ACCP COMMENTARY

The Need for PGY2-Trained Clinical Pharmacy Specialists

American College of Clinical Pharmacy
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The American College of Clinical Pharmacy and other stakeholder organizations seek to advance clinical pharmacist practitioners, educators, and researchers. Unfortunately, there remains an inadequate supply of residency-trained clinical specialists to meet the needs of our health care system, and nonspecialists often are called on to fill open specialist positions. The impact of clinical pharmacy specialists on pharmacotherapy outcomes in both acute care and primary care settings demonstrates the value of these specialists. This commentary articulates the need for postgraduate year two (PGY2)-trained clinical specialists within the health care system by discussing various clinical and policy rationales, interprofessional support, economic justifications, and their impact on quality of care and drug safety. The integrated practice model that has grown out of the American Society of Health-System Pharmacists Pharmacy Practice Model Initiative (PPMI) could threaten the growth and development of future clinical specialists. Therefore, the ways in which PGY2-trained clinical pharmacist specialists are deployed in the PPMI require further consideration. PGY2 residencies provide education and training opportunities that cannot be achieved in traditional professional degree programs or postgraduate year one residencies. These specialists are needed to provide direct patient care to complex patient populations and to educate and train pharmacy students and postgraduate residents. Limitations to training and hiring PGY2-trained clinical pharmacy specialists include site capacity limitations and lack of funding. A gap analysis is needed to define the extent of the mismatch between the demand for specialists by health care systems and educational institutions versus the capacity to train clinical pharmacists at the specialty level.

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In 2005, the American Society of Health-System Pharmacists (ASHP) established new residency accreditation standards, changing the nomenclature to postgraduate year one (PGY1) and postgraduate year two (PGY2) residencies. Within these new standards, a requirement that pharmacists complete a PGY1 residency (or equivalent experience) before applying to a PGY2 residency was introduced. This change in terminology makes clear to prospective employers a clinical pharmacist's level of postgraduate training.[1] The standards for both PGY1 and PGY2 residencies are continually assessed and revised to meet the evolving needs of practitioners, patients, and employers.[1, 2] American

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Society of Health-System Pharmacists currently recognizes three types of PGY1 programs and 19 different PGY2 programs, each of which has its own accreditation standards.

During the past decade, multiple national pharmacy organizations, including the American College of Clinical Pharmacy (ACCP) and the American Association of Colleges of Pharmacy, have emphasized the importance of increasing the number of pharmacy students who complete residencies before entering professional practice.[3, 4] In 2006, ACCP released a position statement advocating that, by 2020, postgraduate training be a prerequisite for providing direct patient care or for being appointed to a position of adjunct clinical faculty or pharmacy student preceptor. This statement also recommends that, before being appointed to the rank of assistant professor, new full-time clinician-educator faculty complete at least 2 years of residency training.[4]

Value and Justification of Specialty-Trained Clinical Pharmacists

Support from Pharmacy and Non-pharmacy Organizations

As PGY2-trained clinical pharmacy specialists continue to demonstrate their value in improving patient care, the need for expertise in specialized direct patient care is more widely recognized by other professions, accrediting bodies, and governmental agencies. One widely recognized role for specialty-trained clinical pharmacists is in the care of patients receiving solid organ transplants. Clinical pharmacists have been extensively involved in the care of transplant patients for more than 30 years.[5] Their ability to improve patient outcomes has been well recognized by professional organizations within pharmacy, nursing, and medicine. In 2004, the United Network of Organ Sharing (UNOS) bylaws were amended to identify pharmacists as necessary members of the multidisciplinary transplant team.[6] Compliance with UNOS policies is necessary for a transplant program to receive funding through the Centers for Medicare and Medicaid Services (CMS). The document stipulates that "all transplant programs should identify one or more pharmacists who will be responsible for providing direct patient care." The bylaws define specific responsibilities the pharmacist must fulfill, including the oversight of drug use during the peri- and postoperative periods, the monitoring and recommendation of modifications in treatment plans, and the provision of patient and family drug education.

