A Randomized Controlled Trial of a Discharge Nursing Intervention to Promote Self-Regulation of Care for Early Discharge Interventional Cardiology Patients

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A RANDOMIZED CONTROLLED TRIAL OF A DISCHARGE NURSING

INTERVENTION TO PROMOTE SELF-REGULATION OF CARE FOR EARLY

DISCHARGE INTERVENTIONAL CARDIOLOGY PATIENTS

a dissertation

by

KATHLEEN AHERN GOULD

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A Randomized Controlled Trial of a Discharge Nursing Intervention to Promote Self-Regulation of Care for Early Discharge Interventional Cardiology Patients

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Abstract

This randomized controlled trial (RCT) examined a discharge nursing intervention (DNI) aimed at promoting self-regulation of care for early discharge interventional cardiology patients. The purpose of this study was to compare medication adherence, patient satisfaction, use of urgent care, and illness perception in patients with cardiovascular disease (CVD) undergoing interventional revascularization procedures who receive usual care and those who receive a DNI.

The Common Sense Model (CSM) of illness representation provided the theoretical foundation for this study. The CSM is a cognitive parallel processing model that draws relationships between illness representation, coping methods, and illness outcomes to help explain the process by which people make sense of their illness. Intervention research aimed at life style changes to reduce secondary events after treatment for CVD is needed to guide evidence based care. Treatment for CVD has shifted from surgical repair with prolonged hospitalizations to interventional procedures requiring shorter hospital stays. This trend reduces nursing time to monitor complications and provide education about medication management and

lifestyle changes. Patients recover in short stay areas and return home within hours or one to two days of the procedure. Cardiac disease is then managed as a chronic, but often stable condition. With this change in the delivery of care, several trends have emerged that have implications for quality nursing care and patient outcomes: a) the burden of care shifts from the hospital setting to home, b) patients are discharged without extensive education about complications and disease management, c) the occurrence of secondary events and disease progression remain a valid threat, and d) nurses with expert practice are in a unique position to assist patients and families with CVD management.

This study addressed the following questions.

   1. Do patients receiving the nursing intervention differ significantly from those receiving usual care on medication adherence?

   2. Do patients receiving the nursing intervention differ significantly from those receiving usual care on patient satisfaction?

   3. Is there a significant difference in the utilization of urgent care between those patients receiving the nursing intervention when compared to those patients receiving usual care?

   4. Does a difference exist between the patients receiving the nursing intervention and those patients receiving usual care on illness perception, as measured by seven components of the IPQ-R: time line (acute and chronic), consequence, personal control, treatment (cure) control, illness coherence, timeline (cyclical), and emotional representations?

Purposive sampling was used to select a sample of patients admitted for interventional procedures at an academic teaching hospital. One hundred and fifty four patients were and randomized into control and experimental groups. Final analyses included data from 129 patients. Sixty-four participants in the experimental group received the DNI which included: 1) additional written information about taking medications, 2) a medication pocket card, 3) a list of 3 cardiac internet sites, and 4) a phone call, 24 hours post procedure, from an expert cardiac nurse to review discharge instructions. Sixty-five participants in the control group received usual care.

Analyses on four outcome measures, medication adherence, use of urgent care, patient satisfaction, and illness perception, revealed one statistically significant result. Participants in the experimental group, receiving the DNI, scored significantly higher than the control group on one measure, the timeline (acute/chronic) component of illness perception ($p = .006$) indicating a greater appreciation of the chronicity of their disease. Otherwise, there were no significant group differences found.

This study provides support for nursing intervention research guided by self-regulation theory that examines the patient's perception of illness. Patients with cardiac disease who received the DNI were statistically more likely to acknowledge that their illness would last a long time. This awareness, may improve adherence to a prescribed regimen of medication and lifestyle modification.

Nursing interventions guided by an understanding of patients' belief that their cardiovascular disease is chronic will add to the body of knowledge that informs providers about decisions patients make concerning medication adherence and lifestyle modifications. However, the results underscore the limitations of adding

additional discharge care to this population of patients to improve medication adherence, use of urgent care, and patient satisfaction. Future research should include a longitudinal study to examine how patients who perceive their disease to be chronic in nature managed their medications and care decisions at home.

Dedication

This work is dedicated to my parents Timothy and Mary "Jo" Ahern. Their unconditional love and support has been the cornerstone of my personal and professional life. Dedicated to family and a life of work and service, my parents instilled values that serve as the underpinning for this work. Quality, safety, and compassion for the patients we care for are values that were instilled in me at an early age. Although they can not be here to see this work completed I feel their presence and love as I complete this process.

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My children, Kevin, Kara, and Keri, have taught me to persevere and keep moving towards my goal. I am in awe of their accomplishments academically and athletically, competing and advancing in everything they do, while supporting me and taking on additional responsibilities at home and at school. They protect and care for each other everyday.

My siblings, Mary, Sheila, Peggy, and Frank supported me during this time as we loving cared for our mother at the end of her life. It was our honor and privilege to care for this wonderful woman together. I will always be grateful for their love and support.

The staff at Massachusetts General Hospital provided a supportive and professional environment for this nursing intervention. Dr. Dorothy Jones and Dr. Dianne Carroll in the Yvonne Munn Research Center were available for consultation throughout the study. Sharon McKenna RN, nurse manager of the Knight Cardiovascular Center, Kelly Trecartin RN, and the entire cardiology staff offered

essential support, and allowed me to become part of their professional environment. Their work with this patient population defines nursing excellence.

Finally, I would like to acknowledge that I could not have accomplished this goal without the expertise, guidance, and generosity, of Dr. Barbara Hazard, Dr. Cathy Read, and Dr. Jane Flanagan. As educators and mentors they offered me expert advice, kindness, and focused direction in each phase of this work. I will always be grateful for their professional and forthright guidance as I maneuvered in often unfamiliar areas. This work is a tribute to their persistence and hard work. Dr. Hazard has served as my chair and has been a constant source of encouragement from our first meeting. I am blessed to have her in my life.

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CHAPTER 1

Statement of the Problem

Overview and Incidence of Cardiac Disease

This study of patients requiring interventional cardiology procedures examines cognitive-behavioral experiences expressed as choices or adherence when patients self-manage medications and treatment protocols. The study examines the influence of a nursing discharge intervention on patient outcomes of medication adherence, use of urgent care, patient satisfaction, and illness perception as patients return to a home setting.

Significance of the Problem

Heart disease remains the number one health risk and the leading cause of death for adults in the United States. Cardiovascular disease (CVD) strikes 1 in 3 adult men and women with major cardiovascular events occurring between ages 35 to 94 (Thom et al., 2006) Epidemiological data recorded in the United States since 1900 ranks CVD as the number one cause of death every year, excluding 1918. It is predicted that 1,100,000 people will suffer a new or recurrent acute cardiac event, resulting in myocardial infarction (MI) each year. Mortality rates for those affected are as high as 45 % (American Medical Association, 2005). Annually, over 152, 000 Americans under age 65 die from CVD. Over 32% of these deaths are considered premature, occurring before age 75. Every 26 seconds someone suffers an acute cardiac event and approximately every 60 seconds, someone dies from it (Thom et al., 2006).

The epidemic of heart disease is global. Alarming rates of death and disability throughout industrialized countries and across multiple ethnic and socio-economic groups

are attributed to CVD, which remains the number one cause of death and disability in men and women in most industrialized countries (Strong, Mathers, Leeder, & Beaglehole, 2005). Treatment of CVD often requires revascularization procedures (RP). As a result of advances in technology, the treatment for CVD has shifted from surgical RP requiring extended hospital stays to emergent interventional radiological RP performed on an outpatient or short stay basis. This trend results in earlier discharge to home.

Survivors of cardiac events now benefit from rapid diagnosis and timely intervention. Intervention may consist solely of medical therapy or medical therapy in combination with non-invasive or surgically complex procedures (Banks & Dracup, 2006). Continued vigilance throughout the course of the acute event, immediately following the procedure, and during hospital or home recovery is essential to prevent secondary events and progression of disease (American Heart Association, 2004; Elsaesser & Hamm, 2004; Thom et al., 2006).

The incidence of chronic disease is increasing as a correlate of aging. In 2000, one in every five Americans was reported to have a chronic disease, many with co-morbidities, with dramatic increases in people age 65 and older (Wu & Green, 2000). Over the last 50 years, cardiovascular care has advanced from primarily medical treatment comprised of activity modification and limited cardiac pharmacotherapy, through an era of aggressive surgical revascularization and repair, to the current state of less-invasive interventional care. The primary diagnostic tool of angiography expanded into angioplasty to revascularize coronary vessels. An era of angio-dynamics was supported by clot-busting drugs, drug–eluting stents and improved imaging technology. Minimally invasive

diagnosis and treatment of vascular and cardiac structures currently replace surgical repair, in many cases. A growing population of patients undergoing interventional care such as, revascularization, structural repair, electrophysiology, and vascular remodeling with stem cell delivery, are treated with techniques described as percutaneous cardiac interventions (PCI) (Dixon, Grimes, & O'Neill 2006; Topal et al., 1988).

As a result of the new era of angio-dynamics, the care trajectory following a cardiac event has changed dramatically. The traditional care of extended bed rest, surgery, prolonged hospitalizations, and the support of cardiac rehabilitation classes and educational support groups is no longer the standard, which is now reserved primarily for unstable or severely compromised patients. Today's cardiac patients are more often fast tracked through rapid care protocols. Interventional procedures are provided within hours of the acute event. Patients recover in short stay areas and return home within hours or 1 to 2 days of the procedure. Cardiac disease is then managed as a chronic, but often stable condition, as patients continue their recovery at home (Thom et al., 2006).

The occurrence of secondary events and disease progression after a cardiac event remains a valid health threat for over 70% of CVD patients (Smith et al., 2006). Over 40 to 50% of these patients will need additional treatment because of re-stenosis of ballooned and stented coronary vessels or progression of vascular disease (Gentz, 2000; Thom et al., 2006; Veazie et al., 2005). Despite advances in technology, patients with cardiac disease must continue to manage a chronic condition. Care aimed at lifestyle changes and the reduction of secondary events, is needed to improve patient outcomes. Nursing care of the patient with CVD is occurring in very different settings as recovery from acute care moves from the hospital to home. Attention to "after care" of short stay

patients requires new models of discharge care that are evidenced based and focused on engaging the patients to self-manage their disease.

Incidence of Cardiac Disease and *Reperfusion Procedures*

Heart disease is the primary diagnosis of 1.4 million patients currently receiving traditional home care (National Center for Health Statistics, 2000). These numbers, however, mainly represent heart failure and cardiac surgical patients. A new population of interventional cardiac patients has the potential to increase the number of patients managing treatments at home. The care trajectory will be extended to include those who fall into an early discharge gap following an acute event. Interventional cardiology patients will continue to fast track through the hospital, resulting in more patients recovering in their home with or without care assistance. This population will surge as community hospitals and free standing cardiology centers expand services.

At the start of this decade, over 1 million PCI were performed annually. PCI provides less invasive treatment options for reperfusion of cardiac tissue (AHA, 2004). Medicare data from 2004 confirm the placement of 800,000 cardiovascular stents during almost 1 million PCI procedures. Current reports by the AHA and Healthy People 2010 indicate PCI and diagnostic cardiac catheterization procedures are rapidly approaching 3 million per year. From 1979 to 2002, the number of cardiovascular operations and procedures increased 470% (United States Department of Health and Human Services, 2000). This significant increase may be an indicator of increased reporting of CVD, increased longevity, improved access to health care and expanded interventional cardiology centers offering lower risk non-surgical procedures (Phelps-Fredette, 2005). This increase may also reflect patients' non-adherence to medication and lifestyle guidelines. Due to the

minimally invasive nature of PCI, patients who are older, sicker, and medically complex are good candidates for interventional cardiac procedures, during both acute and chronic phases of their cardiovascular disease.

Medical Advances and Health Care Delivery Challenges

Medical advances contribute to an increase in longevity leading to greater numbers of people living with and self-regulating chronic diseases. By 2030, over 71 million people in the United States will be over the age of 65, double the population of the same age at 2000 (National Association of Area Agencies on Aging, 2006). A critical tipping point for health care is rapidly approaching. Healthcare systems will experience increased stress as the baby-boomer generation, born between 1946 and 1964, begin to reach ages associated with CVD and related illnesses. Nursing interventions that extend beyond the scope of acute care facilities are vital to address the health care needs of this growing population.

People are living longer with more complex health conditions that are managed at home. Debilitating affects of CVD disease manifest themselves economically and emotionally, affecting families, businesses, and personal security (Bartels, 1990; Bent, 2003; Cleary et al., 1991; Ewald, 2002; Pesut & Massey, 1992; Veazie et al., 2005). Chronic disease accounts for approximately 70% of healthcare expenditures in the United States, with CVD responsible for the major amount of this cost (Thom et al., 2006). Maintaining quality patient care and cost efficiency creates challenges in the acute care setting. This burden extends through discharge, continuing as patients manage chronic conditions. Studies are needed to determine the individual needs of acute cardiac patients, and more specifically the needs of the interventional cardiac patients, whose population is

expected to triple over the next decade as less invasive procedures expand to deliver genetic therapy, bio-technology, and nano-technology (AHA, 2004).

Economic Indicators of Interventional Cardiology Expansion

Economic indicators of cardiac disease estimate that direct and indirect costs will rise from 129.9 billion dollars in 2003 to 133.2 billion dollars in 2004. Between 1997 and 2004, the Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project (HCUP) reported an increase in percutaneous transluminal coronary angioplasty (PTCA) procedures for coronary disease from 581,000 to 791,000. In 2004, cardiac catheterization, PTCA, and echocardiogram were among the most frequently performed non-obstetrical procedures in United States hospitals. HCUP statistics from 2004 also report that of the 1.6 million cardiac catheterizations conducted about 92% of the patients were 45 years and older (AHRQ, 2006). Reducing mortality and morbidity in this age group is essential because work and family responsibilities are extensive during these years.

Disease management costs continue to rise for a number of social, political, and economic reasons. Interventional cardiac technology however is expanding, at a time when expense reduction is a primary concern for healthcare providers, insurers, and patients. Currently, the medical industry is producing some of its best-selling cardiac devices, adding cost and complexity to care in efforts to improve efficiency, decrease acuity during hospitalization, and reduce the number of hospital days. PCI is one of the fastest growing healthcare fields, identified in a Morgan Stanley market report as an investment modality to watch. The 2005 Investors Guide to Interventional Cardiology projected the global number of PCI procedures to exceed 2.6 million by 2008 (Morgan

Stanley, 2005; Paquin, 2006). There are economic advantages for hospitals to provide PCI, as the procedure is highly reimbursable and requires significantly less hospital resources.

Until recently, PCI procedures were only performed in hospitals equipped with a cardiac surgical team to provide emergent care for failed or complicated PCI. Because of improved technology and highly developed medical teams, interventional cardiology procedures require minimal surgical support, allowing for safe expansion to centers without cardiothoracic services. Research is ongoing to address issues related to safety, quality, and cost to determine the evidence based value of this type of procedure in community hospitals and free standing care centers. There is sufficient evidence, beyond expert opinion and confirmed by empirical study, to support the expansion of PCI procedural sites (Wharton, 2005).

Although the American College of Cardiology (ACC) and the American Heart Association (AHA) do not recommend full PCI without cardiac surgical services on site, a growing body of evidence continues to demonstrate the safety and efficacy of primary PCI with or without the presence of cardiac surgery back-up (Lim & Kern, 2006). The ACC National Data Registry will assess and monitor outcomes and further adapt or expand guidelines for PCI centers. A large scale research study by Wharton et al. (1999) reported that emergency bypass surgery due to cardiovascular lab incidents has been less than 1% at centers without cardiac surgical services. Currently, local and global studies report adequate safety of PCI procedures without on site surgical back-up. (Ting et al., 2006; Wennberg, Lucus, Siwers, Kellett, & Malenka, 2004; Wharton et al., 2004; Wharton, 2005).

The decision to perform PCI with or without cardiac surgical support is determined by individual state's Department of Health regulations. Twenty five states permit PCI without cardiac surgery on site. Of the remaining 25 regulated states, all but five are involved in clinical studies, petitioning for permission, or have been grandfathered to perform PCI without cardiac surgical support despite regulatory restrictions (Miracle, Rodgers, & Schaadt, 2006).

Three Massachusetts community hospitals have recently received permission to offer elective angioplasty. Angioplasty procedures in Massachusetts have increased by 50% since 1998. In 2004, 17,000 PTCA were performed in the Massachusetts. In a joint venture, the Department of Public Health and Harvard Medical School are conducting a study to compare performance results of patients treated electively in the community hospital or in a Boston teaching hospital. Using a random assignment system and two sets of comparable data, the study will compare outcome data for four years (Sweeney, 2006).

Over 1,279 million angioplasties were performed nationally in 2004 (Wharton, 2006). There appears to be tremendous value in offering PCI in community settings and expanding services to free standing cardiovascular centers. Patients receive quality care closer to home as new cardiovascular centers receive lucrative reimbursements for PCI. This expansion will require new models of discharge care. Successful community hospital PCI programs report superior quality outcomes and patient satisfaction determined by patient phone calls within 24 hours of discharge (Miracle et al., 2006).

Demographics and Geography

Economic incentives often fail to consider that demographics have a tremendous impact on healthcare outcomes, especially self-care issues. A 2005 census report

indicates that 26% of the U.S. population lives alone, reflecting a shift in support

systems. This is complicated by the fact that married people live in less than half of

households. In 1915, the average household contained more than four people. Currently,

the average household has only 2.57 members. In 2006, approximately 6.1% of the 300

million U.S. residents were over 75 years old. This number is projected to increase by

2040, to 11.6% of 400 million people, living beyond 75 years (United States Census

Bureau, 2005).

Healthcare redesign is often indifferent to these shifts in family structure.

Today's demographics indicate an increased prevalence of chronic cardiac disease with a

corresponding rise in fast track treatment for an aging population. The logistics of caring

for this population at home requires research that encompasses social, educational, and

economic factors represented by current demographic trends (Thom et al., 2006).

Complex Care with Shortened Length of Stay

Medical treatment for patients during an acute cardiac event is achieved within

hours or a few days. Advanced technology and less-invasive interventions create

opportunities for patients to recover more rapidly, generating a growing population of

outpatient or short stay cardiac patients. Patients receive care in a non-surgical setting and

require minimal sedation. Smaller catheters and improved vascular closure devices

reduce bleeding and instability of the arterial access site. Consequently, patients achieve

consciousness and ambulation rapidly; many patients resume activity within hours. Early

discharge is facilitated by medical stability and hemostasis of the arterial puncture site.

Smaller catheters used to guide devices to the heart also allow access through the radial

artery as an alternative to femoral arterial puncture, minimizing mobility restrictions.

Medications essential to sustaining vascular patency are available by mouth, rather than traditional intravenous routes, and require only self monitoring.

Although there are many benefits to expedient care, the short length of stay introduces new challenges. Short stays often deprive patients of nursing time or "dose" necessary to meet proficiency levels for self-regulating their own care after discharge. A problem exists because much of the recovery and continuing care has transferred to the patient and family. As a result, new models of care and rapid response guidelines for acute cardiac events have been created within traditional settings because of thrombolytic drugs, and non-invasive access (AHA, 2004). A gap still exists however, in relation to discharge models. Because of this new trajectory of care, which places increased burden on patients and families, it is unknown how patients view their disease and how their interpretation directs self-care (Astin & Jones, 2006). More studies are needed to fully understand how these patients and families view their disease and manage post-hospital care.

Patients enter the hospital at various stages of health, often returning home feeling repaired and recognizing that the problem was "fixed," yet, they are not fully healed, or recovered. Physical, cognitive, and emotional functions are disrupted during the procedure and may not be fully restored at discharge. Knowledge about discharge protocols and the urgency of strict adherence may not be adequately communicated or comprehended. Because of the logistics of a short stay, often comparable to office or day procedures, and the less-invasive nature of PCI, patients and families may underestimate the severity of the disease. This hastened trajectory presents a gap between discharge from the hospital, where nursing intervention would provide valuable support and

information, and home care. Consequently, hospital discharge arrangements, including

individual discharge planning to ensure safe passage, are critical components in the

recovery of this short stay population.

Rapid deployment of drugs and interventional procedures, in conjunction with

short stay or outpatient care, falsely implies lower acuity. This often does not translate

into a less acute experience for the patient and family self-managing their care at home.

Implications for nursing intervention work for early discharge PCI patients are timely, as

more patients receive outpatient care for highly complex conditions.

Currently, transitional care interventions, such as medication reconciliation, exist

to improve quality and safety consistent with national safety outcomes as patients move

through health delivery settings. Inherent in this goal is a need for nurse directed

discharge interventions to ensure that patients' medication management is consistent

across transitions in care and continue at home (Haynes, McDonald, Garg, & Montague,

2002; Haynes et al., 2005).

Disease management programs (DMP) exist for chronic illness, yet many patients

fail to receive recommended standards of care (Weingarten et al., 2002). A critical

tipping point for transitional care is at discharge from an acute care facility. A problem

exists when cardiac patients experience early discharge without specific discharge

support protocols that connect them with resources and healthcare providers.

Traditionally, patients' chronicity and care needs are determined by healthcare

professionals, who define care in terms of resource allocation and acuity. Short term

recovery and management of a "stable" condition may escape the definition of chronic

illness. Increasing numbers of acute and chronically ill patients require continued

healthcare support (Krumholz et al., 2006). These patients fall into a healthcare gap, in which traditional home care is not required, but nursing consultation and education may be needed.

Researchers have identified nurse-led model intervention models to address this gap in care between hospital and home. Nursing interventions that consider multiple care delivery modes, dose of nursing time, and alternative communication methods may support self-regulation of care for patients receiving contemporary cardiac care (Blue et al., 2001; Brennan et al., 2001; Brooten, Youngblut, Deatrick, Naylor, & York, 2003; Brooten et al., 1988; Chinn & Kramer, 2004; Faxon et al., 2004; Naylor, 2003; Page, 2003; Pesut & Massey, 1992).

Acute to Chronic Disease

Although the often sudden emergence of CVD and the immediate treatment mimics an acute condition, CVD, in all forms, is a chronic disease. Prescriptions and procedures do not "cure" the chronic conditions associated with the disease, its progression, and prevalence of secondary events. Revascularized patients require anti-coagulation, cardio-dynamic medications, and a spectrum of lipid lowering drugs to reduce the incidence of immediate or long term secondary events. Electrophysiology and peripheral vascular patients also require continued medical therapy to maintain post procedure stability and reduce the incidence of secondary events.

The current health care system is seriously challenged on all fronts, clinically, fiscally, and humanely, to care for patients with chronic illness (Weingarten et al., 2002). The current system is designed to cure conditions and human events with more defined parameters. CVD may not be "curable," however, cardiac patient are surviving longer

with more complex ongoing health challenges that can be managed successfully (AHA, 2004).

Collaborative DMP that are guided by nursing research and patients' perception of illness may enhance the patient and family experience of discharge care. Gortner's (2000) vision of healthcare encourages an interface of nursing science with biological science as a basis for research. Nurses, patients, and families acknowledge that the home environment is the social context for health. Cognitive and behavioral theories provide frameworks for nursing interventions that promote self-management of disease by linking patients' perception of their illness to decisions about how to execute medication and care protocols. Social issues concerning employment, activities, and family structure may affect patients' perceptions of illness and duration of illness after cardiac events (Veazie et al., 2005). Patients' adherence to hospital based protocols may not transfer to a home setting without reinforcement and connections to the healthcare providers. The ability of the patient to perceive that the illness is controllable is associated with attendance at educational sessions, and with compliance to disease management programs (Wyer, Joseph, & Earll, 2001; & Zerwic et al., 1997).

Healthcare policy groups such as The Institute of Medicine (IOM) have called for interventions that respond to conditions and events with uncertain parameters, such as heart attacks, injuries, and diseases that can be successfully self-managed. The IOM (2001) report, "Crossing the Quality Chasm," describes the gap between the current acute illness care model and the needs of the patients with chronic illness. It challenges healthcare to describe characteristics of a new chronic care model that is patient centered and features self-management support.

Self Regulation of Care

Patients create personal models of illness and wellness from their own perceptions. The success of self-regulation during the illness event, recovery, and heath restoration depends on how they regulate responses to this model. Illness information comes from three primary sources available to the general population; previous social or cultural, educational, and experiential. These sources, considered to be "lay" or non – medical, include social environments, significant others, or knowledgeable sources such as a medical associate (acquaintance, not the patient's healthcare provider) or parent. Personal representation is influenced by the patient's experience with the illness. Patients attempt to find meaning and make sense of the experience, searching memory for cues, labels, and stored information linking abstract thoughts to the concrete experience of body symptoms related to the current illness or threat (Johnson, 1999; Leventhal, Diefenbach, & Leventhal, 1992).

The population of short stay PCI patients is understudied; therefore little is known about how and why they make decisions about medication adherence, medical advice, or urgent care (Astin & Jones, 2006). If it is expected that patients are to understand their illness to the degree that they can manage the very real threat of secondary events and severity of chronic cardiac disease, it is essential to first understand how they perceive the illness. Linking symptoms with meaning and self-diagnosis is automatic and intuitive, leading patients to respond to health threats with individual responses, such as to seek help or to delay seeking help (Dracup et al., 2003). Often, patients have little time to research medical data or process behavioral pathways during acute events and sudden

changes in health status. This issue is compounded when patients also have reduced exposure to nurses and other expert healthcare providers.

Complex Interpretation of Secondary Events

Imprecise definitions of early and late thrombosis and the magnitude of possible secondary events, amid controversy between drug-coated and bare metal stents, create challenges to follow-up care (Boden, 2007; Eisenstein et al., 2007). Expert cardiovascular nurse coaching may be needed as patients reconcile the complex issues involved in what appears to be a simple mechanical revascularization procedure. To determine best outcomes for PCI patients, Bavry et al. (2006) conducted a meta-analysis of randomized control trials and found that post-procedure medication adherence is one defining factor in the prevention of secondary events. These findings suggest that medication adherence must include the patient's adherence with all medications, including over the counter drugs. This includes aspirin, taken as anti-platelet therapy by more than 50 million American adults for long term prevention of CVD (Campbell, Smyth, Montalescot, & Steinhubl, 2007).

The controversy regarding bare metal and drug coated stents alone may warrant extended patient teaching (Bavry et al., 2006). Post procedure medication adherence is essential to suppress the neo-intimal vascular response to stent invasion. Ongoing research, however, continues to inform healthcare providers about the ideal dose and duration of drugs to reduce thrombosis. Anti-platelet therapy is highly individualized and may vary depending on a number of factors: procedure, device implanted, existing medication and co-morbidities, physician preference, and new evidence based research (Eisenstein et al., 2007; Kereiakes, 2007; Kereiakes et al., 2007).

Developing Disease Management Programs for PCI Patients

Disease management programs (DMP) and discharge nursing interventions (DNI) serve to reorganize care in a more patient-centered approach during transitions to home and alternative settings. New DMP that support improved patient outcomes, increase patient satisfaction, and decrease cost, are needed for this rapidly growing population.

As technology improves, more patients will utilize hospitals only as procedural centers or for care during acute illness. Conditions traditionally cared for within the hospital settings are now being self-managed by the patient at home and this trend is expected to continue. Some examples include medication administration and self assessment of medication affect, titration of activity levels, pain assessment, and incision site care.

Patients seek advice from both medical and popular literature, enhanced by the internet, for education and information about how to manage their experiences of health and illness (Berland et al., 2001; Fox, 2006). Patients are guided by primary care providers, hospital discharge instructions, and outpatient services. Many care decisions and health behaviors, however, are determined by patients who may not understand the severity or chronicity of cardiac disease and the high incidence of secondary events (Pesut & Massey, 1992).

A redesigned healthcare system is necessary because hospitals are encouraged to discharge patients as soon as they are medically stable to reduce cost associated with traditional in-hospital services. This may require new models of care for PCI patients that return home with discharge instruction and prescriptions, yet little is know about how patients interpret their illness and how that interpretation affects self-care behaviors.

Early discharge gives rise to a population of recovering patients for whom essential components of their treatment plan take place at home. This shift from hospital to home creates a gap in care, between the time patients are discharged and their next scheduled appointment with a healthcare provider. Ironically, economic and technological successes in healthcare challenge healthcare providers to develop new ways to revive an old idea: people caring for themselves and their loved ones at home. Self-regulation models are appropriate to guide nursing interventions that address discharge management needs of a growing number of PCI patients at risk for secondary events, who are managing their illness, medications, and symptom assessment primarily at home.

Self-Regulation Theory for Nursing Interventions

Nursing support during acute and post treatment phase may enhance the patient's ability to understand the event, treatment, and recovery trajectory. Nurse coaching through the immediate recovery period assists the patient to manage symptoms, treatments, and information in a more efficient manner. Patients may respond more appropriately to symptoms and utilize health resources more efficiently, thereby averting secondary events. Nurses are uniquely suited and positioned to examine how cognitive-affective variables affect communication among patients, practitioners, and families to achieve best outcomes (Naylor, 2003).

Nurses deal with the embodied persons as well as personal meanings. It is the attention not only to symptoms but to the person's meaning that distinguishes nursing from biomedicine and other social and spiritual services (Roy, 1995; Thorne et al., 1998). Moving beyond knowledge acquisition, patients make decisions based on individual values and life experiences. The shift from medical control to individual control is

occurring in conjunction with hospital redesign and the expanding economic crisis in national healthcare. Reduction in hospital length of stays achieved fiscal outcomes, but it is unknown what the impact this redesign care has on self care and patient outcomes (Galvin, 2005; Harrington & Estes, 2004; Heartfield, 2005; IOM, 2003; Meleis, 1987; Page, 2003).

The Common Sense Model of Illness Representation

Leventhal, Myer, & Nerenz (1980) Common Sense Model (CSM) of illness representation provides the theoretical foundation for this study. This model provides a structure for explaining individual interpretations and actions throughout the illness experience. The CSM is a valid framework for nursing interventions that include expert support during home recovery, and sustained support to manage the chronicity of cardiovascular disease. The CSM is a cognitive-emotional parallel processing model that identifies beliefs that a patient's condition can be controlled or cured. Cognitive dimensions of illness perception may direct self care in many chronic illness and acute health threats.

Recovery from acute cardiac events and continued self-management of disease may be defined by adherence to care, return to work and activities, and appropriate use of health seeking behaviors. Self-regulation of care has been studied by behavioral and medical researchers within a framework of personal models. Leventhal's illness representations such as identity, cause, time, consequence, and cure or control are examined in evidence based collaborative research (Dracup & Moser, 1997; Fabbri, Kapur, Wells, & Creed, 2001; Leventhal & Cameron, 1987; Petrie, Camerson, Ellis, Buick, & Weinman, 2002; Petrie, Weinman, Sharpe, & Buckley, 1996; Weinman, Petrie,

Moss-Morris, & Horne, 1996). This growing body of knowledge suggests that adherence to healthcare protocols is largely determined by a patient's perception of the illness, with social and cognitive variables governing motivations.

Leventhal et al. (1980) CSM model supports expert nursing knowledge and recognizes decision making and authority of the patient to fully enhance the lived experience of their illness. Nursing research examining the relationships of cognitive and emotional representations of illness and its effect on the ability of the patient to manage self-care using the CSM, may provide a credible framework for nursing interventions that help patients make sense of their symptoms, and direct action during recovery.

Patient self-regulation of medication and care protocols may require additional nursing support during recovery and regulation of the chronic illness. Nursing interventions, guided by the CSM utilizing the revised Illness Perception Questionnaire (IPQ-R), have been used in a wide range of studies. The IPQ-R has been adapted for use in investigational studies for people undergoing coronary angioplasties and genetic testing (Moss-Morris et al., 2002).

