ACCP White Paper

The State of Science and Research in Clinical Pharmacy

American College of Clinical Pharmacy
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In late 2002, the president of the American College of Clinical Pharmacy (ACCP), Mary Beth O'Connell, Pharm.D., charged the ACCP Research Affairs Committee with developing a White Paper on The State of Science and Research in Clinical Pharmacy. Its purpose would be to address the current state of research conducted by clinical pharmacists in terms of prevalence, scope, funding, location, and impact; describe the current state of research training for clinical pharmacists; envision the state of research conducted by future clinical pharmacists in 2030 and the training required for these future scientists, if ACCP's vision is to be realized; describe any gaps that exist between current and envisioned states of clinical pharmacy research; and formulate recommendations to the profession and to ACCP in order to narrow any identified gaps. Member surveys, additional research, and committee deliberations in preparation for this White Paper began in October 2002. It is in accordance with these goals the following observations, analyses, and recommendations have been developed.

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Background

As with any discipline, research is critical to the advancement of clinical pharmacy. The need for pharmacist-researchers who possess both clinical pharmacotherapy knowledge and biomedical research skills was recognized in the Millis Commission Report in 1975.[1] The Millis Commission defined "clinical scientist" as an individual equally skilled and trained in a science and in pharmacy practice. Their definition is consistent with the general definitions of clinician-scientist used by the National Institutes of Health (NIH) and the Canadian Institutes of Health Research.[2, 3]

The American Association of Colleges of Pharmacy (AACP) conducted a survey that documented the severe shortage of pharmacy faculty in the United States. In 2002, of 67 schools responding to the survey (80% response rate), 417 faculty positions were open, almost all of which were for positions in either pharmacy practice (223 positions) or the pharmacy sciences (190 positions).[4] With the steadily increasing number of pharmacy schools and class sizes, the need for qualified individuals to teach and advance the field of clinical pharmacy will continue to expand. The need for pharmacist-researchers who possess both clinical pharmacotherapy knowledge and biomedical research skills (of which clinical pharmacy research is a subset) is critical as overall drug use

increases and as technology and science allow us to move toward better targeting of and more individualized approaches to drug therapy.

Despite a societal need for clinical pharmacy scientists, some barriers exist. Challenges that pertain to all clinical investigators, including pharmacist-researchers, are enhancing public participation in clinical research, guaranteeing an adequately trained workforce, and obtaining funding.[5] The difficulties facing clinical pharmacy researchers are similar to and in some cases amplified compared with those faced by some other clinical researchers. In addition, the increasing competition for suitable patients, conflicts of interest and their impact on public opinion of clinical research, increasing regulation, and privacy concerns all affect the ability of pharmacists to recruit necessary participants for clinical research.[6]

Since the Millis Commission Report in 1975, the development of clinical scientists in colleges of pharmacy has been the topic of several thoughtful articles. In 1986, one author assessed whether clinical pharmacists were meeting the clinical scientist role.[7] This author concluded that "the number of individuals who have demonstrated the capacity of independent research is much too small; the number of programs to train such individuals are too few; and the research output from clinical faculty is too little." He favored the 2-year post–doctor of pharmacy (Pharm.D.) fellowship (vs the Pharm.D.–doctor of philosophy [Ph.D.] degree) as the ideal mechanism to train clinical scientists; however, others have questioned whether a fellowship, particularly following an entry-level Pharm.D. degree, can achieve the competencies necessary for one to be both clinically and scientifically prepared for an independent research career. In fact, whether an individual can be competent and comfortable in both the patient care area and in research also has been debated.[8] In 1991, an ACCP White Paper was published in an effort to recognize and describe the issues relevant to clinical pharmaceutical scientist training programs.[9] That article generated the following questions regarding these training programs:

- What is the definition of a clinical pharmaceutical scientist?
- What is the market for these individuals?
- How is our profession currently training these scientists?
- How should they be trained?
- How should these programs be structured and implemented to meet the future needs of the profession?

Although more than 10 years have passed since the publication of that document, many of the same questions remain. Even as late as 1998, then president Jordan Cohen addressed the AACP and called for colleges of pharmacy to develop Ph.D. programs in the clinical pharmaceutical sciences in order to meet the stated interest of NIH in funding multidisciplinary translational research and the needs of the pharmaceutical industry in drug development.[10]

Of interest, for more than a decade, the literature has been devoid of any meaningful discussion regarding advances in the education of clinical pharmaceutical scientists. It is likely that, faced with the challenge of implementing the entry-level Pharm.D. degree and providing experiential training for large numbers of pharmacy students, the attention of pharmacy leadership has been directed elsewhere. Although it is difficult to quantify, the research productivity of clinical pharmacists has continued to grow, largely unnoticed by the profession as a whole. Clinical pharmacist research productivity has increased despite a decline in access to industry-sponsored research funds, partly due to increased restrictions on these funds and competition from the growing number of contract research organizations.[11] Peer-reviewed funding for clinical research, especially at the federal government level, has become the standard for achieving success in academic institutions. Approximately 37% of the total NIH extramural budget was awarded to clinicians in 2001; however, pharmacists are a distinct minority in the demography of the NIH grantee population. Although increasing since 1995, the rate of full-time U.S. pharmacy practice NIH awardees is 1.2% of all full-time U.S. pharmacy practice faculty.[12] To continue the advancement of clinical pharmacy research, concerted efforts are needed to provide guidance and training to increase the competitiveness of clinical pharmacy scientists in private and peer-reviewed funding opportunities, including federally funded grant programs.

