OPINION PAPER

(Pre-publication Draft)

Recommendations for Training and Certification for Pharmacists Practicing, Mentoring, and Educating in Infectious Diseases Pharmacotherapy

An opinion of The Society of Infectious Diseases Pharmacists and the Infectious Diseases Practice and Research Network of the American College of Clinical Pharmacy

Erika J. Ernst, Pharm.D., Michael E. Klepser, Pharm.D., John A. Bosso, Pharm.D., Michael J. Rybak, Pharm.D., Elizabeth D. Hermsen, Pharm.D., Marisel Segarra-Newnham, Pharm.D., and Richard H. Drew, Pharm.D.

This commentary was prepared by the The Society of Infectious Diseases Pharmacists and the Infectious Diseases Practice and Research Network of the American College of Clinical Pharmacy. Received by the ACCP Board of Regents on October 17, 2008.

This paper represents the opinion of the Infectious Diseases Practice and Research Network of the American College of Clinical Pharmacy and the Society of Infectious Diseases Pharmacists. It does not necessarily represent an official ACCP commentary, guideline, or statement of policy or position.

Address reprint requests to the American College of Clinical Pharmacy, 13000 W. 87th Street Parkway, Lenexa, KS 66215; e-mail: accp@accp.com; or download from http://www.accp.com.
Introduction

A number of publications regarding the training and competencies of pharmacists entering into clinical practice have recently been published (1,2,3,4). Although such documents facilitate the clarification of expectations for generalists, they do not specifically recommend training requirements for clinical pharmacy practitioners in infectious diseases. In 2007, guidelines were jointly created by the Infectious Diseases Society of America (IDSA) and the Society for Healthcare Epidemiology of America (SHEA) which outline the development of institutional antimicrobial stewardship programs (5). Prominently highlighted in these guidelines was the recommendation that a pharmacist with infectious diseases training be included along with an infectious diseases physician as core members of antimicrobial stewardship teams. Training and certification requirements have been established and endorsed for infectious diseases physicians (6,7) but not for infectious diseases-trained clinical pharmacists.

The purpose of this document is to provide overarching recommendations for future training and certification for pharmacists practicing, mentoring and educating in infectious diseases pharmacotherapy. These recommendations have been jointly developed by the Society of Infectious Diseases Pharmacists (SIDP) and the American College of Clinical Pharmacy Infectious Diseases Practice and Research Network (ACCP-IDPRN). For purposes of this document, an infectious diseases-trained pharmacist will be defined as a pharmacist having received formalized training in infectious diseases pharmacotherapy whereas an infectious diseases clinical pharmacist is one currently practicing in the collaborative care of patients with infectious diseases. Practice settings for infectious diseases clinical pharmacists will be varied and responsibilities could include a combination of clinical service, research, or educational
facilities. Capitalizing on the infectious diseases clinical pharmacist’s unique expertise, functions would vary slightly from setting to setting, and would include direct patient care (pharmacotherapy/pharmacokinetic evaluations, therapeutic monitoring, drug information/patient education regarding antimicrobial therapy, antimicrobial stewardship participation/coordination); collaborative scholarship (in vivo/in vitro antimicrobial assessments, pharmacokinetic/pharmacodynamic analyses, resistance surveillance, pharmacoeconomic analyses, etc.) and education (patients, trainees, students, healthcare workers).

It is hoped that these recommendations should be employed in the future by hospitals and clinics seeking to define the qualifications and scope of practice of pharmacists with a focus in infectious diseases pharmacotherapy. Importantly, this is a forward-looking document, with recommendations for requirements for infectious diseases-trained clinical pharmacists from this point forward.

**Formalized Training for Pharmacists in Infectious Diseases**

Both the American College of Clinical Pharmacy (ACCP) and the American Society of Health-System Pharmacists (ASHP) have issued position papers recommending postgraduate year-one residencies (PGY1) for pharmacists involved in direct patient care, and additional training for pharmacists practicing in a specialty or focus area (1,8). There is active debate among pharmacy organizations regarding whether pharmacy practice residency training should be required for all pharmacists engaged in the provision of direct patient care. The paucity of data regarding patient and practice outcomes following pharmacist-delivered care has likely given rise to these deliberations, making the task of devising a universal recommendation for all
pharmacists quite daunting (3,9). Despite this uncertainty, advanced training has been suggested to benefit pharmacists engaged in specialized roles (1,3,8).

