Assessing Post-Hip Surgical Pain in Hospitalized Older Adults with Severe Dementia

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To the families with loved ones succumbed to the effects

of dementia and pain.

I hope this study will attempt to find solace

by informing care providers that

unrelieved pain affects everyone.

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TABLE OF CONTENTS

Appendix

LIST OF TABLES

LIST OF FIGURES

CHAPTER I

INTRODUCTION

Pain in cognitively impaired older adults with Alzheimer's disease (AD) is poorly understood, especially when they lose the ability to communicate. Without a verbal response, it is difficult to ascertain pain because cognitive impairment can alter or mask responses to painful stimuli. Alzheimer's disease and related dementias are common diseases that result in memory loss. Depending on the severity of memory loss, people may display behaviors that may not be reflective of pain (Becouze, Hann, Chase, & Shaw, 2007; Orgeta, Orrell, Edwards, Hounsome, & Woods, 2014). Moreover, loss of cognition will eventually result in poor recognition of pain on the behalf of the health care provider because people with severe dementia eventually lose the ability to communicate. Pain is considered a subjective phenomenon; therefore, pain assessment is based on self-report. As self-reports are not possible in people who are unable to communicate, afflicted individuals may experience under-treated pain and compromised quality of life.

Prevalence of Pain in Older Adults with and without Cognitive Impairment

Prevalence of pain in older adults with and without cognitive impairment ranges from 22 percent to 86 percent of the studies examined (Ellis-Smith et al., 2016; Fuchs-Lacelle & Hadjistavropoulos, 2004; Fuchs-Lacelle, Hadjistavropoulos, & Lix, 2008; Kaasalainen, Akhtar-Danesh, Hadjistavropoulos, Zwakhalen, & Verreault, 2013; Takai et al., 2013; van Nispen tot Pannerden et al., 2009). The wide disparity of pain prevalence among older adults is multi-factorial; one factor is the difference in study methodologies examined. Cross-sectional, descriptive designs are predominant in pain studies in older patients living in nursing homes or long-term care facilities because they allow for natural observation of the phenomenon (Blomqvist & Hallberg, 1999; Ferrell, Ferrell, & Osterweil, 1990; Ferrell, Ferrell, & Rivera,

1995; Lin, Lin, Shyu, & Hua, 2011). For example, a seminal cross-sectional study by Ferrell (1990) was undertaken to examine pain prevalence of nursing home residents (n=88) and it was found that 71 percent had at least one complaint of pain (Ferrell et al., 1990). Studies with similar designs gave evidence of similar prevalence rates, with some having lower prevalence rates than expected due to the methodology of the study (e.g., retrospective investigations using chart reviews) (Proctor & Hirdes, 2001; Sengstaken & King, 1993). Prospective, quasi-experimental designs also have demonstrated varying prevalence rates (Patel, Guralnik, Dansie, & Turk, 2013; Shega et al., 2008; Zwakhalen, van't Hof, & Hamers, 2012) and some differences may be attributed to small sample size (Horgas, Elliott, & Marsiske, 2009; Lukas, Barber, Johnson, & Gibson, 2013; Zwakhalen et al., 2012). The pain stimulus used in most of these studies employed care activities (e.g., bathing) and examining patient medical history for pain-associated diseases, e.g. osteoarthritis (Horgas et al., 2009; Patel et al., 2013).

While these pain stimuli generally elicit a response in some cognitively intact patients, such a response may not be as apparent with patients suffering from cognitive impairment (Lukas et al., 2013). An inherent interest is cognitive status among the studies reviewed as pain is considered subjective and self-report is the gold standard. When patients become severely cognitively impaired and lose the ability to communicate, pain assessment presents a challenge among health care providers. Thus, in studies where the goal was to assess pain in cognitively impaired patients, the researchers needed to ascertain the level of impairment and thus how severely a patient's ability to communicate may be impacted. They did so by employing various measures as discussed in the following section (Blomqvist & Hallberg, 1999; Ferrell, 1995; Ferrell et al., 1990; Horgas et al., 2009; Shega et al., 2008).

Measures of Cognitive Status and Pain

The most common cognitive measure used to ascertain levels of impairment was the Mini Mental Status Exam (MMSE), which has been found to be a reliable and valid tool to measure cognitive performance and function (Folstein, Folstein, & McHugh, 1975). While these studies used this instrument to assess older adults with mild, moderate and severe cognitive impairment, cut-off scores were arbitrary in determining level of cognitive impairment (Cheung & Choi, 2008; Costardi et al., 2007; DeWaters et al., 2008; Herr, Bjoro, & Decker, 2006; Hutchison, Tucker, Kim, & Gilder, 2006; Jordan, Hughes, Pakresi, Hepburn, & O'Brien, 2011; Liu, Briggs, & Closs, 2010; Lukas et al., 2013; Mosele et al., 2012; Sampson et al., 2015; Schuler et al., 2007; Takai et al., 2013; Warden, Hurley, & Volicer, 2003{Chan, 2014 #682). Further studies used cognitive measures that did not demonstrate solid psychometric properties and could elicit different responses to pain stimulus (Ferrell et al., 1990; Lin et al., 2011; Patel et al., 2013), especially in regard to a patient considered to be severely cognitively impaired and lacking the ability to communicate pain. Regardless of the technique utilized to assess the level of cognitive impairment, it is evident throughout the literature that the ability to accurately assess pain is a major concern when working with cognitively impaired older adults (Hadjistavropoulos et al., 2014; Herr et al., 2006; Herr, Bursch, Ersek, Miller, & Swafford, 2010; Horgas et al., 2009; Horgas, Nichols, Schapson, & Vietes, 2007; Mezinskis, Keller, & Luggen, 2004).

Pain in cognitively impaired older adults has shown to be prevalent in nursing home and long-term care facilities nationally (Patel et al., 2013) and internationally (Blomqvist & Hallberg, 1999; Lin et al., 2011; Proctor & Hirdes, 2001). Health care providers employ various assessments that may not detect pain adequately. Studies compared self-report and physical observations of pain in older adults with varying degrees of cognitive function. Findings that indicate that where cognitive loss is more substantial, self-report may not be appropriate and

other means of assessing pain is needed. Observations of physical behaviors that indicate an individual is experiencing pain are necessary when severe cognitive function renders loss of verbal communication.

Researchers studying pain have commonly employed one dimensional pain scales, e.g. Numerical rating scale, and multi-dimensional scales, e.g. McGill Pain Questionnaire(Hawker, Mian, Kendzerska, & French, 2011; Sriwatanakul et al., 1983; Taylor, Harris, Epps, & Herr, 2005; Wewers & Lowe, 1990; Williamson & Hoggart, 2005). However, the common trait among these tools is a reliance the patient's ability to verbalize and comprehend language and are highly subjective. While these assessments are recommended in assessing pain in older adults with cognitive impairment, it may not be appropriate when the impairment is severe and the patient's ability to communicate is compromised or non-existent. Pain assessments based on physical behaviors are generally considered to be useful, however more studies are required to determine the clinical relevance in a variety of settings and patient conditions. Shega et al. (2008) found that when controlling for cognitive function, physical behaviors indicating pain were consistent in both cognitively impaired and intact patients.

Pain is prevalent in older persons living in nursing homes or long-term care facilities, especially when there is cognitive impairment and thus there is a risk of underreported pain given the patient's inability to communicate it. It is therefore necessary for health care providers to rely on behavioral observation of patients with cognitive impairment in order to adequately assess pain and provide relief (Horgas et al., 2009). To that end, it is essential to understand how people with severe dementia behaviorally display pain. Effective and reliable assessment will provide health care providers the necessary information to guide pain treatment in older adults with severe cognitive impairment.

The Gold Standard in Pain Assessment

Pain is a subjective phenomenon, and self-report is the gold standard of pain assessment (Cleeland & Ryan, 1994; McCaffery & Moss, 1968; Melzack & Wall, 1965). Pain can be conceptualized along three dimensions: sensory, affective and cognitive (Melzack & Wall, 1965). The ability to perceive stimuli as a potential threat is considered sensory; the affective component is the unpleasantness associated with pain; understanding pain in the context of previous experience and knowledge is cognitive (Melzack & Wall, 1965). Sensory and affective dimensions can be measured using one dimensional scale. The Numerical Rating Scale (NRS) (Huskisson, 1974), Visual Analog Scale (VAS) (Huskisson, 1982; Price, McGrath, Rafii, & Buckingham, 1983), and Verbal Descriptor Scale (VDS) (Beecher, 1957) are examples of common one dimensional scales used in clinical settings to assess pain intensity. The cognitive dimension requires a comprehensive evaluation using multi-dimensional scales, e.g., Brief Pain Inventory (BPI) (Cleeland & Ryan, 1994) or McGill Pain Inventory (MPI) (Melzack, 1975). These tools with well-established psychometric properties are used to measure differing dimensions of the pain experience – with an assumption that the patient is cognitively intact. Obtaining a subjective pain measure presents a challenge when patients with severe cognitive impairment are unable to communicate. Therefore, pain assessments that are not reliant upon a patient's ability to verbalize are necessary to guide health care providers in the selection of appropriate treatments.

To address the need of under treated pain from indecisive selection of optimal analgesia across various clinical settings, The World Health Organization (WHO) established an analgesic ladder, using opioids and non-steroidal anti-inflammatory drugs (NSAIDs) (Vargas-Schaffer, 2010). Analgesia selection was based on patient's self-report of pain severity (mild, moderate, or severe) providing a standardized approach in selecting proper treatment. An NSAID is used for

mild pain, and a strong opioid plus a NSAID is used for severe pain. For pain that is difficult to treat with opioids alone, adjuvant medications (e.g. anti-depressants, anti-epileptics) are used in conjunction with the opioid to provide relief. The difficulty in applying the analgesic ladder in non-communicative patients with severe cognitive impairment could potentially mean the proper analgesics are not selected.

As nurses are the front-line leaders responsible for managing pain, their ability to accurately assess pain is critical. Assessing a severely cognitively impaired patient who is unable to communicate entails the nurse's reliance on the behavioral display of pain. Although more than 20 observational tools are in existence, a gold standard of measuring pain in non-communicative patients has not been established. Further psychometric testing of such observational tools is necessary in order to promote confidence in their use in clinical practice. Use of an established, standardized pain assessment tool will likely decrease health care providers' concern in administering opioid medications in severely cognitively impaired people. Additionally, the use of established, standardized observational tools to measure pain may increase the likelihood of receiving an appropriate pain treatment and therefore improve quality of life.

Pain Assessment in Cognitively Impaired Older Adults

Numerous studies suggests a comprehensive pain assessment is important to detect pain and treat it with appropriate measures (Bachino, 2001; Carezzato, 2014; Herr et al., 2006; "The management of chronic pain in older persons: AGS Panel on Chronic Pain in Older Persons. American Geriatrics Society," 1998). When health care providers fail to detect pain, patients experience psychological and physiological effects of undertreated pain (Corbett et al., 2012). Many are undertreated because subjective pain assessment is inappropriately used in cognitively impaired patients. This makes more effective means of assessment necessary. While health care

providers are aware of a variety of assessment practices to manage patient conditions and provide necessary care in treatments, pain assessment remains a challenging endeavor for many not familiar with assessing pain in non-communicative patients.

Bachino (2001) found that health care providers fail to routinely assess patients with dementia who were unable to provide self-report of pain. Because assessments commonly used in clinical settings rely on subjective reports, this can lead to under treated pain in non-communicative patients. Bachino (2001) concluded that approaches to assessing patients with cognitive impairment necessitate the use of observational diagnostic tools. Ferrell (1995), a seminal 1995 study found that 45 to 80 percent of nursing home patients regularly experience some degree of pain. While many nursing home residents with dementia have additional co-morbidities related to advanced age, pain is often not adequately assessed leading to decreased quality of life. Ferrell (1995) determined that health care providers fear the effects of administering opioids that may further deteriorate patients pre-existing conditions despite the psychological and emotional impact of pain. However, the recommendation was made for a structured approach to assessing patients with dementia in order to optimally treat pain (using non-pharmacological modalities that avoid the side effects of opioid medications).

While the above studies indicate the need for thorough pain assessments in dementia patients, Ferrell and Rivera (1995) examined 325 geriatric adults in nursing homes to determine the prevalence of pain. Evidence was given within the study that 83 percent of those residents who had substantial cognitive impairment were in pain and were not routinely assessed by nurses. It is inferred from those results that often nurses fail to use the available tools to assess or document pain in patients with severe cognitive impairment. The findings indicated that 65 percent of the patients were able to cooperate in the assessment and convey pain.

Brecher and West (2014) studied patients with end-stage dementia and determined that dementia is associated with high prevalence of physical pain and related behavioral symptoms. The study provided an indication that observations of physical behaviors are an important assessment technique. A comprehensive approach to treat end-stage dementia patients in pain requires a collaborative interdisciplinary team to improve patient care. Chapman (2008) and Chatterjee (2012) examined the state of pain assessments using physical observations of patients with moderate to severe dementia. Both of these studies emphasized the need for health care professionals to assess patient's behaviors as indicators of pain when self-report is not possible. For example, Chapman (2008) focused on how human facial expressions of patients with dementia in pain could be used as a pain metric. Hadjistavropoulos et al (2014) reviewed a variety of pain assessments that encompass many dimensions of pain which could be utilized to assess patients with differing levels of cognitive impairment. The review emphasized the use of facial expressions related to differing pain pathways as a way to inform novel tools for assessment. While available tools are useful in assessing patients in pain, Hadjistavropoulos et al (2014) indicated that proper pain management relies on the use of pain assessments that match the patient's level of cognitive impairment.

In addition, Chatterjee (2012) reviewed pain tools used to assess pain in patients with differing levels of cognitive impairment. The results gave evidence that as the patient's cognition declined, assessment of pain became difficult because the ability to self-report was diminished. Further, Chatterjee (2012) recommended essential elements in assessing cognitively impaired patients using a method that encompasses physical and emotional behavioral aspects of pain, providing nurses multiple modes of assessing patients with differing levels of cognition in order to treat such pain adequately. Fuchs-Lacelle et al. (2008) examined the use of the Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC) screening

instrument in assessing pain in patients with severe dementia. In this study, the investigation focused on the nurse burden (in using the instrument), and pain behaviors on the behalf of the patients, and whether the pain was adequately managed. Results indicated that the tool did not contribute to further nurse burden and showed that routine assessment decreased the number of pain behaviors, suggesting that the pain was sufficiently managed (Fuchs-Lacelle et al.,2008).

Herr (2006) examined the state of the science of pain tools in patients with cognitive impairment. This review included a summary of multiple assessment tools that have clinical utility. It was posited that thorough examination of cognitively impaired patients in pain is a vital in reducing the emotional and physiological burden of pain that impact quality of life. Although many studies indicated the use of behavioral measurements in assessing pain, cognitively impaired patients in pain are under- managed, especially when self-report is lacking (Brecher & West, 2014; Chapman, 2008; Chatterjee, 2012; Ferrell, 1995; Hadjistavropoulos et al., 2014).

Impact on Society

Healthy People 2020 addresses monitoring physical, mental and social status within the community through self-rated health assessments. In addition to the various dimensions comprising quality of life, self-rated pain is included (Healthy People 2002). Improving health in the community includes appropriate and optimal management of pain. One objective in Healthy People 2020 is to measure health-related quality of life and well-being, which encompasses optimal pain management. The focus of pain assessment and treatment is enhanced by additional government involvement, such as the National Institute of Health, who adopted research goals established by Healthy People 2020 objectives. Non-communicative people with diseases affecting neurocognition are more likely to have poor quality of life and a poor sense of well-being due to inadequate pain assessment and management. Therefore, national guidelines to improve pain management in clinical settings have been established to ameliorate the egregious

effects of unrelieved pain and increase remaining quality of life in patients with severe cognitive impairment.

Treatment Barriers among Health Care Providers

Ferrell (1995) concluded that assessment and management of pain in older adult patients with and without cognitive impairment living in nursing homes or long-term care facilities is dependent on educating health care professionals on the importance of addressing this phenomenon in clinical settings. Klopfenstein et al. (2000) studied both nurses and physicians, and found the assessment and management of pain was ineffective (Klopfenstein, Herrmann, Mamie, Van Gessel, & Forster, 2000). According to Green et al. (2003), less than one percent of the curriculum in medical and nursing schools is dedicated to pain management. Nurses provide the major workforce in clinical settings with constant contact with patients; as such they are responsible for managing care, including addressing pain issues. However, studies have reported that nurses were uncomfortable in managing pain as they felt their training did not prepare them adequately (Feldt, Ryden, & Miles, 1998; Feldt, Warne, & Ryden, 1998; Fothergill-Bourbonnais & Wilson-Barnett, 1992).

As the need to manage pain is dependent on health care provider's assessments, instituting early education may alleviate the national burden of pain socially and economically. Therefore, undertreated pain stemming from inadequate pain assessments can impact patient's quality of life (Cavalieri, 2002; "The management of chronic pain in older persons: AGS Panel on Chronic Pain in Older Persons. American Geriatrics Society," 1998), increase health care costs (Bachino, 2001; Gaston-Johansson, 1996), and proliferate a culture of apathy to treat vulnerable groups (Blomqvist & Hallberg, 1999; Medicine, 2011). Despite the overwhelming evidence that inadequate pain control is detrimental to patients and access to the tools/resources necessary to provide pain relief, pain has not been adequately addressed (Green et al., 2003)

The Sociocultural and Socioeconomic Impact of Pain in Healthcare

Every individual perceives and expresses pain differently. These differences are dependent on various factors, e.g. race, culture, and gender, which impact how pain is assessed and treated by health care providers. Day and Thorn (2010) studied a rural population consisting mostly of African American females with low socioeconomic status to determine if demographic, socioeconomic, and access to health care factors affected adequate pain management. The study gave evidence for socioeconomic status and gender contributions to differences in pain management. Thus, treatment biases exist among marginalized populations indicating an American healthcare system where people who need treatment are currently the most underserved (Day & Thorn, 2010; Steglitz, Buscemi, & Ferguson, 2012).

Communication about pain treatment is usually twofold between provider and patient. Sociocultural factors, such as race/ethnicity, can affect this communication, which may lead to poor pain control (Day & Thorn, 2010). According to the seminal study, Chapman and Jones (1944), African Americans reported lower pain tolerance thresholds compared to non-Hispanic Whites. Further, experimental studies examining pain thresholds using various stimuli (e.g. cold pressor, electrical, thermal) consistently found that African Americans report more pain than their White counterparts (Green et al., 2003; Kapoor & Thorn, 2014; Kim et al., 2004). These racial differences were supported in the clinical setting where African Americans with chronic pain reported higher pain intensity and pain interference than their White counterparts (Day & Thorn, 2010; Kapoor & Thorn, 2014). While more studies are needed to compare pain among racial/ethnic groups, it is evident that sociocultural differences exist and need to be accounted for in treating pain adequately.

In addition to differences in race, vulnerable groups, such as older adults with AD or related dementias, are at risk of poor pain management primarily because of inadequate reliable

and valid pain assessment tools. For example, many older residents living in long term care facilities may not have easy access to diagnostic or laboratory equipment commonly found in hospital settings. Therefore, distinguishing the etiology of pain in cognitively impaired patients can be difficult, especially when self-report is unobtainable (Ferrell, 2004). Many of these highly vulnerable people living in nursing homes have lower socioeconomic status and are at further risk or poorly managed pain because of lack of resources in resource strapped environments such as Medicaid funded nursing homes (K. Jones, 2006).

Approximately 4.5 million Americans with AD or a related dementia will experience pain ("2014 Alzheimer's disease facts and figures," 2014). This means that as AD severity increases, health care providers must assess pain based on understanding clinically painful diagnoses and recognizing behavioral indicators of pain (Herr et al., 2006). An individual's response to pain is influenced by and learned within the context of sociocultural and socioeconomic norms. Therefore, the health care provider caring for AD patients with differing socioeconomic and/or sociocultural backgrounds could misinterpret behaviors, leading to poor pain assessment and management (Green et al., 2003).

Current Standards of Care in Pain Management

Standardized pain tools are integrated in many hospital settings to guide health care providers in managing pain. It is well-known that common pain assessments depend on verbal accounts, such as the numeric pain scale (0-10 scale, 10= worse pain). While pain assessments may differ in every institution across different geographic areas in the United States, these assessments share a similar characteristic -- the subjective response to pain. Health care providers trust the self-report as the gold standard in subjective pain assessments (Cleeland & Ryan, 1994; McCaffery & Moss, 1968; Melzack, 1975). However, patients who are cognitively impaired may not be able to verbalize pain effectively or are considered an unreliable source.

Further, patients with AD will lose the ability to speak, which makes assessing pain more complex, particularly for health care providers who are more familiar with the traditional, patient-reported pain assessments. Therefore, health care providers need a standardized, established observational method for assessing pain in patients who are unable to articulate their pain symptoms.

The American Pain Society of Pain Management Nursing (ASPMN) recommends a comprehensive, hierarchical approach to managing pain in patients diagnosed with Alzheimer's disease and unable to communicate, which is congruent with Herr et al. (2010) review of observational pain assessment of dementia patients (Herr et al., 2006; Herr et al., 2010). The recommendations are:

1) Find the source of pain

2) Attempt to obtain a self-report

3) Obtain a proxy report of pain through family caregivers

4) Use an institution-approved pain assessment tool

5) Attempt an analgesic trial and observe change in behavior that could be related to pain

Two observational pain assessment tools have been recommended by the ASPMN, the PACSLAC and the Pain Assessment in Advanced Dementia (PAINAD). While these tools have been studied extensively, health care providers have not adopted them due to concerns regarding their validity. However, psychometric properties of both of these tools were estimated with various patient populations of cognitively impaired and used by different health care professionals. Construct validity of these instruments has been supported by correlation to other pain tools and with each other. However, construct validity has not been considered firmly established as most of the studies were conducted on samples with suspected pain or used conditions suspected to be painful as a source of pain stimuli. Determination of construct validity

can be estimated by use of known groups, thereby improving confidence of the tool to be used in clinical practice. Standardization of an observational pain tool can provide a gold standard for use in patients with differing levels of cognitive impairment and clinical settings. The APSPMN indicates further research is needed to strengthen observational pain tools before adopting in current standards of pain management.

Snow's Conceptual Model for Non-Communicative Patients with Dementia

Pain is multifaceted. It is particularly challenging in patients with AD because there is as of yet no gold standard for observed pain assessment. Snow's conceptual model (Snow, O'Malley K, et al., 2004) can be used to develop and evaluate observational pain tools for clinical use. The conceptual model incorporates sensory, behavioral, emotional and cognitive domains of pain perception. For example, sensory is the ability of the patient to perceive painful stimuli; behavioral is the physical movement associated with pain; emotional refers to patients consolability when in pain; and cognitive domain is how the patient understands pain derived from past experiences or learned behaviors. While pain is a primal defense mechanism for survival, the cognitive domain is imperative to form an understanding of perceived pain stimuli. Patients with AD will eventually lose the ability to self-report pain and may have diminished emotional cues to detect their own pain. Thus, nurses will have to rely on an observational method to assess pain adequately based on a multidimensional model with enhanced reliability and validity for clinical practice. Snow's model provides a framework for testing observational tools in patients with AD and related dementias.

The conceptual model will be used to guide the present study. The multiple components of the model that affect rater's pain assessment in cognitively impaired patients will be examined. The PACSLAC will be used to evaluate the tool's sensitivity to detect pain in patients with severe dementia who cannot verbalize. The PACSLAC is an observational-based pain tool

that consists of a list of behaviors that are indicative of pain. Sub-components of the tool include facial expression, social/personality/mood, activity/body movement, and other behaviors (specifically, physiological changes, eating/sleeping changes, and vocal behaviors). These subcomponents address the sensory, behavioral, emotional, and cognitive expressions of pain perception.

