

POLICY STATEMENT

NANS Training Requirements for Spinal Cord Stimulation Devices: Selection, Implantation, and Follow-up

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Introduction

Spinal cord stimulation (SCS) has been used since the late 1960s as a treatment for chronic neuropathic pain. Approximately 4000 SCS systems are implanted each year in the United States. Over the past 15 years, more than 60,000 U.S. patients have undergone SCS surgery, many with very successful results. It has become clear, however, that SCS outcomes are heavily influenced by physician expertise in patient selection, implant technique, and follow-up care. Despite the large number of implants performed, no standards have been developed for training or expertise in SCS. Many different medical and surgical specialties participate in patient selection, implantation, and follow-up, including neurosurgeons, anesthesiologists, physiatrists, neurologists, orthopedic surgeons, and others. Core knowledge and training in SCS can differ widely among specialties, including varying degrees of familiarity with the implantation of SCS devices and management of SCS patients.

Objectives of Policy Statement

Given the marked differences in training for each discipline involved in SCS, the North American Neuromodula-

tion Society (NANS) believes that uniform guidelines for training and competency are critically important to standardize core knowledge across these multiple disparate specialties. In response to this need for standardization, a committee was formed to develop training requirements for SCS patient selection, implantation, and follow-up care. The committee decided to base this policy statement on the successful implementation of training requirements for interventional procedures in other specialties (1,2). The NANS believes that this policy statement will help establish guidelines for training physicians in SCS that are applicable regardless of medical or surgical discipline, and that it might also be of help to medical licensure boards and hospital accreditation committees.

Background

Spinal cord stimulation for the treatment of chronic pain was first introduced in 1967. The earliest devices consisted of individual electrodes which were implanted in the subdural space over the dorsal surface of the spinal cord. Since a laminectomy and dural opening were required, these procedures were performed exclusively by neurosurgeons.

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In the late 1970s, a technique was developed whereby electrodes could be percutaneously implanted into the epidural space, thus simplifying the performance of SCS procedures. The ability to place electrodes percutaneously led to two important advances: 1) the expansion of SCS to physicians other than neurosurgeons, providing an effective tool to other medical specialists interested in the treatment of pain; and 2) the concept of temporary trial lead placement for screening of SCS efficacy prior to placement of a permanent system.

Implantation and management of SCS systems is a multidisciplinary undertaking. As such, it creates some unique problems in obtaining appropriate training. Neurosurgeons and orthopedic surgeons are unlikely to have been trained in epidural access techniques, or in the programming and management of SCS systems, which can be complex. Anesthesiologists, neurologists, and other medical specialists are unlikely to have been trained in surgical techniques. Post-residency fellowship programs in a multidisciplinary academic setting are often the only means for obtaining this kind of advanced training.

The NANS believes that any physician implanting SCS systems should also be familiar with the appropriate selection criteria for patients requiring such devices and should be capable of postoperative care and follow-up. Conversely, some physicians interested in pre-implantation care, patient selection, and postoperative care and follow-up might not be interested or trained in the actual implantation techniques. Different training tracks should be available to allow physicians to obtain the appropriate knowledge for those services he or she plans to provide.

Definition of an SCS Service

An "SCS service" refers to a physician or group of physicians with allied health professionals who collectively have the requisite knowledge of the indications, techniques, and management of SCS systems. A SCS service might have multiple physicians with different interests and expertise, but the service should offer all facets of SCS patient care. For example, one member of a team might have expertise in prescription of the therapy, another with device implantation, and a third might be available to assist with complications or complicated cases involving more than usually invasive approaches. The division of labor in an SCS service will mirror physician training and expertise; for example, some physicians involved in pre-implantation care and patient selection and postoperative care and follow-up might not perform implantations.

A SCS service should, thus, include the following:

1. A physician or group of physicians with the appropriate knowledge and training for implantation and management of the devices.
2. A physician or group of physicians who are available to manage the immediate complications related to the implantation or management of the devices.
3. Pertinent equipment, including SCS programmers from at least one, and preferably several vendor(s).
4. Appropriate paramedical personnel who are familiar with SCS systems and their management. This might include representatives of the medical device companies who frequently assist with intraoperative and postoperative programming.
5. A caseload of at least 30 implants or trials per year.
6. Periodic conferences which include SCS and neuro-modulation topics.
7. Periodic peer review of complications related to SCS implantation.
8. Access to a sterile environment for placement of the temporary and permanent devices.

NANS Policy Recommendations

Recommendation 1: SCS training programs should offer three tracks (see below) so that physicians can acquire the necessary competence to offer the SCS services appropriate to their specialties and interests.

Recommendation 2: All physicians implanting SCS systems should be familiar with appropriate selection criteria for patients who will benefit from SCS therapy and should be capable of providing postoperative and follow-up care.

Recommendation 3: The Residency Review Committee should consider requiring non-interventional pain fellowship programs to provide the core training listed in Track I below, which does not imply competence in the selection, implantation, or adequate follow-up of SCS patients.

Recommendation 4: The Residency Review Committee should consider requiring interventional pain fellowship programs to provide training in the implantation and management of SCS systems and patients as outlined in Tracks II and III below.

Recommendation 5: All SCS training should take place under the guidance of an experienced mentor (a physician who participates in an established SCS service), who will attest to the trainee's competence.

Training Programs

Although training might most easily be attained under the auspices of an interventional pain fellowship, it can also be attained by working with a recognized mentor associate with an established SCS service. A cadaver course with full implantation of an SCS system can substitute for one of the ten required procedures in Tracks II and III.

