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# A Comparison Study of the Effects of Methods of Pain Control on Client Outcomes

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A COMPARISON STUDY OF THE EFFECTS OF  
METHODS OF PAIN CONTROL ON CLIENT OUTCOMES

By

Susan K. Cristofori

A THESIS

Submitted to  
Grand Valley State University  
in partial fulfillment of the requirements for the  
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## ABSTRACT

### A COMPARISON STUDY OF THE EFFECTS OF METHODS OF PAIN CONTROL ON CLIENT OUTCOMES

BY

Susan K. Cristofori

A correlational ex post facto design was used to study the relationships between methods of pain control and client perception of pain, achievement of the physical therapy regime and length of stay following total joint replacement surgery. Continuous epidural infusion and patient controlled analgesia (PCA) were the pain control methods examined in the study.

Perception of pain was measured using a 6-word descriptor verbal rating scale. Achievement of physical therapy was measured using the activity criteria on the case care map used at the study hospital. Length of stay was measured using daily census records. 1) The study site was a 112 bed acute care hospital. 2) The convenience sample consisted of 30 subjects using epidural and 30 subjects using PCA pain control methods. All measurements were taken on the second post-operative day following total joint replacement surgery.

Clients using epidural analgesia reported less pain ( $p = .00$ ) than those using PCA analgesia. There were no significant difference between the two groups with regard to ability to achieve physical therapy regime or the length of stay.

To my sister June,  
Forever in my heart,  
1940-1994

## Acknowledgments

I would like to acknowledge my husband and family for their constant love, support, and patience this past two years. I need to express my deep appreciation to Dr. Louette Lutjens who provided support and encouragement during a very difficult time in my life. Also, I would like to thank Dr. Jean Nagelkerk and Dr. Theresa Bacon-Baguley for their guidance and expertise.

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## CHAPTER 1

### Introduction

Total joint replacement is a common surgical intervention to treat joint pain and immobility experienced by many people with chronic osteoarthritis. Joint replacement is now performed an estimated 120,000 times a year in North America (Harris & Sledge, 1990). The surgery is designed to provide substantial relief of pain and good, but not normal, range of motion.

The effects of pain on the post-operative client can have a significant impact on recovery. The sympathetic nervous system response to pain has been implicated to be responsible for complications seen on the cardiovascular and gastrointestinal systems in the post-operative client. The sympathetic nervous system effect on the cardiovascular system results in an increase in heart rate and blood pressure resulting in a greater work load on the heart. In addition, the sympathetic nervous system induced vasoconstriction can predispose the client to a decrease in venous return and thrombophlebitis. Harris & Sledge (1990) reported that a frequent complication of joint replacement surgery is pulmonary embolism resulting from femoral thrombi. The sympathetic nervous system response to post-operative pain may contribute to pulmonary embolism following total joint replacement. The gastrointestinal system responds to sympathetic nervous system activity by

decreasing gastric mobility which predisposes the client to paralytic ileus.

Changes in pain management are occurring in all health care settings, particularly in the acute care setting. The traditional system of narcotic administration is based on an as needed or prn approach causing the client to be in pain for a considerable period of time, prior to a short time period of pain relief (Jackson, 1989). Edwards (1990) found that many studies have concluded that clients often suffer from uncontrolled post-operative pain and are often undertreated.

Recent advances in the management of post-operative pain have included continuous epidural infusion of fentanyl and on demand patient controlled analgesia (PCA) by intravenous administration of morphine or meperidine. The effectiveness of both epidural infusion and intravenous PCA infusion of narcotics for management of post-operative pain has led to increased use of these methods on the surgical unit.

Fentanyl given through an epidural catheter diffuses slowly from the epidural space into the cerebrospinal fluid in the subarachnoid space and then to the opiate receptors in the dorsal horn of the spinal cord. The delivery of the drug close to the opiate receptors allows pain relief with minimal side effects and trauma. Afferent pain sensory neurons carry information regarding pain into the spinal

cord via the dorsal root. The afferent neuron subsequently synapse with a second order neuron in the dorsal horn of the spinal cord. The neurotransmitter responsible for conveying the information from the pain afferent neuron to the second order neuron is Substance P. Once the second order neuron binds to Substance P, the information travels up the cord to the somatosensory cortex for processing. Epidural fentanyl diffuses from the epidural space into the spinal cord where it binds to opiate receptors on the presynaptic afferent neurons. After binding to the opiate receptors, Fentanyl interrupts the transmission of pain related impulses to the brain by preventing the release of Substance P.

PCA devices have been in use in the United States since 1984. Most PCA devices use digital electronics to control the dose of the narcotic delivered intravenously by an infusion pump. Morphine and meperidine act by binding with opiate receptor sites in the central nervous system. Pain mediation from opiates is a chemical intervention on opiate receptors sites at various levels in the central nervous system. A G protein is activated by the opiate, which in turn activates adenylate cyclase increasing intracellular cyclic AMP. The threshold of the nociceptor terminal is elevated and pain sensation is decreased. Opiates also block the release of the pain producing inflammatory mediator substance P.

In a competitive health care market, client

satisfaction is highly valued. Effective pain relief is closely related to client's overall satisfaction with care (Hull, 1989). In hospitals, it is the nurse who has more contact with the client experiencing pain (McCaffery & Beebe, 1989) therefore, it is important that nurses have adequate and appropriate knowledge about methods of pain control.

The method of pain control may influence the perception of pain enabling the client with joint replacement to use the reconstructed joint sooner. Early mobilization of the joint results in increased range of motion enhancing joint mobility and promotion of a normal gait. The ability of the client to ambulate following total joint replacement is an important criteria for discharge and therefore, has a major influence on length of hospitalization.

The purpose of this study is to compare the differences in perception of pain, ability to achieve the physical therapy regime, and length of stay between clients receiving epidural analgesia and those clients receiving patient control analgesia (PCA).

