

NASPE POLICY STATEMENT

NASPE Training Requirements for Cardiac Implantable Electronic Devices: Selection, Implantation, and Follow-Up

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Introduction

Cardiac implantable electronic devices (CIEDs) have become frequently used therapeutic modalities. CIEDs include pacemakers, implantable cardioverter defibrillators (ICDs), devices for heart failure management (cardiac resynchronization), and implantable hemodynamic monitors. Selection of the appropriate CIED, its implantation, and follow-up care require expertise to achieve optimal therapeutic results. Training requirements in cardiac pacing have previously been defined by the North American Society of Pacing and Electrophysiology (NASPE) and the American College of Cardiology (ACC).¹⁻³ In the initial report of the NASPE Policy Conference Training Requirements for Permanent Pacemaker Selection, Implantation, and Follow-Up, core training requirements in cardiac pacing were defined. NASPE believed that defining core training guidelines was especially important for this discipline because pacemaker and ICD selection, implantation, and follow-up are performed by various medical and surgical specialists, including cardiologists, internists, general surgeons, cardiothoracic surgeons, and pediatric cardiologists. Because training is obviously quite different for each discipline, and core knowledge and training for pacemaker therapy are potentially varied, it is critical that there be definitions for training.

Objectives of Policy Statement

The original policy statement on training guidelines originated from a conference held in 1992 and was published as a policy statement

Parts of this manuscript are from Hayes DL, Naccarelli GV, Furman S, Parsonnet V, and the NASPE Pacemaker Training Policy Conference Group: Report of the NASPE policy conference training requirements for permanent pacemaker selection, implantation, and follow-up. *PACE* 1994; 17:6-12, by permission of Futura Publishing Company.

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Received March 18, 2003; accepted March 20, 2003.

in 1994. The purpose of the original conference was to establish NASPE-endorsed training requirements for pacemaker selection and follow-up care, in addition to suggested training requirements for implantation of permanent pacemakers. Such training requirements should be applicable regardless of medical or surgical discipline. It is believed that the original policy statement did provide guidelines for training physicians in cardiac pacing and was of help to medical and surgical certifying boards and hospital accreditation committees. However, given the continued growth of cardiac pacing and defibrillation, along with new procedures that are related to these disciplines, an update of the original policy statement is warranted. It is hoped that the updated policy statement will provide additional information regarding maintenance of skills related to device implantation, more detailed training guidelines for CIED implantation and lead extraction, and initial guidelines for implantation of cardiac resynchronization devices that require additional leads to be placed at alternative pacing sites.

Background

Cardiac pacemakers and ICDs can be implanted either by thoracotomy or transvenously. Although thoracotomy was the initial route of pacemaker and ICD insertion as well as for left ventricular lead placement for CRT, it has been supplanted by the transvenous approach, except in special circumstances.

Simultaneous with the change from thoracotomy implantation to the transvenous approach for device implantation, there has been a change from implantation by surgeons to implantation by cardiologists. According to the most recent surveys of cardiac pacing practices in the United States, more than 75% of pacemakers are implanted by cardiologists.⁴ Implantation of a CIED device has five distinct components: (1) proper indications, (2) the surgical element of implantation, (3) venous access, (4) intracardiac manipulation of leads and lead placement, and (5) electrophysiological interpretation during implantation. Any proposed criteria for proper training should include these key

elements in addition to providing knowledge and a skill base in preimplantation and postimplantation concerns.

Surprisingly, there are few subspecialty board requirements for device implantation and management. As of January 1991, the American Board of Thoracic Surgery has required familiarity with a minimum of only ten permanent pacemaker procedures for purposes of board certification. No distinction is made between endocardial and transthoracic implantation. It must be recognized that transvenous lead implantation is the "state of the art" for all CIED systems, and the training requirements outlined in this manuscript should apply to anyone performing transvenous CIED implantation—that is, physicians trained as surgeons and those trained in cardiology or related fields. The ten procedures required by the American Board of Thoracic Surgery may be adequate for training of epicardial lead placement. It is not the intent of this statement to provide training requirements for epicardial lead placement. Epicardial lead placement will be performed by surgeons and should therefore be defined by a surgical "board."

