RELATIONSHIPS AMONG PAIN, PAIN MEDICATION, AND PAIN OUTCOMES IN
OLDER ADULTS WITH ARTHRITIS

BY

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OF THE UNIVERSITY OF FLORIDA IN PARTIAL FULFILMENT
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To hope, love, and faith.

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Abstract of Dissertation Presented to the Graduate School
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Persistent pain is a common experience among older adults and is largely due to chronic

diseases, such as osteoarthritis. Pain is associated with many negative consequences, including

functional limitations. Despite research and clinical attention to this problem, evidence suggests

that pain management remains inadequate. Thus, the purpose of this longitudinal study was to

examine the extent to which the adequacy of prescribed pain medication influences the

relationship between the pain and pain outcomes (physical, social, and emotional functioning)

among older adults with arthritis over a 5-year time span. The study was conducted in a sample

of 1,409 community-dwelling older adults (male = 18.4%, female = 81.6%), with a mean age of

74 years. The study was a secondary analysis of data collected in the ACTIVE Study, a multi-

site, randomized clinical trial of cognitive training interventions. Data were analyzed from 3 time

points: baseline, 3 years later (time 2) and 5 years later (time 3). Measures included the OARS

checklist for demographic, health, and pain location variables; Medical Outcomes StudySF-36

surveys for bodily pain and pain outcomes (e.g., physical, social, and emotional functioning); the

Center for Epidemiological Studies-Depression (CES-D) scale; and the Pain Management Index

(PMI), a computed indicator for the adequacy of prescribed pain medication. Data were analyzed

using descriptive and bivariate statistics, as well as mixed effects modeling and longitudinal structural equation modeling. Results indicated the majority of participants experienced pain that interfered with their activities, were prescribed inadequate pain medications, had moderate functional limitations at each measurement and across time, and that increased pain interference was related to worse functioning.

In longitudinal models, limitations in social, physical, and emotional functioning were predicted by pain experience and this relationship was partially mediated by lower adequacy of prescribed pain medication at each time of measurement. However, relationships cross time showed that individuals improved in their functioning as the adequacy of their prescribed pain medications improved. These results highlight prevalence of pain interference as a significant problem in older adults with arthritis, and the importance of adequate pain medication in the management of adverse pain related outcomes.

CHAPTER 1
INTRODUCTION

Chronic or persistent pain (pain lasting more than 3 months) is a common experience among older adults (American Geriatric Society (AGS), 2002; Hall-Lord, Johansson, Schmidt, & Larsson, 2003; Higgins, Madjar, & Walton, 2004; Hutt, Pepper, Vojir, Fink, & Jones, 2006; Koltyn, 2002; Reid, 2003). Over 50% of older adults have a significant problem with persistent pain (Hall-Lord et al., 2003; Hutt et al., 2006; Won et al., 2004). The high prevalence of persistent pain in elderly adults is linked to equally high prevalence of chronic and co-morbid diseases in this population (AGS, 2002; Ferrell & Ferrell, 1990; Harden et al., 2005; Patel, 2003). Studies have shown that over 860% of adults over the age of 65 years have at least one chronic illness (CDC, 2003), and overall, more than 80% of older adults surveyed reported one to more than three chronic illnesses (Chan, Chong, Basilikas, Mathie, & Hung, 2002).

Joint disorders such as arthritis, are recognized as the most common cause of chronic or persistent joint pain among the elderly (AGS, 2002; Lawrence et al., 1998). Currently, 46 million Americans are diagnosed with Arthritis (CDC, 2006). Projection studies estimate that as many as 18.2% or 59.4 million will be diagnosed with arthritis by the year 2020 (Lawrence et al., 1998). By 2030, as many as 67 million persons (25% of American adults population) are expected to be diagnosed with arthritis, over 50% of them will be older than 65 years of age, and more than 37% (25 million) are projected to have activity limitation (CDC, 2006; Hootman & Helmick, 2006). These projections are consistent with Lawrence and colleagues' projection of 49% prevalence of arthritis among persons 65 years and older (1998). As the prevalence of arthritis increase, persistent pain as a public health problem is also expected to increase.

Persistent joint pain contributes to an array of adverse consequences that include adverse psychological symptoms such as depression and anxiety (AGS, 2002; Kurtze & Svebak, 2001; Leveille, Cohen-Mansfield, & Guranik, 2003); interference with physical and role functioning such as walking, gripping, and general and instrumental activities of daily living (ADLs and IADLs); and difficulty with usual tasks (Arthritis Foundation, 2006; Donald & Foy, 2004; Duong, Kerns, Towle, & Reid, 2005, 2005; Zarit, Griffiths, & Berg, 2004). Persistent joint pain interferes with performance of usual activities (activity limitation) in majority of older adults with arthritis (Arthritis Foundation, 2008; CDC, 2006). About 11.6 million Americans aged 65 years and older who are diagnosed with arthritis are projected to have activity limitations by the year 2020 (Lawrence et al., 1998). This an increase of 60% from Lawrence and colleagues' 1998 projected prevalence.

Presence or diagnosis of arthritis was also found to be associated with depressed moods in people with persistent pain. This association is attributable to the role of arthritis (attributable risk =18.1%) in creating functional limitations among the individuals affected (Donald & Foy, 2004; Dunlop, Lyons, Manheim, Song, & Chang, 2004; Duong, Kerns, Towle, & Reid, 2005). According to several sources reviewed, persistent joint pain is associated with limitation in physical and social functioning (AGS, 2002; Donald & Foy, 2004; Duong et al., 2005; Jinks, Jordan, & Croft, 2007). These relationships were validated in studies where greater arthritis-related pain was correlated with poorer physical and lower social functioning (Bookwala, Harralson, & Parmalee, 2003), and occurrence of new joint pain at 1 year (Donald & Foy, 2004) and 3 years (Jinks et al., 2007) follow-up periods produced more severe limitation in physical functioning.

Effective chronic pain management should result in reduction of adverse consequences across multiple dimensions, including physical, emotional, psychological, social, and spiritual (AGS, 2002; Kurtze & Svebak, 2001). Thus, pain management should include the use of both pharmacologic and nonpharmacologic strategies (AGS, 2002; Ferrell, 1995). Pharmacologic pain management, however, is the most commonly used approach among elderly adults (AGS, 2002). Often, the scope of pharmacologic pain management is expanded to include nonpain drugs such as anti-anxiety, antidepressants, muscle relaxants, anti-inflammatory agents, sedative, and anti-epileptics, to treat a variety of chronic symptoms or conditions associated with persistent pain (AGS, 2002; Harden et al., 2005; Leininger, 2002). However, analgesic medications (opioid and nonopioid) are prescribed most often to treat a variety of persistent joint pain among older adults (AGS, 2002; Clark, 2002; Jakobsson, Hallberg, & Westergren, 2004).

It is expected that when analgesic medications are used appropriately and in adequate amounts to treat persistent pain, individuals achieve better pain control (Furlan, Sandoval, Mailis-Gagnon, & Tunks, 2006; Hutt et al., 2006), inactivity is reduced (Allen et al., 2003), and there are better functional outcomes (Furlan et al.). On the other hand, inadequate pain treatment is associated with more adverse clinical outcomes such as unrelieved pain, depression, poor perception of health (Herrick et al., 2004; Won et al., 1999), and poor functional outcomes due to activity limitation (Herrick et al.; Mossey & Gallagher, 2004). Studies examining prescription/use of pain medication and pain experience among elderly with chronic pain have found a prevalence of inadequate prescription of pain medications (Hutt et al., 2006; Horgas & Tsai, 1998; Won et al., 2004). These studies accentuate the fact that under-treatment of pain is widespread among older adults (Berry & Dahl, 2000; Grant & Haverkamp, 1995; Horgas & Tsai;

Mzorek & Werner, 2001; Won et al., 2004), and highlights the need for more study on this important issue.

Background and Significance of the Problem

Persistent pain may be considered one of the most pervasive and expensive health care problems in the twenty-first century due to the high prevalence of adverse responses among individuals affected (Arnstein, Vidal, Wells-Federman, Morgan, & Caudill, 2002). Therefore, the goal of effective pain therapy is to prevent, control, or relieve adverse symptoms associated with persistent pain. However, evidence of high prevalence of persistent pain among older adults, poor treatment of pain, and prevalence of adverse outcomes, suggests that these goals have not been achieved. Clinical trials and longitudinal pain studies have thus focused on isolating specific contributing factors associated with non-achievement of pain management goals.

Studies have shown that pain management in older adults is inadequate (Berry & Dahl, 2000; Grant & Haverkamp, 1995; Horgas & Tsai, 1998; Mzorek & Werner, 2001; Won et al., 2004). Although older adults typically consume a large amount of medication, studies on pain management have shown that under-treatment of persistent pain is prevalent in this population (Mzorek & Werner; Rodriguez, 2001; Sofaer, 1984). Among the elderly, suboptimal prescription is a major contributing factor to inadequate use of pain medication (Hutt et al., 2006). This may occur if the healthcare provider fails to assess pain adequately (Gloth, 2000; Wagner, Goodwin, Campbell, French, & Shepherd, 1997), has difficulty choosing the right pain drug, fears the consequences of opioids or of polypharmacy complications such as drug side effects, interactions, and addiction (AGS, 2002; Green, Wheeler, LaPorte, Marchant, & Guerrero, 2002; Tarzan & Hoffman, 2004). Suboptimal prescription of analgesics may also results if inappropriate medication scheduling is prescribed for the type and nature of pain the patient presents (Hutt et al.), or if the prescriber lacks knowledge of standardized approaches to treating

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pain (AGS, 2002; Tarzan & Hoffman, 2004; World Health Organization [WHO], 1986). The clinical implication of suboptimal prescription of pain medications for older adults with persistent pain is poor management and negative functional and psychosocial outcomes. The extent to which suboptimal prescription of analgesic medications impacts pain outcomes in older adults over time warrants further investigation.

Several studies have reported on outcomes of pain experience among older adults (Ferrell & Ferrell, 1990; Gonzalez, Martelli, & Baker, 2000; Harden et al., 2005; Zarit et al., 2004). For example, depression is well documented as a correlate of persistent pain (Zarit et al.). Persistent pain negatively also impacts clinical outcomes such as self-perceived health, emotional status, and functional status (Mantyselka, Turunen, Ahonen, & Kumpusalo, 2003; Oster, Harding, Dukes, Edelsberg, & Cleary, 2005; Silkey et al., 2005). These studies support clinical evidence that pain related outcomes such as depression and functional limitations are prevalent among older adults with chronic pain (Won et al., 2004).

To date, most of the studies of the relationship between the inadequacy of pain management/medication and adverse pain outcomes have used cross-sectional research designs. These studies fail to explain the direct effects of analgesic medication on pain outcomes over time, because cross-sectional analysis limits the analytical ability of such studies to adequately inform and predict relationships between prescribed analgesic therapy and pain outcomes. According to Portney & Watkins (2000), validity of cross-sectional studies is threatened by the difficulty of estimating the effects of age or the passage of time on study results. Hence, longitudinal studies are needed to analyze documented growth or change over time, as empirical evidence of developmental change (Portney & Watkins).