## CHAPTER 2

### Conceptual Framework

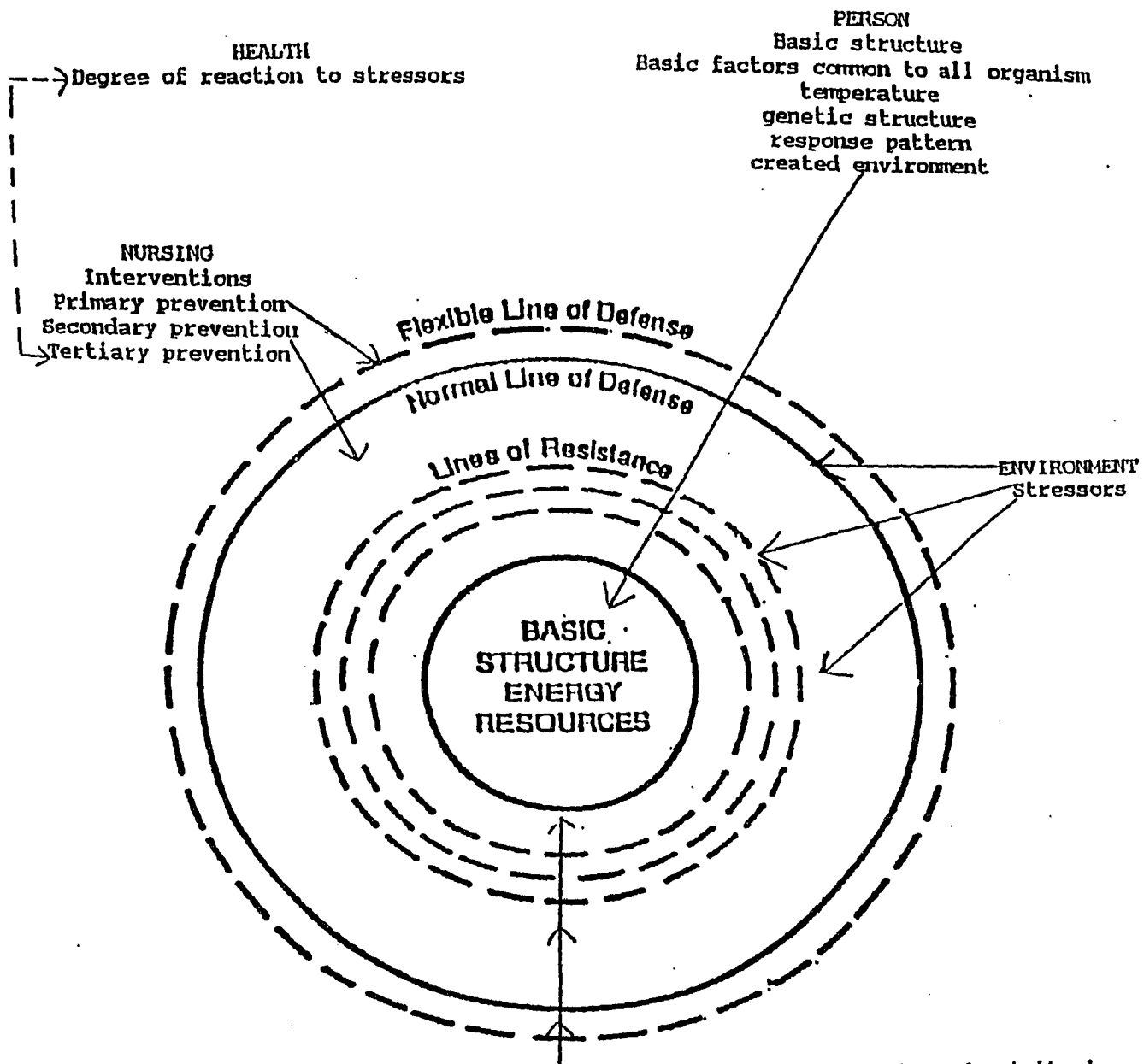
Betty Neuman's System Model, provides the framework for identification of stressors, interventions, and client outcomes for this study.

#### Client/Client System

Neuman (1989) defines person as a client/client system composed of physiological, psychological, sociocultural, developmental, and spiritual variables (see Figure 1). The client system is viewed as an open system in interaction with the environment. Neuman (1989), contends that the system's boundary must be identified. She views the client theoretically as a series of concentric rings surrounding a basic core structure. The core consists of basic survival factors common to all human beings and unique characteristics for each client system. This basic core structure contains the energy resources required to maintain life. The concentric circles function as a protective mechanisms for the integrity of the client system. In this study client is defined as the person following total hip or knee replacement surgery using either epidural or PCA pain control methods.

#### Environment

The environment is broadly defined as all internal and external factors surrounding the client system. The internal environment consists of forces contained within the



Physiological, psychological, sociocultural developmental, and spiritual variables are considered simultaneously in each client concentric circle.

**Figure 1.** The Neuman Systems Model. *Note.* Adapted from The Neuman Systems Model (p. 26), by B. Neuman, 1989, Norwalk: Appleton & Lange.

boundaries of the defined client system and is intrapersonal in character. The external environment is described as all forces or influences external to or existing outside the client system and is considered interpersonal and extrapersonal in nature. Neuman (1989), theorizes a created environment representing an "open system exchanging energy with both the internal and external environment" (p. 32). This environment is unconsciously developed by the client and is an expression of the system's wholeness. Neuman states that the created environment "acts as an immediate or long range safe reservoir for existence or maintenance of the system integrity expressed consciously, unconsciously, or both simultaneously" (p. 32). The created environment represents the unconscious mobilization of all system variables to protect the basic core structure. It can override the internal and external environments and change the responses to stressors. In this study, the created environment is the client's conscience and unconscience response to the pain experience. This response is governed by the client's gender, age, cultural, spiritual, and social background. The client's use of coping mechanisms previously learned to manage pain is incorporated in the created environment and plays an essential role in the pain experience.

### Health

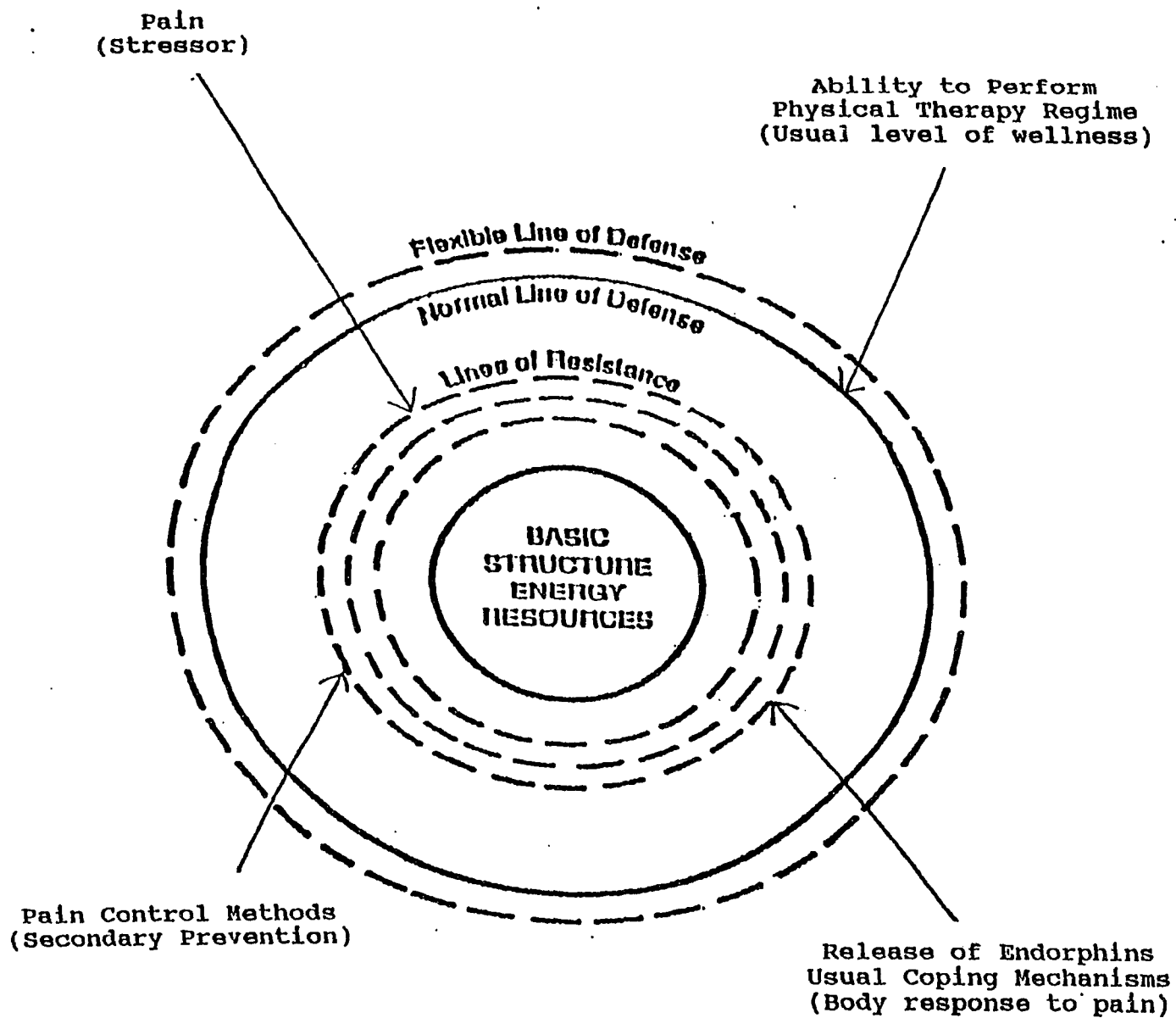
Health, according to Neuman (1989), is the best



