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Hospital Fall Prevention Using Interactive Patient Care Technology

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Abstract

The impact of patient engagement in hospital fall prevention using interactive patient care technology is not known. The purpose of this investigation was to examine the engagement of hospitalized patients in a computer-based, interactive patient care fall prevention pathway, comprised of a self-assessment of fall risk questionnaire and a fall prevention video, and hospital fall outcomes. The aims were to 1) formulate an interactive patient care technology conceptual framework to guide the study, 2) provide reliability and validity evidence for a patient self-assessment of fall risk questionnaire, and 3) explore the relationship between the fall prevention pathway engagement characteristics and a fall outcome. A conceptual framework for interactive patient care technology was developed and applied to the research investigation. The methodology included a retrospective, cross-sectional design using a convenience sample of 120 subjects to establish preliminary reliability and validity evidence for the patient self-assessment of fall risk questionnaire, and a matched 1:4 case-control design using 73 cases and 292 controls to examine the relationship between the fall prevention pathway engagement characteristics and a fall outcome. Findings indicated the patient self-assessment of fall risk questionnaire is reliable, with a Cronbach's alpha of .73, and valid, with a statistically significant correlation to the nurses fall risk assessment tool, $r(118) = .45$, $p < .001$. Using conditional logistic regression, length of stay, number of automatic video prompts, and fall prevention video completion status were significantly associated with a hospital fall. As length of stay increased by one day, the odds of a fall were 11% higher. With each additional automatic video prompt, the odds of a fall increased by a factor of 1.58. Cases were .38 times less likely to complete the fall prevention video than

to complete it. Conclusions included an interactive fall prevention pathway promoted engagement and engagement at the empowerment level (video completion) prevented a fall. Limitations of this investigation included the use of secondary data, subject related assumptions, and the inability to generalize due to site, technology, and sample. This investigation contributes new knowledge regarding patient engagement in hospital fall prevention using interactive patient care technology.

Dedication

I dedicate this dissertation to my family including my husband, children, mother, and mother-in law. Thanks to my loving and supportive husband, who has instilled in me the value of lifelong learning. It has been quite a journey - - from you teaching me the differences between osmolality and osmolarity in my BSN program to me learning the rigorous research methods and statistical analyses in the PhD program. You have shouldered a large financial burden over the past several years to get all four of us through school. Thank you for believing in me, encouraging me to keep on learning, and being my biggest cheerleader. To my three children who I have watched set goals, work hard, and have fun along the way, you are my role models. Thank you for looking out for me physically, emotionally, socially, and intellectually. To my mother who is a real life example of true caring. As a nurse midwife, you started the chain of future generations of nurses. It is incredible that as I complete this doctoral education, my daughter is also completing her baccalaureate in nursing. Thank you for sharing all the stories of how nursing was done in the past. We have come a long way in nursing. To my mother-in-law who has been instrumental in my pursuit of advanced education. You are one of the wisest women I know. You manage to say the right things at the right time. Thank you for putting things into perspective. I love you all so much. I could not have turned this dream into a reality without your love and support.

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Table of Contents

List of Figures

List of Tables

CHAPTER 1

Introduction

Patient falls in any healthcare setting is of great concern to patients, healthcare providers, and third party payers. Patients seeking care for their primary health problem do not expect to sustain a fall or an injury related to a fall, while in the care of a health provider or healthcare system. Care providers, especially nurses, aim to protect patients from injury or harm (Fowler, 2010). Consumer advocates, government agencies, and third party payers, demand safety, quality, and cost effective care. With these expectations, it is imperative that falls be prevented. However, fall prevention continues to be a challenge especially in acute care hospitals, where fall rates can average 4.76 falls per 1000 patient days (Agency for Healthcare Research and Quality [AHRQ], 2010). The challenge can be attributed to the complex nature of patient falls, as well as the prevention strategies for falls. Numerous factors contribute to patient falls. Some factors are intrinsic or extrinsic to the patient, while others are precipitates of falls (Rubenstein & Josephson, 2006). In acute care settings, preventing falls is multifaceted, beginning with an assessment of the patient for risk factors. When risk factors for a potential fall are present, a plan for prevention is developed, implemented, and evaluated for effectiveness. Ideally, these steps in the process involve the patient, particularly, those who are

cognitively intact (Tzeng, 2010). Patients need to understand the factors that place them at risk and actively participate in the plan or program to prevent a fall from occurring.

Statement of the Problem

The role and impact of patients participating in hospital fall prevention programs on fall rates is not clearly known. What is known, is patient falls continue to be a problem and there are different approaches taken to prevent them. Approaches may include fall risk assessment, fall risk alerts, fall risk communication, targeted risk interventions, equipment aids, staff education, and patient education (Oliver, Healey, & Haines, 2010). Also evident, there is no one strategy for preventing a fall and a multi-interventional approach is needed (Spoelstra, Given, & Given, 2012; Stern & Jayasekara, 2009). Extant research supports the nurse is key in implementing fall prevention interventions. Despite implementation of fall prevention programs that incorporate evidence-based recommendations, attaining, and maintaining low fall rates in acute care hospitals remains a challenge (Krauss et al., 2008). A novel approach is needed; one that provides hospitalized patients with an active role in preventing falls. Provided with an opportunity to conduct a self-assessment of fall risk, will patients participate? If self-assessment indicates a risk for falling, will patients participate in viewing a recommended fall prevention video? Will this approach of having patients conduct a self-assessment of their fall risk and subsequent viewing of a fall prevention video, both administered through a computer-based program, impact hospital fall rates? An approach that preserves patients' sovereignty in decision-making and provides an opportunity to obtain safety information is congruent with redesigning care delivery (Institute of Medicine,

2001). The purpose of this investigation is to examine the impact of such an approach on hospital falls.

Background and Significance

Fall prevention has long been a focus for hospitals. In recent years, this focus has intensified with recommendations and directives from prominent organizations. The Institute of Medicine's (2000) landmark report, *To Err is Human: Building a Safer Health System*, moved patient safety to the forefront of hospitals' quality improvement efforts. The report delineated strategies to improve basic safety knowledge, public reporting of adverse events, safety related performance standards, and organizational systems to enhance patient safety. The Joint Commission (Joint Commission on Accreditation of Hospitals, 2010), incorporated fall risk assessment and management into the hospital accreditation performance standards. The standards requires hospitals to assess patients' risk for falls and to implement interventions to reduce falls if they are determined to be at risk. In 2008, the Centers for Medicare and Medicaid Services (CMS; 2011), as a component of the 2005 Deficit Reduction Act, enacted payment implications for preventable conditions termed Hospital Acquired Conditions (HAC). Patient falls was and continues to be included in the HAC categories. Hospitals will not be reimbursed for care related to a patient fall with associated injury. Subsequent to this act, CMS (2012) initiated the Hospital Value-Based Purchasing (VBP) Program under the 2010 Affordable Care Act, to incentivize and reward acute care hospitals for quality care provided to Medicare patients. Beginning in the year 2014, the VBP program will include patient falls under the category of HAC measures. Hospitals striving to be recognized for excellence in nursing care through the Magnet Recognition Program®,

must demonstrate exceptional performance in patient care quality measures (American Nurses Credentialing Center, 2013). Patient falls is one of the quality measures.

The cost, both in human and financial terms, of not meeting safety and quality goals is difficult to quantify. For patients and their families, falls can be traumatic both physiologically and psychologically (Centers for Disease Control and Prevention [CDC], 2012). For hospital administrators and nurses, falls reflect the quality of care as it is a nursing-sensitive indicator (National Quality Forum, 2011), affect Medicare reimbursement (CMS, 2011; CMS, 2012), and may influence consumer selection of health care organizations through comparison of performance measures (Medicare, 2013).

Patient falls are a commonly reported adverse event in hospitals (Schwendimann, Buhler, De Geest, & Milisen, 2006). Although the definition of a fall may vary slightly among institutions, as a publically reported quality indicator, the measure has been standardized to a fall rate. The number of patient falls per 1000 patient days is the standard for reporting falls (AHRQ, 2010). Fall rates vary based on patient population and setting. Patient fall rates have been reported to range from 3.1 to 6.36 falls per 1000 patient days (Fischer et al., 2005). Falls are the leading cause of injury especially in older adults over 65 years of age (CDC, 2008). Approximately six percent of hospital falls result in injuries such as lacerations, fractures, and hematomas (Fischer, 2005). Rates of falls with resulting injury are reported to range from .64 to .96 per 1000 patient days (AHRQ, 2010). Hospitalization costs for an injury fall is approximately $17, 500 (Roudsari et al., 2005). In U.S. health care systems, the cost of care for falls among older

adults is projected to be over $28 billion dollars and will continue to increase as the population ages (CDC, 2012).

Meeting the goals for improving patient safety and quality care in relation to preventing patient falls, is a complex process. The environment of care contributing to falls has been previously described and include: staffing (Lake, Shang, Klaus, & Dunton, 2010), teamwork (Dykes, Carroll, Hurley, Benoit, & Middleton, 2009), and climate of safety (Black, Brauer, Bell, Economidis, & Haines, 2011). Nurses play a primary role in preventing patient adverse events and injury as directed by their professional licensure, practice standards, and hospital safety policies (American Nurses Association, 2010). Yet, fall prevention programs have not been shown to be effective in reducing falls (Coussement et al., 2008). Patients who are at risk for falls make mobility decisions, which can cause them to fall (Johnson, George, & Tran, 2011).

Numerous studies have reviewed and/or analyzed the characteristics of falls, assessments of fall risk, and interventions to prevent falls in hospitalized patients (Oliver et al., 2010; Spoelstra, Given, & Given, 2012). Multifactorial fall prevention interventions are recommended (Stern & Jayasekara, 2009), but components vary between studies or are not defined (Ang, Mordiffi, & Wong, 2011; Coussement et al., 2008). Studies with significant results have had their intervention(s) incorporated into best practice guidelines for consideration in fall prevention programs (Boushon et al., 2008; Degelau et al., 2012; Spoelstra, Given, & Given, 2012). Fall prevention programs that incorporate evidence-based practices have resulted in decreased fall rates however; these rates are seldom sustained (Krauss et al., 2008; Schwendimann et al., 2006). Though many studies describe characteristics of fallers, assessment of risk factors, or

evaluation of single or multiple interventions in the hospital setting, none describes the active role of the patient in fall prevention.

Conceptual Framework

Three models were integrated to create the Interactive Patient Care Technology conceptual framework for the proposed research: Donebedian's (1966) Structure-Process-Outcome approach, the Quality Health Outcomes Model (QHOM; Mitchell, et al., 1998), and Patient Engagement Framework (PEF; National eHealth Collaborative, 2012). Using the Structure-Process-Outcome model as the foundation, structure represents characteristics of the setting, process includes activities in giving or receiving care, and outcome is the impact of structure or process. The QHOM builds upon this foundation by incorporating feedback among the system, interventions, and client in evaluating the outcomes of care. System is represented by organizational characteristics such as use of technology, interventions are direct or indirect care delivery methods, client is comprised of patient characteristics including demographics and engagement level, and outcomes are patient results. The PEF serves as a guide for the engagement level in the client domain of the QHOM. This five-phase model assists organizations in the development, implementation, and evaluation of health related technology used to engage or involve patients in their care. The Patient Engagement Framework phases are: Inform me, Engage me, Empower me, Partner with me, and Support my e-community.

Purpose and Aims

The purpose of this investigation is to examine the engagement of hospitalized patients in a computer-based, interactive patient care fall prevention pathway, comprised

of a self-assessment of fall risk questionnaire and a fall prevention video, and hospital fall outcomes. To accomplish this purpose, the specific aims for this investigation include:

1. Formulate an interactive patient care (IPC) conceptual framework to guide the study.
2. Provide reliability and validity evidence for a patient self-assessment of fall risk (SAFR) questionnaire.
3. Describe the engagement characteristics of fall risk patients using the IPC fall prevention pathway.
4. Explore the relationship between the fall prevention pathway engagement characteristics and a fall outcome.

CHAPTER 2

Review of Literature

This chapter will provide an overview of the conceptual framework informing the proposed study. A review of relevant findings on patient engagement, interactive patient care technology, patient self-assessment of fall risk, and fall prevention patient education will be discussed as it relates to patient falls.

Conceptual Framework

Interactive Patient Care Technology is the conceptual framework developed to inform the proposed research. Three models were integrated to create the Interactive Patient Care Technology conceptual framework. The foundational model is Donebedian's (1966) structure, process, and outcome approach to evaluating health care. The Quality Health Outcomes Model (QHOM; Mitchell, Ferketich, & Jennings, 1998) builds upon Donebedian's approach by establishing relationships among system characteristics (structure), interventions (process) and client characteristics (patient) in evaluating the outcomes of care (American Academy of Nursing, 2002). A final model, the Patient Engagement Framework (PEF; National eHealth Collaborative, 2012), provides the engagement levels within an information technology context. The engagement levels represent client characteristics within the QHOM.

Structure-Process-Outcome. Donabedian (1966) developed and described a model for evaluating the quality of care through three components: structure, process, and outcome. Structure represents characteristics of the setting such as roles, relationships, and resources. Process includes actions or activities of health care providers and patients in giving and receiving care. Outcome is the result and impact of care structures and processes on the patient(s). Donabedian (1988) postulated good structures lead to good processes and then lead to good outcomes, although some of the evidence for these relationships was not fully developed.

Quality Health Outcomes Model. Donabedian's linear approach to quality of care evaluation was modified by Mitchell et al. (1998) in the QHOM to include a reciprocal influence among the components (Figure 1). This adaptation served to reflect the dynamic nature of the health care environment, care practices, and results of care. Structure is represented as system characteristics, process is delineated as clinical interventions, and outcome is made plural to emphasize the evaluation of care structures and processes. System characteristics may include models of care, staffing skill mix, and technology. Clinical interventions include both direct and indirect activities in the provision of care to health care clients. Outcomes of care may include patient results related to self-care, healthy behaviors, quality of life, symptom management, and satisfaction with care, as well as health care costs. This model includes an additional component, client characteristics, as a mediator for system characteristics and clinical interventions in affecting outcomes. Client characteristics may include demographic factors, health status, and risk factors, which can directly affect the outcome of care.

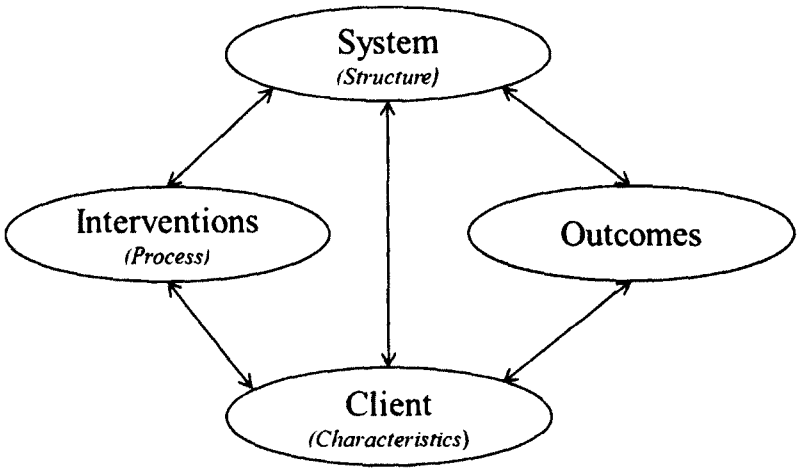

Figure 1. Quality Health Outcomes Model (Mitchell et al., 1998)

The QHOM is a more useful model in establishing relationships among characteristics of the system, interventions, and client in affecting outcomes (Mitchell et al., 1998). Although the model describes two-way feedback among the components, it is evident such a relationship does not exist between interventions and outcomes. An intervention does not independently and directly affect or produce outcomes, as its effect is facilitated by both system and client characteristics. This tenet of the model has been modified by others to reflect a direct reciprocal relationship between interventions and outcomes (Mayberry & Gennaro, 2001).

Refined Quality Health Outcomes Model. The American Academy of Nursing Expert Panel on Quality Health Care (American Academy of Nursing, 2002) sanctioned the development of the QHOM to guide quality of care evaluation and research. In 2002, the American Academy of Nursing clarified the model further by separating client characteristics into trait and state attributes (Figure 2). Trait attributes are client aspects, which cannot change such as age, gender, race/ethnicity, and medical history. Client trait characteristics have unidirectional relationships affecting the system, interventions,

and/or outcomes; but cannot be affected by these same components. State attributes are client aspects, which can change such as mentation, perceptions, and health status. The reciprocal relationships between client characteristics and system characteristics, clinical interventions, and outcomes remain intact only for state attributes.