Longitudinal studies of the relationships between pain, analgesic medications, and pain outcomes are few, the time intervals are different, and the concepts and variables investigated have varied. For example, in one cohort study of exercise training trials after hip surgery (Herrick et al., 2004), correlations of pain severity with pain medication use, depression, difficulty with activities of daily living, and measures of quality of life, among others, were measured at baseline as well as 1-year post-training intervention. In another study conducted over a period of 6 months, Mossey and Gallagher (2004) measured pain intensity, comorbid depression, and presence of activity limiting pain, as predictors of poor physical functioning. In other outcome studies, improvement in pain experience with analgesic treatment was assessed at various follow-up evaluation periods ranging from 7 days to 4 years (Doleys, Brown, & Ness, 2006; Jensen, Mendoza, Hanna, Chen, & Cleeland, 2004; Rosenthal, Silverfield, Wu, Jordan, & Kamin, 2004). Findings of these studies validate evidence of bivariate relationships between pain, treatment with analgesic medications, and stated pain outcomes. However, the paucity of published studies highlights the need for more systematic evaluation of the impact of pain and pain management on an individual's outcomes over time. Therefore, the proposed study will examine longitudinal relationships between pain and pain outcomes (such as functional limitations and emotional distress) among elderly with persistent arthritic pain, and the mediating role of prescribed analgesic medications in this relationship.

Rationale and Need for this Study

According to these reviews, pain experience, under-treatment of pain, and adverse pain outcomes are prevalent among older adults. Numerous empirical studies and scholarly publications have described the chronic pain experience of the elderly and associated outcomes as multidimensional and multi-factorial phenomena (AGS, 2002; Harden et al, 2005; Patel, 2003). Hence, effective management goals should be directed to understanding the complexity of

the experience of individuals with persistent pain, preventing severe consequences and disabilities, and improving their quality of life. Measured against these standards, numerous studies have examined the profile of pharmacologic pain regimens (quality and quantity) of older adults with chronic pain, to determine congruence between pain experience and (1) amount of prescribed pain medications or medication use (Fisher et al., 2002), (2) pain severity and relationships to pain outcomes (Hutt et al., 2006; Mantyselka et al., 2003; Mzorek & Werner, 2001; Won et al., 2004) or pain severity and interference, and (3) relationships to functional limitations (Donald & Foy, 2004; Duong et al., 2005). Results of these studies consistently support cross-sectional evidence of the inadequacy of pain management among the elderly, and prevalence of emotional distress (e.g., depression) and functional limitations (physical and social) among older adults with chronic pain.

In light of the above reviews, this study seeks empirical evidence to document the consequences of poor pain management over time. Hence, a longitudinal analysis was considered appropriate to examine the relationships between pain, pain management, and pain outcomes over time. Findings indicating that poor management of persistent pain worsened the impact of pain on severity of pain outcomes or vice versa, will validate ample cross-sectional evidence and expand limited longitudinal evidence of these relationships in the pain literature. Clinically, such findings will contribute to the basis for decision-making regarding prescription of analgesic medications for older adults with persistent pain. Health care providers will be able to utilize evidence-based support to formulate and implement treatment goals for the purpose of management and/or prevention of functional and emotional decline in older adults with persistent joint pain.

Theoretical Framework

The Model of Symptom Management (MSM; Dodd et al., 2001) provided the theoretical underpinning for this study (Figure 1-1). This theoretical model is comprised of three interrelated constructs: symptom experience, symptom management strategy, and outcomes. Symptom experience describes an individual's perception of symptom, evaluation of the meaning of a symptom, and response to a symptom. Symptoms are perceived when an individual notices a change from the usual pattern of feeling or behavior. Perceived symptoms are evaluated by making judgments about severity, cause, prognosis, and effects on their lives. An individual's response to symptoms perceived or evaluated may have physiological, psychological, sociocultural, and behavioral components, which are involved in a bi-directional relationship. Symptom experience is usually obtained through self-report.

Symptom management is a dynamic process, which involves the assessment of the symptom experience from an individual's perspective and the identification of intervention strategies. Symptom management strategies includes the specification of what (nature of strategy), when, where, why, how much (intervention dose), to whom (recipient of intervention), and how (route of delivery). The goal of symptom management is to relieve symptoms and avert or delay negative outcome through biomedical, professional, and self-care strategies.

Outcomes are expected results and consequences that emerge from symptom management strategies as well as from the symptom experience. The outcomes dimension focuses on eight interrelated factors, which also relate to the symptom status of the individual. These factors include functional status, emotional status, self-care, quality of life, morbidity and co-morbidity, mortality, and cost.

The Model of Symptom Management (MSM) has several important assumptions:

- The gold standard for the study of symptoms is based on the perception of the individual experiencing the symptom and his/her self-report.

- An individual does not have to experience any symptoms in order to apply the model; an intervention may be initiated if a risk factor is determined.

- All uncomfortable symptoms must be treated. Individuals' experiences of chronic pain are multidimensional and usually associated with multiple symptoms (AGS, 2002; Ferrell & Ferrell, 1990; Harden et al., 2005; Patel, 2003). Thus, pain medications (analgesics and adjuvant analgesics) are prescribed for the treatment/management of pain symptoms experienced by individuals (Dodd et al., 2001; Harden et al.).

- Management strategies may also be multidimensional and targeted not only individuals, but their families, groups, or work environments.

- Symptom management is dynamic process, modified by individual outcomes and the influences of the nursing domain of person, health/illness, or environment. Interference caused by pain experience is influenced by prescribed pain medications and ultimately affects severity of pain outcomes over time. Therefore, persistent or worsening pain experience and pain outcomes may implicate inadequate modification of pain medications.

A middle range theoretical model to guide the present study was derived from the Model of Symptom Management (Figure 1-2). A middle-range theory focuses on aspects of a complex human experience or reality (Polit & Hungler, 1995), considers a limited number of variables, and is more susceptible to empirical testing (Meleis, 1997). Thus, deriving a middle range theory for this study permitted selection of only the concepts, variables, and relationships specific to the study (Meleis; Polit & Hungler).

In the derived model, the three main constructs of the MSM and three corresponding concepts are included (Figure 1-3). The constructs are symptom experience, symptom management strategy, and outcomes. The corresponding concepts are pain experience, prescribed pharmacologic pain management, and clinical pain outcomes, respectively. Pain experience was indicated by report of pain that limits usual activity (severity of pain interference and number of pain locations). Prescribed pharmacologic management was indicated by participants' prescribed pain medication regimens (analgesic and adjuvant analgesic

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medications). Clinical pain outcomes associated with the experience of persistent pain were indicators of the concept of functional status (physical functioning, social functioning, and emotional functioning). See Table 1-1 for definition of concepts. The study examined relationships between pain and pain outcomes, and the role of prescribed pharmacologic pain management in this relationship.

Purpose of Study

The purpose of this study was to (a) examine the relationship between pain (e.g., pain interference and number of pain locations) and pain outcomes (e.g. physical functioning, social functioning, and emotional functioning) in older adults with arthritic pain and (b) determine whether the adequacy of prescribed pain medications (e.g., pain management index—PMI) mediates the relationship between pain and pain outcomes. These relationships are examined cross-sectionally at three different time points and longitudinally over a 5-year time period. A model of the proposed study is shown in Figure 3. The following research questions and hypotheses were investigated:

Research Questions

- What are the characteristics of pain (e.g., severity of pain interference, number of pain locations), the adequacy of prescribed pain medication (e.g., PMI), and pain outcomes (e.g., physical functioning, social functioning, and emotional functioning) among older adults with arthritis at Time 1 (baseline), Time 2 (3 years later), and Time 3 (5 years later)?

  o **Hypothesis 1a**: The majority of the sample will report pain that interfered with activities at each measurement point, and this rate will increase significantly across the 5-year study period.

  o **Hypothesis 1b**: The majority of the sample will have inadequate analgesic prescription relative to their reported level of pain at each measurement point, and this rate will increase/remain stable over the 5-year study period.

  o **Hypothesis 1c**: More than 50% of the sample will have moderate levels of physical, social, and emotional functioning at each time of measurement, and these levels of functional impairment will increase over the 5-year time frame.

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- What demographic (e.g., age, sex, race) and health variables (e.g., number of diseases diagnosed) are related to pain (e.g., severity of pain interference, number of pain locations), adequacy of prescribed pain medications (e.g., PMI), and pain outcomes (e.g., physical functioning, social functioning, and emotional functioning) at each measurement point [e.g., Time 1 (baseline), Time 2 (3 years later), and Time 3 (5 years later)]?

  o **Hypothesis 2a**: Age will demonstrate no significant relationship with pain, but older age will be significantly associated with less adequate pain management and poorer functional outcomes at each time point.

  o **Hypothesis 2b**: Females will report higher levels of pain, less adequate pain management, and poorer pain outcomes (physical, social, and emotional functioning) at each time point.

  o **Hypothesis 2c**: Race will demonstrate significant relationships with the study variables. Non-white participants will report higher levels of pain, less adequate pain management, and poorer pain outcomes (physical, social, and emotional functioning) at each time point.

  o **Hypothesis 2d**: Number of diseases diagnosed will be significantly related to the study variables such that more diagnosed medical conditions will be associated with more pain, less adequate pain management, and poorer pain outcomes (physical, social, and emotional functioning) at each time point.

- Is pain (e.g., pain interference and number of pain locations) related to the adequacy of prescribed pain medications (e.g., PMI) and pain outcomes (e.g., physical functioning, social functioning, and emotional functioning) among older adults with arthritis at each time of measurement [e.g., Time 1 (baseline), Time 2 (3 years later), and Time 3 (5 years later)]?

  o **Hypothesis 3a**: Pain (e.g., interference and number of pain locations) will be significantly and negatively related to the adequacy of prescribed pain medications at each time point.

  o **Hypothesis 3b**: Pain (e.g., interference and number of pain locations) will be significantly and negatively related to pain outcomes at each time point such that more pain will be associated with poorer physical, social, and emotional functioning..

  o **Hypothesis 3c**: Pain (e.g., interference and number of pain locations), adequacy of prescribed medications, and pain outcomes (physical, social, and emotional functioning) will be significantly intercorrelated positively and negatively at each time point and across time points.

