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UNIVERSITY OF SAN DIEGO
Hahn School of Nursing and Health Science
DOCTOR OF PHILOSOPHY IN NURSING

DELIRIUM RATE AND RISK FACTORS IN PALLIATIVE CARE OUTPATIENTS
AND CAREGIVER COPING STRATEGIES

by

Sarah Deur Livermore, PhD, FNP

A dissertation presented to the
FACULTY OF THE HAHN SCHOOL OF NURSING AND HEALTH SCIENCE
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In partial fulfillment of the requirements for the degree
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Dissertation Committee

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ABSTRACT

Background: Delirium causes suffering and in terminal illness undermines important goals to die at home. Improved knowledge about delirium among palliative outpatients can lead to improved patient outcomes through early identification and treatment in the home. Conversely, a missed diagnosis leads to costly hospital admissions, and is the most common reason to seek long-term care placement (Breitbart & Alici, 2008).

Medicare stresses the importance by listing it as a common cause of falls among non-reimbursed hospital events. Prior evaluation of outpatient delirium rate was 14% among demented community dwelling elders (Steis, Evans, et al., 2012a). It is hypothesized that frail, palliative care outpatients have high rates of missed delirium, and it is the most common neuropsychiatric disorder that terminally ill patients face, with prevalence as high as 88% (Breitbart & Alici, 2008).

Objectives: To identify the prevalence rate of delirium among palliative care outpatients and correlate patient factors associated with delirium. Caregiver coping strategies associated with the episode were also examined.

Methods: This study was a descriptive, correlational study conducted over a three-month period in late 2013. A convenience sample of patient/caregiver dyads were recruited at an urban cancer center. Patients with a life-limiting illness undergoing non-curative therapy consented to a chart review for demographic risk factors. Caregivers were asked to complete two survey instruments at the time of their usual visit. Caregivers were asked to reflect upon the patient's behavior over the past month using the 12 simple yes/no questions on the Family Administered Confusion Assessment

Method (FAM-CAM) (Inouye et al., 2011). Risk factors such as age, gender, marital status, medications and diagnosis were correlated with delirium. The Folkman Lazarus Ways of Coping Questionnaire (1988) was also administered to caregivers comparing positive and negative coping techniques. Data was analyzed with ANOVA correlations.

Results: The rate of delirium among palliative care outpatients in this sample of 52 patient/caregiver dyads was 27%. The results suggested that opioid use slightly increases the odds for an episode of delirium, and approaches significance ($r(50) = .270, p = .052$). The majority of caregiver participants reported positive coping styles, however positive reappraisal and emotion-focused coping mechanism were more common in caregivers with a cognitively intact patient. When a patient screened positive for delirium, problem-focused coping was more common than emotional methods among caregivers ($m = .22, SD = .073$).

Implications: Clinicians caring for frail, vulnerable outpatients must promote increased awareness and screening for delirium. Knowledge and communication about these symptoms in the home can increase quality of care and lower costs by increasing safety, quality of life, and lower hospital readmissions. This feasibility study suggests that caregivers cope using an analytic approach during an episode of stress and delirium in the home, which may preclude healthy grief and coping mechanisms. Outpatient delirium screening can improve quality of care and safety by lowering costs and hospital admission rates.

Dedication and Acknowledgments

My heartfelt gratitude to Drs. Jane Georges, Cynthia Connelly, and Patricia Roth at the Hahn School of Nursing and Health Science for their leadership, and for making nursing research a reality for me. This project was only possible due to the generosity of the many patients who shared their time and their reflections. Drs. Marin Xavier and William Stanton graciously offered their mentoring and expertise at a time when this proposal needed it most. This work was funded in part by a grant from the Research and Education Fund of Scripps Clinic Medical Group, La Jolla, California.

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CHAPTER I

The intersection of social, spiritual, and physical realms in palliative care is a crucial time for patients and their families. Family caregivers experience an intense experiential learning curve grounded in trial and error. Although they have formal and informal educational venues, such as health care providers, friends, relatives, and the Internet, the journey holds many challenges. Globally, families perform Herculean tasks in caregiving for their loved ones, but despite these efforts, often seek custodial placement for their loved ones. The need for residential placement many times takes place due to suffering.

Delirium causes suffering and undermines important goals of care to stay home, among palliative care patients. It also impairs comfort and meaningful interaction with family (Ganzini, 2007). Delirium is the most common neuropsychiatric disorder terminally ill patients face, with prevalence estimates as high as 88% percent among terminally ill patients with cancer (Breitbart & Alici, 2008). Delirium is associated with increased morbidity and mortality, and universally causes distress among patients, family members, and professional caregivers alike (Breitbart & Alici, 2008).

Delirium is a common problem among the chronically ill, and Inouye describes it as a marker of a vulnerable patient (2012). It is defined as an acute decline in cognitive functioning and attention, commonly occurring in the elderly. It is now statistically associated with increased mortality, due to the fact it is seen as a physiological event, one causing neurological damage equal to traumatic brain injury. Delirium is thought to be

multifactorial, and leads to a cascade of events including: impaired safety, increased caregiver burden, functional decline, and long term dementia.

Policy Implications

The policy implications of this problem run deep through the health care budget. Delirium has costs associated with increased homecare needs, rehabilitation, and institutionalization (Ely et al., 2004; Inouye et al., 2006; Leslie, Marcantonio, Zhang, Leo-Summers, & Inouye, 2008). The physical, emotional, and financial needs of the palliative care patient can outweigh the family's resources, and may precipitate relocation to an inpatient setting such as a skilled nursing unit or inpatient hospital. Indeed, delirium at home is the most common reason to seek inpatient placement (Breitbart & Alici, 2008). Steis, Evans, et al. (2012a) found delirium prevalence in the home to be 14%. Delirious hospitalized patients have been studied extensively and are estimated at 2.4 million individuals. This totals 17.5 million additional hospital days each year in the United States and costs between \$15,303 and \$64,421 per patient, which totals roughly \$152 billion annually (Leslie et al., 2008).

Background

Delirium is defined as an acute change in alertness, awareness, and attention with a fluctuating state (DSM-V, 2013). It is a confusional state characterized by signs and symptoms such as sudden onset inattention, hallucinations, agitation, and in some instances autonomic nervous system over-activity. It may result from toxic/metabolic conditions and often has a medical cause (Breitbart & Alici, 2008). There are three types of delirium, which often complicate the picture. Delirium may be hyperactive,

hypoactive, or mixed. Hyperactive is characterized by restlessness and agitation, while hypoactive symptoms are lethargy and psychomotor deficits. Following recent workgroup contributions, the latest publication of the *Diagnostics and Statistical Manual of Mental Disorders* (5th ed.) adds neurocognitive disorders and includes delirium in this chapter. The DSM-5 lists these disorders as acquired disorders of cognition that acutely decline from baseline (2013). There is no exact ICD-9 billing code for delirium, but 13 other codes overlap and have some coverage (AHRQ, 2012). This reflects the relatively recent identification of this problem and hinders ability to receive reimbursement.

In delirium, subjective symptom reports are possible, although a key feature of the condition is confusion and inattention. Hypoactive or mixed delirium patients are more likely than hyperactive to verbally report symptoms of hallucinations, confusion, and fear. Due to this confusion, only three to five percent of cases are ever diagnosed. It is difficult to diagnose from a chart review, but certain key words enable chart review screening, and accurately predict delirium. Large-scale chart reviews attempt to stratify risk factors, but lack clinical assessment to confirm a delirium diagnosis. Close (2012) expressed frustration that most patient charts lack information necessary for delirium assessment. Wachter (2012) points out that delirium is often confused with dementia, depression, and underlying mental illness, which complicate its diagnosis.

Historically, delirium was seen as an inevitable part of hospitalization for a certain portion of the elderly (AHRQ, 2012). Delirium is the most common neuropsychiatric disorder that terminally ill patients face, with prevalence estimates as high as 88% among terminally ill patients with cancer (Breitbart & Alici, 2008). This

typically led clinicians to develop tolerance to the condition. Anecdotal reports reveal that until recently, medical and nursing students learned the elderly normally got confused in the hospital, without further need for evaluation.

Studies in the past ten years associate delirium with increased morbidity and mortality. It also increases the use of health care resources (Breitbart & Alici, 2008). Medicare has proposed delirium as a quality indicator, making it a hospital acquired, and non-reimbursable condition. Inouye, and other nursing and health care leaders, advocate against specific legislation per diagnosis, and instead, ask for generalized measures to improve outcomes and safety. This focus on a national scale lends weight to the gravity, cost, and high prevalence in the hospital setting (Wachter, 2012).

Family members and professional caregivers alike feel stressed during this time. Coping style, and coping strategies employed, indicates a person's psychological wellbeing more than simply identifying stress level. Everyone has stress to some degree. Positive or negative life choices indicate whether stress affects our mental stability and somatic health. Coping is process-oriented and dependent on the person managing a situation without expectations (Folkman & Lazarus, 1980).

Significance

The guiding philosophy of this research was to maintain the home environment for as long as the patient desires. By definition, palliative care patients are those for whom a cure is unavailable. Patients see unnecessary hospitalizations, and associated treatments, as frustrating and stressful. Patients experience better outcomes at home and death in a hospital may seem a failure to many families (Waldrop & Meeker, 2011). This

study may help gain an understanding of how to facilitate homecare success among palliative care. In palliative care, patient's goals of care dictate the plan. Goals of care are paramount in decision-making and many times do not include hospitalization.

Identifying the rate of delirium in the homecare palliative patient is a first step in helping patients and their families cope with this problem. It is important to identify those who were not previously confused and make reversing symptoms a priority. There is an exponential cost of hospitalization versus homecare. There is also a cost associated with a missed delirium diagnosis that may have been treated at home. Lastly, there is a cost to decreased quality of life experienced by family and patient. Long-term intervention studies will identify strategies to prevent delirium and maintain the homeostasis of the patient and family in their own environment.

Purpose

In an effort to improve patient outcomes and quality of life, the overall purpose of this study was to identify the rate of delirium occurrence in palliative care outpatients, and examine the relationship between relevant patient risk factors, caregiver ways of coping and occurrence of delirium. This study hypothesized that delirium occurs in the home among frail palliative patients at a rate similar to those in the hospital and that caregivers cope poorly with this event.

Specific Aims

Aim I. Describe the rate of delirium among a cross-section of palliative care outpatients.

Aim II. Examine the relationship between patient factors, including: age, gender, ethnicity, medication use, diagnosis, marital and economic status, and delirium occurrence.

Aim III. Describe caregiver coping strategies associated with an episode of delirium.

Aim IV. Examine the relationship between ways of caregiver coping and an occurrence of delirium.

Research Questions

What is the rate of delirium among palliative care outpatients? Which factors increase the odds for an episode of delirium in this population? What are caregiver coping strategies associated with an episode of delirium? What is the relationship between caregiver coping and an episode of delirium?

