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NASPE POSITION STATEMENT

Clinical Competency Statement: Implantation and Follow-Up of Cardioverter Defibrillators

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Implantable cardioverter defibrillators (ICDs) are widely used for the management of patients with serious ventricular arrhythmias. To provide optimal care for patients, physicians require knowledge and expertise in the indications, techniques for implantation, complications, programming, and follow-up of these devices. Physicians requesting clinical staff privileges at a given institution must be able to prove their ability to uphold the quality of care. The Joint Commission on Accreditation of Health Care Organizations requires the granting of continuing medical staff privileges to be based on assessments of applicants against professional criteria specified in the medical staff bylaws. Physicians themselves are charged with identifying the criteria that constitute professional competence and with evaluating their peers accordingly. Yet, the process of evaluating physicians' knowledge and competence often is constrained by the evaluator' s own knowledge and ability to elicit the appropriate information, problems compounded by the growing number of highly specialized procedures for which privileges are requested. Therefore, physicians must identify the criteria that constitute professional competence.

The recommendations in this statement have been developed by the North American Society of Pacing and Electrophysiology (NASPE) to assist in the assessment of physician competence in the implantation and follow-up of ICDs. The minimum education, training, experience, and cognitive and technical skills necessary for the competent performance of these procedures are specified. Whenever possible, the specifications are based on published data linking these factors with competence or, lacking such data, on the consensus of expert opinion. The recommendations are applicable to any practice setting and can accommodate a number of ways in which physicians might substantiate competence in this area (see also Guide to the Use of American College of Physicians Statements on Clinical Competence[1]).

Overview of the Procedure

The ICD originally was developed for the management of survivors of cardiac arrest. The first human implant took place in 1980. Initially, placement and testing of epicardial defibrillating and rate-sensing electrodes required a thoracotomy and usually involved the cooperation of a cardiac surgeon and an electrophysiologist.[2] Device follow-up was simple and straightforward, as limited information was obtainable on interrogation other than number of discharges. Little more than routine reforming of the capacitors was required during follow-up. Devices were not programmable, which dramatically limited the range of therapy.[3] Despite limitations of size, the highly invasive surgical approach, and resultant morbidity and mortality, these devices were effective in reducing deaths from recurrent cardiac arrest.[4-6]

Second-generation devices incorporated a transvenous electrode that allowed for improved arrhythmia recognition, the ability to abort shocks if arrhythmias spontaneously terminated, and improved telemetered data.[7] Subsequent improvements included both bradycardia pacing and antitachycardia pacing. The latter enabled tiered therapy for ventricular arrhythmias. The third generation of devices had improved memory for both sensed and therapeutic events, programmable current pathways, and the capability of noninvasive programmed stimulation.[8]

Development in all aspects of ICDs, including leads, shock waveforms, device miniaturization, memory capacity, and arrhythmia recognition, has led to practical nonthoracotomy implantation of highly sophisticated devices. These fourth-generation devices have improved electrograms for better diagnostics and can be programmed for advanced tiered therapy.[9,10] Fifth-generation devices permit dual-chamber rate responsive pacing with attendant improved hemodynamics in some patients and improved recognition of supraventricular tachycar-

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dia with avoidance of inappropriate therapies. It is estimated that supraventricular tachycardias cause unnecessary therapy delivery in about 10% to 20% of patients with ICDs. Dual-chamber ICDs are somewhat more difficult to implant because they require an additional atrial lead, but they allow enhanced detection criteria that may decrease the rate of unnecessary therapy to <5% of patients.[11,12]

The technical aspects of a routine ICD implant are now only moderately more complex than implantation of a permanent pacemaker. It is common for nonsurgeons to implant ICDs in a suite also used for placement of permanent pacemakers. Conscious sedation may be used for ICD implants rather than general anesthesia. As a result of these changes, some physicians with inadequate training and experience have begun to implant ICDs. However, the same technology that has streamlined routine implants also has dramatically increased the complexity of other aspects of patient management.

