Published in final edited form as:

Am J Health Syst Pharm. 2017 March 15; 74(6): 409–415. doi:10.2146/ajhp160174.

Development of a Post-Graduate Year 2 Pharmacy Residency in Clinical Pharmacogenetics

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Abstract

Purpose—The structure and development of an innovative clinical pharmacogenetics post-graduate year 2 (PGY2) ASHP-accredited residency program is described.

Summary—The advent of the era of genomics has left practitioners wondering how to interpret the data obtained from sequencing and genotyping patients. In order to train the next leaders in the area of implementing pharmacogenetics, St. Jude Children's Research Hospital established the first accredited residency program in clinical pharmacogenetics. The 12-month long PGY2 residency was created in accordance with the ASHP standards for advanced practice residencies. The resident learns to optimize patient outcomes through the expert provision of evidence-based, patient-centered precision medicine as an integral part of an interdisciplinary team. The resident gains hands-on experience in a dynamic environment regarding all aspects of running a clinical pharmacogenetics service. Since the first resident graduated in 2012, the program has graduated one resident each year.

Conclusion—To fill a need for pharmacists trained in pharmacogenetics, an innovative PGY2 residency in clinical pharmacogenetics was successfully developed. Upon completion of the program, residents are equipped with the clinical skills and necessary experience to drive precision medicine forward and lead the implementation of pharmacogenetics in various healthcare settings.

Introduction

Post-graduate education is increasingly important across all areas of pharmacy practice. Initiatives launched by the American College of Clinical Pharmacy (ACCP) and the American Society of Health-System Pharmacists (ASHP) seek to increase pharmacists' involvement in direct patient care and to foster support for expanded post-graduate education through pharmacy practice residency programs.^{1,2}

Pharmacogenetics, the study of how genetic variability influences drug response, is increasingly being used clinically to personalize medication therapy.³ The importance of this burgeoning field has been emphasized at the national level through President Obama's Precision Medicine Initiative.⁴ As medication experts, pharmacists are well-positioned to lead clinical pharmacogenetics (sometimes referred to as clinical pharmacogenomics) efforts.^{5,6,7} The 2015 "ASHP Statement on the Pharmacist's Role in Clinical Pharmacogenomics" states that pharmacists have a "fundamental responsibility to ensure that pharmacogenomic testing is performed when needed and that the results are used to optimize medication therapy."⁸ Pharmacy leaders have called for pharmacists to proactively lead the implementation of pharmacogenetics and be at the forefront of its clinical application to improve medication-use outcomes.^{9,10}

As more health systems evaluate their ability to train pharmacy residents in specialty practice areas, summaries of the process to create an innovative residency program may be valuable to help other institutions anticipate potential problems, recognize their particular strengths, and use them to their advantage. We describe the design, implementation, and ongoing evaluation of the first accredited post-graduate year 2 (PGY2) clinical pharmacogenetics residency program.¹¹

Site description

St. Jude Children's Research Hospital (St. Jude) provides comprehensive inpatient and outpatient care for children with catastrophic illnesses focusing on childhood cancer, infectious diseases, and sickle cell disease. St. Jude provides care across the patient care continuum including inpatient care, outpatient care (including home infusion therapy) as well as an on-site infusion center to approximately 8,000 active patients each year. The Pharmaceutical Department provides comprehensive clinical services and all inpatient, clinic, and home prescriptions to approximately 4,200 patients each year. Since the early 1980s, the Pharmaceutical Department has operated both clinical and laboratory aspects of the hospital's clinical pharmacokinetics service which provides therapeutic drug monitoring for a variety of drugs used in the treatment of St. Jude patients. Because St. Jude has a history of research and discovery in pharmacogenetics and genomics, a clinical pharmacogenetics service was created in 2007.⁵ The initial focus was on single gene tests by

providing two pharmacogenetic tests (thiopurine methyltransferase-*TPMT*- and cytochrome P450 2D6-*CYP2D6*)^{12,13} directed to patients who were expected to receive drugs affected by these genes.⁵ The hospital has an established pediatric oncology residency program which was started in 1990 and ASHP-accredited in 2007. In 2011 we used the knowledge gained from the oncology PGY2 residency to start the clinical pharmacogenetics residency.

