual is to adopt new ideas as compared to other members of the organization. The categories include innovators (risk takers who seek out and embrace innovations), early adopters (open to change and respected within the social system but not as risky as innovators), early majority (tend to adopt measures just prior to the average members of the organization), late majority (slower to adopt and skeptical of the innovation), and laggards (traditionalists suspicious of new ideas and processes).

Social System

The fourth element in Rogers' diffusion of innovation theory is the *social system*. The social structure, opinion leaders, change agents and champions, consequences, types of innovation decisions within organizations, and organizational structure and characteristics comprise the social system (Rogers, 2003).

All diffusion innovation occurs within a social structure which may be made up of individuals, groups, subsystems, or organizations that share a common goal or objective that link together as a social system. Opinion leaders, change agents, and champions are people within the social system that have the ability to influence the transmission of an innovation within a social system (Rogers, 2003). Opinion leaders are crucial to the innovation and are internal members of the social system whose expertise and competence, accessibility and leadership are central to interpersonal communication networks (Lundblad, 2003). Change agents are external to the system and represent innovation to the system. They are seen as possessing special knowledge and expertise. Innovation champions have the ability to overcome barriers within the organization and contribute to the success of an innovation within an organization (Rogers, 2003).

Typically, discharge assessment and orders for discharge are the responsibility of the physician and/or a mid-level provider. In the medical model, registered nurses do not have the authority to discharge without a physician order. The current discharge process is often fragmented and requires multiple steps and handoffs to different members of the healthcare team, leading to a high potential for errors and compromised patient safety.

The innovation in this research study was the nurse-driven discharge planning protocol. The innovation was the healthcare organization providing a dedicated registered nurse to assess, educate, reconcile medications, and discharge without a physician order. Under an approved protocol, this innovation had the potential to diffuse

quickly into the organization and possessed characteristics that promote rapid adoption by the healthcare organization.

The nurse-driven discharge planning protocol had the potential to improve overall organizational efficiency and result in a significant return on investment. The innovation lacked complexity and was compatible with the mission and vision of the organization. Trialability of the innovation was tested in the research through a pilot study before full implementation and adoption of the innovation.

Communication of the intervention used the nurse-driven discharge protocol as the innovation and the healthcare organization as the unit of adoption. The principal investigator and the intervention registered nurses were well known to the organization thereby enhancing the rate of adoption of the nurse-driven discharge protocol.

The intervention of a nurse-driven discharge planning protocol fit in with the strategic aims within the identified healthcare organization. A major strategic aim was to improve flow management and patient satisfaction scores. The organization has an overall problem of decreased efficiency and throughput issues resulting in increased length of stay and decreased patient satisfaction scores. During the winter months patients are typically held in the emergency department awaiting bed placement. The adoption of the discharge planning innovation into the practice of the organization fit in with the structure and decision to implement a new idea for patient care. Figure 2 provides a high-level concept map of the discharge planning process at the healthcare organization.

Discharge Process

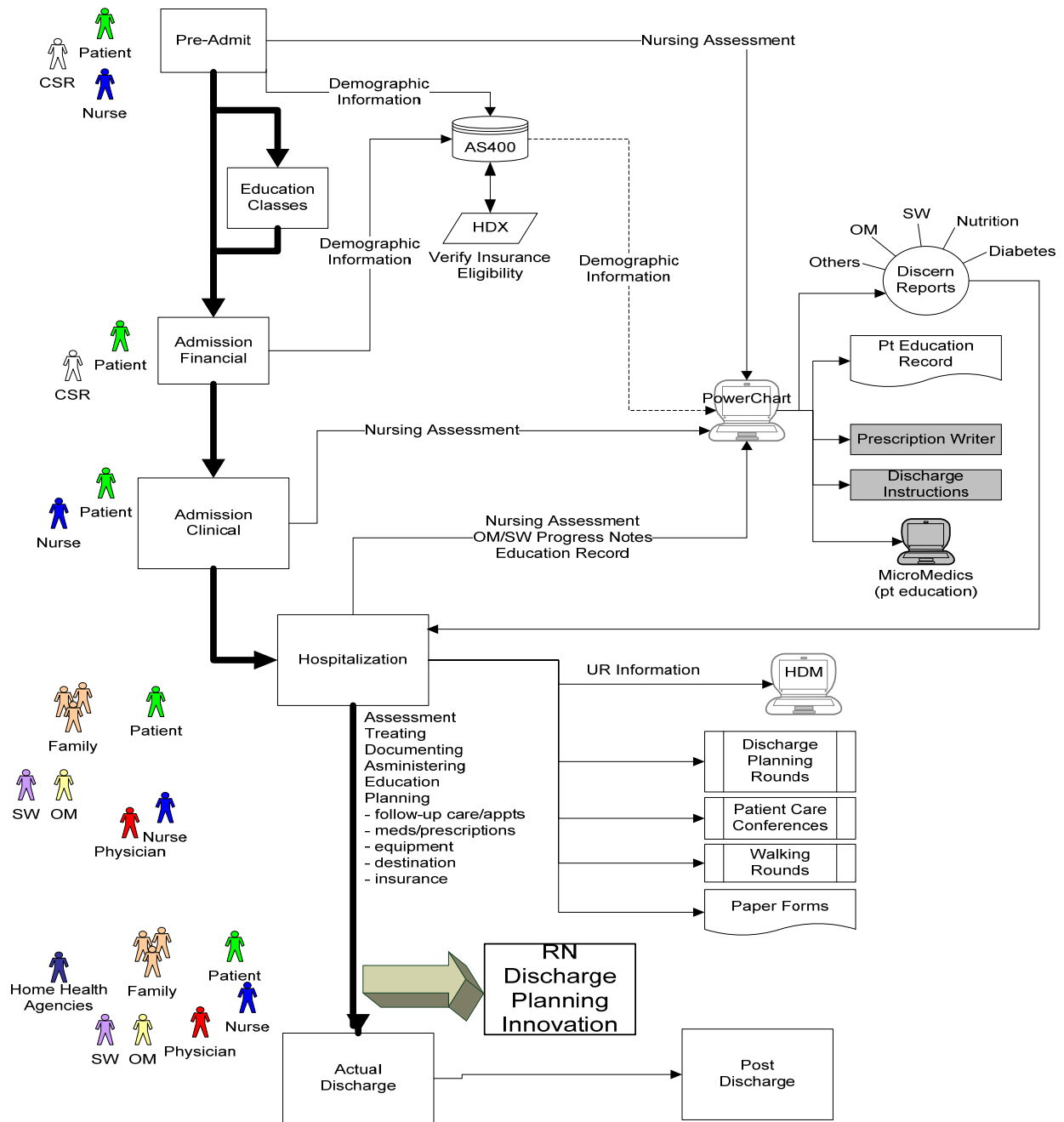


Figure 2: Concept Map of Discharge Planning Process

The Principal Investigator (PI) was viewed as an innovator and the intervention registered nurses were viewed as early adopters within the healthcare organization. The cardiac service line has a record of adopting new ideas before other service lines within the healthcare facility. The intervention of a discharge planning protocol for cardiac patients status post-cardiac implant placement had the potential to be readily adopted by individuals in the healthcare organization.

The intervention of a discharge planning protocol occurred within a social system of opinion leaders, change agents, and champions. The opinion leaders were the electrophysiology physicians who are viewed as experts and have the ability to push the intervention to the organizational leaders. The change agents were the intervention registered nurses who were clinical experts who had typically been ancillary to the actual discharge process. The PI was the innovation champion who had the ability to overcome barriers within the organization and contribute to the overall success of the intervention.

Summary

The discharge process is a high-risk process that involves numerous patient safety concerns. Nursing professionals are crucial since they touch the patient at all transitions of care. Studies thus far have targeted portions of the discharge process (mainly medication reconciliation) and are limited as to the nurse's and patient's role in the healthcare organization.

An adaptation of Rogers' diffusion of innovations was used as a theoretical framework to conduct this study. Patient characteristics have been incorporated into the

framework as a relevant aspect to the discharge planning process. The portions of the framework tested in this study was the evidence-based discharge planning protocol and its effects on discharge time, length of stay, patient satisfaction, variable cost per case and safe discharge and its effects on medication reconciliation rates and 30 day readmission rates.

CHAPTER THREE: METHODS

This chapter explicates the design of the study, the sample, and the study intervention. A description of the instruments, data collection procedures, ethical considerations, and data analysis procedures are included.

Design

The study was conducted using a two-group posttest random assignment experimental design. The independent variable was a nurse-driven evidence-based discharge planning protocol. The dependent variables were medication reconciliation rates, 30-day readmission rates, discharge time, length of stay, direct cost per case, and patient satisfaction scores. Operational and conceptual definitions were summarized in Table 1.

The study design is shown below:

R → X → O

R → O

R – Randomization of subjects to groups

X - Nurse-driven discharge planning innovation

O - Posttest measures

Sample

A priori power analysis for an independent group two-tailed t-test was performed by computer software. Estimations of standard deviations and population means were obtained from a prior study on the variable of overall patient satisfaction with discharge

planning. To have a resultant 80% power, a medium effect size of 0.5, and a significance of 0.05, it was determined that 128 subjects would be needed (64 in each group).

After implementation of the study and with further review of the patient safety literature it was determined that the main variable of interest was medication reconciliation rates. After a year of data collection an interim power analysis for an independent group one-tailed t-test was performed by computer software on the main variable of medication reconciliation after enrolling 40 subjects (experimental group = 17 and control group = 23) after a one-year period of data collection. (An additional subject was enrolled using random assignment but data collection had not occurred; therefore, the subject's data was not included to the power analysis). Using population means of 10.0 and 71.5 and a standard deviation of 22.1 (effect size of 2.8), the power analysis revealed a resultant 100% power. Since randomization did not result in equalization of groups and after consultation with the dissertation chair (Dr. Byers) a decision was made to enroll 5 more subjects using quota sampling to have equal numbers in the experimental and control group for a total of 46 subjects.

Inclusion and Exclusion Criteria

The following inclusion criteria were used to enroll subjects into the study:

1. Age 18 or older
2. Scheduled for short stay hospitalization
3. First-time cardiac implant placement
4. Able to see and hear

5. Able to communicate in English
6. Scheduled for discharge to home post cardiac implant procedure

Subjects who met the following criteria were excluded for participation in the study:

1. Scheduled for inpatient admission
2. History of cardiac implant placement
3. Unable to see and hear
4. Complication post cardiac implant procedure requiring inpatient admission

Intervention

The intervention was designed to be a significant change from the traditional discharge process in which nurses were dependent upon a physician to initiate the discharge process. The intervention empowered nurses to assess and educate patients, reconcile medications, and discharge patients under protocols without having to wait for physician input or written orders. The discharge planning innovation drastically reduced the number of hand-offs required among caregivers and streamlined the entire discharge planning process.

All cardiac implant patients require specific education about their new device and discharge instructions that outline specific activity restrictions, what to do if their symptoms worsen, incisional care, follow-up appointments, and medications. The intervention allowed specially trained intervention registered nurses to spend one-on-one time with the patient without the time constraints of caring for other patients. The intervention RN was the process owner and was able to focus solely on individual

patient assessment, education, and medication reconciliation thereby streamlining the discharge process.

The traditional discharge planning process involved the coordination of numerous caregivers, which created delays. The actual discharge planning process was not initiated until the physician or mid level provider conducted patient rounds to assess readiness for discharge and wrote orders for to discharge the patient. Most physicians in this practice conducted rounds in the early afternoon after completing their scheduled cases in the cardiac catheterization laboratory or after the completion of their office hours. In time of high census and increased patient acuity, the physicians often addressed needs of higher acuity patients first and completed patient discharge rounds later in the day. This practice resulted in later discharge times and organizational throughput issues due to a lack of available beds for patients waiting in the emergency department. In the standard discharge process, delays in discharge were also attributed to waiting for a cardiac rehabilitation nurse to provide patient education about the cardiac implant device. Bedside nurses focused on caring for patients newly admitted to the unit and completing interventions for patients that required immediate attention before implementing discharge orders, causing further discharge delays.

Prior to the pilot study, education on the discharge planning protocol, medication reconciliation, and physical assessment of the post procedure cardiac implant patient was provided to the intervention registered nurses (IRN) by the principal investigator and the electrophysiology physicians. Two IRNs were selected to participate in the study due to their specialized expertise in cardiovascular and critical care nursing. One IRN was the clinical educator for the cardiac units at the healthcare organization and the

other IRN functioned as a clinical outcomes specialist with overall responsibility for the implementation of quality initiatives within the healthcare organization. Both IRNs (early adopters) have baccalaureate degrees in nursing and are pursuing of their master's degrees.

The PI was also a member of the IRN team. The PI (innovation champion) trained the registered nurses on the discharge planning innovation and the process of medication reconciliation. Inter-rater reliability was established during the pilot study for medication reconciliation and the discharge planning innovation. The electrophysiology physicians (opinion leaders) provided an overview of cardiac implant placement and the assessment parameters necessary for patient discharge.

Figure 3 depicts the standard process flow for the discharge planning. Figure 4 depicts the process flow for the discharge planning innovation.

