Educational strategies to enable expansion of pharmacogenomics-based care

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Purpose. The current state of pharmacogenomics education for pharmacy students and practitioners is discussed, and resources and strategies to address persistent challenges in this area are reviewed.

Summary. Consensus-based pharmacist competencies and guidelines have been published to guide pharmacogenomics knowledge attainment and application in clinical practice. Pharmacogenomics education is integrated into various pharmacy school courses and, increasingly, into Pharm.D. curricula in the form of required standalone courses. Continuing-education programs and a limited number of postgraduate training opportunities are available to practicing pharmacists. For colleges and schools of pharmacy, identifying the optimal structure and content of pharmacogenomics education remains a challenge; insufficient numbers of faculty members with pharmacogenomics expertise and the inadequate availability of practice settings for experiential education are other limiting factors. Strategies for overcoming those challenges include providing early exposure to pharmacogenomics through foundational courses and incorporating pharmacogenomics into practice-based therapeutics courses and introductory and advanced pharmacy practice experiences. For practitioner education, online resources, clinical decision support–based tools, and certificate programs can be used to supplement structured postgraduate training in pharmacogenomics. Recently published data indicate successful use of "shared curricula" and participatory education models involving opportunities for learners to undergo personal genomic testing.

Conclusion. The pharmacy profession has taken a leadership role in expanding student and practitioner education to meet the demand for increased pharmacist involvement in precision medicine initiatives. Effective approaches to teaching pharmacogenomics knowledge and driving its appropriate application in clinical practice are increasingly available.

Keywords: education, pharmacy, continuing; genomics/education; pharmacists; pharmacogenetics/education; pharmacogenetics/trends; precision medicine; schools, pharmacy

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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 implementation of pharmacogenomics in clinical practice remain, including challenges incorporating genomic data into the electronic health record (EHR), ethical concerns, and challenges in the areas of 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-oriented clinical service implementation efforts.[1-3]

Pharmacogenomics content in pharmacy education has increased over the last decade. The percentage of colleges or schools of pharmacy

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with pharmacogenomics in the 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 examination content in this area.[6] Pharmacy students have also begun to recognize the importance of this discipline, with over 62% of participants in a recent survey of 2500 students expressing the view that pharmacogenomics should be a required curricular component.[7]

In spite of increased awareness of the importance of pharmacogenomics, 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 pharmacist uptake of pharmacogenomics in clinical practice, point to the persistent educational 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 in nature and scope, the teaching techniques used, and curricular placement.[4,5] Pharmacogenomics content is especially limited in experiential and practice-based training, with few advanced pharmacy practice experience (APPE), residency, and 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 to assist educators in overcoming these challenges are emerging. This article summarizes existing educational standards, competencies, and practice resources to support the pharmacist's role in clinical pharmacogenomics; it also outlines specific needs and challenges and proposes potential solutions for educators.

KEY POINTS

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

Educational standards and competencies for pharmacists

The Center for the Advancement of Pharmacy Education educational 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 of the standards, 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 for pharmacy educators that identify specific knowledge areas that must be addressed in order to enable pharmacy graduates to "recommend and interpret the results of pharmacogenetic/pharmacogenomic tests and make therapy recommendations based on test results" have been established and were recently updated.[10] These competency and outcome statements, initially developed in 2002, were updated in 2012 to align with health professional genetics competency statements developed by the National Coalition for Health Professional Education in Genetics.[11-13] Representatives from nine pharmacy and pharmacy-related organizations achieved consensus on and approved these competency statements (Appendix A).[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 online at the Genetics/Genomics Competency (G2C2) Center website (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 pertaining to ordering, interpreting, and reporting pharmacogenomic test results; and guiding optimal drug selection and dosing based on test results (Appendix B).[3] This statement identifies key roles for hospital and health system–based pharmacists 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 pharmacists in 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]

Pharmacogenomics-oriented linical resources have 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 under-