The American Board of Internal Medicine (ABIM) requires that 2 months be devoted to electrophysiology, pacemaker follow-up, and ICDs as part of cardiovascular training.⁵ Both the cardiology and the thoracic surgery examinations ask a limited number of questions, usually relatively simple, about cardiac pacing and defibrillation. The examination in cardiac electrophysiology administered by the ABIM includes more questions regarding pacemakers and ICDs; however, it is estimated that pacing questions constitute only 5% to 10% of the examination.

It is also recognized that during the minimum 2 month ABIM requirement for electrophysiology, pacemaker follow-up, and ICD⁵ that Level II training described below cannot be achieved. It would require additional elective time during the standard cardiology fellowship to achieve Level II training. It would then require formal electrophysiology training to complete Level III training requirements.

Because cardiac pacing is a multidisciplinary specialty, unusual problems arise in obtaining proper experience during training. The cardiologist is unlikely to have been trained in surgical techniques, and the surgeon is unlikely to have been trained in intracardiac electrode manipulation or in interpretation and management of atrial and ventricular arrhythmias. The consensus of the original policy conference is that surgeons can, and should, be sufficiently trained in techniques of intracardiac catheter manipulation to allow them to implant electronic arrhythmia control devices, and that cardiologists can, and should, be trained in the surgical techniques required for successful

transvenous implantation. This goal may require that a pacemaker training center develop training agreements that cross over to both specialties and that a surgeon and a cardiologist both scrub in on cases to share expertise and experience.

Any physician who implants arrhythmia control devices must have the necessary training to select patients for whom such devices are appropriate. The implanting physician should also be capable of providing postoperative care and follow-up. On the other hand, some physicians who are interested in preimplantation care and selection and postoperative care and follow-up may not be interested in or trained for the actual implantation techniques. Training programs should allow different levels of training so that the physician can train appropriately for those services he or she plans to provide.

Definition of a CIED Service

Centers that provide specialized training in cardiac pacing and defibrillation should have a well-defined service, which should include the following:

1. Two or more physicians who are specialists in device implantation and management. At least one of the physicians should also be an electrophysiologist, or the physicians performing the implantations should work directly with the electrophysiologist who is prescribing the implantable devices.
2. Appropriate nursing and technical personnel (at least one allied professional who works regularly in implantable device management).
3. Pertinent equipment, including pacing system analyzers, programmers from multiple manufacturers, and access to transtelephonic monitors and receivers. Facilities for computer storage of data are also desirable. Appropriate services related to cardiology—echocardiography and so on—should be available.
4. An institutional case load of at least 100 device implantations per year, with a mix of types of implants—single and dual chamber pacemakers, ICDs, and cardiac resynchronization devices. In addition, a training center should ideally implant more than one manufacturer's devices and both active and passive lead systems in order to expose the trainee to a broad selection of software and hardware.
5. An identifiable and dedicated pacemaker and ICD follow-up service. In addition, if cardiac resynchronization devices are implanted, appropriate heart failure follow-up services must be available.
6. Periodic conferences devoted to implantable device management.

7. Periodic peer review of complications related to device implantation.

CIED Prescription, Follow-Up, and Implantation Training Requirements

NASPE adopts the previously published ACC position that recommended three levels of training for persons involved in the field of implantable arrhythmia control devices.³ All training should be under the guidance of an experienced mentor who participates in a recognized implantable device service. Regardless of the level of training chosen and successful completion of the requirements in that level, the mentors of the training program must be willing to attest to the trainee's competence. Requirements for the three levels of training as they apply to device implantation and management are as follows.