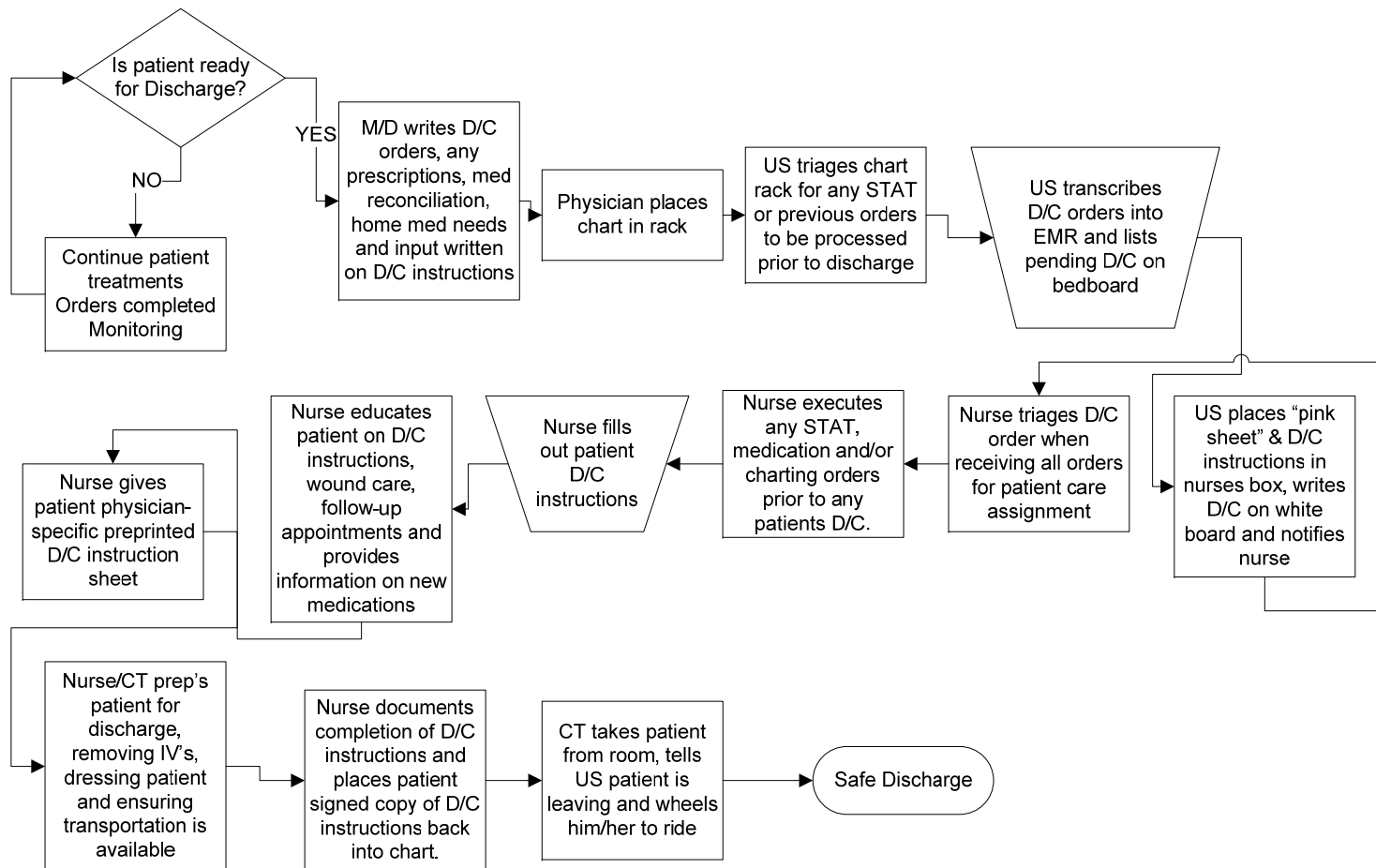


Figure 3: Standard Discharge Process

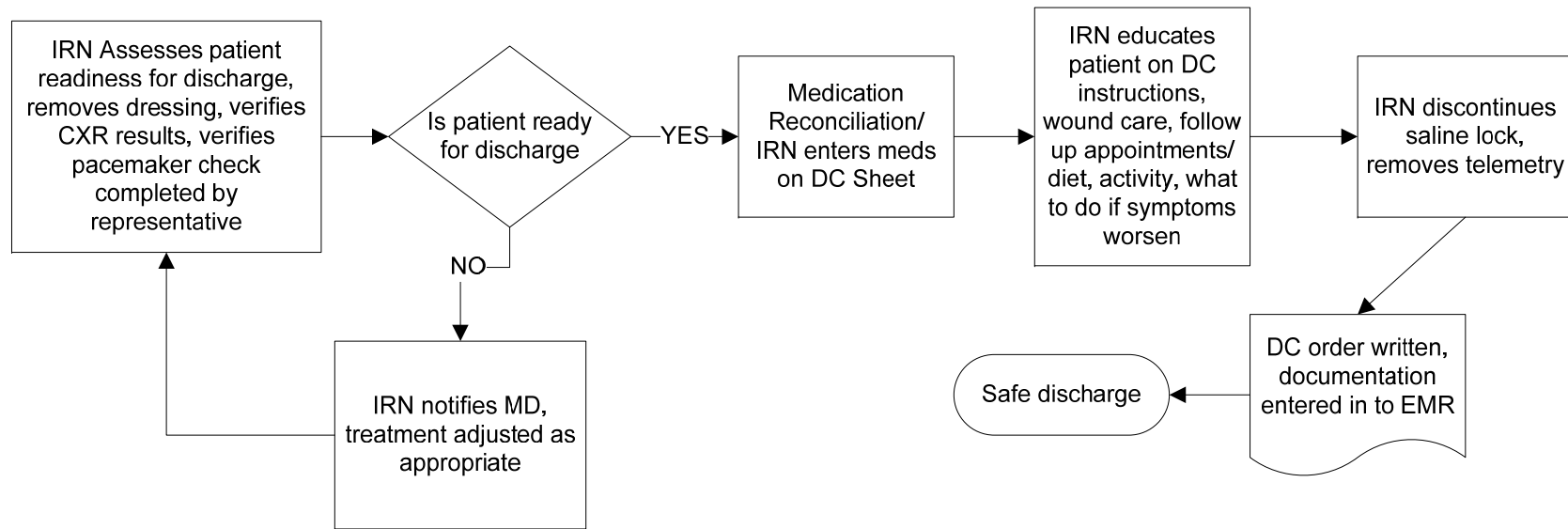


Figure 4: IRN Discharge Planning Innovation

Once the patient was randomized into the experimental group, a member of the research team was notified by the PI to review the patient's history and nursing assessment via the electronic medical record. The morning following the cardiac implant procedure, the IRN assessed the patient for readiness for discharge. Table 2 outlines the clinical and process indicators necessary to assess for discharge readiness.

Table 2: Clinical and Process Indicators to Assess for Discharge Readiness

Review of EMR and paper chart for any complications throughout the evening
Vital signs reviewed in the EMR and within normal limits
Cardiac monitoring shows properly functioning cardiac implant
Morning CXR obtained and without evidence of pneumothorax
Written documentation of cardiac implant check by pacemaker representative indicating appropriate thresholds and implant function
Incision inspected and without signs and symptoms of excess redness, swelling, or drainage
Access sites without redness or evidence of hematoma, neurovascular checks within normal limits
Physical assessment within baseline for patient

If the patient met criteria per the discharge planning innovation, the IRN educated the patient and family members on post procedure care, what to do if their symptoms worsen after discharge, follow-up appointments, activity, diet, and care of the incision site. If the patient did not meet the criteria for discharge, a call was placed to the physician or mid-level provider. All medications were reconciled per the process outlined in Figure 5. Preprinted educational materials regarding cardiac implants and

the patient's medications was given to the patient along with any prescriptions left in the patient chart by the physician post procedure. For those patient's who were on oral anticoagulants, a call was placed to the mid-level provider for discharge anticoagulant orders and directions for laboratory follow-up appointments. The written educational materials were obtained from the healthcare organization's Intranet and the Cardiac Rehabilitation Department. All patient educational materials were reviewed by the PI to guarantee that the content met quality standards. The IRN then discontinued all intravenous lines and cardiac monitoring equipment. A formal discharge order was written by the IRN and the bedside caregiver was notified of the patient's readiness for discharge. The IRN, family members, or clinical technician then escorted the patient to the lobby for discharge. The Unit Secretary was notified to discharge the patient from the EMR. The day after discharge, the PI conducted a scripted follow-up phone call to ask the patient questions about follow-up care, the incision site, if prescriptions had been filled and overall satisfaction with the hospital.

Pilot Study

Following Institutional Review Board approvals, a pilot study was conducted on four patients at the healthcare facility to assure that the research methods were sound and that the electrophysiology physicians, mid-level providers, office staff, IRNs, bedside caregivers, and ancillary staff of the healthcare organization understood the intervention and the data collection procedures. Data from the four subjects in the pilot study were not included in the final analysis.

Inter-rater reliability of the discharge planning innovation and the medication reconciliation process was established during the pilot study. Inter-rater reliability of the discharge planning innovation was established with the PI and the IRN. A written data collection protocol was established and all required tasks and skills were reviewed with the IRNs prior to the pilot study. Each IRN met with the electrophysiology physician to review the physical assessment parameters necessary for patients after cardiac implant placement. Inter-rater reliability for the medication reconciliation process was established with the unit-based pharmacist, PI, IRN, and the electrophysiology physician. All four patients in the pilot study had medication reconciliation completed independently by the IRNs and the PI to ensure that the same medications were observed and reconciled. Midway through data collection the process was reaffirmed.

Instruments

All instruments were pilot tested with a volunteer group of four cardiac implant patients to assess the clarity of instructions and the amount of time needed to complete them. The Hospital Discharge Survey was developed by the PI and pilot tested on a volunteer group of fifteen post-cardiac intervention hospitalized patients.

Medication Reconciliation

Medication reconciliation is the process of identifying the most accurate list of all medications a patient is taking, including name, dosage, frequency, and route, and using this list to provide correct medications for patients in the healthcare system (Institute for Healthcare Improvement [IHI], 2004). Reconciliation involves comparing

the patient's current list of medications against the physician's admission, transfer, or discharge orders. After discharge from the healthcare organization, it is extremely important to compare the patient's discharge medication orders with the current medication administration record. If a medication a patient has been receiving in the hospital is not on the discharge orders, and there is no acceptable documentation of why the medication has been omitted, the nurse or pharmacist should contact the physician to verify whether or not to continue the medication. Figure 5 outlines the discharge medication reconciliation process.

Discharge Medication Reconciliation Process Flow Chart

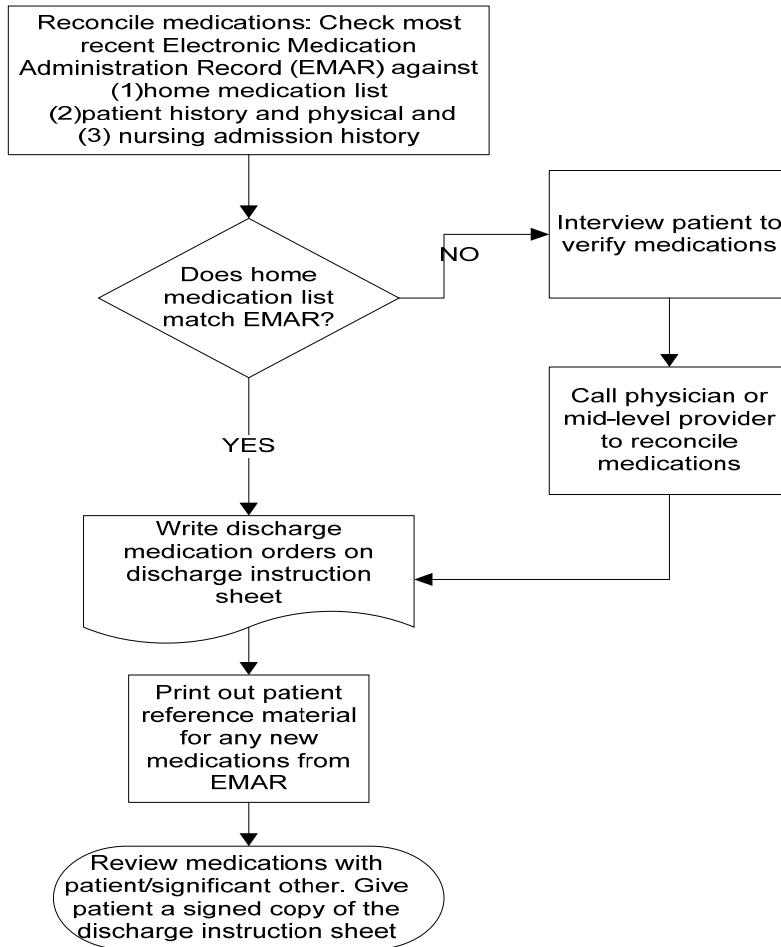


Figure 5: Medication Reconciliation Process

Appendix A outlines the data collection form for medication reconciliation.

Length of Stay

Length of stay (LOS) is a term used to measure the duration of a single episode of hospitalization. LOS was calculated in hours and minutes. LOS started when the

patient had completed the cardiac implant procedure and was transferred from the cardiac catheterization laboratory to the cardiac post-procedure area. The post procedure admission time is reflected in the EMR. The time of discharge is noted by a nursing progress note that is time and date stamped with the actual discharge time or is noted in the EMR as the time the patient was discharged from the nursing unit (Appendix B).

30-Day Readmission Rate

Thirty-day readmission rates are defined as patients readmitted to the hospital up to 30 days after discharge. Causes of readmissions were categorized into structure, process, or outcomes to determine causative factors for readmission back to the healthcare facility (Appendix C).

Variable Cost per Case

Variable cost per case refers to a cost associated with output charges for the patient. Variable cost per case and overall patient charges were obtained from the healthcare organization's cost accounting system for each study participant. Appendix D outlines the data collection form for variable cost per case and total charges.

Follow-up Discharge Phone Call

All patients in the intervention group received a post discharge follow up phone call from the PI. The PI used an eight-question script that assessed post discharge care,

patient perceptions, medications, follow-up appointment time, the incision, and understanding of the discharge instructions (Appendix E).

American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR™)

The ACC-NCDR™ is a Web-based, audited registry, which is designed for ICD data reporting (American College of Cardiology [ACC], 2006). The Centers for Medicare and Medicaid Services mandates that all hospitals collect data on all implants placed in Medicare patients. The registry collects demographic data and looks to see who is receiving implants, who is implanting the device, what device is being implanted and how is it programmed, and what are the in-hospital outcomes (ACC, 2006). A demographic tool was adapted from the ACC-NCDR™ form (Appendix F).

Hospital Discharge Survey

Patient satisfaction was measured using the Hospital Discharge Survey (Appendix G). The Hospital Discharge Survey is a 10-item tool that was adapted from The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS™) and Press-Ganey. The Hospital Discharge Survey was adapted to measure the domain of discharge information (3 items), overall rating of the hospital (2 items), and demographic information (5 items). The discharge items included extent you felt ready to discharge, speed of discharge and instructions for care at home on a 1-5 Likert- scale. Overall rating of the hospital included at 0-10 rating of the hospital and a

1-4 Likert scale for would you recommend the hospital. A composite satisfaction score was calculated ranging from 4 to 29.

Content validity of the survey was established by a group of clinical experts in discharge planning at the healthcare facility. Readability statistics of the Hospital Discharge Survey showed a Flesch-Kincaid grade level of 6.6 and a Flesch reading ease of 70.1. The Hospital Discharge Survey was pilot tested for readability, usability, and internal consistency on a group of 15 post-cardiac intervention patients. The time to complete the survey was 10 minutes. Post hoc reliability statistics showed an overall Cronbach's Alpha of 0.562 based on standardized items for four categories on the discharge survey: efficiency, readiness, instructions, and global satisfaction.

Data Collection Procedures

The following steps were completed as part of the data collection. Detail regarding these steps follows.

1. Recruit participants
2. Obtain informed consent
3. Randomize into intervention or control group
4. Notification of IRN to review EMR for intervention patients
5. Discharge planning innovation/ medication reconciliation for intervention group
6. Follow up phone call by the PI the day after discharge for intervention patients
7. Hospital Discharge Survey taken by PI to physician's office to be completed by the patient during follow up office visit (7-10 days post discharge).