Table 1. Challenges of Incorporating Pharmacogenomics Education into Pharmacy Curricula[a]

Challenge	Potential Solutions
Lack of faculty with practice and teaching expertise in pharmacogenomics	1. Shared curricula and teaching resources 2. Train-the-trainer programs for educators 3. Collaborations involving the application of existing resources (e.g., G2C2, G3C) to increase awareness and use of these resources among pharmacy educators
Limited depth and breadth of instruction, such as • Limited coverage of domains such as genomic basis of disease, bioinformatics, proteomics, metabolomics, genetic testing processes, and ethical, social, and economic implications • Limited fidelity of instruction (understanding testing process or providing pharmacogenomics communication firsthand) • Limited space within most curricula to incorporate new topics	1. Development of early foundational education in pharmacogenomics and related "omics" topics for pharmacy and undergraduate students 2. Working with real pharmacogenomic data and/or offering an optional opportunity for learners to personally undergo genetic testing to experience the process 3. Development of resources to enable educators to weave pharmacogenomics into existing pharmacotherapy coursework (e.g., teaching cases) 4. Incorporation of non–patient care elements (e.g., test ordering and evaluation, ethical issues, bioinformatics, communication of results) into pharmacogenomics patient cases to allow synergy in teaching these topics
Varying degrees of clinical implementation. Inconsistent implementation may • Affect clinical faculty expertise and hamper delivery of pharmacogenomics-based experiential education (i.e., IPPEs and APPEs) • Pose challenges for preceptors and/or faculty in terms of staying current with clinical pharmacogenomics applications and emerging literature	1. Teaching of implementation science in conjunction with pharmacogenomics education aimed at knowledge attainment and its application when local implementation programs are not yet available 2. Disseminating practice models in which students and trainees actively participate in clinical implementations to support further development of implementation practices 3. Establishment of practitioner- and faculty-focused mechanisms (e.g., discussion board, listserver) to increase communication, collaboration, and awareness of practice and learning activities and emerging literature
Variable needs and opportunities for practitioner education. For example: • Requisite knowledge and skills may differ based on practice setting • Opportunities for post-Pharm.D. residency and fellowship training may be limited	1. Residency program collaboration to increase awareness of opportunities for and content of postgraduate training 2. 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 3. Development of national preceptor training programs for teaching pharmacogenomics competencies

[a]G2C2 = Genetics/Genomics Competency Center, G3C = Global Genetics and Genomics Community, IPPE = introductory pharmacy practice experience, APPE = advanced pharmacy practice experience, PGY1 = postgraduate year 1.

stand 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 pharmacogenomic data are also provided by the Dutch Pharmacogenetics Working Group,[18] the Canadian Pharmacogenomics Network for Drug Safety,[19] and other organizations.[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 (CPE) (Table 1).

Pharmacy students. Within colleges and schools of pharmacy, pharmacogenomics 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 versus content integration into other courses or a combination approach). When delivered as a standalone course, pharmacogenomics content is taught at many institutions 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 (i.e., they can devote more time to and provide more in-depth coverage of pharmacogenomics because pharmacotherapy is covered in other courses), increased flexibility to keep pace with emerging research, and reduced resource needs (by having fewer faculty experts teaching a single course instead of training multiple-domain experts to integrate the content into their courses). However, the intricate

relationship of pharmacogenomics to 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 approach allows educators to emphasize specific areas through repeated exposure; however, threading may be inconsistent or "lost" over time.[22]

Colleges and schools of pharmacy may also be challenged to identify the amount of coverage and type of content needed. Results of a 2010 survey indicated that the required amount of pharmacogenomics didactic content was identified by 69 respondent institutions as at least 10 hours (41.0%), 11–30 hours (42.0%), or 31–60 hours (14.5%).[5] In that survey, 63.8%, 76.8%, and 50.7% of respondents reported content in the first, second, and third professional years, respectively. Even with successful efforts to include pharmacogenomics in pharmacy school curricula, 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 because 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 during 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/AIDS care), 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 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 practice behaviors.[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 programs can result in short-term knowledge gains, information retention wanes over time.[27] The complexity of pharmacogenomics and the great quantity of information presented within a one-hour offering have been cited as potential reasons for partial knowledge retention.[27] There is also a significant need for learning activities that include practice-based application of pharmacogenomics concepts, which is a challenging aspect of practitioner education. Postgraduate residency and fellowship training opportunities in pharmacogenomics for pharmacists remain limited.