Patients with chronic disease self-manage their illness by determining what they eat, whether they exercise, and to what extent they will adhere to prescriptive medication regimes. Self-management is not easy, because it requires an understanding of complex medical regimens and life styles alterations. The concept of self-management requires a shift in perspective for providers who are used to taking total charge of a patient's illness (Cameron & Leventhal, 2003). Increasing evidence supports the fact that collaborative efforts of patients and health providers result in the best outcomes. Research using social cognitive models of planned behavior, self-efficacy, and common sense models of illness

representation, have integrated these theories to develop trans-contextual models to guide studies in clinical and transitional settings (Byrne, Walsh, & Murphy, 2005; Cooper, Lloyd, Weinman, & Jackson, 1999; Fabbri et al., 2001; & Weinman et al., 1996).

Although this model will be discussed in more detail in chapter two, a brief introduction of the components of the model introduce the link between cognitive and emotional processing, illness perception, and self-regulation of care for the short stay cardiac patient. Illness representation is measured using the IPQ-R, initially published in 1996 to assess concepts previously identified through interview or individually constructed scales (Moss-Morris et al., 2002). The questionnaire provides a quantitative assessment of components of illness perception as identity, cause, consequence, control/cure, time line, emotional representation, and illness coherence. Examination of these components help researchers measure how patients "make sense" of their illness and ultimately how emotional representations affect coping behaviors and perhaps illness outcomes.

Purpose of the Study

The purpose of this study is to examine the relationship between cognitive and emotional factors associated with self regulation of care for PCI patients experiencing early discharge. Specifically, this study examined whether a DNI that includes: 1) written information about taking medication, 2) expert nurse telephone follow-up support, and 3) consultation to review discharge instruction, will affect the following four outcomes: 1) medication adherence, 2) urgent care visits, 3) patient satisfaction, and 4) illness perception.

This study examined if the patient's ability to manage self-care is affected by

illness cognitive and emotional representations as measured by the IPR-Q. These findings add to the body of knowledge about illness perception in interventional cardiovascular patients. This study provides data for the newer factors of the IPR-Q such as, emotional representations, causal attribution, and the identity dimensions.

Definitions

Acute cardiac event. A sudden change in health causing a wide range of symptoms, possibly caused by vascular or mechanical disruption within the cardiovascular system.

Myocardial infarction. Irreversible injury to the muscle fibers of the heart.

Cardiac catheterization. A non-invasive procedure used for the diagnosis and treatment of congenital and acquired cardiovascular disease.

Interventional cardiology. A minimally invasive approach to the heart and great vessels. Percutaneous vascular access allows diagnostic and therapeutic repair of vascular and functional structures within and around the heart.

Percutaneous cardiac intervention (PCI). Approaching the heart by inserting a catheter through a blood vessel. Many of the procedures require moderate conscious sedation. A small incision in the patient's arm or leg allows the interventional cardiologist to thread a small tube with a tiny balloon, cutting device, or instrument through the cardiovascular system into the coronary vessels and cardiac structures. As a diseased or damage area is discovered, repair or restructuring of the vessel, valve, or structure is completed. Drugs and genetic therapies may also be delivered using this procedure.

Angioplasty. Opening of narrowed, diseased, or plaque-filled blood vessel using a

catheter with a balloon tip. The balloon inflates at the point of obstruction, compressing the plaque against the vessel wall.

Coronary stent. A bare metal or drug coated metal coil, transported by the balloon tipped catheter deployed within the artery at the point of balloon compression. This permanent device acts as scaffolding, mechanically keeping the vessel open and improving blood flow. Drug coating prevents scarring, tissue growth, and clot formation that may narrow the lumen of the repaired vessel.

Secondary events. Adverse events occurring after a primary or acute injury. Commonly, secondary events are the result of disease extension or progression, complications from treatment or procedures, medication complications, or conditions related to co-morbidities. These events may include a single symptom such as chest pain or a cluster of different symptoms such as fatigue, shortness of breath, or chest discomfort.

Medication reconciliation. Procedures to ensure that patients receive all intended medications and no unintended medications. This process includes identifying the most accurate list of all medications including, name, dosage, frequency, and route currently prescribed. Confirmation of this list against physicians' orders at admission, transfer, or discharge may be completed by healthcare providers and may include patients and families.

Adverse drug event. Any unwanted, unintended, or unnecessary outcome of prescribed or self-administered medication.

Conscious sedation. A drug induced state of minimal consciousness.

Self-regulation. The ability of the client to control actions and responses.

Theoretical and operational definitions of dependent variables appear in Table 1.

Table 1

Dependent Variables: Medication Adherence, Urgent Care, Patient Satisfaction, Illness Perception

Dependent Variable	Theoretical Definition	Operational Definition
Medication Adherence	The extent to which a person continues the agreed upon prescriptive therapy. A non-judgmental statement of fact indicating the extent to which a person continues prescriptive therapy. Medication adherence may be measured by biological assay, pill counts, or by self-report. This study will measure general adherence to all medications and specific adherence to ASA and Plavix.	Self-reported Responses to question 4 will be scored by a Visual Analog Scale of 0 to 100%.
		Responses will be represented as continuous variables. Questions to numbers 5-8 include a likert scale with 5 point response options, 0(rarely)-4(always). Non-adherence is indicated by scores of one or more for any one item.
		Questions 9 and10 will measure adherence to specific drugs, Aspirin and Plavix, using a Visual Analog Scale of 0-100%.

Dependent Variable	Theoretical Definition	Operational Definition
Urgent Care	Unscheduled attention for medical problem.	Sum of the responses to questions numbers 1-3 measured at an ordinal level, during the 72 hour interview.
Patient Satisfaction	The positive response expressed by a patient.	Measured by questions number 9 and 10 during the 72 hour interview. Two items with scales of 1-5 will represent patient satisfaction scores of 2-10. A score of ten indicates the highest level of patient satisfaction.
Illness Perception	Beliefs or ideas a person may have that form cognitive models of health and illness	The IPQ-R will measure seven* components of illness representation. The score for any one component will range from 4-30. Items on the IPQ-R are measured on a 1-5 scale, 1 = strongly disagree to 5 = strongly agree.

*Timeline (acute/chronic) is measured by the sum of items IP1 - IP5 + IP18, scores may range from 6 to 30.
*Consequence is measured by the sum of items IP6 - IP11, scores may range from 6 to 30.
* Personal control is measured by the sum of items IP12 - 1P17, scores may range from 6 to 30.
*Treatment control items are measured by the sum of items IP19 – IP23, scores may range from 5 to 25.
*Illness coherence items are measured by the sum of items IP24 – IP28, scores may range from 5 to 25.
*Timeline cyclical is measured by the sum of items IP29 – IP32, scores may range from 4 to 20.
*Emotional representations are measured by the sum of items IP33 – IP38, scores may range from 6 to 30.

Assumptions

- Patients are physically and emotionally able to care for themselves within a home setting.

- Patients will have a functional understanding of verbal and written discharge instructions when recovering from a cardiac interventional procedure.

- Medications and treatments prescribed at discharge will be accessible in the home setting.

- Patients will be available by telephone and will respond honestly to interviews and/or surveys.

- Illness perceptions are cognitive and emotional processes of an illness event. Patient's behavior will be influenced by the disease, event, and education experiences available to them.

Research Questions

1. Do patients receiving the nursing intervention differ significantly from those receiving usual care on medication adherence?

2. Do patients receiving the nursing intervention differ significantly from those receiving usual care on patient satisfaction?

3. Is there a significant difference in the utilization of urgent care between those patients receiving the nursing intervention when compared to those patients receiving usual care?

4. Does a difference exist between the patients receiving the nursing intervention and those patients receiving usual care on illness perception, as measured by seven components of the IPQ-R: time line (acute and chronic), consequence, personal control,

treatment (cure) control, illness coherence, timeline (cyclical), and emotional

representations?

CHAPTER 2

Review of the Literature

A literature review was guided by the researcher's clinical experience as a cardiovascular nurse. A search was conducted to assess the current trajectory of care for short stay interventional cardiac patients, and disease or discharge management programs for this population of acute, but chronically ill, ambulatory medical patients. Recurring themes of self management, prevention of secondary events, cost, quality and safety, and health care redesign directed the review to inform this study of a discharge nursing intervention designed to support self-regulation of home care. Leventhal et al. (1980) Common Sense Model (CSM) provided a structure to review studies in nursing, medical, and behavioral literature that relate to study outcomes of medication adherence, patient satisfaction, use of urgent care, and illness perception.

Healthcare Redesign Within a Self-Management Model

In 1999, the Institute of Medicine (IOM) in Washington, DC, released the report "To Err Is Human: Building a Safer Health System," bringing public attention to the crisis of patient safety in the United States (Kohn, Corrigan, & Donalson, 1999). The IOM (2001) continued efforts to promote safety and quality with "Crossing the Quality Chasm: A New Health System for the 21st Century." This second report outlined six overarching "Aims for Improvement," creating a strong surge in efforts to redesign healthcare. At the same time, the public, as patients or prospective patients, lost trust in the traditional medical model and began monitoring their own health and illness episodes more closely.

A paradigm shift in healthcare began. Local and national groups responded to this shift with credible models, expert panels, and technology enhanced data to direct redesign. The Institute of Healthcare Improvement focused on specific target areas consistent with quality and safety, and cautioned that redesign efforts: a) remain time-specific and measurable, b) define specific populations, and c) allocate the correct people and resources (www.inh.org).

Opportunities for expert nurses to redesign practice exist as a result of this shift. Nursing intervention research is necessary to test contemporary practice models, generate new data, and produce evidence based knowledge. There are, however, many complexities of data interpretation. Knowing what to measure and how to measure it can be confusing and contradictory (Levitt & Dubner, 2005). Data through the lens of quality and safety unites healthcare providers and patients and may untangle the problems within the healthcare delivery system. The focus of this research is to examine a discharge nursing intervention (DNI) that supports quality care and patient safety following discharge after percutaneous cardiac interventions (PCI) and extending to the self-regulation of chronic cardiac disease.

The current safety movement has created major improvements to reduce system errors within hospitals, but much work is needed to incorporate these gains in the home care setting. Central to this movement is the voice of the patient and family. Interventions that reflect understanding and respect for the unique experience of the patient during the illness episode, recovery, and health maintenance recognize patients as active partners in their care. DNI must begin during acute hospitalization and continue through discharge and recovery.

Current Trends for Cardiovascular Patient Management

Despite advances in interventions and medical therapy, cardiovascular disease (CVD) remains the most common cause of morbidity and mortality in western countries. More than two decades of study suggests that coronary bypass surgery, angioplasty, bare metal stents, and drug coated stents do change the trajectory for cardiac patients Acute, unstable patients receive reperfusion, reducing the immediate risk of significant cardiac muscle damage and death. Recent studies, however, confirm that no form of revascularization independently improves the survival rates of most *stable* patients experiencing an acute cardiac event (Kereiakes et al., 2007). Although surgical and non-invasive technologies provide what appears to be an instantaneous result, ongoing study reinforces the importance of continued medical therapy. Large multi-site, randomized controlled trials (RCT) support pharmacologic advances to reduce secondary events and complications (Bavry et al., 2006). Cardiac experts and national advisory groups support life style changes, continued medical follow-up, and adherence to a number of secondary preventative medications to reduce lipid levels, reduce cardiac work load, and promote cardiovascular conditioning. Recent studies recommended extending the use of dual anti-platelet therapy from under three months to over one year after an acute coronary event with or without PCI (Mitka, 2007).

Preliminary results of the Clinical Outcomes Utilizing Percutaneous Coronary Revascularization and Aggressive Guideline-Driven Drug Evaluation (COURAGE) trial found that PCI, when added to an optimal drug program, does not reduce mortality or a secondary heart attack in patients with chronic stable angina (Kereiakes et al., 2007). Results suggest that stents alone would not reduce death and secondary events by 20%, as

proposed. This reduction is only appreciated when pharmacologic support of revascularization follows stent placement (Boden, 2007). The COURAGE RCT of 2,287 patients in 50 hospitals followed patients for a median of 4.6 years, and determined that only 33% of patients benefited from PCI alone. This resulted in a shift of care from PCI as a singular intervention to PCI in conjunction with medication therapy as treatment for acute and long term CVD. These findings refocused attention to the role of patients' adherence to cardio-dynamic and anti-platelet medication, essential to the revascularization process. Study results from COURAGE reinforce the importance of post discharge protocols that encourage medication adherence. Adherence to medications remains a primary challenge for patients and providers. Simpson (2006) cautions: "there is still a wide and persistent separation between evidence based recommendations and the care patients actually receive (p. 2614)."

A treatment gap exists when patients do not receive appropriate information and medications at discharge. Researchers report significant improvement in adherence and secondary prevention when discharge medications are appropriately ordered. Even when medications are prescribed correctly, however, over 30% of patients do not fill prescriptions or adhere to dosing and administration of medications on hand (Horne, James, Petrie, Weinman, & Vincent, 2000; Lappe et al., 2004; Muhlestein et al., 2001).

Transitional Care of the Interventional Cardiac Patient

Prevention of Secondary Event

Maintaining safety and health at home requires discharge protocols that enhance adherence to medical therapy and support health seeking behaviors. In 2004, the American College of Cardiology (ACC) and the American Heart Association (AHA)

revised the 1999 practice guidelines for management of acute myocardial infarction (MI) patients with an emphasis on discharge protocols and aftercare (Antman et al., 2004). Informed by data compiled on 1, 680,000 acute MI patients identified in secondary discharge data for 2001, the revised guidelines recommend the following before hospital discharge: 1) all ST-elevation myocardial infarction (STEMI) patients should be educated about and actively involved in planning for adherence to the lifestyle changes and drug therapies that are important for the secondary prevention of cardiovascular disease; 2) all post MI patients and their family members receive discharge instructions about recognizing acute cardiac symptoms and appropriate action to take in response to effectively utilize urgent care procedures; and 3) that a daily dose of Aspirin (75mg to 162 mg orally) be given indefinitely for STEMI patients who can tolerate aspirin therapy or are not allergic to the drug or its components. Clopidogrel (Plavix) 75mg orally per day may also be indicated as a replacement for aspirin or as adjunct therapy. Clopidogrel is in a class of drugs known as anti-platelet agents that are used to prevent strokes and heart attacks in patients at risk for harmful blood clots.

Results of the Antithrombotic Trialist Collaboration (2002) a meta-analysis of 12 randomized trials of MI and stroke patients ($N = 18,788$) receiving anti-platelet therapy, suggest that adherence to anti-platelet therapy was an essential component of successful revascularization and preventive care. Researchers reported a 25% reduction in the risk of infarction, stroke, or vascular related death in patients receiving prolonged anti-platelet therapy. The group concluded that no anti-platelet therapy has proved to be superior to aspirin in doses of 80 to 325 my daily. Clopidogrel serves as the best alternative to

aspirin or as concurrent therapy. Although evidence in incomplete, many cardiologists are instructing patients to take one or both drugs for periods of 3, 6, or 12 months.

The ACC and AHA 2006 evidence based practice guidelines emphasized extended use of all evidence based secondary prevention cardiac medications. Essential secondary prevention medications for patients with myocardial infarction, atrial fibrillation, and congestive heart failure include anti-platelet therapy, statins, and cardio-dynamic drugs. These recent guidelines for transitional care of the cardiac patients are based on two key developments: 1) an aging population resulting in over 13 million people being diagnosed with coronary heart disease and 2) studies reporting that many patients are not receiving or adhering to therapies that are proven to reduce secondary events (Smith et al., 2006).

Often, patients are instructed to continue anti-platelet therapy indefinitely. Eisenstein et al. (2007) studied an observational cohort of 4,666 patients with drug-eluting stents, and found that patients continuing anti-platelet therapy for over 6 to 12 months had a lower mortality at 24 months. Kereiakes et al. (2007) reported similar results in patients with bare metal stents. As the debate continues about the risk and benefits of bare metal and drug eluting stents, patients require immediate and continued support of their healthcare providers to advocate the most up to date evidence based recommendations (Boden, 2007; Simpson, 2006; Shuchman, 2007).

Researchers continue to report that up to 50% of cardiac patients fail to either receive or comply with medication protocols at discharge or over time and that patients frequently stop medications within one year (Rasmussen, Chong, & Alter, 2007). Kulkarni, Alexander, Lytle, Heiss, and Peterson (2006) studied adherence in 1,326

patients who had undergone cardiac catherization. Using self-report to measure adherence, this study found that only 54% were compliant with all initial discharge medications one year post-procedure. Lappe et al. (2004) studied 57,465 cardiac patients adherence to specific evidence based cardiac medications recommended to prevent secondary events. Using a medication plan developed to enhance physician orders at discharge, prescription rates improved to at least 90%. One year follow-up of patients showed significant reduction in secondary events. Lappe's group illustrates that improved adherence to the prescriptive process begins with effective medication discharge protocols.

Patients are required to comprehend medication orders and care protocols over increasingly short periods of time as a result of short hospital stays. Additional challenges exist as physical, social, cultural, and economic issues complicate the patient's ability to obtain and complete medication requirements. Kaul and Peterson (2007) remind healthcare providers that cardiovascular care is complicated by regional practices and healthcare financing issues that affect care decisions. Consequently, hospital discharge is a critical period for cardiovascular patients. Individual follow up support is needed to ensure that patients receive prescriptions, fill, begin, and continue, all medications. An understanding of patients' cultural and personal beliefs may be as important as the scoio-economic or educational effect on adherence to therapy.

Limited exposure to healthcare providers due to shorter hospitalizations creates new urgency for continued discharge support. A gap may continue to exist as patients and families interpret medication instructions at home. Discharge programs that improve

medication adherence at home are a strategy to close this gap and prevent secondary events.

Early Discharge and Short Stay Trajectory

In 1994, the U.S. Department of Health and Human Services Agency for Health Care Policy and Research standard protocols identified low risk angioplasty patients eligible for discharge within one to two days. This report called for changes in traditional discharge protocols outlining specific patient counseling requirements and definitive discharge regimens for this population (Brunwald, Mark, & Jones, 1994).

Prior to the extensive use of PCI, early discharge after a cardiac event was considered to be one to two weeks. In clinical studies over fifteen years ago, low complication rates were reported between 4 to 30 days after a cardiac infarct following PCI and anti-thrombolytic therapy. The Thrombolysis and Angioplasty in Acute Myocardial Infarction (TAMI I-III) Registry was the first study to utilize multivariate analysis to identify the best predictors of safe, early discharge. As a result, the authors constructed early discharge algorithms (Mark et al., 1991). Clinical risk scores such as the TIMI Risk score captured prognostic information from a full logistic regression model for practical use at the bedside to direct treatment protocols (Morrow et al., 2000).

Newby et al. (2000) conducted a retrospective data analysis on the Global Utilization of Streptokinase and Tissue Plasminogen Activator for Occluded Coronary Arteries (GUSTO-1) trial to examine data from 22,361 patients with acute myocardial infarction who had an uncomplicated course for 72 hours after thrombolysis. Using a decision-analytic model to examine the cost effectiveness of an additional day of hospitalization, findings were consistent with (De Luca, et al., 2004) univariate and

multivariate analyses, which support early discharge. The results of these studies suggest that a broad policy of early discharge can safely be applied to a large group of low risk patients.

As economic pressure increases the need to reduce length of stay and deliver care in alternative settings, simplification of risk stratification and cost analysis provides practical tools for reshaping the acute cardiac patient trajectory (De Luca et al., 2004; Newby et al., 2000). Angioplasty and stenting of coronary vessels with a bare metal or drug coated stent is a highly reimbursable procedure, replacing the need for more costly, and riskier, surgical procedures. The estimated cost of PCI is $38,203.00. This represents half of the cost of cardiac bypass surgery, estimated at $ 83,919.00 (Marchione, 2006). Healthcare economics encourage PCI because they are associated with reduced complications and length of stay.

Measures supported by the AHA and the National Heart Lung and Blood Institute (NHLBI) call for reductions in "door to balloon" time from emergency treatment centers to cardiac catherization procedure areas. This addresses the urgent need for rapid PCI in about one third of the 865,000 heart attacks in the United States and 10 million worldwide. To assess systems efficiency, Bradley et al. (2005) found that inter-disciplinary collaboration was an essential component of rapid treatment and resulted in improved door to treatment times by 8 to 20 minutes. Rapid deployment of personnel and medication protocols that moved patients more quickly through emergency treatment to PCI, resulted in less cardiac muscle damage, and consequently, reduced morbidity and mortality rates.

Studies examining cardiovascular system efficiency in over 365 hospitals inform nursing and medical practice in the design of post procedure and discharge care (Bradley et al., 2006; Cannon et al., 2000; Moscucci & Eagle, 2006). Approximately 1,250 of the 5,000 hospitals in the United States perform emergency angioplasty, one of the most common types of PCI. Because PCI are associated with decreased rates of complications, morbidity, and debilitating chronic illness, as well as shortened length of stay, they are economically advantageous as compared to surgical interventions. As studies continue to support the efficacy of non-surgical cardiac care, hospitals continue to meet the challenge of rapid care by building new cardiovascular centers. The PCI population is expanding and adding new knowledge and challenges to the way care is delivered for the acute cardiac event (Dixon et al., 2006).

Large numbers of cardiovascular patients are discharged to home following acute coronary events and PCI. It is currently both safe and cost efficient for patients to leave the medical facility within hours or 1 to 4 days. Patients undergoing PCI for diagnostic work, requiring no immediate intervention may leave the hospital within 2 to 7 hours post procedure. Therapeutic PCI patients without complications require lengths of stay averaging 2.4 days (Miracle et al., 2006). Creative flow designs, continuous improvement programs, and expansion to non-surgical cardiac centers support a reduction in length of stay and improved cost efficiency.

In cardiac special procedure areas, patients with complex medical conditions follow an outpatient flow, essentially managing them as day procedures patients. A maximum capacity 14 bed unit, open 16 hours per day, could treat over 40 patients each day with an average census of 15 to 30 patients per day. A seven hour stay within a 14

bed unit doubles the capacity of one inpatient bed, increasing the revenue per square foot by decreasing length of stay and increasing capacity. Moving patients quickly in and out of this lucrative space requires expert nursing knowledge and innovative disease management plans; as long term success of PCI may depend on continued adherence to specific medical therapy.

Medication enhanced reperfusion, initiated during PCI, is a process that continues at home. Rasmussen et al. (2007) followed 31,455 elderly cardiovascular patients for an average of 2.4 years. The findings of this longitudinal study supported the hypothesis that an improved mortality rate is more likely a pharmacologic rather than a behavioral effect, reinforcing the current belief that good outcomes are related to medication adherence. Adherence to prescriptive therapy enhances the immediate treatment and ultimately reduces the burden of chronic cardiac disease. Medication protocols, however, are often complex and poorly understood. Patients' adherence to medications and care instructions is affected by their perception of their illness.

Study Outcomes

Adherence

This study examine patients' adherence to medication and provides information about beliefs and perceptions of their illness. Nurse coaching through discharge instructions may assists the patient to correctly interpret dosing and time requirements, therefore reconciling unintentional medication errors.

Understanding illness representations may be helpful to assess the social process of risk analysis that guides or motivates patient adherence. Adherence, defined as the extent to which patients follow the instructions for prescribed medication and treatments, is an

important factor in the outcome of all medical treatments, and an essential factor to reduce secondary events for acute cardiac patients. Non-adherence to medication is defined as missing a few doses of one drug to discontinuation of all medications. Other interpretations include using medication for something other than intended or prescribed use, to taking an erroneous dose or combination of drug.

Adherence to any medical or non medical behavior is highly individual. Medication administration is difficult for patients to manage, and even more difficult to measure. Objective measures such as biological markers and technology monitoring are costly, and self-report is often difficult to validate. Patients' beliefs and interpretation of adherence or compliance may also be very different from medical definitions. Patients become non-adherent when they forget to take some or all of the prescribed medication, misunderstand the time, dose, and length of therapy, or choose to withhold some or all of the medication.

Studies reveal that the mechanism and rationale for self-regulation of medication is complex. Medication adherence requires the coordination of complex health behaviors and may be associated with a person's confidence in the ability to self-administer prescriptive therapy (DiMatteo, Giordani, Leeper, & Croghan 2002; Eagle et al., 2004; Haynes et al., 2002; & Haynes et al., 2005). Research conducted by Ho et al. (2006) report an increased mortality rate in cardiac patients who discontinue medications. In 1,521 patients studied one month after a myocardial infarction, 184 patients discontinued all medications, significantly lowering their one year survival rate. An additional 56 patients discontinued 2 out of 3 medications, and 272 patients discontinued at least 1. Only 1,009 patients continued all 3 medications throughout the first month. This study

suggests that discontinuation of medication after MI is: a) common, b) occurs quite early after discharge, and c) requires further study to examine the levels of non-adherence and related outcomes, such as a reduction of secondary events.

A review of cardiac secondary prevention literature indicates that adverse events can be reduced by smoking cessation, improving food choices, maintaining ideal weight and cholesterol levels. Rasmussen et al. (2007) challenged the role of behavioral modifications, calling attention to the pharmacological benefits of long term cardiac survival. An essential component of life style modifications is strict adherence to medications to control blood pressure, heart function, cholesterol, and control of the platelet stickiness factor associated with early and late thrombosis following cardiac intervention (McAlister, Lawson, Teo, & Armstrong, 2001b).

Strict adherence to medication therapy is essential for the PCI patient, as the prescribed medication regimen is a continuation of reperfusion therapy and cardiac remodeling. The mechanical procedure to provide coronary vessels revascularization is a primary attempt to re-establish blood flow within the coronary circulation. Acute secondary occlusion of the vessel may occur immediately, within hours, or days. Early and late re-stenosis has been attributed to thrombolytic events. These events may occur at the site associated with the acute event, or continue in other vasculature as a progress of the process of CVD.

Adherence to anti-platelet and anti-thrombolytic drugs post PCI is necessary for a successful outcome. The benefits of these and other medications span beyond one site or the protection of any one stent or lesion. Prevention of secondary events extends beyond maintaining the patency of a stented or cleared blood vessel. The vascular disease that

causes the obstruction is not isolated, but part of a physiological process that occurs in response to aging and disease. This physiological process occurs throughout the cardiovascular system, although attention to a specific "lesion" or treatable obstruction retains the distinction of being the cause of the acute event.

Tremendous controversy exists within the medical community regarding time, duration, and dose effects of aspirin and Plavix; common anticoagulants used for post angioplasty, stent, and acute coronary syndrome patients. This presents economic, education, and access issues for a large population of patients. Physicians describe this as a major public health issue because so many people are involved, and, the cost of essential drugs such as Plavix extends to over $4.00 a day. Current reports indicate that Bristol-Myers receives 30% of its total profit from the sales of Plavix which is used by over 48 million Americans, accounting for over 3.5 billion dollars in sales within the United States alone. The economic impact of this drug has created controversy and judicial oversight as patients attempt to purchase a generic form of this drug for approximately $2.50 per dose in Canada (Saul, 2006). Cost issues related to adherence may be difficult to measure. Patients may not report efforts to conserve drugs for economic reasons.

Findings from a recent meta-analysis of 14 RCT ($N = 6,000$) on late thrombosis of drug eluting stents suggest that drug-eluting stents may increase the risk of clots (Bavry et al., 2006). It is essential that patients understand and comply with therapy that appears instantly curative, yet requires continued adherence to expensive and often controversial medication regimens. Patient with drug-eluting stents are currently advised to continue Plavix therapy for extended periods. Based on this type of scrutiny, it is alarmingly clear

that adherence to prescribed anti-coagulation is essential for patient safety and successful outcomes.

Evidence supports the benefits of these medications; however, long term adherence is significantly higher when medications are provided at a critical juncture in care, such as hospital discharge. Often, hospital admission for cardiac patients is a result of a new diagnosis, and survival of a life threatening event. It is an ideal time for patients to commit to new life style recommendations upon discharge (DiMatteo et al., 2002; Eagle et al., 2004; Lindsay, 2004). In one longitudinal study, physician-nurse collaboration resulted in improved clinical outcomes from a discharge medication program (Lappe et al., 2004). This study also suggested that a gap existed between prescribing and patient adherence.

Patient adherence and treatment outcomes have been studied across acute and chronic conditions. In studies of adherence to medical regimens, illness cognition was extracted as a theme and introduced a self-regulatory model for conceptualizing the process of adherence (Leventhal et al., 1992). In a meta-analysis of 63 studies, DiMatteo et al. (2002) found: 1) an outcome difference between high and low adherence of over 26% and 2) illness cognition was central to the construct. Astin and Jones (2006) studied patients before and after elective PCI using Leventhal's theory in a descriptive, repeated measures design using the Revised Illness Perception Questionnaire (IPQ-R). Findings indicate that participants initially displayed inaccurate illness representations but developed more realistic perceptions over time. Zerwic, King, and Wlasowicz (1997) investigated illness perception with 105 patients undergoing angiography and found,

through timeline dimension of the IPQ-R that over 40% of patients believed their illness would last a short time or were unsure of the expected timeline.

Previous studies in patients with hypertension and cardiac disease support that the timeline dimension does influence adherence to treatment. Patients who perceived that their illness would last a long time were less likely to discontinue medical therapy (Meyer, Leventhal, & Gutman, 1985). Petrie et al. (1996) study reported that timeline and consequence scores of post MI patients correlated with return to work. Patients in this study scoring high on cure control scales were more likely to attend cardiac rehabilitation. These studies used the IPQ-R to show how illness perception influenced adherence and behaviors associated with recovery and positive outcomes.

The Cochrane Database Systemic Review reviewed RCT that examined interventions designed to help cardiac patients follow prescriptive medication regimes (Haynes et al., 2002). Interventions within this review were identified as: 1) distribution of additional patient education; delivered by a team within a physician's office, nurses, or other medical personnel, delivered pre-hospital, during the hospital stay, at discharge, and post discharge, 2) the introduction of additional written material, 3) verbal instructions, 4) media enhanced education, 5) face to face visits, 6) telephone counseling, 7) automated telephone contact, 8) return to hospital visits, and 9) internet mediated programs. Measures were adherence and patient outcomes. Findings suggest that patients have improved adherence to medical regimens and experience better outcomes when additional discharge support is provided.

A more recent Cochrane Review included 57 RCT of interventions designed to enhance medication adherence associated health outcomes over multiple disease groups

(Hayes et al., 2005). Findings suggest that short term interventions, noted in four of nine interventions, including eight RCT, had a positive effect on adherence and at least one other clinical outcome. The short term interventions were relatively simple, and considered successful. Long term interventions, of at least six months were highly complex, multilayered and less conclusive. Both short and long term interventions included follow-up using telephone contact only or combinations of personal phone calls, written information, and individual counseling. Interventions were delivered by specialized nurses, physicians, and pharmacists. Five of eight short term interventions were delivered by telephone. Overall, in 57 trials, only 50% of all interventions resulted in a statistically significant improvement in outcomes.

Adherence is difficult to establish using self report. Studies of medication adherence commonly utilize self-report by yes or no responses or numerical scales ranking from 1 (none) to 7 (all). Some patients may report only the doses or drugs they "forget" and not the ones they withhold, because they feel better or because the drugs make them feel worse. Adherence is often reported as a dichotomous variable or responses that vary along a continuum of 1 to 100. Objective calculations of adherence are represented by manual pill counts (number of doses prescribed divided by numbers of pills taken) or through electronic microchips in medication caps (Haynes et al., 2005).