possible wellness state at any given time. It is viewed as living energy flowing along a wellness-illness continuum. Optimum wellness is achieved through retention, attainment, or maintenance of client stability. Energy flow is continuous between the client and the environment. If the client is generating more energy than will be used he/she is in a wellness state. When more energy is required than is being generated illness occurs. This study views health as the state of wellness attained when an acceptable perceived level of pain enables the post-operative total hip or total knee replacement client to generate the energy needed to achieve the physical therapy regime and thus meet the length of stay guidelines required by the case care maps.

The actual or possible effects of stressor invasion is essential to explain wellness or health. Stressors are defined by Neuman (1989) as "tension-producing stimuli or forces occurring within both the internal and external environmental boundaries of the client system" (p. 22). Stressors have the capability for causing disequilibrium within the client system. "When the normal line of defense is penetrated by a stressor, symptomatology may begin to appear" (Neuman, 1989, p. 29). In this study, stressor is defined as the post-operative pain experienced by the joint replacement client (see Figure 2).

It is theorized in this study that post-operative pain, a stressor, will cause the client to expend more



**Figure 2.** The Neuman Systems Model applied to pain control methods and client outcomes. **Note.** Adapted from The Neuman Systems Model (p. 26), by B. Neuman, 1989, Norwalk: Appleton & Lange.

energy than is being generated contributing to the illness state. When more energy is expended, the client will have difficulty achieving the physical therapy regime established by the case care map resulting in an increase in length of hospital stay specified on the case care maps.

### Nursing

Nursing is concerned with all stressors whether actual or potential that cause a reaction by the client system. Assessment of the effects and possible effects of stressors and the client system's ability to adjust are crucial to assist the client system to maintain optimal health.

Intervention can begin at any point at which a stressor is suspected or identified. Nursing actions are initiated using three preventions as interventions to keep the system stable. Primary prevention is viewed as health maintenance and illness prevention. Secondary preventions are initiated when a reaction from a stressor has occurred. Tertiary prevention is used during the rehabilitation phase of illness. In this study, epidural infusion and PCA are methods of pain control initiated at the secondary level of prevention as an intervention when pain has produced a reaction by the client system.

The basic structure of person is surrounded by concentric circles that function as protective mechanisms. The flexible line of defense acts as a buffer system for the client's stability. It prevents stressors from penetrating

the normal line of defense keeping the client system free from symptomatology. The normal line of defense is conceptualized as a solid boundary that encircles the broken internal lines of resistance. It represents what the client has become, the state to which the client has evolved over time, or the usual wellness level. When the normal line of defense is penetrated by a stressor such as post-operative pain, adverse reactions occur in the client system and symptoms of the stressor are apparent. The ability to perform activities required to enhance mobility of the replaced joint is considered to be the normal line of defense in this study. The lines of resistance are activated following invasion of the normal line of defense by environmental stressors. The resistance lines contain internal factors that protect the client system's integrity. Such internal factors may be mobilization of white cells following an injury or the use of effective coping skills during psychological stress. The lines of resistance important in this study is the release of endorphins, a narcotic-like substance, by the system in response to the pain stimuli and the clients' usual coping mechanism established in their created environment. If these factors fail to protect the basic core, expenditure of energy will deplete the systems integrity and result in multiple insults to the basic core.

### Theoretical Definition of Terms

According to Neuman's model, pain is a subjective intrapersonal stressor that has penetrated the flexible and normal lines of defense threatening the basic structure energy resources. The use of epidural and PCA methods of pain control reduces the impact of the stressor.

Achievement of the physical therapy regime is viewed as the willingness and ability of the client system to strengthen the lines of resistance by actively participating in physical therapy activities. Length of stay is theoretically defined as the episode of care during a single inpatient hospital admission.

Nursing can intervene at any point to assess the effects and possible effects of environmental stressors (pain) and assist client adjustment through secondary prevention as an intervention (methods of pain control) required for an optimal wellness level (acceptable perception of pain, achievement of the physical therapy regime, and conformity with specified length of stay).

### Hypothesis

The study will test the following null hypotheses:

1. There will be no difference in perception of pain between those clients who receive continuous epidural infusion and those who receive PCA.

2. There will be no difference in achievement of the physical therapy regime between those clients who receive

continuous epidural infusion and those who receive PCA.

3. There will be no difference in length of stay between those clients who receive continuous epidural infusion and those who receive PCA.

The close monitoring of epidural analgesia requires an increase in nursing care hours. Vital signs and careful assessment of side effects must be done frequently. It is often difficult for the staff nurse to monitor the epidural client in addition to caring for the normal client load on a busy surgical unit. Many nurses have felt the frustration of too much to do with too little time to complete the care needed. If there are no differences between epidural and PCA pain control methods and client outcomes, the PCA method of pain control should be the treatment of choice to reduce nursing care hours.

#### Review of the Literature

Early studies of epidural and PCA methods of pain control discussed the efficacy of the various medications used, safe administration, and various devices to infuse the narcotic. Later studies compared methods of pain control on perceptions of pain, side effects, length of stay, efficacy of narcotics and devices used to deliver the medication. Most studies comparing epidural to PCA found, to date, have been conducted by physicians to discover side effects, efficacy of certain narcotics, and occurrence of complications.

## Epidural Infusions

Early studies suggested that the epidural route provided better post-operative analgesia (Harrison, Sinatra, Morgense 1988; Eisenach, Grice, Dewan 1988). Studies by Loper, Ready, Downey (1990), Ellis, Millar, Reisner (1990), and Camu, Debucquoy (1991) revealed that the epidural route and PCA are equally effective in providing post-operative analgesia. A study conducted by Benzon, et al (1993), using a prospective randomized double blind comparison of an epidural fentanyl infusion versus patient controlled analgesia with morphine in the management of post-thoracotomy pain showed client perception of pain relief higher in the epidural group. Thirty six clients were randomized into one of two groups. The total pain relief scores in the epidural group were significantly higher ( $p = .02$ ) indicating better pain control. Allaire, et al. (1992) conducted a prospective, randomized study comparing PCA morphine and continuous infusion of epidural fentanyl in 66 men after a radical retropubic prostatectomy. They found that both methods provided satisfactory analgesia. The epidural infusion of fentanyl provided better analgesia during resting, ambulation, deep breathing, and coughing, as evidenced by the lower mean, maximal, and minimal comfort level scores. No statistically significant differences were found in length of hospital stay between the two groups (7.3 days in the epidural group and 6.9 days in the PCA group).