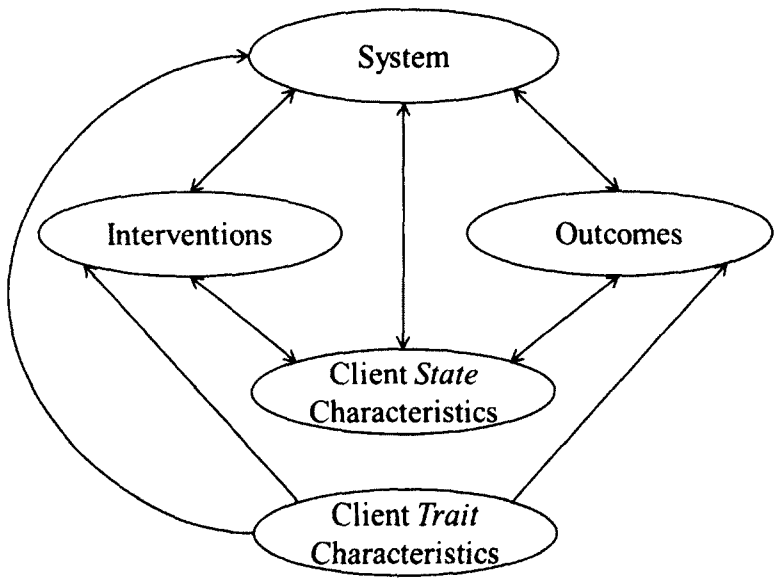

Figure 2. Refined Quality Health Outcomes Model (American Academy of Nursing, 2002)

Mitchell et al. (1998) and the American Academy of Nursing (2002) propose further evaluation and testing of the QHOM to determine is usefulness in quality of care assessment. Since its inception, the QHOM has been used as a framework for understanding how model components affect outcomes and to identify nursing sensitive outcome indicators (Mitchell & Lang, 2004). Its usefulness in generating evidence-based recommendation for practice, research, and policy has also been demonstrated (Swan & Boruch, 2004).

Patient Engagement Framework. The PEF (National eHealth Collaborative, 2012) is a guide for active involvement or engagement of patients in their health care.

Levels of engagement are client state attributes within the QHOM and are synonymous with the five phases of the PEF framework. Phases of the PEF are: inform me, engage me, empower me, partner with me, and support my e-community. This five-phase framework assists organizations in the development, implementation, and evaluation of health related technology to engage or actively involve patients in their care. Each phase builds on the previous phase with additional tools and resources available to both patient and healthcare provider. Patient education is a component of all five phases.

Patient Engagement

The dynamic and complex nature of healthcare requires an active role from the patient. Redesigning healthcare to better meet the needs of patients requires innovative approaches that provide information and accommodate patient choices, preferences, and control (Institute of Medicine, 2001). The latest technologies are being introduced and integrated within healthcare at a startling rate to assist with various aspects of patient care including patient activation and patient engagement. Patient activation and engagement are terms used by healthcare providers to describe the active role necessary to impact care and outcomes. Patient activation is a recent term referring to knowledge, skills, and willingness of patients to participate in their healthcare management (Greene & Hibbard, 2011). Patient activation is enveloped in patient engagement, which seeks to increase patients' role in managing their health care and health outcomes (Hibbard & Green, 2013). There is no consensus on the definition of patient engagement. Gruman et al. (2010) offers a definition of patient engagement emphasizing the role of a person in health care as "actions individuals must take to obtain the greatest benefit from the health

care services available to them" (p. 351). The investigators created an engagement behavior framework of over 45 behaviors characterizing actions individuals take in managing their health and health care. Grouped under categories of preparation or action, behaviors included seeking opportunities to gain knowledge, understanding risks, and acting to meet health goals.

The landmark publication on medical errors in American hospitals (Kohn, Corrigan, & Donaldson, 2000) catapulted the role of patients in safety as a focus and a priority (AHRQ, 2013). Numerous initiatives were launched to promote the active role of patients in their safety including the Speak Up patient education campaign series from The Joint Commission (TJC; 2013a). Recent releases in the Speak Up series included a campaign on ways patients can reduce the risk for falling (TJC, 2013b). Active involvement of patients can impact medical errors and healthcare outcomes; however, limited studies address patients' active role in fall prevention.

Few studies attend to aspects of patient engagement in fall prevention while in the hospital setting. Dykes et al. (2009) conducted qualitative interviews throughout a hospital system to investigate nurses' (n = 23) and aides' (n = 19) perceptions about reasons for falls and ways to prevent them. Six themes surfaced addressing both aims: patient report, information access, signage, environment, teamwork, and involving patient/family. The interviews revealed requirements for preventing falls including involvement of all care providers, the patient, and family in carrying out the fall prevention plan. This study provided information on barriers and facilitators surrounding

falls and fall prevention efforts from direct care providers. Although patient involvement was mentioned, specific behaviors or actions to take in fall prevention were not specified.

Fifteen nurses were interviewed in a qualitative study exploring acute care nurses' experiences with patient falls (Rush et al., 2008). The main theme discovered among the nurses' experiences was knowing the patient was safe. Knowing the patient was safe was influenced by accuracy of fall risk assessment, monitoring for changes in patients' safety, and communicating the need for help by patients and families. Patients' communication of need for assistance varied based on their perceptions of risk for falling. Those patients who were highly independent or had misperceptions of their abilities, did not communicate a need for help to the nurse. To facilitate ownership in fall prevention, the investigators recommended patient involvement in assessing their own risk for falling and approaches that empower patients.

Johnson, George, and Tran (2011) conducted a quantitative and qualitative analyses of fall incident reports (577 and 40 reports, respectively) in an Australian acute care hospital to identify certain behaviors for nurses and patients around fall prevention. Quantitative findings of patient falls showed a majority of falls were unwitnessed (77%) occurred during the day, and did not have associated injury (82%). Qualitative findings themed around incident nature, location, and behaviors, revealed in the majority of cases, nurses were not present when patients attempted an activity related to moving in and out of bed. Patients did not request help or follow instructions due to perceptions of ability or unwillingness. Despite the contribution in understanding hospital falls in relation to nurse and patient behaviors, the role of the nurse was emphasized in this study.

Patient perception of risk has been associated with reluctance in engaging fall prevention activities. Patients may heed advice from care providers but may not modify their actions or behavior based on perceptions of personal applicability (Yardley, Donovan-Hall, Fancis, & Todd, 2006) and/or threat to identity (Dollard, Barton, Newbury, & Turnbull, 2012; Yardley et al., 2006). Davis, Jacklin, Sevdalis, and Vincent (2007) delineated a framework of factors affecting patient involvement in patient safety. Factors for care providers to consider were framed into five categories: patient, illness, health-care professional, healthcare setting, and task. Strategies facilitating engagement of patients in their health care include addressing health literacy, shared decision-making, and improving care processes (Coulter, 2012).

Interactive Patient Care Technology

The use of computers in healthcare continues to expand in purpose and function. Recently, fall prevention activities were incorporated into computer-based programs for risk assessments, decision support, and patient education. Projections on the use of computers in an interactive manner to support patient care including self-care and patient education were made through a Delphi method conducted in 2001 and 2002 (Jauhiainen, Saranto, & Tossavainen, 2006). The future projection of information and communication technologies in every patient room and computer literate patients using them was felt to be desirable but improbable among the 81 clinical, professional, and patient participants. Interactive patient care (IPC) is the term applied to this current reality; where computer-based programs engage patients at the bedside to be active participants in their care (GetWellNetwork, 2013).

A thorough review of the literature on computer-based patient education conducted by Lewis (1999, 2003) highlighted the use and effectiveness of this technology on patient outcomes. Computer-based approaches have been used with patients for obtaining medical histories, knowledge transfer, skill development, decision support, social support, and patient-provider communication. Technologies included computer assisted tutorials, internet-based applications, and interactive video programs. Improvements in patient outcomes were noted in areas of knowledge acquisition, self-care, social support, adherence, and clinical outcomes. Findings also revealed the use and applicability of computer-based technology across all age, literacy levels, and socioeconomic groups. Interactive programs integrating visuals with audio enabled patients with low literacy levels to better understand information. Other benefits of computer-based information and education technology included on demand availability, consistency of information, immediate feedback on learning, possible customization, and support to human resources.

Another systematic review of randomized controlled studies also found the ability and benefit of interactive computer-based programs to support patient education (Fox, 2009). The definition of an interactive computer-based education program was offered as "employing video, still, and audio presentations that interact with the user through required program manipulations, questions, or by allowing users varying levels of control over program sequence or level of detail" (Fox, 2009, p.7). Reviewing 25 studies, the investigator established positive educational outcomes (88% of studies) across all ages, education levels, and medical conditions. In 28% of the studies, education provided

through interactive computer-based programs was as effective as education provided by healthcare providers. Patients of all ages were generally satisfied with this education delivery method. Although shown to be as effective as direct face-to-face education, interactive computer-based programs deployed for hospital fall prevention is supplementary to healthcare provider interaction and its integration into care processes requires thoughtful delineation.

Interactive patient care is a growing strategy to engage hospitalized patients in their care including fall prevention. The premise of IPC is engaged patients will have better healthcare outcomes and satisfaction with their experience (GetWellNetwork, 2013). Interactive patient care technology is congruent with the Patient Engagement Framework (National eHealth Collaborative, 2012). An IPC system presents patients with information to explore and use the system's features (Inform me); enables exchange of messages, responses, and feedback (Engage me); provides information, tools and resources on a variety of topics and through various mediums (Empower me); integrates with the electronic medical record and informs providers (Partner with me); and provides access to the IPC system's information and functions beyond the healthcare facility (Support my e-community). Features offered by IPC systems are consistent with best practices recommendations gleaned from systematic reviews of computer-based programs (Fox, 2009; Lewis, 2003).

Patient Self-Assessment of Fall Risk

The literature abounds with instruments for assessing the fall risk of patients within and out of the hospital primarily by healthcare providers. In contrast, there is a

paucity of literature on instruments for self-assessment of fall risk by hospitalized patients. Although a number of factors (i.e. timing, condition, health literacy) may influence the participation of patients in self-assessment while in the hospital, an opportunity for an active role may help support fall prevention efforts. Exploring patients' views around fall prevention, Carroll, Dykes, and Hurley (2010) interviewed nine patients who sustained a fall while hospitalized. The most common reason cited by patients as to why they fell was a loss of balance when needing to eliminate urgently. To prevent such falls, patients wanted to know they were at risk, why they were at risk, and what they could do to prevent falling. This descriptive, qualitative study introduced fall prevention from the patient's perspective and acknowledged the active role patients wanted to assume. However, there was no mention of how this could be integrated in the process of providing care.

A cross-sectional study investigating how hospitalized patients (n = 125) perceive the threat of falls found 21 (17%) felt they were at risk for falling while in the hospital and 28 (22%) felt they would sustain injury if they fell (Haines & McPhail, 2011). The study also found an association between patients' general perception of falls and injury and the perception of their own risk of falls and injury. The investigators use this finding to suggest raising the general perception of risk for falls and injury will also elevate patients' perception of their own risk for falls and injury; thereby facilitating patient education and active participation in fall prevention activities.

Wiens, Koleba, Jones, and Feeny (2006) developed and validated a questionnaire evaluating patients' awareness of fall risk factors. The Falls Risk Awareness

Questionnaire (FRAQ), comprised of multiple-choice questions, included established (i.e., age, balance problems, health conditions) and controversial (i.e., visual problems, medications) risk factors. Three groups, formed through convenience sampling, were administered the FRAQ: health clinic older adults (n=102), hospitalized older adult patients (n = 50), and health professionals (n = 50). The FRAQ took patients approximately 15 minutes to complete. There was a statistically significant difference in mean scores between the two patient groups (clinic, 13.0 ± 3.3 and hospital, 13.2 ± 3.6) and health professionals (19.5 ± 3.6, $p < .001$). This finding was used as preliminary construct validity for the instrument. Only nine percent of patients stated receiving fall risk information from a healthcare professional. The investigators emphasized a need to provide patients with information on fall risk factors and fall prevention education.

Fall Prevention Patient Education

A component of many fall prevention programs is providing education to patients. Titler, Shever, Kanak, Picone, and Qin (2011) conducted a study examining retrospective data of 10,187 hospitalizations of 7,851 patients (mean age 73.4) to identify variables associated with falls in a tertiary care hospital. The investigators included numerous patient demographic and medical condition variables, as well as nursing unit and intervention characteristics. Many positive and negative associations were found among the variables and the outcome variable of falls. Among the associations found to impact patient falls, teaching was a nursing intervention not associated with falls. In addition, fall prevention interventions were not found to be associated with falls, although the specific interventions were not delineated.

In two Australian hospitals, Hill et al. (2009) randomized and compared patients (who were in stable condition, cognitively intact, over the age of 60, and without visual or auditory impairment) on their perceptions of fall prevention education provided by video ($n = 51$) or written material ($n = 49$). A quasi-experimental control group ($n = 122$) receiving usual care was also included. Age, gender, and cognitive state of participants were similar among the education format groups and between both interventions groups and the control group. Both education formats had the identical custom-designed content including fall risk factors, potential injuries, preventive methods, and the impact of active participation in fall prevention. Following the education, patients were surveyed on their perceived risk for falling, knowledge of fall prevention, and confidence and motivation to take action to prevent falling. No statistically significant difference was found in patients' perceived risk for falling between the two format groups prior to ($p = .72$) and following ($p = .70$) the education. However, in the video group, patients' perceived risk for falling increased ($p = .04$), as well as confidence ($p = .03$) and motivation ($p = .03$) to take action. Knowledge of fall prevention improved for both format groups compared to the usual care only group ($p < .001$). This study demonstrated a video format is an effective strategy to engage older hospitalized patients in fall prevention. Actual fall prevention actions taken by patients or the impact of the video format on subsequent fall rates were not investigated.

In a similar investigation, Haines et al. (2011) conducted a randomized controlled three-arm trial in Australian acute and subacute hospital units evaluating two patient education programs on the outcome of patient falls: a complete program ($n = 401$)

included written and video materials with follow-up by a physiotherapist and, a materials only program (n = 424) which provided only the written and video components. A control group (n=381) received usual care. The three groups were similar in demographic characteristics including age, gender, diagnoses, and cognitive function. No statistically significant difference was found in fall rates (falls per 1000 patient days) between the complete program (7.63), materials only program (8.61), and control group (9.27). Between-group comparisons for cognitively intact patients who received the completed program had statistically significant lower fall rates (4.01) when compared to the control group (8.72; adjusted hazard ratio 0.43, 95% confidence interval [CI] 0.24-0.78; p = .006) and materials only group (8.18; adjusted hazard ratio 0.51, 95% CI 0.28-0.93; p = .03). For cognitively impaired patients who received the completed program, statistically higher rates of falls with injury (7.49) was found compared to the control group (2.89; adjusted hazard ratio 2.63, 95% CI 1.19-5.84; p = .02). Although there was no difference in fall rates between the three groups, patient education appears appropriate for cognitively intact patients and inappropriate for cognitively impaired patients who had a significantly higher injury fall rate. In addition, providing only materials to educate cognitively intact patients on fall prevention may not be as effective in reducing falls. Follow-up support from healthcare providers is necessary.

A performance improvement project by Ryu, Roche, and Brunton (2009) on a neuroscience unit resulted in a reduction in fall rates from prior quarters. Using the Plan-Do-Study-Act model for quality improvement (Institute for Healthcare Improvement, 2012), the authors described the steps of the patient education improvement process for

patients assessed at high risk for falling and when available, their family members. One-to-one education sessions were planned over a six-week period using content from a hospital-developed written pamphlet. Conduct of the education sessions was provided by one clinical nurse leader student to patients ($n = 67$) and families (39%), including cognitively impaired patients (42%). Analysis of incident reports during the project period revealed no patient falls among educated patients. This project reinforces the role of patient education in fall prevention programs. However, other initiatives were occurring at the same time as the education program, limiting the ability to associate study outcomes to the improvement effort. The use of basic data analysis tools for performance improvement projects was not demonstrated (American Society for Quality, 2013).