Conceptual Framework

The conceptual frameworks guiding this study take into account the causes of delirium. Delirium commonly occurs in the vulnerable elderly who have hypoxia, polypharmacy, or metabolic imbalance; however no specific causes of delirium have been identified in the research. An acute cognitive impairment has a strong correlation with prior cognitive impairment, dementia, sleep deprivation, and renal failure. Common

medication culprits causing delirium are the use of anti-cholinergic medications including benzodiazepines and opioids (Goy & Ganzini, 2011; Inouye, 2006; Rogers, 2006).

Pathophysiology Framework

Most theoretical mechanisms focus on change or disruption in brain chemistry, function, or structure. Rigney (2010) created a model (see Figure 1-1) illustrating the effects of chronic and acute stressors on allostasis. Delirium is a tertiary outcome that occurs when the metabolic imbalance is triggered by chronic and acute stressors. This model helped to guide selection of variables in research. Independent variable selection was based on these stressors identified by Rigney (2010).

Figure 1-1 Rigney's Allostatic Load and Delirium in the Hospitalized Patient, 2010.

Maldonado's Basic Pathoetiological Model of Delirium (2008a) illustrates how critical illness triggers neurochemical changes. In this model, delirium results from an impairment of central cholinergic transmission, which is already impaired due to normal aging. Stress can further impair acetylcholine release and transmission. Mild hypoxia, Alzheimer's disease, and the use of anti-cholinergic medications all increase the risk of delirium (Maldonado, 2008a).

Finally, McEwen (2000) summarized the physiologic response to environmental stress (see Figure 1-2) based on covariates including individual differences in genetics leading to a physiologic response to stress.

Figure 1-2 McEwen Stress Response and Allostatic Load Diagram (2000)

Significance to Nursing

An evaluation of delirium occurrence at home is the first step. Anecdotal evidence suggests this problem is occurring in the home at a rate great enough to warrant further investigation. One isolated study recently completed by Steis et al. (2012a) showed delirium is occurring in the home, even among functional elders. Future research may use this data to create an instrument to predict palliative home-care success and identify those at risk for delirium. Next steps include an intervention aimed to decrease delirium in the outpatient setting, both at home and in long term care settings. Inouye et al. (2000) successfully implemented a similar delirium prevention program in the post-operative, critically ill patient. The hospital based intervention HELP decreased the development of delirium, or incidence, in the critical care unit. Additionally, the HELP protocol shortened the duration a delirium event should it occur.

Data from this study will help patients remain at home, where their emotional and physical needs can be met in the most natural fashion, at the lowest cost. Outpatients might be identified who are at risk for homecare stress, so nursing and inter-disciplinary support can intervene. Positive health outcomes result from early identification and support of at risk individuals.

CHAPTER II

Review of the Literature

Delirium is the most common acute mental status change among those who are frail (Inouye, 2012). It is defined as an acute decline in cognitive function and attention, commonly occurring in the elderly due to a medical cause. It is increasingly associated with mortality, due to the fact it is seen as a physiological event causing damage equal to traumatic brain injury. Synonyms for delirium include acute brain injury, acute confusional state, or toxic-metabolic encephalopathy, which are equally dangerous as traumatic brain injury. Delirium is thought to be multifactorial and leads to a cascade of secondary events including impaired safety, increased caregiver burden, functional decline, and long-term dementia (Inouye, 2012).

Dignity and comfort care are a priority for many terminally ill people, but create tremendous unintentional burden for family members and informal caregivers. Living in a hospital is admittedly easier on the family. Safety, both at home and in the hospital, is severely impaired when a patient experiences restlessness and hallucinations. As a result, there is a high rate of mortality due to secondary falls, wounds, and infections. A patient who is out of control can emotionally test the finest caregiver. Delirium is a medical concept that has tremendous physical, mental, mortality, and financial burden (Breitbart & Alici, 2008). Delirium rocks the stability of the family and causes suffering to patients.

A delirium concept analysis is conducted within the classic framework developed by Walker and Avant (2011). While neuropsychiatrists and nurses generally agree upon the definition of delirium, inaccurate synonyms are still used both in the medical literature and common print. It is of vital importance to clarify terms regarding this cluster of symptoms. A concept analysis, and description of critical attributes, is necessary to contrast delirium with psychosis, insanity, confusion, dementia, psychosis, and mental illness. The word delirium has pop culture appeal. It has been used to name rock bands, beer, wrestlers, and even Eddie Murphy's profane stand up comedy routine in 1983. Delirium can mean uncontrolled excitement or happiness, and when used colloquially indicates a lack of control in mental state.

Definition

For the purpose of this research study, the concept of delirium was defined as an abrupt onset of disturbances of consciousness, attention, cognition, and perception, fluctuating over time (Breitbart & Alici, 2012). Each criterion in this definition must be met in order for a diagnosis to be made, and the temporal profiles of acute onset fluctuant symptoms help differentiate delirium from dementia.

Psychosis is a similar term. This general descriptive term has been phased out of scientific use, but exhibits many of the same symptoms as delirium, and may appear as a symptom of a number of mental disorders in *The Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; DSM-5; American Psychiatric Association, 2013), including mood and personality disorders. The main difference is that psychosis does not exhibit a

change in level of consciousness and is characterized by an impaired sense of reality associated with schizophrenia.

Insanity is another word proposed as a synonym to delirium. This term is often legally applied to a mentally ill person who has difficulty separating fantasy from reality. It is important to differentiate that there is no medical diagnosis called insanity.

The last term confused with delirium is dementia. An experienced clinician recognizes dementia as confusion that is chronic and non-fluctuating in nature. Dementia may have an impaired level of alertness or level of consciousness, without an acute onset. The chronic dementia process follows years of steady decline, however delirium has an acute onset of hours to days. Dementia is closely associated with delirium, and Ganzini lists dementia as a risk factor for delirium (2007). Furthermore, the presence of chronic dementia leads clinicians to miss the opportunity to diagnose delirium and pain. Dementia patients present common palliative symptoms in atypical ways. Overall, the relationship between dementia, delirium, and pain are poorly understood, but they are hypothesized to have a strong correlation (Ganzini, 2007).

Symptomatology and Diagnosis

Delirium is defined as an acute change in alertness, awareness, and attention with a fluctuating state (DSM-V, 2013). It is an acute confusional state characterized by signs and symptoms including inattention, hallucinations, agitation, and autonomic nervous system dysregulation. Common features are an acute onset, fluctuating course, inattention, disorganized thinking, and altered level of consciousness (Inouye, 2006).

The Latin etiology literally means to swerve from a furrow in plowing or crazy (Collins, 2003). Weber first documented it in 1865 as an acute insanity associated with advanced physical illness. He provided case studies of otherwise healthy young people who hallucinated and became restless and combative with acute febrile illness due to measles and scarlet fever.

Delirium is a medical concept that has tremendous physical and mental impact. It also has increased mortality and financial burden related to caregiving (Breitbart & Alici, 2008). Safety, both at home and in the hospital, is severely impaired when a patient experiences delirium. As a result, Ganzini (2007) reports an elevated rate of mortality due to secondary falls, wounds, and infections. A patient who is out of control can test the finest caregiver. Delirium rocks the stability of the family and causes suffering to patients who experience it. It is debilitating and has multiple medical causes, which often can be reversed with medical treatment (Ganzini, 2007). It may result from toxic or metabolic conditions (Breitbart & Alici, 2008). Educating family and care providers regarding delirium is key to reducing distress; efforts to minimize its impact are important. Morita et al. (2005) determined two-thirds of family members rate delirium-related symptoms as very distressing. A careful analysis of palliative delirium symptoms enhances understanding, and results in an operating definition that can be assessed empirically for research (Walker & Avant, 2011).

Patients at end of life have an alarmingly elevated rate of delirium, up to eighty-four percent, yet clinicians including nurses, nurse practitioners, and physicians often miss these symptoms (Breitbart & Alici, 2008). In order to avoid caregiver breakdown,

early identification of changes in alertness and orientation are key to early treatment. Medical treatment is often successful, and symptom management should be initiated while results of tests are pending (Rogers, 2006).

This confusion is cataclysmic in the family. Early diagnosis and treatment is the difference between a successful family balance and a family in crisis. Delirium causes the patient fear. The patient rarely sleeps for more than 1-2 hours at a time, due to the fluctuating nature of symptoms. A sleep-deprived family is at risk for depression and associated cognitive fatigue. The patient has fluctuating disturbances in consciousness, cognition, and perception, and is at risks for falls (Plonk & Arnold, 2005). In addition, delirium may cause a patient to stop smiling, talking, or expressing appropriate gratitude for care delivered. Most agree caring for a family member is the single most difficult job anyone will ever do. Caregivers quickly tire, and express despair in their abilities to continue in the caregiving role without small rewards such as a nostalgic memory, joke, or smile.

Subtypes

Due to the autonomic nervous system dysfunction, level of consciousness can be stimulated and restless, or somnolent and barely responsive (Breitbart & Alici, 2008). This creates three types of delirium, which often complicates the picture. Delirium may be hyperactive, hypoactive, or mixed. Hyperactive is commonly characterized by restlessness and agitation, while the hypoactive patient shows lethargy and psychomotor deficits. A key feature of the concept is confusion and inattention, and due to the fluctuating nature of the illness, brief patient reports may be possible at times.

Hypoactive or mixed delirium patients are more likely to be verbally able to report their feelings of confusion and fear. In general, patient subjective reports are possible, but not probable. Diagnosis is often missed due to this wide fluctuation in symptoms. Eighty-three percent of delirium patients in the emergency room were missed in one study. The same study offered early evidence that the three-month mortality rate increased (Lewis, et al., 1995).

Incidence and Prevalence

Delirium causes suffering and undermines important goals of care at the end of life. It also impairs comfort and meaningful interaction with family (Ganzini, 2007). Delirium is the most common neuropsychiatric disorder palliative patients face, with prevalence estimates as high as eighty-eight percent among terminally ill patients with cancer (Breitbart & Alici, 2008). Delirium is associated with increased morbidity, mortality, and distress among patients, family members, and professional caregivers alike (Breitbart & Alici, 2008).

Total financial costs of delirium are \$20-60,000 per patient per episode, which totals \$40-150 billion annually in United States. There is evidence the event causes neurological damage equal to traumatic brain injury (Goy & Ganzini, 2011; Hosie, 2013; Inouye, 2006; Steis, 2012a, 2012b).

The hospitalized patient has been extensively evaluated for prevalence rates of delirium. Among patients at home, Steis, Prabhu, et al. (2012b) tested reliability and validity of the Family Confusion Assessment Method (FAM-CAM) in community-dwelling, demented elders. They used electronic, handheld devices with thirteen

participants; 3 participants had recurrent episodes of delirium. Reliability of the CAM was paired with the FAM-CAM, and they explored the cause of delirium based on a physician created algorithm. More than 75% percent of the delirium cases were responsive to rehydration according to family symptom report. This is one of few studies using caregivers not only to screen for delirium in the home, but also to use caregiver knowledge of the patient to evaluate possible etiology.

