INSTRUCTIONAL DESIGN AND ASSESSMENT

Core Competencies for Research Training in the Clinical Pharmaceutical Sciences

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Submitted October 15, 2010; accepted November 29, 2010; published March 10, 2011.

Objective. To identify and apply core competencies for training students enrolled in the clinical pharmaceutical scientist PhD training program at the University of Pittsburgh School of Pharmacy.

Design. Faculty members reached consensus on the required core competencies for the program and mapped them to curricular and experiential requirements.

Assessment. A rubric was created based on core competencies spanning 8 major categories of proficiency, and competencies of clinical versus traditional PhD training were delineated. A retrospective evaluation of the written comprehensive examinations of 12 former students was conducted using the rubric. Students scored above satisfactory in 11 out of 14 comprehensive examination metrics, with a mean score greater than 3.8 on a 5-point scale.

Conclusions. The core competencies identified will provide an essential foundation for informed decision-making and assessment of PhD training in the clinical pharmaceutical sciences.

Keywords: graduate education, competencies, clinical research, pharmaceutical sciences, doctor of philosophy degree

INTRODUCTION

Clinical pharmaceutical research is essential for the progression of novel preclinical discoveries into meaningful changes in patient care. Scientists with the unique skills to integrate basic pharmacology and the clinical pathogenesis of disease are highly sought in academia and the pharmaceutical industry. Clinical pharmacologists' ability to integrate preclinical and clinical evidence as it relates to drug response is a key factor necessary to reduce both the time of drug development and the likelihood of late-phase drug failures.¹ As with the pharmaceutical industry, translation of preclinical research discoveries into meaningful therapeutic interventions has been a major initiative within academic settings. The creation of an infrastructure for clinical research within academic institutions by the National Institutes of Health (NIH) Clinical and Translational Science Awards (CTSA) has fueled the need for highly skilled researchers in the clinical pharmaceutical sciences.

Despite the demand by academia and the pharmaceutical industry, colleges and schools of pharmacy and

medicine graduate too few researchers with skills in clinical pharmaceutical sciences and clinical pharmacology. Pharmaceutical scientists with skills in pharmacogenetics, pharmacometric modeling and simulation, clinical pharmacotherapeutics, and pharmaceuticals are in short supply.¹⁻³ In response to this demand, the number of colleges and schools of pharmacy offering fellowship training, master's degrees, and PhD degrees in the clinical pharmaceutical sciences has grown significantly. In 2006, more than 40% of colleges or schools either offered or were planning to offer PharmD/PhD training programs in the pharmaceutical sciences.⁴ Fellowship training programs also have attempted to address the need for more clinical researchers. The ideal method to train individuals with the skills to conduct clinical and translational research within the pharmaceutical sciences has been discussed extensively.⁵⁻⁷ Nevertheless, the relatively small number of trainees produced by all training programs is not meeting the needs of the research community.

In 2006, the American Association of Colleges of Pharmacy (AACP) appointed an Educating Clinical Scientists Task Force to explore how academic pharmacy can increase the capacity and impact of pharmacy researchers in clinical and translational research. This task force developed several essential policy statements focused on the

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education and training of future clinical pharmaceutical scientists.⁸ In 2009, a follow-up summit was held with the goal of reaching a consensus on the common and/or best practices among institutions offering clinical pharmaceutical scientist PhD training. General agreement was reached that training individuals to conduct clinical and translational research is distinctly different from training individuals with a PharmD degree to conduct traditional PhD research in the pharmaceutical sciences. In other words, the addition of a basic science PhD to a prior PharmD degree will not result in a scientist with the research skills necessary to rapidly initiate a career in clinically-oriented research. The summit participants universally agreed that clinical pharmaceutical scientist training programs need to differentiate and specify the training requirements that prepare graduates in the distinct discipline of clinical research in the pharmaceutical sciences. Furthermore, delineation of the specific core competencies for these students was deemed necessary to provide guidance for new program development and to identify the specific skills attained by individuals completing a PhD in the clinical pharmaceutical sciences.