Various strategies are aimed at engaging patients in their care. A comprehensive review and synthesis of evidence summarized the effectiveness of these strategies aimed at improving patient literacy, decision-making, self-care, and safety (Coutler & Ellins, 2007). Critical to fostering engagement or involvement of patients in their safety is their ability to understand health related information. Health literacy is an essential ingredient for patient engagement. Limited health literacy has been associated with poor adherence to screenings, preventative care and prescribed treatments, frequent hospitalizations, inability to take medications properly, poorer overall health status, and high mortality rates (Berkman, Sheridan, Donahue, Halpern, & Crotty, 2011).

Educational methods may vary from traditional formats to computer-based programs. Interventions may involve verbal transfer, written material, pictures, audio

and/or video information, and checking for understanding (Clement, Ibrahim, Crichton, Wolf, & Rowlands, 2009). Computer-based patient education has been shown to be an effective approach to improve knowledge, skills, and outcomes (Coutler & Ellins, 2007; Lewis, 2003). Strategies that increase patients' role in and understanding of their care can impact health outcomes, experiences, and costs (Hibbard & Greene, 2013). Patients benefit most when they are actively involved in their care and when they receive ongoing support from health care providers.

An imperative exists for active involvement of patients in their safety. There is limited research focusing on the role hospitalized patients play in fall prevention. Innovative approaches are needed to engage patients. Interactive, computer-based programs are an effective strategy for patients to gain knowledge. Designed and deployed properly, an IPC system has the potential to engage patients of all ages, languages, and literacy levels in their care. The ability for patients to assess their own fall risk and receive information on how to prevent falls can assist in the development of and adherence to a safety plan. To date, there has been no published research examining the relationships among IPC system-administered patient self-assessment of fall risk, completion of a fall prevention education video, and patient falls. This proposed investigation seeks to fill this void.

CHAPTER 3

Methodology

The purpose of the proposed investigation is to examine the engagement of hospitalized patients in a computer-based, interactive patient care (IPC) fall prevention pathway, comprised of a self-assessment of fall risk (SAFR) questionnaire and a fall prevention video, and hospital fall outcome. The Interactive Patient Care Technology conceptual framework, integrating Donebedian's (1966) Structure-Process-Outcome approach, Quality Health Outcomes Model (Mitchell, Ferketich, & Jennings, 1998), and the Patient Engagement Framework (National eHealth Collaborative, 2012) informs the research questions and designs for this investigation. In this chapter a description of the proposed study designs, setting, sampling, measures, data collection methods, data analysis techniques, and human subjects protection will be presented.

The research questions for this investigation include:

1. What is the reliability and validity of the SAFR questionnaire?
2. What are the engagement characteristics of fall risk patients using the IPC fall prevention pathway?
3. Is there an association between the fall prevention pathway engagement characteristics and a hospital fall outcome?

Design

The proposed investigation will use two observational research designs to answer the research questions. A retrospective, cross-sectional design will be applied to establish reliability and validity evidence for the patient SAFR questionnaire. A matched, case-control design will be used to examine the relationship between IPC fall prevention pathway engagement characteristics and a fall outcome. Cases (fallers) will be matched to controls (nonfallers) based on the confounding variables of patient care unit, gender, and age. Matching is a technique to control for confounding variables and enhance the ability to make inferences about the independent variables (Polit & Beck, 2012). Matching the same number of cases to controls assists in reducing bias; however, a greater reduction in bias and an increase in statistical efficiency can be achieved by matching each case to four controls (Mandrekar & Mandrekar, 2008).

Setting

The investigation will be conducted in a non-profit community hospital located in southern California. The hospital has acute care services, emergency services, and a level II trauma center with 420 licensed beds and an average daily patient census of 250. The health care setting is a Magnet® (American Nurses Credentialing Center, 2011) designated hospital of nursing excellence, Planetree (www.planetree.org) designated hospital for patient and family centered care, and as part of a larger healthcare system, has also been recognized with the Malcolm Baldrige National Quality Award (The National Institute of Standards and Technology, 2011) for performance excellence. This hospital recently installed IPC technology as a patient engagement strategy to further improve the patient experience and organizational safety goals such as fall prevention.

Access to this setting for the proposed study is likely given the investigator's employment at the facility.

A standardized fall prevention program is used throughout the hospital. The program consists of registered nurses performing an initial and ongoing fall risk assessment, placement of fall risk/communication alerts when patients are assessed to be at risk (i.e., fall risk wrist band, red colored non-slip socks, red maple leaf signage outside and inside room), development and implementation of an individualized fall prevention plan of care (i.e., visual plan of care posted on room bulletin board and written plan of care in the electronic medical record), and evaluation of the fall prevention plan every shift. Registered nurses provide informal patient education on fall risk and fall prevention during the course of patient care.

Patient information on fall risk and fall prevention is supported by the IPC system installed in four acute care units, four progressive care units, and one short-stay observation unit. The IPC system is provided by GetWellNetwork (2012), Patient Life System version 4.0. Acute care units admit stable patients requiring general medical and/or surgical treatment for a variety of diagnoses and conditions. Progressive care units admit moderately stable patients requiring an intermediate level of nursing care and monitoring including trauma, transplant, and cardiac surgical patients. The short stay observation unit admits pre and post procedural patients requiring less than 24 hours of nursing care.

Interactive Patient Care System

An IPC system is a computer-based application that informs, engages, and empowers cognitively-intact patients using the in-room television as a monitor and the

bedside pillow speaker or keyboard to navigate and select various features. Patients receive orientation to the IPC system and basic control functions through a mandatory, customized, hospital orientation and general hospital safety video. Basic IPC control functions may be reinforced as needed by the healthcare provider. Upon completion of the orientation and safety video, the IPC system menu displays categories for hospital services, health education, communication, entertainment, and feedback. The IPC system incorporates various pathways or automated prompts and tasks to facilitate patient engagement and support care processes.

One of the IPC pathways is customized for fall prevention and includes the SAFR questionnaire and the fall prevention education video (Figure 3). The fall prevention pathway begins six hours after patient admission. A prompt provides information about the potential risk for falling and asks patients to answer questions determining if they are at risk for falling. Additional prompts occur every two hours if the request is deferred. Prompting ceases when patients accept the request or when the maximum number of programmed prompts is reached. A "yes" response to any of the SAFR questions, results in a message stating the patient's risk for falling and an invitation to watch a fall prevention education video. Prompting for the video begins and continues every two hours until the patient views the video or reaches the maximum number of programmed prompts. An IPC web-based management console allows nurses to access a variety of information including patients' completion status for the hospital orientation and safety video, SAFR questionnaire, and fall prevention video. Other information that can be accessed is who responded (e.g., patient, family, and other options) and specific answers to the SAFR questionnaire.

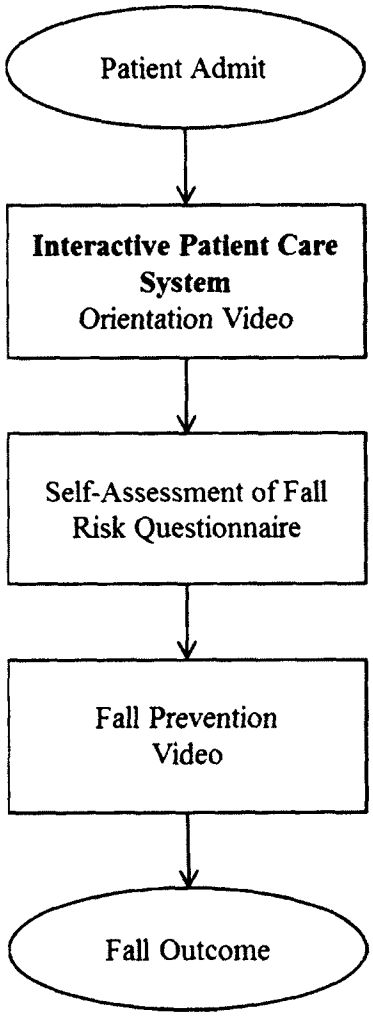

Figure 3. Interactive Patient Care Fall Prevention Pathway

Sample and Sampling Plan

The sample will be comprised of retrospective data on hospitalized patients admitted to IPC-equipped units over a two-year period, from September 2011 to September 2013. The cross-sectional design to establish reliability and validity evidence for the patient SAFR questionnaire will use convenience sampling to obtain the estimated sample size. Purposive sampling will be applied for the case-control design. Cases will be patients who have sustained a fall during their hospital stay. Controls will be patients who did not sustain a fall during their hospitalization. Four controls will be matched to each case based on patient care unit, gender, and age.

The sampling frame for the cross-sectional design will be obtained by the investigator from the IPC computer database. The sampling frame for the case-control design will also be obtained by the investigator for each IPC-equipped unit through a query of the electronic medical record (EMR) database. Database queries will be stratified by unit and month. A hospital-developed fall risk report will also be generated. The fall risk report lists patient names and fall risk variables including level of orientation and fall risk scores based on nursing assessment. The investigator will obtain a query of fallers from the hospital electronic incident reporting system to identify cases in the sampling frame.

Subjects for inclusion in both design samples will be adult inpatients $\geq$ 18 years of age; alert and oriented to person, place, time, and situation; and have English as the primary language (fall prevention pathway content is in English). Subjects will be excluded when the hospital orientation and general safety video has not been completed as documented in the EMR. The IPC functionality for the fall prevention pathway only occurs with completion of this orientation video. Subjects included in the case-control design will have a score of three or greater on the Schmid Fall Risk Assessment Tool (Schmid, 1990), as documented by the registered nurse.

Power, effect, and sample size is generally determined a-priori using various methods based on planned statistical analysis. To estimate the sample size needed for the cross-sectional design using Pearson's correlation as the planned statistical analysis, Polit's (2010) table for estimating sample size was used. For a two-tailed test with α = .05, power at .80, and a medium effect size (.30), the estimated sample size needed is 85 subjects. Power analysis for the matched case-control design using conditional logistic

regression procedure is a complex process. The lack of consensus for how to best determine power for (unconditional) logistic regression has led to several methods for crude estimation of sample size. With binary independent variables, a large sample size is needed with low event proportions (Hsieh, Bloch, & Larsen, 1998). Polit (2010) recommends at least 15 - 20 cases per predictor with 20 being the preferred amount. Given the difficulty estimating the sample size for this design, an online resource was located specifically for case-control studies (Sampsize, 2005). Assumptions for 5% alpha risk, 80% power, and an odds ratio of two, for a case-control ratio of 1:2 or 1:4 at various possible exposures are presented in Table 1. An approximate sample size of 100 cases and 400 controls (1:4 ratio) will be obtained for this investigation.

Table 1

Estimated Sample Sizes for Percent Exposed among Controls

Est. Sample Size	15% Exposed		25% Exposed		35% Exposed	
# Controls/Case	2	4	2	4	2	4
Number of cases	151	123	112	92	101	83
Number of controls	302	492	224	368	202	332
Total	453	615	336	460	303	415

Measures

Measures for both observational designs include subject demographic variables. The nurses' Schmid scores and subjects' SAFR responses will be correlated for the cross-sectional design. Measures for the case-control design includes attribute or engagement characteristics selected based on the Interactive Patient Care Technology conceptual framework. Engagement characteristics for both components of the IPC fall prevention

pathway relate to system interventions and subject responses. The outcome variable is fall status.

Demographic Data

Sample demographic information will include IPC unit, gender, age, race/ethnicity, marital status, and length of stay. These sample characteristics will assist in understanding the population under study and in the interpretation of results (Polit & Beck, 2012). Table 2 summarizes the demographic variables and measurement levels.

Table 2

Demographic Variables and Measurement Levels

Type	Variable	Measurement Level
Demographics	Unit	Nominal
	Gender	Nominal, dichotomous (M/F)
	Age	Ratio
	Race/Ethnicity	Nominal
	Marital status	Nominal, dichotomous (Y/N)
	Length of stay (LOS)	Ratio
	Schmid scores	Interval
	SAFR responses	Interval

Schmid Fall Risk Assessment Tool

The Schmid Fall Risk Assessment Tool (Schmid, 1990) has established psychometric properties and is used by registered nurses to determine a patient's risk for falling while in the hospital. The Schmid has five categories; mobility, mentation, elimination, prior fall history, and medications. Each category is scored based on an assessment of weighted factors and summed for a total score. The maximum score that can be achieved is six. A total score of three or greater indicates the patient is at risk for

falling. Evidence for reliability was demonstrated through test-retest with 100% agreement (r= 1.0) between scores on admission and four hours later, and inter-rater reliability between the researcher and nurse with 91% agreement for mobility, 96% agreement for mentation, 93% agreement for elimination, 83% prior fall history, 99% medications, and 88% on total score agreement. Evidence for validity was demonstrated through content validity, criterion-related validity, and construct validity. Sensitivity of the Schmid tool for correctly identifying patients at risk for falls was 93%. Specificity for correctly identifying patients not at risk for falls was 78%.

Self-Assessment of Fall Risk (SAFR) Questionnaire

The SAFR questionnaire was developed by the investigator for the purpose of incorporation and administration in the IPC fall prevention pathway. At the time of IPC implementation, a review of the literature revealed a dearth of instruments for patient self-assessment of fall risk in the hospital setting. Consequently, the SAFR content was formulated using the Schmid (1990) Fall Risk Assessment Tool as a blueprint. As an integrated component of the IPC fall prevention pathway, the SAFR is used by patients to conduct a self-assessment of their fall risk. The questionnaire is comprised of six questions with a yes or no response and takes approximately one minute to complete. The questions target the following categories; prior fall history, mobility, elimination, medications, injury risk factors, and perception of risk. A "yes" response to any of the questions indicates the patient has a risk factor for falling. A cut score was not established, as the questionnaire is informative rather than predictive. Completion status of the SAFR is documented within the IPC computer database.

Engagement Characteristics

Interactive patient care engagement characteristics are described using the levels of the Patient Engagement Framework's (National eHealth Collaborative, 2012): Inform me, Engage me, and Empower me. Prompting with messages from the IPC system corresponds to the Inform me level. Subjects' responses to the prompts corresponds to the Engage me level. Completion of either component of the fall prevention pathway (SAFR questionnaire or fall prevention video) corresponds to the Empower me level. Table 3 summarizes the engagement characteristic variables and measurement levels.

Table 3

Engagement Variables and Measurement Levels

Type	Variable	Measurement Level
Independent Variables	SAFR Questionnaire	
	# Prompts	Interval
	# Responses	Interval
	# Final response prompt	Interval
	Completion status	Nominal, dichotomous (Y/N)
	Fall Prevention Video	
	# Prompts	Interval
	# Responses	Interval
	# Final response prompt	Interval
	Completion status	Nominal, dichotomous (Y/N)
Dependent Variable	Fall status	Nominal, dichotomous (Y/N)

Fall Prevention Video

The fall prevention video, included in the IPC fall prevention pathway, was developed by Envision, Incorporated (2010) and is approximately fifteen minutes in

length. Content includes risk factors for falling and actions patients and care providers can take to help prevent falls in the hospital. Completion of the video is documented within the IPC computer database and EMR.

Patient Fall

A patient fall is defined as an unplanned descent to the floor including those events when care providers assist a patient to the floor to minimize the impact of a fall. This definition is in accordance with the hospital and established nursing databases. Patient falls are reported through and documented within the hospital's electronic incident reporting system. A patient's fall status is the outcome measure for the case-control design.

Data Collection Procedures/Data Management Plan

Retrospective data collection for the study variables will be conducted by the investigator using three hospital electronic documentation systems including the EMR, IPC computer database, and incident reporting system. Demographic data will be obtained from the EMR. Responses to the SAFR questionnaire and IPC fall prevention engagement characteristics will be obtained from the IPC computer database. Subjects who have fallen over the two-year investigation period will be retrieved from the incident reporting system.

