

Frequently Asked Questions on the Training Pathways for Implantation of Cardioverter Defibrillators (ICD) and Cardiac Resynchronization Therapy (CRT) Devices

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For the 2005 Addendum, 2004 Clinical Competency Statement and other HRS clinical documents, please visit our webpage at www.HRSonline.org/clinicaldocuments. For further education and policy on implantable cardioverter defibrillators (ICD) and cardiac resynchronization therapy (CRT), please visit our webpage at www.HRSonline.org/icd_crt_info. The recommendations found in the 2004 Clinical Competency Statement Training Pathways and 2005 Addendum, sunset in October 2008.

Special Announcement: The NASPExAM® Has Changed Its Name to the:
INTERNATIONAL BOARD OF HEART RHYTHM EXAMINERS (IBHRE)

Q. Why was the 2004 HRS Clinical Competency Statement on Training Pathways for Implantation of Cardioverter Defibrillators (ICD) and Cardiac Resynchronization Therapy (CRT) (*Clinical Competency Statement*) published?

A. There was an increased demand for ICD/CRT therapy based on data derived from peer-reviewed clinical trials indicating that survival can improve by the proper placement of such devices and that the need will increase over time. The Heart Rhythm Society (HRS) was informed through its membership that non-electrophysiologists were implanting ICDs after completing only a weekend course sponsored by device companies. The Society believed that, if it had not published the 2004 *Clinical Competency Statement*, the practice of industry-sponsored abbreviated training in device implantation for non-electrophysiologists may have continued or even expanded; thereby undermining the efforts of those (including HRS) who believed that the establishment of a more rigorous training standard would better ensure higher quality and safety. In addition, as stated in the *Clinical Competency Statement*, the Heart Rhythm Society 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 Centers for Medicare and Medicaid Services (CMS) has now stated that physicians should be credentialed to be competent in ICD implantation and that the ABIM and the Heart Rhythm Society *Clinical Competency Statement* are ways of determining competency. For this and further information on ICD/CRT education and policy, please visit our webpage: www.HRSonline.org/icd_crt_info. For all HRS clinical documents, please visit www.HRSonline.org/clinicaldocuments.

Q. Did HRS sanction non-electrophysiologists to implant ICD/CRT (bi-ventricular devices)?

A. No. The *Clinical Competency Statement* was developed to prevent those MDs who are not deemed to have adequate training from implanting devices. It is expected that physicians implanting ICD/CRT devices understand the potential for complications and know how to treat these complications. In addition, there is the tacit expectation that these physicians understand how to program these devices and know the proper way to follow the patients. The purpose of the guideline is to recommend training pathways for ICD/CRT device implantation for non-electrophysiologists who have expertise in pacemaker implantation.

Q. What does the 2004 *Clinical Competency Statement* say?

A. The *Clinical Competency Statement* is intended for physicians experienced in pacemaker implantation who have implanted at least 100 pacemakers over the preceding three years. The competency statement mandates completion of a Heart Rhythm Society endorsed didactic course and passage of the NASPExAM (IBHRE), within the last ten years, or its successor examination, to ensure that content related to ICDs was included in the examination passed. It also requires adequate and acceptable implantation proctoring. It is important to understand that even extensive experience with pacemaker implantation combined with most current industry-sponsored ICD implantation courses does not constitute sufficient training to implant ICDs or to follow patients who need proper device follow-up. HRS states that only those physicians with documented appropriate training should implant ICDs/CRTs. The criteria in the

Clinical Competency Statement are not easily satisfied. The *Clinical Competency Statement* and the *Addendum*, along with other educational and policy information, can be downloaded from the ICD/CRT information page: www.HRSonline.org/icd_crt_info.

Q. What changes and clarifications are in the Addendum to the Clinical Competency Statement on Training Pathways for Implantation of Cardioverter Defibrillators (ICD) and Cardiac Resynchronization Therapy (CRT)?

A. The *Addendum* serves to clarify and expand on the *Clinical Competency Statement* to detail the required didactic coursework and competency examination; the role of an ICD/CRT proctor and proctorship; pediatric implantation considerations, and grandfathering requirements for ICD/CRT implantation.