Maibach and Murphy (1996) described one method of adherence measurement using a standard self-efficacy format which asked patients to rate their degree of confidence when administering medication. Self-efficacy in this sense indicates the degree of confidence one has that they can successfully perform a behavior rated as 0 (not at all) to 4 (completely confident). The Morisky Medication Scale is a commonly

used adherence screen tool comprised of four yes/no questions about past medication patterns. This self-reporting scale is often used to obtain a brief drug history (Morisky, Green, & Levine, 1986). Shalansky (2004) found that a combination of structured interview and Morisky scale was a significant predictor of non-adherence in patients taking cardiovascular medications. Due to low internal consistency (alpha =.32), Morisky suggested using graded response options and increasing the number of questions to improve consistency. Morskiy's questions allow patients to explain their medication behaviors in some detail and may be a better indicator of motivations.

Ogedegbe, Mancuso, Allegrante, and Charlson (2003) developed a self-efficacy medication adherence scale using qualitative methods to identify 26 situations using a rating scale of 1 to 4 to determine the degree of certainty about taking medications in different situations. Machtinger and Bansberg, (2005) discussed the use of visual analog scales (VAS). Patients are asked to choose a point on the scale that most represents the percentage of doses completed. The VAS was found to be highly correlated to more objective measures such as adding a microchip to the medication cap and equivalent to three consistent days of verbal self-report. Percentages of 80 to 100% are reported as achieving adherence. Researchers caution that low adherence reduces treatment benefit and must be measured in relation to outcomes. (Al-Eidan, McElnay, Scott, & McConnell, 2002; Haynes et al., 2005; McDonald, Garg, & Haynes, 2002).

Health beliefs and patient characteristics including personal routines, perceived barriers to refilling and obtaining medications must be considered. Improved adherence may be associated with a higher number of medications. This suggests that increased

volume creates different perceptions of illness or demands a different level of patient attention (George & Shalansky, 2006; Morisky et al., 1986).

Adherence to medication may be further complicated by errors or omissions during self-administration. Medication errors occur at transition points in patient care. Outpatient safety issues are often related to the use of prescription and non-prescription drugs ordered by the healthcare provider, administered by the patients and families. Medication adherence may be affected by improper ordering of medications or dose, or inaccurate interpretation of the prescription by patients and caregivers.

The Institute of Medicines (IOM)' "To Err is Human" report (Kohn, et al., 1999) informed the public about the extent of medical error, including medication error. Together, the Agency for Healthcare Research and Quality (AHRQ), the Institute for Healthcare Improvement (IHI), and the National Institute of Nursing Research (NINR), focus on safety, support of nursing research and interventions to ensure patient safety in hospitals and as patients return home (AHRQ, 2001; Galvin, 2005; IOM, 2001; Jennings & McClure, 2004; Sharp, Hubbard & Jones, 2004).

In the outpatient population, medication errors, including non-adherence to prescription medication, and unintentional over or under dosing are under-reported. The national scope of this problem was identified using population based surveillance data estimating that more than 700,000 patients are treated at emergency rooms annually for adverse drug events occurring at home, when medication is self-administered by patients, with the help of family, or caregivers. Data from that study emphasizes the need for targeted implementation of current safety interventions currently employed during in-patient stays that help patients reduce medication errors at home (Budnitz et al., 2006).

Patient Satisfaction

This study will examine if a DNI improves patient satisfaction with care. The study is informed by work on evolutionary models of discharge care. Anthony and Hudson-Barr (2004) reported that patients have difficulty obtaining the information they need, leading to dissatisfaction and feelings of abandonment when they were discharged from the hospital. This descriptive longitudinal trial studied 44 patients across three time points: prior to admission, within 24 hours of discharge and 10 to14 days following discharge, examined information needs, and preference for participation in discharge planning. Seventy-seven percent of subjects reported satisfaction with the level of involvement they had in their discharge care. The study suggests that shortened lengths of stay create a need for new discharge models based on patients' perceptions. Additionally, this study indicates that patients' need for information varies at different points of care but clearly continues post discharge. Anthony and Hudson-Barr reinforces the AHA and the Picker Institute reports that recommend additional discharge support for all diagnostic groups including the short stay cardiac patient.

The researcher's clinical experience and pilot work with this patient population support the hypothesis that patient satisfaction may be adversely affected with shortened hospital stays. A reduction in nurse to patient interaction results in decreased time that nurses need to identify discharge needs, assess patients' readiness to learn, and prepare an adequate discharge plan.

Patients report having difficulty obtaining the information they need to care for themselves properly and to make informed decisions about their care. Nurses recognize that health information and disease management planning is important at discharge, but

they report that lack of time and shortened stays interfere with their ability to provide

satisfactory education. Both nurses and patients experience an unsatisfactory discharge

experience. This potential for dissatisfaction clearly exists with a high acuity short stay

patient. (Anthony & Hudson-Barr, 2004; Anthony, Hudson, Lonsway, & Liedtke, 1998).

Dissatisfaction may occur because interventional patients experience a treatment gap.

This may occur during the time period immediately following the procedure, through

discharge, and until the next scheduled encounter with a health care provider. For many

patients, this may be weeks. Patients are required to manage new symptoms, medications,

and life style changes after minimal exposure to the health care system. Discharge

instructions are often reviewed when patients are most anxious and possibly still

recovering from conscious sedation, complicated by extended amnesic effects. Written

discharge instructions are required for all patients receiving conscious sedation. As

patients return home, however, they must comprehend written instructions of varying

complexity.

The cardiac patient may experience a planned procedure in the immediate

aftermath of an acute event or be admitted urgently for a life saving intervention. In both

instances, the patient often experiences a new disease label and identity. Patients and

families require information, reassurance, and education about the cardiac event and its

meaning. Inadequate time for patient teaching results in dissatisfaction and frustration,

often evident only after the patient returns home and is required to understand and

manage his or her care alone. During illness recovery, patients relate concrete elements of

the current illness experience to past experiences. Patients who are happy with their care

develop confidence in their healthcare providers and support systems, enhancing their

ability to choose and execute health seeking and physical behaviors that promote recovery (Johnson, 1999).

Patient satisfaction determines where patients will seek treatment and who they will choose as healthcare providers (Press Ganey, 2006). Self-regulation theory acknowledges patient choice and control over healthcare issues. Patients have a central role in determining their care, one that fosters a sense of responsibility for their own health. The CSM of self-regulation moves beyond a functional capacity for care, embracing the life experiences, beliefs, and cognitive reactions to illness and wellness (Veazie et al., 2005; Weinman et al., 1996).

Use of Urgent and Emergency Care

This study collected data that adds to knowledge about health seeking behaviors demonstrated by interventional cardiac patients recovering at home. Specifically, the study examined patients' use of urgent care, described as urgent calls to healthcare providers or visits to urgent care centers. The DNI provided expert nurse coaching to help patients interpret discharge instructions at home. Discharge instructions provide an opportunity for health care providers to help the patients and families use health system resources most effectively during recovery. Healthcare resources include: phone, electronic or physical access to health providers, local emergency care, and access to community hospitals or medical centers for observation or readmission. This study does not propose that urgent care be reduced or limited, but examined how patients utilize these resources to achieve the best outcomes. A review of discharge instructions may reduce unnecessary use of resources and reinforce the appropriate use of urgent care to prevent secondary events.

Approximately 50% of persons experiencing an acute MI (primary or secondary) die before reaching a medical facility. Over half of the patients arriving in emergency rooms do not arrive by ambulance. The most critical action a person may take when experiencing a cardiac event is to call 911. The utilization of this emergency response program, formed in response to staggering statistics about heart attack survival, was studied using Leventhal et al.(1980) CSM to explore the individual decision to call 911. Meischke et al. (1995) used a telephone interview to study 2,316 post MI patients four weeks after hospitalization. Investigators reported using the CSM because it incorporated elements of the Health Belief Model, but expanded the emotional and cognitive perceptions. The study revealed that the most frequently mentioned reasons for delay or not calling 911 was the patient's thinking that the symptoms would go away. The study cautioned that understanding patients' decisions in health seeking behavior requires theoretic context to understand how patients track the illness threat and begin to form a self-diagnosis. Determining that the threat is real or harmful may be viewed as the individual's ability to shift his or her illness representation and alert him or her to seek care. Descriptive statistics revealed, however, that few patients call 911 as an initial response. Variables that factored into the decision to seek care included age, presence of other people, education, medical history, and personal beliefs.

Meischke, Eisenberg, Schaeffer, and Henwood (2000) used an intervention program that included educating seniors about the use of urgent care. The education program used the CSM to shorten the cognitive behavioral process to change the coping strategies heart attack patients apply to a cardiac emergency. The intervention included a "Heart Attack Survival Kit" delivered by emergency medical personnel, by mail, with

follow-up telephone calls asking seniors how they would respond to a cardiac emergency. The design included a control group, mail group, and personal delivery group. Telephone interviews were done using open ended questions. Results of the study suggest that door to door delivery of educational materials was somewhat more effective than mailing; however, all methods were effective in educating seniors about health seeking behaviors during perceived or actual cardiac emergencies.

Streamlining urgent care is a national and local goal of healthcare redesign. Emergency care is a valuable resource, but is costly for non-urgent health situations. Consequently, emergency rooms are inappropriately utilized and overcrowded. Unnecessary admission and readmission of patients complicates fiscal management and resource allocation. Although medically unnecessary admission or readmission is costly, delays in responding to symptoms may result in unnecessary mortality and morbidity. At critical balance points are cardiac patients entering from home, often in various states of recovery from acute events. Rapid diagnosis and time dependent therapies for stroke and acute cardiac events often depend on patients' ability to triage themselves into the system. Self-management theory provides a framework to guide patients and caregivers through this process.

Zerwic, Ryan, DeVon, and Drell (2003) studied cognitive variables related to health seeking behaviors across gender, age, and ethnicity, examining factors that contributed to prolonged delays in populations at risk, including people with socio-economic challenges. Nursing and collaborative studies of cardiac patients and readmission to acute setting are supported by self-regulatory theory (Brice et al., 2001; Cannon et al., 2000; Horne et al., 2000; Moser et al., 2006). Banks and Dracup (2006)

found that African Americans may have specific fears or inaccurate perceptions of illness

that resulted in delays to treatment and appropriate use of urgent care. Dracup et al.

(2003) used Leventhal's Model of Self-Regulation as a cognitive-behavioral framework

to examine how patients determine when and how to seek treatment for acute cardiac

events. Dracup's international nursing study encouraged the use of this model for future

nursing research to examine how illness perception influences decisions to seek medical

care. Findings suggest that decisions and behaviors related to self-care correlate with

specific illness perceptions.

Nursing management, specifically the role of the expert nurse delivering an

intervention at discharge and post discharge, can improve the outcomes of patients

seeking care during recovery from acute and chronic conditions at home (Brooten et al.,

2003). Blue et al., 2001 conducted a RCT of patients with chronic heart failure receiving

interventions that included telephone support and home visits. The study followed

patients for one year after discharge. Findings report that specially trained nurses were

linked with improved outcomes, measured in fewer days in hospitals and fewer

readmissions.

Theory based research for urgent care and recidivism is necessary to understand

the complexities of problems related to chronic disease management and health

disparities. Studies combining self-efficacy, chronic illness and disease management

across ethnic and disease groups have demonstrated that these issues are complicated by

health literacy problems and language barriers (Loring, Ritter & Gonzales, 2003).

This study will direct discharge interventions that reinforce the appropriate use of

urgent care resources for patients at risk for secondary events. In the presence or absence

of a structured disease management program, patients' beliefs about their illness determine how they seek information, medical advice, and urgent care.

Recovery, pain management, chronic illness, and social needs often depend on the ability of the patient and family to self-manage the continuum of care, which includes self-triage. An understanding of the patient's strengths is measured in terms of physical abilities and resources for self-care, including the ability to seek information and support from multiple resources. To adequately navigate the system of home, hospital, and accessible resources patients are required to be rational, responsible, knowledgeable, and calculative. Currently, negative outcomes or consequences of reduced length of stay are elusive, measured simply as readmissions to hospitals, urgent care visits, or a combination of both. Readmission is a poor indicator as it may or may not be related to the original diagnosis. Organizational consequences of delays to treatment as well as inappropriate use of urgent care resources include additional costs to the patient, third party payers, and the hospital itself (Heartfield, 2005, 2006).

Illness Perception

Health behaviors immediately after PCI procedures have a significant impact on secondary events. Linking health behaviors to illness representation may inform interventions that build new disease management programs to improve the immediate and long term health of this population. It is the premise of this study that short stay PCI patients have inaccurate perceptions of their cardiac disease, which may be altered by a DNI that provides nursing consultation to help patients interpret discharge instructions and guidelines for self-regulation of their illness.

Patients undergoing PCI may have restricted access to knowledgeable resources, simply as a result of reduced in-hospital time. Rapid, less-invasive treatment of acute cardiac events may lead to inaccurate illness representations which may influence health behaviors during recovery. Behaviors, related to adherence to treatment protocols or delays in responding to symptoms, are solutions people find to deal with problems as they perceive them. Healthcare threats, often complex and foreign to the person facing them, require common sense behaviors as well as learned or coached behaviors. Patients are left to deal with these threats alone or with the support of lay family members.

The paradigm of self-care, symptom management, and illness perception has shifted over the last 30 years in relation to myocardial infarction, the usual course of which includes an initial crisis, recovery, and return to normal activities or a life forever changed. Reigel, Dracup, and Glaser (1998) describe a causal model of cardiac invalidism (perceptions of illness severity and degree of social, emotional, and physical impairment) following myocardial infarction as patients evaluate relationships among components of health perception, emotional distress, and feelings of interpersonal dependency. This group found that health and illness perception may have positive or negative effects on the degree of impairments patients report during recovery from an acute cardiac event. Healthcare providers may be able to alter the incidence of cardiac invalidism by helping patients modify their perceptions of health changes using self-management strategies, such as careful self-monitoring of medication effects, attention to salient symptoms, and empowerment techniques such as education and information about their disease (Clark et al., 2006; Dracup & Moser, 1991; Lorig, Sobel, & Stewart, 1999; Loring & Holman, 2003).

From a medical perspective, morbidity, and mortality were the most common indicators of health. Nursing research introduced concepts of health and illness along a continuum where health and illness represent qualitatively different concepts defined from the patient's perspective and suggesting self-care as a means to achieve health potential during acute, chronic, and stable health conditions (Pender, 1996, 2002). Fundamental changes in the way nurses conceptualized health began to emerge as patients became collaborative partners in care. Studies include the use of self-efficacy theory to move beyond physical outcomes (Allen, 1990; Gillis, 1983; Gortner et al., 1988; Gortner & Jenkins, 1990).

In 2000, the United States Department of Health and Human Services published a landmark report, *Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention*, reflecting a shift in goals for improving health outcomes for all Americans. The report suggested that major improvements in health care, including self-management, behavioral changes, and life style management, could alter traditional medical care. The series shifted health policy from the traditional curative and disease focus to one that enhances healthy lifestyles and measures outcomes related to patients' perspectives. This expanded health promotion model, with themes of self-care and self management of illness threats, is consistent with the CSM, which expands the constructs of Pender's self-care model to encompass a broader view of health through cognitive and emotional perception. This publication of Healthy People 2010 contains specific goals that include self-management of both acute and chronic illness (Committee on Quality Health Care in America, 1999; United States Department of Health and Human Services, 2000).

Designing A Discharge Nursing Intervention

Nursing Challenges

Today's cardiac patients are offered a quick fix with PCI; consequently, they may underestimate the degree to which they must monitor their condition. Evidence continues to support that prognostic information and education are essential to good patient outcomes during home recovery, however, nurses report that a lack of time and shortened hospital stays impede their ability to prepare many patients for discharge (Anthony & Hudson-Barr, 2004).

Wharton (2005, 2006) reported that the number of PCI patients will increase exponentially, as a result of evidence based practice guidelines that eliminate the mandate for on-site cardiac surgery for this service. New nursing models of care delivery are necessary as care moves beyond the in-patient disease management model toward a wellness-at-home model where patients will assume increased responsibility to self-regulate their care.

Nursing interventions and case management models continue to evolve in response to early discharge. Discharge management programs (DMP) focus on earlier return to work, activities, and self-management of cardiovascular disease as a chronic illness. Prevention of complications and reduction of secondary events require patient adherence, influenced by cognitive and emotional interpretation of the illness. Nurses have the ability to create interventions that are highly individual, easily monitored, and include expert support through telephone calls, support groups, and e-mail. Because of its focus on health, holism, and continuity of care, nursing is uniquely poised to develop new

models as nursing care continues to evolve and change with the needs of the cardiac patient, from forced bed-rest, to arm chair treatment, and now to ambulatory care.

Why Nursing Discharge Support is Needed

Hospital nursing care has been impacted by a new concept of time. Patients and families seek information from a variety of sources since expedited care reduces time and teaching that was traditionally completed in the hospital setting. Patients often experience life-altering events, and struggle with a new disease label; however, their contact with expert cardiac nurses is limited. Patients undergoing PCI receive care in cardiovascular centers where early ambulation is an indicator of discharge readiness. Early discharge and a shortened time for nurses to prepare patients for discharge create problems, especially when coupled with functional needs or uncertainty regarding their illness.

Financial issues and biotechnology also impact care. New devices and drugs are continuously introduced, adding new risks and uncertainty for patients discharged to home. The ever changing state of fiscal reimbursement creates challenges as providers balance cost effectiveness against standards of care. Reduced lengths of stay require new models of care driven by patients' needs. The focus on length of stay, combined with expanding health care needs, calls for advanced knowledge about healthcare institutions and responsibilities for self-care (Heartfield, 2006).

Global and local efforts support nursing research to create new models that address chronic care, self-management, and behavior change. The World Health Organization (WHO) (2003), The Cochrane Organization , The Robert Wood Johnson Foundation (RWJF) and recently, in 2004, the United States Office of National Coordination for Health Information Technology Commission, are working to address

the needs of people self-managing chronic illness (Barrett, 2005; IOM, 2001). A Health Research and Educational Trust project is currently funded by The Robert Wood Johnson Foundation to help health care organizations create effective, culturally sensitive self-management support programs (RWJF, 2004, 2009).

Transitional Care Models for Cardiac Patients

Interventional cardiology clearly represents a major growth area for medicine, technology, and nursing practice. As this patient population moves into community hospitals and cardiovascular centers, connections that extend beyond the acute phase of care are essential. Healthcare economics and technology create experiences that quickly overwhelm patients and the systems that serve them. Nursing expertise, education, and advocacy post discharge move patients forward in managing their own care. Comprehensive discharge planning with post discharge support for this population extends to a demographically diverse group.

Nursing interventions designed to improve the transition of patients from hospital to home currently exist for patients identified at risk, including the elderly or those with complex symptoms such as congestive heart failure. Collaborative models of care for cardiac and chronically ill patients inform practice, reduce re-admission rates and mortality, and support decreased length of stay, improved quality of life, and reduced medical cost (Phillips et al., 2004).

Behavioral Theory to Guide New Models

Transitional care models, designed for specific conditions and procedures, are grounded in behavioral theory. A review of cardiac surgical discharge programs

identified the need for nursing research to evaluate the effect of information on patient

behaviors that affect recovery outcomes (Weintraub et al., 1998).

Studies using the parallel response model of coping examined the responses of

cardiac surgical men and women receiving an audio-taped message about the recovery

process. This research is important to nursing science as it aimed at symptom

management through self-regulation, illustrating the use of the dual coping pathways

(parallel processing) that patients mobilize, which are directed at cognitive and emotional

outcomes and the positive effects they exhibit on physical or functional outcomes

(Johnson, Fieler, Jones, Wlasowicz, & Mitchell, 1977; Moore & Dolansky, 2001).

Ambulatory surgery models have extended to surgical cardiac and congestive heart

failure patients as this population manages recovery and self care at home. McAlister,

Lawson, Teo, and Armstrong (2001a) performed a meta-analysis of 11 studies, informed

by behavioral theory that used multidisciplinary team for patient follow-up. In a study of

over 2,000 patients with heart failure, McAlister et al. (2001a) reported significant

reductions in re-admission and overall cost.

Models Based on Quality and Outcomes

The AHA (2004) quality improvement program, *Get with the Guidelines-CAD,* is

designed to capture teachable moments by introducing acute care and secondary

prevention guidelines immediately after an acute cardiac event. Endorsed by the AHA

and the ACC, the guidelines and tools direct hospital based rapid response teams (RRT)

to provide medical intervention in the hospital before a patient becomes critically ill. This

approach supports and assesses patients' adherence to medical treatment following acute

coronary events, stroke, and heart failure. The program begins in the hospital and

continues at home. *Get with the Guidelines* programs improve adherence to discharge interventions in patients of all ages. The AHA and ACC suggest that a nationwide commitment to similar programs for secondary prevention could save more than 80,000 lives a year (Smith et al., 2006).

Existing Transitional Care Models

Nursing research on discharge planning and transitional care (Naylor, 2003; Naylor et al., 1994, 1999) has emphasized either in-hospital or post-hospital experience, often targeting specific populations at risk (Brooten, et al., 2003; Anthony & Hudson-Barr, 2004). The studies, focused on discharge care, demonstrated significant reductions in health care cost while supporting advanced practice and expert nurse coaching. The work addressed transitions across care environments, and focused on the need for skilled, educated nurses to extend care and achieve better outcomes.

Brooten et al. (1988) developed a transitional model that provides continuity of care for vulnerable patients by matching the specialized skills of advanced practice nurses to patients' needs. The model offered a safety net to vulnerable groups at a time when managed care began to recognize the extreme cost of hospital care. Patients were being discharged early, but hidden costs emerged related to secondary events and readmission.

Naylor et al. (1999) evaluated a highly complex hospital discharge protocol administered by advanced practice nurses (APN) in conjunction with patients' physicians, caregivers, and other home-based service providers. Program components included individualized discharge planning; assessment of functional, cognitive, and emotional health; extensive self-management education; and regularly scheduled home visits and telephone contact. Naylor's group found that APN-centered discharge planning and home

care intervention for at-risk hospitalized elders reduced readmissions, and extended the time between discharge and readmission. The intervention, consisting of individual discharge planning and home follow-up, demonstrated great potential as a model for DMP, by promoting positive outcomes for hospitalized elders at high risk for re-hospitalization. A hallmark of this study was the use of expert nurses to decrease the cost of providing health care. Both groups were followed at 2,6,12, and 24 weeks post discharge. Cost savings were measured using total Medicare reimbursements for health services, reported as approximately $1.2 million in the control group as compared to $0.6 million in the intervention group ($p < .001$). There were no significant group differences in post discharge acute care visits, functional status, depression, or patient satisfaction.

Case management continues to support nurse-managed, physician directed, home based case management for elderly, frail, or complex patients requiring specially trained medical support or counseling (DeBusk et al., 1994). Self-management interventions for chronic disease and acute events extending beyond usual care at discharge and delivered by skilled professionals appear to improve health status while reducing hospitalization (Lorig et al., 1999). Patients are encouraged to articulate their self-care needs as nurses identify resources, and recovery is understood in terms of a defined length of stay, with patients assuming responsibility for a portion of their care at home.

Previous research has established that patients with both acute and chronic conditions benefit from collaborative and nurse-led interventions that coach patients during transitions to self-management (Latour et al., 2006; Naylor, 2000; Naylor et al., 1999; Naylor et al., 1994; Phillips et al., 2004).

Alonzo and Reynolds (1997) used a social-psychological model to guide community education based on self-regulation theory. This model recognized that patients label their symptoms and activate affective and emotional responses into behaviors that will determine how they seek care. This model focuses on three issues: information about symptom recognition and labeling, behavioral characteristics about choosing what to do, and information about how to control the emotional response affecting coping. Study characteristics reinforce cognitive and emotional components measured by the IPQ-R and suggest that additional information such as coaching or educational material may affect individual choices concerning medication or delaying urgent care. This study further validates the use of the CSM to measure the outcomes of the proposed study.

Role of the Expert Nurse

Expert cardiovascular nurses will deliver the discharge nursing intervention. Expert nurse support is important to successful disease management. There is a growing body of evidence that suggests nursing time, level of competency and educational preparation is related to patient outcomes (Aiken, Clarke, Cheung, Sloane, & Silber, 2003; Benner, 1984; Bobay, 2004). Comprehensive attempts to match the "dose" and site-specific need for informed expert nursing may range from telephone-only models to home visits. A recent intervention study revealed that patients followed for up to 1 year by specialized nurses required significantly fewer readmissions and fewer in-hospital days on average, for any reason, when compared to the control group (mean 3.43 - 7.46) (Blue et al., 2001).

Nursing interventions, delivered by expert cardiac nurses, often address complex patient issues. Interventions must also be: a) economically justifiable, b) measure outcomes that reflect quality and safety, and c) create new partnerships between healthcare providers and patients. The investigator's experience reinforced by a review of medical, nursing, and social science literature over the last two decades suggests that nurse "dose" measured in time, access, and expert knowledge improves patient adherence to home based recovery protocols, health seeking behaviors, and patient satisfaction. Theoretically-based research models, supported with valid instruments, have been utilized to study this patient population (DiMatteo et al., 2002; Eagle et al., 2004; Hagger & Orbell, 2003, 2005).

Telephone Support

Discharge information and telephone follow-up has been part of standard care for cardiac surgical patients for over 30 years. Although not always studied for cost effectiveness and specific outcomes in all patient populations, there is a growing body of evidence that supports telephone coaching as an effective intervention. Often telephone care effectively replaces face to face care and offers potential to decrease cost. Combined with expert advice, prescriptive services, and disease management plans, telephone contact may substitute for an office visit or urgent care visit. (Pieffe, Weinberger, & McPhee, 2000; Piette, 2005; Piette, Weinberger, Kraemer, & McPhee, 2001; Rice & Katz, 2001; Rice, 2006; Stead, Perera, & Lancaster, 2006).

Practice surveys report that telephone consultation by physicians and nurses accounted for over 20% of all care in general pediatric practice and as much as 80% in after-office hour care. Telephone care models include triage, advice, disease

management, medication adjustment, acute illness care, test result interpretation, counseling, and education. Widely used in emergency care and ambulatory surgery care, telephone contact serves to increase compliance with care protocols and ensure follow-up care. For patients with chronic illness, telephone care has been shown to reduce medical cost, in-patient admissions, and emergency room visits (American Academy of Pediatrics, 2006).

Adult and pediatric healthcare providers support payment for specific telephone encounters that benefit patients and serve as a cost-effective alternative to face to face encounters (American College of Physicians, 2003). Telephone use is extensive, commonly available across economic groups, and requires minimal skills or education competency.

Studies using telephone interviews examined emotional and cognitive responses, gender differences, and family roles during recovery (Beckie, 1989; Gillis, 1983; Hawthorne, 1994; Moore, 1996). Laramee, Levinsky, Sargent, Ross, and Calas (2003) compared patients receiving follow-up telephone calls with those receiving usual care within a case management model of congestive heart failure and found no significant difference in hospital readmissions, but did find that the intervention group reported increased satisfaction with care and improved adherence to the treatment plan when compared to those patients receiving usual care.

Keeling and Dennison (1995) studied 21 male post MI patients and spouses and found that follow-up was an effective nursing intervention to examine family needs. Qualitative methods resulted in emerging themes supporting those reported in previous studies by Topal et al. (1988), which found that early convalescence from acute cardiac

events is stressful, and patients and families report that they are discharged with unmet needs for information and support. Keeling and Dennison predicted cardiac patients' needs following early discharge to include information regarding activity progression, diet, management of chest pain, medication review, and smoking cessation. Emotional needs included the need for normalization and to be heard. Investigators suggested that early discharge for this cardiac population will continue, reducing psychological support and education necessary for recovery, coping and self-management of care. Keeling and Dennison also recommend the use of expert nurse-initiated telephone follow-up to address stress reduction and information about self-care in this population. They suggest that a RCT is needed to support their findings.

A review of cardiac rehabilitation programs revealed a reduction in on-site attendance due to many factors including: a) improved mobility and early return to work; b) changes in referral and insurance practices; and c) patients assuming more responsibility for self care and rehabilitation. Patients utilized alternative methods to enhance recovery such as home walking programs, nurse-guided instruction and telephone or online support or educational programs in outpatient settings. All methods supported improved patient outcomes during recovery (Wyer et al., 2001). Weintraub et al. (1998) measured cost versus outcomes using telephone support during home recovery, after an average hospital stays of six to ten days and found that telephone support was associated with improved patient outcomes. Findings were consistent with the assumption that telephone support remains a cost effective method to support patients and achieve good outcomes.

Health Seeking Behaviors

The DNI was evaluated using questions about how patients seek help or use urgent care. Written patient education materials relating to cardiac medications were included with suggested Internet sites that are cardiac specific and reviewed for accuracy and content. Pilot work and clinical experience with this population indicates that patients are actively seeking information about procedures, equipment, and medications using the internet and personal networking.

As the cardiac event shifts from the acute phase to the chronic phase, patients must be continually informed about treatment to manage their disease properly. Information about cardiac disease, new drugs, and technology is readily available on the internet and widely discussed in the media and among peer groups. Medical information is often confusing to patients and caregivers and public services sources can be unreliable.

Traditional medical models focus on expert opinion and paternal structures where the physician was in charge of care and information given to patients. The internet has added a new dimension to the asymmetry of expert information available to healthcare professional and the public. The power once held only by experts, as keepers of information, has shifted to the patient. Patients retrieve information that leverages their decisions and behaviors. This process of information sharing may affect a patient's decision to seek care or change prescribed medical protocols. Informed patients are more confident, better prepared to manage their illness, and achieve better outcomes.

In a longitudinal telephone survey conducted by Princeton Survey Research Associates, The Pew Internet and American Life Project compiled information about

internet usage. The number of people using the internet has grown considerably each year, with variations associated with age, education, and income. Based on this report, internet use for American adults includes 73% or 147 million people, increasing from 62% in 2005. The top four reasons for accessing the internet include; job related activities, shopping, hobbies, and obtaining health related information (Fox, 2006; Fox & Rainie, 2006). Health related information or health seeking behaviors increased from 17% to 20% from March 2005 to March 2006 (Madden, 2006).

The Internet allows medical professionals to rapidly disseminate new knowledge, consolidate research findings, and seek health information. It is an efficient tool to enhance evidence based practice and to inform patients and families. Cyber information transcends time, language, and professional barriers, empowering patients to become informed partners in care (Berland et al., 2001; Bessell et al., 2002; Brennan et al., 2001; Fox & Rainie, 2006; Rice & Katz, 2001; Wensing, 2000).

At least 80% of internet users seek health information. Fifty-eight percent of those who found the Internet to be crucial or important during a recent health crisis report the single most important source of information was something they found online (Madden & Fox, 2006). Alarmingly, a large number of people admit that they did not check for accuracy of information on internet sites. Most users start at a search engine, with only 15% reporting they consistently check the source for accuracy or check the date for timeliness. At least three quarters of all health seekers admit to inconsistent checking for accuracy and date, citing "sometimes" to "never" when surveyed (Fox, 2006).

Patients seek health information from multiple sources, including medical professionals, friends, and family. Enhanced health seeking behaviors such as Internet

use may improve illness perception, patient satisfaction, and impact other health seeking behaviors such as urgent calls and visits.

Current and Future Therapeutic Modalities: Creating New Urgency to Close the Gaps

In 2000, the AHA and Healthy People 2010 report projected that PCI and diagnostic cardiac catheterization procedures were rapidly approaching 3 million per year (United States Department of Health and Human Services, 2000). Expanding uses for PCI since that report included valve repair, drug delivery, and gene therapy; including the injection of patients' own stem cells. A two year study reporting the injection of autologous CD34+ stem cells into the hearts of 18 patients with severe coronary artery disease paved the way for continued (Phase II) study, expanding PCI procedures to patients with the most severe form of CVD, commonly not eligible for PTCA and stenting procedures (Losordo, 2006). Expanded use of these less-invasive cardiac procedures continues, forcing patients to confront their own self-care abilities and resources in the face of experimental and complex procedures.

