Heart Rhythm Society/Pediatric and Congenital Electrophysiology Society Clinical Competency Statement: Training pathways for implantation of cardioverter-defibrillators and cardiac resynchronization therapy devices in pediatric and congenital heart patients

Developed in collaboration with the American College of Cardiology and the American Heart Association.

Endorsed by the Heart Rhythm Society, the Pediatric and Congenital Electrophysiology Society, the American College of Cardiology and the American Heart Association.

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Background

Implantable cardioverter-defibrillators (ICDs) are widely used for the management of patients with life-threatening ventricular arrhythmias.[1] The indications for ICD therapy in adults have expanded, due in large part to the results of clinical trials for the primary prevention of sudden cardiac death.[2–4] Although no prospective trials have been performed or published in the pediatric population, reductions in the technical barriers to implantation in smaller pediatric patients and most of those with congenital heart abnormalities[5,6] have also led to increased use in pediatrics.[7–10] This task force is focused on these patients, who are either in the pediatric age range (0–18 years of age) with or without congenital heart disease, or adults with congenital heart disease. Hereafter this patient group will be referred to as "pediatric and congenital heart patients."

Cardiac resynchronization therapy (CRT) without or with defibrillation (CRTD) has been an important development for the treatment of ventricular dysfunction in both adults and children. As with ICD therapy, the data supporting CRT use have been well established in prospective clinical trials in adults with ventricular dysfunction.[11,12] Although the use of CRT is increasing in pediatrics and evidence of utility in some patient populations is increasing,[13,14] as with ICD therapy, no prospective clinical trials have been published. Further, the technical barriers to implantation of CRT/CRTD devices in pediatric congenital heart patients are considerably higher than those in adult patients with normal cardiac anatomy.[13,15]

Pediatric and congenital heart patients are different from adult patients in a variety of ways. Patients are often smaller than an adult, the anatomy can be more complex, and there may be unique hemodynamic and physiological consequences of device selection, lead placement and pacing modality. Further, the emotional and psychological support provided may be as important to care delivery as the technical aspects of the procedure. These issues are particularly relevant for children $\leq$12 years of age. Thus, as more pediatric and congenital heart patients receive ICD and CRT devices, it is important for patient safety and well being to assure the following. The health care team involved in the care of these patients should have knowledge and expertise about the implantation indications, implantation techniques, complications, programming and follow-up for these devices, as well as the non-technical issues relevant to children.

In coordination with the Heart Rhythm Society (HRS) and the Pediatric and Congenital Electrophysiology Society (PACES), this task force recently performed a survey to assess

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1547-5271/$ -see front matter doi:10.1016/j.hrthm.2008.04.012

Table 1 Summary of Device Implant Numbers per Year from Survey of Pediatric EP Programs

	All Centers (n = 49)				EP Training Programs (n = 11)			
	Mean	Median	Min	Max	Mean	Median	Min	Max
New Transvenous Pacing	13.2	10	0	80	21.5	16	2	80
Pacing Generator Replacement	9.9	6	0	60	15.7	10	2	60
Total: Transvenous Pacing	21.0	14	0	140	37.2	30	6	140
New Transvenous ICD	6.9	6	0	30	10.9	10	1	30
ICD Generator Replacement	3.0	2	0	19	5.1	4	0	19
Any Transvenous CRT	2.0	1	0	12	3.5	2	0	12
Total: Transvenous ICD/CRT	10.2	8	0	61	19.5	15	1	61
Total: Transvenous Procedures	31.2	24	0	201	56.6	50	7	201
New Epicardial Pacing	9.8	7	0	30	17.1	17	7	29
New Epicardial ICD	2	1	0	8	2.2	2	0	8
New Epicardial CRT	1.7	1	0	12	2.4	1	0	8
Total: Epicardial ICD/CRT	2.7	1	0	21	5.0	4	0	21
Total: Epicardial – All	10.6	9	0	43	20.5	16	0	43