As with other specialty therapeutic environments, practice in the specialty of infectious diseases requires an in-depth understanding of a unique, complex, and dynamic knowledgebase and set of practice skills. As a result, broadly-focused or short-term training experiences (such as advanced pharmacy practice experiences and PGY1 residencies) are able to provide only a rudimentary introduction to infectious diseases in a limited practice setting. To cultivate specialty practice knowledge and skills, the ASHP Commission on Credentialing and SIDP have recently revised the goals, objectives and targeted educational outcomes for postgraduate year two (PGY2) residencies in infectious diseases [Required and Elective Educational Outcomes, Goals, Objectives and Instructional Objectives for Postgraduate Year Two (PGY2) Pharmacy Residency in Infectious Diseases, 2007](10). Such guidelines are intended to establish standards to “increase the resident’s depth of knowledge, skills, attitudes, and abilities to raise the resident’s level of expertise in medication therapy management and clinical leadership” in infectious diseases. Seven required and three potential outcomes intended to serve as the foundation of a solid specialty training experience are presented (Table 1). Importantly, these outcomes include learning to participate as an integral member of an interdisciplinary team (or as an independent clinician), manage and improve the anti-infective use process, and demonstrate leadership.

In the past, pharmacists have been able to nurture their interest in infectious diseases via self-directed learning and years of “on-the-job” experiences. These infectious diseases clinical pharmacists effectively cultivated their skills despite the lack of PGY2 residencies in infectious diseases. However, limitations associated with this means of professional development in the
future are numerous. Therefore, this mode of training is not considered to be a viable or sufficient means of reliably training future clinical specialists in infectious diseases.

At this time, there are no criteria that identify those pharmacists who have not yet undertaken formalized training in infectious diseases, but have developed specialty practice skills in infectious diseases through extensive practice experiences.

A number of diverse postgraduate opportunities are available for pharmacists seeking training in infectious diseases. Among these are specialty residencies, post-doctorate fellowships and Ph.D. programs. However, the educational objectives and focus of these experiences differ greatly with respect to cultivation of clinical practice skills. Specialized infectious diseases residencies (usually 1 year, clinical-focused practice experiences) provide clinical experiences that prepare candidates to function in a patient care setting. Fellowships (commonly 2-3 years, research-focused programs) may or may not provide some clinical practice experience. Ph.D. programs, as well as most fellowships, are generally intended to nurture the development of research skills. More often than not, such programs do not provide the depth of clinical training needed to enable the candidate to successfully practice in infectious diseases in a patient care setting.

The educational outcomes, goals, objectives, and instructional objectives for PGY2 residencies in infectious diseases approved by the ASHP Commission on Credentialing and the Society of Infectious Diseases Pharmacists provide a framework of experiences to guide clinical infectious diseases training programs (10). In addition to providing requirements for programmatic structure, this document provides examples of learning experiences in which the trainee should demonstrate proficiency (Table 2). Taken together, the practice experiences and educational outcomes of a PGY2 residency in infectious diseases should include a solid
foundation in the principles of antimicrobial stewardship. These principles of antimicrobial stewardship combine the areas of pharmacokinetics, pharmacodynamics, pharmacoeconomics and outcomes of patients receiving antimicrobial agents. In addition, antimicrobial stewardship includes understanding the principles of optimizing the use of antimicrobial agents in order to decrease costs of care, decrease medical errors and avoid adverse outcomes. Principles of programmatic approaches and implementation should also be included.(11,12,13,14) Following completion of a PGY2 residency in infectious diseases, individuals should exhibit competency in the educational domains outlined by the commission on credentialing and they should possess the knowledge base and practice skills needed to practice as a clinical specialist in infectious diseases. Presently, there is a limited availability of accredited PGY2 residencies in infectious diseases. Implied within our recommendation is the need for new and/or existing unaccredited programs to pursue accreditation.

