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Falls And Hospitalized Cancer Patients

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FALLS AND HOSPITALIZED CANCER PATIENTS

by

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DISSERTATION

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DEDICATION

I would like to dedicate my dissertation to my husband Chris, and my mother Jean, for all of their love and support during the past 7 years.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1
Introduction

Globally, fall prevention has been a priority for both the hospital and community settings for many decades. Hospital falls in particular have been found in the literature dating back to the 1940's (Morgan, Mathison, Rice, & Clemmer, 1985). Many recent hospital fall prevention studies have been performed that review the characteristics and circumstances of falls which show that that the problem of hospital falls is still in existence (Chu et al., 1999; Enloe et al., 2005; Fischer et al., 2005; Hitcho et al., 2004; Krauss et al., 2005; Lakatos et al., 2009; Rohde, Myers, & Vlahov, 1990; Stevenson, Mills, Welin, & Beal, 1998). The percentage of inpatient falls varies, but has shown to be between three and 20% (Inouye, Brown, & Tinetti, 2009). When falls occur in unfamiliar hospital surroundings injuries can result. Serious injuries have been reported in about 30% of falls that occur in the acute care setting (ERCI Institute, 2006). According to Hendrich and colleagues, "Few adverse events that occur in the hospital have as serious consequences for patient outcome, quality of life, and increased healthcare cost as injurious patient falls (Hendrich, Nyhuis, Kippenbrock and Soja, 1995, p. 130)." Life threatening injuries may occur from a fall such as head trauma, broken bones, and most significantly, death. In addition to being hazardous, the cost of falls has been reported to be in the billions when serious injuries have been sustained by patients in hospitals (and nursing homes) (ERCI Institute, 2006). Despite the serious nature of hospital falls, there has been limited documented research over the last twenty years about hospital falls when compared to community falls. A literature search was conducted using CINAHL which found almost double the amount of literature conducted on community falls than when compared to the literature conducted in the hospital setting.

Many of the hospital-based and community fall prevention studies collectively have similarities such as the study of fall risk factors, medications that contribute to fall risk, mobility and the physical condition/functioning of the patient at risk for falls, in addition to information about elimination patterns and cognitive state of those who have fallen. Even though there are many similarities, there are many more differences when hospital and community fall prevention studies are compared. The most apparent difference is that of the dynamic and ever-changing hospital environment where patients are introduced to unfamiliar hospital surroundings when they are faced with acute conditions that necessitate nursing care. In addition, "The continued migration of specialty procedures from acute care to the outpatient setting has raised the acuity and complexity of all acute care delivery units as care for those who are less sick moves outside the hospital environment (Hendrich, 2006, p. 4)." Unfamiliar environments, lack of knowledge about hospital equipment (bed, bedrails, IV pole, lack of own/familiar mobility aids) may increase the risk of a patient fall. Patients who are admitted to a hospital setting are treated for acute problems (versus chronic problems in the community setting) that may warrant medications that need to be administered either alone, or in combination. These medications have a variety of side effects that can contribute to a fall. The intravenous route, a frequent route of medication delivery in the hospital setting, may have a greater impact on how the patient's body responds. Elimination patterns may change and treatment may cause bowel or bladder urgency or frequency often requiring more frequent ambulation. Also, normal activity patterns may change, cognitive impairments may be heightened or worsen due to acute problems/medications, eating patterns may change which could potentiate weakness, patients may have a history of falls which could place them at risk for future falls, and they may experience other conditions/problems that exacerbate fall risk such as sensory/physical deficits,

fatigue, and depression. Patients may be reluctant to ask staff for assistance because of embarrassment. The hospital environment and the patient's health condition are in continuous transformation which produces labile surroundings for the patient at risk for a fall. Therefore, there are unique characteristics of the hospital setting environment and health conditions of the patient when compared to a community environment that makes generalizability of community-based findings to the hospital setting limited. The lack of stability in the hospital environment and dynamic patient health conditions when compared to the community environment, clearly demonstrate why more research and investigation are needed to study the phenomenon of hospital falls.

Many disciplines such as nursing, medicine, gerontology, psychology, public health and physical medicine have conducted research over the years trying to determine the causes/contributing factors of hospital falls. These disciplines independently or in collaboration with one another have all demonstrated commitment to the prevention of falls over time. However, the discipline of nursing has emerged as the leader in this area for many years. Preventing falls is of particular importance to nursing professionals as patient safety is a standard that all nurses must work toward as a common goal to prevent unnecessary harm to patients while they are hospitalized. In addition, nursing as a discipline has the most contact with patients who are hospitalized compared to other disciplines, and the most experience to tackle this multifaceted hospital problem.

A major theme that has appeared consistently over the years involves studies that have attempted to accurately identify hospital patients at risk for falls. Ultimately, what nurse researchers have found is that hospital falls are multi-factorial in nature which adds to the complexity in identifying direct causes. Most existing work in fall prevention has focused on the

etiology of falls in the elderly, over a variety of settings (Yauk et al., 2005). A plethora of intrinsic and extrinsic risk factors have been linked to hospital falls which have been reported to be psychological, physiological, and/or environmental in nature.

Based on the multi-disciplinary research that has been conducted, hospitals have incorporated a diversity of interventions to prevent patients from falling. The most widely reported interventions that have been utilized in fall prevention research are: identifying those at risk by utilizing research-based nursing assessment tools, reducing environmental risk factors, educatingpatient/family/hospital staff about fall prevention, proper use of body mechanics/muscle strengthening, and providing knowledge about specific medication groups and their side effects that may contribute to falls.

There is a lack of agreement among hospital fall prevention studies about the relationship between identified fall risk factors. In addition, findings are inconsistent from one acute care setting to another. Hospitals and nursing units vary in size and in the diversity of variables chosen to be included in each study. It is common for hospital fall prevention studies to report numbers of falls, but not all examine the actual severity of injury sustained from falls. Some studies report simply on the numbers of injuries. Not all fall prevention interventions are effective in reducing falls consistently across studies. Study designs also vary from one hospital fall prevention study to another; however, most are quantitative and retrospective in nature. Sampling designs are relatively consistent across studies where the majority of fall prevention studies utilize convenience sampling. The samples of patients consist of a mixture of different hospitalized patient populations (e.g. medicine, oncology, rehabilitation, orthopedics.). All studies do not sample from the same populations from one study to the next which provides little information about each population. Exploration of specific groups of hospital populations may

bring a new understanding to hospital falls, particularly those that have a high number of falls and/or injuries. One of those hospital populations, in particular, is the oncology population that has proven in multiple studies to be an indicator of fall risk and/or falls with injury (Alcee, 2000; Chu et al., 1999; Fischer et al., 2005; Hendrich et al., 1995; Hitcho et al., 2004; Rohde, Myers, and Vlahov, 1990; and Stevenson, Mills, Welin, and Beal, 1998), but few studies have investigated fall prevention solely in patients with cancer in the hospital setting (Capone, Albert, Bena, and Tang, 2012; Capone, Albert, Bena, & Morrison, 2010; Pautex, Herrmann, and Zulian, 2008; Pearce & Ryan, 2008). The oncology population may be unique when compared to other hospitalized populations, but more research is needed to determine why this is true.

There is a lack of nursing theory in most fall prevention work. In general, nursing theories are integral to understanding nursing problems and assist the researcher with a systematic process to conduct hospital fall prevention research. In addition, using nursing theory as a foundation for nursing research contributes to a new understanding and provides different information that has not been exposed by current methods. Using a nursing theory to provide the foundation for this type of quantitative research is innovative and may provide outcomes that atheoretical based research has not provided to date.

Despite all the work that has been done, high numbers of hospital falls continue to occur which is a significant problem for patients, nurses, and healthcare delivery systems. Methodological problems such as limitations in designs, samples, settings, and lack of theoretical support have prevented generalizability across settings. This problem can be addressed through the use of a theoretically supported investigation, as well as a population specific sample. The results of this study can lead to the future development of nursing interventions that may reduce falls in cancer patients in the hospital setting.

Statement of Problem

Many hospital fall prevention studies have shown that having a diagnosis of cancer places patients at higher risk for falls and falls with injury when compared to other hospitalized groups of patients. Few studies have chosen to focus solely on cancer patients at risk for falls in the hospital setting. Complications from falls can lead to life threatening injuries; therefore, knowing why cancer patients are at high risk is necessary to prevent harm to this specific population.

Statement of Purpose

To support the aims of this study, a theoretically supported approach was used where selected variables are consistent with the concepts in the chosen theory. Specifically, this study used Dorothea Orem's theory of self-care (Orem, 2001), and Albert Bandura's, social cognitive theory (2001) to determine if factors such as age, gender, health state, healthcare system factors, self-care agency, and self-care have an association with falls in hospitalized cancer patients. The major objective of this study will be to: identify factors that are associated with falls in the hospitalized cancer patient population and to report on the characteristics of falls and falls with injury.

Specific Aims

The specific aims of this study were as follows:

Specific Aim 1. To describe the characteristics of falls that occur in hospitalized patients diagnosed with cancer.

Specific Aim 2. To describe the basic conditioning factors, self-care agency, and self-care in a prospective sample of hospitalized patients diagnosed with cancer who do not fall.

Specific Aim 3. To describe the basic conditioning factors in a retrospective group of hospitalized patients diagnosed with cancer who fall and who do not fall.

Specific Aim 4. To examine the relationships between the basic conditioning factors in hospitalized patients diagnosed with cancer who fall and who do not fall.

Specific Aim 5. To identify the basic conditioning factors that predict falls in hospitalized patients diagnosed with cancer.

Significance

New knowledge gained from this study will provide useful information for healthcare professionals who care for cancer patients in the hospital setting. Nurses who care for oncology patients, in particular, will benefit from the information gained, such as knowing what factors are linked to inpatient falls.

Significance to the Science of Nursing

Nursing theory provides a valuable framework to guide nursing research. This study utilizes Orem's theory of self-care (Orem, 2001) to understand the phenomenon of cancer patients and hospital falls. Using nursing theory to understand hospital falls is a new concept which has never been done solely with hospitalized cancer patients in a quantitative design. Research that utilizes nursing theory defends the need for the development of systematic research that contributes to nursing science. Using nursing theories to understand clinical problems, such as fall prevention in the cancer population can shed new insight onto old problems that may ultimately lead to saving lives. In addition, theories or knowledge outside of the discipline of nursing (such as those in the field of psychology) also enhances the process of inquiry as it pertains to this phenomenon (Donaldson and Crowley, 1978).

Significance to Clinical Practice

Safety plays a key role when patients are introduced to new and ever-changing hospital environments. It is the nurse's responsibility to ensure that patients are kept free from falls while under nursing care. According to the literature, cancer patients have proven to be at high risk for falls, and/or injuries from falls. Nurses who care for cancer patients must be informed about who is at risk and why they are at risk to prevent a fall from occurring. The results of this study may assist the nurse clinician in recognizing which types of cancer patients are at risk for falls, and

what significant patient factors play a role in those falls. Knowing information about factors that lead to falls in cancer patients who are hospitalized can lead to changes in the way that nurses currently educate cancer patients about their individual fall risk status. This information can improve the way the nurse communicates changes to patients about their health, such as including how the patient's current health state affects their risk for falls, in addition to establishing nursing interventions to prevent falls in this specific population. Ultimately, these changes can significantly impact how nurses care for hospitalized cancer patients at risk for falls.

Significance for Society

The results of this study may help to improve patient outcomes by providing evidence that may lead to fall prevention. It has been documented that cancer patients are at a high risk of serious injury from falls when compared to other hospitalized patient populations. Hospital falls in the cancer patient may cause unnecessary surgery, pain, decreased quality of life, increased morbidity and mortality, increased dependence on others, economic expenses, and most significantly, death can result. Hospitals that lack awareness about cancer patients and fall risk may suffer, as falls can lead to increased lengths of hospital stay which, therefore, increase hospital costs. Hospitals may have to deal with the negative consequences of a fall with serious injury, or a death from a fall, if litigation from a patient or family ensues. Hospitals will be able to use the results from this study to educate their staff about factors that influence falls in the hospitalized cancer population.

CHAPTER 2
Review of the Literature & Theoretical Framework

Fall prevention is a complex phenomenon to which a considerable body of evidence exists. Less is known about hospital falls, in particular, which still continues to be reported in large numbers in hospitals today. What is known is that there are many factors that contribute to hospital falls. One of these factors that has been reported in a variety of hospital fall prevention studies is the fact that the diagnosis of cancer is a risk factor for falling and that these patients are at risk for serious injury.

Cancer Patients and Hospital Falls

A diagnosis of cancer has shown to be a risk factor for hospital falls and/or falls with injury (Alcee, 2000; Chu et al., 1999; Fischer et al., 2005; Hendrich et al., 1995; Hitcho et al., 2004; Rohde et al., 1990; and Stevenson et al., 1998), but few studies have investigated fall prevention solely in patients with cancer in the hospital setting (Capone et al., 2012; Capone et al., 2010; Pautex et al., 2008; & Pearce & Ryan, 2008). See Table 1.

Table 1. below presents studies that focused exclusively on falls in the cancer population, and Table 2. presents studies that examined falls that did not exclusively involve oncology patients, but reported oncology findings in their studies. Two of the four oncology specific hospital research studies described actual fall risk factors in the hospitalized cancer population. Capone and coworkers (2012) reported that predictors of a fall episode were low pain level, abnormal gait, cancer type, presence of metastasis, antidepressant and antipsychotic medication use, and blood product use. Pautex and colleagues (2008) found that delirium and chronic obstructive pulmonary disease (COPD) were significant factors predicting a fall during hospitalization. In this same study, fallers were more often prescribed neuroleptics when compared to non-fallers. Pearce and Ryan (2008) and Capone et al. (2010) reported

characteristics of cancer patients who fall in the hospital setting. Pearce and Ryan (2008) reported in their retrospective audit, that metastatic disease was found in more than half of patients that fell, and lung cancer patients fell more often than other cancer types. Capone et al. (2010) reported that hospitalized cancer patients have characteristics similar to general hospitalized patient populations. Holley (2002) (not listed in the table) published an evidenced-based feature article about fall risk factors in the cancer population. This author comprehensively described and identified the following falls risk factors in the cancer population: age, impaired physical functioning, sensory-neurologic deficits, use of multiple medications (chemotherapy), and deconditioning often caused by treatment-induced fatigue.

Cancer patients have been reported to experience injury from their falls in the hospital setting when compared to other hospital groups of patients, however, only three studies could be found that described cancer patients and hospital fall injuries in detail. Hitcho et al. (2004) reported that the fall injury rate was the highest in the oncology service (74% of first falls resulting in injury) and 11% percent of first falls resulting in moderate/severe injury (study did not specify which injuries). Fischer et al. (2005) compared seven hospital services and found that the oncology service had the highest (42.6%) percentage of falls resulting in injury (both minor and serious; study did not specify which type of injuries). Lastly, Yang (2006) reported that having a cancer diagnosis was a significant predictor for falls with injuries. By looking at the studies above, we can see that the research about hospitalized cancer patients and falls remains limited, as these studies do not explain why cancer patients continue to fall and incur serious injuries from their falls.

Table 1.

Hospital Fall Prevention Studies-Oncology Specific (in order of publication date)

Study	Description
#1	Capone et al., 2012
Purpose	To determine predictors of fall events in hospitalized patients with cancer and develop a scoring system to predict fall events
Design/Sample	Retrospective N=145 hospitalized patients with cancer who did not fall compared with 143 hospitalized patients with cancer who had a fall
Findings	Predictors of a fall episode weere low pain level, abnormal gait, cancer type, presence of metastasis, antidepressant and antipsychotic medication use, and blood product use
Strengths/Weaknesses	Strengths: large sample size, described multiple variables/characteristics, and predictors of falls. Weaknesses: data collected from charts where data might not be complete
#2	Capone et al., 2010
	To describe characteristics of hospitalized patients with cancer who fall
Design/Sample	Descriptive prospective and retrospective 1-year period N=158 cancer patients who fell
Findings	Characteristics of hospitalized cancer patients who fell were similar to those of the general hospital patient population
Strengths/Weaknesses	Strengths: large sample size, described multiple variables/characteristics Weaknesses: data collected from charts where data might not be complete, characteristics of falls instead of predictors were reported

Table 1. (continued)

#3	Pautex et al., 2008
Purpose	To determine the incidence rate of falls, the consequences related to falls, and to identify other related factors in patients with cancer hospitalized in palliative care wards
Design/Sample	Exploratory 1-year period N = 198 patients 36 patients had fallen at least once Sample included patients with cancer in the palliative care ward
Findings	Incidence of falls was 6.9%. Delirium in patients and neuroleptics were significantly associated with falls; 25% of fallers had lung cancer
Strengths/Weaknesses	Strengths: large sample size; listed diagnosis-specific information; multiple variables collected Weaknesses: Only patients with advanced cancer were included
#4	Pearce & Ryan, 2008
Purpose	To explore the relationship between cancer as a disease process and patient falls
Design/Sample	Retrospective 12-month period N = 119 patients The study did not report whether the population was inpatient exclusively; however, incident reports were audited, suggesting that the sample included an inpatient population
Findings	Among patients who fell, 22% had lung cancer, 17% had head and neck cancers, 15% had hematologic cancers, and 64% had metastatic disease
Strengths/Weaknesses	Strengths: large sample size; described falls by specific cancer diagnosis Weaknesses: Limited information was provided on variables collected; the study did not report whether the population was inpatient versus outpatient

Table 2. Hospital Fall Prevention Studies-Not Oncology Specific (in order of publication date)

Study	Description
#1	Lakatos et al., 2009
Purpose	To determine the prevalence of diagnosed and undiagnosed delirium in patients who fell during their hospital stays
Design/Sample	Retrospective 3-month period N = 252 patients
Findings	6% of falls occurred on the oncology service; 3 of 15 (20%) patients who fell had minor injuries; 12 were not injured
Strengths/Weaknesses	Strengths: large sample size Weaknesses: Study did not describe details about patients with cancer who fell or injuries sustained, or report exact statistics per clinical service
#2	O'Connell, Cockayne, Wellman, & Baker, 2005
Purpose	To explore and identify factors associated with patient falls in the oncology and palliative care setting and to provide empirical evidence to guide fall-prevention interventions in oncology and palliative care settings
Design/Sample	Prospective cohort, qualitative 9-month period N = 227 patients admitted to oncology and palliative care units 34 patients had a fall
Findings	Many factors were significantly associated with fall status: age, difference in muscle strength in right push and left arm push, physical functioning, confusion, participants'orientation to person, time, and place, and self-rated fatigue level
Strengths/Weaknesses	Strengths: Many variables were measured; study used quantitative and qualitative methods Weaknesses: The authors did not differentiate the results between patients with cancer and those receiving palliative care who may not have had cancer

Table 2. (continued)

#3	Fischer et al., 2005
Purpose	To characterize inpatients who fall and to determine predictors of serious fall-related injury
Design/Sample	Retrospective, observational 18-month period N = 1,082 patients who fell
Findings	The oncology service had the highest percentage of injurious falls (42.6%) and the third-highest hospital fall rate (3.83 falls per 1,000 patient days)
Strengths/Weaknesses	Strengths: very large sample size Weaknesses: Sample was not oncology specific; study did not describe details of falls in patients with cancer
#4	Hitcho et al., 2004
Purpose	To describe the epidemiology of hospital inpatient falls, including characteristics of patients who fall, circumstances of falls, and fall-related injuries
Design/Sample	Descriptive, prospective 13-week period N = 183 falls 19 patients with cancer experienced falls; 12 cancer patients had minor injury, 2 of 19 sustained moderate /severe injury
Findings	Patients with cancer had the highest rate of injury (74%) for first falls resulting in injury. They also had the highest rate of major injury, with 11% of first falls resulting in moderate/severe injury
Strengths/Weaknesses	Strengths: Large sample size; study provided characteristics of hospital falls from a variety of services Weaknesses: Sample was not oncology specific; study reported that patients with cancer had high numbers of injuries but did not describe the injuries or provide details about the falls

Table 2. (continued)

#5	Alcee, 2000
Purpose	To quantify the number of patient falls and identify what factors resulted in these falls
Design/Sample	Retrospective 8-month period N = 209 total falls
Findings	The greatest number of falls occurred on the medical/oncology unit at 26% (54 falls)
Strengths/Weaknesses	Strengths: large sample size Weaknesses: Sample was not oncology specific; study did not provide details about falls in patients with cancer; medical patients and patients with cancer were combined
#6	Stevenson et al., 1998
Purpose	To extend knowledge beyond known risk factors of age and medical diagnosis by comparing characteristics of 301adults who fell while hospitalized with a matched sample of adults who did not fall while hospitalized
Design/Sample	Descriptive, retrospective, comparative 10-month period N = 301 falls
Findings	8.1% of patients who fell had a cancer diagnosis
Strengths/Weaknesses	Strengths: large sample size Weaknesses: Sample was not oncology specific and did not provide details about falls in patients with cancer
#7	Rohde et al., 1990
Purpose	To identify groups at risk for falls and fall injuries in an acute-care hospital population
Design/Sample	Retrospective 1-year period N = 874 falls
Findings	62 falls (7%) occurred in the oncology service
Strengths/Weaknesses	Strengths: large sample size Weaknesses: Sample was not oncology specific and did not provide details about falls in patients with cancer

Table 2. (continued)

#8	Chu et al., 1999
Purpose	To investigate the clinical and performance-oriented functional factors associated with falls in the older hospitalized patient
Design/Sample	Case-control 17-month period N = 51 cases and controls
Findings	11 of 51 patients (22%) who fell had an active neoplasm; active neoplasm was significantly associated with falls
Strengths/Weaknesses	Strengths: multiple clinical and functional risk factors studied Weaknesses: Sample was not oncology specific and did not provide details about falls in patients with cancer
#9	Morgan et al., 1985
Purpose	To identify high-risk patients and/or situations for systematic intervention
Design/Sample	Retrospective, descriptive 22-month period N = 229 patients and 250 falls
Findings	Patients with a neoplasm experienced 46 falls and had the longest median number of patient days (8.37)
Strengths/Weaknesses	Strengths: large sample size Weaknesses: Study did not describe details about patients with cancer who fell or injuries sustained, Information was obtained from patient incident reports

Basic Conditioning Factors, Self-Care Agency, Self-Care, and Health

A literature search was conducted to better understand the current knowledge about the relationships of selected basic conditioning factors, (e.g., age, gender, health state, and healthcare system factor), self-care agency (i.e., general self-efficacy), self-care (i.e., Safe Hospital Activity Questionnaire, and health (falls) in hospitalized cancer patients. Self-efficacy is currently a component of fall prevention research which is evident by the numerous studies that link the concept of fall prevention with the concept of self-efficacy (Cheal & Clemson, 2001; Denkinger et al., 2010; Hellström, Vahlberg, Urell, & Emtner, 2009; Hutton et al., 2009; Fukukawa et al., 2008; Kato et al. 2008; Li, Fisher, Harmer, & McAuley, 2005; Li et al., 2002; Tinetti & Powell, 1993; Tinetti, Richman, & Powell, 1990).