Recommended Training Tracks

Track I

Track I—Responsibility:

TABLE 1. Knowledge Required to Perform SCS Follow-up Patient Care

1. Recognize symptoms (including increased pain) that suggest a need for reprogramming or indicate a possible complication
2. Recognize the normal appearance of the generator pocket and incision and signs of system complications
3. Recognize when radiographic assessment will help diagnose a complication and the alternatives to magnetic resonance imaging for imaging the spine and neural elements
4. Understand programmed data, measured data, and other diagnostic data, including implanted pulse generator usage, program preference, battery life, recharge intervals, and impedance
5. Understand uses of available programming modes and multiple patient programs
6. Diagnose and treat complications, including pulse generator failure, lead/electrode failure, loss of pain relief, extraneous stimulation, postural effects, and development of a new area of pain

SCS, spinal cord stimulation.

1. Patient selection
2. Routine follow-up patient care, including recognition of complications (see Table 1)

Track I—Training requirements:

1. Successful completion of one of the following:
 - neurosurgery residency
 - pain medicine fellowship (American Board of Anesthesia)
 - orthopedic spine surgery fellowship
 - American Board of Anesthesiology certification, with special certification in pain medicine
 - American Board of Pain Medicine certification
 - American Board of Interventional Pain Physicians certification
2. Participation as primary operator and evaluator in at least 25 follow-up visits with patients implanted with SCS systems. The trainee must demonstrate knowledge of routine follow-up and the hands-on troubleshooting of implantable devices, involving interrogation and programming of devices, including rechargeable systems.
3. Active participation in the diagnosis, prescription, and management of at least 12 patients who require SCS implantation is desirable.

Track I—Knowledge requirements:

1. Mechanisms of action
2. Indications and contraindications
3. Patient selection and screening procedure
4. Interaction of SCS systems with cardiac pacemakers and defibrillators
5. Interaction of SCS hardware with and contraindications to magnetic resonance imaging
6. Patient precautions, including interaction with magnetic fields

7. Recognition of and knowledge about management of pulse generator end-of-life
8. Recognition of complications

Track II

Track II—Responsibility:

1. Patient selection
2. Placement of percutaneous screening trial electrodes
3. Follow-up patient care, including treatment of or referral for complications

Track II—Training requirements:

1. Completion of all Track I requirements.
2. Didactic training in spinal anatomy, spinal cord anatomy and physiology, principles of neural stimulation, selection of patients and devices, surgical techniques, management of complications, device programming, and follow-up management.
3. Supervised instruction in techniques required for accessing the epidural space under fluoroscopic guidance with participation in at least 25 lumbar and ten cervicothoracic interlaminar percutaneous procedures as the primary operator.
4. Participation and supervised instruction in fluoroscopically guided placement and manipulation of at least ten electrode arrays in the epidural space as the primary operator but under the direct supervision of a recognized mentor (see above for definition of a “recognized” mentor).
5. Instruction should include training in intraoperative electrode programming, securing percutaneous arrays, and postoperative care.
6. Regardless of training venue, the trainee and mentor must keep a log suitable for review by certifying bodies or credentialing committees to document fulfillment of requirements. The mentor must be willing to attest that the trainee is technically competent.
7. Maintenance of established competence by participation in at least ten procedures yearly is desirable.

Track II—Knowledge requirements:

1. All of Track I knowledge requirements
2. SCS electrophysiology, including electrical parameters
3. Principles of component selection, e.g., percutaneous vs. surgical plate/paddle electrodes, primary cell vs. rechargeable pulse generators
4. System programming at time of implantation
5. Causes and differential diagnosis of device failure and malfunction
6. Management of complications, including when to refer to Track III physician

Track III

Track III—Responsibility:

1. Patient selection
2. Device selection
3. Implantation of SCS electrodes and of pulse generators
4. Follow-up patient care (see Table 1), including treatment of complications

Track IIIa—Training and knowledge:

1. All Track II requirements
2. Supervised instruction in techniques required for subcutaneous surgical dissection, lead anchoring and tunneling, subcutaneous pocket formation for internal pulse generator, wound closure, and postoperative wound management
3. Participation and supervised instruction in surgical implantation of at least ten percutaneous (cylindric) electrodes and pulse generators as the primary operator but under the direct supervision of an experienced mentor
4. Participation in at least five revisions of SCS systems, including replacement of pulse generators as well as revision and replacement of leads/electrodes
5. Ability to treat complications
6. Maintenance of established competence by participation in at least ten device implants/revisions yearly is desirable

Track IIIb—Training and knowledge:

1. All Track IIIa requirements with the exception of percutaneous epidural electrode placement (desirable, but not required)
2. Participation and supervised instruction in surgical implantation of at least ten surgical (paddle) electrodes

and pulse generators as the primary operator but under the direct supervision of an experienced mentor

3. Specialized training in neurosurgery or orthopedic spine surgery resulting in the skill to enter the epidural space by means of open exposure, laminectomy, hemilaminectomy, or laminotomy for implantation of surgical plate/paddle electrodes

Accreditation and Certification

Although the purpose of this policy statement is to describe adequate training for the prescription and implantation of SCS systems, the NANS, as a specialty society, neither accredits training programs nor certifies individuals to perform SCS. The NANS hopes, however, that this statement will provide guidance for entities such as the Accreditation Council for Graduate Medical Education or specialty boards who might wish to offer such accreditation or certification. The NANS encourages widespread adoption of these requirements to ensure proper training of physicians involved with SCS, with the goal of providing better and more uniform care for SCS patients.

Conflict of Interest

Authors have reported no conflicts of interest.

References

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