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DEVELOPMENT AND IMPLEMENTATION OF A QUALITY IMPROVEMENT INITIATIVE: SYSTEMATIC FOLLOW-UP OF PATIENTS WHO HAVE SPINAL CORD STIMULATOR IMPLANTS

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UNIVERSITY OF NEVADA LAS VEGAS

THE GRADUATE COLLEGE

We recommend the doctoral project prepared under our supervision by

Irina Rajala

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ABSTRACT

Recent medical advances and the rising prevalence of chronic pain in the US population contribute to the use of spinal cord stimulator (SCS) implant as a treatment modality for chronic pain management. As the numbers of patients receiving SCS implants steadily increases, the challenge of managing this device grows and the need for SCS implants follow-up programs rises. Follow-up programs need to focus on implant longevity and efficacy to improve the quality of care outcomes.

This Doctor of Nursing Practice (DNP) quality improvement initiative was developed to provide systematic follow-up for patient with SCS implant. The project includes the creation of a database for all of the SCS implants currently managed by this medical center; development and administration of the questionnaire to improve the effectiveness of this modality; development of a multidisciplinary team, including the representatives of the device manufacturers, to improve device management; and maintenance of the treatment space to assure timely access by appointment.

Data were collected via a questionnaire, administered to 80 patients as part of the follow-up program. Analysis of the data yielded these patient outcomes: 33 (41.25% of respondents) had satisfactory pain coverage requiring no further intervention; 27 (33.75%) needed SCS device reprogramming; 7 (8.7%) required surgical intervention for SCS implant management; 6 (7.5%) needed interventions but were not ready to receive the intervention; and 7 (8.75%) patients requested additional procedure for pain management augmentation.

Post hoc comparisons using the Bonferroni adjustment for Type I error rate

inflation showed that patients who reported a remodulation time of less than 6 months (M = 4.97, SD = 2.35) reported significantly less pain than patients who reported a remodulation time between 6 and 12 months (M = 5.65, SD = 2.16) and more than 12 months (M = 5.86, SD = 2.66). The pairwise comparison between patients who reported remodulation time between 6 and 12 months and more than 12 months was not significant, $p > .05$. Thus, the greater the time since remodulation of SCS implant, the more pain patients reported.

DEDICATION

I would like to dedicate this to Dr. Michele Clark, my committee chairperson, for her encouragement, dedication, amazing patience, long hours of editing, and guidance in writing and implementing this QI initiative. Her words—"We can do this"—inspired me and provided the confidence I needed to overcome my hesitations and limitations in order to reach beyond my safety zone in my personal and professional growth.

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CHAPTER 1

INTRODUCTION

A QUALITY IMPROVEMENT INITIATIVE: SYSTEMATIC FOLLOW-UP OF PATIENTS WHO HAVE SPINAL CORD STIMULATOR IMPLANTS

The Institute of Medicine (2011) released a report stating that more than 110 million Americans suffer from chronic pain and that the cost totals $635 billion each year in medical treatment and loss of productivity; however, the emotional burden for those afflicted by chronic pain and for the whole society is impossible to calculate. Chronic pain results in depression, poor quality of life, and ultimately loss of livelihood. Chronic pain is a major driving force for a patient to seek medical attention (Kumar, Wilson, & Taylor, 2006; North, Kidd, Farrokhi, & Piantadosi, 2005; North & Shipley, 2007). The spinal cord stimulator (SCS) implant was first implemented by Shealy et al. in 1967 as a treatment modality for chronic pain management. Since then it has been used with increasing success for management of Failed Back Surgery Syndrome (FBSS), chronic regional pain syndrome (CRPS), peripheral vascular disease, refractory angina, and pain secondary to multiple sclerosis (Horsch, Schulte, & Hess, 2004; North et al., 2005). An increasing body of clinical evidence illustrates the effective use of this modality for the treatment of pain from post-herpetic neuralgia, peripheral neuropathy, occipital neuralgia, and other neuropathic conditions. Further clinical evidence illustrates that neurostimulation is effective in treating ischemic pain produced by cardiovascular and peripheral vascular diseases, along with interstitial cystitis pain (Atkinson, Sundaraj,

Brooker, O'Callaghan, Teddy, Salmon, . . . Majedi, 2011; Mekhail, Cheng, Narouze, Kapural, Mekhail, & Deer, 2010; North et al., 2007).

Mekhail et al. (2010) noted that 50,000 neurostimulators are implanted worldwide each year for the treatment of a variety of painful conditions, and total sales of SCS implants are predicted to rise. When all traditional interventions have failed, the SCS is considered one of the most effective modalities for chronic pain management (Atkinson et al., 2011; Mekhail et al., 2010). North and Shipley (2007) outlined the potential beneficial outcomes associated with the SCS implant placement, such as significant pain relief and improvement quality of life, reduction of consumption of health care resources, improvement in ability to engage in the activities of daily living and return to work, patient satisfaction with treatment, and improvement in symptoms of depression and neurological function. Atkinson et al., (2011) asserted that unlike surgical pain relief procedures the placement of the specific types of SCS implants does not change the anatomy or ablate pain pathways, which makes it completely reversible. The United States (U.S.) Food and Drug Administration currently approved the use of SCS implant therapy for chronic pain of the trunk and limbs, FBSS, and intractable low back pain (LBP) (Compton, Shah, & Hayek, 2012). As the U.S. population ages, there is a growing population suffering from neurodegenerative diseases such as Parkinson's, incontinence, chronic pain, and other conditions that create an opportunity for neurostimulation use and increase of use of this treatment modality (Krames, Peckham, & Rezai, 2009).

Despite multiple benefits and applications of SCS implant as treatment modality Turner and colleagues (2004) reported in their comprehensive meta-analysis of 22 studies that complications of any sort occurred in 34.3% cases. Hardware complications included

equipment failure (10.2%), required surgical stimulator revision other than battery change (23.1%), or stimulator removal (11.0%). Biological complications included superficial infection (4.5%), deep infection (0.1%), pain in the region of stimulator components (5.8%), and complications other than infection or local pain (2.5%).

It should be also noted that this treatment modality is not long term; the pain-alleviating effect of the SCS implant in complex regional pain syndrome patients diminishes over time despite fully functional stimulating system (Kemler, De Vet, Barendse, Van Den Wildenberg, Van Kleef, 2008). Kumar and Wilson (2007), using their active database of 424 patients, examined causes of long term failures. They identified a group of 85 patients who, after an initial period of good pain relief, started to require increasing amplitude of current (SCS implant reprogramming) to maintain satisfactory pain control; the researchers labeled this as development of the "tolerance." Since the effectiveness of this modality is constantly changing with a gradual decrease over time, the patient's needs and satisfaction with the SCS implant therapy also change (Atkinson et al., 2011).

The development of a systematic follow-up program for patient with SCS implant would help address patients' needs in a timely manner, improve pain management, and provide ongoing assessment of malfunction and complications associated with the device; therefore, the creation of follow-up program would contribute to the longevity of SCS implant function and its efficacy. This project focuses on the development and implementation of the quality improvement initiative (QI) that encompasses the creation of systematic follow-up for patients with SCS implants. The QI initiative can bring expedited, focused changes into clinical practice by incorporating multilevel process with

a multidisciplinary approach, evidence-based practice, and individual innovations within the clinical area (Sollecito & Johnson, 2013). This QI initiative is designed and incorporated as part of the Anesthesia Pain Clinic' s protocol. The clinic is within medical center that is part of Veterans Health Administration (VHA) located in western U.S. The goal of the QI project is aligned with the goal of the Anesthesia Pain Clinic: to provide continuity of care and the best possible outcomes for patients with chronic pain.

Background and Significance

The Veterans Health Administration (VHA) National Pain Management Strategy, initiated November 12, 1998, established pain management as a national priority with an objective to develop a comprehensive, multidisciplinary, integrated, system-wide approach to pain management. The intended outcome of this priority is to reduce pain and suffering while improving quality of life for veterans experiencing acute and chronic pain (VHA Directive 2009-053, 2009). The VHA is a centrally administered, publicly supported entity that provides care to a defined population of veterans without concern for their ability to pay or preexisting health conditions (Feussner, Kizer, & Demakis, 2000). Between 2000 to 2007, the incidence of chronic pain (including LBP) rose, and the number of individuals with a LBP diagnosis increased from 10,955 to 15,205 per 100,000 VHA users at an annualized prevalence rate increase of 4.8% per year. This increasing prevalence of LBP is even more evident in reports among recently returning veterans (Gironda, Clark, Massengale, & Walker, 2006; Sinnott & Wagner, 2009).

Due to increase in patients with pain of the VHA has implemented the "Pain as the 5th Vital Sign" initiative for all inpatient and outpatient clinical settings to ensure consistent recognition, the assessment of pain intensity, and the effects of pain on the

veteran's function and quality of life. The VHA asserts that an effective pain treatment plan must be developed and implemented, and the reassessment of the effectiveness of this plan must be completed and documented (VHA Directive 2009-053, 2009). Also the VHA National Pain Management Strategy Objectives 6 and 7 delineate the appropriate level and frequency of monitoring to improve the outcomes of pain management. The use of an interdisciplinary, multimodal approach to pain management that emphasizes the optimal pain control and improved functionality and quality of life are important elements of this directive as well (VHA Directive 2009-053, 2009).

VHA Directive 2009-053 (2009) emphasized the importance of non-pharmacological interventions aimed toward optimal pain control and emphasized individualized patient care and pain medicine specialty procedures, such as injections, nerve blocks, and ablations including neuromodulation or SCS implants. Unfortunately, the SCS implant is a costly intervention; it is a labor intensive and invasive procedure, with possible complications and long-term problems that require the skills and judgments of specialists, involving lifetime management, adjustment, and follow up (Atkinson et al., 2011; Hollingworth, Turner, Welton, Comstock, & Deyo, 2011). However, Simpson and colleagues (2009) concluded that the SCS implant is a cost effective modality when compared with alternative pain management techniques. Evidence of the benefits of this treatment for conditions such as FBSS and CRPS supported this (Cameron, 2004; Compton, Shah, & Hayek, 2012). However, regular follow up visits are required in the first year following the implant to adjust stimulation parameters. In subsequent years, annual visits are necessary to assess the need for the modification of the pain management plan and to monitor the implantable pulse generator (IPG) battery life

(Atkinson et al., 201; North et, al., 2007). The SCS team should be available at all times, as problems or complications arise. For patients located a significant distance away from the SCS team need to handle travelling arrangements and follow up care (Atkinson et al., 2011).

In 2007, North and colleagues evaluated costs associated with the SCS implant, and when compared with reoperation for FBSS, the SCS provided significant savings for the patient, as well as for society ($48,357 for the SCS, compared to $105,928 for reoperation). This holds true even with the decline of effectiveness of the SCS implant over time, as demonstrated by Kemler, De Vet, Barendse, Van Den Wildenberg, and Van Kleef (2008). In their study they found that 95% of all patients who had received this intervention would still consider it even if the outcome were the same.