Patients who have cancer and are admitted to the hospital setting have various challenges they must overcome. Some challenges may be more difficult than others and each human is different in the way that they meet these challenges based on their self-efficacy beliefs. Humans are agents of their own self-care. For persons to care for self and take action they must believe or not believe that they can produce certain outcomes. These beliefs influence what challenges people take, how much effort to expend, how long to persevere, and whether failures are motivating or demoralizing (Bandura, 2001). If falls self-efficacy was found in the literature, it was included in the table below. The relationships between self-care agency and self-care, and self-care and health (falls) were not included, as the construct used for self-care was a new instrument Literature could be found that linked self-care agency (general self-efficacy) and falls. Literature regarding the basic conditioning factors and self-care agency and the basic conditioning factors and health (falls) are reported below in Table 3.

Table 3.
Basic Conditioning Factors and Their Relationships to Self-Care Agency (General Self-Efficacy) and Falls

Age and Gender
Age and general self-efficacy
o In a study of advanced cancer patients on a palliative care unit, Mystakidou et al. (2009) found that while using the General Perceived Self-Efficacy Scale, that self-efficacy was predicted by age and that older patients experience higher levels of self-efficacy.
Age and falls
o The aging process may place persons at risk for falls due to various progressive changes in the human body over time (Rawsky & Digby, 2000).
o As people age they are more likely to suffer from long-term conditions that place them at risk for a fall (Nazarko, 2009).
o O'Connell et al. (2005) specifically noted that age was found to be significantly associated with patient fall status in their oncology and palliative care population reporting that fallers had a higher mean age of 74.79 years than when compared to non-fallers with a mean age of 66.45 years.
Gender and general self-efficacy
o In a study of advanced cancer patients on a palliative care unit, Mystakidou et al. (2009) found that while using the General Perceived Self-Efficacy Scale, that self-efficacy was predicted by gender.

Table 3. (continued)

Gender and falls

- O'Connell et al. (2005) reported that in their hospital fall prevention study, that 19/34 (55.9%) participants who fell were women. However, Hendrich, Bender, & Nyhuis (2003) found that men were 1.69 times more likely to experience a fall than women.
- Gender was found to be insignificant as it relates to falls in a study by Stevenson et al. (1998).

Health State

Previous history of a fall and general self-efficacy

- Balance and falls self-efficacy are associated with a fall history (in patients with chronic stroke in the community) (Belgen, Beninato, Sullivan, & Narielwalla, 2006).

Previous history of a fall and falls

- Several studies have shown that a history of falling is a fall risk factor in hospital fall prevention studies (Hendrich et al., 1995; Krauss et al., 2005).

Elimination and general self-efficacy

- No relevant literature could be found.

Elimination and falls

- The relationship between altered elimination and falls have been noted in several fall prevention studies (Enloe et al., 2005; Fischer et al., 2005; Hitcho et al., 2004; Krauss et al., 2005; Stevenson et al., 1998).

Table 3. (continued)

Vision impairment and general self-efficacy

- No relevant literature could be found.

Vision impairment and falls

- Krauss et al. (2005) found that vision impairment was related to a fall injury
- Vision impairment was associated with increased falls risk in a community fall prevention study (Lopez et al., 2011).

Hearing deficit and general self-efficacy

- No relevant literature could be found.

Hearing deficit and falls

- Hearing impairment was associated with increased falls risk in a community fall prevention study (Lopez et al., 2011).

Peripheral neuropathy and general self-efficacy

- No relevant literature could be found.

Peripheral neuropathy and falls

- Tofthagen, Overcash, & Kip (2012) evaluated the risk for falls in patients with chemotherapy-induced neuropathy. The risk of falls increases with each cycle of chemotherapy.
- DeMott, Richardson, Thies, & Ashton-Miller (2007) found that older persons with neuropathy have a high rate of falls (community fall prevention study).

Assistive device and general-self-efficacy

- No relevant literature could be found.

Table 3. (continued)

Assistive device and falls
○ Use of any type of walking aid was associated with a fall event during hospitalization (Capone et al., 2012).
○ A walking aid was a significant factor in those who fell in the hospital (Chu et al., 1999).
○ A meta-analysis by Rubenstein and Josephson (2006) supported the relationship that use of assistive device is a risk factor for falls in multiple studies.
Type of cancer and general self-efficacy
○ No relevant literature could be found.
Type of cancer and falls
○ A relationship between lung cancer and falls was reported where lung cancer patients fell more than other types of cancer (Pearce & Ryan, 2008)
Admitting diagnosis and general self-efficacy
○ No relevant literature could be found.
Admitting diagnosis and falls
○ No relevant literature could be found.
High risk fall medications and general self-efficacy
○ No relevant literature could be found.

Table 3. (continued)

High risk fall medications and falls
o In cancer specifically, Capone et al. (2012) and Pautex et al. (2008) reported dissimilar findings. Capone et al. (2012) reported that predictors of a fall episode were antidepressant and antipsychotic medication use. Pautex et al. (2008) reported that more fallers were on neuroleptics, but neuroleptics were not predictive in the model.
Depression and general self-efficacy
o In a study of lung cancer participants, those who had low self-efficacy reported higher levels of depression (Porter, Keefe, Garst, McBride, & Baucom, 2008).
Depression and falls
o Hendrich et al. (1995) found that clinical depression was the second most significant risk factor (most significant risk factor was recent history of falls) contributing to a hospital fall in their fall risk model. A primary cancer diagnosis was also a contributing risk factor in their model
o Antidepressants used to treat depression can contribute to falls (Darowksi, Chambers & Chambers, 2009).
Comorbidity and general self-efficacy
o Relationships between physical functioning and fear of falling in the presence of comorbidities were presented in this study (Sharif & Ibrahim, 2008).

Table 3. (continued)

Comorbidity and falls
o Medical diagnoses and neuromuscular impairments mediated the association between medications and fall (Lee, Kwok & Woo, 2006).
Fatigue and general self-efficacy
o Lung cancer patients low in self-efficacy reported significantly higher level of fatigue (Porter et al., 2008).
o Perceived self-efficacy (for fatigue self-management) influenced cancer-related fatigue and physical functional status. Perceived self-efficacy served as a mediator between cancer-related fatigue and physical functional status (Hoffman et al., 2011).
Fatigue and falls
o Two hospital fall prevention studies were found that included fatigue as one of their study variables (O'Connell, 2005; O'Connell, Baker, & Graskin, 2007).
Functional (performance) status and general self-efficacy
o In a study of patients undergoing chemotherapy, perceived self-efficacy (in fatigue self-management) influenced cancer-related fatigue and physical functional status (Hoffman et al., 2009).
o Lung cancer patients low in self-efficacy reported significantly worse levels of physical and functional well-being (Porter et al., 2008).
o Dekinger et al. (2010) found a strong effect of falls related self-efficacy on physical function.

Table 3. (continued)

○ Falls self-efficacy mediated the effects of fear of falling on functional outcomes (Li et al., 2002).
○ Falls self-efficacy was the single highest predictor of both the SF-36 physical component summary score and the SF-36 physical functioning domain (Stretton, Latham, Carter, Lee, & Anderson, 2006).
Functional (performance) status and falls
○ The best physical fall predictor was a lower score on the Physical Performance Test (community study) (Delbaere et al., 2006).
Healthcare System Factor
Length of stay and general self-efficacy
○ No relevant literature could be found.
Length of stay and falls
○ Hospital length of stay did not contribute to a logistic regression model in a hospital study of cancer patients (Capone et al., 2012).

Theoretical Frameworks

Two frameworks were used in this study. Orem's theory of self-care was taken from the field of nursing and the social cognitive theory was borrowed from the field of psychology. Both theories provided conceptual guidance for this work and were philosophically compatible. The use of self-efficacy, from the social cognitive theory was borrowed as a parent construct of self-care agency.

Orem's Theory of Self-Care

Dorothea Orem's theory of self-care will be the nursing framework used for this research to:

1. Provide and support that idea that quantitative research methods are necessary to understand the concepts of self-care and how this method can inform an investigation using a sample of cancer patients who fall in the hospital setting.
2. Provide evidence as to how theory can guide research-show why certain patient data (variables) will be collected and why they are important.
3. Link nursing theory to actual nursing practice with the goal of producing a systematic approach to study this phenomenon.
4. Discover factors that contribute to falls in hospitalized cancer patients to prevent future harm and injury to this population.

The theory of self-care (Orem, 2001) will be used to explore relationships of the basic conditioning factors (BCFs), self-care agency (SCA), self-care (SC), and health in this study. The concept of self-efficacy, borrowed from the social cognitive theory, was integrated at a theoretical level to reflect a construct within self-care agency. See Figure 1 for the conceptual model of this study.

The theory of self-care assists in understanding the complexities of cancer patients and their own self-care in the hospital setting as it relates to the prevention of falls. Self-care continues from one environment to the next. From home to the hospital, patients continue to use their own skills and abilities to maintain their daily functions.

Conceptual and Theoretical Definitions

Basic Conditioning Factors

The BCFs are important to this work as they affect individual's abilities to engage in self-care (Orem, 2001, p. 245). Of the ten known basic conditioning factors, four are chosen for this research: age, gender, and health state, and healthcare system factor. These concepts were chosen based on the current literature about the contributing factors related to falls within the hospital setting.

Age is significant because self-care requisites vary depending on which period of the human life cycle the individual is in (Orem, 2001, p. 372); individuals may make different decisions about care of self depending on what stage of life they are in; in addition, injuries from falls in patients who experienced them later in life can lead to higher morbidity and mortality due to factors that contribute to the normal aging process. (Study variable: age)

Gender may condition what choices are made to care for one's self. There is inconclusive data to support which gender is at higher risk for hospital falls. (Study variable: gender)

Health state can be defined as a physical illness which can interfere with or create obstacles to meeting universal requisites (Orem, 2001, p. 246); patients who are in later stages of their cancer may have more functional or physiologic issues that affect their gait and/or mobility. (Study variables: history of a fall, altered elimination, vision impairment, hearing deficit,

peripheral neuropathy, use of an assistive device, admitting diagnosis, type of cancer, type of high risk fall medication, depression, comobidities, fatigue, and performance score.

Figure 1 depicts from left to right how the basic conditioning factors influence self-care agency (self-care agency described below). Specifically, Orem's propositional statements reflect the "Individuals' abilities to engage in self-care or dependent-care are conditioned by age, developmental state, life experience, sociocultural orientation, health, and available resources (2001, p. 147)."

Self-Care Agency

Cancer patients make decisions and judgments about meeting their needs or activities while in the hospital, otherwise known as self-care operations. However, prior to patients actually engaging in self-care, patients must have human powers to be capable of such decision making. The "ability to make decisions about care of self and to operationalize these decisions (Orem, 2001, p. 265)" is required to follow through with the self-care behaviors to be performed.

Orem names three types of self-care operations, but only one was used in this study to understand fall outcomes (estimative operations). Estimative type of self-care operation can be defined as an "Investigation of internal and external conditions and factors significant for self-care (Orem, 2001, p. 259)." The result of this operation is that the person will have empirical knowledge of self and the environment. This can be related to cancer patients in the hospital setting in that they need to be aware of their new environment and their own capabilities so that they can successfully operate and perform self-care behaviors. (Study variable: General Self-Efficacy Scale).

The concept of self-efficacy, originally taken from the field of psychology, has been integrated into Orem's theory of self-care in this study. Borrowing concepts from different fields

must share the same logical congruence of worldviews that support the conceptual model and theory (Villarruel, Bishop, Simpson, Jemmott, & Fawcett, 2001). Using a concept from psychology within a nursing framework may provide new insight into that may lead to a new theoretical understanding of this phenomenon. Walker and Avant (2005) encourage the use of a "parent concept" from another field in the derivation process.

The concept of self-efficacy was chosen as there is already an established relationship between self-efficacy and fall prevention that has been demonstrated in the literature; however this relationship has not been established in cancer patients in the hospital setting. Self-efficacy aligns itself with Orem's concepts of self-care agency, particularly estimative operations. Both the concepts of self-efficacy and estimative operations have very similar theoretical underpinnings in that for actions to take place, persons must have knowledge of self and of their surrounding environment (Bandura, 2004; Orem, 2001). In addition, they must possess the desirability to bring about the action they want to take. The components of the decision-making process are based on both the concepts of self-efficacy and estimative operations. Using self-efficacy as a way to empirically measure estimative operations is a new idea.

Figure 1 depicts how the empirical indicator of general self-efficacy influences self-care, specifically, safe activity (which is described below). Safe activity and its relationship to general self-efficacy is supported through the use of Orem's propositional statements suggesting that,

> Conditions that are provided or maintained through self-care or dependent-care are concerned with safe engagement in human excretory functions, sanitary disposal of human excrements, personal hygienic care, maintenance of normal body temperature, protection from environmental and self-imposed hazards, and what is needed for

unhampered physical, cognitional, emotional, interpersonal, and social development and functioning of individuals in their life situations (Orem, 2001, p. 144).

Self-Care

According to Orem, self-care contributes in specific ways to human functioning. Self-care is a deliberate "….action of mature and maturing persons who have the powers and who have developed or developing capabilities to use appropriate, reliable, and valid measures to regulate their own functioning and development in stable or changing environments (Orem, 2001, p. 43)." Patients, who are able, can and will continue to care for one's self while hospitalized, even if they are not completely aware of the limitations that they possess (which may be specific to their current health problems or their new environment).

Self-care as it relates to safe activity in the hospital setting may be positively or negatively affected by general self-efficacy scores. It was important to determine the relationship between general self-efficacy and safe activity because patients who are more or less confident may take risks that may precipitate a fall. Falls may occur when safe activity does not occur. (Study variable: Safe Hospital Activity Questionnaire, defined as hospital specific fall prevention behaviors).

Health

Orem specifically defines health as "…the sense of a state of a person that is characterized by soundness or wholeness of developed human structures and of bodily and mental functioning (Orem, 2001, p. 186)." Components of Orem's theory of self-care were used to describe the relationships that exist between the basic conditioning factors and self-care agency, how self-care agency affects self-care, and how self-care affects health outcomes, specifically defined as hospital falls in this study. This complexity of interactions is supported

by the reality that all aspects of health are inseparable from the individual (physical, psychologic, interpersonal, and social). Therefore, attempting to understand the associations between these components can led to a deeper understanding about what contributed, or did not contribute to hospital falls (and falls with injury). (Study variable: falls, falls with injury).

Social Cognitive Theory

In examining existing health psychology theories, Albert Bandura's social cognitive theory (SCT) was chosen as its concepts are most likely to explicate and predict why cancer patients fall while they are hospitalized. The theory structure operates together with self-efficacy beliefs, goals, outcomes expectations, and perceived environmental impediments and facilitators that regulate motivation, behavior, and well-being. Self-efficacy is at the core of the SCT, where a person's need to produce a desired effect is affected by their personal beliefs of self-efficacy (Bandura, 2004).

Perceived self-efficacy can be defined as the control that one exercises over one's health habits and affects health behavior both directly and indirectly (Bandura, 2004). It is an influential factor in the goals and aspirations that persons set for themselves. The way that obstacles and impediments are viewed is the result of self-efficacy beliefs. Desire, power, and motivation all play a key role in self-efficacy (Bandura, 2004). Therefore, unless persons believe that they can produce the desired effect they are looking to achieve, then they are less likely to persevere when faced with life's obstacles. According to Bandura (2004), "The stronger the perceived self-efficacy, the higher the goals people set for themselves and the firmer their commitment to them. Those of high efficacy expect to realize favorable outcomes. Those of low efficacy expect their efforts to bring poor outcomes (p. 145). "

The four concepts of the SGT lay the groundwork for understanding Orem's concept of human agency: intentionality, forethought, self-reactiveness, and self-reflectiveness (Bandura, 2001). Imbedded in the human agency concept of self-reflectiveness is that of efficacy. Bandura refers to efficacy beliefs as "…the foundation of human agency (Bandura, 2001, p. 10). Self-reflectiveness can be defined as persons who self-examine their own functioning (2001);

Self-efficacy beliefs drive the action and change that is desired by the human agent. These beliefs are critical as they influence how people think and act, are shaped by a variety of factors, and can help to explain why hospital falls occur.

According to Bandura (2004) levels of self-efficacy affect behavior change and are based on the participant's readiness for change:

Level 1: high sense of self-efficacy and positive outcome expectations; person will succeed with minimal guidance

Level 2: self-doubts about their self-efficacy and benefits of their efforts, persons are quick to give up; need additional support and guidance

Level 3: beliefs that health habits are beyond their person control; need great deal of personal guidance

Typically, high levels of self-efficacy would be necessary for positive behavior changes such as weight loss, or smoking cessation; however, for fall prevention, high levels of self-efficacy could place patients at risk for falls, such that those patients who like a challenge or take greater risks, or patients who are confident and think they will be successful at meeting their self-care activity needs. These patients may not be aware of the environmental factors, and personal risk factors that can place them at risk for a fall.