The specifications for transplant pharmacists have been further defined through a collaboration of the American Society of Transplantation Transplant Pharmacy Community of Practice and the ACCP Immunology/Transplantation Practice and Research Network (PRN). The result of this collaboration includes support for completion of both a PGY1 pharmacy practice residency and a PGY2 pharmacy residency in solid organ transplantation for transplant pharmacists.[5] In 2007, CMS adopted the UNOS standards, requiring that approved transplant centers include the clinical pharmacist as a core member of the transplant team.[7]

The Joint Commission also recognizes the role of specialized clinical pharmacists in the care of pediatric patients. In a 2008 Sentinel Event Alert on preventing pediatric drug errors, institutions were instructed to "ensure full pharmacy oversight" in all aspects of drug use and to employ pharmacists with pediatric expertise to provide care in areas such as neonatal and pediatric intensive care and pediatric oncology units.[8] The recommendations for pediatric pharmacy expertise in drug error prevention and the management of high-risk pediatric patients are based, in part, on earlier work from the American Academy of Pediatrics (AAP). During the past decade, AAP has routinely incorporated pediatric-trained pharmacists into its recommendations for multidisciplinary patient care. In its 2003 policy statement on the prevention of drug errors in the pediatric inpatient setting, AAP recommended that prescribers have access to pharmacists for consultations on drug dosing or dosage adjustment.[9] The group suggests that hospitals "integrate clinical pharmacists into patient rounds. . .particularly in intensive care and oncology units." In its 2004 guidelines for pediatric and neonatal intensive care units (ICUs), AAP reaffirmed the need for specialty pharmacist expertise, recommending the inclusion of specialized pediatric clinical pharmacists as part of the multidisciplinary team.[10, 11] The AAP recommendations for pediatric cancer centers also call for specialized pediatric pharmacists to serve as members on a multidisciplinary team.[12] Recent publications describe the role of pediatric clinical pharmacists in the care of pediatric oncology patients as well as in children with other complex medical needs, such as those with pediatric kidney disease.[13, 14] The ACCP Pediatrics PRN and

the Pediatric Pharmacy Advocacy Group have published a joint opinion paper that elaborates on the need for clinical pharmacists practicing in specialized pediatric areas to complete a PGY1 residency, followed by a PGY2 residency in pediatrics. Specialized training in pediatric pharmacy is generally available only through PGY2 training programs; therefore, to meet the expectations of AAP as well as those of other organizations, PGY2 training is the preferred and only formal, accredited option available.

The Society of Critical Care Medicine (SCCM) has long considered clinical pharmacists essential members of the patient care team.[15, 16] In 2000, ACCP and SCCM published a joint position paper on critical care pharmacy services that delineates the role of critical care pharmacists, dividing their efforts into categories of fundamental, desirable, and optimal activities.[15] These activities range from evaluating drug orders and providing drug information and pharmacokinetic consults to participating in guideline development and conducting clinical research. Although the authors of the document did not specify the educational requirements for critical care pharmacists, they suggested that the necessary qualifications and competence could be achieved by "advanced degrees, residencies, fellowships, or other specialized practice experiences." A subsequent 2001 paper by the American College of Critical Care Medicine, the consultative body of SCCM, further emphasized the role of the ICU-dedicated pharmacist and defined that individual as "a practitioner who is licensed. . .and has specialized training or practice experience providing direct patient care for the critically-ill patient."[16] In a subsequent opinion paper, members of ACCP, SCCM, and ASHP provided more specific recommendations for the level of training and credentialing of clinical pharmacists practicing in critical care. The authors state that the specialized knowledge and skills required by a critical care pharmacist to provide optimal clinical pharmacy services are best gained through the completion of PGY2 training.[17]

