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Efficacy of Epidural Steroid Injections in the Treatment of Chronic Low Back Pain

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EFFICACY OF EPIDURAL STEROID INJECTIONS IN
THE TREATMENT OF CHRONIC LOW BACK PAIN

BY

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ABSTRACT

Low back pain (LBP) is the most common chronic pain in the United States. The estimated cost of evaluation and treatment, not including time lost from work, runs into the billions of dollars annually. LBP places a huge burden on the health care industry.

There are several different treatments modalities available to treat chronic LBP. Epidural steroid injections (ESIs) are one option in the treatment of chronic LBP. The traditional and more common approach for LBP management has been surgery.

A limited number of studies have been conducted to address the issue of efficacy of ESIs in the treatment of chronic LBP. These studies have been inconclusive. Further studies are needed to explore the efficacy of ESIs in the treatment of chronic LBP to provide healthcare professionals with the most current information on the most effective modalities.

Low back pain involves not only physical factors but demographic characteristics, psychosocial factors, and a multitude of psychological conditions. It is crucial that nurses with advanced education have a broad knowledge base of chronic LBP management.

Using Nola Pender’s Health Promotion Model (HPM) and the Gate Control Pain Theory, this quasi-experimental, prospective analysis investigated the correlation between the demographic characteristics of the patients with their perception of pain and quality of life prior and subsequent to ESI treatment. The results of the study were positive in regards to the efficacy of ESIs in the treatment of chronic LBP, with 67.2% of the participants answering ‘yes’ that the ESIs were effective and 32.8% answering ‘no’ that they were not effective.
Correlational analyses between demographics and patients perception of pain and level of disability revealed demographic characteristics (gender, age, BMI, race/ethnicity, marital status, preexisting health conditions, and county of residence-urban vs. rural) have a positive correlation with perception of pain and level of disability. In general the efficacy of ESIs in the treatment of chronic LBP indicated a slightly higher relief rate than previous studies.

Further studies are still needed to analyze the correlations between demographic characteristics, patient’s perception of pain, patient’s quality of life and the efficacy of ESIs in the treatment of LBP.
CHAPTER 1

INTRODUCTION

It is estimated that episodes of low back pain that are frequent or persistent have been reported in 15% of the US population, with a lifetime prevalence of 65% to 80% (Lawrence, 1998). Waddell described low back pain as a 20th century medical disaster (Kane, 1997). Epidural steroid injections (ESIs) are one option in the treatment of chronic low back pain. The traditional and more common approach for low back pain management has been surgery. Today, ESIs have become an integral part of non-surgical management of low back pain. An epidural injection is typically used to alleviate chronic low back pain (Spine, 2004). Treatment via epidural injection of corticosteroids was first described in 1952 and first reported in the United States in 1961 (Stanczak, 2003). It is postulated that corticosteroids reduce inflammation by inhibiting either the synthesis or release of a number of pro-inflammatory substances and by causing a reversible local anesthetic effect (Manchikanti, 2002). Currently, ESIs are used by multiple disciplines for the treatment of chronic low back pain. Since low back pain is the most common chronic pain in the United States, it is imperative that the efficacy of ESIs be studied, providing healthcare professionals the information necessary to treat their patients with the most effective treatment modalities available.
Statement of the Problem

The use of epidural steroid injections to relieve chronic low back pain is extremely controversial and inconclusive (Koes, 1995). Approximately 60-75% of patients receive some relief from ESIs. Benefits include relief of low back pain (LBP), reduced level of disability, reduction of analgesic consumption, improved maintenance of work status, and obviating the need for hospitalization and surgery in some patients (Chen, 2004). Although numerous articles support the benefits of ESIs for LBP, other studies dispute the efficacy of these procedures. Unfortunately, most of these studies (that failed to show benefit from the injection) were fraught with problems (Chen, 2004). More studies are needed to elucidate further the efficacy of ESIs in the treatment of chronic low back pain.

Significance of the Problem

Back pain is the most common chronic pain in the United States, affecting about 59% of adults during their lifetime (Marcus, 2003). Low back pain is the second most common cause, behind the common cold, that precipitates a person’s visit to the primary care physician’s office. It is the number one cause of disability in the youth population (less than 45 years old) and the third leading cause of disability in patients older than 45 years old (Robinson, 2002). A multitude of determinants of LBP include not only physical factors such as frequent lifting, postural stress, and vibration; social demographic characteristics and individual factors such as lifestyle and physical capacity, gender, age, race, genetic factors, height, and weight; habits such as smoking and alcohol consumption; poor general health; but also psychosocial factors including personality and a multitude of psychological conditions (Manchikanti, 2002). Small gender differences were reported in the majority of epidemiological investigations of the prevalence of LBP according to Waddell (Waddell, 1998). Wood and Bradley reported that, in the general population, at least 25% of the
people who have serious impairment due to LBP are over 65 (Wood, 1980). Lavsky-Shulan found that LBP was reported by approximately 24% of the women and 18% of the men in a study of rural elderly (Lavsky-Shulan, 1985). The estimated cost of evaluation and treatment, not including time lost from work, runs into the billions of dollars (approximately $90 billion) annually (Stanczak, 2003). Guo conducted a study that showed that the magnitude of the LBP problem is so large that even a 1% reduction in overall prevalence could considerably reduce morbidity and save billions of dollars (Guo, 1999). LBP places a huge burden on the healthcare industry; it involves time and money to treat these patients over an extended period of time. With people living longer, the issue of chronic low back pain is going to become more prevalent incorporating a majority of the population and placing a huge financial burden on the healthcare industry.

Although healthcare providers are becoming better educated about the science of pain management, there is an educational void about the art of caring for patients with chronic low back pain, who make up a population that is often difficult to treat (Marcus, 2003). The consultation itself offers a major opportunity to influence the long-term course of LBP. An essential aspect of the consultation is the involvement of the caregiver and the ability to work with and listen to the patient’s perceptions on LBP, mainly how it impacts on daily life. The opportunity for the primary care provider and the patient to arrive at a common understanding about the nature and course of LBP is of major importance for the prognosis and is highly dependent on a good patient-primary care provider relationship (Swedish Council on Technology Assessment in Health Care, 1991). It is crucial that nurses with advanced education, such as educators, consultants, clinical nurse specialists (CNSs), nurse practitioners (NPs), and case managers (CMs) have a broad knowledge base of chronic low back pain management because they will be doing the educating, consulting, managing, and treating of a large portion of the client population suffering from chronic low back pain.

Chronic back pain has become such a prevalent healthcare problem that the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has
recently revised their guidelines on chronic pain. JCAHO has called for an increased awareness of the impact of chronic low back pain and have recommended that physicians assess and treat pain complaints seriously (Marcus, 2003). Since APNs such as CNSs, NPs, and CMs are often working in physicians’ offices, clinics, and independently and are responsible for the management of their patients, it is imperative that they are able to recognize, diagnose, treat, and educate the patients with chronic pain. Management of patients with chronic pain can be both time-consuming and emotionally draining. Therefore, if the APN is able to collaborate with his/her colleagues they can form a multi-disciplinary team to address the patients’ medical, psychosocial, and disability issues. The efficacy of ESIs, if found to be high, would provide healthcare professionals with the ability to treat patients suffering from chronic LBP, avoid surgical intervention if possible, decrease the use of drug therapy, reduce their level of disability, and reduce the huge financial burden placed on the healthcare industry. If ESIs are found to be ineffective, chronic LBP will remain an issue that can be devastating physically, emotionally, and financially.

**Statement of the Purpose**

The purpose of this study is to determine the efficacy of epidural steroid injections in the treatment of patients with chronic low back pain, focusing on the patient’s perception of pain and his/her level of disability. With further knowledge regarding the efficacy of ESIs, healthcare professionals will be able to apply the findings to their practice and provide their patients with chronic low back pain the treatment modalities that have been found to be most effective. The findings will contribute to the ESI literature, which presently, is scarce.
Research Questions

The investigator will utilize a survey approach to examine the following questions:
1. What are the demographic characteristics of the patients sampled for this study?
2. To what extent do the demographic characteristics of the patients correlate with their perception of pain (POP) and their level of disability (LOD) prior and subsequent to ESI treatment?
3. What is the efficacy of ESIs in the treatment of chronic low back pain?

Hypothesis

The following hypothesis was generated by the research questions and was tested:
1. ESIs will be effective in the treatment of chronic LBP.

Operational Definitions

For the purpose of this inquiry, several terms in the research questions are defined:
1. Demographic characteristics: Age, gender, race/ethnicity, marital status, highest educational level achieved, health conditions, county of residence, and annual household income range, as indicated on the Demographic Questionnaire.
2. Chronic low back pain: Persistent or intermittent low back pain that lasts for 6 months or more (Davis, 1988) as found documented in the McGill Pain Questionnaire by the scores of the sensory component and the affective component.
3. **Epidural steroid injections (ESIs):** An injection of a steroid into the epidural space surrounding the spinal cord and spinal nerves (Chen, 2004) as documented on the Demographic Questionnaire in questions 10-14.

4. **Pain intensity:** The amount of pain experienced by an individual before and after ESI as measured by a 100 millimeter (mm) visual analog scale where one end point is “no pain” (0) and the other is “pain as severe as it could possibly be (100)” (Davis, 1988) as documented in questions 11-13 on the demographic questionnaire, section 1 on the Oswestry Questionnaire, and the total score on the McGill Pain Questionnaire.

5. **Perception:** Perception of external events varies with each individual, and is shaped during the course of one’s life based on individual experiences. Perception is defined as the ability to perceive, insight, or understanding (Boyer, 1993) as measured by sections 1, 8, and 9 on the Oswestry Questionnaire.

6. **Efficacy:** The power to produce an effect (Merriam-Webster, 1995) as determined in this study by the pain score in mm. on the Visual Analogue Scale compared to question 15 on the Demographic Questionnaire.

7. **Disability:** The loss of functional ability and activity consequent upon impairment (World Health Organization, 2000) as measured by the score on the Oswestry Questionnaire. Disability includes a patient’s perception and response to the physical change, and thus involves other components such as psychological and social factors. Levels of disability will be as interpreted as: 0%-20%-minimal disability; 21%-40%- moderate disability; 41%-60%-severe disability; 61%-80%-crippled; 81%-100%-these patients are either bed-bound or exaggerating their symptoms. These scores were categorized by Jeremy Fairbank, the author of the Oswestry low back pain disability questionnaire.

**Conceptual Framework**

*The Health Promotion Model*
Nola Pender’s Health Promotion Model (Pender, 1987) will serve as part of the theoretical framework for this study. Pender’s model identified cognitive-perceptual factors in the individual that are modified by situational, personal, and interpersonal characteristics to result in the participation in health-promoting behaviors in the presence of a cue to action (Tomey, 1998). A health promoting lifestyle is of interest to all nurses. Besides the cognitive-perceptual factors described below, the author reviewed theoretical frameworks and questionnaires and other instruments used in the research. The review will be discussed further in the theoretical section of chapter 2. The following are cognitive-perceptual factors related to health promotion: importance of health, perceived control of health, perceived self-efficacy, definition of health, perceived health status, perceived benefits of behaviors, and perceived barriers to health-promoting behaviors. Modifying factors include age, gender, education, income, body weight, family patterns of healthcare behaviors, and expectations of significant others also play roles in the determination of healthcare behaviors (Tomey, 1998). The Health Promotion Model (HPM) is based on the following theoretical propositions: prior behavior and inherited and acquired characteristics influence beliefs, affect, and enactment of health-promoting behavior; persons commit to engaging in behaviors from which they anticipate deriving personally valued benefits; persons are more likely to commit to engage in health-promoting behaviors when significant others model the behavior, expect the behavior to occur, and provide assistance and support to enable the behavior; families, peers, and health care providers are important sources of interpersonal influence that can increase or decrease commitment to and engagement in health-promoting behavior; situational influences in the external environment can increase or decrease commitment to, or participation in, health-promoting behavior (Pender, Murdaugh, & Parsons, 2002). By studying the demographic factors, the participants’ perception of pain and their level of disability, the researcher will utilize the HPM to support the findings of this study.

Based on the HPM, Pender adapted this concept to clinical nursing practice with an emphasis on the individual and his/her perceptions. Individuals
who value health highly are more likely to seek it. The individual’s perception of his/her own ability to change his/her health can motivate his/her desire for health. An individual’s current state of feeling well or feeling ill can determine the likelihood that health-promoting behaviors will be pursued. Individuals may be more inclined to begin or continue health-promoting behaviors if the benefits to such behaviors are considered high (Tomey, 1998).

The purpose of this study was to determine the efficacy of ESIs in the treatment of chronic LBP. Efficacy was measured by a change in patients’ perception of pain and level of disability from prior to ESI treatments compared to after either two or three ESI injections. The tools used to measure pain perception and level of disability were the Visual Analog Scale (VAS), the Oswestry Low Back Pain Questionnaire, and the McGill Pain Questionnaire (MPQ). Also, demographic data were obtained in the Demographic Questionnaire. The tools utilized in this study identified cognitive-perceptual factors and modifying factors in the participants. Pender’s HPM incorporates cognitive-perceptual factors, as well as modifying factors, to determine healthcare behaviors and perceptions. Wellness, as a nursing specialty, has become extremely important over the past decade. Nursing education is just beginning to use the HPM. APNs are educators and the more knowledge APNs have about the efficacy of ESIs, the better prepared they will be to treat patients with chronic LBP and promote health and wellbeing. Pender (1987) has identified health promotion as a goal for the twenty-first century: just as disease prevention was a task of the twentieth century. If pain is not managed, it can lead to both physical and psychological complications; i.e., hypertension and depression. Since pain management is a vital part of an individual’s health and well-being, the HPM will be appropriate to guide this study. In this study, the data will be collected by review of the literature and questionnaires. The findings can be used to guide clinical practice.
The Gate Control Pain Theory

This non-nursing theory, completing the framework for this study, is changing the way chronic back pain may be understood, diagnosed and treated. Gate Control is one theory of how pain is transmitted. It says that there are bundles of nerve fibers, 'gates', along the nerve pathway that must be open to allow the pain sensation to travel to the brain. The theory is that if there is a sufficient stimulus the gate closes, preventing further pain sensations from passing through. Normally, the brain perceives pain when a noxious stimulus is applied to a receptor; due to the interaction between psychological and environmental factors this is not always the case. These factors are a normal, but variable, part of our sensory and emotional experiences. The idea of pain as purely psychological or purely physical is invalid. It has been postulated that sensory neurons in the associated dorsal root ganglia are affected by the chemical injury, and the behavioral pattern changes observed in the irritating nerve root model are caused, in part, by a high level of phospholipase A2 activity initiated by inflammation (Korovessis, 2000). The mechanism of action of ESI is inhibition of phospholipase A2 activity. This provides clinical support for the use of ESIs in managing chemical irritation and inflammation around the discs and nerve roots (Lee, Weinstein, Meller et al., 1998). All pain is a mixture of these factors (Chronic Pain Haven, 2003). The Gate Control Pain Theory was proposed by Ronald Melzack and Patrick Wall in the early 1960’s. Melzack recalled the theory was not an instant hit with other pain specialists. The prevailing view back at that time was that pain was a fairly straightforward phenomenon; Melzack and Wall believed it was not quite that simple (McCabe, 2001). The Gate Control Theory prompted the introduction of the spinal cord stimulator and continues to have a significant influence on pain research (Melzack, 1967).

A more recent theory is Loeser’s ‘onion’ theory (See Fig.1.). This theorizes that the pain mechanism is a series of nested layers like an onion. The nerve stimulus or damage is at the center, the next layer is the perception of pain, then come suffering, pain behavior, and finally interaction with the environment. These
last two layers, pain behavior and interaction with the environment, are the only factors able to be clinically observed (Chronic Pain Haven, 2004). The currently accepted model of pain theory is an amalgamation of the “Onion” and the “Gate Control” theories. As can be see in Figure 1, pain involves many aspects: physiological, perceptual, psychological, and environmental. This pain theory will be used in conjunction with Nola Pender’s model to guide this study. Both theories are based on similar principles; pain is a multifactorial phenomenon and before any treatment modality can be deemed effective all factors involved must be addressed.

![Loeser’s Onion Theory (1980)](image)

*Figure 1:* Loeser’s Onion Theory as a Schematic Representation of Pain Theory.

**Assumptions**

Throughout this inquiry, the following assumptions are implied:

1. The patients will provide valid answers to the questionnaire
2. The same medication will be used for all the participants of the study.
3. Analytical assumptions will be dealt with in Chapter 3.
Limitations

A random sample of patients with chronic low back pain residing in North Florida was obtained from one pain management clinic. Varying degrees of pain, length of pain experienced, and types of patients served may have provided different results. The sample may not be representative of the chronic low back pain population. Also, pain is purely subjective.

Summary

The incidence of chronic low back pain is rising for a multitude of reasons, including the fact that people are living longer. By treating chronic low back pain effectively, health care providers can improve the quality of their patients’ lives considerably (Fishman, 2003, Swedish Council on Technology Assessment, 1991, Tomey, 1998.) As the scope of the advanced nursing practice encompasses health promotion, health maintenance, and teaching methods appropriate to the patient’s needs, the APN must possess the knowledge to assess and intervene accurately to hasten improvement or prevent the devastating effects of chronic low back pain (Marcus, 2003, Swedish Council on Technology Assessment, 1991). Pender’s HPM focuses on health promotion with an emphasis on the individual and his/her perceptions. Cognitive-perceptual factors, modifying factors, and expectations of significant others play a role in the determination of healthcare behaviors (Pender, 2002; Tomey, 1998). The Gate Control Pain Theory and Loesor’s Onion Theory describe the pathophysiology of pain and the fact that pain is a multifactorial phenomenon (Korovessis, 2000; Melzack, 1967). These theories are based on similar principles and will be used together to guide this study. According to the research that has been done thus far, the efficacy of ESIs remains controversial and inconclusive (Chen, 2004; Koes, Bouter, VanDerHeijden, 1995). The need to determine the efficacy of ESIs is imperative in order for them to be deemed an effective treatment modality for
chronic low back pain. Chapter 2 provides a review of the literature that supports this study.
CHAPTER 2
REVIEW OF LITERATURE

This chapter provides a review of the literature that supports this study. The reported efficacy of epidural steroid injections for chronic low back pain patients has been examined for this study. Aspects included are prevalence and implications in the population; the effectiveness of ESIs; and the patient’s perception of pain management and his/her level of disability. The type of patient served and the clinical setting was also examined. Finally, Nola Pender’s HPM and the Gate Control Pain Theory were utilized as the framework to guide the study. The information obtained from the review of literature is presented from the two perspectives: theoretical and empirical.