This information and the VHA National Pain Management Strategy helped formulate the following two questions:

1. What can be done to maximize the efficacy of the SCS implant for chronic pain management?
2. Which steps or alterations in the management of this modality would produce significant and positive benefits for patients who are using this modality to achieve maximum pain relief?

One way to determine the answers to these questions is the creation of a comprehensive follow-up program that would provide a systematic evaluation and timely interventions to for pain management and detection of early complications; the ability to effectively communicate this data to all healthcare providers; and engagement of a multidisciplinary team to manage patients with SCS implant using lessons learned from research and

evidence-based practice. The program would aim to provide uniform improvements across the organization for patients with SCS implant suffering from chronic pain.

Purpose

In recent years, the Veterans Health Administration (VHA) has required that research informs practice so that practice is guided by evidence-based medicine, clinical practice guidelines, reduction of unnecessary practice variations, and improvement of clinical information management systems (Feussner, Kizer, &Demakis, 2000). The VHA Quality Enhancement Research Initiative (QUERI) focuses on translating research into clinical practice to improve patient outcomes at the systems level. As well the QUERI supports additional epidemiological, economic, and statistical expertise to practice decisions by increasing interactions among researchers, clinicians, management, and others involved in quality assessment and improvement (Feussner et al., 2000; Hayward, Hofer, Kerr, & Krein, 2004).

The purpose of the development and implementation of this systematic follow-up QI initiative focused on patients who have SCS implants is to (a) create a database for all of the SCS implants currently managed by the Anesthesia Pain Clinic within the VHA medical center located in western part of U.S.; (b) develop a questionnaire to collect necessary information to guide the management of SCS implants and evaluate the effectiveness of the modality at 6 and 12 month intervals followed by a yearly follow ups; (c) create a multidisciplinary team (within the Anesthesia Pain Clinic and Neurosurgery Department) with the integration of manufacturing representatives who will provide timely and effective reprogramming of the SCS device with the goal of achieving the best possible pain coverage for patients; and (d) maintenance of a physical

space where the reprogramming and management of the device will occur with appointments arranged and managed by the Anesthesia Pain Clinic.

Policy Implications

One implication of this QI initiative is the development a policy that requires the systematic follow-up of patients who have SCS implants. This will assure timely and appropriate assessments and access to care. Also research demonstrates that this would affect the longevity and the efficacy of SCS implant as the modality for chronic pain management. The questionnaire administered within this QI project uncovers the areas needed for the follow-up intervention and provides area for ongoing communication within the members of the multidisciplinary team. The QI initiative also addresses the need for access to additional space for patient education and the reprogramming of devices. The positive evaluation of the interventions provided during this QI project along with multiple patients request for follow up led to the approval and development of the Neuromodulation Clinic that is now part of Anesthesia Pain Clinic. The new Neuromodulation Clinic is now open every Monday to accommodate the pre-scheduled appointments for patients with SCS implants who need or require additional interventions or education. As an additional benefit part of this QI initiative, manufacturing representatives from St. Jude company agreed to provide a comprehensive one hour educational sessions prior to the implantation of SCS for patients with chronic pain.

CHAPTER 2

REVIEW OF THE LITERATURE

A search of literature focusing on SCS implant modality was undertaken through a computerized database search of Medline, Cochrane, and the UNLV library using search terms, such as spinal cord stimulation, chronic pain, failed back surgery syndrome, chronic regional pain syndrome, neuromodulation, Veteran Health Administration, quality improvement and quality improvement in Quality Enhancement Research Initiative, follow up systems, multidisciplinary team, and Kotter's Change Theory.

Theories Related to the SCS Implant for Pain Management

The gate theory presented by Melzack and Wall (1965) laid the foundation for understanding the mechanism of pain production and pain reduction by balancing the input between the large and small fibers in the spinal cord. The concepts of gate theory were placed in practice by Shealy et al., (1967) when they developed the concept of SCS implant and performed the first placement of stimulated electrodes. However the gate theory does not fully explain the mechanism of SCS pain control, as stimulation does more than directly inhibit pain transmission (Kumar & Wilson, 2007). Today, the biopsychosocial (BSP) model of chronic pain first proposed by George Engel is the most appropriate conceptual framework for understanding the clinical course of persistent pain and for organizing treatment (Gallagher & Verma, 2004). The BSP model incorporates the fluidity of how physical, psychological, social factors affect pain perception, neurophysiology of nociception, pain modulation, patients' personal suffering, and their behavior (Borrell-Carrio, Suchman, & Epstein, 2004). In this model patients' pain level, their responses to treatment, and their disability levels are affected by a factors such as

attitude, beliefs, expectations, mood, and social support system and the status of their compensation case (Gallagher & Verma, 2004). The BPS model is both a philosophy of clinical care and a practical clinical guide, as it provides a way of understanding how suffering, disease, and illness are affected by multiple levels of organization, from the societal to the molecular. It opens the possibility of understanding the patient's subjective experience as an essential contributor towards accurate diagnosis, health outcomes, and humane care. This model also allows for the incorporation of a psychological evaluation as a significant part of the criteria necessary for the successful long-term management of pain with the SCS implant placement (Gallagher & Verma, 2004; VHA Directive 2009-053, 2009).

Mechanism of Action and Evidence Related to the SCS Implant for Pain Management

An SCS implant placed into the epidural space is able to produce and transmit an electrical current to the dorsal column, creating a tingling sensation in the corresponding dermatomes, although the mechanism of this action is not completely understood. The SCS implant produces non-painful paresthesia in areas where pain is located (Falowski, Celii, & Sharan, 2008). Two different mechanisms of action are accepted today: the relief of neuropathic pain produced by the suppression of hyper-excitability of dorsal horn neurons and the relief of ischemic states/pain produced by restoring the oxygen demand/supply by the inhibition sympathetic system (Kunnumpurath, Srinivasagopalan, & Vadivelu, 2009). The SCS system consists of a generator with controls, conductive leads, and implanted stimulating electrodes. Although SCS implant commonly described as "totally implanted" the system still requires external equipment to control stimulation

parameters (Kumar & Wilson, 2007). The patients have a small portable control unit available to make simple adjustments, and larger system adjustments are made by the manufacturing representatives or physicians (Krames, 2006; North, Khalessi, Calkins, Piantadosi, Campbell, Daly,…Taylor, 2004).

The internally powered, implanted pulse generator (IPG) has been used for more than 20 years, and it has its own battery that needs to be replaced periodically (Kumar, Wilson, Taylor, Gupta , 2006). When battery is depleted the IPG requires a surgical replacement, incurring additional risk and cost. It should be noted that IPG life is determined by the programmed settings of the SCS implant, thus making effective reprogramming and remodulation of the SCS implant a valuable option for the extending the longevity of IPG (North et al., 2004; Atkinson et al., 2011). As of 2006, the number of companies manufacturing devices for the treatment of pain has increased from one major company, Medtronic, Inc., to five major companies, including Medtronic, Inc.; Advanced Bionics, Inc. of Sylmar, California, a subsidiary of Boston Scientific Corporation; Advanced Neuromodulation Systems of Plano, Texas, a subsidiary of St. Jude Corporation of St. Paul, Minnesota; Cyberonics of Houston; and Codman, a Johnson and Johnson company (Krames, 2006). Various current, voltage, and waveform configurations are possible, and the effectiveness of the SCS implant can be optimized by adjusting stimulation parameters to prolong battery life by systematic reprogramming the device to provide better pain coverage and minimize the incidence of complications related to equipment design (Kunnumpurath, Srinivasagopalan, &Vadivelu, 2009).

A randomized, controlled trial in the late 1990s with chronic, refractory CRPS pain patients supported the effectiveness of the SCS implant for treatment of chronic pain

(Kemler et al., 2004). These patients were evaluated at yearly intervals for up to five years. A variety of measures, such as the visual analog scale (VAS), McGill Pain Questionnaire, the global perceived effect (7-point scale), and the quality of life profile (Sickness Impact Profile and Nottingham Health Profile) were used to evaluate the effectiveness of treatment related to pain. At two years, the SCS group continued to have a significant ($P < 0.001$) mean decrease in the VAS of 2.1 cm, compared to 0.0 cm for the physical therapy (PT) treatment alone group. Furthermore, 43% of those in the SCS group continued to rate themselves as "much improved" compared with only 6% in the PT-alone group (Kemler et al., 2004).

SCS implantation is considered most effective for the pain of neuropathic origins, such as in FBSS and CRPS (Atkinson et al., 2011; North & Shipley, 2007). The SCS modality is often considered the last resort for persistent or recurrent pain after lumbarsacral spine surgery, which is often associated with nerve root compression and is treated by repeated operations or by the SCS implant (North et al., 2005). Harke, Gretenkort, Ladleif, and Rahman (2005) completed a prospective study on 29 patients with type I CRPS. Their study illustrated the importance of the SCS implant for chronic pain management and its positive impact on patient's quality of life. These patients' pain was not relieved by pain medication and PT and they had only a temporary positive response to a sympathetic block. All patients in the study had an implantation with the SCS system, and a 12-month follow-up revealed that deep pain had decreased from a mean of 10 cm to 1.7 cm and allodynia (pain due to a stimulus which does not normally provoke pain) had been essentially resolved ($P < 0.01$). In a patient follow-up roughly

three years later, deep pain remained at a mean of 2 cm on the VAS scale, and 70% of these patients had returned to work (Harke et al., 2005).

The SCS implant is more effective than reoperation for FBSS, and it significantly decreases the use of opiates. In 2005, North et al. performed a prospective, randomized study with 50 patients who were randomly assigned to receive SCS implants or reoperation for FBSS. At a follow-up of about three years, 90% (45/50) of patients were evaluated. The SCS was significantly more successful in terms of pain control than reoperation; 47% of SCS patients versus 12% of reoperation patients reported 50% or greater pain relief ($P < 0.01$). The changes in work status and activities of daily living did not differ between the groups, but the group with the implantable SCS used significantly less narcotic analgesics (North et al., 2005).

Bannet and Brookoff (2006) pointed out that the SCS modality has a restorative effect that currently offers the best chance of obtaining long-term pain relief in CRPS patients, while it re-establishes and sustains blood flow to the affected area to preserve muscle and soft tissue. Harke et al.'s (2005) study revealed that in a 12-month follow up after the placement of the SCS implant, all the patients had complete ablation of allodynia, 70% showed more than 50% reduction in the Pain Disability Index scoring, and 58.6% had stopped all medication.

Hollingworth, Turner, Welton, Comstock, and Deyo (2011) studied the cost-effectiveness of the SCS implant for FBSS in a study that sampled of the worker's compensation population. They concluded that the mean medical cost per patient of the SCS implant over 24 months was $52,091. This was $17,291 higher than in the pain clinic (PC) group and $28,128 higher than the usual care (UC) group. The mean total

medical and productivity loss costs per patient of the SCS group were $20,074, which was higher than both the PC group and the UC group. The study concluded that the SCS implant was highly unlikely to be the most cost-effective intervention. It should be noted that this was a 24-month study; studies that were three years in duration supported an opposite view of the one accepted in current clinical practice.

