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Educational Strategies to Provide Pharmacogenomics-Based Care

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Abstract

Purpose—Educational barriers hinder the widespread application of pharmacogenomics in clinical practice. This review summarizes requisite pharmacist competencies, educational standards, and the current state of pharmacogenomics education to propose best practice solutions for educators to meet the specific needs and challenges of this complex topic.

Summary—Consensus-based pharmacist competencies and clinical guidelines have been published to guide knowledge attainment and application of pharmacogenomics concepts. Pharmacogenomics education is often integrated into existing courses and increasingly, within required standalone courses within PharmD curricula. Continuing education programs and limited

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postgraduate residencies/fellowship training opportunities are available to practitioners. However, challenges in identifying the optimal structure and amount of coverage, limited number of faculty experts, and inadequate availability of advanced pharmacogenomics practice settings for experiential education are limiting. Fortunately, successful approaches are emerging for both students and practitioners. In pharmacy schools, strategies include early exposure through foundational courses, incorporation into practice-based therapeutics courses, and introductory and advanced pharmacy practice experiences. For practitioners, institution-specific training, online resources, education within clinical decision support tools, and certificate programs can supplement more robust structured post-graduate training programs. Recent data also show the success of shared curricula and participatory education models involving an opportunity for learners to undergo personal genomic testing first-hand.

Conclusion—The pharmacy profession has taken a leadership role in expanding student and practitioner education to meet the demands of precision medicine initiatives. Effective approaches to attain pharmacogenomics knowledge and to drive its appropriate application in clinical practice are increasingly available.

There has been a growing emphasis on strategies to advance precision medicine and the clinical use of pharmacogenomic data. Although progress has been made, barriers to clinical implementation remain, including challenges of incorporating genomic data into the electronic health record, ethical concerns, reimbursement, and practitioner education.¹ As medication experts, pharmacists are uniquely qualified to help overcome these barriers and are increasingly recognized as leaders in pharmacogenomics clinical implementation efforts.^{1–3}

Pharmacogenomics content in pharmacy education has increased over the last decade. The percentage of colleges or schools of pharmacy with pharmacogenomics in their curriculum increased from 39% in 2005 to 89% in 2010.^{4, 5} Today, this proportion is likely even higher given Accreditation Council for Pharmacy Education (ACPE) requirements and pharmacist licensing exam content in this area.⁶ Student pharmacists have also begun to recognize the importance of this discipline, with over 62% of student pharmacists expressing that pharmacogenomics should be a required curricular component in a survey of 2,500 students.⁷

In spite of this advancement, pharmacists and other health professionals consistently state that they lack confidence in their pharmacogenomics knowledge and feel poorly prepared to apply this information in practice.^{8, 9} These findings, in combination with slower than expected uptake in pharmacogenomics clinical implementation, point to the persistent education and training needs in this area. Indeed, while it is laudable that inclusion of pharmacogenomics content is increasing in colleges and schools of pharmacy, this content is often inconsistent with regards to its nature and scope, teaching techniques used, and curricular placement.^{4, 5} Pharmacogenomics content is especially limited in experiential and practice-based training, with few Advanced Pharmacy Practice Experiences (APPEs), residency, or fellowship training opportunities.

A number of challenges must be overcome to ensure that practitioners are equipped to use pharmacogenomic information efficiently and effectively. Fortunately, resources and

strategies are emerging to assist educators in overcoming these challenges. This paper summarizes existing educational standards, competencies, and practice resources to support the pharmacist's role in clinical pharmacogenomics. It further outlines specific needs and challenges and proposes potential solutions for educators.

Pharmacist Educational Standards and Competencies

The Center for the Advancement of Pharmacy Education (CAPE) Outcomes and ACPE curricular standards provide a blueprint for pharmacy education. In the ACPE 2016 standards pharmacogenomics is incorporated into the clinical realm of pharmacy education —within the pharmacotherapy and clinical sections, pharmacogenomics is included as one of four factors that should be emphasized in the "evidence-based clinical decision making, therapeutic treatment planning, and medication therapy management" strategies for patient care.⁶

Building on these accreditation standards, consensus-based pharmacogenomics competencies have been established and recently updated for pharmacy educators that identify specific knowledge areas to enable pharmacy graduates to "recommend and interpret the results of pharmacogenetic/pharmacogenomic tests and make therapy recommendations based on test results".¹⁰ These competency and outcome statements were initially developed in 2002 and updated in 2012 to align with health professional genetics/ genomics competency statements developed by the National Coalition for Health Professional Education in Genetics.^{11–13} Representatives from 9 pharmacy and pharmacy-related organizations achieved consensus on and approved these competency statements (Table 1).¹⁰ This guidance provides specific information for educators about the knowledge and skills that pharmacists should possess upon graduation. Teaching resources for pharmacogenomics that are mapped to individual competencies are available to pharmacy educators on the Genetics and Genomics Competency Center (http://g-2-c-2.org).