A retrospective review of 76 clients who underwent radical retropubic prostatectomy indicated a significant decrease in duration of hospital stay post-operatively among clients who received a narcotic agent via the epidural route in comparison with those who received narcotics intramuscularly (IM) or intravenously (PCA) (7.8 days for the epidural group versus 9.7 days for the IM or PCA group, ( $p < .05$ ) (Lamer 1990).

#### Patient Controlled Analgesia

Research on PCA began in the late 1960s. Sechzer (1969), using a nurse observer, evaluated the analgesic response of 20 clients to small intravenous doses of a narcotic given on demand. He found that, given in small amounts, intravenous analgesia provided improved pain relief over other methods. In 1971, Sechzer described his experience with the PCA system. He concluded that the system was a highly satisfactory method for treating post-operative pain and that good analgesia could be achieved with a relatively low total drug dose.

Many studies comparing PCA and intramuscular administration of narcotics have been conducted. Church (1979); Bennett and Griffen (1983); Rayburn, Geranis, Ramadei, Woods, and Patil (1988); Albert and Talbott (1988); Kluger and Owen (1990) found that clients were more satisfied when receiving the analgesic using the PCA device. Clients reported significantly less discomfort, less



sedation, and greater activity.

Clinical trials have used PCA to compare the efficacy and potency of various analgesics. Although there are a number of drugs that can be used in PCA therapy, morphine and meperidine have been used more extensively (White, 1988). McLintock, Aitken, Downie, & Kenny (1990), documented both the efficacy and safety in use of the PCA for post-operative pain. Other studies have suggested that clients using PCA for pain control reported reduced anxiety (Hecker & Albert, 1988), and shortened lengths of stay (Scalley, Berquist, & Cochran, 1988).

Articles in the nursing literature began appearing in the late 1980s on techniques of continuous infusion of medication using PCA (Bast & Hayes, 1986; Dunwoody, 1987; Jones & Brooks, 1990; McCaffery, 1987; McGuire & Wright, 1984). DeFede, Dhanens and Keltner (1989), reported on the effectiveness of PCA to reduce cost and enhance nursing care. Edwards (1990) estimated that up to 80 minutes of nursing time in every 4 hour cycle is saved by using PCA.

Many of the nursing findings in the late 1980s supported medical findings. A prospective randomized study of 300 total joint replacement clients by Teter, Viellion, and Keating (1990) compared the amount of narcotic used among morphine, meperidine, and nalbuphine given by PCA and gastrointestinal side effects of the narcotics. They found that the nalbuphine clients used significantly more narcotic

than morphine and meperidine clients from day of surgery through post-operative day 3 ( $p < .01$ ).

Patient-controlled analgesia devices are promoted as safe, effective, and time-saving (Bennett & Griffen, 1983). Kleiman et al. (1988) compared pain ratings of client using PCA versus the traditional intramuscular administration method. They found that PCA did not reduce the group's perception of pain significantly from the traditional method group. The mean pain ratings for the PCA group (1.5 plus or minus 0.42) and the intramuscular group (1.43 plus or minus 0.49) were similar. Both groups were in the mild to discomfort level of pain and no one considered themselves to be pain-free. Bennet et al. (1982) found, in contrast, that clients in the PCA group reported pain less than a third as often as clients in the intramuscular control group: 3.9% versus 11.8%. Clients reported that they were in pain more frequently in the intramuscular group than those in the PCA group. The study can not be generalized due to the small sample size of 12 in each group.

#### Summary

There are many studies on post-operative pain control using epidural or PCA. The various population groups studied include thoracotomy, radical prostatectomy, and orthopedic surgical clients. There were no studies found addressing the effects of methods of pain control on the client's ability to achieve physical therapy activities.

Several studies address the effect of methods of pain control on length of stay. Little has been found in the literature comparing epidural and PCA methods of pain control on client outcomes from a nursing perspective.

## CHAPTER 3

### Methodology

#### Design

An correlational ex post facto design was used to study the relationships between methods of pain control and client perception of pain, achievement of the physical therapy regime and length of stay.

#### Study Site and Subjects

The study was conducted in a 112-bed acute care hospital in a small Mid-Western city. A convenience sample of 30 subjects using epidural and 30 subjects using PCA pain control methods was used for the study. Clients were asked to participate in the study during pre-admission testing (PAT). A questionnaire was used by the PAT nurse to assess the clients eligibility for the study (see Appendix A). To be considered for the study the client must (a) have the ability to speak and understand the English language, (b) be admitted to the medical-surgical unit for either hip or knee joint replacement surgery, and (c) have had no previous experience with epidural or PCA pain control methods. Excluded from the study will be those clients having the following pre-existing conditions that may influence the length of stay: (a) diabetes mellitus, (b) acute infections, (c) congested heart failure.

Subjects rights were protected through approval of this study by the Grand Valley State University Human Research

Review Committee and the study hospital's Research Review Board.

Description of the Sample

The sample consisted of 60 subjects admitted to the surgical unit between May 5, 1995 and July 22, 1995 following total hip or knee replacement surgery. There were 28 males and 32 females. Subjects ranged in age from 35 to 84 years with a mean age of 68.5 year; the median age was 71 years (see Table 1).

---

Table 1

Age Distribution

---

Age	<u>n</u>	<u>%</u>
30-39	1	1.7
40-49	2	3.3
50-59	6	10.0
60-69	17	28.3
70-79	29	48.3
80-89	5	8.4
	<u>60</u>	<u>100</u>

---

One hundred percent (100%) of the participants were white. Fifty percent (50%) of the subjects used the epidural pain control method and 50% used the PCA pain control method. There were 18 subjects who had a total hip replacement and 42 subjects who had a total knee replacement. Of the subjects who had a total hip replacement, 66% used epidural pain control methods and 33%

used PCA. Of the subjects who had total knee replacement, 43% used epidural pain control methods and 57% used PCA. The length of hospital stay for both groups ranged from 4 to 8 days with a mean length of 5.76 days.

### Instruments

#### Perception of Pain

Pain perception was measured using a verbal rating scale (VRS). The tool consists of five numerically ranked choices of word descriptors used to determine the intensity of the painful sensation (see Appendices B & C). The descriptors are 0 = no pain, 1 = comfortable, 2 = in mild discomfort, 3 = in pain, 4 = in bad pain, and 5 = in very bad pain. The effects of anesthetic on pain management and the length of time epidural analgesic is used on post-operative joint clients were considered to determine a critical point in time to measure perceptions of pain (R. Gillian M.D., personal communication, June 10, 1994). Perceptions of pain by client's receiving epidural infusion and those receiving PCA analgesia were measured at 4:00 P.M. on the second post-operative day.

Verbal rating scales (VRS) consist of three to five numerically ranked choices of word descriptors. The number corresponding to the word chosen is used to determine the intensity of the painful sensation on an ordinal level. Keele (1948) was one of the first researchers to devised a VRS scale which he called a Pain Chart. Reliability of this

tool was said to be established through repeated administration to clients with a variety of medical conditions. Validity reportedly was determined by administering the pain chart to clients with conditions known to produce pain and by observing that time-intensity curves of ratings showed increases and decreases of pain over time and in relation to physical activity. Today virtually all VRS use words similar or identical to those in Keele's chart (1948). However, few authors using such scales have discussed reliability or validity. Statistical data to support the reliability and validity of Keele's instrument have not been found by the author. Keele's instrument (1948) originally was developed to assess responses to analgesics. It is, therefore, possible to use VRS in situations where one wishes to measure the intensity of pain in relation to therapeutic interventions.

