

## INSTRUCTIONAL DESIGN AND ASSESSMENT

### A Model for Supporting and Training Clinical Pharmaceutical Scientist PhD Students

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**Objectives.** To enhance the clinical training and financial support of graduate students in a Clinical Pharmaceutical Scientist PhD Program at the University of Pittsburgh School of Pharmacy.

**Design.** The School of Pharmacy and University of Pittsburgh Medical Center entered into a collaborative agreement to develop the Clinical Scientist Associate (CSA) program, as well as financially support students enrolled in a Pharmaceutical Sciences PhD program. These clinical training experiences are in addition to the didactic and laboratory experiences in the pharmaceutical sciences graduate program.

**Assessment.** Since 2002, three students have participated as CSAs, simultaneously working on their graduate research and meeting the requirements of the CSA program.

**Conclusions.** The CSA program is a novel model for clinical training and support of post-PharmD graduate students enrolled in a PhD clinical pharmaceutical scientist program.

**Keywords:** clinical pharmaceutical sciences, graduate education, research, financial support, clinical pharmacy training

## INTRODUCTION

The Commission on the Future of Graduate Education in the Pharmaceutical Sciences has recommended that schools of pharmacy take measures to increase the enrollment of doctor of pharmacy (PharmD) students in pharmaceutical sciences PhD programs.<sup>1</sup> Some mechanisms suggested include exposing PharmD students to research early in their education and encouraging them to consider graduate programs that build on their expertise in clinical pharmacotherapeutics.<sup>2</sup> A recent survey of schools and colleges of pharmacy demonstrated that the number of clinical pharmaceutical scientist PharmD/PhD programs is rapidly increasing nationally with 16 existing programs and 10 programs currently in planning.<sup>3</sup> Each institution that offers or is planning to offer a clinical scientist PhD program is faced with the issue of development of students' clinical pharmacy skills as a component of the training, as well as identifying mechanisms to support students.

An important challenge facing clinical pharmaceutical scientist programs is the continued development of clinical skills during students' development as independent research scientists. An editorial by Cohen identified

the need to further develop and nurture clinical pharmaceutical scientists and for pharmacy schools to reexamine the content and outcomes of their programs.<sup>4</sup> In fact, other health science disciplines have developed and implemented clinical scientist training programs, which incorporate both research and clinical practice.<sup>5</sup> PharmD graduates who enter clinical pharmaceutical sciences programs typically do not have the opportunity to develop clinical practice skills. The enhancement of clinical pharmacy practice skills is an important aspect, which must be a central component to the development of the clinical pharmaceutical scientist. These skills are essential to the conduct of clinical research and provide a greater understanding of translational research, from the bench to the bedside.

The second major challenge in recruitment of PharmD students to graduate school is financial support. Programmatic support for these new programs may be particularly difficult because implementation may consume existing resources for graduate student support provided within the school. Financial support for graduate students in the pharmaceutical sciences has historically involved teaching assistantships, teaching fellowships, and research assistantships. PharmD graduates entering PhD programs typically have been supported through these mechanisms and have also frequently subsidized

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their income by working in pharmacy positions that offer flexible schedules. These positions provide supplemental income, but are entirely independent of the students' academic pursuits.

With these 2 challenges in mind, we set out to develop a novel part-time pharmacy support mechanism for PharmD graduates enrolled in our Clinical Pharmaceutical Scientist PhD Program. The goals of this mechanism were to (1) provide a mentored clinical pharmacy experience; (2) allow for a clinical experience that coincides with the students' dissertation research to create synergy of learning; (3) offer clinical preceptor experience and didactic teaching opportunities; (4) foster relationships with physicians and other health-care professionals; and (5) provide a competitive part-time pharmacist salary.

In order to meet these goals, the School of Pharmacy and University of Pittsburgh Medical Center (UPMC) entered into a collaborative agreement to develop a 3-year clinical training and financial support program, called the Clinical Scientist Associate (CSA). This paper describes the CSA program and how it interfaces with the University of Pittsburgh School of Pharmacy Clinical Pharmaceutical Scientist PhD Program.

## **DESIGN**

In 2002, the CSA training program was developed to supplement graduate education with a mentored clinical pharmacy experience and to support students in the clinical pharmaceutical scientist program through part-time employment. The program was also designed to enhance classroom work and graduate dissertation research, which comprise the majority of the PhD program content. Faculty members in the School's Pharmaceutical Sciences Department and the Pharmacy and Therapeutics Department of UPMC developed the CSA program. Support was received from UPMC executive directors and School of Pharmacy administration. This program was designed to benefit both the student, through clinical training experiences, and UPMC, through the hiring of a part-time pharmacist. The CSA program required that graduate students possess a doctor of pharmacy (PharmD) degree and an active Pennsylvania pharmacy license. PharmD graduates first applied to the School of Pharmacy Pharmaceutical Sciences program and if accepted, had the choice of participating in the CSA program or the traditional teaching assistant/teaching fellowship (TA/TF) program.

