

ACCP COMMENTARY

Research Fellowship Programs as a Pathway for Training Independent Clinical Pharmacy Scientists

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The American College of Clinical Pharmacy (ACCP) Research Affairs Committee published a commentary in 2013 on training clinical pharmacy scientists in the context of changes in economic, professional, political, and research environments. The commentary centered on the opportunities for pharmacists in clinical/translational research including strategies for ACCP, colleges of pharmacy, and the profession to increase the number and impact of clinical pharmacy scientists. A postdoctoral fellowship is cited as a current training pathway, capable of producing independent and productive pharmacy researchers. However, a decline in the number of programs, decreased funding availability, and variability in fellowship program activities and research focus have brought into question the relevance of this research training pathway to meet demand and opportunities. In response to these points, this commentary examines the state of research fellowship training including the current ACCP research fellowship review process, the need for standardization of research fellowship programs, and strategies to strengthen and promote research fellowships as relevant researcher training pathways.

KEY WORDS clinical pharmacy, fellowship, research training, graduate training, clinical pharmaceutical scientists.

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In 2013, the American College of Clinical Pharmacy (ACCP) Research Affairs Committee (RAC) published a commentary, “Preparing Clinical Pharmacy Scientists for Careers in Clinical/Translational Research: Can We Meet the Challenge?” summarizing its reexamination of the ACCP’s

position on training clinical pharmacy scientists amid changes in economic, professional, political, and research environments.¹ The potential impact of these changes on opportunities for pharmacy scientists and investigators in clinical/translational research is discussed, as well as strategies for ACCP, colleges of pharmacy, and the profession to increase the number and impact of clinical pharmacist investigators. The authors note that “failure of our profession to take advantage of these opportunities risks our ability to contribute substantively to the biomedical research enterprise and ultimately improve the pharmacotherapy of our patients.” They also emphasize the crucial need for clinical pharmacy investigators who can compete for research dollars from both the National Institutes of Health (NIH) and other prominent research funding organizations.¹

A central element to this reexamination is the assessment of research training pathways and their ability to produce highly competitive, independent clinical/translational pharmacy scientists

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and investigators necessary to meet growing societal research demands. Although fellowship training is cited as a relevant and effective pathway, decline in the number of programs, dilution of research focus, and fewer awards to fund fellow candidates and related research present distinct challenges to the sustainability of fellowship programs. Strategies to increase the number of programs and develop a critical mass of qualified mentors will require contributions across the profession, and an imperative first step is addressing the structural quality of research fellowship programs. A minimum level of standardization needs to be ensured to strengthen the rigor of research-related training experiences while still maintaining program individuality consistent with the uniqueness of each program and its research focus. Moreover, the diversity of fellowship training needs to be addressed to differentiate programs appropriately aimed at developing independent, highly competitive clinical investigators from otherwise focused programs. In response to these points, this commentary (1) outlines the current ACCP research fellowship review process; (2) discusses the need for standardization of research fellowship programs; and (3) presents strategies to strengthen and promote research fellowship as a relevant research training pathway.

ACCP Research Fellowship Review Committee and Process

The ACCP Research Fellowship Program Review Committee (RFPRC) was formed in 1988. In concert with the ACCP Board of Regents, the RFPRC is committed to providing guidance for research fellowship programs and advancing fellowship training pathways that develop independent, highly competitive clinical pharmacy scientists. This is achieved through peer and committee review of voluntarily submitted programs using ACCP-approved research fellowship program guidelines (Appendix 1).² Originally developed in 1988, these guidelines were revised in 2004 to establish minimum training program requirements and criteria-based assessment of fellowship applicant criteria and fellowship experiences. In addition, documentation of institutional support and preceptor qualifications (specifically a track record of independent research accomplishments, expertise, and grantsmanship) are evaluated. The intent of the peer review process is to promote program quality by assessing measur-

able training minimums while maintaining a highly individualized experience within the program's area of expertise.

The RFPRC is composed of 10 ACCP members, with two members of the committee assigned as primary reviewers for each fellowship program application. Fellowship programs can choose to apply for initial review or full review. Initial review is intended for new or recently established programs that have graduated no more than one fellow. The purpose of the initial review is to provide important feedback to new/developing programs seeking to fully meet the criteria for all elements of the fellowship guidelines. Full review is intended for established fellowship programs that have graduated at least two fellows. If the review process determines that the program has met the ACCP guidelines for research fellowship training, programs that have undergone initial review must complete a re-review in 2 years, whereas programs that undergo full review are re-reviewed in 5 years. The purpose of the re-review is to show that the program has sustained the efforts and activities necessary to meet ACCP criteria. This comprehensive review process helps ensure that each research fellowship training program is well positioned to produce independent clinical/translational pharmacy scientists.