Also in the community, Steis et al, (2012) evaluated occurrence of delirium among 52-paired dyads of elderly adults with cognitive impairment. These elders were otherwise physically healthy who regularly met at a day treatment program. The point prevalence of delirium was thirteen percent among these patients, and confirmed with physical exam by a research assistant. Caregivers appropriately used the FAM-CAM to screen for delirium; data were collected at six visits over the course of one year. This study supported the reliability and validity of the FAM-CAM instrument paired with the CAM instrument, with excellent results.

Pathophysiology

There are multiple causes of delirium in the elderly, all of which are poorly understood. The most common theories are listed here. Delirium is interplay of multiple forces associated with illness in the older adult including pharmacologic agents, metabolic disturbances, and nutritional deficiencies compounded by impaired functional ability (Gillis & MacDonald, 2006).

Cellular inflammatory theory. Proinflammatory cytokines are considered among the possible causes of delirium on a cellular level. Most theories proposed are

“complementary, rather than competing” (Maldonado, 2008a, p.790). Hypoxia often precedes an episode of delirium. Causality is hypothesized to be CNS inflammation following that trauma (Inouye, 2012). Other inflammatory markers proposed as potential causes of delirium include neurotransmitter dysfunction. Hypoxia, dehydration, trauma, surgery, severe illness, decreased cholinergic function, and aging are also potential causative agents. Dehydration is a reliable predictor of impaired cognitive status and delirium (Maldonado, 2008a).

Acute stress theory. Recent research is exploring the theory that certain individuals have a pathological tendency toward delirium, which a stressful event like surgery initiates. Frailty and delirium are shared expressions of vulnerability to stress (Inouye et al., 2011). There is a great deal of clinical overlap in the elderly between frailty and delirium that cannot be separated (Quinlan, Marcantonio, Inouye, Gill, Kamholz, & Rudolph, 2011). The Inouye Predictive Model (2000) takes into account baseline vulnerability among the elderly. In general, the more vulnerable an elder, the most prone he or she is to delirium symptoms.

Conceptual Framework

Three conceptual frameworks guide this study. The Rigney allopathic load model of delirium incorporates many factors which experts agree commonly cause a disruption in balance. McEwen (2000) summarized that individuals respond to stress based on their individual differences in genetics. Maldonado (2008a) has conducted an in-depth biomarker review, and implicates melatonin, serotonin, dopamine, GABA noradrenergic, and NMDA as possible chemoreceptive problems in the regulation of

cognitive function (2008b). Among these models, the Rigney model readily applies itself to non-invasive, descriptive research, and serves as a guide for independent variable selection among this research study.

Risk Factors for Outpatient Delirium

There are a number of ways to statistically evaluate patient risk of developing delirium. Large-scale chart reviews attempt to stratify risk factors, but lack clinical assessment of the research participant to confirm a delirium diagnosis by a qualified clinician. Other studies might evaluate one population, such as post-operative patients and track incidence of delirium that develops in the post-operative period. Lastly, a common study design is to evaluate hospitalized patients and examine point prevalence and related risk factors for delirium.

An interesting study by Kalisvaart et al. (2006) used predictive factor modeling to validate a medical risk stratification model. He found delirium risk stratification predicted up to thirty-seven percent of cases in the high-risk group based on health status, renal function, age, and sensory impairment. Age was not found to be a risk factor, but those with an acute fall were found to have four times the delirium as other post-operative patients (Kalisvaart et al., 2006).

Age. Many changes associated with aging cause an increased risk for delirium. Older people have chronic illness at a higher rate, especially hepatic-renal dysfunction associated with delirium. The elderly take more medications, have sensory impairment, and dementia all at a higher rate predisposing them to delirium episodes (Ganzini, 2007).

Pre-existing cognitive impairment. It is expected that twenty-five percent of Alzheimer's disease patients will develop delirium while hospitalized (Fong et al., 2012).

Gender. Conventional wisdom suggests males have delirium at a higher rate than women, but that has been discredited with risk factor analysis (Kakuma et al., 2003; Kalisvaart et al., 2006). Alcoholism is a predictive variable for delirium later in life, regardless of current consumption, and may explain the higher predominance in men than women.

Frail and vulnerable populations. Quinlan et al. (2011) commented in a recent article that the frail elders are simply waiting for a stressful event, and delirium and frailty are clinical phenotypes with similar manifestations.

Medications. All medications, but especially anticholinergic ones, are suspicious in multifactorial delirium. The anticholinergic category is often missed, due to their apparently benign uses. Common anticholinergic medications include anticoagulant, antibiotic, diuretic, and antihypertensive medication. Corticosteroid medications have anticholinergic properties, and are often used for a myriad of uses in palliative patients, such as pain and dyspnea. Other suspicious medications include opioids and benzodiazepines (Maldonado, 2008b).

Maldonado (2008b) has conducted detailed biomarker evaluation of hospitalized, demented elders. Specific targets of research included melatonin, GABA, serotonin, NMDA, and calcium channels (Maldonado, 2008b). A fall is also strongly associated with an adverse drug event. Wierenga et al. (2012) found among 641 patients, twenty-six percent had delirium with a fall correlated with an adverse drug reaction.

Sleep deprivation. A recent study by Stuck (2012) did not demonstrate sleep deprivation as a cause of delirium, but Maldonado cites sleep deprivation as a likely contributor with unknown etiology in his meta-analysis of multi-factorial causes of delirium (2008a).

Long-Term Outcomes

Health policy. Safety has always been important to families, but now has increasing policy importance with Medicare and The Agency for Healthcare Research (AHRQ). In a 2012 interview with AHRQ, Dr. Sharon Inouye reports ongoing discussions regarding including delirium as an unreimbursed hospital event. To date, delirium continues to be listed as a common cause of falls, and is not listed as a hospital related complication and unreimbursed event (Inouye, 2012).

Persistent cognitive impairment. When looking at one-year outcomes, delirium significantly contributes to poor cognitive outcomes. Following hospitalization for an acute change in cognitive function, delirium is associated with a significant decline in cognitive ability and prolonged impairment (Bickel 2008; Capezuti, 2008; Fong et al., 2012).

Increased morbidity and mortality. Multiple studies indicate increased three-month and six-month mortality, when compared to hospital patient admissions that were not confused. This body of research has increased in recent years. Lewis, Miller, Morley, Nork, and Lasater (1995) began epidemiological investigation in 1995, and showed 14% three-month mortality versus 8% for those without confusion. The data indicates those with missed delirium diagnosis have a significantly higher rate of death

(31%), even when controlling for age, gender, functional level, and cognitive status (Inouye, 2006; Kakuma et al., 2003; Kiely, 2009; Lewis et al., 1995). With a sample size of 771 elderly with Alzheimer's, hospitalized patients who developed delirium have a six percent increased risk for death (Fong et al., 2012).

Institutional relocation. Relocation to a group care setting has been studied extensively. Qualitative methods describe patients and family members in confusion and crisis with an inpatient transfer. Families describe feelings of failure, guilt, and stress with an overall negative impression of the experience (Coffey, 2006; Lundh et al., 2000; Reed et al., 2003). Institutional relocation is quantitatively associated with health deterioration and high mortality rates. All hospitalized patients are at increased risk of institutionalization due to their transitional health needs. However, those who have delirium are fifteen percent more likely to receive institutional placement than their hospitalized counterparts (Fong et al., 2012).

Institutionalization at end of life is a non-normative event, and often an untimed role transition (George, 1980). Ninety percent of patients hope to die at home, which is diametrically opposed to institutionalization (Stanford, 2012). Only forty-four percent actually achieve dying at home (NHPCO, 2010). Caregiving roles need to be redefined at end of life as the context rapidly changes. The home caregiving arrangement and social norms informal caregivers rapidly change due to the declining patient. Important variables associated with institutionalization are the impact of age and marital status. Older patients, and those who are unmarried, utilize institutional beds at a higher rate

than those who are younger and married, when controlling for all other variables (AHRQ, 2012).

Role stress. When a patient's health status deteriorates, role stress occurs due to the rapidly changing role (George, 1980). For example, consider a patient who previously walked, talked, and dressed herself. With a delirium episode, the patient may now need prompting to complete activities of daily living such as dressing and bathing, and may be resistant to help during these procedures. In addition to this, patients with delirium, and their families, don't usually sleep well at night due to restlessness. Sleep deprivation compounds stress and impacts coping at every level. Tired caregivers must now assume a new role as nurse to a rapidly declining patient, when just a week earlier the patient was independent.

Bruera et al. (2009) evaluated 99 patient-family caregiver dyads with advanced cancer and a previous history of delirium. They correlated family report symptomatology of delirium with the bedside nurse and palliative care specialist. Patients had difficulty remembering the episode, but those who remembered were far more distressed than those who had no memory of the event. Family caregivers were equally distressed as their dyadic patient. This was measured as a three out of four on the Distress Experience Questionnaire (Bruera et al., 2009).

Delirium Assessment

Clinicians miss the opportunity to diagnose delirium (Inouye, 2000). This often happens due to hypoactive symptoms in the elderly. A difficult assessment is confounded by senile sensory impairment and chronic dementia. Nurses need bedside

clinical tools to aid in screening. Physicians need quick, effective screening tools for outpatient diagnosis. An evaluation instrument involving the family is important in identifying otherwise missed episodes of delirium, due to patient cognitive impairment and poor subjective report (Inouye, 2000).

Caregiver Stress and Palliative Care

In-home caregivers provide a combination of physical, household, and emotional care. Informal caregivers are historically female children who are assigned the duties of caring for aging family members. Male caregiver numbers remain small, but are steadily increasing as families are fully employed, especially with the recent recession and re-defined workforce. Hired household staff may gradually assume medical caregiving duties, as the household ages. Some non-traditional caregiving arrangements are highly functional, with few studies to suggest which patient factors are associated with success. Non-traditional caregiving arrangements may include former spouses, stepchildren, friends, neighbors, and co-workers. One hospice patient appointed her manicurist as sole caregiver. Given the rapidly increasing population of older adults (National Institute on Aging/US Census Bureau, 2005), home based care improves quality of life, lengthens life expectancy, and lowers health-care related costs when compared to nursing home institutions (Marek et al., 2005).

Thirty-four million informal or family caregivers provide personal assistance to adults with a disability or chronic illness; nine million of those have dementia (CDC, 2013). Ninety percent of long-term care is provided by unpaid caregivers (CDC, 2013). According to one old estimate, 22 million households were providing informal help with

an economic value of approximately \$196 billion (Arno, Levine, & Memmott, 1999).

Caregiver satisfaction and symptom control are influential on caregiving success at home.

Exposure to palliative care doubles the chances a person will then die at home.

Palliative care decreases symptom burden, and increases caregiver satisfaction with end of life experience causing less grief (Casarett & Inouye, 2001; Gomes, 2013).