current implant volumes and physician backgrounds for programs that implant pacemakers, ICDs and CRT/CRTD devices in pediatric and congenital heart patients. A total of 49 pediatric programs responded, of which 42 were in the United States, 2 from Canada, 3 from Europe and 2 from South America. Of the 49 centers that responded, 29 were from a *freestanding Children's Hospital*. These programs centers were less likely to be associated with an adult electrophysiology program than the 20 programs from a *Children's Hospital within a Hospital*. Eleven of the 49 programs provided specialized 4th year training in electrophysiology (EP) with device implantation experience, but in one of those programs the pediatric cardiac surgeons were the primary implanters for all device procedures. The reported results in Table 1 include pacing only device implants even though the competency guidelines in this document only address ICD/CRT/CRTD implants. Procedure numbers were generally low (Table 1). For all the programs, the median number of pacing only procedures per year was 14 (10 new implants), with a median of 8 transvenous ICD/CRT/CRTD procedures. For the 11 programs with dedicated EP training, there were a median of 30 pacing only procedures (16 new), with a median of 15 transvenous ICD/CRT/CRTD procedures. These data highlight an important paradox concerning implantable devices in pediatric and adult congenital patients: the number of ICD/CRT/CRTD procedures is very small, but the average complexity is high, requiring the unique knowledge, skills and experience of a specialist trained in congenital heart disease. Further, a significant minority of the implants in this patient population require the skills of a cardiac surgeon, who may have limited experience in device management. Implantation and follow-up of these devices in pediatric and congenital heart patients also generally involves a team of individuals who coordinate their activities to optimally care for the patient. For all the above reasons, the competency guidelines for ICD/CRT/CRTD implantation will of necessity be considerably different than those for the typical adult patient, leading to the formation of this task force and the creation of this document.

Adult Cardiovascular Medicine Core Cardiology Training (COCATS) and the Heart Rhythm Society Training Pathways (Table 2)[16–19]

In 2004, the Heart Rhythm Society published a clinical competency statement defining training pathways for ICD/CRT implantation in adult patients[16]; this was followed with a 2005 addendum that clarified the competency guidelines for implanting non-electrophysiologists.[17] For physicians currently in an adult electrophysiology training program, the guidelines for ICD implantation were left the same as the prior COCATS 2 Task Force 6 training guidelines[19]: 25 primary ICD implants, 10 ICD revisions or replacements and 50 ICD follow-up visits. For CRT, 15 supervised implants were required. For experienced pacemaker implanters, defined as 35 device implants per year and 100 over the prior 3 years, the requirements are for 10 ICD implants, 5 ICD revisions and 5 CRT implantations, to

Table 2 Recommended HRS Alternate Training Pathway for Implantation of ICD/CRT Devices in Adult Patients (training expires October 2008)

Trainees
- ICD
  - 25 primary implants
  - 10 revisions/replacements
  - 50 follow-up visits
- CRT
  - 15 primary implants

Experienced Implanters* (35 device implants per year, 100 over 3 years)
- ICD
  - 10 proctored primary implants
  - 5 proctored revisions/replacements
- CRT
  - 5 proctored primary implants
- IBHRE certification
- **This pathway can no longer be used after October 2008*
- Organized program for tracking outcomes and complications

be proctored by a Board Certified electrophysiologist who meets certain proctoring criteria[16,17]; the use of this pathway, as published in the 2005 Addendum, will expire in October 2008. Maintenance of competency requires 10 ICD/CRT/CRTD procedures and 20 patient follow-up visits per year.

Of note, an updated version of the new COCATS 3 Task Force 6 training guidelines has been completed, with a change to requiring 50 ICD (25 single-chamber, 25 dual-chamber) and 25 CRT primary implants, 30 revisions, and 200 follow-up interrogations/programming for all device categories together[20]; these numbers reflect increased utilization in the adult population. With the October 2008 expiration of the HRS training pathway, the updated COCATS 3 Task Force 6 training curriculum must be completed for all those who wish to independently implant ICD/CRT devices in adult patients. After input from the Pediatric and Congenital Electrophysiology Society (formerly Pediatric Electrophysiology Society), it became clear to HRS leadership that in part for the reasons discussed in the Background section above, the guidelines developed for adult patients could not be applied directly to the care of pediatric and congenital heart patients. Consequently, the following paragraph was included in the Training Pathways Addendum.[17]