American College of Clinical Pharmacy's Strategic Plan

The ACCP's strategic plan lays out a direction for advancing their research mission. The ACCP envisions that within the next 10–30 years, a significant increase will occur in the number of

Table 1. Survey Results for Number of Original Research Articles Published According to Work Setting and Research Intensity

	No. of Articles Published		
Setting	Mean	Median	Range
Academic, non–research intensive (n=52)	3.3	2.0	1–26
Academic, research intensive (n=133)	13.1	9.0	1–120
Academic, administrative (n=18)	10.6	6.5	1–30
In-training, non–research intensive (n=2)	1.0	1.0	1
In-training, research intensive (n=15)	2.5	2.0	1–9
Practitioner, non–research intensive (n=56)	2.6	1.0	1–14
Practitioner, research intensive (n=33)	6.3	4.0	1–24
Industry, non–research intensive (n=7)	3.0	3.0	1–5
Industry, research intensive (n=16)	8.1	5.0	1–21
Other, non–research intensive (n=11)	2.6	2.0	1–7
Other, research intensive (n=18)	20.3	10.0	1–175
Setting not specified (n=3)	12.3	8.0	7–22
Total respondents (n=364)	8.46	4	1–175

clinical pharmacy scientists who will serve as principal investigators for pharmacotherapy research, generate a substantial portion of the research that guides drug therapy, and compete successfully with other health care professionals for research funding. It is also envisioned that ACCP members will commonly serve as principal investigators for pivotal clinical trials and other pharmacotherapy research, and will compete successfully for research funding that creates new knowledge and guides drug therapy. The ACCP has set goals to increase the impact of pharmacist-initiated research, to encourage the pursuit of research careers by clinical pharmacists, and to foster individual members in their research and scholarly capabilities.

Current State of Research Conducted by Clinical Pharmacists

At the time of drafting this White Paper, little information was available on the current state of research conducted by clinical pharmacists. Information was available regarding the success of clinical pharmacists in obtaining NIH grants, but a more general measure estimating "success" in obtaining research funding and conducting research was not available. Although the NIH is considered by many to be the pinnacle of grant support, it is not the major source of funds for clinical research. Many clinical researchers practice outside the academic setting and may not have access to federal grant funds. Keeping this in mind, the ACCP Research Affairs Committee developed two surveys aimed at quantifying clinical pharmacists' involvement in research.

A survey was developed by members of the ACCP Research Affairs Committee and approved by the Oregon State University institutional review board. The survey was administered by e-mail, using the Internet-based survey support program Zoomerang (MarketTools, Inc., Mill Valley, CA). The survey, sent to all ACCP members, requested information on current job description, research training, number of original research articles published in last 5 years (since September 1, 1998), quantity of grants awarded to an individual as the principal investigator in the last 5 years, and the source and dollar amount of these grants. Data were summarized by using MS Excel 2000, version 9 SR-1 (Microsoft Corp., Redmond, WA) and SPSS, version 11.5 (SPSS Inc., Chicago, IL).

An invitation to participate in the survey was sent to 7757 ACCP members. A total of 780 (10.1%) individuals responded to the e-mail and completed the online survey. Among the 780 respondents, most were in either academic (29%) or practice (28%) settings. The remaining respondents were classified as being in training programs (10%), industry (7%), or other (6%) practice sites. Sixty-four percent of individuals considered themselves to be working in a "research-intensive" setting, with research constituting 20% or more of their time. When describing their training, 22.9% had completed a fellowship, 7.1% a master's degree, and 3.8% a Ph.D. degree.

During the 5-year period (September 1,

1998–November 12, 2003), 46.7% of all respondents reported publication of at least one original research article. For those individuals who reported at least one published article, the mean number of publications was 8.5 (median 4, range 1–175). When divided by discipline, individuals in research-intensive positions or in academic settings reported a higher number of publications than their counterparts in clinical practice or industry (Table 1). Those who listed their positions as "other" also had a relatively high number of publications, although the sample size was small for this group and there was an obvious outlier (175 publications). It was of particular note that among all academic researchers (regardless of whether they had one published article or not), 53.4% of individuals had fewer than 10 published articles in the 5-year period.

Three hundred twelve (40%) of the 780 respondents had been awarded at least one research grant in the past 5 years. Of those who had at least one grant, 51.6% were awarded at least one grant over $60,000, 42.9% had at least one grant over $100,000, and 19.6% had at least one grant over $500,000. Of those in academic, research-intensive positions, the percentage of individuals with grants in these categories was even higher (70.0%, 60.8%, and 30.8%, respectively). Ten percent of individuals in academic, research-intensive positions reported that they had not held a grant in the past 5 years. Similarly, those in research-intensive positions who listed themselves as "other" (17 respondents; 76.5%, 76.5%, and 47.1%, respectively, in the funding categories listed above) or "practitioner" (32 respondents; 59.4%, 40.6%, and 9.4%, respectively, in the funding categories listed above) had more individuals with large grants than those in non–research-intensive positions.

Most grants obtained by individuals (60.0%) came from corporate or industry funds. The proportion of grants divided by granting agency is shown in Figure 1. For those in academic, research-intensive positions, 49.6% of the grants were from corporate or industry sources and 15.6% were from federal agencies.

Interpretation of these results is somewhat difficult due to the low response rate and the lack of a comparator group. We believe, however, that this survey can serve as a baseline with which to measure the future progress made by clinical pharmacists in research. In addition, a few meaningful observations can be made from this survey. Although not surprising, the proportion of pharmacists with formal research training (27–34%) was considerably less than the 64% of pharmacists currently in research-intensive positions. This indicates a significant gap between training and role expectations, while exemplifying the need for continued instruction and mentorship even after an individual's terminal degree and formal training.