The VRS is short, easy to use by the client, and easy to score and analyze by the nurse. It is applicable to any kind of clinical pain. The VRS may artificially categorize the intensity dimension of pain by forcing the patient to select a single word or phrase on the scale which may not accurately reflect the client's true sensation (Ohnhauser & Adler 1975).

Studies comparing the VRS and the Visual Analog Scale (VAS) have been conducted to clarify issues of sensitivity of measurement, reliability and validity, ease of client

use, and client preferences. Ohnhaus and Adler (1975) and Woodforde and Merskey (1972) found strong correlations ( $r = .81$  to  $.87$ ,  $p = .01$  to  $.001$ ) between the VRS and the VAS. In a study conducted by Kremer, et al. (1981), clients were asked to express their preferences for scales. A visual analog scale (VAS), numeric rating scale (NRS), and a five-point verbal rating scale (VRS) were compared. The results indicated that most subjects preferred the verbal rating scale. All of the subjects were able to complete the VRS, 11% failed to complete the VAS and 2% failed to complete the NRS.

The study hospital has used the verbal rating scale for 6 years. The tool was developed to measure pain perception on all post-operative clients using either epidural or PCA as pain control methods. The scale was developed by the pain management committee. Content validity was established by the committee consisting of an anesthesiologist, nurse anesthetist, and several staff registered nurses. The tool was introduced to staff by structured inservices throughout the facility. All nursing units use the VRS scale to assess the client's response to pain following criteria presented in the inservices.

#### Achievement of the Physical Therapy Regime

Achievement of the physical therapy regime was measured using the activity criteria of the case care maps used at the study hospital. The case care map activities for



orthopedic clients were devised by several orthopedic surgeons practicing at the facility in collaboration with the physical therapy department (see Appendices D & E). The activities for the second post-operative day include ambulating to the bathroom using a walker, using the continuous passive range of motion machine (CPM), participating in a continuing exercise program, and continued client involvement in activities of daily living (ADL). The physical therapist works with each joint replacement client on the unit twice a day following the case care map. The physical therapist records the client's achievement of the activity criteria on the progress notes as met or not met for each day's activity. All physical therapists were inserviced on the use and documentation of the activity criteria on the care map. The majority of epidural clients' with joint replacements are discontinued from the pump 72 hours after surgery. In order to measure achievement of physical therapy regime activities while the client is still using the epidural for pain control, measurement was made on the second post-operative day. A review of the chart was conducted to determine if the client met or did not meet all the activities for that day. A score of 0 was assigned if the client did not meet all the activity criteria. A score of 1 was assigned if the client did meet all the activity criteria.

### Length of Stay

Length of stay was defined as actual client care days beginning with the admission day and ending with the discharge day. A day was defined as a 24 hour period beginning 12:00 A.M. and ending at 11:59 P.M.. The data were collected by using the admission date and discharge date documented in the Daily Census Summary used by the study hospital.

### Data Collection Procedure

Steps to recruit subjects were taken after obtaining permission from Grand Valley State University Human Research Review Committee and the study hospital. Selection of participants occurred during the pre-admission testing (PAT) visit. The anesthesiologist assesses each client during this visit to determine the type of anesthetic and post-operative pain control methods. Total hip and total knee replacement clients using epidural or PCA pain control methods who met the criteria described earlier were asked to take part in the study by the PAT nurse. The client received an explanation of the study and a consent form for consideration. The PAT nurse obtained the client's signature during the PAT visit (see Appendices F & G). When consent was given by the potential subject they received the researcher's name and telephone number. The signed consent form was attached to the client's PAT chart and sent to the surgical unit. On the unit a label stating

"Pain Study" was attached to the front of each participant's cardex and chart. This label served as a reminder for staff that the client was in the study.

Data were retrieved by the investigator during a chart review. Collection of the data was done on the second post-operative day following total hip or knee replacement surgery.

### Measurement

#### Perception of pain.

Perception of pain was measured in the client's room by the staff nurse and documented using current documentation forms. The client's perception of pain was recorded on either the epidural/intrathecal flow sheet or the PCA monitoring sheet (see Appendixes B and C). The staff nurse assessed and documented perceptions of pain every 4 hours around-the-clock. Measurement for this study of perception of pain occurred at 4:00 P.M. on the second post-operative day.

#### Achievement of the physical therapy regime.

Achievement of the physical therapy regime was measured by the physical therapist in the client's room and documented using the study hospitals' Progress Notes (see Appendix H). The ability of the client to perform the activities listed in the activities section of the case care map for the second post-operative day was recorded by the physical therapist on the progress notes. The physical

therapist documented whether the client had met or not met the activity criteria on the case care map for the day.

Length of stay.

Length of stay was recorded by the orthopedic case manager using the daily census summary on all clients. The data were collected by reviewing the records for admission and discharge dates and calculating the length of stay for each participant in the study.

## CHAPTER 4

### RESULTS/DATA ANALYSIS

The purpose of this study was to determine the differences in perception of pain, achievement of physical therapy regime, and length of stay between clients receiving epidural analgesia and those clients receiving patient control analgesia (PCA). Descriptive and correlational statistics available through the Statistical Package for The Social Sciences were used to describe the sample and to test the null hypotheses. A  $p = .05$  was used for all tests.

#### Description of the Study Variables

The variables of interest in this study included method of pain control, perception of pain, the ability to achieve physical therapy regime, and length of stay. Each variable in the study was analyzed separately using descriptive statistics (frequency and percentage). In addition, perception of pain, the ability to achieve physical therapy regime, and length of stay were analyzed separately according to the method of pain control received.

#### Hypothesis 1

In the majority of clients the pain relief obtained by both epidural (96.7%) and PCA (93.3%) groups was rated as 2 (mild discomfort) or less on the VRS. However, scores of 1 (comfortable) or less (86.7%) were reported more often by clients in the epidural group than in the PCA group (40%). The mean comfort level scores were lower in the epidural

group ( $\underline{M} = .60$ ,  $\underline{SD} = .81$ ) than in the PCA group ( $\underline{M} = 1.63$ ,  $\underline{SD} = .67$ ). Perception of pain by both groups' is shown in Table 2.

Table 2

Perception of Pain by Group (N = 60)

Pain Perception	Epidural		PCA	
	<u>n</u>	<u>%</u>	<u>n</u>	<u>%</u>
None	17	56.7	1	3.3
Comfortable	9	30.0	11	36.7
Mild Discomfort	3	10.0	16	53.3
In Pain	1	3.3	2	6.7
Bad Pain	0		0	
Very Bad Pain	0		0	
	<u>30</u>	<u>100</u>	<u>30</u>	<u>100</u>

The Mann-Whitney U was used to determine differences in the perception of pain between the two groups. The mean rank for the epidural group was 20.70. The mean rank for the PCA group was 40.30. The results revealed a significant difference in perception of pain between those who received epidural infusion and those who received PCA for pain control ( $\underline{U} = 156.0$ ,  $p = .00$ ). The finding rejected the null hypothesis that there are no differences between the two groups in perception of pain.

Hypothesis 2

The ability to achieve the physical therapy regime by the epidural and PCA groups was analyzed. Chi-square was

used to determine differences in achievement of the physical therapy regime between those who received continuous epidural infusion and those who received PCA on the second post-operative day. The results revealed no significant difference in the ability to achieve the physical therapy regime between the groups  $\chi^2(1, N = 60) = 3.35, p = .07$ . The null hypothesis was accepted. The achievement of the physical therapy regime by both groups' is shown in Table 3.