Theoretical Framework

Studies using behavioral theory using illness representations or perception as a framework are reported over a wide range of diagnostic groups, genders and age throughout the 1980's and 1990's (Johnson, Christman, & Stitt, 1985; Johnson & Lauver, 1989; Melnyk, 1995; Moore, 1996). Behavioral and cognitive theory related to self-regulation of care provides a consistent model for cardiovascular patient research. The model remains relevant to patient needs despite; new technology, improved access to cardiac structures, reduction in anesthesia, and dramatic reductions in length of stay and morbidity.

Leventhal's Common Sense Model of Self-Regulation

Behavioral science is an integral part of comprehensive disease management and prevention. Theoretically derived models for new intervention work must target a broad range of subjective, emotional, cognitive, behavioral, environmental, and physical conditions. Behavioral science offers insights to interpret the patient's response and to develop population based strategies to complement clinical strategies. A new social model of healthcare will emerge as the sociology of health and illness introduces new models of symbolic interaction. Patients will control more of the power in medicine as they become invested in healthy aging. For example, recent reports from the AHA indicate a reduction in heart disease mortality of 39% related to clinical strategies and 54% related to life style changes following public health education from 1968 to 1978 (Faxon et al., 2004; Thom et al., 2006; Veazie et al., 2005).

The dominant movement in psychology today is cognitive psychology. Paul Bloom, (2006) author of "The Next Fifty Years", explains cognitive psychology as an analysis of mental life, in terms of the dynamics of parallel distributed processing:

> We now have a huge amount of data on chess playing, deductive reasoning, object recognition, language comprehension, and different forms of memory. But the emotions, sexual behavior, motivation, personality, and the like have been largely relegated to more applied areas, such as clinical psychology. This is all changing. An optimistic view of psychology in the next fifty years is that of a mature science, applying methods and theoretical perspectives that have worked so well in other domains such as perception. (p. 289)

Research studies using cognitive models of patients' perception have demonstrated that patients with cardiac disease delay treatment for hours or months and often misinterpret symptoms, waiting for fatigue to extend to immobility. Consequences of this are increased severity and urgency during the acute event, risking increased

morbidity and mortality (Dracup & Moser, 1991, 1997; Dracup et al., 2003). The improved trajectory of cardiac disease is clearly related to early intervention and revascularization to reduce muscle damage. Cardiac experts teach the concept of "time is muscle" to elucidate the importance of immediate medical attention when patients experience symptoms even suggestive of cardiac ischemia. Symptom appraisal across diagnostic groups is part of a disease label or identity as patients create personal models to guide health behaviors such as adherence, self diagnosis, and help-seeking behavior (Astin & Jones, 2006; Baumann, Cameron, Zimmerman, & Leventhal, 1989; Horne et al., 2000; Johnson & King, 1995; Johnson, 1999; Linz, Penrod, & Leventhal, 1982; Meyer et al., 1985; Moser et al., 2006). Consistent themes of self-regulation span over two decades of study as Leventhal's theory has been used to support nursing and healthcare research.

Leventhal's Common Sense Model (CSM) of Illness Representation, a cognitive parallel processing model, serves as the theoretical framework for this study (Leventhal et al., 1980). The CSM focuses on the individual response to illness using the narrative framework of Self-Regulation Theory (SRT) to explain how individuals represent their experiences with illness threats. Patients need to make sense of their experiences to begin to manage their illness, recovery, and general health by acknowledging their own beliefs and expectations. Leventhal et al. self-regulatory theory seeks to explain patients' motivations associated with illness. It explores how patients emotionally avoid fear or rationally respond to perceived threats or dangerous experiences. An understanding of illness perception is essential for effective patient management and improved patient outcomes across multiple diagnostic groups and populations, as illustrated in Figure 1.
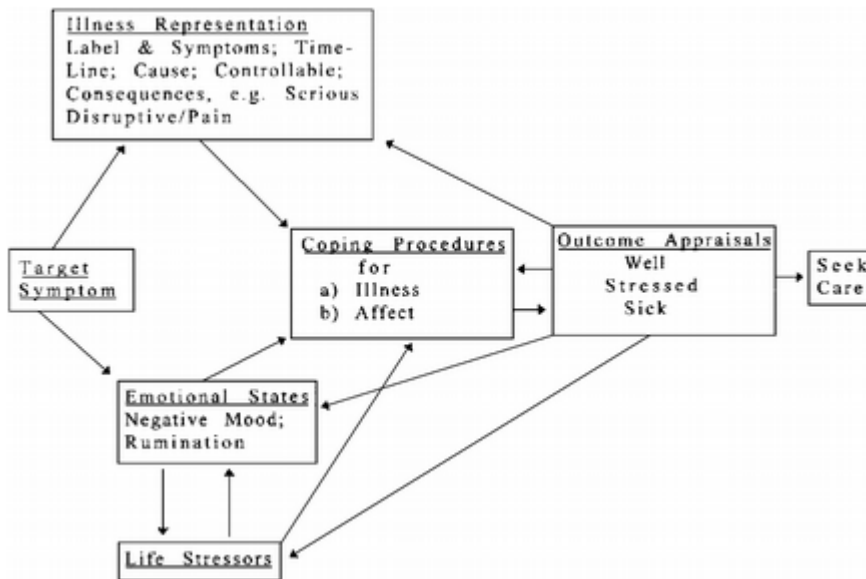
Figure 1.The Self-regulatory Model of Health and Illness Behavior (Weinman & Petrie, 1996, 1997). Symptoms are perceived and elaborated on to generate both a cognitive representation of the symptom episode and emotional responses, typically distress. Both the illness representation (cognitive) and the emotional states (emotional responses) lead to the selection and initiation of coping procedures. The effectiveness of the coping attempts are appraised, and appraisals of coping failure lead to modifications of the representation or coping strategies and to decisions that one is well, stressed, or sick. Failure to cope either with the symptom episode itself or with the distress induced by the episode can motivate healthcare use.

Using this model, researchers explored how people decide to seek and utilize medical care. Two factors affect the decision process: (a) cognitive factors forming the representation of the symptom, procedures for coping with it, and appraisals of success in regulating its progression and (b) emotional factors affecting distress reactions during the symptom episode and procedures for regulating distress. These factors are the key constructs in the self-regulatory model of illness, supported by the theoretical framework

of the CSM. This model has been used to examine health promotion and illness behaviors constructed within a classical notion of personal models or representations (Baumann et al., 1989), adherence to preventive and medical treatments (Leventhal & Cameron, 1987), and the elicitation of worry and preparation for stress during and after medical treatment (Easterling & Leventhal, 1989). According to this model, symptoms are salient factors in the cognitive representation of health threats, as targets for coping. Symptom interpretation is critical for the appraisal of progress in justifying the health threat.

Leventhal and Cameron (1997) early self-regulatory model proposes that patients construct emotional and cognitive representations of health threats that guide and regulate behavior, organized around seven components of illness representation. The Revised Illness Perception Questionnaire (IPQ-R) provides a quantitative assessment of the components of the self-regulatory model (Moss-Morris et al., 2002)

Leventhal et al. CSM (1980) represents comprehensive themes of self-regulation theory for use in nursing intervention research. This health-specific model serves to promote health and quality of life by recognizing symptoms as salient motivators. A dynamic feedback system provides motivation for goal setting, appraising progress, revising goals, and developing strategies. Systemic processes common to all models require conscious effort to modulate thoughts, emotions, and behaviors. The CSM links emotional processing and cognitive mechanisms. This process draws meaning from experience and existing knowledge creating an extension of the parallel processing model. The dynamic within the model includes time and duration, two of the most powerful elements of symptom interpretation, as noted in Figure 2.
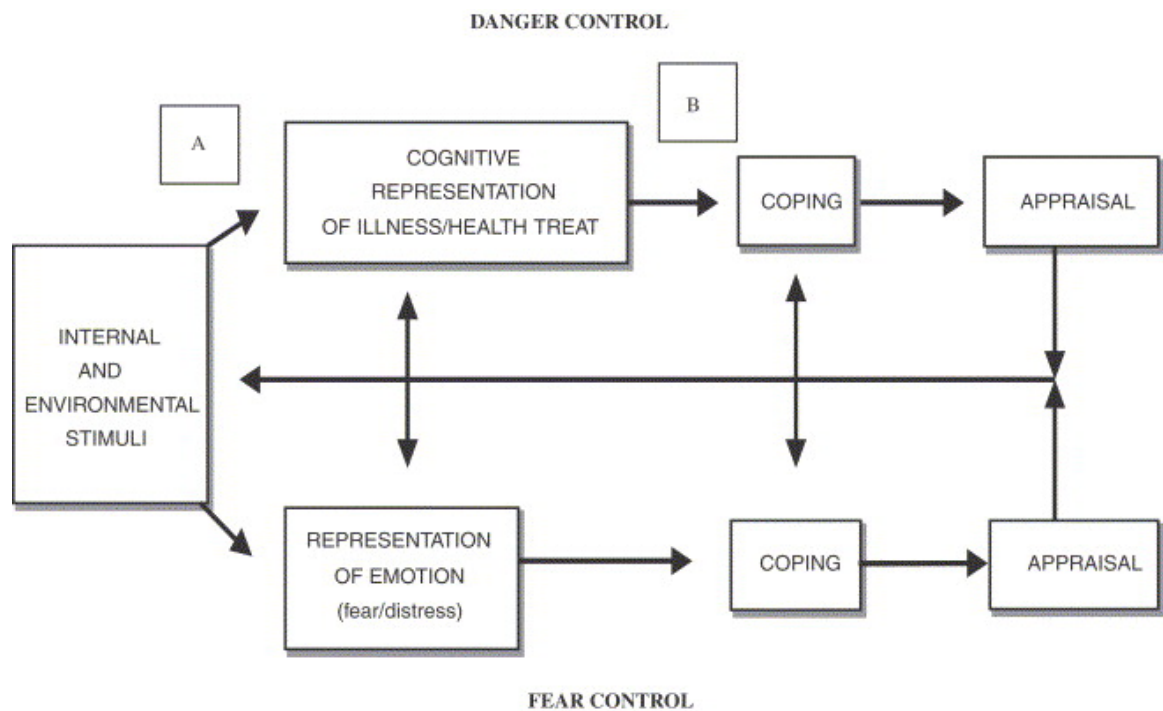
Figure 2. Leventhal's Common Sense Model of Self-Regulation of Health and Illness, adapted to predict responses to health risk information. A and B may be configured to represent specific health threats or illness (Marteau & Weinman, 2006).

Cognitive representation of a threat mobilizes coping responses that fit with existing representations. Faced with health threats, many people will change their behavior. Personal perception of a threat affects the likelihood of behavior change. Leventhal's CSM is widely used to understand responses to illness as health threats. Health risk information actives a cognitive representation of a threat. Cognitive representation has five domains: identity, cause, timeline, consequences, and control (Cameron & Leventhal, 2003). Health risk information also activates an emotional response. Emotional and cognitive processes work in parallel, and include both abstract

and concrete experiential components. Combining conceptual and propositional knowledge with imagery and perceptual-affective memories creates cognitive representations. Concrete images such as photo or media images of vascular disease may provoke emotional responses, strongly influencing behavior.

Self-regulation theory distinguishes between cognitive and emotional processes, and moves beyond models commonly used in social cognitive theory, which require the individual to feel confident in his or her ability to perform the behavior (Bandura, 1986). In self-regulation theory, behavior is guided by goals which he or she can attain through choice. Links between threats and coping are described by Leventhal as an "if-then" with the assumption of control or uncontrollability activating a belief. Examples of both include statements similar to:

"If high blood pressure is caused by being unfit, then exercise will reduce it", or "If heart disease is caused by genes, then there is nothing that can be done" (Marteau & Weinman, 2006, p 1364).

The Common Sense Model Utilization

Application of social psychology to health related behavior allows providers to examine self-regulation of care with a comprehensive understanding of patients' perceptions and intentions. Knowledge development about positive health practices arise from social psychology. Personal values and degrees of personal self management affect the practice of health behaviors. The CSM is ideally suited to understanding and improving patients' self-management of illness and wellness. It simply conceptualizes how individuals monitor their efforts and outcomes while implementing strategies based on individual comprehension of the experience. This model represents a dynamic

process, consistent with interventions, sensitive to behavior change over time. This model is well suited to early discharge or short stay patients, because it relies on a person's "common sense" or lay interpretation of their illness. It utilizes existing knowledge and concepts, an essential strategy when limited exposure to nurse-mediated teaching becomes the norm.

Nursing interventions designed to capture the patient's perceptions of illness and stimulate symptom management may decrease unnecessary readmissions, and enhance care seeking behaviors crucial to reducing secondary effects. Perceptions of consequences, control/cure, identity, and timeline follow a logical pattern of illness representation that may be conceptually different for each patient.

Linking the Model to Study Outcomes

Research developed within this model provides links to health behaviors of people following hospitalization. The model has been used to understand disease coping procedures consistent with the outcomes of this study: adherence, use of urgent care, and perceptions of illness that alert patients to the degree of self care their illness requires. Because the model places value on both emotional and cognitive features of patient decision, it supports patient choice to act upon healthcare issues, including providers and the care facility.

The validity and reliability of the IPQ-R has been supported in several analyses across multiple populations of patients with acute and chronic conditions. Through factor analysis, the constructs have been corroborated in numerous studies and remain the core components of illness representation with discriminant validity across age, gender, and illness types, including cardiovascular, hypertensive, and diabetic patients (Hagger &

Orbell, 2003; Moss-Morris et al., 2002; Weinman et al., 1996). In a cervical cancer screening study, a confirmatory factor analysis model was tested against observed data. Results from the psychometric evaluation provided further empirical support for the IPQ-R and overall discriminant validity of seven IPQ-R dimensions (Hagger & Orbell, 2005). Hagger and Orbell corroborate patterns of relationships that match Moss-Morris et al. (2002) original development study and previously reported in Hagger and Orbell's (2003) meta-analytic findings with studies using the IPQ-R, suggesting that the structure of illness representations is generalized across illness types.

Hagger and Orbell collaborate on research looking beyond the theory of planned behavior, self-efficacy, and motivational social cognition. In a meta-analysis they, reviewed 45 empirical studies that illustrated a pattern of theoretically predictable relationships within the dimensions self-regulation theory. The most frequently used instrument in these studies was the IPQ-R. The analysis revealed discriminant validity of the dimensions over 20 chronic illnesses. Strong positive correlations were found on consequence, identity, and timeline and the outcome of psychological distress, and strong positive relations between cure/control and psychological well being (Hagger & Orbell, 2003). These results support a link between the illness dimensions and emotional well being in chronic illness.

Additional research using the revised IPQ-R confirms that treatment and personal constructs were negatively related to identity, timeline (acute/chronic), consequence, and emotional constructs. Correlations were consistently greater for treatment control, indicating that the patient's perception of the chronicity, seriousness, and emotional salience of the condition were strongly related to beliefs that the condition was treatable,

rather than perceptions that they have control over the outcomes. Findings overall confirm that retention of adequate construct and predictive validity, test-retest reliability and internal consistency across a number of illnesses offered a more complete picture of cognitive representation (Hagger & Orbell, 2005).

Hagger and Orbell (2006) used self-regulation theory to move beyond chronic illness to study the effects of abnormal test results, in patients previously free of illness. The relationship of cognitive and emotional representations of illness and the emotional response of patients with abnormal screening tests support the internal validity of self-regulation theory. This study of 1,258 subjects extends the use of self-regulation theory beyond chronic illness to more acute or emergent illness experiences. Factor analysis of cause components resulted in 3 factors; psychological stress, biological stress, and behavioral causes. After controlling for demographic variables using regression analysis, the dimensions of illness identity, consequence, and causal attributions to psychological stress accounted for variance in emotional response.

A Model for Acute and Chronic Illness

Chronic health conditions require sustained self-management, developed over time as disease patterns begin to make sense to patients. Studies using the CSM hypothesize that individuals create mental representations of their illness based on existing concrete and abstract sources of information. Nerenz and Leventhal (1983) re-defined the SRT theory for chronic illness, defining stages and assuming parallel processing of the danger control system and the emotion control system. Nerenz and Leventhal conceptually defined these stages as:

> Representation is the reception and interpretation of information for the definition of the potential or actual health threat. It is action, planning, coping, or

the assembly, selection, sequencing and performance of response alternatives, and appraisal, or the setting of criteria for evaluating responses and appraising one's coping efforts against them. (p.15)

Specific illness episodes were identified from the patient's perspective and categorized into hierarchical organization, from concrete physical manifestations to more abstract knowledge. Illness representation assigned attributes of: Identity, Cause, Consequence, and Duration (Nerenz & Leventhal, 1983). This model is currently used as a guide to the international Risk Analysis Social Process and Health Research Group (RASPH) and nationally at the Center for Study of Health Beliefs and Behaviors, funded by the NIH National Institute on Aging, originally chaired by Dr. Howard Leventhal.

Application to Nursing Knowledge

Decreasing length of stay coupled with increasing the volume of patients is part of a process that produces new knowledge about an organization, a practice, patient care, and for a profession. As organizational dynamics change, new knowledge must emerge about patients' responsibilities for self-care. Ward (1993) demonstrated the potential for the CSM for guiding knowledge development in nursing. Similarly, Pesut and Massey (1992) explored self-management in patient recovery and its implications for nursing practice, and encouraged expanded use of self-regulation theory in research about health seeking behavior.

Dracup and Bryan-Brown (2006), Dracup and Moser (1991, 1997), Dracup et al. (2003) and Moser et al. (2006) utilized self-regulatory theory to explain delay to treatment and symptom recognition. Fabbri et al. (2001) used self-regulation to create a model for outpatient management. Eagle et al. (2004) connected adherence to the CSM, while Astin and Jones (2006) used the model to explain how percutaneous transluminal

coronary angioplasty (PTCA) patients misinterpret symptoms before and after cardiac interventional procedures. Another study to predict measures of self-efficacy in patients with coronary disease indicated a significant relationship between illness representation and self-efficacy. Lau-Walker's (2006) longitudinal study suggests that an integration of both theories may guide approaches to individualized interventions for cardiac rehabilitation and home recovery. The CSM has utility for helping providers and patients execute self-care.

The Model of Self Regulation was studied to examine indicators that were congruent with factors considered in chronically ill patients' approaches to decision making about caring for themselves at home (Bartels, 1990). Leventhal's CSM has been used as a theoretical base for nursing intervention work in pain management and patient education, suggesting it as a model that includes patients in all phases of health education (Donovan & Ward, 2001).

Collaboration with Patients

This self-regulation theory is also supported by the American Nurses Association (ANA) position on patient autonomy, which places more power with the patient to determine care needs (ANA, 2001, 2002). This theory informs nurse sensitive and collaborative interventions empowering and partnering with patients. This serves to remind caregivers that it is the patient who ultimately determines most aspects of continuing care. Patient perspective is significant to all nursing research, giving breadth and depth to cultural, social, economic, and educational considerations. Patients' representations or disease constructs include cultural perceptions of illness. Cultural competence or cultural knowledge of diverse populations creates challenges for all

healthcare providers. The CSM allows patients to construct unique perceptions of illness, seek treatment, or maintain self-care based on these perceptions, further empowering the patient's ability to assume self care responsibilities (Kleinman, 1980; Leininger, 1988).

Implications for Nursing Intervention Work

Patients do not attend cardiac rehabilitation for a variety of reasons including, rapid intervention, reduced hospital stays, rapid recovery from acute events, non-referrals, and reimbursement issues, (Cooper et al., 1999). Interventions targeting patients at home are extremely important in the face of decreasing numbers of patients enrolled in cardiac rehabilitation. Cardiac rehabilitation is the traditional delivery of coordinated interventions for cardiac recovery and life style adaptation. Reports indicate that less than half of all eligible patients participate in hospital based programs.

Theoretically guided interventions based on empirical evidence are needed to evaluate, revise, and move forward with nursing science. (Donabedian, 1992; Donaldson, 2000; Meleis, 1987; Meleis & Im, 1999). Leventhal's CSM of illness perception provides a credible framework to link patient behaviors to outcomes.

Nursing Interventions Linking Patient Perceptions to Outcomes

Disease management programs (DPM) tailored to the patient with acute events and sensitive to the reality of secondary events provide credible solutions for cardiac interventional patients. Systemic reviews of randomized controlled studies of DMP for related conditions such as heart failure, diabetes, and asthma, using nurse-led and multi-disciplinary teams, report success in physical, emotional, and fiscal outcomes.

Weingarten et al. (2002) conducted a meta-analysis of 102 studies comprising 118 diseases, which revealed that more than one intervention was used to improve patient

adherence to prescribed guidelines using a working definition of disease management. Interventions were designed to manage or prevent a chronic condition using a systematic approach to care and potentially employing multiple treatment modalities. Only experimental or quasi-experimental studies as defined by Cochrane Review were included. Of the many interventions reviewed, 92 used patient education, 47 used provider education, 32 used provider feedback, 28 used patient reminders, 19 used provider reminders, and 6 used financial incentives for patients. Intervention components were consistent with both patient and provider factors supporting self-management of care theory, using provider guidelines or protocols and patient self-care resources. This review compiled disparate information of disease management, considering qualitative and quantitative interpretation. The authors' comprehensive analysis of 16, 917 article titles identified 102 different disease management studies. Unique to this study was the analysis of the process of care, provider adherence to guidelines, the outcome of care, and disease control (Weingarten et al., 2002).

Krumholz et al. (2002) investigated a program of intermediate complexity in which heart failure patients received a nurse-led hour long education session shortly after discharge, followed by telephone based reinforcement for one year. Although the program did not provide individualized care plans, nurses encouraged patients to contact physicians and reinforced care guidelines. Heart failure patients in this study had significant reductions in hospital readmissions.

Most recently, Krumholz et al. (2006) led the AHA Disease Management Writing Group, to address the problem of identifying which programs are effective and define some way to compare and contrast the merits of each offering. The AHA Disease

Management Taxonomy Writing Group developed a system of classification that can be used both to categorize and compare disease management programs and to inform efforts to identify specific factors associated with effectiveness. Programs include multiple communication formats (one on one, in a group setting, or electronically mediated), media (face to face, by telephone, or through the internet), and functions (symptom monitoring, patient education, or pharmacological management).

Evidence suggests that all features of any one intervention need to be satisfied and clearly described for the intervention to be effective. Many studies reviewed by this group for the AHA Scientific Statement on Disease Management were associated with simple, single-intervention designs as well as with highly complex programs, all reporting positive outcomes. Interventions designed to improve outcomes and/or reduce medical resource utilization in patients with heart failure, diabetes, or symptoms of depression were incorporated into clearly defined protocols. Two or more components, traditionally associated with disease management, were defined using qualitative research. As lead author for the American Heart Association's Disease Management Taxonomy Writing Group, Krumholz (2006) explains:

> The final model includes the 8 domains: (1) *Patient population* is characterized by risk status, demographic profile, and level of co-morbidity. (2) *Intervention recipient* describes the primary targets of disease management intervention and includes patients and caregivers, physicians and allied healthcare providers, and healthcare delivery systems. (3) *Intervention content* delineates individual components, such as patient education, medication management, peer support, or some form of post acute care, that are included in disease management. (4) *Delivery personnel* describes the network of healthcare providers involved in the delivery of disease management interventions, including nurses, case managers, physicians, pharmacists, case workers, dietitians, physical therapists, psychologists, and information systems specialists. (5) *Method of communication* identifies a broad range of disease management delivery systems that may include in-person visitation, audiovisual information packets, and some form of electronic

or telecommunication technology. (6) *Intensity and complexity* distinguish between the frequency and duration of exposure, as well as the mix of program components, with respect to the target for disease management. (7) *Environment* defines the context in which disease management interventions are typically delivered and includes inpatient or hospital-affiliated outpatient programs, community or home-based programs, or some combination of these factors. (8) *Clinical outcomes* include traditional, frequently assessed primary and secondary outcomes, as well as patient-centered measures, such as adherence to medication, self-management, and caregiver burden. (p. 1436)

The AHA taxonomy provides guidance for a nursing intervention designed with self-regulation of care as a theoretical framework. It also supports many of the components of this RCT of interventional cardiology patients. The expanding use of self-regulation theory for acute and chronic illness strengthens the validity of its application in intervention work for cardiac patients. Although many of these patients had pre-existing chronic illness, such as vascular disease or diabetes, many experienced a sudden event, or received abnormal test results as a consequence of a cardiac diagnostic procedure. This framework supports the design of this study by recognizing the acute cardiac event or PCI treatment as merely a management step within the chronic disease.

Literature Review: Guidance and Gaps

Cardiovascular disease presents the greatest health challenge for acute and chronic care. This population is growing exponentially, with care centers expanding into community and outpatient care centers. Although well over a million patients have undergone PTCA, with a growing number of interventional procedures, little is known about how these individuals and cardiovascular patients in general make sense of their condition. Early discharge transfers care directly to the patient and family. Many of these patients are vibrant and healthy, working or enjoying normal activities until the acute cardiac event occurs suddenly. In other situations it may be the result of a more insidious

decline in health.

Restricted activity and debilitation is often time limited in this era of rapid intervention, immediate revascularization of coronary vessels, and clot-busting medications. Patients are quickly restored to non-acute health status; however, their ability to recover completely is largely self-determined. Healthcare literature reports the use of cognitive and behavioral theory to confirm that the appraisal of symptoms and health threats is an important indicator to health seeking behavior, adherence, and life style modifications across acute and chronic illness.

Within the literature cardiac patients are often categorized into diagnostic groups, as cardiac surgical, acute cardiac syndrome, or congestive heart failure. Patients receiving interventional procedures are further classified as receiving percutaneous transluminal coronary angioplasty (PTCA) with or without coronary stenting. The focus on technology issues such as bare metal or drug coated stent delivery reinforces the significant contribution of secondary prevention drugs as a continuation of the revascularization process. Central to this discussion is the role of adherence to medication and prescribed discharge protocols, self-regulated by the patient at home. Patient choice, satisfaction with care and home protocols, and use of health resources may be linked to the patient's perception that their condition is time sensitive, controllable, and within the scope of their own self-management.

Nursing research on illness representations in cardiac patients is beginning to emerge in an attempt to study delay to treatment and use of urgent care as early indicators of self-regulation of care. Additionally, nursing research is beginning to address illness perception specific to interventional cardiac patients. Astin and Jones (2006) utilize a

descriptive, repeated-measured, nurse-led study of PTCA patients using the IPQ-R to assess illness perception before and after elective angioplasty. They found that some patients displayed inaccurate illness representations surrounding their illness, some of which remained unchanged after the procedure. This study was limited by a non-random design and lack of control group, however, it suggest that the IPQ-R is a useful tool for nurses to understand how a PTCA patient perceives illness. The authors suggest that PTCA patients may have inaccurate illness representation related to short hospital stays with limited exposure to advice and support from healthcare professionals and poor attendance at cardiac rehabilitation.

Gentz (2000) conducted an integrative review of 19 studies to examine the perceived concerns and learning needs of patients in the early recovery period after a coronary angioplasty. This review illuminates challenges that are unique to patients undergoing PCI, where patients may have inaccurate perceptions of the seriousness of their cardiac condition because of shorter hospital stays, shorter recovery time, and minimal discomfort. Although nine studies had no theoretical framework, others used Bandura's self efficacy theory, model of reasoned action, cognitive appraisal theory, Canfield model of learning style, and Leventhal's CSM of illness. Gentz presented several conclusions: 1) this population in understudied with few studies extending over three months, 2) a focus on behavior demonstrates the importance of prevention of secondary events, 3) adherence to lifestyle and health behavior changes lessened over time, and 4) meeting information needs (rated as very important) remains a challenge because of short hospital stays. Patients viewed PCI as fairly routine and minimally invasive. Patients felt that their condition posed a low health threat, suggesting that health

professionals may not be adequately communicating to patients that they have heart disease even after undergoing PTCA. Overall, patients placed the highest level of importance on informational knowledge and survival management. Limitations to the studies include small sample size, self-report, and limited generalizability as married white men represented most of the total sample. Researchers recommended individualized education, continued availability of education and resources extending beyond hospitalization, and suggest that additional studies informed by behavioral theory are necessary to uphold the significance.

Using Leventhal et al. (1980) theory, a recent study in Ireland examined reported secondary prevention behavior of cardiac patients explained by two sets of beliefs: illness perceptions and beliefs about medication. Only one illness dimension, emotional representation, proved to be predictive of health-related behavior. This dimension related to exercise and alcohol consumption, indicating that alcohol consumption was perceived as a behavior associated with cause of illness. The author suggests further research because these samples expressed low illnesses identity scores which were generally inconsistent with much of the published research using IPQ-R and self-regulation theory. Adherence to medication, however, was significantly predicted by patients' beliefs about their illness, although illness perceptions alone were weak predictors of adherence. A strong belief in the necessity of medication and fewer concerns about medications, as measured with the Beliefs About Medication Questionnaire, was consistent with improved medication compliance. Using the timeline (acute/chronic) dimension of the IPQ-R, the only significant finding related to illness perception and medication adherence was a strong perception that illness was chronic (Byrne et al., 2005). In this study, as in

an earlier study using the same instruments, adherence was positively correlated with advanced age, and identified types of beliefs that are linked to adherence (Horne & Weinman, 1999). Both groups incorporated the patient's cost-benefit analysis. This suggests that patients may choose to continue medication if the perceived benefits outweigh personal cost of the medication. These studies support the use of the IPQ-R; however, researchers are cautioned on the complexities of adherence, beliefs, socioeconomic factors, and lifestyle habits. Nursing is challenged to develop and test interventions that measure elements of these complex relationships with specific outcomes to develop DMP that embrace the patient's perceptions of their illness.

Findings from many studies suggest that non-adherence to medication is common and is associated with poor outcomes. Although it is well accepted that personal beliefs and experiences with medication and sustained illness can influence medication use, additional research continues to examine other characteristics associated with medication adherence. As the volume of self-administered therapies continues to grow, there is a need for greater comprehension about patient adherence.

A gap exists in the literature regarding nursing intervention work that links illness perception to specific outcomes of medication adherence, patient satisfaction, and use of urgent care in this population of patients. Conceptually in this study the population is defined as short stay ambulatory medical patients, treated for acute cardiac events, but self-regulating their chronic illness at home. The cost, quality work of Brooten et al. (1998, 2003), Naylor et al. (1994, 1999) , Naylor (2000, 2003) informed this study because the DNI was considered to be a cost effective, but high quality, care model that may reduce cost associated with the unnecessary use of urgent care and treatment for

secondary events.

A gap also exists in the literature concerning the role of the expert cardiac nurse in directing the delivery of DMP for this population. Although there is an absence of data about the effectiveness of nursing interventions managing this type of post procedure patients at home, models or statistical survey data exist for similar patient groups such as post surgical patients, heart failure, and chronic diseases, including diabetes and asthma, that offer credible blueprints for interventional cardiac patients.

This study attempts to link expert nurse communication to illness representations and self management of care at home. Table 2 represents the current dimensions as they relate to the intervention described in this study.