8. Review of EMR 3 days post discharge to record LOS, discharge time, and medication reconciliation rates.
9. 30 days post discharge, PI reviewed EMR for any readmission to the healthcare facility.
10. Account number sent to contact in finance office to obtain direct cost per case.
11. Focus groups conducted after data collection complete.

Ethical Considerations

The study involved minimal risk. Expedited review was sought and granted by the University of Central Florida Institutional Review Board (IRB) (Appendix H). Expedited review was also sought and granted by the healthcare organization that provided the setting for the research study. Written informed consent was obtained during one-on-one meetings between the PI and potential participants.

Recruitment and Consent Process

The research was conducted between December 2006 and January 2008. The PI had access to the cardiac catheterization schedule and all participants who met the inclusion criteria were approached for informed consent. All patients scheduled for short-stay cardiac implant placement were explored for applicability to the defined inclusion and exclusion criteria. All patients meeting the inclusion criteria were approached for participation in the study. If the patient verbally agreed to participate, informed consent was obtained by the PI. A written consent was obtained and a copy of the consent form was given to the patient.

Implementation of the Intervention

Following informed consent from each participant, the subjects were randomized, a copy of the signed informed consent was provided to the participant (Appendix I), and demographic data were collected. Randomization was accomplished by means of sealed envelopes that denoted membership in either the experimental or the control group. All sealed envelopes were shuffled and the contents were unknown to the Principal Investigator (PI) . The envelope was opened after the individual had consented to participate in the study and had signed the informed consent. Notification was made to the individual IRN once the patient was randomized into the intervention group. The IRN reviewed the patient's history and physical and home medications in the EMR. The day after the procedure the IRN or PI reviewed the patient's vital signs, cardiac telemetry, and EMR. Verification of the morning Chest X-ray (CXR) and interrogation of the patient's cardiac implant were verified in the EMR and paper medical record. Medication reconciliation was completed and any unclear medications were called to the electrophysiology physicians or discussed with the patient for clarification. The patient's dressing was removed and the incision site inspected. A physical assessment was conducted by the IRN to assess the patient's readiness for discharge. If the patient was ready for discharge, the IRN filled out the healthcare organization's discharge instruction sheet and printed out information on any new medications. The IRN then educated the patient and family on their individual discharge instructions and discharged the patient. The day after discharge, the PI conducted the post cardiac implant follow-up phone call and delivered a copy of the Hospital Discharge

Survey to the electrophysiology physician's office. After the patient's follow-up visit, the PI picked up the survey.

Three days following the patient's discharge, the PI reviewed the EMR and completed the medication reconciliation data collection form. Thirty days post discharge, the PI reviewed the EMR for any readmission within 30 days.

Data Analysis Procedures

Descriptive and inferential statistics was used to describe the sample and to evaluate the hypotheses using Statistics for Social Scientists (SPSS) v 14.0 and Minitab 15. Demographic data were evaluated via descriptive statistics, independent t-tests, and chi square. Independent t-tests and Mann-Whitney U tests with a comparison between means was done to determine if there are statistically significant differences between the control group and the experimental group with regards to length of stay, readmission rates, variable cost per case, actual charges, medication reconciliation rates, and patient satisfaction.

Summary

Chapter 3 has outlined the research design, defined the variables, and described the population and sample for the research study. Identification of the setting, ethical considerations, instruments, and a detailed description of the data collection protocol has been outlined along with the plans for data analysis.

CHAPTER FOUR: RESULTS

Characteristics of the participants are described in this chapter as well as type of primary insurance coverage, highest grade level of school, and type of cardiac implant. Findings related to length of stay, variable cost per case, 30-day readmission rates, medication reconciliation rates, and patient satisfaction scores are reported.

The Statistical Package for Social Science (SPSS) v 14.0 and Minitab 15 were used to conduct analyses, generate tables, and construct graphs. All data were screened to assess for outliers and to determine if assumptions were met for the proposed statistical analyses. Hypotheses were tested by means of t-tests (continuous data), Mann-Whitney U (continuous data with non-normal distributions), and chi square analysis (categorical data). The default level of significance for rejection of the null hypothesis was 0.05 (alpha α). Since all hypotheses were directional, one-tailed tests were run. Demographic data related to the sample are shown in Table 3, and data related to the hypotheses are listed in Table 4.

Description of Participants

Fifty-three participants were enrolled in the study: 25 (47%) in the experimental group and 28 (53%) in the control group. Forty-six (86%) participants completed the study, with 23 subjects in each group. Of the seven who did not finish, all were involuntary withdrawals. These seven participants required admission to the hospital as inpatients related to complications associated with the procedure. Two were admitted to the critical care unit (one for a myocardial perforation and the other for prolonged hypotension); two patients had a pneumothorax post procedure requiring the placement

of a chest tube; and three participants required medical treatment for pre procedure comorbid conditions.

Characteristics of Participants

The sample consisted of 14 females (30%) and 32 males (70%). The overall mean age for participants was 73.5 with ages ranging from 47 to 90 years of age. The type of insurance for the sample included 85% Medicare (n=39) and 15% commercial insurance (n=7).. All but one participant reported English as their primary language. Of the thirty-seven participants that completed the Hospital Discharge Survey 3% (n=1) reported less than an 8th grade education, 3% (n=1) some high school but did not graduate, 38% (n=14) high school or equivalent, 31% (n=12) some college, 11% (n=4) college graduate, and 14% (n=5) more than a 4 year college degree.

Data were analyzed to determine equivalence of subjects randomized to each group. No difference was found in age, type of insurance, type of cardiac implant , education, and language. Using Chi-square analysis, no differences were noted between control and experimental groups on the following variables: gender ($\chi^2 = .411$, $df = 1$, $p = .522$), type of insurance ($\chi^2 = .168$, $df = 1$, $p = .681$), education ($\chi^2 = 5.90$, $df = 5$, $p = .316$), or type of cardiac implant ($\chi^2 = 1.48$, $df = 2$, $p = .478$). Figure 6 shows the type of cardiac implant between the two groups. An independent samples t-test with equal variances found no significant age difference between groups $t(44) = -.164$, $p = .870$.

Table 3: Characteristics of Participants (n = 46)

General Characteristic	Both Groups (n = 46)	Experimental (n = 23)	Control (n=23)	P-Value
Gender				.522 ^a
Female	14 (30%)	6 (26%)	8 (35%)	
Male	32 (70%)	17 (74%)	15 (65%)	
Mean Age years (s.d.)	73.5 (9.67)	73.26 (10.28)	73.74 (9.43)	.870 ^b
Range (years)	47-90	47-90	52-86	
Type of Insurance				.681 ^a
Medicare, n (%)	39 (85%)	20 (87%)	19 (83%)	
Commercial n, (%)	7 (15%)	3 (13%)	4 (17%)	
Race				
White, n (%)	46 (100%)	23 (100%)	23 (100%)	
Language				
English	45 (98%)	23	22	
Spanish	1 (2%)	0	1	
Education, n (%)				.316 ^a
8 th grade or less	1 (2.2%)	0 (0%)	1 (5%)	
Some high school, did not graduate	1 (2.2%)	1 (5%)	0 (0%)	
High school or GED	14 (30.4%)	10 (50%)	4 (24%)	
Some college or 2 year degree	12 (26.1%)	5 (25%)	7 (41%)	
4 year college graduate	4 (8.7%)	1 (5%)	3 (18%)	
More than 4 year college degree	5 (10.9%)	3 (15%)	2 (12%)	
Total	37	20	17	
Type of Cardiac Implant, n (%)				.478 ^a
Permanent Pacemaker	21(46%)	12 (53%)	9 (39%)	
Implantable Cardioverter Defibrillator	4 (8%)	1 (4%)	3 (13%)	
Biventricular Implantable Cardioverter	21 (46%)	10 (43%)	11 (48%)	

^a p-value Chi-square test for independence

^b p-value for independent samples t-test

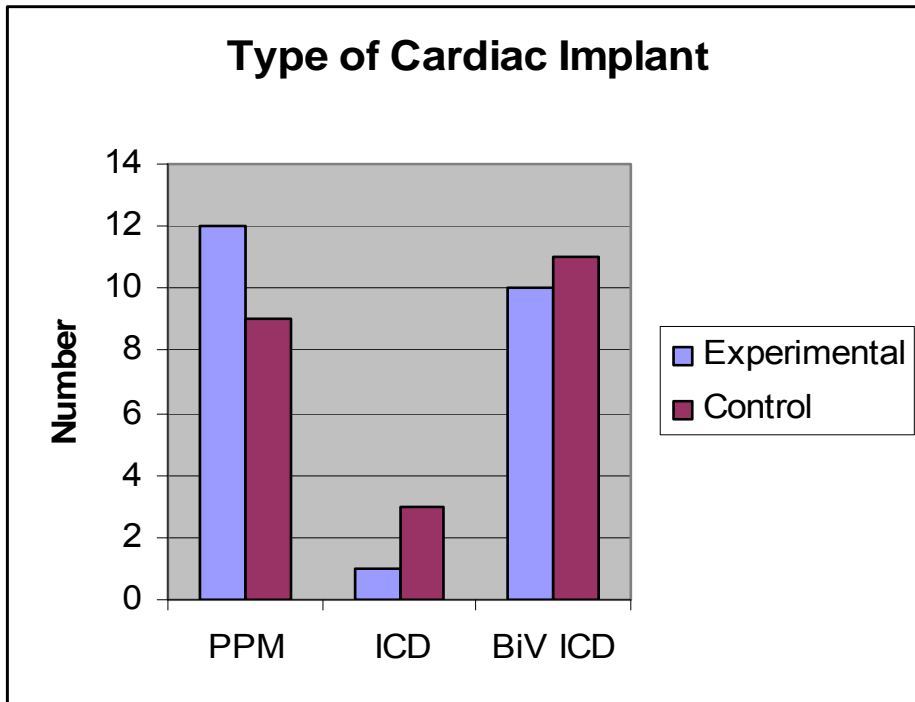


Figure 6: Type of Cardiac Implant

Table 4: Outcomes of Hypothesis Testing

Outcomes	Mean (s.d.)	Median	Min/Max	P-Value
Average Length of Stay (hrs/min) Experimental (n = 23) Control (n = 23)	26:07 (7:16) 27:44 (7:15)	24:37 26:09	21:26-50:06 21:17-52:59	.014 ^a
Discharge Time of Day (hr/min) Experimental (n = 23) Control (n = 23)	10:48 (0:55) 12:44 (1:55)	10:35 12:38	8:51-12:37 10:03-17:48	.000 ^b
Variable Cost per Case (\$) Experimental (n = 20) Control (n = 23)	14,970 (5,062) 15,718 (4,203)	15,753 15,727	4279-20085 4464-19693	.437 ^a
Actual Charges (\$) Experimental (n = 20) Control (n = 23)	49,565 (33,090) 55,805 (32,143)	26,605 64,769	19411-93302 18204-93758	.403 ^a
Readmission within 30 Days Experimental, n = 3 Control, n = 2				.520 ^c
Medication Reconciliation (% unreconciled) Experimental (n =23) Control (n =23) Unreconciled discharge medications Experimental (n=23) Control (n=23)	8.869 (18.42) 71.82 (21.39) .565 (1.079) 6.13 (3.507)	.000 75.00 .000 6.00	0.00-80.00 0.00-100.00 0.00-4.00 0.00-12.00	.000 ^b
DC Composite Score Experimental (n = 20) Control (n = 17)	26.50 (2.69) 25.00 (3.16)	27.50 26.00	19.00-24.00 17.00-24.00	.05 ^a
Overall Health Experimental (n = 20) Control (n = 17)	2.60 (.754) 3.12 (.697)	3.00 3.00	1.00-4.00 2.00-4.00	.02 ^a

^a p-value Mann-Whitney U Test (one-tailed)

^b p-value for independent samples t-test (one-tailed)

^c p-value Chi-square test for independence

Hypothesis 1: The implementation of a nurse-driven discharge planning protocol for patients undergoing a cardiac implant will result in reduced length of stay when compared to patients receiving traditional discharge planning services.

The mean length of stay was 26 hours and 7 minutes for the experimental group and 27 hours and 44 minutes for the control group. Data were non-normally distributed, and a Mann-Whitney *U* test was conducted to evaluate the hypothesis that patients receiving the nurse-driven discharge planning protocol had a lower length of stay than

patients receiving traditional discharge planning services. Participants in the experimental group ($M = 26:07$, $SD = 7:16$) had on the average a lower length of stay than those in the control group ($M = 27:44$, $SD = 7:15$); The results of the test were in the expected direction and significant, $z = -2.197$, $p = .014$ (one-tailed). Patients in the experimental group had an average rank of 19.15, while patients in the control group had an average rank of 27.85.

Data were screened for outliers with four outliers removed. An independent samples t-test with equal variances assumed was conducted to evaluate the hypothesis that patients in the experimental group had a lower length of stay compared to those in the control group; $t(40) = -2.72$, $p = .005$. The 95% confidence interval for a difference in means ranged from -0:25 to - 2:58. On the average, patients in the experimental group were discharged in 23 hours and 58 minutes ($SD=1:32$) and patients in the control group in 25 hours and 41 minutes ($SD= 2:25$).

Results of both the Mann Whitney U test and an independent samples t-test supported by the hypothesis. Figure 7 shows the distribution of the two groups.