The need for clinical pharmacists with expertise in infectious diseases has been highlighted in several publications. In the 2007 guidelines for the development of institutional antimicrobial stewardship programs, the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America recommended that a pharmacist with infectious diseases training and an infectious diseases physician be considered the core members of the stewardship team.[18] Recommendations for training and certification of clinical pharmacists in this area of practice were described in a 2009 joint opinion paper from the Society of Infectious Diseases Pharmacists (SIDP) and the ACCP Infectious Diseases PRN.[19] The authors recommended PGY1 residency training, followed by a PGY2 residency in infectious diseases, and then board certification. Specific educational outcomes for PGY2 training were defined by ASHP and SIDP in 2007, as were the learning experiences necessary to achieve these outcomes.[20] Clinical pharmacists trained at this level are well equipped to participate as a core member of a multidisciplinary antimicrobial stewardship program, provide consultative services, and serve as a preceptor, mentor, and educator.

Role in Improving Quality of Care and Drug Safety

Specialized clinical pharmacists have contributed to patient care and drug safety by participating in treatment guideline preparation and publication, serving as Institute of Medicine members, and being appointed to United States Food and Drug Administration advisory panels. Most recently, a clinical pharmacist with specialized experience in anticoagulation was listed as the third author in the ninth edition of *Oral Anticoagulant Therapy: Antithrombotic Therapy and Prevention of Thrombosis*, and five other specialized pharmacists were also credited with developing the guidelines.[21] All of these clinical pharmacists have completed postgraduate training, and many have completed PGY2 residencies. Of note, many older clinical pharmacists who have been in practice for several years may have completed a PGY1 residency and then compiled additional years of clinical experience instead, because PGY2 residencies were not readily available at the time of their training.

Clinical pharmacists have also been instrumental in preparing some of the most widely recognized practice guidelines in the area of critical care. Prolonged sedation and analgesia guidelines published in 2002, with updates in progress, were written by several clinical pharmacists who had PGY2 training in critical care.[21] Clinical practice guidelines for the management of pain, agitation, and delirium in adult patients in the ICU were also written in part by clinical pharmacists with PGY2 training.[22] Other evidence-based guidelines written by clinical pharmacists with

postgraduate training include the evaluation and management of status epilepticus, stress ulcer prophylaxis in ICU patients, and prolonged neuromuscular blockade in adult critically ill patients.[23–25] Perhaps the most frequently implemented and well-known guideline in primary care that includes clinical pharmacist contribution is The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure.[26] The clinical pharmacists involved in writing these guidelines completed fellowship training in clinical pharmacy.

Specialized clinical pharmacists have also had impact on reducing the number of prescribing errors and increasing the reporting of drug errors to improve patient safety. Emergency departments often have significant drug-related adverse events, and recent reports have identified an integral role for clinical pharmacy specialists in preventing drug errors with procedural sedation and analgesia.[27] An additional study illustrates the impact of clinical pharmacy specialists in the emergency department with respect to health care–associated pneumonia.[28] Clinical pharmacy specialists in the medical ICU setting have been shown to reduce the prescribing error rate by two-thirds.[29]

Clinical pharmacists with PGY2 training have also made significant contributions to the quality of care and drug safety in ambulatory care settings during the management of hypertension, anticoagulation, diabetes, and heart failure. These contributions have shown the value of a team-based approach that includes a clinical pharmacist specialist. Many studies have shown that the participation of clinical pharmacists on a multidisciplinary team in the treatment of essential hypertension can result in reduced blood pressure and a meta-analysis showed that clinical pharmacist intervention has a greater impact than nursing intervention and can also improve the chances of achieving blood pressure control versus only lowering blood pressure.[30–33] In a systematic review of randomized trials, it was shown that direct patient care by clinical pharmacists in the treatment of heart failure significantly reduces the risk of all-cause and heart failure hospitalizations.[34]