Educational approaches and strategies

The ideal approach to pharmacogenomics education depends on multiple factors, including the target audience, program or course goals, faculty expertise and availability, class size, type of curriculum (primarily didactic, primarily team based, or a blended-learning approach), and administrative support. However, some important concepts and approaches have consistently risen to the top (described below) and can inform initial recommendations for pharmacy student and practitioner education. Additionally, resources are increasingly available to support educators (Table 2).

Pharmacy student education. *Early foundational education in genetics.* The "early and often" approach introduces pharmacogenomics in secondary, undergraduate, and professional education, including a recommendation that the preprofessional pharmacy curriculum include coursework in genetics or molecular biology (or both).[22,28-30] Based on our analysis of American Association of Colleges of Pharmacy data, prepharmacy genetics, molecular biology, and cellular biology content are required by only 9.0%, 0.8%, and 5.2% of pharmacy degree–conferring institutions, respectively.[31] However, most programs require general biology content, and 26% of programs require biochemistry content; both types of content may include coverage of genetics and molecular or cellular biology.[31] As an example of strategies to address these preprofessional 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 foundation of basic genetics knowledge that is subsequently built upon and integrated into second- and third-year courses in the curriculum.[29] Other approaches to meeting this need include giving special attention to genetics during first-year foundational science courses and 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 knowl-

Table 2. Resources to Support Pharmacogenomics Education and Educators[a]

Source	Resources Provided
Genetics/Genomics Competency Center (G2C2) http://g-2-c-2.org	Consensus genomics competencies for pharmacists in 4 areas (basic genetics concepts; genetics and disease; pharmacogenomics; and ethical, legal, and social implications); peer-reviewed educational resources for group instruction or self-directed learning mapped to the competencies
Global Genetics and Genomics Community (G3C) http://g-3-c.org	Case studies for students and practicing healthcare providers in basic genetics 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 www.genome.gov/education	Basic educational materials about genetics and genomics
Pharmacogenomics Knowledgebase (PharmGKB) 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) www.cpicpgx.org	Peer-reviewed, clinical practice guidelines for gene–drug pairs to guide translation of genetic laboratory test results into actionable prescribing decisions for specific drugs
FDA "Table of Pharmacogenomic Biomarkers in Drug Labeling" www.fda.gov/Drugs/ScienceResearch/ResearchAreas/Pharmacogenetics/ucm083378.htm	Listing of FDA-approved drugs with pharmacogenomics information in the labeling, with information including therapeutic uses of listed drugs, associated genetic biomarkers, affected populations, and labeling section where recommendations can be found

[a]FDA = Food and Drug Administration.

edge, pharmacy students must be equipped with the skills needed to apply pharmacogenomics to patient care decisions; these skills are based on concepts that are often covered in the third year of pharmacy education and beyond (e.g., in clinical capstone courses, during experiential training).[4,5,32-35] In our experiences, this sequencing capitalizes on students' previous pharmacotherapy knowledge to deliver pharmacogenomics content in parallel with higher-level courses such as oncology and advanced infectious diseases courses, both of which cover numerous examples of precision medicine. Appropriate integration of pharmacogenomics into management, communication, public health, informatics, leadership, entrepreneurship, and research courses should also be considered.

