

# 7 The Harvard clinical effectiveness training programme

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A landmark paper by James B Wyngaarden was published in 1979 with the ominous title *The Clinical Investigator as an Endangered Species*.<sup>1</sup> Wyngaarden noted a decline in interest in biomedical research by young physicians and warned that unless measures were taken to encourage talented physicians to pursue research, opportunities would be lost. Nearly two decades later the problems described by Wyngaarden and others<sup>2-5</sup> persist, and about 5% of physician investigators in the United States end their research careers every year.<sup>6</sup> Factors that are often cited as reasons for leaving clinical research include inadequate preparation, difficulty in gaining research support, and clinical responsibilities that do not permit sufficient time for the performance of research.<sup>7</sup>

Although several programmes have been developed to support rigorous training of physicians who pursue basic science research, few options are available to physicians who are interested in patient oriented investigation. Increased awareness of the need for more careful examination of the determinants of quality of medical care, however, together with economic pressures on the health care system have intensified the demand for investigators who can study issues such as:

- Risk stratification of patients with common clinical syndromes
- Assessment of cost effectiveness of alternative management strategies
- Measurement of patient outcomes, including quality of life
- Measurement of quality of care.

A critical first step in meeting these needs has been the recognition that patient oriented researchers have needs for training that are

analogous to those of physician investigators who perform basic research.<sup>8</sup> These needs include training in research methodologies of clinical investigation such as those listed in the box.

## Methodological skills for patient oriented research

- Study design
- Multivariate statistical techniques
- Measurement of comorbid medical conditions
- Assessment of severity of disease
- Measurement of health status and quality of life
- Definition of "appropriateness" of procedures
- Measurement of costs
- Determination of cost effectiveness
- Measurement and improvement of quality of care

Programmes to teach methods in clinical research are now established at some teaching hospitals and are in development at several others.<sup>9</sup> Funding for such programmes is uncertain and highly variable, but important progress has been made in defining optimal models of postdoctoral training for clinical research. These programmes vary in structure considerably, and there is probably no single best strategy for obtaining and integrating these skills for all investigators.

One common feature among the new training programmes at many institutions is their interdisciplinary nature—a reflection of a paradigm shift described by Kelley,<sup>10</sup> in which new "horizontal" relations are formed within a medical centre, crossing the "vertical" divisions defined by clinical specialties and subspecialties. These horizontal relations may be defined by diseases, such as cancer, or by research methodologies. At many universities molecular biologists have developed informal or

formal research interactions that may have a more critical role in their lives than their subspecialty affiliations. Analogous cross disciplinary associations are developing among investigators interested in advanced patient oriented research methodologies.

### Harvard programme

The Harvard clinical effectiveness programme is among the largest training initiatives for patient oriented researchers. It provides methodological training to postdoctoral trainees during an intensive two month summer session at the Harvard School of Public Health.<sup>11</sup> This programme was founded in 1986 after a Harvard Medical School postdoctoral fellowship training programme for general internists began to attract medical subspecialty fellows from Harvard teaching hospitals. These subspecialty trainees desired instruction in biostatistics, epidemiology, and related disciplines to bring scientific rigour to patient oriented research within their subspecialties.

With support from the WK Kellogg Foundation and the Klingenstein Fund, the clinical effectiveness programme began a formal training curriculum for these subspecialty fellows. The programme has expanded to include 80-90 new enrollees each summer during each of the past few years. Most of the "fellows" are trainees, but nearly one quarter in recent years have been faculty members seeking additional skills. About 15% of the current enrollees are from general internal medicine, another 30-50% are from internal medicine subspecialties, and the remainder are from the other specialties. Most of these fellows come from Harvard teaching hospitals, but nearly half come from other institutions in the United States and hospitals from other countries including the United Kingdom, Switzerland, Germany, Australia, Mexico, Brazil, Canada, Taiwan, and Japan.

A requirement of all applicants is a commitment to an academic career in which the methodological skills of the programme would be applied. All applicants must be sponsored by the director of their clinical subspecialty division, department, or institution, who must guarantee payment for the trainee's tuition for this programme with institutional funds. (Tuition is based on the number of course credits at the Harvard School of Public Health whether or not a trainee enters a formal degree granting track in the programme.) During the programme, enrollees are required to be completely free of clinical responsibilities.

These requirements force the institutions of the candidates for the programme to "screen" the applicants carefully. Domestic applications are not generally interviewed, while international applicants are evaluated via telephone, especially in terms of their proficiency with English. Also, to qualify for a degree from the School of Public Health, an option chosen by more than half of the enrollees, a student must fulfill school requirements for formal testing in English language. These policies have facilitated the enrollment of students who, each year, are characterised by motivation and strong intellectual skills and who are likely candidates for faculty positions on completion of the programme.