The conceptual model also takes into account the raters' inherent traits that could affect pain assessment, such as, nurses' years of experience, past information on pain management techniques, and pain beliefs (McCaffery & Moss, 1968; Orgeta et al., 2014; Sengstaken & King, 1993; Ward et al., 1993). Other factors will be considered using this conceptual model that affect pain assessment are the patient's level of cognitive function and pain source.

The other pain tool that will be examined in conjunction with the PACSLAC is the PAINAD, which is a movement-based pain tool that was developed using similar constructs of behaviors indicative of pain. The PAINAD is widely used because of its brevity in clinical situations and will be used parallel to the PACSLAC in this study. Comparisons of both tools will be conducted and guided by Snow's Conceptual Model, incorporating the rater's observations, patient factors, pain assessment utility, and a known pain source/stimulus.

Statement of the Problem

Pain is a common symptom experienced across the lifespan. Self-report is the gold standard of pain assessment. Thus, verbal communication between the patient and health care provider is essential to accurately assess and manage pain. People who cannot communicate verbally are thus at high risk for inadequate pain management. Current pain management guidelines for people with severe dementia recommend that pain be assessed by way of observing pain related behaviors. While several tools exist to measure pain behaviors in severe

dementia, no tool has been established as the gold standard for assessing pain in people with severe dementia.

Purpose of the Study

The purpose of this quasi-experimental, single group within subject's design was to evaluate the psychometric properties of selected observational assessment tools in patients with severe cognitive impairment. This study was guided by Snow's conceptual model. The study involved the examination of cognitively impaired patients over the age of 60 years who had undergone hip fracture repair. Pain was assessed at three times during the first 72 hours; from time of admission to a general medical or surgical floor for recovery. This study was designed to investigate the use of two observational tools recommended for use in assessing pain in severe dementia. The PACSLAC is a 60-item checklist where each behavior is rated as present or absent. In contrast, the PAINAD is a five-item observational scale where each pain behavior is rated on a 3-point Likert type scale. The PACSLAC was compared to the PAINAD for construct validity via interrater reliability, and comparison of reliable changes from one time period to another.

Interrater reliability was examined by determining degree of congruence between two raters. Snows conceptual model incorporates specific constructs of pain perception, particularly the influence of cognitive loss on sensory, emotional, and behavioral dimensions of pain. Demographic and clinical variables that potentially impact the experience of pain and the assessment of pain were considered in the interpretation of findings. Snow's conceptual model guided the selection of assessment tools used in this study. A short survey was given to the staff nurses who participated at the conclusion of the study in order to determine which observational tool was preferred and why. This was the first step of a long-range goal to develop safe

empirically-based interventions that improve pain management in cognitively impaired patients unable to speak based on reliable and valid tools.

Summary

Accurate pain assessment of patients with severe cognitive impairment is an important step in guiding nurses and health care professionals to appropriate pain-relieving modalities. Pain that is adequately treated will improve patients' quality of life by alleviating emotional and psychological impact of unrelieved and unrelenting pain and prevent potential adverse effects of unnecessary opioid medication administration and treating known acute pain can deter chronic symptoms and thereby reduce costs from frequent hospital visits for pain relief. By developing interventions that are safe and effective, utilizing a proven psychometrically sound observational tool will provide quality care in symptom management of pain. Further studies are needed to understand the impact of pain in cognitively impaired patients and changes in observational pain behaviors in assessment to fully examine a multi-dimensional tool for clinical practice.

CHAPTER II

LITERATURE REVIEW AND THEORETICAL FRAMEWORK

Pain in Cognitively Impaired Patients

Prolific researchers have defined pain as a noxious stimulus derived from either tissue trauma/injury, disease state, or no discernable pathology that may lead to potential dysfunction of the human being (McCaffery & Moss, 1968; Melzack & Casey, 1968; Melzack & Wall, 1965). The International Association for the Study of Pain (1994) defined pain as 'an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage' (International Association for the Study of Pain, 1994; Kalso, 2004). While various pain definitions exist to describe the essence of pain and what pain encompasses, it is well-known that pain is a predominant nociceptive perception that can have detrimental effects on an individual's psychological, psychosocial, and emotional aspects (Main & Watson, 1999; Moayedi & Davis, 2013; Poleshuck, Talbot, Moynihan, Chapman, & Heffner, 2013).

The pain literature supports basic nociception and proprioception from a biological perspective with subsequent explanation of psychological components related to perception (Gerstle, All, & Wallace, 2001; Main & Watson, 1999; McCaffery & Moss, 1968; Medicine, 2011; Melzack & Casey, 1968; Melzack & Wall, 1965). The information derived from multiple sensory neurons is processed in the brain, which activates all neurocognitive domains. Previous pain experiences sensitize the pain stimuli by considering psychosocial and emotional dimensions. Confirmation of pain perception stimulates actions to preserve tissue integrity or survival. While explanation of pain can be considered physiological, perceptions remain subjective based upon psychological and emotional makeup, including past pain experiences, of the individual. Alzheimer's disease patients lose the ability to self-report when language is lost. Moreover, with differing degrees of neurocognitive compromise of more than two or more

domains, perceptions of pain are suspect when considering verbal and physical behaviors. Hence, pain in AD is considered an elusive phenomenon to assess because distinction of pain varies widely in these patients, principally if literature consists of various evaluations of pain.

The pain experience in AD is difficult to describe, despite numerous studies that have examined this phenomenon. Studies examining early onset AD with intact but limited cognitive domains have found that patients are able to self-report pain. However, as the disease progresses the centers of the brain responsible for pain perceptions and evaluation are deteriorating, which could be a challenge to convey pain verbally. Some research exists that there is pain inhibition associated with diminished cognition (Cole, Farrell, Gibson, & Egan, 2010; Edwards, Fillingim, & Ness, 2003; Gibson & Helme, 2001; Marouf et al., 2013). In other words, AD patients may not experience pain when the disease progression is severe enough to interfere with the ability to evaluate the sensation of noxious stimuli.

Conversely, Lin et al (2011) investigated pain severity of 112 elderly patients with advanced dementia. Measures of dementia showed advanced stages and pain assessments were corroborated with an on-site pain expert to identify behaviors indicating pain. Results showed that 36.6% of demented patients who had been subjected to morning care routines associated with pain by health care providers demonstrated high levels of pain behaviors. These investigators assumed morning care was painful in this group of patients. A recent study by Loosen et al. (2012) examined temporary cognitive impairment and pain perception. A group of 12 healthy volunteers were subjected to standard pain stimuli with and without temporary cognitive loss, which was induced by using a dissociative anesthetic called ketamine. Results indicated that healthy volunteers expressed more pain with the temporary induced cognitive loss than without illustrating the psychological and emotional impact on pain perception. Hence, AD

patients experience more pain because cognitive decline inhibits the psychological and emotional aspects that regulate pain perception.

Horgas (2007), evaluated the use of a behavioral scale model to determine pain perception of demented clients. Nurses were trained to use observations of pain behaviors to assess these clients undergoing daily care routines. The results showed that demented patients exhibited pain behaviors, despite not being able to self-report. Contextual views of pain among nurses are influenced by increased knowledge of behaviors indicating noxious stimuli. Nurses play an important role in detecting pain and reducing stressors that trigger painful experiences of cognitively impaired patients. In addition, this research suggested that demented clients could experience pain. On the other hand, Zwakhalen et al (2012) suggested frequent pain assessments were necessary to address undertreated pain in cognitively impaired nursing home patients. However, results of the study indicated that frequent assessments of demented clients lead to increased panic and anxiety, which increased pain behaviors. As a result, pain among cognitively impaired patients is influenced by multiple factors that could cause over or under estimation of pain because assessment tools do not consider the degree of emotional and mental function.

While subjective report of pain is the gold standard, observational methods could be enhanced and explored further to establish firm reliability and validity of these measures. Objective pain assessment for AD requires astute observations of physical behaviors characteristic of pain and may use subjective self-reports if the patient is capable. The use of objective pain behavior assessment tools may be useful in mitigating unrelieved pain by providing appropriate treatments, especially for those who are non-communicative and self-report is suspect in cognitively impaired patients. Therefore, identifying clinically relevant tools based on firm research for patients with AD is an important endeavor for application to clinical practice.

History of Observational Assessment of Pain

Facial expression throughout human development is a form of communication. In infants, facial wrinkling with crying captured mothers' attention to provide essential tasks for survival, i.e. feeding (Chapman, 2008; Prkachin, 2007). Similarly, infants conveying pain communicates the need for safety and protection (Chapman, 2008; Kunz, Mylius, Schepelmann, & Lautenbacher, 2008; Prkachin, 2007). As humans develop throughout the lifespan, facial expressions change respective to specific social needs. Children and adult facial expressions were indicators of emotional states to facilitate socialization (Kunz et al., 2008). For example, children and adults who experience pain may exhibit expressions to elicit social support (Kunz et al., 2008; Prkachin, 2007, 2009). Human facial expressions were consistent with emotional states and rather were acquired through the context of socialization factors along with cognitive development. In other words, individual facial expressions were taught within context of environmental influences and intact neurocognitive functions. Emotions are attached to specific facial expressions attained through environmental immersion of other human beings displaying similar facial expressions, which is a cultural phenomenon. It is believed that despite different social norms and cultural environments, a gamut of facial expressions indicating various emotions are similar across populations.

Research into infant facial expression initiated the movement of objectifying a pain tool that could be used in clinical settings. Historically, the intent was to determine if newborns experience pain, especially male newborns undergoing circumcisions without anesthesia (Lehr et al., 2007). It was believed that newborns' immature brains did not have the well-developed cognitive areas for perceiving noxious stimuli (Serpa et al., 2007). However, after extensive review of facial measurement in various infant ages, the consistency of specific muscles contracting around eyes and wrinkling of the mouth with crying were indicators of pain (Serpa et

al., 2007). Studies have determined that newborns do feel pain. Investigators have employed similar constructs of facial expression with cognitively impaired adults (Hurley, Volicer, Hanrahan, Houde, & Volicer, 1992; Warden et al., 2003) .

Ekman and Friesen (1976) constructed preliminary documentation of facial behaviors indicative of an emotional response. It was known as the Facial Action Coding System (FACS), which was used to quantify the psychopathology of emotions in individuals. Testing of the FACS was the first known study to distinguish a range of facial movements that provided preliminary information for quantifying affect. Ekman and Friesen (1978) revised the FACS to incorporate methodological rigor to provide stronger psychometric properties for measuring emotional expressions.

Prkachin (1992) investigated the facial expressions of adults receiving experimental pain using the FACS. Testing on healthy subjects, the study delineated core facial expressions of pain such as brow lowering, tightening and closing of the eye lids and nose wrinkling with upper lip raising with different pain stimuli. These actions were used to refine the FACS for assessing pain, which motivated other researchers interested in constructing observational tools for assessing pain in various populations unable to communicate. While the FACS seems ideal for use with demented populations, literature suggested that physical behaviors may not be related to pain because the tool was conceptually based and tested on young children not with older persons with dementia (Herr et al., 2006; Merkel, Voepel-Lewis, Shayevitz, & Malviya, 1997).

Various populations may endure different neurological anomalies that could impair neurocognitive processes for language and memory (Chapman, 2008; Kunz, Mylius, Schepelmann, & Lautenbacher, 2004; Kunz, Scharmann, Hemmeter, Schepelmann, & Lautenbacher, 2007; Morello, Jean, Alix, Sellin-Peres, & Fermanian, 2007; Prkachin, 1992, 2009; van Herk, van Dijk, Baar, Tibboel, & de Wit, 2007; Voepel-Lewis, Merkel, Tait, Trzcinka,

& Malviya, 2002; Voepel-Lewis, Zanotti, Dammeyer, & Merkel, 2010). Compromised brain regions related to language may inhibit verbalization of pain, however, intact motor functions of face and body could convey pain behaviors. Numerous observational pain assessments were constructed for application of patients with differing neurological anomalies affecting speech/language abilities. However, the issues common to all these assessments were related to psychometric properties (Prkachin, 2009; van Herk et al., 2007; Voepel-Lewis et al., 2002; Voepel-Lewis et al., 2010). Despite quantifying an observation that measures pain objectively, the witnessed behavior remains open to interpretation by either the health care professional or researcher. Further, pain behaviors seen in infants and children may not be similar to adults because of cognitive and social maturation (Kunz et al., 2008). Therefore, research in pain tool development for adults with cognitive impairments was constructed using different facial expressions for older adults.

Aside from facial expressions, body postures or physical movement indicating pain have been used to develop observational pain assessments. While the idea of examining physical behaviors to indicate pain seems ideal, many researchers would argue the conceptual soundness applied to older adults with dementia. Some researchers suggested that leg kicking, arched, or jerking activity, squirming, and quivering chin have not been conveyed in the literature to be pain behaviors in dementia (Herr et al., 2006). Thus, development of observational pain assessments based on physical behaviors need further investigation to determine clinical utility with multiple patient populations with different types of cognitive impairment to suggest specific behaviors are inherently found in painful situations.

Neurocognition in Cognitively Impaired Patients

To understand pain in patients with severe cognitive impairment, a basic understanding of neurocognition is important in order to understand why and how patients respond to different

stimuli (Hugo & Ganguli, 2014; Knox, Lacritz, Chandler, & Munro Cullum, 2003). Neurocognition identifies specific anatomical regions of the brain and their domain over functions that are used to interpret and respond to stimuli (Berker, Berker, & Smith, 1986; Boake, 2002; Davies, 1955; Fox, 1931). There are six neurocognitive domains that function together to provide individuals a sense of identity and understanding of their environment (Bradford, Jentzsch, & Gomez, 2015; Knox et al., 2003). Further, these domains determine how individuals behave in response to their environment and its stimuli (Bradford et al., 2015; Jahshan & Sergi, 2007). When these domains are compromised, patients' ability to communicate their needs and to interact with others is also compromised (Hugo & Ganguli, 2014). The six neurocognitive domains are: 1) perceptual-motor function; 2) language; 3) learning and memory; 4) social cognition; 5) complex attention; and 6) executive function (See Table 1) (Henderson, 2010; Sachdev et al., 2014).

Table 1
Definitions of Neurocognitive Domains

Perceptual-motor function	Includes ability to use objects under appropriate context.
Language	Expressive language which includes naming, word finding, fluency, grammar, and syntax.
Learning and memory	Immediate and recent memory, long-term memory, and implicit learning
Social cognition	Recognition of emotions, theory of mind
Complex attention	Ability to sustain, divide, and selectively focus attention; processing speed
Executive function	Planning, decision-making, working memory, responding to feedback/error correction, over-riding habits/inhibitions

The three common types of dementias are Alzheimer's disease, Lewy Body dementia, and vascular dementia. Eventually, as a disease that impairs neurocognition progresses, individuals become unable to understand or use language; effectively process environmental stimuli, recognize family members or themselves. As a result, they are totally dependent on

others to determine their basic needs ("2014 Alzheimer's disease facts and figures," 2014). For example, when a patient with dementia experiences pain, depending on the severity of his or her dementia and affected neurocognitive domain, various behaviors are exhibited (Manfredi, Breuer, Meier, & Libow, 2003; Shega et al., 2008; Zwakhalen, Hamers, Abu-Saad, & Berger, 2006). Although these common dementias have differing etiological mechanisms, disease progression will lead to complete neurocognitive compromise resulting in similar behaviors to painful stimuli (Shega et al., 2008; While & Jocelyn, 2009; Zwakhalen et al., 2006). Therefore, observations of physical behaviors are an essential component in understanding a patient's pain process, especially when self-report is difficult to obtain (Prkachin, 1992, 2007; Zwakhalen et al., 2012).

Alzheimer's disease (AD) is a neurological disorder that results in insidious loss of cognitive function from the progression of β-amyloid plaques that destroy healthy brain tissue (Glenner & Wong, 1984). The brain consists of over 100 billion neurons with 100 trillion synapses that allow continuous flow of information (Braak, Braak, Bohl, & Lang, 1989). In AD, β-amyloid plaques invade and crowd synapses, which inhibits communication from neuron to neuron (Braak et al., 1989; Hugo & Ganguli, 2014; Lim et al., 2014; Prince et al., 2013; Villemagne et al., 2013). Brain damage stems from accumulation of protein tau, known as tau tangles, inside the neuron. This impedes transport of vital nutrients, which causes neuronal death and affects cognition. Diagnosis of AD as defined by the Diagnostic and Statistical Manual for Psychiatric Disorders (DSM-5) is the loss of two or more cognitive domains, one of which must be memory. When loss of neuronal communication progresses a random display of cognitive decline may occur in any of the six domains. However, severe forms of AD affect all neurocognitive domains rendering individuals unable to care or communicate for themselves.

Dementia with Lewy Body (DLB) is the second most common dementia (Hugo & Ganguli, 2014). Unlike AD, a specific protein called alpha-synuclein folds and aggregates inside the neuron becoming a Lewy Body that disrupts cell function ("2014 Alzheimer's disease facts and figures," 2014; Hugo & Ganguli, 2014; Ihl, Frolich, Dierks, Martin, & Maurer, 1992; Spillantini et al., 1997). These patients often exhibit early signs and symptoms of neurocognitive damage, beginning with sleep disturbances, visual hallucinations, slowness, and gait imbalance. While neurocognitive changes occur slowly with this form of dementia, the result will be similar to AD, that patients will be rendered unable to use language and executive function (Gomperts, 2016) making it difficult for them to understand environmental stimuli and verbally convey their needs.

Vascular dementia involves the blood vessels in the brain that provide essential metabolites and nutrients to neuron cells ("2014 Alzheimer's disease facts and figures," 2014). When blood circulation is compromised either by hemorrhagic or ischemic strokes the neuron cells begin to die. The affected neurocognitive domain is dependent on the location of the insult in the brain. For example, patients who have suffered a stroke in the Broca's triangle, which is responsible for speech production, will lose the ability to verbally communicate (Burns & Fahy, 2010). While surrounding areas preserve speech comprehension, the patient is able to understand language but cannot speak. The progression of vascular dementia will result in further neurocognitive compromise in the domains of executive function, language, memory, and perceptual-motor rendering the individual unable to speak, remember routine tasks, and perform activities to meet their basic needs.

Global Cognitive Impairment

While other forms of dementias exist, cognitive impairment is a shared trait that makes pain assessment of these patients difficult, especially when verbal communication is

compromised. Aside from language use and comprehension, other neurocognitive domains are also needed to convey pain. For example, perceptual-motor and executive function are necessary for patients to express pain through writing or pointing. Despite the level of cognitive impairment, care givers are still required to ask the patient for confirmation of pain. In the case of severely cognitively impaired patients, other physical behaviors which indicate pain must be recognized. Health care providers that work in long-term care facilities, nursing homes, and other institutions which care for older clients will encounter patients with cognitive impairment. Thus, it is imperative for health care providers to assess pain using observational methods of assessment.

Identification of Mild and Major Cognitive Impairment in Dementia

Assessment of mild cognitive impairment in dementia is relevant to clinical practice and research. In either setting, mild cognitive impairment (MCI) is defined as a neurocognitive disorder affecting function of one or more cognitive domains. The challenge of MCI is to identify dementia as the cause, separate from other brain-related anomalies. Various diseases that mildly affect cognition all demonstrate similar characteristics and are indistinguishable from most dementia types. Researchers are investigating other means to determine accuracy of dementia diagnosis by adapting novel techniques, e.g. biomarkers (Hugo & Ganguli, 2014; Rolstad et al., 2009; Sachdev et al., 2014). While innovative approaches are being used to enhance current assessments surrounding diagnostic accuracy, the reliability and validity of these novel methods have not been confirmed and are not used in clinical practice settings. Currently, the DSM-5 is the standard to diagnose mild cognitive impairment and does not specify dementia type. Typically, diagnostic confirmation is made through the slow observation of symptoms affecting memory and their progression to the point when the individuals are no longer able to care for themselves.

The Diagnostic and Statistical Manual for Psychiatric Disorders (DSM-5) criteria for MCI manifests as a memory complaint (preferably substantiated by a family member or health care provider); compromised memory function for age and education; preserved general cognitive function; intact activities of daily living; and without confusion (Hugo & Ganguli, 2014; Sachdev et al., 2014).

The following are common neurocognitive domains affected by dementia. Clinical manifestations vary depending on the extent of disease progression.

Learning and memory. Individuals have difficulty recalling recent events. A marked characteristic is the inability to retain information, despite visual or auditory repetition. The individual also may lose track of tasks and may repeat the same one over again without realizing the repetition. Other noted findings are religious use of written reminders or lists to maintain normal daily activities.

Complex attention. The individual takes longer to perform normal tasks, especially in the presence of external stimuli. Further, individuals with dementia are easily distracted and need tasks that are simplified to maintain successful performance. Learning new information could be a challenge because attention is needed to facilitate information retention. Recalling information to do mental calculations such as dialing a familiar phone number can be a challenge.

Language. Individuals with MCI may experience difficulty in finding correct words to use and may use general phrases to convey the meaning of a word. Noted findings are the inability to comprehend what others relay through verbiage, especially written material.

Perceptual-motor/visuospatial function. There is a loss of understanding maps or directions, despite familiarity of certain geographical locations. Often individuals get lost in familiar areas and/or are unable to use common appliances or tools. Additional use of maps and notes are used to compensate for fleeting memory loss.

Social cognition. Behavioral changes ensue, which manifest as apathy and loss of empathy. In addition, individuals may engage in inappropriate behavior because of poor insight and lack of judgement. Poor impulse control is also noted because of diminished inhibition.

Identification of Major Cognitive Impairment in Research

Major cognitive impairment is recognized when memory including one or more cognitive domains are affected ("2014 Alzheimer's disease facts and figures," 2014; Hugo & Ganguli, 2014; Sachdev et al., 2014). At this latter stage of dementia, individuals have severe cognitive loss resulting in the inability to recognize others or themselves; long-term memory is diminished and could only briefly reminisce on past memories. Additional domains that clinically define major cognitive impairment involve loss of language, inability to comprehend directions and convey needs necessary for activities of daily living. Primary domains to comprehend environmental factors for survival are affected, which involve visuospatial and executive functions. Individuals are unable to process visual information appropriate for normal activity, familiar objects and people are not recognized and interpretation is flawed. Eventually, severe disease progression of dementia leads to death when areas of the brain that control involuntary function become inactive.

A major obstacle in pain research is the recruitment and retention of severe cognitively impaired participants. Due to their inability to provide informed consent and/or to convey their needs these individuals are considered vulnerable (Monroe, Herr, Mion, & Cowan, 2013). Studies that utilize the inducement of pain through applied stimuli to vulnerable subjects are considered unethical. These patients will need proxy assent from next of kin or legal guardians to participate in pain research activities (Monroe et al., 2013). The Mini Mental Status Exam (MMSE) will be used to confirm severe cognitive function and the individual's reaction to a painful stimulus without self-report or reliance on developed psychological pain experience.

Therefore, without the neurocognitive domains that produce the understanding of pain stimulation and learned social cues to express pain, behavioral observations are important findings in assessing pain in cognitively impaired patients because of dementia.

Dementia and Pain Outcomes

Pain is subjective, the statement that "pain is whatever the patient says it is" (McCaffery & Moss, 1968) is the crux of the problem of assessing pain in cognitively impaired patients. They are unable to verbally express their pain. Some health care providers believe that pain in patients with severe cognitive impairment is elusive. In other words, severely cognitively impaired patients may not be experiencing pain if they cannot verbalize it. However, further research has demonstrated the complexity in dementia by investigating the brain's anatomical and physiological components that process pain. For example, Monroe and colleagues (2012) reviewed pain network literature that involves neuroimaging and psychophysical studies of pain processing among Alzheimer's disease patients. The review revealed that some neuroimaging studies of severely demented patients in pain have similar neuroimaging scans to healthy controls (Monroe, Gore, Chen, Mion, & Cowan, 2012), which demonstrates that patients with severe dementia experience pain. Although demented patients may not verbalize pain, neuroimaging is not a feasible alternative to assessing behavioral responses to painful stimuli. Lautenbacher et al. (2005) used experimental pain on both healthy young subjects and older nursing home patients. While heat and mechanical pain were used, the results showed that pain summation reports of both groups were not affected by age. Another study experimenting with controlled pain stimulus was conducted by Kunz (2009), recruiting both healthy and demented subjects. Cognitive function was assessed using the MMSE; healthy and demented subjects average MMSE score were 29.5 (SD 0.8) and 16.4 (SD 5.3), respectively. The results showed that using a subjective rating scale, dementia patients rated the stimuli as similarly painful as

healthy controls. However, self-report of pain was dependent on severity of cognitive impairment, as the level of cognitive ability decreases so does the ability to self-report pain ($r=0.692$, $p<0.001$). Further, diminished cognitive capacity did not affect how dementia patients experience pain. Therefore, severely demented patients experience pain equally as their cognitively intact counterparts and other ways of detecting pain must be used when the neurocognitive domain for language becomes compromised (Parmelee, Smith, & Katz, 1993).

