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Identifying Patients with Cancer at Risk of

Experiencing a Fall While Hospitalized

by

Joann M. Heaton

A thesis submitted in partial fulfillment of the requirements for the degree of Masters of Science College of Nursing University of South Florida

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Keywords: oncology, acute care, anemia, hemoglobin, alkaline phosphatase

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# Identifying Patients with Cancer at Risk of Experiencing a Fall While Hospitalized Joann M. Heaton

#### ABSTRACT

Inpatient falls are the most reported incidents in the acute care setting. Symptoms associated with a diagnosis of cancer and treatment may increase risk for falls. The objectives of this study were to identify the risk factors, and the most common risk factors, of adult patients with cancer who fell while hospitalized. A retrospective, matched, case-control audit of electronic medical records and occurrence reports was conducted for 30 patients who fell and 30 patients who did not fall while under the care of the inpatient oncology unit in a community hospital. Fall subjects and controls were matched by cancer diagnosis and age. Results of the study (N = 30) revealed altered cognition (p = .010), muscular weakness (p = .037), and a history of a fall in the past six months (p = .045) as statistically significant fall risk factors. The audit of the electronic medical records revealed variations in the nursing documentation of fall risk factors that could increase the chance of assessments being omitted or communicated inaccurately to other members of the care team. Additional studies are needed to examine risk factors for falls in hospitalized oncology patient populations.

#### Chapter One

#### Introduction

Patient harm resulting from falls is a recognized event of hospitalization that may be reduced through nursing interventions. The Joint Commission, an independent, notfor-profit organization that sets standards and accredits health care organizations in the United States (The Joint Commission, 2007b), lists reducing the risk of patient harm that results from falls in the hospital as an important goal in national patient safety goals for 2007 (The Joint Commission, 2007a).

Inpatient falls are the most frequently reported incidents in the acute care setting (Gowdy & Godfrey, 2003). Falls and the injuries related to the falls result in approximately \$20.2 million annually in costs for diagnostic tests, injury repair, rehabilitation, legal expenses, and patient and family dissatisfaction (Gowdy & Godfrey, 2003). A patient fall is categorized as a sentinel event which is an unexpected occurrence that involves death or serious psychological or physical harm, or the risk of involving death or such harm (The Joint Commission, 2007d). Patient falls are the sixth most reviewed sentinel event of the 21 events reviewed by the Joint Commission. As of June 30, 2006, 5.4% of the sentinel events reviewed since January of 1995 were patient falls (The Joint Commission, 2007e).

Nursing and medical research conducted on falls in hospitalized patients have explored multiple risk factors. Characteristics that are associated with falls in hospitalized patients include gait or balance deficits, lower extremity problems, confusion, the use of sedatives or hypnotics, the use of diabetic medications, increasing patient-to-nurse ratios, and requiring transfer assistance (Krauss et al., 2005). The use of benzodiazepines, a previous history of falls, and the need for maximum assistance are also considerations for older aged inpatients (Frels, Williams, Narayanan, & Gariballa, 2002). Blood pathology values that are associated with patient falls include anemia in older ambulatory patients (Dharmarajan, Avula, & Norkus, 2006) and elevated alkaline phosphatase levels (O'Hagen & O'Connell, 2005). Patient activities that are associated with falls included elimination-related activities, especially in patients over 65 years old (Hitcho et al., 2004). Risks for falls recognized by the Joint Commission include: a recent history of falls; cognitive impairment and dementia; functional or mobility problems; balance impairment; advanced age; use of assistive devices or ambulatory aids; attachment to equipment; urinary incontinence; urinary frequency or urgency; postural hypotension; dizziness or vertigo; medications; depression; visual or hearing deficits; decreased peripheral sensation; and peripheral neuropathy (The Joint Commission, 2007c).

Risk assessment tools have been developed and evaluated for identifying risk factors for falling. Simple fall risk assessment tools that had similar variables were shown to exhibit sensitivity and specificity but could not be validated in a variety of clinical settings or in routine clinical use (Oliver, Daly, Martin, & McMurdo, 2004). Many of the tools developed for use with elderly populations were found to have wide variability in overall usefulness and diagnostic accuracy (Perell, Nelson, Goldman, Luther, Prieto-Lewis, & Rubenstein, 2001). The accuracy of nurses' clinical judgments for identifying hospitalized patients at risk for falls has been found to vary based on the educational preparation of the nurse (Myers & Nikoletti, 2003).

#### Problem Statement

Many falls occur in inpatient settings. Few research studies have been conducted on falls in hospitalized patients with cancer. In research that explored falls on different specialty units in a hospital, the three units with the highest fall rates were the general medicine, neurology, and oncology services (Hitcho et al., 2004). More research is needed to explore fall occurrence in hospitalized patients with cancer in order to identify fall risk factors related to cancer symptoms and side effects of treatments.

#### Research Objectives

The objectives of this research study are to:

1. Identify the fall risk factors of adult patients with cancer who fell while hospitalized;

2. Identify the most commonly occurring fall risk factors of the patients with cancer who fell; and

3. Compare the fall risk factors of the adult patients with cancer who fell to matched adult patients with cancer who did not fall while hospitalized.

#### *Conceptual Definitions*

A *fall* has been defined similarly by researchers conducting studies on patient falls. The Kellogg International Work Group proposed that a fall be defined as "an event which results in a person coming to rest inadvertently on the ground or other lower level and other than as a consequence of the following: sustaining a violent blow; loss of consciousness; sudden onset of paralysis, as in a stroke; (or) an epileptic seizure"

(Kellogg International Work Group, 1987, p. 4). Another research group defined a fall as "a sudden, unintentional change in position causing an individual to land at a lower level, on an object, the floor, or the ground, other than as a consequence of sudden onset of paralysis, epileptic seizure, or overwhelming external force" (Feder, Cryer, Donovan, & Carter, 2000, p. 1007). The Prevention of Falls Network Europe and Outcomes Consensus Group defined a fall as "an unexpected event in which the participants come to rest on the ground, floor, or lower level" (Lamb, Jorstad-Stein, Hauer, & Becker, 2005, p. 1619). The institution where this study was conducted uses the Veterans Health Administration's definition of a fall as "a sudden, uncontrolled, unintentional downward displacement of the body to the ground or other object excluding falls resulting from violent blows or other purposeful actions" (Sarasota Memorial Hospital, 2008, p. 1; Veterans Health Administration, 2004). For this study, the definition of a fall incorporates the elements of the previous researchers' proposed definitions and the research institution's definition. A fall is defined as a sudden uncontrolled and unintentional change in position in which a person comes to rest on the ground, floor or lower level that is not the consequence of a violent blow, sudden onset of paralysis, or epileptic seizure. The fall can be witnessed or un-witnessed when the patient is found on the floor or when the patient reports the fall.

A *fall risk factor* is a characteristic that increases a patient's risk for falling. Common patient characteristics assessed for risk for falling using various assessment tools include mental status or cognitive impairment; history of a previous fall; mobility impairment; specific or secondary diagnoses known to affect the risk for fall; difficulty

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with toileting or incontinence; medications that affect balance or cognition; polypharmacy; sensory deficits that involve vision, hearing, or sensation; balance impairment; age; limitations in activities of daily living; physical status deficits such as weakness or amputation; use of assistive devices; gender; and acuity of illness (Perell et al., 2001).

#### Significance of the Study

From 2000 to 2003, the Surveillance Epidemiology and End Results cancer statistics revealed the median age at diagnosis for cancer of all sites was 67 years (National Cancer Institute, n.d.) and 55.9% of the cancer diagnoses were in patients 65 years or older (National Cancer Institute, n.d.). The increased age at diagnosis can place patients with cancer at risk for falls when hospitalized.

Patients with cancer experience symptoms from their disease and the effects from their treatments that increase their risk for falls. Patients with cancer may experience diminished functional status, sensory-neurological deficits, nutritional deficits, polypharmacy, and de-conditioning from fatigue (Holley, 2002). Patients with cancer may experience nausea, vomiting, diarrhea, and suppression of bone marrow function from chemotherapy or radiation therapy. Anemia from bone marrow function suppression and malnutrition and electrolyte imbalances from gastrointestinal side effects may cause the patient with cancer to experience fatigue and muscle weakness. Older patients with cancer may also have other existing co-morbidities that place them at an increased risk for falls.

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Assessments of hospitalized patients with cancer need to focus on identifying risk factors associated with the cancer disease process, the cancer treatment, and the unique characteristics of the individual patient. Research on fall occurrences in hospitalized patients with cancer will contribute to the existing knowledge. With better identification of risk factors exhibited by oncology patients due to their disease process and treatments, nurse awareness of fall risk can be enhanced and interventions can be implemented to reduce the patient's chance of falling.

The results of this study may provide more information concerning risk factors associated with falls in hospitalized patients with cancer. The study may reveal risk factors, such as cognitive, muscular or sensory deficits, that may affect a patient's ability to participate in care-related activities and also increase their risk of experiencing a fall while in the hospital.

#### Chapter Two

#### Review of Literature

Oncology patients in the hospital are at risk of falling due to multiple factors including altered cognition, muscular weakness, motor or sensory deficits, impaired elimination, nausea and vomiting, a previous history of a fall, the use of sedating medications, physical effects related to anemia or elevated alkaline phosphatase, and the use of attached medical equipment. Inpatient falls are the largest reported incident in the acute care setting (Gowdy & Godfrey, 2003). Falls can result in injury and increased hospital stay (Hendrich, Nyhuis, Kippenbrock, & Soja, 1995).