Table 3

Achievement of Physical Therapy Regime by Group (N = 60)

Pain Control Groups	Achievement	
	Met	Not Met
Epidural	26	4
PCA	20	10
	<u>46</u>	<u>14</u>

Hypothesis 3

Length of stay was analyzed for both groups. A t-test was used to determine differences in length of hospital stay between clients using epidural infusion and those using PCA during their hospitalization. The mean length of stay in the epidural group was  $M = 5.77, SD = 1.07$ . The mean length of stay in the PCA group was  $M = 5.77, SD = .97$ . The null hypothesis was accepted. The length of stay by both groups, is shown in Table 4.

### Summary of Findings

The method of pain control had a significant difference on the clients' perception of pain. Clients' receiving epidural analgesia reported less pain than those clients' receiving pca analgesia. Participants in the epidural group ( $n = 30$ ) rated having no pain.

Table 4

Length of Stay by Group (N = 60)

Pain Control	4 days	5 days	6 days	7 days	8 days
Epidural	2	13	7	6	2
PCA	3	8	13	5	1

Only one subject in the PCA group ( $n = 30$ ) rated having no pain. No one in the epidural group or in the PCA group rated the pain beyond 3 on the 6-word descriptor VRS. Only three participants in both groups ( $N = 60$ ) rated their pain at a 3 on the VRS scale. Of the three that rated their pain at a 3, one was in the epidural group and two were in the PCA group.

The method of pain control in total joint replacement clients' had no significant difference in their ability to achieve the case care map criteria for physical therapy. Overall, 76.7% of all participants' met the case care map criteria.

Pain control method had no significant difference in length of hospital stay. The length of stay for both groups



ranged from 4 to 8 days. The mean length of stay of all participants' (N = 60) was 5.7 days and the mode was 5 days.

## CHAPTER 5

### DISCUSSION/IMPLICATIONS

The observed increase in nursing care hours required by clients receiving epidural analgesia prompted this study. The study's null hypotheses stated that there would be no differences between those who had continuous epidural for pain control and those who had PCA for pain control in pain perception, ability to achieve physical therapy regime, and length of stay.

#### Discussion

The results of this study indicated that although there were no differences in the ability to achieve physical therapy and the length of stay between the two pain method groups, there was a significant difference ( $p = .00$ ) in the groups' perception of pain. Clients' receiving epidural analgesia reported less pain than those receiving PCA analgesia. This finding supports those of Benzon, et al. (1993) and Allaire, et al. (1992) who found that client's perception of pain relief was higher in the epidural group than the PCA group in their studies of post-thoracotomy and post-radical retropubic prostatectomy clients. The results of this study suggest that the use of epidural analgesia for post-operative pain control in total joint replacement clients would be the method of choice for pain management.

At the study hospital, the anesthesiologist is responsible for increasing or decreasing the dose of

narcotic infusing via the epidural space. When a client rates pain at a 3 (in pain) on the VRS the staff nurse is required to notify the anesthesiologist. This notification results in an increase in the dosage of epidural analgesic used. The orthopedic surgeon orders PCA using parameters established by the pain committee for increment dose, lockout, and booster dose. A booster dose may be administered every 3-4 hours in addition to the increment dose for PCA. It was interesting to see that in this study the booster dose was not given in any case for the clients' using PCA as a pain relief method. Clinically, pain relief could have been enhanced in the PCA group by the booster dose.

Pain control is an important factor in the ability of joint replacement clients' to perform exercises needed to insure good ROM. There was no significant difference in the ability to achieve physical therapy regime between the two groups ( $p = .07$ ). PCA pain control method appeared to be as effective as continuous epidural pain control method in the ability of the clients to the achieve physical therapy in this study. The results were close to significant and must be viewed with caution. The difference between the two groups may have been significant if the sample was larger. Studies that support or refute this finding have not appeared in the literature.

There was no significant difference in length of stay

between the two groups. This finding was not surprising because the case care maps for both hip and knee joint replacement surgeries specified discharge on day 5. This study supported Allaire, et al. (1992) findings that there was no statistically significant difference between the epidural group and the PCA group of post radical retropubic prostatectomy clients in length of stay.

There are many factors to be considered when dealing with subjective perceptions of pain. The subject's response to pain is influenced by previous experiences, gender, age, coping strategies and the type of surgery.

The pain experience is not an isolated occurrence, each episode is affected by previous pain experiences. This effect causes the individual to develop expectations of the pain experience which can produce anxiety. The physiological response to anxiety produces the same sympathetic nervous system response as pain. Thus, anxiety may have a role in potentiating pain by enhancing the physical symptoms.

The gender of the subject may have had an influence on the outcomes of interest in this study. It was interesting to note that crosstabulation of pain by gender showed women reported pain at a 2 or above (40.6%) on the VRS more often than men (32.1%).

Age may affect how pain is perceived. Many studies have revealed inconclusive results between the relationship

of age and the perception of pain. McCaffery (1983) suggested that the indecisive information gained from research about the relationship between age and pain may be due to the fact that individuals express their pain differently.

The client will respond to pain sensation using previous coping mechanisms. Lazarus (1966) suggests that the individual experiencing stress will develop coping mechanisms either by reducing the danger of the perceived threat or by reducing its significance. The response of the individual experiencing pain reflects their coping strategies to previous experiences thus influencing their perceptions of pain.

The type of surgery may have influenced the outcomes of interest in this study. There may be differences between total hip replacement surgery and total knee replacement surgery in client's perception of pain, ability to achieve physical therapy, and length of stay.

Another important consideration is the level of pain that is acceptable for the post-operative total joint replacement client. For this study, pain perception must have been at a perceived level at which the client was able to participate and achieve the physical therapy regime. Although statistically nonsignificant, 87% of the epidural group were able to achieve the physical therapy regime compared to 67% of the PCA group achieving the physical

therapy regime (see Table 4). The difference between groups' in the ability to achieve the physical therapy regime may significantly change using a larger sample.

#### Relationship of Findings to the Neuman Systems Model

The Neuman Systems Model provided a conceptual framework to identify stressors, interventions, and client outcomes for this study. Pain, an intrapersonal stressor, can penetrate the flexible and normal lines of defense to the lines of resistance threatening the energy resources of the basic structure. The use of epidural pain control method appeared to be more effective in reducing the impact of the stressor.

When the flexible and normal lines of defense are strengthened, the lines of resistance can protect the system's integrity leading to health. Health, defined in this study as the state of wellness attained when an acceptable perceived level of pain enables the client to generate the energy needed to achieve the physical therapy regime and thus meet the length of stay guidelines, was enhanced using the secondary level of prevention. This study supported Neuman's theory that interventions initiated at the secondary level of prevention reduce the impact of the stressor and strengthen the flexible and normal lines of defense.

#### Limitations

The major limitation of this study was the inability to

generalize due to the nature of the research design. Pre-existing differences in the groups under study could be a possible alternative explanation of the findings. The findings only apply to hip or knee replacement clients on the second post-operative day. The same results may not occur if the sample was different or if measurements were taken on the first or third post-operative day.