A recent American Society of Health-System Pharmacists position statement summarizes the pharmacist's roles and responsibilities in pharmacogenomics, which include leading interdisciplinary efforts for ordering, interpreting, and reporting pharmacogenomic test results and guiding optimal drug selection and dosing based on test results (Table 2).³ This statement identifies key pharmacist roles in formulary development, medication-use processes, patient safety, clinical pharmacy practice, informatics, research and ethics, education and training, evidence-based literature analysis, pathology, and quality assurance. Guidance for other practice settings is provided in a 2011 white paper by the American Pharmacists Association outlining the pharmacist's role in pharmacogenomics within a framework of medication therapy management services.¹⁴

Clinical resources have also been developed, including guidelines from the Clinical Pharmacogenetics Implementation Consortium (CPIC) and information in the online Pharmacogenomics KnowledgeBase (www.pharmgkb.org).¹⁵ CPIC publishes guidelines to help clinicians understand how available test results can be used to optimize drug therapy (www.cpicpgx.org).¹⁶ PharmGKB is an online resource that provides access to pharmacogenomics information in clinical dosing guidelines and drug labels.¹⁷

Recommendations for the clinical application of pharmacogenomics data are also provided by the Dutch Pharmacogenetics Working Group,¹⁸ the Canadian Pharmacogenomics Network for Drug Safety,¹⁹ and others.^{20, 21}

Educational Needs and Challenges

Although a framework of best practices and resources is emerging, there remain significant educational needs and challenges that span didactic, laboratory, and experiential teaching environments for professional, postgraduate, and continuing pharmacy education (Table 3).

Student Pharmacists

Within colleges and schools of pharmacy, pharmacogenomics educational content is most likely to be included as part of existing required didactic coursework.^{4, 5} Colleges and schools of pharmacy are often challenged by fundamental questions such as the structure of pharmacogenomics content, i.e., a standalone course, content integration throughout other courses, or a combination of both. When delivered as a standalone course, many institutions place pharmacogenomics course content in parallel with higher-level pharmacotherapy classes (i.e., in the second or third year of pharmacy school). Advantages of this approach include enabling educators to focus on pharmacogenomics (more time/depth of coverage since pharmacotherapy is covered in other courses), increased flexibility to keep pace with emerging research, and less resource needs (fewer faculty experts teaching in a single course versus training all multiple domain experts to integrate into their courses). However, the intricate relationship of pharmacogenomics with other disciplines (e.g., pharmacokinetics) and therapeutic areas (e.g., cardiology) may not be fully realized in a standalone model.²² Alternatively, an institution may thread pharmacogenomics throughout pharmacology, pharmacokinetics, and pharmacotherapy courses. This allows educators to emphasize specific areas with repeated exposure; however, threading may be inconsistent or "lost" over time.²²

Colleges and schools of pharmacy can also be challenged to identify the amount of coverage and type of content that is needed. A 2010 survey indicated that the required amount of pharmacogenomics didactic content was 10 hours (40.6%), 11 to 30 hours (42%), and 31 to 60 hours (14.5%) at 69 respondent institutions.⁵ In that survey, 63.8%, 76.8%, and 50.7% of respondents reported content in the first-, second-, and third-professional years, respectively.⁵ Even with successful efforts to include pharmacogenomics, there continues to be insufficient content on the ethical, legal, social, and economic implications of pharmacogenomics, key concepts that are included in pharmacist competencies.^{4, 5} There is also a need to address other components of personalized and precision medicine, such as proteomics, metabolomics, epigenetics, and bioinformatics, within didactic portions of pharmacy curricula.²²

These needs and challenges extend into the experiential (practice-based) training environment as well. This is an especially important area since it is essential for future clinical pharmacists to have the opportunity to apply pharmacogenomic data to optimize therapeutic outcomes. To accomplish this, there is a need for experienced clinical faculty and advanced pharmacogenomics practice settings. In addition to other challenges cited within

didactic teaching, experiential training in pharmacogenomics is especially affected by an inadequate number of pharmacogenomics clinical practices, few experienced preceptors, and limited training opportunities. In addition, many preceptors who use pharmacogenomics routinely practice in specialized areas (e.g., oncology, HIV), further limiting the pool of available Introductory Pharmacy Practice Experiences (IPPEs) or APPEs that incorporate clinical pharmacogenomics content.

Practitioners

The profession must also meet educational needs in the pharmacy workforce, including postgraduate training and continuing pharmacy education (CPE). In many ways, the needs of practitioners are similar to those of students (e.g., practical application of complex genetic information, access to faculty experts) but other needs are unique to practitioners. For example, while many pharmacists prefer home-based, passive CPE offerings, these types of programs have not been shown to advance or change a pharmacist's practice behavior.²³ In recent years, a number of live, lecture-based, introductory pharmacogenomics programs have been delivered, with many providing CPE credit.^{24–26} While these can result in short-term knowledge gains, retention of this information wanes over time.²⁷ The complexity of pharmacogenomics and the quantity of information presented within a one-hour offering have been cited as potential reasons for the partial retention of the knowledge.²⁷ There is also a significant need for learning activities that include practice-based application of pharmacogenomics concepts, which is challenging in practitioner education. Postgraduate residency and/or fellowship training opportunities in pharmacogenomics for new graduates or practitioners are available but also remain limited for pharmacists.

Educational Approaches and Strategies

The ideal pharmacogenomics educational approach will depend on multiple factors, including target audience, program or course goals, faculty expertise and availability, class size, type of curriculum (e.g., primarily didactic, team-based, blended-learning), and administrative support. However, some important concepts and approaches are consistently rising to the top within the profession and can inform initial recommendations for student pharmacist and practitioner education. Additionally, increasingly resources are available to support educators (Table 4).