- Does the adequacy of prescribed pain medications (e.g., PMI) mediate the relationships between pain (e.g., pain interference and number of pain locations) and pain outcomes (e.g. physical, social, and emotional functioning) at each occasion and across the 5-year

- o **Hypothesis 4a***: The adequacy of prescribed pain medications (PMI) will significantly mediate the relationships between pain (pain interference and number of pain sites) and pain outcomes (physical functioning, social functioning, and emotional status) at each measurement occasion, and across occasions over a 5-year time span, after controlling for age, sex, race, and number of diseases diagnosed.
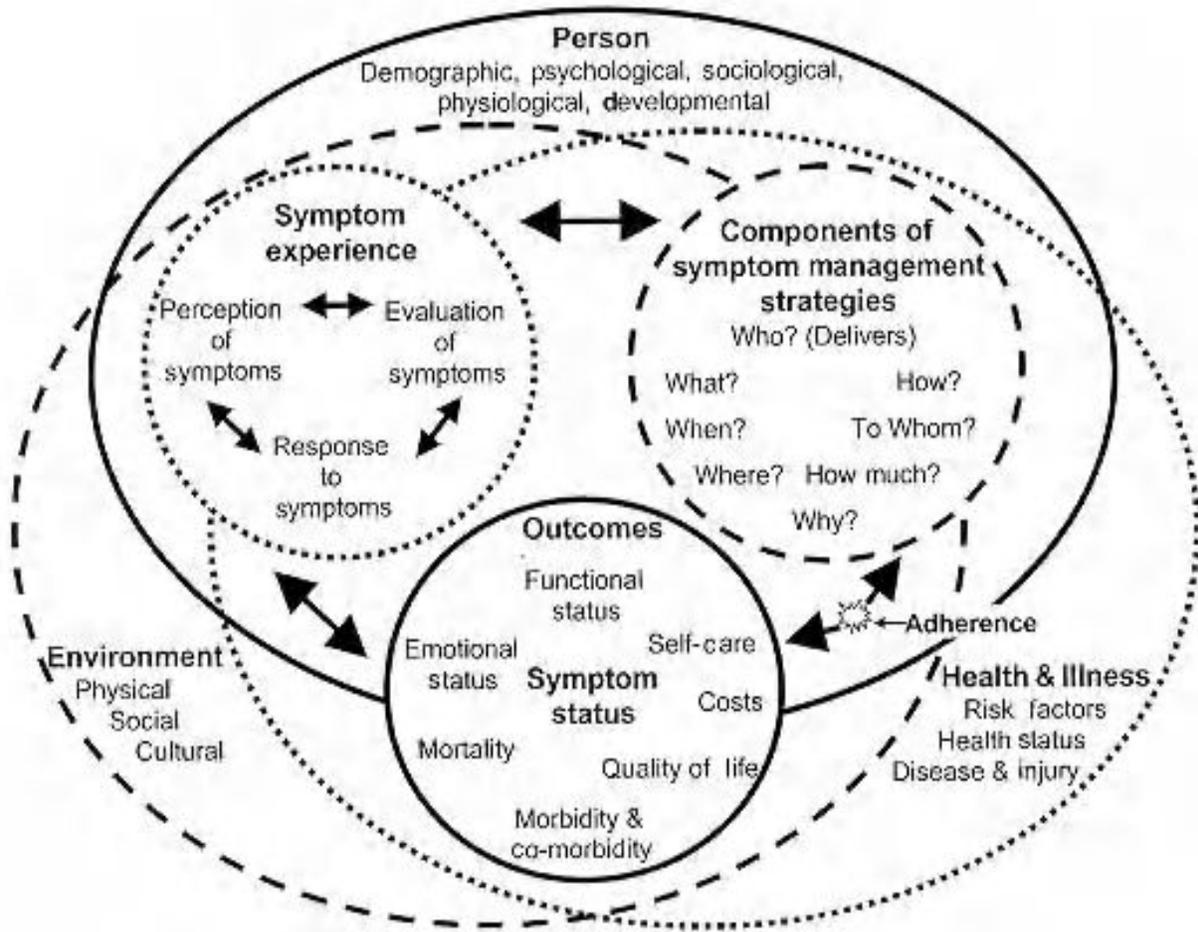
Figure 1-1. Model of symptom management (Dodd et al., 2001)
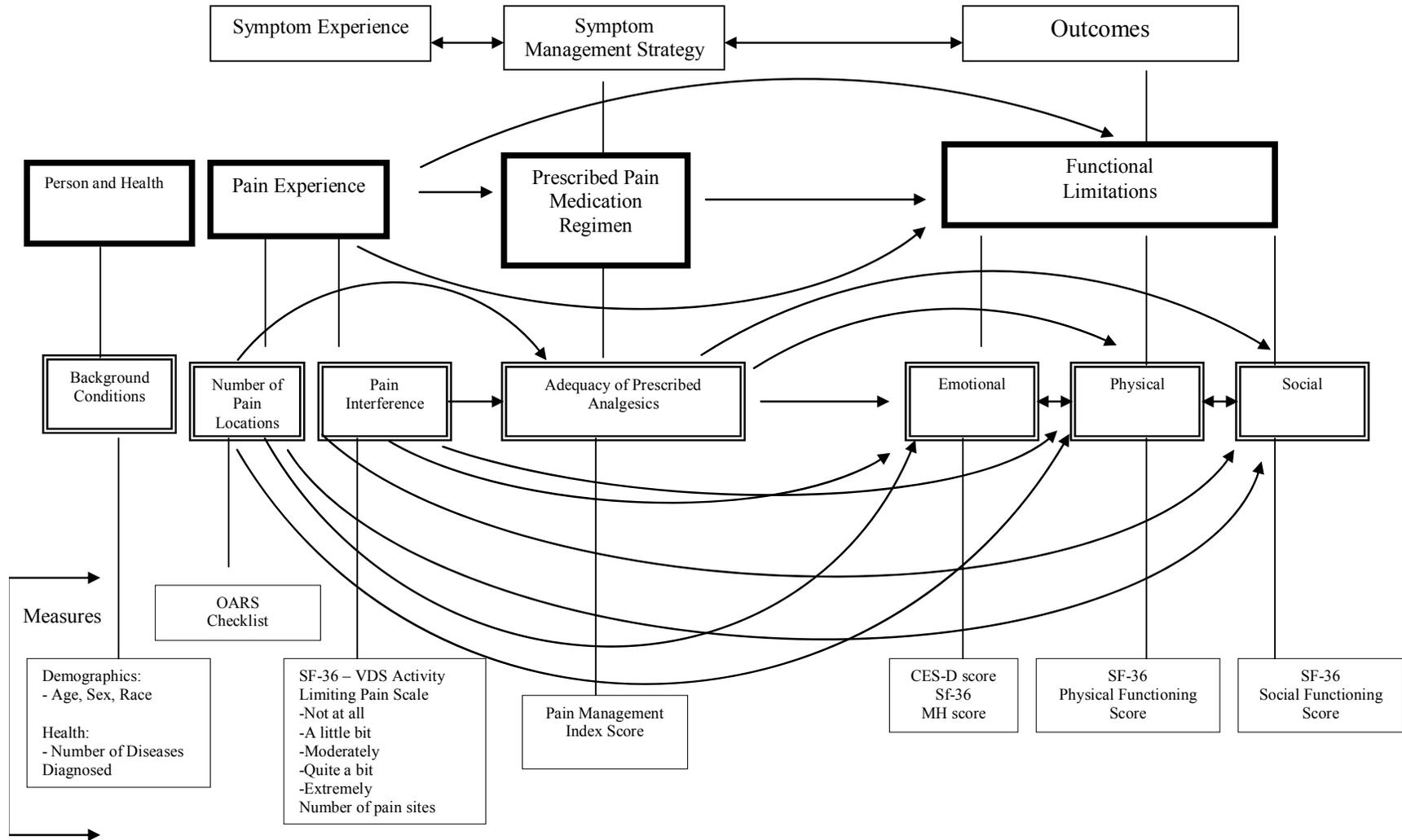
Figure 1-2. Derived model showing constructs, concepts, variables, relationships, and measures

| Age | Sex | Race | DZ |

VITAL

DEP

EMOT-R

PHYS -PF

PHYS-PR

EMOT-F

PAIN

PHYS-F

PAIN-INT

PAIN-LOC

PMI
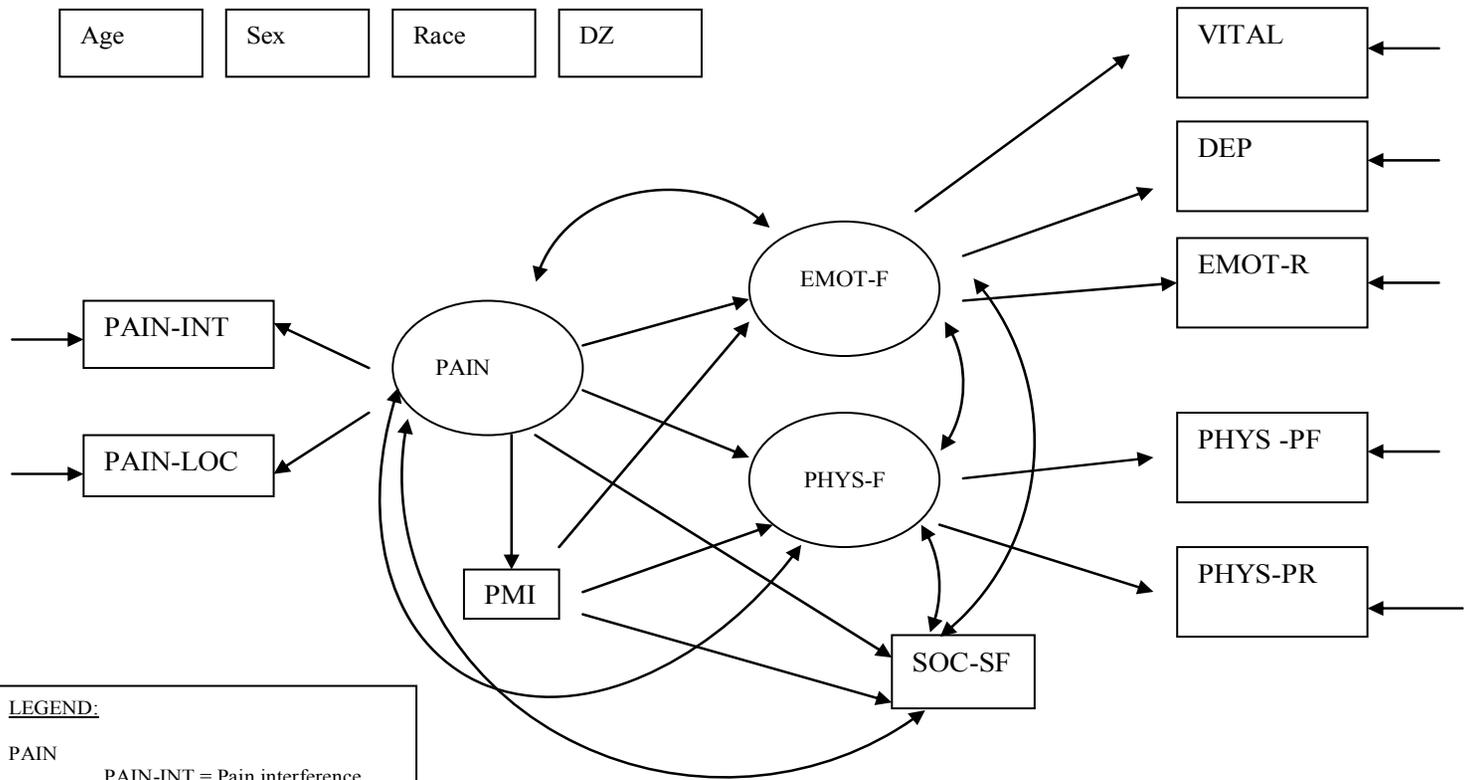
SOC-SF

LEGEND:

PAIN
        PAIN-INT = Pain interference
        PAIN-LOC = Pain locations
EMOT-F = Emotional Functioning
        VITAL= Vitality
        DEP= Depression
        EMOT-R = Emotional role
PHYS-F = Physical Functioning
        PHYS-PF = Physical functioning
        PHYS-PR = Physical role
SOC-SF = Social Functioning
PMI = Pain Management Index
DZ = Number of diseases diagnosed

Fig 1-3. Conceptual model of the study

Table 1-1. Constructs, variables, operational definitions, and measures

Constructs	Variables	Operational Definition	Instrument (Level of Measurement)
Background characteristics	Demographic characteristics	Self-reported age, sex, race	Demographic survey: Age (continuous), sex (categorical), race (categorical)
	Health conditions	Self-reported number of diagnosed diseases (DZ)	OARS checklist: Number of diseases (Continuous)
Pain experience	Pain interference	Self-report of the extent to which bodily pain interferes with activities (on a 6-point Verbal Descriptor Scale)	SF-36: Bodily pain subscale (ordinal)
	Number of pain locations	Self-report of the number of painful body locations that interfere with activities	OARS Checklist: Summary of the number of painful locations (continuous)
Prescribed pain medication	Adequacy of prescribed analgesics	Calculated score of the relationship between ordered analgesic medications (AHFS scores of opioids, nonopioids, and adjuvant analgesic medications) and self-reported pain.	Pain management index (PMI) (ordinal)
Pain outcomes Physical functioning	Physical functioning Physical role	Self-report of the number/the severity of functional limitations in the physical, social, and emotional domains	SF-36: Physical Functioning Subscale
Social functioning Emotional functioning	Social functioning Emotional role		SF-36: Social Functioning Subscale
	Emotional vitality Depression	Self-reported level of disturbances in mood and affect	SF-36: Emotional Functioning Subscale CES-D (ordinal)

CHAPTER 2
REVIEW OF THE LITERATURE

This review focuses on the following study concepts: pain, pain medication, and pain outcomes among older adults with persistent pain related to chronic skeletal/joint conditions, especially arthritis. Prevalence of persistent pain and pain interference among older adults in general populations, specifically among those with arthritis is examined. Further, the relationship between pain, pain medications, and pain outcomes (e.g., functional status - physical and social functioning; and emotional status) is discussed.

Persistent Pain in Older Adults

Within the last two decades, literature on chronic pain among older adults has focused mostly on establishing the high prevalence of pain and the pattern of the pain experience in terms of severity (intensity), frequency, and duration (Ferrell & Ferrell, 1990; Hutt et al., 2006; Rutledge, Donaldson, & Pravikoff, 2002; Nour & Laforest, 2003; Won et al., 2004). Recently, researchers have begun to examine other descriptors of the pain experience, such as pain-related interference with activity (Jinks et al., 2007; Mossey & Gallagher, 2004; Zarit et al., 2004). These reports have been documented mostly in relation to older adults in nursing home settings where persistent pain is most prevalent (Allcock, McGarry, & Elkan, 2002; Brockopp, Brockopp et al., 1998; Fox, Raina, & Jadad, 1999; Hall-Lord, 2003; Hutt et al., 2006; Tse, Pun, & Benzie, 2003). Thus, this review will encompass reports on persistent pain experience in the general population of older adults, and specifically in those with a diagnosis of arthritis.

Pain, is defined by the International Association for the Study of pain (IASP, n.d.) as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. Pain is further viewed as a complex phenomenon associated with interplay of psychological and pathophysiological processes that cause pain perception or expression (Hawthorn & Redmond,

1998; McCaffery & Pasero, 1999; Zimmermann, 2004). Often, pain is described or measured by its intensity (level of severity), duration (length of time it has occurred), frequency (how often it occurs), or interference (extent to which pain interferes with usual activity or function) (Arthritis Foundation, 2008; Ferrell & Ferrell, 1990; McCaffery & Pasero, 1999; Donald & Fay, 2004; Zarit et al., 2004).

Duration of pain is classified clinically as acute and persistent (e.g., chronic), or pathophysiologically by type of neuronal activity such as nociceptive and neuropathic (Hawthorn & Redmond, 1998; McCaffery & Pasero, 1999). The terms *chronic pain* and *persistent pain* are used interchangeably to denote pain that has exceeded three months in duration and is associated with chronic pathological process (AGS, 2002; Hawthorn & Redmond, 1998). The AGS (2002) panel further defines persistent pain as "a painful experience that continues for a prolonged period of time that may or may not be associated with a recognizable disease process" (p. S205).

Pain *chronicity*, according to Zimmermann (2004), "is the result of prolonged nociceptive activity which leads to nervous system sensitization and progressive intensification of pain" (p. 2). Thus, individuals with chronic pain perceive complex stimuli that may be facilitated and sustained by a multitude of physiological and psychological reactions. As such, chronic pain may progress from being a disease symptom to being an independent chronic disease in itself. Therefore, it is important to recognize that persistent pain could be either the manifestation of a biophysiological process or the outcome of ineffectively treated pain.

Persistent pain can result from a poorly healed or poorly treated primary injury, or abnormal functioning of the nervous system (McCaffery & Pasero, 1999). Sources of chronic pain can be found in many body systems. Commonly, pain occurs in the musculoskeletal, cardiovascular, and neurological systems, and manifests as chronic joint pain, headaches, angina,

and neuralgias respectively. Musculoskeletal joint disorders such as arthritis are the most common cause of chronic pain among the elderly (AGS, 2002; Brooks, 2005).

The prevalence of persistent, unrelieved pain is high among the elderly population. Generally, about 49% to 84% of elders experience persistent pain (Nour & Laforest, 2003; Rutledge, Donaldson, & Pravikoff, 2002; Won et al., 2004). Over 60% of elders (Jakobsson, Hallberg, & Westergren, 2004; Thomas, Peat, Harris, Wilkie, & Croft, 2004) and more than 80% of nursing home residents have significant problems with persistent pain (Allcock, McGarry, & Elkan, 2002; Brockopp et al., 1998; Fox et al., 1999; Hall-Lord et al., 2003; Tse, Pun, & Benzie, 2005). Recently, Hutt and colleagues (2006) reported an even higher prevalence of pain (95%) among elderly nursing home residents. High prevalence of persistent pain in older adults is attributed to equally high prevalence of chronic painful musculoskeletal conditions such as arthritis (AGS, 2002). Over 46 million U.S. adults (>21%) reported a diagnosis of arthritis according to 2003-2005 CDC surveys (CDC, 2006). Within the stated adult population, about 50% of persons over age 65 years reported a current diagnosis of arthritis. It is projected that the prevalence of persistent joint pain and related interference with activity will increase due to the aging of the U.S. population, as more older adults are diagnosed with arthritis (CDC). Together, these reports support persistent pain as a common problem for a large portion of the population, and they provide evidence for the clinical problem that is the basis for this proposed study.

Interference with activities due to pain is common among older adults (Donald & Foy, 2004; Mossey, et al., 200; Mavandadi et al., 2007; Ross et al., 1998; Thomas et al., 2004), particularly for those diagnosed with arthritis (Arthritis Foundation, 2008; CDC, 2006). The CDC summary report for 2003-2005 indicated that 46 million U.S. adults reported a diagnosis of arthritis and more than 38% reported activity limitation attributed to arthritis. Among older

adults with arthritis, Hybels, Blazer, & Pieper (2001) reported pain interference ranging from 21.9% for those 65 to 74 years to 32.3% for those 85 years and above. Thomas and colleagues (2004) reported a high prevalence (58.7%) of pain interference among a general population of elderly persons who reported pain. These findings provide evidence that the prevalence of pain interference rises with increasing age (Hybels et al., 2001; Thomas et al., 2004).

Pain with its interference in daily activities and functioning of individuals exerts adverse effects on depressive symptoms, thereby delaying improvement of symptoms (Mavandadi et al., 2007). As more and more people join the ranks of 65 years and older, more pain interference will likely be associated with increased prevalence of depressive symptoms among this population. Thus, empirical evidence is needed to direct effective clinical pain management and decrease pain interference as individuals age.

Pharmacologic Pain Management

Pharmacologic pain management is the most commonly used approach to treat persistent pain (AGS, 2002), and effective treatment is typically multidimensional. Based on symptom assessment, treatment may incorporate specific or various categories and classes of pharmacologic agents (AGS; Roberto & Gold, 2001), including analgesics, nonsteroidal anti-inflammatory agents (NSAIDs), antidepressants, anxiolytics, muscle relaxants, anti-spasmodics, and others (AGS; Harden et al., 2005).

Analgesics are the most commonly used pain relieving drugs (AGS, 2002; Ferrell, 2004). Analgesics include nonopioids (e.g., non-narcotics such as acetaminophen and NSAIDs), opioids (e.g. narcotics such as opioid receptor agonists and antagonists), and adjuvant analgesics (e.g., antidepressants) (AGS; McCaffery & Pasero, 1999). NSAIDs have both a central nervous system (CNS) effect and a strong peripheral action that inhibit prostalglandins at the site of injury. However, the common side effects of gastric irritation may be problematic in terms of gastric-

intestinal bleeding. Examples of NSAIDs include such drugs as ibuprofen, ketoprofen, naproxen, and acetylsalycilic acid (aspirin). Unlike the NSAIDs, the mechanism of action by which acetaminophen relieves pain is not well known (AGS; McCaffery & Pasero, 1999). However, acetaminophen is believed to produce analgesia via mechanisms in the central nervous system (CNS). Overall, adverse effects associated with acetaminophen are considerably fewer compared to other analgesics. Thus, it is one of the first lines of treatment for elderly with chronic mild to moderate nociceptive pain. Opioid agonist analgesics are useful in managing a wide variety of moderate to severe acute and chronic pain, particularly pain of nociceptive origin. Analgesia is achieved through a CNS mechanism that modulates descending pain thereby diminishing its discrimination and perception (American Academy of Pain Management [AAPM], 2005). Opioid agonists are safe if used within existing guidelines (AGS, 1999, 2002; McCaffery & Pasero).

