

ACCP

Update: The Clinical Pharmacist as Principal Investigator

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This paper summarizes the history of the clinical pharmacist as a principal investigator across a wide range of research venues and disciplines. Clinical pharmacists have served as principal investigators on a wide range of grants and contracts from all available funding sources, including peer-reviewed funding from the National Institutes of Health (NIH). The NIH Conference on Pharm.D. Pathways to Biomedical Research in 2006 (<http://www.nigms.nih.gov/Training/PharmD/>) is a strong endorsement of current and future opportunities for clinical pharmacist-directed research. Both research funding and resultant scholarship have increased during the past decade, primarily in academic settings. Through an American Association of Colleges of Pharmacy database, the number of faculty with a Pharm.D. as their terminal degree who received NIH funding increased from 5 in 1998 to 24 in 2007. Use of *www.ClinicalTrials.gov* provided a stronger picture of clinical pharmacist research, with 523 studies performed by those with a Pharm.D. degree when searched in 2009. Because of the lack of a central database, it is difficult to discern the true number and extent of clinical pharmacist research funding and scholarship. Scientific efforts are still required to completely understand the impact of research and scholarship by clinical pharmacists. Most important, clinical pharmacist development needs to be an academic and practice priority to ensure an adequate supply of clinical pharmacists as principal investigators to continue making substantial and meaningful contributions in meeting the needs of patients, improving public health, and expanding the roles of clinical pharmacists.

Key Words: clinical pharmacist, principal investigator, faculty development, research funding, pharmacist roles

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The role of the clinical pharmacist as principal investigator (PI) was first described in a commentary by the American College of Clinical Pharmacy (ACCP) in 2000.¹ From 2000 to the present, the number of individuals with the doctor of pharmacy (Pharm.D.) as a terminal degree who have served as PIs has grown.

Clinical pharmacists have served as PIs either by directing their own investigator-initiated research or by working within sponsored clinical trials. Moreover, a small but increasing number of clinical pharmacists have been funded by the National Institutes of Health (NIH).

The NIH has strongly endorsed the role of the

clinical pharmacist as an investigator. In 2006, the NIH held a conference titled “Pharm.D. Pathways to Biomedical Research” to promote the expansion of NIH-funded clinical pharmacists.² Today, pharmacists are widely accepted as PIs by foundations, industry, and government.²⁻⁸

History of the Clinical Pharmacist as PI: The Past 10 Years

In 1975, the Millis Study Commission on Pharmacy definitively stated that the “clinical scientist” is an individual equally skilled and trained in the science and practice of pharmacy, setting the stage for the widespread development of postgraduate fellowship training programs.⁹ Recognition first came in May 1983 by Stuart L. Nightingale, M.D., then-U.S. Food and Drug Administration (FDA) Associate Commissioner for Health Affairs, who stated, “It has long been FDA policy to accept Doctors of Pharmacy as principal investigators of studies of investigational drugs within their expertise.”¹⁰ In 1990, recognition of the clinical scientist was reestablished and described in the original ACCP commentary, “The Clinical Pharmacist as a Principal Investigator,” setting the foundation for the expansion of pharmacist-directed research.¹

Several documents or regulations support Pharm.D.s or clinical pharmacists as PIs across a range of research types. The FDA and European Medicines Agency provide consolidated guidance to industry according to Good Clinical Practice, stating:

The investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the

IRB/IEC, and/or the regulatory authority(ies).^{11,12}

This statement is consistent with federal regulations as described Section 312.53 of the 5/1/2003 Code of Federal Regulations (21CFR312), Chapter 1 FDA, Part 312, on the role of PIs.^{11,12}

Evidence Supporting the Pharm.D. as PI

In the past 3 decades, there has been a substantial increase in pharmacist-directed research, as evidenced by the growth in funded grants and scientific publications. Pharmacists have served as PIs for a wide variety of grants and contracts from all available funding sources, including the NIH, the FDA, the Agency for HealthCare Research and Quality, the Department of Veteran Affairs and other federal departments, state and local governments, private organizations and foundations, and the pharmaceutical industry.¹³

Increased NIH Funding of Pharmacists

Although the NIH does not provide a complete listing of clinical pharmacists who have been funded as PIs, the American Association of Colleges of Pharmacy (AACCP) tracks NIH funding for colleges of pharmacy. AACCP has worked diligently to differentiate Pharm.D.-trained faculty from others and has provided a listing of NIH-funded faculty since 1998 (Kenneth Miller, personal communication, 2009). Specifically, five individuals with a Pharm.D. as their terminal degree were funded in 1998. By contrast, a minimum of 24 were funded in 2007. Types of funding ranged from the R to the K and U series of grants. These data do not include notable NIH-funded pharmacists working in institutes, foundations, research hospitals, or similar institutions. Thus, the total number of Pharm.D.s who have received NIH funding as PIs is likely higher.