Student Pharmacists

Early Foundational Education in Genetics—The "early and often" approach introduces pharmacogenomics in secondary, undergraduate, and professional education, including a recommendation that pre-professional pharmacy curriculum include coursework in genetics and/or molecular biology.^{22, 28–30} Based on our analysis of AACP data, pre-pharmacy genetics, molecular biology, and cellular biology content are required by only 9%, 0.8%, and 5.2% of pharmacy degree institutions, respectively.³¹ However, most programs require general biology, and 26% of programs require biochemistry, both of which may include coverage of genetics and molecular or cellular biology.³¹ As an example of strategies to address these pre-professional educational gaps, Shenandoah University, in collaboration with George Washington University, developed a pharmacogenomics primer

course for first-year pharmacy students.²⁹ This course provides a basic genetics foundation that is subsequently integrated into second- and third-year courses in the curriculum.²⁹ Other approaches to meet this need include giving special attention to genetic material during first-year foundational science courses or providing web-based, self-directed genetics learning modules in the early professional years.

Incorporation of Practice-Based, Patient Care Applications—In addition to early foundational science knowledge, student pharmacists must also be equipped with skills needed to apply pharmacogenomics to patient care decisions, concepts which are often covered in the third year of pharmacy education and beyond (e.g., in clinical capstone courses or during experiential training).^{4, 5, 32–35} In the authors' experiences, this sequencing enables capitalizes on students' previous pharmacotherapy knowledge to deliver pharmacogenomics content in parallel with higher-level courses such as oncology and advanced infectious diseases (e.g., HIV), both of which contain numerous examples of precision medicine. Appropriate integration of pharmacogenomics into management, communication, public health, informatics, leadership, entrepreneurship, or research courses should also be considered.

In addition to curricular content that covers pharmacogenomics-based pharmacotherapy recommendations (e.g., therapeutic dose change), other concepts should also be explored by educators such as assessing how varying clinical actionability, laboratory test availability, insurance reimbursement, and other factors influence the practical use of pharmacogenomic testing.³⁶ Because these practical factors are often driven by the strength of the evidence supporting clinical effects of genetic variability, many institutions focus applications-based activities on gene-drug pairs that have published CPIC guidelines and therefore have undergone a rigorous evidence review. Additional concepts unique to pharmacogenomics include the use of web-based genetics databases and other resources (e.g., PharmGKB), evaluation of pharmacogenomics studies, application of models for evaluating genetic tests, (e.g., clinical validity and utility), and consideration of ethical, legal, and social implications of pharmacogenomic testing.

Once the desired practice-based content is defined, teaching and learning activities may include traditional didactic lectures, self-directed and active-learning exercises (i.e., assignments), group discussion of patient cases, student-led clinical debates or presentations, journal club exercises, and others.^{35, 37} Table 5 lists representative topics and learning activities that have been used by the authors.

Collaboration among Colleges/Schools of Pharmacy and Shared Teaching

Resources—Specific efforts to enable teaching collaboration among educators are also needed due to the wide range of clinical faculty expertise in pharmacogenomics. Currently available shared resources include the Pharmacogenomics Education Program (PharmGenEd[™]): Bridging the Gap between Science and Practice, developed by the University of California San Diego Skaggs School of Pharmacy.^{38, 39} This program created educational materials that were disseminated through continuing education programs, train-the-trainer programs for clinical practitioners and faculty, and web-based presentations. Of the pharmacy faculty trainers who participated in a train-the-trainer webinar (n=58), 55%

reported no previous formal pharmacogenomics training and 78% reported no formal training in pharmacogenomics teaching.⁷ Participation in the train-the-trainer program was associated with a significant increase in the instructors' self-reported ability to teach pharmacogenomics to pharmacy students.⁴⁰ From the student's perspective, there was also a significant increase in students' self-reported ability to educate patients about pharmacogenomics and their self-efficacy for applying pharmacogenomics in clinical practice.⁷

The National Institutes of Health (NIH) has also worked closely with pharmacy and other health professions to support sharing of educational resources through the establishment of the Genetics/Genomics Competency Center (G2C2, http://g-2-c-2.org) and the Global Genetics and Genomics Community (G3C, http://g-3-c.org). G2C2 is a peer-reviewed resource that curates existing educational resources and aligns them with professional educational competencies; G3C provides use-case scenarios for genetics and genomics, including for pharmacogenomics.¹¹

Representative teaching materials for genetic and genomic concepts may also be integrated into massive open online courses (MOOCs).⁴¹ An editorial by Ma and colleagues suggested that a pharmacogenomics MOOC may address some educational challenges (e.g., inadequate depth of instruction and insufficient faculty expertise).⁴² However, MOOCs and MOOC-like courses have been criticized for limited personal interactions with students, lack of rigor, low completion rates, challenges with assigning academic credit, complex business models, and required technology infrastructure.^{41, 42} Future work is needed to determine whether MOOCs are viable educational alternatives in pharmacogenomics.

