The Development of Clinical Research Training: Past History and Current Trends in the United States

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Abstract

This article provides a brief account of the history of the development of training opportunities in clinical research in the United States. It highlights some developments in the clinical research enterprise since World War II and focuses examination on the involvement of the U.S. government and academic sector. Clinical research training is a relatively new academic field, and curricula in the design and conduct of clinical research have only emerged since the 1980s. The growing complexity of clinical trials and the emergence of evidence-based medicine in the last several decades created great demand for clinicians with knowledge of clinical epidemiology and biostatistics. Amidst alarm bells rung by physician–scientist leaders about the endangered species of clinical researchers, numerous proposals and solutions emerged to address these workforce and educational problems in the 1990s. Traditionally, physicians wishing to expand their education had to get a master's degree in public health or participate in unique programs such as the Robert Wood Johnson Clinical Scholars Program. Since the 1990s, the National Institutes of Health, through K awards, the Roadmap Initiative, and other funding mechanisms, has furnished tremendous support for the development of clinical research training opportunities from predoctoral immersion programs to degree-granting graduate programs. The author discusses key components of successful clinical research training programs and concludes with empirical recommendations for promoting careers in clinical research.

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The demand for training in the conduct of clinical research can be traced back to the increasing complexity and sophistication of medical research design after World War II. One of the earliest large-scale randomized controlled trials (RCTs) was the Salk polio vaccine field trial of 1954. Landmark cardiovascular studies initiated in the late 1970s and early 1980s such as the Hypertension Detection and Follow-up Program Cooperative Group[1] and the Physician Health Study[2] further helped establish RCTs as a highly effective method for clinical research. List 1 shows a timeline of some of the key events in the evolution and development of clinical research training in the United States. The term "clinical research," for the purposes of this article, refers to the National Institutes of Health (NIH) definition, which encompasses patient-oriented research, epidemiological and behavioral studies, and outcomes and health services research.[3]

As the complexity (e.g., RCTs and meta-analyses) and scale (e.g., multicenter trials) of clinical research have grown, so has the technical expertise necessary to execute it. Human participants, trials involving healthy individuals, and involvement of pharmaceutical companies are examples of thorny issues that require conduct of the highest ethical standard. Data manipulation requires a mastery of difficult mathematical concepts in statistics and facility with software to analyze raw data. Writing skills, too, are indispensable in securing funding from grants and institutional review board approval of research protocols. The result is a diverse skill set too difficult to master without formalized curriculum and training.

With the increased focus on RCTs and clinical research, clinical epidemiology, described as the "basic science"[4] of clinical medicine, and biostatistics started to move from a peripheral intellectual field to an important presence within medical schools and an indispensable ally in modern clinical medicine. David Sackett founded Canada's first department of clinical epidemiology and biostatistics in 1967 at McMaster University, and he published a seminal article introducing the concept of clinical epidemiology two years later.[5] Public health schools, which also taught the topics, became more linked to medical schools.

Sackett and his colleagues at McMaster University also receive credit for starting the global evidence-based medicine (EBM) movement by making available reliable information on therapies to all clinicians. It was not until 1992, however, that the term "evidence-based medicine" was first widely disseminated in another seminal article that described it as a "new paradigm in medical practice."[6] Medical school and residency programs nowadays include EBM to varying degrees in their curricula.[7,8]

Tackling a Crisis in the Clinical Research Workforce

By the 1980s, a number of eminent research-oriented physicians publicly warned about an impending shortage of clinical researchers. James Wyngaarden,[9] then at Duke University but later head of the NIH, rang the first warning bell in 1979. Using a series of line graphs depicting the decline in NIH grants and fellowships awarded to MD investigators in contrast to the steady rise among PhD

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List 1

A Timeline of the Development of Clinical Research Training in the United States

1955. James Shannon begins his directorship of the National Institutes of Health (NIH), largely driving a vast increase in the biomedical research enterprise at the NIH and across the country.