Q. Does the Heart Rhythm Society state that I only need an HRS endorsed didactic course and the NASPEXAM (IBHRE)?

A. No. This is only one part of the requirements that non-electrophysiologists need to achieve. The published 2004 *Clinical Competency Statement: Training Pathways for Implantation of Cardioverter Defibrillators and Cardiac Resynchronization Devices* details what is expected to achieve competency:

- Documentation of current experience: 35 pacemaker implantations per year (**of which at least 75% should be “new full-system” implants**) and 100 implantations over the prior 3 years;
 - Proctored ICD implantation experience: 10 implantations and 5 revisions;
 - Proctored CRT implantation experience: 5 implantations;
 - Completion of an HRS endorsed didactic course and passing NASPEXAM (IBHRE), within the last ten years, or its successor examination;
 - Monitoring of patient outcomes and complication rates: to be kept by the implanter and made available to their respective hospital credentialing committee(s).
 - Established patient follow-up: follow-up should include device interrogation and reprogramming, including evaluation of pacing thresholds, lead impedances, sensing, and rate cut-offs for defibrillation therapy;
 - Maintenance of competence: 10 ICD and CRT procedures per year and 20 patients per year in follow-up.
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Q. Do I have to pass both the NASPEXAM (IBHRE) and take an HRS endorsed didactic course on ICD implantation before being able to independently implant devices?

A. Yes. The NASPEXAM (IBHRE) is currently the only full exam that provides a comprehensive and uniform peer-reviewed formal assessment of competency. The NASPEXAM or its successor, the IBHRE examination, must be passed within the last ten years, along with taking an HRS endorsed didactic course on ICD/CRT device implantation before independent implantation should occur.

Q. What if I passed the NASPEXAM (IBHRE) over ten years ago, or if when I took the test it was exclusively on pacing?

A. If you passed the NASPEXAM (IBHRE) before it contained content on ICD device implantation; or if it has been over ten years ago, you will need to retake the test. The NASPEXAM (IBHRE) rules now state that you need to recertify every ten years in order to keep up with the advances in device implantation.

Q. If an MD has met all the requirements stated in the *Clinical Competency Statement* and *Addendum* but is waiting for the next NASPExAM (IBHRE) (for the physician), can he/she implant on a provisional basis until completing (or getting his/her score from) the NASPExAM (IBHRE)?

A. No. In addition to the technical skills of implanting these complex devices, the *Clinical Competency Statement* provides that a physician also needs to demonstrate an understanding of how to manage and program these devices. As the NASPExAM (IBHRE) (for the physician) is currently the only full exam that provides a comprehensive and uniform peer-reviewed formal assessment of competency, this needs to be successfully passed before independent implantation of these devices can occur.

Q. When will the next NASPExAM (IBHRE) be offered?

A. The examination of special competency in Cardiac Pacing and Cardioversion Defibrillation for the Physician will be held several times a year. For current information and registration visit: www.naspexam.org.

Q. When is the next HRS endorsed didactic course on implantable cardioverter defibrillator and cardiac resynchronization therapy devices?

A. The Heart Rhythm Society will offer its last didactic ICD/CRT device course in November 2006, visit: www.HRSonline.org/icd.

The Heart Rhythm Society ICD/CRT didactic course was developed to fulfill one of the recommendations in the 2004 Clinical Competency Statement (Table 2). The alternate training pathway for ICD/CRT device implantation will conclude in October 2008, as stated in the 2005 *Addendum to the Clinical Competency Statement*. After October 2008, non-electrophysiologists wishing to independently implant ICD/CRT devices must be trained in an approved fellowship training program and should follow the requirements in the COCATS 3 – Task Force 6 (successor to COCATS 2; expected publication in 2007). The Heart Rhythm Society will not offer its course on ICD and Cardiac Resynchronization Devices: Fundamentals of Patient Selection, Implantation, and Follow-Up, after November 2006.

Q. Does the Heart Rhythm Society disclose all financial relationships associated with the ICD/CRT didactic course and NASPExAM (IBHRE)?

A. The Heart Rhythm Society follows full disclosure at the ICD/CRT Didactic Course. NASPExAM (IBHRE) has no funding, we don't do NASPExAM (IBHRE) prep courses and the NASPExAM (IBHRE) online prep course is not sponsored. If it was, we would disclose as such. When HRS begins licensing the ICD didactic course, one of the standard requirements from the Continuing Medical Educational Courses (CME) is full disclosure of sponsors for the course as well as each faculty doing full disclosure. The rules around anything with CME are so strict that one can be assured disclosure will always be included.

Q. When completing the minimum recommendation of 35 pacemaker implants/year (100 over the prior three years), how many “new full-system” implants vs. “revisions” were intended?

A. Over three-quarters of the 35 implants/year should be new “initial” implantations with lead(s). The remainder can be revisions. Any procedure in which one does a device procedure on a patient with an existing device is a revision. When doing revisions they should include: revision with upgrade (various types), revision with lead extraction and replacement, revision with pulse generator change and new lead(s) insertion.

Q. Do I have to complete all the requirements stated in the *Clinical Competency Statement* before being proctored?

A. You may be proctored before passing the NASPExAM (IBHRE) or before attending an HRS endorsed didactic course. However, before independent implantation of ICD/CRT devices can take place, all training requirements as stated in the *Clinical Competency Statement* and *Addendum* must be completed and documented.