SCS implantation has been proven cost effective in the longer term. North et al.'s (2007) study examined the cost effectiveness in a follow-up of 42 patients for three years after their initial enrollment in a randomized controlled crossover trial evaluating SCS versus reoperation for FBSS. The cost was $48,357 for SCS implanted patients, compared with $105,928 for patients who had a reoperation. When treated with SCS therapy, patients generally required less follow-up care, which significantly decreased health care resource utilization and made SCS less expensive than conventional treatments over time (Mekhail et al., 2004). North and Shipley (2007) noted that the cost-effectiveness of the SCS implant could be optimized by periodically adjusting stimulation parameters to prolong battery life, minimizing the incidence of complications, and improving equipment design and careful patient selection.

Patient selection is critical for successful long-term SCS implantation for chronic pain management (North, Kidd, Wimberley, & Edwin, 1996). Patients' understanding of the procedure, realistic expectations of pain relief, and the ability to follow directions are critical and can be evaluated from interactions with the pain practitioner. With appropriate patient selection, neurostimulation is a valuable option to reduce pain, optimize function, improve the quality of life, and decrease health care costs in many of those suffering debilitating pain conditions. The SCS implant does not

provide pain relief in all patients and is an expensive, labor intensive, invasive procedure with complications and ongoing management that requires specialists with specific skills and judgment (North, Kidd, Wimberley, & Edwin, 1996). A multidisciplinary selection of appropriate patients for SCS is essential to achieving maximum benefit from the procedure (Doleys, 2006).

Currently, psychological testing has been conducted in an effort to identify predictors of success in SCS therapy. Dumoulin, Devulder, Castille, De Laat, Van Bastelaere, and Rolly (1996) reported a correlation of greater than 0.8 on scores from a 24-item questionnaire, and calculated an 80% accuracy rate using the Multiphasic Personality Inventory and Beck Depression Inventory and other tests. Long and Webb (1980) also reported a 33% success rate in using SCS for chronic pain management in unscreened patients compared with 70% in screened patients. Kumar, Toth, Nath, and Laing (1998) also found that patients considered appropriate for SCS therapy based on the results of psychological screening had better outcomes than those deemed inappropriate (North & Shipley, 2007).

Eighteen percent of SCS modalities fail due to lead migration, and it is the primary cause of a decrease in the effectiveness of SCS (Bannet & Brookoff, 2006). Lead migration is primarily due to falls or other accidents, and after the lead migration, it has been noted that there is a decrease of paresthesia coverage of the painful area. In a review, Turner et al. (2004) found on average, 34% of patients had stimulator-related complications, and they also noted that the most common complication was electrode migration (11%). Atkinson et al. (2011) pointed out that lead migration might occur at any time. Lead migration terminates or decreases the paresthesia in areas associated with

pain which leads to a lack of pain relief. It has been recommended that patients should not undertake activities that require excessive twisting or stretching during the first 3 month after SCS implant (Atkinson et al., 2011). Education about SCS implant therapy and PT are critical for reconditioning patients after the SCS implantation (North, 2007).

Careful follow up of patients with an implantable SCS device is necessary for successful long-term therapy. Equipment-related problems can arise at any time after implantation, including discomfort at the IPG site, electrode breakage or migration, and infections. As a result, open dialog with patients is vital for the continued successful use of this modality (Falowski, Celii, & Sharan, 2008). Cameron (2004) reported the following complication rates based on reviewed studies:

1. Lead migration – 13.2%
2. Lead breakage – 9.1%
3. Infection – 3.4%
4. Hardware malfunction – 2.9%
5. Unwanted stimulation – 2.4%

The most frequently seen issue is a loss of stimulation in the desired area due to lead migration and breakage, epidural fibrosis, or disease progression (Atkinson, 2011; North, 2006). Diagnosis of these problems is made by plain films of a computer analysis of the impedance, a physical exam, and information obtained via the patient's follow up interview/questionnaire. Reprogramming the device is the initial step in correcting these situations (Deer & Stewart, 2008).

In the application of SCS for chronic pain management, it is crucial to cover the patient's painful areas with paresthesia, which results in a "tingling sensation." In order

to optimize this result, the SCS system must provide adequate neural selectivity; that is, maximal control over stimulation of the targeted nerves while avoiding stimulation of undesired neurons (Bradley, 2008). Complex pain patterns require a high degree of flexibility in the implanted SCS system. The medical team's willingness and ability to provide extensive reprogramming in the long-term follow up is of utmost importance (Sharan, Cameron, & Barolat, 2002). Brook, Gregory, and Olan (2009) pointed to issues with the SCS implant, such as a loss of stimulation due to wire fracture or battery depletion, stimulation of the wrong area due to lead migration, intermittent stimulation due to a lead in the wide epidural space, or painful stimulation. All these issues require immediate attention.

It is critical to evaluate and document patient progress and the utility of the SCS implant for chronic pain management (Brook et al., 2009). From the inception, and as the therapy progresses, pain scales, disability scores, and charts that detail location, duration, and degree of pain provide evidence of how effective the SCS implant is for pain management (Brook et al., 2009). VASs are among the most commonly used measures of pain intensity in clinical and research settings, and the evidence supports the validity of this instrument to measure pain intensity in patients' population (Ferreira-Valente, Pais-Ribeiro, & Jensen, 2011).

Needs Assessment

The current needs for the implementation of this QI program were identified using a comprehensive evaluation of current practices at the Anesthesia Pain Clinic and a review of practice recommendations based on research literature, evidence-based

practice, and input from Anesthesia Pain Clinic, Neurosurgery Department, medical records review, and patients' requests.

The evaluation included:

Interviews. This study interviewed a number of health care providers to establish ways to improve care to the patients with SCS implant. Interviews were done with three members of the Anesthesia Pain Clinic, one representative from the Neurosurgery Department, two representatives from the device manufacturing companies, and three patients who came to the Pain Clinic for evaluation/reprogramming of their SCS device. The interviews revealed a need for current information about individual SCS device's efficacy in relieving pain; a database of current patients with SCS implant who are managed by this facility; a comprehensive systematic follow-up of patient with SCS implants to improve device efficacy; development of effective communication between members of multidisciplinary team and manufacturing representatives; and creation of space to accommodate reprogramming of the device and necessary interventions. One of the representatives from the manufacturing company stated, " VHA patients are very different from the patient that had the device implemented in a private practice. After the device was placed (in this population), they disappear, and do not stay in touch." The veterans population's high prevalence of depression, homelessness, and post-traumatic stress disorder partly explain this disappearance (Rozanov & Carli, 2012). As well, and in some instances patients must drive more than 600 miles to get to this medical center. The interview with patients identified following issues: the effectiveness of the device decreased, but patients were not sure of how to follow-up on it; and they were not sure what changes in the modality would necessitate reprogramming of the device, contact

with the physician, which department to contact to report changes in SCS implant functions.

Review of computerized patient record system (CPRS). The review of the CPRS information of five patients who received SCS implants revealed a lack of information about the effectiveness of the device for more than 2 weeks after implantation. There were also no systematic evaluations of the device's effectiveness as well no protocol on documenting the changes in this treatment modality for chronic pain management.

These findings revealed the need for the comprehensive systematic follow-up system that incorporates adherence to the recommendations from latest research and evidence-based practice to improve management of chronic pain and maximize the efficacy of this modality. The development of this QI project incorporates systematic follow-up for patients with SCS implants and is aligned with the goals of the VHA system and the Anesthesia Pain Clinic. The goal of the project is to improve chronic pain management and provide quality care for patients.

According to the minimum requirements of the Australian Pain Society, pain services are responsible for ongoing care and follow up after the SCS implant has been placed (Atkinson et al., 2011). Postoperative support—including physical rehabilitation, psychological support, medication adjustment, SCS system programming and management of any complications, and the eventual replacement of non-rechargeable IPG systems—is required (Atkinson et al, 2011). The VA Anesthesia Pain Clinic evaluation revealed the need for a comprehensive follow-up program that would reflect the latest research and evidence data, comply with the VHA directives, actively respond to patient requests and needs, and be at forefront of safety and quality of care delivered to

veterans. Having an active data base of these patients and placing this information into CPRS is critical for the systematic follow-up program.

Turner et al. (2004) found that on average 34% of patients who received a stimulator experienced complications. Delayed complications, such as lead migration, could occur any time and cause paresthesia in areas not associated with pain and lead to a lack of pain relief (Atkinson et al., 2011). This validates the need for the systematic follow-up program that encompasses all patients with SCS implant with the incorporation of patient-orientated assessment methods that values the evaluation of treatment outcomes and detection of potential problems (Mannion, Junge, Fairbank, Dvorak, Grob, 2006). Follow-up questionnaires administered face to face or by phone in the first 6 and 12 months and yearly are also critical for identifying problems related to the optimizing the use of the SCS implant for chronic pain management. The QI project should also incorporate the special considerations related to the management of the SCS implant: reprogramming the device, the need for early detection of complications, and identifying the need for IPG replacement or repositioning. The SCS implant compatibility evaluation with cardiac pacemaker/defibrillators is critical for the success of both therapies. Magnetic resonance imagining (MRI) studies post-SCS implantation would be contraindicated because the magnetic field could produce lead migration or heating of the components (Atkinson et al., 2011). The secure database created by this project would provide the information about patients with SCS implant and help assure that appropriate interventions are provided for patients with SCS implant.

Population identification

This QI project will be directed toward all patients who have placed and currently managed the SCS implant as a modality for chronic pain management in this medical center, which is part of VHA system in western part of U.S. Both genders will be represented in the group, and all patients will be over 18 years old. The majority of the patient in the group have been diagnosed with FBSS and/or CRPS. The SCS implants that are currently managed come from one of three manufacturing companies: Boston Scientific, Medtronic, and St. Jude Medical.

Settings

The primary settings for the development and implementation of this QI initiative took place in the Anesthesia Pain Clinic that is open five days per week and is staffed with an Anesthesiologist, a Certified Registered Nurse Anesthetist (CRNA), and a Registered Nurse (RN). The Anesthesia Pain Clinic is an integrated part of the medical center and is located at close proximity to Same Day Surgery (SDS) unit. This allows for sharing financial and intellectual resources and creates continued collaboration toward the goal of proving the best possible care for veterans.

Organizational Assessment and Assessment of Valuable Resources

Anesthesia Pain Clinic Team.

1. Anesthesiologist: identifies the need for the SCS implant as a treatment modality, places temporary/trial and percutaneous SCS implant, participates in determination of the suitability for a permanent SCS implant; and, after the permanent implant is placed, is involved in the reprogramming decisions, the replacement of the IPG, and maintenance of the SCS implant.

2. Certified Registered Nurse Anesthetist: participates in the decision making of patient selection for the SCS implant, provides anesthesia delivery during the placement of the trial/percutaneous SCS implant, evaluates the outcomes of SCS modality, and involved with patient's care during the follow up period.
3. Registered Nurse: coordinates, monitors, and records information throughout the process, as well as communicates to members of Anesthesia Pain Clinic received from the telephone calls and nursing assessments.

Neurosurgery Department.