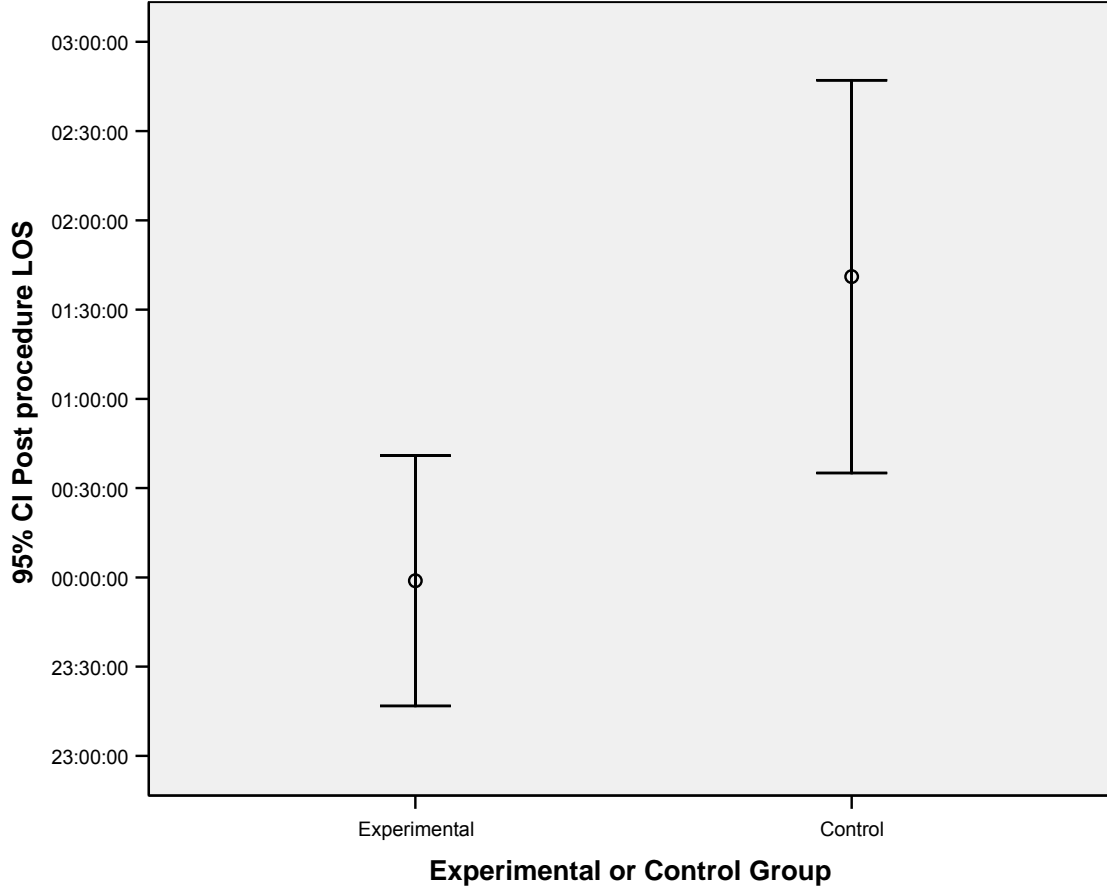


Figure 7: Error Bars Length of Stay

Hypothesis 2: The implementation of a nurse-driven discharge planning protocol for patients undergoing a cardiac implant will result in earlier discharge times when compared to patients receiving traditional discharge planning services.

An independent samples t-test with unequal variances was conducted to evaluate the hypothesis that a nurse-driven discharge planning protocol will result in an earlier discharge time; $t(31.44) = -4.246$, $p = .000$. Patients in the experimental group were discharged at an average time of 10:48 am compared to those in the control who

were discharged at an average time of 12:44 pm. The hypothesis was supported by the study results. Figure 8 shows the distribution of the two groups

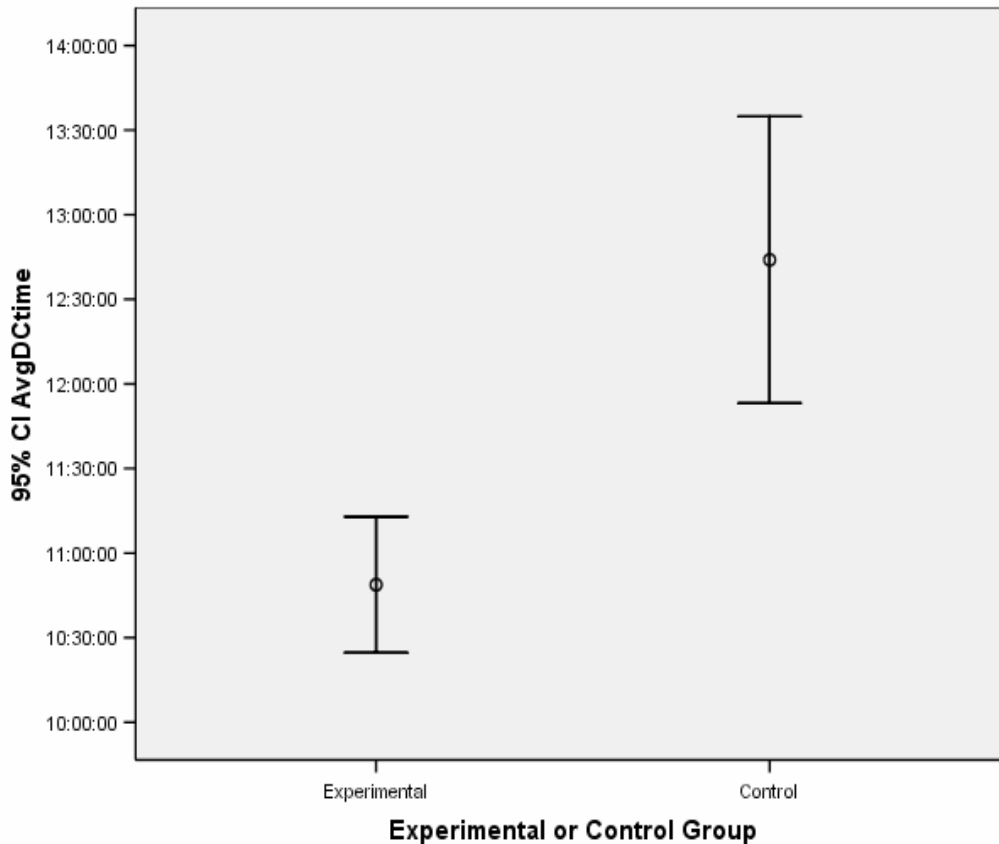


Figure 8: Error Bars of Discharge Time

Hypothesis 3: The implementation of a nurse-driven discharge planning protocol for patients undergoing a cardiac implant will result in a decreased variable cost per case when compared to patients receiving traditional discharge planning services.

Average variable costs per case were \$14,970 for the experimental group and \$15,753 for the control group. Data were non-normally distributed. A Mann-Whitney *U*

test was conducted to evaluate the hypothesis that patients receiving the nurse-driven discharge planning protocol had a lower variable cost per case than patients receiving traditional discharge planning services. The results of the test were in the expected direction and not significant, $z = -.219$, $p = .437$ (one-tailed). Patients in the experimental group had an average rank of 21.55, while patients in the control group had an average rank of 22.39. The hypothesis was not supported by the study results. Figure 9 shows the variable cost per case distribution for the two groups.

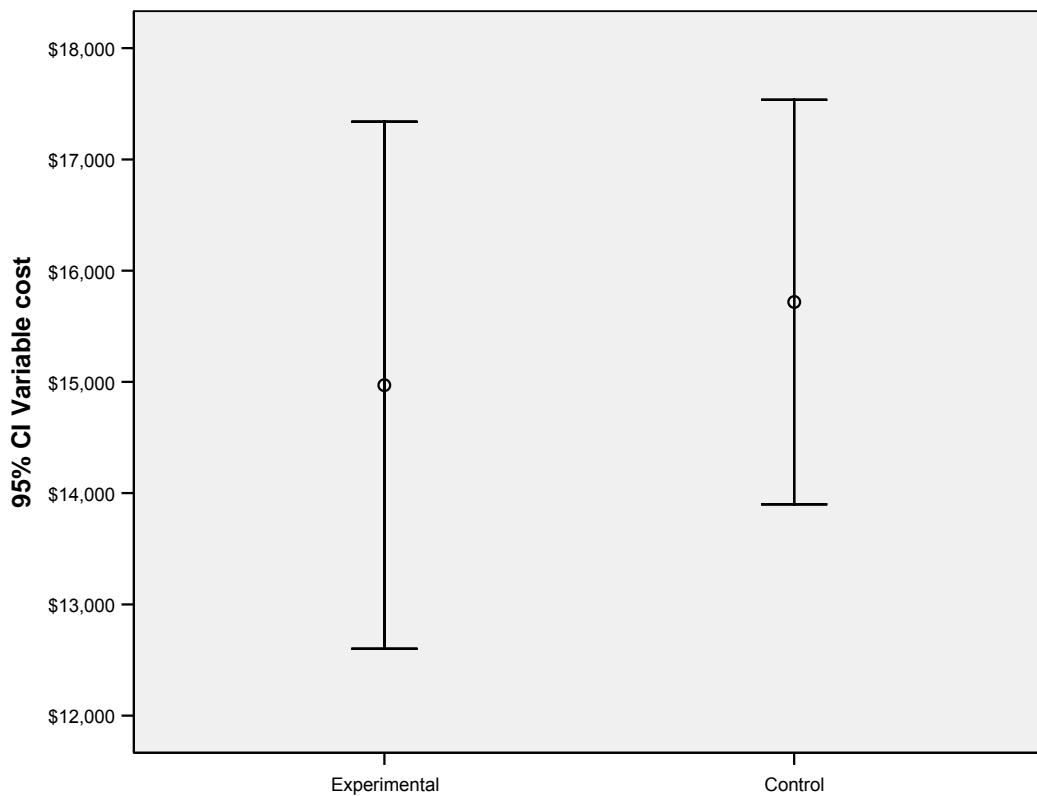


Figure 9: Variable Cost per Case Distribution

Hypothesis 4: The implementation of a nurse-driven discharge planning protocol for patients undergoing a cardiac implant will result in reduced 30-day readmission rates when compared to patients receiving traditional discharge planning services.

Readmission rates were low for both groups. Three subjects from the experimental group and two subjects from the control group were readmitted. A chi-square analysis was conducted to evaluate whether 30-day readmission rates were lower in the experimental or control group. Readmission to the healthcare facility within 30-days was not significantly different between groups ($\chi^2 = .414$, $df = 1$, $p = .520$). The hypothesis was not supported by the study results. Figure 10 shows a clustered bar chart of readmission for the experimental and control group.

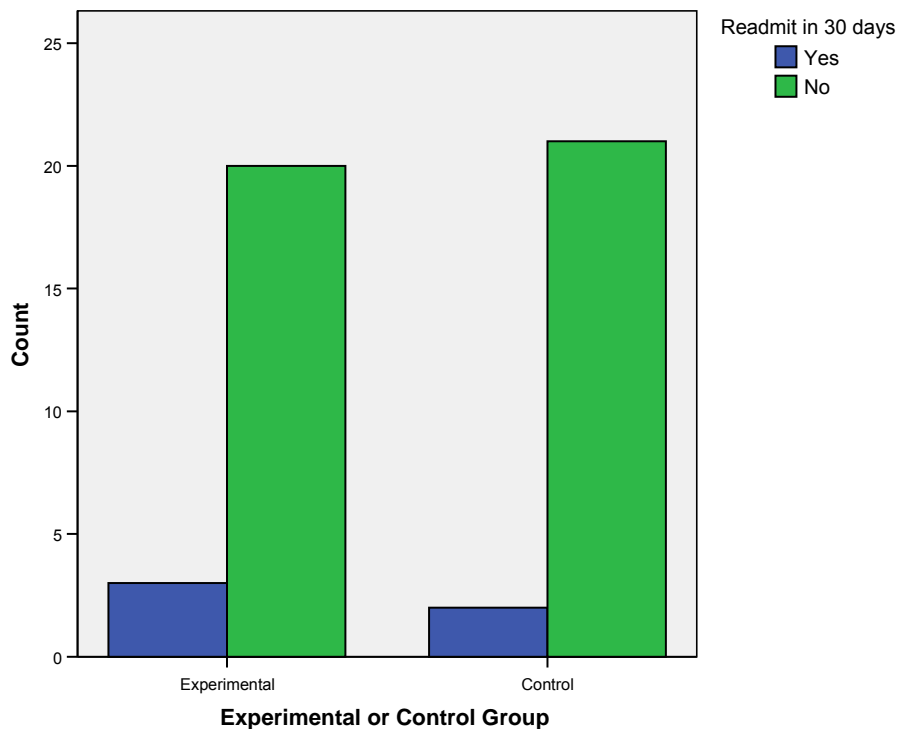


Figure 10: A Clustered Bar Chart of Readmission

Hypothesis 5: Cardiac implant patients who receive a nurse-driven discharge planning protocol will have greater rates of medication reconciliation at the time of discharge when compared to patients who receive traditional discharge planning services.

An independent sample t-test with equal variances assumed was conducted to evaluate if medication reconciliation rates were greater for the experimental group or the control group. Participants in the experimental group ($M = 8.869$, $SD = 18.42$) had on the average a lower percentage of unreconciled medications than those in the control group ($M = 71.82$, $SD = 21.39$); $t(44) = -10.69$, $p = .000$. The 95% confidence interval for a difference in means ranged from -74.82 to -51.09.

Forward logistic regression was conducted to determine if being in the experimental was a predictor of medication reconciliation (reconciled or unreconciled medications). Regression results indicate that the overall model was statistically reliable in distinguishing reconciled medications ($-2 \text{ Log Likelihood} = 36.49$; $\chi^2(1) = 24.109$, $p = .000$). The odds of having all medications reconciled in the experimental group were significantly higher (odds ratio 50.27; 95% CI 5.62-450.22; $p = .000$).

Results of both t-test and logistic regression supported the research hypothesis. Figure 11 shows the error bars for both groups.

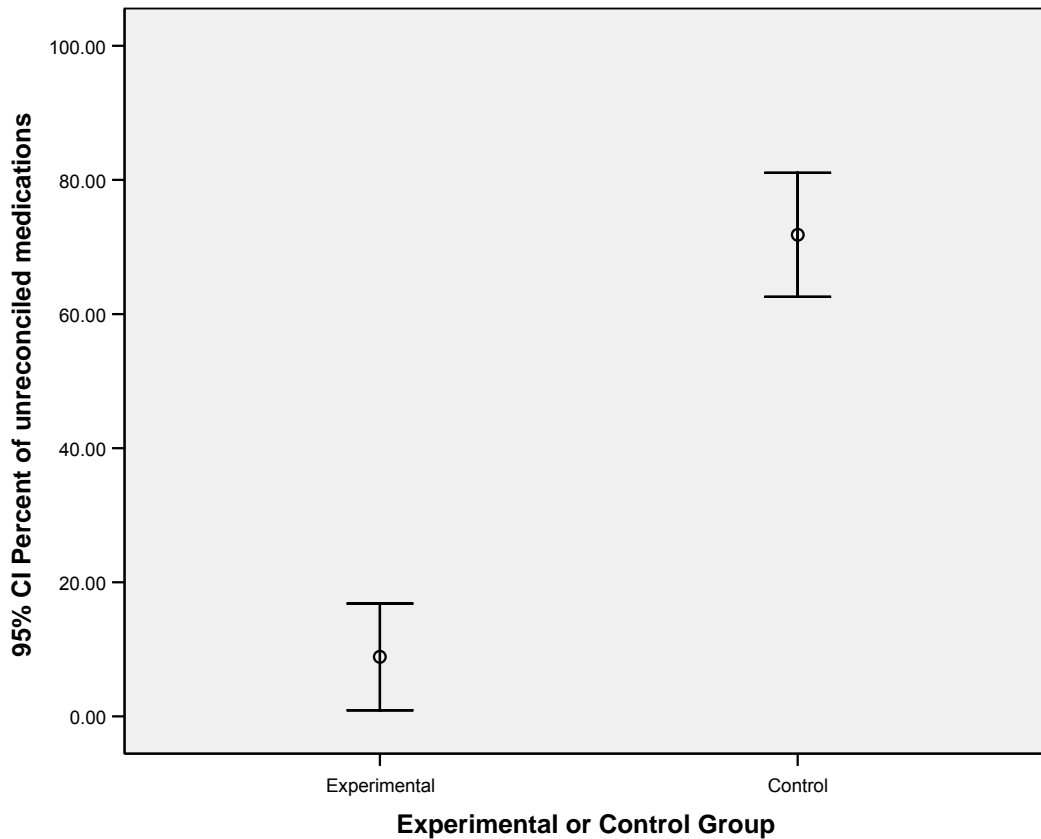


Figure 11: Error Bar of Medication Reconciliation

Hypothesis 6: The implementation of a nurse-driven discharge planning protocol for patients undergoing a cardiac implant will result in greater patient satisfaction scores when compared to patients receiving traditional discharge planning services.