Theoretical

The Health Promotion Model

The HPM was developed to provide a framework for predicting health promoting behaviors. The model seeks to explain individual characteristics and experiences, as well as how behavior-specific cognition and affect influence these behavioral outcomes (Pender, 1996). According to Pender, there are two types of individual characteristics and experiences that affect behavioral outcomes. The first is prior related behaviors that an individual possesses. The second is personal characteristics that are comprised of biological, psychological, and socio-cultural experiences. These individual characteristics and experiences interact with the interpersonal and situational influences to shape the behavioral
outcomes (Pender, 1996). Pender focused on the individual and his/her perceptions. An individual's current state of feeling well or feeling ill can determine the likelihood that health-promoting behaviors will be pursued. Demographic factors play a role in how individuals see themselves, how they perceive pain, and how they choose to control their health. This model identifies and defines six behavior-specific cognitions and affect that may impact on health promotion behavior changes (Pender, 1996). Perceived benefits of action are a mental picture of positive consequences. If a person considering ESIs perceives the injections as a beneficial treatment to relieve chronic low back pain, he/she may be more positive about the outcome. Perceived barriers to actions are real or imagined hurdles that can decrease commitment to a plan of action. Whether the hurdles are real or imagined, a person considering ESIs must be committed to the series of injections and not allow the hurdles to stand in the way. Perceived self-efficacy is judgment of one's ability to perform a specific task at a particular level. A person should believe that tasks can be accomplished, even if they have not been able to perform the task in the past. ESIs may provide him/her the ability to perform the task, due to the decrease in their pain. Activity related affect is subjective feelings prior to, during, and after a behavior. If a person was not able to stand for more than 10 minutes without pain prior to ESI and was able to stand for 30 minutes after ESI, he/she should feel positive. Interpersonal influences are ideas concerning the beliefs and attitudes of others. If a person who is considering ESIs talks to a person who had a positive experience with ESIs, he/she should be more positive also. Situational influences are perceptions of the options available and features of the surroundings that can affect a behavior. If a person views ESIs as a minimally invasive, fairly painless procedure, providing relief, and short recovery time, he/she may be more willing to try the ESIs.

The focus of the HPM is to move people to an improved state of health and well-being (Pender, 2002). The goal of ESIs is to provide pain relief and improve a person's quality of life. According to Dr. Pender, advanced practice nurses (APNs) must take leadership in incorporating the findings of research
about health promotion into clinical practice and protocols. As an APN, one must understand the dynamics of behavior through research to build interventions with huge potential effectiveness (Pender, 2002). Pender’s HPM incorporates multitude of factors that will influence health outcomes. Pender’s HPM has been utilized by researchers and graduate students as a framework to guide their studies (Adams, Bowden, Humphrey & McAdams, 2000; Lambert, Fearing, Bell & Newton, 2002; Neely, 1998). The HPM was chosen to guide this study since the purpose focuses on the patient’s perception of pain and his/her level of disability. Three studies will be discussed under the empirical section of this chapter.

*The Gate Control Pain Theory*

Electrical stimulation of the nervous system arose as a direct consequence of the Gate Control Pain Theory in 1965. In Melzack and Wall’s Gate Control Pain Theory (GCPT), there are postulated gating mechanisms located within the dorsal aspect of the spinal cord (Melzack & Wall, 1965). Pain messages travel along the peripheral nervous system until they reach the spinal cord. The GCPT proposes that there are “gates” on the bundle of nerve fibers in the spinal cord between the peripheral nerves and the brain (Deardorff, 2003). These spinal nerve gates control the flow of pain messages from the peripheral nerves to the brain. Many factors determine how the spinal nerve gates will manage the pain signal. These factors include the intensity of the pain message, competition from other incoming nerve messages (such as touch, vibration, heat, etc), and signals from the brain telling the spinal cord to increase or decrease the priority of the pain signal. Depending on how the gate processes the signal, the message can be handled in any of the following ways: allowed to pass directly to the brain, altered prior to being forwarded to the brain, or prevented from reaching the brain. Once a pain signal reaches the brain, several things can happen. Certain parts of the brain stem (which connects the brain to the spinal cord) can inhibit or muffle incoming pain signals by the production of endorphins, which naturally occur in the body. Stress, excitement, and high impact exercises may stimulate the production of endorphins Pain messages
travel along different pathways in the brain. Chronic pain tends to move along a “slow” pathway. Once they reach the brain, however, the slow pain messages take a pathway to the hypothalamus and limbic system. The hypothalamus releases certain stress hormones in the body, while the limbic system processes emotions (Deardorff, 2003). This is one reason why chronic back pain is often associated with stress, depression, and anxiety.

There are multiple factors that have to be considered when dealing with pain: the normal physiological response, psychological issues, and environmental conditions. According to the GCPT, one’s thoughts, beliefs, and emotions may affect how much pain one feels from a given physical sensation. The fundamental basis for this theory is the belief that psychological, as well as physical factors guide the brain’s interpretation of painful sensations and the subsequent response (Ullrich & Burke, 1999). Many pain sufferers find that their pain is worst when they feel depressed and hopeless - feelings that may open the pain gate. They find that it’s not bothersome when they are focused on doing something that demands attention i.e., working or studying. Although the physical cause and level of pain may be identical to the previous episode, the perception of pain is dramatically different. Perception of pain is one of the key components of this research study.

Pain signals can be of different types (slow or fast); can travel along different pathways in the brain; and can be influenced by such things as endorphins in the brain stem (Ullrich & Burke, 1999). The brain can send signals down the spinal cord to open and close the nerve gates. Factors that can open or close the pain gates as messages move up and down the spinal cord include sensory (physical being and activities), cognitive (thoughts), or emotional (feelings). The events and conditions that may open the pain gates and cause more suffering include sensory factors, such as injury, inactivity, long-term narcotic use, and poor pacing of activities; cognitive factors, such as focusing on the chronic pain, having no outside interests or distractions, worrying about the pain, and other negative thoughts; and emotional factors, such as depression, anger, anxiety, stress, hopelessness, and helplessness. Alternatively, influences
that can close the pain gates and reduce suffering include sensory factors, such as increasing activities and short-term use of pain medication; cognitive factors, such as outside interests, thoughts that help the patient cope with the pain, and distracting oneself from the chronic pain; and emotional factors such as having a positive attitude, overcoming depression, and taking control of one’s chronic pain and life (Ullrich & Burke, 1999).

Chronic pain involves inflammation which can be caused by a high level of phospholipase A2 and the mechanism of action of ESI is inhibition of phospholipase A2 (PLA2). PLA2 is an inflammatory mediator which regulates free arachidonic acid and eicosanoid production and plays a role in a variety of musculoskeletal conditions (Kapural, McLain, & Mekhail, 2004). Levels are elevated in the serum and synovium of patients with rheumatoid arthritis, and high levels have also been found in the human intervertebral disc (Ginsburg, Schuger, & Varani, 1989). PLA2 may play a role in painful disc disease and may have humoral effects on local and remote neural tissues (Dobrow, Franson, Goldthwaite, Saal, & White, 1990). ESIs have been used to treat various spinal pathologies generating low back pain. The therapeutic benefits of ESI are attributed to reduction of inflammation caused by the chemicals released from the ruptured disc such as phospholipase A2, which causes nerve root irritation and swelling (Tandon, Weaver, & Gordin, 2002). Chronic pain can cause inflammation, which can be caused by a high level of phospholipase A2, which can be inhibited by ESIs due to their ability to inhibit phospholipase A2. The HPM and the GCPT will be used together to guide this study.

Overview of Efficacy of Epidural Steroid Injections

A review of the literature showed several studies that looked at the efficacy of epidural steroid injections related to patients with chronic low back pain (Koes et al., 1995; Rocco et al., 1989; Yates et al., 1978). However, studies that measured the benefits of steroids on low back pain are conflicting (Chen, 2004; Spaccarelli, 1996). Another issue is the limited number of studies that have
been conducted on the use of lumbar epidural steroid injections (Koes et al., 1995).

Technology and knowledge exist today to provide satisfactory pain management in most people who suffer from low back pain, but studies indicate that adequate pain management is still controversial (Chen, 2004, Koes et al., 1995; Rydevik, Bjorn, Cohen, & Kostuik, 1997). Spaccarelli (1996) indicated there has been considerable debate over the last few years as to whether epidural steroid injections work. Swerdlow & Sayle-Creer (1970) found that epidurally injected steroids may remain in situ for more than 2 weeks and repeating the injection in less than 2 weeks may not be beneficial according to their study. On the basis of data from Green and associates (1980), on patients who had relief of pain after ESI, they reported that improvement was noted in 2 days or less in 37% and in 4 to 6 days in 63%. Various reports of clinical effectiveness include randomized clinical trials with, or without, blinding; prospective trials (Breivik et al., 1976; Mathews et al., 1987; Yates et al., 1978); retrospective studies, either randomized or nonrandomized (Ridley et al., 1988; Rocco et al., 1989); case reports (Bush & Hillier, 1991; Cuckler et al., 1985); and, finally meta analysis (Manchikanti, Slipma, & Fellows, 2002). Unfortunately, clinical trials of the efficacy of commonly used interventions in low back pain reviewed by Koes et al.; 1995, Van Tulder et al.; 1995, and others led to the conclusion that the methodological quality in these studies was disappointingly low (Manchikanti, Slipma, & Fellows, 2002). Further, most of the studies of ESIs have been performed by multiple speciality groups, i.e., sports medicine, orthopedics, and rehabilitation specialists (rarely including interventional pain specialists) and without fluoroscopy. Epidural administration of steroids is ideally performed under fluoroscopic guidance (Manchikanti, Bakhit, & Pakanati, 1999). One review examined 12 randomized trials of epidural steroid injections. The author, Koes, used a grading system to test the methodology of each study. One half of the studies showed no improvement. Most of the studies did not examine long-term outcomes: Only six trials included a follow-up measurement after 6 months or longer. In most of these trials no long-term
effects were found. The benefits of epidural steroid injections, if any, seem to be of short duration only (Koes et al., 1995).

Only 12 published controlled, randomized studies of the use of lumbar epidural steroid injections were found. Koes et al; 1995, assessed the methodological quality of 12 of these studies and found that 8 of the 12 had a methodological score of less than 50 on a 100-point scale, indicating significant methodological flaws. Of the four best studies, two reported positive (beneficial) results (Breivik, 1976; Mathews et al., 1987) and two reported negative results (Cuckler et al., 1985; Snoek et al., 1977). He stated that most of the studies (that failed to show benefit from the injection) were plagued with problems. Aside from less than desired research methodology, most of these studies did not use fluoroscopy and radiographic contrast to document accurate placement of the injected substance into the epidural space. According to Chen, 2004, studies have reported that without fluoroscopy and radiographic contrast confirmation, incorrect injection placement (i.e., not into the epidural space) occurs in 30% of cases, on average, even with the experienced injectionist. These methodological problems most likely are the major factors leading to the mixed assessment of ESIs.

In the United States, ESIs have become an integral component in the care algorithms of managed care providers. However, as stated previously, the value of therapeutic corticosteroid injection for the treatment of chronic low back pain has not been proven (Rydevik, Bjorn, Cohen & Kostuik, 1997).

Chronic Low Back Pain

Chronic low back pain (LBP) is usually defined by symptoms of 6 months duration, or more (Davis, 1988). Low back pain is second only to upper respiratory illness as a cause for visiting a physician. Up to two thirds of the population will have low back pain symptoms at some time in their lives (Levin, 2003). Five percent of the patients will become disabled from back pain spending approximately $36 billion per year for medical management (Zenz, 2000). There are a lot of hypotheses about why low back pain is common. Basic biologists
may talk about it in terms of pressure on the spine. Gravity puts a lot of pressure on the spine, and specifically the lower spine, which is where most back pain occurs. Among individuals with a chronic LBP without neurological deficits, a number of factors play a role in length of disability. Recurrent LBP and prolonged disability tend to correlate with prior history of LBP, advancing age, job dissatisfaction, emotional distress, heavy or repetitive lifting and physical work, prolonged sitting or standing, and the presence of a worker’s compensation claim or pending litigation (Levin, 2003). Women, especially, suffer from LBP because of the onset of osteoporosis after menopause (Melton, Kan, & Frye, 1989). Obesity is probably an important risk factor for developing LBP (Deyo & Bass, 1989). Our society is plagued with a population of obese people (Flegal, Carroll, & Kuczmarski, 1998).

**Epidural Steroid Injections**

An epidural steroid injection places corticosteroids around the spinal nerves. ESIs are used to treat conditions that affect the spine from the neck to the lower back. These conditions include herniated discs, protruding discs, degenerated discs, osteoarthritis of the spine, spinal stenosis, and scar tissue or other changes following neck or lower back surgery. Patients’ complaints can include pain in the neck, shoulder, mid or lower back, arms, or legs. Patients may also have complaints of numbness or weakness in the extremities. While the effects of the injection tend to be temporary - providing relief from pain from 1 week up to 1 year – an epidural can be very beneficial for patients during an episode of severe back pain (Woodward, Herring, & Windsor, 2000).

With the patient lying flat, face down, on an x-ray table, the needle or catheter is placed at the appropriate segment of the spinal column with the use of a rotating x-ray machine called a fluoroscope. A front to back and side to side image is needed to determine the position of the needle in three dimensions. After determining the needle tip position with respect to the bony landmarks, contrast dye is injected to help confirm placement. After dye confirms proper placement, the medications are then injected. X-ray guidance significantly
improves accuracy and safety. The ESI procedure takes approximately 15
minutes (Kumar & Agorastides, 2000).

Most patients will experience some injection site tenderness for 1-3 days
following the injection. This can be remedied with an ice pack on the injection site
immediately following the procedure, and heat if the pain persists after 24 hours.
Headaches may occur if the needle enters the spinal fluid. This occurs much
more commonly when procedures are performed without x-ray guidance.
Infection, bleeding, and nerve injury are very rarely reported side effects (Stein,
2002). Diabetics must carefully monitor their blood sugar after the procedure
because the ESI can dramatically increase their blood glucose levels (Botwin et
al., 2000).

It usually takes 1-3 days for the corticosteroids to have their effect.
However, some patients take up to 7 days to notice the full effect. Most patients
experience partial relief after the first injection. Subsequent injections are
performed to increase the degree of pain relief (Stein, 2002). The injected
corticosteroids are active for about a month. There is no definitive research to
dictate the frequency of ESIs for low back pain. In general, it is considered
reasonable to perform up to three injections per year (Staehler, 2000). Typically,
ESIs are done in 2- week intervals. However, there is not a general consensus
in the medical community as to whether or not a series of injections need always
be performed (Bogduk, Christophidis, & Cherry, 1994).

Benefits of ESIs include relief of low back pain (LBP), reduced level of
disability, reduction of analgesic consumption, improved maintenance of work
status, and preventing the need for hospitalization and surgery in many patients.
Although several articles support the benefit of ESIs for LBP (Breivik, 1976;
Mathews et al., 1987; Yates, 1978), other studies dispute the efficacy of these
procedures (Cuckler et al., 1985; Serrao et al., 1992). As stated above,
unfortunately, most of these studies (that failed to show benefit from the injection)
were fraught with problems (Chen, 2004).

Under most circumstances, a person cannot have ESIs if they have any of
the following conditions: a local or systemic infection, a severe bleeding disorder
or are taking oral anti-coagulants (e.g., Coumadin), have uncontrolled diabetes, congestive heart failure, or pregnancy, if an x-ray is to be used (Cannon, 2003). If a person is taking an oral anti-coagulant it may be stopped 7 days prior to the procedure and, if necessary, the patient may be placed on subcutaneous heparin therapy in the interim (Cannon, 2003).

How then did ESIs become such a popular treatment for low back pain? Its popularity seems to relate, to a large degree, to a means of quickly dealing with a patient presenting with back pain. The only rationale for ESI appears to be based on the anti-inflammatory action of steroids. There remains considerable controversy over the efficacy of ESIs universally (Rydevik, 1997).

**Physiology and Pharmacology of Corticosteroids**

Cortisone is a type of steroid that is produced naturally by a gland in the body, called the adrenal gland. Cortisone is released from the adrenal gland when the body is under stress. Natural cortisone is released into the bloodstream and is relatively short acting. Injectable cortisone is synthetically produced and has many different trade names, such as, Celestone and Kenalog (Cluett, 2004). Corticosteroids act to regulate salt and water balance, as well as decrease inflammation. The anti-inflammatory action helps to reduce pain by blocking inflammatory chemicals that sensitize nerves and nerve receptors. Saal and colleagues (1990) determined that material from lumbar herniations contains phospholipase A2 that directly induces membrane injury. They hypothesized that corticosteroids may decrease inflammation by inhibiting the synthesis of phospholipase A2, a phenomenon that decreases the production of multiple mediators of inflammation (Spaccarelli, 1996). It usually takes 1-3 days for the corticosteroids to have their effect. Corticosteroids are fat soluble and generally are active for about 1 month. Injections may offer some pain relief for up to 4 to 6 months (Cluett, 2004).

In the short term, corticosteroids can make a person feel dramatically better. But when used for many years, they may become less effective and cause serious damage to cartilage and ligaments, easy bruising, thinning of
bones, cataracts, weight gain, a round face, and high blood pressure. At the two clinics utilized for this study, ESIs are usually administered in a series of 3 injections per 6-12 months, according to the medical directors. The medical directors stated that they rarely see patients for more than 2 series of injections from their professional experiences.

Demographic Factors

Age, gender, race/ethnicity, marital status, highest educational level achieved, health conditions, county of residence, annual household income, and current employment status are the demographic variables that were reviewed in the literature for this study. These characteristics will be looked at alone and in conjunction with other variables.

A United States national survey of physician visits among patients age 75, or older, revealed that back pain is the third most frequently reported symptom in general and the most commonly reported in the musculoskeletal system (Koch & Smith, 1985). Increasing age has been associated with an increase in LBP. The passage of time has been shown to correlate with disc degeneration. Dehydration and desiccation of the disc, especially in the nucleus, become prominent in the middle-aged and the elderly (Manchikanti et al; 2000).

Race has been addressed in regard to the prevalence of LBP; however, confounding variables such as obesity, heavy physical occupation, and smoking have skewed the findings (Bonham, 2001). The effect of obesity has been studied by Leboeuf-Yde (2000); it has been theorized that the increased mechanical demands resulting from obesity cause LBP through excessive wear and tear.

Gatchel et al. (1989) showed a much higher number of married patients than divorced or single patients (61% vs. 39%) with LBP. These trends may be due to very complex relationships between physical, psychosocial, and economic factors (Waddell, 1998).

The connection between educational level and health status was examined in a 1997 study by Leigh and Dhir. They hypothesized that those with
a higher level of education have a higher level of self-efficacy that leads to good health and health promotion. Education is also closely associated with income. Those with more education usually have higher paying and safer occupations and have low unemployment rates throughout their lives (Leigh & Dhir, 1997). Troup and Edwards (1985), reviewed many studies and suggested that LBP is more common in people performing heavy manual jobs. In addition, lumbar disc degeneration was to have increased by the occupational loads (Luoma, Raininko et al., & Riihimaki, 1998).

Gender differences and pain perception can be examined. As a rule, women have a higher pain tolerance than men. Men tend to delay seeking medical attention more than women do. Men are more likely to perform manual labor increasing their risk of physical injury (Anderson, Ejlertsson, & Leden, 1993). However, Oleinick et al. (1996) analyzed nine covariates for their role as risk factors for return to work (RTW) after work-related low back injury. In the acute phase of injury, female workers over the age of 35 years were less likely to go back to work (Oleinick, 1996). In the chronic phase (>8 weeks), gender had no effect on outcome. There is limited and conflicting evidence that gender correlates with incidence of chronic pain and with disablement associated with chronic pain (Hunter, 2001). Individuals with a history of arthritis, osteoporosis, scoliosis, or any other pre-existing back problems are considered to be at risk of recurrent or persistent low back pain. Both retrospective and prospective studies have demonstrated increased risk of experiencing episodes of LBP in individuals with a history of back pain (Bigos, 1991; DeGirolamo, 1991; Thomas, 1999).