The sampling frame will be used to select subjects meeting inclusion criteria. For the cross-sectional design, one month will be chosen in which the IPC computer database will be queried for subjects from all IPC-equipped units. Subjects who have completed the SAFR questionnaire will comprise the sampling frame. Demographic data will be obtained on a convenience sample. For the case-control design, the sampling frame,

consisting of subjects meeting inclusion criteria and cases previously identified within the sampling frame, will be used to select four controls for each case. Controls will be exactly matched to each case based on unit and gender, then ranged matched to ± 5 on age. An attempt will be made to approximate the length of stay for each case when matching controls. Purposive sampling will be used to select the four controls closest in proximity to each case based on age and admission month. Demographic data and IPC engagement characteristics will be obtained for the case-control subjects.

An electronic data collection form will be developed and used by the investigator to record subjects' unique identifier, hospital visit account number, demographics, and variable data. The hospital visit account number, considered protected health information, is required for the investigation to link and obtain subject data from the various electronic documentation systems. Values obtained for study measures will be entered into the electronic data collection form by the investigator on a password-protected computer. During the investigation period, all study related printed records (if any) will be stored in a locked file cabinet in the investigator's office, accessible only to the investigator. Upon completion of the study, all study related printed records will be destroyed using the hospital's document shredding service.

Data Analysis Plan

This investigation is exploratory in nature and seeks to determine if there are any relationships among the variables. Descriptive statistics will be used to describe the samples and study variables including measures of central tendency (mean, standard deviation) and distribution (count, percentages). Inferential statistics will be used to examine the relationships among study variables. To establish preliminary reliability and

validity for the SAFR questionnaire, the Kuder-Richardson's 20, Pearson's correlation, and percent agreement will be applied. A conditional logistic regression procedure will be used to explore the association between IPC engagement characteristics and a fall outcome. Conditional logistic regression is recommended for matched case-control studies as it takes into account which case is matched to which controls in the analysis (Mandrekar & Mandrekar, 2008). The Mantel-Haenszel test, which also takes into account the case-control groupings, will be used to analyze associations between dichotomous variables. Descriptive and inferential statistical analyses will be conducted using IBM® (2012) SPSS®. Table 4 summarizes the statistical analysis plan.

Table 4

Research Questions and Corresponding Statistical Analysis

Research Question	Statistical Analysis
1. What is the reliability and validity of the patient SAFR questionnaire?	Reliability: *KR* 20 Validity: Pearson's *r*, % agreement
2. What are the engagement characteristics of fall risk patients using the IPC fall prevention pathway?	Central tendency (M, SD) Frequency distribution (n, %)
3. Is there an association between the fall prevention pathway engagement characteristics and a hospital fall outcome?	Conditional logistic regression Mantel-Haenszel

Methodological Assumptions and Limitations

Data extraction procedures from the computer databases rely on specific rules and conditions. It is expected that queries made by the investigator based on unit and

parameter dates, will produce accurate patient lists. Some information obtained through the EMR can be verified against the IPC computer database and incident reporting system and vice versa.

A major limitation of this study is the use of secondary data. Collecting pre-existing data assumes the data is consistent and accurate. Registered nurses assess and document a patient's risk for falling in the EMR. The Schmid score (≥3) will be used to identify subjects at risk for falling in the case-control design. It will be difficult to identify those patients who did not meet the cut off score but whom the nurse had reason to believe was a fall risk and treated as such. Nurses also have the ability to order the fall prevention video for patients outside of the IPC fall prevention pathway. These events will be recorded in the data collection and described.

Conditions under which patients were presented with the fall prevention pathway are unknown. It can be assumed patients who were able to use the bedside pillow speaker to operate the television and make channel and volume selections were able to interact with the IPC system on a basic level. Another assumption is patients watching TV would have worn their eyeglasses and/or hearing aid if needed to see and hear content. When questioned by the IPC regarding who was completing the SAFR or watching the fall prevention video, it was presumed the patient made the correct selection. Only those cases where it was indicated that the patient completed the SAFR and/or watched the fall prevention video will be included in data collection.

The specifics of the study site and customized IPC fall prevention pathway will limit generalizability of results should significance be found among variables. However, results of this study will allow the hospital to make decisions about interactive patient

care technology as an engagement strategy for fall prevention. As a descriptive study, findings may be useful for other hospitals considering IPC technology.

Human Subjects Considerations

The proposed investigation will be submitted and reviewed by the Institutional Review Board of the participating hospital and the University of San Diego. A waiver for consent will be requested on the Institutional Review Board proposals as secondary data is being collected and examined. Identifying and contacting potential subjects, although not impossible, would not be feasible.

The proposed investigation poses minimal risks to subjects as it involves reviewing electronic medical records and hospital system databases for study related information that would not change the care subjects already have received. To protect subject protected health information, data retrieved by the investigator in electronic format will be entered directly into the electronic data collection form stored on a password-protected computer in a locked office. All study data will be accessible only to the investigator. Subject demographic and study variables collected will be aggregated and will not in any way be used to identify individual characteristics of subjects. Protected health information will be removed from the study data collection database prior to delivery to a statistician for statistical analysis.

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CHAPTER IV

Manuscripts

Aim #1	Formulate an interactive patient care conceptual framework to guide the investigation.
Manuscript #1	Applying a Conceptual Framework to Investigate Interactive Patient Care Technology in Fall Prevention
Aim #2	Provide reliability and validity evidence for a patient self-assessment of fall risk questionnaire.
Manuscript #2	Development of an Automated Self-Assessment of Fall Risk Questionnaire for Hospitalized Patients
Aim #3	Explore the relationship between the fall prevention pathway engagement characteristics and a fall outcome.
Manuscript #3	Interactive Patient Care Technology and Hospital Falls: A Case-Control Study

Manuscript #1

Applying a Conceptual Framework to Investigate Interactive Patient Care Technology in Fall Prevention

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Abstract

Little information exists in the literature to assist the clinical nurse specialist in determining an evaluation process for interactive patient care technology. A research approach can be undertaken when an evidence gap is present. A conceptual or theoretical framework is instrumental in guiding the entire research process. These frameworks represent how the researcher views the topic of interest and provides context for the why and how of a study. Knowing the differences between a conceptual and theoretical framework can assist the clinical nurse specialist in choosing an appropriate structure to shape the research. A framework decision guide was created following a review of key definitions. This guide led to a decision to formulate a conceptual framework for interactive patient care technology. Application of the interactive patient care technology conceptual framework to a research proposal is demonstrated.

Introduction

Clinical nurse specialists (CNS) play an important role in implementing and evaluating structures and processes of patient care. More often than not, the literature is the go-to source for implementation and evaluation strategies. When a gap exists in the literature, research becomes a potential strategy. However, with a dearth of information, where does the CNS begin? This article will present the application of a conceptual framework in the development of a research proposal. The author seeks to investigate the role of interactive patient care technology in the prevention of hospital falls.

Interactive Patient Care Technology

Interactive patient care is technology designed to engage patients in their care.[1] Many technologies fit this broad description. In the delivery of health information, interactive patient care (IPC) systems use a computer, a monitor, and an input device. Recent technological advances have enabled computers to deliver various forms of health information to hospitalized patients via the television and receive patient responses through input devices such as the call light and/or a keyboard. Hospital interactive patient care systems also offer other features such as digital communication, service requests, entertainment, and feedback solicitation. Organizations implement these systems to improve strategic imperatives such as patient engagement, satisfaction, and outcomes. Clinical nurse specialists, operating in the organizational sphere of influence[2], are consulted to evaluate the effectiveness of IPC in meeting strategic goals.

Changes in the healthcare reimbursement landscape have influenced the decision of organizations to implement IPC technology. Hospitals are particularly interested in IPC features aimed at improving patient engagement, patient satisfaction, and clinical

outcomes. A variety of modules may be selected and customized to impact these imperatives. One feature available on an IPC system is a fall prevention pathway.[3] A pathway is a computer algorithm that delivers message prompts and related content, and adjusts further prompting and content delivery based on patient responses. The fall prevention pathway can consist of a patient self-assessment of fall risk questionnaire and a fall prevention video. In acute care hospitals, falls remain a challenge for administrators and healthcare providers in terms of safety and costs, particularly with Medicare non-reimbursement for falls with injury[4]. The fall prevention pathway via an IPC system is an innovative approach to augment fall prevention efforts; however, the pathway has not been empirically evaluated for effectiveness.

Conceptual Framework

Role of a Framework

Research is a key component of CNS practice.[5,6] Review of published research may reveal inconsistent mention of a conceptual or theoretical framework underpinning a study. This may be intentional, unintentional, or implicit. Whatever the reason, a framework has purpose and value especially when it is relevant, easy to understand, and applicable. A framework guides the entire research process from the identification of a research question to interpretation of study findings. The framework is the researcher's view of the phenomena of interest and provides context for the why and how of a study. Conceptual framework and theoretical framework are terms often used interchangeably in the literature and warrant an attempt at clarification. There is no consensus on definitions for these two terms. Different scholars take different stands on their meanings. What is common to both terms and their associated meanings is the incorporation of models and

theories. Models and theories are based on concepts. Definitions for key terms used in frameworks are found in Table 1.

Table 1. Definitions

Concept "A mental image of a phenomenon, an idea, or a construct in the mind about a thing or an action." [7(p59)]
Relational Statement (Proposition) "A relational statement declares a relationship of some kind between two of more concepts." [7 (p60)]
Conceptual Model "A set of interrelated concepts that symbolically represent and convey a metal image of a phenomen[on]." [8(p16)]
Theory "A set of interrelated constructs (concepts), definitions, and propositions that present a systematic view of phenomena by specifying relations among variables, with the purpose of explaining and predicting the phenomena."[9(p9)]
Framework "A framework is the overall conceptual underpinnings of a study." [11(p128)]
Conceptual Framework "Helps explain the relationship between concepts, but rather than being based on one theory, this type of framework links concepts selected from several theories, from previous research results, or from the researcher's own experiences." [10(p87-88)]
"An argument (series of sequenced, logical propositions the purpose of which is to convince the reader of the study's importance and rigor) about why the topic one wishes to study matters, and why the means proposed to study it are appropriate and rigorous." [19(p7)]
Theoretical Framework "A broad, general explanation of the relationship between the concepts of interest in a research study; it is based on one existing theory." [10(p87)]
"Represent a combination or aggregation of formal theories in such a way as to illuminate some aspect of your conceptual framework." [19(p12)]

In their work on theory construction in nursing, Walker and Avant[7] delve into the meaning of a concept and relational statement (proposition) as the basis of theories.

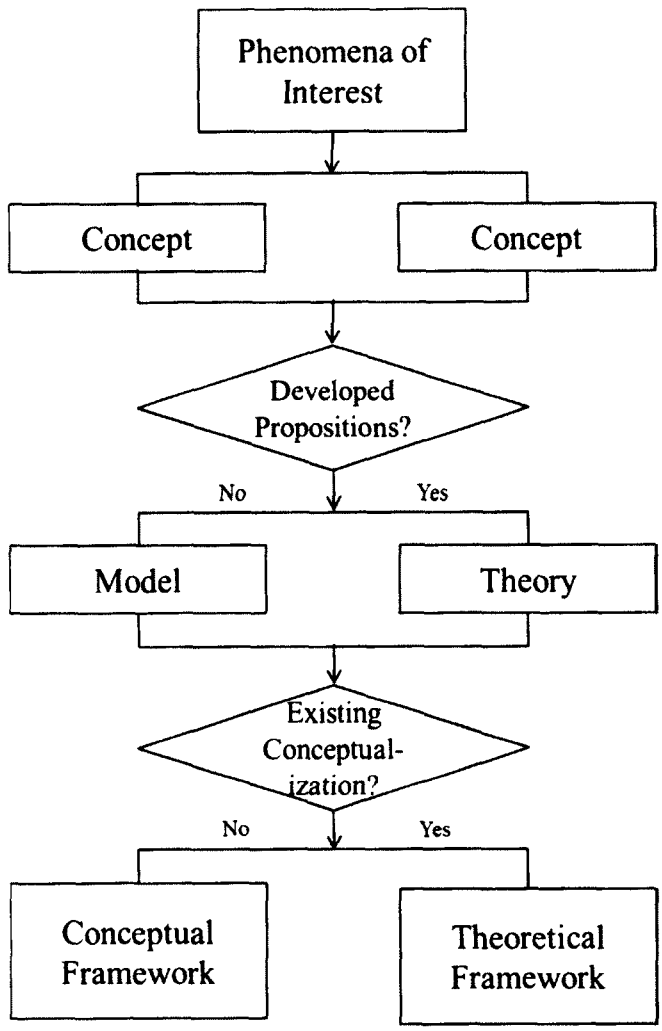
Fawcett[8] views conceptual models as abstract with general concepts and propositions, and theories as concrete with specific concepts and propositions derived from conceptual models. The purpose of theories is to explain or predict.[9] Models and theories have been distinguished from each other by what they emphasize; theories focus on relational statements and models focus on structure and composition.[10]

Polit and Beck[11] simplify the definitions of theoretical framework and conceptual framework as the former being based on a theory and the later on a conceptual model. These framework definitions are supported by Nieswiadomy[10] who differentiates a theoretical framework from a conceptual framework based on the existence of a theory. Both explain the relationships between concepts of interest; a theoretical framework is based on a theory and has implied proposition testing, while a conceptual framework is applied when there is no existing theory, and concepts are related to each other in a logical manner. Tappen[12] proposes the use of a concept tree to clarify and guide conceptualization and articulation of a conceptual framework underpinning a research study. Figure 1 depicts a decision guide constructed by the author to gain understanding and perspective in selecting a framework for a proposed study.

A conceptual framework was formulated to guide the development of a research proposal to investigate interactive patient care technology and patient outcomes. Specifically, the author wanted to examine a fall prevention pathway and patient falls. Three models were examined and integrated to create the Interactive Patient Care Technology conceptual framework. Each model expands another to provide clarity and usefulness. The foundational model is Donebedian's[13] structure-process-outcome approach to evaluating health care. The Quality Health Outcomes Model[14] builds upon

this linear approach by incorporating the client of health care and establishing interrelationships among the model components. A final model, the Patient Engagement Framework[15], highlights client characteristics within an information technology context.

Figure 1. Framework Decision Guide

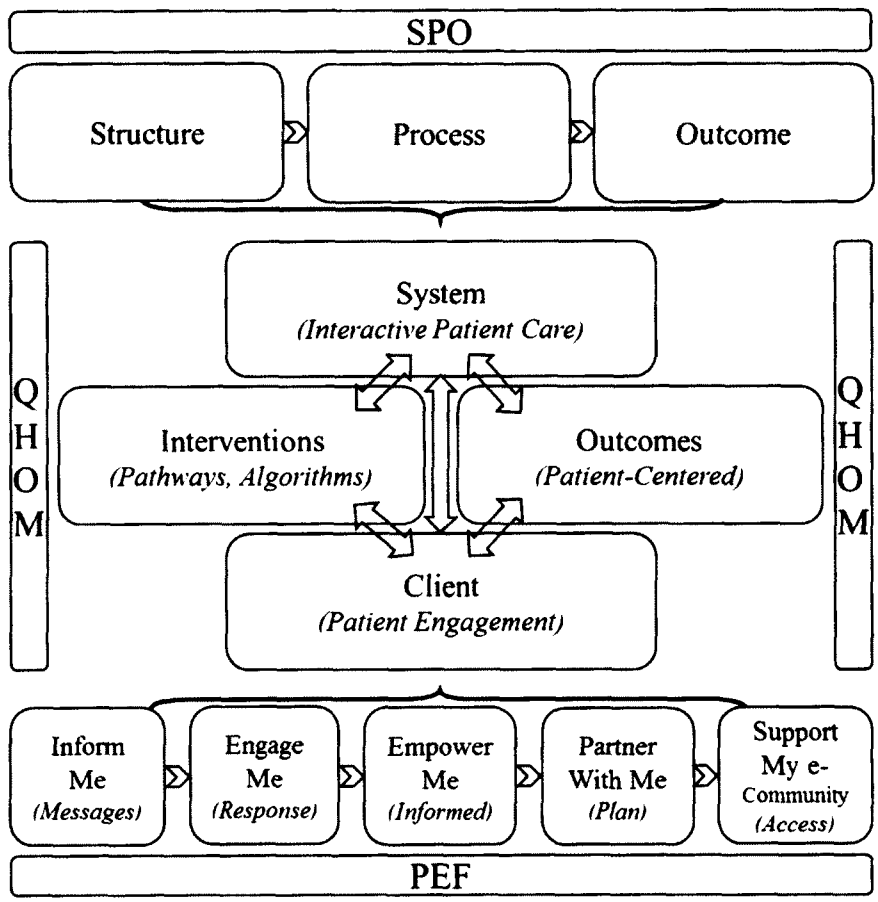


Structure-Process-Outcome

Donabedian[13] developed and described a model for evaluating the quality of care through three components: structure, process, and outcome (SPO) (Figure 2). Structure represents characteristics of the setting such as roles, relationships, and resources. Process includes actions or activities of health care systems, providers, and patients in giving

and/or receiving care. Outcome is the result and impact of care structures and processes on the patient(s). Donabedian[16] postulated that good structures lead to good processes, which then lead to good outcomes, although some of the evidence for these relationships was not fully developed.