1964. The NIH establishes the Medical Scientist Training Program (MSTP), supporting training leading to a combined MD/PhD degree at medical schools and designed to train translational researchers.

1972. The Robert Wood Johnson Foundation launches the Clinical Scholars Program with $6,000,000 to train physicians in broad health care issues and health services research.

1979. James Wyngaarden, who later became director of the NIH, publishes an article in the *New England Journal of Medicine* describing the physician scientist as an "endangered species."[9]

1984. Gordon Gill points out that research-oriented physicians have abandoned patient-oriented research in favor of molecular biology.[10]

1990–1999. The Clinical Research Summit brings together diverse stakeholders for a series of focus groups and conferences.

1992. Edward Ahren's book, *The Crisis in Clinical Research*, fully details the problems previously noted by Wyngaarden, Gill, Goldstein, and others.[11]

1992. Evidence-based medicine is described as a "new paradigm in medical practice."[6]

1994. An Institute of Medicine report, *Careers in Clinical Research: Obstacles and Opportunities*, estimates that just 10% of NIH research is clinical in nature.[12] (A later NIH-commissioned study disagrees, finding more than one third of the NIH budget devoted to clinical research.[13])

1995. Harold Varmus, director of the NIH, initiates a campaign called the NIH Director's Panel on Clinical Research to review and renew clinical research including support for clinical research methods training programs.

1997. The final report (the "Nathan Report") of the NIH Director's Panel on Clinical Research is released, containing a series of recommendations to foster more support for clinical research and training of clinician investigators.[13]

1997. The one-year NIH Clinical Research Training Program for medical and dental students is inaugurated.

1998–2003. The NIH annual budget doubles from $14 to $28 billion.

1998. Physician–scientists found the Association for Patient-Oriented Research to promote the centrality of the human subject in advancing medical research.

1999. The NIH establishes K30 awards to support clinical research training curriculum development.

1999. The American Association of Medical Colleges publishes a report entitled *Clinical Research: A National Call to Action* describing the "scientific bottleneck" as part of the Clinical Research Summit project and highlights the need for more clinical investigators.[14]

2000. The Institute of Medicine convenes the first Clinical Research Roundtable to improve the national clinical research enterprise.

2002. NIH Director Elias Zerhouni begins discussions resulting in the Roadmap Initiative to accelerate translation of basic science findings to clinical practice.

2002. The NIH starts loan repayment programs for young scientists committed to clinical research.

2004. The NIH Clinical Research Training Program for medical and dental students doubles in size.

2006. The first recipients of the NIH Clinical and Translational Science Awards are announced.

2006. The Association of American Medical Colleges releases a major report advocating the role of medical schools and teaching hospitals in training all medical students and residents in clinical and translational research.[26]

investigators, he famously heralded the clinical investigator an "endangered species." Wyngaarden and other doctors were particularly concerned about the lack of physician–scientists pursuing research that directly involved patients and that could be applied to improving care for their diseases. They suggested that the problem was not so much a lack of interest in clinical research per se but, rather, competition with careers in booming areas of basic science such as molecular biology.[10]

The 1990s saw more detailed analyses of the problem. Edward Ahrens,[11] for one, produced a 200-page book. He was particularly concerned about a gap in the spectrum from basic bench research to applied clinical research, the area of "basic patient-oriented research" that investigates topics such as physiology and the fundamental mechanisms of human disease. Major national organizations like the Institute of Medicine, the NIH, and the Association of American Medical Colleges (AAMC) followed suit with reports focused on clinical research. The Institute of Medicine estimated that just 10% of NIH research at the time was clinical in nature.[12] In 1995, Harold Varmus, then head of the NIH, formed a special blue ribbon panel that released the so-called "Nathan Report" two years later. This report was instrumental in fostering more clinical research by offering a series of key, concrete recommendations.[13] Among them was the recommendation for awards that would support the development of clinical research training curriculum, realized in 1999 with the introduction of K30 awards. And, the AAMC, though slower in response, issued its own report delineating nine core problems and recommendations, including a specific call for formalized training programs.[14] Medical specialties, spurred by NIH recommendations, funded clinical research training grants for junior faculty motivated by an academic career in clinical investigation.[15] Concerned about the rapid decline in the number of clinical investigators, a group of physician–scientists committed to seeing medical science advanced by the active participation of real patients and bedside observations by such clinical investigators formed the Association for Patient-Oriented Research in the late 1990s.[16]