From 1996 to 2003, funding from the NIH for colleges of pharmacy as a whole increased by 123%. This increase was primarily because of the increased amounts awarded, not the number of awards. The greatest percent increase was in social and administrative (from about 2% to 3%) and pharmacy practice (from less than 1% to about 1.5%) faculty. Nonetheless, NIH funding remains modest, with only 1.15% of pharmacy practice faculty having received an NIH grant, despite an increase in the absolute number of practice faculty. Pharmacy faculty members with

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either a Pharm.D. or Ph.D. degree received more than 600 NIH awards in FY 2004, representing a 59% increase from 1998 and a 153% increase in NIH funding from 1998 to 2004.^{13, 14} The findings provided in the AACP reports are supported by Touchette and colleagues,¹⁵ who found a non-significant 6.3% increase in the results of federally funded research grants published by pharmacists in clinical journals from 1993 to 2003.

Growth in Funding and Publication of Research by Clinical Pharmacists

Funding from the pharmaceutical industry remained the most common source of grant support to clinical pharmacists through 2003.¹⁵ A survey conducted by the ACCP Research Affairs Committee in 2003 found that 40% of ACCP member respondents had been awarded a research grant, with 60.0% of these grants from industry sources and 11.6% from the federal government.³ Furthermore, 46.7% of respondents had published at least one original research article. The mean number of publications among respondents was reported to be 8.5 during the 1998–2003 survey period. The number of pharmacist-written research publications increased by 29.2% from 1993 to 2003, with 94.2% involving human subjects.¹⁵ Most pharmacist-directed research (about 70%) has been conducted in academic settings,¹⁵ but there is wide variation in publication rates by pharmacists in departments of pharmacy practice in the United States.¹⁵

NIH-Sponsored Conference on Pharm.D.s as Researchers

As noted, few Pharm.D. clinical scientists have succeeded as PIs in receiving peer-reviewed research funding at the NIH. From the proceedings of the NIH conference on Pharm.D. Pathways to Biomedical Research in 2006, there appears to be a deficiency of opportunities and commitments to train, develop, and support Pharm.D. researchers. This deficiency contributes considerably to the gap in NIH funding for Pharm.D. clinical scientists as PIs. A summary of the conference can be found at <http://www.nigms.nih.gov/Training/PharmD/>.^{2, 16, 17} This conference provides a series of recommendations intended to increase the number of eligible and qualified clinical pharmacist researchers competing for extramural

NIH support. Some of the important recommendations of this conference are exposure to research during the Pharm.D. curriculum and postgraduate training, high-quality mentoring, grant writing experience and education, strong clinical practice skills, and participation in hypothesis-driven research. The extent to which these recommendations are acted on will likely critically influence clinical pharmacists' research productivity.

During the 2006 NIH conference on Pharm.D. Pathways to Biomedical Research, several presentations were made by NIH-funded pharmacist researchers. In developing this paper, we used www.PubMed.gov (U.S. National Library of Medicine) to search for publications by the eight NIH-funded conference faculty. (One faculty member did not have clear name differentiation and was excluded.) The number of publications for these conference Pharm.D. faculty ranged from a low of 117 citations to a high of 459 citations for seven of the eight presenters. Based on the collective experience of the committee, this level of publication is comparable to other non-Pharm.D. researchers.

Data from ClinicalTrials.gov on Pharm.D. Researchers

The committee searched for a mechanism to capture the number of clinical pharmacist PIs outside the federally funded system. In September 2007, federal laws were changed to require the registration of trials for FDA-approved (or cleared) phase II–IV drug and device trials at www.ClinicalTrials.gov. All NIH-funded clinical trials must be included in this database. Currently, www.ClinicalTrials.gov contains more than 70,000 trials and receives more than 40 million page views per month.¹⁸ To that end, the committee searched the expansive www.ClinicalTrials.gov database using three different forms of the term *Pharm.D.* (*Pharm.D.* OR *Pharm.D* OR *PharmD*). A total of 523 studies were found. Most (466) of the studies were interventional, compared with 57 observational studies. Table 1 shows the number of clinical studies stratified by funding category.