The literature review presents studies that were conducted to evaluate patient and care-related characteristics that increase a patient's risk for fall in the hospital setting and methods used to assess fall risk factors. Studies are also reviewed that focused on abnormal blood pathologies that may result in signs or symptoms that increase a patient's risk of experiencing a fall.

#### Identification of Fall Risk Factors

#### Falls in Acute Care Settings

Hendrich, Nyhuis, Kippenbrock, and Soja (1995) conducted a retrospective casecontrol study to explore fall risk factors in order to develop a concise risk model for falls to be used in the clinical setting. The purpose of the study was to use logistic regression to develop a risk model that could be used to assess and identify the various levels of risk for fall in acute care populations, and to identify key areas based on the patients' intrinsic risk factors associated with the fall events that could be used for nursing interventions and fall-prevention programs. The study was conducted at an 1120-bed acute care tertiary hospital. The study sample consisted of 102 fall charts identified from all hospital incident reports during a one month period. The fall charts were reviewed for risk factors that were present at the time of admission and within 24 hours of the fall. The control sample consisted of 236 non-fall charts reviewed at the time of admission and midpoint through the hospital stay.

Data collection was performed for 22 risk factors the authors had identified as being statistically significant in fall-related literature or had been known to be prevalent in clinical practice. The median age of the fallers was 58 years, with a range of 9 to 104 years. The researchers used the logistic regression coefficient to calculate relative risk values for the 22 risk factors. The analyses identified seven significant fall risk factors: recent history of falls (RR = 9.1), depression (RR = 3.6), altered elimination (RR = 3.0), dizziness or vertigo (RR = 2.9), primary cancer diagnosis (RR = 2.7), confusion or disorientation (RR = 2.6), and altered mobility or generalized weakness (RR = 1.9) (Hendrich et al., 1995).

The authors recognized that the risk factor model based on the identified significant fall risk factors may not be of value for use in specialized areas of pediatrics, obstetrics, critical care, or rehabilitation. This study did identify the diagnosis of cancer as a risk factor for falls. The researchers noted that many of the patients who fell were not identified as being at risk for fall at admission, but became at risk hours or days later.

This suggested the need for continuous monitoring of patients for changes (Hendrich et al., 1995).

Hitcho et al. (2004) conducted a prospective descriptive study to describe the epidemiology of hospital falls. The objectives of their study were to identify and analyze the characteristics of patient falls, the types and circumstances of the falls, and the fall rates by service and staffing patterns. The extent of serious injury as a result of the inpatient falls was also assessed. The sample included all inpatient falls for medicine, cardiology, neurology, orthopedics, surgery, oncology, and women and infant services.

In a sample of 183 patients who fell during the 13 week study period, the mean age of the fallers was 63.4 years with a range from 17 to 96 years. Forty-four percent (n = 81) of the fallers were confused or disoriented at the time of the fall, 81% (n = 148) had general muscle weakness, 36% (n = 66) had urinary frequency, and 38% (n = 70) had lower extremity problems including weakness, swelling, loss of sensation, or missing limbs. Medications received by fallers within 24 hours prior to the fall included agents with central nervous system activity (58%, n = 106) and sedative-hypnotics (12%, n = 22). The patients who received a sedative-hypnotic at night fell more than patients who did not receive the medication (p = .03) (Hitcho et al., 2004).

Activities associated with the falls included elimination-related activities (50%, n = 92) and ambulation (19%, n = 35). Multivariate analysis revealed elimination-related falls as a significant predictor of being injured from a fall (aOR = 2.4, 95% CI = 1.1-5.3). Elimination-related falls were more common in patients who were aged 65 years or older

(p < .001). Being of age 65 years or older was of borderline significance for serious injury (cOR = 3.5, 95% CI = 0.95-13.1) (Hitcho et al., 2004).

The oncology service had the third highest fall rate (3.75 per 1000 patient days) and the second highest number of hospital days prior to fall (7 days, M = 10.5). The oncology service had the highest rate of injury and highest rate of major injuries of the seven services studied. Injuries were sustained in 74% of the oncology service falls with 11% resulting in moderate to severe injury. The authors suggested that oncology patients may be at higher risk for fall-related injuries due to the anemia, thrombocytopenia, and the increased risk for pathologic fractures typically experienced by this group. However, it was unclear to what extent pathologic fractures may have been a cause rather than a result of the fall (Hitcho et al., 2004).

Krauss et al. (2005) performed a prospective case-control study to analyze potential risk factors for inpatient falls and to describe the circumstances surrounding the falls at a 1300-bed urban academic hospital. The fall sample was drawn from the hospital's online adverse events reporting system for the period from June 6 through July 13, 2003. The fall sample consisted of 98 inpatient first falls reported for the medicine, cardiology, neurology, orthopedics, surgery, oncology, and psychiatry services. Excluded from the study were falls in the obstetrics service, falls during physical therapy sessions, and second falls by the same patient. Three controls per patient fall were randomly selected and matched based on the approximate length of stay. The fall and control patients were age 18 years and above. Results of the study showed that at the time of the fall, 46% (n = 45) of the patients were ambulating and 47% (n = 46) of the falls were elimination-related. Muscle weakness was reported as the primary reason for the fall in 36% (n = 35). Thirty-seven percent (n = 36) of the falls resulted in injury. The risk of falling increased as age increased (Pearson's chi-square = 7.04, p = .008). A multivariate analysis revealed significant predictors for an increased risk for fall including gait/balance impairment or lower extremity problems (aOR = 0.9, 95% CI = 2.0-41.0), confusion (aOR = 3.6, 95% CI = 1.6-8.4), use of sedatives or hypnotics (aOR = 4.3, 95% CI = 1.6-11.5), and activity level of "up with assistance" compared to "bathroom privileges" (aOR = 8.7, 95% CI = 2.3-32.7). Having urinary or stool incontinence or frequency was identified as a borderline significant fall predictor (aOR = 2.3, 95% CI = 0.99-5.6) (Krauss et al, 2005). *Falls in Oncology and Palliative Care Settings* 

O'Connell, Wellman, Cockayne, and Baker (2005) used a prospective cohort design study to examine fall risk factors and the nature of falls in oncology and palliative care units at a private hospital. The purpose of this study was to explore and identify the factors associated with patient falls in the oncology and palliative care setting, and to provide empirical evidence that could be used to guide fall prevention interventions in these settings. The participants were recruited from the oncology and palliative care units at a private hospital. The sample consisted of 227 patients aged 26 to 90 years with a mean age of 67.7 years (SD = 13.83).

Data were collected twice over a nine month period, within the first four days of admission (T1) and within four days post-fall (T2). Of the 227 participants, 34

experienced falls. The mean age of fallers (M = 74.79 years, SD = 9.97) was significantly higher (t[58.96] = 4.20, p = .000) than the mean age for non-fallers (M = 66.45 years, SD = 14.06). Two-tailed *t*-test analysis revealed that fallers (n = 18, M = 2.61, SD = 0.78) had a significantly higher (t[25.14] = -5.35, p = .000) mean ECOG (Eastern Cooperative Oncology Group) score than non-fallers (n = 193, M = 1.53, SD = 1.19). As a patient's ECOG performance score increases, the patient's ability to carry out activities of daily living decreases. The Non-parametric Mann-Whitney U test was used to analyze total confusion scores, orientation, and muscular functioning. Results showed that fallers were less alert (U = 1532.00, p = .03), less attentive (U = 1317.50, p = .04), and more confused (U = 1210.00, p = .01) than non-fallers. Fallers were significantly more likely to respond with the incorrect month (U = 1308.50, p = .000) and incorrect year (U = 1362.50, p =.001). Fallers had significantly decreased muscle strength as measured by the right arm push (U = 1170.0, p = .01) and the left arm push (U = 1198.5, p = .01). The two-tailed ttest was used to analyze self-rated fatigue level, resulting in a significant difference between faller reported fatigue (t[199] = -2.62, p = .01) and non-faller reported fatigue. The results suggested that the fallers were more fatigued at T1 than non-fallers (O'Connell et al., 2005).

Post-fall interview data collection revealed that falls occurred more often in the morning (40.6%, n = 13) and in the bathroom (50%, n = 14). Of the patient and nurse participants, 46.4% (n = 13) indicated that nothing could have been done to prevent the fall or that they did not know what could have been done to prevent the fall. Causes of falls were identified as poor patient condition, patient's lack of knowledge of equipment

use, lack of nursing assistance due to either the nurse not being available or the patient not seeking assistance, ambulating factors, and toileting issues (O'Connell et al., 2005). *Blood Pathology Values as Fall Risk Factors* 

In their study on the epidemiology of hospital falls, Hitcho et al. (2004) suggested that oncology patients may be at higher risk for fall-related injuries due to the anemia, thrombocytopenia, and the increased risk for pathologic fractures typically experienced by patients with cancer. O'Hagen and O'Connell (2005) investigated possible correlations between blood pathology values and patient falls in their retrospective study at a 220 bed acute-care hospital. The objectives of the study were to determine if blood pathology values differed between patients who fell and patients who did not fall, and to determine if the number and type of identified fall risk factors differed between the patients who fell and the patients who did not fall. The sample consisted of 110 patients who fell and 110 patients who did not fall matched by case-mix type and length of stay. Information collected from the patients' medical records included, age, gender, a history of falls, confusion, continence status, medications, presence of intravenous therapy, and various blood values. Blood values reviewed included electrolytes, proteins, liver enzymes, alkaline phosphatase, hemoglobin, and blood cell counts.