An important backdrop to these increases in funding for clinical research training was the general increase in funding for medical research. From 1998 to 2003, the NIH underwent a boom in funding, thanks to political support, and its annual budget doubled from $14 to $28 billion.[17]

This allowed the NIH to provide funding mechanisms such as the K awards that have been essential in encouraging the development of clinical investigators. Most K awards provide salary support to clinical investigators so that they can devote themselves to research, a critical concept called "protected time." The K23, K24, K08, and K12 awards, for instance, are specifically for those pursuing clinical research careers. The

K23 award is formally called the Mentored Patient-Oriented Research Career Development Award and aims to develop independent clinical research scientists. It is designed for young faculty members at academic health centers and provides them with three to five years of salary support for protected clinical research time. Importantly, these grants compensate researchers for salary: About $120,000 can be designated per trainee, and, of that, $90,000 can be allocated to salary.[18] Though K23 awards began as a minor fraction of K awards, they now compose approximately 20% of the dollar amount of total K grants.[19] K24 awards continue the support of K23 awards for midcareer investigators in patient-oriented research. K08 and K12 awards are similar multiyear awards designated for those with a clinical doctorate (e.g., MD or PharmD) interested in developing a clinical scientist research career.

Early Examples of Clinical Research Methods Coursework

Public health schools probably offered the first major educational experience to integrate topic areas essential to conducting clinical research—epidemiology, statistics, and research methods. Decades before departments of epidemiology and biostatistics gained a presence in medical schools, they held a central position in public health schools. Though the training was geared toward those interested in health at a population level, the skill set was still applicable to clinical research.

Thus, many of the early pioneers in developing clinical research training programs were MD/MPH physicians who applied their additional training in public health to patient-oriented research. Nonetheless, there were still limitations to the applicability of master of public health (MPH) training for clinical research. Prime among them was that MPH coursework was just that—coursework. It lacked an applied component, like a practicum, in which trainees would actually design and implement a research protocol.

The Robert Wood Johnson Clinical Scholars Program, begun in 1972 after a pilot program, is an example of a small but well-known program that includes components of clinical research design. It has evolved over the decades, but it has remained true to a goal of training young physicians to conduct research, particularly in the area of health services and outcomes research, to help rectify the imbalance between basic biomedical research and patient- or population-oriented research.[20,21] Then as now, it is a two-year integrated educational experience for doctors who have completed their residencies. Participants take coursework in population health, epidemiology, research methods, health care organization, economics, and health policy. They are rewarded with a master's degree on completion. Training is conducted at major universities' academic health centers and under a plethora of potential research mentors. More than a thousand scholars have graduated since the program's inception.

Like public health schools, however, the primary goal of the Robert Wood Johnson Clinical Scholars Program is by no means to merely create clinical researchers. It was designed for physicians interested in leadership roles within medicine who would learn about the big, broad issues in health care. And, like those who earned MPH degrees, Clinical Scholars Program graduates acquired as a fringe benefit knowledge about some aspects in the design and execution of clinical research.