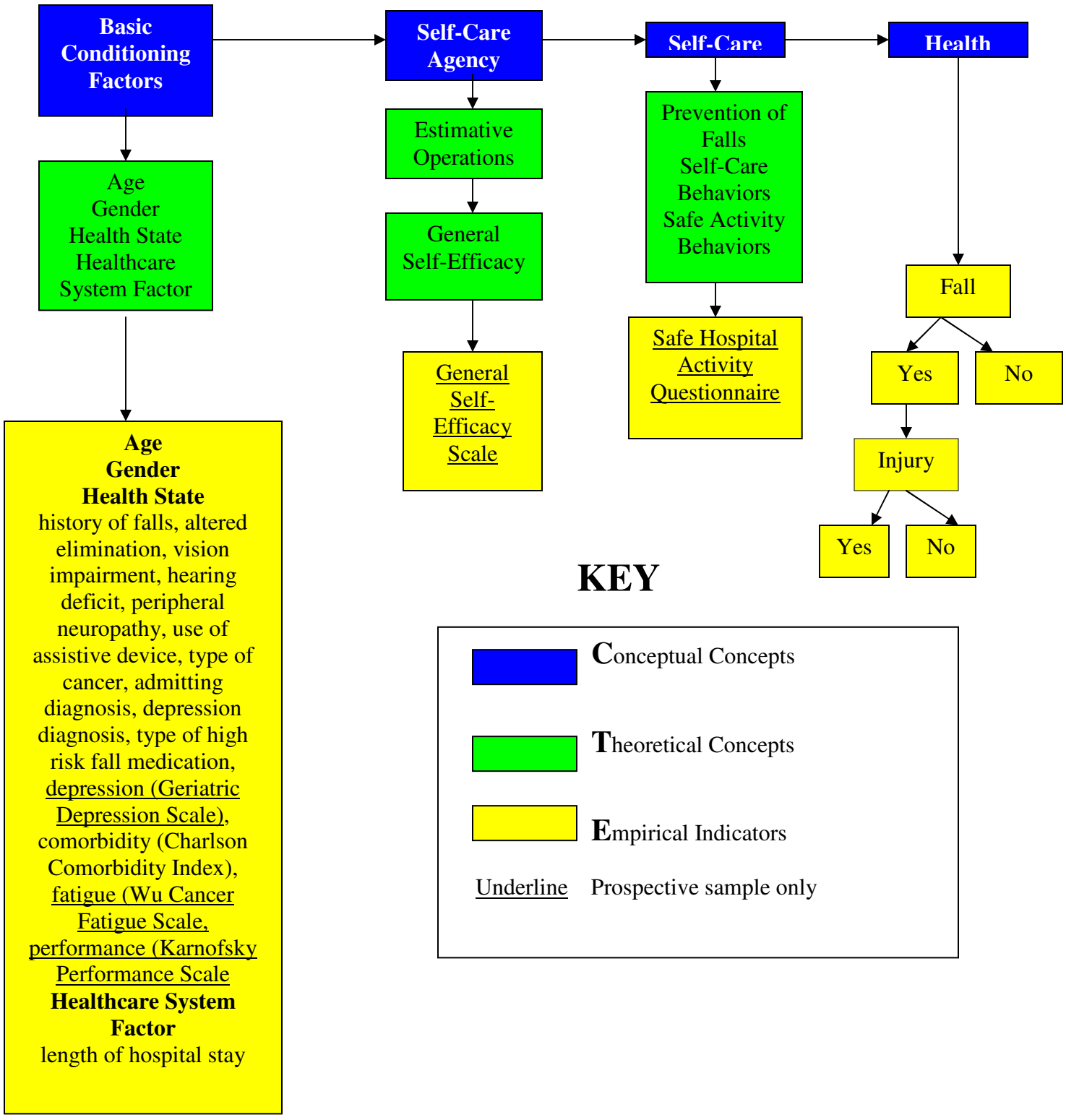


Figure 1: Falls and Hospitalized Cancer Patients Substruction (C-T-E)

CHAPTER 3
Methods

This study identified characteristics of oncology patients who fall and determined the relationships between selected factors and fall outcomes using quantitative methods.

Design

Quantitative methodologies were used in this study to assess falls in hospitalized cancer patients. The original study was designed to collect only prospective data, however prospective data to predict fall was not available. Due to human subjects institutional review board restrictions, the Principal Investigator (PI) had to stop data collection and change the study design to a retrospective approach. The final study used both prospective and retrospective design components. For the purposes of this study, the data collected prospectively was used to describe the sample of patients who did not fall. In addition to the prospective design, a retrospective, case-control design method was utilized for this study.

Human Subjects Protection

Full board human subjects institutional review was required from a hospital system in Detroit, Michigan. This hospital granted permission for the use of both hospital sites used in this study. An expedited review was granted from Wayne State University. For the prospective component of this study, a consent form was discussed with each patient who met the study criteria. This consent provided all the necessary information about the study including, but not limited to: study purpose, participant selection, procedures, potential risk/costs, potential benefits, confidentiality statement, voluntary consent, right to withdraw, and PI contact information. Participants gave written and verbal consent prior to enrollment into the study and were informed that their treatment would not be affected by choosing, or not choosing to participate in the study. Participants had the opportunity to decline during any point during the

study and were told that their information and responses would remain anonymous. Only participants themselves were allowed to consent into the study as inclusion criteria stated that patients must be cognitively intact to participate. For the retrospective part of this study, a Waiver of Consent and HIPAA Waiver were obtained.

Sample

For the prospective component of this study, a convenience sample of 32 hospitalized participants who met the inclusion criteria were asked to participate in the study. Of those 32, 26 came from Hospital A and 6 came from Hospital B.

Data for the cases and controls were collected retrospectively via electronic chart review. Participants who experienced a fall in this study served as the cases (n=30), and those who did not experience a fall served as the controls (n=74). A total of 98 cases and controls came from Hospital A and six came from Hospital B. Twenty-nine cases came from Hospital A, and one from Hospital B. Sixty-nine controls came from Hospital A and five came from Hospital B. Cases and controls were selected from participants who were hospitalized less than three years prior to the initiation of the study and had a length of stay of at least two days. A control to case ratio was chosen to achieve at least 80% power, with an alpha at .05 (medium effect size). The total final study sample size was 104; 30 cases and 74 controls.

Inclusion Criteria

Participants had to meet the following inclusion criteria:

1. Patient was hospitalized (defined as participants who had been assigned a room located on the oncology unit).
2. Primary oncology diagnosis that was diagnosed in any time frame with any type/stage/location of the cancer; palliative care participants who had a Do Not Resuscitate (DNR) status but were actively seeking treatment and not officially under the care of the hospice team, were included as long as they met other inclusion criteria
3. Patients may or may not have been receiving active cancer treatment (defined as chemotherapy/biotherapy, endocrine therapy, radiation, and/or surgery)
4. Alert and oriented to person, time, place, and situation (patients who were alert and oriented times three, or times four were included)
5. 18 years of age, or older
6. Able to speak, read, and understand the English language

Exclusion Criteria

Exclusions to the study included participants who were in hospice care, participants who required a "sitter" for 24 hour observation, or those requiring restraints during their hospital stay. Participants who met inclusion criteria were enrolled into the study and then if they acquired any of the prior listed exclusionary treatments during their hospital stay was removed from the study at that time.

Recruitment

Prospective Participants: Participants were recruited from two adult hospital oncology units. The recruitment of participants was solely the responsibility of the PI. The PI was informed that potential candidates were on the unit by registered nurses (RNs) on each oncology unit (see Appendix A, Data Collection Sheet #5). The PI conducted all enrollment, consent, and instrumentation activities. The PI informed the designated research assistant which patients had been enrolled into the study via secure email. The designated research assistant assisted the PI by collecting specific patient information when a patient was discharged (See Appendix A Data Collection Sheet #4). This data was then given back to the PI for review and analysis.

Retrospective Cases and Controls: Potential controls from both hospital sites were identified by a query of a data warehouse conducted by the human subjects institutional review board coordinator from one of the hospital sites. The list of potential cases from both sites was identified by Risk Management at one of the hospital sites. The list contained all hospital falls going back to 36 months. The PI then determined which patients met criteria by selecting patients starting with the most recent admission or the most recent fall first, and then working backwards. Patients were selected if they met study criteria.

Setting

Two oncology units in two different hospitals were utilized for this research study; one in the city of Detroit, Michigan and the other in the city of Macomb, Michigan. These hospitals were chosen due to the ease of accessibility and the higher numbers of hospital falls on their inpatient cancer units. These units were active in fall prevention activities and encouraged fall prevention research to take place on their units.

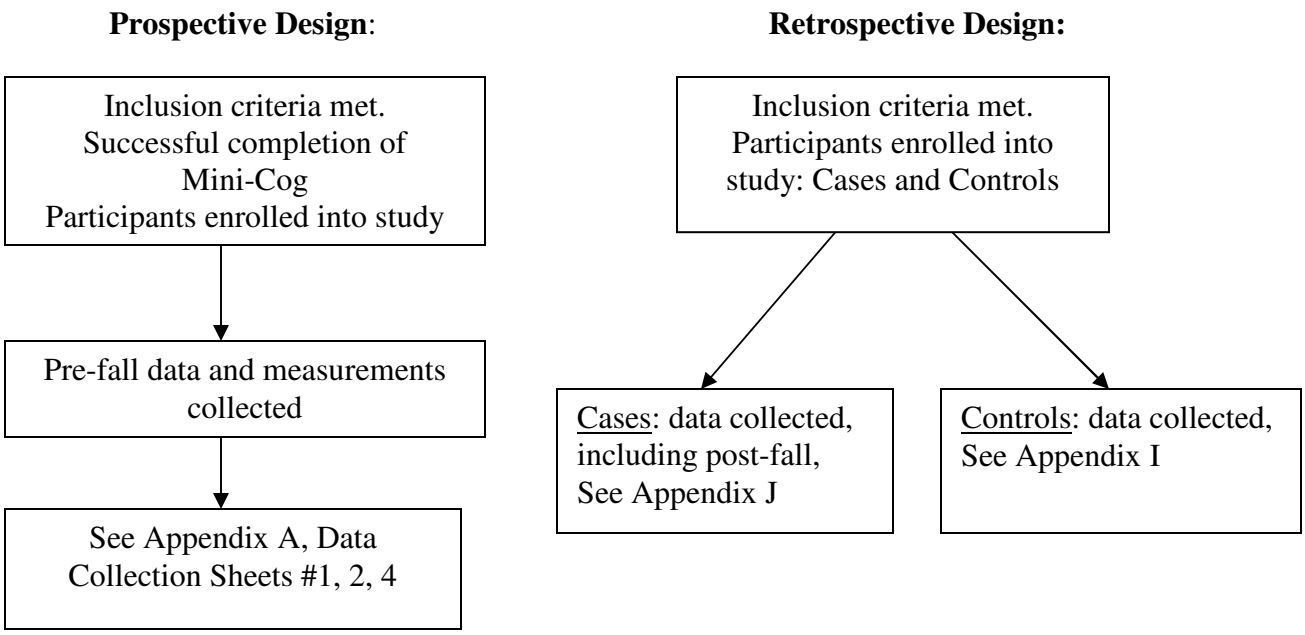


Figure 2: Sampling Tree

Major Study Variables

Prospective data: The major study variables of interest were **age**, and **gender; health state** which included: history of falls, altered elimination, vision impairment, hearing deficit, peripheral neuropathy, use of an assistive device, admitting diagnosis, type of cancer, depression, medication, co-morbidity, fatigue state, and performance score, general self-efficacy, and safe hospital activity fall prevention behaviors; and **healthcare system factor** which included: length of hospital stay, For purposes of this study, the major study variables are defined in Table 4.

Table 4. Definitions of Major Study Variables

Basic Conditioning Factors	Definition
Age and Gender	
Age	The numbers of years that a person has been alive
Gender	Being male or female
Basic Conditioning Factors - Health State	
History of falls	Any previous fall
Altered elimination	Current elimination problem/s, (urgency, frequency, or diarrhea)
Vision impairment	Any current vision impairment, such as the use of glasses for any reason
Hearing deficit	Hard of hearing from either ear
Assistive device	The use of any device to assist with ambulation
Peripheral neuropathy	Any numbness or tingling to any extremity
Type of cancer	Type of cancer the participant was diagnosed with
Admitting diagnosis	The reason that the participant was admitted to the hospital
High risk fall medications	Specific class of high risk fall medications or an individual high risk fall medication
Depression	A positive diagnosis of depression using the Geriatric Depression screen, or a diagnosis found in the electronic medical record
Comorbidity	A person who has more than one disease/condition
Cancer-related fatigue	Scores based on the Wu Cancer Fatigue Scale
Performance status	Functional status in the cancer patient

Table 4. (continued)

Basic Conditioning Factor - Healthcare System Factor	
Length of stay	The total number of days from hospital admission to hospital discharge
Self-Care Agency	
General self-efficacy	Coping with daily hassles, not behavior specific
Self-Care	
Safe hospital activity behaviors	Safe activity behaviors are specific fall prevention behaviors

Measurement of Major Study Variables

The following instruments were used to measure each of the major study variables presented in Table 4.

Basic Conditioning Factors: Age and Gender

- Age: measured in years
- Gender: male or female

Basic Conditioning Factors: Health State

History of a fall

- One prior fall was considered a history; documented as yes/no

Altered elimination

- Altered form of elimination (urgency, frequency, or diarrhea); documented as yes/no

Vision impairment

- Any vision impairment; documented as yes/no

Hearing deficit

- Any hearing deficit; documented as yes/no

Peripheral neuropathy

- Presence of neuropathy (arms/legs); documented as yes/no

Assistive device

- Use of at least one device to ambulate; documented as yes/no

Type of cancer

- Current or most recent cancer diagnosis; documented as yes/no

Admitting diagnosis

- Main hospital admitting diagnosis; documented as yes/no

High risk fall medications

- Use of one of the high risk fall medication categories/individual high risk fall medications. A one time dose was considered positive; documented as yes/no

Depression

- Depression is common in the cancer population and may be a risk factor for falling in the hospitalized cancer population. The Geriatric Depression Scale (GDS) (Yesavage et al., 1983) short form was used to measure depression. It is a 15 item self-report questionnaire that best describes how the patient feels over the past week. The 30 item Geriatric Depression Scale was developed to screen for depression in older adults and a score of greater than 10 almost always is indicative of depression. This scale has shown to have reliability with a Cronbach's alpha of .94, and a test-retest

reliability of .85. The main effects for the classification variable were highly significant at 99.48 showing the validity of the scale (Yesavage et al., 1983). The measure took five minutes or less to complete with each participant in the study (See Appendix D).

Comorbidity

- Comorbidities can increase mortality and are common as people age. The updated Charlson Comorbidity Index (with revised weights) was used to measure comorbidity in the patients in this study. The original Charlson Comorbidity Index was developed in 1987 based on data from hospitalized breast cancer patients (Hall, Ramachandran, Narayan, Jani, & Vijayakumar, 2004) and it is useful for classifying co-morbid conditions which alter the risk of mortality (Charlson, Pompei, Ales, MacKenzie, 1987) in longitudinal studies. According to Hall and colleagues (2004), the original Charlson Comorbidity Index has been validated in numerous studies, and good reliability scores have been reported. Nineteen conditions are included in the Index and each condition has a weighted score based on relative risk. Quan and colleagues, (2011) updated and validated the original Charlson Index and found that the updated weights showed good to excellent discrimination in predicting in-hospital mortality. This measure took five minutes or less to administer to each participant (See Appendix C).

Cancer-related fatigue

- Fatigue is common in the cancer population. Fatigue can cause weakness and may increase the risk for falls. It was important to identify if fatigue is a factor for those cancer patients admitted to the hospital setting. The Wu Cancer Fatigue Scale (WCFS) is a multi-dimensional 9-item questionnaire that addresses specific fatigue symptoms such as the physical, emotional, and psychological symptoms of fatigue. This measure has been tested in breast cancer patients. Reliability was shown to be .91 with a predictive validity of r=.73 (Wu, Wyrwich, & McSweeney, 2006). The Wu Cancer Fatigue Scale revised version was utilized in this study where levels of fatigue are measured on a 0-10 rating scale with higher scores suggesting higher amounts of fatigue, asking a person to report on a specific symptom that they experienced yesterday. Scores can range from 0-90. Cut-off scores were as follows: no fatigue (0), mild (1-3), moderate (4-7), and severe fatigue (8-10). This measure took five minutes or less to administer to each participant (See Appendix E).

Performance status

- The Karnofsky Performance Scale (KPS) is a scale that classifies cancer patients according to their functional impairments. The Index ranges from 0-100, with 0 being "dead" and 100 being "normal no complaints, no evidence of disease." Intervals increase from 0-100 by 10. Schag, Heinrich, and Ganz (1984) reported that the Karnofsky Scale had good inter-rater reliability, with a correlation of .89; construct validity was shown by 18 variables that were significantly correlated at the .05 level or less with the comparison physician's KPS scores. Inter-rater reliability was proven moderate with the Pearson correlation of .69; validity was shown to be high with

strong correlations for all 10 variables most closely related to physical functioning (Yates, Chalmer, & McKegney, 1980). This is a valuable tool as it relates to the activities that patients can perform. This measure took one minute or less to complete with each participant (See Appendix G).

Basic Conditioning Factor: Healthcare System Factor

- Length of stay: Total number of days spent in the hospital

Self-Care Agency: General Self-Efficacy

- Self-efficacy scales have been utilized in a variety of research studies. The concept of self-efficacy is an important component of fall prevention research as patient's behaviors may be dependent on patient's levels of self-efficacy. Specifically, the General Self-Efficacy Scale, by Schwarzer and Jerusalem is a 10 item questionnaire that was created to assess a general sense of perceived self-efficacy with scores ranging from 10-40. The aim of the scale is to predict coping with daily hassles, but does not measure specific behavior change. It has shown to be a valid and reliable tool with many of the Cronbach's alphas ranging from the high 80's, low 90's (Luszczynska, Scholz, & Schwarzer, 2005). This measure took 4 minutes or less to administer to each participant (See Appendix F).

Self Care: Safe Hospital Activity Questionnaire

- Using the conceptual model (Figure 1), fall prevention hospital activities were originally intended to be used to predict falls. To quantify and measure hospital activities, the Safe Hospital Activity Survey instrument was completed at enrollment. Currently, there are no instruments to measure self-care activities in the hospital setting as they relate to falls. This tool was developed by the PI to measure self-care

activity behaviors. Thus, the process of instrument development and testing is in its beginning stages. The construct of interest in each question is self-care (while hospitalized). The questions on the instrument are hospital activities that have been shown in the literature to decrease falls. Therefore, literature supports each question chosen. This instrument consists of 7 questions and uses a five point Likert scale. To test the development of the items, each item (complete survey) was subjected to an expert review panel at a Metro Detroit's area hospital. Cronbach's alpha was .61. This measure took five minutes or less with each participant (See Appendix H).

Screening Measure

Mini-Cog

- To screen for cognitive impairments at the start of the study the Mini-Cog was utilized. One of the screening variables for this study was impairments in cognitive functioning. For purpose of this study, impairments in cognitive functioning was defined as deficits in alert and orientation to person, time place, and situation. In the clinical setting, evaluation of cognition can be subjective if not enough time is spent with the patient. In addition, patients may not demonstrate cognitive impairments initially, or they may have mild impairment. This is relevant to this study, as patients who have mild cognitive impairments may, or may not, have the ability to make good decisions about their safety while they are in the hospital setting, or be able to follow, or remember to follow safety instructions given to them by the nursing staff. It was necessary to determine if there were any underlying impairments prior to enrollment in the study. For those who were not able to successfully pass the cognitive assessment prior to enrollment, they were <u>not</u> enrolled in the study as different

nursing interventions are needed to protect those patients who are not cognitively intact. The Mini-Cog was chosen compared to other well-known cognitive measures due to its ease of use and support in the literature that it is a better predictor of dementia than the Mini Mental State Examination (MMSE). Borson, Scanlan, Watanabe, Tu, & Lessig (2005) found in their study of 371 elderly community residents that the overall accuracy of detecting cognitive impairments was 83% for the Mini-Cog and 81% for the MMSE. The Mini-Cog uses a 3-item recall test, in addition to clock drawing test. The patient was instructed to listen carefully to three unrelated words. The patient then proceeds to draw the face of the clock with numbers, and place the hands of the clock to represent the specific time requested. The patient then was asked to recall the 3 previously stated unrelated words. This measure took 3 minutes or less to administer to each participant (See Appendix B).

Data Collection Procedure

Prospective Participants: For the prospective component of this study, the PI spoke with the RNs on each of the nursing units to initially identify potential participants and collected data using Appendix A, Data Collection Sheet #5 to determine which patients met initial study criteria. Once participants gave written and verbal consent and successfully completed the Mini-Cog screening tool, documentation of the data was collected on paper copies of the data collection using Appendix A, Data Collections Sheets #1 and #2 and recorded by the PI. A designated research assistant collected data from Appendix A, Data Collection Sheet #4 from all prospective participants. Data was locked in a briefcase when carried to and from the hospital and later transferred to a computer with a security password.

Retrospective Case and Controls: For the retrospective component of this study, cases were randomly selected by the PI from a list generated by a Risk Management representative starting from the most recent and working backwards. Controls were randomly selected by the PI from a list generated by the human subject review board coordinator, taken from the hospital warehouse where data is stored. The PI accessed the hospital electronic medical record to determine if each of the randomly selected participants met study criteria. Appendices I and J were the forms used to collect the data. If the participant was selected, paper copies of the data collection forms were used and then later transferred to a computer with a security password. After transfer to the computer, paper that was used for testing was kept secure, and will later be shredded. All identifying information was de-identified prior to transfer to the computer.