The ten item Hospital Discharge Survey was used to measure patient satisfaction. Items one through three on the Hospital Discharge Survey measured discharge readiness, speed of discharge, and instructions for care at home. Items four through five measured the overall rating of the hospital. Scores on these five items generated an overall discharge composite score ranging from 4-29. The mean score for

the experimental group was 26.50 and 25.00 for the control group. Data were not normally distributed. A Mann-Whitney U test was conducted to evaluate the hypothesis that patients receiving the nurse-driven discharge planning protocol had higher patient satisfaction composite scores compared to patients receiving traditional discharge planning services. The results of the test were in the expected direction and significant, $z = -1.617$, $p = .05$. The control group had an average rank of 15.91, while the experimental had an average rank of 21.63. The hypothesis was supported by the study results. Figure 12 shows the distribution of the two groups.

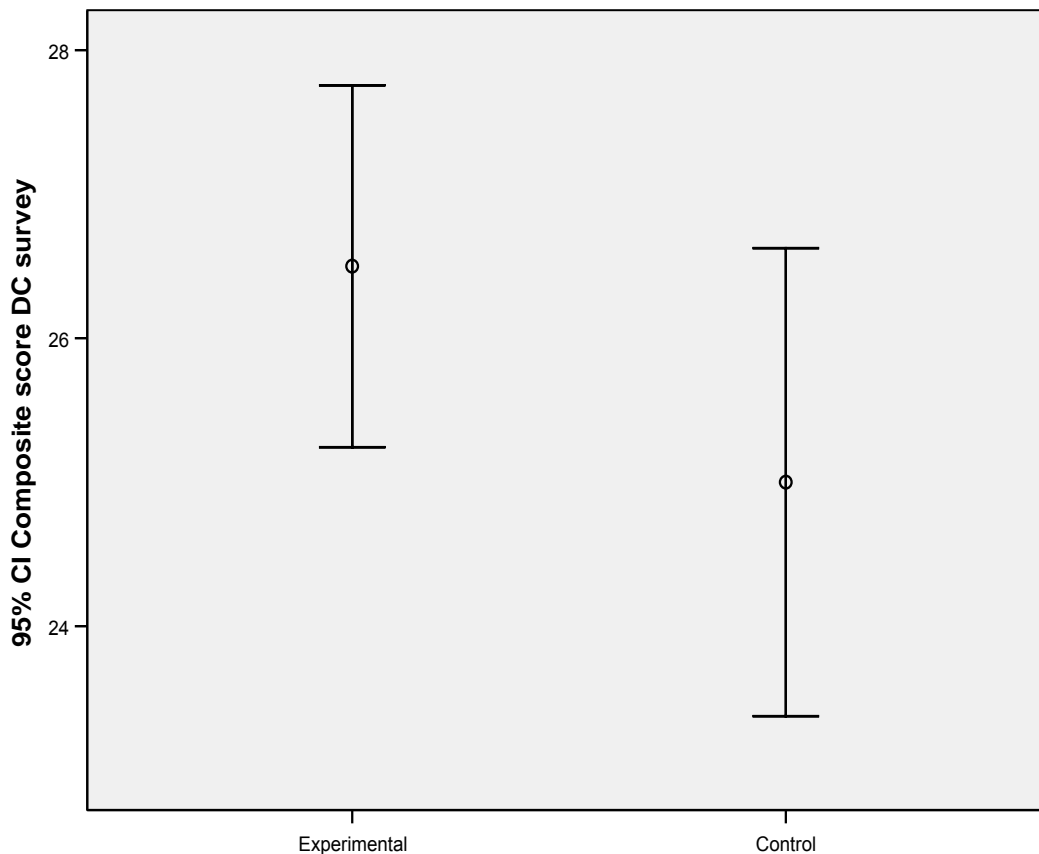


Figure 12: Discharge Composite Score

Another variable measured on the discharge survey was overall health. The mean was 2.60 for the experimental group and 3.12 for the control group. Data were not normally distributed. A Mann-Whitney U test was conducted on the discharge demographic of overall rating of health. The results of the test were significant, $z = -1.972$, $p = .02$. Participants in the experimental group had an average rank of 16.10, while participants in the control group had an average rank of 22.41. The results show that patients in the experimental group had a higher rating of their overall health when compared to the control group Figure 13 shows the distributions for both groups.

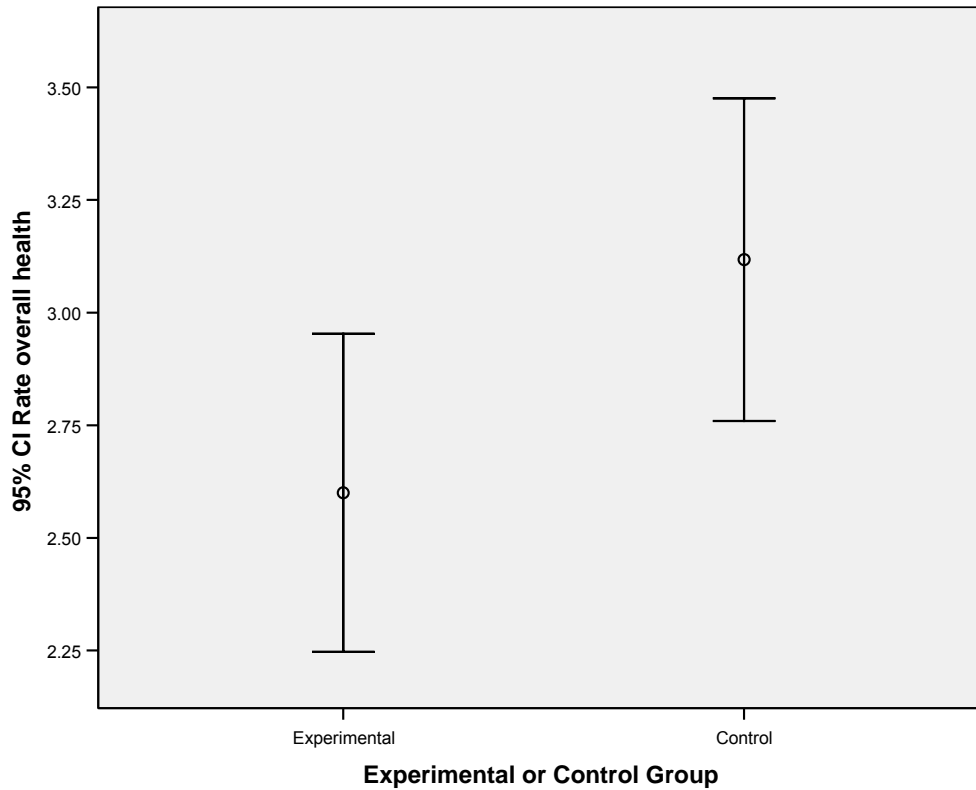


Figure 13: Overall Health

Discharge Survey Comments

The Hospital Discharge Survey provided a space for comments from the participants. Table 5 lists all comments from the survey.

Table 5: Hospital Discharge Survey Comments

Group	Comments
Control	The nurses were very good. At night there was too much noise from the nurse's station.
Control	I was never told that I would be here overnight. I had to wait for a room and there was only one bathroom for 25 patients in the recovery room.
Control	The nursing care was extraordinary. The problem we noticed was pill distribution with Sinemet. He takes pills every 2 hours. We made every effort to communicate between xxx, preadmissions, nursing and Dr xxx's office but there were gaps on his meds and this caused increased symptoms. Meds process improvements (pharmacy protocol interfered with meds).
Control	Hospital care excellent; however, patient in second bed kept me and the nurses awake.
Control	Second floor operating area was very patient oriented
Control	Failure to notify next of kin. Discharge and physician care great. Nurses also wonderful.
Control	Had very good experience with discharge and care at hospital.
Experimental	Excellent care!
Experimental	Everything seemed to go smoothly. Nurse (xxx) was great.
Experimental	Discharge process very good
Experimental	Ask for insulin, no air conditioning until discharge time, no nurse to talk before discharge
Experimental	Had to wait a couple of hours to get pacemaker checked so late breakfast but got out couple hours late is all. Xxx did a good job discharging.
Experimental	All very good
Experimental	Very satisfied
Experimental	Generally good but when trans to perm room after surgery was put in bed with blood everywhere. Patient should be cleaned up.
Experimental	Excellent nursing care

Summary

The nurse-driven discharge planning protocol resulted in a lower length of stay, earlier discharge times, lower rates of unreconciled medications, and higher patient satisfaction scores, supporting the research hypotheses. Additionally, overall rating of health was higher in the experimental group. The research hypotheses of decreased variable cost per case and a reduction on 30-day readmission rates were not supported by the research study.

CHAPTER FIVE: DISCUSSION

This chapter discusses the findings and conclusions of the study and relates those findings to the review of the literature and to the guiding theoretical framework for the research study. Several results are cutting edge and have major implications for patient safety, nursing professional practice, and organizational efficiency. Limitations of the study as well as implications for clinical practice and future nursing research are identified and discussed

Hypothesis One: Length of Stay

The study found that the implementation of a nurse-driven evidence-based discharge planning protocol was associated with a decrease in overall length of stay as compared to the control group. The average length of stay was over 1 hour and 43 minutes earlier in the experimental group. The average length of stay was 23 hours and 58 minutes for the experimental group and 25 hours and 41 minutes for the control group. Decreased lengths of stay are extremely important to healthcare organizations who strive to improve patient throughput. If elective surgical cases can be placed in an inpatient bed earlier, healthcare organizations can occupy beds with cases that provide additional revenue to the healthcare organization. If the healthcare organizations are reimbursed by a diagnosis related group (DRG) payment and can discharge before the target length of stay duration they still receive the full DRG payment and can make additional revenue.

The findings support the patient throughput issues identified in research studies by Scalise (2006) and Liu, Hobgood, and Brice (2007) of inefficient processes,

ED overcrowding, poor communication, percentage of outliers, avoidable days, and length of stay for medical surgical patients. The use of a nurse driven discharge protocol was able to overcome throughput issues (length of stay on medical-surgical units, inpatient bed utilization) that were identified by Scalise (2006). A decrease in length of stay can provide accelerated admissions to inpatient units and potentially decrease the amount of time a patient has to wait in the emergency department for an inpatient bed.

An additional throughput issue contributing to the length of stay for subjects in the study related to delays in obtaining results of the morning chest radiograph. Part of the assessment for readiness to discharge was verification of the morning chest x-ray to verify the absence of a pneumothorax post procedure. All morning chest x-rays are scheduled and obtained by 6 am. Three participants in the experimental group did not have the chest x-ray completed when the PI or IRN completed discharge rounds in the morning. Chest radiograph results were delayed secondary to overcrowding and increased patient volume in the ED. ED patients were a priority for the radiology department which caused a delay for all other patients in the health care facility. LOS was increased by 90 minutes to 2 hours awaiting the x-ray results. As innovation leaders and early adopters, the PI and the IRN were able to call the radiology department to expedite the morning x-ray; however, delays in obtaining results were common.

The results of hypothesis one do not support the findings of Preen et al (2005) who studied the impact of a coordinated hospital discharge plan and its effects on hospital length of stay, quality of life, and satisfaction with discharge procedures. The authors found that the impact of a hospital-coordinated discharge plan affected quality

of life for the patient and provider and improvements with discharge planning but no difference was found in hospital length of stay. The results on length of stay for the experimental group indicate that a coordinated nurse driven protocol can lower length of stay in cardiac implant patients.

Hypothesis Two: Discharge Time

The study found that the average discharge time was over 1 hour and 55 minutes earlier in the experimental group. The average time of discharge for the experimental group was 10:48 am compared to 12:44 pm for the control group. The results show that a specially trained baccalaureate prepared nurse can impact discharge times and potentially improve patient throughput for health care organizations. Discharge of patients prior to noon is a goal for many acute care institutions; however, achieving the goal has not been demonstrated. This is a dramatic finding for healthcare organizations and is the first research study to evaluate the role of the RN in improving patient throughput. The findings supported the use of evidence-based practice in relation to discharge care to improve quality and efficiency in the health care system (Papes, 2003).

The use of the evidence-based nurse-driven discharge planning protocol provided a support system to the bedside clinicians to assist with patient assessment and education. This corresponds with the research findings of McKenna, Ashton & Keeney (2004) which outlined the identification and importance of continued support to health care professionals when implementing evidence-based care. The bedside nurses who interacted with the PI and the IRN displayed a positive attitude and interest in the

discharge planning innovation. The research findings show that clinical leaders (the PI and IRNs) who were on the nursing unit had the ability to educate and break down the barriers to evidence-based practice. This supported the research findings of Olade (2003) who concluded that the development of a favorable attitude among nurses to integrate evidence into practice must involve clinical nurse leaders. Mid-way through the data collection process, bedside nurses were asking the PI if their patients were enrolled in the study and referred to any patient who received a cardiac implant as a “study” patient whether or not the patient was enrolled in the study.

The findings from the study supported those of Anthony et al. (2005) in relation to a newly engineered discharge process to improve communication and efficiency of a safe hospital discharge. This study used probabilistic risk assessment, process mapping, qualitative analyses, failure mode and effect analyses, and root case analysis to identify and address the sources of error at discharge. Inadequate patient education, lack of timely follow-up, and lapses in communication were found to impact health care organizations. The authors recommended a discharge process with clear role delineation and patient education. The authors also recommended a discharge process that begins before an actual discharge order is written.