The relationship between occupational risk factors and low back pain is not simple because exposure is usually difficult and sometimes impossible to quantify (Manchikanti, 2000). There are five job-related factors that load the spine which may relate to back pain: back injury and work loss, which include heavy manual work, lifting, twisting, sitting, and driving (Waddell, 1998).
Pathophysiology of Low Back Pain

The lumbosacral spine supports the upper body in a balanced, upright position while allowing movement. In an upright position, maintenance of erect posture is achieved through a balance of the pressure of the intervertebral discs, the stretch placed on the longitudinal and facet joint ligaments, and the sustained involuntary tone generated by the surrounding lumbosacral and abdominal muscles. The balance of the spine is also related to the physiologic curves in the cervical, thoracic, and lumbosacral areas of the vertebral column. During flexion and extension of the lumbar spine, tension is produced in the paraspinous, hamstring, and gluteal muscles, the fasciae that surround the muscles, and the ligaments that support the vertebral bodies and discs (Dunphy & Winland-Brown, 2001). LBP may also occur during motion, if the stress is greater than the supporting structures can sustain, or if the components of the lumbosacral spine are abnormal. If the lumbosacral spine is in a mechanically disadvantaged position (rotated, flexed) the force may not need to be that great to cause a disruption of annular fibers. These fibers may tear when stressed, which in turn causes degeneration of the disc (Dunphy & Winland-Brown, 2001).

The most commonly encountered causes of LBP include lumbar disc herniation, degenerative disc disease, spondylolysis, spondylolisthesis, and spinal stenosis. In a herniated disc the ligament and posterior capsule of the disc usually are torn, allowing the gelatinous material (the nucleus pulposus) to extrude. This extrusion compresses the nerve root. Occasionally the injury tears the entire disc loose, and it protrudes onto the nerve root or compresses the spinal cord. One or more nerve roots may be compressed. Tissue injury, from fractures or strains of the musculoskeletal system is accompanied by local manifestations of inflammation (McCance, Huether & Leo, 2002).
Empirical Review

The Health Promotion Model

A study that utilized the framework of Pender’s HPM was a comparative study of prostate screening health beliefs and practices between African American and Caucasian men. Pender’s HPM stipulated a relationship between personal perceived health variables and actual health-promoting behaviors (Pender, 1997). In relation to this study, the goal was to empower the men to make their personal decision to participate in the health-promoting behavior of annual prostate screening, based on current information. Fifty-five African American and 49 Caucasian men, over the age of 45, completed a self-administered questionnaire for this study. The convenience sample was recruited from fraternal organizations, health fairs, and churches in a Midwestern community. The results stated that African American males were less likely to have had a digital rectal examination (75%) than were Caucasians (82%). Sixty-nine percent of Caucasians and 71% of African Americans reported having the PSA (prostate specific antigen) done. Twenty-six percent of the entire sample indicated they had never had the test. Sixty-seven percent of the sample had the PSA drawn as part of a routine physical exam, and 15% had the test done because of prostate symptoms. Ninety-eight percent of the total sample indicated they were at least fairly comfortable discussing health problems with their health care provider. Caucasians were slightly less comfortable than African Americans. This study showed that there were still a significant number of men reporting never having had a PSA test done, even though 75% had knowledge that the test is recommended for early detection of prostate cancer. Therefore, continued efforts by advanced practice nurses are still needed to educate and increase screening participation among both African American and Caucasian men. Pender’s HPM was appropriate for this study because the goal was to empower the men to make their personal decision to participate in the health-promoting behavior of annual prostate screening (Lambert, Fearing, Bell & Newton, 2002).
Another study was a master’s thesis written by a registered nurse (Neely, 1998). The purpose of this descriptive study was to describe the current status of primary care nurse practitioners (NPs) in the performance of smoking cessation counseling (SCC). The target population (\(N = 144\)) consisted of members of an NP association in southwestern Pennsylvania (PA). Data were collected using a yes/no questionnaire. Pender’s HPM was used to guide this study. Of the 144 practitioners surveyed, 20% (\(n = 29\)) returned usable questionnaires that met the criteria for inclusion in this study. Ninety-three percent of NPs established smoking status at every contact with their patients. Only 86% reported asking if the individual was interested in stopping smoking now. Quantitative analysis of the surveys revealed the NPs were most likely to provide interventions to stop smoking and least likely to arrange follow-up. Correlation of survey results and reported practices to the HPM (Pender, 1996) concepts suggested that health promotion is an integral part of the NP’s SCC practices. Because commitment to a plan of action is key to follow-up and preventing relapse, this supports a weakness in NP performance of follow-up interventions (Neely, 1998).

A third study was on social support and health promotion lifestyles of rural women (Adams, Bowden, Humphrey & McAdams, 2000). The framework for the descriptive correlational study was Pender’s (1996) revised HPM. The study participants were 400 women whose names were obtained by a simple, random sampling of the voter registration list of a rural county in a southeastern state responding to questionnaires. The study required a sample size of 100 study participants to have a power level of .80. Of the 6,367 registered female voters, 400 women were selected with the inclusionary criteria of the ability to read and write English. Social support was found to be a strong predictor of whether an individual engaged in health promotion. Pender’s (1996) perspective that social support is directly related to health and well-being was affirmed by this research. Since only 10.8% of the sample respondents were non-Caucasian, no conclusions regarding race as a demographic variable that predicts health-promoting lifestyle was drawn. Education was one of the factors that showed a statistically significant relationship critical to social support, health promotion
lifestyles, and the subscale of health responsibility. The researchers postulated that one possible explanation for the sample’s high level of educational preparation may have been the county’s close approximation to a major metropolitan area and a major university. The data strongly supported Pender’s (1996) HPM and the significant role that social support plays in promoting a healthy lifestyle (Adams, Bowden, Humphrey & McAdams, 2000).

The Gate Control Pain Theory (GCPT)

This study was on the effect of topical lidocaine anesthetic on reported pain in women who undergo needle wire localization prior to breast biopsy (Olbrys, 2001). The GCPT was utilized to guide this study. The research sample was limited to 40 female patients who were scheduled for needle wire localization. Twenty women were assigned to the experimental group and 20 were assigned to the control group. The experimental group received a lidocaine cream; the control group received a similar cream without the active lidocaine ingredient. The results produced a test statistic of -2.74, greater than the critical t-value of -1.68. Thus, the null hypothesis was rejected as there was sufficient evidence to support the research hypothesis that women who received the lidocaine cream would have significantly less pain than women who received the placebo cream. The mechanism described in the GCPT was the lidocaine cream and the study showed that the mechanism decreased sensory impulses generated by injury-sensitive receptors (Olbrys, 2001).

This next study looked at the relationship between electrical stimulation and the GCPT. Electrical stimulation of the nervous system arose as a direct consequence of the GCPT. In 1997, researchers conducted a prospective study of 45 patients with symptoms recurrent following lumbar discectomy. These patients were then randomized to either spinal cord stimulation or re-operation, and were followed over a mean of 3 years. In those patients who underwent spinal cord stimulation, 47% reported significant relief. Those re-operated had significant relief only 12% of the time. This important study underscored the
potential usefulness of electrical stimulation in treatment of low back pain as much as it does the apparent futility of re-operation (UMHS Neurosurgery, 2004).

Overview of Efficacy of Epidural Steroid Injections

In a prospective, double-blind study of 100 patients the injection of methylprednisolone into the epidural space by the lumbar route was compared with normal saline injected into the interspinous ligament (Mathews, Mills, Jenkins, Grimes, Morkel, Mathews, Scott & Sittampalam, 1987). All patients aged 18-60 years were screened with a general medical examination and a specific history and examination relating to the spine. Radiographs of the lumbar spine, blood count, erythrocyte sedimentation rate, alkaline phosphatase, and routine urine test were obtained. Patients with abnormalities or complicating problems were excluded from the study. Twenty-three patients were in the treatment group and 34 patients were in the control group. An epidural injection of 20 ml. 0.125% marcaine and 2 ml. of methylprednisolone was given at 2 week intervals, up to three times, as needed, to the treatment group. Control patients were given an injection of 2 ml. of normal saline over the sacral hiatus or into a tender spot. The first assessment after the three injections was at 1 month. At this stage, 14/21 (67%) treated and 18/32 (56%) controls had recovered, the difference not reaching statistical significance. At 3 months, the treated group was shown to be significantly more painfree (p < 0.05). No significant differences were demonstrated at any other stage. Epidural anesthetic and steroid injections have a dual action caused by the rapidly-acting anesthetic and the delayed effect of the steroid. A larger proportion of the treated patients were improved at every assessment point up to 1 year, with the most marked effect at 3 months (Mathews, Mills, Jenkins, Grimes, Morkel, Mathews, Scott & Sittampalam, 1987).

In another study by Bowman, Grahame, Newman, Wedderbum & Whaley (1993), 35 patients were recruited from rheumatology outpatient clinics between April 1988 and March 1989. Selection was made on the basis of a clinical history and signs consistent with nerve compression. Patients were assessed clinically before the procedure and again 1 week later. They also filled out questionnaires
at these times and a postal questionnaire 3 months later. The procedure was performed using methylprednisilone injected into the lumbar epidural space. Analyses were carried out using two-tailed paired $t$ tests, analysis of variance, and correlation tables using Pearson coefficients of correlation. The study included 19 men and 16 women. The median age was 41 years (range 20-75 years). The median duration of their low back pain was 2 years (range 3 months to 20 years). A $t$ test indicated that the clinical score showed a reduction from before to 1 week after the procedure ($t = 6.64$, $df = 32$, $P < 0.001$). The patients were asked to rate their improvement on a 4-point scale at 1 week: 5 had no improvement, 16 had some improvement, 11 were markedly improved, and 1 was completely cured (missing data = 2). At 3 months (on a 5-point scale), 17 had had only temporary or no improvement, while 13 had had some persisting improvement ever since (missing data = 5). At 3 months, five patients rated their treatment totally unsatisfactory to poor, ten rated it satisfactory, five rated it good, and nine rated it excellent (missing data = 6). At 3 months, 22 people were undergoing no treatment or conservative treatments only (narcotics, hydrotherapy, physiotherapy, repeat epidural), while seven were waiting to see an orthopedic surgeon or had done so for consideration of a back operation (missing data = 6).

Epidural injection of corticosteroids has been used with success in a proportion of patients with back pain, as demonstrated by two double-blind controlled trials (Spaccarelli, 1996). These two studies (Dilke et al., 1973; Breivik et al., 1976) as reviewed by Spaccarelli showed significant improvement in pain relief 1-3 weeks after the procedure, compared to controls, and one showed a greater likelihood of return to work at 3 months. The researchers held the view that epidural injections of corticosteroid act during the short to medium term (1 week to 3 months). It, therefore, is not surprising that two other studies which Spaccarelli reviewed (Snoek et al., 1977; Cuckler et al., 1985) that examined the patients at 24-48 hours (too early) and then at 8-30 months (too late) failed to find a benefit (Spaccarelli, 1996). Nevertheless, at 3 months, 13 of 30 patients felt there had been some persisting improvement, markedly so in 5, and most
patients were still being treated conservatively, with only 7 of 30 being considered for surgery. Therefore, to conclude, epidural corticosteroid injection is an effective, well-tolerated procedure in some, but not for all patients with low back pain.

Chronic Low Back Pain

In one study on chronic LBP, 463 new patients were followed by a primary care physician regarding their pain. Pain and difficulty in performing activities of daily living were reported by 73% of patients at initial evaluation and by 50% after both 3 months and 12 months. In addition, 29% of patients continued to report ongoing pain or disability at 3 months, and 25% at 12 months. Although patients did not return for appointments, pain or significant disability, or both, continued in 79% of cases after 3 months and 75% after 12 months (Marcus, 2003). The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) recently revised guidelines called for an increased awareness of the impact of chronic low back pain and recommended that physicians assess and treat pain complaints seriously.

Physiology and Pharmacology of Corticosteroids

The study of the pharmacokinetics of corticosteroids is complex. The first cases in the United States were reported by Goebert and colleagues (1961), who believed that painful nerve root compression syndromes were associated with inflammation and edema. These investigators observed roentgenologic evidence that fluid injected into the epidural space followed the nerves out of the intravertebral foramens and along the peripheral nerves. Thus, they believed that this finding supported administration of a corticosteroid in such a way that its anti-inflammatory action could be concentrated at the pathologic site. In this report, 113 patients received corticosteroid epidural injections and results were good in 72%.

In 1978, Yates described a prospective, randomized, crossover study of patients with low back pain. In this study, four types of injections were used in the
lumbar epidural space: 50 mL of 0.5% lidocaine, 50 mL of isotonic saline with 3 mL of triamcinolone, and 47 mL of 0.5% lidocaine with 3 mL of triamcinolone. One of each type of injection was given in a random sequence until symptoms were relieved; thus, the patients served as their own control. A total of 49 injections were given to 20 patients. Improvement in lumbar spinal mobility and straight-leg raising was noted after the corticosteroid injections but not after the injections without corticosteroids. Subjective improvement correlated with these objective criteria. The role of systemic absorption of epidural steroids has been explored in only a handful of reports. Jacobs studied 12 patients following administration of a single lumbar ESI of Kenalog 80 mg. and found no absorption of the corticosteroid into the systemic circulation (Jacobs, Pullan, & Potter, 1983.

Pathophysiology of Low Back Pain

The pathophysiologic emergence of chronic LBP is as unclear as its diagnostic criteria. It is mostly accepted that muscular systems, as well as connective tissues and neural systems, are involved in the pathophysiology of chronic LBP. A randomized controlled trial to compare lumbar extension exercise and whole-body vibration exercise for chronic LBP was conducted by Rittweger, Just, Kautzsch, Reeg & Felsenberg (2002). In this study, 60 patients with chronic LBP devoid of specific spine diseases, who had a mean age of 51.7 years and a pain history of 13.1 years, practiced either isodynamic lumbar extension or vibration exercise for 3 months. Sixty patients with chronic LBP were recruited by a local newspaper announcement. After the patients had given their informed consent, they were randomly assigned to a group that practiced whole-body vibration exercise (VbX) or a group that practiced isodynamic lumbar extension exercise (LEX). The primary measures of outcome were pain sensation and pain relief. Pain sensation was assessed on a visual analogue scale ranging from 0 (pain free) to 100 (maximum pain). In the LEX group, seven participants had an increased lumbar range of motion after completion of the program, whereas only three participants in the VbX group had a gain in range of motion. This difference, however, was not significant. The current data indicate
that poor lumbar muscle force probably is not the exclusive cause of chronic LBP (Rittweger, Just, Kautzsch, Reeg & Felsenberg, 2002).

**Summary**

Studies that looked at the efficacy of ESIs are conflicting and indicate that adequate pain management is still controversial (Rydevik, Bjorn, Cohen, & Kostuik, 1997). From the early 1970’s until the mid 1990’s, only 12 controlled, randomized studies of the use of ESIs were published (Koes, Scholten, Mens, & Bouter, 1995). Few studies have been conducted since the mid 1990’s; however, one study conducted by Boswell, Cruz, Grabinsky, Kooser, & Rosenberg (2001), concluded that ESI’s may provide significant relief of pain even one year after the initial injection. The effects of ESI tend to be temporary- providing relief from 1 week up to 1 year; an epidural can be very beneficial for patients during an episode of severe back pain (Woodward, Herring, & Windsor, 2000). Benefits of ESIs include relief of LBP, reduced level of disability, reduction of analgesic consumption, improved maintenance of work status, and preventing the need for hospitalization and surgery in many patients (Chen, 2004). According to Chen (2004), the studies that failed to show benefit of ESIs were fraught with problems; i. e. non-use of fluoroscopy and radiographic contrast.

According to Pender’s Health Promotion Model, individual characteristics and experiences interact with the interpersonal and situational influences to shape the behavioral outcomes (Pender, 1996). Demographic factors play a role in how individuals see themselves, how they perceive pain, and how they choose to control their health (Pender, 1996). The HPM was chosen to guide this study since the purpose focuses on the patient’s perception of pain and his/her level of disability. The fundamental basis of the GCPT is the belief that psychological, as well as physical factors guide the brain’s interpretation of painful sensations and the subsequent response (Ullrich & Burke, 1999). Loesor’s Onion Theory also theorizes that pain involves many aspects: physiological, perceptual, psychological, and environmental.
Further study on the efficacy of ESIs in the treatment of chronic LBP is warranted due to the scarcity of research found reported in a complete review of the literature (Koes et al., 1995). Chapter 3 discusses the study methodology. The research design, setting, sampling plan and protection of human subjects are discussed in detail. The instruments and procedure that were used to collect the data and statistical analysis of the obtained data are also discussed.
CHAPTER 3

METHODOLOGY

This chapter describes the methodology of the study. The design, setting, population and sampling instruments to be used for collecting data and procedures are included in this discussion. This chapter also addresses the efforts that will be made to protect the confidentiality of the human subjects in the study.

Design

Few studies have been published investigating the efficacy of ESIs. Additionally, the results of those studies were either contradictory or inconclusive. Efficacy for the purposes of this study was operationalized by a change in patients' perception of pain and level of disability from prior to ESI treatments and 2-4 months following ESI. This study was a quasi-experimental, prospective analysis of repeated measures on the dependent variables: patients’ perception of pain and patients’ level of disability. The primary independent variable for this study is the ESI treatment. Other variables, e.g., age, gender, height, weight, marital status, race/ethnicity, highest educational level achieved, health conditions, county of residence, and annual income range which are typically considered to be independent variables and may, in fact, be associated with the dependent variables and were scrutinized subsequent to data collection and reported for their contribution to the net effect observed on the dependent variables. A prospective, repeated measures design is appropriate for the
accomplishment of the study objectives because the subjectivity associated with the dependent variables dictates that using the subjects as their own control minimizes threats to internal validity.

**Setting**

This study was planned to be conducted in one pain management clinic in North Florida. North Florida includes Leon County which has a population of approximately 239,000. The clinic has a client base of 1,200 patients. Patients at the pain clinic come from surrounding counties including Gadsden, Wakulla, Jefferson, and Franklin. Not only do patients come from North Florida but approximately 20% come from South Georgia. The facility employs four anesthesiologists, one advanced registered nurse practitioner, 10 registered nurses, one medical assistant, two secretaries, one radiology technician, one office manager, and three receptionists. The clinic accepts all insurances but are not providers for Blue Cross/Blue Shield. They also see Worker’s Compensation patients and patients in litigation cases. The pain clinic sees an average of 30 patients per day. These include first time consults, follow-ups, and patients scheduled for procedures. The majority of the patients is referred to the clinic due to chronic pain and is seeking pain management. Pain management includes invasive procedures such as ESIs, nerve blocks, and trigger point injections, as well as drug therapy. The clinic has two operating room suites in which to perform these procedures.

**Population/Sampling Plan**

The target population included adults at these particular pain clinics, diagnosed with chronic low back pain and meeting the following inclusion criteria.

- Age: between the ages of 25 and 75 inclusive
- Eighth grade education
• Diagnosis of chronic low back pain for at least 6 months
• Having received at least two Epidural Steroid Injections between August and December, 2004.

The accessible population included those patients meeting these inclusion criteria who agreed to participate in the study. Random selection of subjects from the sampling frame was planned, using a table of random numbers. A minimally adequate sample size was determined to be approximately 170 subjects, based on alpha = .05 (directional), Power = .90 and Effect Size = .25. Alpha is the researcher’s subjectively set long-range probability of incorrectly claiming that ESIs are effective for the target population, when in fact, they are not. Power is the long-range probability of correctly claiming that ESIs are effective when, in fact, they are, to the degree specified by effect size. Effect Size (ES) is the researcher’s subjectively determined opinion of the degree of ESI effectiveness which would be of clinical importance.