The graduate program in pharmaceutical sciences at the University of Pittsburgh School of Pharmacy was comprised of a Basic Pharmaceutical Sciences Program and a Clinical Pharmaceutical Sciences Program. Stu-

dents in both departments were required to complete the same core curriculum, consisting of didactic coursework and are required to successfully complete a qualifying examination in order to gain admittance to PhD candidacy. Students enrolled in the Clinical Pharmaceutical Scientist PhD program at the University of Pittsburgh learned to be independent scientists by utilizing clinical and mechanistic approaches in their dissertation research. It typically took students 2 years to complete required classroom courses and laboratory rotations and an additional 2 years to complete their dissertation research. The CSA program was an additional training experience within the framework of the Clinical Pharmaceutical Program for students with PharmD degrees to serve a part-time blended clinical and operational pharmacy role in place of the traditional TA/TF responsibilities, under the direction of a clinical pharmacy faculty mentor. As the student's dissertation work was a full-time commitment to developing their research skills, the CSA program was a part-time commitment, aimed at developing clinical skills which may not be fully developed during graduate training. These clinical experiences also supplemented the students ongoing clinical research project. Both the hours of work and the clinical responsibilities were standardized under the framework of the program requirements; however, the Program allowed the CSA student to individualize these time commitments in order to provide a complementary training experience relating to the student's PhD research as determined by the student's graduate dissertation committee.

## **Clinical Practice Experience**

The clinical practice experience of the CSA program at UPMC includes 2 major components: a clinical pharmacy position in the Drug Use and Disease State Management Program (DUDSM),<sup>6</sup> and an operational pharmacy position in the inpatient dispensing pharmacy.

The CSA was involved in direct patient care through medication profile review in a similar patient population as the student's dissertation focus and was expected to demonstrate accomplishments in 3 areas: (1) direct interventions in care; (2) development of guidelines for medication use; and (3) clinical research.

**Direct Interventions in Care.** Interventions were focused both on individual patients and on populations of patients within the institution. A clinical pharmacy faculty mentor was assigned to each CSA student to provide the training in order to assure competency, which is demonstrated by direct observations, verbal discussions, and departmental competency examinations. Examples of clinical experiences where the CSA participates are outlined in Table 1.

**Development of Guidelines for Medication Use.**

One of the primary goals for the CSA was the development of an evidence-based clinical practice guideline focused on drug therapy management of a disease state. This process included collaborating with an interdisciplinary care team, reviewing literature, evaluating baseline prescribing practices, designing guidelines, and presenting the work at the Pharmacy and Therapeutics Committee meeting.<sup>6</sup>

**Clinical Research Project.** The CSA program required the development of a clinical hospital-based research project, which is an additional research experience to the dissertation work. The CSA participated in research forums with School of Pharmacy faculty members and pharmacy residents, a process that catalyzed the development of a multidisciplinary hypothesis-driven Institutional Review Board-approved clinical project. Presentation at a national meeting and publication in a peer-reviewed journal was expected. This experience was also meant to foster collaborations for future clinical research projects that could be related to the CSA's dissertation work.

Half of the time the CSA spent at UPMC was devoted to staff pharmacist functions, with growing opportunities in decentralized pharmacy locations on patient care units, which included transplant, cardiothoracic surgery, and general medicine. In the first year of the program, students were trained in multiple aspects of medication safety interventions through patient chart review, consultations with physicians and nurses, and interactions with patients. These interventions included: (1) dose adjustments of

medications based on patients renal function, (2) avoiding dangerous drugs in the elderly, (3) review for unnecessary or duplicate drug therapy, and (4) evaluation of elderly patients for administration of pneumococcal vaccine. The clinical pharmacy experiences and outcomes are listed in Table 2. The purpose of these clinical pharmacy experiences was to develop the student's ability to evaluate the appropriateness of drug therapy in multiple patient populations. Furthermore, this skill set aided in the ability of the student to identify clinical issues during the development of clinical research protocols for their dissertation work.