Data Analysis

Data was entered into SPSS 18 which was used for statistical analysis.

Specific Aim 1: To describe the characteristics of falls that occur in hospitalized patients diagnosed with cancer.

Analysis: Descriptive statistics (total numbers/percentages)

Specific Aim 2: To describe the basic conditioning factors, self-care agency, and self care in a prospective sample of hospitalized patients diagnosed with cancer who do not fall.

Analysis: Descriptive statistics (means, standard deviations, range values, total numbers/percentages)

Specific Aim 3: To describe the basic conditioning factors in a retrospective sample of hospitalized patients diagnosed with cancer who fall and who do not fall.

Analysis: Descriptive statistics (means, standard deviations, range values, total numbers/percentages)

Specific Aim 4: To examine the relationships between the basic conditioning factors in hospitalized patients diagnosed with cancer who fall and who do not fall.

Analysis: Independent Samples T-test and Chi-square

Specific Aim 5: To identify the basic conditioning factors that predict falls in hospitalized patients diagnosed with cancer.

Analysis: Logistic Regression

CHAPTER 4
Results

The sample description and findings for the prospective and retrospective components of the study are reported for each specific aim. Specific Aim 2 reflects the prospective component of the study, while specific aims 1, 3, 4, and 5 describe the retrospective component of the study.

Specific Aim #1: To describe the characteristics of falls that occur in hospitalized patients diagnosed with cancer.

In the retrospective sample, the total number of falls was 30 cases, while those who did not fall were 74 cases. Characteristics of falls included the time and the location of falls, and the number and types of fall injuries. One participant fell three times during her hospital stay, and three participants each fell twice. Multiple falls accounted for 30% of the total falls.

Falls were categorized as either not witnessed or witnessed. Non-witnessed falls were defined as falls that occurred when hospital staff was not present. Witnessed falls were defined as falls that took place in the presence of hospital staff. Ten (33.3%) of the participants had non-witnessed falls, as compared to three (10.0%) whose falls were witnessed by hospital staff. Six participants (20.0%) had non-hospital staff in the room at the time that they fell.

Table 5. Time and Location of Falls in Retrospective Sample (n=30)

	Fall	
Time	N	%
[1]Mornings	6	20.0
[2]Afternoons	15	50.0
[3]Midnights	9	30.0
Location		
Bathroom	7	23.3
Participant Room	17	56.7
Missing	6	20.0

[1]Morning is defined as 7:01am-3:00pm
[2]Afternoon is defined as 3:01pm-10:59pm
[3]Midnight is defined as 11:00pm-7:00am

Time and location of falls are shown in Table 5. Of the 30 participants that experienced a fall, 6 (20.0%) fell in the morning, 15 (50.0%) fell on afternoons, and 9 (30.0%) fell during the midnight time period. Of the 30 participants who experienced a fall, 7 (23.3%) fell in the bathroom, and 17 (56.7%) fell in the participant's room. Documentation was missing for 6 (20.0%) of the participants who fell.

Table 6. Number of Fall Injuries in Retrospective Sample (n=6)

Injury[1]	N	%
No	20	66.7
Yes	6	20.0
Missing data	4	13.3

[1]Injury is defined as type of bodily harm caused from the fall.

Table 6 presents the number of fall injuries. Of the 30 participants who experienced a fall, 6 (20.0%) acquired an injury from their fall as compared to 20 (66.7%) of participants who did not. Injury data was not found for 4 (13.3%) of the falls. Five (83.3%) participants were attempting to meet their elimination needs when they fell and were injured. Four participants (66.7%) who were injured were male. Three (50.0%) of the participants who were injured has either someone (hospital or non-hospital stay with them in the room at the time of the fall.

Table 7. Categories of Fall Injuries in Retrospective Sample (n=6)

		Fall	
Injury Type	Location	N	%
Hit body part	head/forehead	2	33.3
Swelling	forehead	1	16.7
Abrasion	forehead	1	16.7
Laceration	eye/wrist/elbow	2	33.3

Table 7 presents data on location and type of fall injury. Fall injuries were defined as minor or moderate, as no serious injuries occurred. Minor injuries included participant's hitting their head/forehead, forehead swelling, and an abrasion to the forehead. Moderate injury was defined as lacerations to locations such as the eye/wrist/elbow. Of the 6 (20.0%) participants who experienced an injury, 2 (33.3%) hit their head/forehead (without any further specification of injury); one (16.7%) had swelling to the forehead, one (16.7%) had an abrasion to the forehead, and two (33.3%) participants had a fall that resulted in eye/wrist/elbow lacerations. Of those six (20.0%) participants who were injured, it was documented that five of those falls were related to participants trying to meet their elimination needs.

Table 8. Time and Location of Fall Injuries in Retrospective Sample (n=6)

	Fall	
Time and Location	N	%
Time		
[1]Mornings	3	50.0
[2]Afternoons	0	0.0
[3]Midnights	3	50.0
Location		
Bathroom	3	50.0
Participant Room	1	16.7
Missing	2	33.3

[1]Morning is defined as 7:01am-3:00pm
[2]Afternoon is defined as 3:01pm-10:59pm
[3]Midnight is defined as 11:00pm-7:00am

Table 8 shows the time and location of falls for participants who suffered fall injuries. Of the 6 (20.0%) participants who were injured, 3 (50.0%) fell during the morning and 3 (50.0%) fell during midnights. There were 0 (0.0%) falls in the afternoon. Of the 6 (20.0%) participants who were injured, 3 (50.0%) fell in the bathroom, 1 (16.7%) participant fell in the participant's room and 2 (33.3%) were not documented in the medical record.

Specific Aim 2: To describe the basic conditioning factors, self-care agency, and self care in a prospective sample of hospitalized patients diagnosed with cancer who do not fall.

Table 9. Basic Conditioning Factors of Prospective Sample-No Falls (n=32)

Variable	Mean (SD)	Inclusive Range	Number	Percent
Age (years)	62.0 (14.9)	27-85	---	---
Gender				
Females	---	---	20	62.5
Males	---	---	12	37.5
History of falls	---	---	19	59.4
Altered elimination	---	---	9	28.1
Vision impairment	---	---	6	18.8
Hearing deficit	---	---	8	25.0
Peripheral neuropathy	---	---	21	65.6
Use of assistive device[1]	---	---	6	19.4
Depression	3.66 (3.36)	0-15	---	---
Comorbidity	4.28 (1.91)	2-7	---	---
Fatigue	36.03 (21.39)	0-79	---	---
Performance	73.13 (14.24)	50-90	---	---
Length of stay	9.1 (6.76)	2-26	---	---

[1]valid percentage, missing data

Table 9 depicts the personal characteristics of the prospective sample. Twenty participants were female (62.5%), and 12 (37.5%) were male. The mean age was 62 (±14.9) years, with the youngest being 27 years old and the oldest 85 years old. Participants had to have a minimum length of stay of 2 days to be included in the study and the longest hospital stay was 26 days. The average length of stay was 9.1 (±6.76) hospital days.

Fall risk factors were included in the sample of prospective participants: 19 (59.4%) had a history of a previous fall, 9 (28.1%) had altered elimination, six (18.8%) had vision impairment, 8 (25.0%) had a hearing deficit, 21 (65.6%) had peripheral neuropathy and six (19.4%) used an assistive device.

Depression. The minimum total score as reported by the participants was zero; maximum total score was 15, with an overall mean of 3.66 (±3.36). Three (2.2%) participants each had a score of zero, and 1 (0.7%) participant had a score of 15. Twenty-six (81.3%) of the participants had a score that was not suggestive of depression (scores from 0-5). Six participants had scores that were suggestive of depression (scores >5), and of those scores that were greater than 5, two participants had scores that were almost always indicative of depression (>10).

Comorbidity. Only 51 (37.5%) participants with solid tumor metastases were included in the Metastases category, where as participants that had a non-solid tumor type diagnosis such as leukemia, lymphoma, or multiple myeloma were excluded; however these participants were included in all other categories. Twenty-four (17.6%) participants had COPD, 5 (3.7%) had "CHF", or "plegia", or "rhematic" (conditions). Two (1.5%) participants each had "renal", or "mild liver", or HIV. Only one (0.7%) participant had "diabetes end organ" (condition).

Cancer-related fatigue. The mean cancer-fatigue scores for this sample was 36.03(±21.39), with an inclusive range of 0-79, with a possible range from 0-90. The higher the score the more fatigue.

Performance. The scale is scored in units of 10 from 0 "dead" to 100 "normal no complaints, no evidence of disease." The minimum total score for the participants in this study was 50, "requires considerable assistance and frequent medical care," and the maximum was 90, "able to carry on normal activity; minor signs or symptoms of disease." Five (15.6%) of the participant had a performance score of 50-"requires considerable assistance and frequent medical care, "4 (12.5%) had a score of 60-"requires occasional assistance, but is able to care for most of personal needs", 8 (25.0%) had a score of 70-"care for self; unable to carry on normal activity or do active work," 6 (18.8%) had a score of 80-"normal activity with effort; some signs or symptoms of disease," and 9 (28.1%) participants had a score of 90-"able to carry on normal activity; minor signs or symptoms of disease."

Type of cancer. Twelve participants (6 with lymphoma; 6 with lung cancer) comprised 37.5% of the sample, with 5 (15.6%) having a diagnosis of multiple myeloma, three (9.4%) having breast cancer, 2 (6.3%) each having pancreatic cancer and stomach cancer, and 1 (3.1%) participant each having colorectal, endometrial, esophageal, prostate, leukemia, ovarian, vaginal, and peritoneal cancers.

Admitting diagnosis. The majority of patients 8 (25.0%) were admitted to the hospital with a diagnosis of fever/infection, or an "Other" diagnosis. Five (15.6%) were admitted for surgery, three (9.4%) participants with GI/GU problems, two (6.3%) each with pain or dehydration, and one (3.1%) participant each were admitted with abnormal labs, respiratory diagnosis, weakness, or bleeding.

High risk fall medications. Six classes were chosen as having the highest number of participants (>25%) who received these drugs during their hospital stay. Participants could have received these drugs once, or multiple times. Twenty-two (68.8%) participants received a narcotic, 17 (53.1%) received an antiemetic, 13 (40.6%) received an antihypertensive, 11 (34.4%) received a benzodiazepines, 10 (31.3%) received a steroid, and 9 (28.1%) received a diuretic. More importantly, participants were likely to receive combinations of these drugs, with an average of 3.75 medications received. Twenty-one (65.6%) participants received 3 or more medications.

Self-Care Agency and Self-Care

Self-care agency was operationalized as general self-efficacy. The mean general self-efficacy score for this sample was 34.22 (± 4.29), with an inclusive range of 28 to 40. Scores on can range from 10-40. Self-care was operationalized as scores from the Safe Hospital Activity Questionnaire**.** The overall mean score for this sample 28.72 (±5.78), with an inclusive range of 15-35. Scores can range from 7-35.

Specific Aim 3. To describe the basic conditioning factors in a retrospective sample of hospitalized patients diagnosed with cancer who fall and who do not fall.

Table 10 below presents the basic conditioning factors from the retrospective sample. The mean age was 64.1 (±14.6), with a range from 21-96 years. Fifty-nine of 104 participants in the study were females (56.7%), and there were 45 males which accounted for 43.3% of the sample. Twenty-four (23.1%) were found to have a diagnosis of depression. The average length of stay was 8.5 days (±5.9), with a range from two to 34 days. Complete data was missing on the following six fall risk characteristics: 17 (81.0%) participants had a previous history of a fall, 29 (28.2%) with some form of altered elimination, 60 (89.6%) had a vision

impairment, 23 (67.6%) had peripheral neuropathy, and 33 (50.0%) participants used an assistive device.

Table 10. Basic Conditioning Factors of Retrospective Sample (n=104)

Variable	Mean(SD)	Inclusive Range	Number	Percent
Age (years)	64.1(14.6)	21-96	---	---
Gender				
Females	---	---	59	56.7
Males	---	---	45	43.3
History[1] of falls	---	---	17	81.0
Altered elimination[1]	---	---	29	28.2
Vision deficit[1]	---	---	60	89.6
Hearing deficit[1]	---	---	17	73.9
Peripheral neuropathy[1]	---	---	23	67.6
Use of assistive device[1]	---	---	33	50.0
Diagnosis of Depression				
No	---	---	80	76.9
Yes	---	---	24	23.1
Length of stay (days)	8.5(5.9)	2-34	---	---

[1]valid percentages, missing data

Table 11. Type of Cancer in Retrospective Sample (n=104)

Variable	N	%
Type of Cancer		
Breast	25	24.0
Lung	16	15.4
Lymphoma	15	14.4
Leukemia	9	8.7
Colorectal	9	8.7
Endometrial	6	5.8
Multiple Myeloma	3	2.9
Ovarian	3	2.9
Prostate	3	2.9
Laryngeal	3	2.9
Pancreatic	2	1.9
Tonsillar	2	1.9
Esophageal	1	1.0
Bladder	1	1.0
Gallbladder	1	1.0
Cervical	1	1.0
Renal	1	1.0
Sarcoma	1	1.0
Tongue	1	1.0
Stomach	1	1.0

Table 11 presents types of cancer. The majority of participants in the study had breast cancer, where 25 participants accounted for 24.0% of the total sample. Lung cancer was the second most common with 16 (15.4%) participants having this diagnosis. Fifteen (14.4%) participants had lymphoma, 9 (8.7%) each had leukemia or colorectal cancer, six (5.8%) had endometrial cancer, 3 (2.9%) each had multiple myeloma, ovarian, prostate, or laryngeal cancer. Two (1.9%) participants each had pancreatic or tonsillar cancer, and one (1.0%) participant each had a cancer diagnosis of ether esophageal, bladder, gallbladder, cervical, renal, sarcoma, tongue, or stomach cancer.

Table 12. Admitting Diagnoses in Retrospective Sample (n=104)

Variable Admitting Diagnosis	N	%
Pain	20	19.2
Fever/infection	19	18.3
GI/GU	14	13.5
Respiratory	13	12.5
Dehydration	9	8.7
Chemotherapy	9	8.7
Abnormal labs	8	7.7
Weakness	7	6.7
Bleeding	4	3.8
Other	1	1.0

Table 12 presents admission diagnoses for the study participants. The most frequently recorded admission diagnosis was pain with 20 (19.2%) participants having this recorded in their chart, followed by 19 (18.3%) participants having fever/infection, 14 (13.5%) having a GI/GU diagnosis, 13 (12.5%) had a respiratory condition, 9 (8.7%) participants each had dehydration upon admission, or were admitted for chemotherapy, 8 (7.7%) were admitted with some type of abnormal blood lab value/s, 7 (6.7%) were admitted for weakness, 4 (3.8%) for bleeding, and 1 (1.0%) participant had a diagnosis categorized as "Other."

Table 13. Comorbidities in Retrospective Sample (n=104)

Variable Comorbidity	N	%
Metastasis	38	59.4
COPD	18	17.3
CHF	4	3.8
Plegia	3	3.0
Rheumatoid	3	2.9
Mild Liver	1	1.0
HIV/AIDS	1	1.0
Total Numbers of Co-morbidities		
Zero	53	51.0
One	35	33.7
Two	14	13.5
Three	---	---
Four	1	1.0

Table 13 presents individual and total number of co-morbidities. Of the 7 co-morbidities, 38 (59.4%) participants had "metastasis", followed by 18 (17.3%) participants having "COPD", four (3.8%) having "CHF," three (3.0%) each having "plegia", or "rheumatoid", and one (1.0%) each having mild liver or "HIV/AIDS." The majority of participants had zero comorbidities, 53 (51.0%), 35 (33.7%) participants had one comorbidity, 14 (13.5%) had two, and 1 (1.0%) participant had four co-morbidities.

Table 14. High Risk Fall Medications in Retrospective Sample (n=104)

Variable Medication Class/Individual Medication	N	%
Narcotics	70	67.3
Antihypertensives	65	62.5
Antiemetics	53	51.0
Steroids	37	5.6
Diuretics	32	30.8
Benzodiazepenes	29	27.9
Antidepressants	24	23.1
Laxatives	21	20.2
Chemotherapy	19	18.3
Antiepileptics	15	14.4
Diphenhydramine	12	11.5
Zolpidem	11	10.6
Midazolam	8	7.7
Antipsychotics	4	3.8
Muscle relaxants	4	3.8

Table 14 presents high fall risk medication classes/individual medications. Participants may have received these drugs one or more times during their hospital stay. Narcotics were most frequently received with 70 (67.3%) receiving them, 53 (51.0%) participants received antiemetics, 37 (35.6%) received a steroid, 32 (30.8%) received a diuretic, 29 (27.9%) received a

benzodiazepine, 24 (23.1%) received an antidepressant, 21 (20.2%) received a laxative, 19 (18.3%) received chemotherapy, 15 (14.4%) received an antiepileptic, 12 (11.5%) received diphenhydramine, 11 (10.6%) received zolpidem, 8 (7.7%) received midazolam, 4 (3.8%) participants each received antipsychotics or muscle relaxers. Midazolam, a benzodiazepine was separated from the category of benzodiazepines because it is specially used for anesthesia purposes.

Table 15. Total Numbers of High Risk Fall Medications in Retrospective Sample (n=104)

Variable Medication Class/Individual Medications	N	%
Zero	4	3.8
One	5	4.8
Two	19	18.3
Three	21	20.2
Four	22	21.2
Five	16	15.4
Six	8	7.7
Seven	4	3.8
Eight	2	1.9
Nine	3	2.9
Ten	1	1.0

Table 15 presents the total numbers of high risk fall medication classes/individual medications that participants received, categorized from zero to ten. The highest number of high fall risk medication combinations was 4, received by 22 participants which accounted for 21.2% of the sample. Three medications accounted for the second highest combination with 21 (20.2%) participants, followed by 19 (18.3%) of participants taking two combinations of drugs, 16 (15.4%) participants a total of 5 high fall risk medications/individual medications, and 8 (7.7%) participants were on a combination of 6 medications. All other categories had five or less participants in each category: 5 (4.8%) participants each received one, 4 (3.8%) each received either zero or seven, three (2.9%) participants received 9, two (1.9%) participants received 8, and 1 (1.0%) participant received a total of 10 high fall risk medications/individual medications.

Specific Aim 4: To examine the relationships between the basic conditioning factors in hospitalized patients diagnosed with cancer who fall and who do not fall. Table 16 presents this data.

Table 16.
Falls and Basic Conditioning Factors in Retrospective Sample (n=104)

Variable	No Fall M (SD)	N	%	Fall M (SD)	N	%	test statistic (p value)
Age	63.5 (15.1)	---	---	65.5 (13.7)	---	---	t=-.621(.536)
Gender							
Females	---	42	56.8	---	17	56.7	---
Males	---	32	43.2	---	13	43.3	χ^2=.000(.993)
History of a fall[1]	---	7	63.6	---	10	100.0	χ^2 = 4.492(.034)*
Altered Elimination[1]	---	25	33.8	---	4	13.8	χ^2= 4.116(.042)*
Vision Impairment[1]	---	43	89.6	---	17	89.5	χ^2=.000(.989)
Hearing Deficit[1]	---	13	68.4	---	4	100.0	χ^2=1.709(.191)
Peripheral Neuropathy[1]	---	17	68.0	---	6	66.7	χ^2=.005(.942)
Use of Assistive Device[1]	---	16	37.2	---	17	73.9	χ^2=8.075 (.004)**
Length of hospital stay	7.1 (3.7)	---	---	11.9 (8.6)	---	---	t=-.403(.000)**

*p <.05
**p< .01
[1]valid percentages, missing data

Table 16 presents the relationship between conditions factors and fall status. There was no difference in age between those who fell and those who did not (t=-.621, p=.536).

A Pearson Chi-Square test was used to determine if there was a relationship between categorical variables and fall status. Of those who had a fall, female falls totaled 17 and accounted for 56.7%, which is greater than when compared to males, who had a total number of 13 (43.3%) falls. There was no significant difference between gender and fall status (p=.993). Vision impairment (p=.989), hearing deficit (p=.191), and peripheral neuropathy (p=.942) were not statistically associated with falls. The basic conditioning factors that were associated with falls were: previous history of a fall (p=.034), altered elimination (p=.042), use of assistive devices (.004), and length of hospital stay (p=.000).