**Protection of Human Subjects**

Participation was strictly voluntary. A cover letter was sent to the medical director of each pain clinic providing information and instructions regarding the study (Appendix A &B). Upon informal approval from the medical directors at the pain clinics, the researcher submitted an application to the Institutional Review Board (IRB) for Florida State University. Following approval by the IRB of Florida State University (Appendix C), the researcher began data collection. The potential participant was informed about the study at the end of his/her initial consultation/examination if he/she met the criteria to participate in the study on ESIs. The potential participant was given the informed consent to read if he/she was interested in participating; the researcher or the research assistant left the room while the potential participant was reading the informed consent. If the participant decided to participate in the study, he/she signed the informed consent. Every attempt was made in this study to protect the participants to the fullest extent allowed by law. The researcher or the research assistant informed
the participants that they were not bound by a contract and may withdraw from the study at any point with no penalties. The questionnaires were filled out after the initial consultation/examination was completed and the participant had met the inclusion criteria. Participants were aware that, although there may not be many, if any, direct benefits to them, the possible benefits of participation in this research include the valuable insight that this may provide healthcare workers who care for patients with chronic low back pain. If ESIs prove beneficial in the treatment of chronic LBP, it could improve a person’s level of disability. Participation began upon the researcher’s or research assistant’s receiving informed consent from each participant (Appendix D). To minimize the risk of breach of confidentiality, the identity of the participants was protected by identifying data only by code numbers. These code numbers were used on all data collection instruments. The researcher, the research assistant, the physicians at the pain clinic, the statistician, and the thesis chair were the only people who had access to the data. The data/records were kept in a locked drawer in the desk in the consultation/physical exam room. The only people who had keys to the drawer were the researcher, the research assistant, and the physicians at the pain clinic. The data collected from the study will be kept for 5 years after the completion of the study. The link will be destroyed following the last questionnaires. The data will then be destroyed on April, 30, 2010.

**Instruments**

In this study, the four instruments that were utilized to gather the data were a demographic questionnaire (Appendix F), the Visual Analog Scale (VAS) (Appendix G), the McGill Pain Questionnaire (MPQ) (Appendices H & I), and the Oswestry Index Questionnaire, also called the Oswestry Disability Index (Appendices J & K). Demographics included age, gender, height, weight, race/ethnicity, marital status, highest educational level achieved, health conditions, county of residence, and annual household income range, as indicated on the questionnaire.
The Visual Analog Scale and the McGill Pain Questionnaire were the tools utilized for this study to measure patients' perception of pain. The Visual Analog Scale (VAS) is a straight, horizontal line usually 100 mm. in length with clearly defined boundaries (Davis, 1988). The patient was asked to make a mark on the line at a point that describes the intensity of his or her pain. The beginning of the line was 0 which indicated no pain at all and the end of the line was 100 which indicated the worst possible pain. Several studies have shown the VAS to provide a reliable method of measurement (Aitken, 1969; Gift, 1989; Huskisson, 1983). The McGill Pain Questionnaire (MPQ) provides quantitative information that can be treated statistically, and is sufficiently sensitive to detect differences among different methods to relieve pain (Melzack, 1975). Additional questions related to past medical history, medications, effects of pain, personal history, and patient perceptions were added to the questionnaire. The McGill Pain Questionnaire (MPQ) focuses on pain description (Davis, 1988). The MPQ is a start toward the measurement of clinical pain and permits research on the effects of therapeutic procedures on pain in clinical rather than laboratory conditions (Melzack, 1975). This tool has probably been one that is most clinically useful in measuring qualitative and quantitative pain experiences (Torgerson & BenDebba, 1983). The MPQ is reported to have good reliability and validity.

Melzack reported that consistency of word choices by ten cancer patients over three days ranged from 50% to 100%, with a mean of 70.3%. Reading found that repeated administrations of the MPQ to cancer patients revealed a consistency index of 75% (range 35 to 90%) between the first two administrations, which decreased to 66% and then increased to 80% over the course of weekly assessments (Melzack, 1975). Face validity of the tool is indicated by the fact that it has been selected as the instrument of measurement in a number of different studies (Davis, 1988; Kremer, 1981; McCreary, 1981).

The Oswestry Index Questionnaire (OIQ) was utilized to measure the patient’s perception of his/her back pain and how it has affected his/her ability to manage everyday-life activities and overall level of disability. There are ten sections in the questionnaire with six possible answers in each section. The
highest possible score is 50 indicating 100% disability. The following is an interpretation of the disability scores: 0%-20%= minimal disability, 20%-40%= moderate disability, 40%-60%= severe disability, 60%-80%= crippled, and 80%-100%= bed-bound or exaggerating his/her symptoms. It has been rigorously tested to assess its validity and reliability. The OIQ has strong internal consistency (alpha=0.85) and is strongly correlated to the RM ($r = .70$, $p = .0005$) (Tibbles, Waalen&Hains, 1998). The OIQ face and content validity has been established by multiple authors including Kopec, Beurskens, Fairbank, Cohen, and Fisher (Beurskens, 1996). The OIQ appears to possess stable psychometric properties (Tibbles, 1998). Further, the questionnaire can be completed in less than 5 minutes and scored in less than 1 minute.

**Procedure**

The potential participant was informed about the study at the end of his/her initial consultation/examination should the patient qualify for inclusion. The potential participant was given the informed consent to read if he/she was interested in participating; the researcher or the research assistant left the room while the potential participant read the consent. If the participant decided to participate in the study, he/she signed the informed consent. The participant was then given time to complete the questionnaires. Some of the questions required the participant to answer at the time of his/her second or third injection. The researcher or research assistant then had the opportunity to review the document individually with each participant during his/her consultation. The participant was also be given a piece of paper with a 100 mm. line on it and a ruler with increments in mm. If the participant did not come in for a third injection or he/she did not come back after the third injection, it was then the responsibility of the researcher to follow-up with the participants by telephone. The participant was instructed to mark an X on the line on the piece of paper and then measure it with the ruler. The researcher then asked the participant to tell her the numerical measurement of where the X was placed. If the participant lost the
ruler, it was the responsibility of the researcher to either mail the participant another ruler or deliver it to the participant’s house personally. The researcher also completed the OIQ and the MPQ (post-treatment) while on the phone with the participant.

All completed questionnaires were coded with the number assigned as the participants are recruited. The questionnaires were kept in a locked drawer in the consultation office at the pain clinic until they are entered for analysis. Only the researcher, the research assistant, the physicians, the thesis committee members, and the statistician had access to the data collected.

**Data Analysis**

In this section, the analytical design that was used for answering the research questions is discussed. Research question one inquired about the demographic characteristics of the patients sampled in this study. Distributional properties of the demographic variables were reported in frequencies, percentages, cumulative percentages, and skew (when appropriate). Variable associations were described with association measures appropriate for the nature of the variable(s) and their defensible scale of measurement. Graphical displays were also provided where appropriate and informative. For variables, continuous in nature and at least interval in scale, central location was described utilizing the mean and median. Score dispersion was described with range, standard deviation and interquartile range. Discrete variables (DV) were described with frequencies and percentages.

Research question two addressed the extent to which the demographic characteristics of the patients correlated with their perception of pain and level of disability prior and subsequent to ESI treatment. Pearson’s Correlations represent linear relationships between continuous variables and assume that all variables are of at least interval scale. This statistical tool also assumes linearity between the variables tested. Correlations between ordinal variables were described with Spearman Rank Correlation Coefficients and associations.
between discrete dichotomous variables and the DV’s were accomplished with Point Bi-serial Correlation Coefficients.

Research question three dealt with the efficacy of ESI’s with respect to the treatment of chronic LBP and the patients’ level of disability. This was an inferential question and was answered with a related samples $t$-test of the change in patients’ perceived pain and level of disability pre- and post- ESI treatment. The assumptions required for this test were:

- The population of “difference scores” was normally distributed.
- The sample was selected at random.
- The difference scores were independent.

The degree to which the data conform to these assumptions is addressed in Chapter 4. The nulls for this analysis are:

$H_0: \mu_{pre}=\mu_{post}$ or that the difference in patients’ perceptions of pain and level of disability pre -and post- ESI treatment is zero. $H_0: \mu_{pre} - \mu_{post} = 0$ or that the difference in patients’ perceptions of pain and level of disability pre- ESI treatment minus post- ESI treatment is zero.

The alternate hypotheses were directional:

$H_a: \mu_{pre} > \mu_{post}$ (For Perception of Pain DV) Perception of pain pre-injection was greater than perception of pain post-injection.

$H_a: \mu_{pre} > \mu_{post}$ (For Level of Disability DV) Level of disability pre-injection was greater than level of disability post-injection.

Summary

This study was a quasi-experimental, prospective analysis of the cross-sectional data collected by the researcher. The demographic data were reported in frequencies and percentages. Correlational studies were utilized to examine the relationship between demographics and the patient’s perception of pain and level of disability. Regression procedures were conducted to predict the dependent variables, demographic factors and efficacy, from the independent
variable, ESIs. Chapter 4 reports the results of these analyses and Chapter 5 addresses the results and implications.
CHAPTER 4
RESULTS

This chapter will provide the results, conclusions, and a summary of findings established through analysis of the data collected for this study. The primary objectives for the study were: to determine the efficacy of epidural steroid injection in the treatment of chronic low back pain, focusing on the patient’s perception of pain and his/her level of disability prior, and subsequent, to ESI treatment. With further knowledge regarding the efficacy of ESIs, healthcare professionals will be able to apply the findings to their practice and provide their patients with chronic LBP the treatment modalities that have been found to be most effective. The findings will contribute to the ESI literature, which presently is scarce.

The four instruments that were utilized to obtain data were a demographic questionnaire (Appendix F), the Visual Analog Scale (VAS) (Appendix G), the McGill Pain Questionnaire (MPQ) (Appendices H & I), and the Oswestry Index Questionnaire, also called the Oswestry Disability Index (Appendices J & K).

This quasi-experimental, prospective study provided evidence as to the efficacy of epidural steroid injections (ESIs) in the treatment of chronic low back pain. The patient’s perception of pain and his/her level of disability were the dependent variables. The primary independent variable was the ESI treatment. Initially, the sample was taken from one pain management clinic in North Florida. A second clinic was utilized after the researcher determined that the minimally necessary sample would not be obtainable from the one clinic. The researcher approached the medical director of a second pain clinic in North Florida to ask permission to utilize his patients for the study. Upon receiving approval from the
medical director, Dr. Mullin (Appendix B), the researcher created another participant informed consent (Appendix E), and requested permission from the Chief Medical Officer of a local hospital, where Dr. Mullin performed his procedures. Once permission was received from Dr. Mac Arthur, the Chief Medical Officer (Appendix N), the researcher then sent a request for a change in the research protocol to Florida State University’s IRB. Once the request was approved (Appendix O), the researcher was able to start collecting data from the second clinic. The target population included adults from age 25 through age 75, having at least an eighth grade education, having been diagnosed with chronic low back pain for at least 6 months, and having received at least two epidural steroid injections between August and December, 2004. The time frame for the data collection was extended through January, 2005 in order to obtain an adequate sample size, determined to be 170, after consideration of the researcher’s preset levels of alpha, power, and effect size. The fact that the researcher was able to obtain only 122 participants suggests that the Power of the inferential results will be less than expected and thus constitutes a study limitation. Of the 122 participants sampled, 100% completed the data collection instruments prior and subsequent to at least two injections. Subjects within the sampling frame were not able to be selected at random due to difficulties in obtaining a random sample from what was ultimately, a limited sampling frame.

Research Question 1

Description of Demographics

Research question one inquired about the demographic characteristics of the patients sampled for this study. Demographic data were obtained using a demographic instrument developed by the investigator.

The study sample ($n = 122$) consisted of 51 (41.8%) males and 71 (58.2%) females. The different racial/ethnic groups represented were: 85 (69.7%) Caucasian, 33 (27%) African-American, two (1.6%) Hispanic, and two (1.6%)
were unspecified. The median age for the sample was 56 years (mean = 55.7 years, \(SD = 13.1\)) with the youngest participant specifying an age of 23 years and the oldest, 75 years. It was subjectively decided that the data originating from the one 23 year old participant would be retained due to the fact that the majority of his/her responses did not indicate variance due to age. Of the 122 participants, the highest educational levels achieved were as follows: 16 (13.2\%) 8th grade, 36 (29.8\%) 12th grade, 5 (4.1\%) having completed Vocational/Technical training, 26 (21.5\%) some college/no degree, 11 (9.1\%) Associate degree, 20 (16.5\%) Baccalaureate degree, and 7 (5.8\%) Master’s/Doctorate degree.

The majority of the participants, 70 (57.4\%), came from Leon County; 51 (41.8\%) came from outlying counties, including Gadsden, Wakulla, Jefferson, Jackson, Franklin, Taylor, Bay, Liberty, Madison, and Calhoun, and one (0.8\%) came from Decatur County in South Georgia. Based on the results, 31 (25.4\%) of the participants had an annual household income of under $25,000; 45 (36.9\%) had an annual household income of $25,000-$49,999; 32 (26.2\%) had an annual household income of $50,000-$74,999; 9 (7.4\%) had an annual household income of $75,000-$99,999; and 5 (4.1\%) had an annual household income of $100,000 or greater. Table 4.1 provides a summary of descriptives for age by demographic subgroups.

<table>
<thead>
<tr>
<th>Gender</th>
<th>n</th>
<th>Percentage</th>
<th>Mean</th>
<th>St. Dev.</th>
<th>Min</th>
<th>Max</th>
<th>Skew</th>
</tr>
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<tbody>
<tr>
<td>Male</td>
<td>51</td>
<td>41.8</td>
<td>55.12</td>
<td>12.88</td>
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<td>75.00</td>
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<tr>
<td>Female</td>
<td>71</td>
<td>58.2</td>
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<td>75.00</td>
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<td>Total</td>
<td>122</td>
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<td>55.77</td>
<td>13.12</td>
<td>23.00</td>
<td>75.00</td>
<td>-.26</td>
</tr>
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</table>

<table>
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<th></th>
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<tr>
<td>White/Non Hispanic</td>
<td>86</td>
<td>70.5</td>
<td>56.64</td>
<td>13.33</td>
<td>23.00</td>
<td>75.00</td>
<td>-.41</td>
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<tr>
<td>African American</td>
<td>33</td>
<td>27.0</td>
<td>53.67</td>
<td>12.67</td>
<td>29.00</td>
<td>75.00</td>
<td>.05</td>
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<td>Hispanic</td>
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<td>1.6</td>
<td>56.50</td>
<td>17.68</td>
<td>44.00</td>
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<tr>
<td>Other</td>
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<td>48.00</td>
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<table>
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<tr>
<td>Single</td>
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<td>18.0</td>
<td>47.00</td>
<td>12.88</td>
<td>23.00</td>
<td>72.00</td>
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<td>Married</td>
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<td>52.5</td>
<td>54.58</td>
<td>12.41</td>
<td>29.00</td>
<td>75.00</td>
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<td>Separated</td>
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<td>2.5</td>
<td>61.33</td>
<td>10.69</td>
<td>52.00</td>
<td>73.00</td>
<td>.94</td>
</tr>
</tbody>
</table>
### Description of Personal Health Factors

Variables used to describe the personal health of the participants included **body mass index (BMI)**, as well as the frequency and percentage of specific preexisting health conditions. The sample, as expected, produced BMI values that placed them at risk for chronic LBP and an increased level of disability. (See Table 4.2)

As can be seen in Table 4.2, 91 (75%) of the sample was classified as overweight or obese. Males and females were essentially even in this category. The median age for the participants categorized as overweight or obese was 55 years. Among those classified as overweight, or obese, were African-Americans \(n = 29; 88\%), single participants \(n = 20; 90\%), divorced participants \(n = 12; 85\%), and participants with an education level of vocational/technical degree \(n = 5; 100\%). The number of females was slightly higher in the normal category. There were no apparent trends with respect to income. Of the 61 (50\%)

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### Table 4.1 - continued

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Percentage</th>
<th>Mean</th>
<th>St. Dev.</th>
<th>Min</th>
<th>Max</th>
<th>Skew</th>
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<td>Divorced</td>
<td>15</td>
<td>12.3</td>
<td>54.13</td>
<td>6.78</td>
<td>42.00</td>
<td>66.00</td>
<td>-.04</td>
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<td>Widowed</td>
<td>18</td>
<td>14.8</td>
<td>71.17</td>
<td>5.84</td>
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<td>8th Grade</td>
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<td>13.1</td>
<td>64.88</td>
<td>11.03</td>
<td>44.00</td>
<td>75.00</td>
<td>-1.06</td>
</tr>
<tr>
<td>12th Grade</td>
<td>37</td>
<td>30.3</td>
<td>58.00</td>
<td>13.77</td>
<td>29.00</td>
<td>75.00</td>
<td>-.32</td>
</tr>
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<td>Some College/No Degree</td>
<td>26</td>
<td>21.3</td>
<td>56.96</td>
<td>11.38</td>
<td>38.00</td>
<td>75.00</td>
<td>-.18</td>
</tr>
<tr>
<td>Associates Degree</td>
<td>11</td>
<td>9.0</td>
<td>50.18</td>
<td>8.44</td>
<td>32.00</td>
<td>62.00</td>
<td>-.58</td>
</tr>
<tr>
<td>Bachelors Degree</td>
<td>20</td>
<td>16.4</td>
<td>49.10</td>
<td>11.24</td>
<td>23.00</td>
<td>64.00</td>
<td>-1.21</td>
</tr>
<tr>
<td>Masters/Doctorate</td>
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<td>5.7</td>
<td>55.57</td>
<td>15.49</td>
<td>33.00</td>
<td>75.00</td>
<td>-.16</td>
</tr>
<tr>
<td>Vocational/Technical</td>
<td>5</td>
<td>4.1</td>
<td>43.20</td>
<td>14.13</td>
<td>29.00</td>
<td>66.00</td>
<td>1.26</td>
</tr>
<tr>
<td><strong>Annual Household Income</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Under 25K</td>
<td>31</td>
<td>25.4</td>
<td>57.90</td>
<td>16.38</td>
<td>23.00</td>
<td>75.00</td>
<td>-.75</td>
</tr>
<tr>
<td>25K – 49K</td>
<td>45</td>
<td>36.9</td>
<td>56.84</td>
<td>12.42</td>
<td>29.00</td>
<td>75.00</td>
<td>-.25</td>
</tr>
<tr>
<td>50K – 74K</td>
<td>32</td>
<td>26.2</td>
<td>52.63</td>
<td>10.29</td>
<td>32.00</td>
<td>74.00</td>
<td>.36</td>
</tr>
<tr>
<td>75K – 99K</td>
<td>9</td>
<td>7.4</td>
<td>60.44</td>
<td>10.62</td>
<td>43.00</td>
<td>75.00</td>
<td>-.26</td>
</tr>
<tr>
<td>100K or Greater</td>
<td>5</td>
<td>4.1</td>
<td>44.60</td>
<td>10.74</td>
<td>33.00</td>
<td>57.00</td>
<td>.37</td>
</tr>
</tbody>
</table>
participants who were currently working, 47 (77%) were categorized as overweight or obese.