The subjects were selected after determination of post-operative pain control methods by the anesthesiologist. The use of a convenience sample in this study limits the ability to generalize. Also, the small number of subjects in this study may have influenced the ability to detect relationships among the variables of interest.

The results of this study may not represent the general population. The convenience sample included only Caucasian subjects. Other races were not represented in the study. Data on the cultural background of subjects were not collected. Race and cultural background may influence expression of pain.

Another limitation of the study was using the study hospital 6-word descriptor VRS. It is difficult to discern the difference between no pain and comfortable adjective descriptors.

Achievement of the physical therapy regime was measured as met or not met. The imprecision of this method of measurement was a limitation. There was no way to determine

if clients' were exceeding expectations noted on the case care maps or the degree to which expectations were met. The difference between the two groups may have reached significance if documentation by the physical therapists included the specific criteria met by clients on any given day and the degree to which the criteria had been met.

#### Recommendations

Assessment of the pain experience is a major nursing responsibility. Studies by McCaffery & Beebe (1989) support that nurses must have the appropriate knowledge about methods of pain control. While there is considerable research concerning epidural and PCA methods of pain control, few address client outcomes from a nursing perspective. There is a need for further studies using larger samples on the relationship of epidural and PCA methods of pain control and client outcomes.

In an attempt to capture the client's perception of the pain experience following joint replacement surgery, the study hospital's VRS was used. The word descriptors should clearly differentiate between the perception of no pain and being comfortable in future studies. Clinical practice guidelines by the Agency for Health Care Policy and Research (AHCPR) report the need for carefully selecting adjective descriptors when using a VRS (Department of Health and Human Services, 1992). Moreover, 10-point scales are recommended.

Perception of pain may be influenced by: (a) previous



experiences, (b) gender, (c) age, (d) coping strategies, and (e) race. Previous experiences with pain was not addressed in this study. Research about gender differences in clients with pain is relatively new and has revealed conflicting results. Further studies on perception of pain between men and women need to be completed to determine if differences exist. Perception of pain may be influenced by the age of the client. Older persons may experience reduced sensory perception and increased pain threshold because of degeneration of neurons in the dorsal column of the spinal cord. Acute pain may not be as sharply perceived in the elderly. Coping strategies developed as a response to stress of pain were not addressed in this study. Future studies should include assessment of the clients coping strategies used with previous experiences of pain.

The sample in this study included total hip and total knee replacement clients. There may be differences in perception of pain between the two groups. Future studies should be conducted on clients with the same type of joint replacement surgery.

The need to study Newman's (1989) concept of the created environment and pain perception is recommended. The created environment is the client's conscience and unconscious response to the pain experience. The clients' response to pain is governed by previous experiences, gender, age, coping strategies, and race. The investigator

suspects that this created environment plays an essential role in the pain experience.

#### Implications for Nursing

The nurse has a unique role in the management of pain. This role includes implementing pain relief methods, identifying the need to change pain relief methods, and assessing the impact of pain relief methods on the client. Each nurse is responsible for maintaining a knowledge base regarding pain and pain therapy that is accurate, current, and helpful to clients.

Although clients receiving PCA therapy are in control of relieving their pain, the nurse is responsible for assessing the effectiveness of the therapy. Administering the booster dose prescribed by the physician when needed may have augmented PCA's effectiveness resulting in better pain control for the PCA group in this study.

Nursing education must provide students with knowledge of assessment, management, and evaluation of pain. Effective pain control methods using advanced technology such as epidural infusions and PCA should be incorporated into pain management instruction. Pain assessment and management must be continuously reinforced by the clinical instructor and incorporated into the plan of care for each client experiencing pain.

Implications for nursing administration include continuous evaluation of the effectiveness of pain

management techniques use on the nursing units. Effective pain control enhances client satisfaction. In competing for health care dollars, client satisfaction is paramount. Nursing administration must provide comprehensive pain management programs for post-operative clients on a surgical unit. Keeping staff current on methods of pain control must be done through frequent inservices on pain assessment and management.

This study has added to the body of literature on the efficacy of pain control methods. The results of the study supply data to assist health care professionals to provide effective pain-management for the total joint replacement client. As new technology continues to develop, nurses must examine client responses to new pain management methods and provide the most effective care possible.

## APPENDICES

Appendix A

A Comparison Study of the Effects of  
Methods of Pain Control on Client Outcomes

Instructions: Please ask each client scheduled for total hip or knee replacement surgery the following questions. Circle Y for a yes response and N for a no response. If all underline responses are circled, please give the client a copy of the explanation of the study and obtain his/her consent.

1. Can the client speak and understand English? Y N
2. Is the client being admitted to 4th floor for either hip or knee replacement surgery? Y N
3. Has the client had previous experience with epidural or PCA pain control methods? Y N
4. Does the client have any of the following conditions that may influence his/her length of stay.
  - Diabetes Y N
  - Acute infections Y N
  - CHF Y N

Appendix B

**EPIDURAL/INTRATHECAL NARCOTIC FLOW SHEET**

HR	BASAL/BOL	VOL LIM	PAIN	NEURO	BP / HR / RR / TEMP	LOS	SAO <sub>2</sub>	DSG	SE	TREATED	SIGN.
ARRV											

<b>SE - SIDE EFFECTS</b>	<b>NEURO</b>	<b>LOS - LEVEL OF SEDATION</b>	<b>DRESSING CHECK Q4HR</b>
--------------------------	--------------	--------------------------------	----------------------------

- |   |   |   |  |
|---|---|---|--|
| N - NAUSEA<br>V - VOMITING<br>I - ITCHING<br>R - URINARY RETENTION<br>B - BACK PAIN | AM - ACTIVE MVMT<br>PM - PASSIVE MVMT<br>G - GOOD SENS<br>N/T - NUMB/TING | 1 - WIDE AWAKE<br>2 - DROWSY<br>3 - DOZING INTERMITTENTLY<br>4 - ONLY AWAKES WHEN AROUSED<br>5 - ASLEEP AT THE TIME OF CHARTING | O - NO DRAINAGE NOTED<br>S - SLIGHT AMT OF DRAINAGE<br>M - MOD AMT OF DRAINAGE<br>L - LG AMT OF DRAINAGE |
|---|---|---|--|

<b>VITAL SIGNS:</b>	<b>PAIN SCALE:</b>	<b>MEDICATION:</b>
---------------------	--------------------	--------------------

BP / HR / RR / TEMP ON ARRIVAL VP / HR / RR Q1HR TIMES 12 HOURS THEN Q4HR RR Q1HR TEMP Q4HR	O - NO PAIN 1 - COMFORTABLE 2 - MILD DISCOMFORT 3 - IN PAIN 4 - IN BAD PAIN 5 - IN VERY BAD PAIN	FENTANYL 20MCG/CC FENTANYL _____ MGC/CC-BUPVACAINE _____ MG/CC MS04 _____ MG
---	---	--

**PCA MONITORING SHEET**

Drug/Direction	Time Cartridge Inserted	Loading or Booster	Dose in <u>  </u> ml <u>  </u> cc	Lock out interval	4-Hour Limit	Co-Sign: 2 Nurses
Document q 4 hr						
	11-7		7-3		3-11	
Time						
Respiratory Rates						
Sedation Rating						
Analgesic Rating						
<p>(1) Sedation Rating Scale            1-Wide awake            2-Drowsy            3-Dosing intermittently            4-Only Awakens when aroused            5-Asleep at time of charting</p> <p>(2) Analgesic Rating Scale            Please ask questions verbatim:            Which of the following describes how you have            felt over the last 4 hours:            0 No Pain            3 In pain            1 Comfortable       4 In bad pain            2 In mild discomfort 5 In very bad pain</p>						
	Night Shift		Day Shift		Evening Shift	
Volume in Cartridge						
Amount of mg/ml delivered						
Nurse Signature						