Therefore, although there were some early examples of educational opportunities related to clinical research, programs or classes devoted primarily to clinical research design did not emerge until about the 1980s. Using the search term "clinical research AND (training OR curriculum OR methods)," a PubMed search indicated that the earliest publication to describe how to conduct clinical research dates back to 1980. Two biostatisticians at the University of Washington wrote a practical paper describing a model class in clinical trial design and management.[22] The University of California, San Francisco (UCSF) was one of the pioneers, first offering an intense summer course in designing clinical research in the early 1980s. Likewise, texts on clinical research design began to be published in the 1980s.[4,23] Duke University was one of the nation's first to create a master's degree program in clinical research as early as 1986.[15]

The Development of Formal Clinical Research Training Programs

One type of K award, the K30, is largely responsible for the development of current clinical research training programs. It provides up to $200,000 per year in funding to institutions specifically for the development of clinical research curricula. The first set of grants expired in 2005, and the second set, many of which have been renewed by the same institutions, will end in 2010. Fifty-one institutions across the United States have received K30 awards.[18]

This funding, which supports on average 64% of a program operating budget,[24] has inspired nearly 60 institutions across the United States to date to develop degree-granting clinical research training programs. Of those surveyed in 2004, 80% of K30 grant recipient institutions offered a certificate, 78% a master of science, 31% an MPH, and 20% a PhD.[24] The AAMC has assembled a collection of such training programs with detailed information available online at (http://www.aamc.org/research/clinicalresearch/training/start.htm).[25] The institutions that created these programs typically are large universities with major medical schools and university hospitals that share a mission to educate a new cadre of health professionals, from nurses to pharmacists to physicians, interested in careers in clinical research. Through a combination of coursework, practical hands-on experience, and mentorship, students learn all about how to design and conduct clinical research.

Besides degree-granting options, some clinical research training programs offer abridged curricula for clinicians interested in clinical research but too busy to take a year or two to earn a degree. Thus, these nondegree or certification programs still serve an important function: They provide the bare essentials in clinical research training for clinicians who otherwise might not get such training. They also seem to be slightly more popular, as 56% of graduates of K30-funded clinical research training programs earned certificates compared with 50% who earned a master's degree and 4% who earned PhDs.[24]

Two illustrative examples of such programs are at those at UCSF and Harvard University. UCSF began offering an intensive two-month workshop in the

List 2

Examples of Yearlong National Clinical Research Training Opportunities for Predoctoral Students

- **NIH Clinical Research Training Program**
  http://www.training.nih.gov/crtp/index.asp
  Year started: 1997
  Number of students: 30
  Stipend: $24,000
- **Doris Duke Clinical Research Fellowship**
  http://www.ddcf.org/page.asp?pageId=292
  Year started: 2000
  Number of students: 80 (in 2006–2007)
  Stipend: $27,000
- **Fogarty International Clinical Research Scholars Program**
  http://www.aamc.org/students/medstudents/overseasfellowship/start.htm
  Year started: 2004
  Number of students: about 25
  Stipend: $18,000–20,000 plus $6,000 for expenses

early 1980s (http://www.epibiostat.ucsf.edu/courses/summerworkshop.html), which more than 100 students complete each summer. Students take a package of three classes: (1) Designing Clinical Research, (2) Responsible Conduct of Clinical Research, and (3) Building an Academic Career. The first class provides a core overview of the chronological process of designing a study, from formulating a research question all the way to writing a short research protocol. The second class focuses on ethical considerations. In the third class, students learn about finding mentors and getting grants and must sketch a two-year career plan. Harvard's equivalent is called the Summer Program in Clinical Effectiveness (http://www.hsph.harvard.edu/clineff). Participants take two core courses in biostatistics and clinical epidemiology and two electives (such as in quality-of-care research or research with large databases) during the summer. During its history of more than 20 years, about 1,700 clinicians have completed the program.

Waiting until after medical school and residency to start training in clinical research is late. To build a talented workforce of investigators requires fostering an interest in clinical research careers at earlier stages. The AAMC, which oversees curricula nationally in the United States, called for all medical schools to incorporate mandatory education on clinical and translational research in 2006.[26,27] Medical, pharmacy, nursing, and dental schools, especially research-oriented ones, may also foster interest by offering scholarships or grants for student research projects or encourage students to use a summer vacation to work with a researcher on an ongoing clinical trial. On a national level, several programs have been developed in recent years that seek to both make students aware of the excitement of clinical research and train some of the brightest young minds (List 2).