Table 17. Falls and Type of Cancer in Retrospective Sample (n=104)

Variable	No Fall		Fall		
Type of Cancer	N	%	N	%	χ^2(p value)
Breast	19	25.7	6	20.0	.377(.539)
Lung	8	10.8	8	26.7	4.123(.042)*
Lymphoma	11	14.9	4	13.3	.041(.840)
Leukemia	7	9.5	2	6.7	.211(.646)
Colorectal	8	10.8	1	3.3	1.51(.219)
Endometrial	4	5.4	2	6.7	.062(.803)
Multiple Myeloma	3	4.1	0	0.0	1.252(.263)
Ovarian	1	1.4	2	6.7	2.153(.142)
Prostate	3	4.1	0	0.0	1.252(.263)
Laryngeal	2	2.7	1	3.3	.030(.862)
Pancreatic	2	2.7	0	0.0	.827(.363)
Tonsillar	0	0.0	2	6.7	5.03(.025)*
Esophageal	1	1.4	0	0.0	.409(.522)
Bladder	1	1.4	0	0.0	.409(.522)
Gallbladder	1	1.4	0	0.0	.409(.522)
Cervical	1	1.4	0	0.0	.409(.522)
Renal	0	0.0	1	3.3	2.491(.115)
Sarcoma	0	0.0	1	3.3	2.491(.115)
Tongue	1	1.4	0	0.0	.409(.522)
Stomach	1	1.4	0	0.0	.409(.522)

*p<.05

Table17 shows falls and their association to the type of cancer a participant had. Twenty types of different cancer were found, however only two were significantly associated with falls. Both lung cancer (p=.042), and tonsillar cancer (p=.025) were found to be significantly related to falls. The 18 others cancer types were not significantly associated with falls.

Table 18. Falls and Admitting Diagnosis in Retrospective Sample (n=104)

Variable	No Fall		Fall		
Admitting Diagnosis	N	%	N	%	χ^2(p value)
Pain	13	17.6	7	23.3	.457(.499)
Fever/infection	15	20.3	4	13.3	.688(.407)
GI/GU	10	13.5	4	13.3	.001(.981)
Respiratory	10	13.5	3	10.0	.241(.624)
Dehydration	4	5.4	5	16.7	3.424(.064)
Chemotherapy	7	9.5	2	6.7	.211(.646)
Abnormal labs	6	8.1	2	6.7	.062(.803)
Weakness	5	6.8	2	6.7	.000(.987)
Bleeding	3	4.1	1	3.3	.030(.863)
Other	1	1.4	0	0.0	.409(.522)

Table 18 presents falls and admitting diagnoses of the participants. Ten different admitting diagnoses were found. Of those 10 admitting diagnoses, none of them were found to be associated with falls.

Table 19. Falls and Comorbidities in Retrospective Sample (n=104)

Variable	No Fall		Fall		
Comorbidity	N	%	N	%	χ^2(p value)
CHF	2	2.7	2	6.7	.907(.341)
Plegia	1	1.4	2	7.4	2.517(.113)
COPD	14	18.9	4	13.3	.465(.495)
Mild Liver	0	0.0	1	3.3	2.491(.115)
Metastasis	22	48.9	16	84.2	6.91(.009)*
Rheumatic	1	1.4	2	6.7	2.153(.142)
HIV/AIDS	0	0.0	1	3.3	2.491(.115)

*p<.01

Table 19 presents co-morbidities and their individual association to falls. Of the 7 comorbidities listed above, only metastasis was significantly associated with falls (p=.009).

Table 20. Falls and Comorbidity Totals in Retrospective Sample (n=104)

Variable	No Fall		Fall		
Comorbidity Totals	N	%	N	%	χ^2(p value)
Zero	42	56.8	11	36.7	3.447(.063)
One	23	31.1	12	40.0	.760(.383)
Two	8	10.8	6	20.0	1.547(.214)
Three	---	---	---	---	---
Four	0	0.0	1	3.3	2.491(.115)

Table 20 presents the total number of comorbidities for each participant to determine if the number of comorbidities had an association with falls. Categories were separated from zero to four. No participants had three co-morbidities. None of the comorbid totals were significantly associated with falls.

Table 21. Falls and Depression in Retrospective Sample (n=104)

Variable	No Fall		Fall		
Depression	N	%	N	%	χ^2(p value)
No	56	75.7	24	80.0	
Yes	18	24.3	6	20.0	.225(.635)

Table 21 presents depression and falls. Of the 30 participants who had a fall, 6 (20.0%) had a documented diagnosis of depression. Depression was not significantly different between those who fell and those who did not (p=.635).

Table 22.
Falls and Relationship to High Risk Fall Medications in Retrospective Sample (n=104)

Variable	No Fall		Fall		
High Risk Fall Medication[1]	N	%	N	%	χ^2(p value)
Narcotics	47	63.5	23	76.7	1.678(.195)
Antihypertensives	50	67.6	15	50.0	2.811(.094)
Antiemetics	41	55.4	12	40.0	2.027(.155)
Steroids	27	36.5	10	33.3	.093(.761)
Diuretics	29	39.2	3	10.0	8.538(.003)**
Benzodiazepenes	23	31.1	6	20.0	1.303(.254)
Antidepressants	15	20.3	9	30.0	1.138(.286)
Laxatives	16	21.6	5	16.7	.325(.568)
Chemotherapy[2]	17	23.0	2	6.7	3.801(.051)
Antiepileptics	7	9.5	8	26.7	5.121(.024)*
Diphenhydramine	10	13.5	2	6.7	.980(.322)
Zolpidem	5	6.8	6	20.0	3.958(.047)
Midazolam[3]	8	10.8	0	0.0	3.514(.061)
Antipsychotics	3	4.1	1	3.3	.030(.863)
Muscle relaxants	3	4.1	1	3.3	.030(.863)

[1]Medications are listed in the chart above if the participant received them 24 hours prior to their fall. For those that did not have a fall, all medications given at least one time during the hospital stay were included.
[2]Chemotherapies and biotherapies were combined.
[3] Midazolam is a benzodiazepine, but was categorized separately.
*p< .05
**p<.01

Table 22 presents high risk fall medications/individual medications and their association to falls. Fall outcomes had the highest association with the medication class of diuretics, p=.003. Significant associations were also seen between fall outcomes and antiepileptics p=.024. All other high risk medications listed above did not show any association with falls.

Table 23.
Falls and Numbers of High Risk Fall Medications in Retrospective Sample (n=104)

Variable	No Fall		Fall		
High Risk Fall Medication	N	%	N	%	χ^2(p value)
Zero	3	4.1	1	3.3	.030(.863)
One	4	5.4	1	3.3	.200(.655)
Two	9	12.2	10	33.3	6.408(.011)*
Three	16	21.6	5	16.7	.325(.568)
Four	17	23.0	5	16.7	.509(.476)
Five	10	13.5	6	20.0	.690(.406)
Six	5	6.8	3	10.0	.316(.574)
Seven	4	5.4	0	0.0	1.686(.194)
Eight	2	2.7	0	0.0	.827(.363)
Nine	3	4.1	0	0.0	1.252(.263)
Ten	1	1.4	0	0.0	.415(.519)

*p< .05

Table 23 presents total numbers of high risk fall medication classes/individual medications from zero to 10. A combination of two was significantly associated with falls (p=.05). All other combinations were not significantly associated with falls.

Specific Aim 5: To identify the basic conditioning factors that predict falls in hospitalized patients diagnosed with cancer.

The four independent variables that were selected for the model were: lung cancer, diuretics, antiepileptics, and length of stay. They were selected because they were found to be significantly associated with falls and a complete data set was found with each of these variables. Multicollinearity was used to test the relationships between the independent variables (using collinearity diagnostics procedure). When all independent variables were tested, all tolerance values were greater than 0.1, and VIFs were approximately 1, indicating that multicollinearity was not an issue with the variables selected.

Table 24. Logistic Regression Predicting Likelihood of Hospital Falls (n=104)

Variable						95% C.I. for EXP (B)		
	B	**S.E.**	**Wald**	**df**	**p**	**Odds Ratio**	**Lower**	**Upper**
Lung cancer	1.35	.66	4.20	1	.04	3.87	1.06	14.11
Diuretics	-2.07	.75	7.74	1	.01	.13	.03	.54
Antiepileptics	1.2	.67	3.21	1	.07	3.33	.89	12.45
Length of stay	.16	.05	10.95	1	.00	1.17	1.07	1.28
Constant	-2.3	.52	19.81	---	.00	.10	---	---

Table 24 shows the logistic regression that was performed to determine the predictors of hospital falls. The model contained 4 independent variables (lung cancer, diuretics, antiepileptics, and length of stay). The model was statistically significant, $X^2(4, N=104) = 32.7$, $p<.001$, which suggests that the model was able to identify factors associated with falls. The model as a whole explained between 27% (Cox and Snell R square) and 38.6% (Nagelkerke R

squared) of the variance in falls, and classified 80.8% of cases. As shown in the table, three of the independent variables lung cancer, diuretics, and length of stay contributed to the model. The strongest predictor of falls was lung cancer, recording an odds ratio of 3.87. This indicated that participants who had a diagnosis of lung cancer were 3.87 times more likely to fall than those who did not have a lung cancer diagnosis controlling for all other factors in the model. The odds ratio for diuretics (.126) which is less than 1, indicating that when diuretics were taken, participants were .126 times less likely to fall, controlling for other factors in the model.

CHAPTER 5
Discussion

This chapter discusses the key findings of the study as they relate to the specific aims. A case-control design was used to better understand the factors that played a role in cancer patients who fell in the hospital setting. Elements of Orem's theory of self-care were used as a guide and concepts were chosen to understand the relationships between falls and the selected variables associated with falls. Variables were selected based on their established connection with hospital falls as reported in the literature. Determining these relationships for oncology patients in the hospital setting is important as evidence has demonstrated that a diagnosis of cancer has shown to be a risk factor for falling/falls with injury (Alcee, 2000; Chu et al., 1999; Fischer et al., 2005; Hendrich et al., 1995; Hitcho et al., 2004; Rohde, Myers, and Vlahov, 1990; and Stevenson, Mills, Welin, and Beal, 1998). This section provides a summary of the study and its findings and recommendations for future research on hospital falls in the cancer population.

Sample

The final sample used to determine predictors of falls included a total of 74 retrospective controls and 30 retrospective cases. In addition, data from 32 participants were collected prospectively. Two hospitals were used to collect the data to be able to have access to more participants; however, when participants did not experience a fall at either hospital site, the design of the study was changed; two hospital sites were still utilized for data collection. For the prospective data, 26 (81.3%) participants were from hospital site A, and 6 (18.8%) participants were from hospital site B. For the retrospective data, 98 (94.2%) participants were from hospital site A, and 6 (5.8%) participants were from hospital site B.

Specific Aim 1: To describe the characteristics of falls that occur in hospitalized patients diagnosed with cancer.

The total number of falls (cases) was 30, compared to the 74 participants who did not fall. One participant fell three times, and the other three participants fell twice, all during the same hospital admission, accounting for 30% of the sample. Multiple falls in the same patient have been noted in other hospital fall prevention studies (Capone et al., 2010; Fischer et al., 2005; Hitcho et al., 2004). The majority of falls were non-witnessed falls; therefore, nursing staff was not present at the time of the falls. Half of the total number of falls occurred on the afternoon shift (3:01pm-10:59pm) and more than half occurred in the patient's room. Capone (2010) found the majority of hospitalized cancer patients fell in the patient's room. Hitcho and colleagues (2004) also found that the participant's room was the location of the majority of the falls in her study.

Of the 30 falls, it was documented that six falls resulted in participant injury. Falls injuries were defined as minor or moderate, as no severe injuries occurred. Minor injuries included participant's head/forehead hitting the floor, forehead swelling, and an abrasion to the forehead. Moderate injury was defined as lacerations to locations such as the eye/wrist/elbow. Of the six participants who were injured in this study, five of those falls were related to participants trying to meet their elimination needs. Hitcho et al. (2004) reported that falls related to patients trying to meet their elimination needs increased the risk of suffering a fall-related injury. Krauss et al. (2005) reported that patients who fell in the bathroom were more like to suffer an injury compared to those fell in the patient's room. Three studies support the fact that patient fall are related to patients trying to meet their elimination needs (Capone 2010, Fisher et al., 2005; Hendrich, 2006).

Specific Aim 2. To describe the basic conditioning factors, self-care agency, and self-care in a prospective sample of hospitalized patients diagnosed with cancer who do not fall.

The prospective data was separated from the data collected retrospectively due to differences in design and the way the data was collected. Results collected from each design are reported separately in this paper. Predictors of falls were unable to be determined from this prospective sample of participants since none of these participants fell; however, valuable information was still gained by knowing the characteristics of hospitalized cancer participants who did not experience a fall, as few studies have been undertaken with this unique population.

Basic Conditioning Factors: Age and Gender

For the prospective sample, ages ranged from 27-85 with an average age of 62 years. Gender was not equally distributed with 62.5% of the sample females and 37.5% males.

Basic Conditioning Factors: Health State

The most frequent cancer diagnoses were lung cancer and lymphoma which accounted for almost 40% of the prospective sample. The number of participants diagnosed with lung cancer was not surprising as lung cancer is second in reported new cancer cases (American Cancer Society, 2014). The majority of participants had cancer that had metastasized, or spread to other parts of the body, outside of its origin. The most common reason for admission was fever/infection (25%), with another 25% of participants having an "Other" diagnosis, both totaling half of the participants. This was also not unexpected due to the risk for fever and infection which occurs 2-3 weeks post chemotherapy when patients reach their nadir and are at their lowest neutrophil blood counts (highest risk for infection) and return to the hospital for antibiotic treatment. Over half (59.4%) of the participants stated that they had a previous fall. Almost 30% of the prospective participants reported some type of elimination issue with which

they were currently dealing with. Vision impairment was noted in 18.8% of the sample, with 25% having a hearing deficit, 65.6% reporting that they currently have peripheral neuropathy, and 19.4% reporting the use of some form of assistive device. Over half, 68.8% received some form of a narcotic at least once, followed by slightly over 50% who received an antiemetic.

Depression has shown to be a common psychological response in someone who has cancer (Brown et al., 2009); however, the majority of participants' depression scores were not suggestive of depression. Total scores indicated that six participants might have depression. Of those six, two had a score high enough to almost always indicate depression. Lack of high scores on the depression scale in this study might be a reason that this group of participants did not fall.

Total fatigue scores varied greatly, from one participant who did not have any fatigue to one participant who indicated their fatigue was 79 points out of 90. Higher scores indicated more fatigue; however, high fatigue scores were not seen on average in this group of participants. The average fatigue score was 36.03. Fatigue has been identified as a fall risk factor (O'Connell et al., 2005). Results from this study did not support that finding as high scores were not seen in this group of prospective participants who did not experience a fall.

Participants answered questions about their ability to work, or care for themselves. Based on their answers, the Karnofsky Performance Status scale (KPS) was used to assign a number from 0-10 provided on the scale. The KPS is a proven indicator of functional status in the cancer patient (Yates et al., 1980). The average score of the prospective participants was 73.13, which means that the majority of participants were able to "care for self; unable to carry on normal activity or do active work."

Basic Conditioning Factors: Healthcare System Factor

The average length of stay was 9.1 days which is not an unexpected finding in this oncology population admitted for a variety of reasons. One study reported an average length of stay of 6.6 days for hospitalized cancer patients, which was 1.6 days longer than other hospitalizations for other conditions (Price, Stranges, and Elixhauser, 2012).

Self-Care Agency: General Self-Efficacy

General self-efficacy scores did not vary greatly across prospective participants. Five participants had the highest total score possible which was 40, with the total number of participant scores totaling 28 or higher. Overall, this group of participants had a high general sense of perceived self-efficacy. Self-efficacy is an important component to fall prevention research as it can indicate one's belief in performing a task (Bandura, 2004). Participants may have been confident enough in their abilities and aware of their limitations to prevent falls. A study of advanced cancer patients by Mystakidou, Tsilka, Parpa & Gogu (2009) found a significant correlation between general self-efficacy with performance, where those patients with good performance scores had increased self-efficacy beliefs. This could be true for this study as on average, participants had high self-efficacy scores, good performance scores where they were able to care for themselves, although they could not work, and did not fall. More research is needed to see if other samples of hospitalized cancer patients are high functioning and confident in their abilities.

Self-Care: Safe Hospital Activity Behaviors

The Safe Health Activity Questionnaire was used to determine the activities that participants would perform to care for themselves while they were in the hospital setting. All the activities were related to the prevention of falls. With an average score of 28.72 (total maximum

score of 35), participants overall were willing to execute the behaviors that would decrease their risk of having a fall. Some of the participants did not feel it was necessary to put the call light on before getting out of bed, or did not want nursing staff with them in the bathroom. Some participants did not like the non-skid footwear that was provided. Further testing of this questionnaire is necessary for future use, but it does provide initial data on the types of fall prevention behaviors cancer patients are willing to perform to keep themselves free from falls.

Health: Falls

According to the data obtained in this study, the prospective sample of participants, who did not experience a fall, had low levels of depression, had moderate levels of cancer-related fatigue, had high levels of self-efficacy, were unable to work, and reported that they would follow the safe hospital activity behaviors to prevent falls. Since very few studies have been conducted thus far with regard to falls and hospitalized cancer patients, it is difficult to compare these results to other studies, and since none of the participants fell, no associations with falls can be made. However, this is important data on whether or not the basic conditioning factors chosen in this study may be important factors in why cancer patients didn't fall. The instruments utilized in the study should be used in future prospective designs to determine if similar results are obtained.

Additional factors to consider as to why cancer participants did not fall might include: unit RN awareness and knowledge of a nurse led fall prevention research study which may have affected the RN to change behavior, or interventions implemented, support from the RN manager for the PI, and for the unit RNs to participate in the study, or own self-awareness or experiences of the dangers of hospital falls and repercussions for the cancer participant.

Specific Aim 3: To describe the basic conditioning factors in a retrospective sample of hospitalized patients diagnosed with cancer who fall and who do not fall.

The mean age of the 104 participants in the retrospective sample was 64.1 years with a wide range of ages that varied from 21-96 years. The majority of participants were female. The average number of days in the hospital was 8.5, with a wide range of length of stay that varied from 2-34 days. From the information that was documented in the participants' charts, 17 had a previous history of a fall, 29 had some form of altered elimination, 60 had a vision deficit, 17 had a hearing deficit, 23 had peripheral neuropathy, and 33 participants used some type of assistive device. The most frequent cancer diagnosis was breast cancer followed by lung cancer, and lymphoma. The most infrequent diagnoses were esophageal, bladder, gallbladder, cervical, renal, sarcoma, tongue, and stomach cancer. The most common reason for admission to the hospital was pain, followed by fever and infection. The most common comorbidity was the presence of metastasis, or advanced cancer. A diagnosis of depression was found in 24 participants. The most frequently received high fall risk medication was narcotics, followed by antihypertensives, and antiemetics. The least infrequent high fall risk medications were anti-psychotics and muscle relaxants. The most frequent total number of high fall risk medications/individual medications received by participants was four, followed by three. The least frequent total number of high fall risk medications was one participant who received a total of 10 of the high fall risk medications/individual medications.

Specific Aim 4: To examine the relationship between the basic conditioning factors in a retrospective sample of hospitalized patients diagnosed with cancer who fall and who do not fall.

It is known that the aging process itself can place patients at risk for falls (Rawsky & Digby, 2000); however the results of this study showed that age itself was not associated with falls. Capone et al. (2012) and Pautex et al. (2008) found similar results. In addition, hospitalized cancer patients were studied by Capone et al. (2012) who also did not find a relationship between falls and age. Other studies have found a positive correlation between age and falls (Krauss et al., 2005; O'Connell et al., 2005). The reason for this difference could be that the participants in this study were younger than other groups of cancer patients that have been studied. Pautex et al. (2008) reported that the average age of participants was 71(±12.1) years in a hospitalized sample of palliative care patients with cancer, compared to this study in which the average age was approximately 64.1 (±14.6) years. In general, two studies found that the average age of the hospitalized cancer patient was older when compared to other hospitalized groups by either two (Suda, Motl, & Kuth, 2006), or two-and-a-half years (Price et al. 2009).

Gender was not found to be significantly associated with falls. Stevenson and coworkers (1998) found similar results in their acute-care retrospective study. Higher numbers of female fallers is supported by several hospital fall prevention studies, including this one (Hitcho et al., 2004; Krauss et al., 2005; O'Connell et al., 2005, Stevenson et al., 1998). Female one-time fallers accounted for more falls than men in a study by Fischer and colleagues (2005). In general, it has been shown that women comprise slightly over half (50.7%) of those hospitalized with a diagnosis of cancer (Price et al., 2009) which may contribute to the findings in this study.