Patients with severe dementia may exhibit various physical behaviors that indicate pain. The challenge then is to determine the pain behavior of these patients through the observation of other confounding sources. For example, dementia patients could be found rocking back and forth, which can be interpreted as a pain behavior or anxiety. The seminal study conducted by Marzinski (1991) investigated the ability of licensed practical nurses to assess non-verbal cues that indicate pain with a sample of severely demented patients suffering with a pain-related chronic condition. Results varied with each patient depending on the severity of cognitive loss. Patients who were diagnosed with a health condition that was associated with pain did not exhibit any behaviors, while others exhibited facial expressions, eye blinking, or disjointed vocalizations as pain indicators (Marzinski, 1991). While it may appear that the nurses in the study used intuition as a means to assess pain in these patients, it was later revealed that the nurses used a system of verbal and nonverbal cues (Marzinski, 1991).

A common behavior found in severely demented patients is aggression, which could be another non-verbal cue of pain. Feldt (1998) explored aggression in cognitively impaired patients as an indicator of pain. Study samples included older patients with severe dementia, who were unable to verbally express their pain (mean MMSE score was 6.4, SD 6.9) and who were diagnosed with a pain-associated medical condition such as osteoporosis. Aggression was measured using the Ryden Aggression Scale (RAS). Results showed that subjects who had a

pain-causing diagnosis scored higher aggression scores than subjects without (13.9, SD 11.3 vs 8.2 SD 6.4, respectively). This further perpetuates the complexity of pain in patients with severe dementia and could justify reasons to explore this behavior specific to pain. Husebo et al. (2014) also examined agitated behavior of persons with dementia. The study posited that there is an association between pain and increased agitation. The subjects were patients in a nursing home with moderate to severe dementia who also had a pain-associated medical diagnosis. The study showed a decrease in agitated behavior in patients who received individualized pain treatment as opposed to general, standardized pain treatment (Husebo, Ballard, Cohen-Mansfield, Seifert, & Aarsland, 2014). In other words, patients with severe dementia displaying agitation may be doing so in response to pain. With individualized pain management techniques, it was observed that their agitation diminished. While agitation incorporates many types of behaviors, e.g. complaining, negativism, or verbal aggression not indicative of pain, facial grimacing is a specific response that is receiving pain research attention (Kunz et al., 2004, 2008; Kunz et al., 2007). Kunz (2007) examined the facial expressions in patients with dementia that may be explicit to pain, using videography to record the facial effects of induced experimental pain in both demented and healthy subjects. Results showed that patients with dementia exhibited the same facial expressions in response to the frequency and intensity of pressure stimulation as their healthy counterparts (group main effect: $F= 8.33$, $df=2, 91$, $p<0.001$). While there is an array of behavior that could indicate pain, these behaviors could also indicate conditions other than pain. However, facial grimacing has shown to be a consistent feature of pain across many dementia populations (Kunz et al., 2004, 2008).

To objectively measure the pain response in subjects, an equal amount of pain stimuli must be applied to both cognitively healthy and impaired subjects. Again, older patients with cognitive impairment are considered vulnerable and unable to give consent, therefore it is

unethical to induce pain in order to study their response. Hence, most studies surrounding pain and dementia recruit older adults with pain-associated conditions. The weakness in these studies is that patients who have lived with chronic pain, may have developed a tolerance for the pain associated with their condition, rendering the measurement of pain response inaccurate.

Hip fracture surgery is commonly known to be painful in both cognitively intact (Gille, Gille, Gahr, & Wiedemann, 2006) and impaired older patients (Feldt, Ryden, et al., 1998). Feldt (1998) investigated pain in both cognitively impaired and intact subjects undergoing hip fracture surgery. Cognitively impaired subjects had an MMSE score ≤ 23 were followed between 2 and 5 days post-operatively. Pain was measured using a dichotomous movement-based observational rating tool of pain behaviors, such as: verbal and nonverbal vocalizations, grimacing, bracing, rubbing, and restlessness, scored from 0 (no pain) to 6 (pain). Results showed that cognitively impaired adults scored higher, indicating more pain, than healthy controls with the same surgery (P= .0453). However, the study showed that patients with cognitive impairment received fewer opioid analgesics compared to cognitively intact subjects during the post-operative recovery phase (prescribed amount: impaired, 78.57mg±35.4 vs intact, 90.77mg±28.4). The study employed a movement-based observational pain tool, patients with cognitive impairment were assessed at rest during the post-operative period. Yet, these patients were assessed by mobilization and use of a self-report tool. Despite the cognitively impaired patient's ability to provide self-report, behavioral indicators of pain were not present, leading the health care providers to believe that pain was not present. As a result, health care professionals' beliefs about pain in cognitively impaired patients can result in the underutilization of available analgesia. Undetected and under treated pain can lead to poor functional outcomes in mild to moderate cognitively impaired patients who can self-report. Perhaps then significantly more

negative effects on functional outcomes are especially apparent in severe cognitively impaired patients who are unable to verbalize pain.

In a later study, Feldt and Oh (2000) investigated outcomes of older adults after hip fracture surgery. The sample consisted of older adults with and without cognitive impairment (MMSE mean scores were 12.0 (7.1) and 26.5 (1.8), respectively), those with cognitive impairment were able to self-report pain. Pain outcome measures were assessed using the Verbal Descriptor Scale at rest and in motion. Functional status is the ability to walk or transfer from bed to chair and measured using the Functional Status Index, scores ranged from 6 to 30, higher scores meaning more dependency. Although most of the cognitively impaired patients reported "moderate" or "severe" pain when assessed, analgesia opioid doses were not adjusted accordingly between groups. Post-operative pain was difficult to assess without mobilization and self-report from the cognitively impaired patients. Cognitively intact patients were freely able to provide self-report of pain during the post-operative phase. Results showed that after a two-month follow-up of both groups, the cognitively impaired patients fared worse in Functional Status compared to the cognitively intact. The study suggested that inadequate acute pain relief during post-operative period can impact the long-term function in patients with cognitive impairment who have difficulty providing self-report of pain.

In summary, depending on the severity and type of dementia, these patients experience pain similarly to those without. The display of pain behaviors varies because different neurocognitive domains are compromised in varying degrees. The source of pain stemming from pain-associated medical conditions may affect cognitively impaired patients differently. Common pain behaviors found, such as facial grimacing, agitation, and aggression could manifest differently across older populations with dementia and could be confounded with other causes. While self-report remains a gold standard in assessing pain even in cognitively impaired

patients who are able to verbalize, severe cognitive impairment warrants the health care provider to use behavioral observations when subjective pain tools are not appropriate.

The Mini Mental Status Examination (MMSE) is useful in pain research to measure the patient's cognitive ability to comprehend environmental stimuli. In cases of severe dementia without the ability to self-report pain, physical behaviors indicative of pain must be used in assessment. Currently, no gold standard in observational pain assessments exists. Thus, the current tools developed to measure pain in this population need further investigation to validate their usefulness in clinical settings because undetected pain in cognitively impaired patients can lead to under treatment and affect functional status in the remaining years of life.

The Mini-Mental Status Examination (MMSE)

The MMSE is a widely used tool to assess cognitive function in both clinical and research settings (Tombaugh & McIntyre, 1992). Folstein (1975) developed two parts of the MMSE; the first part requires vocal response from the subject to test orientation, memory, and attention. The highest score for this section is 21. The second part tests the ability to name, follow verbal and written commands, write sentence spontaneously, and copy a complex polygon. The highest score for this part is nine. Thus, scores for the MMSE range from zero to 30, with higher scores signifying intact cognitive function. The test has evolved over the years into an initial assessment of mental status to differentiate organic and functional disorders, and has become an assessment tool to detect and track the progression of cognitive impairment, e.g. Alzheimer's disease (Jones et al., 2002). Psychometric properties of the MMSE has been well established in several studies with internal consistency ranging from 0.82-0.84 (Cronbach alpha) (Folstein et al., 1975); inter-rater reliability found to be 0.827 in a study of patients with dementia (Folstein et al., 1975; Jones et al., 2002); and with test-retest reliability ranging from 0.75-0.94 (Pearson r) (Folstein et al., 1975). Concurrent validity of the tool was determined by

correlating MMSE scores with the Wechsler Adult Intelligence Scale in both the Verbal IQ and Performance IQ scores (Folstein et al., 1975), Pearson r was 0.776 ($p < 0.0001$, verbal) and 0.660 ($p<0.001$, performance)(Folstein et al., 1975).

In pain research, MMSE cutoff scores are arbitrary because it is dependent on the aims of the studies using the test (Chan, Hadjistavropoulos, Williams, & Lints-Martindale, 2014; Cheung & Choi, 2008; DeWaters et al., 2008; Lukas et al., 2013; Mosele et al., 2012; Takai et al., 2013). Folstein (1975) considered a cutoff score of less than 20 in the cognitively impaired. Other studies employed similar cutoff scores of less than 21 in the cognitively impaired patients and who were able to provide self-report of pain (Corbett et al., 2012; Horgas et al., 2007; Lukas et al., 2013). Subjects who obtained the cutoff score of less than 23 not only were cognitively impaired but they were able to self-report and demonstrate associated behaviors (Shega et al., 2008). While these cutoff points were used to point out a mild degree of cognitive impairment with relative preservation of language and executive function domains to comprehend pain experience, they did not solely rely on physical attributes that pertain to pain in severe cognitive impairment. A cutoff score that was less or equal to 10 or a mean MMSE score of 12 among subjects showed severe cognitive loss and indicated lack of verbal comprehension and communication. Pain studies used this cutoff score to examine observational assessment tools that did not rely on self-report (Feldt, Warne, et al., 1998; Ferrell, 1995; Husebo, Strand, Moe-Nilssen, Husebo, & Ljunggren, 2009, 2010; Husebo et al., 2007; While & Jocelyn, 2009). Therefore, the MMSE was used to confirm the level of cognitive impairment of the sample and a cutoff score of 10 was used to indicate severe cognitive impairment for this study that investigated observational pain tools with a known pain source, e.g. hip fracture surgery.

In summary, identification of mild and major cognitive impairment is important to observe various changes in verbal and physical behaviors that indicate pain. A pain assessment

that incorporates a multidimensional model is useful in understanding the neurocognitive functions affected when observing patients with AD, particularly with an observational pain tool that examines domains related to neurocognition. While assessing the degree of neurocognitive compromise is an important factor in deciding the best observational method to assess pain, conceptual and theoretical models are required to link concepts between neurocognition and the multifaceted dimensions of pain.

Theoretical Model of Pain

Snow's Conceptual Model of Pain Assessment for Persons with Dementia

Pain is considered multifaceted. To address issues surrounding unrelieved pain across different samples diagnosed with AD, a comprehensive conceptual framework is required. Lynn Snow's conceptual model of pain demonstrates bidirectional relationships of the identified constructs that are problematic to assessment and treatment leading to undertreated pain in persons with dementia. Several constructs are used in this conceptual framework, but the focus is primarily observer's ratings that are the basis of observational tool development for assessing pain in the cognitively impaired (See Figure 1. Snow's Conceptual Model).

The constructs of the model are borrowed from other pain research disciplines and are explicit in the approach to understanding pain behaviors derived from external observations (Abbey et al., 2004; Cleeland & Ryan, 1994; Melzack & Casey, 1968; Melzack & Wall, 1965). The basic construct is a sensorial foundation that incorporates the 1) nociceptive stimulus, 2) pain sensation, and 3) pain perception. Each of these constructs possesses other factors that may alter patient responses to pain. For example, the initial construct of nociceptive stimulus could be influenced by the following factors: location, intensity, duration, frequency, and quality (Snow, O'Malley K, et al., 2004). These factors could affect the nociceptive stimulus and alter pain sensation.

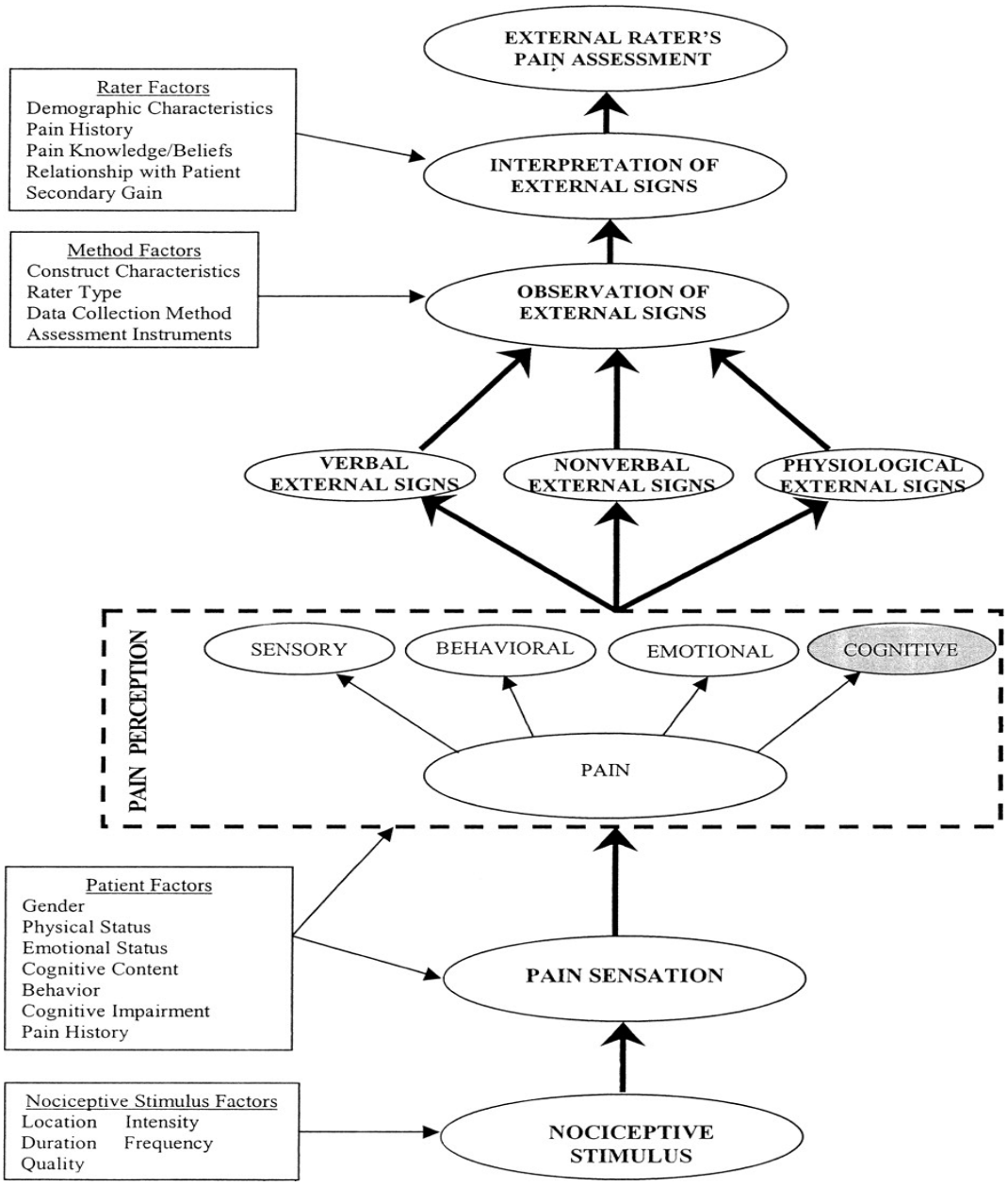

Figure 1. Snow's Conceptual Model

Pain sensation is the direct and basic experience generated by a stimulus. Many inherent factors could alter pain sensation, such as, gender, physical status, emotional status, cognitive content, behavior, cognitive impairment, and pain history (Snow, O'Malley K, et al., 2004). These demographic factors have demonstrated moderating or mediating effects that lead to variations in pain perception in research and clinical settings (Atkinson et al., 2012; Cole et al., 2010; Corbett et al., 2012; Day & Thorn, 2010; Gibson & Helme, 2001; Meghani & Chittams, 2015; Vallerand & Ferrell, 1995). While these factors are influential in understanding the variability in pain responses, pain perception is an elusive construct to define in patients with AD because the area of cognition used to evaluate sensation is compromised. The conceptual model warrants further investigation in pain sensation of cognitively impaired patients through observations of behaviors for tool development.

Pain perception is defined as what the patient interprets as painful dependent on sensory, behavioral, emotional, and cognitive domains. This concept is well defined in pain research and widely used to explain the different arrays of verbal and behavioral expressions of pain (Cleeland & Ryan, 1994; Huskisson, 1974; Main & Watson, 1999; Melzack & Wall, 1965). Pain perception in cognitively intact patients is understood as a verbal qualitative evaluation of a nociceptive stimulus; perception can be altered in AD. Therefore, the conceptual model suggests observation of external signs as a measure of pain in cognitively impaired populations.

Observation of external signs with interpretation of external signs is influenced by methodological and rater factors, respectively. Methodological factors incorporate construct characteristics, rater type, data collection method, and assessment instruments that affect how observers determine painful stimuli. These methodological factors suggest that subjects have various interpretations of external signs and this further suggests uncertainty that behaviors reflect pain in cognitively impaired patients. Rater factors, specific to demographic

characteristics, pain history, pain knowledge/beliefs, and relationship with patient affects interpretation of external signs. Interpretation of these external signs is key to understanding the use of this conceptual model to develop observational pain assessments in patients with AD.

Empirical research using this conceptual model developed the Non-Communicative Patient's Pain Assessment Instrument (NOPPAIN) for nursing assistants to use for assessing pain behaviors in demented patients (Snow, Weber, et al., 2004). No other tools since 2004 have been constructed with this conceptual model. However, the model exists to guide other researchers interested in developing tools that can measure pain in cognitively impaired patients. Although many tools were developed before Snow's model was published, they fit well within the framework she developed. However, in AD, current tools used for assessing pain are subject to suspect psychometrics, use of this conceptual model could prove beneficial to enhance psychometric properties. The pragmatism of this conceptual model addresses the key component that threatens most observational pain assessments in empirical research which is the raters' interpretation of the observed behavior that indicate pain leading to under treatment.

Pain Assessments used in Alzheimer's Disease

Alzheimer's disease will be a prevalent age-related disorder as the population continues to live longer. Pain assessments that rely on observational methods will be crucial for detection and management of pain in clinical settings, particularly in long-term care facilities. Observational pain scales have been developed to assess pain in these patients who cannot communicate as the degree of cognitive impairment increases. Many researchers have examined the feasibility of observational methods to construct various tools to detect pain dependent on the source of cognitive impairment.

A systematic literature search was conducted to find existing tools used to assess pain in demented patients. Although this is a relatively new concept in pain assessments, over 24

observation pain tools were identified that were used in both research and clinical practice. However, selection of specific tools was based on reliability and validity of these tools to measure pain in demented patients, which limited the selection to 15 tools. Further examination of these tools narrowed the search to three discrete tools that have the strongest psychometric properties to measure pain in cognitively impaired patients in both clinical and research settings. However, with further investigation of these three pain tools, one tool is lauded as the best for assessing pain in patients with AD, the Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC). However, another tool widely used in clinical settings is the Pain Assessment in Advanced Dementia (PAINAD). This tool is known for its brevity in pain assessment and has demonstrated good psychometric properties. Granted, the PACSLAC is a comprehensive observational pain tool because it addresses the sensory, behavioral, emotional and cognitive components of Snow's Conceptual Framework, comparisons with the PAINAD in this study can be used to show differences in results from nurses use of these tools. While the PACSLAC seem promising for standardized clinical use, enhanced psychometrics through research are necessary.

Description of the PAINAD

The Pain Assessment in Advanced Dementia scale (PAINAD) is a brief movement-based tool that observes five items: 1) negative vocalizations, 2) body language, 3) consolability, 4) breathing, and 5) facial expression. Moderate psychometrics of internal consistency and concurrent validity have been noted in studies that have been recommended for use in various clinical settings (Lukas et al., 2013; Paulson-Conger, Leske, Maidl, Hanson, & Dziadulewicz, 2011; Snow, Weber, et al., 2004). The PAINAD is popular in clinical settings because of its ease of use among health care providers.

Summary of PAINAD Tool Psychometrics in Studies

Reliability

Nine studies that examined the internal consistency of the PAINAD obtained Cronbach's alphas ranging from 0.57 to 0.85 (See Appendix E. Research Studies of PAINAD). The original study (2003) obtained a Cronbach's alpha range of 0.57-0.83 of elderly inpatient residents with advanced dementia, 19 of which were non-verbal. Joint reliability of the PAINAD was found to be 0.74 in a study of demented geriatric patients (N=20), 0.85 in a study of patients with Alzheimer's disease or other dementia types (N=99), and 0.71-0.85 in two studies with cognitively intact, non-verbal patients (N=124 and 100). Additional Cronbach's alpha ranges from 0.85 in a study of older hospitalized patients for surgical hip fracture repair (N=30), 0.90 in a study of patients seen in an Acute Geriatric Department (N=600), and 0.55-0.66 in a study of Chinese demented elderly patients (N=112). Intraclass correlation coefficients ranging from 0.80 to 0.98 were obtained from two studies of demented elderly (N=112) and older patients hospitalized for hip fractures (N=30). A kappa of 0.54 was obtained when two raters separately scored 16 residents with moderate to severe dementia. Kappa coefficients of 0.75 and 0.90 were also obtained from a sample of non-verbal patients (N=100) and cognitively impaired elderly from nursing homes (N=124), respectively. One study obtained test-retest reliability of the PAINAD in patients with dementia of 0.88 (Pearson's r) that employed test-retest intervals of 1 day (baseline) to 15 days (N= 20). An intra-class coefficient of 0.71 for test-retest reliability for elderly patients with dementia in China (N=112) employed a test-retest interval of two weeks. Therefore, the PAINAD has demonstrated moderate to good internal consistency and stability over short periods of time.