Recommendations for the treatment of arthritic pain must consider pain control, reduction of joint inflammation, and preservation of function with minimal side effects (Arthritis Foundation, 2008; Stone, Wyman, & Salisbury, 1999). Thus, pharmacologic management of arthritic pain usually requires regular use of acetaminophen to provide analgesia. However, opioid medication such as codeine may be used alone or in combination with acetaminophen to control more severe symptoms (Arthritis Foundation; Stone et al., 1999). Short-acting NSAIDs such as naproxen and ibuprofen are considered safer to use with the elderly due to altered absorption, distribution, elimination, and higher risk for gastro-intestinal damage in this population (Stone et al.).

Adjuvant analgesics serve a multi-purpose in the treatment of pain (McCaffery & Pasero, 1999). This category of drugs includes antidepressants, anticonvulsants, and antispasmodics.

These drugs also exert effects on the CNS and have been found to be effective with neuropathic pain such as that caused by stroke and neuralgia. Other pain modulating drugs identified in this group are steroids, anti-arrhythmics, and local anesthetics (AGS, 2002). Harden and colleagues (2005) profile 22 pain medication classes, which include all the above as well as anxiolytics, muscle relaxants, antispasmodics, sedatives, antipsychotics, and anti-hypertensives. Clearly, there is a large array of potential medications available to treat pain.

The AGS (2002) panel examined the role of pharmacologic agents in the treatment of chronic pain and posited that analgesics and pain modulating drugs can be used safely and effectively in the older adult population. Safe and effective use of pain drugs may be achieved through adherence to evidence-based guidelines, which include simplifying drug regimens as much as possible. Contrary to these recommendations, however, medication regimens of older adults continue to show higher complexity due to overall increase in the rate of drugs prescribed to treat multiple symptoms and conditions prevalent among this population (Chin et al., 1999; Patel, 2003; Sloane, Zimmerman, Brown, Ives, & Walsh, 2002).

Consequently, many older adults typically consume a large variety of medications, despite the fact that studies on pain management report prevalence of under-treatment of persistent pain in this population (Mzorek & Werner, 2001; Rodriguez, 2001; Sofaer, 1984). Recently, Oster and colleagues (2005) reported that 31% of elderly adults with post-herpetic neuralgia stated they were a little or not at all satisfied with their pain medication. This finding is supported by a more recent report that prescribing of pain medication was adequate for only 40% of nursing home residents with neuropathic pain (Hutt et al., 2006).

Problems of inadequate relief of chronic pain have been related to inadequate and ineffective prescription of pain medications (Berry & Dahl, 2000; Grant & Haverkamp, 1995;

Horgas & Tsai, 1998; Hutt et al., 2006; Mzorek & Werner, 2001; Rodriguez, 2001; Won et al., 2004). Horgas and Tsai surveyed analgesic drug prescriptions and use among 339 elderly nursing home residents. They found that while the majority of residents were prescribed at least one analgesic medication, very few were actually administered any doses of that medication during the one-month study period. In addition, they reported that cognitively impaired residents were prescribed and administered significantly less equianalgesic medications than those who were cognitively intact. In a more recent study, Won and colleagues investigated persistent nonmalignant pain and analgesic prescribing patterns in over 21,000 elderly nursing home residents. Their results showed that one quarter of the residents received no analgesics and less than 50% of all analgesics were given as standing doses.

Hutt and colleagues (2006) recently provided further evidence of inadequate pain management among elderly adults in their study. These authors screened the quality of nursing home pain medication prescribing practice using a pre-post intervention design aimed at nurses and physicians. They found that fewer than 50% of residents with predictable recurrent pain were prescribed scheduled pain medications pre-intervention. The mean score on the pain medication appropriateness scale (PMAS) was 64% optimal pre-intervention, but was better (69%) in nursing homes in which nurses' knowledge of pain assessment and management improved post-intervention. Overall, PMAS scores for residents in pain improved from baseline (60%) to intervention (65%). In a primary care population of 83,000 adult patients aged 60 and above, only a small sample of 209 (.25% of patients) was identified as taking opioids for relief of their chronic pain (Adams, Plane, Fleming, Mundt, & Saunders, 2001). These finding indicate that chronic pain is generally undertreated in primary health care setting and lend support to

other research findings of inadequate pain treatment in a wide range of patient groups, including those living with a variety of painful chronic conditions and across various settings.

Evidence suggests that the under-treatment of pain is often related to knowledge deficits among physicians and other healthcare practitioners regarding pain assessment and pain management (Green et al., 2002; Rodriguez, 2001; Mzorek & Werner, 2001; Puntillo, Neighbor, O'Neil, & Nixon, 2003; Simpson, Kautzman, & Dodd, 2002). Specifically, knowledge deficits about pain medication (Allcock et al., 2002; Mzorek & Werner; Puntillo et al.; Rodriguez; Simmonds & Scudds, 2001) and decision making about pain treatment have been cited (Erkes, Parker, Carr, & Mayo, 2001; Puntillo et al.; Simpson et al.; Tarzian & Hoffman, 2005). A prospective cohort study of pain physicians found that physician's personal experiences with chronic pain, frequency of prescribing pain medication, knowledge of treatment choices, and opinions or goals for pain management are variables that impact effectiveness in managing persistent pain (Green et al.). These authors found that fewer than 10% of respondents had received any pain management education; however, the majority reported they do treat chronic pain. A large number exhibited poor knowledge of pain treatment, e.g., many physicians chose a poor or worse treatment option for rheumatoid arthritis. A majority also agreed that chronic pain was under-treated but expressed concern that prescription of strong opioids would attract regulatory scrutiny or medical sanction. Thus, most physicians usually chose to refer the patient to a specialist rather than provide treatment for pain. Overall, physicians' goals for pain relief were poor, averaging only 2.2 on a scale of 1-5, 1 being absolute and complete pain relief and 5 being no pain relief. An important finding of this study is that physicians with a goal of more pain relief were more likely to provide high quality care.

In a survey report of nursing home directors, Tarzian and Hoffman (2005) also documented that lack of knowledge about pain management among nurses and physicians, including fear of addiction, overdose, and difficulty choosing the right analgesics, are barriers in providing adequate pain management. Sometimes, poor assessment of pain by the practitioner directly results in poor treatment choice for pain management (Herr, 2002). The result is suboptimal pain management (Tarzan & Hoffman; Won et al., 2004). These factors and associated outcomes will also be true for older adults with arthritic pain whose recommended regimens include the use of both opioid and/or nonopioid analgesics (Arthritis Foundation, 2008).

There are also patient-related factors implicated in the problem of poor pain management. Among some community dwelling cancer patients receiving treatment for pain, age (more than 70 years), female gender, black ethnicity, and perception of being less ill have been listed as factors that contribute to under-treatment of pain (Cleeland et al., 1994). Other community based studies of older adults with non-cancer related pain corroborate some of the above findings (Breitbart et al., 1996; Shega, Hougham, Stocking, Cox-Hayley, & Sachs, 2006) and implicate dementia as a factor in suboptimal pain management (Shega et al.). Thus, without exception, persistent pain among older adults is poorly treated.

In summary, patients with less adequate analgesia will report less pain relief and greater pain-related impairment of function (Cleeland et al., 1994). Studies have shown that both health care provider and patient related factors impact pain management. Prescription of pain medication among the elderly remains inadequate, due to inadequate scheduling, inadequate amount, and/or inappropriateness of prescribed drug(s). Factors that contribute to this

phenomenon include health care professionals' lack of knowledge and accurate clinical decision making ability about pain management and pain relief.

Pain and Related Pain Outcomes

Persistent pain in older adults negatively impacts the general health and the emotional and functional status of individuals affected (Mantyselka et al., 2003; Oster et al., 2005; Silkey et al., 2005). There is consistent evidence that supports a significant relationship between persistent pain and outcome measures such as depression and functional limitations (Mantyselka et al.; Zarit et al., 2004). Pain variables that have been implicated in the relationships with depression and functional outcomes include pain intensity, pain interference with activity, duration of pain experience, frequency of the pain experience, as well as number of pain sites or locations present (Mavandadi et al., 2007; Scudd & Robertson, 2004; Thomas et al, 2004; Zarit et al.). Also, various components of functional limitations such as physical and social functions are affected by pain (Bookwala, Harralson, & Parmalee, 2003; Williams, Tinetti, Kasl, & Peduzzi, 2006). This section explores evidence of the relationships between pain and functional limitations (social, physical, and emotional) among older adults with persistent pain. Specific attention is paid to emerging significance of pain interference with regard to depression and other functional limitations.

Pain and Emotional Distress

Depression is well documented in the literature as a correlate of persistent pain (Bookwala et al., 2003; Sharp, Sensky, & Allard 2001; Zarit et al., 2004) as well as a major indicator of emotional distress among patients with chronic pain (Greenberg & Burns, 2003). Depression is known to initiate, exacerbate, and maintain the pain experience (McCracken, Spertus, Janeck, Sinclair, & Wetzel, 1999). Among a primary care sample (N= 209) of individuals 60 years and older with reported persistent joint pain, 36% were diagnosed with

depression (Adams et al., 2001). A higher prevalence of self-reported depression was reported by over 50% of a general population of older adults with persistent pain (Mossey & Gallagher, 2004). More depressive symptoms in persons with persistent pain may be attributed to their response to multiple distressing symptoms from increased sensory and emotional stimuli (AGS, 2002; Ferrell & Ferrell, 1990; Gonzalez, Martelli, & Baker, 2000; Harden et al., 2005). For example, Ryan and Frederick (1997) found that vitality (indicator of affective well-being or disposition) was lower among older adults with chronic pain, especially if they perceive their pain to be disabling or frightening. This further contributes to their emotional distress. When assessed longitudinally at six points over a period of 21 months, Sharp and colleagues (2001) found that pain intensity was one of two variables that consistently predicted level of depression in a population of older adults. Following another longitudinal study of the relationships between pain severity, pain interference, and change in depressive symptoms in older adults at baseline and 3, 6, and 12 months, Mavandadi and colleagues (2007) found that at higher pain intensity levels, improvements in depressive symptoms of persons surveyed were blunted. However, when pain interference was considered alongside pain intensity, these authors found that the extent to which pain interfered with functioning had greater negative impact on individual's recovery from depression. Further study is needed to determine which factors mediate this relationship.

Pain and Functional Limitations

Persistent pain is an important predictor of functional limitation or disability in older adults (Arthritis Foundation, 2006; Mossey & Gallagher, 2004; Rudy, Weiner, Lieber, Sloboda, & Boston, 2007). The relationships between persistent pain and functional limitations have been examined for both physical functioning and social functioning (Bookwala et al., 2003; Elliot, Ranier, & Palcher, 2003; Rudy et al.; Williams et al., 2006). Researchers have found that persistent pain was correlated with poorer physical functioning, lower social functioning, and

greater depressive symptomatology (Bookwala et al.; Elliot et al.). A wider scope of investigation of functional limitations in these studies is supported by the multidimensional nature of persistent pain and its related outcomes which involve not only the physical but also social, emotional, and other dimensions (Osborne, Jensen, Ehde, Hanley, & Kraft, 2007). The following paragraphs concentrate on the impact of persistent pain on physical and social functioning among older adults, a focus of specific interest in this study.