Pearlin et al. (1990) historically documented caregiver stress in the Stress Process Model. Primary stressors related to role and psychic strain combine with the diminishment of self-concept and lead to caregiving stress. These interrelated conditions are compiled with the socioeconomic resources a caregiver brings to the family. It is important to note when planning interventions for caregivers, social support leads to improved coping (Pearlin et al., 1990). Palliative caregiving is a unique arena, and has unique stressors, which Brazil et al. (2010) began to describe using qualitative research. Communication, interpersonal and family relations were reported in several participants as a unique stressors at end of life. Secondary stressors unique to this population included advanced, end of life caregiving skills, and access to a health care provider when no longer ambulatory (Brazil, 2010).

Folkman Lazarus Ways of Coping Questionnaire Reliability

Lazarus offered the starting point for coping in 1966, arguing that stress consists of three processes: primary appraisal, secondary appraisal, and finally coping is executing a response. The Ways of Coping Questionnaire (1988) has eight factors to evaluate methods of coping; including confrontive, distancing, self-controlling, seeking social support, accepting responsibility, escape avoidance, painful problem solving, and positive

reappraisal (see Appendix C and Table 3-1). Each of these portrays a coping thought or action people may engage in during stressful situations.

Literature Summary

Patients may have a stable home caregiving setting for years, and without warning, there may be a rapid transition to an inpatient caregiving situation. Reasons for transfer include social stigma associated with death, lack of reimbursement for home support services, and the convenience of hospital based treatment and evaluation (Mor & Hiris, 1983).

There are social and financial incentives to keep patients at home with palliative care. Palliative services help the integrity of the family when a member has a life-limiting illness (Waldrop & Meeker, 2011). In a meta-analysis, palliative services are highly valued by patients and families, reduce health care costs, and increase the likelihood of symptom palliation such as pain management (Candy et al., 2011). Despite soaring costs at end of life, home-based care is the least expensive option. In 2010, 1.58 million US patients received services from hospice, which totaled forty-two percent of the patients who died that year. Sixty-seven percent of those hospice patients received services in their place of residence. Among those on hospice, Medicare saves \$2309 per patient (National Hospice and Palliative Care Organization, 2012).

Delirium causes incredible stress to both the patient and their caregiver. The majority of frail, vulnerable elders live at home. They largely have informal caregivers, who are untrained to recognize the complex set of symptoms defining delirium. Delirium remains a leading cause of hospitalization, and rehospitalization, among the elderly.

Hospitalized patients have benefited from years of delirium research. Studies are extensive and include qualitative description, epidemiological tracking, risk factor stratification, staff education, and interventions aimed at preventing delirium in critical care. Clinicians need to become skilled at screening for delirium in outpatients. With education and awareness, in the future we may identify ways to treat outpatient delirium in the home.

In order to preserve the dignity of our rapidly aging population in a cost effective fashion, supporting the palliative patient in the home must become the normal continuum of care. Hospice has attempted to meet this need, only to be met with regulatory barriers at the expense of excellent patient care. Palliative care providers need to meet the patient where they live. Caregivers have unique needs, and social support has been shown to increase homecare success, and improve patient outcomes. Identifying and treating delirium early improves patient outcomes, including: safety as a result of decreased falls, decreased medication use, and decreased hospital readmission.

CHAPTER III

Methods

The purpose of this study was to identify the rate of delirium in palliative care outpatients, and examine the relationship between relevant patient risk factors, caregiver ways of coping, and occurrence of delirium. This chapter includes a description of the design, sample and sampling, data collection, and analytic procedures. The protection of human subjects is also presented.

Specific Aims

Aim 1: Describe the rate of delirium among a cross-section of palliative care outpatients.

Aim 2: Examine the relationship between patient factors, including: age, gender, medication use, diagnosis, marital and economic status, and delirium occurrence.

Aim 3: Describe ways of coping used by caregivers of palliative care outpatients experiencing delirium.

Aim 4: Examine the relationship between ways of coping and occurrence of delirium.

Research Design

A descriptive, correlational design was used for this study. A descriptive, correlational design facilitates examination of a phenomenon in a single sample in which little is known, and describes relationships among the variables (Polit & Beck, 2012). Description of the variables provides increased knowledge among the study population, which can be used for future research in the area.

Based on the review of the literature, assumptions were made regarding prior studies associating delirium with hospitalized patients, occurring at rates up to forty-four percent in Alzheimer's disease patients (Fong et al., 2012). Few research studies chronicled delirium among chronically ill palliative patients at home, but most speculated that delirium is due to multiple causes. Previous studies established delirium as a serious health problem associated with increased morbidity and mortality, long-term cognitive decline, and decreased functionality in the elderly (Breitbart & Alici, 2008; Ganzini, 2007; Van Rompaey, et al., 2009). Among the risk factor profile, sleep deprivation correlates with delirium. Evidence also suggests an electrolyte imbalance due to dehydration, renal failure, or medication leads to delirium (Maldonado, 2008). Normal changes of aging predispose the cholinergic system toward these changes (Maldonado, 2008). Hospitalized patients with an acute stressor are at risk for delirium, which is confounded by hypoxia. Definitive causes of delirium among elderly, chronically ill outpatients remain a mystery, however there are many correlated risk factors suggested in the literature.

This cross-sectional, descriptive study evaluated the proportion of a population who has a condition, at some time, during a given period during a three-month period in late 2013. A cross-sectional study cannot tell why conditions exist, but is valuable in generating hypotheses surrounding the causes of disease. Data generated from cross-sectional studies can be used to initiate health interventions in the future. A prevalence study can be used for the same reasons as cross-sectional studies, to determine health care

needs and planning health services. However, a true epidemiological prevalence requires larger participant numbers than this site allows (Page, 1995; Vetter & Matthews, 1999).

Relative Risk

Rate is the occurrence of an episode of delirium among the sample of high risk, chronically ill outpatients. Prevalence studies are usually surveys conducted at the local level to investigate trends and suggest causality (Kahn & Sempos, 1989). Relative risk ratios can be calculated using the variables associated with developing delirium in this population. For example, a relative risk of 1.0 means both groups have equal risk of getting delirium. Statistical tests can determine whether any increase in risk is greater than would be expected by chance alone, among the variables (Valanis, 1986).

Coping Style

Caregivers have positive or negative coping styles due to an acute stressful situation. This study examined coping styles among caregivers related to a delirium episode: a specific, stressful encounter. When patients are confused, it is associated with increased caregiver burden, and may correlate with negative coping strategies, such as escape-avoidance and confrontive coping (Folkman & Lazarus, 1988).

This investigation identified the rate and risk factors that increased the odds for a delirium episode among palliative care outpatients. Caregiver coping strategies associated with the episode were also examined.

Setting and Sample

Data were collected from patients receiving palliative oncology services at a clinic associated with a large, not for profit, urban health center. This was a convenience

sample of patients and family caregiver dyads in 2013. Inclusion criteria for the study were English or Spanish-speaking patients enrolled in palliative, non-curative, oncology services referred by their oncologist. These participants had no curative treatment options available. Caregiver inclusion criteria included: 1) must spend more than 20 hours a week with the patient, and 2) should be established in their role in the setting of chronic illness. Research materials were translated from English to Spanish, and validated through back translation; participants could choose English or Spanish study materials.

Recruitment procedure

Palliative patients are a vulnerable population due to terminal illness, and need careful consideration of their ability to consent to research. At the time of their usual appointment, physicians initially approached the patient regarding a research study, and determined if a patient had a palliative, non-curative life limiting illness. Once referred, the investigator met with the participant in a private location (exam or conference room) to assess interest in the study. This informational interview usually took place the same day as referral, and all information was gained at one data collection visit. Risks and benefits of the study were discussed with the patient and caregiver. Questions were all answered at this time. Written consent was obtained from both the patient and his/her caregiver according to Institutional Review Board (IRB) protocol. Participants had the right to refuse participation, could withdraw at any time, and were under no obligation to participate. Participants received a small gift card for their time for a local coffee shop.

Power, Effect, and Sample Size

Power and sample size can be computed numerous ways, however Polit & Beck (2012) argue ten participants for each independent variable, per outcome, as appropriate among logistic regression. Therefore, fifty-two patient/caregiver dyads were each consented for this study in order to avoid Type II error. A small effect size was anticipated due to a new area of research inquiry (Polit & Beck, 2012).

In logistic regression, no assumptions were made regarding the independent variables (Mertler, 2002). The relationship may be non-linear, linearly related, and can have non-normal distribution (Polit & Beck, 2012). According to Mertler (2002), homoscedasticity is not necessary, and there can be wide variance for each level of the independent variables. Logistic regression analyzes the relationship between multiple independent variables, and a dichotomous dependent variable to yield a predictive equation (Polit & Beck, 2012). Logistic regression showed the probability and risk ratios of each independent variable correlating with a delirium episode, rather than predicting an occurrence of delirium. The probability of an independent variable leading to the outcome delirium was analyzed, the odds ratio, among this outpatient palliative sample. Overall statistical significance was tested with the likelihood ratio test $p < 0.1$, which demonstrated logistic regression model fit. Since this was a descriptive study without hypothesis testing, individual factors in the model were tested with significance defined by $p < .05$, with p from the Wald test for Confidence Interval for the Odds Ratio (Polit & Beck, 2012).

Variables and Operational Definitions

Independent conditioning variables, including demographic data of interest were selected based on the conceptual framework of McEwen (2000) relating to social and physiological stress factors. Those five variables included: age, gender, insurance, marital status, and medication use. The dependent variable was delirium. Delirium was measured by screening caregivers.

Dependent Variable

Delirium. Any positive screen using the Family Confusion Assessment Method (FAM-CAM) in the past month indicated a delirious episode (Inouye et al., 2011), which is the dependent variable in this study. Delirium is defined as: a disturbance of consciousness, with decreased clarity, that has an acute onset, and fluctuates over the course of the day (Bond, 2009). It is common among palliative and home hospice patients at end of life due to exacerbation of chronic illness, or the onset of an acute illness. Unfortunately, delirium is associated with increased morbidity and mortality, and is often poorly recognized (Irwin, 2008). Caregivers reflected upon their loved one's behavior, and screened for behavior they observed, which makes it unique among delirium screening instruments (see Table 3-1 for all variables).

Coping. The cognitive and behavioral efforts to manage specific external or internal demands appraised as taxing or exceeding the resources of the individual. The Folkman and Lazarus Ways of Coping Questionnaire (1988), is a 66-item four level Likert type scale and identified six categories of coping, including positive and negative strategies.

Independent variables

Demographics. Age, gender, diagnosis, insurance coverage or charity, and marital status are all found in the patient chart.

Age. Defined as the chronological age of the patient, measured by years, the day the chart was reviewed for the clinic, and data collection session.

Gender. Defined as male or female

Diagnosis. The reason the patient is seeing the provider for today's visit.

Insurance information. Insurance, including Medicare, offers insight into the patient's socio-economic status when compared to a charity patient.