The setting for this research study was a health care organization that had struggled with patient throughput issues and had targeted a discharge time of 11:00 am but never reached compliance with that standard. The experimental group had a one hour and 55 minute earlier discharge time when compared to the control group. This resulted in an average discharge time before 11 am, which has a dramatic impact on patient throughput. Earlier discharge times free up inpatient beds so emergency department

patients can be admitted to the nursing unit and patients waiting to be seen in the ED can receive treatment, thereby decreasing ED wait times. Prior to conduct of this study, many of the bedside nurses and physicians practicing at the health care organization struggled with time constraints and did not view a patient discharge order as a priority. Additionally, physicians would postpone inpatient rounds to later in the day, also resulting in delayed discharge time. This study demonstrated that a nurse-driven protocol can achieve hospital target times for discharge to improve throughput. The results correlate with the Rogers' Diffusion of Innovation conceptual framework that guided this nursing research study. The significant finding of an earlier discharge time of 10:35 am was viewed as a *relative advantage* (Rogers, 2003) for the bedside RN's and the health care organization. The *observability* of the nurse-driven discharge planning innovation was supported by the research findings of an earlier discharge time in the experimental group.

Hypothesis Three: Variable Cost

Variable costs per case and actual charges were not significantly different between the experimental group and the control group. The cost associated with each implant device differs with a permanent pacemaker the least expensive and the biventricular pacemaker the most expensive. The three experimental patients that spent additional time in the cardiac catheterization laboratory had additional costs associated with charges for recovery room time which may have caused an increase in actual charges and variable cost per case.

The author was unable to capture the potential cost savings for the electrophysiology physicians. The physician time spent on patient discharge is not reimbursed and with the IRN discharge planning innovation, the physician would have additional time to round on new patient consults or spend more time in the office, which could result in additional revenue for the physician. The research literature is silent on cost savings associated with improvements in patient throughput and organizational efficiencies. Additionally, the cost of the time saved for the bedside caregivers was not captured. If patients can be safely discharged sooner in the day, the ability to turn over the bed quicker can result in increased revenue for the organization. Additionally, there was no additional cost associated with the IRNs as they were able to implement the discharge planning protocol during their normal working hours.

Hypothesis Four: Readmission

The study found no difference in 30-day readmission rates between the experimental and the control group. Three participants were readmitted to the health care facility from the experimental group and two patients were readmitted from the control group. All five readmissions were due to outcomes after the procedure, none were due to structure or process. The two readmissions in the control group were associated with a cardiac arrest at home and physical injury to the pacemaker implantation site. The three readmissions in the experimental group were due to a deep vein thrombosis in the left arm, community acquired pneumonia, and pain management issues. One of these readmissions in the experimental group had a second readmission related to an acute dislodgement of a pacemaker lead (wire placed in the heart

chamber). Another of the readmissions was re-hospitalized for pain management issues. Interestingly, that same participant was readmitted for a third time with cardiac tamponade one week later that was due to a procedural microperforation that was not found on chest x-ray of CT scan on the second admission.

The results did not support the findings of Naylor and McCauley (1999) who found decreased readmission rates in patients that received a coordinated discharge planning and follow-up by an advanced practice nurse. The study involved an extensive 24-week discharge program and home follow up by an advanced practice nurse. Additionally, the results did not support the findings of Lappe et al. (2004) that found decreased readmission rates and mortality in cardiovascular patients who received a basic quality improvement program. The study followed patients for one year after a discharge medication program. The current study was conducted prior to discharge and limited follow up to one discharge phone call and an evaluation of 30-day readmission rates.

Hypothesis Five: Medication Reconciliation

Participants in the experimental group had significantly lower rates of unreconciled medications when compared to the control group. The experimental group had a 50 times greater likelihood of having medications reconciled compared to the control group. These astounding findings support the use of a nurse-driven protocol for medication reconciliation. The findings supported numerous conceptual studies identified in the patient safety literature regarding medication errors during patient transitions of care (AHRQ, 2000; IOM, 1999; Leape et al., 1991; Leape, 1994; West & Reeves, 2005). The findings support the results of Manning et al. (2007) who used a

new discharge medication sheet to reduce self reported medication errors compared to a standard discharge education sheet and the research findings support the study by Boockar, LaCorte, Giambanco, Fridman, & Siu (2006) who found that medication reconciliation conducted by a pharmacist reduced the occurrence of discrepancy-related adverse drug events. The finding also support the research conducted by Kramer et al. (2007) that investigated the feasibility of implementing an electronic system for targeted pharmacist and nurse conducted medication reconciliation which found greater patient understanding of the medications prescribed after discharge, including medication administration instructions and potential adverse events.

The study supports the use of an innovation leader and identified early adopters to carry out the process of medication reconciliation for patients status post cardiac implant procedure. The PI and the IRNs identified several high alert medications (coumadin, anti-hypertensive medications, and insulin) that were not reconciled at transitions in care for several study participants. Numerous patients in the control group had the instructions to “resume home medications” on discharge instructions, which could lead to dangerous adverse drug events. In two cases, the PI had to reconcile medications with the experimental group subject and/or family member. In one case, amiodarone (an antidysrhythmic) was on the home medication list and was not reconciled post procedure. Upon interview with the participant it was found that the patient was told to discontinue the medication prior to the procedure. In this case, “resume home medications” would have included a medication that should have been discontinued. In another case, the antihypertensive Norvasc was not reconciled until the IRN interviewed the participant.

This researcher found that a defined process for medication reconciliation and the clear delineation of a process owner facilitated accurate and complete reconciliation. Collaboration with the physician and the patient and/or family member was instrumental to accurately and safely reconcile medications at discharge. The results of hypothesis five underscore the importance of medication reconciliation across the continuum and specifically the importance of medication reconciliation for high-risk cardiac patients at discharge.

Hypothesis Six: Patient Satisfaction

Patient satisfaction was significantly higher in the experimental group compared to the control group. The findings support the results of Preen et al (2005) who found that a hospital-coordinated discharge plan improved confidence with discharge procedures, discharge-planning involvement, health services access, and the opinion of discharge based on the previous experience of patients. The findings also support the work of Manning et al (2007) who found that patient satisfaction was higher for patients who received a discharge medication worksheet and specific discharge instructions.

Patient satisfaction was measured by the Hospital Discharge Survey. Overall patient satisfaction was high for both groups. Research participants in the experimental group received a follow up phone call by the PI the day after the procedure. Several issues were identified and resolved for the subjects in this group. For example, the PI intervened for a participant that was presumably having an allergic reaction (total body rash) to an antibiotic post procedure and was told to discontinue the medication and call the physician's office immediately. Another participant requested home health care

during the follow up phone call which the PI then coordinated with the patient and the physician. Three participants had not looked at their incision site until the PI asked about their incision during the follow up phone call. Two participants had episodes of “light-headedness” and were told to call the physicians’ office to report their symptoms. This finding was important to assess because patients that have a successful cardiac implant experience greater cardiac output after the procedure. Typically, the same medications are continued post procedure, including diuretics. The symptoms of lightheadedness may be indicative of the need to alter medication dosages. The significance of these results can be related to the conceptual patient safety literature that emphasizes the importance of the multidisciplinary team and the involvement of the patient and family in their own healthcare.

Focus Groups

After completion of the study, the PI conducted a focus group of the IRN’s, midlevel providers, and the electrophysiology physicians to give their opinions and impressions of the discharge planning innovation. The purpose of the focus group was to provide an organizational gestalt and obtain an overall perception of the discharge experience in order to lead to further improvement of the discharge process.

The main comments from the IRNs centered on the medication reconciliation process and their personal satisfaction with having the time to spend with patients to deliver “high-quality” targeted education. The midlevel providers expressed satisfaction with the discharge follow up phone call and their wish that all patients receive a follow up call to ensure good outcomes for their patients. The electrophysiology physicians expressed

satisfaction with the overall intervention and how they felt that the patient were receiving “excellent” education that was crucial to the patients overall outcome after the cardiac implant procedure.

Limitations

The research was limited to patients at a community hospital in Southwest Florida. Research participants lacked ethnic diversity and were comprised of predominantly white males. As a result, the participants sampled may not be representative of all patients who receive cardiac implants. The results might have been more generalizable if the samples had been more diverse and if additional participants had been sampled at another healthcare facility.

The Hospital Discharge Survey was found to have limited reliability and may not have adequately measured overall patient satisfaction. Although the study was adequately powered to detect differences between groups on many of the variables, the sample size may have been underpowered for overall length of stay and variable cost per case to identify a statistical significance.

Implications of Findings

This study is instrumental and adds to the body of knowledge addressing the nurse role as a team leader in the discharge planning process. The significance of an earlier discharge time, decreased length of stay, increased medication reconciliation rates, and patient satisfaction demonstrates the crucial role of a clinical nurse leader within health care organizations.

Healthcare organizations should consider the designation of clinical nurses within their organization to take the lead in the discharge planning process. The results of this research show that a nurse leader working under the direction of defined medical protocols can safely and efficiently discharge patients for a defined patient population without the direct involvement of physicians. The dramatic result of a two-hour earlier discharge time has enormous implications for patient throughput within healthcare organizations. Freeing up a bed two hours earlier allows hospitals to decrease the time that patients wait in emergency departments for an inpatient bed, which may improve patient safety and potentially increase the amount of revenue generated for hospitals. Revenue can be generated by making an inpatient bed available for elective surgical cases and increasing the number of bed turns throughout the healthcare organization which allows for increased reimbursement. Although numerous performance improvement projects that address patient throughput are reported in the literature, this is the first research study that addresses the role of the nurse in the improvement of patient throughput.

The results of the study support the crucial role of a specially trained nurse in ensuring reconciliation of all medications at discharge. Subjects in the experimental group had a 50 times higher chance of complete medication reconciliation compared to the control group. Transitions of care (which include discharge from the hospital) are a dangerous time for patients. Medication errors are the number one cause of medical errors for patients at discharge. The subjects enrolled in the study were complex cardiac patients who had an average of 8 medications prescribed. The results of the study demonstrated that nurses operating under an approved protocol improve and promote a

safe transition for complex patients at discharge. Hospitals should consider the nurse as the team leader in the medication reconciliation process to reduce medication errors at discharge. Some institutions hire advanced practice nurses to discharge patients and improve throughput. This study demonstrated that a nurse leader without an advanced degree could safely discharge patients under the established protocol.

The research demonstrates that specially trained registered nurses can improve patient safety and be a team leader for the discharge process. The findings of this research should empower nurses to take an active role in not only the discharge planning process but in organizational efficiency. Of paramount importance, this research supports the role of the nurse in patient safety. Nurse leaders, with responsibility for the organizations largest number of employees can use these findings to lead the way to safe passage and transitions for patients throughout the continuum of care. The findings of this study support the use of a nurse-driven discharge planning protocol to promote an earlier discharge time, decrease length of stay, improve the medication reconciliation process, and improve patient satisfaction for patients status post cardiac implant placement.

Future Research Recommendations

Replicating this study in varied patient populations and in different health care organizations with larger sample sizes may be advantageous to further test outcomes of nurse-driven protocols to facilitate the discharge process and improve organizational efficiency. Further research is indicated to explore the role of the nurse as a clinical leader in the medication reconciliation process not only for discharge but for all

transitions of care. Future research is indicated to identify the role of the nurse as an innovation leader in the discharge planning process for other patient populations. Additionally, further research is indicated to define the role of the nurse as a leader in patient throughput.

Summary

This study has examined the outcomes of a discharge planning innovation after cardiac implantation and has addressed some of the gaps that exist regarding discharge planning for a specific patient population from an organizational and patient perspective.

APPENDIX A: MEDICATION RECONCILIATION

Participant Number	Control =1 Study=2	Home Medications	EMAR Medications	DC Medications
Number of Unreconciled medications	Total Number of Medications	Percent of Unreconciled medications		

APPENDIX B: LENGTH OF STAY DATA FEBRUARY 2008

Length of Stay Data Collection Tool

Definition: Total time in hours and minutes from the time the research participant arrives to unit post procedure to the time of discharge.

Arrival time definition: Time the research participant arrives in unit post procedure as documented in electronic medical record (Patient Hand-off/Transfer Form).

Time of discharge definition: The time patient physically leaves nursing unit as documented in electronic medical record.

Participant Number: _____

Experimental Group

Control Group

Date: _____

Arrival date/ time to unit (hours:minutes): _____

Discharge date/time (hours:minutes): _____

Total Length of Stay (hours:minutes): _____

APPENDIX C: READMISSION DATA COLLECTION FORM

Readmission Data Collection Form

Definition: Research participants readmitted to the healthcare facility within 30 days post cardiac implant placement. Data will be obtained by review of the Electronic Medical Record.

Participant Number: _____

Experimental Group

Control Group

Discharge Date/Time: _____

Readmission: Yes

No

Reason for readmission:

Structure: _____

Process: _____

Outcome: _____

APPENDIX D: VARIABLE COST PER CASE

MULTIPLE DATABASE
REPORT
EXPORT TEXT FILE
39,492.00
COLUMN 10.00 1.00

MULTIPLE DATABASE REPORT
14-FEB-2008 1:34 PM
Dschg,Days,Chgs,V&F Cost,Net Rev. by Type by
Pay Sum(2db)

DATE/TIME:

TABLES
Report table:
INCOME_STMT.RPC
Data bases: DCDB:NCN07.DBC
DCDB:NCN08.DBC
MBE tables: 7TRACEY.MBE
8TRACEY.MBE
Cost tables: NCNCOST0712.COS
NCNCOST08X.COS
Physician table: PHYSICIANS.PSP
PHYSICIANS.PSP
Payor summary table:
PAYORJIM.PYS
Inlier/outlier table: HCFA OUTLIER
TABLE

DISCHARGE						
RANGE OF DATABASE SELECTED	CASES SELECTED	FACILITY NAME	HOSP	DATE RANGE OF CODE DATABASE	DATE	CASES
DCDB:NCN07.DBC 03/21/2007-09/25/2007	41	NAPLES COMMUNITY HOSPITAL		NCN	10/01/2006-09/30/2007	
DCDB:NCN08.DBC 11/29/2007-01/11/2008	4	NAPLES COMMUNITY HOSPITAL		NCN	10/01/2007-01/31/2008	

ROW SORTS
First row sort:
Patient type
Second row sort: Payor summary group
name
Third row sort: Patient
identification

REPORT
QUALIFIERS
None

LOG FILE(S):
jerry.log

FORMAT OPTIONS
Text file for exports: jerry.prn
Text file data:
All levels
Text file output: Include report header
page

NOTE THE
FOLLOWING

Department 6027 in cost file references a cost factor not found in DB1
data base.

Department 7034 in cost file references a cost factor not found in DB1
data base.

Department 6027 in cost file references a cost factor not found in DB2
data base.

Department 7034 in cost file references a cost factor not found in DB2
data base.