In the literature, *physical functioning* generally refers to performance of general/instrumental activities of daily and performance of physical activities such as walking, gripping, reaching, gait, speed, etc. (Kothe, Kohlmann, Klink, Ruther, & Klinger, 2007; Mossey & Gallaher, 2004; Rudy et al., 2007; Weiner et al., 2006). Researchers have found that physical activity limitations are prevalent in older adults with persistent pain. Scudd & Robertson (2000) examined the association between the presence of physical activity limitations and specific characteristics of musculoskeletal pain. Approximately, 73% of the respondents (N = 885) reported presence of musculoskeletal pain during the two weeks prior to the study, while about 69% were identified as having physical limitations. The majority reported some difficulty performing numerous physical tasks, including heavy household or yard work chores, standing up from an armless chair, reaching above the head to get a 5-pound object, and climbing stairs. These researchers found that the odds of having a physical disability from the effect of moderate pain intensity was almost twice as likely (OR=1.54, CI=0.97, 2.44, p=.00) and more than four times as likely (OR=4.32, CI=2.01, 9.31) if severe, extreme, or worst pain intensity was present. Further analysis revealed that individuals whose pain experience occurred all or nearly all of the time were at least twice as likely (OR=2.00, CI=1.07, 3.72, p= .03) to have physical disability. Consistent with above findings, other investigators reported that 79% of their sample was

bothered by pain in the two weeks before they were surveyed, and up to 50% of them were limited in the performance of their usual activities (Mossey & Gallagher). They also found that individuals who reported pain interference were more than four times as likely to have impaired physical performance. These findings highlight the clinical importance of evaluating pain interference as a strategy for effective pain management.

Social functioning usually refers to performing roles, responsibilities, and activities such as visiting with friends or relatives, attending social engagements, and recreation (Ross & Crook, 1998; Ware, 1993). Persistent pain has been found to impact the social functioning of individuals (AGS, 1998, 2002; Ware). In a study investigating the relationship between pain and indices of disability and functional competence, researchers found that pain frequently interfered with aspects of social responsibilities such as recreational and family activities in 36% of the respondents (Ross & Crook). For 22% of the respondents, interference was experienced most of the time. In a study examining the effects of pain on functioning and well-being in older adults with osteoarthritis of the knee, Bookwala and colleagues (2003) measured both physical and social functioning. They found that more intense pain was correlated with poorer physical functioning and lower social functioning. To support this finding, Elliot and colleagues (2002) reported that limitation with social functioning significantly predicted an individual's ability to recover from chronic pain over time. This finding extends the clinical role of social functioning as an outcome measure in pain management. These reviews highlight the need to recognize the role of social functioning limitations when developing pain interventions and to maintain pain relief in order to sustain recovery (Williams et al., 2006).

Summary

This review has highlighted important research findings that document the prevalence of persistent pain and its deleterious impact on the emotional, physical, and social functioning of

older adults (AGS, 1998, 2002; Creamer, Lethbridge-Cejku, & Hochberg, 2000; Williams et al., 2006). Although the safest and most effective pharmacologic strategies for pain management are recommended (AGS, 2002), evidence of suboptimal prescription and treatment of persistent pain among older adults with persistent pain continues to be supported. Pain management recommendations for older adults address concerns about unrelieved pain, inadequate prescription of pain medications, and high prevalence of adverse pain related outcomes. However, these reviews do not completely explain the role of inadequate prescription of pain medications in pain-related emotional and functional outcomes. Therefore, this study proposes to extend existing cross-sectional research by investigating longitudinal relationships between pain and related outcomes, and the role of prescribed pain medications in determining these outcomes. This review underpins the study's primary hypothesis that the relationship between pain (e.g., pain interference and number of pain locations) and pain outcomes (e.g., emotional, physical, and social functioning) over time is mediated by the adequacy of prescribed pain medications (e.g., pain management index [PMI]).

CHAPTER 3
METHODS

Design

This study investigated relationships between pain, pain medications, and pain outcomes in older adults with arthritic pain, and examined whether adequacy of prescribed pain medications mediates any of these relationships. The study was conducted using existing data from a large-scale, NIH-funded, parent study: *Advanced Cognitive Training for Independent and Vital Elderly (ACTIVE).* A description of the ACTIVE study, specific measures used in the study, and procedures used to extract and manipulate the data are presented below. Finally, statistical procedures used for data analysis are presented.

The ACTIVE Study

The ACTIVE study is a randomized, controlled, single-masked clinical trial designed to test specific interventions selected to determine the effects of cognitive training on memory and functioning. The ACTIVE data was collected at five time points: baseline and annual follow-up points at Years One, Two, Three, and Five. Baseline data included measurements of demographics, health conditions (medical diagnoses), cognitive status, health outcomes surveys (e.g., bodily pain, emotional, and functional status), and prescribed medications. Each annual follow-up measurement included all of the above data except demographics. To be eligible for the study, prospective participants had to be age 65 years or older, cognitively intact, and without a diagnosis of terminal illness (e.g., cancers) or conditions causing functional decline (e.g., stroke or dementia). An initial telephone interview was used as the first-level screening for eligibility. Subjects who passed this screening were invited for a subsequent in-person interview to obtain additional data for eligibility (cognitive testing). Eligible subjects were then given a

take-home packet of measures to be completed and brought on their next interview one week later.

Measures

For the purpose of this secondary analysis study, data collected from several ACTIVE study measures at baseline screenings (telephone and follow-up in-person interviews), 3-year, and 5-year follow-up data collection points were used. A description of selected measures and application to the current study is provided below. Table 3-1 summarizes selected variables.

Demographic and Health Data

A demographic and health status screening to determine basic eligibility was conducted at baseline via a telephone screening interview. Self-reported date of birth (to compute age), sex, race, medical conditions (diagnosed diseases assessed via OARS checklist), and cognitive status assessed via the telephone interview for cognition (TIC) were collected. A subsequent in-person interview was conducted to obtain additional data, including a mental status screening, to determine eligibility. Variables selected for this study were age, sex, race, and medical conditions (diagnosed diseases).

The SF-36 Health Survey

The Medical Outcomes Short Form-36 (SF-36) was used to assess participants' self-reported pain and functioning at baseline (Time 1), year 3 (Time 2), and year 5 (Time 3). Participants were asked to complete the SF-36 at home as part of a take-home packet of measures and return the packet at their next interview session, typically one week later. If participants failed to bring the completed measure with them to their next appointment, the SF-36 was administered in-person during the interview in order to minimize missing data.

The SF-36 is a generic, multi-purpose, Likert-type 36-item health survey, which yields 8 scales and psychometric physical and mental health summary measures (Ware et al., 1993).

Four subscales applicable to the proposed study are bodily pain, physical functioning, social functioning, and mental health functioning. The bodily pain subscale was used to assess pain intensity and pain interference. Pain intensity was evaluated as self-report of how much bodily pain an individual has experienced in the past four weeks. A 6-point Likert-type verbal descriptor scale was used to score pain intensity as follows: 1= none, 2 = very mild, 3 = mild, 4 = moderate, 5 = severe, and 6 = very severe. Pain interference referred to the degree to which pain interfered with normal activities (housework and outside work) during the past four weeks. A 5-point verbal descriptor scale was used to score pain interference as follows: 1= not at all, 2 = a little bit, 3 = moderately, 4 = quite a bit, 5 = extremely.

The SF-36 physical functioning subscales were used to evaluate physical activity and physical role limitations. Physical functioning limitation was measured by the extent to which participants reported that10 typical activities were limited by their health. For example, "Does your health now limit you in lifting or carrying groceries?" Responses were scored on a 3-point scale scored as 1 = yes, limited a lot; 2 = yes, limited a little; 3 = no, not limited at all.

The social functioning subscale was used to evaluate social activity limitations. Social functioning limitation was evaluated with 2 items measuring the extent and amount of the time physical health interfered with social activities (e.g. visiting friends or relatives) on a 5-point scale. The extent of social functioning limitation scores ranged from 1 = not at all, to 5 = extremely. The amount of time health interfered with social function was scored from 1 = all of the time to 5 = none of the time. The mental health subscale was used to evaluate emotional limitations. Scores from emotional role and emotional vitality subscales were used to indicate level of emotional functioning. Three items measuring interference with participants' daily activities in the past week as a result of emotional problems (e.g. depression or anxiety) were

scored as 1 = yes, had problem; or 2 = no, did not have problem. Scores on vitality assessed how participants felt in the past four weeks, e.g., "During the past 4 weeks, have you felt downhearted and blue?" Responses to nine items in this measure were scored on a 6-point verbal descriptor scale. Scores ranged from 1 = feeling occurred all the time, to 6 = feeling occurred none of the time.

As a general health measure, the SF-36 is beneficial in comparing the relative burden of diseases and symptoms (e.g., pain), and in differentiating the health benefits of various treatments (Ware et al., 1993). The pain and functioning subscales measured for the proposed study are summated scores that have been transformed to range from zero (lowest score) to 100 (highest possible score) for each subscale (Ware et al.). Scores between these values represent the percentage of the total possible score achieved; lower scores represent worse health outcomes. A cutoff score of 42 has been applied to the mental component summary scale yielding a sensitivity of 74% and a specificity of 81% in detecting patients diagnosed with depressive disorder (Ware, Kosinski, & Keller 1994). Overall reliability of the SF-36 scales using both internal consistency and test-retest methods has exceeded the minimum standard of 0.70 in many studies (McHorney, Ware, Rachel, & Sherbourne, 1994; Tsai, Bayliss, & Ware, 1997; Ware et al., 1994; Ware et al., 1993), and content, concurrent, criterion, construct, predictive evidence of validity, and the meaning of high and low SF-36 scores are well supported in validity studies (Ware et al., 1993, 1994). For example, empirical validity of all 8 scales of the SF-36 scales has been achieved in studies involving physical and mental health (McHorney et al.).