In addition to providing feedback regarding the quality of the fellowship program, the peer review process can benefit a fellowship program in other ways. Programs may indicate in advertisements and fellowship descriptions that they meet ACCP's guidelines, which will aid in fellow recruitment. Such recognition can also help secure continual funding for some fellowship programs, thus contributing to the sustainability of these programs.

The Need for Standardization of Research Fellowship Programs

The ACCP guidelines for research fellowship training programs are designed so that trainees can gain appropriate research training and experience while having the flexibility and autonomy individually to develop a focus in a particular research niche and associated skill set. In that respect, it is difficult to find a specific guideline formula that works for all programs. Nevertheless, the current requirements and criteria outlined for research fellowship programs establish a rigorous minimal time commitment to

research training including didactic coursework, regulatory training, independent hypothesis generation and active research participation, grant writing, and abstract and manuscript completion. In addition, programs must have a documented foundation of administrative, educational, facility, and qualified personnel support. Unfortunately, the impetus to submit for peer review is largely internal to the program, as evidenced by only 8 of 57 known fellowship programs currently having the peer-reviewed designation.³ The lack of tangible external incentive for research fellowship programs to undergo peer review significantly limits the impact of the process. Moreover, following program peer review, ongoing adherence to the guidelines and postfellowship research productivity (i.e., track record of producing successful clinical pharmacy scientists) are not assessed.

In its recent commentary on preparing clinical pharmacy scientists, the RAC noted the potential advantages of pursuing research fellowships and other postgraduate training programs, given the landscape of the current pharmacy job market.¹ However, the committee also cited inconsistencies across fellowship training programs as a major challenge to assuring the quality and rigor of these programs. One of the weaknesses identified in the commentary is the lack of a core curriculum for research fellowship programs. Furthermore, the term *fellowship* is used inconsistently in today's postgraduate pharmacy training environment.⁴ Some fellowships may include predominantly clinical training experiences, industry-sponsored training pathways, combined clinical and research activities, or mixed research and graduate education experiences. Although these experiences are often specialized and important in postgraduate training, the clear delineation of research fellowship programs, whether in an academic or an industry setting, and the criteria-based approval of these programs are necessary to provide minimum standards that ensure quality, an issue important for both the pharmacy profession and external funding agencies (e.g., NIH and industry).

We recommend that ACCP embrace the diversity in fellowship program training and develop a new framework to address four major fellowship categories: (1) clinical scientist fellowship programs designed to develop independent, highly competitive pharmacy investigators in clinical/translational and outcomes research; (2) industry fellowship training programs designed to develop pharmacists with the tools to excel in

industry-based research and development, medical affairs, or regulatory affairs; (3) clinical pharmacy fellowship programs that incorporate substantial time in clinical practice with an emphasis on research but with less time devoted to research-related activities than clinical scientist fellowships; and (4) other fellowship training programs not included in the categories just described that may or may not require research (e.g., academic education, global engagement).

In addition, encouraging fellowship programs to incorporate the concurrent acquisition of an advanced research-related degree would strengthen both the utility of the training and the competitiveness of the fellow. Relevant examples of such degrees are the master of public health (MPH) and the master of science (M.S.) including programs focused on clinical research, research administration, or epidemiology. Furthermore, as more interprofessional team-based activities are included in evolving health sciences curricula and academic accreditation standards, direct involvement of the fellow with researchers in medicine, nursing, and allied and behavioral health can be expected to strengthen the fellowship program. Fellow involvement in joint research seminars, interdisciplinary journal clubs, interprofessional educational symposia, and formal or informal research collaboration should be sought whenever possible.

To further support research fellowship programs, we recommend that ACCP work with schools and colleges of pharmacy and other professional organizations to actively promote research fellowship training. Indeed, research fellowship training, which has produced highly qualified and productive translational scientists, should continue to be supported as a relevant, structured option for post-Pharm.D. specialization. Collaborative strategies, under ACCP's leadership, are needed to ensure program quality, strengthen consistency in core competencies, and reestablish broad confidence in research fellowship training as a relevant pathway. However, such efforts (including program peer review) will not fully be effective unless they are more strongly supported by the academy, current and prospective fellows, and competitive funding entities.