Table 4.2

Descriptives for BMI by Demographic Sub-groups

<table>
<thead>
<tr>
<th>BMI</th>
<th>Normal</th>
<th>Overweight</th>
<th>Obese</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>n</td>
<td>f (%)</td>
<td>f (%)</td>
</tr>
<tr>
<td>Male</td>
<td>51</td>
<td>11 (22.0)</td>
<td>22 (44.0)</td>
</tr>
<tr>
<td>Female</td>
<td>71</td>
<td>22 (26.8)</td>
<td>25 (35.2)</td>
</tr>
<tr>
<td>Total</td>
<td>122</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Race</th>
<th>n</th>
<th>f (%)</th>
<th>f (%)</th>
<th>f (%)</th>
<th>Mean (Median)</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>White/Caucasian</td>
<td>86</td>
<td>26 (30.6)</td>
<td>32 (37.6)</td>
<td>27 (31.8)</td>
<td>28.73 (27.42)</td>
<td>21.16</td>
<td>48.81</td>
</tr>
<tr>
<td>African American</td>
<td>33</td>
<td>4 (12.1)</td>
<td>12 (36.4)</td>
<td>17 (51.5)</td>
<td>31.31 (30.18)</td>
<td>20.32</td>
<td>46.97</td>
</tr>
<tr>
<td>Hispanic</td>
<td>2</td>
<td>0.0</td>
<td>2 (100.0)</td>
<td>0.0</td>
<td>26.24 (26.24)</td>
<td>25.86</td>
<td>26.62</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>0.0</td>
<td>1 (100.0)</td>
<td>0.0</td>
<td>25.37 (25.37)</td>
<td>25.37</td>
<td>25.37</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Marital Status</th>
<th>n</th>
<th>f (%)</th>
<th>f (%)</th>
<th>f (%)</th>
<th>Mean (Median)</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single</td>
<td>22</td>
<td>2 (9.1)</td>
<td>7 (31.8)</td>
<td>13 (59.1)</td>
<td>31.64 (31.54)</td>
<td>22.48</td>
<td>46.87</td>
</tr>
<tr>
<td>Married</td>
<td>64</td>
<td>18 (28.1)</td>
<td>26 (40.6)</td>
<td>20 (31.3)</td>
<td>28.72 (27.44)</td>
<td>20.32</td>
<td>48.81</td>
</tr>
<tr>
<td>Separated</td>
<td>3</td>
<td>1 (33.3)</td>
<td>1 (33.3)</td>
<td>1 (33.3)</td>
<td>32.45 (28.57)</td>
<td>23.91</td>
<td>44.87</td>
</tr>
<tr>
<td>Divorced</td>
<td>15</td>
<td>2 (14.3)</td>
<td>7 (50.0)</td>
<td>5 (35.7)</td>
<td>30.38 (27.98)</td>
<td>22.59</td>
<td>44.28</td>
</tr>
<tr>
<td>Widowed</td>
<td>18</td>
<td>7 (38.9)</td>
<td>6 (33.3)</td>
<td>5 (27.8)</td>
<td>27.49 (27.03)</td>
<td>21.16</td>
<td>40.14</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Educational Level</th>
<th>n</th>
<th>f (%)</th>
<th>f (%)</th>
<th>f (%)</th>
<th>Mean (Median)</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>8th Grade</td>
<td>16</td>
<td>5 (31.3)</td>
<td>4 (25.0)</td>
<td>7 (43.8)</td>
<td>28.97 (27.29)</td>
<td>21.16</td>
<td>44.87</td>
</tr>
<tr>
<td>12th Grade</td>
<td>37</td>
<td>13 (35.1)</td>
<td>11 (29.7)</td>
<td>13 (35.1)</td>
<td>27.95 (27.46)</td>
<td>20.32</td>
<td>40.14</td>
</tr>
<tr>
<td>Some College/No Degree</td>
<td>26</td>
<td>4 (15.4)</td>
<td>12 (46.2)</td>
<td>10 (38.5)</td>
<td>31.54 (28.49)</td>
<td>22.67</td>
<td>48.81</td>
</tr>
<tr>
<td>Associates Degree</td>
<td>11</td>
<td>3 (27.3)</td>
<td>3 (27.3)</td>
<td>5 (45.5)</td>
<td>30.92 (27.93)</td>
<td>22.59</td>
<td>47.89</td>
</tr>
<tr>
<td>Bachelors Degree</td>
<td>20</td>
<td>3 (15.8)</td>
<td>9 (47.4)</td>
<td>7 (36.8)</td>
<td>29.77 (27.70)</td>
<td>22.48</td>
<td>44.28</td>
</tr>
<tr>
<td>Masters/Doctorate</td>
<td>7</td>
<td>2 (28.6)</td>
<td>5 (71.4)</td>
<td>0.0</td>
<td>25.75 (25.77)</td>
<td>22.47</td>
<td>29.28</td>
</tr>
<tr>
<td>Vocational/Technical</td>
<td>5</td>
<td>0.0</td>
<td>3 (60.0)</td>
<td>2 (40.0)</td>
<td>29.67 (29.05)</td>
<td>27.80</td>
<td>31.87</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Annual Household Income</th>
<th>n</th>
<th>f (%)</th>
<th>f (%)</th>
<th>f (%)</th>
<th>Mean (Median)</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 25K</td>
<td>31</td>
<td>7 (22.6)</td>
<td>10 (32.3)</td>
<td>14 (45.2)</td>
<td>29.66 (28.57)</td>
<td>21.16</td>
<td>44.87</td>
</tr>
<tr>
<td>25K - 49K</td>
<td>45</td>
<td>12 (26.7)</td>
<td>19 (42.2)</td>
<td>14 (31.1)</td>
<td>28.95 (27.46)</td>
<td>20.32</td>
<td>48.81</td>
</tr>
<tr>
<td>50K - 74K</td>
<td>32</td>
<td>7 (22.6)</td>
<td>10 (32.3)</td>
<td>14 (45.2)</td>
<td>30.67 (28.60)</td>
<td>21.21</td>
<td>47.89</td>
</tr>
<tr>
<td>75K - 99K</td>
<td>9</td>
<td>1 (11.1)</td>
<td>7 (77.8)</td>
<td>1 (11.1)</td>
<td>27.05 (27.33)</td>
<td>23.33</td>
<td>33.00</td>
</tr>
<tr>
<td>100K or Greater</td>
<td>5</td>
<td>3 (60.0)</td>
<td>1 (20.0)</td>
<td>1 (20.0)</td>
<td>26.97 (24.69)</td>
<td>22.47</td>
<td>37.60</td>
</tr>
</tbody>
</table>

Note: BMI (Normal = 18.5 - 24.9; Overweight = 25 - 29.9; Obese = 30 and above)(Mosby,2003)
Other preexisting health conditions of interest for this investigation were whether or not the patient was suffering from arthritis, osteoporosis, scoliosis, and other prior back problems. Of the 122 participants, 65 (53.3%) reported having arthritis, the most frequently reported preexisting condition. Of the 122 participants reported having arthritis, 45 (69%) were female, 20 (31%) were male, with a mean age of 54 years. Of the 65 participants reporting arthritis, 40 (62%) were overweight or obese. Osteoporosis was reported by 27 participants (22.1%), 100% being female, 14 (52%) were overweight or obese, with a mean age of 66.6. Scoliosis was reported by 8 participants (6.6%), 7 (87.5%) were female, 1 (12.5%) was male, and 6 (75%) were overweight or obese. Twenty participants (16.4%) reported other preexisting back problems, 12 (60%) were female, 8 (40%) were male, and 16 (80%) were overweight or obese. Thirty-one participants (25%), reported two or more preexisting conditions, 27 (87%) were female, 4 (13%) were male, and 20 (64.5%) were overweight or obese.

Seventy-three (59.8%) of the patients reported having one or more of these pre-existing conditions. Among those who reported having one or more of these pre-existing conditions, 57 (78.1%) had arthritis, 27 (37.0%) had osteoporosis, 8 (11.0%) had scoliosis, and 20 (27.4%) had pre-existing back problems (Table 4.3). The participants with osteoporosis were older (66.6 years) than the participants with arthritis (54 years).

Table 4.3

<table>
<thead>
<tr>
<th>Frequency of Pre-existing Health Conditions</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-existing Conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.00</td>
<td>42</td>
<td>57.5</td>
</tr>
<tr>
<td>2.00</td>
<td>24</td>
<td>32.9</td>
</tr>
<tr>
<td>3.00</td>
<td>6</td>
<td>8.2</td>
</tr>
<tr>
<td>4.00</td>
<td>1</td>
<td>1.4</td>
</tr>
<tr>
<td>Total</td>
<td>73</td>
<td>59.8</td>
</tr>
<tr>
<td>Arthritis</td>
<td>57</td>
<td>78.1</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>27</td>
<td>37.0</td>
</tr>
<tr>
<td>Scoliosis</td>
<td>8</td>
<td>11.0</td>
</tr>
<tr>
<td>Preexisting Back Problems</td>
<td>20</td>
<td>27.4</td>
</tr>
</tbody>
</table>
Table 4.4 addresses the work status of the participants with a pre-existing condition compared to the entire sample. Of the 122 participants, 50% were currently working, 20% were not working due to pain, and 30% were not working due to other reasons. While 50% \((n = 61)\) of the entire sample was currently working at the time of data collection, only 25 (34.2%) of those with at least one pre-existing condition were working at the time the study was conducted. Among those 25, 20 had only one pre-existing condition and the remainder had two. For the 48 (65.8%) patients with pre-existing conditions who were not working at the time of the study, 13 (27%) were not able to work due to pain. Most \((n =10; 77\%)\) had one pre-existing condition with arthritis \((n = 7)\) and pre-existing back problems \((n =3)\) being the most frequently reported causes for their pain.

Table 4.4

*Comparison of Work Status by Number of Preexisting Conditions*

<table>
<thead>
<tr>
<th>Currently Working</th>
<th>Pre-existing Conditions</th>
<th>No</th>
<th>Due to Pain</th>
<th>Other Reasons</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>36</td>
<td>10</td>
<td>3</td>
<td>49</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>25</td>
<td>13</td>
<td>35</td>
<td>73</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>20</td>
<td>10</td>
<td>12</td>
<td>42</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>5</td>
<td>2</td>
<td>17</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>0</td>
<td>1</td>
<td>5</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>61</td>
<td>23</td>
<td>38</td>
<td>122</td>
<td></td>
</tr>
</tbody>
</table>

As can be seen in Table 4.5, as the number of affected areas increased, the mean age of the participants increased.
Table 4.5

Descriptives for Age by Number of Pre-existing Personal Health Conditions

<table>
<thead>
<tr>
<th>Number of Pre-existing Health Conditions</th>
<th>Age</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>48.960</td>
<td>56.310</td>
<td>65.000</td>
<td>66.667</td>
<td>68.000</td>
<td>68.000</td>
</tr>
<tr>
<td>Median</td>
<td>47.000</td>
<td>57.000</td>
<td>68.500</td>
<td>70.500</td>
<td>68.000</td>
<td>68.000</td>
</tr>
<tr>
<td>Maximum</td>
<td>73.000</td>
<td>75.000</td>
<td>75.000</td>
<td>74.000</td>
<td>68.000</td>
<td>68.000</td>
</tr>
<tr>
<td>Minimum</td>
<td>29.000</td>
<td>23.000</td>
<td>45.000</td>
<td>46.000</td>
<td>68.000</td>
<td>68.000</td>
</tr>
<tr>
<td>St. Dev.</td>
<td>10.180</td>
<td>13.810</td>
<td>9.468</td>
<td>10.386</td>
<td>.000</td>
<td>.000</td>
</tr>
<tr>
<td>Skew</td>
<td>.395</td>
<td>-.679</td>
<td>-.858</td>
<td>-2.186</td>
<td>.000</td>
<td>.000</td>
</tr>
<tr>
<td>n</td>
<td>49.000</td>
<td>42.000</td>
<td>24.000</td>
<td>6.000</td>
<td>1.000</td>
<td>1.000</td>
</tr>
</tbody>
</table>

Research Question 2

The second research question inquired of the associations between the study participants’ demographic/personal health variables and the study dependent variables: Perception of Pain and Level of Disability. In essence, this question was intended to determine those factors which were associated with varying degrees of pain and level of disability for the study participants at the outset of the study and their ESI treatments. For the purposes of this question, the data derived from the Visual Analog Scale on the demographic instrument (Question 11: “What is your pain rating the day of your first injection?” were used as the perception of pain dependent variable scores. Similarly, the data derived from the Oswestry instrument (pre-treatment) were used for the level of disability dependent variable. Results for this question are provided in the following order:

1. Descriptive results for the entire sample on both dependent variables
2. Multivariate descriptions of demographic subgroups for the two dependent variables (Perception of Pain and Level of Disability)
3. Associations between demographic/personal health variables and the two dependent variables.

Pre-treatment Descriptions of Sample Perception of Pain and Level of Disability
Table 4.6 presents descriptive summaries for patients’ perception of pain and level of disability prior to ESI treatment. Data for these descriptors originated from the Demographic and Personal Health instrument (VAS data), Section One of the Revised Oswestry instrument, the McGill (short form) instrument and the total score on Oswestry (Level of Disability). The pain on day of first injection was scored utilizing the VAS, which goes from 0-100mms. The mean score was 65.39. The pain intensity score was taken from section one of the Oswestry, which allowed the participant to check 0-5, with 0 being “the pain comes and goes and is very mild” and 5 being “the pain is severe and does not vary much.” With a mean score of 3.75, this represents a pain that is moderate to severe. The PRI score was calculated by the total score on the McGill. With a mean score of 13.21 and the maximum score being 45, this indicates a low PRI pre-injection. However, some participants only checked a couple of adjectives to describe their pain which would skew the mean and median. The way in which the author of the McGill instrument established the method for scoring has the potential for providing data that may not lead to the same kind of conclusion as another instrument which provides an expected number of answers. The Oswestry total had a maximum score of 50 and the mean for the sample was 28.43. As mentioned in Chapter 3, 28.43 would be categorized as moderate disability.

Table 4.6

Descriptives for Pain and Level of Disability Pre and Post-treatment

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Pain on Day of First Injection</th>
<th>Pain 2-Weeks after 2nd Injection</th>
<th>Level of Disability Pre</th>
<th>Level of Disability Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>65.39</td>
<td>35.86</td>
<td>28.43</td>
<td>22.55</td>
</tr>
<tr>
<td>Median</td>
<td>69.00</td>
<td>30.00</td>
<td>29.00</td>
<td>22.00</td>
</tr>
<tr>
<td>Minimum</td>
<td>.00</td>
<td>.00</td>
<td>9.00</td>
<td>6.00</td>
</tr>
<tr>
<td>Maximum</td>
<td>100.00</td>
<td>100.00</td>
<td>41.00</td>
<td>39.00</td>
</tr>
<tr>
<td>Std. Deviation</td>
<td>22.19</td>
<td>25.20</td>
<td>6.66</td>
<td>7.87</td>
</tr>
<tr>
<td>Skewness</td>
<td>-.76</td>
<td>.51</td>
<td>-.39</td>
<td>.07</td>
</tr>
<tr>
<td>n</td>
<td>122.00</td>
<td>122.00</td>
<td>121.00</td>
<td>122.00</td>
</tr>
</tbody>
</table>
In addition to the descriptive results provided in Table 4.6, the reader is directed to the Disability frequencies and percentages provided in Table 4.7. These categories were the result of a scoring process provided and validated by the author of the revised Oswestry instrument and are used to describe the level of disability. Table 4.7 indicates 102 (83.9%) of the participants were categorized as severely disabled, or crippled, pre-injection. One participant was listed as bed-bound/exaggerating; however, the participant completed the physical examination which required standing, walking, sitting, etc. The participant arrived at the pain clinic and was seated in a wheelchair. This indicated the participant's answers were exaggerated.

Table 4.7

<table>
<thead>
<tr>
<th>Oswestry Level of Disability Classification</th>
<th>Pre ESI Treatment</th>
<th>Post ESI Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency</td>
<td>Percentage</td>
</tr>
<tr>
<td>Minimal Disability</td>
<td>1</td>
<td>.8</td>
</tr>
<tr>
<td>Moderate Disability</td>
<td>17</td>
<td>14.0</td>
</tr>
<tr>
<td>Severe Disability</td>
<td>52</td>
<td>42.6</td>
</tr>
<tr>
<td>Crippled Disability</td>
<td>50</td>
<td>41.3</td>
</tr>
<tr>
<td>Bed-bound/Exaggerating</td>
<td>1</td>
<td>.8</td>
</tr>
</tbody>
</table>

Table 4.8 shows a positive correlation between the *perception of pain* variables and the *level of disability* variables. Pearson Product Moment Correlation Coefficients were calculated to determine the association between the perception of pain and level of disability variables. The positive associations illustrated in Table 4.8 confirm that patients experiencing more pain, were, in general, classified with greater levels of disability. Nine of the ten subscales that measured level of disability on the Oswestry were compared pre- and post-injection and the results mirrored the results for the two inferential analyses. The *perception of pain* pre-ESI is greater than *perception of pain* post-injection. The *level of disability* pre-ESI is greater than *level of disability* post-injection.
Table 4.8

**PPM Correlation Coefficients for Perception of Pain and Level of Disability**

<table>
<thead>
<tr>
<th></th>
<th>Pain on Day of First Injection</th>
<th>Pain 2-Weeks after 2nd Injection</th>
<th>Level of Disability Pre</th>
<th>Level of Disability Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain on Day of First Injection</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain 2-Weeks after 2nd Injection</td>
<td>.40</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level of Disability Pre</td>
<td>.59</td>
<td>.52</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Level of Disability Post</td>
<td>.39</td>
<td>.79</td>
<td>.81</td>
<td>1.00</td>
</tr>
</tbody>
</table>

Multivariate Descriptions of Demographic Subgroups for the Two Dependent Variables (Perception of Pain and Level of Disability)

This section of the discussion provides a more in-depth description of the sample with respect to their pre-treatment perception of pain and level of disability. While Age was positively associated \( r = .103 \) with the amount of pain perceived by patients, the strength of this association was less than expected. Increases in the Oswestry Totals pre-injection were interpreted as increases in the patient’s level of disability. Table 4.9 provides summary statistics for the other demographic variables with respect to the patient’s perception of pain. According to Table 4.9, the majority of the participants with greater intensity of pain were females, African-Americans, separated, with an Associate’s Degree, and an annual household income of under $25,000. Under race, the Hispanics and ‘other’ had a greater intensity of pain and level of disability scores than the other races. This is due to the fact that there were so few participants in these groups.
Table 4.9

Summary Statistics for Pain and Level of Disability by Demographic Sub-groups: Pre and Post ESI Treatment