Patient-Centered, Team-Based Approach to Experiential Education—One of the largest, and most difficult to overcome, challenges for pharmacy education in pharmacogenomics is within experiential education, due to the need for both faculty expertise and an active clinical pharmacogenomics practice. To equip student pharmacists with the needed training, it is important that experiential learning opportunities are clinically robust in practice and student activities.^{6, 43, 44} Practice-based experiences that incorporate pharmacogenomics and its integration with other therapeutics topics, though, it most likely fits best during APPE training. Consistent with ACPE 2016 standards, experiential education in pharmacogenomics should, when possible, incorporate the following elements:⁴³

- 1. An emphasis on team-based, patient-centered care with use of electronic health record resources;
- 2. Opportunities for students to enhance patient-centered problem-solving and communication skills within clinical pharmacogenomics; and
- **3.** Structured institutional and professional leadership opportunities ideally with exposure to best practices for precision medicine.

Regardless of its placement, experiential education in clinical pharmacogenomics should include interprofessional team-based and patient-centered care, with an emphasis on the process of clinical pharmacogenomics and how this content integrates across other

disciplines, from both an individual case management and a population-based perspective (Table 6). Complementary education roles of physician medical geneticists and genetic counselors specifically should be emphasized as collaborative practice models are increasingly being implemented.^{45, 46} Practice activities should align with electronic health record infrastructure (e.g., informatics), require patient and interprofessional communication and education, and provide opportunities for leadership development when possible.^{44, 46} Additionally, given the importance of monitoring and applying emerging medical literature in this field, experiential educational strategies in clinical pharmacogenomics should include opportunities to respond to pharmacogenomics-based drug information questions and other activities that incorporate analysis and interpretation of pharmacogenomics literature (e.g., participation in journal clubs, use of pharmacogenomics databases [i.e., PharmGKB], and application of available clinical practice guidelines).^{44, 47, 48}

An important element of the student pharmacist's role in experiential education for any emerging practice area is the contribution that the student can make to practice development. Since a majority of practice settings have yet to implement routine pharmacogenomic testing, there are novel opportunities for students to be involved in developing and implementing pilot programs, educating patients and other health care disciplines, and even encouraging targeted pharmacogenomic testing when appropriate to optimize patient care.⁴⁸ Instruction in implementation science and review of "lessons learned" from published experiences of other institutions (institutional profiles, practice models, and design of clinical services) can be used to guide these experiences if local experience in unavailable. Current experiential practice settings offer an unprecedented opportunity for student pharmacists and their preceptors to engage in pharmacogenomics in practice and in interprofessional collaboration.⁴⁷

Finally, introducing the concepts of leadership, professional development, and entrepreneurship to student pharmacists during a clinical pharmacogenomics experience is crucial.^{6, 43} As an emerging field, implementation of clinical pharmacogenomics combines clinical practice and leadership skills and provides an ideal opportunity to develop these skills. In addition, involving student pharmacists in meetings with clinical and administrative stakeholders, as well as allowing them to assist with development and implementation of new services, is critically important. Routinely incorporating clinical pharmacogenomics into experiential training is a tremendous opportunity to position pharmacists to be leaders in pharmacogenomics-based care.

Participatory Teaching Models—A participatory model involving the opportunity for learners to personally undergo genomic testing provides an innovative opportunity to increase the fidelity of pharmacogenomics education. This approach is made possible by plummeting costs of genotyping technology and pharmacy schools have been leaders in deploying such testing in the classroom. Farrell and colleagues created laboratory exercises where students genotyped cancer cell lines and applied results to cases to learn the basics of oncology pharmacotherapy.⁴⁹ Krynetskiy and Calligro took the laboratory exercise a step further by asking students to determine their own genotype for a single drug metabolism gene.⁵⁰ Similarly, Knoell and colleagues reported a personal genotyping exercise of 10 volunteers in their large classroom clinical pharmacogenomics course.⁵¹ In each of these

examples (cell lines, a single gene, or small numbers of students), faculty and students rated each of these experiences favorably and recommended expanded offerings.

More recently, the commercial availability of inexpensive genetic testing panels that interrogate hundreds of thousands of variants have made testing even more accessible. But, it has also introduced a myriad of ethical, privacy, and logistical concerns when used in the classroom setting. Stanford University carefully navigated these issues to offer personal genomic testing to 31 medical and graduate students taking an elective genomics course.³⁷ Objective data showed participation in genomic testing increased students' self-reported and assessed genomics knowledge and did not cause significant anxiety.⁵² The authors concluded "utilizing personal genotype data can augment the educational value of courses teaching concepts of genomics and personalized medicine." But, course faculty also stipulated teaching approaches that addressed potential ethical, legal, and society implications were necessary.⁵³

