

implantable cardioverter-defibrillator implantation, or both. The same amount of surgical experience with bradycardia pacemaker implantation is required and may be supplemented with surgical training for implantable cardioverter-defibrillator implantation. If the level 3 trainee chooses this option, he or she must participate as the primary implanter (under direct supervision) in at least 20 implantable cardioverter-defibrillator system implantations as well as the management and follow-up skills addressed under level 3. The trainee must also participate in the surgical replacement or revision of at least 10 implantable cardioverter-defibrillator systems and follow-up of at least 50 implantable cardioverter-defibrillator patient visits. Level 3 training with the option of pacemaker or implantable cardioverter-defibrillator implantation, or both, requires a minimum of 1 year of dedicated clinical cardiac electrophysiology and device implantation training beyond the 3-year cardiology program.

Evaluation, Competency and Privileges

The program director should maintain adequate records of each individual's training experiences and performances of various procedures for appropriate documentation for levels 1, 2 and 3. The trainees should also maintain records of participation in the form of a logbook containing clinical information, procedure performed and outcome of procedures, including any complications encountered.

Competency examinations in electrocardiography and other self-assessment programs are available through the ACC. Training directors and trainees are encouraged to utilize the resources. The ACGME has recently published the essential components of a specialized program for training in clinical cardiac electrophysiology. The ABIM provides a special examination for additional certification in clinical cardiac electrophysiology. Information concerning the training requirements for admission to the examination can be obtained from the ABIM; NASPE also has a written examination of special

competency in device therapy, but it does not provide certification.

Subsequent privileges to perform invasive procedures should be primarily granted on the basis of the technical expertise acquired in the training program, the documented training and the recommendations of the directors of electrophysiology/pacing programs.

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Task Force 7: Training in Cardiovascular Research

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All cardiology training should be carried out in institutions in which the opportunity to participate in research is available. The training site should be one that will provide an atmosphere of intellectual inquiry and support of the investigational process.

It is important that every cardiovascular trainee participate directly in research. Cardiology is a dynamic clinical field where rapid transfer of knowledge from basic and clinical research to clinical care will continue to occur. This pattern will only accelerate in the future. Cardiovascular research is defined in

the broadest terms possible because recent history makes it abundantly clear that advances in the care of patients with cardiovascular disease have come from diverse areas of medical science. If the clinical cardiologist is to maintain clinical competence and improve clinical knowledge in step with the progress of the field, it is crucial that he or she thoroughly understands the concepts, methods and pitfalls of the research process.

Every trainee should have direct involvement in the practical aspects of research, with emphasis on review of published data, research design, data analysis and logical deduction. The research experience plays a unique role in developing the skills in continuing self-education needed by all cardiovascular specialists. Trainees contemplating a career in investigative cardiology bear a special responsibility to prepare effectively to advance understanding in the broad area of cardiovascular science and especially the clinical application of new knowledge.

General Standards

Training Institution

The training institution must have staff and facilities for research. Opportunities for research for the trainees should be available not only within the clinical cardiovascular division, but also within the basic biomedical science departments of the institution. Availability of expertise in epidemiologic methods, outcomes evaluation, biostatistics and biomedical ethics must be readily available. Optimally, cardiovascular training should be carried out in a university teaching hospital or similar institution. Where this is not feasible, an active ongoing affiliation with a university is essential.

Preparation

Individual trainees should have, before their appointment, appropriate preparation in the biologic, epidemiologic and physical sciences basic to medicine. If additional course work is desirable and appropriate, it should be available, and trainees should be encouraged to avail themselves of it.

Faculty

Faculty of the training program must include several trainees with proved skill as investigators, demonstrated by published original research in peer-reviewed journals. The critical mass of the faculty requires several cardiovascular investigators, not all of whom need to be clinical cardiologists. In general, there should be no more than one trainee per full-time staff member for research training. At least one full-time faculty member from each training program should have demonstrated skill as a clinical investigator.

Content of Training Program

Research "Tracks"

Research training will ordinarily take place in one of three "tracks": *level 1* = trainees entering the clinical practice of cardiovascular medicine; *level 2* = trainees planning a commitment to teaching and clinical investigation; *level 3* = trainees

planning a substantive commitment to basic cardiovascular research.

Clinical Investigation

Clinical investigation must be carried out under the supervision of an experienced investigator and according to approved principles of biomedical ethics and institutional rules for patient protection. It must be recognized that clinical research is difficult because of the complexity of achieving valid scientific conclusions while working with a diverse population and simultaneously protecting the interests of each patient.