Again, the NIH offers a good example of one such program. The NIH Clinical Research Training Program, begun in 1997, is a one-year experience that targets medical and dental students. Because the program is clinical in nature, students must have completed a year of clinical rotations to be eligible. In exchange for delaying graduation by a year, participants receive a living stipend of approximately $24,000. The program, held on the NIH campus near Washington, D.C., doubled in size in 2004 to 30 students annually. It includes a series of classes and seminars, requires participants to conduct research under the guidance of an NIH researcher, and culminates in a conference at which trainees share their results at the end of the year.

Recommendations for Maintaining a Robust Culture of Clinical Research Training

Model clinical research training programs use multiple teaching methodologies and components, as enumerated in List 3. First, they include a traditional core didactic curriculum to establish a theoretical foundation and base of knowledge. Second, they reinforce such lectures with seminars and small discussion groups. This allows clarification of difficult topics. More important, it offers a forum for richly experienced students to share with peers examples of research projects in which they have been involved. Third, a practical experience based on the student's own research interest is required; participants often write and carry out a research protocol as part of the curriculum. Fourth, each student has an individual mentor. Having a faculty member who carefully and critically evaluates one's protocol is indispensable. Fifth, these programs should include supplementary workshops on the assortment of tools used in clinical research. For instance, every clinical researcher should be skilled in using bibliography-organizing software such as EndNote, statistical software such as SPSS or SAS, medical literature databases (particularly a thorough knowledge of PubMed), and writing grants. Sixth, the program should result in at least a certificate, if not a degree, as evidence of the rigor of study.

A "build it and they will come" mentality is insufficient, though, to ensure that young clinicians pursue careers in clinical research. To avoid another workforce crisis like that observed in the 1980s, I have assembled a series of eight recommendations along with their theoretical justifications (List 4). It is worth mentioning that the very rigorous evidence basis that is so central to contemporary clinical research is difficult to apply to measures to enhance clinical research training and careers. The limited studies of the impact of programs have tended to be either of qualitative descriptions of what graduates have done[20,28] or of programs that failed to find a conclusive benefit.[15] One of the most methodologically rigorous studies demonstrated a static number of physicians applying for first major research grant (R01) from the NIH during 40 years, suggesting no increase in new physicians pursuing clinical research careers[27]; however, the impact of reforms beginning in the late 1990s may not have been observed by 2004 when the study data ended. What these recommendations do represent is a synthesis of empirical strategies that have been used with anecdotal success.

Looking Toward the Future

The NIH again served as the key impetus for change in 2002 when Director Elias

List 3

Suggested Components of a Clinical Research Training Program

- Core didactic curriculum
- Seminars and small groups
- A practicum including protocol writing and actual research
- Individual mentorship
- Supplementary workshops on research tools (e.g., EndNote, PubMed)
- Certificate or degree

List 4

Eight Recommendations for Promoting Clinical Research Careers

1. **Recommendation:** Allow grant budgets to include salary support and provide "protected time" for research and mentorship.

   Justification: The combination of salary and work days devoted to clinical research allows researchers to focus on their work and generate high-quality research results. Without it, clinical research and mentorship is treated as simply a volunteer activity, and little effort is made to do them well.

2. **Recommendation:** Offer training opportunities at several stages of a potential researcher's career with a special emphasis on early career.

   Justification: People become interested in clinical research at different times. Having opportunities available at multiple career stages helps make sure these potential researchers are not lost.

3. **Recommendation:** Offer clinical research training opportunities of several different levels of depth (e.g., summer, one year, multiyear).

   Justification: People in clinical research have differing amounts of time to devote to formal training, so programs should be customized.

4. **Recommendation:** Encourage involvement of people of different academic backgrounds (i.e., not only physicians).