<table>
<thead>
<tr>
<th>Variable</th>
<th>n</th>
<th>Pain on Day of First Injection</th>
<th>Pain 2Wks After 2nd Injection</th>
<th>Level of Disability Pre-ESI</th>
<th>Level of Disability Post-ESI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean</td>
<td>Median</td>
<td>Mean</td>
<td>Median</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>51</td>
<td>60.96</td>
<td>68.00</td>
<td>29.74</td>
<td>21.00</td>
</tr>
<tr>
<td>Female</td>
<td>71</td>
<td>68.58</td>
<td>70.00</td>
<td>40.24</td>
<td>38.00</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White/Caucasian</td>
<td>86</td>
<td>64.52</td>
<td>66.50</td>
<td>33.84</td>
<td>28.50</td>
</tr>
<tr>
<td>African American</td>
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<td>66.27</td>
<td>70.00</td>
<td>40.79</td>
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<td>Hispanic</td>
<td>2</td>
<td>75.50</td>
<td>75.50</td>
<td>31.00</td>
<td>31.00</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>91.00</td>
<td>91.00</td>
<td>56.00</td>
<td>56.00</td>
</tr>
<tr>
<td>Marital Status</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Single</td>
<td>22</td>
<td>71.00</td>
<td>71.50</td>
<td>31.40</td>
<td>26.00</td>
</tr>
<tr>
<td>Married</td>
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<td>62.82</td>
<td>65.00</td>
<td>33.80</td>
<td>30.00</td>
</tr>
<tr>
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<td>74.33</td>
<td>73.00</td>
<td>55.66</td>
<td>60.00</td>
</tr>
<tr>
<td>Divorced</td>
<td>15</td>
<td>64.53</td>
<td>72.00</td>
<td>45.13</td>
<td>51.00</td>
</tr>
<tr>
<td>Widowed</td>
<td>18</td>
<td>66.88</td>
<td>69.00</td>
<td>37.56</td>
<td>44.00</td>
</tr>
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<td>Educational Level</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8th Grade</td>
<td>16</td>
<td>64.00</td>
<td>67.50</td>
<td>48.68</td>
<td>54.00</td>
</tr>
<tr>
<td>12th Grade</td>
<td>37</td>
<td>68.05</td>
<td>72.00</td>
<td>38.51</td>
<td>39.00</td>
</tr>
<tr>
<td>College/No Degree</td>
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<td>66.42</td>
<td>69.50</td>
<td>31.96</td>
<td>27.50</td>
</tr>
<tr>
<td>Associates Degree</td>
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<td>70.36</td>
<td>70.00</td>
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<td>Bachelors Degree</td>
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<td>60.55</td>
<td>64.50</td>
<td>28.70</td>
<td>28.50</td>
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<td>Masters/Doctorate</td>
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<td>60.00</td>
<td>21.71</td>
<td>17.00</td>
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<tr>
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<td>68.80</td>
<td>72.00</td>
<td>38.40</td>
<td>27.00</td>
</tr>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Under 25K</td>
<td>31</td>
<td>70.20</td>
<td>70.00</td>
<td>48.87</td>
<td>53.00</td>
</tr>
<tr>
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<td>45</td>
<td>63.86</td>
<td>69.00</td>
<td>33.98</td>
<td>29.00</td>
</tr>
<tr>
<td>50K - 74K</td>
<td>32</td>
<td>68.68</td>
<td>68.50</td>
<td>30.50</td>
<td>30.00</td>
</tr>
<tr>
<td>75K - 99K</td>
<td>9</td>
<td>67.11</td>
<td>65.00</td>
<td>34.44</td>
<td>22.00</td>
</tr>
<tr>
<td>100K or Greater</td>
<td>5</td>
<td>47.00</td>
<td>35.00</td>
<td>12.40</td>
<td>14.00</td>
</tr>
<tr>
<td>County of Residence</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leon</td>
<td>70</td>
<td>63.77</td>
<td>68.00</td>
<td>36.56</td>
<td>29.50</td>
</tr>
<tr>
<td>Other</td>
<td>52</td>
<td>67.58</td>
<td>70.00</td>
<td>34.90</td>
<td>30.00</td>
</tr>
<tr>
<td>Total Sample</td>
<td>122</td>
<td>65.39</td>
<td>69.00</td>
<td>35.85</td>
<td>30.00</td>
</tr>
</tbody>
</table>
Multivariate Descriptions of Personal Health Subgroups for the Two Dependent Variables ( Perception of Pain and Level of Disability)

The following discussion further describes personal health subgroups of the sample, with respect to their perceptions of pain and level of disability. Pearson Product-Moment (PPM) Correlation Coefficients were used to describe the linear association between BMI and perception of pain and level of disability. The sign on the correlation coefficient indicates the direction of the linear relationship, and the absolute value of the correlation coefficient indicates the strength. As can be seen in Table 4.10, the correlations between BMI and pain on the day of the first injection ($r_{ppm} = -.124$) and BMI and pain 2 Wks after 2nd injection ($r_{ppm} = -.126$) which were determined by the participant’s markings on the VAS are negative. The participants that were categorized under normal weight, based on their BMI, had the highest pain rating on the day of the first injection (mean = 70.7, $SD = 25.9$). There is virtually no correlation between BMI and level of disability according to the results of the Oswestry total score pre-injection ($r_{ppm} = -.024$) and post-injection ($r_{ppm} = -.032$). Spearman rank correlation coefficients were used to describe the linear association between educational level, family income, and total pre-existing conditions (arthritis, osteoporosis, scoliosis, and preexisting back problems) and perception of pain and level of disability. A Spearman Rank correlation indicated a negative correlation between education level and pain on day of first injection, pain 2 Wks after 2nd injection, and level of disability pre-ESI and post-ESI. Family income was also negatively correlated with pain and level of disability. This indicates that neither educational level nor family income influenced pre- and post- scores on pain and level of disability. There was a positive correlation between total pre-existing conditions and pain and level of disability pre- and post-scores.
### Table 4.10

**Spearman and PPM Correlation Coefficients for Pain, Level of Disability and Selected Demographic and Personal Health Variables**

<table>
<thead>
<tr>
<th></th>
<th>Pain on Day of First Injection</th>
<th>Pain 2Wks After 2nd Injection</th>
<th>Level of Disability Pre-ESI</th>
<th>Level of Disability Post-ESI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Education Level</strong></td>
<td>-.116</td>
<td>-.186</td>
<td>-.326</td>
<td>-.309</td>
</tr>
<tr>
<td><strong>Family Income</strong></td>
<td>-.146</td>
<td>-.283</td>
<td>-.277</td>
<td>-.371</td>
</tr>
<tr>
<td><strong>Body Mass Index</strong></td>
<td>-.124</td>
<td>-.126</td>
<td>-.024</td>
<td>-.032</td>
</tr>
<tr>
<td><strong>Total Pre-existing Conditions</strong></td>
<td>.184</td>
<td>.156</td>
<td>.301</td>
<td>.315</td>
</tr>
</tbody>
</table>

*Spearman Rank Correlation Coefficients ($r_s$)

**PPM Correlation Coefficients ($r_{ppm}$)

---

**Research Question 3**

This is an inferential question about the efficacy of epidural steroid injections in the treatment of chronic low back pain. The inferential results were obtained utilizing a related samples $t$-test of the change in patients' perceived pain and LOD pre-and post-ESI treatment. The assumptions required for this test are:

1. The population of “difference scores” is normally distributed. The researcher is reasonably comfortable with the normality assumption for all four variables (3 pain variables and 1 level of disability variable) because the scores were derived through a summing process and the Central Limit Theorem will ensure that the population of difference scores on these variables is, for all practical purposes, normal. Additionally, the distributions of difference scores for all dependent variables were scrutinized to the degree for which the normal assumption is tenable and no evidence was found to warrant questioning this assumption.

2. The sample is selected at random. Unfortunately, the accessible population was not of sufficient size to obtain a random sample, and the failure of this assumption, therefore, constitutes a study limitation.
3. The difference scores are independent. Although the researcher could not guarantee independence, the sampling plan for this study served as a measure of comfort.

When correlating the patient’s perception of pain and level of disability, focusing on the efficacy of the ESI treatment, the researcher found a level of comfort in concluding that ESIs were effective for the majority of the population sampled.

The null hypotheses for this analysis are:

\( H_0: \mu_{\text{pre}} = \mu_{\text{post}}, \) or that the pre-injection pain scores equal the post-injection pain scores. \( H_0: \mu_{\text{pre}} - \mu_{\text{post}} = 0, \) or that the difference in patients’ perceptions of pain and level of disability pre-and post-ESI treatment is zero.

The alternate hypotheses were directional. ESIs are effective for reducing pain as well as level of disability.

\( H_a: \mu_{\text{pre}} > \mu_{\text{post}} \) (For Perception of Pain DV) perception of pain pre-ESI is greater than perception of pain post-ESI

\( H_a: \mu_{\text{pre}} > \mu_{\text{post}} \) (For Level of Disability DV) level of disability pre-ESI is greater than level of disability post-ESI

Both null hypotheses for this study were rejected.

The reader will note that in Table 4.11 pain on the day of the first injection and the pain 2 weeks after the second injection were derived from the Visual Analogue Scale on the demographic instrument (Questions 11 and 13). The pain intensity pre- and post-injection were derived from the first section of the Oswestry, and the pre- and post-PRI were derived from the McGill Tool. The Oswestry total score pre- and post- were used to analyze the participants’ LOD pre- and post-injection. The nine other variables that were used to measure LOD demonstrated the post-scores to be dramatically lower than the pre-scores, which is what one would expect. Walking had the highest correlation, with sleeping, standing, and traveling having the next highest correlations. These data demonstrate that the LOD of the majority of the participants was dramatically decreased after treatment.
Table 4.11

*Related Samples t-tests of Pain and Level of Disability: Pre vs. Post ESI*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Means</th>
<th>Mean Difference</th>
<th>Std. Error</th>
<th>t</th>
<th>df</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain on Day of First Injection</td>
<td>65.39</td>
<td>29.54</td>
<td>2.36</td>
<td>12.54</td>
<td>121</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Pain 2 Weeks post 2nd Injection</td>
<td>35.85</td>
<td>-29.54</td>
<td>2.36</td>
<td>12.54</td>
<td>121</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Pain Intensity Pre</td>
<td>3.75</td>
<td>2.30</td>
<td>0.45</td>
<td>5.15</td>
<td>121</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Pain Intensity Post</td>
<td>2.30</td>
<td>-1.45</td>
<td>0.42</td>
<td>3.37</td>
<td>121</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>PRI Pre</td>
<td>13.21</td>
<td>4.58</td>
<td>0.50</td>
<td>9.15</td>
<td>121</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>PRI Post</td>
<td>8.63</td>
<td>5.88</td>
<td>0.42</td>
<td>13.90</td>
<td>120</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

The study found there to be a positive correlation between perception of pain and level of disability prior to, and subsequent to, ESI treatment. The findings of the study were positive in terms of the ESIs efficacy (67% of the population studied stated the ESIs were effective and 33% said they were not). See Table 4.12. In past studies, the findings were typically 50-50.

Table 4.12

*Efficacy of Injections*

<table>
<thead>
<tr>
<th>Injections Effective</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valid</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>40</td>
<td>32.8</td>
<td>32.8</td>
<td>32.8</td>
</tr>
<tr>
<td>Yes</td>
<td>82</td>
<td>67.2</td>
<td>67.2</td>
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</tr>
<tr>
<td>Total</td>
<td>122</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

Conclusions

The Health Promotion Model (Pender, 1987), the Gate Control Pain Theory (Melzack, 1967), and Loeser’s Onion Theory (1980) suggest pain is a multifactorial phenomenon. Pender identified health promotion as a goal for the twenty-first century. Low back pain, the most common chronic pain in the United States, can be managed by health-promoting behaviors and the most effective treatment modalities available. The findings of this study support Pender’s
framework and the non-nursing theories that health promotion is a major component of pain management and that pain is a multifactorial phenomenon. This is evidenced by the correlations between perception of pain and level of disability prior and subsequent to ESI treatment.

Prior studies on the efficacy of epidural steroid injections have been controversial and inconclusive. The literature was also scarce. The findings of the study were positive in terms of the ESIs efficacy (67% of the population studied stated the ESIs were effective and 33% said they were not). In past studies, the findings were typically 50-50.

The researcher inquired of the associations between the study participants’ demographic/personal health variables and the study dependent variables: Perception of Pain and Level of Disability. The majority of the participants with greater intensity of pain were African-American females with a BMI > 25%. Separated (marital status) participants with an Associate’s Degree and an annual household income of < $25,000 also had a greater intensity of pain. The pre-existing conditions were reported by more overweight/obese females than any other group. There is virtually no correlation between BMI and level of disability. According to the disability index, the number of crippled participants decreased by 50% post-injection. Therefore, there is a positive correlation between ESI treatment and level of disability. According to the reduced pain scores on all three tools and a reduced level of disability post-injection, this indicates the injections were effective.

Demographics/ Personal health conditions of the participants were scrutinized and correlations existed between the majority of the demographic characteristics/ personal health conditions and the dependent variables prior to, and subsequent to, ESI treatment. This also indicates the injections were effective for the majority of the participants.
Summary

In summarizing the findings, the sample studied ($N = 122$) had a mean age of 56 years with ($n = 71; 58.2\%$) being female and ($n = 51; 41.8\%$) being male. The majority of the participants were Caucasian, with a median weight of 181 pounds, at least a 12th grade education, living in Leon County, and an annual income of $25,000.-$49,999. More of the participants ($n = 65; 53.3\%$) suffered from arthritis than any other conditions and 75% of the participants were overweight or obese. African-Americans accounted for 88% of those classified as overweight or obese. The participants classified as normal weight rated their pain higher than those that were overweight or obese. This may indicate that overweight or obese people have a higher pain tolerance. According to the disability index, 102 (83.9%) of the participants were categorized as severely disabled, or crippled, prior to ESI. According to the scores post-ESI, 72 (59%) of the participants were categorized as severely disabled or crippled. This indicates a 24.9% decrease in disability scores post-injection. The researcher had an Effect size of .25$\sigma$, therefore, the results were of clinical significance. The rest were minimally to moderately disabled post-ESI. There is a positive correlation between perception of pain and level of disability pre and post injection.

Chapter 5 will present the conceptual framework, discussion of the findings, limitations and strengths of the study, implications for the healthcare profession and advanced practice nursing, and recommendations for future research.
CHAPTER 5

DISCUSSION

This chapter will discuss the findings revealed with the analysis of data collected on the efficacy of epidural steroid injections in the treatment of chronic low back pain. How these findings may support, or not support, the literature, Nola Pender’s (1987 & 1996) Health Promotion Models, the Gate Control Pain Theory, and Loeser’s Onion Theory and the interpretation of their clinical significance will be addressed. Limitations of the study, both those that were anticipated and those encountered during the study will be explained, as well as the assumptions made. Implications for the nursing profession, specifically, nursing education, administration, practice, and advanced practice, are discussed. Lastly, the recommendations for further study in the area of ESIs will be presented.

Discussion of the Findings

Demographics / Personal Health

The findings of this study were statistically significant and of practical importance. The study sample consisted of 51 (41.8%) males and 71 (58.2%) females. This balance is consistent with the small gender differences which were reported in the majority of epidemiological investigations of the prevalence of LBP (Waddell, 1998).
Many people move to Florida when they retire and there tend to be more female widows than male widowers. This may be one reason the researcher had more female participants than males. Among the younger female LBP population, oral contraceptives have been specified as a minor contributor of LBP. However, this study did not ask the female participants if they were on oral contraceptives. Wood and Bradley (1980) reported that, in the general population, at least 25% of the people that had serious impairment due to LBP are over 65. In this study, 30% of the participants were 65 and over; therefore, this is representative of the population. According to the literature, increasing age has been associated with an increase in LBP. However the median age for this sample was 56 years. The study's findings do not support a positive correlation between age and LBP. The United States Census Bureau in 2000 reported that 8.2% of the population in Tallahassee was 65 and older.

Leboeuf-Yde (2000) conducted a systematic review of epidemiologic literature to establish whether body weight is truly associated with LBP. The results of this review were that 32% of all the studies reported a statistically significant positive weak association between body weight and LBP. Leboeuf-Yde concluded that body weight should be considered as a possible weak risk indicator, but there is insufficient data to assess whether it is a true cause of LBP. The present study sample produced BMI values that placed them at risk for LBP. More than 75% of the sample was classified as overweight, or obese. Among those classified as overweight or obese, were African-Americans (n = 29; 88%), single participants (n = 20; 90%), divorced participants (n = 12; 85%), and participants with an education level of vocational/technical degree (n = 5; 100%).

The study participants were comprised mostly of Caucasian (n = 85; 69.7%), with African-Americans (n = 33; 27%), the next largest group. The researcher did not find any specific trends in the literature on race/ethnicity and LBP. Race has been addressed in regard to the prevalence of LBP; however, confounding variables such as obesity, heavy physical occupation, and smoking have skewed the findings (Bonham, 2001). In 2000, the U.S. Census Bureau reported 60.4% of the population in Tallahassee was Caucasian and 78% of the
population in Florida was Caucasian. African-Americans represented 34.2% of the population in Tallahassee and 14.6% of the population in Florida. The larger number of Caucasians in the study sample is representative of the larger Florida population.

Reisbord and Greenland (1985), in a population based study, analyzed the factors associated with self-reported back pain prevalence. Using gender, education, marital status, and age, the results showed: high prevalence, consisting of those 50- to 64-year-olds who were no longer married, regardless of education, with a prevalence of 44% to 46% for women and 42% for men; intermediate prevalence, consisting of 35- to 49-year-olds who were no longer married, regardless of education, with prevalence in women at 27% to 31%, and in men at 23% to 27%. This study sample reported results representative of the findings in the literature. The median age was 56, falling almost in the middle of the literature’s range of 50-to 64-year olds. The study had a slightly higher percentage of married participants (52.5%) than unmarried participants (47.5%).

Women consistently reported a higher level of pain than men; this is representative of the population studied in the literature as indicated by Reisbord and Greenland (1985). There was a higher prevalence of LBP among women than men.

Over 85% of the participants had a 12th grade education or higher. According to the U.S. Census Bureau (2000), 89.9% of the population in Tallahassee had graduated from 12th grade. One reason for the higher education level may be the area from which the sample was taken. Tallahassee has two universities, one community college, and one vocational/technical school. Cross-tabulation analysis of educational level did not show any remarkable trends in relation to other demographics.

Individuals with a history of arthritis, osteoporosis, scoliosis, or any other pre-existing back problems are considered to be at risk for recurrent or persistent LBP. In this study, 65 participants (53.3%) reported having arthritis, the most frequently reported preexisting condition. Osteoporosis was reported by 27 participants (22.7%), all of whom were Caucasian females with a mean age of
Many of the participants may not be aware that they have osteoporosis unless they have had a bone density scan or sustained a fracture. According to the National Osteoporosis Foundation (2004), of the 10 million Americans estimated to have osteoporosis, 8 million are women and 2 million are men. Caucasian women aged 50 and older account for 20% of the population having osteoporosis. African-American women over age 50 account for 5% of the population having osteoporosis. Risk factors for developing osteoporosis include; being female, being thin, advanced age, estrogen deficiency as a result of menopause, and being Caucasian. The current study showed a positive correlation between osteoporosis and all of the risk factors except for being thin. Over 80% of the sample participants who circled osteoporosis were categorized as overweight, or obese. The study did not ask the menopausal women if they were on hormone replacement therapy. Of the sample, 31 participants (25%) with a mean age of 66.6 had two or more preexisting conditions. This placed them at greater risk for developing LBP.

The majority of the participants ($n = 70; 57.4\%$) lived in Leon County while 51 participants (41.8%) came from outlying counties. One participant came from South Georgia. Since the two pain clinics used for the study are located in Leon County, this makes them more accessible to the participants living in Leon County and may contribute to the higher number of participants from Leon County. The researcher did not find any literature that addressed LBP and county of residence. Do people living in metropolitan areas experience more LBP than people living in rural areas? The participants living in Leon County reported less pain on the VAS prior to- and subsequent to- ESI treatment than did the participants from outlying counties. The Leon County participants had the largest population of Caucasians and also had a higher educational level than the rest. People who live in outlying areas may wait longer to seek medical attention, therefore increasing their pain levels when they do seek treatment.

The evidence concerning the relationship between the prevalence of back pain and socioeconomic class (income) is conflicting according to the literature. The effect is weak between LBP and lower socioeconomic class. However, there
is good evidence that LBP leads to more work loss in people of lower socioeconomic class according to Waddell (1998). The findings of this study were representative of the literature in relation to the weak effect between LBP and lower socioeconomic class. The study participants who had an annual household income of under $25,000 had the highest pain score on the VAS (mean = 70.2, S.D. = 22.3). The participants in the other income categories pain scores were only slightly lower, except the participants who had an annual household income that was much lower (mean = 47.0, S.D. = 28.1).

Of the 122 participants, 50% were currently working, 20% were not working due to pain, and 30% were not working due other reasons. The mean age of the participants currently working was (mean = 49.2, S.D. = 10.9). The mean age of the participants not working due to pain was (mean = 51.2, S.D. = 9.0). The mean age of the participants not working for other reasons was (mean = 69.1, S.D. = 7.2). The mean age of the participants currently working was lower than the participants not working. This may indicate the younger participants had families to support and had to go to work whether they were in pain or not. The participants who were not working for other reasons may have been retired.