Level I Training Requirements

1. Successful completion of a fellowship in cardiovascular medicine, general or cardio-

thoracic surgery (NASPE recognizes that surgical training programs do not generally allow this degree of time devoted to arrhythmia management. However, the surgeon who intends to be actively involved in the field of CIED must be able to demonstrate the competency listed), or pediatric cardiology, during which there should be at least 2 months of clinical exposure to arrhythmia management, allowing the trainee to acquire experience in the management of bradyarrhythmias and tachyarrhythmias. For Fellows in cardiovascular diseases, all Accreditation Council for Graduate Medical Education (ACGME) core requirements (see below) in cardiac pacing should be met.

2. Demonstration of competency in all pacing principles listed in Table I. Specifically, the implanting physician should have a thorough understanding of the indications and nonindications for permanent and temporary pacing therapy and defibrillation therapy,⁶ the preimplantation evaluation of the patient, and interpretation of all information applicable to the patient's pacing history, such as capture threshold measurements,

Table I.

Level I Training Requirements

History: Symptoms that suggest a pacing system complication, e.g., loss of capture, extracardiac stimulation, inappropriate rate response, and pacemaker syndrome.

Physical examination: Physical signs of pacing system complications. Expected appearance of pacemaker pocket and incision.

Mode codes: Understand the accepted nomenclature (NBG pacemaker code) for pacing modes.

Indications for implantation of devices for bradyarrhythmias and tachyarrhythmias: Understand the current ACC/NASPE American Heart Association (AHA) guidelines for pacemaker and ICD indications. Proper prescription of, contraindications for, and understanding of complications of single chamber, dual chamber, rate adaptive, and antitachycardia devices.

Electrocardiography: Interpretation of paced electrocardiograms.

Telemetered pacemaker data: Programmed data, measured data, rate histograms, electrograms, and other diagnostic pacemaker data.

Programming:

Sensing threshold.

Stimulation threshold.

Atrioventricular conduction assessment.

Ventriculoatrial conduction assessment.

Assessment of chronotropic incompetence.

Optimization of hemodynamic function.

Initiation and management of pacemaker-mediated tachycardia.

Uses of available programmable pacing modes, rate programming, output programming, sensitivity programming, refractory period programming, rate adaptive parameters.

Complications of programming: loss of capture, rate changes, oversensing, undersensing, cross-talk.

Transtelephonic monitoring: understanding of its role in follow-up.

Troubleshooting: pulse generator failure (battery depletion), lead failure, rate changes, sensing abnormalities, noncapture, cross-talk. Indicators of battery depletion, methods for appropriate monitoring, and detection of indicators.

Differential diagnosis of device malfunction

strength-duration relationships, sensing threshold measurements, unipolar and bipolar electrograms, and impedance measurements. The physician must also be able to interpret electrocardiograms in patients with pacemakers to determine whether function of the pacing system is normal or abnormal.

Level II Training Requirements

It is recognized that there may be a desire to be a CIED expert and yet not pursue a full electrophysiology training track. Level II training would therefore refer to the person who wishes to develop expertise in device implantation and management. The requirements for Level II include all those listed for Level I, in addition to those listed in Table II.

The amount of dedicated time it requires to complete Level II training is somewhat difficult

to define because it depends on the percentage of time that is dedicated to learning and to the case load and case composition of the teaching institution. It is agreed that a *minimum of 6 months* should be devoted to Level II training requirements. Depending on the training institution, it may take longer to complete all the implant requirements detailed in Table II.

Level III Training Requirements

Level III applies to the fully trained electrophysiologist.³ It is not the purpose of this document to outline training requirements for electrophysiology. However, to be considered Level III trained for the purpose of CIED implantation and management, the electrophysiology trainee must complete all the requirements outlined in Tables I and II, in addition to completing all the requirements of the accredited electrophysiology training program.

Table II.