One pharmacy-specific example of this strategy is University of Pittsburgh's Test2Learn[™] program.⁵⁴ Core components of this program include optional personal genomic testing, the use of student individual-level and population-level genetic data, a phenotyping activity, pharmacogenomics information retrieval and clinical decision making cases, and communication exercises using personal genomic testing data. Instructors address potential issues regarding privacy and confidentiality, coercion versus a right to know (or not know), maintaining equal learning opportunities, psychosocial issues, and incidental findings through specific course policies. For example, students received data directly (not through the University), genomic testing was optional and blinded, anonymous datasets were made available, software tools were used to control specific data analyses, new ethics instruction was added, and availability of a genetics counselor was provided as a safety net. Students in the course (n = 122) were highly engaged (82% underwent genomic testing and 100% remained pleased with their decision) and testing was feasible. Students who underwent personal genomic testing reported a greater increase in confidence in understanding test results and had a greater self-perceived ability to empathize with patients compared to those not genotyped. Pharmacogenomics knowledge and understanding of risks and benefits of testing also improved (independent of whether students were personally genotyped). Most students felt personal genomic testing was an important part of the course and believed they had a better understanding of pharmacogenomics because of the opportunity, findings that are consistent with similar investigations at other colleges.⁵⁵ Although no students accessed the provided genetic counseling services, their availability and importance of incorporating ethics instruction was emphasized. Subsequent deployments to two additional cohorts (to over 350 students and within practitioner continuing education programs) and published reports of similar programs have consistently demonstrated high participation rates and that participatory education models can be sustainable based on testing availability, costs, and demonstrated outcomes relative to potential risks and course time requirements.^{33, 52, 54, 55}

Online Resources and Software to Support Education—Learning strategies incorporating online resources may also enhance knowledge in this area. Beyond the online resources discussed earlier (CPIC, PharmGKB), the National Library of Medicine: Genetics Home Reference (http://www.genome.gov/education) and the National Human Genome

Research Institute (www.genome.gov) provide easily accessible modules/talking glossaries of basic genetics terminology. Farrell and colleagues developed unique exercises to introduce students to online pharmacogenomic resources and to apply pharmacogenomics to clinical scenarios.⁵⁶ Other examples of online educational innovations include development of web-based learning tools to expose middle- and high-school students to pharmacogenomics concepts and educational partnerships with secondary and undergraduate educators to develop pharmacogenomics teaching resources.^{57–59}

Practitioners

Just as there are common needs among student pharmacists and practitioners, many of the strategies cited above can also be applied to practitioner audiences, including a focus on practice-based applications, shared teaching resources, online tools, and participatory genotyping. However, some additional recommendations should be considered for practitioner audiences.

Traditional CPE Programs—Over the last two decades, pharmacogenomics education for practitioners has fallen largely to CPE programs, typically as short, internet-based lectures or live presentations. Presentations at national meetings are often driven by the organization's membership and have increasingly focused on the applications of pharmacogenomics in patient care in recent years. Our analysis of pharmacogenomics educational programming at the ASHP Midyear Clinical Meetings from 2006 to 2015 revealed that although the amount of content has remained steady during this time period (average 4.35 hours per year, range 1.5 to 7 hours), the focus of the content has shifted from an emphasis on foundational pharmacogenomics knowledge to applications-focused and clinical pearls sessions that include implementation guidance and practitioner experiences. Written articles (print and online) have also been provided in various state, national, and trade journals/publications. While these have the advantage of being self-paced for learners, they are also static resources that are not updated over time and are not ideal for facilitating adoption of new practices.

Pharmacogenomics certificate training programs provide another alternative for practitioner education that allows more in-depth exposure to clinical pharmacogenomics than a traditional CPE program.⁶⁰ As an example, one such certificate program consisted of a sixweek self-study covering precision medicine, the science of pharmacogenomics related to pharmacokinetics and pharmacodynamics, and eight specific representative drug-gene interactions.⁶⁰ The self-study was followed by a live, one-day session involving participant-simulated and live patient interactions. Program surveys indicated the pharmacists had a statistically significant increase in self-perceived competence and participants correctly addressed recommendations related to specific drug-gene interactions in 95% of the simulated patient encounters.⁶⁰ Although this training program only reached a small number of individuals (n = 17 pharmacists), the approach is promising and additional programs of this nature are emerging nationally.

Institution- or Implementation-Specific Training—An alternative strategy involves a more integrated approach that incorporates institution-specific resources. At Children's

Hospital of Wisconsin, educators offered training that incorporated institution-specific information and recommendations for clinical implementation of pharmacogenomics services to pharmacists, residents, interns, and students.⁶¹ This program included a self-paced knowledge-based training session, a 40-minute, live session incorporating patient cases and institution-specific resources, followed by pharmacist involvement with a pharmacogenomics program at the institution. Unlike shorter, less immersive educational programs for professionals, at six months post-program, pharmacists retained a significant amount of pharmacogenomics knowledge.⁶¹

Structured Post-Graduate Training Programs—Post-graduate year-one (PGY1) residencies augment general competencies, while the post-graduate year-two (PGY2) programs enhance competencies in a focused area. According to the ASHP Online Residency Director, there are currently three PGY2 pharmacogenetics residencies accredited by ASHP or seeking accreditation (St. Jude Children's Research Hospital, University of Florida College of Pharmacy, and University of Illinois at Chicago College of Pharmacy). In addition to a focus on therapeutic areas in which pharmacogenomics data are most often used (e.g., cardiology, psychiatry, oncology), pharmacogenomics residency training includes clinical and practice knowledge and skills needed for implementation such as drug information, informatics, medication safety, medication-use processes, and evidence-based literature analysis.^{47, 62} Fellowship training and formal graduate programs in pharmacogenomics are available at the masters and doctoral level, although these types of post-graduate training opportunities most typically lead to research pharmacogenomics careers in academia or industry.

