

Clinical Research in the Pharmacy Academy

Milap C. Nahata

College of Pharmacy, The Ohio State University, 500 West 12th Avenue, Columbus OH 43210-1291

Research is an important component of our academic mission. Our clinical faculty have contributed greatly to patient care through clinical research over the last three decades. The main purpose for conducting clinical research is to generate new knowledge for improving health care. Clinical research involves human subjects and can include a broad spectrum of research: pharmacokinetics, clinical trials to evaluate efficacy and safety, translational research, epidemiological studies, and health services and outcomes research.

In "The Clinical Investigator as an Endangered Species," Wyngaarden emphasized the need to expand clinical research. He proposed encouraging young physicians to pursue careers in clinical research and initiating new funding opportunities from the National Institutes of Health(1). Aherns' book *The Crisis in Clinical Research: Overcoming Institutional Obstacles*, highlighted similar and some additional issues. The concerns included the shift from patient-oriented research to research in molecular biology; conflicting demands on faculty to perform patient care, teaching, and research; limited collaboration between MDs and PhDs; disproportionate number of researchers seeking funding; and, the lack of collegiality in medical schools(2).

An obvious question is: should we in academic pharmacy be concerned about the health and future of clinical research led by pharmacy faculty or practitioners? There are several indicators that are alarming. Most importantly, many colleges of pharmacy are facing difficulty in recruiting well-trained clinical researchers for tenure-track positions. It is not unusual to search for several years to identify a qualified candidate. After an unsuccessful search, the position may be changed to a nontenure track or to a different but less needed area of emphasis simply to fill it. Many experienced clinical faculty have left academia, creating a void in conducting clinical research.

The number of PharmD students and residents seeking research fellowship training appears to be declining. After completing general or specialty residencies, most individuals enter some type of pharmacy practice or join industry or academia. Those with a definite interest in an industry career may seek fellowships in pharmaceutical industry being offered jointly with a few colleges of pharmacy. Most of the academic positions, however, are being filled with residents with limited research training on a nontenure track or a tenure track with low expectations of research productivity. They are needed to achieve the teaching and practice missions of our institutions. The research mission, however, may be unfulfilled.

Why are PharmD students and residents not interested in pursuing careers in clinical research? Most PharmD graduates have numerous opportunities for employment, and some accept residencies. Fellowship positions are sought only by a small number of individuals. Even those completing a fellowship may not seek a tenure-track faculty position. In an informal survey at three colleges, the residents and fellows indicated perceived difficulty and uncertainty of attaining tenure, stress associated with success in four activities (practice, teaching, research, and service), lack of confidence in receiving competitive funding and publishing refereed research articles, and concerns about balancing faculty responsibilities with family commitments. Some have seen their favorite teachers not receive tenure. Moreover, the rewards associated with clinical practice and teaching are more immediate than those associated with research.

The current ACCP directory lists about 100 fellowship programs in the U.S. It is unknown how many of these are normally full. Interestingly, less than 20 percent of these have received approval by an ACCP peer review committee, which evaluates the quality of fellowship programs. The remaining programs may not have sought approval or some may have been disapproved by the peer review committee. Although the lack of approval from peers does not equate with lack of quality, it is one way to guide the development and improvement of programs to achieve some uniformity in terms of desired standards. In absence of such a process, the fellowship programs are likely to produce fellows of varying quality to accept faculty positions.

The data on research productivity (funding, presentations, and publications) of pharmacy practice faculty are not readily available. Based on the data from the Science Citation Index for 1976-97, only 18 percent of the U.S. schools or colleges of pharmacy averaged more than one publication and 54 percent averaged fewer than 0.5 publication per faculty per year. The publications included all types (*e.g.*, research or review articles, abstracts, and letters) and duplicates were eliminated from analysis(3).

Some have suggested that research productivity could be higher if the faculty had less teaching and practice responsibilities. The demands of managed care have been identified as an important problem in a recent survey of the status of clinical research by physicians in academic health centers(4). Another concern is that an increasing amount of industry-funded clinical trials is being done through clinical research organizations. This limits opportunities for an investigator to design studies as well as present and publish research papers.

WHAT CAN WE DO TO ADDRESS THE CURRENT SITUATION?

1. **Attract students to participate in clinical research during the PharmD program**

Many students view research only as "laboratory work" and do not like it based on their experience in laboratory courses. They need to be informed that clinical research is much broader than laboratory work. Most have never done any clinical research and may enjoy it. Availability of stipends may improve recruitment of students to conduct research projects.

2. **Share the excitement of clinical research with students, residents, and fellows**

We may appear overworked and stressed, but it is crucial to show our enthusiasm for what we do and demonstrate how our work helps improve patient care. The application of our research to patient care should be shared during teaching. They should see how publications and presentations of research work at local, regional, or national meetings can change practice.

3. **Offer course content and elective rotations in clinical research**

The PharmD curriculum should cover elements of drug information, literature evaluation, research methods, and biostatistics. The students should be able to do an elective rotation in clinical research. Some colleges require students to propose or complete a research project. Those completing a project and writing a thesis may be considered for graduation with honors or distinction.

