October 4, 2005:1401-3

Task Force 7: Training Guidelines for Research in Pediatric Cardiology

Advanced Training (Level 3): Advanced Expertise in Adults With CHD

The COCATS 2 guidelines recommend an additional year of continued participation in clinical practice relating to ACHD to achieve advanced level 3 training. In addition to the guidelines for advanced level 2 training, level 3 should include active participation in clinical and/or laboratory research in conjunction with clinical activities and direct participation in additional cardiac catheterization and echocardiographic procedures in adults with CHD.

doi:10.1016/j.jacc.2005.07.020

REFERENCES

- 1. Skorton DJ, Garson A. Training in the care of adult patients with congenital heart disease. Cardiol Clin 1993;11:717–20.
- Child JS, Collins-Nakai RL, Alpert JS, et al. Task force 3: workforce description and educational requirements for the care of adults with congenital heart disease. J Am Coll Cardiol 2001;37:1183–7.

APPENDIX

The authors of this section declare they have no relationships with industry pertinent to this topic.

Task Force 7: Training Guidelines for Research in Pediatric Cardiology

D. Woodrow Benson, JR, MD, PHD, *Chair*, H. Scott Baldwin, MD, FACC, FAHA, Larry T. Mahoney, MD, FACC, FAHA, Tim C. McQuinn, MD, FAAP

Historically, pediatric cardiology has been a dynamic clinical field where a rapid transfer of knowledge from the research laboratory to the bedside occurred regularly. Conversely, many problems on which laboratory effort was focused were first identified at the bedside. This pattern continues today, and there is every reason to believe it will accelerate in the future. Research in pediatric cardiology is defined in broad terms because it is anticipated that future advances in the care of pediatric patients with cardiovascular disease will go beyond current practice and come from diverse areas of biomedical science. If the pediatric cardiologist is to maintain clinical competence and improve clinical knowledge in step with the progress of biomedical science, it is crucial that he or she thoroughly understands the concepts, methods, and pitfalls of the research process. It is important that every pediatric cardiology trainee participate directly in research as training that is limited to practical experience can teach only the status quo, and the status quo cannot improve patient care. The guidelines that follow are based in part on recommendations published in 1995 and revised in 2002 (1,2) and a Task Force Report on Pediatric Cardiovascular Diseases (3).

In addition to direct involvement in research, every trainee should gain practical experience in 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 essential to all pediatric cardiologists. Trainees contemplating a career in investigative cardiology bear a special responsibility to prepare effectively to advance understanding in the broad area of clinical, translational, and basic cardiovascular science as well as population science, behavioral science, quality of care, and outcomes research. Because the research experience is such an integral component, pediatric 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 provides an atmosphere of intellectual inquiry and support of the investigational process.

GENERAL STANDARDS

The training institution must have staff and facilities for research. Opportunities for research for the trainees should be available not only within the clinical cardiology division, but also within biomedical science, epidemiological, or other clinical programs of the institution. Availability of expertise in cardiac development, cardiovascular genetics, epidemiology, outcome evaluation, biostatistics, population science, behavioral science, quality of care, outcomes research, and biomedical ethics should be readily available. There should be a critical mass of investigators, and it is expected that cardiovascular investigation be well represented. Not all investigators need to be clinical cardiologists, but at least one full-time faculty member from each training program should have demonstrated skill and research productivity as an investigator.

DURATION OF RESEARCH TRAINING

For trainees planning careers in education and patient care, the core research training should include substantial research time devoted to a specific research project or projects. In most cases, this will encompass a full 12 months of the training period. For those planning a career with a major emphasis on investigation, an additional one to two years beyond the core research training, working directly with an experienced funded mentor, is needed in most cases.

CONTENT OF TRAINING PROGRAM

Research training is an important part of the core instruction of every trainee. Those planning a substantive commitment to clinical, translational, or basic cardiovascular research, as well as population science, behavioral science, quality of care, and outcomes research, will need advanced research training.

Core Research Training

It is anticipated that in most instances core research training will be devoted to a specific project or projects with a clinical or translational research focus. Such research training 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 such 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. Advanced educational activities as outlined by the American Board of Pediatrics may meet the core research training objectives when appropriately planned, supervised, and evaluated by faculty with expertise in this area.

Components of Core Research Training

With appropriate mentoring, 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 that 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 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.
- 8. Health policy implications of research.

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 might 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. Core research training in the eight skill areas in the previous text could be most easily obtained as part of a master's program in Clinical Investigation, Public Health, or some other structured program.

Advanced Research Training

Trainees preparing for research careers in pediatric cardiology need an extensive foundation in scientific investigation. Some trainees may have obtained extensive research preparation in combined MD/PhD programs, but may lack the special skills appropriate to their personal research goals. These may be obtained during a postdoctoral research fellowship or as part of the cardiology traineeship. Advanced research training should be a mentored investigational experience with a productive and active scientist, MD or PhD, working in the appropriate fields of clinical, epidemiological, genetic, developmental, or biomolecular investigation as well as population science, behavioral science, quality of care, and outcomes research.

Trainees who aim for a career in investigative cardiology but who have not had the opportunity to obtain a PhD or equivalent training prior to embarking on their cardiology traineeships should have the opportunity and be encouraged to obtain the essential coursework and laboratory experience necessary for a productive research career. Several types of individual or institutional research training grants are important resources to support such training.

The advanced research training previously outlined constitutes only the beginning of the education of an independent cardiovascular investigator. Individuals who pursue this path will require additional research mentoring as junior faculty, and compensation during the prolonged period of research training and mentoring should be sufficient to allow a substantial time commitment to this training. To prepare for a successful investigative career, mentored training during and following fellowship of two to five years is usually necessary. Current models to support young faculty during these critical times of career development include the American Heart Association Scientist Development Grant and the National Heart, Lung, and Blood Institute K08 or K23 awards.

The fundamental demonstration of successful training for a pediatric cardiology investigator is successful competition for external funding obtained via peer-reviewed mechanisms. Advanced research training plans should be formulated with this goal in mind.

EVALUATION

Evaluation of a trainee's research progress and research skills should be subjective as well as objective, based on agreedupon criteria and standards, and should be ongoing throughout the training period. Each trainee's competence and understanding should be documented at the completion of training. The American Board of Pediatrics requirements for research oversight should guide the evolution process.

Trainees should be strongly encouraged to publish substantive results, thereby providing an evaluation by peerreviewed 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 might 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 three years of training while guaranteeing full clinical competence. Blocked research time of 12 to 18 months with clinical duties limited to one-half day per week plus weekend and night call during this time is highly desirable.

SUMMARY

It is vital to the future intellectual health of cardiovascular medicine and the welfare of pediatric patients with cardiovascular disease that all future pediatric 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.

doi:10.1016/j.jacc.2005.07.021

REFERENCES

- 1. Sonnenblick EH, Ryan TI, Starke RD. Task force 7: training in cardiovascular research. J Am Coll Cardiol 1995;25:25–8.
- Roberts R, Alexander RW, Loscalzo J, Williams RS. Task force 7: training in cardiovascular research. Available at: http://www.acc.org/ clinical/training/cocats2.pdf 2002. Accessed August 10, 2004.
- 3. NHLBI Task Force Report on Pediatric Cardiovascular Diseases. Available at: http://www.nhlbi.nih.gov/resources/docs/pediatric_cvd.pdf. Accessed August 10, 2004.

APPENDIX

Dr. D. Woodrow Benson declared that he had the following relationships with industry relevant to this topic—stock ownership in Medtronic, Guidant, and Proctor & Gamble. The other authors of this report declared that they have no relationships with industry pertinent to this topic.