Statistical significance of the variables was determined using measures of central tendency, chi-square tests, and *t*-tests. The difference between the mean age of the patients who fell (M = 78.90, SD = 9.58) and the patients who did not fall (M = 74.72, SD = 10.43) was statistically significant (p < .05). Of the fall risk factors examined between the two groups, only confusion was found to be statistically significant (chi-square =

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27.78, df = 1, p = .001). Of the blood pathology values analyzed, only alkaline phosphatase (chi-square = 4.47, df = 1, p = .036) was found to be significantly related to the patients who experienced a fall. Anemia was not found to be statistically significant for the patients who had fallen (O'Hagen & O'Connell, 2005).

The sample of this study was small and the results do not support the findings of other fall risk factor research studies. This study did support advanced age and confusion as fall risk factors. The researchers did identify a blood pathology value, alkaline phosphatase that could be used as an objective measure for risk of falling. The enzyme alkaline phosphatase is used as a tumor marker and is elevated in conditions involving bone disease, metastases to the bone or liver, leukemia, and other malignancies (Jacobs, Oxley, & DeMott, 2002). The authors noted that patients with these conditions may experience lethargy, weakness, confusion, or malnutrition that may increase their risk for falling (O'Hagen & O'Connell, 2005).

Patients with cancer experience anemia as the result of the cancer disease process and treatment. Existing co-morbidities may also increase a patient's with cancer risk of developing anemia. Patients with anemia experience fatigue and muscular weakness that may increase their risk for falling. Dharmarajan, Avula, and Norkus (2006) performed a prospective case-control study to examine the relationship between anemia and the risk of falling during hospitalization in ambulatory older adults. The sample consisted of 362 ambulatory older male (n = 166) and female (n = 196) adults admitted to the university medical center from June 2001 through December 2004. The ambulatory older adults were from the community (n = 210) and from nursing homes (n = 152). Patients who fell were matched by age and gender with patients who did not fall. The study participants had a mean age of 76.9 years (SD = 9.9) with a range of 59 to 104 years.

Analyses were performed to detect significant differences in patient characteristics using student *t*-tests, chi-square analysis, and one-way analysis of variance testing. Analysis of the 362 participants revealed that females (M = 78.4 years, SD =10.0) were significantly older (p = .002) than males (M = 75.2 years, SD = 9.5). Mean hemoglobin levels were significantly (p = .036) higher in males (M = 12.7 g/dL, SD =1.9) than in females (M = 12.3 g/dL, SD = 2.0). Anemia occurred more often (p = .032) in males (54%) than in females (42%) (Dharmarajan et al., 2006).

Analyses of fall characteristics were performed using student *t*-tests, chi-square analysis, and Fischer's exact tests. Falls occurred in 198 (54.7%) of the 362 patients studied with 82% of the falls occurring in patients with anemia or borderline anemia. There were no significant differences between fallers and controls for age (p = .283) or gender (p = .554). Patients who fell had significantly lower mean hemoglobin levels (12.0 vs. 13.0 g/dL, p < .00005), lower mean hematocrit (36.6% vs. 39.2%, p < .00005), higher prevalence of anemia (56% vs. 38%, p = .001), and a longer length of hospital stay (14.2 days vs. 7.3 days, p < .00005) than did the controls. Multivariate logistic regression analysis revealed that patients with anemia had a significantly higher risk of falls than patients without anemia (OR = 1.86, 95% CI = 1.16-2.82, p = .008). Age, gender, and place of residence were not found to be independent predictors of falling while hospitalized (Dharmarajan et al., 2006).

#### Neurological Fall Risk Factors

In their study on inpatient falls, Krauss et al. (2005) found that gait or balance impairment or lower extremity problems were significant risk factors for falling. Peripheral neuropathy is a known side effect of cancer treatments. Peripheral neuropathy can cause limitations in lower extremity function that can place a patient with cancer at risk for falling. Richardson and Hurvitz (1995) conducted a retrospective case-control study to examine the association between falls in the elderly and peripheral neuropathy. They hypothesized that peripheral neuropathy was not a risk factor for falls and that peripheral neuropathy was just a marker for some other condition that is the actual cause of falls in the elderly population. The sample was drawn from the researchers' medical center patient database and consisted of 20 patients with axonal peripheral neuropathy and 20 control subjects matched by age and sex. The average age for the peripheral neuropathy subjects was 66.7 years with a range of 52 to 80 years, and the average age of the control group was 67.3 years with a range of 50 to 82 years. The matched pairs consisted of 15 male pairs and 5 female pairs.

Data collection consisted of interviews and physical examinations. The interviews gathered information on the subjects' past medical histories, present medications, falling incidents in the previous year, injuries associated with the falls, experiences of repetitive stumbles, and feelings of unsteadiness. Fall events were excluded if the patient could not provide information about the fall or if the fall involved symptoms of dizziness, weakness, dyspnea, or altered consciousness. The physical examinations collected neurological information on deep tendon reflexes, plantar responses, vibratory sense,

position sense at the toe and ankle, Romberg testing, finger to nose and heel to shin maneuvers, rapid altering movements of the hands and feet, pronator drift, gait, rigidity or spasticity by passive range of motion, and unipedal stance time. The lower extremity musculoskeletal examination looked for evidence of over-pronated feet, hammer toes, arthritis, or restricted range of motion of the hips, knees, or ankles (Richardson & Hurvitz, 1995).

Comparisons were made of the odds of falling or having a near fall for the subjects with peripheral neuropathy and the controls. Peripheral neuropathy was found to be significantly associated with the study participants' self-reports of falls and postural instability. In the previous year, the peripheral neuropathy group experienced 11 (55%) falls and the control group experienced 2 (10%) falls (OR = 17, 95% CI = 2.5, > 100). Of the 9 peripheral neuropathy subjects who did not report a fall, 7 (77%) reported repetitive stumbles or unsteadiness with no reports of stumbles or unsteadiness from the control group (OR = 13, 95% CI = 1.5, > 100) (Richardson & Hurvitz, 1995).

The role of risk factors was examined and analyzed using chi-square analysis. A total of 24 fall-associated risk factors were identified in the peripheral neuropathy group and 18 identified in the control group. There were no significant differences between the groups in the total number of other known fall-associated risk factors. There were significantly more (p < .01) peripheral neuropathy subjects (n = 10) on medications associated with falls than control subjects (n = 1). The control group (n = 6) had significantly more (p < .05) musculoskeletal abnormalities than the peripheral neuropathy

group (n = 1). No statistically significant differences were found when these risk factors were compared between the faller or non-faller groups (Richardson & Hurvitz, 1995).

Differences in physical examinations were analyzed using chi-square or Fischer's exact test. When compared to the control group, the peripheral neuropathy group had a significantly greater number of participants with abnormal deep tendon reflexes (p < .001), abnormal gait (p < .05), abnormal position sense at the toe (p < .0005), abnormal position sense at the ankle (p < .05), Romberg testing unsteadiness (p < .005), decreased unipedal stance time (p < .01), and decreased vibratory sense at the toe (p < .001), ankle (p < .005), and finger (p < .005). The peripheral neuropathy participants who fell had significantly worse vibratory sense at the finger (p < .05) and ankle (p < .05), and significantly decreased unipedal stance time (p < .05) than the peripheral neuropathy participants who fell and significantly decreased unipedal stance time (p < .05) than the peripheral neuropathy participants who fell and those who did not fall. Between the peripheral neuropathy participants who fell and those who did not fall, no significant differences for toe and ankle position sense, or any of the nerve conduction parameters were found (Richardson & Hurvitz, 1995).

Visovsky and Daly (2004) conducted an exploratory pilot study to determine the pattern of change in the function of peripheral nerves that occurs among individuals receiving cancer treatment with known neurotoxic agents. They conducted the first prospective study using comprehensive clinical measures of muscle and peripheral nerve changes resulting from either a biotherapy or combination chemotherapy regimen.

The participants were recruited from three Midwestern cancer centers. The small convenience sample consisted of 16 people diagnosed with cancer who were receiving either the combination chemotherapy of carboplatin and paclitaxel or the biotherapy

interferon alpha-2b. The eight men and eight women had a mean age 59 years with an age range from 28 to 79 years. All of the participants were European Americans. Seven were receiving treatment for malignant melanoma, four for ovarian cancer, and five for non-small cell lung cancer (Visovsky & Daly, 2004).

Various instruments were used by an experienced nurse practitioner to collect physical assessment data on visual acuity, hearing, deep tendon reflexes, vibratory sense, sensory perception of touch, lower extremity strength, and supine and standing blood pressure. Descriptive statistics were used to analyze the data. Regression slopes were calculated to show the changes in the different peripheral nerve function measures with treatment progression. Changes were noted from baseline to completion of the 12 weeks of therapy in vision (8% decline), deep tendon reflexes (6% decline), vibratory sense (10% decline), cutaneous sensation (3% decline), balance (18% decline), muscle strength (minimal decline), and positional blood pressure (mean change of 6 mm Hg at baseline to 15 mm Hg at four weeks and 7.5 mm Hg at twelve weeks). The researchers suggested that the orthostatic blood pressure changes may have been due to volume depletion as a result of the side effects of the therapy (nausea, vomiting, or a decrease in food and fluid intake). Hearing was affected as evidenced by the onset of conductive or sensorineural hearing losses after the total 12 weeks of treatment. The magnitudes of the changes were small and not statistically significant. No changes in gait were noted (Visovsky & Daly, 2004).