Short of an accreditation process, the pharmacy research community should adopt a collaborative and unified fellowship program review strategy to ensure consistency and strengthen the utility and impact of research fellowship training while balancing program and fellow individuality. Similar to the consideration

given federal fellowship funding processes,⁵ post fellowship outcomes—including the professional position secured by the fellow, grants received, scientific publications, and professional honors and awards—should be evaluated to measure the individual objectively and aggregate the strength of research fellowship programs.

In the near term, ACCP should identify organizational incentives unique to peer-reviewed research fellowship programs. For example, the ACCP Research Institute could once again consider supporting a research fellowship program grant, where these grants are earmarked specifically, or provide score incentives, for ACCP peer-reviewed research fellowship programs. Additional incentive examples for fellows from peer-reviewed programs include ACCP investigator development program discounts, opportunities for fellows to participate in research symposia and platform presentations at ACCP's meetings, and professional development support including fellow discounts on texts and other ACCP resources.

Strategies to Promote Research Fellowship Training Programs

The ACCP RAC commentary identified two main obstacles that limit the pharmacy profession in contributing talent to clinical and translational research.¹ One obstacle pertains to the “critical mass of precursor talent,” or pharmacy students, working in environments that promote research. The authors identified several challenges to attracting qualified students to careers in research; one in particular has to do with students' lack of awareness of research fellowship training programs and, perhaps most importantly, the roles that fellowship experiences can play in the successful pursuit of a research career.

A survey assessing the factors that motivate pharmacy students to pursue postgraduate training suggests that the likelihood of securing a job after training is one of the top three motivating factors.⁶ The survey also identifies important obstacles such as inconvenient timing of when information is given, lack of information, unavailability of informed individuals to ask questions about postgraduate programs, and advisers who do not advocate for postgraduate education. Strategies that may address some of these obstacles include making available within the professional curriculum opportunities to learn about research training including an emphasis on fellowships to highlight the characteristics of various programs,

explain the application process, share a day in the life of a fellow, and discuss career paths after training. Faculty might consider challenging students with clinical questions to research, analyze, assimilate, and present data on an approach that emphasizes the commitment to research as well as the role that research plays in pharmacy practice, even if on a basic level. Elective courses have been designed to promote residency training and have been shown to increase student knowledge as well as confidence.⁷ Similarly, courses focused on research training pathways, including research fellowship programs offered early in the curriculum, could increase student interest.

Offering research electives and incorporating research activities into advanced pharmacy practice experiences can create student interest in research and foster the preliminary development of important research skills. Research electives should include opportunities for students to participate in activities that range from study design and protocol development to bench or laboratory research. The culmination of these courses should be a poster and/or podium presentation with the ultimate goal of manuscript publication.

Using student professional organizations to conduct research expert panel discussions, research seminars, or research training workshops could help promote fellowship training. These sessions could be offered at various times and during multiple semesters. The expert panel might share experiences and provide information on qualifications and career paths. Furthermore, these panels could help develop meaningful mentor-mentee relationships. Institutions affiliated with fellowship training programs should consider having their fellows serve as mentors to students. This approach would not only help improve students' perceptions of research and increase their interest but would also help prepare fellows for future mentor-leader roles.⁸

Fostering collaborations through the development of undergraduate research programs would provide students with opportunities for mentored learning by allowing them to work closely with faculty and fellows on a scholarly project. Students should be expected to formulate clinically relevant questions, propose hypotheses and solutions, examine the proposed solutions, and effectively communicate the outcome.

Another source of clinical scientist “precursor talent” is postgraduate residency training programs. It is unrealistic to expect every student to decide during pharmacy school whether to pur-

sue a research career. Residency training may provide a more viable introduction to clinical and translational research and the opportunities associated with fellowship training. Although residency accreditation standards require the development, implementation, and completion of a project to provide appropriate “project management skills,”⁹ this experience is unlikely to produce independent successful clinical pharmacy scientists. The limited availability of qualified research mentors within many residency programs and the practicalities of incorporating research into an already intense residency year can distract residents from acquiring a positive research experience. Potential strategies to facilitate introductory research involvement include designing research-related elective learning experiences or research certificate programs; working with professional organizations to provide mentorship or networking opportunities to foster clinical pharmacy research careers. For example, the ACCP Practice and Research Networks may provide programs or opportunities for residents to interact with clinical scientists in specialty areas of practice, thereby facilitating enhanced exposure to research career paths, offering expert panel discussions as part of resident education sessions or meetings focused on research and scholarly career paths. As the RAC commentary suggested, early exposure to research is critical to researcher development. Thus opportunities to provide research experiences during student and resident education and training are imperative to the enculturation of future clinical pharmacist scientists.