Due to improved technologies, the types of clinical situations appropriate for device management also have expanded. Indications for ICD insertion now include selected patients who have not experienced a symptomatic arrhythmia.[13-15] The approved indications for ICD therapy have changed to reflect the outcomes of recent clinical trials and are presented in the guidelines published by the American College of Cardiology/American Heart Association (ACC/AHA).[16] Although the actual implant techniques have been simplified due to technologic advancements, patient evaluation and management have become more complex. Physicians participating in device therapy for patients need to know these indications and to keep abreast of current trials as well as new technologic developments that may affect future recommendations for implantation. This knowledge is critical in the selection of the appropriate candidate for device therapy and in determining the optimal device for the individual patient.

Device implantation should be performed by physicians in centers prepared to provide appropriate preoperative evaluation and support throughout all phases of device treatment: preprocedural, intraoperative, and postoperative.

Preoperative and Intraoperative Evaluation

Preoperative decisions other than device and patient selection include evaluation of any suspected venous anomaly that might interfere with implantation. Several lead systems are available, and selection will be determined by the individual patient's needs and may be affected by the presence of prior devices. A sound approach is to keep the system as simple as possible. Nevertheless, to deliver a defibrillation shock, there must be at least two sites between which energy is delivered. If more than two electrodes are used, two or more will need to be combined to act as a single electrode.[17] The operator needs to have knowledge of the choices available and to understand how to evaluate each system for effectiveness of therapy.

The physician also requires knowledge of the physical characteristics of the variety of devices available. Depending on the patient's body habitus, certain device characteristics may be better tolerated. The default site of implantation for the active can device is the left pectoral region, yet certain clinical situations may mandate a right-sided implant.[18] The operator must have knowledge of different techniques appropriate for pectoral or subpectoral implantation and for postoperative wound management.

Defibrillation testing performed intraoperatively is critical to long-term success. The operator must have knowledge of the methods of arrhythmia induction and therapies available as well as techniques for emergency management of refractory arrhythmias. Assessment of defibrillation threshold is an obligatory part of the implantation procedure and may be performed during follow-up as well. Some patients also may require testing of antitachycardia pacing and cardioversion thresholds. Clinical judgment is needed to reduce patient risk through either overly aggressive or inadequate therapy. Most devices deliver a biphasic truncated exponential waveform, but the operator must be capable of determining the best pathway polarity.[19,20] The operator also requires knowledge of the device sensing algorithms to choose optimal lead placement.

Troubleshooting intraoperatively and during follow-up demands considerable skill and experience. The implanting physician must be familiar with methods for managing inadequate rate sensing (e.g., placement of a separate active fixation lead). Even more important are strategies for lowering defibrillation energy requirements, such as the use of additional high voltage electrodes, manipulation of shock waveforms, and the addition of drugs. The implanting physician should be familiar with the effects of drugs on arrhythmia rate and defibrillation threshold, and the possibility of adverse device–device interactions.

ICD Programming

The programming of ICDs has become increasingly complex as the result of a myriad of new features. For optimal function (and therefore greatest benefit to the patient), the physician must be aware of all aspects of device programmability.[8,21,22] As in permanent pacemakers, parameters for bradycardia pacing must be programmed. Appropriate testing and programming to avoid oversensing of far-field R waves[23] and to assure recognition of atrial fibrillation[24] in dual-chamber units is critical. Decisions regarding programming of the bradycardia pacing component of the defibrillator must be based on an understanding of an individual's needs, knowledge of pacemaker therapy, and understanding of the specifics of programming as it pertains to the underlying ventricular arrhythmia.

Appropriate programming of tachyarrhythmia detection criteria requires knowledge of the individual patient's electrophysiologic abnormality. Tachyarrhythmia detection often involves multiple zones; care must be

taken to choose zones appropriately to avoid leaving undetected potentially lethal arrhythmias.[25] Enhancements such as assessment of sudden onset and/or rate stability are available for discrimination of supraventricular from ventricular tachyarrhythmias. Dual-chamber ICDs offer the possibility of using the relationship of atrial and ventricular activation to increase the specificity of ventricular tachycardia detection. Some devices are capable of quantifying the morphology of the ventricular electrogram to differentiate supraventricular from ventricular tachycardia.