Concurrent with the summit meetings, faculty members at the University of Pittsburgh School of Pharmacy identified the core competencies for the Clinical Pharmaceutical Scientist PhD Program. This effort was based on the need to: (1) identify the specific training requirements for PharmD and non-PharmD students entering such programs; (2) determine which courses from the University of Pittsburgh's CTSA educational offerings should be included as curricular requirements for the program; and (3) increase the clarity of the differences in research training offered by the clinical pharmaceutical sciences versus traditional graduate training. In March 2010, the University of Pittsburgh School of Pharmacy finalized the core competencies and completed a mapping of these competencies to the specific curricular and experiential offerings during training. Presented in this paper are the core competencies, the mapping of the competencies to the current curriculum, and a retrospective evaluation of written comprehensive examinations to assess the utility of these competencies in evaluating student outcomes. The experiential components of our training program and their use in the assessment of programmatic outcomes also are discussed.

DESIGN

The rationale for developing core competencies was based on a programmatic need for informed decision-making on several issues, including core course requirements, admission of non-PharmD students, and experiential requirements for clinical pharmaceutical scientist students.

Since inception of the Clinical Pharmaceutical Scientist PhD Program at the University of Pittsburgh in the 1980s, 34 students have completed PhD degrees and 1 student has completed a master's degree. Of these graduates, 15 entered the program with a PharmD degree, 1 entered with a bachelor of science in nursing (BSN) degree, and 19 entered with a master or bachelor of science degree in pharmacy or another science-related discipline. The program had several informal requirements for training BS versus PharmD students; however, consensus on the specific training requirements for students based on their entry degree could not be reached. An informed group decision could not be made unless a consensus was reached on the key competencies expected of all students within the graduate program regardless of their training background. Therefore, our goal was to develop a set of core competencies to guide decision-making processes with respect to curricular and experiential requirements for the Clinical Pharmaceutical Scientist PhD Program.

Core competencies were developed using a 3-step process. First, the core competency task force was charged with identifying the key competencies necessary for completion of the Clinical Pharmaceutical Scientist PhD Program. The group was asked to develop these competencies without considering the content of currently offered courses. Once consensus on the core competencies was achieved, the group refined and mapped the competencies to the current required and elective curricular offerings in the Clinical Pharmaceutical Scientist PhD Program. The final step was to align the mapped core competencies to our previously developed assessment matrix of learning outcomes for the entire graduate program in pharmaceutical sciences.

The final core competencies then were opened for review and recommendations from all faculty members prior to implementation and dissemination. Feedback also was solicited from several students who had completed the program and had taken many of the classes being considered as requirements for the curriculum. The learning objectives for our traditional PhD program and the core competencies of our Clinical and Translational Science Institute were used as guides in the development of the core competencies described.

Eight major categories of core competencies were identified (Table 1). Under each category, specific competencies were listed. An excerpt of the full core competency document is provided in Figure 1. (The complete document is available at www.pharmacy.pitt.edu/cps). The highest levels of Bloom's Taxonomy were used to create these individual competencies at the appropriate level for graduate training outcomes. Each competency was then mapped to the curricular and experiential offerings to

Table 1. Eight Major Categories of Core Competencies

Literature Review and Evaluation
Hypothesis Generation
Research Methods and Study Design
Statistical Methods and Data Evaluation
Grantsmanship
Presentation and Delivery of Oral and Written Scientific Information
Scientific Leadership, Management, and Cross-Disciplinary Teamwork
Ethical Conduct of Research

which it corresponded in the Clinical Pharmaceutical Scientist PhD Program.

A significant issue addressed by the core competency document was the identification of the elements unique to clinical pharmaceutical scientist PhD training versus traditional PhD training in the pharmaceutical sciences. The clinical pharmaceutical scientist competencies detail the skills necessary to conduct independent, hypothesis-driven, ethically sound research in humans. This skill set is the key differentiator between training in the clinical versus traditional pharmaceutical sciences. Examples of these specific skills include demonstration of the student's ability to recognize and explain the clinical and public health implications of a given research hypothesis, and the ability to identify important outcome measures to incorporate into a patient-oriented clinical trial design. Fifteen clinical pharmaceutical scientist-specific competencies were identified (Table 2).