### Curriculum overview

The "core" of the clinical effectiveness programme curriculum begins on 1 July of each academic year with an intensive seven week summer curriculum that provides 15 credits (out of 40 needed for a Master of Science or Master of Public Health degree) at the Harvard School of Public Health. Required courses are clinical epidemiology (5 credits) and biostatistics (5 credits). Elective courses (2.5 credits) include health services research, decision sciences, outcomes measurements, quality improvement, ethics, and clinical trials. These courses are tailored specifically for the programme's trainees. Thus, the epidemiology course emphasises patient oriented research as opposed to classic population based epidemiology.

Visiting faculty members and fellows who take the summer curriculum usually then return to their institutions, whereas local postdoctoral fellows spend from September of the first year to June of the second academic year (22 months) undertaking their own original research. These fellows often perform their research under the codirection of a senior member of their own clinical division or department and faculty members from the clinical effectiveness programme. During this 22 month period most trainees take additional course work in epidemiology, biostatistics, or health policy and management to supplement their core training. Several of these courses, including an advanced summer course, are designed explicitly for the programme. A seminar course meets weekly throughout the year and provides a forum for students to present "work in progress" or data analyses that have not yet culminated in a published manuscript.

## Core curriculum

During the summer core curriculum trainees spend an average of five hours a day (25 a week) in the classroom, and, by self report, require an additional 25-30 hours a week to complete out of class assignments. The courses include workshops and computer laboratories and also emphasise practical skills, such as how to write a grant proposal. Fellows participate in mock study sections during which they review an actual grant proposal previously submitted by one of the programme faculty. During these sessions the "reviewers" are assigned areas of responsibility such as "data quality", "state of the science", and "human subjects". The "reviewers" discuss the proposal in an executive session, pose questions to the proposal's principal investigator, and then assign it a priority score. The goal of these highly popular sessions is to provide the trainees with insight into the mechanics of the grant review process and to encourage them to read a proposal critically.

The clinical epidemiology course includes basic epidemiological principles but also seeks to introduce trainees to all of the steps in performing patient oriented research, including:

- Identification of an appropriate topic
- Review of the literature
- Choosing an appropriate study design
- Definitions of exposure and outcome variables
- Designing a data form or questionnaire
- Pilot test of data collection protocol
- Data collection
- Data management and quality control
- Data analysis
- Abstract preparation and presentation
- Manuscript preparation.

Students are taught in detail the strengths and weaknesses of alternative study designs, including case-control studies, cohort studies, randomised trials, and meta-analysis. Small workshops are used to review published articles.

During the course the trainees develop a research plan for studying a clinical problem of their choice and conclude the course with a presentation of their research plan to the class, including a discussion of the study design, data collection instruments, analytic strategies, and the anticipated problems and limitations. These sessions provide an opportunity for feedback from the faculty and other trainees.

The biostatistics course covers basic quantitative techniques commonly used in clinical research and provides an overview of more advanced techniques. Workshops introduce fellows to the use of microcomputers and appropriate software packages, and analyses are performed with data from actual research projects. By the conclusion of the summer programme fellows should be able to choose and use an appropriate statistical technique for an analysis.

More than half of the trainees take additional courses at the Harvard School of Public Health and ultimately earn the 40 credits required for a master's degree. Up to 10 of these credits can be earned for supervised research. Enrollees, whether local or visiting, can complete a master's degree in epidemiology, for example, by returning for a second summer to take an additional 15 credits and by completing a required research project under the supervision of the programme's faculty.

## Conclusions and future directions

Because these trainees are so highly selected the contribution of the clinical effectiveness programme to their future research is difficult to assess. Of the physicians who have enrolled in the summer curriculum and who have finished their clinical training, about 80% are in full time academic positions and another 5% are in government or non-profit research positions.

In the past two years faculty members have noted that growing numbers of enrollees are not seeking futures in the traditional grant supported research track. Instead, these fellows have been sent by their institutions to acquire skills in quality improvement and data analysis, and many return to positions in which much or all of their salary is provided by their hospitals. They are expected to assume major roles in measuring quality of care and patient outcomes and in the development of quality improvement programmes. Because of these needs formal course work in quality management has become an increasingly popular component of the curriculum.

In summary, the needs of patient oriented investigators are analogous to those of bench scientists in that formal instruction in research methodologies can be a critical factor in their development. Also critical are the availability and support of qualified mentors.

On the basis of our experience with the Harvard clinical effectiveness programme, we recommend:

#### HARVARD TRAINING PROGRAMME

- Recognition that patient oriented investigators require training in specific skills including biostatistics and study design
- Development of cross disciplinary training programmes that can provide formal instruction in these skills to trainees and junior faculty
- Requirement of a minimum commitment by prospective patient oriented researchers of at least two years for research training, including performance of initial investigations
- During research training these fellows should have clinical responsibilities restricted to 20% of their time or less
- Improved support for the career development of patient oriented researchers during research training and early years after training.

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