Level II Training Requirements

1. Completion of all requirements described for Level I.
2. Physiology of electrical stimulation and genesis of the endocardial electrogram.
3. Basic pulse generator design and function.
4. Understanding interactions of pacemakers with drugs and implantable cardioverter defibrillators.
5. Pacing system analyzer (PSA) measurements and electrical testing at time of implantation, including minimally acceptable PSA measurements, excitation threshold measurements, and endocardial electrogram measurements.
6. Methods for pacemaker follow-up, including the use of programmers.
7. Recognition and management of postimplantation complications.
8. Participation in at least 100 follow-up visits of patients with implanted arrhythmia control devices. The trainee should be the primary operator and evaluator during the 100 follow-up appointments. The trainee must demonstrate knowledge of the approach to routine follow-up and troubleshooting of implantable devices. Hands-on assessment should include interpretation of paced and nonpaced electrocardiograms, interrogation and programming of devices, evaluation of pacemaker dependency, and interpretation of telemetry information. Active participation in diagnosis, prescription, and management for 50 patients who require device implantation is desirable.
9. Participation in a minimum of 50 and ideally greater than 75 initial implantations of CIED (i.e., transvenous pacemakers and/or ICDs, resynchronization devices, hemodynamic monitoring devices) as **the primary operator** but under the direct supervision of a recognized mentor. For surgeons, some allowance should be made for epicardial implantations completed. However, since the state-of-the-art for implantable devices is a transvenous approach, it is essential that the bulk of the training experience be with transvenous devices. Cardiovascular surgery trainees should be given the exposure to transvenous implantation of pacemakers and ICDs in training centers where these devices are implanted by cardiologists. The reverse should also be true.
10. Participation in a minimum of 20 and ideally 30 revisions of CIED systems. This experience should include replacement of pulse generators, revision of leads, and replacement of leads.
11. A thorough knowledge of recognizing and treating CIED surgical complications and emergencies.
12. Throughout at least a portion of the training, responsibility for emergency treatment of patients with CIEDs. This will allow the trainee to obtain experience in dealing with acute device related problems, including those arising from temporary pacing and the use of emergency transcutaneous pacing techniques.
13. Lead extraction requires special consideration. The following recommendations are excerpted from the NASPE Policy Statement entitled, Recommendations for Extraction of Chronically Implanted Transvenous Pacing and Defibrillator Leads: Indications, Facilities, Training.⁹

(Continued)

Table II.
(Continued)

Lead extraction is an invasive procedure requiring training and experience to perform safely and effectively. Physicians wishing to perform this procedure should be properly trained in technique. The simple act of watching an instructional video demonstration or observing an operator performing the procedure is not adequate. Other procedures with similar operator skill requirements and patient risk (e.g., percutaneous angioplasty of coronary or peripheral vessels) require at least an additional year of training. The following issues must be considered when determining a minimal number of extraction procedures that should be performed under supervision.

1. Analysis of lead extraction outcomes suggests that the frequency of procedural (radiographic) failure drops dramatically after the first 10-20 procedures have been performed.
2. Lower complication rates are associated with prior experience of 50 procedures.
3. A minimal number of procedures should be performed on an annual basis to maintain skills.
4. Performing a specific number of procedures does not guarantee proficiency, competency, or safety; outcome data are necessary to assess performance.
5. Training should be obtained at centers with adequate volume, experience, and expertise.
6. The number of lead extractions that need to be performed annually does not justify a wide dissemination of this technique.

Therefore, based on the available data, it is recommended that physicians being trained in this technique perform a *minimum* of 20 lead extractions as the primary operator under the direct supervision of a qualified training physician. Exposure to venous entry site as well as femoral retrieval techniques should be included. The supervisor should have in excess of 100 lead extractions performed with an efficacy and safety record that is consistent with published data.

14. In addition to the Level II training requirements already described, if training is intended to be inclusive of implantation of devices for heart failure management, additional participation in at least 15 such systems as the primary operator is required. The definition of "systems" for heart failure management will continue to evolve. However, the intent of this requirement is that the trainee participates in a minimum of 15 systems that include implantation of a coronary sinus lead for left ventricular pacing. (This may include upgrades of existing pacemakers or ICD systems.) The trainee must have a thorough understanding of the principles of device management for congestive heart failure including an understanding of coronary venous anatomy, electrocardiographic interpretation of left ventricular and biventricular pacing, ability to interpret chest Xrays that include a coronary sinus lead, and understanding methods to optimize AV and VV timing intervals following implantation of such a system.