Conclusions

A resurgence of clinical pharmacy research fellowship training programs could help close the gap between supply and demand for independent, competitive clinical pharmacy scientists. The future of the research fellowship as a relevant research training pathway depends on ensuring consistency, demonstrating effectiveness, and reestablishing confidence in the rigor of the training obtained. ACCP should work with its partners to initiate steps toward achieving this end, including differentiation and categorization of major fellowship program types (e.g., research, industry, clinical, academic) and development of new peer review criteria, where needed; demonstration of support for criteria-based peer review of research fellowship programs by a broad group of research and

employment stakeholders including those representing the academy, industry, and funding sources; expansion of formal standardization and program criteria/requirements for research fellowship programs including a requirement to complete a graduate-level research-related academic degree and an assessment of fellowship outcomes related to independent fellow productivity beyond the period of fellowship training; stimulation of interest in research among students and residents, emphasizing research fellowships as a viable pathway to pursue a research career; and creation of ACCP-specific organizational incentives for peer-reviewed fellowship programs and their fellows.

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APPENDIX 1. GUIDELINES FOR RESEARCH FELLOWSHIP TRAINING PROGRAMS

Definition

A research fellowship is a directed, highly individualized, postgraduate training program designed to prepare the participant to function as an independent investigator.

Introduction

The purpose of fellowship training programs is to develop competency and expertise in the scientific research process, including hypothesis generation and development; study design; protocol development; grantsmanship; study coordination; data collection, analysis, and interpretation; technical skills development; presentation of results; and manuscript preparation and publication. A fellowship candidate is expected to possess appropriate practice skills relevant to the knowledge area of the fellowship. Such skills may be obtained through prior practice experience or completion of a residency program.

Under the close direction, instruction, and supervision of a qualified investigator-preceptor, the fellow receives a highly individualized learning experience, using the fellow's research interests and knowledge needs as a focus for his/her education and training. Fellowships are typically offered through schools/colleges of pharmacy, academic health centers, the pharmaceutical industry, and/or specialized care institutions. A fellowship graduate should be capable of conducting independent and collaborative research and functioning as a principal investigator.

Training Program Requirements

1. A minimum of 3000 hours of the fellow's training time should be devoted to research-related activities for a minimum of 2 years.
2. Administrative institutional support for the preceptor's research program and the fellowship training program.
3. Availability of advanced educational opportunities (e.g., graduate-level coursework) in research-related topics. Such coursework may include, but is not limited to, courses in research design and methods, biostatistics, ethical issues, pharmacokinetics, pharmacodynamics, pharmacoeconomics, and others as appropriate to the specific fellow and program.
4. Availability of appropriate facilities (e.g., laboratory and/or clinical) to conduct research.
5. Availability of qualified personnel to teach clinical, laboratory, and/or computer technology-based research skills.
6. Ready access to scientific literature and computer facilities.

Preceptor Qualifications

1. A clinical scientist with an established and ongoing record of independent research accomplishments and expertise in the area of specialization related to the fellowship, which may be exemplified by:
 - a. Fellowship training, a graduate degree, and/or equivalent experience;
 - b. Principal or primary investigator on research grants and/or projects; and
 - c. Published research papers in peer-reviewed scientific literature in which the preceptor is the primary or senior author.
2. Active collaborative research relationships with other scientists.

Fellowship Applicant Criteria

1. Master's or doctoral degree in a health science discipline required.
2. Residency or equivalent clinical experience preferred.
3. Demonstrated interest in or an aptitude for a career in research.

Fellowship Experiences

Ideally, a research fellow should initiate and complete at least one original research project. However, it is recognized that this may not be possible in every case. Whether through the completion of one project from start to finish or through participation in multiple projects, the fellow should obtain extensive experience in:

1. Development of at least one scientific hypothesis.
2. Development of experimental methods to test the developed hypothesis.
3. Preparation of a protocol and submission of the protocol to the appropriate institutional review committee.
4. Grantsmanship, including identification of appropriate funding sources for specific projects and the preparation and submission of a grant for extramural funding consideration.
5. Study design and coordination and data collection.
6. Statistical analysis of data.
7. Data analysis and interpretation.

8. Development of clinical, laboratory, and/or computer-based research skills as appropriate to the specific training program.
9. Abstract preparation and submission.
10. Presentation of research at peer-reviewed scientific meetings.
11. Manuscript preparation and submission for publication in peer-reviewed journals.
12. Participation in journal clubs, research workshops, and/or seminar series.
13. Instruction in biomedical science ethics.

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