Programming optimal therapy also requires considerable expertise. If the patient is treated for ventricular fibrillation only, programming of therapy is straightforward and, to a large extent, is dictated by the defibrillation threshold information gained at implantation. Indications for, and selection of, antitachycardia pacing and cardioversion parameters mandate an understanding of the patient's arrhythmia substrate as well as the capabilities of the ICD being used. Several choices must be made in programming tiered therapy, including number of tiers, types of therapy delivered, energy level for shock therapy, waveform (in some ICDs), and defibrillation current pathway. For ventricular tachycardia therapy, the operator must determine how many and what types of antitachycardia pacing therapies to permit before cardioversion or defibrillation. Other decisions are necessary regarding antitachycardia pacing coupling intervals, number of pulses, mode of therapy delivery (burst vs ramp), number of sequences, and any decrement between sequences. In addition, standard parameters such as pulse width and amplitude must be chosen. The operator must have solid knowledge of the principles of tachyarrhythmia therapy best gained through training in clinical cardiac electrophysiology.

The operator should be aware of parameters requiring assessment immediately postoperatively as well as during long-term device follow-up.[26,27] Recognizing that components may fail over time[28] and that patient requirements vary as disease course progresses, regular follow-up evaluation has been recommended by the ACC/AHA Task Force.[16] The physician involved in device management of patients must be aware of the spectrum of complications, which range from those related to the technical aspects of implantation to those seen during device follow-up.[29-32] Knowledge of the potential shortcomings of each device is critical.[19,22,33] Optimum device follow-up also requires the ability to interpret information gained from stored electrograms.[34,35]

Justification for Recommendations

The recommendations for the minimum education, training, experience, and skills necessary to implant ICDs and to provide follow-up for patients with these devices are derived principally from the opinion of a NASPE Task Force appointed by the NASPE Committee on the Development of Position Statements. In addition, we have referred to previously published guidelines for training in clinical cardiac electrophysiology as well as guidelines for implantation and follow-up of patients with antiarrhythmia devices and permanent pacemakers.[13,16,36-39] The numbers of implantations and follow-up visits recommended are in accord with those published in previous statements and are the best available recommendations at the present time. However, there is a need for objective data to be obtained over the coming years to support or to alter these recommendations.

TABLE 1
Some Cognitive Skills Required for ICD Implantation and Follow-Up

Knowledge of current indications
Knowledge of contraindications
Knowledge of complications and their management
Ability to interpret intraoperative electrogram recordings and to determine pacing and defibrillation thresholds
Knowledge of normal and abnormal cardiac anatomy
Knowledge of ICD programming
Understanding of drug–ICD and pacemaker–ICD interactions
Understanding of the differential diagnosis of device malfunction
Ability to differentiate appropriate from inappropriate shocks
Knowledge of the appropriate management of patients with frequent shocks

There are two levels of expertise that may be achieved by physicians who care for patients with ICDs. The first level is expertise in the indications for ICDs, follow-up, and troubleshooting for these devices (Table 1). This type of expertise is necessary for physicians who do not implant ICDs, but who follow patients with these devices in their practices. It is necessary for such physicians to have knowledge of the results of recent clinical trials on the indications for ICDs,[13-16] to be thoroughly familiar with programming and interrogation of ICDs, to be able to interpret intracardiac electrograms, to understand drug–device interactions, to be expert in the differential diagnosis of appropriate versus inappropriate shocks, and to be able to analyze changes in ICD function over time. Such expertise may be attained during a fellowship in cardiovascular diseases but will require elective time in addition to the core training provided in arrhythmia management in order to acquire the necessary skills.

A more advanced level of training is required for implantation of ICDs. Physicians who implant ICDs are required to be expert in implantation techniques and the complications of ICD implantation. Implantation of ICDs demands expertise in cardiac anatomy, central venous access, manipulation of leads in the heart, sterile operative technique, pacing and defibrillation threshold testing, ICD programming, and postoperative care (Table 2). If the implanting physician is not responsible for follow-up of the patient, as is the case in some institutions, then there must be available at the same institution a physician with the required expertise in device indications and selection, troubleshooting, and follow-up.