In addition to curricular content that covers pharmacogenomics-based pharmacotherapy recommendations (e.g., therapeutic dosage adjustments), other concepts should be explored by educators. Such concepts might include assessing how the clinical actionability of genetic data, laboratory test availability, insurance reimbursement issues, 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 the clinical effects of genetic variability, many institutions center applications-based activities on gene–drug pairs that are the focus of published CPIC guidelines and therefore have undergone a rigorous evidence review. Additional concepts unique to pharmacogenomics include the use of Web-based genetics databases (e.g., PharmGKB) and other resources, evaluation of pharmacogenomic studies, application of models for evaluating genetic tests (e.g., for 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 3 lists representative topics and learning activities that we have used.

Collaboration among colleges and 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 and Pharmaceutical Sciences.[38,39] In this program, educational materials were created and disseminated through continuing-education programs, "train-the-trainer" programs for clinical practitioners and faculty, and Web-based presentations. Of the

Table 3. Examples of Topics and Learning Activities in Clinical Pharmacogenomics Didactic Courses[a,b]

Topic	Credit Hours	Sample Active Learning Exercise(s)
Fundamentals of human genetics and pharmacogenomics	2–4	Discussion board or in-class discussion activities
Advanced concepts in pharmacogenomics (e.g., haplotypes, genomewide approaches)	1 or 2	Web-based self-directed learning activities
Genomic basis of disease and "omics" (i.e., genomics, proteomics, metabolomics)	1 or 2	Participatory genotyping
Direct-to-consumer-based genotyping	1 or 2	Phenotyping exercise (e.g., PTC tasting)
Use of pharmacogenomics databases (e.g., PharmGKB)	2	Database activity or assignment in which students answer specific clinical questions
Commercially available genotyping tests: ordering, sample collection and processing, interpreting and evaluating results	2	Compare and contrast genetic testing processes described in primary literature and assess tests for validity Interpret genotyping reports in context of clinical cases
Types of clinical pharmacogenomics evidence and guidelines	1 or 2	Compare and contrast clinical pharmacogenomics study designs
Interpretation of clinical pharmacogenomics literature	1 or 2	Compare and contrast guidelines for specific gene–drug pairs (e.g., guidelines from CPIC, DPWG) Identify pharmacogenomics information in FDA labels Journal club or other literature evaluation activity
Pharmacogenomics in the drug development and FDA approval process (e.g., ivacaftor)	1 or 2	Discussion board or in-class discussion activities (e.g., discussion of targeted therapies) Evaluation of genomic data in various trial designs
Genetics and clinical pharmacology (drug metabolism, transport, PK, and PD)	3 or 4	Integrated patient case activities that include laboratory reports, primary literature, CPIC guidelines, and a patient education component
Oncology: influence of germline mutations (e.g., on thiopurines) and somatic mutations (e.g., on trastuzumab)	3–5	Use of G3C pharmacogenomics cases
Drug-induced hypersensitivity reactions (e.g., reactions to abacavir, allopurinol, carbamazepine, phenytoin)	2 or 3	Use of real genomic data (if available)
Pharmacogenetic considerations in specific therapeutic areas:		Interdisciplinary laboratory sample collection and result reporting exercise
Infectious diseases (response to pegylated interferon, voriconazole)	1 or 2	
Pain management, neurology, psychiatry (response to codeine, phenytoin, SSRIs, tricyclic antidepressants)	2–4	
Cardiology (e.g., response to clopidogrel, statins, warfarin)	2–4	
Transplant medicine (e.g., response to tacrolimus)	1 or 2	
Controversial evidence (e.g., data on pharmacogenetic influences on tamoxifen response)	1	
Ethical, social, and economic implications	1 or 2	Student debate activity or assignment
Clinical implementation (e.g., clinical decision support tools)	2 or 3	Student-led proposal or development of business and operational plan to establish new clinical pharmacogenomics service
Communicating pharmacogenomic information and recommendations	1 or 2	Role-playing exercise in communicating with patients or providers (e.g., "think-pair-share" activity)

[a]PTC = phenylthiocarbamide, PharmGKB = Pharmacogenomics Knowledgebase, CPIC = Clinical Pharmacogenetics Implementation Consortium, DPWG = Dutch Pharmacogenetics Working Group, FDA = Food and Drug Administration, PK = pharmacokinetics, PD = pharmacodynamics, G3C = Global Genetics and Genomics Community, SSRI = selective serotonin reuptake inhibitor.