Validity

Performance on the PAINAD has been shown to correlate with a variety of other tests that measure self-reported pain, physical pain behaviors, and other pain scales for non-communicative patients. Scores on the PAINAD significantly correlated with proxy reports of pain from nurses, self-report of pain, and physiological indicators in patients with intact cognition; early, moderate, and late dementia; and elderly patients experiencing acute surgical pain. Six studies indicated concurrent validity of the PAINAD with the Numerical Rating Scale (NRS) (self-report or proxy), FLACC scale, Visual Analog Scale (VAS), and the Abbey Pain Scale. One study found that pain scores from self-report from patients (NRS) correlated significantly with the PAINAD (N=600, Kendall's τ= 0.73, $p<0.0001$). Another study of geriatric elderly patients showed concurrent validity with significant correlation with VAS (N=20, r= 0.65, p=0.045) and NRS (N=30, r= .92, $p<0.001$) of hospitalized hip fracture patients with cognitive impairment. One study showed correlation with nurse reported pain scores of patients and PAINAD with nursing home patients with dementia (N= 88, Kendal τ= 0.84) but in another study of moderate to severe dementia patients living in nursing homes was not significant (N= 125, r= 0.24, p= 0.066). Further, the same study (N=125) showed statistical differences between self-reported pain of patients from nurses' ratings (r= 0.31-0.68, p= 0.015 and <0.001, respectively). Two studies demonstrating convergent validity of nursing home residents with moderate to severe pain with movement (N= 124, Kendal τ= 0.54) and cognitively impaired elderly in Hong Kong with exercise (N= 124, Kendal τ= 0.90). Content validity of PAINAD with Critical-Care Pain Observation Tool (CPOT) of nonverbal adults in critical care was statistically significant (N= 100, r= 0.86, $p< 0.001$). Seven additional studies using PAINAD were not used to establish psychometric properties in a longitudinal study in London (N=230), with severely demented elderly patients in nursing homes in UK (N= 79), stroke

patients treated in a rehabilitation department (N= 106), patients with cognitive impairment in pain (N=80), demented elderly patients in Taiwan nursing homes (N= 112), patients with severe dementia living in nursing homes in UK (N= 79), and hospital in-patients with dementia (N=45). Two additional studies lacked validity metrics in a retrospective review of literature (N= 18 articles) and a case study of an Alzheimer's disease patient (N=1). Thus, the PAINAD has shown to have convergent and concurrent validity in measuring the concept of pain in patients with dementia using known sources of pain.

Description of the PACSLAC

The Pain Assessment Checklist for Seniors with Limited Ability to Communicate is a 60-item tool that is the most comprehensive of all tools assessing pain in non-verbal populations. Studies of this tool have established good internal consistency, inter-rater, and test-retest reliability. The tool is able to differentiate pain from non-pain states in varying samples with multiple neurocognitive impairments with existing painful conditions. This is the only tool that recognizes assessment guidelines established by the American Geriatric Society to cover all domains of neuro-cognition because of its comprehensive approach in clinical settings.

Summary of PACSLAC Tool Psychometrics in Studies

Reliability

Two studies that examined the internal consistency of the PACSLAC obtained Cronbach's alphas of 0.74 and 0.78 in elderly residents in a long-term care facility in Canada (N=124) and elderly demented Japanese patients (N=274) (See Appendix F. Research Studies of PACSLAC). Intra-class correlation coefficient for inter-rater agreement of 0.92 and 0.87 was obtained in the study of Japanese patients (N=274) and elderly residents with and without dementia living in a long-term center homes (N=338). An inter-rater agreement represented by Pearson's r between researcher and caregiver was obtained for facial expression= 0.59, abnormal

body movements= 0.72, social/personality/mood= 0.85, and others= 0.67 of demented patients living in dementia rest homes in New Zealand (N=50), total PACSLAC inter-rater correlation coefficient was 0.83. None of the studies contained test-retest statistical analysis. Despite the larger number of items in a checklist format which identifies the behavior is present or absent rather than using a Likert scale found in other pain tools, inter-rater reliability did not suffer.

Validity

Performance of the PACSLAC has been shown to correlate with painful events, physical pain behaviors, and self-reports of pain. Scores on the PACSLAC correlated with self-reports of pain with and without activity in patients with dementia (N= 338, ICC= 0.81, $p < 0.01$) and global intensity ratings of painful incidents in demented patients living in long-term care facility (N= 40, r= 0.39, $p< 0.001$) which demonstrates concurrent validity. Construct validity was determined in the study of demented patients (N= 338) that compared PACSLAC scores with the Pain Assessment in the Communicatively Impaired (PACI) before and after administration of pain medications ($t= 9.95$; df= 309, $p< 0.001$). PACSLAC scores correlated with the Abbey Pain Scale in elderly demented Japanese patients (N 274, $r_s= 0.45$, $p= 0.004$). However, in the study of demented Japanese patients (N= 274) weak correlations existed between the Gottfries-Brane-Steen body movement subscales with PACSLAC facial expressions subscale scores, which demonstrated discriminant validity between physical behaviors related to dementia or painful stimuli. Concurrent validity was shown in the study of dementia patients (N= 338) with scores correlating with verbal reports (NRS) (ICC= 0.81, $p< 0.01$). Convergent validity of the PACSLAC as determined by the study of demented patients living in long term care facilities in Canada (N= 124, r [98] = 0.89, $p<.01$), and discriminant validity of demented patients with depression was not statistically significant using the Cornell Scale for Depression in Dementia (CSDD). Two other studies did not have validity metrics of patients with dementia in New

Zealand (N= 50) and elderly residents with severe dementia living in a long-term care facility in Canada (N= 59). The PACSLAC has shown convergent, concurrent, and construct validity in measuring pain in patients who are unable to communicate pain using ambiguous pain sources based on medical history of pain-associated diseases. Validity of the PACSLAC can be enriched by using a known source of pain, such as a surgical intervention.

Summary

Both tools have demonstrated adequate psychometric properties for use in clinical and research settings. Psychometric analysis of these tools guided by Snow's conceptual model can be used to indicate components that influence observational assessment rater's results. The PACSLAC has moderate to high psychometrics and is a tool that encompasses Snow's conceptual model of sensory, emotional, behavioral, and cognitive domains that facilitate understanding of pain behaviors. This study was used to augment psychometrics of the PACSLAC in patients with severe cognitive impairment using a known pain source. Comparisons of the PACSLAC to the PAINAD will be helpful to analyze differences between patient results and characteristics of nurses that influence their decisions in detecting pain using the available tools and specific patient characteristics.

CHAPTER III

METHODOLOGY

Research Aims

The current study used a repeated measures single group design to examine two tools recommended for observational pain assessment in severe dementia (PACSLAC and PAINAD). The aims are as follows:

Aim #1: To determine inter-rater reliability of the PACSLAC and PAINAD in assessing pain behaviors in patients with severe cognitive impairment after hip fracture surgery.

H_1: Both the PACSLAC and PAINAD will demonstrate good (> .70) inter-rater reliability

Aim #2: To determine the consistency of the reliable changes between and within the two instruments.

$H_{0b:}$ There will be no discernable association between the reliable changes of each instrument

H_{1b}: The reliable changes calculated for both the PACSLAC and PAINAD will be consistent between and within each other.

Aim #3: To assess the preferences of nurses using both the PACSLAC and PAINAD on severely cognitively impaired patients with post-hip fracture surgery.

Research Design

A single-group, within-subject repeated measures design was implemented with each participant assessed at three time points in the first 72 hours following surgery for addressing these aims.

Description of Research Setting

St. Joseph Mercy Health System, one of three hospitals in the Trinity Health System, provided the setting for the study. This particular health care system provides orthopedic surgical services and regularly conducts surgeries on severely cognitively impaired older adults. In this facility, 7 South is an exclusively dedicated 40 bed orthopedic unit. In addition, 4 South is another medical surgical unit that admits orthopedic patient overflow when the primary unit is at full capacity. St. Joseph Mercy Hospital has adopted the PAINAD to assess pain in cognitively impaired patients.

Sample and Sampling Plan

The target population for this study was older (ages 60 and older) patients with diagnosed severe cognitive impairment experiencing pain post-surgically and the nurses who care for them during the post-surgical period. Older adults with severe dementia may not reliably self-report their pain placing them at great risk of suffering. Nurses typically observe behaviors to assess pain in people with severe dementia.

The sample size proposed for this study was 30 complete cases. The sample size of 30 cases proposed for this research was based on two primary factors. Sufficient numbers of scores to achieve stable estimates of inter-rater reliability were necessary. A sample of 30 with two observations per patient (primary rater, secondary rater) would achieve 80% power in order to detect an intra-class correlation (ICC) as small as 0.43 (alpha=0.05). This is much smaller than the hypothesized ICC for evidence of good inter-rater reliability in this study (> 0.70). Secondly, it was expected that there would be detectable changes in pain levels for both measures included in this study. Therefore, the sample needed to be of sufficient size to detect the amount of expected change in pain. A sample of 30 patients is generally considered sufficient to detect effects sizes in the range 0.50 for the change in pain scores. In terms of the PAINAD measure,

assuming that initial pain scores were around 5 (on the 0-10 scale) with an SD of 1, a decrease in mean pain level to 4.5 or less would be detectable with this sample. Reductions in pain at 24-72 hours post-surgery are expected to be considerably larger than this (Gille et al., 2006). To account for an expected attrition rate of 15 percent, 35 were consented into the study.

Inclusion/Exclusion Criteria

Convenience sampling was used to obtain participants meeting the inclusion and exclusion criteria below and to focus on one particular characteristic of interest which is severely cognitively impaired patients experiencing pain

Older adults who met the following criteria were recruited for the study: 1) at least 60 years of age or older; 2) severe cognitive impairment as evidence by documentation in the medical record; 3); unable to consistently verbalize needs; 4) sustained a hip fracture; 5) surgically treated in St. Joseph Mercy Hospital- Oakland ; 6) have legal guardian or next of kin available to provide informed consent; and 7) admitted to the orthopedic or surgical floor for post-operative nursing care. For criterion #2, if a current MMSE score was not documented in the medical record, the PI administered the instrument. MMSE scores of 10 or less are considered severe cognitive impairment while MMSE scores of 5 or less are considered very severe cognitive impairment (Tombaugh & McIntyre, 1992). The instrument was then used to describe the cognitive level of the sample studied.

Older adults were excluded using the following criteria: 1) patients who are able to reliably provide self-report, and/or express pain by other means (e.g., writing or pointing at a visual scale); 2) cognitive impairment related to injury or trauma (e.g., renders patient unable to feel pain); 3) cognitive impairment related to cerebral vascular accident (these injuries sustain static brain injury without diminished cognitive loss over time); and/or 4) prescribed seizure

medications (e.g., Phenytoin, etc.); 5) physical aggression/combativeness; 6) other reasons determined by investigative team to ensure study fidelity and subject safety).

Methods for Subject Recruitment

A Vanderbilt University Affiliation Agreement Form was completed electronically by St. Joseph Mercy Hospital- Oakland provided the PI electronic medical record privileges to examine medical records of eligible patients. The PI instructed the charge nurse to determine any potential patients that met inclusion criteria for recruitment during the weekends. During the weekdays, the orthopedic nurse practitioner notified the PI when a potential participant was admitted for surgical repair of a hip fracture. The PI verified medical records to confirm diagnosis of severe dementia and consulted with the patient's legal guardian or next of kin to explain the study and obtain legal surrogate consent for study participation and subject assent when possible. A recruitment log using de-identified data was used to document the surgical case, signed consent form, day and time of surgery, facility name, location of fracture, and dementia diagnoses, and eligible participants who screened out of the study because of extenuating circumstances, e.g. no next of kin or legal guardian for consent.

Strategies to Ensure Human Subjects Protection

Procedures for this study were reviewed by the Human Subjects Review Committee of Vanderbilt University and the Institutional Review Board of St. Joseph Mercy Hospital-Oakland. Confidentiality of all respondents was maintained by using a number coding system on the questionnaires. Computer systems to link the number to the respondent were password protected and only available to the principal investigator (PI). All original files were secured in a locked file cabinet. Subjects had the right to discontinue participation at any point during the study. Because the nature of this research was observational, risk to the subjects was low.

Instruments

The current study employed two observational pain measures. At the conclusion of the patient data collection portion of the study, nurses were asked to identify the measure that they preferred to use in assessing patients with cognitive impairment.

PACSLAC

The PACSLAC has been used with elderly patients in long term care facilities with mild to severe forms of dementia or cognitive impairment with limited ability to communicate who may be experiencing various forms of pain. The tool contains 60 items that incorporate four categories that are pain indicators: 1) facial expressions, 2) activity/body movements, 3) social/personality/mood/physiological indicators, and 4) sleep changes/vocal behaviors. Each of the items are scored using a dichotomous scale of "present" (1) or "absent" (0). The item scores are summed to arrive at a PACSLAC score ranging from 0 to 60. A score of 0 indicates no pain and higher scores reflect greater pain intensity.

PAINAD

The PAINAD is a 5-item behavioral observation instrument designed to assess pain in patients who are unable to self-report and incorporates three pain categories: facial expression, verbalizations/vocalizations, and body language. Each item is rated on a three-point scale from 0 to 2 for intensity. The individual item scores are summed to arrive at PAINAD scores ranging from 0 to 10, 0= no pain and 10= severe pain.

MMSE

The MMSE is a widely used exam to measure degree of cognitive impairment and takes approximately 5–10 minutes to administer (Folstein et al., 1975). The test is designed to be administered by any health care professional or trained technician who has received minimal instruction in its use. The MMSE is not commercially available, but the test items, instructions

for administration, and extensive normative data have been published (Crum et al. 1993; Folstein et al. 1975). Two studies that examined the internal consistency of the MMSE obtained Cronbach's alphas of 0.82 and 0.84 in elderly patients admitted to a medical service and elderly nursing home residents, respectively. The test-retest reliability of the MMSE in patients with dementia (usually of the Alzheimer's type) has ranged from 0.75 to 0.94 (Pearson r) in 10 studies that employed test-retest intervals of 1 day to 9 weeks. The MMSE demonstrated moderate to high validity by correlating with a variety of cognitive tests, specifically the Dementia Rating Scale (r=-.71 to -0.86), Clinical Dementia Rating Scale (r=0.78), the Brief Cognitive Rating Scale (r=-0.79), and Global Deterioration Scale (r=0.89-0.90) (Folstein et al., 1975). MMSE scores were used in this study to confirm cognitive impairment.

Demographic/Clinical Information

Patient demographic data collected in this study included gender, race, marital status, education, religion, and age. The following patient clinical information was collected: dementia diagnosis type (as confirmed by attending physician), and inpatient analgesic medication regimen including analgesia type, dose, and time of pain medications prior to mobilization. Opioid-related analgesics were subsequently converted to morphine equivalent standard dose. Treating surgeon records were used to monitor hip fracture repair post-surgical intervention and/or any surgical-related complications during the study time period (72 hours post-surgery).

Nurses were given informed consent to participate in the End of Study Nurse Survey. The survey obtained the nurses demographic data; such as gender, race, marital status, highest degree earned, and years of experience. The nurse survey included hours of continued education in pain management, confidence in assessing pain in non-verbal patients, confidence in managing analgesic decisions in treating pain, and which tool was preferred. An area in the survey included nurses written responses to the tools used.

Data Collection

Pre-Study Procedure and Training

Training of Nurses

The principal investigator (PI) scheduled sessions in the facility's designated unit to provide training to staff nurses on specific instructions on how to use both the PACSLAC and PAINAD tools. In each session, a 15- minute presentation was given to discuss the purpose of the study and the pain tools, 6 sessions total were needed to assure nurses understood how to use them. The PI provided a brief description of both the PACSLAC and PAINAD, with specific instructions on scoring, the ideal time and day to perform the assessment, and how the random, concurrent PI and nurse assessments of patient's pain would occur. Further reinforcement of teaching sessions was in the form of visual instructional aids provided to all the nurses in the unit detailing how to score the pain tools and ideal time points to assess the patient, and where forms were to be stored. The instructional aid contained the researcher's contact information for addressing potential questions or concerns as they arose.

Booster Teaching Sessions for Tool Use Fidelity

The PI provided booster teaching sessions on how to complete the pain assessment tools on a bi-weekly basis. The sessions lasted 10 minutes or less depending on the nurses available to attend the session, a few nurses attended with a couple of them attending twice. Time was set aside after each session to answer any questions by the nurses. The average completion time for both instruments is five minutes per patient; however, time may vary depending on the nurse's confidence in assessing pain with unfamiliar tools. Over time and with repeated use of these tools, nurses were expected to demonstrate increased confidence in using the tools and to do so in a shorter period of time. The PI provided additional sessions during nurse break times or when necessary to hold booster sessions, until such time as there are few or no questions regarding tool

use. The PI was available via cellular phone or email regarding any concern in using the pain tools or any other study related procedures or questions.

Patient Data Collection Procedures

Once consent had been obtained by the PI, a research packet with an ID number was placed in the patient's medical record. The ID number was specific to each patient consented and was used to de-identify the subject and track data for that specific patient. The research packet contained four PAINAD tools and four PACSLAC tools for use during the first 72 hours of the patient's post-operative admission. After surgery was complete, the patient was admitted to the surgical unit with the research packet attached to the medical record. The attached research packet signified to the previously trained assigned nurse that the patient was a research subject. The nurse documented the date and time of admission to the unit and that was used as a starting point for the first 24-hour scores of pain assessment.

Within the first 24 hours of admission, the assigned nurse provided patient pain medication before mobilization. Within 60 minutes of mobilization and after pain medication administration, the nurse completed the first set of pain tools. The first set of pain tools was dated and timed to indicate the first 24-hour assessment. The PACSLAC was completed first, followed by the PAINAD. After completing the pain tools, the nurse returned the tools to the research packet. At 48 hours post-operative admission, the assigned nurse followed the identical protocol of administering pain medication prior to mobilization. Within 60 minutes the nurse assessed the 48-hour pain assessment tools dated and timed to indicate the second set of time administration. The completed tools were returned to the research packet. At 72 hours post-operative hospital stay, the assigned nurse completed the third time set of pain tools. After administration of pain medication prior to mobilization, the assessment tools were administered within 60 minutes, returning completed tools in the research packet.

Inter-rater Reliability and Mini-Mental Status Exam Process

To provide data for inter-rater reliability, the PI completed the same tool sets simultaneously with the assigned nurse for one randomly selected assessment (1st= 24 hour; 2nd= 48 hour, or 3rd= 72 hour) per patient. Therefore, each participant packet noted the time point when the PI was to assess simultaneously with assigned nurse. Instructions were provided to the assigned nurse to notify PI regarding the time point for the concurrent pain assessment administration of both nurse and PI. The scores generated by the PI were recorded along with the date/time on the data collection form. (see Appendix A.).

To ensure study eligibility of severe cognitive impaired patients, the MMSE was obtained from either electronic medical record or physical medical record from nursing home transfer to hospital after proxy informed consent. If MMSE data was not present in either of these two formats, the PI would administer the MMSE tool to obtain level of cognition. A few patients did not have documentation of cognitive function; therefore, PI would meet the patient to administer the MMSE and determine study eligibility.

Chart Review for Demographic and Medication Data

The PI collected all demographic and clinical information from the patient's medical record (see Appendix B. Demographic Chart Review Form and Appendix A. Data Collection Checklist).

End of Study Nurse Survey and Incentives

Once data collection was completed, informed consent was provided to the nurses who used the PACSLAC and the PAINAD to complete the Staff Nurses Survey (see Appendix D) and obtain demographic information. The primary purpose of this survey was to assess preferences for, and issues related to the use of the measures. At the completion of the study, nurse participants received a check totaling the sum of each pair of assessments completed

($25.00/each pair of assessments) during the study period for compensation. In addition, the hospital unit in the study received a pizza luncheon.

Data Management

Each eligible and consented patient was de-identified and assigned a numerical ID by the PI. The consent form and corresponding master study participant table were the only locations in which any identifying information and the study ID number were linked. The study ID number was used on all study data collection forms. All completed paper data collection forms were securely stored in a locked filing cabinet in the PI's private, locked office. Data on the paper forms were entered into a Vanderbilt University REDCap (Research Electronic Data Capture) database by the PI. The REDCap system is a mature, secure web application for building and managing online surveys and databases. All data were double entered into REDCap databases and verified by the PI. For analyses, the data were exported from REDCap into SPSS and stored on PI's local password-protected computer drive.

Data Analysis

Data analysis was conducted using IBM SPSS Statistics software (version 25). In-depth descriptive evaluations of the raw data were conducted to assess patterns and extent of missing data, identification of outliers and other related data cleaning tasks. Data from the study measures, as well as the demographic and clinical characteristics of the sample, were summarized using mean and standard deviation for normally distributed interval or ratio scaled data. Otherwise medians and inter-quartile ranges were used. Frequency distributions (absolute frequency and percent) were used to summarize all nominal or ordinal scales. Tests of statistical significance used a maximum alpha of .05 ($p < .05$).

Analysis Related to Study Aims

Aim #1: To determine inter-rater reliability of the PACSLAC and PAINAD in assessing pain behaviors in patients with severe cognitive impairment after hip fracture surgery.

Intra-class correlations (ICC) with respective 95% confidence intervals were used to assess the correlation between the PACSLAC scores resulting from both the primary rater (nurse caretaker) and those of the secondary rater (PI). The identical approach was enacted for the PAINAD scores. It was expected that both ICCs would be > 0.70 (**H1.1)**. The internal consistency of the scores generated from the subset of patients evaluated by both the primary and secondary raters was estimated using Cronbach's coefficient alpha. It was expected that these coefficients would be essentially equivalent for both raters, and within ranges observed in previous research for PACSLAC (0.74 to 0.82), and in the higher end of the range observed for PAINAD (0.80-0.83).

Aim #2: To determine the consistency of the reliable changes between and within the two instruments.

Given that raw change values do not take into account the reliability of the self-report scores, reliable change indices (RCI) were generated for each of the study times of assessment and for each of the pain measures after surgery between instruments **(H2.1)** and within instruments (**H2.2)**, each of the original RCI (Jacobson, 1984) was amended (Christensen, 1986) as a measure of whether the change in an individual's score was significant (both statistically and clinically) after taking into account the reliability of the measure. An RCI value will be calculated for each participant for each self-report measure by subtracting the individual's baseline score from their respective post-intervention score then dividing by the standard error of the difference in the test. Calculation of the standard error of the difference for each measure will use the direct method (Jacobson & Truax, 1991). The observed reliability of each measure's

baseline scores was used to generate the respective standard error for the measure. Frequency distributions were used to summarize the proportion of participants demonstrating reliable change (decrease, no change, increase) for each measure between the study time periods (24-48 hours, 48-72 hours, and overall between 24-72-hours post-surgery). Tests of differences between the groups in those distributions were conducted using Chi-Square tests of independence. Post-hoc analyses of the associations of dementia severity (MMSE score) and opioids received (morphine equivalent dose) with reliable change in the pain measures were conducted also using Chi-Square tests of independence. Spearman rank correlations assessed the strength of the associations between MMSE and morphine equivalent dose at each study assessment point (24-, 48, 72-hours).

Aim #3: To assess the preferences of nurses using both the PACSLAC and PAINAD on severely cognitively impaired patients with post-hip fracture surgery.

Finally, frequency distributions were used to summarize nurses' responses to questions regarding their preferences for using the PACSLAC or PAINAD. Qualitative responses were compared to research studies examining both tools in similar clinical settings and patient characteristics.

CHAPTER IV

RESULTS

Participants

A sample of 30 participants was enrolled in the study. During the 24-hour observation period, one patient died, and a second patient was transferred to hospice, resulting in 28 observations. Between the 24- and 72-hour observation period, two patients were transferred to hospice, one was transferred to the ICU, and one was readmitted early to the nursing home. Thus, a resulting total of 24 patients completed data collection for the entire 72-hour observation period.

Demographic summaries of the 30 enrolled patient characteristics are given in Table 2. As severe dementia was an inclusion criterion, the median MMSE score was 3.5 (IQR=.0, 6.5) with 76.7% having an Alzheimer's dementia diagnosis. The average age of the participants was 86.6 years (SD=6.3). A majority were female (73.3%), approximately half were widowed (46.7%), and 66.7% had no more than a high school education.

Table 2
Patient Demographics

Demographic	N	Frequency	Percent
Age	30		
Dementia Diagnosis	30		
Alzheimer's		23	76.7
Vascular dementia		3	10.0
Mixed dementia		4	13.3
MMSE	30		
Gender	30		
Female		22	73.3
Male		8	26.7
Race/Ethnicity	30		
African-American/Black		1	3.3
Asian-American/Asian		1	3.3
White/Caucasian		26	86.7
Other (Hispanic)		2	6.7
Marital Status	30		
Single		3	10.0
Married		11	36.7
Divorced		2	6.7
Widowed		14	46.7
Religion	30		
Catholic		11	36.7
Jewish		1	3.3
Protestant		16	53.3
None		1	3.3
Unknown		1	3.3
Educational Attainment	30		
High School or Less		20	66.7
Post-secondary Education		10	33.4

Distribution of Pain Tool Scores over Time

Summaries of the raw scores for the PACSLAC and the PAINAD at each time of assessment are shown in Table 3. No statistically significant changes in scores were observed for the PAINAD ($p > .05$) however there was a statistically significant increase in the PACSLAC raw scores between 24-hours and 72-hours ($N=24$, $z = 3.24$, $p= .001$).