By defining minimum standards for physicians who implant ICDs and follow patients with these devices, this committee hopes to reduce the risk of inappropriate patient selection, operative complications, and incorrect

TABLE 2
Some Technical Skills Required for ICD Implantation

Operative skills to obtain central venous access and form a pocket
Manual dexterity to place defibrillation and sensing electrodes in the right ventricle and right atrium
Ability to recognize and manage procedural complications
Ability to manage high defibrillation thresholds
Proficiency in the use of external defibrillation and intravenous cardiac medications
Technical knowledge regarding electrical safety and radiation

programming of the device. The following specific recommendations are based on the issues delineated here, published guidelines, and the consensus of the committee.

Minimum Training Necessary for Competence

It is preferable for implanting physicians who have completed their training since 1992 to have matriculated from a dedicated fellowship in Clinical Cardiac Electrophysiology at least 1 year in duration. Training should include a thorough knowledge of the indications for, and contraindications to, ICD therapy. The trainee should have expertise in the techniques of implantation and the complexities of device selection and programming. Familiarity with outpatient follow-up and troubleshooting also are required. For most aspects, although not for implantation, eligibility or certification by the American Board of Internal Medicine (ABIM) Clinical Cardiac Electrophysiology Board is evidence of competency, as is certification by NASPExAM. Trainees should have completed at least 25 initial ICD implants as the primary operator during fellowship as well as replacement or revision of at least 10 ICDs.

It is commonplace for ICD implants to be performed as a joint effort of a surgeon and an electrophysiologist. The surgeon usually is responsible for creating the pectoral pocket. Either member of the team may gain vascular access and position the transvenous lead(s). The electrophysiologist supervises threshold testing and programming of the device. Clearly, neither physician in this situation must possess all of the skills necessary for the implant. In aggregate, the two must have the competencies described. It is desirable to have considerable overlap in the skill sets of the surgeon and cardiac electrophysiologist.

Physicians who follow patients with ICDs must be knowledgeable in all aspects of ICD programming and troubleshooting. Although completion of a fellowship in clinical cardiac electrophysiology may be taken as evidence of competence in this area, it also is possible to attain the necessary training during a fellowship in cardiovascular diseases if elective time is taken in this area in addition to the core curriculum. A minimum of 6 months on the clinical cardiac electrophysiology service is necessary in order to achieve this expertise. Interrogation of at least 50 ICDs with interpretation of the results should be taken as the minimum number necessary for independent performance of this kind of follow-up. Documentation of this experience by training program directors and/or chiefs of cardiology should be required. It should be noted that this level of experience is not adequate for the independent implantation of ICDs. It is not adequate to rely solely on company representatives for interpretation of the results of interrogation of antiarrhythmia devices. Knowledge about, and expertise in, ICD follow-up and troubleshooting must reside in a physician immediately present. If an industry representative is involved, it must be only under the direct and immediate supervision of the physician with this expertise.

Alternate Routes for Achieving Competence

Physicians who completed training prior to 1992 will have more variability in their training experiences than those who finished training more recently. It is important that these physicians possess the same fund of knowledge and set of skills required of the newer trainees. Physicians who have acquired experience outside of a formal fellowship should have comparable experience. Experience with pacemaker implantation (even if extensive) in combination with an industry-sponsored ICD implantation course does not constitute sufficient training to implant or follow-up ICDs independently.

Cardiothoracic surgeons and pediatric electrophysiologists may implant or follow patients with ICDs, yet they would not be eligible for certification in clinical cardiac electrophysiology by the ABIM. Such physicians should have had training comparable to that required in clinical cardiac electrophysiology training programs. In addition, successful completion of the NASPExAM in cardiac pacing and defibrillation may be taken as evidence of expertise in this area.

Maintenance of Competence

A minimum of 10 ICD procedures per year is necessary in order to maintain proficiency in ICD implantation. Physicians also should follow a minimum of 20 patients a year with ICDs if they are to maintain competency in programming and follow-up.

Ongoing continuing medical education is an important part of maintaining competence in the implantation and follow-up of patients with ICDs. Physicians implanting or following ICDs should be cognizant of new devices and technologies and use them as appropriate for the individual patient in order to provide maximum clinical benefit.

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