The Heart Rhythm Society acknowledges that the guidelines set forth in the COCATS document[18,19] as well as those set forth in this document[17] 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.[17]

The current task force was appointed to complete that task, and this document developed as its work product. The task force consisted of 10 members, 2 adult and 8 pediatric electrophysiologists from the Heart Rhythm Society and the Pediatric and Congenital Electrophysiology Society, which also included representation from the American College of Cardiology and the American Heart Association. This statement summarizes the opinion of the writing group members based on their own experience in treating patients, as well as a review of the literature, and is directed to all health care professionals and health care institutions that are involved in the care of pediatric and congenital heart patients. When using or considering the guidance given in this document, it is important to remember that the ultimate judgment regarding care of a particular patient must be made by the health care provider and patient in light of all the circumstances presented by that patient.

Prior Recommendations for Training in Pediatric Cardiology–Task Force 4: Pediatric Cardiac Electrophysiology[21]

A prior task force developed competency guidelines for pediatric physicians who implant pacemakers and ICDs at the end of specialized fellowship training.[21] These original guidelines followed the two track approach recommended for adult training.[19] Track 1 involves electrophysiologists who prescribe and follow patients with pacemakers and ICDs. Track 2 is for individuals who implant, as well as prescribe and follow patients with pacemakers and ICDs. For both Track 1 and Track 2, the guidelines recommended advanced understanding of pacemaker and ICD indications, optimal pacemaker choices, and participation in the evaluation or follow-up of 75 patients with a pacemaker or ICD. In addition, attendance at intra-operative testing of 35 pacemaker or ICD implants (20 new, 10 revisions, 5 ICDs) was recommended. For Track 2, where pacemaker and ICD training includes implantation, direct participation in a total of at least 50 pacemaker and device implants, of which ***a reasonable number*** should be complex devices including ICDs was recommended. It was recommended that participation include scrubbing for the surgery, catheter manipulation, intra-operative testing, and generation of an implant report. It was further recommended that at least 15 of the implantations should be in children $\leq$12 years of age, and that experience with implantation in patients with repaired congenital heart disease was essential.

The data from our survey of 49 pediatric EP centers do not address procedures in patients $\leq$12 years of age. However, it does indicate that about half of the pediatric EP training centers perform fewer transvenous device procedures per year than the number recommended by the prior pediatric training guidelines for an individual trainee. Since most trainees will not be available for every procedure during their specialized EP training year, it is unlikely that many pediatric trainees can achieve the procedure numbers recommended in the previous guidelines during a 1 year period.

The previous criteria for pediatric ICD training were non-specific using the term "a reasonable number." Further, the guidelines were developed simultaneously with the guidelines for adult patients, so coordination of the criteria for ICD devices between adults and pediatric patients was not established. Finally, because CRT implantation in children was rare when the guidelines were being developed, implantation of these devices was not addressed. Consequently, this document is intended to establish new criteria for ICD/CRT/CRTD implantation, replacing the less specific references to ICD implantation in the previously published training recommendations.[21] Nonetheless, a number

Table 3 Universal Criteria for ICD/CRT/CRTD Implantations in Pediatric and Congenital Heart Patients

Physician Criteria
• NASPExAM/IBHRE or CCEP certification
Institutional Criteria
• Facility and staff appropriate for patient population
• Organized program for device tracking and follow-up
• Organized program for tracking outcomes and complications
• For patients with complex congenital heart disease (see text for definition) or ≤12 years, the following must be immediately available:
○ pediatric and congenital interventional catheterization expertise
○ pediatric and congenital cardiac surgical expertise

of the concepts identified in the prior document, such as experience in younger children and patients with complex anatomy, still exist. Finally, these new guidelines recognize that in many pediatric programs, the numbers of ICD/CRT/CRTD implants that occur in the typical one year training period may be too small for adequate training, an observation that is particularly relevant for CRT devices. Consequently, the guidelines below allow for acquisition of the recommended numbers through either the use of additional years after formal training, or participation in cases with an adult training program.