#### Assessment of Fall Risk Factors

In a study performed by Almadrones, McGuire, Walczak, Florio, and Tian (2004), two scales assessing peripheral neuropathy and functional status were evaluated. A repeated measure methodologic design study sought to evaluate the psychometric properties of a functional status scale and a peripheral neuropathy scale secondary to neurotoxic chemotherapy. This study was conducted within a Gynecologic Oncology Group (GOG) phase III clinical trial for women with advanced epithelial ovarian cancer. The clinical trial participants randomly received either six cycles of cisplatin with cyclophosphamide or six cycles of cisplatin with paclitaxel. The subjects were recruited from eight GOG institutions participating in the phase III clinical trial. At the beginning of the study, the sample consisted of 88 women with a mean age of 58 years (SD = 11.2). They were predominately white (89%, n = 78) with a good functional status at baseline.

Standard GOG forms from the clinical trial were used to collect data on patient registration, surgical and pathologic descriptions, chemotherapy and toxicity assessments for each cycle, and response and ongoing follow-up. GOG toxicity criteria were used to grade side effects. The five-point GOG Performance Status Scale was used for criterion validity analysis of the functional status scale and the peripheral neuropathy scale. The GOG Performance Status Scale rates the patient's ability to perform activities on a scale from 0 (fully active) to 4 (completely disabled, no self-care). The functional status scale being tested in this study contained subscales for six physical function items and two role function items. The peripheral neuropathy scale consisted of 11 symptom items. Four-point Likert-type scales were used to score the functional and symptom items from 1 (not

at all) to 4 (very much). The functional status scale and the peripheral neuropathy scales were combined into one questionnaire. The GOG nurses performed neurologic assessments of the patients and assisted the patients with the completion of the questionnaires before they left the clinic. Data were collected prior to the initiation of the chemotherapy (T1) and after six cycles of chemotherapy prior to a second-look laparotomy (T2). Only 67 patients participated at T2 (Almadrones et al., 2004).

Internal consistency reliability was evaluated using Cronbach's coefficient alpha, yielding acceptable levels. Coefficients obtained at T1 (n = 88) and T2 (n = 67) were 0.83 and 0.83 respectively for the physical function subscale, 0.96 and 0.92 for the role function subscale, and 0.91 and 0.89 for the peripheral neuropathy scale. Criterion validity was evaluated using the Rank Correlation test. Physical function (p = .0032) and role function (p = .0088) correlated positively with GOG performance status. The peripheral neuropathy scale correlated positively (p = .0116) with the GOG toxicity criteria. Exploratory factor analysis suggested that the functional status scale had a two-factor structure representing general and specific mobility factors. The analysis also revealed that the peripheral neuropathy scale had a two-factor structure representing foot neuropathy and hand neuropathy factors (Almadrones et al., 2004).

This study included only women being treated for ovarian cancer, limiting generalizability. The sample size decreased from T1 (88 women) to T2 (67 women) resulting in a smaller sample size at T2 that may have affected the outcomes of the factor analyses. The study suggested wording modifications to the scales to increase reliability and validity, and expansion of the scales to enhance clinical sensitivity and application.

The authors proposed that the revised scales could be useful for patient self-reported assessments of the effects of peripheral neuropathy. The scales could be used in the clinical setting to evaluate for declining functional status or increasing peripheral neuropathy. Declines in functional status and increasing peripheral neuropathy can increase a patient's risk for falling at home or when hospitalized (Almadrones et al., 2004).

Myers and Nikoletti (2003) conducted a prospective cohort study at a 570-bed acute care tertiary teaching hospital to evaluate two fall risk assessment tools and nurses' clinical judgments in predicting falls in hospitalized patients. The objectives of the study were to determine the reliability and validity of the selected fall risk assessment tools and the nurses' clinical judgments, and to compare the ability of the selected risk assessment tools and the nurses' clinical judgments to predict patients who fall. The study sample consisted of all consecutive admissions to the study wards over a 14-week period (excluding readmissions) and the nurses caring for the patients. A total of 226 patients were included in the study with ages ranging from 41 to 98 years and a mean age of 84.9 years (SD = 8.53). The majority of the patients were female (71.7%, n = 162). Length of stay ranged from 1 day to 218 days with a mean length of stay of 29.13 days (SD = 31.12). The nurses had a mean of 12.08 years of nursing experience (SD = 10.80) with a range from 1 month to 40 years.

Data collection for the two fall risk assessment tools was completed by the researcher at least one day after patient admission using the patient's record. The fall risk assessment tool 1 (FRAT1) contained nine items for the domains of age, mental status,

elimination, history of falling, sensory impairment, activity, and medications. Possible FRAT1 total scores ranged from 0 to 26 with a total score of 10 identifying a person at high risk for falls. The fall risk assessment tool 2 (FRAT2) contained five items for the domains of mobility, mental status, elimination, history of falling, and medications. Possible FRAT2 total scores ranged from 0 to 6 with a total score of 3 identifying a person at high risk for falls. Nurses caring for the patients were interviewed for data collection on their clinical judgment. The nurse caring for the patient was asked to state whether the patient was at risk for fall and to rate the fall risk on a scale from 0 (no risk) to 10 (high risk). Clinical judgments were given 101 times by registered nurses (44.7%), 69 times by enrolled nurses (30.5%), 36 times by first year registered nurses (15.9%), and 20 times by clinical nurses (8.8%) (Myers & Nikoletti, 2003).

The patients were followed until the time of the first fall, discharge, or death. Data on the fall were collected from hospital accident/incident forms. Data on fall prevention strategies being used for patients were collected from the patients' records. During the study, 34 patients fell (15%). The mean age of the fallers was 85.50 years (SD = 7.84). Analysis using *t*-tests and chi-square tests revealed that there were no significant differences between the ages of fallers and non-fallers (t = -0.439, df = 224, p = .661) or gender (chi-square = 0.321, df = 1, p = .571). There was a significant difference (t =-5.859, df = 224, p = .000) in the mean length of stay between fallers (M = 56.03 days, SD = 34.19) and non-fallers (M = 24.37 days, SD = 28.06). Of the 226 patients in the study, 202 (89.4%) had a risk assessment completed by staff at the time of admission and 199 (98.5%) were placed on a fall risk care plan by the staff. There was no significant difference between fallers and non-fallers based on completion of a risk assessment (chisquare = 0.136, df = 1, p = .712) or implementation of a fall risk care plan (chi-square = 0.321, df = 1, p = .542) (Myers & Nikoletti, 2003).

Good test-retest reliability calculations using intra-class correlation coefficients were shown for the FRAT1 (*ICC* = 0.85), FRAT2 (*ICC* = 0.80), and the nurses' clinical rating (*ICC* = 0.90). FRAT1 showed good sensitivity (91%), poor specificity (25%), and poor positive predictive value (18%), but showed a significant association between risk category and patient fall status (chi-square = 4.326, df = 1, p = .038). FRAT2 showed good sensitivity (91%), poor specificity (27%), and poor positive predictive value (18%), but showed a significant association between risk category and patient fall status (chisquare = 4.998, df = 1, p = .025). Nurses' clinical ratings showed good sensitivity (88%), poor specificity (26%), poor positive predictive value (18%), and no significant association between risk category and patient fall status (chisquare = 3.141, df = 1, p =.076). Nurses gave a correct clinical judgment in 35.3% (n = 79) of the cases. The first year enrolled nurses had the highest level of accuracy (44.4%) and the first year graduate registered nurses had the lowest level of accuracy (8.6%) (Myers & Nikoletti, 2003).

All of the methods showed an inability to discriminate between the patients at risk of falling and those not at risk. The nurses tended to overestimate those at risk. Fall prevention interventions were placed on most of the patients in the study. Ethics prevented the researchers from eliminating the implementation of interventions to prevent falls in order to observe for falls without interventions. This caused a "treatment paradox" where the interventions put in place for those at risk may have reduced the occurrence of falls. The study also revealed that newer graduate registered nurses need additional guidance in developing their ability to assess patients at risk for fall. Accurate nursing clinical judgment and assessment tools used for identifying patients at risk for fall are important in assessing patients for factors that put them at risk of falls (Myers & Nikoletti, 2003).

O'Connell, Baker, and Gaskin (2007) examined patient falls in a private teaching hospital's oncology and medical settings to examine the ability of a brief falls riskassessment tool (FRAT), derived from the Falls Risk Factors Audit Instrument (FRFAI), to differentiate patients who fall from patients who do not fall. The study retrospectively determined if the study participants had fallen in the previous 12 months and if the fall was in the hospital or the community. The retrospective component of the study included 377 participants ranging in age from 23 to 97 years, with a mean age of 73 years (SD =15). Of these participants, 74% (n = 280) were from the medical unit and 26% (n = 97) were from the oncology unit. The study then prospectively determined if the study participants fell during their current hospital admissions. The prospective component of the study included 34 participants ranging in age from 46 to 89 years with a mean age of 77 years (SD = 10). Of these participants, 85% (n = 29) were from the medical unit and 15% (n = 5) were from the oncology unit. Inclusion criteria included being age 18 years or older and speaking conversational English. Patients were excluded if they had dementia or confusion, were comatose, or were expected to die within 24 to 48 hours.