A previous history of falls has been shown to be a significant clinical factor for falls (Chu et al., 1999) and findings were similar in this study as a previous history of falls was associated

with falls. Capone et al. (2012) reported that patients who had a fall were more likely to have a history of a fall within the past six months. Krauss et al. (2005) reported that patients having fallen in or out of the hospital within the past 6 months were significantly associated with falling. Hendrich et al. (1995) reported that a recent history of falls was a significant risk factor for hospital falls in a multivariate risk factor model. Documentation of a previous history of falls was not regularly found in the electronic medical records, thus, data was missing. Because a previous history of falls has shown to be significant in several studies, including this one, asking patients if they have previously fallen is an important part of the history that should be obtained on a consistent basis, particularly at admission. Understanding the type of fall is also necessary to determine why the fall occurred, such that environmental falls are different in nature when compared to physiologic falls.

Altered elimination was found to be associated with falls in this study. The relationship between falls and altered elimination has also been noted in other studies (Enloe et al., 2005; Fischer et al., 2005; Hitcho et al., 2004; Krauss et al., 2005).

Associations between the use of an assistive device and falls were found in only two hospital fall prevention studies (Capone et al., 2012; Chu et al., 1999); however they were significantly associated with falls in this study. A meta-analysis by Rubenstein and Josephson (2006) supported the finding that use of an assistive device is a risk factor for a fall.

Although not associated with falls in this study, vision impairments and hearing deficits have been linked to falls in previous studies. In a meta-analysis of 16 studies, basic physical impairments, such as vision impairments, have been found to be a risk factor for falls (Rubenstein and Josephson, 2006). One study found a significant association between those who suffered an injury from a fall and visual impairment (Krauss et al., 2005).

Peripheral neuropathy was not significantly associated with falls in this study. DeMott, Richardson, Thies, & Ashton-Miller (2007) found that older persons with neuropathy have a high rate of falls in a community fall prevention study.

Of the 20 different types of cancer in this sample, two were associated with falls; lung cancer (p=.042), and tonsillar cancer (p=.025). Sixteen participants in the study had lung cancer and 50% of those participants experienced a fall; two participants had a diagnosis of tonsillar cancer and both of them fell. No literature could be found on tonsillar cancer and hospital falls. Pearce and Ryan (2008) noted similar results and found that lung cancer patients fell more often than patients with other types of cancer. Lung cancer patients may have hypoxia in response to their lung tumor, which could lead to dizziness and falls. Five out of the 8 lung cancer participants who fell were male. Three of the 8 cancer participants who fell were admitted with a respiratory diagnosis (which may have led to hypoxia), three were on antiepileptics and one participant was on diuretics. Lung cancer participants who fell had lengths of stay between four and 19 days.

Pain was the most common admitting diagnosis (n=20), and fever/infection was the second most common (n=19). Admitting diagnoses of the hospitalized cancer participants were divided into 10 categories. Of the 10 categories, none of the diagnoses were significantly associated with falls.

In terms of comorbid conditions, a significant relationship between cancer metastases and falling has been found in this study. Pearce and Ryan (2008) also found similar results in their study of falls. No other medical conditions on the Comorbidity Index were associated with falls, except for metastasis. The most frequently reported comorbid condition for fallers, except for metastasis was chronic obstructive pulmonary disease. The relationship between COPD and

falls was not statistically significant. For those participants who fell, the average mean comorbidity score was 4.8 (±.2.63), out of a possible 28. Pautex et al. (2008) also used the same comorbidity index and found that for both fallers and non-fallers the mean comorbidity score was 5.9. The use of updated weights on the Index could account for the difference in scores, or it may be due to the fact that Pautex et al. (2008) included advanced cancer patients in her study.

A diagnosis of depression was not found to be significantly associated with falls (p=.635) in this study, and was not found to be significant in another study of hospitalized cancer patients (Pautex et al., 2008). However, depression has been found to be a significant factor in other hospital fall prevention studies that were not oncology specific (Hendrich et al., 1995).

A variety of medications are given to patients in the hospital setting. It was important to determine if individual high risk fall medications/individual medications had any association with fall outcomes in the cancer patient. Of the 12 medications and 3 individual medications tested, diuretics (p=.003), and antiepileptics (p=.024), were both associated with falls. Diuretics were not limited to any one specific type of diuretic. The relationship between diuretic medication and falls was found in one study, although not statistically significant (Pautex et al., 2008). A study was found that reported diuretics and their effect on the body, specifically bone mineral density loss in a group of older women (Lim, Fink, Blackwell, Taylor, & Ensrud, 2009). The importance of this finding may be the increased possibility of injury severity if a person were to fall. Multiple hospital fall prevention studies support a relationship between hospital falls and epileptics. In a large study, hospitalized patients were three times more likely to fall if they were taking an antiepileptic (Hendrich, Bender & Nyhuis, 2003). A significant association was found between antiepileptic medication use and falls and fractures in a study of postmenopausal women (Carbone, Johnson, Robbins, & Larson, 2010). In a critical systematic

review, antiepileptic medications and falls were weakly associated (Hartikainen, Lönnroos, Louhivuori, 2007). Pautex et al. (2008) found that the use of antiepileptics were not significantly associated with falls.

It was important to look at whether a combination of high risk fall medications classes/individual medications were associated with falls. Combinations ranged from zero to 10, with the only significant association with falls found in participants who had received two high fall risk medication classes/individual medications (p=.011). All other combinations did not show significance.

Length of stay was significantly associated with falls in this study. Length of stay for fallers in this study was approximately 5 days longer when compared to those participants who did not have a fall. Capone et al. (2012) found length of stay to be significantly associated with falls; however length of stay could not be used to predict falls. Suda et al. (2006) conducted a retrospective study on hospital patients and found that cancer patients had a longer median length of stay.

Specific Aim 5: To identify the basic conditioning factors that predict falls in hospitalized patients diagnosed with cancer.

Of all the variables reported in this study that were significantly associated with falls, only a diagnosis of lung cancer, diuretics, antiepileptics, and length of stay were included as predictors of falls in the regression model. Large amounts of data were missing for several of the other variables that were significant, so only those without missing data were included in the data analysis to predict falls.

The logistic regression showed that the strongest predictor for falls in this study was lung cancer. Other statistically significant variables in the model that predicted falls was the use of diuretics, and length of stay. Of all four of the independent variables included in the model, only diuretics had a negative B value. This negative B value indicated that an increase in the use of diuretics decreased the probability of a fall. More studies are needed to understand this. As more diuretics are given, the frequency of toileting increases and this could potentially lead to a fall. It was interesting to look further at the length of stay and falls with injury. Although falls with injury was not included in the analysis due to the small sample size of fall injuries (n=6) it was considered an important variable. For those participants who experienced a fall with injury, two of those participants had a length of stay of 17 and 25 days, while rest of the injured participants had lengths of stay between 4-6 days. Similarities between the two participants with lengths of stay of 17 and 25 days were the use of assistive devices, and 5 or more, high risk fall medication classifications/individual medications received.

Summary of Prospective Findings

Hospitalized cancer participants in the prospective sample had an average age of 62.0 years, with more than half of the sample being female and a length of stay of 9.1 days. More than half of study participants had peripheral neuropathy and a previous history of falls.

Overall, depression scores were low, fatigue scores were moderate general self-efficacy scores and safe activity behaviors were moderately high, and performance status on average was 70. Fatigue and depression scores did not reflect other study findings reported about fatigue and depression, such that fatigue and depression have a relationship with falls; however, the sample size was only 32 participants. Moderate to high general self-efficacy scores were found in participants who did not have falls in this study which indicated that self-efficacy may play a role in the prevention of falls. This might also be related to their low levels of depression, and only moderate levels of fatigue. The overall performance score of hospitalized participants in this study was 70, which was may related to why these participants did not fall The Safe Hospital Activity Questionnaire is a new tool, and has not been used in others studies, but presents initial data on the types of behaviors that cancer participants were willing to engage in.

Summary of Retrospective Findings

Hospitalized cancer patients in the retrospective sample had an average age of 65.5 years for fallers (compared to non-fallers at 63.5 years), and stayed in the hospital for an average of 11.9 days. Breast cancer was the most common diagnosis with lung cancer the second most common cancer diagnosis. Approximately 60% of the participants had metastasis from their cancer.

Eight statistically significant variables were associated with a fall which included: previous history of a fall, altered elimination, use of an assistive device, lung cancer, tonsillar

cancer, presence of metastasis, diuretics, antiepileptics, and participants who received two categories of high fall risk medication classifications/individual medications, and length of stay.

The majority of falls was not-witnessed and occurred in the participant's room on the afternoon shift. Twenty percent of the falls resulted in injury which varied from minor to moderate in severity. The most serious injury was a laceration to a body part. For five of the six participants who fell and were injured, 5 were related to participants trying to meet their elimination needs. Multiple falls accounted for 30% of the total falls in this study.

The retrospective findings in this study were compared to the findings in the four studies that were found that focused on hospitalized patients and cancer. Capone et al. (2012) reported predictors of fall status: metastasis, previous history of a fall in the last six months, and use of walking aid. Capone et al (2010) did not study predictors of fall but characteristics of their study sample with the only similar finding to this study was that the majority of participants fell in the patient's room. Pautex et al. (2008) reported that 25% of fallers had a "respiratory system," type of oncologic disease. In the same study, fallers received more neuroleptics than non-fallers. Neuroleptics increased the risk of having a fall by 1.94-fold, but it was not predictive of falls in the model. Pearce and Ryan (2008) reported that lung cancer patients fell more often than other types of cancers.

Lung cancer participants in this study who fell (n=8) were compared to lung cancer participants who did not fall (n=8). Fallers were younger (with an average of 58 years compared to 70 years), had a longer length of stay (average length of stay was 9.5 days compared to 8 days), had more depression (38% compared to 25%), but were on less diuretics (13% compared to 50%). The majority of both groups were males.

Study Strengths and Limitations

Study Strengths. Cancer participants were willing to share private feelings about their current situation, such as openly answering direct questions regarding their mental health (depression scale) in the relatively short amount of time the PI spent with each participant. Thus an accurate picture of the state of the participant could be obtained. This may be due to the fact that the PI has extensive experience working with hospitalized cancer patients, which may have made participants, feel at ease. Overall, participants were willing to take part in this research study even under stressful conditions such as a hospitalization and illness. In addition, RNs on the nursing units were very willing to be of assistance in the research process, and administrators at both hospital sites were supportive of this work. There are few studies that have been conducted with hospitalized cancer patients and thus, this study contributes to new knowledge in this area that can benefit future hospitalized cancer patients.

Study Limitations. The original prospective design was initially part of a mixed-methods study which had to be modified. Due to the legal ramifications that hospital falls carry, especially when someone is injured, it was suggested by the hospital review board that the qualitative portion of the study be removed. The ability to speak to cancer participants post-fall would have brought a deeper understanding about the falls that patients experienced, and it would have provided data that has not been reported in the literature. In addition, the ability to make predictions from the prospective sample would have been very beneficial in understanding why cancer patients fall in the hospital.

Due to the change in study design, a large amount of information had to be collected retrospectively which can be less desirable when trying to understand the circumstances of a fall, as documentation found in the electronic medical record was not always complete or thorough.

Missing information such as whether the participant was injured or not from the fall, what the participant was trying to do when they fell, or detailed information about their current health state, such as were they oriented when they fell, were not consistently found in the medical record. Consistent information as a whole was not collected from participant to participant for some variables, which is why some variables in this study had missing data.

Reflecting on the limitations of this study assists in determining what could be done differently in replicating this study in the future. Initially, to replicate the current design, more cases and more controls would be necessary to validate the associations in a larger sample. The study could benefit from a change to a solely prospective design (over a longer period of time), so as to be able to make predictions about falls and determine fall risk factors in this specialized population. Studies using qualitative research are an integral part of this phenomenon and would provide a foundation to support the quantitative work already being done.

Sample

The sample in this study was smaller in comparison to the others studies listed above with the total sample size (n=104). The four other studies that looked at hospitalized cancer patients and falls had different sample sizes: Capone et al. 2012, n=145 who did not fall (61% males, 39% females) and 143 who had a fall (55% males and 45% females); Capone et al. 2010, n=158, (54% males and 46% females); Pautex et al. 2008, n=198, (41.4% males, 58.6% females); and Pearce and Ryan 2008, n=119, (percentages of gender were not reported).

Sources of Error

A large amount of data was collected retrospectively. Relationships in this study might have been different if all the retrospective data had been available. Due to the many places where data can be found in the electronic medical record, some data could have been missed.

Additional sources of error might have occurred from participants in the prospective sample, specifically in remembering answers to their medical history, or unwillingness to share personal information. The nature of a hospital admission can place participants under stress and this can affect their recall of recent or past events. In addition, participants might not have been comfortable sharing personal information which could have skewed the results.

Data on several variables were not collected in this study. These variables were also not controlled for by design and may have influenced fall outcomes. Participants who had a previous fall in a hospital/at home, prior knowledge of falls/fall outcomes or how cancer treatment affects the body, knowledge obtained about someone close who experienced a fall**,** information from healthcare professionals about falls, or a rapid change in acuity of medical condition may all precipitate a positive behavior change regarding fall prevention interventions. Knowing fall prevention information or having prior knowledge may lead participants to report their answers differently or make different decisions about their care and safety while they are hospitalized. Future studies need to account for this.

Unexpected Findings

Overall, depression scores of prospective participants were low and a diagnosis of depression in the retrospective sample was not statistically significant to fall outcomes in this study. This was not expected as previous research has shown a connection between falls and depression (Hendrich et al., 1995). However, the relationship between falls and depression might not be as strong in the hospital environment.

During prospective data collection, the PI found that nurses on the oncology units were reporting that potential study patients met study criteria and were cognitively intact. When the

mini-cog was used on those patients, several patients failed the screening test, indicating that they were not cognitively intact, thus, they could not participate in this study.

Cancer participants in this study had moderate to high levels of general-self-efficacy, which could have led participants to take more risks. If they did take those risks, those risks did not lead to falls. To determine if general self-efficacy plays a factor in hospital fall prevention, more research is needed and this concept should be tested further. A self-efficacy tool that focuses specifically on self-care behaviors, or fall prevention behaviors versus a general self-efficacy tool may be needed to determine the connection between this concept and falls.

For the retrospective findings, diuretics had a negative relationship with falls indicating that the more diuretics participants take the less likely they are to fall. Based on the diuretic effect alone, where participants would increase their frequency to use the bathroom, a decrease in falls doesn't really seem to be logically congruent. More research is needed to understand why this occurred. It may be due to the interactions between the variables chosen for the logistic regression. This may change if different variables were entered into the regression model.

Theoretical Framework

Orem's theory of self-care directed the design of this work. To determine if this framework was a good fit for this study, it was necessary to look at the prospective sample of participants as all theoretical concepts were measured in this group of participants. However, the complete theoretical model could not be used with the prospective sample to predict falls because none of the prospective participants experienced a fall. With the retrospective cases and controls, data on depression, fatigue, general self-efficacy, and safe hospital activity were missing, as these measures could not be completed with the historical group of participants. Information was collected on the basic conditioning factors, and health outcomes in the

retrospective sample, but it was not possible to determine if other factors as identified in the theoretical framework contributed to fall outcomes.

For the prospective group, the basic conditioning factors, specifically health state were represented by low levels of depression, moderate fatigue scores, and moderate comorbidity total scores. In addition, the performance scales showed that participants were able to care for themselves, but were not currently employed. It is likely with these results that the participant's health state may not have interfered with their ability to meet their universal needs, and, if it did, other factors contributed to hospital stays without falls (Orem, 2001, p. 246). Other factors, such as general self-efficacy, may have also contributed to self-care agency. For these participants to carry out their own-self care they had to make decisions about meeting their needs to carry out whatever task was in front of them. Overall, it seems that participants were confident in their abilities to face life's challenges. One's personal beliefs of self-efficacy shape the way that participants produced their desired affect (Bandura, 2004). In this study, the desired effect was likely to prevent a fall, as evidenced by the high average scores on the Safe Hospital Activity Questionnaire, where participants agreed that they would implement fall prevention interventions while they were hospitalized.

All of the above concepts may have positively influenced health outcomes (no falls). Orem's theory of self-care and the social cognitive theory were useful in gaining knowledge about which factors may contribute to a hospital stay without falls. However, in the future, a prospective design and a larger study sample may be helpful in determining whether or not the same concepts in this framework could actually predict fall outcomes.

Implications for Clinical Nursing Practice

Patient safety is the number one priority for nurses who work with any group of patients. Hospitals in particular can bring about many dangers that could potentiate a fall and nurses need to be aware of those dangers to prevent patients from unnecessary harm and injury. External factors, such as environmental hazards, or intrinsic factors, such as physiologic changes, all can place a patient at risk for a fall. It is necessary to determine what fall risk factors exist as a first step in determining if changes to nursing practice are necessary to prevent falls. Research studies have supported the need for further research in the area of hospitalized cancer patients as they have been shown to be frequent fallers and suffer serious injury when they fall.

Preventing hospitalized patients from falling is a challenging task, especially if the patients are cognitively intact, independent and functioning well, or have never had a history of falls. On admission, it may be necessary to consider a cognitive screening test to identify cognitive impairment early in the admission process. It is currently not standard practice that a valid and reliable cognitive screening test be used when the patient is first admitted to the hospital environment. Patients who are alert and oriented times four (A&Ox4) may prove to pass the standardized questions that are asked (correct responses to person, place, time, and situation), but may then prove to fail the actual cognitive test. This test may help the nurse to recognize impairments that are not obvious which may then lead to an increase in fall prevention interventions and less falls.

As nurses, it is necessary that the right questions are asked and that starts when patients are first admitted to the hospital nursing unit. Admission documentation needs to be consistent and previous history of falls needs to be asked of all patients, as well as if the patient has any vision or hearing deficits, or if they use an assistive device when they ambulate. A good

example of the importance of specific documentation is the use of an assistive device. Although use of an assistive device was found in the retrospective medical record review, there was no way to know if the participants actually had the assistive device with them in the hospital setting, and if they did, had they been shown how to use it correctly. In addition, assistive devices are commonly given to patients to use in the hospital setting, but only trained personnel should be advising patients on their use to ensure that the device is the correct device for the patient and it is used correctly.

Participants with lung cancer in this study were almost four times more likely to fall than other participants with difference types of cancer. Nurses should be aware that these participants may be more likely to have a fall.

Metastasis, or advanced cancer, was found to be associated with falls. There was missing data regarding metastasis, where the documentation reported only that the patient had breast cancer, for example, but did not give any information on staging/grading where appropriate. Knowing if the cancer has spread to other parts of the body may indicate potential problems the patient may face, and thus, it is important to document complete information about how advanced the disease is.

Medication use in the cancer patient can be overwhelming for the nurse in that medication records can be long which may make it difficult for the nurse to know which drugs to focus his/her attention. Many of the medications have similar side effects such as hypotension and dizziness which could place a patient at risk for a fall. Multiple high risk fall medication categories/individual drugs were tested in this study where the use of antiepileptics, and diuretics were the only high risk fall medication categories associated with a fall; however, only diuretics were predictive of fall and contributed to the model. Diuretics contributed to the model, but the

negative relationships that were found needs to be supported in other studies to determine why less falls would occur when more diuretics are taken.

Cancer-related fatigue is an important topic that may not be consistently asked of hospitalized cancer patients. Even though fatigue scores were not high in the sample of prospective patients, it is necessary that nurses do not forget the importance that fatigue, as a symptom, has in cancer treatment. Data on fatigue was also collected for the retrospective participants; however, it was not something that was routinely documented on admission. Fatigue measurement scales are not used regularly in the hospital (hence, not regularly documented by healthcare professionals). Fatigue can't be seen, therefore, it is important that additional research be conducted in this specialized group of hospitalized cancer patients who are at risk for falls.

Length of stay was found to be associated with falls and contributed to the model however; it is unknown what other contributing factors led participants to have a long hospital stay. It might have been possible that the fall itself contributed to a longer hospital stay.

Fortunately for participants in this study, they were not severely injured from their falls. It is important to remember, that even minor and moderate injuries can leave patients in pain or debilitated for days to weeks later. This can affect their self-confidence which can lead to more falls. Four patients in this study fell more than one time, and one participant fell three times. Multiple falls are unacceptable, as one fall should call for heightened awareness and an immediate change in the plan of care, with the implementation of additional fall prevention measures.

