

Addendum to the clinical competency statement: training pathways for implantation of cardioverter defibrillators and cardiac resynchronization devices

This document has been endorsed by the American College of Cardiology Foundation

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The Heart Rhythm Society *Clinical Competency Statement: Training Pathways for Implantation of Cardioverter Defibrillators and Cardiac Resynchronization Devices* (Curtis AB, Ellenbogen KA, Hammill SC, Hayes DL, Reynolds DW, Wilber DJ, Cain ME. Heart Rhythm 2004;1:371–375) provides the minimum competency standards for physicians implanting cardioverter defibrillators (ICD) or cardiac resynchronization therapy (CRT) devices. It is important to realize that even extensive experience with pacemaker implantation combined with most current device company-sponsored abbreviated ICD implantation courses does not constitute sufficient training to implant ICDs or provide adequate patient follow-up and that only those physicians with documented appropriate training should be credentialed to implant ICDs. Authored by the task force, the *Addendum to the Clinical Competency Statement: Training Pathways for Implantation of Cardioverter Defibrillators and Cardiac Resynchronization Devices* incorporates suggestions and comments submitted to the Society during the 30-day open comment period. It was prepared without input, influence, or direct support from industry. In addition, as stated in the 2004 *Clinical Competency Statement: Training Pathways for Implantation of Cardioverter Defibrillators and Cardiac*

Resynchronization Devices (Clinical Competency Statement), this training pathway is for device implantation in patients who have not yet had a sustained ventricular arrhythmia (primary prevention). All patients with other ICD indications should be referred to an electrophysiologist.

The *Addendum* serves to complement the 2004 *Clinical Competency Statement* by clarifying recommended ICD/CRT device training requirements for nonelectrophysiologists and was written in response to the expanded coverage provided in the Centers for Medicare & Medicaid Services (CMS) National Coverage Determination for ICDs on January 27, 2005. Based on the *Clinical Competency Statement*, American Board of Internal Medicine, certification in Clinical Cardiac Electrophysiology demonstrates clinical competency to implant ICD/CRT devices and provide patient follow-up. The *Addendum* to the *Clinical Competency Statement* is meant to clarify required testing and course work, define proctoring and proctorship, outline unique pediatric considerations, and state the requirements for those wishing to be grandfathered to independently implant devices. The Heart Rhythm Society will distribute the *Addendum* and the *Clinical Competency Statement* to hospitals and credentialing bodies to inform them of these standards. Answers to frequently asked questions about this *Addendum* and the *Clinical Competency Statement*, along with copies of published Heart Rhythm Society clinical documents, can be found at <http://www.HRSonline.org/clinicaldocuments>.

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Required didactic coursework and competency examination

Demonstration of an adequate knowledge base to implant ICD/CRT devices should consist of passage of the NASPE_xAM for the physician within the last 10 years, or its successor examination, with completion of a Heart Rhythm Society sponsored or endorsed didactic course on ICD/CRT implantation. The rationale for this change is based on the intent of the original Clinical Competency Statement that states, “*The course must have a formal assessment as part of the course, either during the course or to be submitted after the course that tests the individual on the course content. . .successful passing of the NASPE_xAM, which tests knowledge in pacemakers and defibrillators, would provide evidence that the physician has the knowledge base for ICD implantation and follow-up.*” The NASPE_xAM, for the physician when passed within the last 10 years from the date of publication of the *Addendum* in *Heart Rhythm*, provides a more comprehensive and uniform peer-reviewed formal assessment of the critical aspects of ICD/CRT implantation and patient follow-up, than a separate course-based assessment.

Role of an ICD/CRT proctor and proctorship

A physician experienced in ICD/CRT implantation who qualifies as a proctor should have graduated from an Accreditation Council for Graduate Medical Education (ACGME) approved fellowship that meets the current Core Cardiology Training Symposium (COCATS) guidelines in electrophysiology and/or device implantation or have passed the American Board of Internal Medicine (ABIM) Clinical Cardiac Electrophysiology (CCEP) examination; be at least 2 years out of training; currently implanting a minimum of 25 ICDs per year; and personally following a minimum of 50 ICD patients per year. Because successful passage of the ABIM CCEP examination demonstrates significant expertise and experience in device implantation and patient follow-up, these individuals may serve as ICD/CRT proctors.

It is anticipated that only experienced and well-trained cardiac electrophysiologists will meet the requirements to be a proctor. Thus, this will facilitate documentation of successful completion of training requirements, as stated in the *Clinical Competency Statement*, a “*letter documenting the follow-up plan and a corresponding or co-signed letter from the electrophysiologist with whom the individual will be collaborating.*” An ongoing collaboration with an electrophysiologist in the area is essential to maintain competency and an appropriate level of patient care.