[b]Topics, suggested credit hours, and learning exercises are based on authors' experiences teaching clinical pharmacogenomics at the University of Florida, University of Colorado, Manchester University, and University of Pittsburgh.

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 ($p < 0.001$) increase in the instructors' self-reported ability to teach pharmacogenomics to pharmacy students.[40] From the students' perspective, there were significant ($p < 0.0001$) increases in self-reported ability to educate patients about pharmacogenomics and in self-efficacy with regard to applying pharmacogenomics in clinical practice.[7]

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

Representative teaching materials for genetics and genomics concepts may also be integrated into massive open online courses (MOOCs).[41] An editorial by Ma and colleagues[42] suggested that a pharmacogenomics MOOC may address some educational challenges (e.g., inadequate depth of instruction, insufficient faculty expertise). However, MOOCs and MOOC-like courses have been criticized for limited instructor interaction with students, lack of rigor, low completion rates, challenges with assigning academic credit, complex business models, and heavy technology infrastructure demands.[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 pharmacy students with the needed training, it is important that experiential learning opportunities are clinically robust in terms of practice activities.[6,43,44] Practice-based experiences that incorporate pharmacogenomics can occur in IPPEs or APPEs. Given the complex nature of pharmacogenomics and its integration with other therapeutics topics, though, it most likely fits best with APPE training. For consistency with the 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 EHR resources,
2. Opportunities for students to enhance patient-centered problem-solving and communication skills necessary for clinical application of pharmacogenomics, and
3. Structured institutional and professional leadership opportunities, ideally with exposure to best practices in 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 is integrated across disciplines from both individual case management and population-based perspectives (Appendix C). The complementary education roles of medical geneticists and genetic counselors specifically should be emphasized as collaborative practice models are increasingly implemented.[45,46] Practice activities should align with EHR infrastructure (e.g., informatics systems), 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 such as PharmGKB, application of available clinical practice guidelines).[44,47,48]

An important element of the pharmacy student's role in experiential education for any emerging practice area is contributing 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 members of other healthcare disciplines, and even encouraging targeted pharmacogenomic testing (when appropriate) to optimize patient care.[48] Instruction in implementation science and a review of lessons learned from published experiences of other institutions (institutional profiles, practice models, and the design of clinical services) can be used to guide these experiences if local experience is unavailable. Current experiential practice settings offer an unprecedented opportunity for pharmacy students 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 pharmacy students during a clinical pharmacogenomics experience is crucial.[6,43] As with any emerging field, implementation of clinical pharmacogenomics combines clinical practice and leadership skills and provides

an ideal opportunity to develop these skills. In addition, involving pharmacy students in meetings with clinical and administrative stakeholders, as well as allowing students 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 can increase the fidelity of pharmacogenomics education. This approach is made possible by the plummeting costs of genotyping technology, and pharmacy schools have been leaders in deploying such testing in the classroom. Farrell and colleagues[49] created laboratory exercises wherein students genotyped cancer cell lines and applied the results to cases to learn the basics of oncology pharmacotherapy. Krynetskiy and Lee Calligro[50] took the laboratory exercise a step farther by asking students to determine their own genotype for a single drug metabolism gene. Similarly, Knoell and colleagues[51] reported conducting a personal genotyping exercise with 10 volunteers in their large classroom course in clinical pharmacogenomics. In each of these scenarios, faculty and students rated their experience favorably and recommended expanded offerings.[49-51]