Table 2. Theoretical Model Linking Nursing Intervention to Study Outcomes

Model	Intervention	Outcome
Cognitive Representation	*Cognitive Reappraisal*	*Coping-Behavior-Outcome*
Cause	Review discharge instructions within 24 hours. Addresses gaps in discharge teaching attributed to short stay and conscious sedation.	
Consequence		Improved illness perception
Identity		Improved use Urgent Care
Timeline	Problem focused coping and nurse coached medication review reinforces importance of medication to reduce secondary events.	Improved medication adherence to reduce secondary events
Cure/Control		
		Improved patient satisfaction
Emotional Representation	*Emotional Reaction*	*Appraisal of Coping*
		Increased adherence to medications
Coping strategies	Open-ended questions encourages patient voice and partnered decision making.	Increased patient satisfaction
		Improved use of urgent care
	Nurse presence offers support and reassurance.	Improved illness perception as patient recognizes chronicity of illness and the need for continued vigilance and medication compliance.

Summary

DMP exist that improve patient outcomes. There is an absence of data concerning randomized control studies of nursing interventions testing discharge DMP for interventional cardiology patients. This growing population of short stay patients suffers an acute event, with significant risk of secondary events occurring after discharge.

Prevention of secondary events is dependent in large part on adherence to key secondary prevention medications. Self-regulation of medication and care protocols are enhanced with nursing support. Self-regulation care models that address multi-dimensional health information across multiple diseases and populations provide credible theoretical foundations for DMP. Central to an understanding of patients' self-regulatory behavior is the understanding of personal goals and interpretation of health and illness.

Leventhal's self-regulation theory can be used to generate a number of hypotheses to explain behaviors when facing health threats. Understanding how patients make sense of illness and how they make choices that affect the course of the disease and its progression will guide nursing practice in developing new models. The prevalence of cardiovascular disease across all populations in an aging society requires attention to the incidence of secondary events and the chronicity of the disease.

The study of interventional cardiac patients, treated for an acute event, yet assuming a chronic disease label is well suited to self-regulation theory. New subscales add depth and definition to patients' interpretation of their role, often measured by adherence to medical therapy and health seeking behaviors.

Pre-evaluation of the DNI

Expert clinicians, focus groups, pilot study, and advisor recommendations contributed to the design of this study. Discussions with cardiovascular nurses helped identify problems associated with early discharge of PCI patients. Personal experience as a cardiovascular clinician and educator, developing education materials and revising discharge instructions for patients receiving conscious sedation, also helped to inform the DNI. State and federal guidelines directed much of the work to address issues surrounding conscious sedation and written discharge information. Patients that returned to, or called the cardiovascular center, shared questions, concerns, and suggestions about their early discharge experience. Professional experience caring for cardiac surgical and ambulatory surgical patients provided incentive for the pilot study.

Pilot Study

Collaboration and discussion with cardiovascular nurse managers, clinical specialists, cardiac rehabilitation nurses at Caritas St. Elizabeth's Hospital and Massachusetts General Hospital (MGH), nurse researchers at Boston College (BC) and critical care educators in the Boston Intensive Care Unit (ICU) Consortia Group informed the design of this intervention. Focus groups and individual discussion with diagnostic and therapeutic cardiac and electrophysiology patients reinforced the concept that continued nurse follow up is necessary for short stay PCI patients.

Fifteen PCI patients were interviewed post discharge using the initial questionnaire. Response to questions informed redesign of the interview tool and reinforced the time frame for the intervention. Pilot work included administration of the

IPQ-R to 22 adults with cardiovascular disease. Three 12 year old children were asked to evaluate the tool for readability.

Intervention Impact Prediction

A Re-Aim intervention evaluation was conducted electronically, http://www.re-aim.org, to ascertain ways to enhance the overall impact of the intervention. Funded by The Robert Wood Johnson Foundation, Re-Aim work group members are also members of the Behavioral Change Consortium (BCC). The purpose of this workgroup to is to evaluate and enhance the reach and dissemination of health promotion interventions.

The mission of this organization is to measure the impact of an intervention in the broadest sense, evaluating the reach, effectiveness, adoption, implementation, and maintenance of a research plan. Workgroup members represent collaboration among 15 NIH funded grants, investigating methods to improve health-risk behaviors investigating methods to improve health risk behaviors, including smoking, sedentary lifestyle, and poor dietary practices.

A self-rating score of 7 to 10 was achieved by the researcher, suggesting additional attention and revision for the implementation stage which received the lowest score of 7. Issues related to implementation include: organizational supports, clarity of protocols, replication / automation and continued monitoring. Suggestions for revision included: 1) study site adjustments to improve research support and 2) a more detailed description of the intervention to encourage replication. Upon redesign and revision of study site and description of the intervention, the rating for the proposed intervention was graded 9 to 10.

CHAPTER 3

Methodology

Research Design

A prospective, randomized controlled trial (RCT) was used to test the efficacy of this nursing intervention. A two group experimental intervention design was chosen to determine whether there is a cause and effect relationship between a discharge nursing intervention and medication adherence, urgent care, patient satisfaction, and seven components of illness perception.

Patients were selected from a purposive population and randomly assigned into two groups: control and experimental. Assignment to groups was done by simple randomization, allowing equal allocation to both groups without constraints (Altman & Bland, 1999). The investigator prepared one packet for the control group containing group instructions, copies of interview tools and the Revised Illness Perception Questionnaire (IPQ-R). A second packet was prepared for the experimental group containing group instructions, medication review materials, a medication pocket card, suggested internet sites, copies of the interview tools and the IPQ-R instrument.

Eighty packets were prepared for each group. All packets were sealed in identical envelopes. Sealed envelopes containing group assignment and study materials were prepared by the study investigator, however, shuffling of the envelopes to obscure group assignment was done by persons other than the investigator obtaining consent. The consenting nurse had no foreknowledge of group assignments, therefore protecting the patient and consent nurse from overt or covert attempts to influence consent. The

researcher obtaining consent was unaware of the next assignment in sequence at all times. Once group assignment was completed, the study nurse had no involvement in patient care or education.

Control group patients received routine discharge materials and usual care. The experimental group received a discharge intervention, consisting of written discharge materials and telephone follow-up by an expert cardiovascular nurse. Expert nurses were defined as those having advanced education and clinical expertise in the care and management of this population.

Delivery of the intervention was time sensitive. The intervention was offered at discharge and continued within 24 hours of discharge. Previous research has concluded that patients are at risk for secondary events in the immediate post-procedure period, extending weeks or months. Adherence to medications, immediately following percutaneous cardiac interventions (PCI), is essential to prevent the significant risk of secondary events (Bavry et al., 2006; Fox, Kibiro, Eichhofer, & Cuezen, 2005; Thom et al., 2006).

This study is designed in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement (Moher, Schulz, & Altman, 2001). This format is currently recommended for all published RCT. Study quality and conduct was enhanced by this format throughout all stages of the study.

One of the hallmarks of this study is that nurse follow-up can be performed regardless of the patient's location or distance from the medical center offering patients an additional "dose" of nursing time and expertise.

Sampling Methods

Study Sample

The target population for this study was adult male and female patients between the ages of 30 and 80, treated for an acute cardiac event with PCI, and discharged from a hospital setting within 72 hours of the procedure. Male and female patients represented a wide range of ethnic and socio-economic groups. Patients' education ranged from grade school, through advanced graduate degrees.

Random assignment allowed the researcher to assume that the patients in each study group were probabilistically equivalent. A comparison of demographic and clinical variables between experimental and control groups was conducted prior to data analysis.

Inclusion Criteria

Only English speaking persons were selected from a purposive sample of patients undergoing PCI. Adult patients who meet the following criteria were asked to participate in the study: Study participants must

- be able to provide written and verbal consent

- be scheduled for an interventional cardiovascular procedure within 24 hours or be recovering from an interventional procedure and scheduled for discharge within 24 hours

- have a valid telephone number and be available by phone for at least three days post discharge

- be admitted to the medical center for a minimum of eight hours and discharged to a home setting no longer than 72 hours after the procedure.

  Patients were followed for no longer than three days after discharge. The suitability of this time period was reinforced following a pilot study, discussion with collaborative practice and cardiology case management, and clinical experience of the researcher. Recovery time is enhanced with early ambulation and early discharge, allowing the patient to resume mobility outside the home 1 to 3 days after the procedure. Telephone availability was subsequently limited to this time frame. Pilot work guided by this model and conducted within the past year examined patient and family responses that directed the scripted interview, selection of survey questions and instruments. Pilot work, collaborative focus groups, clinical experiences of the study nurse and expert advisors suggest the time frame for telephone calls at 24 hours for the experimental group and 72 hours for comparison of both groups.

Exclusion Criteria

Exclusion criteria included patients:

- with conditions that may impair telephone communication such as hearing or speech impairments, dementia, or acute psychiatric disorders

- identified for other specific home based care management services

- enrolled in clinical trials or other research activity requiring telephone follow-up that may introduce conflict with either study or place undue burden on patients

- returning to countries outside of the United States

- not accessible by telephone

- who are sedated or pharmacologically impaired

- experiencing pain or confusion as assessed by the cardiology nursing or medical staff

- medically unstable at the point of consent.

Withdrawal criteria included patients:

- requesting to be withdrawn from the study

- not available by telephone during the study period

- unable to complete the study because of changes in health status

Study Site

The study site was limited to one hospital. Massachusetts General Hospital (MGH) is an academic medical center that serves as both a city and community care center for up to 45,359 patients each year with an average length of stay of 5.88 days (MHG Office of Public Affairs, 2006). This site accepts referrals from within an integrated network of rural and urban hospitals for interventional cardiovascular procedures. Approximately 5,000 patients receive PCI at this medical center each year. The interventional cardiac patient population may exceed 300 patients each week. Estimates vary as referrals, patient acuity, and hospital resources fluctuate. Patients may be directly admitted from the emergency treatment area, referred by a primary physician, transferred from inpatient beds or community hospitals, or arrive from home for a scheduled procedure. Both urgent and elective patients are treated in the cardiovascular laboratory.

MGH is recognized by the American Nurses Credentialing Center as a Magnet Hospital. Magnet hospitals organizational structure encourages nurses to use advanced knowledge and expertise to provide high quality nursing care. Magnet designated

hospitals report improved outcomes and higher rates of patient satisfaction than non-magnet hospitals. Additionally, MGH has a comprehensive approach to interventional cardiac care. The discharge team in the Knight Cardiovascular Center combines a strong primary nursing staff with an advanced practice nursing (APN) staff to provide care for this patient population. The APN nurse role was added to the multidisciplinary team in 1991, to provide a comprehensive approach to patient care and discharge planning (Giacalone, Mullaney, & Cosma, 1995).The usual care for cardiovascular patients admitted to the Knight Center includes: 1) a pre-admission phone call one day prior to admission by a member of the catherization nursing staff. This call serves to confirm arrival time and to remind patients to refrain from eating or drinking prior to the procedure. The primary nurse may respond to patient questions or concerns during the call, however, the nurse calling may or may not be involved in the patients care on the day of the procedure, 2) on the day of the procedure, pre and post procedure assessments are completed by a physician, a primary care staff nurse, and an advanced practice nurse, 3) standardized, written and oral discharge instructions are given to each patient, and reviewed by a staff nurse and an advanced practice nurse, before each patient leaves the hospital. Follow-up phone calls, or home nursing visits are not standard for all discharge patients, but may added, if any member of the team determines that a patient may benefit from telephone follow-up or home services.

Patients may be enrolled in the study from preadmission testing, cardiac catheterization laboratory, or medical and surgical inpatient units. All patients were enrolled after admission to the Knight Cardiovascular Center on Ellison 9. The patient population was largely representative of the New England area; however, patients from

outside this area, including international patients may be referred or may present emergently during visits or travel to the Boston area. There were no international patients in the study.

<div align="center">*Power Analysis*</div>

Sample Size

Sufficient sample size is necessary to verify that a difference between two groups is clinically meaningful and important (Friedman, Furberg, & Demets, 1998; Munro, 2005). Using a two group design, consideration is given to the null hypothesis, effect size, probability, significance level and Type I error, power and Type II error. Estimations for sample size are determined by various factors. These include: 1) the effect size, described as the anticipated differences between groups, 2) the desired power, or chance of detecting the anticipated difference, 3) and alpha, or statistical significance considered appropriate for the study (Devane, Begley, & Clark, 2004; Polit & Beck, 2004). The significance level is indicated by alpha (ά), a value that is selected to indicate the probability that the null hypothesis is true. Setting the alpha at (.05) accepts a 5% probability of falsely rejecting the null hypothesis that there is no difference in the groups. If the null hypothesis is true and is falsely rejected, a Type I error would exist, rendering a false positive finding that a difference exists when in fact it does not.

According to Cohen (1988), the effect size is the difference between the largest and the smallest mean, when examining mean differences. A medium effect (0.5) is selected for this study as it may appreciate a large enough difference to be observable or statistically significant with adequate subjects.

A robust study controls for Type I and II error and maintains the assumptions of the study using adequate alpha levels, estimating reasonable effect size, and assuming power levels that validate the time, effort and expense of the study. Sample size is an important determination in overall acceptable power. A two group design may also affect the power of the test. Randomization attempts to ensure that factors affecting outcomes are distributed evenly between both groups. Group size was large enough to ensure that group differences are due to the intervention. Early comparisons were done to ensure that no group difference exist that may confound the effects of the intervention and subsequent study findings. Prior to data analysis, distribution of confounding variables between groups were examined.

A sample size of 64 in each group was needed to achieve a moderate effect (.50), power of 80%, and alpha of .05. This is reported in power tables designed to yield power values using a *t*-test for the difference between the means of two independent samples of equal size, drawn from normal populations, assuming equal variances (Cohen, 1988; Elashoff, 2002). Confirmation of this sample size was done using minitab power calculator, www.minitab.com, assuming for variation with a standard deviation of 1, moderate effect of (.50), power of 80% and an alpha of (.05). A sample of 154 patients, experimental group of $n = 83$, and control group of $n = 71$, included oversampling of approximately 10%, to compensate for missing data and attrition. A total of 129 patients completed the study, with $n = 64$ in the experimental and $n = 65$ in the control group.

Consent

Consent rates of approximately 70% are recommended to minimize threats to external validity (Babbie, 1973). Nurses working in Knight Center identified eligible

patients each day. The study nurse then approached patients and invited them to participate. The nurse reviewed study procedures with each patient, discussed the need for random assignment, reviewed time commitments, and risk-benefit ratios. Patients were reminded that participation was voluntary, and that all data respected confidentiality. Adequate time was allowed for comprehensive explanation of the patient's role in the study. If the patient requested, significant others and family were involved in the discussion. Consent was requested in a quiet atmosphere in a location offering privacy. Written and verbal consent were obtained using only documents and techniques approved by Partners Healthcare and Boston College Internal Review Boards (IRB) for Human Subject Research. Patients were asked to participate in the study before sedation was administered.

All consent forms and patient materials were screened for health literacy and leveled for education literacy of the target population. Patients and families had access, by mobile phone, to the research nurse at all times if they felt it was necessary to withdraw consent.

A recruitment log was used to record all eligible patients, indicating those consenting, those who refused study participation, and patients later excluded or withdrawn from the study. Demographic data collected from patients, family members, and medical records was done using approved data collection forms.

Defining the Intervention

At the completion of the consent process, study participants were given a sealed envelope. Subjects opened the envelope to reveal group assignment.

Experimental group patients received usual care and a packet of materials designed by the primary investigator and approved by collaborative practice groups and IRB. Packets contained:

- Patient instructions for participation in the experimental group

- Educational materials reviewing secondary prevention cardiac medication

- A medication pocket card

- A list approved patient education internet sites

- A blank copy of all interview questions and the IPQ-R.

Patients in the experimental group received a telephone call from the study nurse within 24 hours of discharge. No more than five attempts were made to contact each patient. Telephone interviews were conducted by the research nurse, directly with the patient. Telephone interactions were anticipated to take approximately 30 minutes, however often the interview was completed in 5 to 10 minutes. The research nurse reviewed discharge instructions with each patient, using a scripted interview tool including:

- A brief re-introduction and review of study purpose

- A review of materials in the patients study packet

- A review of discharge instructions.

The research nurse's questions were guided by the scripted interview tool and a blank discharge instruction sheet. Control group patients received usual discharge care provided at the study site. Usual care included written and oral discharge instructions. This included formatted discharge sheets, educational materials, discharge appointment schedule, referral information, and selected individualized instructions. Patients and

families in the control group had no contact with the researcher until post discharge day three. Both experimental and control groups received telephone calls 72 hours after discharge. No more than seven attempts were made to contact each patient. Seven attempts were acceptable because PCI patients often resumed routine activities such as driving, work, and family responsibilities within this time period. Control group packets included:

- Patient instructions for participation in the control group

- A blank copy of all interview questions and the IPQ-R.

Both groups were called 72 hours after discharge. Using a scripted questionnaire, the researcher asked about medication adherence, urgent care needs, and satisfaction with care. Both groups were asked to complete the IPQ-R orally with the researcher. Researcher and patient interaction time was approximately 10 minutes. When patients in either group asked for advice or information that was not scripted in the study they were referred back to their primary care provider (PCP) or instructed to review their discharge instructions for the specific information.

Specific guidelines listing all instruments, conceptual definitions of responses, and acceptable responses were reviewed with all nurses and personnel involved in this study. Educational sessions for nurses involved in data collection were provided by the research nurse using a competency based educational plan. Providing medical assessment, telephone triage, and emergency treatment advice was not within the scope of this study.

Maintaining Rigor

Flow charts modeled within the CONSORT statement for randomized clinical trials are used to illustrate randomization and patient placement (Moher et al., 2001). Studies that include flow charts add clarity and rigor to the study offering completeness during presentation and publication. Using a template or flow diagram assists readers to evaluate internal and external validity of a reported trial and encourages replication of the study (Egger, Juni, & Barlett, 2001).

Data Collection Methods

Procedures

Selected demographic information and medical information were collected during the consent process from the patient or abstracted from medical records. Patients were asked to report their age, race, marital status, education, and discharge care arrangements. Clinical data, such as previous procedures and hospitalizations, were confirmed by medical record review. All information was de-identified and recorded using appropriate coding procedures.

Instruments

Materials selected by the researcher and approved by institutional review boards at Boston College and MGH were used to elicit discharge adherence to protocols and medications, patient satisfaction responses and urgent care utilization. Structured interview format and IPQ-R instruments were validated in pilot work by the researcher in this population. Additional instruments were supported and validated as cited in the literature review.

The IPQ-R was used with permission of Dr. Moss-Morris. The IPQ-R is a theoretically derived measure, designed to assess dimensions of illness perceptions. The dimensions include identity, time line, consequence, control, and cause. Revisions include measures of perceptions of duration of illness, and fluctuations in illness over time. Moss-Morris et al. (2002) identified areas within the original identity component that did not appreciate personal judgment and clarity of individual meaning. The illness coherence scale was added to incorporate these beliefs.

Personal control and illness control were defined in separate scales and new scales were devised for the timeline dimension that differentiated beliefs about the chronicity of the illness and the beliefs about symptom fluctuation and changeability of the illness. Two new scales became timeline-acute/chronic and timeline- cyclical. Leventhal et al. (1980) original Common Sense Model (CSM) did include the suggestion of parallel cognitive and emotional representation; however, original instruments neglected the emotional component. A six-item emotional representation scale was added in the 2002 revision, strengthening the true measurement of the self-regulation theory as a parallel processing model.

All subscales demonstrated good internal reliability (Hagger & Orbell, 2003, 2005; Moss-Morris et al., 2002). Cronbach's alpha's for each of the subscales ranged from 0.79 to 0.82. The instrument uses thirty-eight items to measures seven sub-scales, using a 5 point response scale with end points of "strongly agree" or "strongly disagree. Strongly disagree =1, disagree =2, neither agree or disagree = 3, agree = 4, strongly agree = 5. Reverse scoring is necessary for 13 items: IP1, IP4, IP8, IP15, IP17, IP18, IP19, IP23, IP24, IP25, IP26, IP27, and IP36.

High scores on the timeline, consequences, and cyclical dimensions represent strongly held beliefs about the number of symptoms attributed to the illness, the chronicity of the condition, the negative consequences of the illness, and the cyclical nature of the condition.

High scores on the personal control, treatment control, and coherence dimensions represent positive beliefs about the controllability of the illness and a personal understanding of the condition as indicated in Table 3.

Table 3

Measurement of Seven Components of Illness Perception Using the IPQ-R

Illness Component	Measured by	Possible Score
1. Timeline (acute/chronic)	sum items IP1 - IP5 + IP18	6-30
2. Consequences:	sum items IP6 - IP11	6-30
3. Personal control:	sum items IP12 - 1P17	6-30
4. Treatment control items:	sum items IP19 – IP23	5-25
5. Illness coherence items:	sum items IP24 – IP28	5-25
6. Timeline cyclical:	sum items IP29 – IP32	4-20
7. Emotional representations:	sum items IP33 – IP38	6-30

The identity subscale does not demonstrate a relatively high degree of internal reliability, with a Cronbach's alpha of 0.75. This may suggest that patients either attribute a higher or lower number of symptoms to their illness. Cause may not be computed as a scale and may be more sensitive to sample size and co-morbidities. Identity and cause were not included in this study.

The IPQ-R has been used extensively in acute and chronic conditions and validated across multiple diagnostic groups and diverse populations. The internal reliability for each subscale is consistently acceptable in studies with cardiac patients, with Cronbach alpha coefficients ranging from .73 to .82 (Cooper et al., 1999; Petrie et al., 1996). Similarly, good test–retest data for each subscale have been obtained in patients with established chronic illness (Weinman et al., 1996).

Discriminant and construct validity of the CSM dimensions, measured by the IPQ-R, revealed a logical pattern of relationships. The major hypotheses relating to the CSM illness representation dimensions were supported using meta-analytic techniques (Hagger & Orbell, 2003). This evidence supports theoretically predictable relations between illness cognitions, coping and outcomes across 45 studies. Most recently Hagger and Orbell (2005) demonstrated adequate validity and reliability across multiple illnesses, identified in seven dimensions: identity ($\acute{\alpha}$ =.83), timeline cyclical ($\acute{\alpha}$ =.79), consequence ($\acute{\alpha}$ =.76), personal control ($\acute{\alpha}$ =.88), treatment control ($\acute{\alpha}$ =.70), illness coherence ($\acute{\alpha}$ =.92) and emotional representation ($\acute{\alpha}$ =.87).

Components of the IPR-Q, specifically the seven dimensions of cognitive illness perception theory with emotional factors, were examined in relationship to study variables. Internal consistency of scales used was examined using Cronbach's coefficient

alpha prior to comparative analysis. Researchers' confirmation of patterned relationships across the IPQ-R dimensions and chronic illness support the validity of the hypothesis that association of the illness representation is similar across illness. Hagger & Orbell (2005) robust confirmatory factor analysis reports factor intercorrelation supporting discriminant validity of the constructs. All factors exhibited satisfactory composite reliability. This supports Hagger & Orbell (2003) previous work and strengthens the original instrument work of Moss-Morris et al. (2002).

Medication adherence was measured using the Morisky Self-reported Medication-taking Scale (Morisky et al., 1986) and the Machtinger and Bansberg (2005) visual analog scale. Morisky et al. work used interview data to determine the effects of an educational intervention for hypertensive patients. A four item scale was developed based on a theory of omission, which occurs when patients forget, are careless, or stop medication because they feel better or because they feel worse. Reverse wording each question encouraged disclosure of non-adherence and discharged a "yes-response" bias. Negative responses to all four items indicate high levels of adherence. Each item in the scale contributed to an overall reliability with internal consistency of (0.61), with a decrease in reliability if any single item was deleted.

The Morisky scale demonstrated unidimensionality as principal components analysis identified a single factor with convergence being achieved in six iterations. The scale also demonstrated concurrent validity with blood pressure control at the bedside. Important features of this tool include its use as a quick diagnostic measure, an indicator of the patients level of understanding, and an assessment of behavioral and attitude problems. The original tool used a dichotomous variable, although adherence measures

may vary along a continuum from 0 to 100. Shalansky (2004) studied patients'

adherence to chronic cardiovascular drugs using a structured interview that included

Morisky's four item yes/no response tool. This study reports:

> While the Morisky score was a significant independent predictor of non-adherence by multivariate analysis, there was no threshold score or individual question that yielded concurrent high sensitivity and positive predictive values (PPVs) for identifying non- adherent patients. The internal consistency of the questions was low (α 0.32), as were item-to-total score correlations, suggesting that the individual questions were not measuring the same attribute. (p. 1363)

Although the Morisky scale was a significant predictor of non-adherence in this

study of 377 patients, Shalansky recommends using graded responses and additional

items to improve consistency. Based on this recommendation, an adapted Morisky scale

was prepared by the researcher in an attempt to strengthen the validity of the tool. For

purposes of this study, five point response options were added to the original four items.

These options are represented by: never = 0, rarely = 1, sometimes = 2, often = 3, and

always = 4.

Medication adherence to specific anti-platelet medications was measured by two

questions using a visual analog scale (VAS). Machtinger and Bansberg (2005) used this

simple visual method to assess adherence in HIV patients taking anti-viral drugs and

found it to be equivalent to the more commonly used verbal self-report. Researchers

stated that asking patients to indicate a percentage of each drug taken over a time period

of a few days may offer a less judgmental approach, perhaps allowing patients to

consider compensation for isolated lapses. Oyugi et al. (2004) assessed multiple

adherence measures against viral load suppression in the same population. Using pill

counts, electronic monitoring, three day self-report and thirty day visual analog scales,

each achieved a 91 to 94% of adherence with no significant difference between measures. Mean adherence estimates were used to examine the association between adherence measures and biological measures of viral activity with Pearson's correlation coefficients significant at $p < 0001$.

Researchers in these studies identified issues with adherence to antiretroviral therapy, such as acknowledging fears and difficulty, which are transferable to the cardiovascular patient population. Patients who can identify medication and describe dosing and administration correctly may be more adherent or feel more comfortable discussing reasons for missed doses. (Machtinger & Bansberg, 2005; Oyugi, 2004).

Patient satisfaction was assessed using an adaptation of Press Ganey (2006) overall assessment section, "likelihood of your recommending this hospital to others." Press Ganey measures satisfaction on a national level to ascertain loyalty, which most strongly relates to the more personal aspects of the patient-provider interaction. Using a five point measurement scale, only those who respond with 5(very good) are willing to recommend a facility to others. High ratings indicate an excellent level of loyalty. Reichheld (2003) supports this concept, stating that assessing customers "likelihood of recommending" is the only way to measure customer loyalty, regardless of the industry.

It is important to know whether patients discharged early are satisfied with the level of care they receive. Moher and Sullivan (1992) recommend asking questions that apply across diseases after the third hospital day. Reductions in length of stay have changed when and how patients respond to satisfaction interviews. In a large national survey asking about specific aspects of care, length of stay was not a significant predictor. This study encourages research that elicits reports from patients, providing

information not available from medical records or other sources, to evaluate quality and

develop improvement plans. (Cleary et al., 1991)

Data Analysis Plan

Statistical analysis was done with the SPSS version 16 for Windows statistical

software package. Following data entry, descriptive statistics were computed an all study

variables and examined for the presence of random or systematic missing data,

significant skewness and outliers. Data sets were examined for errors related to coding,

entry errors, and missing data. Errors were detected using descriptive statistics,

scatterplots, and histograms. Data were visually screened for problems or suspicious data,

selecting and identifying data out of range or illogical, and for inconsistencies between

related variables. Data cleaning of all variables was achieved by examination of

descriptive statistics with attention to mean prevalence, median, standard deviation, and

maximum and minimum value. Frequencies were run to detect unequal distribution in

groups and selected variables.

Missing data may indicate a problem with the question or interpretation. The

researcher evaluated all missing data to determine the systematic or random effects.

Responses such as "not applicable" were distinguished from missing data in the

instrument design stage. Values for missing data were assigned during the design stage.

Missing data may result in case deletion or substitution based on observed means of the

item for that group (Abraham & Russell, 2004). Missing data were retrievable from

patient charts or log.

When entering data from the IPQ-R, the SPSS version 16 syntax file was used to

compute the IPQ-R subscales if there is missing data on select items. Subscales with 6

items allow for a maximum of two missing items. Other subscales are limited to one missing item. Scores for the IPQ-R were calculated with one missing item. Values considered outliers may or may not be included in the case during analysis. To ensure accuracy of data entry, all outliers were checked against raw data. Outliers were found to be errors of entry and corrected prior to data analysis.

Descriptive statistics indicate the mean prevalence of each variable. Examination of maximum and minimum values as well as the median, and standard deviations were completed. Frequencies were run to detect unequal distribution of selected variables. Scatter plots were used to answer assumptions of the statistical measures including normal distribution, homoscedasticity, and linearity of relationships between independent variables. Psychometric properties of instruments may be analyzed using confirmatory factor analysis.

Selecting Statistical Methods

Researchers compared descriptive statistics of demographic and clinical variables using the chi-squared tests for categorical variables, and *t*- test for continuous normally distributed variables. The Mann-Whitney U test was run on all significantly skewed continuous variables.

Two independent groups were studied (experimental and control). Group assignment was considered a nominal level independent variable. Dependent variables were measured at interval or ratio level. Statistical analysis was completed to answer the following research questions and test the null hypotheses that there are no significant differences between the experimental and control groups.

Research Questions

1. Do patients receiving the nursing intervention differ significantly from those

    receiving usual care on medication adherence?

    Differences between experimental and control groups were measured with

    parametric statistics: independent t- tests, for normally distributed continuous data

    and non-parametric chi-squared analysis for nominal data. The non-parametric

    Mann-Whitney U test was used for skewed continuous variables.

2. Do patients receiving the nursing intervention differ significantly from those

    receiving usual care on patient satisfaction?

    Independent t-test was used to compare the two groups using group assignment

    as the independent variable and the summed scores on patient satisfaction questions

    number 11 and 12 as the dependent variable. Chi-squared analyses were used to

    compare experimental and control groups on two measures of satisfaction.

3. Is there a significant difference in the utilization of urgent care between those

    patients receiving the nursing intervention when compared to those patients

    receiving usual care?

    Three urgent care variables were recoded into new dichotomous variables for final

analyses. Chi-square analyses were used to compare the two groups using group

assignment as the independent variable and three urgent care measures as dependent

variables.

4. Does a difference exist between the patients receiving the nursing intervention and

those patients receiving usual care on illness perception, as measured by seven

components of the IPQ-R: time line (acute and chronic), consequence, personal control,

treatment (cure) control, illness coherence, timeline (cyclical), and emotional

representations?

To measure whether the groups score differently on individual IPQ-R components,

independent *t*-tests were performed on normally distributed variables, consequence and

emotional representation. Five components of the IPQ-R, timeline (acute/chronic),

personal control, cure control, illness coherence, and timeline (cyclical), were

significantly skewed. The Mann-Whitney U tests were used to compare groups on these

variables. A Bonferroni corrections was performed to protect against Type I error.

Threats to Validity

Threats to internal validity were addressed by study design. The two group post-

test only design was used to answer the research questions. All variables were measured

at the highest level of measurement possible to provide the study with maximum

sensitivity. However, bias may still occur unintentionally and affect study outcomes.

Investigator Bias

Investigator bias is possible because the study nurse obtained consent and

administered the intervention. Expert knowledge about the patient population, disease,

and procedures may have contributed to bias during the study. This was addressed by

strict adherence to study protocols. Additionally, researchers deferred to the cardiology

staff to assess patients' suitability for study.

Selection Bias

Selection bias occurs if specific group differences affect the outcome under

investigation. Selection bias was reduced by random assignment to groups, rendering the groups probabilistically equivalent. Differences in group characteristics may be the result of bias or chance; however, there were no significant group differences in this study.

Selection Mortality

This issue did not present a threat to the validity of this study. To counter this risk, clearly articulated verbal and written consent provided guidance to prospective study patients to determine if the study was consistent with time and interest concerns. The intervention presented minimal interruption of patients' activities and instilled no physical pain or discomfort. Drop out rates were anticipated due to inconvenience, accessibility, or changes in patients consent status, however, only one patient requested to be dropped from the study.