Figure 2. Interactive Patient Care Technology Conceptual Framework



Abbreviations: SPO, structure process outcome; QHOM, adapted Quality Health Outcomes Model; PEF, adapted Patient Engagement Framework.

Quality Health Outcomes Model

The American Academy of Nursing Expert Panel on Quality Health Care[17] sanctioned the development of the Quality Health Outcomes Model (QHOM) to guide quality of care evaluation and research (Figure 2). The QHOM is based on

Donebedian's[13] structure, process, and outcome approach. The QHOM establishes relationships among system characteristics (structure), interventions (process) and client characteristics (patient) in evaluating the outcomes of care.[14,17]

Donabedian's[12] SPO linear approach to quality of care evaluation was modified in the QHOM to include a reciprocal influence among the components. [14] This adaptation served to reflect the dynamic nature of the health care environment, care practices, and results of care. Structure is represented as system characteristics, process is delineated as clinical interventions, and outcome is made plural to emphasize the evaluation of care structures and processes. System characteristics may include models of care, staffing skill mix, and technology. Clinical interventions may include both direct and indirect activities in the provision of care. Outcomes of care may include patient results related to self-care, healthy behaviors, quality of life, symptom management, and satisfaction with care, as well as health care costs. The QHOM incorporates an additional component, client attributes, as a mediator for system characteristics and clinical interventions in affecting outcomes.

Client characteristics are either trait or state attributes.[17] Trait attributes are client aspects, which cannot change such as age, gender, race/ethnicity, and medical history. Client trait attributes have unidirectional relationships affecting the system, interventions, and/or outcomes; but cannot be affected by these same components. State attributes are client aspects, which can change such as mentation, perceptions, and health status. The reciprocal relationships between client aspects and system characteristics, clinical interventions, and outcomes remain intact only for state attributes. The QHOM is a more useful model in establishing relationships among characteristics of the system,

interventions, and client in affecting outcomes.[14] Since its inception, the QHOM has been used as a framework for understanding how model components affect outcomes and to identify nursing sensitive outcome indicators.[18]

Patient Engagement Framework

The Patient Engagement Framework[14] (PEF) is a guide for how to actively involve or engage patients in their health care in the context of information technology. The PEF (Figure 2) is comprised of five phases or levels of engagement: inform me, engage me, empower me, partner with me, and support my e-community. These phases assist organizations in the development, implementation, and evaluation of health related technology designed to actively involve patients in their care. Each phase builds on the previous phase with additional tools and resources available to both patient and healthcare provider. Health information is a component of all five phases. Within the conceptual framework, patient engagement phases are considered client state attributes within the QHOM.

Study Rationale

Organizations innovate to affect desired outcomes. Implementation of interactive patient care technology is an innovation designed to facilitate patient engagement. Various modules within the interactive patient care system such as a fall prevention pathway, invite patients to participate in their care. The pathway design integrates both system (message prompts) and patient characteristics (responses) to produce results. Patient engagement with the technology plays a critical role by influencing the system, interventions, and/or outcomes directly. This engagement must be examined in a rigorous manner to determine its impact on patient outcomes.

Application

Background

Organizations investing in resources (structure) to assist in care delivery (process) expect to influence patient outcomes. Interactive patient care systems are a recent addition to an arsenal of technological options augmenting patient care. Although computer-based delivery of patient education has been available for some time, newer generations have embedded features designed to further engage patients in their care. Hospitals investing in interactive patient care technology (systems) deploy pertinent features or modules (interventions) to engage patients (client) as active participants to impact their healthcare results (outcomes). The level of patient participation (patient engagement) and its reciprocal relationship with the system and interventions can affect outcomes (Figure 2).

A fall prevention pathway[3] is a feature provided through an interactive patient care system. Two aspects of the pathway are designed to engage patients. One aspect is a patient self-assessment of fall risk. The other is a fall prevention video. The pathway is customizable in content and delivery. Organizations may use or modify the manufacturer's content and delivery defaults, or customize their own content and delivery scheme. Patient engagement with the IPC fall prevention pathway can be described using the first four phases of the Patient Engagement Framework (Table 2).

Research Problem

A logical step following the acquisition, deployment, and implementation of an IPC technology adjunct is to determine whether it achieved the desired outcome(s). Clinical nurse specialists play a key role in the assessment or evaluation process. A

quality improvement approach can be undertaken to address a problem. With little information in the literature about IPC pathways, particularly how it has been studied or evaluated, the quality improvement approach was not ideal. Quality improvement is typically a prospective approach in determining if changes result in an improved process. Determining whether an IPC fall prevention pathway impacts patient falls after it has been implemented required a retrospective process. The research approach was chosen to address this issue and the limited evidence in the literature.

Table 2. Patient Engagement Framework and IPC Fall Prevention Pathway

	Inform Me	Engage Me	Empower Me	Partner with Me
IPC Fall Prevention Pathway	• Message to watch IPCS system orientation and general safety video	• Message to perform self-assessment of fall risk • Additional timed message prompts if not completed	• Message to watch fall prevention video • Additional timed message prompts if not completed	• Message to call for assistance
Patient Engagement	• Depresses 'select' to watch	• Selects yes, no, or remind later • If yes, selects "patient" watching • Completes self-assessment	• Selects yes, no, or remind later • If yes, selects "patient" watching • Completes video	• Participates in fall prevention strategies • Does not fall

Research Question

Guided by the conceptual framework, the relevant clinical question the CNS asked was, "Is there an association between the fall prevention pathway engagement characteristics and a hospital fall outcome?" Another critical aspect informed by the framework was client characteristics. Client characteristics have a mediator role for system characteristics (IPC technology) and clinical interventions (fall pathway) in affecting outcomes (falls). The CNS also inquired, "What are the engagement characteristics of fall risk patients using the IPC fall prevention pathway?"

Purpose

The purpose of developing a research proposal was to explore the relationship between an IPC fall prevention pathway and falls in hospitalized patients at risk for falling. An additional aim was to contribute new knowledge on the subjects of interactive patient care technology, an automated fall prevention pathway, and patient engagement in technology.

Review of Literature

Reviewing previous empirical evidence is also a component of a conceptual framework as it helps shape a proposed research study.[19] The review not only reveals gaps in what is known and unknown about the topic of interest, but also provides information on the nature of the problem, relevant concepts or variables to include and measure, and approaches that can be taken in formulating the study.

Computer-based patient education is not new. Several studies have shown the effectiveness of computer-based patient education in providing information and improving healthcare knowledge and clinical outcomes.[20,21] Engaging patients in their

care through various strategies impacts healthcare outcomes.[22] Patients can and should play an active role in preventing errors and promoting safety.[23] The Institute of Medicine[24] advocates for redesigning healthcare to better meet the needs of patients through innovative approaches that accommodate choices, preferences, and control. Computer-based interactive systems and programs support patient choices, preferences, and control. However, limited evidence can be found addressing patient engagement with such systems in the prevention of falls.

Education provided by video format to cognitively intact patients without visual or auditory impairment was found to be an effective strategy in engaging older hospitalized patients in fall prevention compared to written materials.[25] In another randomized controlled study, the same investigators compared fall prevention patient education strategies by their effect on fall rates and found no differences.[26] Between-group comparisons revealed lower fall rates for patients who received video and written materials with follow-up from a provider and higher injurious fall rates in cognitively impaired patients. To date, there is no published research examining a computer-based, interactive fall prevention pathway and falls in hospitalized patients.

Design

The driver of the interactive patient care system is a computer program. Therefore, the system includes a database of all patients administered the fall prevention pathway. Guided by the conceptual framework, the CNS chose a retrospective design to 1) explore engagement characteristics of the IPC system and patient in the fall prevention pathway, and 2) investigate the association of the IPC fall prevention pathway engagement characteristics to hospital falls. A case-control design compares two groups

that differ on an outcome of interest based on exposure to some factor(s) or attribute(s). The outcome of interest is falls and the exposure is the fall prevention pathway. Cases in this design are patients who fell and controls are patients who did not fall. This design is appropriate for infrequent events such as falls and to establish an association between exposure and outcomes when little is known.[27] Bias related to sampling and observation is associated with a case-control design. Matching is a technique employed to address bias and to control for confounding variables.[28] Matching each case to more than one control can further reduce bias and strengthen conclusions.[29] Matching to more than four controls per case does not necessarily increase statistical efficiency.[29]

Setting and Sample. The study will be conducted in a community hospital where IPC was installed as a patient engagement initiative. Retrospective data on hospitalized patients admitted to units with IPC installed will comprise the study population. The sample will be obtained from the hospital's electronic medical record including a custom report identifying patients at risk for falling. Cases will be identified from the hospital electronic incident reporting system. Considering client characteristics from the conceptual framework including the literature review, cases and controls will be included based on the following criteria: adult ($\geq$ 18 years of age); alert and oriented to person, place, time, and situation; English as primary language; and classification as fall risk by the registered nurse. The CNS researcher will use purposive sampling to select cases and match four controls to each case on potential confounders of unit, gender, and age. Due to the difficulty in estimating a sample size for this type of study, an online resource for case-control studies was used.[30] With an approximate 25% exposure among controls to

the main attribute variable and an odds ratio of two, alpha risk of 5%, and power set at 80%, an estimated sample size provided was 92 cases to 368 controls.

Measures. Retrospective data to be collected include demographic, attribute or predictor, and outcome variables. These variables were selected based on the conceptual framework. Demographic variables for the proposed study will include client trait characteristics such as age, gender, race, and ethnicity. Predictor variables will include client state characteristics or patient attributes such as level of engagement. The level of patient engagement is operationalized using the Patient Engagement Framework (shown in Table 2) and include number of responses to message prompts, prompt number of final response, and completion status. State characteristics influence or are influenced by the structure (system), processes (interventions), and/or outcomes. An additional predictor variable reflecting an IPC fall prevention pathway engagement characteristic is the number of message prompts delivered as programmed and in response to inputs received. The outcome variable is patient falls. In a case-control study, the dichotomous outcome is the presence or absence of the event of interest.

Data Collection. To ensure human subjects protection, including the protection of patient identifiers necessary to retrieve information from the various data sources, the proposed study will be submitted to the organization's Institutional Review Board. Three data sources will be used to obtain the retrospective data; the hospital's electronic medical record, incident reporting system, and IPC system database. To achieve the estimated sample size, case-control data will be collected from a two-year period beginning at complete installation of the IPC system on inpatient units. The CNS will develop an electronic data collection form to record study measures. Each case with the

four matched controls will be coded as a grouping. The data collection form will be stored on a password-protected computer in the CNS's locked office.

Data Analysis

The statistical analysis plan must be consistent with the conceptual framework, particularly the research question(s), study design, and measures. Descriptive analysis will be used to describe the sample demographics as well as the study variables. Inferential statistics will be used to examine the associations among study variables and the outcome. The association measure for a case-control study is the odds ratio. [31] Statistical analyses for matched case-control studies take into consideration the matched pairs or groups.[32] Appropriate analyses for case-control studies include the McNemar test, Mantel-Haenszel test, and conditional logistic regression[31]. Conditional logistic regression will be used to analyze associations between predictor variables and the outcome variable. Conditional logistic regression is "conditioned" on the matching by taking into account which case is matched to which controls in the analysis.[29] Logistic regression (unconditional) is not the appropriate statistical test for dependent samples such as matched case-control designs.[28] The Mantel-Haenszel test can be applied to analyze the associations between dichotomous attributes or outcomes such as the association between completion of the self-assessment of fall risk and video completion. The analysis takes into account the case-control strata. The CNS researcher will use IBM SPSS[33] to analyze the data and if necessary, consult with a statistician to analyze and interpret the results.

Conclusion

Clinical nurse specialists are commonly involved in change and innovation within an organization.[34] Organizations tap into the knowledge and expertise of their human resources to help implement and evaluate innovative change. Clinical nurse specialists can assume an essential role in these evaluative processes by proposing a research approach, particularly when little is known about the initiative. A conceptual framework helps guide the research process, from research question through analysis and conclusion. Interactive patient care technology is relatively new in hospital settings. Organizations are investing in these systems to facilitate patient care, engagement, and outcomes. The impact of interactive patient care technology is unknown as empirical evidence is lacking in this arena. The clinical nurse specialist operating within the three spheres of influence can impact patients, nursing practice, and the healthcare system through nursing research.

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Manuscript #2

Development of an Automated Self-Assessment of Fall Risk Questionnaire for Hospitalized Patients

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Abstract

Falls in hospital settings continue to challenge healthcare providers. Multifactorial interventions aim to reduce falls but rarely involve the patient as an active participant. A patient self-assessment of fall risk questionnaire was developed and incorporated into a computer-based, interactive patient care system. Designed to engage patients in determining their risk for falling, the questionnaire is a reliable and valid means for patients and nurses to assess risk of falls.

Introduction

Patient falls in hospitals remain a primary concern and a challenge to administrators and healthcare providers. The Institute of Medicine's[1] landmark report, *To Err is Human: Building a Safer Health System* focused organizations to reduce preventable errors including patient falls. Falls continue in hospital settings despite evidence of effective multifactorial interventions.[2] A subsequent publication by the Institute of Medicine[3], *Crossing the Quality Chasm*, emphasized redesigning care delivery and providing patient-centered care. Interactive patient care technology is gaining attention as a way to engage patients in their care. Yet, little has been published about its use in fall prevention.

Nurses use multiple sources to obtain a comprehensive assessment of a patient's risk for falling. In hospital settings, a reliable and valid fall risk assessment instrument or an institution-developed tool is applied to assess a patient's risk for falling. The registered nurse commonly performs the assessment. Other assessments conducted by the interdisciplinary team also assist in determining a patient's risk for falling. Patients participate in the assessment process by providing information and participating in assessment tests (e.g., cognitive and/or mobility tests). An automated patient self-assessment of fall risk while in the hospital has not been described in the literature.

There are many provider-based instruments to assess fall risk in hospitalized patients[4]. These instruments are typically administered by the registered nurse, upon patient admission, and at specified intervals thereafter. Wiens and associates[5] developed and sought to validate a questionnaire evaluating a patient's awareness of fall risk factors. The Falls Risk Awareness Questionnaire (FRAQ) included established (i.e., age, balance

problems, health conditions) and controversial risk factors (i.e., visual problems, medications). The FRAQ was comprised of multiple-choice questions with a completion time of approximately 15 minutes for patients. Evidence for construct validity was through comparison of mean FRAQ scores between two patient groups (clinic older adults, n = 102, 13.0 ± 3.3 and hospital older adults, n = 50, 13.2 ± 3.6) and health professionals (n = 50, 19.5 ± 3.6) with statistically significant findings ($p < .001$). Nine percent of patients stated receiving fall risk information from a healthcare professional. The investigators emphasized a need to provide patients with information on fall risk factors and fall reduction strategies.

Exploring patients' views around fall prevention, Carroll, Dykes, and Hurley[6] interviewed nine patients who sustained a fall while hospitalized. The most common reason cited by patients for why they fell was a loss of balance when needing to eliminate urgently. To prevent such falls, patients wanted to know they were at risk, why they were at risk, and what they could do to prevent falling. The qualitative study introduced fall prevention from the patient's perspective and acknowledged the active role patients wanted to assume.

Purpose

Implementation of a computer-based, interactive patient care system (IPCS) in the hospital setting attempts to engage patients in their health care.[7] Recently, a 420-bed, non-profit, acute care, community hospital installed IPCS technology as part of a strategic initiative to improve the patient and family experience. Interactive patient care technology was installed in all patient care units except the intensive care units and emergency department. Objectives for the IPCS were to promote safety, provide health

information, and increase patient satisfaction. The purpose of this investigation was to develop an automated patient self-assessment of fall risk (SAFR) questionnaire and provide evidence of reliability and validity in a hospital setting. An IPCS computer algorithm or "pathway" automates the delivery of the SAFR to patients.