Program Development

The clinical pharmacogenetics residency program at St. Jude was developed in conjunction with the expansion of the institution's pharmacogenetics service. In 2011, an institution-wide preemptive pharmacogenetic testing program was launched with the goal of selectively migrating array-based pharmacogenetic tests into routine patient care so that results would be available preemptively.¹⁴ The preemptive pharmacogenetics program was launched with the goal of leading such efforts nationally. When we considered who would follow our lead in this new area of implementing pharmacogenetics, it became apparent that pharmacists are naturally positioned to lead such programs in other health systems, yet there were few pharmacists at the time with the necessary specialized training. We simultaneously developed and launched the PGY2 clinical pharmacogenetics residency simultaneously with this new preemptive pharmacogenetics program to integrate training into the effort. The goal is to train the next experts in clinical pharmacogenetics to lead emerging programs throughout the country. We sought for and obtained ASHP accreditation for the clinical pharmacogenetics PGY2 residency in 2013, making this residency the first of its kind to be accredited.

The purpose of this 12-month residency program is to prepare the pharmacy resident to implement pharmacogenetics in clinical practice. The program teaches expertise in the science of pharmacogenetics as well as an understanding of translational research, innovative pharmacy practice model development, and clinical informatics.¹¹ Upon completion of the program, the goal is for the resident to have the clinical skills necessary to practice in the field of clinical pharmacogenetics and to independently implement pharmacogenetic testing in other health-system settings. Because implementation of pharmacogenetics requires the collaboration across many disciplines, the resident works within a multi-disciplinary team of physicians, nurses, informatics specialists, pharmacists, and clinical laboratory personnel to achieve program goals.

Since there are no PGY2 residency standards for pharmacogenetics residencies, our clinical pharmacogenetics program objectives were written based on the ASHP guidelines for PGY2 residencies in an Advanced Area of Pharmacy Practice.¹⁵ The desired outcomes for each resident include:

- Serve as an authoritative resource on the optimal use of clinical pharmacogenetic tests to individualize medication therapy for patients.
- Establish oneself as an expert for pharmacogenetics-related information and resources within an organization.
- Demonstrate leadership in the field of clinical implementation of pharmacogenetics and practice management skills.

- Optimize the outcomes of patients through the expert provision of evidence-based, patient-centered medication therapy as an integral part of an interdisciplinary team.
- Demonstrate excellence in the provision of training and educational activities for health care professionals, health care professionals in training, and the public.
- Conduct research relating to the clinical implementation of pharmacogenetics.
- Contribute to the body of knowledge for clinical pharmacogenetics.

Applicants for the program must have successfully completed an ASHP-accredited PGY1 residency. Previous research experience or expertise in genetics is desirable (but not a requirement) to be considered for the residency program.

Learning Experience Structure

Similar to other residency programs, the first month of the clinical pharmacogenetics residency is dedicated to orientation activities, which include an overview of St. Jude pharmaceutical services, exposure to all facets of pharmacy operations (inpatient, outpatient, and specialty pharmacy services), and didactic sessions focused on advanced pharmacotherapy topics for children with catastrophic diseases. An introduction to St. Jude's pharmacogenetics Service and individualized training with the clinical pharmacogenetics coordinator is also provided.

The core educational experiences for the resident are longitudinal, and the resident plays an integral role in the Clinical Pharmacogenetics Service throughout the year (Figure 1). The resident further develops clinical skills through three 4-week-long direct patient care rotations that allow the resident to see both how pharmacogenetics is implemented in practice, and how genetics fits in the overall care of children with catastrophic diseases.