Section A. Universal Criteria for Implantation for Pediatric and Congenital Heart Patients (Table 3)

A variety of criteria specific to the background and training of the physician implanter are addressed in the sections below under **Additional Criteria by Physician Specialty.** The intent of this section is to assure patient safety by defining a minimum set of criteria related to issues other than the physician's implanting skills, primarily the environment where the implant occurs and patient follow-up. Regardless of background, physicians who are considered competent to implant devices in these patients should all have ***passage within the last 10 years of the NASPExAM, now known as the International Board of Heart Rhythm Examiners (IBHRE,*** www.ibhre.org***), or the Clinical Cardiac Electrophysiology (CCEP) certification from the American Board of Internal Medicine.*** Pediatric cardiologists can obtain only IBHRE certification, whereas adult cardiologists can obtain either IBHRE or CCEP certification. Such certification ensures knowledge of advanced programming and devices. For current physician implanters who are not yet certified by IBHRE, the certification must be completed by 3 years from the date of this document's publication. In addition, the following should be present at every implanter's institution, whether the implanter is a pediatric or adult cardiologist:

- ability to accommodate pediatric and congenital heart patients
- trained staff to care for pediatric and congenital heart patients
- organized program for device tracking and follow-up
- organized program for tracking of outcomes and complications

For implantation of devices in patients with complex congenital heart disease (e.g., current cardiac-based cyanosis, single ventricle physiology, transposition of the great arteries [d-TGA—post atrial switch correction, or L-TGA—"corrected"], shunt physiology, palliated or incomplete repairs), or in patients ≤12 years of age, the following should be immediately available in the same institution and locale where the implantation occurs:

- pediatric and congenital interventional catheterization expertise
- pediatric and congenital cardiac surgical expertise

These 2 criteria are intended to indicate that in the event of an emergency, interventional and surgical expertise can be provided to the patient without inter-hospital transport. The above criteria in this section will be referred to in subsequent sections as the *Universal Criteria*.

It should be noted that for all the classes of criteria below, up to 2 physicians can act as *co-primary implanters* if they both play an integral role in the technical portions of the procedure. Thereby, each physician can count the procedure towards satisfaction of the device number criteria below. This process is allowed because the complexity of many of the implants in pediatric and congenital heart patients often mandates 2 primary operators in a team approach. Further, if the physician plays a critical role for an epicardial implant, including directing lead placement and approach, the procedure can be considered a primary implant for these competency guidelines.

Section B. Additional Criteria by Physician Specialty—Pediatric Electrophysiologists (Table 4)

B1. Physicians Currently in a Pediatric Electrophysiology Training Fellowship (Table 4)

Physicians in this category have already completed or are completing a fully certified fellowship program in pediatric cardiology. Thus, these physicians will either be Board Certified or eligible to take the subspecialty Pediatric Cardiology board exam of the American Board of Pediatrics. Although specific threshold device numbers for patient age and underlying heart disease are given in this category, during prior training all of these physicians will have participated in invasive catheter procedures in a large number of patients of all ages, with and without complex structural heart disease. Consequently, familiarity with the issues specific to the youngest patients and those with complex anatomy is assured. To that end the following guidelines apply to these trainees:

- Universal Criteria (Table 3)
- 25 ICD/CRT/CRTD primary implants, revisions or replacements, the majority of which should be in patients ≤12 years of age and/or with complex congenital heart disease.

Table 4 ICD/CRT/CRTD Criteria for Pediatric Electrophysiologists

Physicians Currently in Training
• Universal Criteria
• 25 primary implants/revisions/replacements
○ majority in patients ≤12 years and/or with complex congenital heart disease.
○ may be accrued over multiple years
○ may be accrued in adult EP training program
• 50 follow-up visits
Physicians Currently Implanting with Prior EP Training
• Universal Criteria
• Board Certified or eligible for subboard in Pediatric Cardiology
• Minimum of 1 year of pediatric EP fellowship or ≥5 years of practice experience in pediatric EP, with ICD device implant experience
• Meet maintenance criteria
○ 10 implants/revisions/replacements per year
○ 20 follow-up visit per year
Alternative Pathway for Low Patient Volume
• Universal Criteria
• Board Certified or eligible for subboard in Pediatric Cardiology
• Minimum of 1 year of pediatric EP fellowship or ≥5 years of practice experience in pediatric EP, with ICD device implant experience
• Documented association with adult EPs who have
○ ICD/CRT/CRTD competency in adults[2,3]
○ CCEP certification
○ credentials to practice in relevant Pediatric Laboratory
○ available for consultation and emergency assistance during all procedures