Center for Epidemiological Studies-Depression Scale (CES-D)

The CES-D tool was used to assess depression as a third variable contributing to emotional limitations in this study. This 20-item Likert-type instrument was developed to detect

major or clinical depression in adolescents and adults (Radloff, 1977). Four components or factors of the CES-D are depressive affect, somatic symptoms, positive affect, and interpersonal relations. Items in the CES-D refer to how an individual has felt and behaved during the last week e.g., "During the past week, I felt depressed." Scores range from 0-3, indicating that the feeling or behavior occurred as follows: for negative items, 0 points = rarely or none of the time (< 1 day); 1 point = some or a little of the time (1-2 days); 2 points = occasionally or a moderate amount of the time (3-4 days); and 3 points = most or all of the time (5-7 days). An example of a feeling in the 3-point is "I did not feel like eating; my appetite was poor." Scoring is reversed for positive items, whereby "most or all of the time" is scored 0 points and "rarely or none of the time" is scored as 3 points. An example of a positive response is "I felt that I was just as good as other people." CES-D scores range from 0-60; higher scores indicate greater depressive symptoms. The cut off score for depression is usually 16 (Radloff; Reid, Williams, Concato, Tinetti, & Thomas, 2003), but a cut off score of 23 has been used to indicate depression (Hybels, Blazer, & Pieper, 2001). Studies using the CES-D indicate that it has high internal consistency (alpha=0.79-0.90, Kothe et al., 2006; Reid et al.), good test-retest stability (k=0.84, Reid et al.,), and adequate construct validity based on positive predictive values reported in several studies (Hybels et al.).

In a study by Geisser and colleagues (1997), the CES-D demonstrated good predictive value in discriminating between types of depression among patients with chronic pain (sensitivity >80%). Hybels and colleagues (2001) also demonstrated that the CES-D could reliably identify clinically significant depression in community dwelling elders. The CES-D short version yielded a Cronbach's alpha of .87 at baseline and .82 at follow-up for a sample of older adults (Zarit et al., 2004). In the ACTIVE study, the CES-D was administered by trained

testers in an interview format. CES-D scores from baseline, 3 years, and 5 years' follow-up were used in this study.

Medications

A medication audit sheet (MedAudit) was used to assess participants' current drug use, both over-the-counter (OTC) and prescription. Participants were asked to bring all currently used medications ordered by their health care provider to the in-person interview. On a standardized form (MedAudit), trained testers recorded drug names, doses, routes, frequency of administration, pro re nata (prn) or routine use status, whether the drugs were prescribed or purchased OTC, and any comments related to medication administration.

Data were cleaned to standardize the drug names and then categorized according to American Hospital Formulary System codes (AHFS) into therapeutic drug categories and subclasses. The AHFS is a functional classification widely used in the health care professions (McEvoy, 1996). Drug categories and identifying codes used in the proposed study are analgesics (AHFS codes: 280802-280892) and adjuvant analgesics (antidepressants, AHFS code: 281604; anti-convulsants, AHFS codes: 281292; and muscle relaxants, AHFS codes: 122004-122008). Only specific drugs known for pain management in the antidepressant (e.g., tricyclic antidepressant) and anticonvulsant (e.g., gabapentin) categories were included. Medication data collected at all study occasions (baseline, 3 years, and 5 years) were used in the proposed study.

Additional data manipulation was required to compute the Pain Management Index Score (PMI). The purpose of the PMI is to assess adequacy of prescribed analgesic medications as an indicator of a prescriber's response to a patient's pain by comparing prescribed analgesics with a patient's reported level of pain. A PMI score was calculated for each study participant based on pain intensity score on a verbal descriptor scale and potency of prescribed analgesic medications on an analgesic ladder. The computed PMI is a numerical rating scale whereby scores can range

from -3 (e.g., a patient with severe pain receiving no analgesic drugs) to +3 (e.g., a patient receiving a strong analgesic and reporting no pain). Negative scores indicate inadequate potency of analgesic drugs to treat pain, and scores of zero or higher are indicative of sufficient or acceptable treatment of pain. Pain management was considered adequate if there is congruence between the patient's reported pain level and the potency of the prescribed analgesic drug. Therefore, inadequate pain management was indicated for those participants with severe pain who received no analgesics or only nonopioids/adjuvant analgesics, or for those with moderate pain who received no analgesics (Breitbart et al., 1996; Cleeland et al., 1994).

Reliability and validity characteristics of the PMI are not documented in the pain literature. However, as a numerical rating scale (NRS) computed from two verbal descriptor scales (rank-ordered verbal descriptor pain scale and analgesic potency ladder), an examination of the reliability and validity status of NRS and VDS in the pain literature was warranted. The NRS and VDS have been independently applied in numerous studies involving pain and analgesic drug therapy and have been found reliable (Gagliese, Weizblit, Wendy, Ellis, & Chan, 2005; Lara-Munoz, de Leon, Feinstein, Puentee, & Well, 2004; Shega et al, 2006). Both the NRS and VDS scales have demonstrated good convergent and divergent validity when used to assess pain in older adults (Gagliese et al.). Thus, as an index of two core components of pain management (assessment and drug therapy), the PMI has the potential to be of clinical value for researchers who evaluate effectiveness of pain management (Cleeland et al., 1994; Shega et al.).

Procedure

In order to access the ACTIVE data, a proposal was submitted to the ACTIVE Steering Committee, consisting of all Principal Investigators and the Coordinating Center that functions as the data repository for all of the ACTIVE data from all of the study sites, the New England Research Institute (NERI). Approval was obtained in February 2007. NERI was responsible for

cleaning the data and on-site statisticians were responsible for coding the data and creating the study constructs for established measures (e.g., the SF-36, MMSE). Thus, the ACTIVE data were considered clean and ready for statistical analysis.

The PMI score was computed as an indicator of the adequacy of pain management. First, level of pain intensity was determined from participants' self reports of bodily pain on the SF-36 VDS. Pain severity (1 = none to 6 = very severe) was collapsed into a 4-point VDS to match the World Health Organization (WHO) 4-point analgesic ladder (Shega et al., 2006): none = 1, very mild and mild = 2, moderate = 3, and severe and very severe = 4. A WHO-score was assigned to each prescribed analgesic according to its rank on the analgesic ladder: 0 = no analgesic drug prescribed; 1 = nonopioid analgesic (e.g. NSAIDs or acetaminophen); 2 = weak opioid analgesic (e.g., codeine or tramadol); and 3 = strong opioid analgesic (e.g., morphine). Adjuvant analgesics (e.g., anti-depressants and anticonvulsants) and low dose aspirin (81mg or 325mg) were included on the analgesic ladder as nonopioids and assigned a score of 1 (Breitbart et al., 1996). Each participant was assigned a score that corresponded to the highest potency of analgesic prescribed. For example, a participant receiving a weak opioid (e.g., codeine—level 2) and an adjuvant analgesic (e.g., antidepressant—Level 1) received a score of 2 (Breitbart et al.). The PMI score was computed by subtracting the pain intensity score from the analgesic score and computed scores level are ordinal.

Sample, Setting, and Recruitment

The ACTIVE study involved 2,802 elderly subjects living independently in six metropolitan areas in the United States: Birmingham, Alabama; Detroit Michigan; Boston, Massachusetts; Baltimore, Maryland; Indianapolis, Indiana; and State College, Pennsylvania. Participants were recruited from senior housing, community centers, and hospital settings. Persons were excluded from the ACTIVE study if they were younger than age 65 years, had

cognitive decline (score ≤ 22 on the MMSE), ≥ 2 ADL disabilities (score on the self-rated ADL/IADL checklist), or verbally reported medical conditions associated with imminent functional decline or death (such as stroke or cancer); and/or exhibited severe loss of vision, hearing, or poor verbal communication.

Selection Criteria

For the purpose of this study, a subsample was selected from the ACTIVE sample based on a reported diagnosis of arthritis and presence of bodily pain rated at least mild on the SF-36 bodily pain scale, at the baseline period. Presence of bodily pain was required at baseline to more accurately reflect the course of pain management for those individuals who manifested symptoms of pain experience. Participants who did not report a diagnosis of arthritis at baseline and did not have self-reported pain were excluded from the study.

Ethical Considerations

The ACTIVE study has approval from the University of Florida Institutional Review Board (IRB), as well as the IRB of each participating university. Approval of the proposed study was obtained from the University of Florida Institutional Review Board prior to accessing existing data. All sample data and related information were handled using approved standards for confidentiality. All identifying information was stripped from the data. Participants were identified using only assigned subject numbers. All study documents and equipments containing participants' information were secured by the Principal Investigator (PI) in locked cabinets and locked offices, and were accessible only to the PI and the designated dissertation committee. Electronic equipment or media used for data storage, processing, or transmission were password secured, and accessed only by the PI.

Data Analysis

Data analysis was conducted using descriptive, correlational, and multivariate statistics.

Appropriate statistical programs were used to analyze relevant data as follows:

- **Descriptive statistics**: SPSS (version 16.0, SPSS Inc., 2007) was used to analyze and describe characteristics of background and health variables at baseline; and pain interference, pain locations, prescribed pain medication regimens, and pain outcomes (e.g., physical, social, and emotional functioning) at all 3 study periods.

- **Univariate and multivariate statistics**: Chi-square statistics, t-tests, and mixed effect modeling in the SPSS statistical program (version 16.0, SPSS Inc., 2007) were utilized where appropriate to compare differences in sample means between study occasions, and between returning and attritted samples, or to analyze longitudinal distribution of mean sample characteristics over time.

- **Bivariate statistics**: Pearson's product-moment correlations in the SPSS statistical program (version 16.0, SPSS Inc., 2007) were applied to analyze (a) correlations of demographic and health variables with pain (e.g., pain interference, number of pain locations), adequacy of prescribed analgesics (e.g., PMI) and pain outcomes (e.g., physical, social, and emotional functioning) at all study occasions; (b) correlations and intercorrelations of pain (e.g., pain interference and number of pain locations), adequacy of prescribed analgesics (e.g., PMI), and pain outcomes (e.g., physical, social, and emotional functioning) at all study occasions.

- **Structural equation modeling**: AMOS program version 16.0 (Arbuckle, 2007, by SPSS Inc., 2007) was used to analyze all steps in the proposed structural model to examine the relationships between pain experience (e.g., pain interference and number of pain locations) and functional status (e.g., physical, social, and emotional functioning); and the mediating role of adequacy of prescribed pain medications (PMI), at each study occasion and across time from baseline to five years later. For the purpose of structural equation model analyses, the seven-level race variable was recoded into a two-level dichotomous (dummy) variable – (0) white and (1) non-white.

Initial data screening for each time of measurement indicated longitudinal loss of data due to attrition (Table 3-1), as well as data missing at random. This result suggested possible violation of multivariate normality criteria, which would normally require listwise or pairwise deletion of missing data or data imputation/transformation procedures to permit model estimation (Kline, 2005). To avoid listwise deletion of data, which can introduce selective attrition biases, direct full-information maximum likelihood estimation (FIMLE) of the

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covariance matrix was utilized for the structural analyses. As a robust statistic, FIMLE handles

missing at random cases such that all sample subjects are retained (i.e., there is no listwise

deletion and participants' data is used at each occasion in which they contributed).