Elective and customized learning experiences are also provided. Because pharmacogenetics is often used in cancer patients, and several of our residents have also had an interest in oncology, the program includes opportunities for an elective rotation in the inpatient or outpatient oncology setting. Informatics plays an important role in the implementation of pharmacogenetics, and the training plan for one resident was customized to include an elective rotation in to conduct informatics projects with the clinical decision support officer.

Clinical Pharmacogenetics Longitudinal Experience

The Clinical Pharmacogenetics learning experience is divided into two, 6-month long components that span the residency year (Clinical Pharmacogenetics I and Clinical Pharmacogenetics II). Over the course of this longitudinal experience, the resident serves an integral role in the institution's pre-emptive pharmacogenetics service. These rotation blocks have distinct goals and activities that have been mapped to ASHP-outlined objectives (Appendix 1).

Resident responsibilities include evaluating the clinical utility of gene-drug pairs in the literature; formulating specific drug selection and dosing recommendations based on an

individual's genotype; writing clinical pharmacogenetic consults; developing language for clinical decision support alerts; creating pharmacogenetic competencies for healthcare professionals; and providing clinician and patient education about pharmacogenetic testing. The resident takes a lead role in implementing at least one gene-drug pair into the St. Jude electronic health record (EHR) from start to finish (from literature review to integration into the medical record and use in clinical care) over the course of the year. The resident also engages in other pharmacogenetics-related research and quality improvement projects as well as fielding clinical pharmacogenetics-related consultations as they arise. The multi-disciplinary pharmacogenetics team meets weekly, and the resident assumes a leadership role within this group early on in the year. This responsibility involves identifying meeting topics, facilitating group discussion, and keeping and circulating meeting minutes. The resident also participates in the quarterly meetings of the Pharmacogenetics Oversight Committee, a subcommittee of the St. Jude Pharmacy and Therapeutics Committee that governs the implementation of pharmacogenetics at the institution.

In addition to these opportunities, the clinical pharmacogenetics resident has the unique experience of working closely with leaders of the Clinical Pharmacogenetics Implementation Consortium (CPIC™). CPIC is a NIH funded international collaboration focused on creating evidence-based guidelines that describe how to interpret and use pharmacogenetic information in clinical practice.^{16,17} The resident participates in all monthly CPIC conference calls and also serves on the CPIC Informatics Working Group.¹⁸

Research

The resident is expected to complete at least one major research project. Other pharmacogenetic research projects arise frequently, and the resident often participates in multiple research projects to further expand their learning experience.¹⁵ Before an incoming resident begins the program, potential topic ideas are developed to provide the resident with a variety of project ideas to choose from. Results of practice-related projects have been reported as poster presentations at the ASHP Midyear Clinical Meeting and other national conferences, as platform presentations at a designated regional residency conference, and through other methods within and outside the institution. Research projects have resulted in a first author publication for each resident who has completed the program.^{19,20,21,22,23}

Professionalism and Leadership

The longitudinal professionalism and leadership rotation provides all St. Jude residents a forum in which to actively discuss timely pharmacy practice topics with the St. Jude Chief Pharmaceutical Officer. These meetings are held on a monthly basis to stimulate discussion on pharmacy practice issues at St. Jude and national pharmacy practice trends. Residents learn about the St. Jude pharmacy organizational structure and reporting relationships, discuss relevant clinical and practice issues that confront pharmacy leaders, and provide input into department action plans. Broader pharmacy practice issues such as provider status, prescribing privileges, reimbursement, and board certification are also discussed. Personal and professional development is supported through critical review and application of concepts presented in prominent leadership literature. These sessions also provide the

opportunity for residents to discuss residency experiences and provide ongoing feedback directly to the Chief Pharmaceutical Officer.