Education Within Clinical Decision Support (CDS)—Integration of education within the electronic health record (EHR), most often through clinical decision support, has also been used to increase the accessibility of pharmacogenomics knowledge by deploying it to providers alongside patients' test results.⁶³ Pharmacogenomics clinical decision support with prescribing recommendations in test reports and alerting in EHRs have been developed.^{64–68} Increasingly, specific language and tools are being disseminated to help educate providers and drive expanded clinical implementations (see the NIH-funded IGNITE and eMERGE networks' Clinical Decision Support Knowledgebase [cdskb.org] and CPIC Informatics working group activities [https://cpicpgx.org/informatics/]). To bolster the effectiveness of clinical decision support, research suggests that patient-specific data, medication information, guidelines, and dosing recommendations of phenotypic information from credible and trustworthy sources are needed.^{69, 70} Recommendations have been put forth suggesting that EHRs should be able to access external educational content and incorporate strategies for context-specific linkages through functionality such as "infobuttons." ^{71, 72} However, early evaluations also suggest the impact of using clinical decision support as an educational strategy may be limited. ⁷³ Additional work is needed to identify optimal approaches to integrate pharmacogenomics education with EHRs at the point-of-care.

Conclusion: A Path Forward

As with other areas of emerging sciences that require disruptive change, clinical pharmacogenomics currently stands at a crossroads. The profession of pharmacy has a tremendous opportunity to provide leadership in pharmacogenomics by forging ahead on this path as leaders in research and practice. However, to realize this vision of clinical pharmacogenomics, there is an immediate and critical need for pharmacy to advance our educational strategies for students and practitioners. These changes in our approach to education – to shift the profession from a *knowledge* of pharmacogenomics to expertise in the *application* of pharmacogenomics in clinical practice – will truly lead us down the road less traveled, and that will make all the difference for patient care.

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Key Points

- **1.** Educational barriers hinder the widespread adoption of pharmacogenomics to achieve precision medicine.
- **2.** Increasingly, effective approaches to attain pharmacogenomics knowledge and to drive its appropriate application in clinical practice are available.
- **3.** The pharmacy profession has taken a leadership role in expanding student and practitioner education to achieve consensus pharmacogenomics competencies.

Pharmacist Competencies in Pharmacogenomics (http://g-2-c-2.org)

<u>Goal:</u>		
The cor – basic	npetencies are to describe pharmacist-specific knowledge necessary to achieve the competencies outcome and are focused in 4 key areas genetic concepts, genetics and disease, pharmacogenomics/pharmacogenetics, and ethical, legal, and social implications.	
Compe	tencies:	
Domaiı	Pharmacist-specific Knowledge	
Basic G	enetic Concepts	
1	To demonstrate an understanding of the basic genetic/genomic concepts and nomenclature.	
2	To recognize and appreciate the role of behavioral, social, and environmental factors (lifestyle, socioeconomic factors, pollutants, etc.) to modify or influence genetics in the manifestation of disease.	
3	To identify drug and disease associated genetic variations that facilitate development of prevention, diagnostic and treatment strategies; appreciate differences in testing methodologies and need to explore these differences in drug literature evaluation.	
4	To use family history (minimum of three generations) in assessing predisposition to disease and selection of drug treatment.	
Genetic	s and Disease	
1	To understand the role of genetic factors in maintaining health and preventing disease.	
2	To assess the difference between clinical diagnosis of disease and identification of genetic predisposition to disease (genetic variation is not strictly correlated with disease manifestation).	
3	To appreciate that pharmacogenomic testing may also reveal certain genetic disease predispositions (e.g., Apo E4 polymorphism).	
Pharma	cogenomics/Pharmacogenetics	
1	To demonstrate an understanding of how genetic variation in a large number of proteins (e.g., drug transporters, metabolizing enzymes, receptor targets) influence pharmaco-kinetics and pharmacodynamics related to pharmacologic effect and drug response.	
2	To understand the influence of ethnicity in genetic polymorphisms and associations of polymorphisms with drug response.	
3	Recognize the availability of evidence based guidelines that synthesize information relevant to genomic/pharmacogenomic tests and selection of drug therapy (e.g. Clinical Pharmacogenetics Implementation Consortium).	
Ethical,	Legal and Social Implications	
1	To understand the potential physical and/or psychosocial benefits, limitations and risk of pharmacogenomic/pharmacogenetic information for individuals, family members and communities, especially with pharmacogenomic/pharmacogenetic tests that may relate to predisposition to disease.	
2	To understand the increased liability that accompanies access to detailed genomic patient information and maintain the confidentiality and security of this information.	
3	To adopt a culturally sensitive and ethical approach to patient counseling regarding genomic/pharmacogenomic test results.	
4	To appreciate the cost cost effectiveness, and raimbursement by insurars relevant to genomic or pharmacogenomic tests, for patients	

- 4 To appreciate the cost, cost-effectiveness, and reimbursement by insurers relevant to genomic or pharmacogenomic tests, for patient and populations.
- 5 Identifying when to refer a patient to a genetic specialist or genetic counselor.