Generalizability and Statistical Power

This was enhanced by adequate numbers of patients completing the study. Over-sampling and diligence during the consent phase as well as repeated attempts to reach patients by phone increased the total numbers of patient contributing to this study.

Social Interaction

Social interaction presented minimal threat. Patients and families entered into the study on the same day may be aware of each other's conditions and study status because they were situated in common waiting and recovery areas. Patients also recover in common areas. However, social interaction was reduced post-procedure because emergent stages of sedation limited conversation. To counter these threats, enrollment of patients extended over days and weeks, minimizing the number of interactions possible in anyone day.

Timeline for Completion

Patient enrollment began immediately following IRB approval and continued until over 70 patients had been assigned to each group. Data collection was completed three days after the last patient had been enrolled. Consent process, contact efforts, interview time and data entry for control group subjects was estimated at 2.5 hours per patient and for experimental group patients as 3.5 hours per patient. Enrollment procedures were completed as illustrated in a logistical grid in Figure 3.

Protection of Human Subjects

All data collected in this study are confidential. Medical records reviewed for demographic data remained on site. Patient confidentiality was maintained by assigning code numbers to study instruments. Protection of the subject's rights was rigorously enforced by using HIPAA regulations and IRB guidelines. Data collection was done only by the investigator approved for this study by the appropriate Institutional Review Boards. All data obtained and recorded electronically or manually were maintained in a secure location in the possession of the investigator. Electronic data was secured on a password protected computer during all stages of the study. Letters of support and approval from the cardiovascular nurse manager, research support staff and collaborative practice groups were provided for final IRB approval.

Figure 3

Logistics Grid

- Patient enrollment (experimental group)   * Call 1   + Call 2

O Patient enrollment (control group)   *   Call 1

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	●●● OO	***		+++ **	●● OOOO	**
	++ **** ●●●	***		+++	●●● OOOO	***
	+++ ****					

Figure 3. Logistical Representation of Study Sequence.

A sample of the enrollment process is illustrated using the following sequence of events: On Monday a total of five patients were enrolled in the study. Three are assigned to the experimental group, requiring phone calls on Tuesday and Thursday. Two patients were assigned to the control group and were called only once, on Thursday. Enrollment of study patients resumed on Friday as six patients agreed to complete the study, two were assigned to the experimental group and four were assigned to the control group.

CHAPTER 4

Results

The results of a study designed to establish the efficacy of a discharge nursing intervention between two randomized groups of patients receiving interventional cardiology procedures are presented in this chapter. A two group experimental intervention design was chosen to determine whether there was a cause and effect relationship between a discharge nursing intervention and medication adherence, urgent care, patient satisfaction, and seven components of illness perception. Data collected through initial patient interviews and follow up telephone surveys were analyzed to answer four research questions.

Randomization procedures, study materials, and consent forms were secured in the nursing office throughout the study. With the approval of a cardiology staff member, patients meeting inclusion criteria were approached by a study nurse. All patients were consented on the day of their cardiac procedure, prior to receiving pre-procedure medication.

The study required that all participants receive usual discharge care and instructions. All participants reported that they had received discharge instructions with only 2% unable to find their written instructions. Ninety-six percent confirmed that they had received both written and verbal instructions. All participants (100%) responded affirmatively when asked if they could describe specific instructions. This high rate of comprehension could be related to the low use of urgent care in both groups. Anecdotally, participants responded favorably to discharge instructions and commented on the clarity and concise manner in which the instructions were presented.

Study Sample and Setting

Data were collected from 154 patients admitted to the Knight Cardiovascular Center at Massachusetts General Hospital (MGH) in Boston, Massachusetts for diagnostic or therapeutic cardiac interventional procedures. MGH is an urban medical center admitting approximately 46,000 patients annually. The Knight Center for Interventional Cardiovascular Therapy consists of six angiographic procedure rooms and a twelve bay holding area to monitor and care for patients requiring diagnostic and therapeutic percutaneous intervention pre and post procedures. Care is provided within a multidisciplinary framework, which includes; cardiologist, staff nurses, advanced practice nurses, and technical support staff. Data collection was conducted in the Knight Center as described in study methodology, within chapter three, between March 2008 and October 2008. MGH is a Magnet designated hospital. Magnet hospitals are recognized for a commitment to nursing excellence and improved patient outcomes. MGH offers a comprehensive approach to interventional cardiac care, which includes the addition of advanced practice nurses to the multidisciplinary team. The usual care (as described in detail in Chapter three) for all patients in the cardiac intervention suite includes a comprehensive team approach to pre-procedure and pre-discharge assessment. The discharge management plan includes standardized written instructions reinforced with oral instructions by many members of the multidisciplinary team.

The investigator obtained participants' demographic data, via interview and review of medical records. Consent was obtained from 154 patients, and final analyses included data from 129 patients. Twenty-five participants did not complete the study for a number of reasons. Eighteen of the original 154 were lost due to extended hospitalization;

patients were no longer eligible for the study if the hospital stay extended beyond 72 hours. Of these 18, eight participants were admitted for urgent cardiac surgery, two for other types of urgent surgical procedures, and eight for extended admissions due to procedural complications or medical issues requiring immediate attention. Six participants were lost to telephone follow-up. Only one participant requested to be released from the study. When contacted by phone the patient simply stated that he did not feel up to completing an interview. However, the patient expressed gratitude for the opportunity and offered to participate in other studies, perhaps at a different time.

Final analyses utilized complete data sets with the exception of one participant, who was unable to complete the IPQ-R section of the questionnaire due to time restrictions. Throughout the study, there were no deaths reported. The total survey response rate was calculated to be 83.7%, using the Centers for Medicare and Medicaid Services HCAHPS Quality Assurance Guidelines (2008).

In this study, 39.9% of participants scheduled for cardiac catherization had known cardiovascular disease, and 29% were studied to rule out new coronary artery, functional or structural disease. Peripheral vascular disease was the primary diagnosis for 10.9% of patients; however, most of those participants had diagnostic testing for both cardiac disease and lower extremity vascular compromise. Seven participants were admitted for structural repair of a septal defect. In this subgroup of participants, the defects were discovered after the patient experienced a neurovascular event. Cardiac transplant patients represented 14.7% of participants.

Transplant recipients require cardiac muscle biopsy at various intervals for the first year, followed by annual diagnostic cardiac catherization in conjunction with muscle

biopsy. Post transplant patients reported from 1 to 20 previous cardiac catherizations. Transplant patients may require percutaneous cardiac intervention (PCI) to the transplanted heart. In this study, one transplant recipient was treated with a coronary stent.

Ninety-four percent of the total sample had previous hospitalizations, with 59% reporting previous cardiovascular procedures including diagnostic catherization, angioplasty, stent placement, and cardiac surgery. Of this group, 29.5% reported having a cardiac catherization within the last year. Thirty-one percent were admitted for their first cardiac procedure. For others, it may have been a repeat procedure, however, many parts of the procedure were different, performed with improved technology, minimal use of sedation, and very different after care procedures. Closure devices, developed to achieve hemostasis at the groin access site, are now widely utilized, resulting in reduced time for leg immobilization and allowing early ambulation. Generally, patients reported improved comfort, rapid recovery and expedited self care.

Although recent technology allows same day discharge, 61.2% of patients stayed overnight. Overnight stays were expected when patients received angioplasty with or without stent placement; however, decisions to monitor patients overnight were not predictable. Each participant was assessed on an individual basis by the cardiology staff. Simple diagnostic cases often required additional monitoring.

Participants were overwhelming white, non-Hispanic (97.7%), male (76.7%), married (72.9%), and educated, with 93% completing high school or advanced degrees. The mean age was 61 years. Inclusion criteria restricted enrollment to patients 30 to 80 years old; however, patients treated in this center during the study period ranged in age

from 14 years to 93 years old. Most participants were discharged to home (93.0%) in the care of a family member (89.2%). There were no significant differences noted between control and experimental groups on demographic characteristics. Final analyses of 129 participants, found that experimental and control groups were similar in size and general characteristics.

Initial Statistical Analysis and Data Management

Data were coded and entered into a personal computer and analyzed using Statistical Program for Social Science (SPSS) version 16.0. The chi-squared test and the Fisher's exact test were used to compare non-continuous variables as appropriate. To assess group differences, the independent *t*-test was run on normally distributed continuous variables. The Mann-Whitney U test was run on all significantly skewed continuous variables.

Study data were entered by the primary investigator and verified by two research assistants. Data were examined for outliers, missing and skewed data. Missing data were minimal and retrieved by further examination of study instruments, logs, or patient records. No single variable was identified with more than .5% missing data. This was limited to illness perception, in a single case. The case was included in the final analysis; since data generated by this case would reasonably contribute to findings for other outcomes.

Descriptors and Frequencies

Although the groups were randomly assigned and were assumed to be equivalent, the researcher compared the groups to validate the assumption of equality of groups. Descriptive statistics were calculated for the total study sample ($N = 129$) and examined

for group comparison. Experimental group participants ($n = 64$) and control group

participants ($n = 65$) were evaluated to compare group differences on 17 categorical

variables using a chi-square analysis. Baseline personal and clinical characteristics were

similar in both groups. Table 4 illustrates study sample descriptive data and group

comparisons.

Table 4.   Study Sample Descriptive Data, Experimental vs. Control Groups

Study variable	Total (N=129)	Experimental Group (n=64)	Control Group (n=65)	*p
Diagnosis				
Rule out CVD	38(29.0%)	16(25.0%)	22(33.8%)	.293
CVD	51(39.5%)	30(46.9%)	21(32.3%)	
Transplant	19(14.7%)	8(12.5%)	11(16.9%)	
PVD	14(10.9%)	8(12.5%)	6 (9.2%)	
Other	7(10.9%)	2 (3.2%)	5 (7.7%)	
Acute	34(26.4%)	14(21.9%)	20(30.8%)	.252
Chronic	95(73.6%)	50(78.1%)	45(69.2%)	
Procedure				
Diagnostic	83(64.4%)	41(64.1%)	42(64.6%)	.438
Intervention	38(29.5%)	21(32.8%)	17(26.2%)	
Structural repair	8(6.20%)	2 (3.1%)	6 (9.2%)	
Discharge				
Same day	50(38.8%)	25(39.1%)	25(38.5%)	.944
Overnight	79(61.2%)	39(60.9%)	40(61.5%)	
Age in Years	M = 61.0	M = 62.07	M = 60.09	.579
Gender				.194
Male	99(76.7%)	46(71.9%)	53(81.5%)	
Female	30(23.3%)	18(28.1%)	12(18.5%)	
Marital Status				.150
Married	94(72.9%)	43(67.2%)	51(78.5%)	
Single	35(27.1%)	21(32.8%)	14(21.5%)	
Living with				.587
With someone	111(86.0%)	54(84.4%)	57(87.7%)	
Living alone	18(14.0%)	10(15.6%)	8(12.3%)	
Education				.853
Less than high school	3 (2.30%)	2 (3.10%)	1 (1.50%)	
Some high school	6 (4.70%)	2 (3.10%)	4 (6.20%)	
Completed high school	3(24.8%)	17(26.6%)	15(23.1%)	
Some college	45(34.9%)	23(35.9%)	22(33.8%)	
Post college	43(33.3%)	20(31.2%)	23(35.4%)	

Ethnicity				.393
White, non-Hispanic	126(97.7%)	63(98.4%)	63(98.4%)	
Black, non-Hispanic	1 (0.8%)	0 (0.0%)	1 (1.5%)	
Hispanic	1 (0.8%)	0 (0.0%)	1 (1.5%)	
Other	1 (0.8%)	1 (1.6%)	0 (0.0%)	
Discharged to				.466
Home	120(93.0%)	59(92.2%)	61(93.8%)	
Family/friends home	8 (6.2%)	5 (7.8%)	3 (4.6%)	
Other	1 (0.8%)	0 (0.0%)	1 (1.5%)	
Responsible for care				.819
Self	6 (4.7%)	3 (4.7%)	3 (4.6%)	
Spouse	89(69.0%)	42(65.6%)	47(72.3%)	
Family	26(20.2%)	14(21.9%)	12(18.5%)	
Friend	8 (6.2%)	5 (7.8%)	3 (4.6%)	
Previous hospitalization				.235
No	7 (5.4%)	5 (7.8%)	2 (3.1%)	
Yes	122(94.5%)	59(92.2%)	63(96.9%)	
How long ago				.785
Never	7 (5.4%)	5 (7.8%)	2 (3.1%)	
< 1 year	59(45.7%)	28(43.8%)	31(47.7%)	
< 5 years	32(24.8%)	16(25.0%)	16(24.6%)	
< 10 years	13(10.1%)	7(10.9%)	6 (9.2%)	
> 10 years	18(14.0%)	8(12.5%)	10(15.4%)	
Previous cardiac procedure				.279
No	40(31.0%)	17(26.6%)	23(35.4%)	
Yes	89(68.9%)	47(73.4%)	42(64.6%)	
Never	40(31.0%)	17(26.6%)	23(35.4%)	.160
< 1 year	38(29.5%)	19(29.7%)	20(30.8%)	
< 5 years	29(22.5%)	13(18.8%)	16(24.6%)	
< 10 years	11 (8.5%)	7(10.9%)	4 (6.2%)	
> 10 years	11 (8.5%)	9(14.1%)	2 (3.1%)	

*p The p values represent a comparison between groups, values < 0.05 are significant

Initial data analysis revealed that skewness was problematic for most continuous variables as determined by Fisher's measure of skewness (Munro, 2005). Fisher's calculation confirmed that 37 of 43 continuous variables were significantly skewed. Since recoding variables using logarithmic and square root transformations failed to eliminate skewness, non-parametric methods were used for skewed variables.

Recoding Variables

Several dependent variables were recoded into *new* variables to create dichotomous measures. Two variables, urgent care and medication adherence, were recoded to create dichotomous variables. First, three questions about the use of urgent care required patients to indicate if they had used urgent care and if so, how many times. Responses ranged from 0 (*no*) and if yes, patients were asked to record the number of times, up to 6 or more times (1to 6). Consistently low use of urgent care suggested that a dichotomous variable would be adequate for analysis. Three urgent care questions were retained. However, each urgent care question was recoded to create a dichotomous variable, with responses categories of 0 (*no)* and 1(*1 or more times*). Table 5 illustrates recoding procedures for the recoded, categorical urgent care variables.

Table 5.   Variables for Urgent Care Recoded to Categorical Variables

Variable	Recoded variable
Urgent call to MD	Urgent call to MD recode
No = 0 1x = 1 2x = 2 5x = 5 3x = 3 4x = 4 6x = 6	0 = No 1 = 1 or more times
Urgent call to hospital	Urgent call to hospital recode
No = 0 1x = 1 2x = 2 5x = 5 3x = 3 4x = 4 6x = 6	0 = No 1 = 1 or more times
Urgent visit to ER	Urgent visit to ER recode
No = 0 1x = 1 2x = 2 5x = 5 3x = 3 4x = 4 6x = 6	0 = No 1 = 1 or more times

Secondly, four medication adherence items using Morisky et al. (1986) questions were combined to create a single adherence measure. The original four items were significantly skewed, with the majority of responses reported as never or rarely. The new variable, Morisky Adherence, remained significantly skewed, and was recoded to a categorical variable in the following manner. Four questions comprising medication adherence items were recoded into a new single variable, with 2 levels of measurement, labeled Morisky Adherence. The original four questions asked patients to report the frequency of forgetting or choosing to take medications. Responses of 0 (*never)*, 1(rarely), 2 (*sometimes*), 3 (*often*), and 4 *(always)* were combined to represent one total with scores ranging from 0 to 16. Scores of 0 to 3 were recoded as *never* and scores of 4 to 8 were recoded as *rarely*. Table 6 describes the formation of the new adherence

variable, labeled Morisky Adherence, which remains skewed at 8.3.

Table 6.   Four Items Recoded to Morisky Adherence

Original Variables Four Morskiy Questions	Recoded variable *Morskiy Adherence	Recoded descriptives	N= 129
Ever forget your medication Have problem remembering Stop taking (because feel better)		0-3= never	123(95.3%)
Stop taking 2(because feel worse)		4-8= rarely	6(4.7%)

* Skew 8.3

Identifying Components of Illness Perception

Recoding procedures were necessary to extract individual subsets or components

of illness perception from the original items**.** The IPQ-R questionnaire was developed to

provide quantitative assessment of individual components, or subsets of illness

representations. Moss-Morris et al. (2002) described how the instrument is used to

identify subsets. Using these guidelines, illness perception items IPQ 1 to 38 were

recoded into seven new variables which represent specific concepts of illness perceptions.

First, selected items in the IPQ-R instrument required reverse scoring. Reverse scoring of

items IP1, IP4, IP8, IP15, IP17, IP18, IP19, IP23, IP24, IP25, IP26, IP27, IP36 was

completed prior to data entry, and was only visible to the researchers. Patient copies of

the IPQ-R retained original scoring format. Second, recoding was necessary to combine

items, derived from the original 38, that identify seven components of illness perception.

Reverse scoring and recoding was completed as directed by the guidelines for scoring the

IPQ-R using SPSS.

Two concepts, consequence, and emotional representation were normally
distributed. Five concepts remain skewed; timeline, personal control, cure/control, illness
coherence, and timeline cyclical. Table 7 identifies the components of illness perception.

Table 7.   Seven Illness Perception Components, Recoded from 38 IPQ-R items.

Variable	Recoded Variable Illness Representation Component	Skew
IP 1-5 + 18	Timeline (acute/chronic)	2.16
IP 6 – 11	Consequence	-1.66
IP 12-17	Personal control	-2.92
IP 19-23	Cure/control	-2.09
IP 24-28	Illness coherence	-3.73
IP 29-32	Timeline cyclical	2.16
IP 33-38	Emotional representation	1.26

- values +/- 1.96 are significantly skewed at the 0.05 level

Group Comparison

Research Question # 1

Do patients receiving the nursing intervention differ significantly from those receiving usual care on medication adherence?

Adherence was examined in three ways. First, participants were asked if they had all medications currently prescribed. Second, they were asked a series of four questions about forgetting or omitting medication. And third, they were asked to indicate what percent of Aspirin and/or Plavix they took as prescribed.

At the start of the 72 hour interview, all participants were asked if they had in their possession, all the medications, including any new since the procedure. This question begins with the premise that adherence may be related to medication availability. Adherence with medication on hand was extremely high 124 (96.1%) for patients reporting that they had all medications ordered. The experimental group had a slightly higher rate of adherence 63 (98.4%) versus 61 (93.8%) in the control group. However, group difference was not significant ($p = .177$).

Adherence as measured by participants self report on four items was recoded into a new variable labeled Morisky Adherence. Data for the recoded variable remained skewed at 8.32. To compare the experimental and control group on Morisky Adherence, a nonparametric test, the Mann-Whitney U, was used. The groups were not significantly different ($p = .266$) as seen in Table 8.

Table 8. Mann-Whitney U Test of Group Differences on Morisky Adherence

	Experimental (*n*=64)	Control (*n*=65)	*p*
Morisky Adherence	mean rank 61.55	mean rank 68.39	.266

*p The *p* values represent a comparison between groups, values < 0.05 are significant

Interview questions for both groups at 72 hours asked participants to rate themselves on a scale of 0 to 100% to show their best assumption of how much of prescribed aspirin and/or Plavix was taken since discharge. It is important to note that these medications were not ordered for all participants. Questions related to adherence to specific medications, aspirin and Plavix, showed very little variation in the total sample and between groups.

Aspirin was prescribed for the majority of participants (82.2%), regardless of treatment choice or procedure. Plavix was prescribed more selectively, in only 39.5% of all participants, often in conjunction with aspirin to reduce thrombosis following stent placement. Adherence was extremely high in both groups.

Aspirin adherence ranged from 75% to 100%. Only one participant reported taking aspirin less than 90% of the time. Ninety-six percent of all participants taking Plavix reported taking it at least 99.9% of the time. Chi-square analyses showed there were no significant group differences in patients taking aspirin (*p* = .652) or Plavix (*p* =.394). Table 9 shows group comparisons.

Table 9. Group Comparison of Aspirin and Plavix Adherence

Aspirin % of Time	Total (N=106)	Experimental (n = 54)	Control (n = 52)
75	1(0.9%)	0(0.0%)	1(1.9%)
90	4(3.8%)	1(1.9%)	3(5.8%)
92	1(0.9%)	0(0.0%)	1(1.9%)
95	3(2.8%)	1(1.9%)	2(3.8%)
99	7(6.6%)	3(5.6%)	4(7.7%)
99.9	4(3.8%)	2(3.7%)	2(3.8%)
100	86(81.1%)	47(87.0%)	39(75.0%

$\chi^2 = 4.184$, $df = 6$, $p = .652$

Plavix % taken	Total (N = 51)	Experimental (n = 25)	Control (n = 26)
90	1(2.0%)	0(0.0%)	1(3.8%)
95	1(2.0%)	0(0.0%)	1(3.8%)
99.9	1(2.0%)	1(4.0%)	0(0.0%)
100	48(94.1%)	24(96.0%)	24(92.3%)

$\chi^2 = 2.982$, $df = 3$, $p = .394$

Research Question # 2

Do patients receiving the nursing intervention differ significantly from those receiving usual care on patient satisfaction?

Participants responded to two questions asking if they would return to the healthcare facility and if they would refer family and friends. Participants responded to a 5 point scale indicating 0 (*no*) and 5 (*definitely yes*). When asked if they would return, 96.9% of all participants responded as definitely yes and 3.1% reported very likely. The

second patient satisfaction question asked participants if they would refer family and friends to the healthcare facility, with 94.6% reporting definitely yes, 3.9% very likely and 1.6% somewhat likely. There were no negative responses to either question. Chi-square analysis was used to compare experimental and control groups on two measures of satisfaction. The first measure, asking if participants would return to the healthcare facility, showed no significant group differences ($p = .317$). In the experimental group 98.4% responded definitely yes and 1.6% very likely as compared to the control group with 95.4% responding definitely yes and 4.6% very likely. Statistical analysis on the second measure, asking patients if they would refer family and friends also reported no significant group differences ($p = .141$). Experimental group participants reported definitely yes 98.4%, very likely 1.6%, and somewhat likely 0.0%. Control group participants reported definitely yes 90.8%, very likely 6.2%, and somewhat likely 3.1%. Table 10 shows group comparisons.

Table 10. Group Comparison on Patient Satisfaction

Variable	Total (N=129)	Experimental (n = 64)	Control (n = 65)	p
Return to this health care facility				.317
Very likely	4(3.1%)	1(1.6%)	3(4.6%)	
Definitely yes	125(96.9%)	63(98.4%)	62(95.4%)	

$\chi^2 = 1.000, \quad df = 1, \quad p = .317$

	Total (N = 129)	Experimental (n = 64)	Control (n = 65)	
Refer friends and family				.141
Somewhat likely	2(1.6%)	0(.0%)	2(3.1%)	
Very likely	5(3.9%)	1(1.6%)	4(6.2%)	
Definitely yes	122(94.6%)	63(98.4%)	59(90.8)	

$\chi^2 = 3.924, \quad df = 2, \quad p = .141$

Research Question # 3

Is there a significant difference in the utilization of urgent care between those patients receiving the nursing intervention when compared to those patients receiving usual care?

Urgent care was measured on three questions during the 72 hour interview. Participants were asked if they had placed an urgent call to their physician, to the hospital, or visited an emergency room (ER) since discharge. Participants assenting were asked how many times the behavior was repeated; allowing patients to report urgent calls or visits up to five or more times. Repeated urgent care behaviors were minimal in both

groups. Three urgent care variables, call to physician, call to hospital, and visit to ER, were recoded into new dichotomous variables; responses included choosing 0 (*no*), or 1 (*yes 1 or more times*).

Chi-square analysis was used to compare experimental and control groups on three measures of urgent care. Overall, participants reported minimal use of urgent care. In the total sample, the modality used most frequently was a call to the physician, although this was utilized by only 13 (10.1%) participants. Only 7 (5.4%) participants called the hospital and 4 (3.1%) participants returned to the emergency room. In all measures there were no significant group differences reported respectively as ($p = .747$), ($p = .682$), ($p = 317$). Table 11 refers to the use of urgent care.

Table 11.Group Comparisons on Use of Urgent Care

Variable	Total (N = 129)	Experimental (n = 64)	Control (n = 65)	* p
Urgent call to MD				.747
No	116(89.9%)	57(89.1%)	59(90.8%)	
1 or more times	13(10.1%)	7(10.9%)	6 (9.2%)	
χ^2 = .104, df = 1, p = .747				
Urgent call to hospital				.682
No	122(94.6%)	60(93.8%)	62(95.4%)	
1 or more times	7 (5.4%)	4 (6.2%)	3(4.6%)	
χ^2 = .168, df = 1, p = .682				
Urgent visit to ER				.317
No	125(96.9%)	63(98.4%)	62(95.4%)	
1 or more times	4(3.1%)	1(1.6%)	3(4.6%)	
χ^2 = 1.000, df = 1, p = .317				

*p The p values represent a comparison between groups, values < 0.05 are significant

Research Question #4

Does a difference exist between the patients receiving the nursing intervention and those patients receiving usual care on illness perception, as measured by seven components of the IPQ-R: time line (acute and chronic), consequence, personal control, treatment (cure) control, illness coherence, timeline (cyclical), and emotional representations?

High scores on the identity, timeline, consequences, and cyclical dimensions represent strongly held beliefs about the number of symptoms attributed to the illness, the chronicity of the condition, the negative consequences of the illness, and the cyclical nature of the condition. High scores on the personal control, treatment (cure) control and coherence dimensions represent positive beliefs about the controllability of the illness and a personal understanding of the condition.

Illness perceptions items (IPQ 1 to 38) were recoded into new variables representing the seven components of the IPQ-R. Since seven comparisons were made, a Bonferroni correction was done to protect against Type I error ($.05/7 = .007$), indicating that a (p of $< .007$) is significant. Because five components were significantly skewed, Mann-Whitney U tests were performed to compare groups on timeline (acute/chronic), personal control, cure control, illness coherence, and timeline cyclical. There was one significant group difference on the timeline (acute/chronic) component. Personal control, cure control, illness coherence, and timeline (cyclical) showed no significant group differences as shown in table 12.

Table 12
Mann-Whitney U Test of Five Components of Illness Perception

Component		Experimental (n=64)	Control (n=64)	U	p*
Timeline (acute/chronic)	Mean rank	73.53	55.47	1470.0	.006
Personal control	Mean rank	64.61	64.39	2041.0	.973
Cure control	Mean rank	64.26	64.74	2032.5	.940
Illness coherence	Mean rank	69.02	59.98	1758.5	.152
Time cyclical	Mean rank	64.46	64.54	2045.5	.990

*p The p values represent a comparison between the experimental and control groups,
    values < 0.007 are significant

Two of the seven components, consequence and emotional representation, were

normally distributed. Independent t-test was used to compare groups on these concepts.

There were no significant group differences on consequence or emotional representation.

Results are shown on Table 13.

Table 13
Independent t-test of Two Components of Illness Perception

Component	Experimental (n=64)	Control (n=64)	t	p*
Consequence	64(20.39)	64(19.59)	.934	.352
Emotional representation	64(16.59)	64(16.79)	-.250	.803

*p The p values represent a comparison between the experimental and control groups,
    values < 0.007 are significant.

Timeline (acute/chronic) is the only component with significant findings (p =

.006). The experimental group scored higher (m = 73.53) than the control group (m =

55.47). This finding indicates that the experimental group represents a stronger

interpretation of cardiac disease, as a condition they will have to manage for a long

period of time. This finding also suggests that the experimental group had a greater

appreciation of the chronicity of cardiac disease.

Summary

This chapter presents the findings of group differences following a randomized

controlled trial of a nursing discharge intervention. The experimental and control groups

of participants receiving interventional diagnostic and interventional cardiac care were

demographically comparable. Analysis on four outcome measures, medication adherence,

use of urgent care, patient satisfaction, and illness perception, revealed only one

statistically significant result. The experimental group scored significantly higher than the

control group on one measure, the timeline (acute/chronic) component of illness

perception (p = .006). Otherwise, there were no significant group differences found.

Chapter 5 discusses these results in detail. Discussion and interpretation of these

findings explores each research question. Limitations and recommendations for evidence

base practice, utilization of the intervention and future research are incorporated.

CHAPTER 5

Discussion

This study addressed four research questions about the effectiveness of a

discharge nursing intervention (DNI) delivered to patients undergoing percutaneous

cardiac interventions (PCI). Evaluation of this study has been completed to address the

null hypothesis stating that there is no difference between groups in a randomized sample

of patients on the outcome variables described in the study. Group differences were

significant for only one measure of illness perception, timeline (acute/chronic), with the

experimental group scoring significantly higher. These findings, study limitations,

clinical and practice recommendations, and implications for future research are discussed

in this chapter.

Study Sample and Setting

A purposive sample of 154 patients, ages 30-80, was recruited into this study at

Massachusetts General Hospital (MGH), a 902 bed medical center, in Boston

Massachusetts. Approximately 46,000 patients are admitted to MGH each year, and out-

patient visits number more than 1.3 million. In 2003, MGH was the first Boston hospital

to receive Magnet recognition status, a prestigious distinction for excellence in nursing

services. In 2008, the American Nurses Credentialing Center redesignated MGH as a

Magnet Hospital.

Patients admitted to the Knight Cardiovascular Center at this academic medical

center are assumed to be representative of patients cared for in similar urban medical

centers providing interventional cardiac care. Patients are admitted for assessment of an

acute cardiac event or referred to the medical center for evaluation of recurrent or

significant symptoms. The available population for this study exceeded twenty patients each enrollment day.

<div align="center">*Group Characteristics*</div>

There was notable consistency across the entire sample. Patients and families responded positively to the concept of cardiovascular nurse telephone follow-up. This attitude was confirmed by participants during the initial stages of consent and throughout the study. Records of comments during the patient interviews, verbal feedback from cardiology staff, and the large number of patients who voluntarily and promptly returned phone calls indicate that participants appreciated the continued contact with a cardiovascular nurse. Many participants shared mobile phone numbers, family phone numbers, and arranged specific times for the first and second phone call. Often participants would invite the study nurse to contact them for follow-up or additional studies.

<div align="center">*Delivery of Intervention*</div>

In addition to usual care information, subjects in the experimental group took home a red packet with group instructions, study instruments, medication pamphlet, medication pocket card, and a list of internet resources. Participants in the control group took home study instruments in a blue packet, containing group instructions and study instruments. Both groups were provided with a resource card listing contact information for the study nurse.

Participants in the experimental group were contacted within 24 hours of discharge and all participants were contacted within 72 hours of discharge. An average of 1.5 phone calls was required to reach participants at 24 hours and 2 phone calls at 72

hours. Discharge instructions clearly limited activity for at least 24 hours and driving for up to three days. These activity restrictions, together with mobile phone use, contributed to participants' accessibility.

<div align="center">*Discussion Related to Study Outcomes*</div>

Adherence

Adherence may be defined as the extent to which a patient's behavior, when taking medication, coincides with medical or health advice. The term adherence is intended to be a nonjudgmental statement of fact rather than of blame. All questions in this study were asked with this intent.

Management of chronic cardiac disease requires individuals to regularly self-administer numerous medications. It is important to study patients in their home setting to provide an integrated perspective about medication adherence after they leave the hospital. In this study, participants were asked about adherence in three ways. First, they were asked if they had all medications prescribed in their possession. Second, a set of four questions asked about omission and decisions about taking medications. Finally, patients were asked to report adherence to aspirin and Plavix, using a visual numeric scale.