Marital status. Married, divorced, separated, or widowed.

Medication use. Benzodiazepines, hypnotics, corticosteroids, and opioids are associated with increased rates of delirium. This information was found in the patient's chart, and was confirmed verbally regarding current use.

Cognitive Impairment. People with cognitive impairment were excluded from this study, which increases risk of delirium. A documented, pre-existing cognitive impairment can include dementia, TBI, CVA or cerebral hemorrhage. This is a confounding variable.

Palliative Outpatient. Any patient who is referred for uncontrolled symptoms not helped by traditional medical interventions and allopathic modalities, with limited treatment options for their diseases, and are chronically ill as a result. Common diagnoses include neoplasms, blood dyscrasias, neuropathy, cardiac disease, and lung disease.

Psychological Stress. A wide range of physical responses to a stressor that upset homeostasis in the body. The nervous, endocrine, and immune systems react, causing physical changes that have both short, and long-term effects on the body.

Data Collection Instruments/Measures

The Family Confusion Assessment Method (FAM-CAM, Inouye et al., 2011) is a screening instrument administered to caregivers. It is unique in that the clinician or researcher does not evaluate patients directly. Caregivers reflected upon their loved one's behavior, and respond in a dichotomous yes or no answer screening for behaviors they observed (Inouye et al., 2011). The Confusion Assessment Method (Inouye, 1990) and FAM-CAM (Inouye et al., 2011) was originally developed to screen for delirium by non-psychiatrists in the geriatric population. Inouye et al. (2011) saw a lack of clear, simple assessment methods to screen for delirium. When evaluating reliability and validity, both must be paired and evaluated (see Appendices A and B for instruments).

Both the CAM and FAM-CAM assess three aspects of delirium: (a) an acute onset of mental status changes or a fluctuating course, (b) inattention and an altered level of consciousness, either hypervigilant or somnolent, and (c) disorganized thinking (Inouye et al., 1990, 2011).

Confusion Assessment Method (CAM) Reliability

Wong, Holroyd-Leduc, Simel, and Straus (2010) performed a systematic review of many bedside delirium instruments, and found the CAM to be the most reliable and valid instrument among those tested. CAM (see Appendix A for instrument) is a diagnostic algorithm, with a positive or negative result for delirium. For example, if the

presence of features one and two, and either three or four are present, then the patient has a high probability of reversible delirium and confusion. Cronbach's $\alpha = 0.79$ for reliability (Inouye et al., 1990).

FAM-CAM Reliability

The FAM-CAM is a sensitive screen for detection of delirium in elderly adults with acute cognitive impairment using caregiver interview (see Appendix B for instrument). FAM-CAM is the only instrument available for family screening of delirium by interviewing family caregivers. Recently, Steis et al. (2012a) paired FAM-CAM with CAM for 88 reliability assessments among 52 dyads of elderly adults. All caregivers could easily navigate the FAM-CAM scale without any study participant withdrawal due to poor comprehension. Demographic data were collected and paired ratings were done weekly, plus more often with any positive delirium screening. The participants were also assessed by a research assistant and received a clinical evaluation for delirium. FAM-CAM $\kappa = 0.85$, 95% CI = 0.65-1.00 (Steis et al., 2012a). Validity is thought to be high, and it is relevant for a wide range of cultural caregiving (see Table 3-1 for all instrument reliability and validity). In this study, FAM-CAM reliability was Cronbach's $\alpha = 0.797$ based on the core seven questions.

Folkman and Lazarus Ways of Coping Questionnaire Reliability

Lazarus offered the starting point for coping in 1966 arguing that stress consists of three processes: primary appraisal, secondary appraisal, and finally coping is executing a response. The Ways of Coping Questionnaire has eight factors to evaluate methods of coping, including: confrontive, distancing, self-controlling, seeking social support,

accepting responsibility, escape avoidance, painful problem solving, and positive reappraisal (see Table 3-1 and Appendix C). Each of these portrays a coping thought or action people may engage in during stressful situations. Reliability is estimated with Cronbach's coefficient alpha = .61- .79 (Folkman & Lazarus, 1988). In this study, reliability = 0.849.

Table 3-1

Variables and Instrumentation

Variable	Instrumentation	Description	Reliability Chronbach α	Validity	Level of Measure- ment
Demographics					
• Age					Interval
• Gender					Nominal
• Diagnosis					Nominal
• Insurance Coverage					Nominal
• Marital Status					Nominal
• Medication Use					Nominal
Delirium	Family Confusion Assessment Method (FAM- CAM) Inouye et al., 2011	11-item yes/no survey given to caregivers to screen for delirium	.65-1.00	Predic- tive validity	Nominal
Caregiver Coping	Ways of Coping Questionnaire Folkman and Lazarus, 1988	66-item 4- point Likert scale	.61-.79	Predic- tive validity	Interval

Data Collection Procedures

A face-to-face interview took place at a quiet time during the patient's usual visit. A trained researcher collected all data over a 3-month period in late 2013. The scheduled appointment included completion of the Family Confusion Assessment Method (Inouye et al., 2011), and Folkman and Lazarus Ways of Coping Questionnaire (1988). A data extraction tool was developed to guide the gathering of information from each participant's medical record. Appendix D describes operationalized variables used in this study. A delirium educational handout was available for caregiver education.

Training of Researcher

The researcher is a certified Palliative and Family Nurse Practitioner who completed training for FAM-CAM and the Folkman and Lazarus Ways of Coping Questionnaire. Investigator was also trained in research ethics and protected health information management.

Data Management and Analysis

All data were entered into a secure, password-protected memory storage device. All study forms and participant consents were kept in a locked file cabinet in the possession of the investigator. All personal data were de-identified and coded. No medical records were removed from the outpatient clinic, and all names were stripped from study information.

Data were analyzed using Statistical Package for the Social Sciences (SPSS) version 21 to address the first aim, the occurrence of delirium among palliative care outpatients. Descriptive statistics including mean, median, mode and standard deviation

were computed for numerical variables, and used to evaluate study sample measures of central tendency. Descriptive statistics also capture frequency of each variable. Some data were grouped, such as marital status and race due to the small number of participants among groups. Inferential statistics were used to screen for outliers and missing data. Outliers can be deleted, transformed to three or four standard deviations from the mean, or substituted with the mean. Due to the small amount of missing data (less than 10%), it was filled in using the mean. Data were screened for normality, skewness, and kurtosis.

Chi-square analysis was completed for the other three aims to examine patient factors predictive of delirium, describe caregiver coping strategies associated with an episode of delirium, and examine the relationship between ways of caregiver coping and an episode of delirium. In a chi-square analysis, nominal data can compare independent variables to estimate the probability of a certain event occurring, with observed frequencies for categorical variables. A t-test was used to compare the mean age to the nominal variable delirium. T-tests are used for interval data like age.

A logistic regression was used to estimate the probability of a delirium event occurring. Logistic regression uses dichotomous data such as a yes or no answer, compared with multiple and linear regression which use continuous interval data. A step-wise approach was considered to evaluate impact of variables and evaluate correlations between delirium and independent variables. Lastly, data from this study was able to report the relative risk of delirium using an odds ratio (see Table 3-2 for data analysis for each study aim).

Table 3-2

Aims and Methods of Analysis

	Aim	Analysis	Description
Aim 1	Describe frequency of delirium among palliative care outpatients	Descriptive statistics to evaluate normality and measures of central tendency.	Basic frequency measurement: # episodes n
Aim 2	Examine patient factors predictive of delirium.	Correlations or logistic regression, depending on power, to correlate risk factors among this nominal data. Odds ratio and relative risk of each factor or independent variable associated with delirium.	
Aim 3	Describe caregivers coping strategies associated with an episode of delirium	Relative mean scores for each coping strategy were compared.	Tabulated relative means were created for each of the 8 coping styles, totaling 100% of participants among the coping styles.
Aim 4	Examine the relationship between ways of caregiver coping and an occurrence of delirium.	ANOVA and MANOVA to evaluate between group differences	

Strengths and Limitations of Methods

The greatest limitation was the extremely vulnerable sample, due to severity of disease burden. Repeat analysis is desirable to evaluate follow-up effects, however this was not realistic due to high mortality and attrition among palliative care. Another limitation of this population was the high level of caregiver psychosocial stress. Neuropsychiatric changes are common among these patients, and are important to document, however these same cognitive changes created a high stress study environment.

The principal investigator was certified in palliative care, and helped minimize research stress with sensitivity, and by redirecting elevated emotions and concerns to the appropriate clinic staff member. Any research study may increase awareness, and add stress and emotional burden, to patients and staff. Other limitations were that this study only observed English and Spanish patients at one clinic in San Diego. No additional languages were available due to limited personnel. Recruitment was slow as a result of only observing one site within a health care system. Despite these limitations, delirium in the home care outpatient has been estimated at thirteen percent in one study of otherwise healthy, demented elders (Steis et al., 2012a). This study helps to further describe the delirium rate in chronically ill outpatients.

Human Subjects Protection

Approval was obtained from all pertinent Institutional Review Board (IRB) committees. The protection of each participant and caregiver dyad's privacy, dignity, and freedom from intrinsic risk or injury was protected in this study by a variety of

protective mechanisms. Level of oversight for the study was obtained from the clinic IRB committee and the university IRB. While medical records were accessed, no personally identifying data were attached to the study information. Each case was assigned a research code number. The code number was recorded on the data extraction instrument. The code number was also recorded in the codebook along with the medical record number. The codebook was stored in a locked file cabinet. Only de-identified data were entered in an electronic data file for analysis. The perceived benefits outweighed the risks, and the appropriate IRB committees approved this study.

Benefit for participation in this study was the knowledge that future families may have decreased suffering. Participants also benefited from increased professional presence, and emotional support, during a difficult chronic illness. People enjoy knowledge, and study participation might associate with increased power in making difficult decisions and care planning. Lastly, participants received a small gift card at a local coffee shop for their participation.

There were minimal risks for study participants. The study instruments did not necessarily elevate emotional stress, and participants received verbal and written information describing the study. Participants were offered an opportunity to ask any questions they had. Due to the vulnerability of a chronically ill participant, it was important to include the patient's representative in the informed consent process.

If they wished, they might have reviewed a copy of the informed consent at home before agreeing to participate in this study. Once the patient and family's questions were answered to their satisfaction, and they agreed to voluntarily participate in the study, they signed an IRB- approved consent form.

CHAPTER IV

Study Results

The purpose of this study was to address a knowledge gap regarding the cognitive ability of palliative outpatients who have a life-limiting diagnosis. Anecdotal reports from hospice and home clinicians point out that delirium wreaks havoc upon the family and household. Delirium is the most common acute neuropsychiatric cognitive change that occurs among inpatients. It is equally important to screen chronically ill patients who reside in the home for acute neurological changes. Risk factors for delirium should also be evaluated, as well as caregiver coping with associated patient cognitive changes. The research questions that provided direction for the study were:

1. What is the rate of delirium among palliative care outpatients?
2. Which factors increase the odds for an episode of delirium in this population?
3. What are caregiver coping strategies associated with an episode of delirium?
4. What is the relationship between caregiver coping and an episode of delirium?