The survey results indicate that only two EP training centers perform more than 25 such procedures per year and one of those centers has multiple 4th year trainees. Consequently, it is unlikely that the recommended number of procedures can be acquired in a single year of training for most trainees, leading to the following:

- ○ Procedures may be accrued over multiple years
- ○ Procedures may be accrued through participation in an adult training program

- 50 ICD/CRT/CRTD follow-up visits

B2. Current Physician Implanters with Prior Training in Pediatric Electrophysiology (Table 4)

As noted in the introduction, relatively few pediatric and congenital heart patients require implantation of an ICD or CRT device. Currently most of these patients are cared for by pediatric cardiologists, but the number of adult patients is growing rapidly and already outnumbers the pediatric ones for some anomalies. Consequently, these guidelines will include a variety of competency pathways. This section of the guidelines addresses the pediatric trained specialist, who is generally trained for and experienced with device implantation and management in pediatric and congenital heart patients. Implanters in this category must meet all of the following criteria:

- Universal Criteria (Table 3)
- Board Certified in Pediatric Cardiology or eligible to take the sub-board examination
- Either have a minimum of 1 year of specialized training in pediatric and congenital electrophysiology with pacing device implantation experience, or ≥5 years of practice experience in pediatric electrophysiology with ICD device implantation experience
- Meet maintenance criteria of
  - ○ 10 ICD/CRT/CRTD primary implants/revisions/replacements per year
  - ○ 20 ICD/CRT/CRTD follow-up visit or evaluations per year

B3. Special Alternative Pathway for Pediatric Electrophysiologists Trained in Device Implantation (Sections B1 and B2), Who Cannot Meet the Criteria for Competence and Maintenance Due to Low Patient Volume (Table 4)

It has been demonstrated that a variety of factors affect the outcomes for pediatric cardiac surgical procedures.[22] Although procedure volume is one of the factors that clearly plays a role,[22] it is equally clear that other factors may dominate in particular programs.[23,24] In fact, there are smaller to mid-sized pediatric cardiology programs with excellent surgical outcomes and a few larger programs with relatively poor outcomes for some complex procedures.[22–24] Although similar data are not currently available for device implantation, several factors are similar to the situation for surgical procedures. That is, excellent outcomes may be achieved by a well trained pediatric electrophysiologist in a program that implants too few devices to qualify for the competency and particularly the maintenance criteria defined above. Further, these pediatric electrophysiologists may be the only individuals in an institution appropriately trained to handle the younger pediatric patients and those with congenital heart disease. To accommodate the needs of these programs and still maintain assurance of safety for the patients and competency for the involved physicians, the guidelines committee agreed that a formal collaboration with an adult electrophysiologist is adequate. To that end the following criteria are given for the implanting pediatric electrophysiologist who cannot meet the case numbers defined above.

- Universal Criteria (Table 3)
- Board Certified in Pediatric Cardiology or eligible for taking the sub-board
- Either a minimum of 1 year of specialized training in pediatric and congenital electrophysiology with pacing device implantation experience, or ≥5 years of practice experience in pediatric electrophysiology with ICD device implantation experience
- Formal association documented by a signed letter of agreement, with adult electrophysiologists who meet all the competency criteria for ICD/CRT/CRTD implantation in adults,[16,17] are board certified by passage of the CCEP, and who are credentialed by their institution to practice in the relevant Pediatric Laboratory. An adult

Table 5 ICD/CRT/CRTD Criteria for Adult Electrophysiologists

Physicians Currently Implanting with Prior Electrophysiology Training
- Universal Criteria for institution
- Meet all the competency criteria for implantation in adults[2,3]
- For implantation in patients ≤12 years of age:
  - implant experience in a minimum of 10 patients ≤12 years
  - documented prior consultation with or direct referral from a pediatric cardiologist
- For implantation in patients with complex congenital heart disease, either
  - have significant experience with implantation in such patients, or
  - documented prior consultation with or direct referral from a specialist in pediatric or adult congenital cardiology, preferably written
- Pediatric or adult congenital cardiologist available for consultation during procedure (does not require physical presence)
- Must assure appropriate device follow-up

electrophysiologist must be available for consultation and emergency assistance during all procedures.