Within the program, several curricular and experiential components are aimed at meeting specific clinical research core competencies. The curricular components specific to the clinical pharmaceutical scientist training include Introduction to Translational Research in the Health Sciences and Clinical Research Methods. Introduction to Translational Research in the Health Sciences is an interprofessional, graduate level course in which students develop and justify a line of research that can have a major impact on human health in the next 10 years. This project is completed as an interprofessional group assignment. The course provides the intellectual framework for a career in clinical and translational research. The Clinical Research Methods course, a curricular offering from the educational initiatives of the CTSA award at the University of Pittsburgh, is aimed at providing students with the skills to design, implement, and interpret clinical research. For experiential requirements, students in the Clinical Pharmaceutical Scientist PhD Program must include a human study in at least 1 aim of their written comprehensive examination. This examination requires

the student to submit a written NIH R01 formatted proposal, followed by an oral defense of that proposal in front of their graduate committee. Students also are required to serve as an investigator on an Institutional Review Board submission during graduate studies. Finally, the student's dissertation research must include at least 1 chapter that involves human research as defined by the National Institutes of Health.⁹ Collectively, these experiential and curricular elements provide the foundation to achieve the identified competencies of the Clinical Pharmaceutical Scientist PhD Program. As we move forward with these identified core competencies, our intent is to assess the entire curriculum and experiences to ensure the desired outcomes.

EVALUATION AND ASSESSMENT

To use the core competencies for assessment purposes, we developed a rubric for the comprehensive examination (Appendix 1). Fourteen core competencies were associated with the comprehensive examination, 6 of which were specific to the clinical pharmaceutical scientist PhD. The goal of this assessment was to identify how many of these 14 core competencies were met by past written examinations, and to identify areas of strengths and weaknesses in our past written proposals. To accomplish this goal, we obtained the written comprehensive examinations of 12 previous clinical pharmaceutical science graduate students. These 12 proposals were selected based on the availability of the written documents from the students who had most recently successfully completed the Clinical Pharmaceutical Scientist PhD Program. Two faculty members graded each of the 12 comprehensive examinations, which yielded 24 assessments. All of the examinations were de-identified prior to grading. The examinations were graded on a scale of 5 (excellent) to 1 (unsatisfactory) for each of the competencies. The average scores for each competency were determined and the percentage of examinations receiving an average score of less than 3 (satisfactory) also was determined. The results are provided in Table 3.

The majority of the core competencies for the written comprehensive examination were achieved (Table 3). Eleven of the 14 competencies were met by the majority of students and had mean scores greater than 3.8 on a 5-point scale. Three areas in which students were not consistently meeting the new competencies were identified. Two of these were related to human rights protection and subject recruiting: (1) develop appropriate methods to recruit and retain study participants for the selected research design, and (2) demonstrate knowledge of the standards of professional and ethical conduct established to guide researchers in protecting the rights, well-being, and dignity in the recruitment and retention of human