Table 3
Summaries of PACSLAC and PAINAD scores at each time of assessment

Time of Assessment	N	PACSLAC Median [IQR]	PAINAD Median [IQR]
24-Hr	30	6 [3, 11]	2 [.0, 4]
48-Hr	27	8 [2, 14]	1 [.0, 5]
72-Hr	24	9 [2, 13]	3 [.0, 4]

To visually illustrate the patterns of change for both measures in a side-by-side way, their scores were converted to a scale of 0-100. An illustration of those resulting distributions is given in Figure 2. There appears to be considerably less variation in the PACSLAC scores compared to that of the PAINAD scores at each time of assessment.

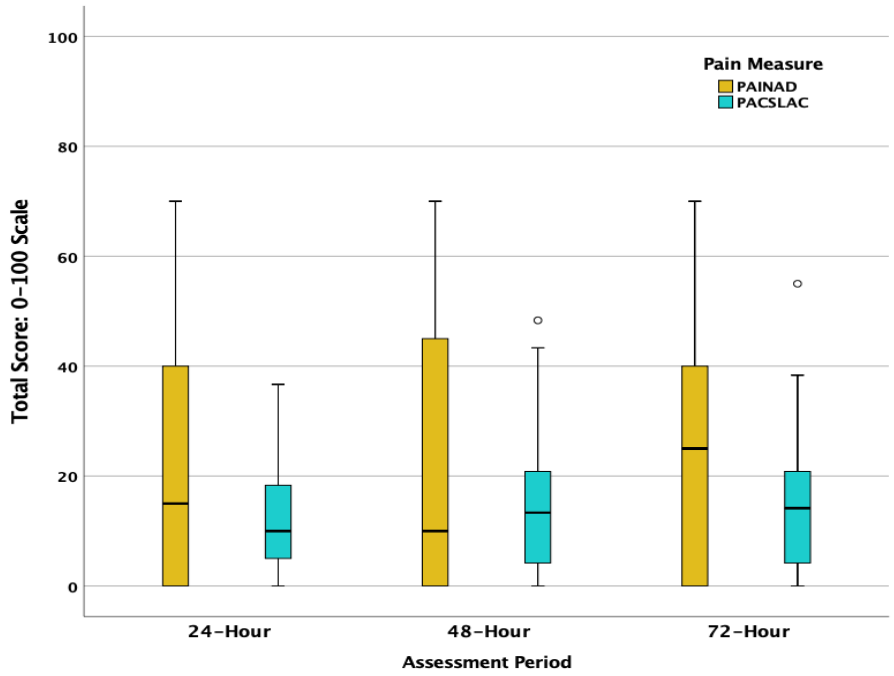

Figure 2. Distribution of Pain Scores Over Time

Aim 1: Interrater Reliability

Summaries of PACSLAC scores and interrater reliability values are displayed in Table 4. No statistically significant differences between the nurse and PI total or subscale scores were observed ($p > .05$). As shown, the median and IQR values for the nurse and PI were very similar

for both the total and subscale scores. The internal consistency of the item responses for the total PACSLAC scores was higher for the nurse than for the PI.

Table 4
PACSLAC Interrater Reliability (N=28)

PACSLAC Area	Nurse Median [IQR]	PI Median [IQR]	Intra Class Correlation	95% Confidence Interval	P-value
Total	5.5 [2, 10]	6.0 [4, 7]	.86	.70-.93	<.001
24-Hr			.91	.64-.98	
48-Hr			.86	.45-.96	
72-Hr			.87	.35-.97	
Facial Expression	1.0 [0, 3]	2.0 [1, 3]	.54	.01-.78	.023
24-Hr			.67	-.32- 91	
48-Hr			.56	-.77-.89	
72-Hr			-.08	-4.4-.78	
Activity	2.0 [.2, 4]	2.0 [1, 2]	.60	.15-.81	.009
24-Hr			.73	-.06-.93	
48-Hr			.57	-.73-.89	
72-Hr			.65	-.70-.93	
Mood	.00 [.0, 1]	1.0 [.0, 1]	.84	.66-.92	<.001
24-Hr			.95	.80-.98	
48-Hr			.93	.74-.98	
72-Hr			.80	.03-.96	
Other	1.0 [1, 3]	1.0 [1, 2]	.83	.64-.92	<001
24-Hr			.89	.56-.97	
48-Hr			.91	.66-.97	
72-Hr			.76	-.20-.95	
	Nurse	PI			
Cronbach's Alpha	.88	.77			

Summaries of the PAINAD scores and interrater reliability values are shown in Table 6. Consistent with the PACSLAC, the internal consistency of the item responses for the total PAINAD scores was higher for the nurse than for the PI (Cronbach's alpha 0.87 and 0.75 respectively.

The ICC value of the PAINAD scores for the two raters was highest at the 24-hour period with all but the ICC for consolability being above the 0.70 threshold. For the total score, the ICC was 0.91 at 24-hours (95% C.I. = 0.64-0.97). However, the ICCs dropped considerably for the subsequent observation periods with the ICCs for the 72-hour period ranging from 0.00 (breathing) to 0.67 (consolability). The pair of 72-hour total scores had an ICC of 0.42, see Table 5).

Table 5
PAINAD Interrater Reliability (N=28)

PAINAD Area	Nurse Median [IQR]	PI Median [IQR]	Intra Class Correlation	95% Confidence Interval	P-value
Total	.00 [0, 3]	2.0 [1, 3] *	.76	.48-.89	< .001
24-Hr			.91	.64-.97	
48-Hr			.73	-.86-.93	
72-Hr			.42	-1.8-.88	
Breathing	.00 [.0, .0]	.00 [.0, .7]	.40	-.28-.72	.092
24-Hr			1.0	1.0-1.0	
48-Hr			.26	-1.9-.81	
72-Hr			.00	-3.9-8.0	
Negative vocalization	.00 [.0, 1]	.00 [.0, .0] *	.73	.43-.87	<001
24-Hr			.94	.77-.98	
48-Hr			.57	-.72-.89	
72-Hr			.25	-2.7-.85	
Facial expression	.00 [.00, 1]	1.0 [.0, 1] *	.68	.32-.85	.002
24-Hr			.61	-.57-.90	
48-Hr			.80	.22-.95	
72-Hr			.61	-.92-.92	
Body Language	.00 [.0, 1]	1.0 [.0, 1] *	.54	.00-.78	.024
24-Hr			.76	.03-.94	
48-Hr			.58	-.66-.89	
72-Hr			.36	-2.1-.87	
Consolability	.00 [.0, .7]	.00 [.0, 1] *	.64	.22-.83	.005
24-Hr			.65	-.38-.91	
48-Hr			.68	-.28-.92	
72-Hr			.67	-.61-.93	

	Nurse	PI
Cronbach's Alpha	.87	.75

Aim 2: Reliable Change for the Two Measures

Reliable change values were used (instead of the raw change scores) for evaluating the usefulness of each measure for detecting change given that those values indicate change beyond random variability in scores. As shown in Table 6, a high percentage of the patients demonstrated no reliable change in either measure within either time of assessment and combined across the entire study. Using the PASLAC, 50% (12 of 24) demonstrated no reliable change in pain. While not statistically significant (p = .160), the respective value using the PAINAD was even higher at 67% (n=16 of 24). No statistically significant differences between the distributions of reliable change between the measures were observed for either of the interim assessment periods (p > .05, see Table 7).

Table 6
Summaries of Reliable Change Rates from 24 to 72 Hours Post-Surgery by Measure (N = 24)

	PACSLAC		PAINAD	
	N	%	N	%
Decrease	4	16.7	2	8.3
No Change	12	50.0	16	66.7
Increase	8	33.3	6	25.0

Note: Difference between the distributions χ^2 (2 df) =3.67, p=.160.

Table 7
Summaries of Reliable Change Rates from 24 to 48 and 48 to 72 Hours Post-Surgery by Measure

	24-48 (N=27)				48-72 (N=24)			
	PACSLAC		PAINAD		PACSLAC		PAINAD	
	N	%	N	%	N	%	N	%
Decrease	4	14.8	7	25.9	4	16.7	4	16.7
No Change	16	59.3	14	51.9	16	66.7	13	54.2
Increase	7	25.9	6	22.2	4	16.7	7	29.2

Note: Difference between the 24-48 distributions χ^2 (2 df) =2.64, p=.267; difference between the 48-72 distributions χ^2 (2 df) =2.81, p=.245

Summaries of the distributions of change in each measure were presented above, the second approach taken to evaluating the ability to detect change was patient-level agreement in

the indicators of reliable change between the measures. Agreement between the two measures of their reliable change values between the 24- and 72-hour assessments is summarized in Table 8. There was a statistically significant disagreement between the two measures (p = .001). Agreement was demonstrated for 74.9% (n= 18 of 24) of the values largely due to the large percentage of both sets of values reporting no reliable change (n=11 of 24, 45.8%). Within the set of PAINAD values indicating no reliable change (n=16), the PACSLAC measure indicated a reliable decrease in 2 cases (8.3%) and a reliable increase in pain in the other 3 (12.5%) (see Table 8).

Table 8
Summaries of the Agreement between the PACSLAC and PAINAD Reliable Change Categories between 24- and 72-Hours Post-Surgery (N=24)

		PAINAD		
		Decrease	No Change	Increase
PACSLAC	Decrease	2 (8.3)	2 (8.3)	0 (0.0)
	No Change	0 (0.0)	11 (45.8)	1 (4.2)
	Increase	0 (0.0)	3 (12.5)	5 (20.8)

Note: The extent of disagreement between the reliable change categories was statistically significant (χ^2 (4 df) =19.15, p = .001).

Agreement between the two measures of their reliable change values between the 24- and 48-hour assessments is summarized in Table 9. There was a statistically significant disagreement between the two measures (p = .001). Agreement was demonstrated for 70.3% (n= 19 of 27) of the values largely due to the large percentage of both sets of values reporting no reliable change (n=11 of 27, 40.7%). Within the set of PAINAD values indicating no reliable change (n=14), the PACSLAC measure indicated a reliable decrease in 0 cases (0.0%) and a reliable increase in pain in the other 3 (11.1%) (see Table 9).

Table 9
Summaries of the Agreement between the PACSLAC and PAINAD Reliable Change Categories between 24- and 48- Hours Post-Surgery (N=27)

		PAINAD		
		Decrease	No Change	Increase
PACSLAC	Decrease	4 (14.8)	0 (0.0)	0 (0.0)
	No Change	3 (11.1)	11 (40.7)	2 (7.4)
	Increase	0 (0.0)	3 (11.1)	4 (14.8)

Note: The extent of disagreement between the reliable change categories was statistically significant (χ^2 (4 df) =19.07, p = .001).

Agreement between the two measures of their reliable change values between the 48- and 72-hour assessments is summarized in Table 10. There was a statistically significant disagreement between the two measures (p <.001). Agreement was demonstrated for 79.2% (n= 19 of 24) of the values largely due to the large percentage of both sets of values reporting no reliable change (n=12 of 24, 50%). Within the set of PAINAD values indicating no reliable change (n=13), the PACSLAC measure indicated a reliable decrease in 0 cases (0.0%) and a reliable increase in pain in the other 1 (4.2%) (see Table 10).

Table 10
Summaries of the Agreement between the PACSLAC and PAINAD Reliable Change Categories between 48- and 72- Hours Post-Surgery (N=24)

		PAINAD		
		Decrease	No Change	Increase
PACSLAC	Decrease	4 (16.7)	0 (0.0)	0 (0.0)
	No Change	0 (0.0)	12 (50.0)	4 (16.7)
	Increase	0 (0.0)	1 (4.2)	3 (12.5)

Note: The extent of disagreement between the reliable change categories was statistically significant (χ^2 (4 df) =28.22, p <.001).

Post-Hoc Analyses of Variables Impacting Reliable Change

Although there were differences in reliable change between tools, the reduction in pain over the 72 hours was not observed. Of interest were patient variables that may have impacted the reliable change in pain during the study period. To address these possibilities post-hoc analysis of the associations of the severity of the patient's dementia (and therefore their level of

communication capability) and the amount of morphine the patient was receiving with reliable change in pain were explored. Of note, there was a tendency for those with higher MMSE scores to have received lower amounts of morphine. That association became statistically significant at 72-hours (24-hrs: r_s = -.07, p=.724; 48-hrs: r_s = -.33, p=.114; 72-hrs: r_s = -.42, p=.046).

Severity of dementia. While not statistically significant, a higher proportion of the patients with MMSE scores > 0 (n=13) had a reliable increase in both PACSLAC and PAINAD scores between 24-72 hours than did patients with an MMSE score of 0 (n=11). Six (46.2%) of the patients with the higher MMSE scores had a reliable increase on the PACSLAC compared to only 2 (18.2%) of those with a score of 0 (p=.240). A similar pattern was observed for the PAINAD scores. Five (38.5%) of the patients with the higher MMSE scores had a reliable increase on the PACSLAC compared to only 1 (9.1%) of those with a score of 0 (p=.240).

Morphine equivalents. During the initial 24-hour period of the study, 3 of the 29 patients for whom medication data were available (10.3%) did not receive any opioid or non-opioid pain medication; 18 (62.1%) received an opioid medication in the form of intravenous morphine or fentanyl, oral opioid doses were given in the form of acetaminophen 325 mg/codeine 30 mg. Of those receiving an opioid, the median morphine equivalent dose was 6.0 mg (IQR=5-10; min=4.5, max=20.0). At the 48-hour assessment period, 1 (4.0%) of the 25 patients with available data had not received any type of pain medication in the prior 24-hours. Eleven (44.0%) had received an opioid during that period and of those, the median morphine equivalent dose was 5.0 mg (IQR=5-10; min=3.0, max=12.5). Of the patients receiving some pain medication during the 24-48-hour assessment period, there was not statistically significant association between whether they received an opioid or not and reliable change in either the PAINAD or PACSLAC scores during that period (p = .676 and p = .979 respectively).

At the 48-hour assessment period, 1 (4.0%) of the 25 patients with available data had not received any type of pain medication in the prior 24-hours. Eleven (44.0%) had received an opioid during that period and of those, the median morphine equivalent dose was 5.0 mg (IQR=5-10; min=3.0, max=12.5). Of the patients receiving some pain medication during the 24-48-hour assessment period, there was not statistically significant association between whether they received an opioid or not and reliable change in either the PAINAD or PACSLAC scores during that period ($p = .676$ and $p = .979$ respectively).

All of the 23 patients with medication data available at 72-hours post-surgery had received some type of pain medication in the past 24-hours. Nine (39.1%) of those 23 patients had received an opioid; of those, the median morphine equivalent dose was 5.0 mg (IQR=4-7; min=3.6, max=9.0). The patients receiving an opioid were more likely to have had a reliable increase in both the PAINAD and PACSLAC scores during that 48-72-hour period. Four of the 9 receiving an opioid (44.4%) had a reliable increase in their PAINAD scores compared to 21.4% (n=3 of 14) of those receiving only non-opioid medications ($p = .003$). Two of the 9 patients receiving an opioid (22.2%) had a reliable increase in their PACSLAC scores compared to 14.3% (n=2 of 14) of those receiving only non-opioid medications ($p = .013$).

Aim 3: Nurse Survey

Summaries of nurse demographics are shown in Table 11. Twenty nurses participated in the study and 7 nurses declined to consent to complete the Staff Nurse Survey. Thirteen nurses consented and completed the survey (65% response rate). The median age of the nurses was 31 years (IQR 26, 43). A majority were female (92.3%), white (92.3%), and had a bachelor's degree (69.2%). Most were working in their normal unit (92.3%) and had a median 5 (IQR 2, 9) years of experience. The number of Pain CEU hours obtained in the past 5 years of these nurses were median of 4 hours (IQR 3.5, 8.5).

Table 11
Nurse Demographics (N=13)

Demographic	Median [IQR]	Frequency	Percent
Age	31 [26, 43]		
Years of Experience	5 [2, 9]		
Gender			
Female		12	92.3
Male		1	7.7
Race/Ethnicity			
White/Caucasian		12	92.3
Asian/Asian American		1	7.7
Normal Unit			
No		1	7.7
Yes		12	92.3
Highest Degree Earned			
Associate Degree/ Diploma/LPN		4	30.8
Bachelor's degree		9	69.2
Pain hour CEUs* past 5 years	4 [3.5, 8.5]		

*=Continuing Education Units

Summaries of the nurse's response to survey item "which tool was preferred in assessing pain with cognitive impairment" are displayed in Table 12. Forty-six percent of the nurses preferred the PACSLAC and 54% preferred PAINAD to assess patients with cognitive impairment.

Table 12
Pain Tool Preferred to Assess Patients with Cognitive Impairment (N=13)

Pain Tool	N	%
PACSLAC	6	46.2
PAINAD	7	53.8

As shown in Table 13, most of the nurses who completed the survey (n=13) were confident in their abilities to assess pain in patients with dementia. None of the nurses reported a lack of confidence in pain assessment. The majority of the nurses were confident in their

analgesic decision to treat pain. Of the 13 nurses responding, eighty-five percent (n=11) were moderate to high confidence in pain assessment and thirty one percent had little or no confidence in managing analgesia decision to treat pain of nonverbal patients.

Table 13
Confidence in Pain Assessment and Analgesia Decision (N=13)

Nurse Confidence	Pain Assessment Confidence (%)	Analgesia Decision (%)
Little to No Confidence	2 (15.4)	4 (30.8)
Moderate to High Confidence	11 (84.6)	9 (69.2)

Summaries of nurse's level of confidence in assessing pain of non-verbal patients and preferred pain assessment are given in Table 14. Nurses with moderate to high confidence showed similarly equal preference to either tool (PACSLAC 83% and PAINAD 86%). Despite level of confidence, either tool was similarly preferred.

Table 14
Instrument Preference by Pain Assessment Confidence (N=13)

	Pain Instrument Preference		
Nurse Confidence	PACSLAC freq. [%]	PAINAD freq. [%]	Total [%]
Little to No Confidence	1 [16.7]	1 [14.3]	2 [15.4]
Moderate to High Confidence	5 [83.3]	6 [85.8]	11 [84.7]
Total	6 [100]	7 [100]	13 [100]

Nurses' provided written comments of tool preference and why. Summaries of nurses written editorials are shown in Table 15. Thirteen nurses participated and 11 provided written responses of their preferred tool.

Table 15
Nurse Comments of Each Tool Preferred (N=13, 2 nurses did not comment)

PACSLAC	PAINAD
much more descriptive	easily accessible
That tool is more specific in these types of patients	Have more experience w/PAINAD
I was able to do a more accurate assessment on my patients.	smaller assessment
Not familiar with the other tool	easier to use
I liked the PACSLAC because I felt that it allows to be truly assess the patient objectively and in a more detailed accurate manner than the PAINAD	
More detailed assessment	
more effective	

In brief, the results of this study used were based on a small sample size for both patient and nurses. Inter-rater reliability measured by intra-class correlations were more stable with the PACSLAC throughout the time period of 24 to 72 hours compared to PAINAD. Reliable change is a novel statistical approach to compare both tools sensitivity to measure pain when mitigating measurement error. The PACSLAC showed stable pain scores within and between time periods compared to the PAINAD. There are no studies using this type of statistical analysis of reliable change index in observational pain research. The nurse survey results showed little variances in the tool preferences to assess pain in patients with severe cognitive impairment, response rate was high but the small sample (n=13) hampered sufficient analysis with tool preference.

CHAPTER V

DISCUSSION

Interpretation of results in this study was based on examining previous literature of these two pain tools. A plethora of systematic reviews and other methodological studies provided a foundation to understand how assessing pain in cognitively impaired patients can be elusive and enigmatic. Inter-rater reliability among nurses using these tools is key to determine clinical utility to measure pain observationally when self-report is not possible. Reliable change is a unique approach to establish which tool is able to detect changes in pain. The pain stimulus used was a surgical procedure stemming from a natural occurrence, a fall, resulting in a hip fracture in this sample of older patients. Using this statistical method to mitigate measurement error can provide support to which tool is better in assessing pain. Each of these tools have distinctive features that can contribute to nurse's preference.

AIM 1: Interrater Reliability

The overall results for aim 1 show that the inter-rater reliability total intra-class correlations (ICC) for the PACSLAC tool are higher than the PAINAD (.86 vs .76, $p<.001$, respectively). The PACSLAC ICC sub-scores of "Mood" and "Other" contributed to the greatest sum of the tool (ICC=.84 and .83, respectively). The lower ICC sub-scores for the PACSLAC was shown in "Facial expression" and "Activity". In the PAINAD, the ICC sub-scores for "Negative Vocalization" and "Facial Expression" were higher (ICC=.73 and .68) than the other sub-scores for "Breathing" and "Body Language" (ICC=.40 and .54). The PAINAD sub-score for "Consolability" contributed moderately to the PAINAD total sum (ICC=.64).

When both tools total ICC and sub-scores were examined over time, the PACSLAC total ICC stayed relatively consistent throughout the three time periods (24, 48, and 72 hours). However, the PAINAD showed a remarkable total ICC decrease over time, especially with the

72-hour period of .42. When examining the ICC sub-scores for each tool, the PACSLAC sub-scores were consistent throughout except for "Facial Expression" (ICC=-.08). At 72 hours the PAINAD showed low ICC sub-scores in "Breathing Independence" (ICC=.00), "Negative Vocalization" (ICC=.25), and "Body Language" (ICC=.36).

Cronbach's alpha for the PACSLAC and PAINAD in both nurse and PI were similar and scores demonstrate adequate internal consistency. Therefore, the inter-rater reliability ICC for PACSLAC remained consistent through time than the PAINAD despite both tools having similar internal consistency reliability metrics.

Fuchs-Lacelle and Hadjistavropolous (2004) found strong inter-rater reliability between two coders with the initial development of the PACSLAC (correlation of .94, $p<.01$), which was similar to this study between nurse and PI (ICC 0.86, 95% CI= 0.70-0.93, $p<.001$). Another study by Fuchs-Lacelle, Hadjistaropoulos and Lix (2008) presented similar results between nursing staff (ICC 0.97). Both studies examined demented seniors living in long-term care facilities experiencing painful conditions with nurses familiar with their pain reactions. Hip-fracture repair surgery was used in this study as a standard pain stimulus on older, severely demented adults admitted to an acute care setting where nurses have no prior history of these patient's pain reactions. Thus, the scores for the PACSLAC have shown consistent reliability in the assessment of pain in non-verbal patients experiencing chronic and acute pain stimuli when rated by nurses familiar and not familiar with patient pain behavior.

In contrast, PAINAD's inter-rater reliability was lower (ICC 0.76, CI .48-.89, $p< .001$) compared to the PACSLAC in this study. Previous PAINAD studies had moderately higher inter-rater reliability scores. DeWater et al. (2008) examined the inter-rater reliability of nurses using PAINAD showed moderately higher agreement between raters (ICC=0.98). However, the sample included mild, moderate, and severe dementia patients using a cut off MMSE score less

than 23. Nurses were able to assess behaviors in mild to moderate dementia patients and cognitively intact patients who were able to reliably report pain with observed behaviors, which could contribute to the higher inter-rater reliability metric. In this study, both the PACSLAC and PAINAD were administered to severely demented patients (median MMSE score 3.5 [IQR=.0, 6.5]) and were unable to reliably report pain. This may have contributed to the differences found in this study.