Historically, pharmacy fellowship training has purposefully been non-standardized and highly variable with respect to practice experiences. Successful graduates of fellow programs are typically recognized as clinical translational researchers, having a firm grasp of the research skills required by their specialty practice area. Unfortunately, since research and practice experiences lack uniformity among programs, it is difficult to ensure that all candidates receive comparable experiences. Often researchers focus their programs on a narrow therapeutic area, and as a result the experience received by the fellow candidate will likely mirror the expertise of the mentor. Because of this variability in research training, a research fellowship is not a substitute for the PGY2 residency in terms of clinical practice competency.

**Recommendations:**
• In the future, an infectious diseases-trained clinical pharmacist should complete an accredited PGY1 residency and an accredited PGY2 residency in infectious diseases.

• A research fellowship or Ph.D. is not a substitute for the PGY2 residency in terms of clinical practice competency, but does provide excellent research training experience.

• No recommendations can be made to establish training requirements for pharmacists with extensive “on-the-job” training in infectious diseases pharmacotherapy.

**Certification**

Maintenance of a practical and contemporary specialty knowledge base is not possible without a considerable amount of thought and effort (15,16,17). Pharmacists with training in infectious diseases are generalists first, and infectious diseases specialists second. This means that an individual must possess a broad understanding of general medicine principles in order to practice safely in a focus area like infectious diseases. Such a knowledgebase can be nearly impossible to develop and maintain independently if one practices in a specialty area. The recommended method to develop such knowledge is the completion of a PGY-1 experience. Achieving and maintaining board certification in pharmacotherapy, while not thought to be essential for certifying competency in infectious diseases pharmacotherapy, is highly desirable. Successful completion of the board certification process demonstrates that the individual possesses familiarity with a broad range of general medicine topics. Since separation of the infection from the rest of the patient is impossible, this general knowledge can serve as the basis for a strong specialty practice in infectious diseases.

At present, there is no specialty examination that would certify infectious disease knowledge. Development of an examination in infectious diseases, similar to the American
Board of Internal Medicine examination for physicians in infectious diseases, should be designed to evaluate the pharmacist’s knowledge and clinical judgment in those areas where an infectious diseases clinical pharmacist should have a high level of competence. Potential competencies for pharmacists practicing in infectious diseases are proposed (Table 3). These competencies are in addition to the five core competencies identified by the Institute of Medicine, that all health care professionals should possess (18). The examination process serves two important functions: 1) the exam would allow those who have obtained their specialty knowledge through unconventional means to demonstrate their proficiency in the specialty; 2) recertification by examination allows for demonstration of continued expertise in the specialty. This is very useful in areas such as infectious diseases where contemporary knowledge is imperative for effective practice. Until such an examination process exists, pharmacists with a clinical practice in infectious diseases possessing certification as a board-certified pharmacotherapy specialist are encouraged to attain added qualifications in infectious diseases from the Board of Pharmaceutical Specialties or other specialty examination related to their scope of practice.

Recommendations:

- All pharmacists practicing in the focus area of infectious diseases should maintain a broad clinical knowledgebase in general medicine and infectious diseases. Achievement and maintenance of board certification as a pharmacotherapy specialist (BCPS) would serve as evidence of such competencies.
- A certification examination in infectious diseases for pharmacists should be developed, independent of requirements to be a board-certified pharmacotherapy specialist. Until such an examination is available, pharmacy practitioners in infectious diseases
possessing BCPS certification should seek added qualifications in infectious diseases from the Board of Pharmaceutical Specialties.

- No recommendations can be made to establish certification for pharmacists with extensive “on-the-job” training in infectious diseases pharmacotherapy.