4. Strengthen clinical research education and training programs

The students and residents should enter well-designed clinical research education and training, *e.g.*, fellowships, MS, or PhD degree programs. Some colleges are offering combined PharmD/MS and PharmD/PhD programs to achieve efficiency, although few students graduate from these programs and the majority have joined the pharmaceutical industry. Many seasoned faculty who once trained fellows have left academia for alternative careers, especially in industry. In such cases, it will take several years before new faculty would assume that role. The scope of clinical research also needs to be broadened and supported by including community pharmacy settings. Some of our colleges have received K-30 Clinical Research Curriculum Awards from the NIH, in which trainees from various health sciences complete courses such as epidemiology, research design, grant writing, biostatistics, and bioethics leading to a certificate or an MS degree in clinical research. The participants may include faculty as well as fellows and residents.

5. Expand multidisciplinary research programs

Rapid growth of knowledge and complexity of research requires the development and expansion of multidisciplinary clinical research programs. Such programs are most likely to succeed in addressing research questions from multiple angles (molecular, cellular, tissue, and whole human) and in securing competitive funding. The multidisciplinary approach should be used in offering education and training programs. The AACP Research and Graduate Affairs Committee has been asked to assess the impact of rise in research centers or institutes and decline in traditional department-based programs on the quality of graduate education and research. The Committee would also evaluate the effect of this trend on student recruitment, financial support, faculty and student careers. Finally, they will suggest strategies and actions to undertake to maximize opportunities for faculty research and graduate education in this new environment.

6. Provide resources and opportunities to faculty

Tenure-track faculty need a start-up package, collaborations, and continued support to establish their research program. Some new faculty may not be ready to be on a tenure track, and thus be placed on a nontenure track during their first few years. However, this group would also need support to succeed in making a transition to tenure track. They may need to complete some courses, and learn how to write competitive grant proposals for funding and manuscripts for publication. A program to facilitate clinical research has been established at the Massachusetts General Hospital(5). Certain campuses with colleges of pharmacy may also be offering similar programs.

7. Recognize the value of clinical research

Although clinical research is considered important, investigator

initiated government-funded nonclinical research has received greater recognition than industry-funded contract clinical research (2,4,6). Clinical research brings prestige, attracts clinically oriented faculty, provides emerging treatments to patients, and generates income. The value of clinical research contributions should be based primarily on the impact of that research on patients through peer-reviewed publications and presentations. The type of research (clinical vs. nonclinical) or source of funding (government vs. nongovernment) should not necessarily dictate the value of research contributions.

8. Achieve balance in departments of pharmacy practice

Departments of pharmacy practice have a broad mission to contribute in teaching, research, practice, and service. To fulfill all these goals, departments must comprise of faculty with excellent teaching skills and additional talents - some who are outstanding researchers while others are superb practitioners. Individual faculty may have varying percentage time commitment to each of four activities, based on their abilities and aspirations, and the needs of the department. However, compensation may not necessarily differ as long as they excel in their responsibilities. In addition to the department chair, senior faculty must be involved with the annual evaluations and mentoring of all junior faculty members. This process has been used effectively at Ohio State with faculty on both tenure and nontenure track.

In closing, academic pharmacy must work seriously to attract more students, residents, and fellows to pursue careers in clinical research within our academic institutions, medical centers, industry, or other settings. As the number of trainees and opportunities increase, we should be ready to expand education and training programs. Availability of high quality clinical research programs to train clinical scientists in pharmacy is of critical importance to allow these individuals to make unique contributions to health care.

References

- (1) Wyngaarden, J.B., "The clinical investigator as an endangered species," *N. Engl. J. Med.*, **301**, 1254-1259(1979).
- (2) Ahrens, E.H., *The Crisis in Clinical Research: Overcoming Institutional Obstacles*, Oxford University Press, New York NY (1992).
- (3) Mathys, M.L. and Thompson, D.F., "Publication rates in U.S. schools and colleges of pharmacy: A 22-year history," *Pharmacy Education*, **1**, 17-23(2000).
- (4) Campbell, E.G., Weissman, J.S., Moy, E. and Blumenthal, D., "Status of clinical research in academic health centers," *JAMA*; **286**, 800-806(2001).
- (5) Crowley, W.F. and Their, S.O., "A Program to facilitate clinical research in an AHC: The first five years," *Acad. Med.*, **76**, 403-409(2001).
- (6) Oinonen, M.J., Crowley, W.F., Moskowitz, J. and Vlasses P.H., "How do academic health centers value and encourage clinical research? *ibid.*," **76**, 700-706(2001).

Clinical Pharmacy Academy is dedicated to advancing pharmacists and health care professionals skills through education, research and services towards better health care outcomes. We are international professional expertise in pharmaceutical sciences including clinical pharmacy and related fields as clinical, academia and research. Clinical Pharmacy Academy was established since July 28th, 2013. Currently we have members from more than 30 countries globally. Our Vision: Clinical Pharmacy Academy is dedicated to advancing pharmacists and health care professionals skills through education, res... Clinical pharmacy is the branch of pharmacy in which clinical pharmacists provide direct patient care that optimizes the use of medication and promotes health, wellness, and disease prevention. Clinical pharmacists care for patients in all health care settings but the clinical pharmacy movement initially began inside hospitals and clinics. Clinical pharmacists often work in collaboration with physicians, physician assistants, nurse practitioners, and other healthcare professionals. Clinical Research is essential to the advancement of pharmacy practice and healthcare. Pharmacists have a pivotal role to play in this strategy. However, there is a paucity of data about hospital pharmacists' competence and ability in conducting health-related research.Â research or the impact of the remedies AHCs are undertaking. Importantly, concerns about clinical research are rarely viewed in a wider context, such as relative to the status of nonclinical research. One window into the world of clinical research in AHCs is the perspective of research leaders, including senior research administrators and department chairpersons in US medical schools.