   Justification: Clinical research requires immense teamwork, and dentists, nurses, nurse practitioners, pharmacists, and physicians all have unique skill sets to contribute.

5. **Recommendation:** Expose students to the concept and examples of clinical research as part of their educational curriculum.

   Justification: Students are often aware of basic science research opportunities but less cognizant of clinical ones.

6. **Recommendation:** Provide financial and institutional support for well-matched faculty mentorship of potential clinical researchers.

   Justification: Mentor support is a strong predictor of career persistence when mentor and mentee share life experiences.[30]

7. **Recommendation:** Furnish rewards/awards for accomplishments of both research trainee and mentor.

   Justification: Recognizing those involved in clinical research education helps them feel their efforts are valued.

8. **Recommendation:** Accentuate to policy makers the link between better clinical research training and better health for the population.

   Justification: Robust funding from the National Institutes of Health and other government agencies is key to growing the next generation of clinical researchers.[31]

Zerhouni began discussions that resulted in the Roadmap Initiative. This huge, ongoing endeavor is designed to accelerate the translation of basic science findings to clinical practice. In particular, the NIH has heavily invested in creating a national consortium of clinical and translational science institutes. So far, 24 academic health centers have received Clinical and Translational Science Awards.[29] Many of these grants place specific emphasis on improving educational programming to train the next generation of clinical researchers.

Concerns over the balance between basic and clinical research will doubtless continue in the future. In particular, the subgroup of clinical investigators that is specifically patient oriented as opposed to laboratory based remains an endangered species because of a dearth of funding opportunities. Nonetheless, it is amazing to consider that in the span of little more than two decades, the United States has gone from experts decrying the state of the clinical research enterprise and a few scattered offerings to a nationwide network of institutions, programs, and funding for education in how to conduct clinical research. It is exciting to consider what the next development will be and the impact of training programs in the coming years.

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Teaching and Learning Moments

Walk With Me

I like walking with my patients. Besides providing information on their physical condition, it builds a good patient–physician relationship; it allows me to evaluate their gait, their need for rehabilitation, their fall risk. But also, walking with my patients gets me closer to them, providing a human touch to the relationship. Walking with a patient does not require any special experience, technology, or instrument, and it should be part of every physical assessment.

Unfortunately, we live in an era in which imaging and laboratory testing have taken priority over a thorough history and physical exam. A renowned professor in cardiology once looked at the book that I was reading and told me, "Stop wasting your time; just do an MRI." The book was one of my favorites: *Localization in Clinical Neurology*. He smiled; I didn't smile back. I did not think it was funny. But it helped me understand why, during my internship, my residents were often intrigued when they saw me walk with a patient. Even though this aspect of the physical exam is simple and routine, I noticed that it was often overlooked, which would sometimes result in unfortunate events. Two interactions from my rotation in neurology consults illustrate my concerns:

A 45-year-old man was admitted for urinary tract infection. It was his third episode within three years. He had had dysuria for those three years and was being treated for benign prostatic hypertrophy. He also had a spastic walk that had never been addressed. Physical exam showed upper motor neuron disease in his lower extremities with a T10-level sensation. A spine MRI revealed a T8–T9 herniated disc compressing the spinal cord. After spine surgery, the patient's symptoms, including his dysuria, resolved.

A 70-year-old woman with mild dementia was hospitalized for pneumonia. She was ambulatory upon admission. Her stay was complicated by hypertension that was aggressively treated. She remained in bed for the total length of stay. Upon discharge, she couldn't walk. Investigation showed that she had had a subacute stroke during her stay.

A focused physical assessment is more efficient than a complete evaluation, particularly for chronic patients. However, omitting certain aspects of the physical exam can sometimes lead to serious consequences. True, time is lacking, and we are always in a rush, but that should not compromise our patients' safety. Solid assessments and wise use of available resources—ones as simple as focused attention to physical assessments—are what make medicine an art. Walk with your patients. They will heal quicker.

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