Continued Competency

Demonstration of continuing education in infectious diseases topics should be added to the requirements for maintenance of this designation. It is imperative for pharmacists desiring to not only maintain, but also expand their knowledge base and practice skills to undertake a structured and focused approach to continuing professional development. One approach to providing the necessary educational guidance may be through the maintenance of a professional portfolio. Such a tool can serve to draw focus to the core domains of practice and assist the individual in planning their self-development efforts. Continuing education should encompass a variety of experiences such as live programs, review of the literature and treatment guidelines, completion of case-based exercises, and hands-on practical experiences or mentorships. The focus and type of each experience can then be documented in the portfolio in order to allow the individual to track their progress, review all core infectious diseases topics, and prevent the formation of gaps in their knowledge base. In particular, educational programs that incorporate an evaluation of learning component, such as an individually completed post-test are advocated.

Recommendations

- Infectious diseases practitioners should maintain a portfolio documenting continuing professional development in infectious diseases-related topics.
**Preceptor/Mentor/Educator Qualifications**

The Accreditation Council for Pharmacy Education (ACPE) accreditation standards for Doctor of Pharmacy professional programs state that pharmacy practice faculty should possess additional professional training (residency, fellowship, or equivalent experience) and either have or be working toward credential (for example specialty certification) relevant to their practice and teaching responsibilities (19). Therefore, these individuals should minimally have appropriate training, such as a PGY2 residency or fellowship with an adequate clinical component in infectious diseases, and documentation of their efforts to maintain their general medicine and infectious diseases knowledge base and practice skills. A requisite review of continuing education efforts should be conducted periodically (minimally once every five years) by peers or supervisors of those wishing to retain their designation as an infectious diseases clinical pharmacist. Furthermore, faculty with a practice in infectious diseases should attain or be working toward certification.

**Recommendations:**

- **In the future, faculty and preceptors of infectious diseases clinical clerkships at accredited schools of pharmacy should meet the above criteria for training.**

- **We support the requirement that directors of ASHP-accredited PGY2 residencies in infectious diseases meet the following: 1) complete a PGY-2 program in infectious diseases plus 3 years experience OR 2) 5yrs experience in absence of PGY-2. Upon the development of a certification exam in infectious diseases, directors should be certified.**

- **Directors of all specialty residencies in infectious diseases are recommended to seek program accreditation by ASHP.**
**Future Directions**

Employers must create incentives (e.g. salary increase) for clinicians to achieve certification, which are currently lacking in many employment settings. We call on directors of pharmacy, hospital administrators, and colleges of pharmacy hiring infectious diseases-trained clinical pharmacists to consider these recommendations during the screening process and as components of performance reviews.

**Limitations of This Document**

As stated at the beginning of this document, purpose of this statement is to provide overarching recommendations for future training and certification for pharmacists practicing, mentoring and educating in infectious diseases pharmacotherapy. With that said, we recognize that full implementation of these recommendations may take several years. However implementation is essential to ensure the future high-level of practice of infectious diseases clinical pharmacists. There is a great need for current training programs to seek accreditation and also for future development of new programs in order to fulfill the potential need for infectious diseases trained pharmacists for health systems and colleges of pharmacy.

**Conclusions**

As clinical pharmacists continue to expand their roles, in many instances providing direct patient care and practicing as part of a multidisciplinary team, we recommend that future pharmacists wishing to attain a clinical position as an infectious diseases-trained pharmacist, complete a PGY1 residency and a PGY2 residency in infectious diseases. Furthermore, we suggest that practitioners in such roles, due to the diversity of such patient populations, become
board-certified pharmacotherapy specialists a means to demonstrate broad knowledge of general medicine. We suggest that an examination in infectious diseases be developed. To ensure continued professional development in infectious diseases we recommend that practitioners maintain a portfolio of educational experiences to maintain these qualifications. Finally, we call on employers and academicians to recognize the desirability of these qualifications for hiring decisions and career ladders.
References:


Table 1: Outcomes for PGY2 residencies in infectious diseases (10)

**Required Educational Outcomes**

- Promote health improvement, wellness, and the prevention of infectious diseases.
- Optimize the outcomes of individuals with an infectious disease by providing evidence-based, patient-centered medication therapy as an integral member of an interdisciplinary team or as an independent clinician.
- Manage and improve anti-infective-use process.
- Demonstrate excellence in the provision of educational activities for health care professionals and health care professionals-in-training centering on optimizing anti-infective pharmacotherapy.
- Serve as an authoritative resource on the optimal use of medications used to treat individuals with an infectious disease.
- Demonstrate leadership and practice management skills.
- Conduct infectious diseases pharmacy practice research.