The commercial availability of inexpensive genetic testing panels that interrogate hundreds of thousands of variants has made testing even more accessible, but the use of this technology in the classroom setting has also introduced a myriad of ethical, privacy, and logistic concerns. Researchers at Stanford University carefully navigated these issues to offer personal genomic testing to 31 medical and graduate students taking an elective genomics course[37]; they found that participation in genomic testing increased students' self-reported and assessed genomics knowledge and did not cause significant anxiety.[52] The researchers concluded that "utilizing personal genotype data can augment the educational value of courses teaching concepts of genomics and personalized medicine."[52] However, the course faculty emphasized the need for teaching approaches that address potential ethical, legal, and society implications of genetic testing.[53]

One pharmacy-specific example of a comprehensive approach to pharmacogenomics education is the University of Pittsburgh's Test2Learn program.[54] Core components of this program include optional personal genomic testing, the use of individual- and population-level student genetic data, a phenotyping activity, pharmacogenomic 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 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 data sets were made available, software tools were used to control specific data analyses, new ethics instruction was added, and access to 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, compared with those not genotyped, had greater self-perceived ability to empathize with patients; their pharmacogenomics knowledge and understanding of the risks and benefits of testing improved (independent of whether they were personally genotyped). Most students believed that personal genomic testing was an important part of the course and that they had a better understanding of pharmacogenomics because of the opportunity; those findings are consistent with findings of similar investigations at other colleges.[55] Although no student participating in the Test2Learn program accessed the provided genetic counseling services, their availability and the importance of incorporating ethics instruction were emphasized. Subsequent deployments to two additional cohorts (to over 350 students and within practitioner continuing-education programs) and published reports of similar programs consistently indicate high participation rates and demonstrate that participatory education models can be sustainable in terms of testing availability, costs, and 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 (e.g., CPIC, PharmGKB), the National Library of Medicine's Genetics Home Reference website (www.ghr.nlm.nih.gov) and the National Human Genome Research Institute website (www.genome.gov) provide easily accessible modules and talking glossaries of basic genetics terminology. Farrell and colleagues[56] developed unique exercises to introduce students to online pharmacogenomics resources and teach them how to apply pharmacogenomics to clinical scenarios. 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]

Practitioner education. Because pharmacy students and practitioners have many common needs in terms of pharmacogenomics education and

training, 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, 1.5–7 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 and publications. While these articles 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 an 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 six-week 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 that the pharmacists had a statistically significant increase in self-perceived competence and that 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 and 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, the program was found to foster substantial pharmacist retention of pharmacogenomics knowledge six months after program participation.[61]

Structured postgraduate training programs. Postgraduate year 1 pharmacy residencies augment general competencies, while postgraduate year 2 (PGY2) programs enhance competencies in a focused area. According to the ASHP online residency directory, at the time of writing three PGY2 pharmacogenetics residencies (at St. Jude Children's Research Hospital, the University of Florida College of Pharmacy, and the University of Illinois at Chicago College of Pharmacy) were accredited by ASHP or seeking accreditation. In addition to a focus on therapeutic areas in which pharmacogenomic data are most often used (e.g., cardiology, psychiatry, oncology), pharmacogenomics residency training covers clinical and practice knowledge and skills needed for pharmacogenetics implementation in areas 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 levels, although these types of postgraduate training opportunities most typically lead to research pharmacogenomics careers in academia or industry.

Education within clinical decision support systems. Educational tools integrated into the EHR, most often in the form of clinical decision support (CDS) tools, have been used to increase the accessibility of pharmacogenomics knowledge by deploying it to providers alongside patients' test results.[63] Pharmacogenomics-oriented CDS tools that provide prescribing recommendations aligned with genetic test data and EHR alerting mechanisms 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 Implementing Genomics in Practice (IGNITE) Network and the Electronic Medical Records and Genomics (eMERGE) Network Clinical Decision Support Knowledgebase (www.cdskb.org) and CPIC Informatics Working Group activities (www.cpicpgx.org/informatics/). To bolster the effectiveness of pharmacogenomics CDS, research suggests that patient-specific data, medication information, guidelines, phenotype information, and dosing recommendations from credible and trustworthy sources are needed.[69,70] Recommendations suggesting that EHRs should be able to access external educational content and incorporate strategies for context-specific linkages through functionality such as "infobuttons" have been put forth.[71,72] However,

early evaluations indicate that the impact of using CDS as an education strategy may be limited.[73] Additional work is needed to identify optimal approaches to integrating tools for pharmacogenomics education into EHRs at the point of care.