Data Analysis

Data were analyzed to address the first aim, the rate of delirium among palliative care outpatients. Descriptive statistics including mean, median, mode, and standard deviation were computed for numerical variables, and used to evaluate study sample measures of central tendency. Inferential statistics were used to screen for outliers and missing data. Due to the small amount of missing data (less than 10%), it was filled in using the mean. Data were screened for normality, skewness, and kurtosis.

Aim two was addressed using univariate correlations to compare risk factors. The second part was to use the same variables with binary logistic variance analysis to estimate the relationship between risk factors and screening positive for delirium (see Table 3-2 for data analysis for each study aim). Aim three was analyzed using a comparison of means of relative score. Aim four was addressed using a multiple analysis of variance (MANOVA) with eight variables, coping style as the outcomes. In order to further explore the data, one-way analysis of variance (ANOVA) was completed for each outcome.

Specific Aims and Results

Aim 1. Describe rate of delirium occurrence among palliative care outpatients.

Patient Sample Description

Recruitment took place by physicians within an urban cancer center. Ninety-one patients were referred for participation in the study; 52 (57%) consented to the study. Reasons for denial included: discomfort with the study topic, self-perception that they were too well or didn't need a caregiver, fear of needing a caregiver, poor literacy, poor English fluency, decline in condition, and emotional stress.

The patient's only responsibility was to consent to a demographic chart review. Demographic information was collected on both patient and their caregiver, with written consent. Caregivers spent at least twenty hours at bedside by their report, but were not necessarily the designated power of attorney for healthcare (DPOA-HC). The caregiver screened for delirium with written completion of the study instrument, FAM-CAM. The caregiver was then asked to reflect upon his/her own coping.

There were 52 participants in this study whose ages ranged from 33-94, mean 65 (SD = 16.18) (see Table 4-1). The sample was relatively young, as 23 participants were less than 65 years old (44%), and gender was evenly distributed (52% female).

Approximately 2/3rd of the sample were married (61.5%), and spoke English (90%), with the remainder Spanish speaking. Sixty-four percent (63.5%) were Caucasian, 21.2% Hispanic, 5.8% Black, 7.7% Asian or Pacific Islander, and 1.8% unknown. The patients suffered from a variety of diagnoses: 46.2% had a type of neoplasm, 23.1% had a type of leukemia, 13.5% had lung cancer, 13.5% had colon cancer, and 3.8% had another blood disorders. There was some duplicity among insurance coverage, however 55.8% of patients had Medicare, 19.2% were charity cases, and 25% had private corporate insurance coverage. Most reported good sleep quality (78.8%). Almost sixty percent of these patients (59.6%) reported pain at the time of the visit, with thirty percent of them reporting moderate to severe pain at the time of interview.

Patient medication use was recorded at the time of the survey (see Table 4-2); 42.3% of patients were using an opioid for pain, 13.5% were using a benzodiazepine for anxiety or sleep, and 9.6% using a hypnotic for sleep. Corticosteroid use totaled 23.1% for this population.

Table 4-1

Demographics

Variables	Categories	Number (%)
Age	33-64	23 (44)
	65-94	29 (56)
	Total	52 (100)
Gender	Male	25 (48)
	Female	27 (52)
	Total	52 (100)
Language	English	47 (90)
	Spanish	5 (10)
	Total	52 (100)
Race	Caucasian	33 (63.5)
	Hispanic	11 (21.2)
	Black	3 (5.8)
	Asian or Pacific-Islander	4 (7.7)
	Unknown	1 (1.9)
	Total	52 (100)
Diagnosis (Collapsed)	Neoplasm	24 (46.2)
	Leukemia	12 (23.1)
	Lung cancer	7 (13.5)
	Colon cancer	7 (13.5)
	Blood disorders	2 (3.8)
	Total	52 (100)
Marital Status	Married	32 (61.5)
	Single/widowed/divorced	20 (38.5)
	Total	52 (100)
Insurance	Medicare	29 (55.8)
	Charity	10 (19.2)
	Private insurance	13 (25)
	Total	52 (100)

Table 4-2

Medication Use

Variables	Categories	Number (%)
Opioids (collapsed)	Morphine, Hydromorphone, Hydrocodone, Oxycodone	22 (42.3)
Corticosteroid	Dexamethasone, Prednisone	12 (23.1)
Benzodiazepine	Lorazepam	7 (13.5)
Hypnotic	Zolpidem	5 (9.6)
None	No medications listed	6 (11.5)
Total		52 (100)

Caregiver Sample Description

The average caregiver age was 55 years old (SD = 15), with a range of 18-84 years (see Table 4-1). Slightly more than $\frac{3}{4}$ of caregivers were women (78.8%); 23% (n=12) were married to the patient. Other relationships included children, parents, siblings, and friends. Forty-eight percent of caregivers have a college degree, and 36.5% have some college education. The sample was diverse with Caucasian (61.5%), Hispanic (23.1%), and a combined grouping of Asian, Black, or unknown ethnicity remained (15.4%).

Delirium Screening Rate

Among 52 patient-caregiver dyads, 14 patients (27%) screened positive for delirium within the past month (mean age = 62, mode = 51, SD = 17.9) using the Family Confusion Assessment Method (FAM-CAM). Among those who had delirium, more

were male ($n = 8$, 57%), and married ($n = 9$, 64%). According to caregiver report, which was unable to be confirmed by medical documentation, 19.2% of all participants reported a history of delirium in the past. This reported history of delirium was unrelated to any data collected at time of study, or reported FAM-CAM score.

Delirium is defined as an acute change in alertness, awareness, and attention with a fluctuating state (DSM-V, 2013). Common features are described as an acute onset, fluctuating course, inattention, disorganized thinking, and altered level of consciousness (Inouye, 2006). The most important qualification when diagnosing delirium is that the patient's symptoms must meet all three criteria outlined above: (a) acute onset or fluctuating course, (b) inattention, and (c) either disorganized thinking or altered consciousness. Any of these individual cognitive changes are meaningful to psychiatrists, however all three criteria combined are necessary for this diagnosis.

The Family Confusion Assessment Method (FAM-CAM) instrument was used to screen for delirium. When scored, reflexive power was given to each "yes" answer, and tabulated toward one of the three criteria. If a participant scores positive or yes answers in all three criteria, then they had a positive screen for delirium. For example, there are three categories in the FAM-CAM instrument, and one positive answer for all three criteria must be yes for a positive delirium screen.

Among the first criteria, 94% of participants in this study screened positive for an acute onset of cognitive changes, usually described as fatigue and fluctuating level of alertness. Inattention was present in 33% of participants, and 48% had disorganized thinking, or an altered level of consciousness in the past month.

Aim 2. Examine patient factors predictive of delirium.

First, risk factors were correlated with the group of participants who screened positive for delirium. For this model, opioid use was used as an explanatory variable to predict delirium status.

Figure 4-1

Opioid Use for Pain Compared to Delirium

A positive weak correlation was found between delirium and the current use of opioids $r(50) = .270$, $p = .053$. This is the only risk factor that approached significance $p < .05$ (see Table 4-3). There was a moderate effect size. In general, individuals who used opioids had slightly higher rates of delirium (see Figure 4-1).

The same variables were analyzed to predict delirium using logistic regression. It was not possible to demonstrate variability for any of the individual risk factors. The risk factors lacked the ability to predict delirium with any sensitivity. Odds ratios were not

able to estimate risk for delirium using this data because each interval spanned zero, suggesting even odds of delirium occurring with each risk factor.

Table 4-3

Patient Factors Correlating with Delirium

Correlations		FAMCAM Screening for Delirium
Patient Age	Pearson Correlation	-.139
	Sig. (2-tailed)	.326
	N	52
Patient Gender	Pearson Correlation	-.110
	Sig. (2-tailed)	.437
	N	52
Patient Marital Status	Pearson Correlation	-.034
	Sig. (2-tailed)	.809
	N	52
Opioid use for pain	Pearson Correlation	.270
	Sig. (2-tailed)	*.053
	N	52
Corticosteroid use	Pearson Correlation	-.127
	Sig. (2-tailed)	.371
	N	52

Aim 3. Describe caregiver coping strategies associated with an episode of delirium.

The Folkman and Lazarus Ways of Coping questionnaire (1988) identifies eight coping strategies that fall into two categories: positive and negative. Relative coping scores were obtained, which determine how each of the eight coping styles compares to one another among this sample (see Table 4-4). The total of all eight relative scores should add up to 100% of the participants. Relative scores control for an unequal number of items within the scales, and for individual differences in response rates (Folkman & Lazarus, 1988). When adding relative scores together, it should reveal relationships among ways of coping that raw scores are not able to reflect. Three participants failed to complete the Ways of Coping questionnaire according to directions, and were lost to follow up for clarification. These participants completed a zero for all items on the 66-item questionnaire, and were treated as missing data. The mean was substituted for these items. Other than those three participants, coping score are reflected in Table

Table 4-4

Relative Mean Score Caregiver Coping

	Con- frontive	Distancing	Self- Control	Social Support	Accepting	Escape Avoid- ance	Problem Solving	Positive Re- Appraisal
Mean	.085	.084	.152	.154	.056	.086	.219	.163
SD	.362	.052	.052	.053	.049	.049	.073	.063

Note: n = 52 valid participants

Figure 4-2

Caregiver Coping Among All Participants Combined

The most common coping style according to highest mean relative score was planful problem solving (see Figure 4-2 and Table 4-4), used by 22% of participants ($m = .22$, $SD = .073$). Planful problem solving describes deliberate problem-focused efforts to alter the situation, coupled with an analytic approach to solving the problem. The next most common coping styles among all participants were positive reappraisal ($m = .16$, $SD = .063$), and social support ($m = .15$, $SD = .052$). Positive reappraisal describes efforts to create positive meaning by focusing on personal growth. It also has a religious dimension. Social support describes efforts to seek informational, tangible, and emotional support (Folkman & Lazarus, 1988).

Figure 4-3

Caregiver Coping Style Comparison

Aim 4. Examine the relationship between ways of caregiver coping and an episode of delirium.

The highest relative mean coping score was obtained, and correlated with the two groups of participants; those with and without delirium (see Figure 4-3). Multiple analysis of variance (MANOVA) was conducted to examine the influence of delirium on coping style, with multiple dependent variables to include all eight coping styles.

Levene's test confirmed that the homogeneity of variance assumption was met, except for one variable, planful problem solving (see Table 4-5).