All participants scored extremely high when asked if they had all medications with them. Only two participants did not have *all* medication in their possession, reporting that they were waiting for prescriptions to be picked up at the pharmacy or delivered by mail, but they had enough medication on hand. Two factors may influence this finding. First, prior to discharge, prescriptions are electronically sent from the hospital to the patient's pharmacy of choice. Most participants were able to pick up their

medications on their way home without significant delay. Second, if participants subscribed to a mail-order drug program they simply informed the staff and they would be given an adequate supply of medication at the hospital. At this point, the cardiology staff reinforced the importance of each dose and the urgency of taking every dose as directed.

The second measure of adherence was examined using four questions, developed by Morisky (1986) asking participants to rate how often they forget to take all medications, cardiac medications, or if they stop taking medications if they feel better or worse. Questions from Morisky's (1986) adherence work were selected because they support a "blameless" philosophy and have been recently updated to retain a non-judgmental tone.

When assessing responses using Morisky's questions, there seemed to be a consistent trend as participants answered "rarely" to the first question but progressively improved, answering "never" to the following 3 questions. This often happens when patients figure out that 0 (*never*) was the desired response, and they want to represent themselves in the most favorable manner.

The second set of questions asked participants to report on how often they omit medication if they are feeling better or worse. Often, participants would qualify their answer with "only if I had spoken to my doctor." Only one participant, a pharmacist, clearly stated that he would immediately stop any medication that may be making him feel worse, and then proceed to notify his physician of this action. Although this study found no group difference on this outcome, it is important to consider that participants responded without hesitation and offered thoughtful suggestions and explanations. Open

ended questions allowed patients to contribute additional information that may provide qualitative data for later review.

The final section addressing medication adherence asks participants to communicate the percentage of time they took aspirin and Plavix. Both drugs are important to secondary prevention of thrombotic events and to maintain stent patency. Aspirin does not require a prescription, is inexpensive, and readily available as an over the counter drug. Conversely, Plavix is costly and is only available with a prescription. The experience of this investigator with cardiac patients has indicated that they have questions about the dose, value, and time requirements of these drugs. In this study, the adherence rate for both drugs was extremely high for all subjects. Additionally, participants clearly articulated the specific dose of aspirin, ranging from 81mg to 325 mg, often adding that they were taking coated tablets and stated that they may be on both medications indefinitely.

Although there were no group differences on medication adherence, it is important to note that all study participants self-report of medication adherence, on all measures, was extremely high 72 hours after discharge. Continued study of this data set and participants' comments may allow the identification of specific factors that contribute to medication adherence. Extending the study to include a longitudinal design would examine medication adherence over time and describe variables that influence continued or reduced compliance.

There is evidence, however, that long term adherence to secondary prevention drugs after cardiac events diminishes over time. Studies reporting that 6% of patients taking beta-blockers and ace-inhibitors stopped taking their medication within 30 days,

18% at 6 months, 28% at 1 year, and 47% at 2 years (Akincigil et al., 2008). Although a 2007 National Healthcare Quality report shows that hospitals have improved in prescribing secondary prevention drugs. They also found that patients do not continue taking all of them over time. Quality measures that address drug adherence are needed to identify factors that lead to discontinuation of drugs over time. Medication adherence of all patient populations at home is understudied (DiMatteo et al., 2002; George & Shalansky, 2006; Rasmussen et al., 2007).

Understanding behaviors or factors that contribute to medication adherence at home is important for many reasons. Paramount to this issue is the common fact that medications only work if people actually take them. There are many stakeholders in the discussion about adherence. Ethical, medical, and economic forces exist that encourage adherence. Current scientific research, widely circulated in the popular press, reports that medical therapy provides evidence based options for the treatment of cardiovascular disease (Boden, 2007; Kereiakes et al., 2007). Patients failing medical therapy or sustaining complications while on medical therapy may be undertreated. Inadequate adherence to medication places patients at risk for secondary events. These are challenging issues for several reasons: 1) medical therapy is only effective if patients adhere to the prescribed course, 2) accurate assessment of medical therapy is dependent on strict adherence, 3) adherence is complex and difficult to measure, 4) there are social, financial, and health concerns that further complicate the problem of non-adherence

From an economic view, insurers report paying twice as much to treat patients who forget to take drugs targeted to fight high cholesterol and other chronic conditions (Copeland, 2008). This confirms that the consequence for non-adherence is more costly

care for patients and insurers. Copeland adds that pharmaceutical companies would also like patients to take all medications prescribed. Companies such as Pfizer collect about 10 billion dollars a year from the sales of Lipitor, but if patients took every dose prescribed, they would collect 17 billion.

Recent studies of cost-effective cardiac care report that medical therapy alone offers better outcomes at lower cost. Weintraub et al., (2008) studied resource allocation when PCI was added to optimal medical therapy (with assumed adherence) in stable patients. Although patients treated with elective PCI showed no difference in MI or death rates, the procedure did improve quality of life. The cost of adding PCI ranged from $112, 876.00 to $154,580.00 per patient.

During the course of this study, investigators from the COURAGE study (Boden, 2007; Kereiakes et al., 2007) reported that medical therapy may be as effective as PCI for many cardiac patients. COURAGE was a randomized clinical trial ($N = 2,287$) that compared PCI with optimal medical therapy, in patients with know cardiac disease, over a median of 4.6 years. Another large study, JUPITER, followed 17,802 men and women at risk for primary cardiac disease. Findings from JUPITER reported that even in low risk patients, treatment with statin drugs, may help cardiac patients stay healthy (Ridker et al., 2008). Results from these large studies were widely disseminated. Patients, families, healthcare personnel, and the public at large became informed through the news media about the effectiveness of medical therapy. Key points of emphasis within both reports reinforced the concept of patient adherence to medication.

Results of the adherence portion of this randomized controlled trial (RCT) may have been influenced by extensive media reports about successful medical management

of cardiac disease. Additional factors reported by study subjects include: patient experience with medication protocols, clear and concise discharge instructions, and detailed discharge teaching by staff nurses and advance practice nurses. Advanced educational preparation levels of subjects may also be considered a prominent factor.

Patient Satisfaction

Patients' rating of hospital care and level of satisfaction are important in many ways. Often they represent the ability of institutions to compete for patients and maintain financial stability. A new survey developed by the Agency for Healthcare Research and Quality (AHRQ), examined data on patient satisfaction. Comprehensive data from the 2008 Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) provided the most recent, comprehensive report of patients' experiences in the United States. The two highest ratings of overall measures of patient experiences were, 1) "overall hospital rating," and 2) "would you recommend this hospital," receiving 9 to 10's on a 0 to 10 rating scale. Responses to both questions were highly correlated ($r =$ 0.87). Although the study showed only a small percentage of patients who were "dissatisfied," very few hospitals received high ratings from 90% or more of patients. Often patients reported dissatisfaction with the discharge portion of their hospital experience. This report concludes that patients' satisfaction with care was associated with the quality of clinical care (Jha, Orav, Zheng, & Epstein, 2008).

The 2008 HCAHPS data presented in this national portrait of more than 2,400 United States hospitals are likely to provide a baseline for measures that will be used to monitor patient-reported quality performance in the future. Random sampling of recently discharged patients asks about important aspects of the hospital experience. Specific

questions address ten topics with the last two questions asking patients to rate the hospital

from 0 (*worst possible*) to 10 (*best possible*) and asking them to indicate if they would

recommend the hospital to friends and family using a similar measure 0 (no) to 10

(*definitely yes*). The 2008 study highlights specific areas for improvement such as nursing

care, communication about medications, pain control, and provision of clear discharge

instructions. The 2007 to 2008 HCAHPS data found moderately high satisfaction with

care, and on average 67.4% of patients reported that they would definitely recommend

the hospital (Jha, et al., 2008). Data retrieved online in February 2009 from,

www.hospitalcompare.hhs.gov/HCAHPS, reflects national and local results from patients

who had overnight stays from April 2007 through March 2008. Overall hospital

satisfaction ratings of 9 or 10 were reported as 64% for all United States hospitals, all

Massachusetts hospitals 65%, and MGH 76%. Results indicating that patients would

recommend the hospital to friends, with a ranking of 9 or 10, report 68% for all United

States hospitals, 71% for all Massachusetts hospitals, and 86 % for MGH (United States

Department of Health and Human Services, 2009).

      The current study compared usual discharge care and instructions with a nursing

discharge intervention that addressed all three areas of concern highlighted by HCAHPS

data. This study addressed specific measures of satisfaction on *returning* and *referring*

exceeded 94 to 96 % for all participants, with no significant differences between groups.

These ratings may exceed national ratings, as very few hospitals received the highest

ratings (9 to 10) from 90% or more patients.

      There are many explanations for these differences, including study design and

survey response rates. Participants in this study were limited to narrowly defined

diagnostic groups, many were returning MGH patients, and all participants received some

additional attention regardless of group assignment by virtue of study enrollment. All

study participants received at least one phone call by the cardiovascular research nurse.

Although most satisfaction research use self-report, the current study required the patient

to respond directly to the study nurse over the phone. Most participants and families had

contact and discussion with the same nurse during the consent process. It is possible that

the patients were more inclined to respond favorably to the nurse they encountered during

the consent process and initial phone call (for the intervention group). Patients

responding to the 2007 to 2008 HCAHPS survey had the option of responding to a person

by phone, active-interactive voice recognition, or return by mail.

 With the introduction of the HCAHPS system in 2007, hospitals are beginning to

bridge data from Picker surveys and other self-reported measures. The results are used to

support hospitals' quality improvement methods, combining formulas to create the most

effective tool to monitor performance improvement efforts (Quigley, Elliott, Hays, Klein,

& Farley, 2008).

Patient Satisfaction at Magnet Hospitals

 The context or environment in which nurses practice is an important factor in

patient outcomes, especially patient satisfaction. High patient satisfaction scores in

Magnet hospitals, such as MGH, may be related to the organizational structure. Magnet

hospitals demonstrate organizational attributes that enable nurses to fully use their

knowledge and expertise to provide high-quality patient care. Early empirical evidence

that this type of organization produces better patient and staff outcomes is compelling

(Havens & Aiken, 1999). Nurse to patient ratio and nursing expertise may also influence

patient satisfaction. Magnet hospitals report improved staffing and higher educational levels of nurses (Aiken et al., 2003). The concept of improving organizations by fostering professional environments, and supporting nursing excellence serve as a catalyst for improving both nurse satisfaction and a wide range of patient outcomes (Stordeur & D'Hoore, 2007). Staffing, nursing expertise and the collaborative discharge model at MGH reflects redesigned care consistent with the Magnet structure, and may have influenced the findings of this study.

Urgent Care

There were no significant group differences on three measures of urgent care. Three participants in the control group returned to the emergency room while only one participant in the experimental group reported using the emergency room for urgent care. Although not statistically significant, this difference should be further studied to determine if there were unique variables present in this subset.

Contacting patients within 24 hours may provide discharge teaching reinforcement, encourage medication adherence early, or answer care questions that are important to early recovery. Any reduction in emergency care admission may provide significant cost savings for patients responsible for co-payment and deductibles. Additional cost savings would be appreciated by insurance providers, and the hospital. Cost savings using these indicators may be easily translated to offsetting the cost of the expert nurse providing a discharge intervention.

Illness Perception

Patients with cardiac disease have increased treatment options with expanded technology. The major difference is rapid treatment, with pharmaceutical or

interventional care. Patients are triaged to medical, interventional, or surgical care within hours of an acute coronary event or worrisome symptoms. In the absence of complicating events, hospital care is limited to hours or days (Dixon et al., 2006; Thom et al., 2006). Patients are expected to recover and manage care at home. Healthcare providers partner with patients to manage their cardiac condition as a chronic illness (Weingarten et al., 2002). How care is managed at home may be directly related to one's individual perception of the illness threat (Leventhal et al. 1980; Petrie et al., 2002; Zerwic et al., 1997). The 38 item Illness Perception Questionnaire (IPQ-R) is a quantitative measure of such perception (Moss-Morris, et al., 2002).

This study demonstrated that the nursing discharge intervention showed no significant group difference on six components of illness perception. Findings revealed only one significant difference on the timeline (acute/chronic) component. Experimental group participants scored significantly higher on timeline. Questions comprising the timeline component asked participants to consider if their illness would last a long time.

What patients perceive or believe may not match existing evidence about disease treatments; however, this is now recognized as a central component for disease self-management programs. Self-management is directly related to illness perception, which may be the most promising and least understood concept within the chronic care model (Lorig et al., 1999). Nursing interventions that influence a patient's appreciation for the chronic nature of disease is important to evidence based discharge practices.

Study significance on the timeline (acute/chronic) component was the single significant finding of this study. Understanding the chronicity of any disease is an important factor in patients' ability to self-manage their disease over time. Patients who

accept their conditions to be long term have better diet and exercise self efficacy scores, and contribute to long term adherence to medication. Lau-Walker (2004) reported that perceiving cardiac disease as chronic may be instrumental in engaging individuals in making lifestyle changes.

In a recent survey, patients who underwent elective PCI for relief of angina believed that the procedure, in itself, was life saving and would prevent heart damage, save, and extend their lives. Continued research, however, continues to reinforce that the procedure is not a one time cure for cardiac disease, but only one part of the care continuum for cardiac disease. In 2007, the COURAGE trial provided the best evidence that elective PCI had no impact on death or myocardial infarction when compared to treating patients with an initial strategy of optimal medical therapy. Investigators from COURAGE (Kereiakes et al., 2007) indicate that PCI did in fact reduce the risk of MI and death for *acute* coronary events, but was shown only to relieve angina and improve quality of life in the *elective* group. Patients treated with elective PCI, followed by medical therapy, and patients treated *only* with medical therapy must know (perceive) that they have a chronic condition. This awareness, may improve adherence to a prescribed regime of medication and lifestyle modification.

A recent study presented by John Lee at the American Heart Institute Scientific Session 2008 (as cited in Wood, 2008, p.247) reviewed surveys from 350 patients who had undergone elective PCI between January 2006 and October 2007. In addition to misconceptions about the effects of PCI, survival rates, and myocardial infarction (MI) risk, patients also thought of their PCI as an emergency procedure. Lee concluded that patients' perceived benefits of elective PCI do not match existing evidence. Concern exist

that patients' perception of illness and of their treatment options are not being examined. Questions brought forth by the 2007 COURAGE study include: Do questions we ask patients about their treatment match what the patients truly believe and are patients well informed about options for treatment? Cardiology leaders agree that we must understand patients' perceptions and provide better education to elucidate evidence-based risk and benefits and to assure genuine informed consent (Wood, 2008).

In the era of promoting self-management among patients living with chronic diseases a clear understanding of illness representation in the context of heart disease is valuable. Astin and Jones (2006) evaluated illness perceptions in 117 patients before and after elective angioplasty using a repeated measure design. Findings were significant for three components; consequence, personal control, and timeline. Consequence and cure/control scores decreased significantly, indicating that representation of illness as having serious consequences and personal control over their illness weakened over time. Timeline (acute/chronic) scores increased significantly in the Astin and Jones study, indicating a shift in patients' representations of their disease from an acute to chronic model.

The IPQ-R is an important research tool that will enable researchers to repeatedly examine the perceptions about cardiac disease and treatment options. Elective and emergent diagnostic and therapeutic PCI are increasingly popular modalities for determining medical regimens for chronic heart disease, but little is know about individuals' cognitive responses to this intervention. Research theory, methods, and instruments described in this study may be employed to further examine this issue. The intervention may be replicated to examine how nursing discharge interventions support

patients as they comprehend the trajectory of disease, in spite of treatment options that may appear offer a quick fix.

Study Strengths

Specific strengths of this study are related to its design. Nursing interventions are based on clinical judgments, knowledge, and skills executed by an expert nurse to enhance patient outcomes. Evidence based practice and advances in nursing care will move forward with this type of rigorous study. A randomized controlled mechanism theoretically guarantees that there is no systematic difference between the groups. Clarity in the design, unambiguous inclusion and exclusion criteria, and timing of the consent processes led to successful enrollment of a large number of available subjects.

Execution of the study by an expert cardiovascular nurse enhanced patient recruitment and ongoing communications. Patients and families appeared comfortable and communicated freely with members of the research team. A Magnet Hospital environment provided support for the researcher. Resource personnel were available at any point in the study to reinforce research principles. In this setting, many patients were familiar with the informed consent process, which often expedited enrollment.

Instruments and survey materials were written in plain language for use with all English speaking patients. Interview questions were given to patients for visual reinforcement during telephone interviews. Telephone interviews were conducted within reasonable time periods, lasting from 5 to 15 minutes, depending on individual patient response times. All items used in this study can be read to the participant and completed by the interviewer, or read by the participant and returned by fax, mail (traditional or electronic), or completed using voice recognition response. Time frames for telephone

follow-up were in synchrony with activity restrictions associated with PCI. Only a few

patients were lost because they were not available by phone. There were no deaths

reported during the study period. Participants completing the study reported substantial

improvement and recovery within three days.

Study Limitations

The findings of this study are limited in several respects that may account

for the apparent lack of effect of the intervention on all study outcomes with the

exception of the timeline component of illness perception.

Research Design

The DNI design included a control group in which data were collected by the

study nurse on two occasions, once during the consent process and again during the 72

hour phone call. Control group subjects received extra nursing time and attention during

this process. Data collection may have served as an intervention, as control group

participants also received additional nurse contact, in addition to usual care.

This type study may be difficult to replicate because of the time requirements.

Time requirements per patient include approximately 40 minutes (including informed

consent), however, it requires a nurse to contact each participant by phone 1 or 2

additional times. Patients regain mobility quickly and return to their normal activities

within a day or two. Continuing the study with a phone call at 72 hours for both groups

resulted in some attrition issues. Mobile phones created additional access to patients and

contributed to the overall success of the study.

The randomized control design of the study removes context from the results.

Because patients, hospitals, and homes are part of a complex system of care, context may

be important in determining the validity of any intervention. It may be necessary to

conduct a similar study or replicate the existing study in more than one setting to examine system issues.

Study Site

The intervention, in its current design, may not be necessary for this patient population or within this setting. Magnet hospitals report improved outcomes and higher rates of patient satisfaction that may not be generalizable to larger populations.

Study Variables

The intervention may not have been of sufficient intensity or duration to observe significant differences in study variables. The intervention may have been too diffuse in focus, attempting to affect four different outcomes. Studies designed to examine one outcome, such as medication adherence, may provide different results. A longitudinal study of each variable of interest would be able to measure the outcome over time.

Subjects

The study sample was large enough to demonstrate the desired effect. However, the non-selective sample of patients did not capture specific ethnic groups or genders. Lack of diversity was a limitation for the generalizability of this study. Patients of diverse cultures were excluded from the study because of language barriers that would be problematic during follow-up phone calls. Women were underrepresented in this group as were patients living alone.

Self report

A study using patient self report must consider the risk of response bias; the tendency of respondents to distort their responses. Patients may have many reasons to report findings that may not be totally truthful in efforts to please the researcher, or select the "correct" answer, or to obscure deficits in their true behaviors, feelings, or actions.

During this study, participants expressed opinions and described their feelings, actions, and intentions in a completely voluntary manner. Participants wanted to contribute to the study and were very supportive of the research nurse. Limitations of self-report methods must be considered in reviewing study outcomes. Researchers addressed response and social desirability bias by creating a non-judgmental atmosphere, reinforcing anonymity, and encouraging open responses.

Study Instruments and Methods

Instruments developed and selected for this study supported a non-judgmental focus. Interviews did require some time burden but were easy to conduct; only one patient was unable to complete all sections of the 72 hour interview because of time restrictions. Use of telephone instead of face to face interviews may have influenced patients' responses. Speaking from the privacy of their own home and responding to a voice versus a person, may have allowed them to feel more protected or in control. Use of rank order or forced choices reduces the richness of data that may be collected with open ended questions. Participants' comments and open responses were documented for clarification and may be used for qualitative analysis.

Researcher Bias

Telephone interviews were typically conducted by the study nurse enrolling patients at the point of consent. Personal contact and time spent with patients and families may have contributed to the success of subject retention. Responses to interview questions may reflect the positive or negative experience of personal contact with the research nurse.

State of the Science

The technology and science for the treatment of heart disease has grown exponentially, however, there remains a need for nursing and social science research that describes how patients manage recovery at home and what nursing interventions may be necessary to improve patient outcomes. This study informs only a small segment of information needed to design discharge nursing interventions for this patient population.

Implications for Clinical Practice

The current study was well received by patients, families, and the entire cardiology staff. The theory and format were well suited to this patient population and would be readily transferable to other settings and populations. Subjects responded very favorably when invited to participate, commenting that a phone call would be most welcome. Participants and significant others reported that they had explored internet sites, including the MGH site, to seek information about the procedure and possible treatment options. Prior to the interventional procedure, many participants revealed they were anxious about home recovery. During the consent process both patients and families often expressed concerns about activity levels and ability to care for themselves or each other at home. Families were anxious to know if their loved one would require medical, surgical, interventional treatment or some combination of each.

The intervention did not result in statistically significant changes in three of the four outcomes. A significant finding, however, seen on the illness perception component of timeline (acute/chronic), indicates that this type of nursing intervention helped patients understand that their disease requires continued management. The study confirmed that

patients receiving the DNI had an increased perception, or awareness that their disease was chronic.

This finding reinforces several concepts.

1. Illness perception is related to patients' self-management of disease (Leventhal et al., 1980). Research grounded in behavioral sciences is important to healthcare. Current thinking is shaped by the study of how human behavior intersects with healthcare and economic decision making. Healthcare researchers, educators, providers, and policy makers represent a wide intellectual range and can not ignore psychology and behavior. Social science guided multi-disciplinary research is needed to make conclusions about what is and is not healthy behavior, and what perceptions contribute to individuals being able to care for themselves.

2. Research that translates complex human interactions and cognitions into data is necessary. The illness perception questionnaire is a valuable tool that achieves this purpose at many points in individuals' health and illness experiences. Participants' comments include self-reflection about how they would have answered the questions differently in the past and about how they may answer them differently in the future.

3. Decisions made by providers must not ignore the crucial role of individuals' expectations, beliefs, and perceptions and manage their own care for chronic conditions. When care improves as a result of patient perceptions, we are building evidence that is meaningful for the patient.

Significance

No significant group differences were found on 3 of 4 outcomes. Adding

additional nursing support, post procedure, did not influence medication adherence, use of urgent care, or patient satisfaction in the time period studied. Non-significant findings are as important as significant ones, as they inform the efficient use of resources and contribute to evidence that more care does not necessarily result in better outcomes. Redesign of discharge processes may be accomplished by re-engineering existing resources rather than adding new or costly interventions.

The Dartmouth Institute for Health Policy and Clinical Practice Report (2008) demonstrates the need to overhaul the ways in which we care for Americans with chronic illness, but cautions the use of simply adding treatments. Another report from the Robert Wood Johnson Foundation (RWJF) discusses variation in Medicare spending. In this report the evidence found that more care does not result in better outcomes. This report challenges providers to ask if some chronically ill Americans are getting more or less care than they or their families actually want or need. These are important questions at a time when 75% of all healthcare spending results from caring for people with chronic disease, with 95 cents of every dollar are spent for acute care of an already sick (chronic) patient (RWJF, 2009). Clearly, it is important to look at existing resources and measure what is working and what is not.

The MGH discharge team combines a strong primary nursing staff with an advanced practice nursing role that creates an alternative to traditional cardiac care. Designed by a multidisciplinary team in 1991, this model provides a comprehensive approach to discharge planning. The lack of significance noted on three outcomes measures may be delineated by the impact of the advanced practice nurse's role,

developed to help restructure discharge care and improve patient satisfaction at MGH (Giacalone et al., 1995).

This study demonstrates that a thoughtfully designed, advance practice nurse supported discharge program, provided as "usual care" in the MGH Knight Center, results in minimal use of urgent care, high scores on patient satisfaction, and high scores on medication adherence. Lack of significance serves as a reminder that interventions work sometimes, somewhere, but are not always generalizable to all settings, especially the complex and diverse settings of the current health delivery system.

Recommendations for Future Research

This study provides insights into medication adherence, use of urgent care, patient satisfaction, and individual perception of illness, reporting significance in one component. This study provides descriptive data that informs patient outcomes at MGH, a magnet hospital with a nursing model that includes advanced practice nurses working as part of the discharge team. Results and further replication of this of study will add to the body of knowledge about what type of discharge support patients need to manage their own care. Additional studies of usual care practices, independently, or in comparison with new interventions, will inform healthcare providers about what works, when and where it works, and for which patients it works best. The relationship between discharge preparation and management of care at home continues to be a major research issue. The current study may serve as a pilot for a larger intervention that continues longer, measures more points in time, and reaches more patients of diversity and transcends language issues.

The appraisal schedule of 24 hours to 3 days allows healthcare providers to reinforce important discharge instructions and reconcile medication and care instructions often before complications occur. This time frame, however, may not capture some of the complexities of care as patients and families continue to manage their care at home, resume work schedules and family activities. A longitudinal design of the same study with multiple measurement points would enable researchers to examine specific times in the recovery period where the intervention is most beneficial. Extending the study to one year with measurement points at three month intervals would provide data that might be relevant to the four study outcomes. Further extension of the study, over a period of years, with evaluation points annually, may be useful to access medication adherence and illness perception over time.

A diverse study population may be obtained with multilingual researchers to obtain informed consent and design study instruments. Language selected, electronic formats may convert study instruments into many languages to provide options for written or electronic response.

The study could be replicated in its current form or in a revised form to address sub-groups within the population, using more specific inclusion and exclusion criteria, with additional or different outcomes. Future study should include understudied populations, such as women, minorities, and, patients living alone. Gallagher, Marshall, Murray, and Elliot (2008) report that another sub-group, women living alone, are an increasing population of patients with cardiac disease who have unique concerns related to vulnerability, recurrent cardiac symptoms, social support, work, and finances.

Study replication in different settings and populations is important because the randomization of this study removes context from the research. Although this is an important feature of experimental research, it may isolate the results to particular settings. Replication of the nursing intervention in settings that do not currently have advanced practice nurses and/or Magnet Hospital status, streamlined discharge instructions, electronic medical records and prescription services may render very different findings.

Future research may include modeling the existing discharge program at MGH Knight Cardiovascular Center. Comparisons of discharge programs with and without advanced practice nurses at the point of discharge are necessary. Benchmarks are needed for the best systems; the MGH program would be one model of comparison.

Participants' comments collected during the study may provide qualitative data about the experience of patients managing their care at home. This valuable information may be used to inform healthcare providers from the patient's voice to redesign care and create new research questions for further study. Participants' open responses from this study may provide qualitative data to further inform the high rate of medication adherence. Continued examination of the existing data set and other patient comments may elucidate specific factors that correlate to improved adherence. Morisky's adherence questions may be used again in direct replication of this study or as a single study examining medication adherence behaviors at home.

Theoretical Framework

Self-regulation theory is well suited to the study of interventional cardiac patients, treated for an acute event, but managing a chronic disease. Leventhal et al. (1980) common sense model of illness perception for self-regulation of care incorporates

elements of traditional health belief models and expands to include cognitive and emotional responses involved in the coordination of complex behaviors. The model provided structure for all study outcomes, as it acknowledges patient choice and control over health decisions. Healthcare threats, often complex and foreign to the person facing them, require common sense behaviors as well as learned or coached behaviors.

This study used self-care theory to guide a nursing intervention that helped patients with cardiac disease acknowledge that their illness would last a long time. Participants in the experimental group, receiving the DNI, scored significantly higher on the timeline (acute/chronic) component, indicating a greater appreciation of the chronicity of their disease. This is an important finding because patients treated with elective PCI, followed by medical therapy, and patients treated *only* with medical therapy must know (perceive) that they have a chronic condition. This awareness, may improve adherence to a prescribed regime of medication and lifestyle modification.

Previous studies, using this model, indicate that cardiac patients often display inaccurate illness representations. Zerwic et al. (1997) found, through timeline dimension of the IPQ-R that over 40% of patients believed their illness would last a short time or were unsure of the expected timeline. Pesut & Massey (1992) concluded that care decisions and health behaviors are often determined by patients who may not understand the severity or chronicity of cardiac disease and the high incidence of secondary events. Astin & Jones (2002) found that over time, patients receiving PCI began to appreciate the chronicity of their disease.

This study illustrates the effectiveness of a DNI that encourages patients to acknowledge the chronic nature of cardiac disease as soon as they begin caring for

themselves at home. This is significant because health behaviors immediately after PCI procedures have a significant impact on secondary events.

This study will add to the body of knowledge that suggests that patients who believed their disease to be chronic in nature were less likely to discontinue medications, made better decisions about urgent care, and reported improved satisfaction with ongoing care (DiMatteo et al., 2002; Dracup et al., 2003; Meyer et al, 1985; Rasmussen et al., 2007). The study suggests that illness cognition is central to the construct of adherence, which may also be related to perception how long the illness will last.

The IPQ-R questionnaire, supported by this model, was easy to administer and was well received by participants and families. The IPQ-R provides a quantitative assessment of the components of the CSM model (Moss-Morris et al., 2002). Participants often stated that the questions encouraged them to think more about how they felt about their illness and their role in managing the illness.

Conclusions

Outcome measures reflect the results of care. Each of the four outcomes measured in this study are essential to healthcare redesign and a move toward evidence based practice that is meaningful to patients. The study found that participants who received the DNI recognized the chronic nature of their disease. This is important because chronic illness, cardiac or otherwise, places the burden of care on the patient and family as they manage their own care at home. Research that identifies how individuals perceive or interpret illness informs providers who design transitional programs.

Responses from patients in this study offer encouraging data about the existing discharge program at MGH. Results from the total data set indicate that patients at this

facility report levels of satisfaction, medication adherence, and reduced use of urgent care that surpasses publicly reported findings.

Nursing research addressing the study outcomes is extremely timely. Interventions described in this study may be replicated in different settings to apply "context" recommendations, combined with other quality studies, or the study may provide a model of discharge care for a wide group of patients. The aims of this study are congruent with data reported by the AHRQ National Healthcare Quality Report (2006, 2007). The report offers perspectives from patients on their experience of care and is a national measure of how the United States is doing on over 200 measures of quality, as hospitals examine how individual diseases are treated with evidence based guidelines, and a team based approach to follow-up care. The report reinforces that including patients' experience of care, perceptions, and understanding will continue to be part of promoting quality and partnering with patients as hospitals are re-engineering the hospital discharge process.

Although the DNI detailed within this study lack sufficient statistical significance between groups on 3 of 4 outcome measures, the total data set provides information about patients' experiences with the existing discharge program at MGH that may be summarized in the following statements. The nursing intervention including, telephone follow-up by an expert nurse, improved patients' perception that their disease was chronic. This is an important concept in self-regulation of care.

Study participants receiving PCI at MGH in the Knight Cardiovascular Center reported extremely high scores on patient satisfaction and medication adherence. This group of participants reported minimal use of urgent care. These findings suggest that the

discharge process described as usual care at MGH for interventional cardiac patients may

serve as a model for other cardiovascular centers.

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APPENDIX A

Institutional Review Board, Notice of Exempt Status

Massachusetts General Hospital, Partners Healthcare

Boston College

PARTNERS.