1. Neurosurgeon: selects candidates for the SCS implant, performs surgical placement of the permanent SCS implant, provides the 3 month postsurgical follow-up, and does the removal and replacement of SCS implant system and IPG.
2. Physician Assistant (PA): participates in placement and provides follow-up after permanent SCS implant placement/removal and IPG exchange/removal.
3. Registered Nurse: coordinates, monitors, and records information throughout the process, as well as communicates information received from the telephone calls and nursing assessment to members of Neurosurgery Department.

Representatives/Equipment Consultants from the manufacturing companies

Representatives/Equipment Consultants from the manufacturing companies (Boston Scientific, Medtronic, and St. Jude Medical): provides SCS implants and responds to staff and patient questions and concerns about the device before and after implantation and are directly involved in reprogramming of SCS implants.

Resources/Support

The financial resources for this QI project are incorporated into the budget of the Anesthesia Pain Clinic, along with support from the Office of Quality and Safety Systems of the medical center. The Neurosurgery Department, Same Day Surgery Department, the information technology (IT) team, and the manufacturing representatives from Boston Scientific, Medtronic, and St. Jude Medical are available to support this QI initiative. Anesthesia Pain Clinic Space: available as resource for this QI project (See Appendix A).

Cost Benefit Analysis

Taylor et al., (2010) used a decision-analytic model to examine the cost effectiveness of the SCS implant as compared to conventional medical management or reoperation. They incorporated in their analysis the frequency and cost of all complications in patients with SCS implant. The study supported previous findings (Kumar et al., 2006; North, et al., 2007) that despite the frequency of complications and their cost, the use of the SCS implant is more cost effective when compared to either conventional medical management or reoperation. This research data provides a solid basis for the cost effectiveness of this QI project, which creates a systematic follow-up of patient with SCS implant to improve this therapeutic modality's efficacy and the quality of life for patient with chronic pain.

Defining the Scope of this QI Initiative

This QI initiative will incorporate the following elements: (a) the creation of a database for all patients with the SCS implants currently managed by the Anesthesia Pain Clinic within this VHA medical center located in west of U.S.; (b) the development of a questionnaire to collect information to guide the management of SCS implants and to evaluate the effectiveness of the modality at 6 and 12 month intervals followed by a

yearly follow ups; (c) the creation of a multidisciplinary team (Anesthesia Pain Clinic and Neurosurgery Department) with the integration of manufacturing representatives who will assist in providing timely and effective reprogramming of the SCS device; and (d) the maintenance of a physical space where the reprogramming of the device will occur along with arranging and managing appointments within the Anesthesia Pain Clinic.

CHAPTER 3

CONCEPTUAL MODELS FOR THE PROJECT THAT SUPPORT THE VHA MISSION AND VISION

"The overarching goal of the Systems Redesign Sub-Initiative is to improve the VHA's health care delivery systems operation to achieve our mission of providing exceptional healthcare. Implementation of continuous improvement is one of the VA's top priorities. This goal requires each employee to engage in improving our work by creating increasingly reliable and timely systems responsive to patient needs." (Department of Veteran Affairs, Office of Health Care Transformation, 2012, p. 19). Kotter's Eight Step Model of Change provides a basis to initiate and implement the process of change within the organization and illustrates the need and urgency for change as well as helping facilitate those changes (Borkowski, 2009).

Kotter's Eight Step Model of Change has been used effectively to implement organizational changes; therefore, the steps identified in this model will be used to implement this project (Campbell, 2008). Borkowski (2009) describes Kotter's dynamic eight-step model for creating organizational changes, as follows:

1. Establish the sense of urgency. The organization members examine current market and existing or potential crises and major opportunities that exist to create sense for urgency about the need for change.

2. Create a powerful guiding coalition. The project manager should create powerful guiding coalitions that have the ability to enhance process and create changes at different levels of organization.

3. Develop a vision. The project manager should create a vision to direct the change effort and develop strategies to achieve that vision.

4. Communicate the vision. The project manager should use all strategies possible to communicate the new vision and the approaches to achieve it.

5. Empower others to act on the vision. The project manager should eliminate barriers to change and should encourage risk taking and creative problem solving.

6. Plan for and create short-term wins. The project manager should plan for visual performance achievements and recognition of the team members who greatly contributing for the project.

7. Consolidate improvements and produce more changes. The project manager should use the credibility achieved in short term wins to create more changes by reinvigorating the process with new projects, themes, and change agents.

8. Institutionalize new approaches. The project manager should reinforce changes by focusing on the connections between new behavior and the success of the project and develop means for the leadership and further success of the project.

These steps create a culture for change by engaging and enabling team members and whole organizations to initiate changes and sustain changes (Campbell, 2008; Shirley, 2011). As pointed by Campbell (2008), Kotter organizes each of these steps into three distinct phases: creating a climate for change, engaging and enabling the whole organization, and implementing and sustaining the change.

The second contribution to the conceptual frameworks of developing and

implementing this QI initiative will be the VHA Quality Enhancement Research Initiative (QUERI). It was developed within VHA system between 1998 and 1999 to help facilitate QI initiatives (Feussner et al., 2000).

In recent years, the VHA has used research to guide practice by the principles of evidence-based medicine, implementation of clinical practice guidelines, reduction of unnecessary practice variations, and improvement of clinical information management systems (Feussner, Kizer, & Demakis, 2000). The VHA QUERI focuses on translating research into clinical practice to improve patient outcomes at the systems level. Therefore the VHA QUERI brings additional epidemiological, economic, and statistical expertise to VHA QI programs by increasing interactions among researchers, clinicians, management, and others involved in quality assessment and improvement (Feussner et al., 2000; Hayward, Hofer, Kerr, & Krein, 2004). The QUERI process is a 5-step approach in creating and implementing QI initiatives (Hayward, et al., 2004):

1. Identify best practices
2. Define existing practice patterns and outcomes
3. Identify and implement interventions to improve practice
4. Document that best practices improve outcomes
5. Document that outcomes are associated with improved health-related quality of life

The QUERI consists of the logical overlap between this evidence-based practice basic principle of QI initiative and health services research (Feussner et al., 2000). Considering the five principles outlined above, the QUERI process will help guide the

implementation of this QI initiative designed for the systematic follow-up of the patient with SCS implant for chronic pain management.

The need for the development of a comprehensive follow up system for SCS implants has been demonstrated by research data (North, 2006; Atkinson et al., 2011) identifying and quantifying complications that can impede the efficacy of SCS implant; these complications can contribute to inadequate pain management (Taylor et al., 2010). The efforts to maintain or even improve efficacy of the SCS implant are aligned with the focus of QUERI and the quality of medical care that encompasses quality assurance and quality innovation (Atkinson et al., 2011; Feussner et al., 2000).

CHAPTER 4

DEVELOPMENT OF QI INITIATIVE OBJECTIVES

The objectives of this DNP based QI project are: (a) the creation of a database for all of the SCS implants currently managed by the Anesthesia Pain Clinic within medical center; (b) the development of a questionnaire to collect information to guide the management of SCS implants and to evaluate the effectiveness of the modality at 6 and 12 month intervals followed by a yearly follow ups; (c) the creation of a multidisciplinary team (Pain Clinic and Neurosurgery) with the integration of manufacturing representatives who will assist in providing timely and effective reprogramming of the SCS device with the goal of achieving the best possible pain coverage for patients; and (d) the maintenance of a physical space where the reprogramming of the device will occur along with arranging and managing appointments within the Pain Clinic.

The project will be developed and implemented at the VHA medical center located in western part of US, and will include all patients who have received the SCS implant for chronic pain management at this facility. The implementation of the project will be completed before December 31, 2012.

Objective 1.

The project will include the creation of a comprehensive database of all SCS implants placed and managed in this medical center. The database will provide continuity of care and initiate systematic collection and evaluation of data related to SCS treatment to maximize the outcomes of SCS implant therapy. The database will also provide information for healthcare providers who want to add the pacer/defibrillator therapies and MRI studies for this patient population.

The database records the number patients who received the SCS implantation and identifies how many of those SCS implants are currently in use. It will not include patients who had their SCS implants extracted. The database has a multiple purposes: it provides easy assess to the number and identity of patients with SCS implant managed by this medical center. The names of the patients and identification data also are placed under Neurostimulation tab, which is directly linked to the CPRS Anesthesia-Neuromodulation Note to provide detailed information about patient surgery and the current assessment of the SCS implant therapy.

Objective 2.

Patient follow-up is a critical component for successful and safe use of SCS implants (Atkinson et al., 2011). This project will develop a comprehensive follow-up questionnaire to evaluate pain coverage and detect possible complications in patients with SCS implant. The questionnaire is administered at 6 and 12 months after implantation, then at a yearly follow up. A number of complications can develop and become exacerbated over time (Cameron et al., 2004). Planned and timely follow up will help detect the onset of problems and can decrease or eliminate potential complications associated with the SCS implantation. The information is saved in CPRS under Anesthesia Neuromodulation Note and will be available to all health care providers. The Anesthesia Neuromodulation Note was developed as a template with the help of Information Technology Department after in approval by Title Committee.

The Anesthesia-Neuromodulation Note (see Appendix B) includes the following information:

Part I: Information obtained from CPRS

1. Disease process for which the SCS implant was intended. The information to complete this question was obtained from the CPRS Surgery Notes on the day of device placement.
2. Date of the device placement and type of the device including time of the last remodulation provided to improve pain coverage.

Part II: Information obtained in face-to-face conversation or by telephone:

1. What is your pain intensity using Visual Analog Scale?

The Visual Analog Scale (VAS) is the most commonly used measure of pain intensity in clinical and research settings. Research supports the validity of this instrument to measure pain intensity (Ferreira-Valente et al., 2011). The VAS is consistently used by the VHA system, and as a result, patients are familiar with its definition and application.

2. Is the quality of your life improved after the SCS implant placement?

The literature reviews provide strong evidence that placement of SCS implant improve quality of life despite the relatively frequent issues with malfunctioning of the device and some inconsistency in pain coverage (North et al., 2006).

3. Is there pain at the battery site?

The review of the literature stated numerous problems at the battery site that require timely intervention (North et al., 2006). Battery position, fluid accumulation, and infection produce pain at the site. The earlier detection can decrease complications associated with SCS implant placement (Atkinson et al., 2011).

4. How mobile is the battery?

Addressing this question helps to determine if there danger that poorly anchored battery will pull on the leads, which increases risk of shifting and repositioning SCS implant (Atkinson et al., 2011).

5. Are there any unusual changes around battery site?

Swelling and redness are symptoms of approaching infection, and timely interventions provide the opportunity to diminish or stop its progression (North et al., 2006; Atkinson et al., 2011).

6. Does the SCS implant sensation cover your pain?

The sensation produced by SCS implant covering the painful area is the primary goal of this treatment modality, and it directly influences quality of life.

7. How often do you utilize the SCS device?

This question provides information about the usefulness of the device and satisfaction with this treatment modality. The questions also helps guide planning for IPG replacement if the device is constantly utilized.

8. At what times did you find the SCS device not beneficial?

The goal of this question was to pinpoint body position or situation where patients avoid using SCS implant or where the implant produced a painful stimulation.

Additional Comments

This part is designed for input of patient's requests and recommendations for management of this modality.