Methods

Questionnaire Design

The SAFR questionnaire provides patients the opportunity to answer questions about whether or not they possess characteristics known to be associated with falling. Completing the questionnaire allows patients to determine if they are at risk for falling. Four main steps guided the development of the SAFR questionnaire: 1) specifying the conceptual model, 2) explicating objectives, 3) defining test specifications, and 4) constructing the questionnaire.[8]

Specifying the Conceptual Model

The conceptual model used to inform the development of the SAFR questionnaire was the Patient Engagement Framework[9]. The Patient Engagement Framework (PEF) is a guide for actively involving or engaging patients in their health care. Phases of the PEF are: inform me, engage me, empower me, partner with me, and support my e-community. This five-phase framework assists organizations in developing, implementing, and evaluating health related technology to engage patients. Each phase builds on the previous phase with additional tools and resources available to both patient and healthcare provider.

Explicating Objectives

The main objective of the SAFR questionnaire was enabling patients to determine their risk for falling. Including the SAFR questionnaire within an automated fall prevention pathway assisted in delivering information about a potential risk for falling to all patients admitted to an IPCS-equipped room. The pathway enabled patients to perform their own fall risk assessment, and notified them of their fall risk status. Completing the questionnaire informed patients about additional resources to prevent a fall such as a fall prevention video.

Defining Questionnaire Specifications

Objectives provided guidance in defining the specifics of questionnaire construction including method of administration, number of items, item format, interpretation of responses, assumptions, and limitations. The IPCS is comprised of hardware and software that uses the in-room television as a monitor to display messages and video content. Patients interact with the system through their bedside TV control device or keyboard. Care providers and patients are able to access various functions offered in the system including health education videos, medication information, and the internet. Pathways are automated messages delivered to and displayed on the television providing information and inviting patients to respond. Several IPCS functions use pathways such as fall prevention, ordered education, and discharge planning.

The plan to use the fall prevention pathway feature influenced the structure of the questionnaire. Since the target population for the SAFR was newly admitted hospitalized patients, it was critical to keep the number of items to a minimum and to address fall risk factors found in hospital assessment tools. Each item was specified to be written in a

question format with yes or no response. Affirmative responses to any of the questions would indicate the patient had a fall risk factor. An assumption with this method of questionnaire administration is most patients would be able to read message prompts and questions and respond accordingly using the input device, as long as they were able to control the TV functions. A major limitation of the SAFR questionnaire was that it targeted only those patients who could read and understand English and did not have any visual impairment.

Constructing the Questionnaire

The nurses' fall risk assessment tool was used as a blueprint for constructing the SAFR questionnaire. The fall risk assessment tool, developed by Schmid[10], had evidence of reliability and validity and reflected fall risk characteristics found in other fall risk assessment instruments.[4] Hence, this tool served as a logical springboard for the development of the questionnaire.

Schmid[10] conducted a two-phase study, 1) to develop a fall risk assessment tool based on fall risk characteristics and 2) to provide evidence of the tool's reliability and validity in hospitalized patients. The Schmid Fall Risk Assessment Tool is comprised of five categories found to be significantly associated with falls: mobility, mentation, elimination, prior fall history, and medications. Each category is scored based on the assessment of weighted factors. This assessment was conducted on newly admitted hospitalized patients, weekly, and when there was a change in the patient's condition. When all five category scores were totaled, the maximum possible score was six. A total score of three or greater was the cutoff score and indicated the patient was at risk for falling.

Evidence for reliability of the Schmid was demonstrated through test-retest with 100% agreement ($r = 1.0$) between scores on admission and four hours later as well as inter-rater reliability between the researcher and nurse with 91% agreement for mobility, 96% agreement for mentation, 93% agreement for elimination, 83% for prior fall history, 99% for medications, and 88% on total score agreement. Evidence for validity was demonstrated through content, criterion, and construct validity. A task group of nurses who agreed on tool items and analysis provided content validity. Criterion-related validity was through evaluation of fall risk scores of 40 patients who fell. Construct validity was demonstrated by comparing characteristics of patients at risk to those not at risk for falls. Sensitivity of the Schmid tool for correctly identifying patients at risk for falls was 93%. Specificity for correctly identifying patients not at risk for falls was 78%.

Four of the five categories included in the Schmid tool were used to structure the SAFR questions. A question formulated for a particular Schmid category was constructed to reflect the intent of the combined fall risk characteristics in the category. The Schmid mentation category was not included. It was assumed patients completing a self-assessment questionnaire would be cognitively intact. Items were developed for the following Schmid categories: prior fall history, mobility, elimination, and current medications. Two additional items were constructed outside of the Schmid categories based on additional fall risk evidence[11]; one to assess risk for injury should a fall occur, and the second to assess the patient's perception of risk for falling based on their medical condition. Six items comprised the SAFR questionnaire.

An item specification was to create simple questions that were easy to read, understand, and answer. Readability statistics are commonly used to evaluate ease of

reading and approximate grade level of patient education materials.[12] To ensure items were easy to read and understand, the Flesch and the Flesch-Kincaid readability formulas were applied for each question and for the entire set of questions using Microsoft Word (Table 1). Reading ease and grade level have a reciprocal relationship. When the reading ease is higher, the grade level is lower. For the six items comprising the SAFR questionnaire, the reading ease was 73.7 and the grade level was 5.8. It is generally acceptable to target patient education materials at the fifth or sixth grade reading level.[12]

Table 1. Blueprint, SAFR Questions, and Readability Statistics

Schmid Fall Risk Assessment Tool Scored Items	SAFR Self-Assessment of Fall Risk Questions	SAFR Flesch Reading Ease	SAFR Flesch-Kincaid Grade Level
Mobility: Ambulation -Unsteady gait, no assistance -Assistive devices or assist	When you walk, do you feel unsteady or use a cane or walker?	89.5	4.0
Mentation: -Periodic confusion -Confusion at all times	Not applicable	-	-
Elimination: -Frequency or diarrhea -Assistance -Incontinence	Do you have the urge to use the bathroom often or have *occasional* accidents?	65.7 (83.0)[a]	7.5 (4.9)[a]
Prior fall history: -Before admission -During this admission	Have you fallen in the past 12 months?	92.9	2.2
Medications: -Psychotropics/ hypnotics	Are you taking any *medications* for pain, sleep, or high blood pressure?	67.7 (87.9)[a]	6.7 (3.7)[a]
	Do you have *osteoporosis* or a bleeding problem?	40.0 (90.9)[a]	9.6 (2.3)[a]
	With your medical condition, do you feel you may be at risk for falling?	77.8	5.8

[a]Result if italicized word in question is removed

A registered nurse and a physical therapist provided content validity for the SAFR questionnaire. Both individuals had 100% agreement on the questionnaire reflecting categories of the nurses' fall risk assessment tool and encompassed fall risk characteristics for the hospital setting. Evidence for face validity was obtained using two members of the hospital's Patient and Family Advisory Council. Both members had 100% agreement on the SAFR questionnaire appearing to address fall risk factors. They also tested the administration process; validating the ability to read messages on the TV monitor and respond using the TV control device. Based on the pretest, the SAFR questionnaire took approximately one minute to complete.

Questionnaire Administration

The SAFR questionnaire was administered to all patients admitted to a room with a television-enabled IPCS. Six hours after admission, the automated pathway sent a message prompt to the patient's TV monitor with information on the importance of safety and potential risk for falling. The message invited patients to answer questions that determined their risk for falling. If the request was declined, additional message prompts occurred every two hours up to a maximum of three prompts. When the request was accepted, the SAFR questionnaire began with a query asking who was completing the questionnaire (e.g., patient, family member, or other). The six questions were then displayed one at a time accompanied by a yes or no response button. A yes response to any of the six questions resulted in a message stating the patient's risk for falling and a subsequent invitation to watch a fall prevention education video. Patients may have chosen to watch the video at that time, received a reminder to view at a later time, or declined the request. A web-based IPCS management console allowed nurses to access

patients' responses (or nonresponses) to the SAFR questionnaire and status of fall prevention video completion.

Results

Following study approval from the hospital's Institutional Review Board, a retrospective, convenience sample of 120 IPCS documented SAFR responses in the month of December 2012 were obtained and linked to EMR Schmid assessments. The EMR was accessed to obtain the Schmid scores at the approximate time the SAFR questionnaire was completed and to validate patients' level of orientation and primary language. Records of patients who were alert and oriented to person, time, place, and situation and had English as their primary language were included in the sample. All statistical analyses were conducted using IBM® (2012) SPSS®.

Respondent Characteristics

Respondents who completed the SAFR questionnaire were 66 male (55%) and 54 female (45%). Their ages ranged from 26 to 87, with an average age of 58 (SD = 14.9) years. Respondents were inpatients on IPCS units including four acute care units (n = 60, 50%), four progressive care units (n = 35, 29.2%), and one short stay observation unit (n = 25, 20.8%). Of these respondents, nineteen (15.8%) were determined to be at risk for falling based on the Schmid score (≥ 3). Linked responses to the six SAFR questions and Schmid categories are found in Table 2.

Reliability

Reliability is concerned with the dependability of an instrument to measure an attribute. Internal consistency reliability is concerned with the degree items in an instrument are measuring the same construct[13]. Internal consistency reliability analysis

using Kuder-Richardson's 20 was conducted on the six SAFR questionnaire items. Kuder-Richardson's 20 alpha coefficient is applied with dichotomous variables[8], such as the SAFR questions, where 1 is assigned for a yes response and 0 is assigned for a no response. The SAFR questionnaire was found to have acceptable reliability (6 items, α = .73), with corrected item-total correlation coefficients greater than .30 for all items. Internal consistency reliability provided information on the extent items in the SAFR questionnaire were assessing the fall risk attribute.

Table 2. Responses to SAFR Questions and Linked Schmid Scores

Variable	Fall History	Mobility	Medication	Elimination	Injury Risk	Perception of Risk
All (n=120)						
SAFR (%)						
No	82 (68.3)	83 (69.2)	31 (25.8)	79 (65.8)	98 (81.7)	82 (68.3)
Yes	38 (31.7)	37 (30.8)	89 (74.2)	41 (34.2)	22 (18.3)	38 (31.7)
Schmid (%)						
0 (No)	108 (90)	68 (56.7)	86 (71.1)	65 (54.2)	na	na
1 (Yes)	12 (10)	52 (43.3)	34 (28.3)	55 (45.8)	na	na
At Risk (n=19)						
SAFR (%)						
No	8 (41.1)	10 (52.6)	2 (10.5)	10 (52.6)	15 (78.9)	7 (36.8)
Yes	11 (57.9)	9 (47.4)	17 (89.5)	9 (47.4)	4 (21.1)	12 (63.2)
Schmid (%)						
0 (No)	12 (63.2)	1 (5.3)	4 (21.1)	1 (5.3)	na	na
1 (Yes)	7 (36.8)	18 (94.7)	15 (78.9)	18 (94.7)	na	na

Abbreviation: na, not applicable.

Validity

Validity is concerned with whether an instrument measures what it purports to measure. Criterion-related validity (CRV) is an approach to obtain evidence of instrument validity.[4] It is concerned with the applicability of the instrument (i.e., SAFR) based on another reliable and valid criterion measure (i.e., Schmid). Simply put, CRV assesses the degree scores on an instrument correlate with scores on another criterion measure.[13]

Evidence of CRV for an instrument obtained at the same or approximate time as the criterion measure is called concurrent validity. The Pearson's product moment procedure was used to correlate the SAFR affirmative response totals with the Schmid scores obtained at the approximate time of SAFR questionnaire completion. As a form of concurrent validity, the SAFR response totals and the Schmid scores were significantly and moderately correlated, $r\,(118) = .45, p < .001$. A significant and moderate correlation was also found between the adjusted SAFR questionnaire response totals (the 4 items matching Schmid categories) and the Schmid scores, $r\,(17) = .41, p < .001$.

Concordant validity is a form of concurrent validity. The context where this approach is applied is between self-reports and another form of assessment.[14] In concordant validity, the level of agreement between one instrument (i.e., SAFR) and another (criterion measure, i.e., Schmid) is evaluated.[14] Four questions in the SAFR questionnaire were crafted from the Schmid tool. The percent agreements between the four SAFR questions and the Schmid items were obtained for the total sample and those at risk for falling based on Schmid score (Table 3). Since the SAFR questionnaire and the Schmid tool were different instruments, each administered separately by different individuals, the kappa statistic was not appropriate.[8]

Table 3. Concordance of SAFR Questionnaire Responses and Schmid Scores

Variable	Fall Hx	Mobility	Medication	Elimination
All (n = 120) *SAFR-Schmid* % Agreement	72.5	72.5	44.2	56.7
At Risk (n = 19) *SAFR-Schmid* % Agreement	68.2	52.6	68.4	42.1

Discussion

This study provides preliminary evidence for reliability and validity of the automated SAFR questionnaire. The internal consistency reliability approach determined the six SAFR questions were dependable in assessing the characteristic of fall risk. Although Cronbach's alpha of 0.8 is optimal, the obtained result was adequate. Initial approaches to increase the validity of the SAFR questionnaire were applied during the construction of the questions. These included readability statistics, content validity by experts, and face validity by target responders. The criterion-related validity approach found significant correlation between the patient SAFR response totals and the nurse Schmid scores. Patients who had lower and higher SAFR response totals had lower and higher Schmid scores respectively. The concordant validity approach revealed discordance or lack of agreement in the matched fall risk categories and warrants further investigation.

Concordance results can be examined to determine the extent of disagreement between SAFR responses and Schmid scores in the four matching item categories. The lack of agreement may be the result of knowledge deficits, communication, and/or item interpretation by either the patient or nurse. Discordance is particularly concerning for those patients at risk for falling based on the Schimd score (≥ 3) and forms the basis of the remaining discussion. Prior fall history has been known to be a strong predictor of falls and is a common component of hospital fall risk assessment tools.[4] The lack of complete agreement in the prior fall history category, with patients' yes responses (57.9%) higher than nurse assessments (36.8%), suggests obtaining and clarifying this history from patients is critical. Lack of agreement for presence of risk in both the

mobility and elimination categories (SAFR 47.4% versus Schmid 94.7%) may be attributed to the fall prevention program. The hospital's fall prevention program used mobility assessment to determine level of toileting assistance needed. This emphasis is consistent with a study conducted by Tzeng[15] who found 45% of falls were related to toileting, with patients either going to or from the bathroom. Nurses may have preferred to err on the side of scoring patients higher in these categories knowing a majority of falls are toileting related. More than half (52.6%) of the patients responded they did not have problems with either mobility or elimination. This finding may be related to implications of being at risk and the need to maintain identity and independence.[16] It could account for why patients may not call for help when toileting. The assessment and plan for preventing toileting related falls must be a joint effort between the nurse and the patient.

Discordance with medication as a risk factor (SAFR 89.5% versus Schmid 78.9%) may be related to how responders interpret medications included in the SAFR questionnaire (i.e., pain, sleep, or high blood pressure) and how raters interpret medications in the Schmid tool (i.e., anti-convulsants/tranquilizers and psychotropics/ hypnotics). Patients may or may not include nonsteroidal anti-infammatory drugs (NSAID) for pain or sleep. Nurses may or may not consider certain agents in the Schmid medication classifications used for analgesia or sleep. Nurses may need to address NSAID use with patients as it has been shown to be a predictor of falls in hospitalized elders.[17]

Limitations

Although the IPCS fall prevention pathway enabled patients to participate in receiving fall risk information and fall prevention education, this benefit was only

possible if the in-room televisions were turned on and if patients were engaged. Also, it was assumed those patients who read and understood English were able to participate in completing the SAFR. Patients choosing to complete the automated SAFR questionnaire may not have sought clarification or assistance when needed. The questionnaire was designed to be administered only once at the beginning of admission and did not repeat to allow updates based on condition changes. Evidence of reliability and validity is applicable for this hospital setting, IPCS system, fall prevention pathway, and patient population thereby limiting the generalizability of these findings to other hospitals and settings.