Table 3-1. Summary of variables and measurement points

Variables (measure)	Time 1 (baseline)	Time 2 (3 years)	Time 3 (5 years)
Background characteristics:			
Age, sex race	X		
Number of diagnoses (OARS checklist)	X		
Pain experience:			
Pain interference (SF-36: bodily pain subscale)	X	X	X
Number of pain locations (OARS Checklist)	X	X	X
Adequacy of pain management			
Pain Management Index (PMI) – calculated from pain intensity score (SP-36) and MedAudit data	X	X	X
Pain outcomes:			
Physical functioning (SF-36: Physical role and physical functioning Subscales)	X	X	X
Social functioning (SF-36: Social functioning subscale)	X	X	X
Emotional functioning (SF-36: Emotional role and emotional vitality subscales)	X	X	X
Depression (CES-D)	X	X	X

CHAPTER 4
RESULTS

The main purpose of this study was to examine (a) the relationships among pain (e.g.,

pain interference and pain location) and pain outcomes (e.g. physical functioning, social

functioning, and emotional functioning) in older adults with arthritic pain, across three time

points over a 5 year period, and (b) the mediating role of the adequacy of prescribed pain

medications (e.g., pain management index [PMI]) in the relationships between pain and pain

outcomes at each time of measurement and across the 5 year time span. The results of these

analyses are presented in this chapter. First, descriptive characteristics of the sample and study

variables are presented, followed by description of the bivariate relationships among the study

variables. Finally, the relationships pain, adequacy of pain medication, and pain outcomes are

examined cross-sectionally at each time point and longitudinally across the 5 years time span.

Sample Selection, Characteristics, and Attrition

Sample Selection

The analyzed sample was derived from a sample of 2,802 community-dwelling older

adults who were enrolled in a study to examine the effects of cognitive training interventions on

cognitive and functional performance. A subsample of 1,409 older adults (hereafter referred to as

the current study sample or simply as the study sample) was selected who were diagnosed with

arthritis and who reported the presence of bodily pain at the baseline period (Time 1). A

flowchart of study inclusion and available sample size on key study variables is presented in

Figure 4-1.

Sample attrition across the 5-year study period is shown in Figure 4-1. Of the original

1,409 participants in the sample at baseline, 1, 032 (73%) remained in the study at Time 2, which

was 3 years later. At Time 5, 910 participants (65% of the baseline sample) remained in the

study. A total of 499 participants were lost to follow-up, yielding a total sample attrition rate of 35%. Comparison of the selected and excluded as well as returning and attritted samples are shown in Tables 4-1 to 4-4.

Sample Characteristics of Selected and Excluded Samples

The study sample consisted of 1,150 females (81.6%) and 259 males (18.4%), with mean age of 74.3 years (S.D.=5.9 years), mean number of diseases of 3.1 (S.D.=1.3), and mean MMSE score of 27.3 (S.D.=2.0). The majority was Caucasian (68.9%). Comparison of the included and excluded samples indicated no significant differences between the samples with regard to age and cognitive status. Significant group differences were found for sex, race, and number of diseases diagnosed. The study sample had significantly more females, a higher proportion of non-white participants, and significantly more diagnosed medical conditions than the excluded sample (Table 4-1).

Description of Key Study Variables for Selected and Excluded Samples

A description of the pain, pain medications, and pain outcome variables for the study sample and excluded sample at baseline are presented in Tables 4-2. Descriptive data on key study variables differed significantly between the two samples. Results showed that the study sample (with diagnosed arthritis) had significantly more severe pain interference, and more painful body locations than the excluded sample. In addition, the study sample had significantly more physical, social, and emotional limitations.

Differences between Longitudinal Sample and Study Drop-outs

Between Time 1 and Time 2, a total of 377 participants dropped out of the study. Differences between the continuing and non-returning participants are shown in Table 4-3. Participants who dropped out of the study after Time 1 have significantly poorer physical functioning and emotional role functioning, lower vitality, and had depression scores. Table 4-4

shows the differences between continuing, longitudinal participants and study participants who

dropped out of the study after Time 2 (n = 122). Time 2 drop-outs had significantly lower

physical and emotional functioning than the longitudinal sample.

Descriptive Characteristics of Pain, Pain Medication, and Pain Outcomes

- **Question 1**: What are the characteristics of pain (e.g., severity of pain interference, number of pain locations), the adequacy of prescribed pain medication adequacy (e.g., PMI), and pain outcomes (e.g. physical functioning, social functioning, and emotional functioning) among older adults with arthritis at Time 1 (baseline), Time 2 (3 years later), and Time 3 (5 years later)?

The characteristics of pain, pain medications, and pain outcomes were analyzed using

descriptive statistics (means, standard deviations, and percentages). Analysis of mean differences

or associations (t-test, chi-square, and mixed models for repeated measures) were conducted to

examine whether descriptive characteristics differed across the 3 measurement occasions.

Pain. At baseline, almost 50% (48.8%) of the sample reported the presence of pain that

interfered with their activity. On average, participants described the intensity of pain interference

at baseline as 2.2 (S.D.=1.14) on a scale of 1-5 (1= no pain interference to 5 = extreme pain

interference). Participants reported an average of 1.0 (S.D. = 1.6) pain locations at baseline.

At Time 2, 3 years later, 42% (n=914) of the sample reported pain that interfered with

their activities, and this proportion increased slightly to 48% (n=780) by Time 3 (5 years later),

and were statistically significantly (χ^2 = 15.698, p = .047). At Time 2, participants reported the

severity of pain interference as a mean of 2.3, which was relatively stable at Time 3

(mean = 2.4). The severity of pain interference was significantly different (t= 10.021, p =.00)

across the 5 year period. On average, participants reported pain in a mean of .91 and 1.1

locations at Time 2 and Time 3 respectively; the number of painful locations was significantly

different across the 3 measurement occasions (t = 3.059, p =.045) (Figures 4-2 and 4-3).

Pain medication. Prescribed pain medications were assessed by reviewing all medications currently prescribed or ordered for study participants. Medications were classified according codes indicating their primary therapeutic category. For the purpose of these analyses, medications in the following classifications were considered pain medications: NSAIDs, opioids, tricyclic antidepressants, muscle relaxants, salicylates (e.g., aspirin), acetaminophen, and anti-convulsants.

At baseline, 43.9% (n=1272) of the study participants were prescribed at least one pain medication. This number decreased to 37.2% (n=861) at Time 2 and 34.1% (n=691) at Time 3. These proportions were statistically different across the 5-year study period (F =3.862, p=.021).

The distribution of pain medication classes is summarized in Figure 4-4. Of the seven different analgesic classes identified at baseline, the majority of participants (about 19%) were prescribed NSAIDs. Only about 6% of participants reported opioid analgesics in their pain regimen at baseline. These distribution of types of prescribed pain medications were statistically significant different across the 3 measurement occasions (F =27.129, p =.00).

Pain medications were evaluated for the adequacy of prescribed analgesics by computing a pain management index score (PMI). The PMI scores is used as an indicator of the adequacy of analgesic treatment and is computed based on the strongest pain medication prescribed for each participant (scored on a 3 point analgesic ladder; 1= mild, 3 = strong analgesic) Computed PMI scores can range from –3 to 3. Negative scores (scores < 0) indicate inadequate pain management and positive scores (zero and higher) indicate adequate pain management relative to the self-reported level of pain intensity.

In this sample, the mean PMI score was below zero across all points of measurement; Time 1 (Mean = -1.0, S.D. = .87), Time 2 (Mean = -.9, S.D. = .94), and Time 3 (Mean = -1.0,

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S.D. = .85). These scores indicate less adequate pain treatment at each measurement occasion, and were statistically significant for each study period (t = 9.726, p < .001, Figure 4-5).

Pain outcomes. Pain outcomes investigated were indicators of physical, social, and emotional functioning obtained from the Short-Form 36 health surveys, as well as the CES-D depression scale. Scores on these pain outcomes were analyzed using descriptive statistics as well as repeated effects mixed models to analyze change over the three study occasions. Physical functioning subscale scores ranged from 0-100 (where 0 = severe impairment and 100 = no impairment). Social functioning and emotional functioning subscales also were evaluated on a 0 to 100 scale, with lower scores indicating worse functioning. Depression scores (based on the CES-D) were evaluated on a 4-point scale, with higher scores indicating more depression.

At baseline, participants' subscale scores for physical functioning and physical role were 60.9 (S.D. = 24.3) and 60.0 (S.D. = 39.6) respectively. These scores indicated moderate limitations in the physical functioning. Participants had high social functioning scores (Mean = 83.1, S.D. =21.6), but had moderate limitations in emotional role and emotional vitality (Mean = 70.1, S.D. =37.9 and 56.9, S.D. = 20.0, respectively). In addition, participants reported mild depressive symptoms at baseline (Mean = 5.8, S.D. =5.4, Table 4-6).

In examining longitudinal change in our study predictors, we conducted repeated measures analyses using mixed effects modeling. This model has the advantage of using all available data (without listwise deletion) at each occasion of measurement. Fixed effects of time on average of each predictor variable was tested. The results were as follows. Significant time effects were found for the following variable: PMI [$F(2245.757) = 635.778$, $p < .001$]; pain interference [$F(1940.645) = 17.595$, $p<.001$], pain locations [$F(2034.222) = 5.467$, $p =.004$]; physical functioning [$F(2048.342) = 113.361$, $p< .001$]; physical role [$F(2144.971) = 30.659$, p

<.001); social functioning [F(2145.450) =25.282, p =<.001]; and emotional vitality [F(2050.929) =22.422, p <.001] (Table 4 – 7).

Relationships among Demographic Variables and Pain, Pain Medication, and Pain Outcomes

- **Question 2**: What demographic (e.g., age, sex, race) and health variables (e.g., number of diseases diagnosed) are related to pain (e.g., severity of pain interference, number of pain locations), adequacy of prescribed pain medications (e.g., PMI), and pain outcomes (e.g., physical functioning, social functioning, and emotional functioning) at each measurement point [e.g., Time 1 (baseline), Time 2 (3 years), and Time 3 (5 years)]?

Sex and race differences in mean pain, pain medications, and pain outcome variables were analyzed using t-tests. With regard to sex differences in pain experience, females reported significantly more pain interference (t = -2.023, p=.04), more number of pain sites (t = -2.083, p=.04), and had significantly less adequate pain medications prescribed (t=-2.688, p <.01) than their male counterparts. This pattern of sex differences was consistent across all three times of measurement (Table 4-8).

With regard to sex differences in pain outcomes, females had significantly lower physical functioning than males at Time 1, but there were no other significant differences in the other pain outcomes investigated. This finding held across all three times of measurement. At Time 2 and Time 3, however, females also showed significantly lower physical role functioning scores. At Time 3, females also had significantly lower emotional vitality scores. Thus, females showed significantly worse functional status scores over time than did men (Table 4-8).

For the purpose of examining race differences, race was categorized as either White or Non-white. Race differences in pain, PMI, and pain outcomes are summarized in Table 4-9. There were no significant race differences in pain interference, number of pain sites, or adequacy of pain management at any time of measurement. There were, however, significant race differences in pain outcomes. At Time 1, non-white participants had significantly lower physical

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