The information collected by this questionnaire provides a wide range of data about the efficacy of this modality and is critical for further interventions to improve the efficacy and the longevity of spinal cord stimulator implants used for chronic pain management.

The questionnaire addresses patients concerns and requests about how the SCS implant will help guide clinical interventions to achieve better pain management as part of comprehensive care.

Objective 3.

The multidisciplinary team includes members of the Anesthesia Pain Clinic and the Neurosurgery Department who work closely with the representatives from the manufacturing companies. The team members work together in the decision making process about device indication, implementation, programming, maintenance, and reprogramming/replacement. Collaborative, multidisciplinary teamwork is widely advocated as the goal of contemporary hospitals, but it is hard to achieve due to role boundaries and power, increased workloads, and a fragmented labor force (Plsek & Greenhalgh, 2001). Despite the challenges, collaboration among healthcare workers is a way to improve care delivery in an increasingly complex healthcare system (IOM, 2001) and is the objective for this QI project.

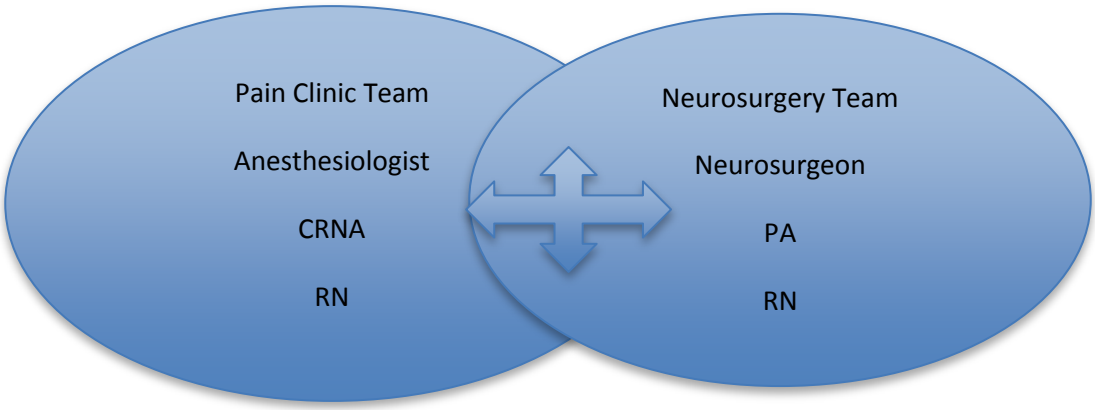


Figure 1. Schematic Approach for Creation of the Multidisciplinary Team and Representatives from the Manufacturing Companies

The creation of a multidisciplinary team will assure a comprehensive and effective follow up process with a focus on achieving the most effective pain coverage for patients with the SCS implant. The manufacturer's representatives are a critical part of the successful management of the SCS implant. They have the ability: to create programs that provide better pain coverage, evaluate and extend the longevity of IPG, and provide hands on education for patients about SCS implant reprogramming and management. The development of accurate and timely communication between all members of the multidisciplinary team is critical. Patient's Responses from the questionnaire will guide the interventions that will be undertaken by the multidisciplinary team and manufacturer's representative.

Objective 4.

The permanent designation of a physical space to arrange and manage appointments within the Anesthesia Pain Clinic will be executed using resources available within Anesthesia Pain Clinic and by developing supporting relationship with

Same Day Surgery (SDS) Department. SDS has an available Assessment Room every Monday and most afternoons. See Appendix D for the SDS Assessment room floor plan. The Associate Director of Quality and Safety Systems and the Manager of SDS support incorporating that space into this QI initiative. This additional area will be used for examination, evaluation, reprogramming of the device, and for patient education during the time when Anesthesia Pain Clinic space is not available. The Anesthesia Pain Clinic team is responsible for assuring that the team members are accessible to patients who need treatment. The Pain Clinic, with input from manufacturer's representatives, will maintain the space and arrange scheduling to assure easy access for the patients.

Risks/Threats to the Project

This QI initiative is solely developed for this VHA medical center incorporates specific characteristics of the patients with SCS implant who are treated at this center (large number of the patients with this particular treatment modality are managed by this medical center, and in some instances a very long traveling time to get the necessary intervention). The QI project is based on a research review, evidence-based data, and interviews with healthcare providers, patients, and manufacturing representatives. No similarly designed program was discovered in the literature review or in community practice. This made the QI program vulnerable to multiple threats during design and implementation phases and the long term establishment phase. The accurate and timely collection and input of the data about SCS implant modality is also concern, as contact with the patients can be inconsistent due to specific characteristics of the veterans population (high rate of homelessness, decreased financial resources, and high rate of posttraumatic stress disorder and depression). Another threat for implementing this QI

initiative is the amount of the time required for the creation and maintenance of the database and for implementing the system of regular follow-up interventions. The length of the project and the magnitude of its interventions will require collaboration and effort from all members of the multidisciplinary team over an extended time period, and it is critical to keep the program going despite possible disinterest over time, availability barriers, or employee turnover/sickness.

Marketing Plan

The following steps are in the marketing plan for this QI initiative:

1. Provide a presentation to the multidisciplinary team involved in this project. Provide information on the current research and evidence-based data about SCS implant use for chronic pain management and the importance of a creation of systemic follow up to maximize the efficacy of this modality.
2. Communicate progress of this QI project to a multidisciplinary team and Associate Director of Quality & Safety System and seek their feedback on the progress and problems of the project. Implement the necessary changes to improve program.
3. Seek input and create awareness about this QI program within this medical center and communicate its importance to representatives from manufacturing companies. Gather commitments from manufacturing company representatives to be available at the Anesthesia Pain Clinic site to provide reprogramming and additional teaching for maintenance of the SCS implant if needed.

Financial Plan

The budget for the creation and incorporation of this QI initiative was incorporated

into the budget of Anesthesia Pain Clinic. The community equivalent costs of creating and incorporating similar projects was analyzed to present the appropriate cost of this project. The cost of the project include employees' pay, cost for the lease of office space, utilities, technical support, and the cost of the maintenance of a physical space where appointments will be provided. The weekly cost and total cost for the project implementation/maintenance are estimated using data from other institutions residing in the same area. Labor costs were broken down by basic pay per hour and included employee benefits. The specific data about costs related to this medical center will not be released. The yearly total cost is approximately $53,404 for the maintenance of the program. See Table 1 for estimated cost, based on the local area.

Table 1

QI Initiative Estimated Cost Based on the Local Area

Services/Expenses	**Numbers Hours per Week**	**Cost per Week**
Labor costs, including benefits, for 1 physician: $110.00 per hour	2 hour per week	$220.00
Labor costs, including benefits, for 1 CRNA: $65.00 per hour	2 hours per week	$130.00
Labor costs, including benefits, for 1 RN: $32.00 per hour	1 hour per week	$32.00
Cost of software/programs to create and maintain the database: $50.00 per hour	2 hours per week	$100.00
Costs for the maintenance of the physical space including equipment: $300.00 per hour	1 hour per week	$400.00
Cost for the use of equipment: $60.00 per hour	2 hours per week, along with the cost of software/programs to create and maintain the database	$120.00
Cost of the phone services: $20.00 per week	1 hour per week	$20.00
Cost of office material: $5.00 per week	1 time per week	$ 5.00

Mentor/Site Arrangements

The project was developed as part of the Anesthesia Pain Clinic at VHA medical center. The project is designed to treat veterans afflicted with chronic pain. The Department Head of the Anesthesia Pain Clinic is the primary mentor for the project and will supervise/evaluate the steps of the project as it progresses.

Timeline and IRB Approval

The quality improvement (QI) project of creating systematic follow–up for patients with spinal cord stimulator (SCS) implants was initiated in November 2012 and completed in December 2012. The project included patients who had the SCS implant placed or managed by a specific medical center, which is located in the western part of the U.S. and is part of the VHA system. The Neurostimulators List or database gathered for this study included all patients with the SCS implant placed between June 30, 2007 and December 31, 2012 to reflect accurate information about the number of patients with SCS implants who been managed by this medical center. The follow-up questionnaire was administered to patients who had the SCS implant placed for chronic pain management before to October 2012, which allowed for at least one reprogramming to be completed after device insertion. The follow-up evaluation was completed using a questionnaire that was approved by the University of Nevada, Las Vegas, (UNLV) for a capstone proposal presentation. The questionnaire was reviewed and approved by the Anesthesia Pain Clinic and Neurosurgery Department of the medical center and was reviewed and approved as part of the Anesthesia-Neuromodulation Note by the Title Committee of this medical center. The Anesthesia-Neuromodulation Note is a permanent part of the CPRS within this medical center.

Exempt status for this QI project was attained by working directly with the Institutional Review Board (IRB) and with the Associate Director of Quality & Safety Systems within this medical center. The VHA *Operations Handbook 1058.05* stated that since this project is solely for the quality purposes, it should thus be initiated and implemented without IRB review. The UNLV IRB on November 16, 2012, deemed that this QI project was exempt from review. This QI project was structured as a process that occurred during and after scheduled working hours to provide the maximum probability of reaching/contacting all patients with SCS implants who are currently managed by this VHA medical center.

CHAPTER 5

SUMMARY OF IMPLEMENTATION AND RESULTS

SCS Implant Database Development

Multiple steps were undertaken to create a database of all SCS implants managed within this medical center. The initial information was retrieved from SCS logbooks, which provided only partial information about the number of the patients who had the SCS implant placed by this medical center. To obtain additional accurate data, the following sources of information were analyzed: (a) the Neurosurgery Department electronic surgical record, (b) the Anesthesia Pain Clinic electronic surgical record, and (c) the electronic referrals to Neurosurgery and Anesthesia Pain Department. The data from all of those sources was reviewed and compared to a prior list of patients to ensure that all patients with SCS implants were included in the database. Those steps initiated a new, on-going process: physicians from Anesthesia Pain Clinic will update the Neurostimulators List bi-weekly, adding the patient's name after an SCS implant been placed.

Presently, the Neurostimulators List includes 92 patients, of whom 80 were able to answer the follow-up questionnaire. Of the 12 patients who were not able to complete the questionnaire, one was unable to answer questions due to his mental status, 2 of the patients declined to participate, and 9 patients could not be reached despite multiple attempts to contact them. This Neurostimulators List includes all patients with SCS implants managed by this medical center, but it excludes patients who had SCS implants that were later removed for various reasons.

Development and Implementation of a Questionnaire for Follow-up about SCS Efficacy

The SCS efficacy questionnaire was developed for the purpose of a creating a systematic follow-up assessment about the effectiveness of SCS implants and to guide the management of this modality (Atkinson at al, 2011; Taylor, 2010). The SCS efficacy questionnaire is now part of the Anesthesia-Neuromodulation Note and is a permanent part of CPRS within the medical center in which this project took place. It is available to be used by all healthcare providers. The SCS follow-up questionnaire was developed based on the literature review, evidence-based practice, patient's requests for the creation of this follow-up program, and on-site clinical practice assessment. In aggregate these evaluations highlighted the existing problems and potential improvements related to SCS implant placement and management. This information directed the design of the questionnaire to identify the areas of interventions need for successful management of this therapeutic modality.