Efficacy of Epidural Steroid Injections

The literature on the efficacy of ESIs in the treatment of chronic LBP is scarce. The studies that have been done are controversial and inconclusive (Chen, 2004; Koes, Bouter, VanDerHeijden, 1995). The literature reviewed and presented for this study included several studies that looked at the efficacy of ESIs, however, some were fraught with problems.

One double-blind study sampled 57 patients; 23 patients were in the treatment group and received an injection of methylprednisolone into the epidural space by the lumbar route and 34 patients were in the control group and received an injection of normal saline into the interspinous ligament. Injections were given at 2 week-intervals, for up to three injections. The first assessment was at 1 month; 14/21 (67%) treated and 18/32 (56%) controls had recovered, the difference not reaching statistical significance. At 3 months, the treated group
was shown to be significantly more pain free (p < 0.05). A larger proportion of the treated group were improved at every assessment point up to 1 year, with the most marked effect at 3 months (Mathews, Mills, Jenkins, Grimes, Morkel, Mathews, Scott & Sittampalam, 1987).

In this study, the researcher assessed the participants 2 weeks after their first injection; there was a 67% reduction in the pain score. The participants typically had their 2 week assessment after their second injection at the 3-month mark. Their mean pain score went from 65.4 on the day of the first injection to 35.8 two weeks after their second injection. The participants experienced almost a 50% reduction in pain at approximately 3 months. Even though the two studies were not conducted in the same way, the findings were similar.

In another study by Bowman, Grahame, Newman, Wedderbum & Whaley, 1993, 35 patients were recruited with symptoms of nerve compression. All 35 patients received a lumbar ESI. The patients were asked to rate their improvement on a 4-point scale at one week: 5 had no improvement, 16 had some improvement, 11 were markedly improved, and one was completely cured (missing data = 5). At 3 months, 5 patients rated their treatment totally unsatisfactory to poor, 10 rated it satisfactory, 5 rated it good, and 9 rated it excellent (missing data = 6).

The researcher did find her participants to have comparable findings; however, her participants had received a second injection at the 3-month mark. There was a decreased pain score after the second injection.

Lumbar ESIs have been used with success in a proportion of patients with LBP, as demonstrated by two double-blind controlled trials (Spaccarelli, 1996). The researchers held the view that epidural injections act during the short to medium term (1 week to 3 months). It, therefore, is not surprising that two other studies which Spaccarelli reviewed (Snoek et al., 1977; Cuckler et al., 1985) that examined patients at 24 – 48 hours (too early) and then 8-30 months (too late) failed to find a benefit (Spaccarelli, 1996). They concluded that ESIs are an effective, well-tolerated procedure in some, but not for all patients with LBP.
The researcher found the ESIs were effective for 67% of her participants. The researcher utilized three different instruments to measure pain and they all provided improvement from prior to- and subsequent to- ESI treatment. There was one tool used to measure level of disability. There was a positive correlation between perception of pain and level of disability. Social factors undoubtedly influence psychological functioning and, therefore, behavior. For example, during the initial consultation, the ARNP listened to the patients’ feelings, validated their feelings, provided them with information concerning the treatment modalities, and included them in the plan of action. The ARNP empowered the patient to participate in health-promoting behaviors and a high level of health. The HPM is an integral part of nursing practice.

**Conceptual Framework**

*Health Promotion Model & Gate Control Pain Theory/ Loeser’s Onion Theory*

The framework that guided this study is a combination of a nursing theory, the Health Promotion Model (Pender, 1987 &1996) and a combination of two non-nursing theories, the Gate Control Pain Theory (Melzack, 1967) and Loeser’s Onion Theory (Loeser, 1980). The combination of these theories identifies factors in both the individual and the environment that will influence his/her perception of pain. Pain is also viewed as a multifactorial phenomenon by the theorists.

*Health Promotion Model (HPM).* Based on the HPM, Pender adapted this concept to clinical nursing practice with an emphasis on the individual and his/her perceptions. The HPM in its 1987 form identified cognitive perceptual factors in the individual that are modified by situational, personal, and interpersonal characteristics that result in the participation in health-promoting behaviors in the presence of a cue to action (Pender, 1987). The 1996 revision of the model added three new variables that served to influence the individual to engage in health-promoting behaviors: activity-related affect, commitment to a plan of
action, and immediate competing demand and preferences (Pender, 1996). The researcher utilized a combination of the two models to guide the study, and it will be from this theoretical basis that the findings have been viewed. The cognitive-perceptual factors related to health promotion according to Pender are: importance of health, perceived control of health, perceived self-efficacy, definition of health, perceived health status, perceived benefits of health-promoting behaviors, and perceived barriers to health-promoting behaviors. Health is seen as a positive high-level state. The individual is assumed to have a drive toward health. The fact that Leon County had one pain management clinic until 2 years ago, and now has three, indicates that there was an enormous population of individuals with chronic pain seeking a high-level state of health from pain management specialists.

One study by Lambert (2002) utilized the HPM and studied individuals’ perceived control of health. The study invited men over the age of 45 to complete a questionnaire regarding prostate screening health-beliefs and practices. The goal of the study was to empower the men to make personal decisions to participate in the health-promoting behavior of annual prostate screening. An individual’s perception of his/her ability to change his/her health can motivate his/her desire for health. This study revealed ESIs are being sought out by individuals who value their health and perceive they have control over their health.

According to Pender (1996), perceived self-efficacy is the individual’s strong belief that a behavior is possible and can influence the occurrence of that behavior. The procedures for this study included the ARNP performing an initial consultation/examination on all new patients. This interaction allows the patient to see that the ARNP is willing to spend the time listening to his/her feelings, validating those feelings, explaining the reasons for his/her pain, and educating him/her as to the treatment modalities available to the patient. By explaining the benefits of procedures such as ESIs, the patients will be more inclined to begin health-promoting behaviors if they feel the benefits are high. By providing literature on the procedures and encouraging the patients to do research
themselves, the ARNP is empowering the patient to take control of his/her health. Ultimately, it is intended that the patient will see that the ARNP has given him/her hope and the desire to pursue health-promoting behaviors. The patient should leave the consultation feeling better about himself/herself; having the commitment to a plan of action; and knowing that a relationship has been formed with a healthcare professional who cares about the individual as a whole.

This discussion leads directly into another cognitive-perceptual factor, perceived health status. An individual’s state of feeling well or feeling ill can determine the likelihood that health-promoting behaviors will be initiated. An individual may enter the consultation/examination with a state of ill feeling; however, after having the ARNP listen, validate, and express genuine concern about his/her feelings, he/she may leave the consultation with a rejuvenated state of wellness.

Perceived barriers to health-promoting behaviors are another factor that the ARNP may be able to influence through the use of a multi-disciplinary approach. Since pain is a multifactorial phenomenon, it typically takes a multi-disciplinary team to address the patients’ physiological, psychological, and psychosocial issues. The ARNP may send a copy of the patient’s dictation to his/her primary care physician and/or his/her referring physician and make recommendations under the assessment and plan.

According to the HPM (1987) modifying factors include demographic characteristics, biologic characteristics, interpersonal influences, situational factors, and behavioral factors (Pender, 1984). The researcher developed a demographic questionnaire to analyze these modifying factors and the relationship that they play in the participants’ perception of pain and level of disability. Each of the modifying factors was analyzed in relation to the study findings and is compared to the literature later in the chapter.

The last part of the 1987 HPM is participation in health-promoting behaviors. The likelihood of engaging in health-promoting behaviors involves all of the cognitive-perceptual factors and modifying factors discussed previously. The 1996 revision of the model added three new variables that serve to influence
the individual to engage in health-promoting behaviors: activity-related affect, commitment to a plan of action, and immediate competing demand and preferences. One study addressed in Chapter Two in the empirical section was a master’s thesis that utilized Pender’s HPM to guide the study. The purpose of the study was to describe the current status of primary care nurse practitioners (NPs) in the performance of smoking cessation counseling (SCC). Quantitative analysis of the findings revealed that NPs were most likely to provide interventions to stop smoking and least likely to arrange follow-up. Commitment to a plan of action is key to follow-up and preventing relapse. This study can be correlated to the patients who are receiving the ESI series. Typically, each clinic follows up with the patients 1-2 days after their injection to see if they are having any immediate problems or concerns. However, the follow-up at 2 weeks is crucial because at that point, the ESI has had an opportunity to have an effect on the patients’ pain. The patient is able to express his/her pain level and be an active participant in the next step of his/her care. The commitment to a plan of action is essential for both the healthcare professional and the patient.

Families, peers, and healthcare providers are important sources of interpersonal influence that can increase or decrease commitment to, and engagement in, health-promoting behavior. Situational influences in the external environment can also increase, or decrease, commitment to, or participation in, health-promoting behavior. In the discussion of findings section of this chapter, the researcher addresses the data gathered from the participants according to their responses on the questionnaires and analyzes the relationships between the variables.

The Gate Control Pain Theory (GCPT) and Loeser’s ‘onion’ theory. These non-nursing theories were used in combination with Pender’s HPM to guide this study. The GCPT focuses on the physiologic aspect of how pain is transmitted. However, the GCPT does not dispute the fact that psychological and environmental factors always have to be considered when discussing pain. Additionally, these theories demonstrate not only how the ESIs relieve the pain physiologically but psychologically. Loeser’s ‘onion’ theory was the schematic
presented in Figure 1 and a revised schematic is presented in Figure 2. The revised schematic is an interpretation of the HPM, GCPT, LOT, and how they coincide with the findings of the study.

Revised Schematic Representation of Pain combines three theoretical concepts. Nola Pender’s Health Promotion Model, which emphasizes the individual and his/her perceptions, is blended with The Gate Control Pain Theory which is based on the belief that psychological, as well as physical factors guide the brain’s interpretation of painful sensations and the subsequent response. Loeser’s Onion Theory theorizes that the pain mechanism is a series of nested layers like an onion. Pain is a multifactorial phenomenon and all the factors above must be considered by the ARNP before ESI treatment can begin.

**Limitations of the Study**

Limitations of this study included the sample size, the use of several different pain instruments, and the difficulty scoring one of the pain instruments.
The sample size was initially determined to be 170 after consideration of the researcher’s preset levels of alpha, power, and effect size. The researcher collected her data at one pain clinic but realized that the accessible population at one clinic would not be of sufficient size to obtain a random sample. A second pain clinic was added in the middle of the data collection and the researcher even extended the data collection time frame. However, even with these additional measures to meet the sample size, the researcher was not able to select the participants randomly. Therefore, due to a sample size which did not meet the requirement from the power analysis and the lack of random selection, the Power of the inferential results was less than expected. However, the results of the study were so extreme that even a loss in Power still provided the researcher with a high level of confidence in claiming that ESIs are effective. Also, the researcher met the effect size of .25σ.

The researcher chose three tools to measure the patients’ perception of pain. This created some confusion during the interpretation of the findings. The McGill Pain Questionnaire (MPQ) was scored in such a way that led the outcomes to be uncertain. The MPQ utilized 15 adjectives that the participant had a choice of checking to describe his/her pain and the intensity of the pain, but with no instructions as to the minimum number, or that any pattern was expected. The MPQ provided qualitative data which then had to be transformed into quantitative findings, in order to compare it to other quantitative outcomes.

**Strengths of the Study**

Since the researcher has been employed by one of the pain clinics for over a year, she noticed the demographic characteristics of the participants were representative of the LBP population. The responses were positive reinforcing the fact that the pre-injection scores were greater than post-injection scores for perception of pain and level of disability. This indicates that ESIs are effective. The review of the literature was scarce on studies on the efficacy of ESIs in the
treatment of chronic LBP. The results of this study (67% efficacy) were higher than any of the other studies conducted. One researcher collected all of the data from the participants prior to and subsequent to ESI treatment. This provided the researcher with a level of control and reassurance that the data were collected accurately, while maintaining patient confidentiality to the fullest extent allowed by law. The researcher had to follow-up with most of the participants by telephone due to the fact that only a handful of participants received a 3rd injection. Communicating with the participants by telephone allowed the researcher to spend more time with the participants, allowing them to verbalize their feelings and opinions, validating their feelings, and answering any questions they might have had. This, like the initial consultation between the ARNP and the patient, formed a relationship based on trust and a level of comfort for the patient.

**Implications for Nursing**

*Nursing Practice*

The nursing profession has demonstrated the responsibility of providing care through knowledge, technology, and an innate desire to serve. With that responsibility comes the expectations from those served that nurses “know it all.” With nursing becoming so specialized, this expectation is almost unrealistic; however nurses all share common fundamentals- to prevent disease, to promote health, and to educate.

The thorough assessment of the patient’s pain is essential to ensure the proper treatment modality is administered. Nurses must continue to expand their knowledge of pain management including the need for non-surgical pain interventions such as ESIs. Accurate assessments of the patient’s pain status, along with all of the other factors that play a role in pain perception are vital to the outcome. Pain has been perceived as hard to manage and is often not given the attention the patient deserves. The studies that have been published on ESIs
have been controversial and inconclusive. The researcher hopes this study will help to confirm the efficacy of ESIs in the treatment of chronic LBP and provide nurses with the statistics that may influence a patient to seek ESI treatment.

**Advanced Practice Nursing**

The advanced practice nurse is the caregiver, consultant, educator, leader, and researcher in providing quality healthcare. These roles are inherent to advanced practice nursing, and, as such, the APN needs to stay abreast in approaches and procedures to promote health and prevent diseases. The science of pain management is complex, there is an educational void about the art of caring for patients with chronic LBP, and APNs need to have a broad knowledge base of chronic LBP management. They will be doing the assessing, treating, managing, consulting, and educating of this population. ESIs have become an integral part of non-surgical management of LBP. It is imperative that the efficacy of ESIs continues to be studied, providing APNs the information necessary to treat their patients with the most effective treatment modalities available.

**Administration**

Administrators of clinical organizations must ensure proper pain management to its patients and the community. Implementation of pain management and epidural steroid injection in-services to increase knowledge base should be advocated. Allowing and supporting APNs to travel to conferences and educational enhancement programs is essential to providing state of the art pain management treatment modalities. Furthermore, they must do continual upgrades in standards of care, based on quality improvement studies.
Health Promotion Model

Nola Pender adapted this concept to clinical nursing practice with an emphasis on the individual and his/her perceptions. Individuals who value health highly are more likely to seek it. The individual’s perception of his / her own ability to change his / her health can motivate his / her desire for health. APNs are educators and the more knowledge APNs have about the efficacy of ESIs, the better prepared they will be to treat patients with chronic LBP and promote health and wellbeing. Pender (1987) has identified health promotion as a goal for the twenty-first century.

Education

Education on pain management, chronic LBP, and ESIs needs to be an essential part of nursing curricula at both the undergraduate and graduate levels. Nursing students should be educated on how the components of the Health Promotion Model and the efficacy of ESIs is beneficial not only to the patient suffering from chronic LBP, but to society as a whole. If students are exposed to these concepts during their educational years, perhaps they will embrace them and implement them throughout their nursing careers.

Recommendations for Future Research

More research in the area of the efficacy of ESIs in the treatment of chronic LBP is needed and welcomed by APNs. The researcher understands that ESI treatment has been used since the 1960’s; however, the ESIs did not become popular until the early 1990’s. Pain management specialists are hiring ARNPs; therefore, ARNPs need to have resources accessible to them in their specialty practice.

The researcher would recommend using only one instrument to measure pain in future studies. The use of three instruments became confusing at times.
The Visual Analog Scale appears to be the most widely recognized and frequently used pain instrument. However, in this study, the researcher did have positive results with all three instruments. The researcher would also make every effort to have a large sample so the participants could be chosen at random.

It would be interesting to look at other variables that may influence a patient’s perception of pain in future studies. The researcher would be interested in looking at variables such as smoking, how long the pain has been going on, depression, stress, and job satisfaction. Since pain is a multifactorial phenomenon, there are an infinite number of variables that could be analyzed. It might also be beneficial to look at other treatments previously tried.

Comparisons of different groups of chronic LBP patients from different areas of the country may provide valuable information about the types of patients these APNs serve, which could invariably assist the profession in addressing the most appropriate treatment modalities available. Cultural differences should always be considered when developing a plan of action. The patient should be an important part of the planning process.

Summary

So what? What has this journey of the efficacy of ESIs in the treatment of chronic LBP, focusing on patients’ perception of pain and level of disability prior to, and subsequent to, ESI treatment brought to the eyes of the reader? It is the hope an acknowledgement would be made that pain is real and there are effective treatment modalities, such as ESI, available to chronic LBP patients. The researcher has acquired a great desire to care for these people in her practice and hopefully provide them with the desire to practice health promoting behaviors and strive for a high level of health.
APPENDIX A

PERMISSION LETTER FROM MEDICAL DIRECTOR OF PAIN MANAGEMENT SPECIALISTS
Kenyon Hranicky
3455 Gentle Wind Way
Tallahassee, FL 32317

June 15, 2004

Dear Ms. Hranicky,

I have reviewed your research proposal "Efficacy of Epidural Steroid injections in the treatment of Chronic Low Back Pain." I find that your research project meets my approval and you may proceed with your research data collection in our facility as soon as it is practical for you to do so.

Sincerely,

[Signature]

Dr. Parveen Khanna,
Medical Director
APPENDIX B

PERMISSION LETTER FROM DR. MULLIN
October 12, 2004

Kenyon Teasley
3455 Gentle Wind Way
Tallahassee, FL 32317

Dear Ms. Teasley,

I have reviewed your research proposal “Efficacy of Epidural in the treatment of Chronic Low Back Pain.” I find that your research project meets my approval and you may proceed with your research/data collection utilizing patients from our facility as soon as it is practical for you to do so.

Sincerely,

Dr. Mullin
Medical Director
APPENDIX C

APPROVAL MEMORANDUM FROM HUMAN SUBJECTS COMMITTEE
Office of the Vice President For Research  
Human Subjects Committee  
Tallahassee, Florida 32306-2753  
(850) 644-8633  •  FAX (850) 644-4392

APPROVAL MEMORANDUM

Date: 8/20/2004

To:  
Kenyon Hranicky  
3455 Gentle Wind Way  
Tallahassee FL 32317

Dept.: NURSING

From: John Tomkowiak, Chair

Re: Use of Human Subjects in Research  
The Efficacy of Epidural Steroid Injection in the Treatment of Chronic Low Back Pain

The forms that you submitted to this office in regard to the use of human subjects in the proposal referenced above have been reviewed by the Human Subjects Committee at its meeting on 8/4/2004. Your project was approved by the Committee.

The Human Subjects Committee has not evaluated your proposal for scientific merit, except to weigh the risk to the human participants and the aspects of the proposal related to potential risk and benefit. This approval does not replace any departmental or other approvals which may be required.

If the project has not been completed by 8/3/2005 you must request renewed approval for continuation of the project.

You are advised that any change in protocol in this project must be approved by resubmission of the project to the Committee for approval. Also, the principal investigator must promptly report, in writing, any unexpected problems causing risks to research subjects or others.

By copy of this memorandum, the chairman of your department and/or your major professor is reminded that he/she is responsible for being informed concerning research projects involving human subjects in the department, and should review protocols of such investigations as often as needed to insure that the project is being conducted in compliance with our institution and with DHHS regulations.

This institution has an Assurance on file with the Office for Protection from Research Risks. The Assurance Number is IRB00000446.

cc: Jeanne Flannery  
HSC No. 2004-546
Title of Research: Efficacy of Epidural Steroid Injections in the Treatment of Chronic Low Back Pain

I freely and voluntarily, and without any element of force or coercion, consent to be a participant in this project. I have been informed that this project is to be conducted, as part of the degree requirements, by Kenyon Hranicky, a registered nurse, who is currently enrolled in the graduate nursing program at Florida State University. The researcher will also utilize a research assistant, Deborah Dilmore, ARNP, who is employed by the pain clinic. The study will take place during the period of August, 2004, through December, 2004, under the guidance of Jeanne Flannery, DSN, ARNP, a professor in the School of Nursing.