The FRAT was used to collect information from medical records and participant interviews on participant attributes including patient type (medical or oncology); patient

age and gender; prior history of falls in the past 12 months; orientation to person, place, and time; confusion; continence issues; physical functioning; muscle strength; and fatigue (O'Connell et al., 2007).

Demographic data and fall status data were analyzed using descriptive statistics. Differences between FRAT components for the participants who fell and those who did not fall were analyzed using *t* tests and chi-square tests. Separate analyses were performed on participants with a prior fall and participants with a current fall. Participants with a current fall were matched with current non-fallers. The participants were matched on diagnosis, age, and gender where possible. Ten of the fallers were matched with two non-fallers. The remaining two fallers were matched with one nonfaller. Statistical significance was set at .00185 for the 27 tests performed. Cohen's delta and phi measures were used to calculate effect sizes (O'Connell et al., 2007).

Results of the analyses of the retrospective components, consisting of the participants who had or had not fallen in the previous 12 months, revealed that the participants who had fallen had a significantly (p < .00185) higher mean age (n = 148, M = 75, SD = 13) than the participants who had not fallen (n = 229, M = 70, SD = 15). Significant differences (p < .00185) were found between the fallers and non-fallers with fallers having lower ECOG scales before and during admission, less muscle strength, and more fatigue. The researchers recognized that the ability to recall having fallen may have caused self-reporting errors and influenced the results of the data analysis (O'Connell et al., 2007).

No significant differences were found between participants with a current fall and their matched non-fallers in the retrospective component of the study. The non-fallers had substantially stronger right and left leg muscle strength than the fallers, but the differences were not statistically significant. The authors propose that the small sample size may have produced inadequate power to detect any significant differences. The results of the study do suggest that overall decline, as evidenced by lower ECOG scores and decreased muscle strength, should be considered when assessing patients for risk of falling (O'Connell et al., 2007).

A retrospective study by Giles, Whitehead, Jeffers, McErlean, Thompson, and Crotty (2006) analyzed computerized hospital documentation to determine if the hospital's units of care (tasks to address the patient's needs on the care plan) data entered by nursing staff into the nursing information system during a patient stay could be used to identify patients at risk for a hospital-related fall, and to contrast the units of care for patients who fell and patients who did not fall in order to identify a set of risk factors for falling in the hospital.

The study was conducted at a 250-bed acute care public hospital whose primary patients are aged 65 and older. Many of the patients were male war veterans. A total of 7167 patient admissions for 2002 were included in the study. Falls were identified in 389 admissions. Demographic information on fallers and non-fallers was similar between the two groups (Giles et al., 2006).

Multiple logistic regression analyses were performed to assess the 28 units of care for fall risk factors. Units of care that were identified as significant risk factors for inpatient falls included safety level 0 (p = .020), safety level 2 (p < .001), safety level 3 (p < .001), confusion (p < .001), impulsive behavior (p = .006), urinary incontinence (p = .001), urinary incontinence management (p < .001), risk management potential for falls (p < .001), use of four to six medications (p = .030), use of more than six medications (p = .029), and sleep disturbance (p = .030). Analysis also revealed that the total number of units of care identified on the care plan was a significant predictor of falls (Giles et al., 2006).

#### Integrated Summary

#### Study Design

Six of the studies were prospective in design, four were retrospective, and one was a repeated measure study. One study had both retrospective and prospective components. Four were case-control studies and three were cohort studies. Nine of the studies were conducted at hospitals. One study was conducted at a medical center, one at three cancer centers, and one as part of a cancer clinical trial.

Nine of the studies examined patient falls and fall risk factors. Two studies examined blood pathology values that may predispose patients to a decreased level of functioning. Two studies analyzed physical measures of peripheral neuropathy, a side effect of chemotherapy experienced by oncology patients that can affect lower extremity function. One study evaluated assessment tools for peripheral neuropathy.

#### Sample

The samples consisted primarily of male and female older adults with mean ages ranging from 58.0 years to 84.9 years. Total sample sizes ranged from 16 to 7167

participants. Fall occurrence sample sizes ranged from 12 to 389. Two small samples of 18 and 20 participants were used for researching physical measurements of peripheral nerve changes. One sample consisted only of white older females with cancer and receiving chemotherapy.

#### Data Collection and Measures

Various tools were utilized to collect patient and care-related data to identify fall risk factors. The Variables of Fall Data Collection Instrument was used in two studies conducted by the same group of researchers (Hitcho et al., 2004; Krauss et al., 2005). This instrument was used to collect fall information from adverse event databases, electronic nursing charting systems, medical records, patient interviews, nurse interviews, and radiological reports. Two studies (O'Connell et al., 2005; O'Connell et al., 2007) used the Falls Risk Factors Audit Instrument (FRFAI) that consisted of the Eastern Cooperative Oncology Group (ECOG) scale for physical functioning; the Total Confusion Score for alertness and attention; the Orientation to Person, Place and Time Score; the Muscle Strength Test; a question on the history of prior falls; and the Selfrated Fatigue Level. One study (Almadrones et al., 2004) utilized the Gynecologic Oncology Group Performance scale to evaluate a proposed functional status scale and peripheral neuropathy scale. Another study (Myers & Nikoletti, 2003) evaluated two proposed fall risk assessment tools: the fall risk assessment tool 1 (FRAT1) and the fall risk assessment tool 2 (FRAT2). Two studies (Richardson & Hurvitz, 1995; Visovsky & Daly, 2004) used physical examinations and tests to collect clinical measurements that included deep tendon reflexes, vibratory sense, position sense, cutaneous sensation,

balance, gait, lower extremity strength, range of motion, vision, hearing, and blood pressure. Hospital accident or incident reports were used in seven studies to collect fall occurrence information. Three of the studies used patient and nurse interviews to obtain information on fall events.

#### Lessons Learned

The literature review revealed that research on fall risk factors has primarily focused on general hospital populations. Significant factors identified by various research studies included increased age, a recent history of falls, confusion or disorientation, impaired gait or balance, muscular weakness, impaired or altered elimination patterns, lower extremity problems, and various medications including sedative and hypnotics. These factors can be utilized in assessing hospitalized patients for risk of falls and are usually included in institutional safety assessment screenings.

Research of studies reviewed also suggest that there may be factors that oncology patients experience that place them at an increased risk for falling while hospitalized. Suggested risk factors included a primary cancer diagnosis and the side effects of anemia and fatigue which are experienced by many patients with cancer. The symptoms of numbness and tingling in the feet experienced by patients receiving neurotoxic chemotherapy is another possible risk factor for falls. One study found that falls on the oncology unit had the highest injury rate which may be attributable to the effects of the patients' with cancer anemia, thrombocytopenia, and increased risk for pathologic fractures. Further investigations into these risk factors may provide additional support to these propositions.

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#### Nursing Implications

Patients with cancer experience a multitude of symptoms that can impair functional ability. Common symptoms experienced by patients with cancer that can increase their risk for falls include anemia, fatigue, reduced muscle strength, impaired lower extremity sensations, and impaired elimination. Proficient assessments by oncology nurses can identify risk factors that increase a patient's risk for fall, but nurses need to know which physical attributes to continuously assess in order to implement the appropriate fall prevention interventions. Additional research on oncology patients may shed light on significant risk factors patients with cancer experience that increase their risk for falling.

#### Gaps in Literature

The literature review revealed that there is a lack of research specific to the oncology patient. Oncology units have been included in research studies, but few have been conducted to address the specific effects of the cancer disease and cancer treatments that can cause physical manifestations that impair the oncology patient's neurological sensory ability and mobility. Additional research on why patients with cancer fall in the hospital can add to the existing inpatient fall knowledge and may assist in identifying risk factors that are not included in standardized safety assessment tools. Fall risk assessment tools can then be modified to include cancer-related fall risk factors.

## Chapter Three

## Methods

A literature review supports the need for additional research on falls experienced by oncology patients in order to identify fall risk factors. Researchers who have included oncology units in their studies have suggested risk factors that can result from the cancer disease process and the side effects of cancer treatment including confusion and disorientation, general muscle weakness, impaired gait, urinary frequency or incontinence, stool incontinence, lower extremity problems, use of sedative-hypnotics, and a history of falls in the past six months (Hitcho et al., 2004; Krauss et al., 2005; O'Connell et al., 2005). This chapter discusses the design of the study conducted on falls experienced by patients with cancer in the hospital, the instrument used to collect patient fall risk factor information, and the statistical analysis processes that were used to examine the data.

## Research Design

A retrospective, matched, case-control design was used to examine oncology patient characteristics in order to identify factors that increase falls in hospitalized oncology patients. The target population for this study was hospitalized adult patients who had a recent diagnosis of cancer or cancer recurrence.

