

Clinical Research Education and Training

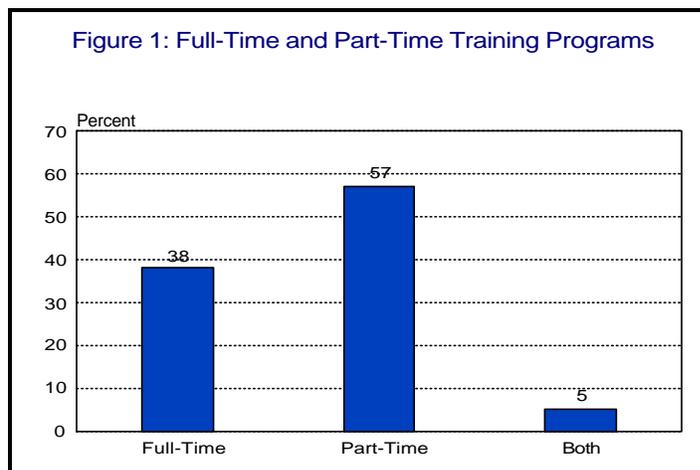
Clinical research is the link between advances in basic biomedical and behavioral science and innovations in medical practice. There is a growing consensus that the increasing scientific opportunities and ethical dilemmas stemming from science and technology will demand a more sophisticated clinical research workforce. This will require innovative educational programs that will help to create a new generation of scientific investigators.

Clinical research training programs at medical schools and teaching hospitals have traditionally been based around the design and analysis of a research project during a subspecialty fellowship under the supervision of a mentor. During the past decade, a number of medical schools and teaching hospitals have initiated new clinical research training programs. These programs have varied from brief two-week "orientations to clinical research" to degree-granting programs in subject areas relevant to clinical research. With the advent of these recent offerings, and new NIH training and career development initiatives, the landscape for clinical research training has been changing at a rapid pace.

AAMC Task Force on Clinical Research

In 1998, the AAMC convened a Task Force on Clinical Research to assess the opportunities and challenges facing clinical research in medical schools and teaching hospitals, and to develop a set of findings and recommendations.

- In 1999, 42% of medical schools offered some form of clinical research training.
- Less than 14% of clinical research training programs offer a formal degree after completion of the program.
- Eight medical schools indicated offering a formal clinical research training program in 1990 while 38 indicated offering such a program in 1999: a 375% increase.



To begin its analysis, the AAMC Clinical Research Task Force surveyed each of the AAMC's institutional members (125 medical colleges and 400 plus teaching hospitals) to determine if it sponsored a formal institutional clinical research training program.

Approximately 74% of the medical schools and 38% of the teaching hospitals responded to the survey, which was completed in the summer of 1999. From those institutions that responded, 42% of medical schools and 22% of teaching hospitals indicated that they offered some form of clinical research training. The Task Force found no examples of formal exposure to clinical research training in the undergraduate medical school experience, and thus, the results of the survey reflect only clinical research training of residents and fellows.

A Sampling of Survey Findings

- At the time of the survey, only ten of the 72 programs (13.9%) indicated that they offered a formal degree after completion of the program. In addition, slightly more than half of these programs involved institutional sponsorship, as distinct from specialty-based research training.
- Most training program directors considered their programs as part-time, involving less than five hours per week of program participation for their trainees (see Figures 1 and 2). The majority of programs required two years or less for completion, regardless of intensity.
- The majority (58%) of formal clinical research training programs have been in existence for less than five years.
- For decades, training in population-based research and advanced clinical trials methodology have been

offered at many institutions in the context of Masters' in Public Health, Health Services/Outcomes Research Program, Preventive Medicine Residency Training Program, or Clinical Epidemiology Program. In contrast, there were only 13 research training programs that clearly focused on patient-oriented or translational research and, for the most part, these programs were newly established.

Case Studies

Task Force members and AAMC staff selected 16 programs for closer examination and interviewed the program directors by telephone. These programs reflected a balance of geography, public or private ownership, and whether or not the program offered an advanced degree. All 16 program directors believe that the optimal training experience should include a defined course curriculum with didactic materials and completion of a mentored research project. More detailed descriptions and analyses of these training programs, along with the findings and recommendations of the AAMC Task Force on Clinical Research, can be found in the AAMC Report: "For the Health of the Public: Ensuring the Future of Clinical Research," Volume I (to order, call: 202-828-0416).

Recommendations

Although significant questions remain about the most effective approach to training (including the optimal duration of the training program, the desirability of additional degrees at the Masters or Ph.D. level, and the level of prior experience of the trainees), the Task Force made the following recommendations regarding clinical research education and training.

- Medical schools and teaching hospitals need to develop a culture supportive of clinical research and transmit the excitement of clinical research to a new generation of medical students, residents and fellows.

- Clinical research training programs must define a rigorous set of competencies, skills, and knowledge-based requirements for their program graduates.
- Programs should develop expected performance measures for their graduates.
- Programs should strive to develop and maintain a demographically diverse cadre of trainees and faculty mentors.
- Programs should plan for long-term (multi-year) funding of trainees and a stable, long-term funding base for the program.
- Systematic outcome data on early career choices and opportunities must be collected and analyzed to evaluate the efficacy of the new generation of clinical research training programs.
- Medical schools and teaching hospitals should develop model training programs and credentialing for clinicians who wish to participate as investigators in clinical trials.

Follow-up

As a result of the Task Force's recommendations, the AAMC has:

- Created a database of clinical research training programs <<http://www.aamc.org/research/dbr/clinicaltraining.htm>>,
- Developed an e-mail listserve for clinical research training program directors and administrators,
- Established a panel to provide guidance to the Medical School Objectives Project (MSOP), and
- Initiated a follow-up survey querying clinical research training program directors about the characteristics of any new or continuing training programs.

Conclusion

Preliminary follow-up survey results indicate that the growth in clinical research training programs over the last decade has continued in the past two years and that a majority of these programs are offering advanced degrees. This trend is expected to continue and expand in the next decade in response to medical opportunities and challenges in the areas of science, technology, and ethics. Thus, funding for such programs will continue to be an important part of the agenda for federal agencies, healthcare foundations, teaching hospitals, and colleges of medicine.

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