Clinical pharmacist specialists with residency and/or fellowship training have demonstrated improved anticoagulation management, as evidenced by anticoagulation control, reduced bleeding and thromboembolic events, and reduced health care costs in multiple settings.[35–37] A multidisciplinary approach has also been proved to provide benefit in diabetes management. Studies have shown that specialty-trained clinical pharmacists provide goal-directed drug review and individualized education that result in decreased A1C values as well as other secondary targets, including normalization of blood pressure and reduction in 10-year cardiovascular risk.[38–40] Recently, clinical pharmacists have been shown to improve the management of diabetes and achieve preventive measures and goals that reduce the risk of diabetes-related complications, as recommended by the Healthy People 2010 initiative and the American Diabetes Association.[41]

Doctor of Pharmacy Education and Clinical Training

The addition of new pharmacy schools in the United States has increased the overall demand for experiential education practice sites, particularly within the institutional or health system practice setting.[42–44] According to a study to project the growth in academic pharmacy, the number of full-time faculty members is expected to increase 13% from 2010–2015.[45] This study revealed that a downward trend in faculty vacancies occurred across all disciplines from 2007–2009.[45] Moreover, the study noted that, during this period, even faculty member retirement trended downward.[45] These trends were in contrast to data gathered before 2007, which suggested growing faculty shortages and likely reflected economic factors that led to the Great Recession of 2008.[45, 46] Although the recession and subsequent slow economic recovery may have eased the manpower shortages forecasted before 2007, the supply of qualified clinical faculty members may be insufficient to meet recent academic pharmacy faculty growth projections.[45] Therefore, in addition to the clinical roles identified above, there is a critical need for PGY2-trained clinical specialists in the health care system to serve as the clinical educators of existing staff, future pharmacists, and other health care professionals.

The number of U.S. colleges and schools of pharmacy rose from 75 in 1996 to 109 in 2008, a 45% increase.[47, 48] As of January 2012, there were 119 accredited colleges and schools of pharmacy and eight more with precandidate status.[49] In addition, since 2005, the number of applications to pharmacy schools has grown by

2–7% annually.[48–53] Given these trends, graduate-training programs, including PGY2 residencies, are increasingly important to the assurance of a sufficient supply of qualified clinical faculty.[45] The growth in college and school of pharmacy–supported PGY1 and PGY2 residency programs and fellowships between 2010 and 2015 is projected to be 60% (4.9–7.8/school or college), or 9.8% annually.[49] Data to define the demand for pharmacists with PGY2 training in either generalist or specialist roles have not been updated since 2004. Given the recent economic climate and the increase in PGY2 residency positions in the past 8 years, some authorities now believe that there is more demand for residency-trained pharmacists and that the profession needs to expand the number of residency positions to meet the demand.[47] As described earlier, the increasing complexity of medical care requires competent practitioners with advanced training, and although entry-level doctor of pharmacy (Pharm.D.) curricula are more clinically oriented than the baccalaureate degree programs of the past, these curricula alone cannot produce graduates with the requisite competency to manage complex drug therapies.[4] Rapid advances in medicine and health care, and the continued evolution of the pharmacist's responsibilities in contemporary medical practice, necessitate continual revision of the accreditation standards and guidelines for professional programs leading to the Pharm.D. degree.

Curricula should undergo frequent programmatic changes to keep pace with advances in medicine and the health care system; however, this is challenging and takes considerable time. Moreover, current pharmacy graduates face complex pharmacotherapeutic and other practice challenges that stem from the continued development and increasing complexity of modern pharmaceuticals, the continued expansion of biomedical knowledge, and the emerging opportunities for clinical pharmacists.[4] Thus, after completing the professional curriculum, students can often master only basic curricular competencies. Postgraduate year one residency-training programs provide additional opportunities for graduates to hone their practice skills and accomplish professional competencies in greater depth.[4] Postgraduate year two residencies allow the degree of specialization required to care for even more complex patients. Therefore, PGY2 residencies provide additional value by incorporating education and training opportunities that cannot be achieved in the professional degree program or PGY1 residencies.