During an ICD/CRT proctorship, the proctee must be the primary operator with hands-on experience while working under the direction of the supervising physician, the proctor. The unique issues of ICD implantations, as compared to

pacemaker implantations, such as the need to test defibrillation thresholds (DFTs) and the evaluation of sensing problems, also should be included in the proctorship.

The proctee must **provide** the proctor, who is the supervising physician, a written statement that documents his/her previous number of pacemaker implantation cases and any periprocedural complications associated with these pacemaker implantations. This written statement documenting pacemaker experience should be given to the proctor **before** beginning the proctorship. As per the *Clinical Competency Statement*, the proctee should be an experienced pacemaker implanter who “*implants a minimum of 35 pacemakers a year, with a minimum of 100 implants over the preceding three years.*” To protect proctors, proctees, and patients, the written statement documenting the pacemaker experience of the proctee must not be in violation of the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

For physicians practicing in the United States, proctoring should be done at a Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accredited hospital or institution at which a proctor, as defined above, practices and implants cardioverter defibrillators.

Before any proctored ICD/CRT device implantation is performed, it should be clearly documented in the patient’s chart that the patient was informed of the proctorship and of the potential risks associated with a proctored implant, and that the patient had the right to refuse the procedure being performed as part of a proctorship. Billing should be consistent with Medicare guidelines. Payment should be considered to the proctor for reasonable reimbursement for his/her time and expertise; this reimbursement must be consistent with any existing laws or statements from the Advanced Medical Technology Association (AdvaMed).

This training pathway in ICD/CRT device implantation should be followed no more than **3 years** from the date of publication of the *Addendum* in *Heart Rhythm*. After the third year, nonelectrophysiologists wishing to implant ICD/CRT devices must be trained in an approved fellowship training program. Anyone wishing to use this pathway should be aware of this and plan to complete all aspects in this limited period.

Pediatric implantation considerations

The Heart Rhythm Society acknowledges that the guidelines set forth in the COCATS document as well as those set forth in this document do not necessarily prepare a practitioner to deal with the implantation issues important for patients with smaller heart size and abnormal cardiovascular anatomy or to care for children prior to and following such procedures. **Therefore, these guidelines should not be considered to apply directly to training and competency requirements for individuals who implant devices in children.** Although it is recognized that there has always

been significant overlap in the patient populations served by pediatric and adult electrophysiologists, board certifications by the American Board of Pediatrics and its sub-board of Pediatric Cardiology are generally considered to be the standard initial requirements for credentialing of physicians to perform procedures in children's hospitals and pediatric cardiac catheterization laboratories. Published guidelines for the training of pediatric implanters are forthcoming and will be developed further by the Heart Rhythm Society and the Pediatric Electrophysiology Society.

Grandfathering requirements for ICD/CRT implantation

For electrophysiologists and nonelectrophysiologists who currently are implanting ICD/CRT devices but who have not taken the boards (ABIM CCEP) and/or have not met the requirements stated in the *Clinical Competency Statement*, the following requirements must be met in order to be grandfathered to independently implant ICDs/CRTs. Those who do not meet the minimum number of ICD/CRT implantations, as listed below, prior to the date of publication of the *Addendum* should be proctored. All of the grandfathering requirements should be met within **1 year** of the date of publication of the *Addendum* in *Heart Rhythm*.

To be grandfathered to independently implant ICDs/CRTs, you must have documentation of current experience: a minimum of 25 ICD implantations over the last 12 months prior to the publication of the *Addendum* in *Heart Rhythm*; pass the NASPEXAM for the physician within the last 10 years, which included ICD knowledge testing; and have completed a Heart Rhythm Society sponsored or endorsed ICD/CRT didactic course.

Grandfathered physicians do not meet the established criteria to serve as proctors in the training of new physicians to independently implant ICD/CRT devices.

Summary

The Heart Rhythm Society *Clinical Competency Statement: Training Pathways for Implantation of Cardioverter Defibrillators and Cardiac Resynchronization Devices* and the *Addendum* provide guidance on the training recommendations for safe, competent, efficient ICD/CRT device implantations. Before clinical competency can be attained and independent implantation of ICD/CRT devices occur, all training requirements as stated in the *Clinical Competency Statement* and the *Addendum* must

be completed and documented. The Heart Rhythm Society strongly encourages adherence to the *Clinical Competency Statement* and the *Addendum*. This guideline provides standards for hospital credentialing bodies to help ensure appropriate patient care and lead to improved patient outcomes.

Disclosures of relationship with industry

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