Components of Research

The trainee should develop skills in at least the following areas:

1. *Literature study*, to ascertain the exact state of knowledge before undertaking new investigation.
2. *Formulation of hypothesis and specific goals*, ensuring that the hypothesis is testable, that the goals are appropriate and statistical power is achievable.
3. *Development of the research plan and the protocol*, including study design, recruitment of subjects, ethical considerations, informed consent and protection of privacy, data collection modes, full description of procedures and institutional approval of human investigation, where appropriate.
4. *Data collection*, including preparation of routine data forms.
5. *Development of analytic methods or procedural skills*, as required, and particularly the handling of artifacts, missing data, outliers and statistical inference.
6. *Presentation of results*, preferably both oral and written, emphasizing that no investigation is complete until it is reported in peer-reviewed journals.
7. *Risk-benefit analysis*, regarding both patient (subject) risk and benefit and societal risk and benefit.

In the case of multiple center clinical trials, participation in the full range of special activities outlined here is required.

The clinician lacking expertise in these areas may be unable to interpret critical reports bearing directly on his or her practice. New data may be accepted uncritically or important advances recognized tardily. The training program should provide frequent opportunities for faculty and trainees to review and analyze small- and large-scale clinical and basic research reports in depth.

Duration of Research Training

For trainees planning careers in the clinical practice of cardiovascular medicine (level 1), a minimum of 6 months (and in many instances up to 12 months) should be devoted to a specific project or projects. For those planning a substantive commitment to teaching and clinical investigation (level 2), 1 full year (e.g., 100% of time for 1 year or 50% of time for 2 years) should be devoted to clinical research. For those planning a career in basic research (level 3), 2 to 3 full-time years, working

directly with an experienced mentor, are now needed in most cases. Such training constitutes only the beginning of the education of an independent cardiovascular investigator.

Advanced Training for Trainees Considering Entering Investigative Cardiology

Trainees preparing for clinical careers in research (level 3) need an extensive foundation in scientific investigation. Some trainees will have obtained thorough research preparation in combined MD/PhD programs, but may lack the special skills involved in clinical research or certain tools that are appropriate to their personal research goals. These may be obtained in a postdoctoral research fellowship experience or as part of the cardiology traineeship.

For full-time training, the trainee should enter the laboratory of a productive and active scientist, MD or PhD, in any qualified institution (not necessarily where he or she is obtaining direct training).

Trainees who aim for a career in investigative cardiology but who have not had the opportunity to obtain a PhD or equivalent training at the time they begin their cardiology traineeships should have the opportunity and be encouraged to obtain the necessary basic science course work and laboratory experience necessary for a productive research career. Current models of this type of training include the American Heart Association Clinician Scientist Award and the National Heart, Lung, and Blood Institute program for clinical scientists and physician scientists (CIDA).

Teaching and Manuscript Review

It is important that the trainee be introduced to basic principles and skills of education because almost all academic cardiologists devote a significant amount of time to teaching. It is also useful to provide opportunities for the critical review and analysis of published manuscripts.

Compensation

Compensation during the often prolonged period of research training should be sufficient to allow a full-time commitment to this training.

Evaluation

Evaluation by the Training Director or Research Sponsor, or Both

Evaluation of a trainee's progress and skills should be subjective as well as objective, based on agreed on criteria and standards, and should be ongoing throughout the training period. The process and documentation currently required for admittance to the American Board of Internal Medicine (ABIM) Subspecialty Board Examination serves as a model for such evaluation. Each trainee's competence and understanding should be documented at the completion of training.

Publication

Trainees should be encouraged to publish substantive results, thereby providing an evaluation by peer-reviewed journals.

Flexibility

It must be appreciated that the education of future investigative cardiologists is a continuing process and that they usually remain in an educational institution where they are immersed in clinical cardiology. They often have unique demands that may require altering the sequence and exposure of clinical training, consistent with their previous clinical experience. Therefore, the program director should be afforded latitude in the assignment of responsibilities for the 3 years of training while guaranteeing full clinical competence.

Summary

It is vital to the future intellectual health of cardiovascular medicine and the welfare of patients with cardiovascular disease that all future cardiologists be familiar with the principles and tools of research. Training in research requires the intense involvement of productive and established investigators. Those trainees preparing for a career in investigative cardiology require a carefully developed but flexible educational plan that will permit them to be successful in their research careers over an extended period.