It was particularly interesting that a significant amount of research occurred outside the typical academic setting. However, it was disconcerting to find that most individuals in academic, research-intensive positions had fewer than 10 articles published during the past 5 years, since this is the primary measure for promotion in many academic institutions. Several potential reasons exist for this finding, including the possibility that many of the respondents in this survey may have been in a research position for fewer than 5 years or that they are actually faculty in professional practice, non–research-oriented institutions. Another possibility is that research performed by clinical pharmacists is lengthy and time consuming, thereby limiting the number of publications that are possible in a 5-year term. It is also possible that education, training, mentorship, support, or resources are inadequate for most clinical pharmacists to be successful researchers. It will be crucial to observe how the number of articles published and the number of grants obtained change over time.

Another notable, but not unexpected, finding is that a large proportion of grant funding is derived from industry sources. Although this

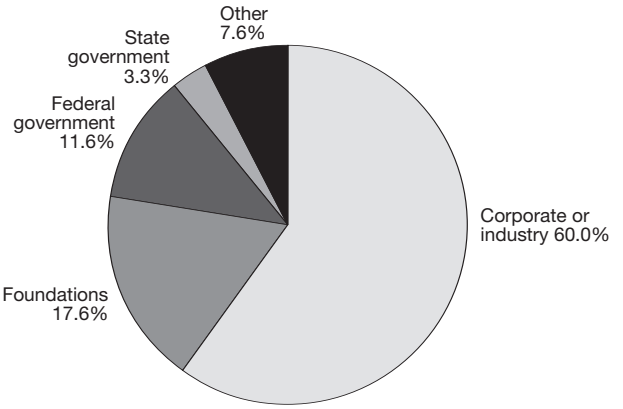

Figure 1. Proportion of research grants by type of granting agency obtained by members of the American College of Clinical Pharmacy. A total of 312 individuals reported at least one grant. Percentages are based on a total of 3079 grants.

type of partnership is essential to both the academic and corporate settings, a definite peril exists in heavy reliance on corporate support for research programs. Government-funded research programs are considered to be more stable and less influenced by market instability. Also, industry-funded studies present the potential for perceived conflicts of interest, which may affect perceptions when the scientific results of studies are disseminated. In addition, peer-review committees for promotion and tenure often view industry-funded grants as less competitive and prestigious than grants awarded by foundations or the federal government. Thus, diversification of funding sources likely strengthens clinical pharmacy research programs while providing a more stable environment for research training programs. However, it was not possible to discern from this survey whether this finding is the result of clinical pharmacists' inability to successfully compete for government funding, a lack of NIH grant applications by clinical pharmacists, or a general paucity of government funding in fields relevant to clinical pharmacy research.

Several limitations are apparent in this initial survey. Our response rate was low and may not be representative of ACCP membership, our intended denominator. For several reasons, the responding sample may be biased toward individuals who are more involved in the research setting. In addition, the career stage of the respondents or how long they have been actively engaged in research or practice is unknown. With regard to articles published, we asked only for the number of articles. We do not know how many of those articles featured respondents as the primary author. We also made no attempt to determine the quality of publications, which arguably should be given the same weight as the number of articles published.

Finally, a variety of researchers are being evaluated in this survey. We acknowledge that some types of research may be more "productive" with respect to number of articles published, may have more grant money available, or require greater resources to conduct quality research. This raises the possibility that, as a profession, we could appear more successful by performing only certain types of research while ignoring research that may have equal or greater benefits to society. We therefore recommend that follow-up surveys attempt to address the shortcomings observed in this first attempt.

Current State of Research Training in Clinical Pharmacy

Early in the history of clinical pharmacy, it was recognized that a better understanding of both the value of drugs and the value of pharmacists, through creation of new knowledge using the scientific method, is an important component of a clinical pharmacist's work.[13] A minority of training programs offering the Pharm.D. degree in the mid-20th century included formal research education, sometimes requiring completion of a research project as a graduation requirement. Most early recipients of the Pharm.D. degree, however, received clinical training exclusively and learned research skills informally while in an academic career. It was not until the early 1970s that clinical research training programs for clinical pharmacists were first developed at the University of California, San Francisco, and the State University of New York at Buffalo. This approach was embraced by the profession as the method to train pharmacists in research and was endorsed by the availability of fellowship funding from the American Society of Hospital Pharmacists (currently, the American Society of Health-System Pharmacists) Research and Education Foundation, starting in 1978.

To distinguish and clarify the objectives of residencies and fellowships for future trainees, in the late 1980s a coalition of national pharmacy organizations published definitions of the two types of programs.[14] A residency was defined as an organized, directed, postgraduate training program in a defined area of pharmacy practice. A fellowship was defined as a directed, highly individualized, postgraduate program designed to prepare the participant to become an independent researcher. In addition, fellowships exist primarily to develop competency in the scientific research process, including conceptualizing, planning, conducting, and reporting research. Recognizing the importance of rigorous requirements in these training programs, the ACCP and AACP jointly developed and published guidelines for clinical fellowship training programs.[15] In this document, the requirement for at least a 75% time commitment to research was promoted. General competencies to be achieved during fellowships were established.