For electrophysiologists that meet the required number of CIED implants/year, 20/year, but who do not have experience in CRT implantation, it would be ideal for that physician to also perform 15 supervised CRT implantations. However, it is realized that logistically this will be impossible for physicians actively engaged in a busy clinical practice. It is therefore recommended that the trained electrophysiologist in practice that is routinely implanting pacemakers and ICDs should complete:

- Observations of 2 CRT cases in the institution of an experienced CRT implanting physician.
- They must perform 5 CRT implants in their own institution in the presence of an experienced proctor.
- Complete a didactic course in CRT, the content of which has been approved by the CME committee of NASPE.

These recommendations for CRT training are intended as initial guidelines during this early adoption period of CRT devices. It is anticipated that these guidelines will evolve and should not necessarily be considered a durable standard. For nonelectrophysiologists that are experienced and active in the practice of pacemaker implantation, i.e., coronary sinus cannulation, and coronary venous lead placement is not part of their skill set, to implant biventricular pacemakers they must complete the guidelines listed below. In addition, if, by standards defined by NASPE and ACC, these nonelectrophysiologists would be allowed to implant biventricular/ICD devices only if an electrophysiologist is available to supervise defibrillation threshold testing (DFT) testing, ICD programming, and follow-up, these guidelines would also apply.

For any physician not actively engaged in implanting CIEDs (i.e., interventionalists, heart failure specialists, noncardiologists in an underserved area), the basic training guidelines in Levels I and II, i.e., a training program, would have to be completed.

The safety and efficacy of epicardial leads for biventricular pacing has not been studied by large randomized trials. If transvenous coronary venous placement is unsuccessful, referral to a surgeon qualified to do epicardial lead placement could be considered but those training guidelines are not in the purview of NASPE. If newer nonsurgical epicardial lead placement designed for placement by the nonsurgeon is developed, training guidelines for new techniques would have to be established.

Maintenance of Skills

Once a physician has been fully qualified to implant CIEDs, there must be evidence that his or her basic skills have been maintained by experience, and that he or she has made an effort to stay abreast of new concepts, devices, methods of implantation, and patient surveillance. Examples of expanding concepts are multisite pacing for enhancement of physiological performance, pacing for congestive heart failure without an associated bradycardia indication, the complexities of proper surgical techniques, lead placement, management of programming of technical complications, and complex arrhythmias.

Volume requirements for maintaining implantation skills should be a minimum of 1 implant procedure per month (12 primary CIED implants/year) and 5 CIED revisions. These procedures should include a mix of CIEDs to maintain some degree of proficiency in pacemakers and ICDs. Obviously, a larger number of procedures per year would result in maintenance of even greater proficiency, and a desired volume of 24 procedures per year seems reasonable.

In addition, the physician should be following a minimum of 25, and ideally at least 50, active CIED patients in his or her practice, and maintaining a working familiarity with a variety of programming devices.

In order to fulfill academic requirements, the division or departmental supervisor should see evidence of the physician's serious interest. This may include attendance at major society meetings where new concepts are taught and updated, the publishing of scholarly manuscripts, membership in pertinent societies such as AHA, ACC, and NASPE, passing the NASPExAM, and participating in an active follow-up program, preferably one associated with a hospital or university.

Although CIED training is most commonly attained within the construct of an electrophysiology fellowship with a defined period of time dedicated to device implantation and management, similar training could be achieved by a specific CIED training experience. For example, this might be accomplished through special training during a sabbatical leave or under the auspices of a recognized mentor. Regardless of training venue, the trainee and mentor should keep a log and submit case lists for review to document fulfillment of the CIED training requirements. The mentor should be willing to attest that the trainee is technically competent. (These additional approaches to CIED training do not imply completion of all Level III training requirements required for true electrophysiology training.)