Section C. Additional Criteria by Physician Specialty—Adult Electrophysiologists (Table 5)

Current Physician Implanters with Training in Adult Electrophysiology

The relevant differences between the typical adult cardiac patient and the pediatric and congenital heart patient have been reviewed in the background section of this document. However, in many locations, the only individuals available for device implantation in these patients are electrophysiologists trained in an adult program. Thus, it is important to define competency criteria for these physician implanters. The individuals in this category must meet all the competency criteria for ICD/CRT/CRTD implantation in adults,[16,17] and the Universal Criteria for the institution (Table 3). In addition, for implantation in patients ≤12 years of age, the implanter should meet the following criteria:

- device implantation experience in a minimum of 10 patients ≤12 years of age (may be acquired over multiple years)
- the procedure can be performed only after documented consultation with, or direct referral from, a pediatric cardiologist
- A pediatric cardiologist should also be available for consultation during the procedure

For implantation of devices in patients with complex congenital heart disease, as defined in Section A above, or congenital heart disease with any residual lesion (e.g., most patients with Tetralogy of Fallot, residual intracardiac shunts, incomplete repairs), the implanter should:

- have experience with the implantation of devices in such patients, and
- have document consultation with, or referral from, a specialist in pediatric or adult congenital cardiology prior to the implantation
- A pediatric or adult congenital cardiologist should also be available for consultation during the procedure (does not require physical presence).

Regardless of patient age or condition, it is the responsibility of the implanting physician (adult electrophysiologist in this case) to assure that appropriate device follow-up is arranged.

Section D. Additional Criteria by Physician Specialty—Non-Electrophysiologists (Table 6)

Physicians Currently Implanting Devices in Pediatric and Congenital Heart Patients, Who Have Not Trained in Electrophysiology

Some ICD/CRT/CRTD implantations in pediatric and adult congenital heart patients involve the need for epicardial leads and/or patches.[5,7] For the vast majority of such implants, the implanter will be a physician trained in cardiac surgery. However, the individual may or may not be trained in pediatric cardiac surgery or regularly implant such devices. Further, in some pediatric cardiology programs, a surgeon has historically been responsible for the implantation of all pacing and defibrillation devices, with referral and follow-up provided by a non-implanting fellowship trained pediatric electrophysiologist. Thus, this category is designed to address two situations. The first is for a surgeon who is an experienced device implanter in pediatric patients, but has not completed formal training in clinical cardiac electrophysiology, so cannot meet any of the above criteria. The second is for a pediatric cardiac surgeon who is familiar with the anatomical complexities of the case or the surgical issues important in small children, but only occasionally has the need to implant pacing and defibrillation devices. Such physicians could use either of the two following criteria sets for assuring adequate competency and patient safety.

- Universal Criteria for institution

Table 6 ICD/CRT/CRTD Criteria for Non-Electrophysiologists

Physicians Currently Implanting in Pediatric and Adult Congenital Heart Patients without Prior Electrophysiology Training
- Universal Criteria for institution
- Perform procedures in collaboration with, either
  - a trained electrophysiologist who meets competency criteria for implantation in pediatric and congenital heart patients, or
  - a trained pediatric electrophysiologist who meets criteria for evaluation and follow-up of ICD/CRT/CRTD in pediatric and congenital heart patients and has passed IBHRE, but does not meet the pediatric implantation criteria
- Must assure appropriate device follow-up

- Perform procedures in collaboration with any electrophysiologist who meets all the competency criteria for one of the pathways for ICD/CRT/CRTD implantation in pediatric and congenital heart patients described in this document; or
- Perform procedures in collaboration with a trained pediatric electrophysiologist who both meets all of the criteria for evaluation and follow-up of ICD/CRT/CRTDs defined in Sections B1 and B2 above, and has passed the IBHRE exam, but does not meet the pediatric competency implantation criteria in this document (Sections B1, B2, B3)

Although an industry representative may be present during the procedure and may have passed the IBHRE for allied professionals, such presence does not eliminate the need for a physician who meets one of the two criteria stated immediately above.