Recommendations for Future Research

More research is necessary to validate the predictors of falls in hospitalized participants diagnosed with cancer reported in this study. Initial findings from this study will contribute to the little knowledge that is known about this topic. It will also provide additional information, insight, and direction into future work in this area. Current hospital studies that focus solely on falls and cancer patients include, Capone et al. (2012, 2010), Pautex et al. (2008), and Pearce and Ryan (2008). These researchers have already begun the investigational work in this area, and found multiple fall risk factors in this specialized population. This study supports several of the reported findings from those four studies.

Of the four studies that have been conducted in hospitalized cancer patients, 75% used a retrospective study design. Those studies, and studies such as this one, show that useful information that contributes to a better understanding of this phenomenon can be discovered using a retrospective approach. A different study design may be helpful now that these retrospective studies, including this one, are reporting similar findings. Prospective designs can provide researchers with an opportunity to speak to patients with may provide additional insight, as missing data is common in the medical record used for retrospective studies. A prospective design was attempted in this study to monitor for falls during the study period, but the PI was unsuccessful in doing this, as falls did not occur. With a focus on hospital safety and safe patient outcomes being reported, it may be difficult to utilize a prospective study design in the future due to the emphasis and education regarding fall prevention in the inpatient setting that is currently taking place. Future research needs to address how qualitative data might be collected in this hospitalized group of cancer patients, as this study was not successful in doing so. The legal ramifications of hospital falls, especially those with negative outcomes, are real and

provide solid barriers to qualitative data collection. Qualitative research, however, may prove insightful and provide data that cannot be collected through quantitative methods. An example of this type of information would be whether or not patients remembered if they were educated about their own personal fall risk, or if they were told about fall prevention interventions while they were hospitalized. Obtaining this information may be best collected after discharge when the patient is home. Initial data may need to come from patients who did not fall, so as not to interfere with the legal process if the patient was going to take legal action because of a fall that occurred while they were hospitalized.

Sub groups of cancer patients, such as lung cancer patients, should be the focus of future work as 50%, two of four of the studies, and now this one, link hospitalized lung cancer patients to falls. However, it is not known why this is true. Antiepileptics and diuretics should also be the focus where studies include high risk fall medications. Antiepileptics have shown to be associated with falls, but not predictive of falls in this study. This study, and one additional study (Pautex et al., 2008), have reported this same finding. Studies need to determine why length of stay is associated with falls and if that increased time in the hospital is due to the fall itself or medical issues not associated with the fall.

The reason studies like this are important is that they add to the understanding of why cancer patients are falling, but more importantly may lead researchers to gather data that may assist in helping to prevent a fall in the first place. As reported earlier, multiple studies have shown that hospitalized cancer patients are at risk for falls and/or injury. This study reported minor to moderate injuries. Because a fall can ultimately lead to death, it is important to determine what factors may lead to injury.

All nurses who care for hospitalized cancer patients will benefit from the information and findings from this study. Nursing research in the hospital setting may prove to be difficult, but the outcomes of this work may save future lives and/or prevent unnecessary injury and decreased quality of life for patients admitted to the hospital setting. Research that is applied to nursing practice that keeps even one cancer patient free from a fall, and more importantly an injury from a fall, is worthy of success!

APPENDIX A

Falls and Cancer Patients Research Study
<u>Data Collection Sheet #1</u> (at time of enrollment into study/completed by PI)

(The following questions will be asked by the PI to each research participant)

1. What is your name _____ Participant Coding # _____
2. Hospital name and room number _____
3. Gender M F
4. Age _____
5. Date of admission _____

Orientation Questions

6. What is your name? _____
7. Where are you right now? _____
8. What year is it? _____

Are questions 6, 7, & 8 correct and patient's behavior appropriate for current situation? If so, continue with research study. If not, stop study and inform patient's RN.

What prevented this participant from continuing in study? _____
_____
_____

Falls and Cancer Patients Research Study
Data Collection Sheet #2 (at time of enrollment into study/completed by PI)

Participant Initials/Coding # _____

1. Type of cancer/location/stage _____
2. Currently receiving cancer treatment

   chemo/biotherapy radiation recent surgery hormone therapy

   Name/type of chemotherapy/radiation _____

   Date of last treatment _____

   First time treatment or previous history of _____
3. Reason for Admission _____
4. Previous falls (how many/what type of fall) _____

   _____
5. Current elimination problems _____
6. Vision impairment _____
7. Hearing Impairment _____
8. Peripheral neuropathy _____
9. Current use of assistive device (which ones) _____

Falls and Cancer Patients Research Study
<u>Data Collection Sheet #3</u> (post-fall/completed by research assistant)

Participant Initials/Coding # _____

1. Type of fall/circumstances of fall _____

   _____

   _____

2. What type of injury/treatment required _____

   _____

3. Time of fall _____
4. Was the patient oriented at time of fall _____
5. Location of fall _____
6. Most recent hemoglobin level _____
7. Most recent platelet level _____
8. Length of hospital stay at time of fall _____
9. Medications patient received 24 prior to the fall (date, time, dosage, route)

   _____ _____ _____

   _____ _____ _____

   _____ _____ _____

If the patient is not able to remember exactly type/stage/location of cancer, type/s of cancer treatment (and names of drug/s), and reason for admission, the research assistant may need to provide this to the PI.

Falls and Cancer Patients Research Study
<u>Data Collection Sheet #4</u> (post-discharge no fall/completed by research assistant)

1. Most recent hemoglobin level prior to discharge _____
2. Most recent platelet level prior to discharge _____
3. Length of hospital stay at discharge _____
4. All medications patient received during hospital stay (dosage, route, frequency)

_____ _____ _____

_____ _____ _____

_____ _____ _____

If the patient is not able to remember exactly type/stage/location of cancer, type/s of cancer treatment (and names of drug/s), and reason for admission, the research assistant may need to provide this to the PI.

Falls and Cancer Patients Research Study
Data Collection Sheet #5 (unit intake form)

Questions PI will ask hospital staff to determine what patients may be eligible for the study:

1. Which patients on this unit have cancer (currently being treated for, or history of cancer?)

_____ _____ _____

_____ _____ _____

_____ _____ _____

2. Which of the patients from Question #1 are alert and oriented to person, place, and time? Of those alert and oriented patients, should have of these patients, not be asked to participate in the study (Examples include: hospice patients, patients who do not fully understand the English language, require a sitter, or restraints?) Of those that meet criteria from Question #1 and #2, what is their admission date?

_____ _____ _____

_____ _____ _____

_____ _____ _____

APPENDIX B

Mini-Cog

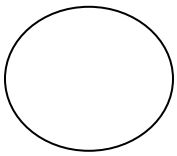
Screen for Cognitive Impairment

The Mini-Cog assessment instrument combines an uncued 3-item recall test with a clock-drawing test (CDT).
The Mini-Cog can be administered in about 3 minutes, requires no special equipment, and is relatively uninfluenced by level of education or language variations

CLOCK DRAWING TEST

1) Inside the circle, please draw the hours of a clock as they normally appear

2) Place the hands of the clock to represent the time: "ten minutes after eleven o'clock"



The test is administered as follows:
1. Instruct the patient to listen carefully to and remember 3 unrelated words and then to repeat the words.

2. Instruct the patient to draw the face of a clock, either on a blank sheet of paper, or on a sheet with the clock
circle already drawn on the page.

After the patient puts the numbers on the clock face, ask him or her to draw the hands of the clock to read a specific time, such as 11:20.
These instructions can be repeated, but no additional instructions should be given.
Give the patient as much time as needed to complete the task. The CDT serves as the recall distractor.
3. Ask the patient to repeat the 3 previously presented word.

Scoring

Give 1 point for each recalled word after the CDT distractor. Score 1–3.
A score of O indicates positive screen for dementia.
A score of 1 or 2 with an abnormal CDT indicates positive screen for dementia.
A score of 1 or 2 with a normal CDT indicates negative screen for dementia.
A score of 3 indicates negative screen for dementia.
The CDT is considered normal if all numbers are present in the correct sequence and position, and the hands readably display the requested time.

APPENDIX C

Charlson Comorbidity Index

1. Have you ever had to be hospitalized for a heart attack? (MI)
___ No
___ Yes (0 points)

2. Have you ever been hospitalized or treated for heart failure? You may have felt more short of breath, and the doctor may have told you that you have fluid in your lungs, or that your heart was not working efficiently. (CHF)
___ No
___ Yes (2 points)

3. Have you ever had pain or cramping in your calf while walking that causes you to stop or slow down? (PVD)
___ No
___ Yes (0 points)

OR

3a. If yes, have you had a peripheral bypass operation on the arteries in one of your legs to fix the problem?
___ No
___ Yes (0 points)

4. Have you ever had a stroke? (CVA)
___ No
___ Yes (0 points for CVA; 0 points for TIA)

5. Do you have difficulty moving an arm or leg, or difficulty talking? (PLEGIA)
___ No
___ Yes (2 points)

6. Do you have chronic lung disease, such as asthma, bronchitis, or emphysema, that makes you short of breath or requires ongoing treatment? (COPD)
___ No
___ Yes (1 point)

7. Do you have diabetes or high blood sugar? (DM)
___ No
___ Yes (0 points)

OR

7a. If yes:(DMENDORGAN) (1 point total only even if >1)

Has your diabetes caused damage to your kidneys?
___ No
___ Yes

Has your diabetes caused problems with your eyes that required treatment by an eye doctor?
___ No
___ Yes

Has your diabetes caused problems with you feet, such as numbness or tingling, or diarrhea at night, or impaired sexual function?
___ No
___ Yes

8. Do you have decreased kidney function?
___ No
___ Yes

8a. If yes, are you on dialysis, or have you had a transplant? (RENAL)
___ No
___ Yes (1 point)

9. Do you have liver disease, such as hepatitis B or C or cirrhosis? (MILDLIVER)
___ No
___ Yes (2 points)

9a. If yes, does the liver disease cause abdominal swelling, vomiting blood or other severe problems or have you had a liver transplant? (SEVERELIVER)
___ No
___ Yes (4 points)

10. Do you have any trouble with ulcers in your stomach or small intestine? (ULCER)
___ No
___ Yes (0 points)

11. Have you had cancer (other than basal cell skin cancer)? (CANCER)
___ No
___ Yes (2 points)

If yes, which:
___ Lymphoma ___ Leukemia ___ Breast ___ Colon ___ Prostate ___ Lung
___ Melanoma Other _____

11a. If yes, has the cancer spread to other locations from its original location? (METASTASES)
___ No
___ Yes (6 points)

12. Do you have Alzheimer's or any other condition that seriously impairs your memory and thinking? (DEMENTIA)
___ No
___ Yes (2 points)

13. Do you have any rheumatic or connective tissue disease? Such as rheumatoid arthritis, polymyositis, systemic lupus erythematosus, polymyalgia rheumatica, vasculitis, sarcoidosis, Sjogren's syndrome, mixed connective tissue disease or other systemic rheumatic disease? (RHEUMATIC)
___ No
___ Yes (1 point)

14. Do you have HIV or AIDS? (HIV)
___ No
___ Yes (4 points)

APPENDIX D

Geriatric Depression Scale: Short Form

Choose the best answer for how you have felt over the past week:

1. Are you basically satisfied with your life? YES / **NO**

2. Have you dropped many of your activities and interests? **YES** / NO

3. Do you feel that your life is empty? **YES** / NO

4. Do you often get bored? **YES** / NO

5. Are you in good spirits most of the time? YES / **NO**

6. Are you afraid that something bad is going to happen to you? **YES** / NO

7. Do you feel happy most of the time? YES / **NO**

8. Do you often feel helpless? **YES** / NO

9. Do you prefer to stay at home, rather than going out and doing new things? **YES** / NO

10. Do you feel you have more problems with memory than most? **YES** / NO

11. Do you think it is wonderful to be alive now? YES / **NO**

12. Do you feel pretty worthless the way you are now? **YES** / NO

13. Do you feel full of energy? YES / **NO**

14. Do you feel that your situation is hopeless? **YES** / NO

15. Do you think that most people are better off than you are? **YES** / NO

Answers in **bold** indicate depression. Score 1 point for each bolded answer.

A score > 5 points is suggestive of depression.
A score > 10 points is almost always indicative of depression.
A score > 5 points should warrant a follow-up comprehensive assessment.

APPENDIX E

Wu Cancer Fatigue Scale (WCFS)

Cancer patients describe their fatigue as having physical, emotional, and mental symptoms. Different people experience different symptoms. You may or may not have experienced some of the symptoms that are listed. I am asking you to tell me about the fatigue symptoms you experienced YESTERDAY.

It may be helpful by thinking back to yesterday. Now give yourself a minute and think about how your day started yesterday? What did you do yesterday? And how did the day end yesterday?

Now I would like you to tell me about the following 9 fatigue symptoms you may have experienced **YESTERDAY**. Please rate **HOW MUCH** you experienced each symptom **YESTERDAY**. Please circle the number that best reflects your experience for each statement below. The scale ranges from (0) *not at all* **to** (10) *as much as possible*.

Please **circle** the number between 0 and 10 that best applies to you:

How much did you experience the symptom yesterday?

1. I was physically drained

0 1 2 3 4 5 6 7 8 9 10
not at all as much as possible

2. I felt like sitting around more than I usually do

0 1 2 3 4 5 6 7 8 9 10
not at all as much as possible

3. I didn't have the energy to get up and do things

0 1 2 3 4 5 6 7 8 9 10
not at all as much as possible

4. I felt guilty that I was too tired to do the things that I normally do

0 1 2 3 4 5 6 7 8 9 10
not at all as much as possible

5. I was more sensitive than usual

0 1 2 3 4 5 6 7 8 9 10
not at all as much as possible

6. I felt upset because I didn't get enough accomplished

0 1 2 3 4 5 6 7 8 9 10
not at all as much as possible

7. I was forcing myself to get up and do things

0 1 2 3 4 5 6 7 8 9 10
not at all as much as possible

8. I was wiped out emotionally

0 1 2 3 4 5 6 7 8 9 10
not at all as much as possible

9. I had trouble remembering things

0 1 2 3 4 5 6 7 8 9 10
not at all as much as possible

APPENDIX F

Karnofsky Performance Status Scale

100	Normal no complaints; no evidence of disease
90	Able to carry on normal activity; minor signs or symptoms of disease
80	Normal activity with effort; some signs or symptoms of disease
80-100	Able to carry on normal activity and to work; no special care needed
70	Cares for self; unable to carry on normal activity or to do active work
60	Requires occasional assistance, but is able to care for most personal needs
50	Requires considerable assistance and frequent medical care
50-70	Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed
40	Disabled; requires special care and assistance
30	Severely disabled; hospital admission is indicated although death not imminent
20	Very sick; hospital admission necessary; active supportive treatment necessary
10	Moribund; fatal processes progressing rapidly
0	Dead
0-40	Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly

APPENDIX G

General Self-Efficacy Scale

1. I can always manage to solve difficult problems if I try hard enough.
2. If someone opposes me, I can find the means and ways to get what I want.
3. It is easy for me to stick to my aims and accomplish my goals.
4. I am confident that I could deal efficiently with unexpected events.
5. Thanks to my resourcefulness, I know how to handle unforeseen situations.
6. I can solve most problems if I invest the necessary effort.
7. I can remain calm when facing difficulties because I can rely on my coping abilities.
8. When I am confronted with a problem, I can usually find several solutions.
9. If I am in trouble, I can usually think of a solution.
10. I can usually handle whatever comes my way.

1 = Not at all true 2 = Hardly true 3 = Moderately true 4 = Exactly true

APPENDIX H

Safe Hospital Activity Questionnaire

The questions below represent hospital activities. Please circle the response that best answers the activities that you will do while you are in the hospital.	
1) I put the call light on before getting out of bed.	1) None of the time 2) A little of the time 3) Some of the time 4) Most of the time 5) All of the time
2) I follow the directions the nursing staff gives me regarding my activity level.	1) None of the time 2) A little of the time 3) Some of the time 4) Most of the time 5) All of the time
3) I report any weakness or dizziness to my nurse before getting out of bed.	1) None of the time 2) A little of the time 3) Some of the time 4) Most of the time 5) All of the time
4) I ensure my non-skid footwear is on before getting out of bed.	1) None of the time 2) A little of the time 3) Some of the time 4) Most of the time 5) All of the time
5) I sit at the side of the bed for a couple of minutes before getting out of bed.	1) None of the time 2) A little of the time 3) Some of the time 4) Most of the time 5) All of the time
6) I pay attention to my surroundings to prevent unnecessary accidents.	1) None of the time 2) A little of the time 3) Some of the time 4) Most of the time 5) All of the time
7) I allow the nursing staff to stay with me in the bathroom when I am at risk for falls.	1) None of the time 2) A little of the time 3) Some of the time 4) Most of the time 5) All of the time

APPENDIX I

Falls and Cancer Patient Research Study

Retrospective Chart Review-CONTROLS

1. Patient Initials: _____
2. Coding Number: _____ _____
3. Select Hospital Site: St. John Main/6N St. John Macomb/5Center
4. Date of Admission/LOS:
5. What type of cancer/location/stage?
6. Gender: M F
7. Age: _____
8. Currently receiving cancer treatment:

chemo/biotherapy radiation recent surgery hormone therapy

Specific name of treatment/type of radiation/surgery: _____

Date of last treatment/surgery/radiation: _____

First time treatment or previous history of: _____

9. Reason for Admission: _____
10. All co-morbidities:

_____ _____ _____

_____ _____ _____

11. Karnofsky Performance Score (if documented): _____
12. Documentation of fatigue in History and Physical: Yes No

If Yes, list score if documented and any supporting info _____

13. Previous falls (how many/what type of fall/when last fall was) _____

_____

14. Current elimination problems _____

15. Vision impairment _____

16. Hearing Impairment _____

17. Peripheral neuropathy _____

18. Current use of assistive device (which ones) _____

19. All medications patient received during hospital stay (dosage, route, frequency)

_____ _____ _____

_____ _____ _____

_____ _____ _____

20. Most recent hemoglobin level prior to discharge _____

21. Most recent platelet level prior to discharge _____

APPENDIX J

Falls and Cancer Patient Research Study

Retrospective Chart Review-CASES

1. Patient Initials: _____
2. Coding Number: _____
3. Select Hospital Site/Unit St. John Main/6N St. John Macomb/5 Center
4. Date of Admission/LOS:_____
5. Gender: M F
6. Age: _____
7. Type of cancer/location/stage: _____
8. Currently receiving cancer treatment:

   chemo/biotherapy radiation recent surgery hormone therapy

   Specific name of treatment/type of radiation/surgery: _____

   Date of last treatment: _____

   First time treatment or previous history of: _____
9. Reason for Admission: _____
10. All co-morbidities:

    _____ _____ _____

    _____ _____ _____

11. Karnofsky Performance Score (if documented/PI to assign based on info documented): _____
12. Documentation of fatigue in History and Physical: Yes No

    If Yes, list score if documented and any supporting info: _____

13. Previous falls (how many/what type of fall/when last fall was): _____

_____

14. Current elimination problems: _____

15. Vision impairment: _____

16. Hearing Impairment: _____

17. Peripheral neuropathy: _____

18. Current use of assistive device (which ones): _____

19. All medications patient received during hospital stay (dosage, route, frequency)

_____

20. Type of fall/circumstances of fall: _____

_____

21. What type of injury sustained/treatment required: _____

_____

22. Time/date of fall: _____

23. Was the patient oriented at time of fall: _____

24. Location of fall: _____

25. Most recent hemoglobin level at time of fall: _____

26. Most recent platelet level at time of fall: _____

27. Medications patient received 24 hours prior to the fall (date, time, dosage, route)

_____ _____ _____

_____ _____ _____

APPENDIX K

Geriatric Depression Scale (Prospective sample, n=32)

Factor	Mean(SD)	Inclusive Range
Geriatric Depression Scale	3.66 (3.36)	0-15

Geriatric Depression Scale	Frequency	Percent
0	3	9.4
1	5	15.6
2	7	21.9
3	3	9.4
4	7	21.9
5	1	3.1
6	1	3.1
7	2	6.3
10	1	3.1
11	1	3.1
15	1	3.1

Score of >5 suggestive of depression
Score of >10 almost always indicative of depression

The Geriatric Depression Scale (GDS) Short Form was used with the prospective sample (n=32). Total scores can range from 0-15. The minimum total score of the participants was zero; maximum total score was 15, with an overall mean of 3.66 (± 3.36). Total score that could be achieved was 15. Three participants each had a score of zero, and one participant had a score of 15. Twenty-six of the participants had a score that was not suggestive of depression. Six participants had scores that were suggestive of depression (scores >5), and of those two participants had scores that were almost always indicative of depression (>10).