A path forward

As during the emergence of other areas of science that entail disruptive change, clinical pharmacogenomics currently stands at a crossroads. The profession of pharmacy has a tremendous opportunity to provide leadership in pharmacogenomics by assuming leadership roles in research and practice. However, to realize the vision of clinical pharmacogenomics, there is an immediate and critical need for the pharmacy profession to advance and expand strategies and programs for educating students and practitioners; only in that way will pharmacists advance from *knowledge* of pharmacogenomics to expert *application* of that knowledge in clinical practice.

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Appendix A—Pharmacist competencies in pharmacogenomics[a,b]

The competencies describe pharmacist-specific knowledge necessary to achieve the competency outcome and are focused on four key areas: (1) basic genetic concepts, (2) genetics and disease, (3) pharmacogenomics/pharmacogenetics, and (4) ethical, legal, and social implications.

Basic concepts

1. To demonstrate an understanding of basic genetic/genomic concepts and nomenclature
2. To recognize and appreciate the role of behavioral, social, and environmental factors (e.g., lifestyle, socioeconomic factors, pollutants) in modifying or influencing genetics in the manifestation of disease,
3. To identify drug- and disease-associated genetic variations that facilitate development of prevention, diagnostic, and treatment strategies and appreciate differences in testing methodologies and the need to explore these differences in drug literature evaluation, and
4. To use family history information (a minimum of three generations) in assessing predisposition to disease and selection of drug treatment.

Genetics 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), and
3. To appreciate that pharmacogenomic testing may also reveal certain genetic disease predispositions (e.g., *APOE*E4* polymorphism).

Pharmacogenomics/pharmacogenetics

1. To demonstrate an understanding of how genetic variation in a large number of proteins (e.g., drug transporters, metabolizing enzymes, receptor targets) influences pharmacokinetics 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, and
3. To 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 guidelines).

Ethical, legal, and social implications

1. To understand the potential physical and/or psychosocial benefits, limitations, and risks of pharmacogenomic/pharmacogenetic information for individuals, family members, and communities, especially with regard to 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 insurance reimbursement issues associated with genomic or pharmacogenomic tests that are relevant to both patients and populations, and
5. To identify when to refer a patient to a genetic specialist or genetic counselor.

[a]*APOE*E4* = a specific allelic variant of the gene coding for apolipoprotein E.
[b]Adapted from Genetics/Genomics Competency Center. Competency map: pharmacist. http://g-2-c-2.org/competency/pharmacist (accessed 2016 Sep 2).

Appendix B—Pharmacist's role in clinical pharmacogenomics[3]

Pharmacist's responsibilities in clinical pharmacogenomics

1. Promote the optimal use and timing of pharmacogenomic tests, including advocating for routine use of pharmacogenomic testing.
2. Interpret clinical pharmacogenomic test results.
3. Educate other pharmacists, fellow healthcare professionals, patients, and the public about the field of pharmacogenomics.

Expected skills of all practicing pharmacists

1. Recommend or schedule pharmacogenomic testing to aid in the process of drug and dosage selection.
2. Design a patient-specific pharmacotherapy regimen to optimize patient outcomes based on the patient's pharmacogenomic profile, taking into account pharmacokinetic and pharmacodynamic properties of the drug and pertinent patient-specific factors such as comorbidities, other drug therapy, demographics, and laboratory data.
3. Educate patients, pharmacists, and other healthcare professionals about pharmacogenomics principles and appropriate indications for clinical pharmacogenomic testing, including the cost-effective use of pharmacogenomic testing.
4. Communicate pharmacogenomics-specific drug therapy recommendations to the healthcare team, including documentation of interpretation of results in the patient's health record.