Report generated by :
TAFLNCN

NUMBER OF CASES SELECTED FOR
REPORT = 45
End of Report Header Page

APPENDIX E: POST CARDIAC IMPLANT DISCHARGE PHONE CALL MARCH 2007

“Mrs/Mr. _____? Hello, this is <name>. You were discharged from the NCH Healthcare System <unit> yesterday. I just wanted to call and see how you are doing today.....”

“Mr/Mrs _____ did you get all of your medications filled?”

“Do you have a follow up appointment?”

“How does your incision look?”

“Mr/Mrs. _____, we want to make sure we do an excellent clinical follow-up to ensure your best possible recovery. Do you understand your discharge instructions?”

“We want to make sure you were very satisfied with your care. How were we, Mr/Mrs. _____?”

“We’re always looking to get better. Do you have any suggestions for what we could do even better?”

“We appreciate you taking the time this afternoon to speak with us about your discharge and follow-up care. Is there anything else I can do for you?”

Participant number _____ †Experimental group †Control group

APPENDIX F: ICDCMS DATA COLLECTION IMPLANT FORM



Heart Rhythm Society

ACC-NCDR® ICD Registry™
v1.08 Data Collection Form
IMPLANT

A. PARTICIPANT ADMINISTRATION:

Participant ID¹⁰⁰⁰/Name¹⁰¹⁰: _____ Medicare Provider #¹¹⁰⁰: _____ Participant NPI¹⁰¹⁶: _____

B. DEMOGRAPHICS:

Last Name²⁰⁰⁰: _____ First Name²⁰¹⁰: _____ Middle Name²⁰²⁰: _____
SSN²⁰⁰⁰: _____ Unique Patient Id²⁰⁴⁰: _____ (automatic) Other ID²⁰⁴⁵: _____
Date of Birth²⁰⁰⁰: ____/____/____ Gender²⁰⁰⁰: Male; Female
Race²⁰⁷⁰: White; Black/African American; Asian; American Indian/Alaska Native; Native Hawaiian; Other
Hispanic Ethnicity²⁰⁷⁵: No; Yes
Auxiliary 1²⁰⁰⁰: _____ Auxiliary 2²⁰⁰⁰: _____

C. ADMISSION:

Admission Date³⁰⁰⁰: ____/____/____ Date of Implant³⁰¹⁰: ____/____/____
Insurance Payor-Primary³⁰²⁰: Government; Commercial; HMO; Non-U.S. Insurance; Nons/Self Pay
→ if Government, Type-Primary³⁰²⁵: Medicare; Medicaid; TriCare; VA Health Plan; Federal Employee Insurance
Insurance Payor-Secondary³⁰²⁷: Government; Commercial; HMO; Non-U.S. Insurance; Nons/Self Pay
→ if Government, Type-Secondary³⁰²⁹: Medicare; Medicaid; TriCare; VA Health Plan; Federal Employee Insurance
Reason for Admission³⁰⁰⁰: Admitted for this Procedure; Cardiac-CHF; Cardiac-Other; Non-Cardiac
Auxiliary 3³⁰⁴⁰: _____ Auxiliary 4³⁰⁵⁰: _____

D. HISTORY AND RISK FACTORS:

Syncope³⁰⁶⁰: No; Yes Family Hx Sudden Death³⁰⁷⁰: No; Yes
CHF³⁰⁶⁰: No; Yes
→ if Yes, CHF Duration³⁰⁶⁰: Within the past 3 months; 3 to 9 months; Greater than 9 months
→ if Yes, Prior CHF Hospitalization³⁰⁶⁵: Not Hospitalized; Yes-Within 6 months; Yes-Greater than 6 months
NYHA Functional Class (Current Status)³¹⁰⁰: Class I; Class II; Class III; Class IV
Cardiac Arrest³¹¹⁰: No Arrest; Brady Arrest; Tachy Arrest
→ if Brady Arrest, Brady Arrest Reason³¹¹⁰: (Check all that apply)
 Acute MI Severe Electrolyte Disturbance Drug Induced Arrhythmia Sinus Node Dysfunction/AV Block
 Unknown Etiology
→ if Tachy Arrest, Tachy Arrest Reason³¹¹²: (Check all that apply)
 Acute MI Severe Electrolyte Disturbance Drug Induced Arrhythmia Primary VT/VF
 Unknown Etiology
Atrial Fibrillation or Flutter³¹²⁰: No; Yes
Ventricular Tachycardia³¹³⁰: No; Yes-VT, Non-Sustained; Yes-Monomorphic Sustained VT; Yes-Polymorphic Sustained VT
Sinus Node Function³¹⁴⁰: Normal; Abnormal
Cardiac Transplant³¹⁵⁰: No; Yes
Non-Ischemic Dilated Cardiomyopathy³¹⁶⁰: No; Yes-Within the past 3 months; Yes-3 to 9 months; Yes-Greater than 9 months
Ischemic Heart Disease³¹⁸⁰: No; Yes-At Least One Epicardial Artery > 70%; Yes-Other Diagnostic Tests
Previous MI³¹⁹⁰: No; Yes-Within 40 days; Yes-Greater than 40 days; Yes-Both Within 40 days/Greater than 40 days
Previous CABG³²⁰⁰: No; Yes → if Yes, Date³²¹⁰: ____/____/____
Previous PCI³²²⁰: No; Yes-Within the past 3 months; Yes-Greater than 3 months
Previous Valvular Surgery³²³⁰: No; Yes
Permanent Pacemaker³²⁴⁰: No; Yes-Atrial Chamber; Yes-Ventricular Chamber; Yes-Dual Chamber; Yes-Biventricular
Previous ICD³²⁵⁰: No; Yes-Single Chamber; Yes-Dual Chamber; Yes-Biventricular
→ if Yes, Date³²⁶⁰: ____/____/____
→ if Yes, Previous ICD Reason³²⁶⁰: (Check all that apply) Primary Prevention Syncope with Inducible VT
 Spontaneous Monomorphic Sustained VT Spontaneous Polymorphic Sustained VT Ventricular Fibrillation
 Cardiac Arrest/Arrhythmia-Etiology Unknown Syncope and High Risk Characteristics AFib
→ if Yes, Previous ICD Implant Site³²⁶⁰: Pectoral; Abdominal
Cerebrovascular Disease³³¹⁰: No; Yes Chronic Lung Disease³³²⁰: No; Yes
Diabetes³³³⁰: No; Yes Hypertension³³⁴⁰: No; Yes
Renal Failure Dialysis³³⁵⁰: No; Yes





E. DIAGNOSTIC STUDIES:

Ejection Fraction Assessed³³⁴⁰: No; Yes → if Yes, EF%³³⁷⁰: _____ %
 → if Yes, EF Timeframe³³⁶⁰: 0-1 month; 1-2 months; 2-3 months; 3-6 months; 6-12 months; >12 months
 Electrophysiology Study Done³³⁹⁰: No; Yes
 → if Yes, EPS Timeframe³⁴⁰⁰: 0-1 month; 1-2 months; 2-3 months; 3-6 months; 6-12 months; >12 months
 → if Yes, EPS Findings³⁴¹⁰: (Check all that apply. *No Arrhythmias Induced* is mutually exclusive.)
 No Arrhythmias Induced VT Induced Non-sustained VT Sustained Monomorphic
 Sustained Polymorphic Ventricular Flutter Induced Ventricular Fibrillation Induced Results Unattainable
 QRS Duration³⁴²⁴: _____ (msec) PR Interval Attainable³⁴²⁹: No; Yes → if Yes, PR Interval³⁴³⁴: _____ (msec)
 AV Conduction³⁴⁴⁰: Normal; Abnormal-1st Degree Heart Block Only; Abnormal-Heart Block 2nd or 3rd Degree(not paced); Paced (any)
 Intraventricular Conduction³⁴⁶⁰:
 Normal; Abnormal-Left Anterior Fascicular Block; Abnormal-Left Posterior Fascicular Block;
 Abnormal-LBBB; Abnormal-RBBB; Abnormal-Intraventricular Conduction Delay, Nonspecific;
 Paced; Abnormal-Bifascicular Block (RBBB Plus LAF); Abnormal-Bifascicular Block (RBBB Plus LPF)
 Creatinine³⁴⁶⁶: _____ BUN³⁴⁷⁰: _____ Sodium³⁴⁶⁸: _____ BNP Drawn³⁴⁶⁵: No; Yes → if Yes, BNP³⁴⁶⁶: _____ Systolic BP³⁶⁰⁰: _____

F. ICD PROCEDURE:

ICD Indication³⁶⁰⁶: Primary Prevention; Secondary Prevention
 Reason(s) for Re-implantation³⁶⁰⁵: (if Previous ICD³²⁵⁰ is Yes) (Check all that apply)
 End of Battery Life Device Upgrade Device Infection Device Malfunction Device Under Manufacturer Advisory/Recalled
 Multiple ICDs implanted during this admission³⁶⁴⁷: No; Yes
 → If Yes, Reason(s) for device replacement during this admission³⁶⁰⁶: (Check all that apply)
 Device Upgrade Device Infection Device Malfunction Device Under Manufacturer Advisory/Recalled
 Implant Operator's UPIN³⁶¹⁰: _____ Implant Operator's NPI³⁶¹⁵: _____
 Implant Operator's Last Name³⁶³⁰: _____ First Name³⁶²⁴: _____ Middle Name³⁶²⁵: _____
 ICD Type³⁶⁴⁴: Single Chamber; Dual Chamber; Biventricular
 → If Biventricular, LV Lead Implant Method³⁶⁶⁰: Coronary Sinus; Epicardial Lead; Other

	Manufacturer, Model Name, Model Number -or- ICD Device ID ^{3666/3670}	ICD Serial Number ^{3666/3671}
Implant:		
if Previous ICD ³²⁵⁰ is Yes then complete Explant below		
Explant:		

G. ADVERSE EVENTS: (During or after the implant procedure until discharge.)

Adverse Events Exist³⁶⁹⁰: No; Yes → if Yes, then complete Adverse Events below.

Adverse Event ³⁶⁹¹		Date ³⁶⁹³	Adverse Event ³⁶⁹¹		Date ³⁶⁹³
Cardiac Arrest ³⁶⁹⁴ :	<input type="checkbox"/>	___/___/___	Phlebitis - Deep ³⁶⁹⁴ :	<input type="checkbox"/>	___/___/___
Drug Reaction ³⁶⁹² :	<input type="checkbox"/>	___/___/___	TIA ³⁶⁹⁵ :	<input type="checkbox"/>	___/___/___
Cardiac Perforation ³⁶⁹³ :	<input type="checkbox"/>	___/___/___	CVA/Stroke ³⁶⁹⁶ :	<input type="checkbox"/>	___/___/___
Cardiac Valve Injury ³⁶⁹⁴ :	<input type="checkbox"/>	___/___/___	MI ³⁶⁹⁷ :	<input type="checkbox"/>	___/___/___
Conduction Block ³⁶⁹⁵ :	<input type="checkbox"/>	___/___/___	Pericardial Tamponade ³⁶⁹⁸ :	<input type="checkbox"/>	___/___/___
Coronary Venous Dissect ³⁶⁹⁶ :	<input type="checkbox"/>	___/___/___	AV Fistula ³⁶⁹⁹ :	<input type="checkbox"/>	___/___/___
Hematoma ³⁶⁹⁷ :	<input type="checkbox"/>	___/___/___	Infection Related to Device ³⁷⁰⁰ :	<input type="checkbox"/>	___/___/___
Lead Dislodgement ³⁶⁹⁸ :	<input type="checkbox"/>	___/___/___		<input type="checkbox"/>	___/___/___
Hemothorax ³⁶⁹⁹ :	<input type="checkbox"/>	___/___/___		<input type="checkbox"/>	___/___/___
Pneumothorax ³⁷⁰⁰ :	<input type="checkbox"/>	___/___/___			
Peripheral Nerve Injury ³⁷⁰¹ :	<input type="checkbox"/>	___/___/___			
Peripheral Embolus ³⁷⁰² :	<input type="checkbox"/>	___/___/___			
Phlebitis - Superficial ³⁷⁰³ :	<input type="checkbox"/>	___/___/___			





H. DISCHARGE: (Complete this section at discharge)

CABG During this Admission⁹⁶⁰⁰: No; Yes → if Yes, Date⁹⁶¹⁰: ____/____/____
 PCI During this Admission⁹⁶¹⁰: No; Yes → if Yes, Date⁹⁶²⁰: ____/____/____
 Vital Status⁹⁶³⁴: Alive; Deceased-Cardiac Death; Deceased-Non-Cardiac Death
 → if Deceased, Date⁹⁶⁴⁰: ____/____/____ → if Deceased, Death in Lab⁹⁶⁴⁶: No; Yes
 Discharge Date⁹⁶⁵⁴: ____/____/____

I. DISCHARGE MEDICATIONS: (Medications prescribed at discharge.)

if Vital Status⁹⁶³⁰ is Alive then complete Discharge Medications below.

Category	Medication Name ⁹⁶⁶⁰	Prescribed ⁹⁶⁶⁶				Category	Medication Name ⁹⁶⁶⁰	Pre scribed ⁹⁶⁶⁶			
		No	Yes	Con	Blind			No	Yes	Con	Blind
Ace Inhibitor	ACE-Inhibitor (any) ^{m001}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Calcium Channel Blocker	Diltiazem ^{m116}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
							Verapamil ^{m017}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
							Other CCB ^{m116}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Antiarrhythmic Agent	Amiodarone ^{m002}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Coumadin	Coumadin ^{m019}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Disopyramide ^{m003}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
	Dofetilide ^{m004}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Digoxin	Digoxin ^{m024}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Flecainide ^{m006}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
	Mexiletine ^{m014}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Diuretic	Diuretic (any) ^{m021}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Procainamide ^{m007}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
	Propafenone ^{m008}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Nitrate	Nitroglycerin SL, PRN ^{m122}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Quinidine ^{m009}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
	Sotalol ^{m110}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Nitroglycerin Long Acting ^{m123}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other Anti. Arrhy. ^{m111}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>							
Antihypertensive	Hydralazine ^{m012}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Platelet Aggregation Inhibitor	Clopidogrel ^{m024}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
							Ticlopidine ^{m025}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ARB	ARB (any) ^{m013}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Statin	Statin (any) ^{m026}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ASA	ASA ^{m014}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
Beta Blocker	Beta-Blocker (any) ^{m115}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						

APPENDIX G: HOSPITAL DISCHARGE SURVEY

SURVEY INSTRUCTIONS

- ◆ You should only fill out this survey if you were the patient during the hospital stay named in the cover letter. Do not fill out this survey if you were not the patient.
- ◆ Fill in the box that best describes your experience. If a question does not apply to you, please skip to the next question.