Regardless of patient age or condition, it is the responsibility of the implanting physician (surgeon in this case) to assure that appropriate device follow-up is arranged for, presumably with the collaborating electrophysiologist.

Summary

The competency criteria presented in this document are intended to account for the limitations presented by low patient numbers and the complexities of small patient size and abnormal anatomy in the pediatric and congenital heart population, while still recognizing the need for device implantation and management expertise in these patients. As with many pediatric issues, patient safety was prioritized by the task force as a primary issue in designing the guidelines. In particular, Universal Criteria were defined that assure a threshold level of physician and institutional expertise, regardless of the background of the physician implanter. To address the spectrum of specialists who participate in the care of pediatric and congenital heart patients, the task force designed criteria that allow for pediatric electrophysiologists, adult electrophysiologists and non-electrophysiologists to either obtain competency status themselves or implant and manage devices with the collaboration of another physician who meets all the training criteria. It should be highlighted that because of the relatively small implant volumes in all current pediatric training programs, obtaining the ICD/CRT/CRTD procedure numbers set for specialty training of a pediatric cardiologist will generally require more than one year. Finally, it is important to note that this task force was composed of both pediatric and adult electrophysiologists who implant devices in the relevant patient population, and are involved with the training of electrophysiology specialists. Despite the broad background of the task force members, complete agreement was reached on all of the criteria set forth in this document.

Acknowledgement

The task force would very much like to thank George van Hare, MD, and Hugh Calkins, MD, members of the Heart Rhythm Society Board of Trustees for their role in setting up the task force and providing review of the document during the writing phase. Further, Donna Goldberg from the staff at HRS, who provided superb support in all phases of the committee's activities.

Appendix I:

Author Relationships with Industry

Committee Member	Consulting Fees/ Honoraria	Speaker's Bureau	Ownership/Partnership/ Principal	Research Grants	Institutional or Other Financial Benefit
Charles I. Berul, MD	• Johnson & Johnson • Boston Scientific	None	None	Medtronic, Inc.	None
MacDonald Dick II, MD	• Medtronic, Inc.	None	• CryoCath Technologies	None	• Medtronic, Inc. (Fellowship Support)
John P. DiMarco, MD, PhD	• Boston Scientific* • CV Therapeutics* • Daiichi Sankyo • Medtronic, Inc.* • Novartis* • St. Jude Medical • Sanofi-Aventis Solvay	None	None	• Boston Scientific* • CV Therapeutics* • Medtronic, Inc. • St. Jude Medical • Sanofi-Aventis	None
Andrew E. Epstein, MD	• Boston Scientific • CryoCath • Medtronic, Inc. • Sanofi-Aventis • St. Jude Medical*	• Boston Scientific • Medtronic, Inc. • Reliant Pharmaceuticals • Sanofi-Aventis • St. Jude Medical	None	• Biotronik* • Boston Scientific* • C.R. Bard/Electrophysiology Division* • Irving Biomedical* • Medtronic, Inc.* • St. Jude Medical*	• Medtronic, Inc.* (Fellowship Support) • St. Jude Medical* (Fellowship Support)
Richard A. Friedman, MD	• St. Jude Medical	None	None	None	• Medtronic, Inc.* (Fellowship Support)
Eric Rosenthal, MD	None	None	None	None	None
J. Philip Saul, MD	Pfizer Pharmaceuticals	None	None	• Bristol-Myers Squibb	None
Michael J. Silka, MD	None	None	None	None	None
Elizabeth A. Stephenson, MD	None	None	None	None	None
Victoria L. Vetter, MD	None	None	None	None	None

This table represents the relationships with industry that were reported by the authors as relevant to this topic.

*Indicates significant level relationship (more than $10,000).

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