#### Setting and Sample

The sample for this study was selected from patients admitted to an 840-bed community hospital. The sample consisted of 30 adult oncology patients who experienced a fall during hospitalization (fall group) and 30 adult oncology patients who did not experience a fall during hospitalization (control group). For all subjects in this study, the inclusion criteria were (a) the subject must be age 18 years or older, (b) the subject must be admitted as an inpatient to the hospital, and (c) the subject must have cancer or a cancer recurrence diagnosed in the last five years. For the fall group, an additional inclusion criterion was that the subject must have experienced a reported fall while hospitalized. If a fall group subject experienced more than one fall during his or her admission to the hospital, only the first reported fall was used for the study. For the matched control group, additional inclusion criteria were (a) the subject must not have experienced a reported fall while hospitalized, (b) the subject's age must be within five years of the matched fall subject, and (c) the subject must have a similar cancer diagnosis as the matched fall subject. Exclusion criteria included fall subjects who could not be matched to a control subject by age and cancer diagnosis.

#### Instrumentation

For the proposed study, a chart review audit form was developed to extract information from the hospital's computerized Fall Occurrence Reports and computerized medical record system. The audit form was based on fall risk factors identified by the review of the research literature and identified by the Joint Commission (2007c). The chart review audit form is displayed in the Appendix.

Data on various factors that may increase a patient's risk for falling were collected from the patient medical records using the chart review audit form. The presence and absence of fall risk factors that are assessed and documented by nursing staff were collected. The risk factors include (a) a prior history of falling (Hendrich et al., 1995; The Joint Commission, 2007c); (b) altered cognition as evidenced by confusion, disorientation, or decreased level of consciousness (Giles et al., 2006; Hendrich et al., 1995; Hitcho et al., 2004; Krauss et al., 2005; O'Connell et al., 2005; The Joint Commission, 2007c); (c) elimination problems including impaired bowel and urinary elimination, nausea and vomiting (Giles et al., 2006; Hendrich et al., 1995; Hitcho et al., 2004; O'Connell et al., 2005; The Joint Commission, 2007c); (d) motor problems including impaired gait and muscular weakness (Hendrich et al., 1995; Hitcho et al., 2004; Krauss et al., 2005; O'Connell et al., 2005; The Joint Commission, 2007c); (e) sensory problems as manifested by numbress or tingling in the extremities (Hitcho et al., 2004; Richardson & Hurvitz, 1995; The Joint Commission, 2007c); (f) the use of sleeping pills or sedatives (Frels et al., 2002; Krauss et al., 2005; The Joint Commission, 2007c); and (g) attached tubing to equipment (The Joint Commission, 2007c). Laboratory values that may increase a patient's risk for falling and that are reviewed by nursing staff were collected. The laboratory values include hemoglobin levels (Dharmarajan et al., 2006) and alkaline phosphatase levels (O'Hagen & O'Connell, 2005). The National Cancer Institute's hemoglobin grading system (U.S. Department of Health and Human Services, 2006) was used to score the patient's anemia as grade 1 (hemoglobin less than

the lab normal level to 10.0 g/dL), grade 2 (less than 10.0 to 8.0 g/dL), grade 3 (less than 8.0 to 6.5 g/dL), or grade 4 (less than 6.5 g/dL).

The beginning evidence of validity for the chart review audit form was based on a careful review of research literature about patient falls. In the proposed study, any differences found between the patients who fell and did not fall, would provide additional evidence of validity for the chart review audit form. An interrater reliability test was conducted during the study to determine the reliability of the chart review audit form.

#### Procedures

#### Institutional Approval and Informed Consent

The study was first presented to the hospital's Nursing Research and Evidence-Based Practice Council. The Council reviews and approves all propositions for research conducted by nurses at the hospital prior to submission to the Institutional Review Board. Permission to begin seeking approval was obtained from the Council. The study was submitted for an expedited review by the hospital's Institutional Review Board and approved. A waiver of informed consent was submitted for the proposed study since there is no more than minimal risk to the subjects and the waiver would not adversely affect the rights and welfare of the subjects. No patient identifiable information was collected from the chart reviews. The retrospective study involved chart reviews spanning the past three years. The waiver was necessary because there could be difficulty in contacting subjects hospitalized in the past three years. The hospital is located in a community where many of the population are part-time retired residents and the contact information in the medical records contained only their local addresses. The higher average age of persons diagnosed with cancer increased the possibility of the subjects being deceased. These factors could make carrying out the research impractical without the waiver. After approval from the hospital's Institutional Review board was received, the study was submitted to the University of South Florida's Institutional Review Board and approval was received.

## Data Collection

Subject identification and data collection using the chart review audit form were performed by the primary nurse researcher. Hospital fall occurrence reports were reviewed retrospectively from October 31, 2007, back to November 1, 2005, to identify falls experienced by adult patients admitted to the hospital's inpatient oncology unit with a cancer diagnosis. Patient age, diagnosis, and patient medical record number were obtained from the fall occurrence report. A total of 37 fall occurrence reports for patients with a cancer diagnosis were identified during the above time frame.

Matched controls were identified using the oncology unit's daily patient lists archive file that included admissions to the unit for the past 12 months. Controls were matched by age (within five years of the fall subject's age) and by cancer diagnosis. The first 30 fall subjects that were matched with a control were used for the study. Sequence numbers ranging from 101 to 130 were assigned to the fall subjects. Sequence numbers ranging from 201 to 230 were assigned to the matched control subjects.

For the fall subjects, the patient record numbers obtained from the fall occurrence reports were used to access and review the computerized medical records. The last nursing assessments and laboratory values prior to the fall were identified using the date and time of the fall occurrence. The fall subject's nursing assessment flow sheets were examined to collect data on the patient factors included on the chart review audit form. The fall subject's laboratory test results were examined to extract information on the hemoglobin level and the alkaline phosphatase level. The number of days from admission to fall occurrence was calculated for each fall subject in order to determine the review date for the matched controls.

For the matched control subjects, the patient record numbers obtained from the archive file were used to access and review the computerized medical records. Using the number of days from the matched fall subject's admission to fall occurrence, the medical record review date was calculated using the control subject's admission date. The last nursing assessments and laboratory values were identified using the calculated date and the matched fall subject's fall occurrence time. The matched control subjects' computerized medical records were reviewed to obtain the same data on patient factors and blood pathology values as collected for the fall subjects.

A secondary nurse researcher, recruited from the hospital's oncology unit, reviewed the computerized medical records and completed the chart review audit forms for 10 random subjects who had been reviewed by the primary nurse researcher. A random number generator program developed by an independent computer programmer was used to generate 10 random numbers from 1 to 60. For random numbers from 1 to 30, a fall subject was selected using the subject's sequence number. For random numbers from 31 to 60, a control subject was selected. The 10 forms completed by the primary nurse researcher and the secondary nurse researcher were compared for agreement and tested for interrater reliability.

#### Data Analysis

Reliability of the chart review audit form was determined using percent of agreement. Since only categorical data were collected by the secondary nurse researcher for comparison, the interrater reliability was calculated by dividing the number of agreements between the primary and secondary nurse researchers by the total number of observations (Garson, 2008).

SPSS analysis software (SPSS Inc., 2006) was utilized to analyze the data collected. Descriptive statistics were used to identify the fall risk factors of the adult patients with cancer who fell while hospitalized and to identify the most commonly occurring fall risk factors of the patients with cancer who fell. A series of chi-square tests were utilized to identify significant differences in the frequency of the fall risk factors between the fall subject group and the control group. A level of p < .05 was used to determine statistical significance.

## Chapter Four

#### Results, Discussion, and Conclusions

This study examined characteristics that may increase an oncology patient's risk of experiencing a fall while in the hospital. A chart review audit tool was developed to collect data on fall risk factors from electronic medical records. This chapter presents the results of the chart review audit tool reliability testing and the analysis of the fall risk factors. Risk factors of the patients with cancer who fell and the most commonly occurring risk factors are identified. Significant differences between the risk factors exhibited by the patients who fell and the control patients who did not fall are presented. The strengths and weaknesses of the sample are identified and the results of the study are discussed. A summary of the results and implications for future studies are presented.

#### Results

#### Chart Review Audit Form

The chart review audit form collected data for nine categories. Table 1 summarizes the number of data collection agreements and disagreements between the primary nurse researcher and secondary nurse researcher for the items in each category. Analysis revealed agreement in 23 of the 26 items researched and disagreement in 3 of the 26 items researched, resulting in a percent of agreement of 88.5%. Disagreements were only noted in the anemia grading items.

Chart Audit Form Categories	Agreements	Disagreements	
Safety	6	0	
Neurologic	3	0	
Peripheral/vascular	2	0	
Gastrointestinal	3	0	
Nutrition	2	0	
Genitourinary	3	0	
Musculoskeletal	2	0	
Hemoglobin (anemia grades)	1	3	
Alkaline phosphatase	1	0	

# Interrater Reliability Testing: Agreements and Disagreements

# Patient Characteristics

The fall subject group consisted of 18 males (60%) and 12 females (40%) with ages ranging from 36 years to 83 years (M = 69.02 years, SD = 10.820). The control subject group consisted of 16 males (53%) and 14 females (47%) with ages ranging from 36 years to 86 years (M = 68.83 years, SD = 11.247). Multiple types of cancer were represented in the 30 matched subjects. Cancer diagnoses included in the study were non-small cell lung cancer (n = 5), acute myelogenous leukemia (n = 3), breast cancer (n = 3), bladder cancer (n = 2), colorectal cancer (n = 2), lymphoma (n = 2), prostate cancer (n = 5).