Expected skills of pharmacists with specialized training in pharmacogenomics

1. Develop pharmacogenomics-specific clinical decision support tools in the electronic health record.
2. Develop institutional guidelines and processes for implementing clinical pharmacogenomics services.
3. Establish mechanisms for communicating test results to patients that incorporate lifetime applications of test results and revisable reporting mechanisms.
4. Serve as an expert pharmacogenomics resource within the institution, including documenting patient outcomes, promoting collaborative relationships with healthcare professionals, contributing to the evaluating of implemented pharmacogenomics services, and other roles.

Appendix C—Sample course activities and assignments for an advanced pharmacy practice experience in clinical pharmacogenomics[a,b]

In the area of precision medicine, students will participate in

1. Ongoing patient care activities to support clinical implementation of pharmacogenomics initiatives, including
   - *CYP2C19* genotype–guided clopidogrel therapy in the cardiac catheterization laboratory,
   - *TPMT* genotype–guided dosing of azathioprine, mercaptopurine, and thioguanine, primarily for pediatric hematology–oncology patients and pediatric and adult gastroenterology patients,
   - *CYP2D6* genotype–guided dosing of select opioids within primary care or pain clinics,
   - *CYP2D6/2C19* genotype–guided dosing of select antidepressants in adult psychiatry clinics,
   - HLA testing in select primary care, neurology, or HIV/AIDS clinics, and
   - *IFNL3* genotype–guided dosing of pegylated interferon, as needed, in hepatitis C clinics.
2. Support of and participation in the personalized medicine subcommittee and related pharmacy and therapeutics committee activities for clinical implementation of genotype-guided therapies.
3. Case-based discussions on pharmacogenetics and precision medicine, including clinical utility of selected gene–drug pairs, and steps for clinical implementation of pharmacogenetics in a healthcare setting.
4. Ongoing medical evidence review and evaluation for existing and potential gene–drug pair–associated implementations.
5. Pharmacogenomic laboratory activities such as sample collection, DNA isolation, and polymerase chain reaction analysis (if available).
6. Development of educational materials for healthcare professionals and patients on pharmacogenomics and precision medicine.

In the area of evidence-based medicine, students will participate in

1. Ongoing daily and systematic review of medical literature, Food and Drug Administration alerts, and new drug approvals,
2. Weekly discussions of recently published pharmacogenetic literature,
3. Research, writing, and preparation of four articles (one per week) for publication in a pharmacogenomics newsletter, and
4. Discussions on clinical trial design and analysis; professional writing, editing, and publishing; and strategies for keeping up with the medical literature.

Rotation assignments and activities will include

1. Patient care responsibilities in targeted areas (as listed above), including weekly patient case discussions,
2. Weekly discussion of current pharmacogenomics literature,
3. A journal club presentation,
4. A patient case or topic presentation,
5. Research and writing of newsletter articles for provider education,
6. Design of a mock clinical decision support algorithm for a sample gene–drug pair,
7. Research and writing of a clinically actionable gene–drug pair monograph,
8. Design of a mock "pharmacogenes chip" (including selection of variants based on clinical evidence), and
9. Attendance and participation in department journal clubs, seminars, and other pertinent educational activities.

[a]*CYP2C19* = gene encoding cytochrome P-450 family 2 subfamily C member 19, *TPMT* = gene encoding thiopurine *S*-methyltransferase, *CYP2D6* = cytochrome P-450 family 2 subfamily D member 6, HLA = gene encoding human leukocyte antigen, HIV = human immunodeficiency virus, AIDS = acquired immunodeficiency syndrome, *IFNL3* = gene encoding interferon lambda 3.

[b]Sample activities and assignments are based on authors' experiences at the University of Florida, University of Colorado, Manchester University, and University of Pittsburgh.