Taki et. al (2013) showed a moderately lower inter-rater reliability (ICC of 0.600) for the PACSLAC. While the PACSLAC was originally in English, the tool was translated to Japanese. Both written and spoken languages of different cultures can alter the meaning of behaviors observed. Various ethnic groups have different social norms to pain behaviors and may alter health care providers rating of pain. The PACSLAC is dependent on behaviors of older patients with limited ability to communicate carries the assumption that neurocognition responsible for such behaviors is intact. Another study conducted in Taiwan demonstrated moderately low inter-rater and test-retest reliability despite keeping the PACSLAC in English. In some cultures, displaying signs of physical or emotional pain is not socially acceptable. Thus, the PACSLAC or PAINAD may not distinguish pain in particular social environments. Translation of PACSLAC from English to other languages showed similar inter-rater reliability results. Culture is a factor that needs to be further examined when translating the PACSLAC in both written or spoken form from English, which could affect inter-rater reliability.

Kaasalainen et al (2013) used a convenience sample of residents with and without dementia and showed similar inter-rater agreement ICC of 0.87 ($p<.01$) in the PACSLAC. The study used nurses assessing pain before and after periods of activity. While there was no clear indication of cognitive measures used to indicate level of dementia, the ICC during activity was low (.76). The PAINAD had similar findings in dementia patients examined during care

activities with an ICC of 0.80-0.86 in a study conducted in Taiwan (Lin et al., 2011). In contrast, a study by Cheung and Choi (2008) showed a low inter-rater agreement between research and caregiver in the sub-score's scales for "Facial Expression" and "Other" but total ICC inter-rater agreement was high at 0.89. Unfortunately, there is a dearth of PAINAD studies that examined inter-rater reliability for comparison. The results suggest that the PAINAD was consistent in assessing pain in patients with various levels of cognitive function in dementia.

While the PACSLAC total ICC scores were consistent over time, ICC sub-scores for both "Facial Expression" and "Activity" at 72 hours were low. I addition, the PAINAD the ICC sub-scores for "Breathing Independence", "Negative Vocalization", and "Body Language" decreased remarkably at 72 hours. Several factors may contribute to this effect, such as, 1) both tools assess different dimensions of pain; 2) orthopedic nurses focus on the first 24 to 48 hours after hip-fracture surgery; 3) patients are mobilized more aggressively from 48 to 72 hours postoperatively; 4) patients with differing severity of neurocognitive impairment show diverse pain behaviors; and 5) the items of the tools themselves.

It is understood that pain consists of sensory, emotional, behavioral, and cognitive dimensions. The results suggest that the PACSLAC sub-scores for "Facial Expression" and "Activity" at 72 hours did not detect the emotional and behavioral pain dimensions. The PAINAD sub-scores for "Breathing Independence", "Negative Vocalization", and "Body Language" which are intended for measuring sensory and behavior scored low at 72 hours as well. The items on each of these tools can be the reason for differences in pain assessment scores over time. Therefore, some of the variance could be due to factors such as less well-defined measures (e.g., questions in an instrument that could be interpreted in different way's dependent on the use). The PACSLAC differences are more consistent across time periods which could be indicative of clearly defined items in the instrument which could also enhance reliability. As

such, difficulty in accurately assessing pain levels in those with compromised neurocognition remains an issue.

The ICC sub-score results over time supports Snow's conceptual framework on pain assessment of dementia patients as both rater and method factors intertwine to understand the observation and interpretation of external signs. For example, orthopedic nurses are trained to stringently assess pain in the first 24-48 hours post-hip fracture surgery but not so thoroughly thereafter, a possible factor in why ICC sub-scores were much lower at 72 hours for both pain tools. As well, patients with severe cognitive impairment may display pain differently contingent on what neurocognitive domain is compromised, resulting in less expected behaviors. While the cognitive dimension of pain is related to distinct verbal pain expression, this was not a factor in this study as both pain tools are observational in nature. With most nurses reliant on verbalized pain responses, facial expressions are often used to approximate verbalizations of pain.

Several pain tools were developed by examining facial expressions in pediatric patients in pain. Facial grimacing and crying are autonomic reflexes of pediatric brains communicating needs to the mother. During maturation to adulthood, socialization and cognitive awareness allows for verbalization of pain along with the autonomic reflexes of facial grimaces. While Prkachin's research and other pain studies elucidated facial expression as an ideal method to measure pain by studying pediatric patients (Prkachin, 2009), older patients with dementia have deteriorating neurological systems that compromise neurocognitive domains for autonomic reflexes to pain stimuli. While the results might suggest that vocalizations and facial expressions are ambiguous indicators of pain, the overall pain scores of these tools remain the best way to assess pain in severely demented, non-verbal, patients.

In conclusion, the evidence in this study suggests that the PACSLAC is a better tool for distinguishing pain behaviors in cognitively impaired patients who are non-verbal compared to the PAINAD. The PACSLAC tool contains 60 items that target all dimensions of pain. While the PAINAD was 5 items based on a Likert-type scale, definitions for each score remain arbitrary and indistinguishable to the behaviors being observed. The results may suggest the variances in PACSLAC are minimal because of its well-defined list of behaviors that target emotional, sensory, and behavioral dimensions of pain in this study. Furthermore, the PACSLAC contains 13 items for facial expression compared to 6 items separated into three ambiguous groupings in the PAINAD. Behaviors linked together in separate categories may overlap with other categories when using a Likert-type scale in the PAINAD that could lend to differences in rating facial expressions.

AIM 2: Reliable Change Index of Pain Tools

Given the extreme level of non-normality of the data, the initial analytical plan to study group differences in pain scores within and between the instruments was discarded and the decision made to use reliable change in pain scores – a novel approach not currently found in the literature. As such, there is little existing evidence to corroborate these findings.

There are no studies that investigate clinical use of PACSLAC and PAINAD using this statistical approach.

Reliable change index is a confirmed statistical method to eliminate measurement error and reduce noise in the resulting data. The data infers truth in observation and value, however any inferences on the basis of these results should be made with caution due to the small sample size in this study. Reliable change index is widely used in psychological/social study research, and its application can be valuable in observational pain tools in various patient populations and settings when randomized controlled trials are not feasible.

The results of the reliable change index of decrease, increase, and no change between PACSLAC and PAINAD across time periods of 24-72 hours show consistent agreement. However, separation into two distinct periods gave evidence of some differences, e.g. 24 to 48 and 48 to 72 hours. Differences were seen at 24-48 hours with the PAINAD detecting more patients with decrease in pain scores (n=7) than the PACSLAC (n=4). Similarly, from 48-72 hours the PAINAD detected more patients with increased pain scores (n=7) than PACSLAC (n=4). This pattern of change is not consistent with the expected reduction in pain over the first three postoperative days (Gille et al., 2006; Klopfenstein et al., 2000; Kornilov et al., 2016).

Despite the differences of the two-time distinctions, the percentage of agreement between instruments was relatively similar at 24 to 48 hours. The highest percentage of agreement was shown at 48-72 hours with no change in pain scores (50%). Observations within the PACSLAC between time periods were similar. However, PAINAD showed a difference in decrease pain scores at 48-72 hours (n=4) than 24 to 48 hours (n=7). Despite the minimal differences between time periods, between instruments, and within time periods of each instrument, the instruments showed proportional changes both within the instruments themselves and compared to each other.

Interestingly, studies investigating post-hip fracture surgical pain indicated a decreased trajectory within 72 hours (Gille et al., 2006; Klopfenstein et al., 2000; Kornilov et al., 2016). Hypothetically this study results should display a decline in pain scores for both instruments. While reliable changes in pain scores between the two instruments over time showed no significant change. The median raw score of each tool over 24-hour to 72-hour time period showed no changes for the PAINAD but a significant increase in the PACSLAC (N=24, $z = 3.24$, p= .001).

Two critical factors were taken into consideration: pain medication and level of dementia. Pain medications were converted to opioid equivalency dosages in order to determine if the amount of opioid had any effect on decrease, increase, and no changes in pain scores amongst the tools in a comparable fashion. Reliable changes between instruments showed no significant differences when observed from 24 to 72 hours overall when factoring opioid dosages. However, significant differences were seen in no change pain scores group with no opioids at 48 to 72 hours of both tools. Still, slightly increased opioid dosages were seen the PAINAD detecting increase pain scores than PACSLAC (17.4% vs. 8.7%). Results of reliable change between instruments and within when considering level of dementia measured with the MMSE showed similar results across time. Thus, it appears that the level of dementia beyond a certain degree does not affect the assessment of pain – but the medication dosage at a certain point may.

Aim 3: Preferable Tool Among Nurses in Study

The nurse survey results showed that a slight majority of the staff nurses preferred the PAINAD compared to PACSLAC. Nurses with moderate to high confidence levels favored the PAINAD over the PACSLAC. Despite nurse confidence levels, both tools were similarly preferred in the small sample of nurses. Nurses with high levels of confidence also demonstrated confidence in analgesic decisions with the use of PAINAD. Even though, median of 4 pain CEU hours were obtained in the past 5 years amongst the staff nurses surveyed, confidence levels of assessing pain in cognitively impaired patients after hip-fracture surgery repair were high.

Initial studies of nurses using the PACSLAC showed that a 60-item tool was lengthy and invests a certain amount of time away from other care obligations (Cheung & Choi, 2008; Ellis-Smith et al., 2016; Fry et al., 2017; van Nispen tot Pannerden et al., 2009). In contrast, early studies of nurses who used the PAINAD preferred it because of its brevity (Herr et al., 2006;

Herr et al., 2010; Warden et al., 2003; Zwakhalen et al., 2006). Nurses were able to comment on the PAINAD in the survey, which resonated with previous PAINAD studies.

Familiarity with the PAINAD was the most frequent comment made by the nurses. The institution uses the PAINAD as hospital standard for assessing pain in non-verbal patients, thus comfort with and preference for the PAINAD is understandable in tie sample.

Conversely, some of the nurses who had high confidence levels favored the PACSLAC because of its comprehensive item-list of observed pain behaviors. PACSLAC studies show that healthcare providers appreciate the wide-ranging nature of the tool when patients are non-verbal and unable to reliably express pain (Cheung & Choi, 2008; Ellis-Smith et al., 2016; Kaasalainen et al., 2013). Comments were parallel to earlier studies of the PACSLAC. The nurse comments highlighted the specificity, accuracy and objectivity of the PACSLAC.

On the other hand, a critical downside of the PACSLAC is the number of items, which takes a certain amount of time invested to complete (van Nispen tot Pannerden et al., 2009). Despite the small sample of nurses surveyed, no comments regarding its length or time needed were addressed. The survey had an open-ended comment area, however, no complaints of length of the PACSLAC were mentioned.

Analgesic administration confidence was moderate to high in this study. Some studies indicated that most health care providers are hesitant to medicate non-verbal cognitively impaired patients (Brecher & West, 2014; Gibson & Helme, 2001; Hadjistavropoulos et al., 2014; Orgeta et al., 2014). A major reason is the nurse's reliance on pain assessments that require self-report. When patients are unable to reliably report their pain, nurses are reluctant to solely base their analgesic decision on observational methods. Therefore, non-verbal cognitively impaired patients who are in pain are inadequately or undertreated. However, the survey results

suggested that nurses were confident in their analgesic decision because of their confidence in the pain tool being used.

The nurse's confidence in pain assessment; interpretation of pain behaviors; and analgesic decisions to treat pain highlight Snow's conceptual framework on pain assessment of dementia patients in that the rater is a significant factor in understanding the arbitrary interpretation of these observational pain tools. More so, the nurses experience in assessing pain in dementia patients, the type of orthopedic surgical intervention, and number of pain education hours all factor into the nurse's ability to rate pain with these assessments. The pain tools used in this population are only as good as the nurses who are able to use them adequately and using the best clinical decision possible to treat pain based on the information obtained.

In conclusion, both pain tools were similarly preferred in this small sample of nurses. However, the PAINAD had a slight advantage because of its brevity and familiarity of use among the nurses in this institution. The PACSLAC was exclusive to nurses who had moderate to high confidence and favored a tool that was able to capture a variety of behaviors that helped with their decision to address the patient's pain needs.

Direct and Indirect Study Benefits

There was no direct benefit to the patient. However, the data obtained in this study contributes to the science of pain assessment in nonverbal populations. The significant effect of addressing pain in cognitively impaired patients remains an elusive process in research, however, the study garnered information that may address gaps in understanding observed behaviors of pain, nurse's role in pain assessments, and the effect of establishing psychometric soundness of existing pain measures. Therefore, the results of this study added to the body of knowledge in pain and symptom management science.

There were noted indirect benefits for the patients and the health professionals during the course of the study. During the initial contact with caregivers and legal guardians, the PI explained that by enrolling their loved one in this study all parties are contributing to improving the science of pain assessment in dementia. Participation in this study may provide knowledge leading to future improved pain assessment strategies in people with dementia. The wealth of data provided by these patients could not be obtained without the willingness of the family member or legal caregiver to offer their consent to benefit humanity and offer a greater cause of helping other patients in pain who are unable to communicate. It is anticipated that nurses in the study gained a greater appreciation for pain assessment in the severely cognitively impaired patient experiencing pain. Further, data findings of the study were shared with St. Joseph Mercy Hospital IRB, which could enhance institutional policies to help health care providers manage pain in patients with severe cognitive impairment.

Credibility, Rigor, Validity of Design and Methods

While the best scenario is a dedicated research facility to conduct studies, pain research is difficult especially with cognitively impaired older patients. Because these patients are considered vulnerable and unable to provide informed consent, inducing a painful stimulus is unethical, thus PIs must use clinical conditions known to be painful that have occurred naturally. Using a pool of participants with a similar painful condition and then assessed using pain tools not reliant on self-report is best for this quasi-experimental observational design with no direct intervention.

An advantage of the repeated measures design is the ability to determine change (and thus reliable change) over time in the same subjects. Post-operative pain provided a standard pain stimulus that typically declines over the first 72 hours after surgery (Gille et al., 2006; Klopfenstein et al., 2000; Kornilov et al., 2016). Another advantage of this design was that it

required fewer participants and resources because participants were exposed to all conditions in the study. Further, both tools were employed on each participant experiencing pain stemming from a known painful source in order to examine the stated aims (interrater reliability and consistent reliable change).

A disadvantage of this design for addressing the particular aims of this study is that the nurses using the same tools repeatedly can be fatigued or burdened by the task and can affect results. The advantages of this design outweigh the disadvantages for the purpose of this study, therefore the single group repeated measures design was implemented.

Limitations of the Study

Low Statistical Power

Sample size was considered a foremost limitation factor. The inclusion and exclusion criteria lend itself to limiting the type of patients. Older cognitively impaired patients are considered vulnerable and obtaining informed consent by proxy, e.g. next of kin or guardian, was a challenge. While the sensitive nature of the study involved a surgical intervention on a natural occurring event, most of the family members and guardians were eager to sign the consent forms. The fact that there were only 30 patients despite intensive recruiting efforts and the plan to consent more patients into the study as well there was attrition of the study which results a sample of 24. The resulting data would be insufficient to power most statistical techniques. Thus, the sample size led to low statistical power.

Selection Threat

The major threat to internal validity of this study was the selection of participants (selection bias) in one hospital. St. Joseph Mercy Hospital- Oakland is located in an area that is predominantly Caucasian and this limits generalizability. While this study did not employ an intervention, securing an adequate sample size to meet statistical needs of older adult patients

with severe cognitive impairment and have hip fracture surgery proved be a challenging endeavor. The frequency of this specific patient sample occurring in hospital settings was difficult to predict. Further, a potential patient that met the inclusion criteria for the study was not always assented by either family member or legal guardian because surgery in these types of patients is high-risk, which likely influenced the family member or legal guardian surgical consent. Therefore, characteristics of the enrolled patients may differ from those of the target population. In addition, use of a single facility limits the generalizability of findings.

Instrumentation

Another threat to this study was the use of both instruments using three different time points posing an additional burden to the nursing staff. The additional burden of using both tools may have subjected the nurse to complete the assessments with laxity or lack of involvement in the study process that may have affected the results.

Another limitation was the PI's inability to be present at the hospital for each observation, in order to correlate results with the nurse on each scale. This limitation was answered in the study by randomizing the time periods where the PI would be present. A potential threat that was not controlled for was order effect, concerning the order the instruments were used. Following the lengthier PACSLAC with the more condensed PAINAD may have influenced the nurses' confidence in their PAINAD assessments. The final notable limitation is the small sample of nurses who participated in the survey thus resulting in an exploratory analysis.

Mortality/Attrition

Another probable threat to the study, considering the age of the patients and co-morbidities associated with dementia and hip fractures, is attrition. Additional patients were recruited to account for potential loss of participants as the study progressed towards completion.

While most participants who did not complete the study suffered from poor health/physical condition (referred to hospice, ICU) at least one returned to the nursing home sooner than expected. Thus, not all patients were lost because of poor health.

Dissemination of Study Findings

All information was disseminated to St. Joseph Mercy Hospital- Oakland to share results of both PACSLAC and PAINAD scores in assessing patients with severe cognitive impairment with hip fractures to staff nurses, nurse managers, and other interested parties. Potential publications for manuscript submission are Pain and Symptom Management and Journal of Pain Management Nursing.

Recommendations for Future Research

A broader and larger patient pool would be necessary to allow for more generalizability. Use of a known pain-producing event, such as hip surgery, is essential; however, including other surgical interventions to increase sample size and statistical power would improve generalizability. Randomizing the order in which the instruments are used to control for any potential order effects is recommended. This is important particularly wherein the more detailed instrument is followed by the more compact instrument.

Study designs implemented in controlled environmental conditions to induce experimental pain in patients with severe cognitive impairment is ideal to test observational assessment tools. Astute monitoring of physical behaviors before and after administration of opioid or non-opioid medications while inducing pain with observational assessments can enhance reliability and validity. Because of this vulnerable patient population, unable to provide informed consent, experimental designs of this nature are extremely difficult and unfeasible. Yet, the use of controlled experimental settings would mitigate factors not otherwise anticipated in clinical sites.

Nurses' medication administration decisions are tenuous in non-verbal cognitively impaired patients because of several identified factors. A major factor is that nurses predominantly believe pain is a subjective experience measured by self-report. Other factors are fear of over medicating, few observational pain tools suited for cognitively impaired patients, and ambiguity to determine behaviors indicative of pain. While these limiting factors may affect generalizability the idea that every nursing assessment completed on a variety of patient populations done in numerous hospitals or clinical settings is data in itself. Studies that can harness all the information through sheer numbers may develop an algorithm for both pain assessment and analgesic modalities. Aside from traditional research methodologies that attempt to control these factors, big data can be another approach to understand how nurses make decisions in pain management.

Another approach to pain assessments in these patients is the use of biomarkers. Despite the application of Magnetic Resonance Imaging (MRI) and Positron Emission Tomography scan (PET) to explain the brains processing of painful stimuli, this approach is expensive and not feasible in hospital settings. Perhaps investigating non-invasive biomarkers that correlate with the PACSLAC would be of value. Confirmation of a biomarker with a reliable and valid assessment tool can support health care providers confidence in pain assessment and analgesic decisions. The use of MRIs and PET scans are important diagnostic tools to further the science of pain but unwieldy to use in clinical settings and investigating non-invasive pain biomarkers are a distant future endeavor but requires advanced understanding of pain processing and behavioral observation. Meanwhile, the best cost-effective way is educating nursing students and staff nurses that pain is more than self-report.

In conclusion, the results of this study suggest that neither instrument produced the expected post-operative pain trajectory. Granted, both tools demonstrated similarly reliable

change in pain scores over time, it seems the PACSLAC showed better detection of pain because of the number of well-defined items and inter-rater reliability. Ideally, a study design that would incorporate reliable change index on the PACSLAC with other observational pain tools to ascertain the most optimal one in assessing pain is recommended. Furthermore, nurses make up the largest section of health care and the sheer number of assessments with various patient populations having differing cognitive impairments can be used in big data research. Despite having standardized analgesic modalities to treat pain established by national, local, and even among hospital agencies, pain in patients with severe cognitive impairment continue to be undertreated. Therefore, the nursing discipline has to be committed to educating and training nurses to use the PACSLAC because of its ability to incorporate all dimensions of pain.

A. DATA COLLECTION CHECKLIST

1. Eligible Patient identified ☐

2. Legal guardian or next of kin informed consent ☐

3. Documentation of dementia in medical record ☐

4. Documentation of MMSE score in medical record ☐

5. Demographic Form complete with information from medical record ☐

6. Orthopedic/surgical floor admission ☐

7. PACSLAC and PAINAD assessment within 60 minutes of mobilization:

Time point #1 (first 24 hours from admission to floor) ☐

Time point #2 (25-48 hours) ☐

Time point #3 (49- 72 hours) ☐

8. Fracture location: Right hip or left hip ☐

9. Randomized meeting with nurse assigned to patient for simultaneous assessment:

Date: _____ Time: _____ ☐

10. Pain medication name, dose, day, and time of administration of each time point:

#1. Name: _____Dose: _____Date: _____ Time: _____ ☐

#2. Name: _____Dose: _____Date: _____Time: _____ ☐

#3. Name: _____Dose: _____Date: _____Time: _____ ☐

11. Distribution of survey to nurses who have participated in study ☐

B. DEMOGRAPHIC COLLECTION FORM

ID Number: _____

Date: _____

Gender: 1. Male 2. Female

Date of Birth: _____/_____/_____

Ethnicity:

1. Native American

2. White or Caucasian

3. African American or Black

4. Asian or Asian American

5. Arabic

Marital Status:

1. Single

2. Married

3. Divorced

4. Separated

5. Widowed

MMSE Score: _____/30

Diagnosis of Dementia:

1. Alzheimer's

2. Vascular Dementia

3. Mixed Dementia

4. Other _____

Religion:

1. Catholic

2. Protestant

3. Jewish

4. Muslim

5. Other (describe): _____

Education:

1. Grammar school

2. High school diploma/GED

3. Associate of Arts Degree

4. Bachelor of Science/ Art Degree

5. Master's Degree

6. Doctorate Degree

7. Vocational/trade

8. Other (describe): _____

C. PATIENT PROCEDURE FLOW CHART

Task	Individual responsible for task
1. Identify eligible patient	Hospital staff nurse
2. Obtain consent from legal guardian or next of kin	Principal Investigator
3. Medical record review to confirm AD or dementia; record MMSE	Principal Investigator
4. Pain Assessment 1st 24 hours, within 60 minutes of mobilization	Hospital staff nurse/Principal Investigator
5. Pain Assessment 25-48 hours, within 60 minutes of mobilization	Hospital staff nurse/Principal Investigator
6. Pain Assessment 49-72 hours, within 60 minutes of mobilization	Hospital staff nurse/Principal Investigator
7. Medical record review to obtain analgesic medications	Principal Investigator
8. Staff Nurse Survey	Principal Investigator

D. STAFF NURSE SURVEY

Date:

Gender: (circle one) Male Female **Age:** _____

Years of Experience: _____ **Normal Unit:** (circle one) Yes No

Highest Degree Earned: (circle one)

1. Associate Degree/Diploma/LPN

2. Bachelor's degree

3. Master's degree

4. Graduate Degree

Ethnicity: (circle one)

1. Native American

2. White or Caucasian

3. African American or Black

4. Asian or Asian American

5. Arabic

How many hours of continued education in pain management in the past 5 years have you had?

How confident are you in assessing pain in patients who are non-verbal?

How confident are you in managing analgesic decisions in treating pain in nonverbal patients?

Which pain tool do you prefer to use in assessing patients with cognitive impairment: (circle one)?