Application: Notification of IRB Approval/Activation

Protocol #: 2007-P-002363/1; MGH

Date: 01/16/2008

To: Jane Flanagan, Ph.D, APRN,BC
        Nursing
        WHT 13

From: Fred Syllien
        PHS Research Management
        116 Huntington Ave Suite 1002

Title of Protocol: A Randomized Controlled Trial of a Discharge Nursing Intervention to Promote
                          Self-Regulation of Care for Early Discharge Interventional Cardiology Patients
Version Date: 09/07/2007
Sponsor: Departmental Funds
IRB Review Type: Expedited
Minimal Risk: 45 CFR46.110 and 21 CFR56.110
Expedited Category/ies: (7) Research on individual or group characteristics or behavior, or research
                          employing survey, interview, oral history, focus group, program evaluation,
                          human factors evaluation, or QA methodologies.
IRB Approval Date: 01/16/2008
Approval Effective Date: 01/16/2008
IRB Expiration Date: 01/16/2009

This Project has been reviewed and approved by the MGH IRB, Assurance # FWA00003136. During the review of this Project, the IRB specifically considered (i) the risks and anticipated benefits, if any, to subjects; (ii) the selection of subjects; (iii) the procedures for securing and documenting informed consent; (iv) the safety of subjects; and (v) the privacy of subjects and confidentiality of the data.

NOTES: The following documents were reviewed and approved by the IRB: Protocol, Protocol Summary, Consent Form, Questionnaire.

As Principal Investigator you are responsible for the following:

1. Submission in writing of any and all changes to this project (e.g., protocol, recruitment materials, consent form, study completion, etc.) to the IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB within 24 hours.
2. Submission in writing of any and all adverse event(s) that occur during the course of this project in accordance with the IRB's policy on adverse event reporting.
3. Submission in writing of any and all unanticipated problems involving risks to subjects or others.
4. Use of only IRB approved copies of the consent form(s), questionnaire(s), letter(s), advertisement(s), etc. in your research. Do not use expired consent forms.
5. Informing all physicians listed on the project of changes, adverse events, and unanticipated problems.

**MASSACHUSETTS
GENERAL HOSPITAL**

BOSTON COLLEGE
Institutional Review Board
Office for Research Protections
Waul House, 3rd Floor
Phone: (617) 552-4778, fax: (617) 552-0948

IRB Protocol Number: 08.226.01

DATE: February 27, 2008

TO: Ahearn, Kathleen Gould

FROM: Institutional Review Board – Office for Research Protections

RE: A Randomized Controlled Trial Of A Discharge Nursing Intervention To Promote Self-Regulation Of Care For Early Discharge Intervention Cardiology Patients

Notice of IRB Review and Approval
Expedited Review as per Title 45 CFR Part 46.110, FR 60366, FR, # 7

The project identified above has been reviewed by the Boston College Institutional Review Board (IRB) for the Protection of Human Subjects in Research using an expedited review procedure. This is a minimal risk study. This approval is based on the assumption that the materials, including changes/clarifications that you submitted to the IRB contain a complete and accurate description of all the ways in which human subjects are involved in your research.

This approval is given with the following standard conditions:

1. You are approved to conduct this research only during the period of approval cited below;

2. You will conduct the research according to the plans and protocol submitted (approved copy enclosed);

3. You will immediately inform the Office for Research Protections (ORP) of any injuries or adverse research events involving subjects;

4. You will immediately request approval from the IRB of any proposed changes in your research, and you will not initiate any changes until they have been reviewed and approved by the IRB;

5. You will only use the informed consent documents that have the IRB approval dates stamped on them (approved copies enclosed).

6. You will give each research subject a copy of the informed consent document;

7. You may enroll up to 150 participants.

8. If your research is anticipated to continue beyond the IRB approval dates, you must submit a Continuing Review Request to the IRB approximately 60 days prior to the IRB approval expiration date. Without continuing approval the Protocol will automatically expire on February 26, 2009.

Additional Conditions: Any research personnel that have not completed CITI education certificates should be removed from the project until they have completed the training. When they have completed the training, you must submit a Protocol Revision and Amendment Form to add their names to the protocol, along with a copy of their CITI education certificate.

Approval Period: **February 26, 2008- February 25, 2009**

Boston College and the Office for Research Protections appreciate your efforts to conduct research in compliance with Boston College Policy and the federal regulations that have been established to ensure the protection of human subjects in research. Thank you for your cooperation and patience with the IRB process.

Sincerely,

Christina Booth Steele, MS, CIPP
IRB Designee
Director of Research Protections

jc

Boston College IRB
Approved

FEB 2 6 2008

Thru: Feb 25 2009

APPENDIX B

Permissions

Inbox Message

back   reply   reply all   forward   delete   flag   next unread   save sender   print

From: "kevin gould" <kgould2250@msn.com>

view source

Subject: Fw:

Date: Fri, 8 Oct 2004 20:16:35 -0400

To: <gouldkc@bc.edu>

----- Original Message -----

From: Rona Moss-Morris

To: kevin gould

Sent: Sunday, October 03, 2004 9:19 PM

Subject: Re:

Hi Kathy

You are welcome to use the IPQ-R. All you need is on this website.

thanks

Rona

http://www.uib.no/ipq/

At 03:21 PM 01/10/04 -0400, you wrote:

> <?xml:namespace prefix="v" /><?xml:namespace prefix="o" />
> My name is Kathy Ahern-Gould. I am a doctoral student at Boston college, Boston MA USA. My area of research is
> interventional cardiology patients returning home within 23 hours. I was attracted to the Leventhal model, and found
> your article in my search. Would it be possible to obtain permission to use or evaluate the revised IPQ?
> I would love to have your thoughts and advice.
>
> I work in a medical center in Boston and have a great study population.
>
> My preferred e-mail is gouldkc@bc.edu

Morskiy Message   https://mail.bc.edu/Session/347200-N6Y6yvkA3FpeXE4uvMtk-kmb...

Back to Morskiy

back   reply   reply all   forward   delete   flag   next unread   save sender   print

From: "Donald E. Morisky" <dmorisky@ucla.edu>   view source
Subject: Re: Permission to use the Morisky scale
Date: Tue, 18 Sep 2007 10:12:50 -0700
To: Kathleen Gould <gouldkc@bc.edu>

Thank you so much, Kathleen, for your note and encouragement for our research on self reported medication taking behavior. We have continued to work on this original scale and have modified slightly by revising the second item regarding "careless" and changed it to "Do you have problems remembering to take your _____(specific health concern) medication, as this does not negatively characterize the patient's behavior. You may use both items if you wish but we found slightly higher levels of internal consistency and equal criterion-related validity using this new item.

I give you permission to use the scale as long as you acknowledge the source and appraise me of your results. Best wishes, and hopefully I will be able to do some fishing in your neck of the woods someday.

Best wishes,

Dmorisky

Donald E. Morisky, Sc.D., MSPH, ScM
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APPENDIX C

Demographic Data Collection Tool

A Randomized Controlled Trial of Self-Regulation of Care in Interventional Cardiovascular Patients: Demographic Data

Diagnosis _____

Procedure _____ Date_____ Time _____

Procedure Site _____R_____L_____

Age in years: ____   Sex: ____M ____F

Married   _____
Single   _____
Living alone   _____
Living with   _____

How many years of school have you completed?
Less than High School   _____
Some High School   _____
Completed High School   _____
Some College   _____
Post College   _____

Race/Ethnicity
White, non-Hispanic   _____
Black, non-Hispanic   _____

Hispanic   _____
Asian   _____
Pacific Islander   _____
Other   _____

Discharged to:

Home _____
Family/Friends' Home _____
Other _____

Person responsible for your care over the next 24 hours:

__ Self
__ Spouse
__ Family (other than spouse)
__ Friend
__ Other

Previous hospitalization? Y__ N__

If Yes, how long ago? (circle)

<1 yr   <5 yrs   <10 yrs   ≥10 yrs

Previous heart procedure? Y__ N__

If Yes, how long ago? (circle)

< 1 yr   <5 yrs   < 10 yrs   ≥10 yrs

code #_____

APPENDIX D

Approved Internal Review Board Study Materials for Experimental Group

Experimental Group Instruction Letter

Medication Pamphlet

Medication Card

Suggested Internet Sites for Cardiac Patients

24 hour Interview Questions

Control Group Materials

Control Group Instruction Letter

72 hour Interview Questions

38 Item Revised Illness Perception Questionnaire (IPQ-R)

**A Randomized Controlled Trial of Self-Regulation of Care in
Interventional Cardiovascular Patients**

**Kathleen Ahern Gould, PhD (c), RN
William F. Connell School of Nursing
Boston College
Chestnut Hill, MA 02467**

Subject Instructions: Experimental Group

Thank you for agreeing to be in this nursing research study. Along with the
usual care and information provided to you by MGH, we have given you
some additional material as part of this study. We have designed this packet
of information to support your recovery at home. A cardiac nurse will
contact you by phone within 24 hours of your heart procedure/test. The
nurse will ask you a series of questions that will take about 20- 30 minutes
of your time to answer.

We will contact you again by phone three days after your heart
procedure/test. Again, a cardiac nurse will ask you a short series of
questions. She will also ask you to complete a brief survey. A copy of this
survey is enclosed in this packet for you to read while you answer the survey
questions the nurse asks you over the phone.

Thank you for your support of nursing research. Future heart patients may
benefit from what we learn by doing this research study.

Kathleen Ahern Gould

Code #_____

Contact # _____

BE MED SMART

Learn to Take
Your Medications
Safely

**MASSACHUSETTS
GENERAL HOSPITAL**

Keep Track
Of Your Medications

Know it...

Bring it...

Show it...

- **Know** and write down the names of your medications and keep the list with you - you can use a wallet card to help you.

- **Bring** your medication list every time you visit a doctor, nurse, pharmacist, or therapist.

- **Show** your medication list to your health care provider, and make sure they compare your list with their records.

Learn More
About Health at
massgeneral.org

84712 (5/06)

Follow Your Medication
Treatment Plan

- Take your medications as prescribed. Never stop a medication unless your doctor tells you to do so, even if you start to feel better.

- Ask your doctor if your prescription needs to be refilled and plan to refill it before it runs out.

- Tell your doctor if you are having any side effects from your medication. You may be able to take a different amount or type of medicine.

- Never give your prescription medication to somebody else.

- Never take another person's prescription medication, even if you have the same diagnosis.

- Ask whether you need blood tests, x-rays, or other lab tests to see if the medication is working.

- Remember to take your medications – use a calendar, a check-list, or a weekly pill container.

You are a Part of Your Health Care Team

Your health care team includes:

- You and your family.

- The doctor, physician's assistant, nurse practitioner, therapist, or other professional who prescribes your medications for you.

- The nurse who helps with your care at home, in the doctor's office, or in the hospital.

- The pharmacist who fills your prescription.

As part of this team, you share a responsibility for safe medication use. Learn as much as you can about your medications, including interactions.

This brochure will give you tips for what you can do to ensure safe medication use for you and your family.

Give Your Health Care Team Important Information

Tell your health care team about:

- Any illness or medical condition you have, like diabetes or high blood pressure.

- Any allergies that you may have to medications or foods.

- Your medications – including prescriptions, over-the-counter medications, herbals, vitamins, creams, eye/ear drops, inhalers, and injectables (like insulin).

- Medications you have received from other doctors.

- Any side effects from your medications.

- Any difficulty you have paying for your medications – there may be another medication that costs less and will work just as well.

Learn About Your Medications

Knowledge is power:

- Know the names of your medications, what they are used for, how much to take, when to take them, and what side effects to watch for.

- Learn the generic (for example, acetaminophen) and brand (for example, Tylenol®) names of your medications.

- If your doctor writes your prescription by hand, make sure you can read it. If the doctor sends your prescription to the pharmacy electronically, ask for a copy.

- Ask questions if you need something explained. If you don't understand the answer, ask again.

Some tips to help you learn about your medications

- Write down your questions and take them with you to your appointment.

- Take notes.

- If possible, bring a friend or family member with you when you visit the doctor. They can help take notes and help you remember the information.

- Try to use the same pharmacy so your medication records will all be in one place.

- Read and save the written information given to you about your medications.

- Keep a list of all the medications, vitamins, and herbals that you take (a wallet card can help you do this).

- Keep your medication list up-to-date: be sure to change the list when you start taking something new or when you change your dose. Remove the names of medications you are no longer taking.

- Make a copy of your list and give it to a friend or family member.

MASSACHUSETTS
GENERAL HOSPITAL

MGH
1811

Important Medication
Information Enclosed

LIST OF MEDICATIONS
(please fill out in pencil)

Check time(s) closest to when you take your medications

Name of drug	Dose	AM				PM				As Needed
		6	8	10	12	2	4	6	8	10

Over-the-counter medications, Vitamins, Herbals

		AM				PM				As Needed
		6	8	10	12	2	4	6	8	10

Anticoagulation Medication		Write number of pill(s) that you take each day and time taken
Name of drug	Dose/Pill size	Sun Mon Tue Wed Thu Fri Sat Time

Suggested Internet Sites for Cardiac Patients

www.massgeneral.org/heartcenter

Massachusetts General Hospital

www.AHA.org

The American Heart Association

www.ACC.org

The American College of Cardiology

Experimental Group: 24-hour telephone interview

Code #
Contact #

As you recover from your heart procedure, it is important to remember that medications and instruction for your care at home are an important part of the treatment for your condition. Please allow me to review these important instructions with you.

Recovering at home while taking new drugs is often difficult. My questions may help you, other patients, and healthcare providers better understand this process. Please remember that this information will be used only for a nursing research study at Boston College. Please feel free to read along as I ask these questions. We included a copy of the questionnaire in the packet you received when you agreed to be part of this study.

1. **Did you receive discharge instructions?**

   No_____   Yes_____
                If yes,   (verbal ____   written ____   Both_____)

   Please review discharge instructions, prescriptions, or over-the- counter medication ordered.

2. **Can you describe:**

None	activity	medications	diet	site care	pain	all
1	2	3	4	5	6	7
y/n	y/n	y/n	y/n	y/n	y/n	y/n

3. **Do you have at home all of the medications that your discharge doctor ordered for you?**

    Yes_____ No_____
    If no, briefly explain

    _____
    _____

4. **Have you taken all of those medications as ordered since your discharge from the hospital?**

    Yes_____ No_____
    If no, briefly explain

    _____
    _____

5. **Do you have a follow-up appointment or instructions for continuing care after you recover from your procedure/test?**

    Yes___   No___

6. **If you have medical questions or concerns, can you reach someone who can answer your questions?**

    Yes___   No___

**A Randomized Controlled Trial of Self-Regulation of Care in
Interventional Cardiovascular Patients**

**Kathleen Ahern Gould PhD (c), RN
William F. Connell School of Nursing
Boston College
Chestnut Hill, MA**

Patient Instructions: Control Group
Thank you for agreeing to be in this nursing research study. Along with the usual care and information provided to you by MGH, we have given you copies of the questionnaires we will be using during the follow up phone call.

 A cardiac nurse will contact you by phone within 72 hours of your heart procedure/test. The nurse will ask you a series of questions and ask you to complete a brief survey that will take about 20- 30 minutes of your time to answer.
   A copy of this survey is enclosed in this packet for you to read while you answer the survey questions the nurse asks you over the phone.

Thank you for your support of nursing research. Future heart patients may benefit from what we learn by doing this research study.

Code #_____
Contact # _____

Kathleen Ahern Gould

Control and Experimental Groups: 72-hour Telephone Interview

Code #
Contact #

Recovering at home and taking new drugs is often difficult. My questions may help you, other patients, and healthcare providers better understand this process. Please remember this information is used only for a nursing research study at Boston College. Please feel free read along, these questions are included in the packet you received when you agreed to be part of this study.

Since your discharge from the hospital, have you:

1. Placed an urgent phone call to a doctor?	No	**Yes**	_____ **times**
2. Placed an urgent phone call to a hospital?	No	**Yes**	_____ **times**
3. Gone to an Emergency Room?	No	**Yes**	_____ **times**

4. Do you have in your home all medications ordered by your doctor, including all medication that is new since this procedure?

Yes_____   No_____
If no, briefly explain _____

The next four questions will ask you about how you decide to take your medications.

Please answer using a four point scale where 0 = never, 1= rarely, 2 = sometimes, 3 = often, and 4 = always.

Thinking of the medications ordered at discharge, please answer the following questions.

Responses include: **Never = 0, rarely = 1, sometimes = 2, often = 3, always = 4**

5. Do you ever forget to take your medications?

Never = 0, rarely = 1, sometimes = 2, often = 3, always = 4

6. Do you have problems remembering to take your heart medication?

Never = 0, rarely = 1, sometimes = 2, often = 3, always = 4

7. When you feel better, do you sometimes stop taking your medication?

Never = 0, rarely = 1, sometimes = 2, often = 3, always = 4

8. If you feel worse when you take your medication, do you sometimes stop taking it?

Never = 0, rarely = 1, sometimes = 2, often = 3, always = 4

If you are taking Aspirin or Plavix, I would like you to place a mark next to the point showing your best guess about how much of each drug you have taken since discharge.

0%   means you have taken none of the drug
50%   means you have taken half of amount ordered
100% means you have taken every single dose of the drug ordered

9. Aspirin   N/A (drug not ordered)

0%   10%   20%   30%   40%   50%   60%   70%   80% 90% 100%

10. Plavix _____ **N/A(drug not ordered)**
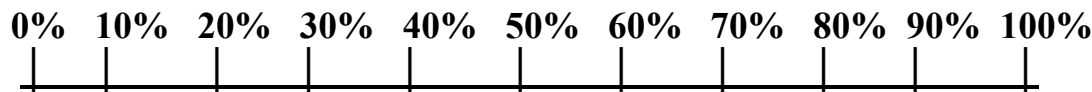
0%   10%   20%   30%   40%   50%   60%   70%   80%   90%   100%

 0%   means you have taken none of the drug
 50%   means you have taken half of amount ordered
 100% means you have taken every single dose of the drug ordered

---

Based on your experience with this hospitalization, would you…

11. Return to this health care facility?

No	Not likely	Somewhat likely	Very likely	Definitely Yes
1	2	3	4	5

12. Refer friends and family to this health care facility?

No	Not likely	Somewhat likely	Very likely	Definitely Yes
1	2	3	4	5

During the next set of questions, I will ask you to score your answer on a scale of 1 to 5.
There is no right or wrong answer.
This part of the interview measures your thoughts and feelings about your heart problems.

A copy of the Illness Perception Questionnaire(IPQ-R) is in your packet for you to read
as I ask each question.

ILLNESS PERCEPTION QUESTIONNAIRE (IPQ-R)

Code……………………………..   Date……………

How you view you illness may help us to examine ways

 to help you manage your condition at home during recovery and in wellness.

Please follow along and complete the following questionnaire as I read each item.

Please indicate how much you agree or disagree with the following statements about your illness by checking the appropriate box.

	VIEWS ABOUT YOUR ILLNESS	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
IP1	My illness will last a short time					
IP2	My illness is likely to be permanent rather than temporary					
IP3	My illness will last for a long time					
IP4	This illness will pass quickly					
IP5	I expect to have this illness for the rest of my life					
IP6	My illness is a serious condition					

	VIEWS ABOUT YOUR ILLNESS	**STRONGLY DISAGREE**	**DISAGREE**	**NEITHER AGREE NOR DISAGREE**	**AGREE**	**STRONGLY AGREE**
IP7	**My illness has major consequences on my life**					
IP8	**My illness does not have much effect on my life**					
IP9	**My illness strongly affects the way others see me**					
IP10	**My illness has serious financial consequences**					
IP11	**My illness causes difficulties for those who are close to me**					
IP12	**There is a lot which I can do to control my symptoms**					
IP13	**What I do can determine whether my illness gets better or worse**					
IP14	**The course of my illness depends on me**					
IP15	**Nothing I do will affect my illness**					
IP16	**I have the power to influence my illness**					
IP17	**My actions will have no affect on the outcome of my illness**					
IP18	**My illness will improve in time**					
IP19	**There is very little that can be done to improve my illness**					
IP20	**My treatment will be effective in curing my illness**					
IP21	**The negative effects of my illness can be prevented (avoided) by my treatment**					
IP22	**My treatment can control my illness**					
IP23	**There is nothing which can help my condition**					
IP24	**The symptoms of my condition are puzzling to me**					
IP25	**My illness is a mystery to me**					
IP26	**I don't understand my illness**					
IP27	**My illness doesn't make any sense to me**					
IP28	**I have a clear picture or understanding of my condition**					
IP29	**The symptoms of my illness change a great deal from day to day**					
IP30	**My symptoms come and go in cycles**					
IP31	**My illness is very unpredictable**					
IP32	**I go through cycles in which my illness gets better and worse.**					
IP33	**I get depressed when I think about my illness**					
IP34	**When I think about my illness I get upset**					
IP35	**My illness makes me feel angry**					
IP36	**My illness does not worry me**					
IP37	**Having this illness makes me feel anxious**					
IP38	**My illness makes me feel afraid**					

APPENDIX E

Consent To Study

General Template
Version Date: November 2005

Subject Identification

Protocol Title: A Randomized Controlled Trial of a Discharge Nursing Intervention to Promote Self-Regulation of Care for Early Discharge Interventional Cardiology Patients

Principal Investigator: Jane Flanagan PhD, APRN,BC

Site Principal Investigator:

Description of Subject Population: Male and female adult patients undergoing interventional cardiac procedures, discharged to home within 72 hours post procedure

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form. If you have any questions about the research or about this form, please ask us. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a copy of this form to keep.

Why is this research study being done?

The purpose of this research is to find out if adding extra follow-up care helps people recover who have had treatment of a blockage in the blood vessels of the heart. We will compare groups of subjects with heart disease who do and do not receive extra follow-up phone contact with a nurse. In this study, follow-up care will be a phone call from a nurse to talk about how best to recover from a heart procedure and live a healthy life.

**Partners HealthCare System
Research Consent Form**

General Template
Version Date: November 2005

Subject Identification

We are studying people who have had interventional procedures (angioplasty) to treat a blocked blood vessel. These are treatments that do not involve open heart surgery. People who have these procedures routinely receive a follow-up phone call from a nurse about 3 days after the procedure. In this study, some subjects will receive an extra phone call on the first day after their procedure. We will compare the two groups of subjects (one phone call vs. two phone calls) to see who recovers better in several ways.

We will compare how satisfied with their care subjects feel and how they feel about their health. We will also look at how carefully subjects take their prescribed medications and how often they use the emergency room in the days right after their procedure.

We are asking you to take part in this study because you will be having a heart procedure and will return home within a day or two to complete your recovery.

This study is being done as part of the nursing program at Boston College, where students can receive a PhD (doctoral degree) in Nursing, in cooperation with Massachusetts General Hospital (MGH). About 150 adults will take part in this study.

How long will I take part in this research study?

You will be in this study for up to 3 days after your procedure. It will take you about 30-60 minutes to answer the study questions. We will contact you by phone 1-3 days after your heart procedure. Some subjects will receive only 1 call, while others will receive 2 calls.

What will happen in this research study?

If you agree to be in this study, and have signed this consent form, we will assign you by chance (similar to a coin toss) to one of 2 study groups. You will have an equal chance of being in each group. You or the study nurse cannot choose your study group.
You will need to answer study questions by telephone after your procedure, no matter which group you are in. If you are in Group 1, the nurse will call you 2 times. If you are in Group 2, the study nurse will call you only once. We hope you will answer all the questions, but you can skip over any questions you don't want to answer. The study groups are described below:

Page 2 of 11

Subject Population: Adult Patients Undergoing Interventional Cardiac Procedures, Discharged to Home Within 72 Hours Post Procedure

IRB Protocol No.: 2007p002363   Sponsor Protocol No.: N/A

Consent Form Valid Date: 01/16/2008   IRB Amendment No.: N/A   Sponsor Amendment No.: N/A

IRB Expiration Date: 01/16/2009   IRB Amendment Approval Date: N/A

❑ If you are in Group 1, a study nurse will telephone you 1 day after discharge to review your discharge instructions and answer a number of questions. This should take about 30 minutes of your time. A study nurse will also call you on the 3rd day after your procedure. This second call will also take about 30 minutes. After the second call, your time in the study will end.

❑ If you are in Group 2, a study nurse will telephone you only once, about 3 days after your procedure, to ask you to answer a number of questions. This should take about 30 minutes of your time and will be the only call you receive from study staff. After this call, your time in the study will end.

At any point in the study, you will be able to withdraw consent and stop taking part in the study. Withdrawal from the study will not affect your care or medical services at MGH.

We will use study information only for educational papers and professional publication. No subjects will be identified if this study is published.

What are the risks and possible discomforts from being in this research study?

This study may disrupt your normal activities or take time from your schedule. Although there are no physical risks associated with the study you may be uncomfortable answering some questions. You may always choose not to answer any question and withdraw from the study at any time.

What are the possible benefits from being in this research study?

You may not benefit personally from taking part in this study. However, what we learn in this study may help heart patients in the future who undergo procedures such as you will have.

Partners HealthCare System
Research Consent Form

General Template
Version Date: November 2005

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

It is possible that we will have to ask you to drop out before you finish the study. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

What will I have to pay for if I take part in this research study?

There will be no additional cost to your routine medical care because of this study.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them.

Giving you care does not mean that Partners hospitals or researchers are at fault, or that there was any wrongdoing. There are no plans for Partners to pay you or give you other compensation for the injury. However, you are not giving up any of your legal rights by signing this form.

Subject Population: Adult Patients Undergoing Interventional Cardiac Procedures, Discharged to Home Within 72 Hours Post Procedure

IRB Protocol No.: 2007p002363   Sponsor Protocol No.: N/A

Consent Form Valid Date: 01/16/2008   IRB Amendment No.: N/A   Sponsor Amendment No.: N/A

IRB Expiration Date: 01/16/2009   IRB Amendment Approval Date: N/A

Subject Identification

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Jane Flanagan PhD, RN is the person in charge of this research study. You can call her at 617-552-4250, Monday –Friday between 9am and 5pm. You can also call Kathleen Ahern Gould, RN at 617-827-2250 24 hours a day, 7 days a week, with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Kathleen Ahern Gould at 617-827-2250.

If you want to speak with someone not directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 617-424-4100.

You can talk to them about:
- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

Federal law requires Partners (Partners HealthCare System and its hospitals, health care providers and researchers) to protect the privacy of health information that identifies you. This information is called Protected Health Information. In the rest of this section, we refer to this simply as "health information."

If you decide to take part in this research study, your health information may be used within Partners and may be shared with others outside of Partners, as explained below.

We have marked with a ☒ how we plan to use and share your health information. If a box is not checked ☐, it means that type of use or sharing is not planned for in this research study.

We will also give you the **Partners Notice for Use and Sharing of Protected Health Information**. The Notice gives more details about how we use and share your health information.

▫ **Health Information About You That Might be Used or Shared During This Research**

☐ Information from your hospital or office health records within Partners or elsewhere, that may be reasonably related to the conduct and oversight of the research study. If health information is needed from your doctors or hospitals outside Partners, you will be asked to give permission for these records to be sent to researchers within Partners.

☒ New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study

▫ **Why Health Information About You Might be Used or Shared with Others**

The reasons we might use or share your health information are:

● To do the research described above

● To make sure we do the research according to certain standards - standards set by ethics and law, and by quality groups

● For public health and safety - for example, if we learn new health information that could mean harm to you or others, we may need to report this to a public health or a public safety authority

● For treatment, payment, or health care operations

▫ **People and Groups That May Use or Share Your Health Information**

Partners HealthCare System
Research Consent Form

┌─────────────────────────────┐
│   │
│   │
│   │
│   │
│   Subject Identification │
└─────────────────────────────┘

General Template
Version Date: November 2005

1. **People or groups within Partners**
   - ☒ Researchers and the staff involved in this research study
   - ☒ The Partners review board that oversees the research
   - ☒ Staff within Partners who need the information to do their jobs (such as billing, or for overseeing quality of care or research)

2. **People or groups outside Partners**
   - ☒ People or groups that we hire to do certain work for us, such as data storage companies, our insurers, or our lawyers
   - ☒ Federal and state agencies (such as the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections) and other U.S. or foreign government bodies, if required by law or involved in overseeing the research
   - ☒ Organizations that make sure hospital standards are met
   - ☐ The sponsor(s) of the research study, and people or groups it hires to help perform this research study
   - ☐ Other researchers and medical centers that are part of this research study
   - ☐ A group that oversees the data (study information) and safety of this research study
   - ☒ Other: Disseration Committee Members at Boston College

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy. However, once your information is shared outside Partners, we cannot promise that it will remain private.

- **Time Period During Which Your Health Information Might be Used or Shared With Others**

  - Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

- **Your Privacy Rights**

  - You have the right not to sign this form permitting us to use and share your health information for research. If you don't sign this form, you can't take part in this research

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Subject Population: Adult Patients Undergoing Interventional Cardiac Procedures, Discharged to Home Within 72 Hours Post Procedure		
IRB Protocol No.: 2007p002363	Sponsor Protocol No.: N/A	
Consent Form Valid Date: 01/16/2008	IRB Amendment No.: N/A	Sponsor Amendment No.: N/A
IRB Expiration Date: 01/16/2009	IRB Amendment Approval Date: N/A	

Subject Identification

study. This is because we need to use the health information of everyone who takes part in this research study.

- You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing.

  If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. This includes information used or shared to carry out the research study or to be sure the research is safe and of high quality.

  If you withdraw your permission, you cannot continue to take part in this research study.

- You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study.

- **If Research Results Are Published or Used to Teach Others**

  The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.

Consent/Assent to take part in this research study, and authorization to use or share your health information for research

Statement of Subject or Person Giving Consent/Assent

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other options for treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.

If you understand the information we have given you, and would like to take part in this research study, and also agree to allow your health information to be used and shared as described above, then please sign below:

Subject Population: Adult Patients Undergoing Interventional Cardiac Procedures, Discharged to Home Within 72 Hours Post Procedure
IRB Protocol No.: 2007p002363   Sponsor Protocol No.: N/A
Consent Form Valid Date: 01/16/2008   IRB Amendment No.: N/A   Sponsor Amendment No.: N/A
IRB Expiration Date: 01/16/2009   IRB Amendment Approval Date: N/A

Signature of Subject:

_____   _____
Adults or Minors, ages 14-17   Date/Time

OR

If you understand the information we have given you, and would like to give your permission for your child/the person you are authorized to represent to take part in this research study, and also agree to allow his/her health information to be used and shared as described above, then please sign below:

Signature of Parent(s)/Guardian or Authorized Representative:

_____   _____
Parent(s)/Guardian of Minor   Date/Time

OR

_____   _____
Court-appointed Guardian or Health Care Proxy   Date/Time

OR

_____   _____
Family Member/Next-of-Kin   Date/Time

General Template
Version Date: November 2005

| Subject Identification |

Relationship to Subject:_____

Signature of a Witness:

_____   _____
Witness (when required by the PHRC <u>or</u> sponsor)   Date/Time

Statement of Study Doctor or Person Obtaining Consent

▪   I have explained the research to the study subject, and

▪   I have answered all questions about this research study to the best of my ability.

_____   _____
Study Doctor or Person Obtaining Consent   Date/Time

In certain situations, the Partners Human Research Committee (PHRC) will require that a subject advocate also be involved in the consent process. The subject advocate is a person who looks out for the interests of the study subject. This person is not directly involved in carrying out the research. By signing below, the subject advocate represents (or "says") that the subject has given meaningful consent to take part in the research study.

Statement of Subject Advocate Witnessing the Consent Process

▪   I represent that the subject or authorized individual signing above has given meaningful consent.

_____   _____
Subject Advocate (when required by the PHRC <u>or</u> sponsor)   Date/Time

Subject Identification

Consent Form Version Date: 8-3-07

Subject Population: Adult Patients Undergoing Interventional Cardiac Procedures, Discharged to Home Within 72 Hours Post Procedure

IRB Protocol No.: 2007p002363

Consent Form Valid Date: 01/16/2008

IRB Expiration Date: 01/16/2009

Sponsor Protocol No.: N/A

IRB Amendment No.: N/A   Sponsor Amendment No.: N/A

IRB Amendment Approval Date: N/A