I understand the purpose of this study is to explore the efficacy of epidural steroid injections in the treatment of chronic low back pain. The goal is to measure my perceptions of pain and quality of life as I receive epidural steroid injections for my pain.

I understand once I give my consent, my participation will involve completing questionnaires after my initial consultation/examination. When I receive the second injection I will be asked to complete the same questionnaires. At my second injection appointment, I will be given a piece of paper with a line 100 millimeters long drawn on it to take home, along with a stamped self-addressed envelope, provided by the researcher. I will be given complete instructions by the researcher or the research assistant as to what I am to do with this paper. If I do not receive a 3rd injection, the researcher will call me at home 2 weeks after my 2nd injection, with my permission, and ask me the same questions asked on the first questionnaires and will also ask me to rate my pain at that time. This will be done using the piece of paper with the line on it. After I have made an X on the line according to my pain rating, I will fold the piece of paper with my X marked on it and place the piece of paper in a stamped self-addressed envelope, provided by the researcher, and then place the envelope in my mailbox for pickup. The researcher will call me the next day, with my permission, to verify that the envelope has been sent back to the researcher.

If I receive a 3rd injection, I will fill out the same questionnaires, along with the piece of paper with the line on it, at the time of my 3rd injection. The questionnaires will be filled out during my scheduled appointment two weeks later the researcher will contact me by phone as described above, and will take approximately 10 minutes of my time to answer the questionnaires. I will follow the procedures as described to mark an X on the paper rating my pain and mailing it back to the researcher.

I understand I was chosen for this study because I am receiving epidural steroid injections as part of the prescribed treatment for chronic low back pain. Participating in this study does not alter the time I will receive now, or in the future, from my healthcare provider, or interfere in any way with my prescribed therapy. It will, in no way, modify the directions given to me at the pain clinic if I require attention for my condition while I am home.
I have been informed that my physician has given his/her approval for my participation, if I desire to do so. I understand that even after consenting to participate, I may withdraw my consent and discontinue participation at any time without penalty or loss of benefits to which I may otherwise be entitled. It will, in no way, modify my planned treatment at the pain clinic.

I understand I will not be paid for my participation in this study. Although there may be no direct benefits to me, the possible benefits of my participation are that I may assist the researcher in determining the efficacy of epidural steroid injections in the treatment of chronic low back pain. There are no foreseeable risks or discomforts to me if I agree to participate in this study.

I understand that my privacy will be protected at all times. Information obtained during the course of the study will remain confidential, to the extent allowed by law. All information will be coded by numbers and no names will be used in any report. As soon as the final questionnaires are completed, the link between my name and the code numbers will be destroyed and there will be no way my identity could be determined. The data will be stored in a locked drawer in the desk in the consultation room at the pain clinic until April, 2005, after which, the researcher will place it in a locked file cabinet at her home until April, 2010. At this point, all data will be destroyed appropriately. Only the researcher, the research assistant, the physicians at the pain clinic, and the statistical consultant will have access to the data. The results of this research may be published but my name, or identity, or the identity of the pain clinic will not be revealed.

Any questions I have concerning the study, or my participation in it, before or after my consent, will be answered by Dr. Jeanne Flannery or the researcher. I can reach Dr. Jeanne Flannery at Florida State University’s School of Nursing at (850) 644-5626, or Kenyon Hranicky at (850) 942-1515.

In the event I have questions about my rights as a participant in this research study, I can contact the Chair of the Human Subjects Committee Institutional Review Board, through the office of the Vice President for Research at (850) 644-8633.

The nature of the demands and benefits of the project have been explained to me. I understand that in signing this consent form, I am not waiving any legal claims, rights, or remedies.

I have read the entire informed consent form and have been offered a copy with my signature.

Participant’s Signature: _____________________________________________

Printed Name of Participant: _________________________________________

Date: ___________________________________________________________
APPENDIX E

INFORMED CONSENT FOR DR. MULLINS PATIENTS
Florida State University  
Human Subjects Committee  
INFORMED CONSENT FORM

Title of Research: Efficacy of Epidural Steroid Injections in the Treatment of Chronic Low Back Pain

I freely and voluntarily, and without any element of force or coercion, consent to be a participant in this project. I have been informed that this project is to be conducted, as part of the degree requirements, by Kenyon Hranicky, a registered nurse, who is currently enrolled in the graduate nursing program at Florida State University. The study will take place during the period of August, 2004, through January, 2005, under the guidance of Jeanne Flannery, DSN, ARNP, a professor in the School of Nursing. 

I understand the purpose of this study is to explore the efficacy of epidural steroid injections in the treatment of chronic low back pain. The goal is to be able to determine whether epidural steroid injections are effective, as determined by a change in patients' perception of pain and quality of life.

I understand once I give my consent, my participation will involve completing questionnaires at the time I am to receive my first injection by Dr. Mullin at the Surgery Center. I will receive, as my regularly prescribed treatment, two to three injections of Kenalog via epidural injection. At my second injection appointment I will be asked to complete the same questionnaires. At my second injection appointment injection, I will be given a piece of paper with a line 100 millimeters long draw on it to take home, along with a stamped self-addressed envelope, provided by the researcher. I will be given complete instructions by the researcher or the research assistant as to what I am to do with this paper. If I do not receive a 3rd injection, the researcher will call me at home 2 weeks after my 2nd injection, with my permission, and ask me the same questions asked on the first questionnaires and will also ask me to rate my pain at that time. This will be done using the piece of paper with the line on it. After I have made an X on the line according to my pain rating, I will fold the piece of paper with my X marked on it and place the piece of paper in a stamped self-addressed envelope, provided by the researcher, in my mailbox. The researcher will call me the next day, with my permission, to verify that the envelope has been sent back to the researcher. If I receive a 3rd injection, I will fill out the same questionnaires, along with the piece of paper with the line on it, at the time of my 3rd injection. The questionnaires will be filled out during my scheduled appointment or over the phone as described above, and will take approximately 10 minutes of my time to complete.

I understand I was chosen for this study because I am receiving epidural steroid injections as part of the prescribed treatment for chronic low back pain. Participating in this study does not alter the time I will receive now, or in the future, from my healthcare provider, or interfere in any way with my prescribed therapy.

(over)
I have been informed that my physician has given his/her approval for my participation, if I desire to do so. I understand that even after consenting to participate, I may withdraw my consent and discontinue participation at any time without penalty or loss of benefits to which I may otherwise be entitled.

I understand I will not be paid for my participation in this study. Although there may be no direct benefits to me, the possible benefits of my participation are that I may assist the researcher in determining the efficacy of epidural steroid injections in the treatment of chronic low back pain. There are no foreseeable risks or discomforts to me if I agree to participate in this study.

I understand that my privacy will be protected at all times. Information obtained during the course of the study will remain confidential, to the extent allowed by law. All information will be coded by numbers and no names will be used in any report. As soon as the final questionnaires are completed, the link between my name and the code numbers will be destroyed and there will be no way my identity could be determined. The data will be stored in a locked cabinet at the Surgery Center until April, 2005, after which, the researcher will place it in a locked file cabinet at her home until April, 2010. At this point, all data will be destroyed appropriately. Only the researcher, the physician at the pain clinic, and the statistical consultant will have access to the data. The results of this research may be published but my name or identity will not be revealed.

Any questions I have concerning the study or my participation in it, before or after my consent, will be answered by Dr. Jeanne Flannery or the researcher. I can reach Dr. Jeanne Flannery at Florida State University's School of Nursing at (850) 644-5626, or Kenyon Hranicky at (850) 942-1515.

In the event I have questions about my rights as a participant in this research study, I can contact the Chair of the Human Subjects Committee Institutional Review Board, through the office of the Vice President for Research at (850) 644-8633.

The nature of the demands and benefits of the project have been explained to me. I understand that in signing this consent form, I am not waiving any legal claims, rights, or remedies.

I have read the entire informed consent form and have been offered a copy with my signature.

Participant's Signature: ________________________________

Printed Name of Participant: ________________________________

Date: ________________________________

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APPENDIX F

DEMOGRAPHIC QUESTIONNAIRE
Demographic Questionnaire

Demographic Characteristics
Please circle the appropriate response

1. Gender:   a) Female   b) Male

2. Age:_________

3. Height:_______  Weight:_______

4. Race/ethnicity:
   a) Caucasian (white)   d) Hispanic
   b) African-American   e) Other ________
   c) Asian/Pacific Islander

5. Marital Status:   a) Single   b) Married   c) Separated   d) Divorced
                    e) Widowed

6. Highest educational level achieved:
   a) 8th grade   e) Bachelor’s
   b) 12th grade   f) Master’s and/or beyond
   c) Some college but no degree earned   g) Vocational -Technical
   d) Associate’s

7. Do you suffer from any of the following conditions? (circle all that apply)
   a) Arthritis
   b) Osteoporosis
   c) Scoliosis
   d) Any other preexisting back problems

8. County of Residence:_________

9. Please indicate your annual household income:
   a) under $25,000
   b) $25,000 to just under $50,000
   c) $50,000 to just under $75,000
   d) $75,000 to just under $100,000
   e) $100,000 or over

10. Are you currently working?
   a) Yes
   b) No; I am not able to work due to the pain
   c) No; I am not currently working for other reasons

11. What is your pain rating today?
    No pain________________________________________Worst possible pain

12. What is your pain rating the day of your first injection?
    No pain________________________________________Worst possible pain
12. What is your pain rating two weeks after your first injection? (to be completed at time of second injection)

No pain  Worst possible pain

13. What is your pain rating two weeks after your second injection? (to be completed at time of third injection or by phone)

No pain  Worst possible pain

14. Overall, do you feel the injections have been effective? (Provided you with pain relief)

a) Yes

b) No
APPENDIX G

VISUAL ANALOG SCALE
No pain________________________________________Worst possible pain
APPENDIX H

THE SHORT FORM McGill PAIN QUESTIONNAIRE
### SHORT FORM McGill Pain Questionnaire

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<th>MODERATE (2)</th>
<th>SEVERE (3)</th>
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<tr>
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<td>Aching</td>
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<td>Heavy</td>
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<td>Tender</td>
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<td>Splitting</td>
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<td>Tiring/Exhausting</td>
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<td>Sickening</td>
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<td>Fearful</td>
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<tr>
<td>Punishing-Cruel</td>
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Patient Information. Please check any word that applies to your pain experience under the heading of NONE, MILD, MODERATE, SEVERE.
APPENDIX I

PERMISSION LETTER FROM AUTHOR OF McGill Pain Questionnaire
Dear Kenyon,

It is a pleasure to give you permission to use the MPQ without charge for your very interesting thesis research.

Sincerely,

Ronald Melzack

At 07:43 PM 6/1/2004 -0400, you wrote:

Dear Dr. Melzack,

I am a graduate student at Florida State University in the nurse practitioner program. I am writing my thesis on the efficacy of epidural steroid injections in the treatment of chronic low back pain. I would like to ask permission to use the short form of the McGill Pain Questionnaire as one of my tools to evaluate the patients' pain. Thank you for consideration in this matter. I will send you a more formal letter stating my intent as I am approaching the end of my thesis process.

Sincerely,

Kenyon Hranicky
3455 Gentle Wind Way
Tallahassee, Fl.32317
phone#850-942-1515
khrntally@msn.com

Chantale Bousquet
Clinical Secretary
Department of Psychology
McGill University
1205 Dr. Penfield Avenue
Montreal, PQ H3A 1B1
Tel: (514) 398-6127
FAX: (514) 398-4896
APPENDIX J

OSWESTRY INDEX QUESTIONNAIRE
Revised Oswestry Chronic Low Back Pain Questionnaire

Please check the one answer in each of the following 10 sections that best describes your condition or situation.

SECTION 1 - PAIN INTENSITY
0 □ The pain comes and goes and is very mild.
1 □ The pain is mild and does not vary much.
2 □ The pain comes and goes and is moderate.
3 □ The pain is moderate and does not vary much.
4 □ The pain comes and goes and is severe.
5 □ The pain is severe and does not vary much.

SECTION 2 - PERSONAL CARE
0 □ I do not have to change my way of washing or dressing to accommodate my pain.
1 □ I do not normally change my way of washing or dressing even though it causes some pain.
2 □ Washing and dressing increase the pain, but I manage not to change my way of doing it.
3 □ Washing and dressing increases the pain, and I find it necessary to change my way of doing it.
4 □ Because of the pain, I am unable to do some washing and dressing without help.
5 □ Because of the pain, I am unable to do any washing and dressing without help.

SECTION 3 - LIFTING
0 □ I can lift heavy weights without extra pain.
1 □ I can lift heavy weights, but it causes extra pain.
2 □ Pain prevents me from lifting heavy weights off the floor.
3 □ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, e.g. on a table.
4 □ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
5 □ I can only lift very light weights, at the most.
SECTION 4 - WALKING
0 □ Pain does not prevent me from walking any distance.
1 □ Pain prevents me from walking more than one mile.
2 □ Pain prevents me from walking more than 1/2 mile.
3 □ Pain prevents me from walking more than 1/4 mile.
4 □ I can only walk using an aid, e.g. cane, crutches, or walker.
5 □ I am in bed most of the time and have to crawl to the toilet.

SECTION 5 - SITTING
0 □ I can sit in any chair as long as I like without pain.
1 □ I can only sit in my favorite chair as long as I like.
2 □ Pain prevents me from sitting more than one hour.
3 □ Pain prevents me from sitting more than 1/2 hour.
4 □ Pain prevents me from sitting more than 10 minutes.
5 □ Pain prevents me from sitting at all.

SECTION 6 - STANDING
0 □ I can stand as long as I want without pain.
1 □ I have some pain while standing, but it does not increase with time.
2 □ I cannot stand for longer than one hour without increasing pain.
3 □ I cannot stand for longer than 1/2 hour without increasing pain.
4 □ I cannot stand for longer than 10 minutes without increasing pain.
5 □ I avoid standing, because it increases the pain right away.

SECTION 7 - SLEEPING
0 □ I get no pain in bed.
1 □ I get no pain in bed, but it does prevent me from sleeping well.
2 □ Because of the pain, my normal night's sleep is reduced by 25%.
3 □ Because of the pain, my normal night's sleep is reduced by one-half.
4 □ Because of the pain, my normal night's sleep is reduced by 75%.
5 □ Pain prevents me from sleeping at all.

SECTION 8 - SOCIAL LIFE
0 □ My social life is normal and causes no pain.
1  My social life is normal, but increases the degree of my pain.

2  Pain has no significant effect on my social life apart from limiting my most energetic interests, e.g. dancing, etc.
3  Pain has restricted my social life and I do not go out very often.
4  Pain has restricted my social life to my home.
5  I have hardly any social life because of the pain.

**SECTION 9 - TRAVELING**

0  I get no pain while traveling.
1  I get some pain while traveling, but none of my usual forms of travel makes it any worse.
2  I get extra pain while traveling, which it does not compel me to seek alternative forms of travel.
3  I get extra pain while traveling, which compels me to seek alternative forms of travel.
4  Pain restricts all forms of travel.
5  Pain prevents all forms of travel except that done lying down.

**SECTION 10 - CHANGING DEGREE OF PAIN**

0  My pain is rapidly getting better.
1  My pain fluctuates, but overall, is definitely getting better.
2  My pain seems to be getting better, but improvement is slow at present.
3  My pain is neither getting better or worse.
4  My pain is gradually worsening.
5  My pain is rapidly worsening.
APPENDIX K

PERMISSION LETTER FROM AUTHOR OF OSWESTRY INDEX QUESTIONNAIRE
Dear Kenyon Hranicky
Your welcome to use the ODI
I suggest you use v2.1

Jeremy Fairbank

I suggest you read the papers and the website. I suggest you use v2.1
called 2.0 in Roland and Fairbank).

Note that there are slight differences in wording from Fairbank and Pynsent
v2.0 because a rogue version found its way into our Fairbank/Pynsent paper.

The scoring system has always allowed sections to be not completed and the
score scaled accordingly.

The ODI website is www.merc.wlv.ac.uk/ODI/index.htm - It may not work - we
are planning to move it to a more stable site

Version numbers are:
version 1.0 (the original version from the 1980 paper: Fairbank J, Couper J,
Davies J, O'Brien J. The Oswestry low back pain questionnaire. Physiotherapy
1980;66:271-3.)
version 2.0 (published in 2000: Fairbank J, Pynsent P. The oswestry
version 2.1 (Roland M, Fairbank J. The Roland-Morris Disability
Questionnaire and the Oswestry Disability Questionnaire. Spine
2000;25:3115-3124)
APPENDIX L

PERMISSION LETTER FROM DR. MacARTHUR, V.P./CHIEF MEDICAL OFFICER, TALLAHASSEE MEMORIAL HOSPITAL
October 20, 2004

Kenyon Hranicky-Teasley
3455 Gentle Wind Way
Tallahassee, FL 32317

Dear Ms. Teasley:

I have reviewed your research proposal, “Efficacy of Epidural Steroid Injections in the Treatment of Chronic Low Back Pain.”

This project meets the criteria for an Expedited Review and you may proceed with your study as soon as it is practical for you to do so.

At the completion of your study, please send a copy of your final paper to the Medical Staff Office at Tallahassee Memorial so that it may be summarized and presented to the Institutional Review Board of Tallahassee Memorial.

Sincerely,

Richard MacArthur, M.D., MS
VP/Chief Medical Officer
Administrative Liaison/IRB
APPENDIX M

REVISED APPROVAL MEMORANDUM FROM HUMAN SUBJECTS COMMITTEE
APPROVAL MEMORANDUM (for change in research protocol)

Date: 10/26/2004

To: Kenyon Hrenicky
3455 Gentle Wind Way
Tallahassee FL 32317

Dept: NURSING

From: John Tomkowiak, Chair

Re: Use of Human subjects in Research:
Project entitled: The Efficacy of Epidural Steroid Injection in the Treatment of Chronic Low Back Pain

The memorandum that you submitted to this office in regard to the requested change in your research protocol for the above-referenced project have been reviewed and approved. Thank you for informing the Committee of this change.

A reminder that if the project has not been completed by 8/3/2005, you must request renewed approval for continuation of the project.

By copy of this memorandum, the chairman of your department and/or your major professor is reminded that he/she is responsible for being informed concerning research projects involving human subjects in the department, and should review protocols of such investigations as often as needed to insure that the project is being conducted in compliance with our institution and with DHHS regulations.

This institution has an Assurance on file with the Office for Protection from Research Risks. The Assurance Number is IRB00000446.

cc: Jeanna Flannery
APPLICATION NO. 2004.546
REFERENCES


Kenyon McCune Teasley graduated from Florida State University with a Bachelor of Science in Nursing in December, 1989. She lives in Tallahassee with her husband, Bill, and her two children, Stephanie and Tyler.

Kenyon is a member of Sigma Theta Tau Nursing Honor Society and the Council of Advanced Practice Nurses. She has worked at Tallahassee Memorial Hospital since 1986 in Family Care, Pediatric ICU, and Outpatient Surgery. In January, 2004, she began working for Pain Management Specialists, an affiliate of Anesthesiology and Associates. She will begin her professional career as an advanced registered nurse practitioner at Pain Management Specialists, Tallahassee, upon her graduation.

Kenyon’s personal interests include spending time with her family, exercising, traveling, and boating. She plans to publish her thesis manuscript to increase awareness of the efficacy of ESIs in the treatment of chronic LBP.