Education and Teaching

A longitudinal learning experience focused on education and teaching provides the resident opportunities to develop teaching skills in small and large group settings. If desired, St. Jude residents may complete a Teaching and Learning Certificate through the University of Tennessee Health Science Center's (UTHSC) College of Pharmacy. St. Jude residents are required to give oral presentations numerous times throughout the year, including case-based presentations, journal clubs, in-services, and research project updates. The clinical pharmacogenetics resident also teaches at least one lecture in the Pharmacogenetics elective for the College of Pharmacy at UTHSC. Each St. Jude resident prepares and presents at least one Accreditation Council for Pharmacy Education (ACPE)-accredited continuing education seminar on a pharmacogenetics topic. Residents also present their research results at the institution-wide Pharmaceutical Sciences research workshop to an audience that includes clinicians and basic scientists. Every formal resident presentation is evaluated by the audience with a standardized evaluation tool, and the resident meets with the pharmacy education preceptor to discuss these results. The resident is expected to evaluate their own performance by discussing strengths and areas of improvement after each lecture. Together, the resident and the pharmacy education preceptor review the audience's evaluations and construct an action plan to improve future presentations.

As a practice site for Advanced Pharmacy Practice Experience (APPE) students from several colleges of pharmacy, St. Jude hosts many students on clinical rotations. The clinical pharmacogenetics resident is charged with developing and facilitating an "Introduction to Pharmacogenetics" topic discussion for APPE students. In addition, the resident serves a co-preceptor for the clinical pharmacogenetics APPE rotation at St. Jude. As a co-preceptor for this rotation, the resident guides the student through assigned project work, serves as the student's primary point of contact, and provides input at both mid-point and final student evaluations.

Pharmacy Operations

During the orientation month, residents rotate through all the pharmaceutical services units so that they understand their functions and operating structure. The first staffing component of the residency starts in July and runs until September. It involves a 4-hour, once a week afternoon block of working in the hospital's central pharmacy. Through this learning experience the resident becomes familiar with medication order review processes for chemotherapy and other orders, evaluate orders for consistency with protocol requirements, prepares and checks of chemotherapy and other parenteral medications, verifies and dispenses outpatient medications, and other general operations of pharmaceutical services. The second staffing component starts in September and involves a weekend clinical call where the residents are included in the clinical pharmacy specialists' weekend coverage of all services of the hospital. Core functions on the weekend includes medication profile

review, entering orders for total parenteral nutrition formulations, therapeutic drug monitoring, and discharge counseling.

Funding

Funding for the residency program was obtained from institutional funds and from grant funding through the National Institutes of Health-funded Pharmacogenomics Research Network.

Lessons Learned

The St. Jude clinical pharmacogenetics residency is currently in its sixth year, and the coordinators have learned a tremendous amount and continually refined the program. A primary challenge was structuring the resident's staffing responsibilities.. Understanding the work flow of pharmaceutical services to become familiar with the operations, policies, and procedures of all inpatient and outpatient pharmacy areas is a key component of any pharmacist's job. Because our institution serves a pediatric specialty population, there is a steep learning curve to becoming skilled in all operations of pharmaceutical services. For that reason, the resident serves as an extra position when fulfilling his/her operations requirements early in the residency experience. It took several conversations with the preceptors and clinical staff pharmacists for the staff to understand the role and expectations of the resident. Ensuring that the resident is scheduled to work with a designated pharmacist was very helpful in meeting the goals of this pharmacy operations learning experience.