1. PACSLAC (Pain Assessment Checklist for Seniors with Limited Ability to Communicate)

2. PAINAD (Pain Assessment in Advanced Dementia)

Briefly explain why you chose the tool you preferred:

E. RESEARCH STUDIES OF PAINAD

Source	Design	Sample	N	Validity	Pain Instruments
Leong, Chong, & Gibson, 2006	Descriptive	Demented nursing home residents	N=88	Concurrent Divergent	PAIN-AD, Self-reported pain scale (SRPS), Nurse-reported pain scale (NRPS)
Analysis	**Cognitive Instruments**	**Inter-rater agreement**	**Internal Validity Threats**	**External Validity Threats**	**Findings**
Bivariate correlational analysis using Kendall's tau statistic= used to determine concurrent and divergent validity. *One way between-group ANOVA*= determine if means scores for different severities of pain were stat. significant. *Post-hoc analysis using Tukey* used to determine where differences lay. *Paired T-test*= to measure differences in the mean	Cornell Scale for Depression in Dementia (CSDD) Abbreviated mental test (AMT)	None	Single group design, susceptible to single group threats. Small sample size Unable to confirm Alzheimer's disease or other dementia related types.	Specific to elderly patients with moderate to severe dementia.	NRPS and the PAIN-AD measure pain differently from the SRPS (Kendal tau= 0.842 vs. 0.304), +depression. PAIN-AD was different between the different severity levels of the NRPS ($P<0.001$) and the SRPS ($P<0.001$). Pain scores differed between the SRPS and NRPS, when residents were depressed, no difference when they were not

scores of the SRPS and the NRPS in the presence and absence of depression. *Wilcoxon rank-signs test* used to confirm significance of the relationships.		

Source	Design	Sample	N	Validity	Pain Instruments
Schuler et al, 2007	Cross-sectional	Eight nursing homes with residents having Alzheimer disease or other dementia types	N=99 Alzheimer disease=68%; other demented types=32%	Construct	PAIN-AD Verbal Descriptor Scale (VDS)

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Pearson correlations= used to determine interrater reliability and construct validity. *Cronbach's alpha*= used to verify internal consistency.	Mini-Mental Status Exam (MMSE) Global Deterioration Scale (GDS) Neuropsychiatric Inventory (NPI) Apathy Evaluation Scale (AES)	interrater stability amounted to r=0.80 and retest reliability to r=0.90	Repeated measures among nurses on same patient. Small sample Clinical pain differs variably. Selection bias-severe demented patients with assumed pain were tested	Small sample size of only severely demented patients-not generalizable to all non-communicative patients.	-Good internal consistency (Cronbach's α=0.85); Validity data of PAIN-AD scores were higher in residents assumed to have pain than those without. -Level of pain rating did not correspond with PAIN-AD scores. -↑ cognitive deterioration = ↑ ratings of pain behaviors. -Measures that indicate non-pain disorders did not correlate with PAIN-AD

Source	Design	Sample	N	Validity	Pain Instruments
Ersek, et al., 2010	Cross-sectional descriptive	14 nursing homes in Western Washington State	N=60 residents with moderate to severe pain	Construct Convergent Discriminant	PAIN-AD Proxy pain reports from CNAs Pain-related diagnoses Nonverbal Pain Indicators (CNPI)

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
<u>*Cronbach's alpha*</u>= internal consistency <u>*Cohen's Kappa*</u>= inter-rater reliability of the two research assistants. <u>*Intra-class correlations (ICC)*</u>= quantify reliability of the total score, represented the relative comparison of the between subject variation and between rater variation. <u>*Correlations*</u>= to determine construct validity of the scale with measures of the same construct using scales	Cognitive Performance Scale (CPS) Pittsburgh Agitation Scale (PAS) Checklist of	Inter-rater reliability for pain presence was fair (K=0.25 for CNPI with movement; K=0.31 for PAIN-ad at rest) to moderate (K=0.43 for CNPI at rest; K=0.54 for PAIN-AD with movement).	Testing threat- floor effects at rest. Small homogenous sample size Instrument threat- changes of observation from one time to another. History threat among research assistants conducting test. Only two raters for comparison No reexamination of reliability rating over time	Small sample Limited to patients with moderate to severe pain	Internal consistency for both tools was good except for the CNPI at rest. Significant differences in mean CNPI and PAIN-AD scores at rest and during movement, support for construct validity. Both tools (CNPI & PAIN-AD) demonstrated marked floor effects with participants at rest.

at are already recognized as the gold standard measures (criterion validity); associations between the scale and other instruments measuring similar (convergent validity) and different (discriminant validity) concepts; correlations between the measure across samples or conditions.

Paired t-test= used to compare scores during rest and movement (discriminant validity)

Spearman correlations= to evaluate convergent validity between each of the two tools and the Pittsburgh Agitation Scale

Source	Design	Sample	N	Validity	Pain Instruments
Zwakhalen, van der Steen, & Najim, 2012	Secondary analysis, retrospective review	1) Literature search of publications between 2003 and 2010. 2) Secondary data analysis of a multicenter study 3)New data collection for establishing a PAIN-AD cutoff score	N= 18 articles retrieved n= 75 (Verbal Rating Scale) n= 55 (VAS, <30) n= 19 (VAS, ≥30) n=19 (affirmatively in pain) n= 31 (denied being in pain) n= 5 (did not respond)	None	PAIN-AD DOLOPLUS-2 Visual Analog Scale

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
(Source 1) cumulative PAINAD scores (mostly means) were extracted and related to pain intensity categories by patient and proxy reports *Pearson correlation coefficients*= (Source 2 and 3) used to correlate PAINAD scores, self-reported pain scores, and nurses VAS scores. *Theoretical Linear*	Minimum Data Set-Cognitive Performance Scale	None	Small sample size in data collection for PAIN-AD cutoff score Experimenter bias- over and under estimation of pain behaviors Testing threat- two different tests used to explore pain behaviors No test-retest of tools	Limited homogenous sample and different settings.	1) 2 studies related PAIN-AD scores to patient self-reports, and/or nurses report. Self-report: mean PAIN-AD scores "no pain" was 1.0 (SD 1.4) vs. 1.4 (SD 3.7) for patients reporting pain. Nurses' proxy reports were more discriminative, mean of 0.1 for "no pain" and mean PAIN-AD scores of 1.9 and 4.4 for patients in pain.

transformation= used for comparing with established cutoff scores of 5 on the DOLOPLUS-2 using the following transformation formula (30-25)/30*10		2) Secondary data of the data of patients who were able to self-report pain using VRS showed that 52% (n=39) confirmed they were in pain. Mean PAIN-AD scores for "no pain" during an intramuscular injection were 0.6 and amounted to 1.7 "mild pain", 2.6 for "moderate pain," and 4.3 for "severe pain." Nurses VAS scores, mean PAIN-AD score was 0.8 was calculated in patients with a VAS score below 30 (n=55). A VAS score ≥ 30 resulted in a mean PAIN-AD score of 3.3 (n=19) 3) 47% (n=14) of the 30 selected patients reported pain. Mean PAIN-AD score of all four assessments

							was 1.5 (SD 1.1) for pain and 0.8 (SD 0.8) for not in pain (p=0.06). 1/3 to ½ of the patients with PAIN-AD scores 0, 1, and 2 were likely in pain. 4 patients with a mean PAIN-AD score of 3, patients were all in pain. Data support a cutoff point for pain lower than 3. Self-reports and proxy reports related to mean PAIN-AD scores derived from 3 sources, scores ≤ 1, represent no pain.

Source	Design	Sample	N	Validity	Pain Instruments
Lukas, Barber, Johson, & Gibson, 2013	Quasi-experimental	8 local nursing home residents with moderate and severe dementia	N=125	Construct Concurrent	PAIN-AD Abbey Pain Scale NOPPAIN Self-reported pain score (SRPS) Nurse reported pain score (NRPS)

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Receiver operating characteristic (ROC) curve-derived cut-off scores used to format three proxy rated instruments as dichotomous variables (yes/no) to enable *Crosstabs calculation* of univariate percentage agreement between self-report and proxy rating of the presence or absence of pain. *Spearman correlations*= to evaluate the association between each self-rated and proxy-rated	Cornell Scale for Depression in Dementia (CSDD) Abbreviated Mental Test (AMT) Mini-Mental Status Exam (MMSE)	None Correlations were used between self-report and observed behaviors of all three tools.	Experimenter bias- all research assistants were trained how to use the tools Single group only Confounding-relationship between psychological awareness of pain among trained research assistants	Suburban nursing homes for sample Videotaped behaviors	**Level of agreement regarding pain presence:** Correlation between self-ratings and proxy behavioral ratings of pain intensity: ranges 66.1% to 80%; impaired cognition group agreement with self-report (<0.001) **Correlations regarding pain intensity:** Self-report and proxy ratings of pain intensity: range from r=0.314 (p=0.015) to r=0.680 (p<0.001). PAIN-AD: r=0.241, p=0.066) NOPPAIN: 0.320, p=0.013 ABBEY: r=0.314, p=0.015

pain intensity.

Discriminant function analysis (DFA)= used to determine how accurate the entire multivariate collection of proxy ratings was compared with self-report

Source	Design	Sample	N	Validity	Pain Instruments
Mosele, Inelmen, Toffanello, Girardi, Coin, Serti, & Manzato, 2012	Prospective descriptive	Acute Geriatric Department	N=600 73.2% female Mean age 83.2±6.9 years	Concurrent	PAIN-AD Numerical Rating Scale (NRS)

Analysis	Cognitive Instruments	Inter-rater agreement	Internal Validity Threats	External Validity Threats	Findings
Shapiro-Wilk test= used to test continuous variables for normal distribution *Chi-square*= used to examine differences in categorical variables *ANOVA*= age-adjusted p values were calculated controlling the differences between of the covariates by cognitive status. *General Linear Models*= used to examine the independent association between	Mini-Mental Status Examination (MMSE) Cumulative Illness Rating Scale (CIRS)	Cohen-kappa= 0.76, $p<0.0001$ (comparing PAIN-AD with NRS)	Selection bias- more females, differences in cognitive decline among sample Maturation- changes in mental status during study from disease progression Experimenter bias- over estimation of pain among cognitively impaired patients.	Single institution of hospitalized patients.	-PAIN-AD internal reliability for demented: $\alpha=0.90$ -Non-demented: $\alpha=0.94$ -Concurrent validity: Kendall's $\tau=0.73$, $p<0.0001$ -Pain prevalence: NRS, cognitive (42.4%) vs non-cognitive (50.3%); PAIN-AD, cognitive (45.1%) vs non-cognitive (62.9%)

NRS classes and PAINAD scores.

Kendall Tau's statistic= used to test concurrent validity between the NRS and PAINAD scale, stratifying for cognitive function according to the MMSE score.

Kappa statistic= to determine inter-rater agreement between the NRS and PAINAD

Cronbach's alpha= used to determine internal consistency between the different PAINAD items.

Source	Design	Sample	N	Validity	Pain Instruments
Liu, Briggs, & Closs, 2010	Descriptive, observational	Cognitively intact and impaired elderly patients from 14 nursing homes in Hong Kong	N= 124, convenience sample.	Convergent Concurrent	Observation-based: PAIN-AD Abbey Pain Scale Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC) Discomfort Scale-Dementia of Alzheimer Type (DS-DAT) Self-report: Verbal Rating Scale (VRS) FLACC scale Proxy-pain: VRS FLACC scale

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Mann-Whitney U test= test differences between the cognitively intact and impaired groups according to age, CMMSE score, and years of educations. *Unpaired T-test*= determine differences between two groups in the length of	Mini-Mental State Examination (MMSE) Verbal Rating Scale comprehension scores	**PAIN-AD**, rest vs exercise: Total group: κ= 0.80 (rest) vs 0.90 (exercise) Intact Group: κ= 0.66(r) vs 0.81 (e) Impaired Group: κ= 0.87 (r) vs 0.90 (e)	Instrumentation-translation to Cantonese from English Regression to the mean: rest vs exercise induced pain	Purposive sampling Limited to cognitively and cognitively impaired Chinese elderly patients	PAIN-AD, rest vs. exercise: Internal consistency: Rest: Total group: α= 0.70 Intact: α= 0.71 Impaired: α= 0.73 Exercise: Total group: α= 0.72 Intact: α= 0.70

participants institutionalization. *Cronbach's alpha*= used to determine the internal consistency of the pain tools PAINAD and PACSLAC			Impaired: α= 0.73 Scores from Raters B/C: Internal consistency: Rest: Total group: α= 0.72 Intact: α= 0.72 Impaired: α= 0.70 Exercise: Total group: α= 0.72 Intact: α= 0.71 Impaired: α= 0.71 PAIN-AD appeared more reliable and valid for assessing OA pain in exercise program, regardless of cognitive ability.

Source	Design	Sample	N	Validity	Pain Instruments
DeWater, Faut-Callahan, McCann, Paice, Fogg, Hollinger-Smith, Sikorski, & Stanaitis, 2008	Descriptive-correlational	Older patients hospitalized for surgical hip fracture repair	N= 30 initially, 5 dropped out Total N= 25	Concurrent Discriminant Validity	PAIN-AD Self-report Numerical Rating Scale (NRS)

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Pearson's r= used to evaluate the association between PAINAD and NRS. *Wilcoxon signed ranks test*= to test discriminant validity comparing pain scores during periods of likely pain and unlikely pain., used because of paired data and pain scores are not normally distributed. *Interclass correlation* (ICC)= used to determine inter-rater reliability	Folstein Mini-Mental State Examination (MMSE) <23= cognitive impaired	Intraclass correlation between raters= 0.98	Attrition- 5 dropped from the study Selection- only patients with hip fracture repairs Instrument- no determination of level of cognition, no identification of type of impairment	Small sample of orthopedic elderly patients	Psychometrics: Internal consistency: α= 0.846 (intact) vs α= 0.847(impaired) Discriminant Validity: Total pain for both groups: (z= -4.086, p <.001, N=25) Impaired group: Z= -2.755, p= .006, n=12) Intact group: Z= -3.129, p= .005, n=13) Correlation: PAIN-AD and NRS All: 0.834, p=.01 Unlikely pain: .639, p=.01 Likely pain: .764, p=.01 Cognitive Intact: .735, p<.001 Cognitive Impaired: .915, p<.001

Cronbach's alpha= used to determine internal consistency

Source	Design	Sample	N	Validity	Pain Instruments
Hadjistavropoulos, Herr, Prkachin, Craig, Gibson, Lukas, & Smith, 2014	Systematic Review	Literature of observation-based pain tools	N=15 from a comprehensive list of 24 observation pain tools	Psychometric observational instrument comparisons	Abbey Pain Scale Checklist of Non-verbal Pain Indicators (CNPI) Certified Nursing Assistant Pain Assessment Tool (CPAT) DOLOPLUS-2 Discomfort Scale in Dementia of the Alzheimer's Type (DS-DAT/DS-DAT modified) EPCA-2 Mahoney Pain Scale Mobilization-Observation-Behavior-Intensity-Dementia (MOBID and MOBID-2) Pain Scale Non-Communicative Patient's Pain Assessment Instrument (NOPPAIN) Pain Assessment in the Communicatively Impaired (PACI) Pain Assessment Checklist for Seniors with Limited Ability to Communicative (PACLSAC and PACSLAC-II) Pain Assessment for the Dementing Elderly (PADE) Pain Assessment in Advanced Dementia (PAIN-AD) Pain Assessment in Noncommunicativ

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
					e Elderly Persons (PAINE) The Rotterdam Elderly Pain Observation Scale (REPOS)
Qualitative investigation of all pain tools current psychometric properties.	None	Important considerati on for selecting observation pain tools.			Five observation pain tools to consider which has acceptable to good internal reliability: 1) Abbey Pain Scale 2) DOLOPLUS 2 3) NOPPAIN 4) PAINAD 5) PACSLAC and the PACSLAC-II

Source	Design	Sample	N	Validity	Pain Instruments
Costardi, Rozzini, Costanzi, Ghianda, Franzoni, Padovani, & Trabucchi, 2007	Descriptive	Geriatric Evaluation and Rehabilitation Unit	N=20 80% female	Concurrent	PAIN-AD Visual Analogue Scale

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Pearson correlation coefficient= concurrent validity determined by comparing PAINAD and the VRS; inter-rater measures and test-retest (baseline and after 15 days) *Cronbach's alpha*= determined to assess internal consistency reliability among the items in PAINAD	Mini Mental State Examination (MMSE) Clinical Dementia Rating Scale (CDR)	Cohen-kappa (κ)= 0.87, p<0.001	Instrumentation-translated to Italian from English Selection bias-patients who can verbalize pain, understand self-report tools	Small sample size	Psychometrics: Test-retest reliability= 0.88, p=0.045 Concurrent Validity: PAINAD and VRS, 0.65, ;0.008 Cronbach's alpha (α)= 0.74

Source	Design	Sample	N	Validity	Pain Instruments
Herr, Bjoro, & Decker, 2006	State of the Science Review	Observation pain tools found in literature, initial search resulted in 14 tools	N=10 pain assessment tools met the critique guide of inclusion criteria.	Critique guide was developed on measurement theory with criteria and indicators in five areas: Conceptualization Subjects Administration Scoring Feasibility Reliability and Validity	Abbey Pain Scale Assessment of Discomfort in Dementia (ADD) Checklist of Nonverbal Pain Indicators (CNPI) Discomfort in Dementia of the Alzheimer's Type (DS-DAT) Doloplus-2 Face, Legs, Activity, Cry and Consolability (FLACC) Tool Noncommunicative Patient's Pain Assessment Instrument (NOPPAIN) Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC) Pain Assessment for the Dementing Elderly (PADE) Pain Assessment in Advanced Dementia (PAINAD)

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Pain tools evaluated according to criteria and indicators in five areas: conceptualization, subjects, administration, reliability, and validity.	Mini Mental State Examination with varying cut-off points indicating cognitive impairment.	Pain tools resulted in good inter-rater agreement	Instrumentation-selection of tools based on literature of pain behaviors	Differing sample populations among studies	The Abbey The ADD The CNPI The DS-DAT The Doloplus-2 The FLACC The NOPPAIN The Pain Assessment Checklist for

No standardized tool based on nonverbal behavioral pain indicators in English that may be recommended for broad adoption in clinical practice			Seniors with Dementia PADE The PAINAD scale All observation pain tools demonstrated adequate reliability and validity. Concurrent validity was evaluated with self-report pain tools.

Source	Design	Sample	N	Validity	Pain Instruments
Warden, Hurley, & Volicer, 2003	Instrument Development	Inpatient dementia special care unit in a Veterans Administration Medical Center	N=19 Advanced dementia, aphasic,	Construct Validity: determined using contrasted groups and hypothesis testing methods.	PAINAD Visual Analog Scale (VAS) Discomfort Scale for Dementia of the Alzheimer's Type (DS-DAT)

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Cronbach's alpha= used to measure internal consistency *Factor analysis with varimax rotation* performed to examine score variance. *ANOVA*= to examine PAINAD scores within participants exposed to three different conditions. *Paired T-test*= used to compare PAINAD scores before and after PRN medication.	Mini Mental State Exam (MMSE) Bedford Alzheimer Nursing Severity Subscale (BANS-S)	Achieved between dyads of the principal investigator with each clinical research rather and between two raters. No cohen-kappa documented.	Instrumentation: frequent observations History-previous knowledge of patient conditions from research assistants	Small sample size of men only, all white, elderly, middle class veterans	Psychometrics: Cronbach's α= 0.57-.83 Pre-pain meds α= .30 Post-pain meds α= .80

Source	Design	Sample	N	Validity	Pain Instruments
Carezzato, Valera, Vale, & Hortense, 2014	Literature Review	1501 relevant articles from CINAHL, Cochrane, Embase, LILACS, PsychINFO, PubMed	N=33 articles, identification of 12 instruments	Construct Criteria Content Concurrent Convergent	Abbey Pain Scale ADD CNPI CPAT DoloPlus-2 MOBID/MOBID 2 MPS NOPPAIN PACSLAC PADE PAIN-AD PAINE

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Qualitative investigation of observational pain tools translated in Portuguese. Selection of tools based on the following constraining questions: 1) What instruments are available in the literature assess pain in persons with severe dementia? 2) Which of these instruments assessing pain in persons with severe dementia are validated for	None	All tools with confirmed psychometric tests.	Language translated to English from Portuguese	Tools investigated have small sample sizes, limited to specific population samples of demented patients, surgical procedures, and different pain stimulus.	Doloplus-2 and PAINAD were validated in Portuguese for use in severe demented patients in Brazil.

the Portuguese language?

Source	Design	Sample	N	Validity	Pain Instruments
Pei-Chao Lin, Li-Chan Lin, Shyu, & Hua, 2011	Cross-sectional	Two nursing homes in northern Taiwan	N= 112 Demented elderly	None	PAIN-AD (Chinese version)
Analysis	**Cognitive Instruments**	**Inter-rater Agreement**	**Internal Validity Threats**	**External Validity Threats**	**Findings**
Chi-square= used to compare for differences in characteristics. *One-way ANOVA*= used to analyze for differences in level of pain among groups by severity of dementia and type of activities. *Univariate logistic regression model*= used to find significant variables *Multivariable logistic regression*= used to find the significant predictors of pain in dementia	Clinical Dementia Rating Scale (Chinese version)	Intra-class coefficient, 0.80-0.86	Instrumentation-Chinese translated. Conducted during activity and at rest, no documentation of pain meds administered prior to observation	Chinese demented elderly patients only. Small sample size	Test-retest reliability: intra-class coefficient 0.71 Cronbach's alpha: ranges 0.55-0.66 36.6% scored above two points of the mean score 1.50 Correlation between pain level and dementia severity Group 1: CDR<3= 2.14 (±1.96) Group 2: CDR=3= 1.75 (±1.82) Group 3: CDR>3= 0.31 (±0.81)

Source	Design	Sample	N	Validity	Pain Instruments
Herr, Bursch, Ersek, Miller, & Swafford, 2010	Retrospective literature critique	Literature review from PubMed, CINAHL, and PsycINFO	N=31 articles, 14 observation pain tools	Rated by experts using criteria critique: 1) Relevance of the tool in the nursing home population 2) Reliability 3) Validity 4) Utility 5) Fit with Minimum Data Set (MDS) 3.0 pain indicators 6) Fit with F-tag 7) Assessment 8) Plan, Implementation, and re-evaluation 9) Staff training: Top: **1) NOPPAIN** **2) PACSLAC** **3) PAINAD**	Abbey Pain Scale Checklist of Nonverbal Pain Indicators Certified Nurse Assistant Pain Assessment Tool Discomfort Behavior Scale Doloplus2 Elderly Pain Caring Assessment 2 Mobilization-Observation-Behavior-Intensity Dementia Pain Scale Nursing Assistant-Administered Instrument to Assess Pain in Demented Individuals Pain Assessment Scale for Seniors with Limited Ability to Communicate

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Qualitative investigation of pain tools that meet psychometric criteria for clinical use.	None	None	Instrumentation-insufficient evidence to label a pain behavior score as mild, moderate, or severe pain.	Limited number of studies of all populations, small sample sizes, low to moderate psychometric properties.	Best approach: use tools to identify the presence or absence of pain and to consider increases or decreases in score as indicators of

	Unclear how to weight and interpret pain behaviors, surrogate report, and other indicators.	change in level of pain for that individual. **Top 2 pain tools:** **PAIN-AD** **PACSLAC**

Source	Design	Sample	N	Validity	Pain Instruments
Sampson, White, Lord, Leurent, Vickerstaff, Scott, & Jones, 2015	Longitudinal cohort	2 large acute general hospitals in London, United Kingdom.	N=230		PAIN-AD FACES scale Self-reports of Pain
Analysis	**Cognitive Instruments**	**Inter-rater Agreement**	**Internal Validity Threats**	**External Validity Threats**	**Findings**
Generalized estimating equations= Used to compute prevalence over all assessments at admission *Confidence interval*= to determine prevalence of pain at admission (self-reported, or observed using PAINAD at rest and movement) *Chi-square*= determine association between demographics and clinical characteristics of the participants and the presence of pain	Cohen-Mansfield Agitating Inventory Behavioral Pathology in Alzheimer's Disease Scale Mini Mental State Examination (MMSE)	None	Reporting bias: family carers, researcher observations, medical and nursing notes. Confounding-residual delirium of demented patients.	Cohort design, not representative of general population	Prevalence/detection of pain: 55.2% could use the FACES scale 27% able to self-report pain PAIN-AD: 9.6% (rest), 43% (movement) Prevalence of agitation and other psychiatric symptoms: CMAI score 30.5 (IQR 29-35) of all study visits. 75% with psychiatric symptoms Association between pain, agitation, and psychiatric symptoms: No association between pain and agitation, measured by the CMAI. Significant association between total BEHAVE-AD score and pain at rest and movement

Source	Design	Sample	N	Validity	Pain Instruments
Smith, 2005	Literature Search	Articles from four databases: MEDLINE, CINAHL, PubMed, EMB	N=5 observational scales, 2 caregiver reports methods reviewed.	Construct (PAINAD): Chart audit data for 25 patients; Prior to medication: mean = 6.7±1.8; after medication: mean= 1.8±2.2	PAINAD PADE Comfort Checklist Observed Pain Behavior Scale DS-DAT CNPI

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Qualitative investigation of observational pain assessments for patients with severe dementia.	None	Described as "adequate" not reported	Various from different study designs investigating various observation pain tool. Instrumentation Research bias Selection bias Confounding	Small sample size Of elderly demented patients.	Psychometrics for PAINAD: Internal consistency of three different conditions: Observation 1: rated during rest or no activity, Cronbach α= .57 Observation 2: rated during pleasant activity, Cronbach α= .59,.63 Observation 3: rated during unpleasant activity, Cronbach α= .50, .67

Source	Design	Sample	N	Validity	Pain Instruments
Aprile, Briani, Pazzaglia, Cecchi, Negrini, & Padua, 2015	Cross-sectional	Inpatients/outpatients of rehabilitation departments	N=106 (subacute/chronic stroke patients)	None	Numerical Rating Scale (NRS) PAINAD DN4- used differentiate neuropathic vs nociceptive pain

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Spearman's Rank Coefficient= correlation between validated pain and quality of life measures. *Mann-Whitney U test*= comparison between two groups DN4<4 and DN4>4, patients with normal sensory vs hypoesthesia *Chi-square test*= compare dichotomous values (abnormality of presence/absence hypoesthesia in patients with/without pain)	None	None	Confounders with pain medications. Cross-sectional nature does not allow to confirm patients with more pain actually have a lower ability to reach their maximum functional potential	Restricted to stroke patients only.	33% with normal/cognitive language reported pain occurrence after stroke; 82% had NRS ≥3. 20% of patients assessed with PAINAD; 18% of them presented a score ≥3

Source	Design	Sample	N	Validity	Pain Instruments
Monroe & Mion, 2012	Case study used to support PAINAD	Case study of Alzheimer's patient	N=1	Several studies indicated accurate assessment tool for use in the adult patient population for whom self-report is not a reliable tool due to their altered cognitive ability	PAINAD

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
None	None	None	Single case study examining use of the PAINAD tool	Limited to one patient with severe Alzheimers	Suggested tool to be used in clinical use for assessing patients with Alzheimer's disease unable to self-report pain. Additional research needed.