Clinical Pharmaceutical Science Specific	Theme, Subject and Competency	Courses													Experiences				
		Statistics PHARM 3040 and CLRES	Pharmacology and Ther PHARM 3028	Seminar PHARM 3024	Teach Me to Teach You PHARM 3043	Journal Club PHARM 3027 or 3000	Intro to Trans Res PHARM 3140	Drug Development II PHARM 5218	Foundations in Pharm Sci PHARM 3023	Pharmaceutical Analysis PAHRM 3005	Grant Writing PHARM 3038	Advanced PK PHARM 3002	Clinical Research Methods CLRES 2010	Ethics & Reg. of Clin Res. CLRES 2050	Research Diss/Thesis	Comprehensive Exam	IRB	Manuscripts	CPSP Fellowship
Learning Outcome from the Graduate Program Assessment Matrix: Acquire expert knowledge of biological, chemical, and analytical processes related to pharmaceutical sciences. Master a field of scholarship related to a specific research topic.																			
LITERATURE REVIEW AND EVALUATION																			
	Extract literature from appropriate bibliographic sources.			X		X					X				X	X		X	X
	Critique clinical and scientific evidence derived from literature.	X		X		X					X				X	X		X	X
*	Describe the current state of knowledge about a biomedical, clinical, or public health problem.		X	X		X	X				X				X			X	X
	Interpret primary research literature within the pharmaceutical sciences							X	X	X		X							
Learning Outcome from the Graduate Program Assessment Matrix: Use the scientific method to generate, analyze, and interpret scientific data relevant to the identification, analysis, and use of therapeutic agents. Generate mechanistic hypotheses based on prior evidence Derive specific predictions that are hypothesis-driven Plan detailed experimental procedures that test specific predictions																			
Gather data via experimentation Appropriately analyze and interpret data																			
HYPOTHESIS GENERATION																			
	Generate a relevant biomedical, clinical, public health, or translational research hypothesis.			X							X				X	X			
*	Defend the clinical and public health implications of a given research hypothesis.			X			X								X	X			
RESEARCH METHODS AND STUDY DESIGN																			
	Design appropriate experiments to address generated research questions in the pharmaceutical sciences.								X	X	X	X	X		X	X			
	Conduct appropriate experiments to address generated research questions.								X	X					X				
	Evaluate possible problems in the design and execution of a study in the pharmaceutical sciences.			X		X			X	X		X	X		X	X			
	Describe the drug development process.							X	X	X		X							
*	Develop appropriate methods to recruit and retain study participants for a selected research design.													X		X	X		
*	Identify important outcome measures for incorporation into patient oriented clinical trial design.												X			X			X
*	Generate a plan for data security/management.													X			X		
*	Identify barriers in translating research discoveries into meaningful changes in human health.						X								X				
*	Develop an approach to overcome barriers in translating research to humans.						X								X				
*	Design appropriate, ethically sound, and hypothesis-driven clinical studies.												X	X		X	X		

Figure 1. Example of the University of Pittsburgh Clinical Pharmaceutical Scientist Core Competency Grid with curricular and experiential mapping. The asterisks indicate clinical pharmaceutical scientist PhD-specific competencies. Competencies not marked with asterisks represent general skills to be acquired by all pharmaceutical sciences graduate students. (www.pharmacy.pitt.edu/cps.)

Table 2. Specific Competencies for Clinical Pharmaceutical Scientists

Literature Review and Evaluation
Describe the current state of knowledge about a biomedical, clinical, or public health problem.
Hypothesis Generation
Defend the clinical and public health implications of a given research hypothesis.
Research Design and Methods
Develop appropriate methods to recruit and retain study participants for a selected research design.
Identify important outcome measures for incorporation into patient-oriented clinical trial design.
Generate a plan for data security/management.
Identify barriers in translating research discoveries into meaningful changes in human health.
Develop an approach to overcome barriers in translating research to humans.
Design appropriate, ethically sound, and hypothesis-driven clinical studies.
Statistical Methods and Data Evaluation
Select the appropriate statistical approach for the interpretation of preclinical and clinical datasets.
Define bias in clinical and translational research.
Grantsmanship
Identify federal and non-federal agencies and programmatic initiatives aimed at translating research to clinical care of patients.
Defend a written research proposal that describes specific research aims, significance, innovation, and approach for a human clinical trial.
Preparation and Delivery of Oral and Written Scientific Information
Assess the clinical implications of scientific information.
Scientific Leadership, Management, and Cross-Disciplinary Teamwork
Develop a therapeutic protocol/guideline for medication-related issues or management.
Ethical Conduct of Research
Demonstrate knowledge of the standards of professional and ethical conduct established to guide researchers in protecting the rights, well-being, and dignity in the recruitment and retainment of human subjects in clinical research.
Give examples of the informed consent process including an understanding of the risk/benefit criteria and its impact on the patient/volunteer.

subjects in clinical research. Although these competencies were being addressed in other portions of the curriculum, we thought that these competencies should be addressed by the capstone comprehensive examination. Therefore, the guidelines for comprehensive proposals now emphasize that the human rights protections section is included (as described by NIH guidelines).¹⁰ Emphasis of this section ensures that this competency will be assessed as part of our comprehensive examination process in the future.

The third competency that was not being met fully was the evaluation of possible problems in design and execution of a study in the pharmaceutical sciences. Although this competency was being addressed in the oral defense of the written proposal, the evaluation revealed that several proposals failed to include a specific section detailing the potential limitations of the proposed work. Therefore, the guidelines for the comprehensive examination now specify that the written proposals include a subsection covering potential limitations after discussing the anticipated results to ensure that this competency is being addressed. The comprehensive examination rubric now is made available to graduate students to provide additional, previously undisclosed, guidance as they prepare

for this capstone assessment. We intend to use a similar on-going assessment approach to evaluate all curricular and experiential requirements and adjust content as needed to ensure achievement of these competencies.