APPENDIX L

Wu Cancer Fatigue Scale (Prospective sample, n=32)

Factor	Mean(SD)	Inclusive Range
Wu Cancer Fatigue Scale	36.03(21.39)	0- 79

Wu Cancer Fatigue Scale	Frequency	Percent
0	1	3.1
1	1	3.1
4	1	3.1
5	1	3.1
7	1	3.1
9	1	3.1
15	1	3.1
17	1	3.1
18	1	3.1
25	1	3.1
31	2	6.3
35	1	3.1
37	3	9.4
38	3	9.4
40	1	3.1
45	1	3.1
48	1	3.1
49	1	3.1
50	2	6.3
54	1	3.1
57	1	3.1
59	1	3.1
62	1	3.1
63	1	3.1
74	1	3.1
79	1	3.1

Total scores of the Wu Fatigue Scale can range from 0-90. The higher the score the more fatigue. The Wu Fatigue Scale was used with the prospective sample, n=32. The minimum total score of the participants was zero, maximum total score was 79, with an overall mean of 36.03 (±21.39).

One participant each had a score of 0, 1, 4, 5, 7, 9, 15, 17, 18, 25, 35, 40, 45, 48, 49, 54, 57, 59, 62, 63, 74, and 79. Two participants each had a score of 31, and 50, and three participants each had scores of 37, and 38.

APPENDIX M

Karnofsky Performance Scale (Prospective sample, n=32)

Factor	Mean(SD)	Inclusive Range
Karnofsky Performance Scale	73.13(14.24)	50-90

Karnofsky Performance Scale	Frequency	Percent
50	5	15.6
60	4	12.5
70	8	25.0
80	6	18.8
90	9	28.1

0	dead
10	moribund; fatal processes progressing rapidly
20	very sick; hospital admission necessary; active supportive treatment necessary
30	severely disabled; hospital admission is indicated although death not imminent
40	disabled; requires special care and assistance
50	requires considerable assistance and frequent medical care
60	requires occasional assistance, but is able to care for most of personal needs
70	care for self; unable to carry on normal activity or do active work
80	normal activity with effort; some signs or symptoms of disease
90	able to carry on normal activity; minor signs or symptoms of disease
100	normal no complaints, no evidence of disease

The Karnofsky Performance Scale was used with the prospective sample (n=32). The scores range from zero to 100. The minimum total score of the participants was 50 and the maximum was 90, with a mean of 73.13 (±14.24). Five of the participant had a performance score of 50, four had a score of 60, 8 had a score of 70, 6 had a score of 80, and 9 participants had a score of 90.

APPENDIX N

General Self-Efficacy Scale (Prospective sample, n=32)

Characteristic	Mean(SD)	Inclusive Range
General Self-Efficacy Scale	34.22(4.29)	28-40

General Self-Efficacy Scale	Frequency	Percent
28	3	9.4
29	3	9.4
30	3	9.4
31	1	3.1
32	4	12.5
33	2	6.3
34	1	3.1
36	3	9.4
37	1	3.1
38	4	12.5
39	2	6.3
40	5	15.6

The General Self-Efficacy Scale was used with the prospective sample, n=32. Scores on the General Self-Efficacy Score range from 10-40. The minimum total score of the participants was 28; maximum total score was 40, with an overall mean of 34.22 (±4.29). One participant each had a total score of 31, 34, or 37; two had total scores of 33 or 39; three had total scores each of 28, 29, 30, or 36; four had total scores of 32, and 38, and 5 participants each had a total general self-efficacy scores of 40.

APPENDIX O

Safe Hospital Activity Questionnaire (Prospective Sample, n=32)

Factor	Mean(SD)	Inclusive Range
Safe Hospital Activity Questionnaire	28.72 (5.78)	15-35

Safe Hospital Activity Questionnaire	Frequency	Percent
15	1	3.1
16	1	3.1
17	1	3.1
20	1	3.1
22	1	3.1
23	1	3.1
26	1	3.1
27	5	15.6
28	3	9.4
30	1	3.1
31	5	15.6
32	1	3.1
33	3	9.4
35	7	21.9

The Safe Hospital Activity Questionnaire was used with the prospective sample, n=32. Scores from the Safe Hospital Activity Questionnaire range from 7-35. The minimum total score of the participants was 15; maximum total score was 35, with an overall mean of 28.72 and a standard deviation of (±5.78). One participant each had a total score of 15, 16, 17, 20, 22, 23, or 26. Three participants had a total score of 28 or 33. Five participants each had a total score of 27 or 31.Seven participants had a score of 35.

APPENDIX P

Human Subjects Institutional Review Board Approvals

Institutional Review Board
19251 Mack Avenue, Suite 340
Grosse Pointe Woods MI 48236
FWA: 00003217

DATE:	April 13, 2012
TO:	Rebecca Allan-Gibbs, RN
FROM:	St. John Hospital and Medical Center IRB
STUDY TITLE:	[306568-4] Falls and Hospitalized Cancer Patients
IRB REFERENCE #:	SJ 0112-14
SUBMISSION TYPE:	Response/Follow-Up to Pkg #14 and #15 - Initial Review
ACTION:	**APPROVED**
APPROVAL DATE:	April 13, 2012
EXPIRATION DATE:	June 15, 2012
REVIEW TYPE:	Administrative Review

The conditions set forth by the IRB on March 15, 2012 and April 2, 2012 have now been met and full approval is granted.

This research presents Low Risk.
Based on the risks, this project requires Continuing Review by this office on an a three-month basis.
Please use the appropriate renewal forms for this procedure.

The St. John Hospital and Medical Center IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

Your protocol, #SJ 0112-14 was APPROVED along with the following documents:

•Amendment/Modification - Rebecca Allan-Gibbs St. John IRB Amendment Revision Form 4-10-12.doc (UPDATED: 04/11/2012)
• Application Form - Rebecca Allan-Gibbs St. John IRB application 4-10-12.doc (UPDATED: 04/11/2012)
• Consent Form - Rebecca Allan-Gibbs St. John IRB Consent 4-10-12.doc (UPDATED: 04/11/2012)
• Letter - rebecca smith email.pdf (UPDATED: 04/11/2012)
• Letter - dawn brzozowski email.pdf (UPDATED: 04/11/2012)
• Other - Rebecca Allan-Gibbs St. John IRB letter modifications 4-10-12.doc (UPDATED: 04/11/2012)
• Proposal - Rebecca Allan-Gibbs St. John IRB Dissertation Proposal 4-10-12.doc (UPDATED: 04/11/2012)

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

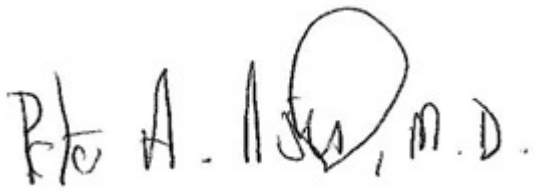
Please be advised, while the IRB has approved your research project under the federal regulations for the protection of human subjects, you are still required by the institution to obtain approval from the appropriate department heads as applicable for the conduct of your research (e.g., Finance, Patient Accounts, Legal, Pharmacy, Laboratory, etc.) before you begin your study. A copy of this approval should be forwarded to the IRB for the project records.
As part of the Institutional Review Board requirements, which are mandated by the FDA and OHRP, you are required to report back to the IRB in the event of any of the following: significant adverse reactions, changes to the previously approved materials, non-compliance issues or complaints regarding the study, major protocol deviations, and termination of the study. Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision
forms for this procedure.

Please note that all research records must be retained for a minimum of three years.

If you have any questions, please contact Suzanne Leialoha at 313-343-3863 or suzanne.leialoha@stjohn.org. Please include your study title and reference number in all correspondence with this office.

St. John Hospital and Medical Center's Institutional Review Board is in full compliance with Good Clinical Practices as defined under the U.S. Food and Drug Administration (FDA) regulations and the International Conference on Harmonisation (ICH-GCP) Guidelines, as adopted by the FDA.

Sincerely,



Peter A. Nickles, MD, Chairperson
Institutional Review Board
St. John Hospital and Medical Center

ST. JOHN HOSPITAL & MEDICAL CENTER

Institutional Review Board
19251 Mack Avenue, Suite 340
Grosse Pointe Woods MI 48236
FWA: 00003217

DATE:	February 22, 2013
TO:	Rebecca Allan-Gibbs, RN
FROM:	St. John Hospital and Medical Center IRB
STUDY TITLE:	[306568-14] Falls and Hospitalized Cancer Patients
IRB REFERENCE #:	SJ 0112-14
SUBMISSION TYPE:	Amendment/Modification
ACTION:	**APPROVED**
APPROVAL DATE:	February 21, 2013
EXPIRATION DATE:	February 20, 2014
REVIEW TYPE: Full	Committee Review
PROJECT STATUS:	Active

This research presents Minimal Risk.

Based on the risks, this project requires Continuing Review by this office on an ANNUAL basis. Please use the appropriate renewal forms for this procedure.

The St. John Hospital and Medical Center IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

Your protocol, #SJ 0112-14 was APPROVED along with the following documents:

• Amendment/Modification - Rebecca Allan-Gibbs St. John IRB Amendment 1-24-13.pdf (UPDATED: 01/25/2013)
• Protocol - Rebecca Allan-Gibbs St. John IRB Dissertation Proposal 1-24-13 clean.doc (UPDATED: 01/24/2013)
• Protocol - Rebecca Allan-Gibbs St. John IRB Dissertation Proposal 1-24-13 track changes.doc (UPDATED: 01/24/2013)

Please be advised, while the IRB has approved your research project under the federal regulations for the protection of human subjects, you are still required by the institution to obtain approval from the appropriate department heads as applicable for the conduct of your research (e.g., Finance, Patient Accounts, Legal, Pharmacy, Laboratory, etc.) before you begin your study. A copy of this approval should be forwarded to the IRB for the project records.

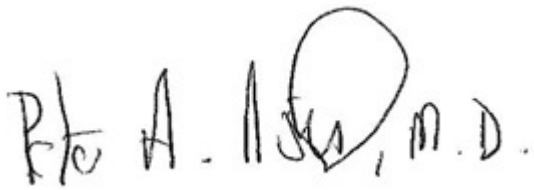
As part of the Institutional Review Board requirements, which are mandated by the FDA and OHRP, you are required to report back to the IRB in the event of any of the following: significant adverse reactions, changes to the previously approved materials, non-compliance issues or complaints regarding the study, major protocol deviations, and termination of the study. Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

Please note that all research records must be retained for a minimum of three years following the final closure of the study.

If you have any questions, please contact Denise Cunningham at 313-343-7813 or denise.cunningham@stjohn.org. Please include your study title and reference number in all correspondence with this office.

St. John Hospital and Medical Center's Institutional Review Board is in full compliance with Good Clinical Practices as defined under the U.S. Food and Drug Administration (FDA) regulations and the International Conference on Harmonisation (ICH-GCP) Guidelines, as adopted by the FDA.

Sincerely,



Peter A. Nickles, MD, Chairperson
Institutional Review Board
St. John Hospital and Medical Center

ST. JOHN HOSPITAL & MEDICAL CENTER

19251 Mack Avenue, Suite 340
Grosse Pointe Woods MI 48236
FWA: 00003217

DATE:	January 30, 2014
TO:	Rebecca Allan-Gibbs, RN
FROM:	St. John Hospital and Medical Center IRB
STUDY TITLE:	[306568-16] Falls and Hospitalized Cancer Patients
IRB REFERENCE #:	SJ 0112-14
SUBMISSION TYPE:	Continuing Review/Progress Report
ACTION:	**APPROVED**
APPROVAL DATE:	January 30, 2014
EXPIRATION DATE:	January 29, 2015
REVIEW TYPE:	Expedited Review
PROJECT STATUS:	Active - Data Analysis Only
REVIEW CATEGORY:	Expedited review category #8.c.

The St. John Hospital and Medical Center IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

Your protocol, #SJ 0112-14 was APPROVED along with the following documents:

- Continuing Review/Progress Report - Rebecca Allan-Gibbs St John IRB Continuing Review1-22-14.pdf (UPDATED: 01/30/2014)
- Other - Rebecca Allan-Gibbs St. John IRB Total List of Participants 1-13-14.doc (UPDATED:01/27/2014)
- Protocol - Rebecca Allan-Gibbs St. John IRB Proposal 1-13-14.doc (UPDATED: 01/27/2014)

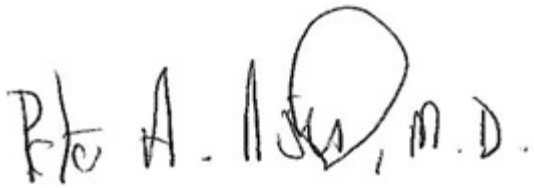
As part of the Institutional Review Board requirements, which are mandated by the FDA and OHRP, you are required to report back to the IRB in the event of any of the following: significant adverse reactions, changes to the previously approved materials, non-compliance issues or complaints regarding the study, major protocol deviations, and termination of the study. Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

Please note that all research records must be retained for a minimum of three years following the final closure of the study.

If you have any questions, please contact Suzanne Leialoha at 313-343-3863 or suzanne.leialoha@stjohn.org. Please include your study title and reference number in all correspondence with this office.

St. John Hospital and Medical Center's Institutional Review Board is in full compliance with Good Clinical Practices as defined under the U.S. Food and Drug Administration (FDA) regulations and the International Conference on Harmonisation (ICH-GCP) Guidelines, as adopted by the FDA.

Sincerely,



Peter A. Nickles, MD, Chairperson
Institutional Review Board
St. John Hospital and Medical Center

WAYNE STATE UNIVERSITY

IRB Administration Office
87 East Canfield, Second Floor
Detroit, Michigan 48201
Phone: (313) 577-1628
FAX: (313) 993-7122
http://irb.wayne.edu

NOTICE OF EXPEDITED APPROVAL

To: Rebecca Allan
Adult Health/Administration
301 Cohn

From: Dr. Scott Millis
Chairperson, Behavioral Institutional Review Board (B3)

Date: May 15, 2012

RE: IRB #: 048912B3E
Protocol Title: Falls and Hospitalized Cancer Patients
Funding Source: Sponsor: AMERICAN CANCER SOCIETY
Protocol #: 1205010875

Expiration Date: May 14, 2013

Risk Level / Category: Research not involving greater than minimal risk

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The above-referenced protocol and items listed below (if applicable) were **APPROVED** following *Expedited Review* Category (#7)* by the Chairperson/designee *for* the Wayne State University Institutional Review Board (B3) for the period of 05/15/2012 through 05/14/2013. This approval does not replace any departmental or other approvals that may be required.

- Protocol Summary Form (received in the IRB Office 04/20/2012)
- Protocol (received in the IRB Office 04/20/2012)
- Receipt of IRB Approval from St. John Hospital & Medical Center (approval period 04/13/2012 to 06/15/2012)
- Receipt of St. John Hospital and Medical Center Consent to Participate in a Clinical Research Study and Authorization to Use or Disclose Protected Health Information For Research (HIPAA)
- Data collection tools

- Federal regulations require that all research be reviewed at least annually. You *may* receive a *"Continuation Renewal Reminder"* approximately two months prior to the expiration date; however, it is the Principal Investigator's responsibility to obtain review and continued approval ***before*** the expiration date. Data collected during a period of lapsed approval is unapproved research and can never be reported or published as research data.
- All changes or amendments to the above-referenced protocol require review and approval by the IRB **BEFORE** implementation.
- Adverse Reactions/Unexpected Events (AR/UE) must be submitted on the appropriate form within the timeframe specified in the IRB Administration Office Policy (http://www.irb.wayne.edu//policies-human-research.php).

NOTE:

1. Upon notification of an impending regulatory site visit, hold notification, and/or external audit the IRB Administration Office must be contacted immediately.
2. Forms should be downloaded from the IRB website at **each** use.

*Based on the Expedited Review List, revised November 1998

WAYNE STATE UNIVERSITY

IRB Administration Office
87 East Canfield, Second Floor
Detroit, Michigan 48201
Phone: (313) 577-1628
FAX: (313) 993-7122
http://irb.wayne.edu

NOTICE OF EXPEDITED CONTINUATION APPROVAL

To: Rebecca Allan
Adult Health/Administration
301 Cohn

From: Dr. Scott Millis
Chairperson, Behavioral Institutional Review Board (B3)

Date: May 14, 2013

RE: IRB #: 048912B3E
Protocol Title: Falls and Hospitalized Cancer Patients
Funding Source: Sponsor: AMERICAN CANCER SOCIETY
Protocol #: 1205010875

Expiration Date: May 13, 2014

Risk Level / Category: Research not involving greater than minimal risk

Continuation for the above-referenced protocol and items listed below (if applicable) were APPROVED following Expedited Review by the Chairperson/designee of the Wayne State University Institutional Review Board (B3) for the period of **05/14/2013 through 05/13/2014.** This approval does not replace any departmental or other approvals that may be required.

- Actively accruing participants
- Waiver of consent for retrospective aim continued and approved

- Federal regulations require that all research be reviewed at least annually. You *may* receive a *"Continuation Renewal Reminder"* approximately two months prior to the expiration date; however, it is the Principal Investigator's responsibility to obtain review and continued approval ***before*** the expiration date. Data collected during a period of lapsed approval is unapproved research and can never be reported or published as research data.
- All changes or amendments to the above-referenced protocol require review and approval by the IRB **BEFORE** implementation.
- Adverse Reactions/Unexpected Events (AR/UE) must be submitted on the appropriate form within the timeframe specified in the IRB Administration Office Policy (http://www.irb.wayne.edu//policies-human-research.php).

NOTE:

1. Upon notification of an impending regulatory site visit, hold notification, and/or external audit the IRB Administration Office must be contacted immediately.
2. Forms should be downloaded from the IRB website at **each** use.

*Based on the Expedited Review List, revised November 1998

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ABSTRACT

FALLS AND HOSPITALIZED CANCER PATIENTS

by

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Major: Nursing

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Problem: Many hospital fall prevention studies have shown that having a diagnosis of cancer places patients at higher risk for falls/falls with injury when compared to other hospitalized groups of patients. Few studies have focused solely on cancer patients at risk for falls in the hospital setting. Specifically, this study used Dorothea Orem's theory of self-care (Orem, 2001), and Albert Bandura's (2001), social cognitive theory to determine if factors such as age, gender, health state, healthcare system factors, self-care agency, and self-care impact falls. Design: case-control with prospective design component. Sample: retrospective, n=104; (74 controls, 30 cases); prospective, n=32 Findings: Statistically significant variables that were associated with a fall and included in the logistic regression model were: a diagnosis of lung cancer, diuretics, antiepileptics, and length of stay. Conclusions: The model as a whole explained between 27% (Cox and Snell R square) and 38.6% (Nagelkerke R squared) of the variance in falls, and classified 80.8% of cases. The strongest predictor of falls was lung cancer, recording an odds ratio of 3.87. This indicated that participants who had lung cancer were 3.87 times more likely to fall. The prospective group of participants did not fall. In the prospective sample, depression scores were low, fatigue scores were moderate, performance status on

average was 70, and general self-efficacy scores and safe activity behaviors were moderately high. The findings from this study provide new knowledge to an area where little is known about cancer patients who fall in the hospital setting. More research is needed in this area to confirm actual fall risk factors that could predict a fall in this specialized population.

AUTOBIOGRAPHICAL STATEMENT

My expertise and passion for adult, hospitalized, oncology patients and their risk for falls developed from the last 10 years of my work as an Oncology Clinical Nurse Specialist. During this time, I saw the importance of work in this area and how little information was known about this phenomenon.

I have been a Registered Nurse for 14 years and received my Bachelor of Science in Nursing from Madonna University, where I currently hold the position of an Assistant Professor in the College of Nursing. My Master of Science in Nursing was obtained from Wayne State University, where I received my Community Health Clinical Nurse Specialist degree. I am Board-Certified as a Clinical Nurse Specialist and I am nationally certified as an Advanced Oncology Clinical Nurse Specialist.

I have published a review of the literature about falls and hospitalized cancer patients in the Clinical Journal of Oncology Nursing. I am fortunate to have received a Doctoral Degree Scholarship in Cancer Nursing from the American Cancer Society which supported this work, as well as the Outstanding Oncology Advanced Practice Nurse award from the Metro Detroit Oncology Nursing Society, the Student Research Achievement Award from the College of Nursing at Wayne State University, and multiple scholarships within the College of Nursing, including the College of Nursing Alumni Association Endowment, and the Dean's Scholarship.