Q. Who can be a proctor?

A. A physician experienced in ICD/CRT implantation who qualifies as a proctor should have graduated from an ACGME approved fellowship that meets the current COCATS in electrophysiology and/or device implantation, or have an electrophysiology board certification; be at least two years out of training, currently implanting a minimum of 25 ICDs a year and following a minimum of 50 ICD patients a year personally.

Q. Can I be proctored by a cardiac surgeon with ICD/CRT privileges?

A. No. While it is certainly possible that a cardiac surgeon may have met the proctor requirements, as stated above, it is extremely unlikely that this will be the case. In addition, 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" needs to be obtained. Thus, the intent was to have the proctoring performed only by an experienced and well-trained cardiac electrophysiologist and that the proctee should continue this collaboration once s/he has met the requirements to independently implant ICD/CRT devices. An ongoing collaboration with an experienced electrophysiologist in the area is essential to maintaining competency and an appropriate level of patient care.

Q. What teaching should the proctorship contain?

A. The proctee must be the primary operator with hands-on experience while working under the direction of the proctor, who would be the supervising physician. The unique issues in ICD revisions compared to pacemaker revisions, such as the need to test defibrillation thresholds (DFTs) and the evaluation of sensing problems, should also be included in proctorship. Before being proctored, the proctee must provide the proctor, the supervising physician, a written statement that provides his/her previous number of pacemaker implantation cases. The proctor should also be made aware of any operator complications the proctee may have encountered during his/her training/practice.

Q. Where can I be proctored?

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

Q. Can I be proctored by more than one proctor?

A. Yes, if the proctor(s) meet the Heart Rhythm Society's recommendation: "A physician experienced in ICD/CRT implantation who qualifies as a proctor should have graduated from an ACGME approved fellowship that meets the current COCATS in electrophysiology and/or device implantation, or have an electrophysiology board certification; be at least two years out of training, currently implanting a minimum of 25 ICDs a year and following a minimum of 50 ICD patients a year personally."

The use of more than one proctor is okay if that is what works out best in that situation. There is no reason why more than one proctor can't be used as long as the case is documented. Exposure to more than one technique can be good. However, it would not be ideal to have 10 different proctors for 10 implants.

Q. Does a proctee need to get temporary privileges at the proctor's hospital or institution?

A. In most cases, temporary privileges will be required before the proctorship can begin. Thus, any necessary privileging should be obtained, in accordance to the hospital's policy, before the proctorship begins.

Q. Can proctors collect payment?

A. 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 AdvaMed (Advanced Medical Technology Association).

Q. Who does the billing in a proctorship?

A. Billing should be consistent with the Medicare guidelines, which generally allows the supervising physician to bill under educational training.

Q. What is the proctor and proctee relationship with the patient?

A. 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 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.

Q. What device implantation training for ICD/CRT is recommended for a pediatric electrophysiologist?

A. HRS acknowledges that the guidelines set forth in the COCATS document, as well as those set forth in the *Clinical Competency Statement* and *Addendum*, do not necessarily prepare a practitioner to deal with the implantation issues important for patients with a 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. While it is recognized that there has always been significant overlap in the patient population served by pediatric and adult electrophysiologists, board certification 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 further developed by the Heart Rhythm Society and the Pediatric Electrophysiology Society.

Q. What device implantation training for ICD/CRT is recommended for a surgeon?

A. Surgeons who intend to implant and follow devices alone should follow the same training requirements for non-electrophysiologists as detailed in the *Clinical Competency Statement*. If the surgeon is working with another physician who has expertise in device follow-up and programming, then that surgeon may only need the technical skills alone.

Q. What happens after this training pathway expires?

A. This training pathway in ICD/CRT device implantation should be followed no more than three years from publication (October 2005) of the Addendum in Heart Rhythm. **After October 2008, non-electrophysiologists wishing to independently implant ICD/CRT devices must be trained in an approved fellowship training program and should follow the requirements in the COCATS 3 – Task Force 6 (publication expected in 2007).** Anyone wishing to use this pathway should be aware of this and plan to complete all aspects in this limited period.

Q. How can I be grandfathered to implant an ICD/CRT if I am a practicing electrophysiologist or non-electrophysiologist who has not taken the boards or met the requirements of the competency statement?

A. 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* (October 2005); pass the NASPExAM (IBHRE) within the last ten years, which included ICD knowledge testing; and have completed an HRS sponsored or endorsed didactic course on ICD/CRT implantation. Those who do not meet the minimum number of ICD/CRT implantations prior to the *Addendum's* publication should be proctored. All of the grandfathering requirements should be met within one year of the Addendum's publication in Heart Rhythm.

Q. Can someone who is grandfathered to implant ICDs/CRTs be a proctor?

A. No. Grandfathered physicians do not meet the established criteria to serve as proctors in the training of new physicians to independently implant ICD/CRT devices.