Please answer the questions in this survey about your discharge at the hospital named on the cover. Do not include any other hospital discharges in your answers.

1. Extent you felt ready to be discharged:

- Very Poor
- Poor
- Fair
- Good
- Very Good

2. Speed of the discharge process after you were told you could go home:

- Very Poor
- Poor
- Fair
- Good
- Very Good

3. Instructions given about how to care for yourself at home:

- Very Poor
- Poor
- Fair
- Good
- Very Good

OVERALL RATING OF HOSPITAL

Please answer the following questions about your stay at the hospital named on the cover. Do not include any other hospital stays in your answer.

4. Using any number from 0 to 10, where 0 is the worst hospital possible and 10 is the best hospital possible, what number would you use to rate this hospital during your stay?

⁰ 0 Worst hospital possible

¹ 1

² 2

³ 3

⁴ 4

⁵ 5

⁶ 6

⁷ 7

⁸ 8

⁹ 9

¹⁰ 10 Best hospital possible

5. Would you recommend this hospital to your friends and family?

¹ Definitely no

² Probably no

³ Probably yes

⁴ Definitely yes

ABOUT YOU

6. In general, how would you rate your overall health?

¹ Excellent

² Very good

³ Good

⁴ Fair

⁵ Poor

7. What is the highest grade or level of school that you have completed?

¹ 8th grade or less

² Some high school, but did not graduate

- ³ High school graduate or GED
- ⁴ Some college or 2-year degree
- ⁵ 4-year college graduate
- ⁶ More than 4-year college degree

8. Are you of Spanish, Hispanic or Latino origin or descent?

- ¹ No, not Spanish/Hispanic/Latino
- ² Yes, Puerto Rican
- ³ Yes, Mexican, Mexican American, Chicano
- ⁴ Yes, Cuban
- ⁵ Yes, other Spanish/Hispanic/Latino

9. What is your race? Please choose one or more.

- ¹ White
- ² Black or African American
- ³ Asian
- ⁴ Native Hawaiian or other Pacific Islander
- ⁵ American Indian or Alaska Native

10. What language do you mainly speak at home?

- ¹ English
- ² Spanish
- ⁸ Some other language (please print): _____

Comments: (describe good or bad experience with the discharge process):

THANK YOU

APPENDIX H: UCF IRB APPROVAL



Office of Research & Commercialization

December 8, 2006

Jacqueline Byers, Ph.D. &
Tracey L. King, RN, MSN, CCRV, CPVR
University of Central Florida
School of Nursing
HPA 225
Orlando, FL 32816-2210

Dear Dr. Byers & Ms. King:

With reference to your protocol #06-4034 entitled, "The Impact of a Nurse-Driven Evidence Based Discharge Planning Protocol on Organizational Efficiency and Cardiac Implant Patient Satisfaction," I am enclosing for your records the approved, expedited document of the UCFIRB Form you had submitted to our office. **This study was approved on 12/7/06. The expiration date for this study will be 12/6/2007.** Should there be a need to extend this study, a Continuing Review form must be submitted to the IRB Office for review by the Chairman or full IRB at least one month prior to the expiration date. This is the responsibility of the investigator.

Please be advised that this approval is given for one year. Should there be any addendums or administrative changes to the already approved protocol, they must also be submitted to the Board through use of the Addendum/Modification Request form. Changes should not be initiated until written IRB approval is received. Adverse events should be reported to the IRB as they occur.

Should you have any questions, please do not hesitate to call me at 407-823-2901.

Please accept our best wishes for the success of your endeavors.

Cordially,

Barbara Ward, BS, CIM
(FWA00000351 Exp. 5/13/07, IRB00001138)

Copies: IRB File

BW:jt

12201 Research Parkway • Suite 501 • Orlando, FL 32826-3246 • 407-823-3778 • Fax 407-823-3299

An Equal Opportunity and Affirmative Action Institution



THE UNIVERSITY OF CENTRAL FLORIDA
INSTITUTIONAL REVIEW BOARD (IRB)

IRB Committee Approval Form

PRINCIPAL INVESTIGATOR(S): Jacqueline Byers, Ph.D. and #06-4034
Tracey L. King, RN, MSN, CCRV, CPVR

PROJECT TITLE: The Impact of a Nurse-Driven Evidence Based Discharge Planning Protocol on Organizational Efficiency and Cardiac Implant Patient Satisfaction

- New project submission Resubmission of lapsed project # _____
- Continuing review of lapsed project # _____ Continuing review of # _____
- Study expires Initial submission was approved by expedited review
- Initial submission was approved by full board review but continuing review can be expedited
- Suspension of enrollment email sent to PI, entered on spreadsheet, administration notified _____

Chair

Expedited Approval

Dated: 12/7/06
Cite how qualifies for expedited review: minimal risk and #57

Exempt

Dated: _____
Cite how qualifies for exempt status: minimal risk and _____

Expiration
Date: 12/6/07

IRB Reviewers:

Signed: Tracey Dietz
Dr. Tracey Dietz, Chair

Signed: _____
Dr. Craig Van Slyke, Vice-Chair

Signed: _____
Dr. Sophia Dziegielewski, Vice-Chair

Complete reverse side of expedited or exempt form

- Waiver of documentation of consent approved
- Waiver of consent approved
- Waiver of HIPAA Authorization approved

NOTES FROM IRB CHAIR (IF APPLICABLE): _____

Informed Consent

Please read this document carefully before you decide to participate in this study.

Project Title: The Impact of a Nurse-Driven Evidence-Based Discharge Planning Protocol on Organizational Efficiency and Cardiac Implant Patient Satisfaction.

Purpose of the research study: The purpose of this research study is to examine the effects of a nurse-driven discharge protocol on organizational efficiency and patient satisfaction following cardiac pacemaker/ICD placement.

What you will be asked to do in this study: You will be randomly assigned to be in a control group or an experimental group. If you are assigned to the control group, you will receive standard discharge planning and patient education following your procedure. If you are assigned to the experimental group you will receive the standard discharge planning that all patients receive following your procedure. You will be visited by a specially trained registered nurse the morning after your procedure. The nurse will perform a physical assessment, provide specific education regarding care of your new pacemaker, and review all of your medications that you have been taking before your hospitalization and any new medications you will be taking after you leave the hospital. You will also receive written instructions on your medications and for care of your new cardiac implant device.

Time required: Approximately 1 hour that day after your procedure and 1 hour on your first post-procedure physician office visit.

Risks: There are no anticipated risks associated with this study.

Benefits/Compensation: There is no compensation or other direct benefit to you for your participation.

Confidentiality: Your study record will be kept in a confidential form at the NCH Healthcare System, Inc. The confidentiality of your record is carefully guarded. No information by which you can be identified will be published in any publication. No information by which you can be identified will be released to any third party except as provided herein or as required by law. Your identity will be kept confidential. Your information will be assigned a code number. The list connecting your name to this number will be maintained under lock and key, with access only to the principle investigator. When the study is completed and the data has been analyzed, the list will be destroyed. Your name will not be used for any report.

Voluntary participation: Your participation in the study is voluntary. There is no penalty for not participating.

Right to withdraw from the study: You have the right to withdraw from the study at any time without consequence.



Whom to contact if you have questions about the study: **Tracey King, Doctoral Candidate, School of Nursing, PO Box 162210, Orlando, Florida, 32816-2210. (239)436-5298.**

Dr. Jacqueline Byers, Faculty Supervisor, College of Nursing. The telephone number is (407)823-2744

Whom to contact about your rights in this study: **UCFIRB Office, University of Central Florida Office of Research, Orlando Tech Center, 12201 Research Parkway, Suite 501, Orlando, FL. 32826. The telephone number is (407)823-2901.**

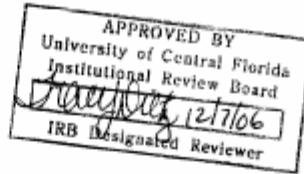
_____ I have read the procedure described above

_____ I voluntarily agree to participate in this research

Participant Signature

Date





School of Nursing

November 20, 2006

Dear Physician,

My name is Tracey King and I work as the Director of Clinical Outcomes Management at the NCH Healthcare System, Inc. I also attend the University of Central Florida where I am pursuing my PhD in Nursing.

I have completed all of the course work required for this degree and am now beginning my dissertation. My dissertation research involves studying organizational efficiency and discharge planning services for short stay patients status post cardiac implant placement. I will have a control group that will receive traditional discharge planning services and an experimental group that will receive a nurse-driven discharge protocol. ALL participants will receive the traditional standard of care, including physician interventions ordered by you, the electrophysiology physician. This research will in no way change the current standards of care that your patient receives. I will only be adding patient education and a discharge protocol to the routine care of those in the experimental group.

This research is voluntary and recruitment of participants will be done when the patient is scheduled for their procedure. There will be no coercion in the recruitment process. The participants will be randomized into the control group or the experimental group.

This research requires IRB approval, and with the IRB packet I would like to include this letter indicating you are aware of my research and you will allow me to conduct this research with your patients that satisfy the inclusion and exclusion criteria. I would be happy to provide you with any additional information at your request.

I will provide a copy of this letter to you for future reference. By signing below you are indicating you are aware of this research and are allowing me access to your patients for this research only. I will not commence this research until IRB approval is obtained from both the NCH Healthcare System, Inc., and the University of Central Florida.

Thank you,

Tracey L King MSN, RN, CCRN, CPUR
Doctoral Candidate
University of Central Florida

Tracey.king@nchmd.org

Physician Signature

Jacqueline Byers, PhD, RN, CNAA, CPHQ
Professor
University of Central Florida
407-823-6311
jbyers@mail.ucf.edu



University of Central Florida Institutional Review Board
Office of Research & Commercialization
12201 Research Parkway, Suite 501
Orlando, Florida 32826-3246
Telephone: 407-823-2901, 407-882-2012 or 407-882-2276
www.research.ucf.edu/compliance/irb.html

EXPEDITED CONTINUING REVIEW APPROVAL NOTICE

From : UCF Institutional Review Board
FWA00000351, Exp. 5/07/10, IRB00001138

To : Jacqueline F. Byers

Date : November 05, 2007

IRB Number: SBE-06-04034

Study Title: **The Impact of a Nurse-Driven Evidence Based Discharge Planning Protocol on Organizational Efficiency and Cardiac Implant Patient Satisfaction**

Dear Researcher,

This letter serves to notify you that the continuing review application for the above study was reviewed and approved by the IRB Chair on 11/4/2007 through the expedited review process according to 45 CFR 46 (and/or 21 CFR 50/56 if FDA-regulated).

Continuation of this study has been approved for a one-year period. The expiration date is 11/03/2008. This study was determined to be no more than minimal risk and the category for which this study qualified for expedited review is:

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Use of the approved, stamped consent document(s) is required. The new form supersedes all previous versions, which are now invalid for further use. Only approved investigators (or other approved key study personnel) may solicit consent for research participation. Subjects or their representatives must receive a copy of the consent form(s).

All data must be retained in a locked file cabinet for a minimum of three years (six if HIPAA applies) past the completion of this research. Any links to the identification of participants should be maintained on a password-protected computer if electronic information is used. Additional requirements may be imposed by your funding agency, your department, or other entities. Access to data is limited to authorized individuals listed as key study personnel.

To continue this research beyond the expiration date, a Continuing Review Form must be submitted 2 – 4 weeks prior to the expiration date. Use the Unanticipated Problem Report Form or the Serious Adverse Event Form (within 5 working days of event or knowledge of event) to report problems or events to the IRB. Do not make changes to the study (i.e., protocol methodology, consent form, personnel, site, etc.) before obtaining IRB approval. Changes can be submitted for IRB review using the Addendum/Modification Request Form. An Addendum/Modification Request Form **cannot** be used to extend the approval period of a study. All forms may be completed and submitted online at <https://iris.research.ucf.edu>.

On behalf of Tracy Dietz, Ph.D., UCF IRB Chair, this letter is signed by:

Signature applied by Janice Turchin on 11/05/2007 09:05:31 AM EST

IRB Coordinator

APPENDIX I: NCH IRB APPROVAL

Naples Campus
350 Seventh Street N.
Naples, Florida 34102
(239) 436-5000



North Collier Campus
11190 Healthpark Boulevard
Naples, Florida 34110
(239) 513-7000

December 19, 2006

Tracey L. King RN,MSN,CCRN,CPUR
NCH Healthcare System
350 Seventh Street North
Naples, FL 34102

RE: The Impact of a Nurse Driven Evidence Based Discharge Planning Protocol on Organizational Efficiency and Cardiac Implant Patient Satisfaction
PI: Tracey L. King RN,MSN,CCRN,CPUR
Sub-Investigator: Jacqueline Byers, PhD, RN,CNAA,CPHQ,FAAN
Professor - University of Central Florida

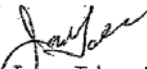
Dear Ms. King,


On December 14, 2006, the NCH IRB met and approved the above-mentioned study and informed consent. This approval covers a one-year period and requires renewal prior to December 14, 2007.

The NCH-IRB is in compliance with the regulations of the Food and Drug Administration as described in 21 CFR parts 50 and 56, as well as the International Conference on Harmonization (ICH) Good Clinical Practices (GCP) guidelines for the IRB's.

If you require further assistance, please contact Kathy Ward at (239)-436-5258.

Sincerely,


James Talano, MD
NCH-IRB Chair


Kathy Ward
IRB Secretary

APPROVED - NCH IRB
Kw and rbs/bk

NCH Downtown Naples Hospital
350 Seventh Street N.
Naples, FL 34102
(239) 436-5000



NCH North Naples Hospital
11190 Healthpark Blvd.
Naples, FL 34110
(239) 552-7000

December 13, 2007

Tracey L. King, RN, MSN, CCRN, CPUR
NCH Healthcare System
350 Seventh Street North
Naples, FL 34102

RE: The Impact of a Nurse Driven Evidence Based Discharge Planning Protocol on
Organizational Efficiency and Cardiac Implant Patient Satisfaction

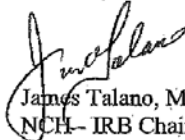
PI: Tracey King RN, MSN, CCRN, CPUR
Sub-Investigator: Jacqueline Byers, PhD, RN, CNAA, CPHQ, FAAN
Professor-University of Central Florida

Dear Ms. King,

On December 13, 2007, the NCH IRB met and approved the renewal of the above
mentioned study for a period of 1 year. This renewal covers a one year period and will
need renewal in December of 2008.

If you require further assistance, please contact Kathy Ward, IRB Secretary (239) 436-
5258.

Sincerely,


James Talano, MD
NCH - IRB Chair


Kathy Ward
NCH - IRB Secretary

APPROVED - NCH IRB

Kw 12/13/07



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