The necessary research preparation required to seek and succeed in a research career for all health care professionals has steadily increased. Universities and colleges of pharmacy over the

years have developed numerous postgraduate programs to provide alternative training opportunities to help meet the needs of all students. Advanced degree routes include, but are not limited to, master of science (M.S.) and Ph.D. programs. This route offers a formal setting for additional research training with clearly defined goals and standards to be achieved before a degree will be conferred. These degrees have been offered in combination with the Pharm.D. degree at many universities and colleges of pharmacy. The issues surrounding the various mechanisms of preparation for the clinical pharmaceutical scientist were reviewed in an ACCP-sponsored White Paper in 1991.[9]

Comparison of Different Training Options

The dilemma of how to optimally prepare clinically trained individuals for research careers is not a problem unique to clinical pharmacy. In 1979, then NIH director, James Wyngaarden, declared clinical investigators to be an "endangered species" and warned of the perils of being unable to make progress in the treatment of serious diseases.[16] Since then, decreasing numbers of physicians pursuing careers in patient-oriented research in the 1980s and 1990s led to an NIH initiative designed to fund and promote the clinical research enterprise in the United States.[17] The problems with clinical research were elevated to crisis level in 2003 with the publication of the findings of the Institute of Medicine Clinical Research Roundtable.[5] Although many barriers were identified, the lack of adequate numbers of qualified clinical investigators was highlighted as a major obstacle.

Whereas formal research training for clinical pharmacists has traditionally been pursued through fellowships, the increasing diversity of available research opportunities has led to the development of different methods of achieving the competencies required to become independent researchers (Figure 2). These methods are described in the following sections.

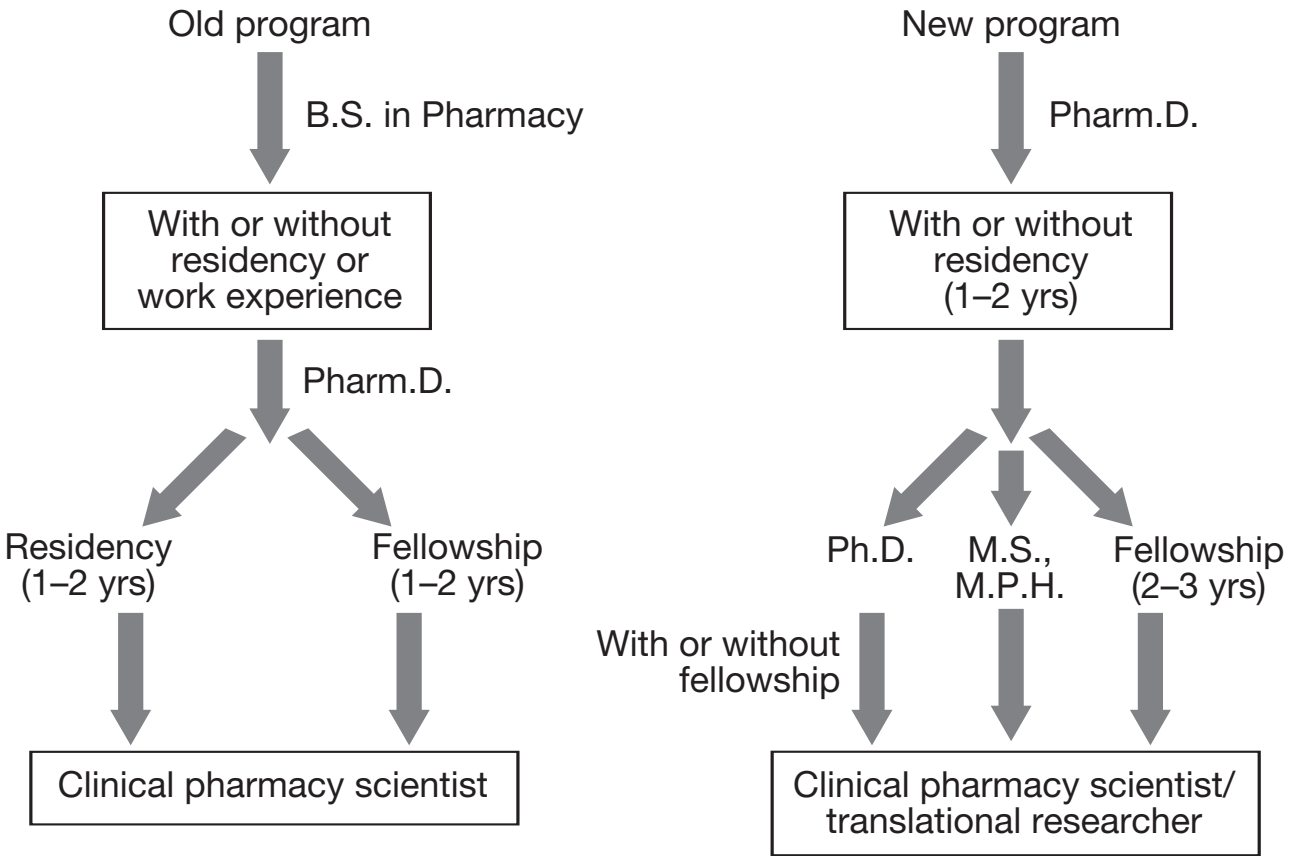

Figure 2. Comparison of old and new training programs to prepare clinical pharmacy scientists. B.S. = bachelor of science; Pharm.D. = doctor of pharmacy; Ph.D. = doctor of philosophy; M.S. = master of science; M.P.H. = master of public health.