Source	Design	Sample	N	Validity	Pain Instruments
Hoyland & Khan, 2013	Audit of a Cross-sectional study	Hospital inpatients with dementia	N= 45, aged between 77-92 years	None	PAINAD
Analysis	**Cognitive Instruments**	**Inter-rater Agreement**	**Internal Validity Threats**	**External Validity Threats**	**Findings**
None, qualitative examination for the use of PAINAD	Mini Mental Status Examination (MMSE)	none	Confounders-behaviors result of pain or another factor, such as distress or dementia related Instrumentation-no cut-off points for MMSE or PAINAD to determine pain intensity threshold	Limited to demented patients admitted to hospital settings.	13% scored more than 7/10, indicating fairly severe pain, with 2 patients scoring 9. 33% were found to have a PAINAD score greater than 4 and of these all 33% received pain intervention. PAINAD is a sensitive tool for detecting pain, it has a high false positive rate and frequently detects psychosocial distress as pain.

Source	Design	Sample	N	Validity	Pain Instruments
Jordan, Regnard, O'Brien, & Hughes, 2011	Cross-sectional	National Health Service continuing care unit for people with severe dementia and three private elderly mentally infirm nursing homes in UK	N= 79	None	PAINAD Disability Distress Assessment Tool

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Wilcoxon signed rank test= to examine changes in scores because data was not parametric. *Kruskal-Wallis test*= differences in mean scores between the three groups (pain group, false-positive group, and no-pain group)	Clinical Dementia Rating Score (CDR)	None reported	Instrumentation: no cutoff on PAINAD	Small sample size	PAINAD to have high sensitivity (92%) but low specificity (62%) for pain. Both tools are useful, however, pain tool also picks up distress, which is not caused by pain.

Source	Design	Sample	N	Validity	Pain Instruments
Hutchinson, Tucker, Kim, & Gilder, 2006	Prospective cohort	Patients with cognitive impairment, 2 case matched groups.	N= 80 n= 53 (control) n= 27 (PAINAD group)	None reported	PAINAD- intervention group Numerical Rating Scale (NRS)- used in control group Parenteral Morphine Equivalent (PME)

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Mann-Whitney U test= was used for comparison of each groups PME median. *Binomial proportions significance test*= was used to compare the rates of unknown pain intensity in each group.	Mini-Mental State Examination	None reported	Research bias Instrumentation- groups not matched by MMSE scores PAINAD score does not equate to NRS	Cognitively impaired patients undergoing hip surgery	Median PME was higher in the PAINAD group vs. control (PME= 11.25mg vs 5.75 mg; p<.01, 99% CI) Overall total score for unknown pain intensity was lower in the PAINAD group vs control group (P<.01, 99% CI PAINAD group lower rate of reported unknown pain intensity compared to control group (15% vs 68%)

Source	Design	Sample	N	Validity	Pain Instruments
Paulson-Conger, Leske, Maidl, Handson & Dziadulewicz, 2010	Descriptive, comparative, prospective	Convenience sample of critical care, nonverbal, adults' patients of varying medical diagnoses who required pain evaluation. Level 1 trauma, academic medical center	N=100	PAINAD: discriminate validity CPOT: content validity	PAINAD Critical-care Pain Observation Tool (CPOT)

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Cronbach alpha= internal consistency reliability for the PAINAD and CPOT *Correlation coefficient*= used to examine the relationship between PAINAD and CPOT scores *Bland-Altman analysis*= used to determine level of agreement between the two tools.	None used	CPOT: κ= 0.52-0.80 PAIN-AD: κ= .75-.97	Confounders-subjective indicators, multiple definitions of behaviors Instrumentation-insufficient psychometric properties, weak statistical analyses Research bias-over and under estimation of pain	Small sample size	Internal consistency: PAIN-AD= .80 CPOT= .76 Correlation between PAIN-AD and CPOT was 0.86 ($p<.001$) Limits of agreement indicated no difference of scores for assessing pain in nonverbal patients in critical care.

Source	Design	Sample	N	Validity	Pain Instruments
Jordan, Hughes, Pakresi, Hepburn & O'Brien, 2011	Cross-sectional, descriptive	One National Health Service (NHS) continuing care unit for people with severe dementia, and three private elderly mentally infirm (EMI) nursing homes in UK	N=79 Three groups: n=13 (P= pain) n=26 (FP=Non-pain, false positive) n=40 (NP=No pain)	None	PAIN-AD Dis-DAT

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Kolmonogorov-Smirnov test= used to assess normality of data. *Wilcoxon signed ranks test*= used because data was non-parametric *Kruskal-Wallis test*= used to compare differences between mean scores for each of the groups. *Mann-Whitney exact test*= used to distinguish contributing	Mini-Mental Status Examination	None	Confounding- false positive from behaviors not stemming from pain source. Research bias- overestimation of subjects having pain. Attrition- only n=13 in the pain group from original N=131. Interventions not controlled.	Small sample size Elderly patients in UK	Sensitivity= 92% Specificity= 61% NP group score ↓ than P and FP scores For intervention observation ($p<0.001$) P group scores > than FB group, no statistically significant ($p=0.066$) Significant different in PAINAD scores ($\chi^2=35.6$, $p<0.001$) between rest

variable, to account for significance set threshold a *Bonferroni method* was used.			(PAINAD mean=1.75), eating (1.78) and intervention (2.46)

F. RESEARCH STUDIES OF PACSLAC

Source	Design	Sample	N	Validity	Pain Instruments
Fuchs-Lacelle & Hadjistavropoulos, 2004	Mixed methods: 3 phases 1st phase: qualitative, focus groups 2nd phase: internal consistency checklist from phase 1. 3rd phase: validation of instrument	<u>Phase:</u> 1: **Caregivers-** primary caregivers (registered nurses, licensed practical nurses, and special care aids) **Patients-** Demented seniors (>65years) living in long-term care facility 2: **Caregivers-** registered nurses and registered psychiatric nurses who worked with older adults with cognitive impairments. **Patients-** elderly patients with dementia (mean age of 85years) 3: **Caregivers-** registered nurses and registered psychiatric nurses. **Patients-** elderly patients with dementia (mean age of 85years)	<u>Phase:</u> 1: N= 28 (caregivers) 2: N=40 (registered nurses and psychiatric nurses) N= 40 (elderly patients) 3: N= 40; n= 34 (registered nurses), n= 6 (registered psychiatric nurses) N= 40 (elderly patients)	Phase: 1: none 2: none 3: concurrent validity, correlations between global intensity (salience) ratings for each of the two painful incidents and the total PACSLAC scores for the same even were calculates. Correlations were r= .39, p< .05 for pain event 1 and r= .54, p< .001 for pain event 2.	Development of the PACSLAC

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
ANOVA= discriminate painful, calm, and distressing events *Correlations*= 1) Consistency across pain events 2) Concurrent validity of global intensity of two painful incidents and PACSLAC scores. 3) Effects of cognitive impairment between dementia severity and pain behaviors *Pearson chi-square*= To determine whether the frequency of three items differed significantly between the calm and each of the pain events.		Phase 1: degree of agreement between two coders determined by correlation between total number of instances that each coder endorsed each behavior on the list. **Correlation of .94 (p<.01)**	Researcher bias Confounders Instrumentation (large number of items)	Elderly patients living in long-term residential care facilities, nurses who have experience in caring for elderly patients and psychiatric nurses familiar with caring for cognitively impaired clients.	Phase 1: development of subscale items of PACSLAC 1) activity/body movement 2) facial expressions 3) vocal behaviors 4) aggressive behaviors 5) social/personality/ mood indicators 6) physiological indicators Inter-rater reliability (correlation= .94, p< .01) Phase 2: *Cronbach alpha* for each subscale **Facial expression, α= .80** **Activity/body movement, α= .84** **Social/personality/ Mood indicators, α=.82** Aggressive behavior, α=.49

						Physiological changes, α=.62 Vocal behaviors, α= .37 Eating and sleeping changes, α.31
						Phase 3: *Discriminate ability to assess painful, calm and distressing events* **ANOVA (F [3, 17} = 108.1, p< .001** Consistency across pain events: between pain event 1 and 2, correlation (r= .80, p< .001) *Effects of cognitive impairment*, **correlation results suggest patients with more severe cognitive impairments react more strongly**
					Cronbach's alpha= 1) Calculated for each subscale for both pain event 1 and pain event 2. 2) Subscales activity/body movement, facial expressions, physiological indicators/eating/sleeping changes/vocal behaviors, and social/personality/mood	

Source	Design	Sample	N	Validity	Pain Instruments
Fuchs-Lacelle, Hadjistaropoulos, & Lix, 2008	3-month comparative longitudinal design (2 groups randomly assigned to either: experimental or control)	Nursing staff regularly caring and assessing dementia patients' pain Patients with a diagnosis of dementia living in long-term care units.	Experimental (nurses) n= 32, Control (nurses) n= 29 Experimental (patients) n= 89, control (patients) n= 84	Strong ecological validity	Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC)

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
T-test= 1) differences between participants in experimental and control conditions *Linear regression*= 1) Pain assessment scores changes over time; covariates- age, sex, physical impairment, and cognitive impairment. Model contained fixed effect of time and a random intercept. 2) Activity log assessment scores changes over time	Present Functioning Questionnaire (PFQ): measure of cognitive and functional impairment	Cohens kappa= 0.61, degree of agreement= 0.97	Attrition/mortality of patients Attrition compliance of nurse's participation	Elderly patients living in long-term care facilities. Registered nurses working with demented clients in long-term care facilities.	PACSLAC pain scores changed over time among caregivers' assessments: statistically significant decrease at the rate of -.01 for each unit of time (β=-.01, P= .03) No discernible change in activity log scores over time (β= 0.00, P=.94) Level of cognitive impairment (β= .05, P< .001), physical condition (β= -.02, P= .97) and the group

					by time interaction (β= .01, P< .001) were statistically significant Average PACSLAC scores as obtained by independent observers did not decrease as a result of increased pain management for resident in the experimental condition

Source	Design	Sample	N	Validity	Pain Instruments
Van Nispen tot Pannerden, Candel, Zwakhalen, Hamers, Curfs, & Berger, 2009	Confirmatory analysis	Nursing home residents of 12 psycho-geriatric wards of 3 nursing homes Nursing personnel: registered nurses, enrolled nurses, and three levels of nurses' aides.	N= 128 elderly residents N= 5 registered nurses N= 7 enrolled nurses or nurses' aides	Concurrent Content Validity	PACSLAC PACSLAC-Dutch version Visual Analog Scale

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Item reduction with Classical test theory= Kaiser-Meyer-Olkin measure, Eigen values. *Confirmatory factor analysis*= Logistic regression model *Power analysis*= Sample size is relatively small (n= 128)	Minimum Data Set (MDS-CPS): standardized assessment tool for functional, medical, psychosocial, and cognitive status of nursing home residents.	none	Small sample size Instrument-translated to Dutch	Elderly residents living in long-term facilities in Australia	ROC analyses: reduced version of the PACSLAC checklist has a greater area under the curve than the original version of PACSLAC. Certain items of the scale are indicators of pain, other areas of the PACSLAC need further attention.

Source	Design	Sample	N	Validity	Pain Instruments
Kaasalainen, Akhtar-Danesh, Hadjistavropoulos, Zwakhalen, & Verreault, 2013	Observational study design	Convenience sample of residents with and without dementia from six long term center homes.	N= 338 residents	Concurrent Construct	1) PACSLAC 2) Numerical Rating Scale (NRS) 3) Present Pain Intensity (PPI) 4) Pain Assessment in the Communicatively Impaired (PACI)

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Interclass correlations (ICC)= to assess interrater reliability of total scores for the PACI and PACSLAC *Correlations*= Between PACI and PASCSLAC conducted with self-report tools (NRS and PPI) during both activity and rest measurement times *T-test*= construct validity examined between periods of activity and rest for each tool. *Chi-square*= Compare frequency of times used between each	none	PACSLAC, during periods of activity (ICC 0.87; p< .01) compared with the PACI (ICC 0.57; p< .01) and higher for the PACSLAC during activity than during rest (ICC 0.76; p< .01) PACI higher during rest (ICC 0.66; p< .01) than during activity	Researcher bias Confounders	Elderly residents living in long term care facilities	Concurrent: strong correlations between two verbal report tools: ICC 0.81; p< .01) during activity period and the lowest between the PPI verbal tool, and PACI observational tool during rest (ICC 0.55; p< .01). Construct validity for all tools except the PPI was supported. Paired t test, largest different was PACSLAC (t= 9.95; df= 309; p< .001) and the PACI (t= 9.29; df= 305; p< .001)

group of residents (those able to self-report pain vs. those unable to self-report pain)											

Source	Design	Sample	N	Validity	Pain Instruments
Taki, Yamamoto-Mitani, Suzuki, Furuta, Sato, & Fujimaki, 2013	Validation study for the Japanese version of the PACSLAC	Elderly demented patients in Japan	N= 274	Construct Convergent/discriminant	PACSLAC-Japanese version (PACSLAC-J) Original PACSLAC Abbey Pain Scale-Japanese version (APS-J)

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Mann-Whitney U test= used to compare PACSLAC-J scores of those who reported pain during movement and those who did not (construct validity) *Spearman rank correlation*= used to assess total and subscale scores of the BEHAVE-AD and PACSLAC-J (discrimin	BEHAVE-AD; measures exhibited behavioral disturbances of Alzheimer's disease patients. Gottfries, Brane-Steen Scale (GBSS-J) The Folstein Mini-Mental-State Examination (MMSE)	ICC 0.917 (two-way random absolute agreement)	Confounders Researcher Bias Instrumentation	Elderly demented patients in Japan.	Reliability: ICC 0.600 for test –retest reliability. **Cronbach's α**: 1) PACSLAC Total score= **0.782** 2) Facial expressions= **0.738** 3) Activity/body movement= **0.242** 4) Social/personality mood= **0.634** 5) "Other" subscales= **0.477** Validity: Comparison with and without pain during movement: PACSLAC-J total score correlated with APS-J

ant validity) *Multiple regression analysis*= used to examine associations between PACSLAC-J score and variables in the study. *Intra-class correlations*= used to determine inter-rater reliability and test-retest reliability. *Cronbach's alpha*= internal consistency *Spearman rank correlation*= used to calculate total score and subscale scores, suggest pain behaviors positive association with		total score (r_s= 0.45, p= 0.004) Spearman rank correlation: no correlation between PACSLAC-J scores and BEHAVE-AD subscale scores. Multiple regression analysis: total transfer assistance, psychiatric medication prescription, affective disturbance scores on the BEHAVE-AD, and sex were independently associated with PACSLAC-J scores. Association with cognitive level: Facial expression and activity/body movement showed weak relationships with scores for GBSS-J subscales. PACSLAC-J total score and facial expressions subscale

cognitive level, and used to calculate PACSLAC-J scores, GBSS-J scores, and MMSE scores.		scores were weakly associated with MMSE scores

Source	Design	Sample	N	Validity	Pain Instruments
Chan, Hadjistavropoulos, Williams, & Lints-Martindale, 2014	Validation study	Elderly residents in 4 long term care facilities in Canada receiving either a needle injection or movement-exacerbated pain	N= 124 elderly residents (n=85 needle injections and movement, n= 15 only needle injections, n= 24 only movement)	Discriminant/ convergent	Checklist of Nonverbal Pain Indicators (CNPI) Pain Assessment for the Dementing Elderly Scale (PADE) PAINADE Non-communicative Patient's Pain Assessment Instrument (NOPPAIN) PACSLAC PACSLAC-II

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Cronbach α= internal consistency (reliability) *Cohen κ*= interrater reliability *Correlations*= Convergent validity assessed between PACSLAC-II and other pain assessment tools Discriminant validity assessed between PACSLAC-11 and CSDD *Repeated measures ANOVA*=	Cornell Scale for Depression in Dementia (CSDD) Mini-Mental State Examination (MMSE)	Cohen K of PACSLAC-II= 0.63	Instrumentation Researcher bias (shorter, convenient tool favored by clinicians) Confounders (size of needle gauge, location of injection, movement not related to pain)	Elderly patients living in long term care facilities in Canada. Multiple treatment interference (same patient experienced needle injection and movement exacerbated pain) Clinicians aware of different pain scales used in clinical settings to assess pain.	Reliability: *influenza vaccine* **α= 0.77** *movement-exacerbated pain* **α= 0.74** Convergent validity: Strong correlation with all pain tools. PACSLAC-II=PACSLAC **(r [98] = .89, P<.01)** Discriminant validity: PACSLAC-II not significantly correlated with the CSDD

between baseline and pain states conducting 2 within-subjects analysis: 1) baseline versus swabbing versus vaccination. 2) baseline vs movement-exacerbated pain.

ANCOVA= with 4 repeated measures to determine whether PACSLAC-II can differentiate across both types of pain-related conditions (baseline vs swabbing vs vaccination vs movement-exacerbated pain)

Source	Design	Sample	N	Validity	Pain Instruments
Apinis, Tousignant, Arcand, & Tousignant-Laflamme, 2014	Observational design- to determine correlation between PACSLAC and PAIN-AD	Elderly residents in one facility in Canada with limited ability to communicate, diagnosed with advanced dementia and or severe cognitive deterioration. Convenience sampling	N= 59		PACSLAC PAIN-AD Interdisciplinary evaluation (IE)- subjective interpretation of pain behaviors by health care providers

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
<u>*Correlations*</u>= 1) Examine associations between PACSLAC and PAINAD. 2) Examine associations between PACSLAC and IE 3) examine associations between PAINAD and IE	Functional Autonomy Measurement System Interdisciplinary Evaluation (IE)- used as a gold standard in this study for evaluating pain in sample	None	Instrumentation- translated to Canadian French from English Attrition/Mortality Confounders	Elderly patients living in Canada Small sample size	Correlation between PACSLAC and PAINAD was high **r= 0.79 [95% CI: 0.67-0.87]** Low to moderate correlation with IE **r= 0.34 [95% CI: 0.09-0.48]** Weaker association with PAINAD and IE r= 0.25 [95% CI: -0.02-0.48] IE concluded that there was

		absence of pain behavior. Detected pain in sample: **PAINAD** **13.6%** **PACSLAC** **27.1%**

Source	Design	Sample	N	Validity	Pain Instruments
Van der Steen, et. al., 2015	Open, inductive and iterative method. **Content Analysis**	8 tools used to assess pain or discomfort	N= 4 pain tools N= 4 (dis)comfort tools	n/a	**Pain tools:** 1) Doloplus-2 2) PAINAD 3) PACSLAC 4) PAIC **Discomfort tools:** 1) DS-DAT 2) EOLD-CAD 3) QUALID 4) DisDAT

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Qualitative analysis: thematic and subsequent content analysis.	None	None	Researcher bias- small selection of tools used in clinical settings for both pain and discomfort	Limited number of pain and discomfort tools examined	Items from both pain and discomfort tools overlap. Inconsistent time uses of tools Various mix of present and past observations.

Source	Design	Sample	N	Validity	Pain Instruments
Cheung & Choi, 2008	Observational study	**Patients:** Residents of four specialist dementia rest homes in New Zealand Caregivers: Medical undergraduate research and caregiver following the caregiver attended to a patient's usual care routine.	N= 50 (patients) N= 10 (caregivers)	none	PACSLAC

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
ANOVA= determine differences in MMSE and PASCLAC scores between groups *Interrater reliability*= estimated with percentage of agreement between researcher and caregivers *Pearson correlations*= between PACSLAC total scores rated by the	Mini-mental Status Examination (MMSE)	**Pearson correlations** between total PACSLAC scores and the subscale scores rated by researcher and caregiver: **Facial expression= 0.59** **Abnormal body movements= 0.72** **Social/personality/mood= 0.85** **Others= 0.67**	Researcher bias Confounders Contamination	Limited to elderly residents living in New Zealand	Total PACSLAC scores ranged from 1-22 with a mean of 5.7 (SD=4.0). **Average percentage of agreement was 0.89.** Pearson correlation coefficient was **0.83 (p<.01) for the total PACSLAC scores** rated by researcher and caregivers.

caregivers
and the
researchers

Source	Design	Sample	N	Validity	Pain Instruments
Ellis-Smith, C., Evans, C., Bone, A., Henson, L., Dzingina, M., Kane, P., Higginson, I., and Daveson, B.	Systematic Review	N=12 (pain studies) N= 2 (oral health) N= 2 (multiple neuropsychiatric symptoms) N=8 (depression) N=2 (anxiety) N=4 (psychological wellbeing) N=2 (discomfort)	N= 40 studies evaluating 32 measures assessing pain	None	PACSLAC PAINAD CNPI PADE NOPPAIN Abbey Pain Scale Doloplus-2 Mahoney Pain Scale

Analysis	Cognitive Instruments	Inter-rater Agreement	Internal Validity Threats	External Validity Threats	Findings
Data extraction: study setting, sample and who the measure was administered by; measurement properties; and psychometric properties	None Examine studies with severe dementia	None	None	None	PACSLAC and PAINAD had the strongest psychometric evidence. All measures require further investigation into agreement, responsiveness and interpretability. Multi-symptom measure to support comprehensive assessment and monitoring is required

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