Pharmacy Practice Model Initiative and Integrated Practice Model

American Society of Health-System Pharmacists, in collaboration with the ASHP Research and Education Foundation, has created the Pharmacy Practice Model Initiative (PPMI). The PPMI was officially launched at the Pharmacy Practice Model Summit in November 2010, a profession-wide invitational conference designed to discuss the development of a new health-system pharmacy practice model. The goal of the PPMI is to advance the health and well-being of patients by developing and disseminating a futuristic practice model that supports the most effective use of pharmacists as direct patient care providers.[54]

Collectively, ASHP and ACCP have declared that clinical pharmacists engaged in direct patient care should be board certified (i.e., and residency-trained or otherwise board eligible) and have established a valid collaborative drug therapy management agreement or have been formally granted clinical privileges in the settings in which they practice.[4, 55, 56] Unfortunately, PGY2-trained clinicians are underutilized in the integrated practice model that has grown out of the PPMI. This approach could threaten the growth and development of future clinical specialists. Therefore, the ways in which PGY2-trained clinical pharmacist specialists are deployed in the PPMI require further consideration.

As Dr. Daniel Ashby stated in his 2011 Harvey A.K. Whitney Lecture "Permission Granted," the "practice model should be team-based" to achieve the desired outcomes of the PPMI, "with a representation of specialist and generalist pharmacists, pharmacy residents, pharmacy students and pharmacy technicians."[57] Furthermore, he asserted that the practice model must be comprehensive, with an appropriate mix of generalist and specialist pharmacist practitioners to provide needed services. Many health care institutions have patient care demands requiring specialized practice knowledge that is most effectively developed through completion of a PGY2 residency.[57, 58] For the PPMI to be successful, and to meet key recommendations such as "all patients should have the right to the care of a pharmacist," pharmacist training at both the generalist and specialist levels is essential.[54, 59]

The increasing complexity of today's drug regimens has fueled the need for specialist pharmacists with advanced training.[4, 19, 47, 60] Similar to the medical model, patient care is best provided by a combination of generalist and specialist clinical pharmacists. In these models, the inclusion of a competent clinical pharmacist who possesses the skills required to manage complex patients is essential to ensure the optimal use of drugs. Comprehensive drug management is needed in order to achieve positive outcomes in high-risk patient populations.[61] Most people would find it unfathomable to be treated by an oncologist who did not have specialized training. This perspective applies to clinical pharmacy specialists as well—improving patient outcomes in complex settings requires training beyond the entry level.

In 2004, ASHP conducted a survey to determine whether organizations were requiring specialized PGY2 residency training for their clinical specialists.[47] Fifteen percent of the respondents indicated that PGY2 training was required, and 67% stated that a candidate with PGY2 training was preferred to a candidate without specialized training. However, 52% stated that it was difficult to fill these positions because of a shortage of qualified candidates.[47] Despite the shortage identified in this 2004 survey, the expansion of PGY2 residencies has not occurred at the rate necessary.[47] Although it may vary by individual practice location, the need for pharmacists with specialized training will likely expand further with the implementation of the PPMI across the nation, since both generalist and specialist pharmacist practitioners will be necessary to deliver comprehensive care to all patients.

Limitations to Training and Hiring PGY2-Trained Clinical Pharmacy Specialists

Capacity and Demand Issues

A primary force driving interest in specific PGY2 programs is the ability of graduates to secure positions that take advantage of the skills and knowledge gained during residency training. Demand by employers for clinicians trained at the PGY2 level has fostered interest in a variety of specialty areas of practice among pharmacy students and PGY1 residents. This is expected to fuel increased interest in offering PGY2 programs at sites with the capacity to do so. Furthermore, if job prospects remain positive and sufficient positions in desired PGY2 specialty areas are available, there will be little to dampen PGY1 resident interest in specialized training. Conversely, if the number of PGY1 residents desiring a particular PGY2 practice focus far exceeds capacity, candidates may decide that the chances of acceptance are too low to consider applying and seek other career pathways.