Doctor of Pharmacy–Doctor of Philosophy

Pursuit of the Ph.D. degree after, or concurrent with, the Pharm.D. degree is attractive because it prepares graduates for a research career through a traditional, structured educational pathway. However, questions exist regarding whether these programs will serve the need for clinical scientists. When the NIH assessed the success of more than 900 graduates of dual-degree doctor of medicine (M.D.)–Ph.D. programs in establishing research careers, it was discovered that many graduates selected laboratory-based careers over patient-oriented research. In addition, less than 8% of the total number of research articles of this cohort were in clinical journals, confirming the suspicion that this career pathway was not achieving the goal of increasing patient-oriented research.[18] This sentiment has been echoed by pharmacy educators.[7, 8] Others have speculated that, because of the intense time commitment, even if the Ph.D. training is reoriented toward clinical research, this avenue will produce only 10% of the physician-investigators needed to conduct patient-oriented research.[19]

To encourage clinical research, some colleges of pharmacy have integrated residency training with their M.S. or Ph.D. programs to ensure that trainees gain clinical competence in a specific practice area to support their research activity and to foster translational research, outcomes research, and other clinically oriented research programs.[20, 21]

Doctor of Pharmacy–Master of Science

The completion of an M.S. degree after, or concurrent with, the Pharm.D. degree offers the student formal course work in subjects such as biostatistics, clinical trial design, and other topics specific to the discipline. For example, at Wake Forest University School of Medicine, medical students complete 42 credit hours of course work, started at the time of matriculation, and graduate 5 years later with M.D. and M.S. degrees.[17] An advantage of a combined professional-research degree program is that it allows the student to choose a research mentor early in the academic experience, and it may increase time efficiency of the education process. If students enroll in a combined program while in pharmacy school, they may also be more likely to pursue an academic career. For example, it has been shown that when medical students are exposed to research, they are significantly more likely to perform research in their postgraduate careers.[22]

Financial advantages may exist for colleges of pharmacy to offer graduate degree programs rather than research fellowships. Graduate students generate budget dollars for colleges through tuition credit hours, funding formulas, and other methods used to determine college and academic department budgets. Fellows often have a less formal status in universities, and they may be viewed as an expense line rather than as a revenue center for the college. For example, teaching funds may be the only university-funding source for a fellow, and it may be easier to justify teaching assistant appointments for graduate students than funding for research fellowship positions. Thus, a possible advantage of both M.S. and Ph.D. degree training over fellowships is the increased likelihood of consistent funding by the institution.

The AACP recently published a position statement in support of dual-degree programs.[20] They support the development of graduate degree programs for the purpose of educating and training pharmacist–clinical scientists at schools and colleges of pharmacy with adequate pharmacy science and clinical faculty and facility resources. The AACP believes that the pharmacist–clinical scientist graduate programs should contain course work and research requirements befitting the appropriate graduate degrees (M.S. or Ph.D.) awarded to those individuals who successfully complete the program.

The option to earn a Ph.D. degree on completion of the Pharm.D. degree is offered commonly at colleges of pharmacy, many since the early 1970s. More recently, the option to earn a dual-degree Pharm.D.-Ph.D. has been introduced and is being offered in at least 15 of the 89 colleges of pharmacy (Table 2). As of June 2004, however, enrollment in the dual-degree programs in the United States totaled fewer than 60 students. The reason for the limited number of students pursuing this training option needs to be clarified. Program representatives report that many students enroll but do not successfully complete the Ph.D. degree, with many citing financial burden as a major reason to leave the program. If the attrition continues at the current level, it is unlikely that this education and training pathway will meet the increasing demand for clinical pharmacy scientists in both the academic and industry arenas.

Table 2. Doctor of Pharmacy–Doctor of Philosophy Programs at Colleges of Pharmacy in the United States by Year Established

Institution, Year Program Established	Postgraduate Doctorate (Ph.D.) Dual-Degree Options	Prerequisite for Enrollment	Average Duration of Program	Stipends Offered
University of Kentucky, 1983 (first graduate)	Clinical pharmacology	GRE, acceptance to graduate school, Pharm.D.	4.75 yrs after Pharm.D.	Stipend ≥ $24,000/yr, ≥ $36,600 with benefits
University of Michigan, 1983	Pharmaceutics-pharmacology	Complete Pharm.D. program; GRE; letters of recommendation	5–6 yrs	Full tuition, health care insurance, and stipend
University of Pittsburgh, 1984 (first graduate 1989)	Clinical pharmaceutical sciences	GRE, acceptance to graduate school	4–5 yrs	TA/RA stipends available on admission to graduate school
University of Southern California, 1990	Molecular pharmacology and toxicology; pharmaceutical economics and policy; pharmaceutical sciences and regulatory sciences	Bachelors degree; admission to Pharm.D. program; GRE; GPA > 3.25	7 yrs	Yes, varies with program
Virginia Commonwealth University, 1990	Pharmaceutical sciences	Enrolled in Pharm.D. program; GRE; class ranking; research experience; faculty sponsor	2–5 yrs after Pharm.D.	Tuition reimbursement; stipend faculty/ program dependent
University of the Pacific, 1991	Pharmaceutical and chemical sciences	Admission to Pharm.D. program; GRE; GPA > 3.0	4–5 yrs	Tuition remission (27 units) + $17,000
Idaho State University, 1992	Pharmaceutical sciences (pharmaceutics pharmacy administration, pharmacology)	Pharmacy student in Pharm.D. program	2 yrs after Pharm.D.	TA/RA stipends available after completion of Pharm.D.
University of Tennessee, 1995	Health sciences administration and pharmaceutical sciences	NR	NR	NR
University of Maryland, 1997	Clinical science, pharmaceutical sciences, pharmaceutical health services research	GRE scores; interview; 3.0 Pharm.D. GPA; letters of recommendation	7 yrs	None in Pharm.D., only graduate component
University of Houston, 1999	Pharmacology, clinical pharmacology, pharmaceutics	Pharm.D. student at this institution; GRE scores	7 yrs	3 yrs at $3000, 3 yrs at $20,000
University of Texas at Austin (Pharmacotherapy Division, San Antonio), 1999	Clinical sciences	Pharm.D.	4–5 yrs	$32,000
University of California–San Francisco, 2000	Pharmaceutical sciences	Pharm.D. study at this institution	NR	For Ph.D. part, not while Pharm.D.
Purdue University, 2000	Industrial and physical pharmacy, medicinal chemistry-molecular pharmacology; pharmacology; pharmacy practice; pharmacy administration	Pharm.D.	4 yrs after Pharm.D.	Department dependent