DISCUSSION

In this manuscript we describe the core competencies for clinical pharmaceutical scientist training developed at the University of Pittsburgh. It is our intent that these competencies can be used to guide faculty members and others to ensure that the quality, consistency, and expectations of training are being met through curricular and experiential requirements. Specifically, the core competencies will be used to develop methods to assess both curricular and experiential components of our Clinical Pharmaceutical Scientist PhD Program. Externally, the competency document will help clarify previously unresolved questions about clinical pharmaceutical scientist training. For example, the 2009 Summit on Clinical Pharmaceutical Scientists Training Programs concluded that training a PharmD to do traditional PhD research in the pharmaceutical sciences differs from specific training in the clinical pharmaceutical sciences. While the position generally was agreed upon, a description of specific clinical

Table 3. Outcomes of the Written Comprehensive Examination Assessment Using the Core Competency Rubric

Competency	Mean Score (1 to 5 Scale)	Examinations Achieving Score > 3, %
Extract literature from appropriate bibliographic sources.	4.6	100
Critique clinical and scientific evidence derived from literature.	4.5	100
Generate a relevant biomedical, clinical, public health, or translational research hypothesis.	4.3	100
Defend the clinical and public health implications of a given research hypothesis.	4.0	92
Design appropriate experiments to address generated research questions in the pharmaceutical sciences.	4.3	100
Evaluate possible problems in the design and execution of a study in the pharmaceutical sciences.	3.0	50
Develop appropriate methods to recruit and retain study participants for a selected research design.	2.9	67
Identify important outcome measures for incorporation into patient-oriented clinical trial design.	3.8	92
Design appropriate, ethically sound, and hypothesis-driven clinical studies.	4.3	100
Apply fundamental principles of statistical analysis, such as power analysis, correlation, causation, regression, and summary statistics.	4.3	92
Select the appropriate statistical approach for the interpretation of preclinical and clinical datasets.	4.2	92
Develop appropriate conclusions based on results from research data.	4.0	92
Assess the clinical implications of scientific information.	4.2	100
Demonstrate knowledge of the standards of professional and ethical conduct established to guide researchers in protecting the rights, well-being, and dignity in the recruitment and retention of human subjects in clinical research.	3.1	64

pharmaceutical science core competencies had not been previously delineated. As a result, the lines have become blurred regarding what constitutes clinical pharmaceutical scientist training. It is our intent to use these core competencies as a guide to define which specific courses and experiences clearly differentiate clinical pharmaceutical scientist training. Such information will be useful for other schools of pharmacy as a guide for the development of competencies associated with new training programs at their institutions. This information also may prove valuable to refine educational initiatives associated with CTSA and other clinical research educational initiatives.

Another issue raised at the 2009 Summit was the need to train both pharmacists and nonpharmacists in the clinical pharmaceutical sciences. In order to have a significant impact on clinical research and secure support for such programs, colleges and schools of pharmacy need to train both PharmD and nonPharmD students in the clinical pharmaceutical sciences. Although there is general consensus on this issue, the specific curricular and experiential requirements for a student entering our program with or without a PharmD degree were not clearly detailed. Because the developed core competencies apply to all students in the clinical pharmaceutical sciences, the com-

petencies will provide a framework for informed decision-making about the curricular and experiential requirements necessary to train all students entering the program regardless of the entry-level degree earned.

SUMMARY

Core competencies were developed for graduate training in the Clinical Pharmaceutical Scientist PhD Program at the University of Pittsburgh School of Pharmacy. We describe the use of these competencies for rubric development and assessment of our capstone written comprehensive examination. Through this process, we identified areas for improvement in our comprehensive examination process, thereby developing additional guidelines to ensure that all competencies are addressed. In addition, development of these competencies has allowed the specific skills that differentiate training in the clinical pharmaceutical sciences from traditional pharmaceutical science PhD training to be defined.