45

Appendix C

Time/Date of Wastage: \_\_\_\_\_ Signature of 2 Nurses: \_\_\_\_\_

Tubing Change: \_\_\_\_\_ Time: \_\_\_\_\_ Date: \_\_\_\_\_ Signature: \_\_\_\_\_

DRG: \_\_\_\_\_  
 TARGET LOS: \_\_\_\_\_  
 HCFA LOS: \_\_\_\_\_  
 ADM: \_\_\_\_\_  
 D/C: \_\_\_\_\_  
 CASE MANAGER: \_\_\_\_\_

Appendix D  
 TOTAL HIP ARTHROPLASTY CARE MAP

DATE: \_\_\_\_\_ DATE: \_\_\_\_\_ DATE: \_\_\_\_\_ DATE: \_\_\_\_\_  
 PRE-OP PAT OR PO DAY 1 PO DAY 2 PO DAY 3 PO DAY 4

CONSULTS

Pre-op  
 PAT Ver med'l if outcomes  
 con. compl. not met  
 Dr. Reina

TESTS  
 CBC T&C 2U CBC PT FT  
 UA RBC Auto  
 PT HGB/HCT  
 PTT I-ray-PARU

Pre-surg  
 Prof of  
 Lytes  
 EKG as wrtn  
 Autology

TRIMTS  
 Fleets NS Surg prep Chge dress /Incls  
 night Hemovac DC  
 Foley Cath DC  
 Antithrom  
 TEDS  
 Ice  
 FOB#20  
 Abd Pillow  
 Heels ↑

MEDS  
 Coumadin IV/IVAB DC IV-HW POAB  
 PCA/IM meds → → → → DC PCA-po PO Anal  
 Epid → → → → meds  
 Stool soft → → → → DC Epic as  
 Coumadin → → → → ord  
 Fleets if → → → →  
 no EM → → → →  
 Coumadin → → → →

NUTR  
 NPO after Clear-full Full liq's DAT  
 midnight liq's Adv as tol. → → → → As tol.

ACTIV.  
 Edge 8° Bedside Adv to gait Cont activ: Car trans.  
 post-op chr/comode with wlkr \*Tub/mock Review  
 Use trap. Stand w Amb to BR car transf activ &  
 Begin walker as tol. \*Tub home exer  
 exerc. prog Cont. → → → → \*Gait on for disch.  
 involve pt Raised unit stairs  
 ADL's toilet seat \*Homesky

TEACHO  
 Review pckt Orient to Hip lit Incl crgvr: Reinf prev. Disch inst  
 Focus Care unit provided \*Dressing home exer  
 Map Review Care \*Meds prog gvn

DISCH  
 PAT Nurse: Case Mngr: DC plans All forms  
 \*Ident. \*Cont to complete: complete  
 prim. crgvr assess \*Home  
 \*Make raf's needs → → → → \*Ext Care  
 as indic \*AFC  
 \*Rehab

REFERRALS  
 Ver Amicare As indic. → → → → Follow-up  
 visit; DO; OP Prog  
 Others as indic. as ordrd



DRG: \_\_\_\_\_  
 TARGET LOS: \_\_\_\_\_  
 HCFA LOS: \_\_\_\_\_  
 ADM: \_\_\_\_\_  
 D/C: \_\_\_\_\_  
 CASE MANAGER: \_\_\_\_\_

Appendix E  
 TOTAL KNEE ARTHROPLASTY CARE MAP

	DATE: _____ PRE-OP PAT	DATE: _____ OR	DATE: _____ PO DAY 1	DATE: _____ PO DAY 2	DATE: _____ PO DAY 3	DATE: _____ PO DAY 4
CONSULTS	Pre-op PAT Ver med'l con compl.	OR day	PO Day 1	PO Day 2 Dr. Reina if outcomes not met	PO Day 3	PO Day 4
TESTS	CBC UA PT PTT Pre-surg profile or Lytes EKG as wrtn Autology	T&C 2U RBC Auto. HGB/HCT X-ray-PARU	CBC	PT	CBC	PT
TRTMTS	Fleets HS night	Surg prep Foley Cath Antithrom TED Ice Hemovac POB†20°	Chge dress DC → No gatch	→ →	→ →	→ →
MEDS	Coumadin HS night	IV/IVAB PCA/IM Epid Stool soft	→ → → → → → → → → → → → → → → →	DC IV-HW DC PCA DC as ord Fleets if no BM	POAB PO Anal → → → → → → → →	→ → → → → → → → → → → → → → → →
NUTR	NPO after midnight	Clear-full liq's	Full liq's Adv as tol.	DAT	→ → → →	As tol.
ACTIV.		Edge 8° post-op Use trap. Begin exerc. prog	Bedside chr/commode Adv. to gait with wlkr ___ Cont. exerc. prog CPM Involve pt ADL's	Up BR with wlkr → → → → CPM†ROM → → → →	*Cont activ > indepen stairs *Gait unit with wlkr *ADL- homenky *Tub transf.	Review act & home exerc. for disch Car trans.
TEACHO	Review pckt Focus Care Map	Orient to unit Review Care Map	Reinf knee lit. provided	Incl crgvr: *Dressing *Meds *S/S Infec *DVT neuro/	Reinf prev. home exer prog gvn	Disch inst Fam. educ
DISCH PLANNING	PAT Nurse: *Ident. prim. crgvr *Make ref's as indic	Case Mngr: *Cont to assess needs	→ → → →	Order nec equip	DC plans complets: *Home *Ext Care *AFC *Rehab	All forms complete
REFERRALS	Ver Amicare visit; Others as indic.	As indic.	→ → → →	→ → → →	→ → → →	CPM if indic. Follow-up DO

## Appendix F

### A Comparison Study of the Effects of Methods of Pain Control on Client Outcomes

The study in which you are being asked to participate will compare the type of pain control you will be using after surgery and your perception of the pain relief obtained. It will assess your ability to participate in the physical therapy regime that your doctor will prescribe while you are in the hospital. Information from your medical records about the length of hospital stay also will be included.

Every effort will be made to protect your confidentiality. All data will be reported in group format, no individual data will ever be reported. It is not anticipated that you will be harmed in any way by participating in this study. You may withdraw from this study at any time without causing any change in the treatment you are receiving.

The results of this study will be useful to determine if the type of pain control influences the recovery of patients after total joint replacement surgery.

Appendix G

I acknowledge that:

"I have been given an opportunity to ask questions regarding this research study, and that these questions have been answered to my satisfaction."

"In giving my consent, I understand that my participation in this study is voluntary and that I may withdraw at any time without affecting the care I receive from my physician or the staff at \_\_\_\_\_."

"The researcher, Susan Cristofori, has my permission to review my hospital records".

"I hereby authorize the investigator to release the information obtain in this study to scientific literature. I understand that I will not be identified by name".

"I have been given Susan Cristofori's phone number so that I may contact her at any time if I have questions."

"I acknowledge that I have read and understand the above information, and that I agree to participate in this study."

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Participant signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

\_\_\_\_\_ I am interested in receiving a summary of the study results.



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