Table 2. (continued)

Average No. of Enrolled Students	Career Pathways of of Graduates (%)		
	Academic	Industry	Other
8 students currently enrolled	33	47	20
2 (first student started in 2001)	NR	NR	NR
4–5 students enrolled at any time	50	20	25
5	100	0	0
6–8	25	75	0
3	0	0	100
4 (many students begin the program but few finish)	0	0	0
4–6	NR	NR	NR
1/class	0	75	25
5	0	0	100
None at present	100	0	0
First student started fall 2004	0	0	0
5	50	50	0

Doctor of Pharmacy–Residency and Fellowship

The traditional "mentor" model for training the clinical pharmacy scientist has evolved to require graduates of Pharm.D. programs to complete 1–2 years of residency training, followed by 1–3 years of research fellowship. This model has the advantage of a strong basis in clinical pharmacy practice and patient-oriented research. Graduates of these programs are skilled within their clinical specialty and have all the required competencies in execution of clinical research. Disadvantages of these programs include difficulty in securing consistent funding for fellowships by the mentors and a wide variation in the number and types of formal course work required during the fellowship training. Variation also exists with regard to outcomes in fellowship programs. Individuals are reported to complete fellowships without actually finishing their fellowship research project(s), which differs from graduate education in which the individual does not complete the degree program until the thesis or dissertation is completed, written, and defended.

Although the profession has been successful in increasing both the number of residency positions and the percentage of graduates seeking these programs (~14% [1079] of all graduates),[21] the number of available fellowship positions may actually be declining. In a 1985 survey, 91 fellowship positions were reported available in colleges of pharmacy and in hospitals across the United States.[7] Despite a steady rise in the number of graduates with Pharm.D. degrees in the last 2 decades, as of June 2004 there were 78 fellowship training opportunities listed in the ACCP directory. As with graduate programs, it has increasingly become difficult to recruit students for postgraduate training. Some programs have omitted the prerequisite to complete a residency before entering a fellowship program because students are not willing to complete a residency first. Even if all fellowship programs had funded positions and successfully recruited each year, it is unlikely that the graduates of these programs would meet the growing need in pharmacy education, industry, and other research enterprises for clinical pharmacy scientists.

Overall, neither graduate education nor fellowship training meets the current or future needs for clinical pharmacy scientists. The

Table 2. Doctor of Pharmacy–Doctor of Philosophy Programs at Colleges of Pharmacy in the United States by Year Established (continued)

Institution, Year Program Established	Postgraduate Doctorate (Ph.D.) Dual-Degree Options	Prerequisite for Enrollment	Average Duration of Program	Stipends Offered
University of Texas at Austin (Pharmacy Practice Division, Austin), 2001	Outcomes research with mental health or psychiatric pharmacy focus	Pharm.D. degree, admission to this institutions's graduate school (GRE > 1000, GPA > 3.0)	(including residency) Ph.D.: 4+ yrs	$32,000
University of Florida, 2004	Doctor of jurisprudence, clinical pharmaceutical sciences, pharmaceutical sciences	LSAT for doctor of jurisprudence; GRE; GPA > 3.2; letters of recommendation; acceptance to graduate school	NR	Tuition remission + $12,500–$30,000

Ph.D. = doctor of philosophy; Pharm.D. = doctor of pharmacy; NR = not reported; GRE = Graduate Record Examination; GPA = grade point average; LSAT = Law School Admission Test; TA/RA = teaching and research assistantships.

transformation of the clinical pharmacy research training system to produce a large number of suitably skilled scientists is imperative for clinical pharmacy research to flourish as a discipline.

Competencies To Be Achieved

Regardless of the method of preparation, all agree that education and training of clinical pharmacists should be highly structured and directed toward achieving a set of predefined competencies, which broadly address all aspects of the research process. The following are five draft competency statements regarding the training of a clinical pharmacy scientist that were created by the ACCP Research Affairs Committee as an amalgam of many different programs:

- Identifies relevant problems in therapeutics, generates hypotheses, and conducts research experiments to test hypotheses; interprets the results of research studies.
- Demonstrates clinical competence in a specialty area of pharmacy practice that complements the graduate's research focus.
- Communicates research and clinical findings to pharmaceutical, medical, and basic science audiences.
- Competes successfully for peer-reviewed grants.
- Applies legal and ethical principles and regulatory requirements when conducting clinical and experimental research.

Each training program should create an individualized list of competency statements appropriate to the particular setting.

Research To Be Conducted by Clinical Pharmacists in 2030

The following has been abstracted from the most recent ACCP strategic plan. The ACCP has a vision for clinical pharmacists and their involvement in research. This vision sees clinical pharmacists as leaders in biomedical research, serving as principal investigators and coinvestigators for cutting-edge translational research, pivotal clinical trials, creative health services studies, and other pharmacotherapy research. Furthermore, clinical pharmacists will successfully compete for research grant funding that creates and applies new knowledge to guide pharmacologic therapy.