2), gastric cancer (n = 1), head and neck cancer (n = 1), hepatic cancer (n = 1), melanoma (n = 1), multiple myeloma (n = 1), myelodysplastic syndrome (n = 1), ovarian cancer (n = 1), pancreatic cancer (n = 1), small cell lung cancer (n = 1), uterine cancer (n = 1), and unknown primary (n = 1).

#### Fall Risk Factors for Patients Who Fell

Data collected for similar fall risk factors listed on the chart review audit form were collapsed into summary categories. Data for the fall risk factors of altered cognition present, disoriented, and decreased level of consciousness were recorded in the altered cognition category. Impaired elimination, gastrointestinal incontinence, diarrhea for three or more days, genitourinary incontinence, genitourinary frequency/urgency, and nocturia data were documented in the impaired elimination category. Impaired gait and unsteady gait data were entered in the impaired gait category. Data for the factors of numbness or tingling and peripheral neuropathy were recorded in the peripheral neuropathy category. Nausea/vomiting, nausea for three or more days, and vomiting for three or more days data were documented in the nausea/vomiting category.

Table 2 displays the frequencies and percentages of the fall risk factors identified for the fall subjects. The six most commonly occurring fall risk factors, in descending order of frequency, include muscular weakness, impaired gait, anemia, attached tubing, alkaline phosphatase level above normal, and altered cognition.

Fall Risk Factors	Frequency	Percent
Muscular weakness	26	86.7
Impaired gait	23	76.7
Hemoglobin – anemia toxicity	23	76.7
Attached tubing	22	73.3
Alkaline phosphatase > lab normal	13	43.3
Altered cognition	13	43.3
History of falls in past six months	12	40.0
Impaired elimination	12	40.0
Use of sleeping pills or sedatives in last eight hours	9	30.0
Nausea/vomiting	3	10.0
Motor/sensory problems	1	3.3
Peripheral neuropathy	1	3.3

Frequency and Percentage of Fall Risk Factors for Patients Who Fell

# Fall Risk Factor Comparison

Analysis results presented in Table 3 compare the fall risk factor data collected for the fall subject group and the control subject group. Further analysis for significance of the individual anemia toxicity grades is illustrated in Table 4.

	Fall Group	Control Group	)		
Fall Risk Factors	Frequency	Frequency	Chi-square	df	р
Altered cognition	13	4	6.648	1	.010
Muscular weakness	26	19	4.356	1	.037
History of falls in past six months	12	5	4.022	1	.045
Use of sleeping pills/sedatives	9	15	2.500	1	.114
Impaired gait	23	18	1.926	1	.165
Motor/sensory problems	1	0	1.017 <sup>a</sup>	1	.313
Attached tubing	22	25	.884	1	.347
Impaired elimination	12	9	.659	1	.417
Nausea/vomiting	3	4	.162 <sup>a</sup>	1	.688
Alkaline phosphatase > lab norma	1 13	12	.069	1	.793
Hemoglobin – anemia toxicity			.546	3	.909
Grade 1 anemia	12	14			
Grade 2 anemia	9	8			
Grade 3 anemia	2	1			
Grade 4 anemia	0	0			
Peripheral neuropathy	1	1	.000 <sup>a</sup>	1	1.000

# Chi-Square Significance Testing of Fall Risk Factors for Fall and Control Groups

<sup>a</sup> Two cells have expected count less than 5.

	Fall Group Control Group				
Fall Risk Factors	Frequency	Frequency	Chi-square	df	р
Grade 1 anemia	12	14	.271	1	.602
Grade 2 anemia	9	8	.082	1	.774
Grade 3 anemia	2	1	.351	1	.554
Grade 4 anemia	0	0			

Chi-Square Significance Testing of Anemia Toxicity Grades for Fall and Control Groups

Pearson's chi-square analysis was utilized to test the difference in frequencies of fall risk factors between the independent fall and control groups (Polit & Beck, 2004). The use of Pearson's chi-square analysis was appropriate for determining statistical significance of the fall risk factors. The sample data collected were nominal, had finite values, and the observations were independent (Garson, n.d.). Three fall risk factors were found to be statistically significant: altered cognition (p = .010); muscular weakness (p = .037); and a history of falls in the past six months (p = .045).

#### Discussion

#### Chart Review Audit Form

The reliability of the chart review audit form used in this study was 88.5%. In their discussion of interrater reliability calculation, Burns and Grove (2005) state that there is no absolute value under which the reliability is unacceptable. However, a reliability of less than 80% should raise concerns about the reliability of the data or the data collector. A reliability of 90% or higher is preferred.

The reliability of 88.5% for the chart review audit form was not ideal, but is more than acceptable. Disagreements were only noted in the anemia grading items. The chart review audit form was constructed using the National Cancer Institute's hemoglobin grading system (U.S. Department of Health and Human Services, 2006). This grading system describes the hemoglobin lab values from the high value to the low value for each grade. For example, grade 2 anemia is described as less than 10.0 to 8.0 g/dL. In reviewing the disagreements, the secondary nurse researcher suggested that the use of a description from a low value to a high level, such as 8.0 g/dL to less than 10.0, would have been less confusing when deciding which grade to select on the chart review audit form.

One limitation of this study was the charting system utilized by the nurses to document their assessments. There is no reliability data available on this electronic charting system. It was developed for the hospital and is updated when approved changes are submitted to the information technology department. Nurses are instructed on the use of the charting system at orientation. Results of this study revealed inconsistent documentation by the nurses. The audit form relied on accurate documentation by nurses of their assessments of the subjects. Data were collected based on the nurses' selections of specific assessments in computerized nursing assessment flow sheets that utilized drop-down boxes for assessment selections. Free text documentation in each category also was reviewed for discussion of the fall risk factors and data were collected for that

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category. The computerized nursing assessment flow sheet is organized by category where the safety category is used by the nurses to determine a patient's risk of fall. Assessments recorded in the safety category are repeated in other categories where the nurses record assessments by body system, requiring the nurse to document some assessments in two different categories. Visual inspections of the chart review audit forms revealed inconsistencies in documentation. The presence of altered cognition was documented in the safety category in two charts but no abnormalities were documented in the neurologic category. Disorientation was documented in the neurologic category in three charts, but no altered cognition was recorded in the safety category. Impaired gait was documented in the safety category in five charts with no abnormalities documented in the musculoskeletal category. Impaired elimination was noted in the safety category in three charts, but there were no abnormalities recorded in either the gastrointestinal or genitourinary categories. Four charts recorded abnormalities in the genitourinary category but did not document impaired elimination in the safety category. Requiring a nurse to document an assessment in multiple locations can lead to incorrect or incomplete documentation. These inconsistencies could affect the results of this study. Due to these inconsistencies, similar fall risk factors were collapsed into summary fall risk categories for data analysis.

#### Study Sample

Limitations of the research study included having a small, nonrandom sample. The research study was conducted using a small sample of 30 subjects in each of the two groups. Having a small sample increases the risk of type II errors resulting in the inability to find relationships between the occurrence of a fall and fall risk factors (Garson, n.d.). The study subjects were drawn from a convenience sample of patients admitted to the inpatient oncology unit at one community hospital. Convenience sampling is the weakest form of sampling, has the risk of sampling bias (Polit & Beck, 2004), and does not meet the assumption of a random sample for chi-square significance testing (Garson, n.d.). Including subjects with a cancer diagnosis from other units at the hospital or collecting data from other area hospitals could decrease the risk of sampling bias.

Other limitations of the study sample may have affected the results. The patients who fell were matched by cancer diagnosis to patients who did not fall. They were not matched by cancer stage or treatment modality. Cancer staging information was not available in the computerized medical records for all of the patients included in the study. The patients were also not matched by gender. Previous research on patient falls in the hospital has shown that males experience a first fall more often that females (Halfon, Eggli, Van Melle, & Vagnair, 2001). It is also conceivable that not all patient falls were reported, limiting the collection of fall data information. Patients may have experienced an un-witnessed fall and may not have reported it to their nurse.

#### Fall Risk Factors

Another limitation of the study was the low number of results revealed for some of the risk factors researched. Inadequate frequency results for analysis, having expected frequencies of less than five (Garson, n.d.), were discovered for 25% (n = 3) of the 12 risk factors analyzed. Results ranged from 0 to 26. The assumption of adequate cell size was not met for chi-square significance testing (Garson, n.d.).

The mean age of the fall subject group was 69.02 years which supports past research showing that being over age 65 years is a risk for falling (O'Connell et al., 2005). However, preliminary statistics revealed that age was not a significant fall risk factor in this study (p = .944) because each fall subject was matched to a control subject having an age within five years of the fall subject's age. This matching doubtlessly affected the finding of age as not being a statistically significant characteristic for occurrence of a fall. Future studies excluding the age criterion and matching the subjects by cancer diagnosis, stage of disease and length of disease process may reveal differences in the mean ages of the study groups.

Analysis revealed three fall risk factors that were statistically significant. Altered cognition was statistically significant (p = .010) and was present in 43.3% (n = 13) of the fall subjects and 13.3% (n = 4) of the control subjects. This result agrees with previous research studies (Giles et al., 2006; Hendrich et al., 1995; Hitcho et al., 2004; Krauss et al., 2005; O'Connell et al., 2005).