The SCS efficacy questionnaire was developed based on the literature review, evidence-based practice, patient's requests for the creation of this follow-up program, and on-site clinical practice assessment. In aggregate these evaluations highlighted the existing problems and potential improvements related to SCS implant placement and management. This information directed the design of the questionnaire to identify the areas of interventions needed for successful management of this therapeutic modality.

The SCS efficacy questionnaire was presented and approved as part of the capstone proposal at UNLV in July 2012, following which it has been reviewed and accepted by the Neurosurgery and Anesthesia Pain Clinic Departments. The

questionnaire was also presented and approved by the VHA Title Committee and was placed by information technology department (IT) as an electronic template under title Anesthesia-Neuromodulation Note into CPRS records. The title for the note and the questionnaire template were consistently used for the follow-up telephone calls and face-to-face assessments with SCS implanted patients. The Anesthesia-Neuromodulation Note is now a permanent part of the CPRS within the medical center and is available for the 6 and 12-month follow-up assessments.

Creation of a Multidisciplinary Team for Management of Patients with SCS Implants

The Anesthesia Pain Clinic staff (MD, CRNA, and RN), Neurosurgery staff (Neurosurgeon and PA, and RN), and manufacturing representatives (from St. Jude, Boston Scientific, and Medtronic) worked together to create a multidisciplinary approach for the managing patients with the SCS implant. This team effectively worked together to communicate data, receive feedback, and discuss SCS implants management to deliver timely and appropriate patient interventions.

The CRNA initiate the follow-up process to evaluate the effectiveness of the SCS implant and the patient's needs in managing the device in order to determine necessary interventions to improve patient outcomes. The follow-up information was recorded in CPRS and the patient's name was added to the Neurostimulators List. This information was electronically forwarded along with the patient's requests/comments to the Anesthesia Pain Clinic physician, so that the team could reference the information for current and future interventions.

The follow-up interventions are incorporated into a treatment plan following predetermined approaches that required close, timely communication among members of multidisciplinary team. The follow-up interventions fall into five categories:

1. The patient is satisfied with this treatment modality, and the SCS implant is functioning well and no interventions were needed. A total 33 patients, or 41.25% of all patients assessed, have satisfactory pain coverage and no problems with management of the SCS implant. No interventions were requested or required.

2. The follow-up questionnaire revealed that paresthesia sensation from the SCS implant was not covering the painful area and the reprogramming of SCS implant was needed. This information would be forwarded to Anesthesia Pain Clinic physician, who would initiate contact with one of the three manufacturing representatives (St. Jude, Boston Scientific, or Medtronic) to inform the representative about the patient's reprogramming needs and facilitate a meeting at the medical center for an evaluation of the SCS implant programming, placement, and function. The reprogramming evaluation would take place at the Anesthesia Pain Clinic or in the Same Day Surgery Assessment Room to accommodate the flow of the patients and the effective and efficient use of time and space. The number of patients who requested or were offered on site evaluation/reprogramming was 27 patients, or 33.75%, and all of them have since their SCS implant reprogrammed.

3. The follow-up requires surgical intervention, including: (a) battery replacement/repositioning (completed by Anesthesia Pain Clinic or Neurosurgery); or (b) SCS implant system removal/replacement (completed by Anesthesia Pain Clinic or

Neurosurgery). Those cases were evaluated on an individual basis, considering each patient's physical status, preferences, and requirements for general anesthesia. Either the Anesthesia Pain Clinic or Neurosurgery scheduled patients for surgery. The total number of patients who required and agreed to surgical interventions was 7, or 8.7% of all patients who had received the follow-up evaluation. All of them received or were scheduled for the necessary surgery.

4. Information about follow-up interventions and care options available to address problems with SCS implants is communicated to the patient, but some patients chose not to proceed with any actions. Information about contact persons is offered to all patients along with an invitation to the patient to contact the Anesthesia Pain Clinic whenever they are ready to discuss issues at hand. The Anesthesia Pain Clinic physician is informed about all SCS implant management issues and patient's desires not to proceed with any interventions. The total number of the patients who are aware of but choose not to address malfunctioning/non-functional SCS implant is 6, or 7.5% of the total patients evaluated.

5. In some cases, the SCS implant has been reprogrammed a number of times and the patient feels that it is at its maximum performance, but they requested additional procedure for chronic pain management, such as trigger points injections, epidural steroid injections (ESI), selective nerve root blocks (SNRB), or radio frequency ablations (RFA) to augment the effect of SCS implant therapy. At this point Anesthesia Pain Clinic physician would initiate an order for the procedure, schedule the procedure, and follow the appropriate steps designed to assure the patient's access to the Anesthesia Pain Clinic

and the desired procedure. The total number of the patients who requested additional procedures was 7, or 8.75%.

Results Analysis

Participants and sample. Eighty patients with SCS implants answered the questionnaire. Of these, 65 (81.3%) had had the SCS implant for 3 years or less while the remaining 15 (18.8%) had the implant for more than 3 years. Due to the nature of the instrument and the context of the data collection process, no demographic information was collected from the sample except information related to gender. Sample included 4 female or 5 % of total sample size of patients who participated by answering items in the questionnaire.

Materials and Instruments

A researcher-developed a questionnaire was used to collect relevant data from the sample regarding various aspects of their SCS implant. The nine-item instrument included a combination of variables that were categorical/qualitative and continuous/quantitative. Items included information about patients' previous remodulation date, their perceived pain using the VAS, perceived quality of life, and outcomes of their SCS implant treatment. With respect to perceptions of pain using the VAS, participants' reported pain ranged from 0-10 ($M = 5.45$, $SD = 2.42$). Appendix C includes a full list of items on the instrument. Due to the nature of the items on the instrument, no composite—that is, overall score—was computed, as would be done on measures with true continuous interval or ratio scales, pseudo-continuous, or ordinal Likert scale items. Therefore, each item was analyzed separately. Also, because the items on the instrument were not unidimensional, no internal consistency reliability or

validation procedures were conducted on the data. The descriptive information of the items on the instrument provided in Appendix C. The descriptive information (frequency and proportions) of the items provided in Appendix D.

Data Preparation

All data were screened for univariate outliers using box plots (i.e., box-and-whisker graphs) for the pseudo-continuous VAS item according to the procedures outlined by Tabachnick and Fidell (2007). No outliers were detected. Furthermore, data for the VAS item were tested for univariate assumptions, including normality (skewness and kurtosis) and homogeneity of error variance with respect to the outcome in order to proceed with data analysis. The data approximated a normal distribution at the univariate level, with kurtosis and skewness values for perceived pain ranging from -.09 to -.23, both > (Tabachnick & Fidell, 2007), which is ideal. Therefore, data transformation procedures were not performed. All other assumptions were also met, and thus, data analysis proceeded without any statistical adjustments to the data.

Data analysis

A series of one-way analyses of variance (ANOVAs) was conducted to ascertain whether there were differences among key independent variables (i.e., remodulation time, quality of life, and utilization of SCS device), with perceived pain scores serving as the dependent variable in each analysis. Because the interpretation of effect sizes, or the strength/magnitude of the association between independent and dependent variables, varies, it is important to establish some guidelines. Cohen (1992) suggested that for η^2 the following guidelines be used for interpreting the practical significance of results: .01 to .05 (modest); .06 to .13 (moderate); and ≥ .14 (strong). The Bonferroni adjustment was

made to obviate Type I error rate inflation, which occurs when conducting multiple analyses (.05/3 = .02). This adjustment is necessary to prevent capitalizing on chance variance—that is, detecting differences when none exist.

Results

In the first analysis, remodulation time (< 6 months, 6-12 months, > 12 months) served as the independent variable. Results of the one-way ANOVA indicated that the difference in patients' perceptions pain was statistically significantly different as a function of remodulation time, $F_{(2,78)} = 2.09$, $p = .02$, $\eta^2 = .04$, suggesting a modest strength of association between remodulation time and patients' perceived pain. Post hoc comparisons using the Bonferroni adjustment for familywise Type I error rate inflation showed that patients who reported a remodulation time of less than 6 months ($M = 4.97$, $SD = 2.35$) reported significantly less pain than patients who reported a remodulation time between 6-12 months ($M = 5.65$, $SD = 2.16$) and more than 12 months ($M = 5.86$, $SD = 2.66$). The pairwise comparison between patients who reported remodulation time between 6-12 months and more than 12 months was not significant, $p > .05$. Thus, the greater the time since remodulation, the more pain patients reported.

Results of the one-way ANOVA with perceived improvements to quality of life due to the SCS device as an independent variable (none, somewhat, significantly) demonstrated that there were statistically significant differences between patients' perceptions of pain, $F_{(2,77)} = 10.05$, $p < .0005$, $\eta^2 = .21$. The post hoc follow up analyses demonstrated that there were significant ($p < .01$) differences between patients who reported significant improvements to their quality of life due to the SCS device ($M = 4.63$, $SD = 2.11$) and those who reported no improvement to their quality of life ($M =$

7.44, *SD* = 2.19), with those who reported significant improvement reporting less perceived pain. The difference in perceived pain between those who reported some improvement (*M* = 5.78, *SD* = 2.37) and no improvement as well as those who reported significant improvement were not significant, all *p*-values > .08.

The one-way ANOVA with utilization of the SCS device (not at all, daytime only, nighttime only, day and night) serving as the independent variable showed that differences in utilization significantly influenced perceived pain, $F_{(3,76)} = 3.39$, $p < .01$, $\eta^2 = .07$. Post hoc analyses indicated that patients who did not utilize the SCS device reported significantly higher perceptions of pain (*M* = 6.47, *SD* = 1.85) than patients who utilized the device during the day (*M* = 4.27, *SD* = 1.79) and during the day and night (*M* = 5.33, *SD* = 2.63). Moreover, those who utilized the SCS device during the day reported significantly less pain than those who used the device at night (*M* = 5.50, *SD* = 3.00). Although none of the other pairwise comparisons reached statistical significance (all *p*-values were > .05), it is interesting to note that those who utilized the SCS device during the day only reported significantly less pain than those who utilized the device during the day and night.

Table 2 contains the correlation coefficients between several key variables. Because the variables under consideration were continuous and categorical, nonparametric correlation coefficients (*Kendall's* τ *b*) were requested and interpreted in lieu of parametric coefficients (*Pearson's r*). Nonparametric correlations, nevertheless, have the same interpretation as their parametric counterpart, *Pearson's r*. All correlations were within normal bounds, ranging from -.07 to .65. Interestingly, the correlations between remodulation time and all other variables were not statistically significant,

suggesting that there is no association between remodulation time and any other variable.

Interpretation of statistically significant correlations follows. The modest inverse correlation between perceived pain and quality of life suggests that as improvements to quality of life due to the SCS device increase, perceived pain decreases. Likewise, the modest inverse correlation between SCS device pain coverage and perceived pain indicates that as reported pain coverage increases, perceived pain decreases. The modest inverse relation between outcomes and quality of life indicates that patients who required no reprogramming (coded as "0") of their SCS device reported significantly greater improvements to their quality of life ("significant improvement" coded as "2") due to the SCS device. The moderate, inverse correlation between outcomes and SCS device pain coverage suggests that patients who required no reprogramming of their SCS device tended to report greater pain coverage of their SCS device (coded as "2"). Finally, the strong, positive correlation between quality of life and SCS device pain coverage suggests that patients who reported greater pain coverage tended to report greater improvements to their quality of life as a function of the SCS device.