The “snapshot in time” exemplifies the use of www.ClinicalTrials.gov to define the Pharm.D.'s role in clinical research. Few clinical trials appeared to involve Pharm.D.s; however, for those with Pharm.D. involvement, it is of interest that in most of the funding/sponsor categories listed in Table 2, the Pharm.D.'s role was that of

Table 1. Trials at www.ClinicalTrials.gov by category, with the number and percent including the search term (*Pharm.D.* OR *Pharm.D* OR *PharmD*)^a

Funding Source or Sponsor	Total of All Studies in the United States.	Total No. with <i>Pharm.D.</i> Search Phrase	Total % with <i>Pharm.D.</i> Search Phrase
Clinical research network	2206	14	0.6
Industry	15,423	307	2.0
NIH	13,462	79	0.5
U.S. federal agency excluding NIH	1776	14	0.8
Universities/organizations	18,357	231	1.3
Total	39,169	523	1.4

^aSite accessed April 6, 2009.

NIH = National Institutes of Health.

Table 2. Trials at www.ClinicalTrials.gov organized by sponsor, with the role of the *Pharm.D.* defined^a

Funding Source or Sponsor	Studies with <i>Pharm.D.</i> as Search Term	Role of <i>Pharm.D.</i>				
		Sole PI	One of two or more PIs or Chair	Study Director/	Site PI	Contact Person or Other Role
Clinical research network	14	0	0	4	2	8
Industry	307 (100 analyzed)	32	7	34	0	27
NIH	79	36	7	11	5	20
U.S. federal agency excluding NIH	14	6	1			7
Universities/foundations	231 (100 analyzed)	57	13			30

^aSite accessed April 6, 2009.

NIH = National Institutes of Health; PI = principal investigator.

PI in about one-third to one-half, modestly more than the role as contact person or subinvestigator. The *ClinicalTrials.gov* Web site divides studies within various domains. Overall, the number of studies that contained the *Pharm.D.* search term phrase as above was between 0.5% and 2% of the total in each category.

Although these data provide important insight into pharmacist-directed research productivity, it remains difficult to determine the extent of pharmacists' activity as PIs. The AACP report statistics do not account for pharmacist grant recipients who hold primary appointments in medical schools, cancer centers, or the NIH intramural program.¹⁷ Clinical pharmacists may not be the primary investigator of a research grant; rather, they may serve as project directors or serve in other investigator roles of subawards. Because of this limitation, a significant component of the multi-investigator collaborative project profile of investigator identity and status may be missed. Such data are not typically

considered in reports of funding awarded to pharmacists as PIs. Furthermore, databases of pharmacists who serve as PIs in research studies are not readily available or accessible. Exceptions to these generalizations are those listed in www.ClinicalTrials.gov.

Notwithstanding, the productivity of pharmacists in research-funded publications is a useful surrogate of pharmacists' activities as PIs. The establishment of Clinical and Translational Science Awards in 2006 promoted research models and structures that would provide new opportunities for colleges of pharmacy to collaborate with schools of medicine that foster interdisciplinary relationships.^{2, 3} Through these partnerships or graduate programs of colleges of pharmacy, master's or doctoral graduate programs for developing clinical scientists are needed.⁴ All *Pharm.D.* students should be introduced to clinical and translational research during the curriculum.⁴ Pharmacy will need to either maintain or increase its focus on

pharmacist-directed research to maintain the trajectory of research apparent during the past 50 years.

Conclusions

The clinical pharmacist has been accepted as a PI by many granting regulatory agencies and the pharmaceutical industry for several years. Further efforts are needed to ensure that the profession of pharmacy understands the need to continue the important contributions to training, educating, and expanding the efforts of those engaged in research. This responsibility begins within our pharmacy schools because all pharmacy graduates have a terminal doctoral degree. Faculty and clinical pharmacist research development efforts should be enhanced to ensure an adequate number of clinical scientists for the profession and to ensure the appropriate use of medications. Clinical pharmacists should continue their research development to ensure the provision of optimal, evidenced-based medication therapy based on sound scientific principles and research data. Finally, a reliable database should be established if the profession is serious about tracking statistics relative to clinical pharmacist funding, publications, and roles as PIs or subinvestigators in basic, clinical, and translational research.

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