The ASHP Commission on Credentialing annually tracks statistics from the Resident Matching Program (the "Match"). These statistics reflect the supply and demand for residency programs, but not necessarily for jobs. Unfortunately, there are no published data regarding the latter. During the past several years, the demand for residency positions has been increasing at a faster rate than the increasing supply. For example, there was a 13% increase in candidates seeking PGY1 residencies and a 25% increase in PGY1 residents seeking a PGY2 residency in 2012 compared with 2011. Results for PGY2 positions from the 2011 Match show there were 524 initial positions, of which 144 were filled early (an option whereby programs with PGY2 programs can directly recruit and obtain commitment from their own PGY1 residents without participating in the Match), 304 were filled on Match day (total of 450 filled by completion of the Match), and 74 were unfilled.[62] No rankings were submitted to the Match for 25 of the unfilled PGY2 positions in 2011, indicating either that no candidates were interviewed for the positions or that candidates who interviewed were not interested in the program after the interview. Results from the 2012 Match show that 505 positions were filled (a 12.2% increase from 2011) by completion of the matching process, including early commitment and Match day, and that 80 positions were unfilled.

Because there were around 1800 PGY1 residents in the 2010–2011 Match, 513 of whom signed up to match in PGY2 programs, it appears that about 29% of the PGY1 residents that year were interested in PGY2 programs. Information on whether some percentage of individuals might actually have been interested but did not apply is not available, nor is information on why individuals who might have been interested didn't apply.

Although there have been no recent comprehensive evaluations of advertisements for clinical pharmacist positions, one analysis of academic position advertisements for clinical faculty showed increasing requests for individuals trained beyond the Pharm.D. degree with PGY1

and specialized residency experience.[63] There are certainly numerous advertisements for clinical pharmacist positions in specialty areas; however, it appears that there are few properly trained individuals to fill these positions. This situation can necessitate on-the-job training for individuals who have not had formal training in the area (at least not at the level of a PGY2-trained individual). The willingness of PGY2-trained individuals to relocate to pursue such available positions will obviously affect whether these positions are filled by specialists.

It is possible to speculate on the need for PGY2-level specialty-trained individuals, but speculating on the actual demand in terms of positions being advertised is more complex. For example, many reports have documented the value of critical care pharmacists in the ICU. If it can be assumed that clinical pharmacists trained in a critical care PGY2 residency generally perform better than individuals who have not, then there is arguably a tremendous shortage of such clinicians. Despite the fact that more residents are trained in critical care than in any other specialized area, the number of ICUs in the United States suggests that the bulk of institutions have less than one dedicated critical care clinical pharmacist. A gap analysis is needed to determine the training capacity for pharmacy specialties compared with clinical demand.

As mentioned previously, there is a CMS requirement for transplant clinical pharmacists, but ASHP lists only 22 programs in this practice area. It is highly unlikely that this number of programs is adequate to meet the needs of the health care system. The antimicrobial stewardship needs of many institutions would also benefit from having individuals from infectious diseases residencies. In fact, most of today's tertiary care centers across the country could benefit from the contributions of clinical pharmacy specialists, yet most do not have them on staff.

Conclusion

The vision of both ACCP and ASHP is that clinical pharmacists who provide direct patient care should be board certified (i.e., and residency-trained or otherwise board eligible) before entering practice. If specialized patient care is to be provided, advanced pharmacy training through a PGY2 residency program should be required. Three major conclusions or opinions regarding the need for PGY2-trained pharmacists are offered by the authors:

- PGY2-trained clinical pharmacy specialists are needed in our health care system to provide direct patient care to the most complex patients in need of specialty care in both the ambulatory and acute care environments. This care cannot be provided as effectively or efficiently by pharmacists without specialized training.
- PGY2-trained clinical pharmacy specialists are needed to train and educate pharmacy students and postgraduate residents and fellows, and the growth in pharmacy education and residency programs is increasing that demand.
- A gap analysis is needed to define the extent of the mismatch between the demand in health care systems and educational institutions versus the capacity to train clinical pharmacists at the specialty level.

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