The progress of each CSA was monitored monthly by the Clinical Pharmaceutical Scientist Program Committee. The Committee consisted of members of UPMC Pharmacy and Therapeutics Department and faculty members of the School of Pharmacy. If performance was deemed to be below standards, appropriate training measures were established to assure competency in all areas of pharmacy practice including additional coursework in the PharmD curriculum, one-on-one tutorial sessions with clinical pharmacy faculty members, or online pharmacy competency materials and examinations developed by the UPMC pharmacy department as determined in conjunction with the students graduate dissertation committee. Furthermore, this evaluation also tracked the student's satisfaction with the CSA program. If the CSA student decided to opt out of the program during the 3 years, School of Pharmacy faculty members would evaluate the request and identify alternate support mechanisms for the student.

For the first 3 years, the CSAs worked approximately 20 hours per week, and were given a part-time salary that was competitive within the western Pennsylvania pharmacy job market. The time-commitment of 20 hours per week is the same requirement for our TA/TFs assisting in activities supportive of University instruction; therefore, the timeline for completion of the PhD program (4-5 years) for CSA students has been the same as for TA/TF students. Since the CSA position required a specialized skill set, monetary inequity between CSA students and TA/TF students in our program was not an issue. The program also offered healthcare and fringe benefits. The CSAs were encouraged to apply for research fellowships from external granting agencies, thereby, allowing for reduced or no commitment to the CSA program once the student progresses to candidacy.

**ASSESSMENT**

Three graduate students have participated in and been supported by the CSA program since its inception in 2002. These students have been involved in activities that

Table 1. Clinical Experiences of Clinical Scientist Associates Enrolled in a PhD Program

<b>Direct Intervention in Care</b>	<b>Description</b>
Renal Dosing Program	Optimize drug therapy for patients with renal insufficiency through changing dosing of drugs renally eliminated.
Safe-Medication Use in the Elderly	Promoting safe medications in elderly patients. Examples include diphenhydramine, meperidine, and anti-emetics.
Intravenous-to-Oral Switch Program	Evaluation of patients for switch of medications from IV to oral dosing.
In-Patient Vaccine Standing Orders Program	Screen in-patient elderly and pneumonia admissions for invasive pneumococcal disease risk and write vaccine orders on eligible patients.

Table 2. Clinical Practice Experiences and Outcomes Expected in a Clinical Scientist Associate Program

<b>Year</b>	<b>Clinical Pharmacy Activity</b>	<b>Outcome</b>
1-3	Patient Safety Interventions Renal dosing of drugs in patients with renal insufficiency Evaluation of elderly patients for vaccine administration Avoiding dangerous drugs in the elderly Medication profile review for unnecessary or duplicate drug therapy	Development of skills to evaluate appropriateness of drug therapy Enhancement of research skills by exposure to clinical relevant issues
1-2	Development of Drug Safety Guidelines Development of a patient safety initiative Presentation of work at the UPMC Pharmacy & Therapeutics (P&T) Committee Development of pharmacist and physician training materials for approved initiative Presentation of work at a national pharmacy meeting Preparation of a manuscript to be submitted to a peer-reviewed journal	Development of scientific writing and presentation skills Fosters collaboration between the student and other clinical researchers
2-3	Clinical Research Development of hypothesis-driven retrospective clinical study Presentation of work at a national pharmacy meeting	Development of clinical projects for students dissertation research Educational experience writing an IRB protocol Development of scientific writing and presentation skills
1-3	Teaching Experiences Training of Pharmacy students, interns, staff pharmacists, and didactic lectures	Enhances interest in academics through early involvement in education
1-3	Pharmacy Operations Pharmacy order entry and computer information systems Sterile Products preparation Creation of Medication Profiles	Educational experience of hospital pharmacy practice

resulted in a number of scholarly accomplishments. Our first CSA published a peer-reviewed article and editorial letter,<sup>7,8</sup> and presented a poster at the American Society of Health-System Pharmacy national meeting in December 2003.<sup>9</sup> This work was prompted by a series of adverse events associated with intravenous colchicine at our facility. The CSA worked with medical staff in Rheumatology and Geriatrics to design guidelines and present the information at the local and health-system P&T Committee. This guideline is now standard practice at 12 hospitals within the UPMC health system. Implementation required the CSA to develop pharmacist educational materials and computer order alerts, as well as provide inservice education to staff pharmacists. An Internet-based physician continuing medical education module

was also designed by the CSA to educate physicians on this safety initiative. This guideline was published as a “Front Line Pharmacist” article in the *American Journal of Health-System Pharmacy* (AJHP) journal. An editorial was written to *AJHP* in response to the article, and the CSA subsequently submitted a response in conjunction with the physician supporting the guideline.