Implications

Nurses typically determine a hospitalized patient's fall risk status based on knowledge and assessment of fall risk factors. However, patients may not know about the risk for falling, fall risk factors, or if they are at risk.[5,6] The SAFR questionnaire provides patients with an opportunity to receive this information soon after admission to the hospital. However, it does not replace the nurse's vital interaction with the patient regarding assessment, communication, and education of fall risk. Nurses can determine patient engagement and responses to the SAFR questions soon after admission. Responses can provide insight into the patient's perception of their fall risk. Discrepancies found between the SAFR responses and Schmid scores allow for clarification and discussion between the nurse and patient. Nurses perform fall risk assessments on their patients upon admission, when there is a change in the patient's condition, and every shift. This frequency was established due to patient responses to treatment plans and the hospital's emphasis on fall prevention. It is imperative that

anytime a patient is assessed to be a fall risk or a fall prevention plan is initiated, this information is communicated to the patient. Patients who know they are at risk for falling may seek information on how to prevent a fall and partner with care providers in developing, implementing, and evaluating an individualized fall prevention plan. The overall goal of fall risk assessment is to identify patients at risk so effective fall prevention strategies can be implemented.

Conclusion and Future Research

An automated IPCS SAFR questionnaire provides patients with a role in their health and safety while in the hospital. The SAFR questionnaire delivers information to patients about their fall risk and can be a valuable source of information for nurses too. A review of the concordance between patient and nurse fall risk assessments can facilitate a more accurate picture of a patient's risk for falling and provide for a more meaningful discussion with patients about risk factors for falling, fall prevention strategies, and the importance of their active role. Future research may focus on understanding the discordance between patients and nurses to improve the SAFR questionnaire or develop guidelines to improve Schmid scoring. The level of concordance as a risk factor itself could be examined as a potential contributor to patient falls. This investigation could be repeated to examine patients who have fallen and whether they participated in completing the SAFR questionnaire, the recommended fall prevention education, and/or partnered with nurses in implementing a fall prevention and safety plan.

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Manuscript #3

Interactive Patient Care Technology and Hospital Falls:

A Case-Control Study

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Abstract

Objective: To examine the association between an interactive patient care fall prevention pathway and falls in an acute care community hospital.

Background: Preventing falls continues to challenge hospital leaders. Interactive patient care technology is an innovative strategy deployed to engage patients. A computer-based, fall prevention pathway involves patients; however, the association with hospital falls remains unknown.

Methods: Investigator conducted a matched 1:4 case-control study with 73 cases and 292 controls using conditional logistic regression to associate engagement factors and falls.

Results: Number of automatic video prompts delivered, fall prevention video completion, and length of stay were significantly associated with a fall. Additional video prompts and length of stay increased the odds of a fall. Cases were less likely to complete the fall prevention video.

Conclusions: Healthcare providers can further optimize the role of an interactive patient care system in fall prevention.

Introduction

Preventing hospital falls is a difficult process. There is no one strategy for preventing a fall. The dynamic and complex nature of healthcare requires innovative approaches and an active role from patients to prevent falls. Redesigning care delivery to provide patients with information and accommodate their choices, preferences, and control is needed.[1] Hospitals are implementing computer-based, interactive patient care (IPC) technology[2] as one approach to patient-centered care. The emphasis on patient involvement, especially with patient safety[3], is a premise of IPC technology. An IPC pathway[4] provides hospitalized patients with an active role in fall prevention; however, the impact on hospital fall outcomes is unknown.

Background and Significance

Fall prevention continues to be a priority focus for hospitals. In recent years, this focus has intensified with recommendations and directives from prominent organizations. The Institute of Medicine's[5] landmark report, To Err is Human: Building a Safer Health System, delineated strategies to improve basic safety knowledge, public reporting of adverse events, safety related performance standards, and organizational systems to enhance patient safety. The Joint Commission[6] incorporated fall risk assessment and management into the hospital accreditation performance standards. In 2008, the Centers for Medicare and Medicaid Services[7] (CMS) enacted payment implications for hospital-acquired conditions (HAC) including falls with associated injury. In 2015, the new HAC Reduction Program[8] will take effect and impose payment penalties for the lowest performing hospitals in relation to hospital-acquired conditions. Hospitals seeking

Magnet®[9] recognition must demonstrate exceptional performance in patient care quality measures which includes injurious falls.

Falls are the leading cause of injury especially in older adults over 65 years of age.[10] Approximately six percent of hospital falls result in injuries such as lacerations, fractures, and hematomas.[11] Rates of falls with resulting injury are reported to range from .64 to .96.[12] Hospitalization costs in 2004 for an injury fall was approximately $17, 500.[13] In 2012, adjusted costs were at $34,294.[14] In U.S. health care systems, the cost of care for falls among older adults is over $30 billion dollars, which will rise further as the population ages.[14]

Numerous studies have analyzed the characteristics of falls, assessments of fall risk, and interventions to prevent falls in hospitalized patients.[15,16] Multifactorial fall prevention interventions are recommended,[16,17] but components vary between studies or are not defined.[18,19] Studies with significant results have had their intervention(s) incorporated into best practice guidelines.[20,21] Evidenced-based fall prevention programs have decreased fall rates; however, these rates were seldom sustained.[19,22,23] Video education has resulted in an increased perception of risk[24] and a lower fall rate.[25] Computer-based education has shown improvement in knowledge, skills, and outcomes.[26,27] No study to date has described the relationship between an IPC fall prevention pathway and hospital falls. A pathway is a series of timed messages and content delivered by a computer program to a display (TV), which can adjust based on inputs (responses) received.

Conceptual Framework

The investigator developed a conceptual framework for interactive patient care technology to inform the study[28]. The conceptualization is comprised of Donebedian's[29] Structure-Process-Outcome concepts, the Quality Health Outcomes Model[30], and the Patient Engagement Framework.[31] Organizations invest in IPC technology to support patient care and achieve certain outcomes. An IPC fall prevention pathway facilitates patient involvement in their safety. Patient engagement has a direct influence on the system (IPC), interventions (fall prevention pathway), and outcomes (falls). In the context of IPC technology, little is known about patient engagement with a fall prevention pathway and the association with hospital falls.

Study Aim

The purpose of this study was to examine the engagement of hospitalized patients in an IPC fall prevention pathway and fall outcomes. The fall prevention pathway is comprised of a patient self-assessment of fall risk questionnaire and a fall prevention video (Figure 1). Specific aims were to 1) describe the engagement characteristics of fall risk patients using the fall prevention pathway, and 2) explore the relationship between the fall prevention pathway engagement characteristics and a fall outcome.

Methods

A matched case-control study was conducted. The investigator observed a two-year period following IPC implementation from September 2011 to September 2013.

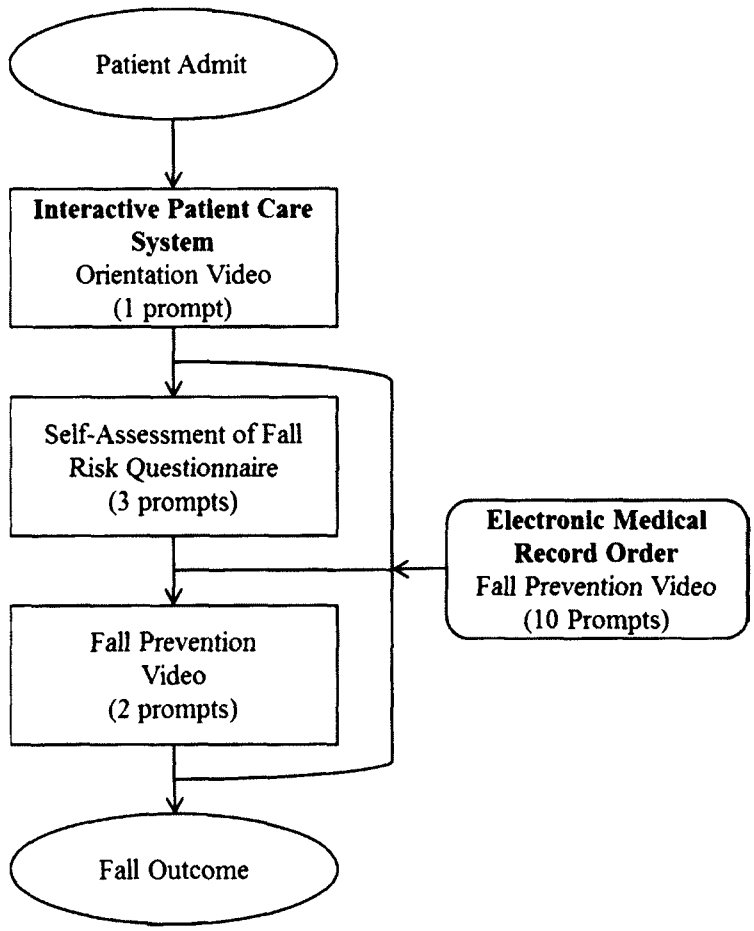
Setting

The study took place in a non-profit, Magnet®-designated, community hospital located in southern California. The hospital had acute care services, emergency services,

and a level II trauma center with 420-staffed beds and an average daily patient census of 250. Acquisition and deployment of IPC technology was a strategy to improve the patient experience and organizational goals. As an entity of an integrated healthcare system, the hospital was the first to implement and evaluate an IPC system.

Figure 1

Interactive Patient Care Fall Prevention Pathway



Interactive patient care technology was provided by the GetWellNetwork Patient Life System.[32] Complete IPC installation and deployment occurred in September 2011 on four acute care units, four progressive care units, and one short-stay observation unit. Acute care units had stable patients requiring general medical and/or surgical treatment for a variety of diagnoses and conditions. Progressive care units had moderately stable

patients requiring an intermediate level of nursing care and monitoring including trauma, transplant, and cardiac surgical patients. The short stay observation unit had pre and post procedural patients requiring less than 24 hours of nursing care.

A standardized fall prevention program was in place throughout the hospital during the study period. Registered nurses performed an initial and ongoing fall risk assessment, initiated fall risk communication alerts, developed and implemented a fall prevention plan of care, and evaluated the fall prevention plan every shift. Registered nurses provided informal patient education on fall risk factors and fall prevention strategies upon patient admission and during the course of patient care.

Participants

Human subjects' protection was obtained through the Institutional Review Board at the study hospital and the University of San Diego. Retrospective data was collected on subjects admitted to four progressive care and three acute care units meeting inclusion criteria. Subjects included in the study were adults $\geq$ 18 years of age; alert and oriented to person, place, time, and situation; English speaking; determined at risk for falling by a registered nurse using the Schmid[33] fall risk assessment instrument and hospital policy/procedure; and admitted at least 18 hours. Two units, the acute care oncology unit, and short-stay observation unit were excluded from the study as many subjects did not meet inclusion criteria or the investigator experienced extreme difficulty in matching cases and controls.

The investigator used the hospital's electronic medical record (EMR) to obtain a record of all subjects discharged from IPC units during the study period. A pre-existing custom report identifying subjects at risk for falls and orientation status was also

obtained. The fall risk report assisted in validating the EMR sampling list and identifying potential study subjects. The investigator queried the hospital's electronic incident reporting system to obtain subjects who fell on IPC units during the two-year period. Subjects not meeting inclusion criteria were removed from the sampling list. Subjects who fell with a classification of an anticipated fall comprised the cases and subjects who did not fall were potential controls.

Each case was matched to four controls (1:4). Matching cases to more than one control assisted in reducing bias and increased statistical efficiency.[34] Controls were matched to cases based on patient care unit and gender, then range matched to ± 5 on age and hospitalization admission date. The investigator attempted to matching length of stay; however, it was challenging to find controls with similar length of stays for many of the cases. The four controls closest in proximity to each case based on age and admission date were selected for inclusion in the study.

Determining the sample size to detect a small or moderate effect for this study was difficult without prior studies to provide exposure estimates. The investigator used an online resource for estimating sample size for case-control studies[35] using various exposures. Assumptions for an odds ratio of two, 5% alpha risk, and 80% power, for a case-control ratio of 1:4 with an estimated 35% exposure for controls, revealed a sample size of 83 cases and 332 controls.

Variables

Subject and IPC engagement characteristics comprised the variables. Subject demographic variables included patient care unit, gender, age, race, ethnicity, marital status, date of admission, and date of discharge. Engagement variables were factors

related to the IPC fall prevention pathway such as number of prompts delivered, number of prompts acknowledged, prompt number of final response, and completion status. The dichotomous outcome variable was fall status. The hospital used a recognized fall definition.[36]

The investigator conducted the retrospective chart review and data extraction. Subject demographic variables were obtained from the electronic medical record. Variables related to IPC engagement were obtained from the web-based IPC computer application, which detailed each subject's history (what was delivered from the IPC system to the subject and the subject's response, if any). Study variables were recorded in an electronic database. Cases and controls were coded as 1 and 0 respectively. Case-control groupings received a consecutive numeric code. When a case had more than one fall during the study period, only the first fall event was included. Cases wherein the fall prevention video was completed after a fall event were classified as not having completed the video.

Statistical Analysis

Subject and IPC engagement characteristics of cases and controls were described using frequency distributions. The matched 1:4 case-control design determined the statistical tests used to analyse associations.[37] Conditional logistic regression was used to examine the association of subject and IPC engagement characteristics with the outcome of hospital fall. Variables used to match cases and controls and control for confounding were not included as factors in the regression model. No specific procedure was applied for missing data due to the low percentages (< 5%).[38] To examine the association of

dichotomous variables, the Mantel-Haenszel test was applied. All statistical tests were performed using IBM® SPSS®, version 21.0.[39]

Results

Subject Characteristics

The number of cases and controls meeting inclusion criteria from the same IPC units was 73 and 292 respectively. Subject characteristics of cases and controls are shown in Table 1. Exact matching was conducted on unit (categorized as level of care) and gender. Range matching on age was performed to within ±5 years with the mean almost identical between the cases (62.5, *SD* = 16.1) and controls (62.6, *SD* = 15.8). Cases and controls were mostly white and not married. The average length of stay for cases was 8.1 days (*SD* = 6.5) and for controls was 6.1 days (*SD* = 4.7).

Cases ranged in age from 23 to 99 years with a majority (62%) being over 60. Falls were slightly higher in females and in the acute care (med-surg) setting. Most falls occurred in those who had a length of stay of either 3-4 days or over 10 days. The average time from admission to fall was 4.2 days (*SD* = 4.6) and from fall to discharge was 3.9 days (*SD* = 4.2). Six cases (8%) sustained moderate injury.

IPC Engagement Characteristics

Characteristics of engagement with the IPC fall prevention pathway for cases and controls are detailed in Tables 2 and 3. The average time (hours) it took to activate the IPC system was nearly identical for cases (6.36, *SD* 6.5) and controls (6.35, *SD* 6.2).

Self-Assessment of Fall Risk (SAFR) Questionnaire

A majority of cases and controls received the maximum programmed amount of prompts to complete the questionnaire and responded to one or more of the prompts.

When prompts were acknowledged, most of the cases and controls responded to one prompt in the series and submitted a final response to the last prompt. Cases and controls had similar SAFR completion percentages. Of those completing the questionnaire (Table 3), the mean age of cases was 64.7 (*SD* = 10.1) and controls was 58.3 (*SD* = 16.0). The highest prevalence was in females (cases 56%, controls 54%) and in acute care (cases 78%, controls 62%). A majority of cases and controls completing the SAFR questionnaire received one invitation prompt, acknowledged one prompt, and submitted a final response to the first prompt delivered.

Fall Prevention Video

Similar to the SAFR prompting, a majority of cases and controls received the maximum programmed amount of prompts to watch the fall prevention video and responded to one or more of the prompts. Cases and controls who responded to the prompts and selected the option to be reminded later, received an additional one or two prompts above the programmed amount. Additional prompting occurred in 27% (n = 20) of cases and 16% (n = 48) of controls. When prompts were acknowledged, a majority of cases and controls responded to one prompt in the series and submitted a final response to either the first or second prompt. From this automatic pathway, the percentage for completing the fall prevention video was higher in controls.

Aside from the automatic fall prevention pathway video prompts, 44% (n = 32) of cases and 49% (n = 143) of controls also received an order from a healthcare provider to watch the same fall prevention video through the IPC system (data not shown). A majority of cases and controls received the maximum programmed amount of prompts to watch the video. Cases tended to respond to four prompts while controls responded to

one prompt in the series. The highest prevalence for submitting a final response was the ninth or tenth prompt for cases and either the first or tenth prompt for controls. From this order pathway, the percentage for completing the fall prevention video was higher in controls.