Table 2

Kendall's τ b Correlation Coefficients Between Key Variables

Variable	1	2	3	4	5
1. Remodulation Time	-	.14 ^{ns}	.15 ^{ns}	-.14 ^{ns}	-.07 ^{ns}
2. Perceived Pain (VAS)		-	.13 ^{ns}	-.36*	-.35*
3. Outcomes			-	-.39*	-.52*
4. Quality of Life				-	.65*
5. SCS Device Pain Coverage					-

* $p < .01$ (one-tailed) ^{ns} = not significant
$N = 80$

An ANOVA was also conducted to ascertain whether time with the SCS device had an effect of patients' perceived pain. Time with SCS device (less than 3 years, 3 years or more) served as the independent variable and VAS pain score served as the dependent variable. Results showed that time did not significantly influence perceived pain, $F_{(1,78)} = 2.13$, p = .15, $\eta^2 = .03$. Although not statistically significant, those with 3 or more years with the SCS device reported higher pain ($M = 6.27$, $SD = 2.52$) than those with less than 3 years ($M = 5.26$, $SD = 2.38$), suggesting that greater time with the device yields greater reported pain by patients.

Designation of a Space for Follow-up for Patients with SCS Implant

The objective of designating a physical space to arrange and manage appointments was achieved by a series of steps. Anesthesia Pain Clinic space (available all the time) and

SDS Assessment Room (available every Monday) were approved for remodulation of SCS implant and for additional consultations with multidisciplinary team. The manufacturing representatives coordinate patients' time preferences and availability of that space. The Anesthesia Pain Clinic MD receives a follow-up note indicating the need for the reprogramming/reevaluation of an SCS implant and forwards the information to manufacturing representative the same day with time availability of all multidisciplinary team members required for the patient's specific condition. The Anesthesia Pain Clinic physician contacts the appropriate manufacturing representative to discuss the specifics of that patient's condition, device placement, and expectations of the therapy. The time and place for reprogramming/evaluation are initiated by the manufacturing representatives in Same Day Surgery (SDS) or in the Anesthesia Pain Clinic Site, depending on site availability and the preferences of the involved parties. If any additional assessment is needed, the Anesthesia Pain Clinic physician is available onsite, so assessment and discussion about surgical intervention and referral and scheduling to Neurosurgery are made at that time. If necessary all members of the multidisciplinary team can be involved in discussions about further interventions and management of the SCS implant during patient visit. The availability of X-ray at the Anesthesia Pain Clinic provide an opportunity to quickly ascertain the position of SCS implant, and if additional information was needed, a CT scan can be ordered on the site.

Implementation of the QI Project Using Kotter's Framework, Incorporating VHA QUIRE

This QI project was successfully implemented using Kotter's Eight Step Model of Change (1995, 1996) for implementing organizational changes. The project also

incorporated VHA QUIRE, which focuses on translating research discovery into patient care and healthcare system improvements (Feussner et al., 2000). The first step in this model is to examine the criteria that create the increased urgency by evaluating potential situation or evaluating potential opportunities or needs.

Research revealed the urgency behind this issue by reporting complications and longevity limitations of the SCS implant treatment modality. Present clinical practice, record evaluation, and responses from providers and patients echo these issues. The need for creation of this QI initiative was communicated to the Anesthesia Pain Clinic, Neurosurgery Department, and Associate Director of Quality and Safety System to create awareness of the need to create systematic follow-up for patients with SCS implants, in order to improve quality of patient care and be in compliance with the VHA initiative for systematic multidisciplinary follow-up for patient with chronic pain (VHA Directive 2009-053, 2009).

Step two in Kotter's model – build guiding teams – is necessary for the successful implementation of this project. This is the creation of powerful guiding teams/coalitions from different levels of the organization (clinical and administrative), including members of the multidisciplinary teams. Explicating the objectives of this project was critical because the multidisciplinary members provide care at different stages of treatment; therefore, it is important for all members to be informed about steps in the treatment and the patient's progress. The presentation about current research data related to SCS implant complications and the potential benefits of implementing this QI initiative (ethical, health maintenance/improvement, financial) (North et al., 2004; Atkinson et al., 2011) was presented to the Anesthesia Pain Clinic, Neurosurgery Department, and the

Associate Director of Quality and Safety Systems

The vision from the project came from developing a detailed plan for this QI initiative (step 3) and effectively communicating it (step 4) to all parties involved. Creating support for this (QI) initiative and offering of additional resources (SDS Assessment Room to be used as part of the clinical space) were vital steps that took place to consolidate organizational effort to create this QI program. Encouraging problem solving behaviors and support for new initiatives is necessary to help decrease/illuminate barriers to change (Maxwell, 2009). During this phase of the project (step 5, enable the action or empower other to act on the vision), the acceptance and support for this QI initiative prompted CRNAs to contact manufacturing representatives and re-negotiate the terms for the reprogramming of the SCS implant based on Anesthesia Pain Clinic requests and renegotiate more timely terms (within one week of request).

The creation of visible short-term wins (step 6), such as approval of the program, multi-organizational level support for the program, and positive patients and team members' feedback created an environment of acceleration and pride for the needed patient care. This helped create critical stepping stones by securing small wins and preparing health care providers to embrace embracing larger changes (Maxwell, 2009).

The project was divided into subprojects, and at certain points different members of multidisciplinary team took more responsibility for specific part of the project (for example, the Pain Clinic physician insisted that all outcomes of reprogramming of SCS implant be reported directly to him by manufacturing representatives). The close contact with manufacturing representatives not only positively influence the time frame for reprogramming the SCS implant, but also encouraged the manufacturing representative

from St. Jude to offer a one hour education session to SCS implants candidates (step 7, reinvigorate the process with new project). The reinforcement of newly created changes is critical (step 8); providing evidence and highlighting how these new behaviors and standards of clinical practice contribute to organizational success created support from all members of multidisciplinary and the organization as whole.

This QI project was successfully guided and implemented by three distinct phases of implementing changes: creating a climate for change, engaging and enabling an organization, and implementing and sustaining change (Campbell, 2007). These steps are the essential structure of Kotter's Eight Step Model of Change and are synchronized with steps of the QUERI which guided implementation of this QI project and contributed to improvement in quality of life for patient with SCS implant.

Conclusion and Recommendations

The increasing use of SCS implants for chronic pain management; and the data analysis of this DNP QI initiative when viewed through the biopsychosocial lens, provides the opportunity to incorporate and evaluate additional elements of care. The unique characteristics of the VHA system, e.g., the use of CPRS and the volume of prescriptions written and filled within VHA system, offer opportunities to evaluate the use of medication for chronic pain management and its cost, prior to and during the use of the SCS implant treatment modality.

The use of SCS implants was demonstrated to be effective in some pain syndromes that were resistant to other treatments. It is well tolerated by patients, is minimally invasive and can be reversed. When compared to chronic pharmacotherapies,

SCS implants had fewer adverse effects. Traditionally, pharmacotherapy had a central role in chronic pain management (Wolf, 2004). The use of SCS implant provides the opportunity for patients and the treatment team to decrease the use of and potential for medication interactions or adverse effects (North, Shipley, & Taylor, 2009).

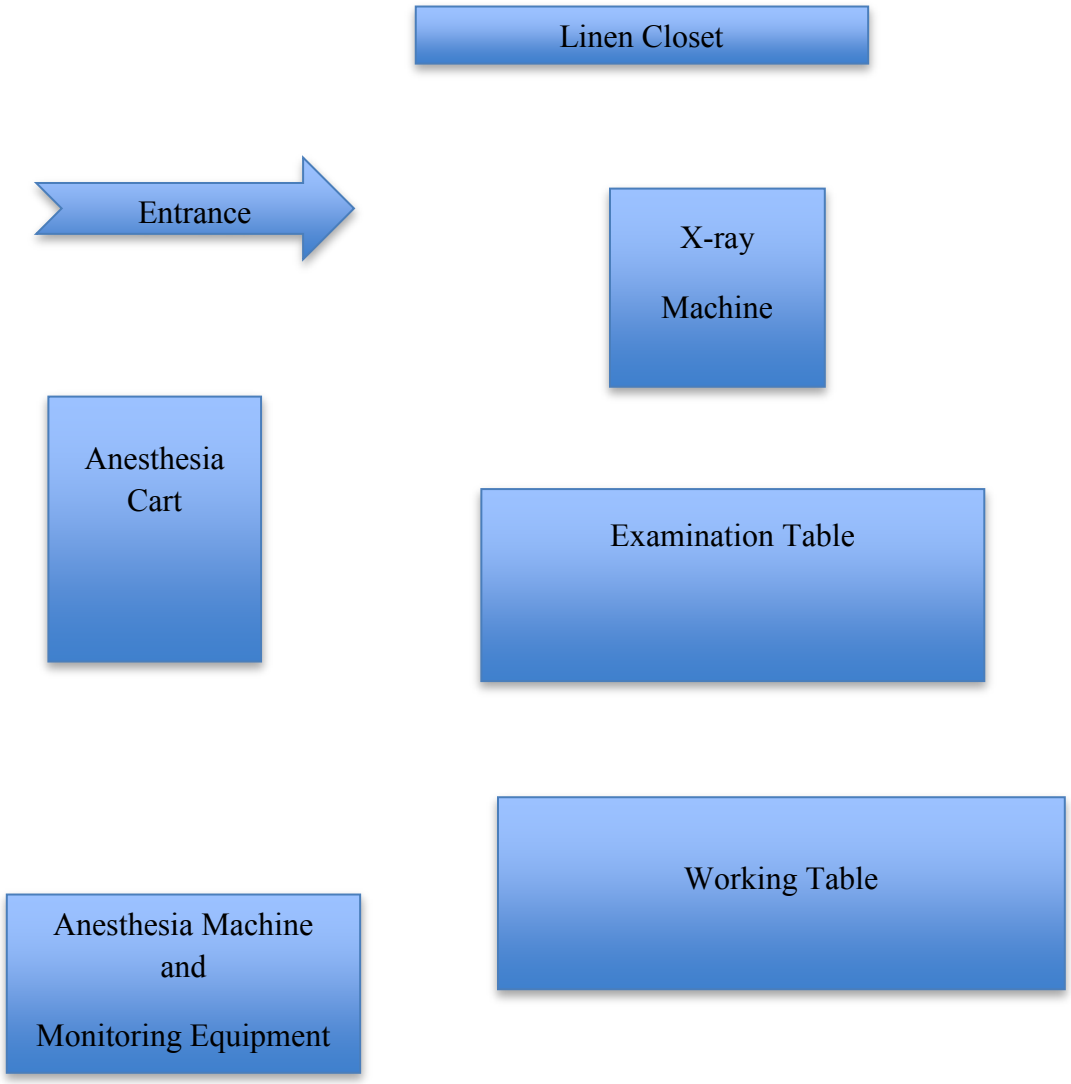
Further development of this QI initiative allows for the opportunity to evaluate and make changes in healthcare consumption, e.g., ESI, cross-over for alternative treatments; and the use of pharmaceuticals as measured by reviewing medical records and incorporating the use of instruments, such as, the Medication Quantification Scale (North & Shipley, 2007). The complete elimination or significant reduction in pain would be the ideal outcome for patients with SCS implants. Incorporation of The Oswestry Disability Index (ODI) which is disease specific for low back pain; and the Pain Disability Index (PDI) within the DNP project questionnaire can provide additional information about patient abilities to engage in activities of daily living and various life activities.