Pharmacist's Role in Clinical Pharmacogenomics (adapted from ASHP Statement³)

Pharmacist's Responsibilities in Clinical Pharmacogenomics				
Promote the optimal use and timing of pharmacogenomic tests, including advocating for routine use of pharmacogenomic testing.				
Interpret clinical pharmacogenomic test results.				
Educate other pharmacists, fellow health care professionals, patients, and the public about the field of pharmacogenomics.				
Expected Skills of All Practicing Pharmacists				
Recommend or schedule pharmacogenomic testing to aid in the process of drug and dosage selection.				
Design patient-specific pharmacotherapy regimen to optimize patient outcomes based on the patient's pharmacogenomic profile that also considers: pharmacokinetic and pharmacodynamic properties of the drug; and pertinent patient-specific factors such as comorbidities, other drug therapy, demographics, and laboratory data.				
Educate patients, pharmacists, and other health care professionals about pharmacogenomic principles and appropriate indications for clinical pharmacogenomic testing, including the cost-effective use of pharmacogenomic testing.				
Communicate pharmacogenomic-specific drug therapy recommendations to the health care team, including documentation of interpretation of results in the patient's health record.				
Expected Skills of Pharmacists with Specialized Training in Pharmacogenomics				
Develop pharmacogenomic-specific clinical decision support tools in the electronic health record.				
Develop institutional guidelines and processes for implementing clinical pharmacogenomics services.				

Establish mechanisms for communicating test results to patients that incorporate lifetime applications of test results and revisable reporting mechanisms.

Serving as an expert pharmacogenomics resource within the institution, including documenting patient outcomes, promoting collaborative relationships with health care professionals, contributing to the evaluating of implemented pharmacogenomics services, and other roles.

Challenges to Incorporating Pharmacogenomics Education into Pharmacy Curricula

Challenges	Potential Solutions
Lack of faculty with practice and teaching expertise in pharmacogenomics	 Shared curricula and/or teaching resources Train-the-trainer programs for educators Collaboration with existing resources (e.g., G2C2, G3C) to increase awareness and use of these resources among pharmacy educators
 Coverage of domains such as genomic basis of disease, bioinformatics, proteomics, metabolomics, genetic testing processes, and ethical, social, and economic implications is often limited. Limited fidelity of instruction (understanding testing process or providing pharmacogenomics communication first- hand) Limited space within most curricula to incorporate new topics 	 Protocomplete or the students of the
 Varying degrees of clinical implementation May affect clinical faculty expertise and hamper delivery of pharmacogenomics-based experiential education (i.e., IPPEs, APPEs). Preceptors/faculty are challenged in staying current with clinical pharmacogenomics applications and emerging literature. 	 Teaching implementation science in conjunction with pharmacogenomics education aimed at knowledge attainment and its application when local implementation programs are not yet available. Disseminating practice models in which students and trainees actively participate in clinical implementations to support further development of these practices Establishment of practitioner/faculty-focused mechanisms to increase communication, collaboration, and awareness of practice and learning activities and emerging literature (e.g., discussion board, listserv) Development of an online journal club to discuss key emerging literature and its clinical relevance
 Variable needs and opportunities for practitioner education Requisite knowledge and skills may differ based on practice setting Limited post-Pharm.D. residency and fellowship opportunities. 	 Residency program collaboration to increase awareness of opportunities for and content of post-graduate training (e.g., residency) Development and dissemination of resources (e.g., sample syllabi, learning activities, assignments) to support creation of an elective pharmacogenomics rotation for APPE students and PGY1 residents Development of national preceptor training programs for teaching pharmacogenomics competencies

Resources to support pharmacogenomics education and educators.

Resource	Information Provided		
Genetics and Genomics Competency Center (G2C2) (http://g-2-c-2.org)	 Consensus genomic competencies for pharmacists divided into 4 areas: Basic Genetic Concepts, Genetics and Disease, Pharmacogenomics, and Ethical, Legal and Social Implications Peer-reviewed educational resources for group instruction or self-directed learning mapped to these competencies. 		
Global Genetics and Genomics Community (G3C) (http://g-3-c.org)	Case studies for students and practicing healthcare provider to learn basic genetic concepts including pharmacogenomics		
National Library of Medicine Genetics Home Reference (https://ghr.nlm.nih.gov/)	Consumer-friendly information about the effects of genetic variation on human health.		
National Human Genome Research Institute (http://www.genome.gov/education)	Basic educational materials about genetics and genomics.		
Pharmacogenomics Knowledgebase (PharmGKB) (http://www.pharmgkb.org)	 Repository of dosing guidelines, annotated information from FDA drug product labels, and data on potentially actionable gene-drug associations and genotype-phenotype relationships. 		
Clinical Pharmacogenomics Implementation Consortium (CPIC) (http:// www.cpicpgx.org)	 Peer-reviewed, gene/drug clinical practice guidelines to guide the translation of genetic laboratory test results into actionable prescribing decisions for specific drugs 		
FDA Pharmacogenomic Biomarkers in Drug Labeling Table (http://www.fda.gov/ Drugs/ScienceResearch/ResearchAreas/ Pharmacogenetics/ucm083378.htm)	 Listing of FDA-approved drugs with pharmacogenomics information in their labeling with reference to gene (biomarker), populations-impacted, and section in the product label where the information can be found. 		

* Topics, suggested contact hours, and learning exercises are based upon authors' experiences teaching clinical pharmacogenomics at the University of Florida (K.W.W.), University of Colorado (C.L.A.), Manchester University (D.F.K.), and University of Pittsburgh (P.E.E.).