Table 4-5

Homogeneity of Error Variance

Coping Style	F	df1	df2	Sig
Confrontive	.116	1	50	.735
Distancing	.066	1	50	.798
Self-Control	.018	1	50	.893
Social Support	.011	1	50	.919
Acceptive	.010	1	50	.920
Escape-Avoidance	.508	1	50	.479
Planful Problem Solving	7.141	1	50	.010
Positive Reappraisal	3.868	1	50	.055

MANOVA was trending toward significant, $p = .064$. To further explore the data, one-way ANOVA was run for each of the outcomes, and indeed there is significant between group differences between planful problem solving ($p = .034$) and positive reappraisal ($p = .001$). There was a significant effect of delirium on caregiver planful problem solving coping style, $F(1, 50) = 4.753$, $p = .034$, partial $\eta^2 = .087$. There was also a significant effect of delirium on caregiver positive reappraisal coping style, $F(1, 50) = 11.62$, $p = .001$, partial $\eta^2 = .189$. Post-hoc comparisons were not done due to only two significant variables. There was no significant negative coping style that emerged when ANOVA was conducted for each outcome.

Summary

The four research questions that provided direction for this study were:

1. What is the rate of delirium among palliative care outpatients?
2. Which factors increase the odds for an episode of delirium in this population?
3. What are caregiver coping strategies associated with an episode of delirium?
4. What is the relationship between caregiver coping and an episode of delirium?

There was a rate of 27% delirium among palliative outpatients in the past month.

Regarding question two, opioid use approached significance as a risk factor increasing the odds for an episode of delirium.

In question three, the majority of caregivers surveyed employed positive coping styles. And lastly, caregiver coping styles differed between caregivers of those who were cognitively intact, and those who had a loved one screen positive for delirium. When faced with a challenge, caregivers employed a more problem oriented, cognitively driven coping style.

CHAPTER V

Discussion of Findings

This study was the first in a program of research designed to increase safety among the terminally ill at home. Patients often create a plan to die at home within a terminal illness, and together with their families, are devastated when an unanticipated hospital transfer occurs. A first step in research was to screen for delirium rate and risk factors in palliative outpatients. This research will be used to develop protocols in order to identify and treat delirium in the future. The purpose of this study was to address a gap in knowledge regarding delirium in community dwelling, chronically ill people, and how their caregivers cope with such an event.

Prior research has demonstrated that delirium causes incredible stress to both the patient and their caregiver, and remains a leading cause of hospitalization among the elderly (Bruera et al., 2009). Inpatient studies are extensive and include: qualitative description, epidemiological tracking, risk factor stratification, staff education, and interventions aimed at preventing delirium in critical care. Clinicians need to become skilled at screening for delirium in outpatients. Caregiver education and awareness will improve recognition of delirium in the home and improve patient outcomes. Informal caregivers can be trained to recognize the complex set of symptoms defining delirium, which will increase independent care in the home.

This study attempted to (a) describe the rate of delirium among a cross-section of palliative care outpatients; (b) examine the relationship between patient factors, including: age, gender, ethnicity, medication use, diagnosis, marital and economic status,

and delirium occurrence; (c) describe caregiver coping strategies associated with an episode of delirium; and (d) examine the relationship between ways of caregiver coping and an occurrence of delirium. Occurrence and rate studies precede future work to identify, treat, and eventually prevent delirium in the community. Further studies also rely on increased knowledge and use of screening instruments for delirium, such as the one used here.

Summary of Current Study

The rate of delirium among palliative care outpatients in this sample population is 27%. Opioid use correlates with slightly increased odds for an episode of delirium. Delirium does not correlate with negative caregiver coping strategies. All participant caregivers reported positive coping styles, however caregivers coped differently depending on whether their loved ones were cognitively intact. Those who had a patient who was not confused used positive reappraisal more often, which is an emotion-focused coping mechanism. When a patient screened positive for delirium within the past month of care, it was more common to buckle down and begin problem-focused coping.

Strengths

Very little literature to date has described the phenomenon of delirium among non-demented outpatients. The high rate of delirium in this population suggests that other palliative clinics may also have high rates of delirium. Stakeholders at the palliative oncology clinic described these results as meaningful. They stated that they anticipated an even higher rate of positive screening for delirium. Stakeholders also question whether palliative chemotherapy begins to open doors to unwanted measures

such as hospitalization, full resuscitation efforts, and artificial life prolonging treatments against the wishes of the patient. This information about the cognitive capabilities of the frail palliative oncology patient may serve as a future arena of research. There may be a future correlation between delirium and impaired ability to decline aggressive therapy.

Palliative care is a vulnerable population due to severity of illness, cognitive changes, and diagnostic difficulties. This study design was cognizant of patient's physical limitations, and required very little of the patient beyond the consenting discussion, and understanding the risks and benefits of the research process. The patient's only responsibility was to consent to a demographic chart review. They were often fatigued, and had minimal cognitive and physical strength for demands placed upon them.

The study design avoided patient performance anxiety, by screening the caregiver about the patient's cognition. Polit and Beck define terminally ill patients as a vulnerable population (2012). Caregiver interviews and questioning about patient cognition avoided potential patient stress induced by asking a fatigued, severely ill person about their memory. It creates stress to ask a self-report of cognitive ability, and has flaws in validity due to protecting the health and comfort of those terminally ill (Polit & Beck, 2012).

The participation rate among those recruited was high, potentially reflecting a feasible study design, and good participant comprehension of study materials. Ninety-one patient-caregiver dyads were referred for potentially participating in the study. Fifty-two of those (57%) consented to the study, and 39 (43%) declined. Reasons for denial

included: discomfort with the study topic, self-perception that they were too well or didn't need a caregiver, fear of needing a caregiver, poor literacy, poor English fluency, decline in condition, and emotional stress. Stress examples cited included distraction, anxiety, crying, and grief among a small number of patient participants.

Participant caregivers generally reported that they enjoyed completing the instrument about their coping and feelings. This validation of their emotions seemed to be appreciated, and qualitative responses from the participants were positive and affirmed the process of inquiry into their emotional health. Coping is a process, and style of coping can vary as the encounter unfolds. Participants in this palliative study coped with a difficult situation in positive ways regardless of amount of stress.

Limitations

External validity. Sampling included patients from diverse ages and ethnic populations, who were evenly matched for gender. While all participants had a life-limiting illness, most were diagnosed with a neoplasm or blood dyscrasia, which does not represent the full spectrum of palliative care diagnoses. The small sample size limits a study of this nature, especially when evaluating a dichotomous variable. Initial power analysis estimates guided that fifty dyad participants would be adequate. However with that number of dyads ($n = 52$), merely fourteen patients screened positive for a delirium event. This small number ($n = 14$ positive delirium screening) can skew statistical significance. Collecting data from one research site limits external validity, due to a homogenous group of diagnoses, treatment regimen and geographic area. Sampling from physician

referral and recruitment is a wonderful example of nurse researcher collaboration.

However, the criteria used for referral were arbitrary as a result.

Internal validity. The FAM-CAM screens for the first category of delirium, inattention, by inquiring whether the patient reports fatigue. Most patients had symptoms of fatigue, which may have resulted in a Type I error, false positive for delirium. Fatigue is normal during chronic illness. All participants in the study had a life-limiting illness, however many were still undergoing palliative chemotherapy to prolong their life expectancy. The FAM-CAM attempts to limit this confusion by adding two additional categories for 1) fluctuating symptoms and 2) an acute change with short temporal profile. A Type II error, risk for false negative, would involve a positive clinical assessment for delirium, with a negative screen on the FAM-CAM. It would be difficult to evaluate the clinical occurrence of Type II errors in the setting of delirium. Clinically, the clinician's judgment and treatment of the patient are far superior to any screening instrument.

There are diagnostic, clinical limitations of the FAM-CAM screening method. A positive screening result requires time-intensive, expensive collaboration of the delirium symptoms by a qualified clinician to evaluate and treat the patient. It is morally and ethically imperative to obtain further evaluation once delirium is suspected in a positive screening test. In this study, each positive screening test was reported immediately to the physician for further evaluation.

Validity limitations among the Ways of Coping instrument include instrument length. It is a relatively long instrument; four pages and 66-items may be perceived as a burden to participants. Three participants consented to the study, then filled in all zeros

for the coping questionnaire. This could be interpreted a number of ways. They may have been uncomfortable discussing their emotions, rushed for time, or not comprehending the instrument. Further information from those who denied all emotion would be valuable in future studies.

The literature reports that more single people living alone without social support exhibit delirium (Breitbart & Alici, 2008). Data from this study suggests that similar rates of married and single people report delirium. Caregivers were asked to reflect upon the patient's behavior over the past month, which can affect the types of behavior noted. Married participants have a different level of intimacy in their relationship, when compared to even the closest caregiving relationship. Another hypothesis is that spouses may tolerate cognitive changes differently than other caregivers, due to an increased emotional response to decline within their loved one.

Another limitation is a measurement error; some psychiatrists feel that the only way to diagnose delirium is a thorough assessment at the time of the event by a trained specialist (Inouye et al., 2011). A screening tool such as the Family Confusion Assessment Method (FAM-CAM) has good reliability and validity, but attempts to capture a very specific collection of symptoms. In order to download the FAM-CAM, researchers must acknowledge this clinical warning by signing an affidavit stating:

A qualified healthcare provider or physician can only make an accurate diagnosis for delirium, confusion, or other psychiatric disorders after a clinical evaluation.

These materials are not intended to address the many situations that may arise in dealing with delirium, and persons must exercise their independent judgment about such clinical situations (Inouye et al., 2011).

Another measurement error is within the chart review. It has room for error due to misrepresentations of facts, and collection errors.

Not only is delirium difficult to diagnose, all three criteria for delirium must be met in order to have a positive diagnosis. There are over twelve delirium-screening instruments that exist in the literature, and all would benefit from additional testing and implementation in practice. The FAM-CAM is an open access instrument, if used with permission and appropriate citation (Inouye et al., 2011). A positive result on the FAM-CAM should be followed by further assessment of the patient, which includes cognitive testing and a formal delirium evaluation (Irwin, 2008).

Study Implications

If 48% of palliative outpatients met one of the three criteria for delirium and have an altered level of consciousness, clinicians may consider delirium screening among outpatients. Depending on state, clinicians are mandated to report patients who may pose a threat when operating a vehicle. In California, clinicians are mandated reporters and the DMV may suspend the driver's license until the driver is clinically evaluated. To address the safety needs and associated outcomes, this study has educational, practice and research implications.

Educational Implications

Knowledge about common signs and symptoms of this disease will aid caregivers in their ability to describe changes they are seeing. Families know when their loved one has an acute cognitive change, but don't understand the implications of those symptoms. Even with the increasingly educated health care consumers, and the Internet, caregivers young and old lack the knowledge and confidence to communicate changes that they see. Knowledge and communication skills improve patient outcomes. Increased caregiving success can mean the difference between quick outpatient treatment, such as a round of antibiotics for a UTI, vs. a lengthy hospital admission with invasive testing, pain and stress.