The ODI is the most commonly used, self-administered outcome-measure questionnaire for low back pain that assesses various activities of daily living (Mehra, Baker, Disney, & Pynsent, 2008). The ODI questionnaire takes 3.5-5 minutes to complete. It helps to measure outcomes of treatment and maintains standards of medical care. Integration of the ODI as part of the systematic follow-up of SCS implant patients would provide the additional patient-oriented assessment methods important in the evaluation of treatment outcomes (Mannion, Junge, Fairbank, Dvorak, & Grob, 2004).

The Pain Disability Index (PDI) was designed to measure the extent to which chronic pain interferes with a person's ability to engage in various life activities. It

focuses on seven categories (Family/Home Responsibilities, Recreation, Social Activity, Occupation, Sexual Behavior, Self-Care and Life Support Activity). Patients are asked to rate their level of disability on graphic scales ranging from 0 (no disability) to 10 (total disability). The disability score is a summary of numerical ratings from all of these categories, ranging from 0 to 70 (Pollard, 1984). The PDI was used in multiple studies that evaluated the effectiveness of SCS implant for pain management (Bennett &Brookoff, 2006). It too can be a useful outcome measurement tool if added to the follow-up questionnaire used in this project. Finally, the development of patient-orientated assessment methods is of paramount importance in the evaluation of treatment outcomes and for detecting potential problems (Mannion et al., 2006); these are critical components in the development and implementation of this QI initiative.

APPENDIX A: ANESTHESIA PAIN CLINIC PLAN



APPENDIX B: THE ANESTHESIA-NEUROMODULATION NOTE INCORPORATING THE QUESTIONNAIRE

The Questions that will be administered to the patients, face to face, or by the phone.

A. The disease process to which the device implementation has been indicated (data obtained from CPRS in the postsurgical note).

B. The date of the device implementation, and the type of device, along with its placement, and the last remodulation date (data obtained from CPRS in the postsurgical note and patient).

1. What is your pain intensity using Visual Analog Scale?

   0 to 10 (0- no pain, 5- moderate pain, 10- worst possible pain)

2. Is the quality of your life improved after the SCS implant placement?

   a. No b. Somewhat c. Significantly

3. Is there pain at the implanted battery site?

   a. No b. Somewhat c. Yes

4. How mobile is the battery?

   a. Not at all b. Somewhat c. Very mobile

5. Are there any unusual changes around the battery site?

   a. Yes b. No

6. Does the SCS implant sensation cover your pain?

   a. Not at all b. Somewhat c. Significantly

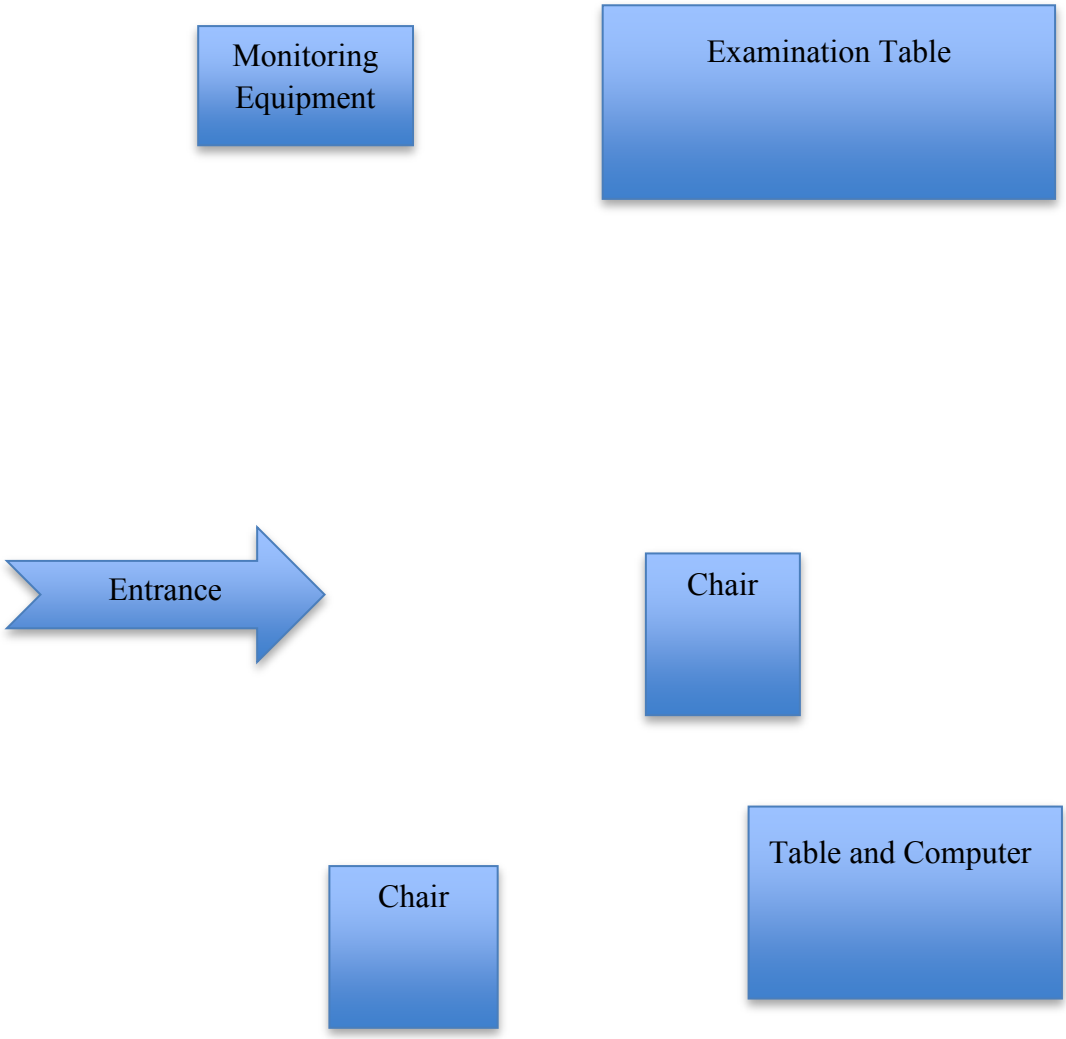
7. How often are you utilizing the SCS device?

a. Not at all b. Daytime only c. Nighttime only d. Day and night

8. At what times did you find the SCS device not beneficial?

Additional Comments: Include information that describes specific details and the patient's concerns with the SCS implant and incorporates the follow-up interventions.

APPENDIX C: ASSESSMENT ROOM PLAN IN SDS DEPARTMENT



APPENDIX D: DESCRIPTIVE INFORMATION OF THE ITEMS ON THE INSTRUMENT

Variable	*N*† (%)
Remodulation Time	
< 6 months	32 (40.0)
6 to 12 months	20 (25.0)
> 12 months	28 (35.0)
Quality of Life Improvement	
None	16 (20.0)
Somewhat	18 (22.5)
Significantly	46 (57.5)
Pain at Implanted Battery Site	
None	61 (76.3)
Somewhat	13 (16.3)
Significant	6 (7.5)
Mobility of the Battery	
None	67 (83.8)
Somewhat	11 (13.8)
Very mobile	2 (2.5)
Unusual Changes Around Battery Site	
No	79 (98.8)
Yes	1 (1.2)
Pain Coverage of SCS Implant	
None	21 (26.3)
Somewhat	24 (30.0)
Significant	35 (43.8)

Frequency of Utilization of SCS Device	
Not at all	15 (18.8)
Daytime only	11 (13.8)
Nighttime only	4 (5.0)
Day and night	50 (62.5)
Perceived Lack of Benefit of SCS Device*	
Extending/flexing	7 (8.8)
Lying down	2 (2.5)
Works all the time	7 (8.8)
Interventions Provided to Patients	
None	33 (41.3)
Device needed/reprogrammed	27 (33.8)
Surgical interventions addressed	7 (8.8)
Interventions addressed, patient not prepared	6 (7.5)
Pain Clinic provided procedures to augment SCS implant function	7 (8.8)

* The majority of patients (80%) did not answer this item.
N = 80

UNLV
UNIVERSITY OF NEVADA LAS VEGAS

Biomedical IRB – Exempt Review Deemed Exempt

DATE: November 16, 2012

TO: Dr. Michele Clark, Nursing

FROM: Office of Research Integrity – Human Subjects

RE: Notification of IRB Action Protocol Title: Systematic Follow-Up of Patients Who Have Spinal Cord Stimulator Implants Protocol # 1211-4305

This memorandum is notification that the project referenced above has been reviewed as indicated in Federal regulatory statutes 45CFR46 and deemed exempt under 45 CFR 46.101(b) 2.

Any changes to the application may cause this project to require a different level of IRB review. Should any changes need to be made, please submit a **Modification Form**. When the above-referenced project has been completed, please submit a **Continuing Review/Progress Completion report** to notify ORI – HS of its closure.

If you have questions or require any assistance, please contact the Office of Research Integrity - Human Subjects at IRB@unlv.edu or call 895-2794.

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Curriculum Vita

Irina Rajala RN, MSN, CRNA

SUMMARY OF QUALIFICATIONS

Advanced Practice Nurse with over 13 years of nursing experience

Anesthesia planning and anesthesia delivery services

EDUCATION

2011 - 2013 Current student in Doctorate of Nursing Practice Program at University of Nevada, Las Vegas/Reno (combined program)

2002 - 2004 Florida International University, Miami, FL – *Masters of Science in Nursing,* Nurse Anesthetist Program

1996 -2000 Valdosta State University, Valdosta, GA – *Bachelor of Science in Nursing*

1984 -1986 Khmelnitsky Teaching College, Khmelnitsky, Ukraine – Associate Degree in Preschool Education

PROFESSIONAL EXPERIENCE

2013 - present CRNA for the VA Southern Nevada Healthcare System, North Las Vegas, NV, 89081

2007- 2013 CRNA for the VHA Salt Lake City medical center, Salt Lake City, UT, 84108

2005-2007 CRNA for the Sheridan Health Corp., Inc, Sunrise, FL, 33323

2000 -2003 ICU Staff nurse for the Archbold Medical Center, Thomasville, GA,

AFFILIATION AND AWARDS

Active Certified Member of American Association of Nurse Anesthetist

Award of Merit, Thomas University, Thomasville, GA

“Special Team” commendation from patients

INTERNATIONAL EXPERIENCE

Diversified background with experience in multi-lingual, multi-cultural environments

Tri-lingual: English, Ukrainian, Russian