Cardiac Pacing Training Requirements for Implantation in Pediatric Patients

Pacing in the pediatric patient is more difficult because of the size of the patient, the greater use of epicardial implantations, the high incidence of congenital cardiovascular anomalies, the problems associated with repair of these anomalies, and the necessity to take into account growth. Thus, a cardiothoracic residency or a pediatric cardiology fellowship and training in pediatric pacing and defibrillator therapy are useful, though the implanter who is skilled in using the transvenous route will provide excellent service for all but the smallest infant. In institutions in which the pediatric cardiologist does not perform the implant procedures, a close working relationship must be present between the pediatric cardiologist and the cardiologist responsible for device implantation. The cardiologist performing the implantation must have an understanding of any congenital cardiac anomaly that is present and have access to the pediatric cardiologist during the implant procedure. The requirements already described for implanting CIEDs in adults should also apply to those implanting CIEDs in pediatric patients. However, it is realized that many excellent pediatric training facilities may not have a CIED volume of 100 procedures per year. Although the knowledge base for prescription, care, and follow-up of CIED should be the same for the physician performing CIEDs in pediatric patients, it may be reasonable to consider a smaller number of cases for training in these institutions. Although the volume of cases previously outlined is preferred, a total of 50 CIEDs and 10 revisions of CIEDs could alternatively be considered for the pediatric trainee.

Cardiac Pacing Training Requirements for Thoracic or General Surgeons

As stated earlier, since a transvenous approach is the "state of the art" for CIED implantation, anyone implanting CIEDs should have met the training requirements outlined above. Although CIED implantation is a "surgical" procedure by definition, in the United States the majority of CIEDs are now implanted by nonsurgeons—that is, cardiologists or physicians in related fields. The requirements of the American Board of Thoracic Surgery for "pacemaker" implantation are not sufficient for transvenous CIED implantation.⁷ It is realized that requirements for epicardial lead placement are not included in this document. Epicardial lead placement, as opposed to transvenous CIED implantation, is a surgical procedure that is performed only by someone with surgical training.

Accreditation and Certification

The purpose of this policy statement is to describe adequate training in cardiac pacing. In the future, proper training may be part of an individual's privileges to practice cardiac pacing. Training programs are accredited by the ACGME. The appropriate board (e.g., ABIM or American Board of Surgery) does the certifying. The hurdles of accreditation and certification in cardiac pacing include the multispecialty nature of cardiac pacing. NASPE, as a specialty society, neither accredits nor certifies. However, NASPE encourages the ACGME, Residency Review Committees, specialty boards, and training directors to follow these proposed training guidelines and to consider voluntary adoption of this policy conference's recommended guidelines to ensure proper training of physicians and, thereby, optimal care of pacemaker patients.

NASPE also encourages use of NASPExAM as another mechanism for objectifying competency in cardiac pacing. In 1985, the Executive Committee of NASPE created a wholly owned subsidiary, NASPExAM, to develop and administer an examination of special competence in cardiac pacing for physicians. The examination was first offered in 1986, and the outcome has previously been reported.⁸ Successful completion of the NASPExAM examination demonstrates knowledge in cardiac

pacing and defibrillation far more completely than the specialty board examinations, which deal in greater detail with issues other than cardiac pacing or implantable defibrillation. NASPExAM is not an examination of board certification at this time, but in some institutions it has become a part of institutional credentialing for implantation and management of arrhythmia control devices.

Summary

NASPE proposes and supports the concept of Level I, II, and III training for implantation and management of CIEDs. Track I training will properly train physicians for the prescription of pacemakers and the monitoring of CIED patients, and track II training will properly prepare physicians for the implantation of CIEDs. Regardless of specialty (cardiologist or surgeon) or training venue (cardiac pacing fellowship, cardiac electrophysiology and pacing fellowship, sabbatical, or mentor-sponsored training), it is recommended that these minimum standards be required for hospital credentialing. Level III applies to requirements for the fully trained electrophysiologist.

As CIED implantation and management continue to become more complex, it is crucial that those involved in these clinical functions are adequately trained.

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