Prevalence

By the year 2030, it will be common for clinical pharmacy scientists to be involved in various key aspects of research. A significant portion of ACCP members will be directly involved as principal investigators playing a role in the design, conduct, analysis, and publication of research. Likewise, members will serve as coinvestigators, acting as an expert in basic and clinical pharmacology, thereby contributing to study design, execution, and interpretation. Others will be active in research at the level of the clinical site, involved in study performance and quality assurance. Early opportunities for research involvement (including protocol development, study implementation, and data analysis and interpretation) for members-in-training will be available as well. These will be important objectives in pharmacy schools and post-Pharm.D. training programs.

Table 2. (continued)

Average No. of Enrolled Students	Career Pathways of of Graduates (%)		
	Academic	Industry	Other
1–2/yr	100	0	0
1	NR	NR	NR

Scope

Clinical pharmacy scientists will act as principal investigators and coinvestigators for a variety of areas of research including, but not limited to, basic science, translational research, drug development, clinical trials, practice-based outcomes, and epidemiologic research. The research conducted will have the objectives of providing direct benefits to patients and society, or indirectly contributing to future pharmacotherapy by understanding the pathophysiology of a disease or condition as it relates to pharmacologic interventions. Clinical pharmacy scientists will be active in publishing the results of their research in reputable scientific journals.

Funding

Clinical pharmacy scientists will be active in the development and submission of grants to fund their research. They will be competitive and successful in obtaining funding. Funding for the conduct of research will be obtained from a wide variety of available sources. These sources will include government agencies, private organizations, professional organizations, and the pharmaceutical industry. In addition, in 2030, the ACCP Research Institute will be among the top 10 professional organizations providing pharmacotherapy research support.

Locations

In 2030, the research by pharmacist-scientists will be conducted in all areas of practice and will not be limited to one particular area. Large numbers of pharmacist-scientists will be principal investigators in translational research that takes place initially in the laboratory, is tested in a clinical environment, and then provides feedback and direction to laboratory-based research. Similarly, pharmacists will expand their leadership role in health outcomes research that examines the clinical and economic outcomes of pharmacotherapeutic interventions. Currently, most pharmacy-based research is conducted by pharmacists who work primarily in academia or industry settings. In 2030, research settings will be broad and include not only the aforementioned settings but also clinical practice settings such as hospitals, ambulatory clinics, and community pharmacies.

Impact

The research conducted by clinical pharmacy scientists will define new practices that shape routine patient care. The findings will serve to maximize patient outcomes and minimize the morbidity that arises from disease, as well as from suboptimal drug therapy choices. It will establish and continue to refine new standards of practice that affect patients and other health care professionals. The research will increase knowledge about individual disease processes and new methods to treat specific conditions. It will also improve the manner in which pharmacists perform as clinicians, educators, and researchers. Likewise, it will continue to expand and recognize pharmacy as an intellectual profession that provides excellence in both patient care and research.

Training

Compared with current training, by 2030 significant changes in the training requirements for clinical pharmacists will occur. More Pharm.D. students will be introduced to research earlier in their training. All graduating pharmacists who wish to provide patient clinical services will complete a residency before entering practice. Most pharmacists will be board certified in a practice area. Residencies will meet minimum standards and be accredited to include objectives aimed at familiarizing the resident with specific aspects of research reflective of their residency discipline.

Multiple pathways will be available for pharmacists to pursue research education and training. These options will include both research fellowships and post-Pharm.D. graduate degree programs. Financial incentives, such as debt support and higher salaries, will be provided to encourage pharmacists to undertake research

training programs. With these incentives in place, a greater proportion of individuals will go on to pursue research education training. Fellowships will have a specific research focus that will prepare the trainee for a research career. Fellowship goals will change from merely completing a single, required, isolated project to performing a project or projects that represent initial steps toward an independent research career. Fellowships will prepare the graduate to be competitive for extramural funding.

The M.S. degree will likely replace or augment fellowship training in many colleges of pharmacy. This is likely to be the case because graduate degree programs offer more quality control than traditional fellowships, and formal graduate education offers a significant financial advantage for many colleges of pharmacy. These programs will either require residency training before entering the graduate program or integrate residency training with graduate training. However, in spite of the continued growth of graduate education programs, research fellowships will continue to be a feasible pathway for many pharmacists pursuing research careers. The fellowship may be a preferred pathway for individuals pursing research training in institutes, hospitals, or the pharmaceutical industry. These environments typically cannot offer a graduate degree but can offer structured, quality research training experiences. Formalized peer review by organizations such as the ACCP will be the norm for fellowship programs.

A portion of pharmacy school graduates will pursue graduate education and possess both Pharm.D. and Ph.D. degrees in lieu of a fellowship. Advanced clinical training will be incorporated into the graduate degree requirements for those individuals pursuing clinical research careers. A significant number of pharmacy schools will offer combined Pharm.D.-Ph.D. programs, and more students will pursue research education early in their pharmacy academic careers. Clinical sciences Ph.D. programs will be aimed at individuals who wish to pursue an educational experience that offers greater theoretic depth, and will likely represent individuals who wish to spend most of their careers in research activities.

Gaps Between the Current State of Affairs and Plans for 2030

The pharmacy profession seeks to produce leading clinical scientists. These individuals will be well funded by peer-reviewed grants and make significant research contributions to the medical and scientific communities. The following are considerations in achieving these goals.