ACKNOWLEDGMENTS

The project described was supported by Award Number KL2 RR024154 (KME, PEE) from the National Center

for Research Resources. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Center for Research Resources or the National Institutes of Health.

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Appendix 1. Example of the Clinical Pharmaceutical Scientist PhD Program Comprehensive Examination Rubric

Category	Excellent 5	Satisfactory 3	Unsatisfactory 1
Extract literature from appropriate bibliographic sources.	A thorough literature review and discussion is provided	Significant amount of relevant literature cited, but some missing information	An incomplete literature evaluation was completed
Critique clinical and scientific evidence derived from literature.	Score (5-1)/Comments: Cited literature is thoroughly discussed and appropriately interpreted	Cited literature is discussed with some inaccuracies or lost clarity	Cited literature is frequently misinterpreted or not well described
Generate a relevant biomedical, clinical, public health, or translational research hypothesis.	Score (5-1)/Comments: The hypothesis demonstrates clear clinical and public health relevance	The hypothesis is apparently clinically relevant but not fully described	The clinical and public health relevance of the hypothesis is not well delineated
Defend the clinical and public health implications of a given research hypothesis.	Score (5-1)/Comments: The overall relevance of the proposal to public health and translational research is well formulated	The relevance of the proposal to human health is presented but not fully justified	The proposal mainly describes the aims with little description of the relevance to human health
Design appropriate experiments to address generated research questions in the pharmaceutical sciences.	Score (5-1)/Comments: Designed experiments will directly address the proposed research hypotheses	Designed experiments will yield some information but not address all proposed hypotheses	Designed experiments are unlikely to generate data that would address the proposed hypotheses
Evaluate possible problems in the design and execution of a study in the pharmaceutical sciences.	Score (5-1)/Comments: Potential limitations of the proposed study are thoroughly described	Some limitations are presented but are not complete	Very little discussion of the potential limitations of the work are presented
Develop appropriate methods to recruit and retain study participants for a selected research design.	Score (5-1)/Comments: The plan to recruit and retain subjects is well delineated	The plan to recruit and retain subjects is mentioned but not completely described	The plan to recruit and retain subjects is not well described
Identify important outcome measures for incorporation into patient-oriented clinical trial design.	Score (5-1)/Comments: Patient outcome measures are appropriate and well developed	Patient outcome measures were considered but not fully developed	Patient outcome measures were not well described
	Score (5-1)/Comments:		

(Continued)

Appendix 1. (Continued)

Category	Excellent 5	Satisfactory 3	Unsatisfactory 1
Design appropriate, ethically sound, and hypothesis-driven clinical studies.	The proposed research is ethically sound and appropriate Score (5-1)/Comments:	The ethics of the research were considered but not fully justified	The ethics of the proposed research were not adequately considered
Apply fundamental principles of statistical analysis, such as power analysis, correlation, causation, regression, and summary statistics.	An appropriate statistical power analysis and approach was developed and justified Score (5-1)/Comments:	Statistical power and approach to analysis was presented with some flaws in understanding	The statistical power and approach were either not presented or were very poorly justified
Select the appropriate statistical approach for the interpretation of preclinical and clinical datasets.	Student selected and appropriately justified the selected statistical approach Score (5-1)/Comments:	Some but not all of the proposed statistics were appropriately selected and/or justified	Significant flaws in the selected statistics with a poor justification and understanding of rationale for selection
Develop appropriate conclusions based on results from research data.	The anticipated results were appropriate and well developed Score (5-1)/Comments:	The anticipated results were generally accurate with some flaws in justification	The anticipated results were either not presented or were poorly justified
Assess the clinical implications of scientific information.	The student wrote and clearly defended the importance of the research question as it relates to the current state of clinical practice Score (5-1)/Comments:	The student stated the importance of the question with respect to clinical practice, but did not clearly state/defend the direct relevance	The student did not clearly state or defend the importance of the proposed aims to clinical practice
Demonstrate knowledge of the standards of professional and ethical conduct established to guide researchers in protecting the rights, well-being, and dignity in the recruitment and retention of human subjects in clinical research.	Student included a thorough, well-described human protections section Score (5-1)/Comments:	Student included a human protection section that was not fully developed	The student did not include a human protections section