Muscular weakness experienced by 86.7% (n = 26) of the fall subjects and 63.3% (n = 19) of the control subjects was statistically significant (p = .037), supporting earlier research (Hendrich et al., 1995; Hitcho et al., 2004; Krauss et al., 2005; O'Connell et al., 2005). Fatigue, which may also be interpreted as muscular weakness by nurses or patients, was not explicitly documented in the nursing assessments for the patients in this study. Earlier research has shown an impact of fatigue on a patient's risk for falling (O'Connell et al., 2005). Future prospective studies including the risk factor of fatigue

may reveal the necessity of explicitly including fatigue in the nursing assessment of a patient with cancer.

Having a history of falls in the past six months was statistically significant (p = .045), supporting prior patient fall risk research (Hendrich et al., 1995). A history of falls was reported in 40.0% (n = 12) of the fall subjects and 16.7% (n = 5) of the control subjects.

Although present in 76.7% (n = 23) of the fall subjects, impaired gait was not found to be statistically significant (p = .165) as it was also present in 60.0% (n = 18) of the control subjects. Impaired elimination problems identified in other studies (Giles et al., 2006; Hendrich et al., 1995; Hitcho et al., 2004: O'Connell et al., 2005) were not found to be significant. Impaired elimination was not statistically significant (p = .417) and was experienced by 40% (n = 12) of the fall subjects and 30% (n = 9) of the control subjects. Nausea and vomiting was experienced by 10% (n = 3) of the fall subjects and 13.3% (n = 4) of the control subjects and was not statistically significant (p = .688). Elimination problems, nausea, and vomiting are experienced by many cancer patients due to the disease process and treatments. Expanding tumors can create bowel and urinary system obstructions. Many chemotherapies cause nausea, vomiting, and diarrhea. Surgical procedures may impede neural transmissions to the gastrointestinal and urinary systems, resulting in decreased control of bowel and bladder functions. These disease related factors may have affected the study subjects in both the fall and control groups, resulting in statistically insignificant analysis results.

Sensory impairments suggested by previous studies (Hitcho et al., 2004;

Richardson, & Hurvitz, 1995) were not found to be statistically significant fall risk factors. Motor/sensory problems were experienced by one fall subject (3.3%, p = .313) and not by any control subjects. Peripheral neuropathy was experienced equally (3.3%) by one fall and one control subject. Peripheral neuropathies that occur as a result of chemotherapies usually resolve with time. Peripheral neuropathy can also be found in patients with diabetes. The scant number of occurrences in this study may be due to the timing of the hospitalizations in relation to the administration of chemotherapy regimens or the lack of assessment by the nurses.

The use of sleeping pills or sedatives identified in previous studies as a fall risk factor (Frels et al., 2002; Krauss et al., 2005) was not found to be statistically significant in this study (p = .114). The control subjects were identified with this risk factor more frequently (50%, n = 15) than the fall subjects (30%, n = 9). Patients with advanced cancer frequently require medication that may be sedating for pain management. Medications for nausea and vomiting can also be sedating. The hospital environment is busy and stimulating, and not conducive to rest. The environmental stimulation may decrease a patient's ability to cope with pain and hospitalized patients frequently require medication to assist with sleeping. The requirement for medications for side effect management and sleep by patients in both the fall and control groups may be reflected in the results of statistical insignificance.

Having tubing attached to equipment was also not significant (p = .347). The frequency of attached tubing was greater for the control subjects (83.3%, n = 25) than for

the fall subjects (73.3%, n = 22). Many patients with cancer require attached tubing for intravenous medications, blood product administration, body fluid drainage, or sequential compression devices for deep vein thrombosis prevention when hospitalized and this common need may be a factor for these results.

Data collected on laboratory values did not reveal statistically significant fall risk factors suggested by a prior study (Dharmarajan et al., 2006). Anemia was experienced by 76.7% (n = 23) of both the fall subjects and the control subjects. Grade 1 anemia was experienced by 40.0% (n = 12) of the fall subjects and 46.7% (n = 14) of the control subjects (p = .602). Grade 2 anemia was experienced by 30.0% (n = 9) of the fall subjects and 26.7% (n = 8) of the control subjects (p = .774). Grade 3 anemia was experienced by 6.7% (n = 2) of the fall subjects and 3.3% (n = 1) of the control subjects (p = .554). None of the subjects experienced grade 4 anemia. The difference in the frequency of elevated alkaline phosphatase levels was not statistically significant (p = .793) as seen in previous research (O'Hagen & O'Connell, 2005). Alkaline phosphatase was elevated slightly more frequently in the fall subjects (43.3%, n = 13) than the control subjects (40.0%, n = 12). The fall subjects were matched to control subjects by cancer type with a diagnosis of cancer or cancer recurrence within the last five years. This matching could place the subjects at similar timelines in their cancer disease process, resulting in similar blood abnormalities. Anemias can occur before, during and after cancer diagnoses and treatments. Alkaline phosphatase becomes elevated as the skeletal system becomes involved with cancer metastasis. Both the fall subjects and control subjects experienced similar frequencies of anemias and elevated alkaline phosphatase.

## Nursing Implications

The findings from this research study support the importance of comprehensive patient assessments by nurses in order to recognize characteristics that may increase a patient's risk for falling while in the hospital. While only three of the fall risk factors were found to be statistically significant, 8 (66.7%) of the 12 fall risk factors studied were experienced by at least 40% of the fall subjects. The nurse's assessment for altered cognition fall risk factors includes assessing for confusion, altered attention, altered level of consciousness, and disorientation. Patients should be asked to state their name, the current month and year, and asked if they know where they are (O'Connell et al., 2005). The presence of muscular weakness should be determined by assessing hand grip and leg push strength (O'Connell et al., 2005). Upper leg strength may be evaluated by observing the patient's ability to rise from a sitting position. The patient, family member or significant other should be asked about any previous falls experienced by the patient (Hendrich et al., 1995; O'Connell et al., 2005).

Documenting these observations accurately is equally important in determining a patient's risk for fall and also for communicating any risk with other members of the interdisciplinary care team. The need for an efficient documentation system that allows the nurse to communicate the patient assessment quickly and accurately is paramount in today's fast paced acute care setting. As illustrated in this study, documentation systems that require nurses to "double chart" nursing assessments increases the risk of assessments being omitted and communicated inaccurately to other members of the care team.

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Specialized nursing units, such as an oncology unit, require focused education on the effects of particular disease processes on the patients. Cancer and its treatments cause the patients to experience many side effects that may increase their risk for falling. Anemia may cause patients to feel weak and impair their ability to ambulate or think clearly. The effects of the cancer, chemotherapy, or radiation therapy may decrease a patient's cognition or cause the patient to become disoriented. The presence of tubing for treatments such as intravenous chemotherapy, antibiotics, and hydration, or catheters for urinary retention or incontinence or effusion evacuation, may impair ambulation. Many patients with cancer require medications to manage pain and discomfort. Anti-emetics needed to control the nausea and vomiting associated with treatments and bowel obstructions can also be sedating. Educating nurses to recognize the importance of these problems may increase their diligence in accurately documenting their assessments and implementing appropriate interventions to reduce a patient's risk of experiencing a fall.

#### Conclusions

This study utilized chart audits of electronic medical recording systems in order to research patient characteristics that may increase an adult patient's with cancer risk of falling while in the hospital. Patient characteristics that were identified in prior research studies as increasing a patient's risk of fall were examined. Patients with cancer who fell while hospitalized were matched by diagnosis and age to control patients who did not fall. Commonly occurring fall risk factors were identified from electronic nursing assessment flow sheets and laboratory values. Results of the study found three statistically significant factors in the patients with cancer who fell. The significant factors

identified were altered cognition, muscular weakness, and having a history of falling in the past six months.

This study was limited by the small sample size and inconsistencies in the nursing documentation audited. More nursing research, focused on falls experienced by patients with cancer in the hospital, is needed utilizing larger samples. This study included a small sample of subjects and was unable to significantly identify many of the fall risk factors suggested by prior studies. Research should be conducted in multiple hospitals that utilize various nursing documentation systems. Research using other types of systems may reveal a system that records more efficient and accurate nursing assessment documentation that supports previous patient fall research. Few of the previous nursing research studies on patient falls focused on patients with cancer only. Many of the research studies were on hospitalized patients in general. Patients with cancer experience a multitude of signs and symptoms from their disease process and the effects of their treatments. Further nursing research looking at complete nursing assessments and laboratory values in large samples of patients with cancer may identify other factors not previously revealed in the currently available nursing research.

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Appendices

# Appendix

# Chart Review Audit Form

Control#	Age	MF		
Cancer Diagnosis				
Date of Record Review				
Time of Record Review				
Length of Stay				
Impaired gait	st 6 months			
Attached tubing				
Neurologic Disoriented	Motor/sensory problems	Decreased level of consciousness		
Peripheral/Vascular Numbness/tingling	Peripheral neuropathy			
Gastrointestinal Nausea/vomiting	Incontinent	Diarrhea for 3+ days		
Nutrition Nausea for 3+ days	Vomiting for 3+ days			
Genitourinary Incontinent	Frequency/urgency	Nocturia		
Musculoskeletal Muscular weakness	Unsteady gait			
Laboratory Values Hemoglobin < lab normal – 10.0 g/dL (Grade 1) < 10.0 – 8.0 g/dL (Grade 2)				
< 8.0 – 6.5 g/dL (G Alkaline Phosphatase > lab normal		/dL (Grade 4)		