Practice Implications

It is imperative that clinicians who treat vulnerable outpatients increase awareness, and screening, for delirium. Nursing and medical training programs must incorporate curriculum regarding treating palliative, frail patients in their homes without admission to the hospital. Many times patients can be screened and treated at home when an acute cognitive change occurs. A first episode of delirium is frightening and requires acute evaluation. However, patients tend to have recurrent episodes of delirium. Subsequent episodes can, and should, be screened and treated at home. A multidisciplinary approach will help clinicians to become skilled at screening for delirium in outpatients. Holistic care for the patient in their home environment is consistent with palliative philosophy. This prevents physical and emotional hospital

costs to the patient, and the health care system. With education and awareness, in the future we may identify ways to treat outpatient delirium in the home.

Family and caregiver coping style may influence grieving at end of life. The results of this study suggest that cognitive changes such as delirium produce task oriented coping strategies. This contrasts with more sensitive coping strategies such as talking with friends, talking about emotions, prayer and support groups. This may interfere with appropriate grief coping (Stroebe et al., 2001).

Research Implications

Extensive documentation exists that delirium places patients at increased risk for falls, caregiver breakdown, and expensive emergency visits (Goy & Ganzini, 2011; Hosie, 2013; Inouye, 2006; Steis, 2012a, 2012b). Prior research widely describes delirium among Alzheimer's patients (Breitbart & Alici, 2008). The data from this study represent an initial documentation of the high rate of delirium among non-demented people, who average 55 years of age. This study population is unique in that only two participants had pre-existing dementia. In general, demented persons are disqualified for complicated chemotherapy regimen. Likewise, this population is unique because they are young, and two participants in their 30's screened positive for delirium.

Current theoretical positions ascribe the etiology of delirium as multi-factorial, and that it is associated with frailty and chronic illness. This study offers early suggestion of the high rate of delirium among patients at highest risk for injury. Outpatient palliative oncology patients often continue to work and drive motor vehicles, despite their cognitive impairment. Social service programs need to support these

individuals with additional resources. The cognitive changes these participants of all ages are experiencing place the patient, and society in a vulnerable position.

The rate of a positive delirium screen among palliative outpatients during the data collection period was surprisingly high. This may suggest that there is a large population of cognitively impaired people in all health care arenas who are under-diagnosed each day. It is increasingly difficult in today's health care arena to spend extensive time with the patient, beyond prioritized chief complaint. With an acute cognitive change, that is likely medically reversible, it becomes a priority to improve screening and treatment of symptoms.

When conducting a feasibility study with a small sample size, one outlier changes everything. Despite a diverse sample and broad sampling generalizability, one outlier was included whom investigators thought perhaps misunderstood the instrument. This one participant diminished significance from $p < .05$ to $p = .053$. When merely fourteen participants are delirious, one unusual respondent can dramatically change results.

In summary, the finding of caregiver coping was significant, and represents an amazing tribute to the human spirit. Regardless of amount of stress placed upon them by a sudden decline in their loved one, caregiver participants continued to cope in positive ways with their situation.

Recommendations for Future Research

Future studies are needed to further elucidate screening efficacy for vulnerable outpatients. Is screening a substitute for skilled clinical mental health services, and what happens when a patient reports positive for delirium? How does a researcher or clinician

mobilize appropriate services for any suspected delirium episode? Outpatient needs differ from inpatient, and the outpatient setting may serve as an area for targeted interventions. Data are needed to test the existing delirium screening instruments, and should take the form of large-scale funded trials to validate the screening instruments, and increase widespread knowledge in the field.

Data from this study further may validate that delirium is multi-factorial and poorly understood. While it loosely demonstrated that opioid use may be correlated as a risk factor for delirium, the meaning of these results are ambiguous. 60% of participants reported pain. Of those in pain, 42% of these participants used opioid medications, and it is unethical to consider discontinuing them. Optimally, identifying opioids as a risk factor may lead to further understanding of opioid involvement in delirium, rather than undertreating pain in any form.

Gaps in knowledge and research continue to exist around how to measure caregiver coping related to a stressful event. Qualitative data are an effective way to capture this lived experience, and may serve as a future means to explore this problem.

Conclusion

This study examined the rate and risk factors for delirium. It also evaluated how caregivers cope, and if there is a coping style associated with a recent episode of delirium. Twenty-seven percent of the sample of palliative outpatients screened positive for delirium in the past month, and opioid use was suggested to correlate as a risk factors. All caregivers exhibited positive coping styles, but focused on problem solving coping style when their loved one was delirious. These findings suggest that patients can remain

in place at home, even when confused, and health care clinicians can screen them appropriately, increasing safety, and decreasing hospital emergency department admissions. This study has discussed one avenue to honor patient wishes at end of life, increase quality of care, and lower costs.

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Appendix A

Confusion Assessment Method (CAM). Inouye et al. (1990).

The diagnosis of delirium requires the presence of features 1 and 2, *plus* either 3 or 4.

Feature 1: Acute onset and fluctuating course

This feature is usually confirmed by comments of a family member or health care professional and is shown by positive responses to the following questions:

- Is there evidence of an acute change in mental status from the patient's baseline?
- Does the (abnormal) behavior fluctuate during the day, tending to come and go, or increase and decrease in severity?

Feature 2: Inattention

This feature is shown by a positive response to the following question:

- Does the patient have difficulty focusing attention? For example, is the patient easily distracted or having difficulty keeping track of what is being said?

Feature 3: Disorganized thinking

This feature is demonstrated by a positive response to the following question:

- Is the patient's thinking disorganized or incoherent, as evidenced by rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching from subject to subject?

Feature 4: Altered level of consciousness

This feature is shown by one answer other than "alert" to the following question:

Overall, how would you rate the patients level of consciousness?

Alert (normal)

Vigilant (hyperalert)

Lethargic (drowsy, easily aroused)

Stuperous (drowsy, difficult to arouse)

Comatose (unarousable)

Appendix B

Family Confusion Assessment Method (FAM-CAM) Instrument. Inouye et al., 2011.

For Research and Clinical Staff

Evaluator:

Caregiver/Informant code:

Date:

Patient ID code:

Time:

Directions: Please circle the answer to each question.

These questions are intended to identify changes to your loved one's thinking, concentration, and alertness during recent weeks. Please stop me at any time if you do not understand the questions.

1. I'd like you to think about the past two months, since your last oncology visit. During this period, have you noticed any changes in her/his thinking or concentration, such as being less attentive, appearing confused or disoriented (not knowing where he/she was), behaving inappropriately, or being extremely sleepy all day?

Yes No Don't Know

2. Did he/she have difficulty focusing attention, for example, being easily distracted or having trouble keeping track of what you were saying at any time?

Yes No Don't Know

3. Was his/her speech disorganized, incoherent, rambling, unclear or illogical at any time?

Yes No Don't Know

4. Did he/she seem excessively drowsy or sleepy during the daytime at any time?

Yes No Don't Know

5. Was he/she disoriented, for example thinking he/she was somewhere other than where he/she was, or misjudging the time of day at any time?

Yes No Don't Know

6. Did he/she seem to see or hear things that weren't actually present, or seem to mistake what he/she saw or heard for something else at any time?

Yes No Don't Know

7. Did he/she behave inappropriately, such as wandering, yelling out, or being combative or agitated at any time?

Yes No Don't Know

8. Please tell us more about the changes you noticed in any of the behaviors in #1-7 above. Record as much detail as possible.

9. Were any of the changes (#1-7) present all the time, or did they come and go from day to day?

All the time Come and go Don't Know

10. When did these changes first begin? Would you say they began:

Within the last week

Between 1 and up to 2 weeks ago

Between 2 and up to 4 weeks ago

More than 4 weeks ago

11. Overall, have these changes been getting better, worse, or staying about the same?

Better Worse About the Same Don't Know

Appendix C

Ways of Coping Questionnaire, Eight Coping Subscales. Folkman and Lazarus, 1988

Coping Style	Description
Confrontive	Describes aggressive efforts to alter the situation and suggest some degree of hostility and risk-taking.
Distancing	Describes cognitive efforts to detach oneself and to minimize the significance of the situation.
Self-Controlling	Describes efforts to regulate one's feelings and actions.
Seeking Social Support	Describes efforts to seek informational support, tangible support, and emotional support.
Accepting Responsibility	Acknowledges one's own role in the problem with a concomitant theme of trying to put things right.
Escape-Avoidance	Describes wishful thinking and behavioral efforts to escape or avoid the problem. Items on this scale contrast with those on the Distancing Scale, which suggest detachment.
Planful Problem Solving	Describes deliberate problem-focused efforts to alter the situation, coupled with an analytic approach to solving the problem.
Positive Reappraisal	Describes efforts to create positive meaning by focusing on personal growth. It also has a religious dimension.

Appendix E

Scripps Healthcare Investigational Review Committee Approval Letter

Office for the Protection of Research Subjects

Scripps IRB

11025 North Torrey Pines Road
Suite 200
La Jolla, CA 92037**Approval Notice**

Investigator: Marin Xavier, MD

Department: Scripps - Cancer Center

Approved

Research Sites: Scripps Cancer Center (Mercy)

Project Title: Delirium Occurrence Among Vulnerable Outpatients, and Caregiver Coping Strategies

Protocol No: IRB-13-6160

Risk Category: Minimal

Type of Review: Expedited – NEW

Your research project indicated above was reviewed and approved by an IRB officer on the review date stamped below. Approval expires **12 months** from this date.

Approval carries with it the understanding that you will inform the Committee promptly should a serious adverse reaction occur, and that you will make no modification to the protocol or consent form (if applicable) without prior IRB approval.

The IRB may suspend or terminate the approval of research that is not conducted in accordance with the requirements set forth by the committee or that has been associated with unexpected serious harm to subjects.

Thank you for your cooperation.

(Informed Consent dated 5-14-13)

Signature applied by Barbara G Bigby on 05/20/2013 12:26:36 PM PDT

IRB Officer

As of January 27, 2009, all Scripps IRBs were combined into a single, system-wide IRB known as "Scripps IRB", which is registered with OHRP as IRB00004335

Appendix F

Scripps Healthcare Investigational Review Committee Approval Letter

Spanish Modifications

Office for the Protection of Research Subjects

Scripps IRB

11025 North Torrey Pines Road
Suite 200
La Jolla, CA 92037**Approval Notice (Modification)**

Investigator: Marin Xavier, MD

Department: Scripps Cancer Center

Approved
Research Sites: Mercy Scripps Cancer Center

Project Title: Delirium Occurrence Among Vulnerable Outpatients, and Caregiver Coping Strategies

Protocol No: IRB-13-6160

Risk Category: Minimal

Type of Review: Expedited

The modification to the protocol above was reviewed and approved by an IRB Officer. This modification does not extend the expiration date of the protocol's last IRB review.

(Study added three (3) translated Spanish documents: Spanish Consent dated 9/3/13, Spanish "FAM-CAM" Survey, and Spanish "Ways of Coping" Questionnaire)

Signature applied by Barbara G Bigby on 09/26/2013 12:09:37 PM PDT

IRB Officer