In total, the fall prevention video was completed by 12 (16%) cases and108 (37%) controls (Table 3). The automatic pathway contributed to 8 (68%) cases and 55 (51%) controls completing the video while the order pathway contributed to 4 (33%) cases and 53 (49%) controls completing the video. The mean age for cases was 67.7 years (*SD* 10.7) and for controls was 62.9 years (*SD* 15.3). A majority of the cases were male (67%, n = 8) whereas controls were female (59%, n = 64). Video completion for cases was highest in acute care (58%, n = 7) and for controls was equal (50%, n = 54) in acute care and progressive care. No clear majority for number of prompts delivered for cases was evident however, in controls; the percentage was highest for up to three prompts. A majority of cases and controls acknowledged up to three prompts in the entire series. The final response submitted for both cases and controls occurred with either the first, second, or third prompt delivered.

Outcomes

Conditional logistic regression examined if fall prevention pathway engagement characteristics were associated with a fall outcome in an acute care hospital employing IPC technology. Subject and IPC engagement characteristics were used in the analysis (Table 4) based on the conceptual framework and univariate and correlational analyses (data not shown). The overall model was statistically significant, likelihood ratio χ^2 = 28.17 (4), p = .001. One subject characteristic, length of stay, was significantly associated

with a risk of a fall outcome. As length of stay increased by one day, the odds of a fall outcome were 11% higher. Two IPC characteristics, number of automatic video prompts delivered and fall prevention video completion status, were significantly associated with a hospital fall. With each additional automated pathway video prompt, the odds of a hospital fall increased by a factor of 1.58. Cases were .38 times less likely to complete the fall prevention video than to complete it. On the other hand, controls were almost 3 times more likely to complete the fall prevention video than not to complete it. Using a Mantel-Haenszel analysis, no significant association was found between video completion and source of video prompt (automatic versus order), χ^2 (1, n = 120) = 1.12, p = .29. No significant association was found between SAFR completion and video completion, χ^2 (1, n = 46) = .00, p = 1.0.

Discussion

The matched case-control design controlled potential confounders related to unit, gender, and age. The investigator attempted to control length of stay as a confounder during the matching process but experienced difficulty. Therefore, length of stay was included in the model to control for confounding. Eight percent of the cases had sustained moderate injury, which could have prolonged hospitalization. The SAFR questionnaire completion was not associated with a hospital fall. Despite maximum prompting by the IPC system to obtain a response, cases and controls had low SAFR completion percentages. Controlling for other factors in the model, number of video prompts (from automatic pathway) and fall prevention video completion were significantly associated with a hospital fall. Cases received almost double the additional prompting to complete the video than controls. Regardless of the prompting source (automatic or order), cases

tended to respond later to prompts while controls responded earlier and were more likely to complete the video.

Perception of risk may account for the low SAFR completion percentages among cases and controls, increased video prompting in cases, and decreased likelihood of video completion among cases. Patient perception of risk has been associated with reluctance to engage in fall prevention activities. Even when informed of a potential risk, patients may heed advice from care providers, but not modify their behaviours based on perceptions of personal applicability[40] and/or threat to identity.[41] A cross-sectional study investigating perceived threat of falls in 125 hospitalized patients found 17% of them felt at risk for falling while in the hospital.[42] In this study, 12% of cases and 13% of controls completed the SAFR to determine their risk for falling and only 11% of cases completed the video. Completion of the SAFR was not associated with subsequent completion of the video.

Computer-based education has improved educational outcomes in different age groups, education levels, and medical conditions.[27] The positive association between IPC fall prevention video completion and fall prevention in controls supports findings of other studies using video education formats.[24,25] A video format engaged older hospitalized patients in fall prevention and increased their knowledge of fall prevention, perceived risk for falling, confidence, and motivation to take action.[24] Combining video education with written materials and follow-up support from a healthcare provider lowered fall rates in cognitively intact patients.[25] In this study, the IPC system delivered invitational messages to subjects and allowed them to have control over if and when they completed the fall prevention video education.

Based on the IPC engagement characteristics of cases and controls with the automatic fall prevention pathway, the programmed amount of prompting was adequate. On the other hand, the addition of an order led to more prompting which was unnecessary since controls tended to respond to two prompts with final response submitted within the first three prompts. The presence of an order for the same fall prevention video may have indicated a lack of knowledge about the automatic pathway. Since there was no association found between the source of video prompting and video completion, the added prompts served more as an annoyance during television viewing. If subjects perceived the amount of prompting as an annoyance, it would conflict with another premise of IPC, which was to improve the patient care experience. The relationship between IPC engagement characteristics and patient satisfaction indicators warrants further investigation.

Limitations

A lack of response and/or completion for either aspect of the fall prevention pathway may be due to other subject or IPC factors not measured in this study. Factors include accessibility, availability, and ability. The pathway was only available when the TV was on and a subject was watching. The pathway began six hours after admission, with scheduled prompting every two hours until maximum prompting or completion occurred. During this period, subjects may not have been available due to treatments, procedures, preference, or rest. Subjects may have had difficulty with the input device and/or low health literacy to read and respond to message prompts. Perception of risk may also have influenced engagement in the pathway. These limitations are areas for future research.

Case-control studies are observational and do not address causation, only association. Although matching more than one control to each case strengthened the study design, selection of controls was purposive rather than randomized. Randomization was not feasible based on the inclusion and matching criteria. The investigator would have had to verify that all potential controls in the sampling frame met inclusion criteria and obtain sophisticated software to assist with matching. Collecting pre-existing data has several limitations including consistency and accuracy. Future studies could use another observational design such as a prospective cohort study or an experimental approach. This study has limited generalizability due to the site, sample, and practice environment characteristics.

Conclusions and Implications

Interactive patient care technology can augment an organization's safety efforts. An automatic pathway engages patients in fall prevention. Findings support the direct influence patient engagement has in achieving outcomes. Leaders can use the engagement characteristics to enhance the IPC system and pathways to strengthen outcomes. Although IPC promotes patient-centered care by enabling patients to exercise their preferences, the care provider's role in the process is essential. Care providers can enhance patient engagement through several avenues. Learning the system avoids an additional video order (and over prompting). In addition, providers can inform patients on what to expect during their TV viewing. Assessing engagement barriers assists in modifying the system, content, and/or educational strategy. A health literacy assessment on admission is one place to start. Facilitating SAFR completion helps providers clarify fall risk status with patients. Emphasizing video completion promotes risk perception and

patient safety. Requesting a teach-back from patients determines reinforcement needed. Lastly, establishing a partnership with patients promotes active human involvement, which is critical in executing the safety plan and attaining fall outcomes. Researchers can add evidence to IPC by examining these interventions on patient engagement and falls.

Table 1

Characteristics of Study Subjects

Demographic Factors	Cases n = 73	Controls n = 292
Age[a] (%)		
<49	15 (20.5)	53 (18.2)
50-59	13 (17.8)	63 (21.6)
60-69	20 (27.4)	75 (25.7)
70-79	16 (21.9)	67 (22.9)
>80	9 (12.3)	34 (11.6)
Gender[a] (%)		
Male	34 (46.6)	136 (46.6)
Female	39 (53.4)	156 (53.4)
Level of Care[a] (%)		
Acute Care	39 (53.4)	156 (53.4)
Progressive Care	34 (46.6)	136 (46.6)
Race (%)		
White	47 (64.4)	220 (75.3)
Other	15 (20.5)	44 (15.1)
Black	5 (6.8)	14 (4.8)
Asian	5 (6.8)	13 (4.5)
Missing	1 (1.4)	1 (.3)
Marital Status (%)		
Not married	44 (60.3)	182 (62.3)
Married	29 (39.7)	109 (37.3)
Missing		1 (.3)
Length of Stay in Days (%)		
1-2	7 (9.6)	50 (17.1)
3-4	22 (30.1)	84 (28.8)
5-6	12 (16.4)	70 (24)
7-10	12 (16.4)	45 (15.4)
>10	20 (27.4)	43 (14.7)

[a]Matching variable

Table 2

Characteristics of Engagement of the Fall Prevention Pathway

Engagement Factors	Cases n = 73	Controls n = 292
Self-Assessment of Fall Risk (SAFR)		
Number of prompts delivered (%)		
1	5 (6.9)	23 (7.9)
2	3 (4.1)	14 (4.8)
3	65 (89)	255 (87.3)
Number of prompts acknowledged (%)		
0 (none)	30 (41.1)	134 (45.9)
1	21 (28.8)	86 (29.4)
2	14 (19.2)	44 (15.1)
3	8 (10.9)	28 (9.6)
Final response prompt number (%)		
0 (none)	30 (41.1)	134 (45.9)
1	10 (13.7)	49 (16.8)
2	13 (17.8)	39 (13.4)
3	20 (27.4)	70 (23.9)
SAFR completed (%)	9 (12.3)	37 (12.7)
Fall Prevention Video		
Number of prompts delivered (%)		
0	1(1.4)	2 (.7)
1	5 (6.8)	47 (16.1)
2	47 (64.4)	195 (66.8)
3	9 (12.3)	32 (11.0)
4	11 (15.1)	16 (5.5)
Number of prompts acknowledged (%)		
0 (none)	32 (43.8)	124 (42.5)
1	22 (30.1)	105 (36.0)
2	9 (12.3)	43 (14.7)
3	5 (6.8)	16 (5.5)
4	4 (5.5)	2 (.7)
Missing	1 (1.4)	2 (.7)
Final response prompt number (%)		
0 (none)	32 (43.8)	124 (42.5)
1	15 (20.5)	77 (26.4)
2	15 (20.5)	63 (21.6)
3	5 (6.8)	20 (6.8)
4	5 (6.8)	6 (2.1)
Missing	1 (1.4)	2 (.7)
Video completed (%)	8 (11.0)	55 (18.8)

Table 3

Engagement Characteristics of Subjects Completing the Pathway

Engagement Factors	SAFR Questionnaire		Fall Prevention Video	
	Cases n = 9	Controls n = 37	Cases n = 12	Controls n = 108
# Prompts delivered (%)				
1	5 (55.6)	17 (45.9)	2 (16.7)	20 (18.5)
2	2 (22.2)	9 (24.3)	1 (8.3)	14 (13.0)
3	2 (22.2)	11 (29.7)	1 (8.3)	20 (18.5)
4	-	-	1 (8.3)	9 (8.3)
5			2 (16.7)	3 (2.8)
6			1 (8.3)	9 (8.3)
7			2 (16.7)	4 (3.7)
8			1 (8.3)	4 (3.7)
9			1 (8.3)	3 (2.8)
10			-	4 (3.7)
11				8 (7.4)
12				7 (6.5)
13-15				3 (2.8)
# Prompts acknowledged (%)				
1	6 (66.7)	25 (67.6)	5 (41.7)	49 (45.4)
2	2 (22.2)	8 (21.6)	-	25 (23.1)
3	1 (11.1)	4 (10.8)	4 (33.3)	8 (7.4)
4	-	-	1 (8.3)	7 (6.5)
5			2 (16.7)	6 (5.6)
6			-	8 (7.4)
7				2 (1.9)
8				2 (1.9)
9				1 (.9)
Final response prompt # (%)				
1	5 (55.6)	17 (45.9)	2 (16.7)	21 (19.4)
2	2 (22.2)	9 (24.3)	2 (16.7)	15 (13.9)
3	2 (22.2)	11 (29.7)	1 (8.3)	20 (18.5)
4	-	-	-	8 (7.4)
5			3 (25.0)	3 (2.8)
6			1 (8.3)	11 (10.2)
7			1 (8.3)	4 (3.7)
8			1 (8.3)	3 (2.8)
9			1 (8.3)	3 (2.8)
10			-	4 (3.7)
11				7 (6.5)
12				6 (5.6)
13-15				3 (2.8)

Table 4

Odds Ratios for Falls Associated with Engagement Characteristics

Variable	AOR	95% CI
Length of stay	1.11**	1.04-1.19
Self-Assessment of Fall Risk (SAFR)		
SAFR completed (Y:N)	1.63	.69-3.81
Fall Prevention Video (Automatic)		
Number of prompts delivered	1.58*	1.07-2.35
Fall Prevention Video Completed (Y:N)	.38**	.19-.79

N = 73:292

* $p < 0.05$; ** $p < 0.01$

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Appendices

Site IRB Approvals

USD IRB Approvals

SHARP. Malcolm Baldrige National Quality Award 2007 Award Recipient

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130985
Sitzer
09/18/2013
8-5

September 13, 2013

Verna Sitzer, MN, RN, CNS
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RE: IRB #130985
Hospital Fall Prevention Using Interactive Patient Care Technology

Dear Ms. Sitzer:

The Sharp HealthCare Institutional Review Board (IRB00000920; FWA00000084) has reviewed and approved your application for the above-referenced research activity in accordance with 45 CFR 46.110(b)(1), Category 5. This approval includes:

- Complete waiver of authorization allowed per 45 CFR 164.512(I)(2)
- Complete waiver of informed consent allowed per 45 CFR 46.116(d)(1-4)
- Data Collection Instrument (Version 1; 2Sept2013)

This action will be reported to all committee members at the September 18, 2013 meeting.

The following site(s) and site personnel are approved:

Site: Memorial

Principal Investigator: Verna Sitzer, MN, RN, CNS

Study Coordinator: None

Sub-investigator and Other Site Personnel: None

The IRB reference number is 130985. Please include this reference number in all future correspondence relative to this research activity.

As a reminder, it is the responsibility of the Principal Investigator to submit periodic status reports to the IRB. Periodic review of this research activity may be conducted via an expedited process and is scheduled for inclusion on the August 20, 2014 IRB meeting agenda. Approval for this research activity will expire if periodic review is not conducted on or before September 11, 2014. Please provide a completed Continuation Request with required supporting documentation to research@sharp.com no later than August 5, 2014 to assure timely review and continuation of this research activity.

Changes or amendments to the research activity protocol, informed consent documents, and to other research activity-related documents, as well as new documents, tools or advertisements to be utilized as part of this research activity, must be reviewed and approved by the IRB before changes are implemented.

It is the policy of Sharp HealthCare IRB that the investigator(s) submit a copy of any abstracts, papers, manuscripts, posters, presentations, articles, etc. to the IRB prior to publication or dissemination. Sharp HealthCare would expect that if the results of the research project came to publication, their role would be properly recognized in the research or have the opportunity to have the organization's name withheld. This also gives the organization the opportunity to prevent disclosure of data or information that is beyond the scope of the research agreement.

Thank you and please feel free to contact me at (858) 499-4836, if you have any questions.

Sincerely,

Caryn L. Burgess, CIP
IRB Specialist

Enc.

Institutional Review Board
8695 Spectrum Center Blvd
San Diego, CA 92123
P (858) 499-4836 / F (858) 499-3105
http://sharpnet/irb/ www.sharp.com/research
E-mail: research@sharp.com

March 17, 2014

Verna Sitzer, MN, RN, CNS
Sharp Memorial Hospital
7901 Frost Street
San Diego, CA 92123

RE: IRB #130985
Hospital Fall Prevention Using Interactive Patient Care Technology

Dear Ms. Sitzer:

The Sharp HealthCare Institutional Review Board (IRB00000920; FWA00000084) has reviewed and expeditiously approved/acknowledged the following item(s) in accordance with 21 CFR 56.110(b)(2) and/or 45 CFR 46.110(b)(2):

- Revised Data Collection Instrument (v02_17Mar2014)

This action will be reported to all committee members via the April 16, 2014 meeting agenda.

This study is scheduled to undergo continuing review at the August 20, 2014 IRB meeting. Approval for this study will expire if continuing review is not conducted on or before 9/11/2014. Please provide a completed Continuation Request with required supporting documentation to research@sharp.com no later than 08/05/2014 to assure timely review and continuation of this study.

Changes or amendments to the study protocol, informed consent documents, and to other study-related documents, as well as new documents, tools or advertisements to be utilized as part of this study, must be reviewed and approved by the IRB before changes are implemented.

Thank you and please feel free to contact me at 858-499-4836, if you have any questions.

Sincerely,

Caryn L. Burgess, CIP
IRB Specialist