Time and Resources

Major limitations for pharmacy research today are time and resources. At many colleges of pharmacy, clinical faculty members are being asked to teach more courses, contribute to administrative committees, increase clinical practice activities because of the need for clerkship sites, as well as conduct their research. If the pharmacy profession is going to make significant research contributions, institutions must make a commitment to support this outcome by first providing protected time for faculty to focus on their research. In addition to time, adequate resources must be available to initiate and build new research programs, which may include laboratory equipment, laboratory space, computer hardware and software, support personnel, support for research trainees, start-up funding, bridge funding, sabbaticals, and funds for development of pilot projects.

Adequate Mentorship

Although time and resources are extremely important, it is critical to fill another key gap by providing adequate mentorship for junior investigators in developing their research programs. In many cases, lack of appropriate mentoring limits the research success of junior faculty.[23–25] Mentoring is needed to assist in building collaborations, to enhance writing and communication skills, to guide expectations, and to encourage persistence as young investigators develop their research careers. However, mentoring takes time and resources away from senior faculty members who are already stretched beyond their limits. Additional protected time and resources need to be provided for senior faculty so that they may provide the necessary mentoring for young and developing faculty researchers.

Critical Mass of Researchers

An additional area of need is the development of a critical mass of researchers within individual institutions. Traditionally, academic pharmacy has followed a clinical service teaching model for its practice faculty. This was desirable from the perspective that it provides students with a variety of different practice environments for

experiential learning. However, a research program model requires a critical mass of complementary faculty researchers within a given research area. This may require three to eight faculty with similar research interests who can collaborate and provide synergy in their research activities. Although common in medical schools and even in college of pharmacy basic sciences departments, few pharmacy practice departments have achieved a critical mass of researchers with a complementary research focus.

Multidisciplinary Collaboration

Pharmacy researchers need to expand their presence in multidisciplinary research programs. These collaborations will in essence help to achieve the critical mass that is necessary for productive research programs. Through active collaboration with successful programs, the clinical pharmacist is provided more opportunities for multiyear funding and high-impact research than is typically possible either through working alone or only with individuals in the same department.

Limitation of Numbers in Research Training

As in many other areas of pharmacy practice, clinical pharmacy research has a limitation of numbers. At this time, few pharmacists appear to be seeking post-Pharm.D. research training, whether by an additional degree or a fellowship. This is confounded by the national shortage of pharmacists, so a "quick fix" will be challenging, but not impossible, in the current environment. As a profession, pharmacy needs to introduce research opportunities during Pharm.D. programs to increase the interest among students to seek out additional research training opportunities. The next concern that arises, though, is what additional training should be sought to advance research in the pharmacy profession. On the one hand, many believe that an additional postgraduate degree (M.S. or Ph.D.) is the best training for pharmacists pursuing research careers. Conversely, others feel strongly that a postgraduate fellowship is preferred. After extensive debate and discussion, no single path was identified as the best approach to meet the needs of the profession. The committee concluded that the appropriate postgraduate training plan is dependent on both individual goals and institutional structure. However, key competencies have been identified that must be achieved for individuals to become successful research scientists, regardless of the organizational structure of the training program.

Recommendations for Narrowing the Gap

The following are recommendations of the Research Affairs Committee for narrowing the gap between the current state of clinical pharmacy research and future contributions to research.

Recommendations to the Profession of Pharmacy

- Increase exposure to research and research careers in Pharm.D. curricula.
- Advocate for, and educate pharmacists regarding, grant programs targeted at clinical scientist training and development. For example, the American Heart Association (health sciences fellowships, predoctoral awards) and the NIH (K awards) have such programs.
- Reward and recognize the contributions that pharmacists make to biomedical research, both inside and outside academic settings.
- Lead or participate in multidisciplinary research programs and projects.
- Develop programs of debt abatement and other incentives for pharmacy graduates to pursue further research training and an academic career. For example, the NIH loan repayment program now recognizes graduates of pharmacy schools working in clinical research as candidates for loan repayment (available from https://www.lrp. nih.gov/NIHLRP/about/index.htm).
- Provide adequate resources within academic pharmacy practice departments to develop a critical mass of clinical pharmacy scientists.
- Develop creative paradigms that increase the number of pharmacists entering and completing clinical research training programs.
- Develop mentoring programs within colleges of pharmacy that provide junior faculty with the necessary infrastructure and research support to foster their success.
- Participate in federally sponsored multidisciplinary training grants and awards. For example, the NIH has allowed an individual with a Pharm.D. degree on a Physician Scientist Award (K12) oncology training grant, recognizing the need for a multidisciplinary approach, and recently funded eight centers through the K12 mechanism with the Request for Application National

Multidisciplinary Clinical Research Career Development Program.

Recommendations to ACCP

- Develop a method to promote accreditation of research fellowship programs in order to decrease the variance among research training programs, increase quality, and ensure that most graduates achieve the necessary competencies. This may involve some incentives such as requiring accreditation as a prerequisite to apply for training grants and seed monies from the ACCP Research Institute.
- Partner with residency directors to increase opportunities for combined residency-fellowship programs. This will allow early exposure to the excitement of discovery.
- Continue to create and provide funding for the support of training programs and junior investigators, and expand support for midcareer investigators.
- Develop a research mentor network. Highlight and provide information on the availability of research mentors to students, residents, research trainees, and young clinical scientists throughout the nation.
- Support the development of clinical pharmacy centers of excellence at various institutions nationwide, where a critical mass of investigators and mentors are available in a given therapeutic area (e.g., infectious diseases, pediatrics, oncology) for training future scientists.
- Continue to support and promote minisabbaticals.
- Support or conduct research that assists in determining the state of clinical pharmacy research and evaluate the changes that occur over time.

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