A second consideration was how to ensure the resident is trained in all aspects of the emerging field of clinical implementation of pharmacogenetics. To work as a clinical pharmacogenetics specialist, a pharmacist must be well-versed in many areas, including interpreting raw genotype results, translating laboratory results into a phenotype, evaluating primary genetic literature, mastering clinical informatics concepts, and educating other clinicians about the relationship between a gene and a drug or class of drugs. Our training model relies heavily on longitudinal experiences during which our PGY2 clinical pharmacogenetics resident is given a proportionate share of the responsibilities for running the service. The resident is treated as a peer by the preceptors from the start of the first rotation. The resident's office space is located next to the preceptor's office, which prompts frequent contact throughout each work day and allows immediate support and feedback. Clinical teaching is incorporated into discussions of individual cases in real time. Weekly team meetings are led by the resident, ensuring that the resident has an understanding of all topics discussed and will be involved in the follow-up actions. Through this model, the resident gains small-group leadership skills and in turn masters each area of implementation. Our experience has shown that treating a trainee as a fully knowledgeable expert in clinical pharmacogenetics facilitates ensuring that the trainee quickly becomes one.

Conclusion

The PGY2 residency in clinical pharmacogenetics provides a unique opportunity for pharmacists to pursue clinical pharmacogenetics as a specialty area of practice and to

become experts in the field. Empowering a resident as a peer practitioner ensures that the resident gains hands-on experience in a dynamic environment regarding all aspects of running the service. Upon completion of the program, residents are equipped with the clinical skills and necessary experience to drive precision medicine forward and lead the implementation of pharmacogenetic testing in other healthcare settings. At the end of the residency year, our residents have accepted pharmacogenetics positions at major academic medical centers, community hospitals, as well as academic and research positions with a pharmacogenetics emphasis. As the field of clinical pharmacogenetics grows, the goals of the residency will expand to grow along with it.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Grants: R24GM115264 from the NIH - National Institute of General Medical Sciences (NIGMS).

References

1. American Society of Health-System Pharmacists. [accessed 2016 Feb 22] ASHP Policy on pharmacy residency training (0917), in ASHP Policy Positions 1982–2015. <http://www.ashp.org/DocLibrary/BestPractices/EducationPositions.aspx>
2. Murphy JE, Nappi JM, Bosso JA, et al. American College of Clinical Pharmacy's vision of the future: postgraduate pharmacy residency training as a prerequisite for direct patient care practice. *Pharmacotherapy*. 2006; 26:722–33. [PubMed: 16637798]
3. Relling MV, Evans WE. Pharmacogenomics in the clinic. *Nature*. 2015; 526:343–50. [PubMed: 26469045]
4. Office of the Press Secretary. [accessed 2016 Jan 19] FACT SHEET: President Obama's Precision Medicine Initiative. 2015. <https://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative>
5. Crews KR, Cross SJ, McCormick JN, et al. Development and implementation of a pharmacist-managed clinical pharmacogenetics service. *Am J Health-Syst Pharm*. 2011; 68:143–50. [PubMed: 21200062]
6. Owusu-Obeng A, Weitzel KW, Hatton RC, et al. Emerging roles for pharmacists in clinical implementation of pharmacogenomics. *Pharmacotherapy*. 2014; 34:1102–12. [PubMed: 25220280]
7. Johnson SG. Leading clinical pharmacogenomics implementation: Advancing pharmacy practice. *Am J Health Syst Pharm*. 2015; 72(15):1324–8. [PubMed: 26195659]
8. American Society of Health-System Pharmacists. ASHP statement on the pharmacist's role in clinical pharmacogenomics. *Am J Health-Syst Pharm*. 2015; 72:579–81. [PubMed: 25788513]
9. Ray MD. Personal reflections 30 years after the Hilton Head Conference. *Am J Health-Syst Pharm*. 2015; 72(11):972–6. [PubMed: 25987693]
10. Stevenson JG. Bold goals for health-system pharmacy: Perspectives of an experienced practice leader. *Am J Health-Syst Pharm*. 2014; 71:1958–9. [PubMed: 25349239]
11. St. Jude Children's Research Hospital. [accessed 2016 Feb 22] Pharmacy residency programs: Clinical pharmacogenetics. <https://www.stjude.org/education-training/advanced-training/clinical-residents/pharmacy-residency-programs/ashp-accredited-pgy2-clinical-pharmacogenetics-residency.html>
12. Relling MV, Gardner EE, Sandborn WJ, et al. Clinical Pharmacogenetics Implementation Consortium Guidelines for Thiopurine Methyltransferase genotype and thiopurine dosing: 2013 update. *Clin Pharmacol Ther*. 2013; 93:324–5. [PubMed: 23422873]