**Potential Elective Educational Outcomes**

- Demonstrate added skills for managing and improving anti-infective-use process.
- Demonstrate skills required to function in an academic setting.
- Conduct outcomes research.
Table 2: Required clinical learning experiences for PGY2 Pharmacy Practice Residency in Infectious Disease (10)

<table>
<thead>
<tr>
<th>Learning Experiences must include care of patients</th>
<th>Examples of Learning Experiences</th>
</tr>
</thead>
<tbody>
<tr>
<td>with the following diseases/infections</td>
<td></td>
</tr>
<tr>
<td>Bone and joint infections</td>
<td>Foundations of the clinical microbiology laboratory</td>
</tr>
<tr>
<td>Cardiovascular infections</td>
<td>Infectious diseases consultation service serving adult patients</td>
</tr>
<tr>
<td>Central nervous system infections</td>
<td>Ambulatory care clinic with an infectious diseases emphasis</td>
</tr>
<tr>
<td>Fungal infections</td>
<td>Antimicrobial surveillance/outcomes programs</td>
</tr>
<tr>
<td>Gastrointestinal/food and water-borne infections</td>
<td>Ambulatory care AIDS clinic</td>
</tr>
<tr>
<td>HIV-infection and AIDS (including opportunistic infections)</td>
<td>Basic or clinical research</td>
</tr>
<tr>
<td>Infections of reproductive organs</td>
<td>Bone marrow transplantation services</td>
</tr>
<tr>
<td>Intra-abdominal infections</td>
<td>Drug information center</td>
</tr>
<tr>
<td>Lower respiratory tract infections</td>
<td>Infection Control</td>
</tr>
<tr>
<td>Ophthalmologic infections</td>
<td>Infectious diseases consult service serving pediatric patients</td>
</tr>
<tr>
<td>Sepsis</td>
<td>Inpatient AIDS service</td>
</tr>
<tr>
<td>Sexually transmitted diseases</td>
<td>Inpatient medical service</td>
</tr>
<tr>
<td>Skin and soft tissue infections</td>
<td>Inpatient surgery service</td>
</tr>
<tr>
<td>Tuberculosis and other mycobacterial infections</td>
<td>Medical intensive care</td>
</tr>
<tr>
<td>Upper respiratory tract infections</td>
<td>Medical oncology and/or hematology service</td>
</tr>
<tr>
<td>Urinary tract infections</td>
<td>Pharmacoeconomics/health economics</td>
</tr>
<tr>
<td>Viral infections</td>
<td>Pharmaceutical industry</td>
</tr>
<tr>
<td></td>
<td>Solid organ transplantation service</td>
</tr>
</tbody>
</table>

Learning Experiences must include the care of patients using the following anti-infective classes

Antibacterials
Antifungals
Antiretrovirals
Antivirals
Antiparasitics
Immunomodulating agents
Table 3: Core competencies for all healthcare professionals and potential competencies for clinical pharmacists practicing in infectious diseases:

All health care professionals should possess the following core competencies (18):

- Provide patient-centered care
- Work on interdisciplinary teams
- Employ evidence-based practice
- Apply quality improvement measures
- Use informatics

In addition, the infectious diseases-trained clinical pharmacist should demonstrate competence in the following areas:

- make empiric, prophylactic, and definitive antimicrobial treatment recommendations based on patient-specific factors
- interpret and make treatment recommendations based on microbiology reports
- interpret and make treatment/formulary recommendations based on antibiogram/microbiology data
- critically evaluate and apply infectious diseases literature and research
- make informed, evidence-based, cost-effective recommendations to relevant parties regarding formulary decisions
- participate in infectious diseases-related continuing professional development
- educate other health professionals (hospital staff, other pharmacists, students, and residents, etc.) and public regarding infectious diseases
• design, implement, and monitor programs to prevent/delay/combat antimicrobial resistance