Examples of Topics and Learning Activities in Clinical Pharmacogenomics Didactic Courses

Торіс	Hours	Sample Active Learning Exercise(s)
Fundamentals of human genetics and	2–4	Discussion board or in-class discussion activities
A dropped concerts in phermacogenemics	1.2	Web-based self-directed learning activities
(e.g., haplotypes, genome-wide approaches)	1-2	Participatory genotyping
Genomic basis of disease and "omics" (i.e., genomics, proteomics, metabolomics)	1–2	Phenotyping exercise (e.g., phenylthiocarbamide [PTC] tasting)
Direct-to-consumer-based genotyping	1–2	
Use of pharmacogenomic databases (e.g., PharmGKB)	2	Database activity/assignment in which students answer specific clinical questions
Commercially available genotyping tests:	2	Compare/contrast genetic testing processes described in the primary
interpreting and evaluating results		Interature and assess tests for varianty
		Interpret genotyping reports in the context of clinical cases.
Types of clinical pharmacogenomics evidence	1–2	Compare/contrast clinical pharmacogenomics study designs.
and guidelines		• Compare/contrast guidelines for specific gene-drug pairs (e.g., CPIC,
Interpretation of the clinical pharmacogenomics literature	1-2	DPWG)
		Identity pharmacogenomics information in FDA labels
		• Journal Club/evaluation activity
Pharmacogenomics in the drug development	1–2	Discussion board or in-class discussion activities (e.g., targeted
and FDA approval process (e.g., ivacattor)		therapies)
		Genomic data in alternative trial designs
Genetics and Clinical Pharmacology (i.e., drug metabolism, transport, PK, PD)	3–4	 Integrated patient case activities which include lab reports, primary literature, CPIC guidelines, and a patient education component.
Oncology: germline (e.g., thiopurines) and somatic (e.g., trastuzumab)	3–5	 Use of G3C pharmacogenomics cases. Use of real genomic data (if available)
Drug-induced hypersensitivity reactions (i.e.,	2–3	Interdisciplinary laboratory sample collection and result reporting
abacavir, carbamazepine, phenytoin, allopurinol)		exercise
Infectious diseases (i.e., voriconazole, pegylated interferon)	1–2	
Pain, neurology, psychiatry (i.e., codeine, phenytoin, tricyclic antidepressants, SSRIs)	2–4	
Cardiology (e.g., clopidogrel, warfarin, statins)	2–4	
Transplant (e.g., tacrolimus)	1–2	
Controversial evidence (e.g., tamoxifen)	1	
Ethical, social, and economic implications	1–2	Student debate activity/assignment
Clinical implementation (e.g., clinical decision support tools)	2–3	Student-led proposal/business and operational plan to establish new clinical pharmacogenomics service
Communicating pharmacogenomics information and recommendations	1–2	Role playing communication to patients or providers (e.g., think- pair-share activity)

* Sample activities and assignments based upon authors' experiences at the University of Florida (K.W.W.), University of Colorado (C.L.A.), Manchester University (D.F.K.), and University of Pittsburgh (P.E.E.).

Sample Course Activities, and Assignments for a Clinical Pharmacogenomics Advanced Pharmacy Practice Experience

In the area of precision medicine, students will participate in: Ongoing patient care activities to support clinical implementation of pharmacogenomic initiatives, including: CYP2C19-guided clopidogrel therapy in the cardiac catheterization laboratory TPMT-guided dosing of azathioprine, mercaptopurine, and thioguanine primarily for pediatric hematology/oncology patients and pediatric and adult gastroeneterology patients CYP2D6-guided dosing of select opioids within primary care or pain clinics CYP2D6/CYP2C19-guided dosing of select antidepressants in adult psychiatry clinics HLA testing in select primary care, neurology, or HIV clinics IL28B (IFNL3) guided-dosing of pegylated interferon as needed in hepatitis C clinic Support of and participation in the Personalized Medicine Subcommittee and related Pharmacy & Therapeutics committee activities for clinical implementation of genotype-guided therapies. Case-based discussions on pharmacogenetics and precision medicine, including clinical utility of selected drug-gene pairs, and steps for clinical implementation of pharmacogenetics in a health care setting. Ongoing medical evidence review and evaluation for existing and potential drug-gene pair implementations. If available, participate in pharmacogenomic laboratory activities such as sample collection, DNA isolation, polymerase chain reaction, etc. Development of educational materials for health care professionals and patients on pharmacogenomics and precision medicine. In the area of evidence-based medicine, students will participate in: Ongoing daily and systematic review of medical literature, FDA alerts, and new drug approvals. Weekly discussions of recently published pharmacogenetic literature. Research, writing, and publication of four articles (one per week) for publication in the pharmacogenomics newsletter. Discussions on clinical trial design and analysis, professional writing, editing, publishing, and strategies for keeping up with the medical literature. Rotation assignments/activities will include: Patient care responsibilities in targeted areas (as listed above), including weekly patient case discussions Weekly discussion of current pharmacogenomics literature Journal club presentation Patient case or topic presentation Research and writing of newsletter articles for provider education Design of a mock clinical decision support algorithm for a sample gene-drug pair Research and writing of a clinically actionable gene-drug pair monograph Design of a mock pharmacogenes chip (including selection of variants based on clinical evidence) Attendance and participation in department journal clubs, seminars, and other pertinent educational activities.