13. Crews KR, Gaedigk A, Dunnenberger HM, et al. Clinical Pharmacogenetics Implementation Consortium guidelines for cytochrome P450 2D6 genotype and codeine therapy: 2014 update. *Clin Pharmacol Ther.* 2014; 95:376–82. [PubMed: 24458010]
14. Hoffman JM, Haidar CE, Wilkinson MR, et al. PG4KDS: A model for the clinical implementation of pre-emptive pharmacogenetics. *Am J Med Genet C Semin Med Genet.* 2014; 166C:45–55. [PubMed: 24619595]
15. American Society of Health-System Pharmacists. [accessed 2016 Feb 22] Program outcomes, educational goals, and educational objectives for Postgraduate Year Two (PGY2) residencies in an advanced area of pharmacy practice. 2008. http://www.ashp.org/DocLibrary/Accreditation/RTP_ObjPGY2AdvanceGoalObj.doc
16. Relling MV, Klein TE. CPIC: Clinical Pharmacogenetic Implementation Consortium of the Pharmacogenomics Research Network. *Clin Pharmacol Ther.* 2011; 89:464–7. [PubMed: 21270786]
17. Caudle KE, Klein TE, Hoffman JM, et al. Incorporation of pharmacogenomics into routine clinical practice: the Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline development process. *Curr Drug Metab.* 2014; 15:209–17. [PubMed: 24479687]
18. Hoffman JM, Dunnenberger HM, Hicks J, et al. Developing knowledge resources to support precision medicine: principles from the clinical pharmacogenetic implementation consortium (CPIC). *J Am Med Inform Assoc.* 2016; 23:796–801. [PubMed: 27026620]
19. Dunnenberger HM, Crews KR, Hoffman JM, et al. Implementing preemptive clinical pharmacogenetics: Reporting on 2 years of experience. *Clin Pharmacol Ther.* 2014; 95:S13–S14.
20. Hicks JK, Crews KR, Hoffman JM, et al. A clinician-driven automated system for integration of pharmacogenetic interpretations into an electronic medical record. *Clin Pharmacol Ther.* 2012; 92:563–6. [PubMed: 22990750]
21. Bell GC, Crews KR, Wilkinson MR, et al. Development and use of active clinical decision support for preemptive pharmacogenomics. *J Am Med Inform Assoc.* 2014; 21:e93–9. [PubMed: 23978487]
22. Dunnenberger HM, Crews KR, Hoffman JM, et al. Preemptive clinical pharmacogenetics implementation: Current programs in five United States medical centers. *Ann Rev Pharmacol Toxicol.* 2015; 55:89–106. [PubMed: 25292429]
23. Gammal RS, Court MH, Haidar CE, et al. Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for UGT1A1 and atazanavir prescribing. *Clin Pharmacol Ther.* 2016; 99:363–9. [PubMed: 26417955]

Key Points

1. The need for pharmacist expertise in pharmacogenetics inspired the creation of an innovative, ASHP-accredited PGY2 residency in clinical pharmacogenetics.
2. The PGY2 Clinical Pharmacogenetics resident gains hands-on experience in running a multi-disciplinary clinical pharmacogenetics service and completes learning experiences in direct patient care, research, leadership, and teaching.
3. Upon completion of the program, residents are equipped with the clinical skills and necessary experience to lead the implementation of pharmacogenetics in various healthcare settings.

Figure 1. Timeline of rotation experiences offered through the St. Jude Children's Research Hospital PGY2 clinical pharmacogenetics residency. Asterisk (*) denotes rotation experiences common to all St. Jude residents.