Another one of the CSAs was involved in the development of documents internal to the hospital system: formulary reviews, patient-safety reviews, pharmacist training materials, a dosing guideline, an IRB proposal, and a retrospective continuous quality improvement evaluation that was presented nationally.<sup>10</sup> Examples of these projects include: an off-label use document of atypical antipsychotics in traumatic brain-injured patients, a

formulary review of drotrecogin alfa (Xigris) use in patients with sepsis, and a review of the use of pharmacotherapeutic options in patients with pulmonary hypertension. One project involved the collaboration of a hospital wide guideline of unfractionated heparin (UFH) for management of venous thromboembolism and acute coronary syndrome including preprinted order sets, nursing medication administration records, and associated in-service education. A retrospective continuous quality improvement evaluation of obese patient's receiving UFH was performed by the CSA and physician content experts, which was presented nationally.

The third CSA was involved in conducting a hypothesis-driven retrospective study that was presented as a research-in-progress poster at a national meeting.<sup>11</sup> This research was a hypothesis-driven retrospective study designed to evaluate the effectiveness of the pneumococcal polysaccharide vaccine by assessing readmission rates in patients with community-acquired pneumonia (CAP) who received the vaccine with patients admitted with CAP who did not receive the vaccine. The project was presented as a research-in-progress poster at the American Society of Health-System Pharmacy national meeting in December 2005.

These experiences augment or complement the primary research focus of the CSAs' dissertation research. Furthermore, these activities enhanced scientific writing and presentation skills. It is also notable that 2 of the 3 CSAs applied for and received an American Foundation in Pharmaceutical Educational (AFPE) predoctoral fellowship in the pharmaceutical sciences as supplemental support of their graduate training at the time of this publication.

The CSAs also gained clinical preceptor and didactic teaching experience. The 3 CSAs trained 10 pharmacy interns, 12 pharmacy rotation students in their last year of school, and multiple staff pharmacists. This role served to replace the teaching experience gained in the traditional graduate teaching assistant position. In addition, the CSA students volunteered to present lectures in the large classroom setting in the PharmD curriculum, including lectures in pharmacokinetics and patient case presentations.

The CSAs also provided pharmacy operations support. Each of the 3 CSA students were successfully trained in the hospital pharmacy practice area of computer information systems and order entry, sterile products preparation, and creation of patient medication profiles. An initial 6-month and then annual performance evaluation charted the CSA's progress in both operational and care intervention practice areas.

Interim evaluation of the program has been highly favorable. To date, we have had one student complete

the requirements of the PhD program as a CSA. This student met all of the requirements for the PhD degree within 4½ years of his entry into the graduate program. Current students have also maintained their graduate program timelines for completion of PhD programmatic milestones. Recommendations for improvement of the program have been aimed at improving the degree of overlap of the CSA duties and the graduate thesis research projects, as well as, flexibility of scheduling for summer industrial internships. Overall, the feedback obtained from the graduate faculty, clinical faculty, and student participants has been highly positive and the decision was made to expand the number of CSA positions in the future.

## **DISCUSSION**

A recent survey conducted by Gourley et al indicates that the number of clinical pharmaceutical sciences programs is increasing nationally in Schools of Pharmacy.<sup>3</sup> The CSA program coupled with recruiting efforts, such as the Graduate Education and Research at the University of Pittsburgh (GEAR-UP) program,<sup>2</sup> have provided a multifaceted approach to recruiting and supporting clinical pharmaceutical sciences students, and has appropriately begun to increase students' interest in this program. Schools of pharmacy can partner with hospitals to implement the CSA program in order to fulfill the recommendation by the Commission on the Future of Graduate Education in the Pharmaceutical Sciences to increase the number of graduate students in pharmaceutical sciences graduate programs.<sup>1</sup>

## **SUMMARY**

We have successfully developed and implemented the CSA program as a novel mechanism for training and supporting clinical pharmaceutical scientist graduate students. The CSA program provides a pharmacist's part-time salary and an individualized clinical training experience that complements the CSA's dissertation work. This program also provides multiple clinical experiences that would not otherwise be available during graduate training. Given that graduate students with pharmacy degrees often take pharmacist positions to supplement their income, the CSA program provides opportunity for equivalent compensation and a mentored experience as opposed to a compartmentalized job experience. Importantly, the CSA program allows clinical science programs to grow without detracting from existing post-graduate TA/TF positions.

Future development of the CSA program will allow for greater clinical practice and research experiences that will further aide in the development of clinical pharmaceutical scientists.

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