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Pharmacogenomics Competencies in Pharmacy Practice: A Blueprint for Change

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Abstract

The emerging use of genomic data to inform medication therapy populates the medical literature and provides evidence for guidelines in the prescribing information for many medications. Despite the availability of pharmacogenomic studies, few pharmacists feel competent to utilize these new data in patient care. The first pharmacogenomics competency statement for pharmacists was published in 2002. In 2011, the Pharmacogenomics Special Interest Group of the American Association of Colleges of Pharmacy led a process to update this competency statement using a consensus-based method that incorporated input from multiple key professional pharmacy organizations to reflect growth in genomic science, as well as the need for pharmacist application of genomic data. Given the rapidly evolving science, educational needs, and practice models in this area, a standardized competency-based approach to pharmacist education and training in

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pharmacogenomics is needed to equip pharmacists for leadership roles as essential members of healthcare teams that implement clinical utilization strategies for genomic data.

Keywords

Competency; pharmacogenomics; pharmacogenetics; genomic medicine; education

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Advances in pharmacogenomic discovery are urging rapid and effective translation of genomic science into clinical practice, with more than 137 medications now containing pharmacogenomic data in their FDA prescribing information.[1] This heightened rate of scientific discovery is driving change in practice, and clinicians consistently recognize the clinical impact of genomic data. As a profession, pharmacy has long assumed a valued role in the leadership of therapeutic drug monitoring (e.g., pharmacokinetics) and pharmacotherapy services due to pharmacy's specialized training and an established practice record in medication management. In the same way, pharmacists are uniquely qualified to be on the front line of efforts to translate pharmacogenomic data into clinical practice across multiple, diverse practice settings.[2]

The Pharmacist's Role in Pharmacogenomics

The pharmacist's role as a practice-based leader in pharmacogenomics is becoming clearer as an increasing number of pharmacists are engaging in clinical pharmacogenomics practice. Indeed, pharmacists are rapidly emerging as professional trailblazers in this area.[3-5] The Clinical Pharmacogenetics Implementation Consortium (CPIC)[6] guidelines provide clinically-useful guidance to enable the use of genetic laboratory test results for drug therapy recommendations in practice for 40 drug–gene pairs. CPIC is a pharmacist-led initiative and many of the published guidelines have been developed and authored by pharmacists.[6]

There is a clear consensus among national pharmacy organizations regarding the important role of the pharmacist in applying pharmacogenomics to patient care. In 2011, the American Pharmacists Association (APhA) issued a white paper encouraging the development and integration of pharmacogenomics into pharmacy practice through medication therapy management (MTM).[4] More recently, the American Society of Health-Systems Pharmacists (ASHP) developed a formal policy statement on the pharmacist's role in clinical pharmacogenomics.[5] The ASHP statement describes a need for all pharmacists to have a basic understanding of the use of pharmacogenomic data for patient care and for pharmacists with specialized expertise to lead the implementation of pharmacogenomics. The ASHP Residency Directory (http://ashp.org) currently recognizes three post-graduate year two (PGY2) pharmacogenetics specialty residencies that are accredited or seeking accreditation, and the number of pharmacists with specialized training in this area is growing.

With guidelines available and national organizations releasing statements elucidating the pharmacist as a clinician integral to the use of pharmacogenomic data, clinical pharmacogenomics is also becoming the standard of care in some practice environments and its applications are expected to grow. In a recent survey of health system pharmacy directors, pharmacogenomic testing was used in 7% of hospitals.[7] In a report on the future of pharmacy practice, 79% of participants expect that at least one academic medical center in their area will have a pharmacy-based pharmacogenomics service within the next five years.[8]

Pharmacy at a Crossroads in Pharmacogenomics

In spite of these advances, practicing pharmacists consistently report feeling ill prepared to evaluate pharmacogenomic test results and discuss implications of these results with patients and other health care professionals.[9-12] This perceived lack of competency is supported by published descriptions that show a lack of formal training and/or understanding among pharmacists regarding pharmacogenomics knowledge and document its limited inclusion in pharmacy education.[13,14] In this paper, we argue that the profession of pharmacy is at a crossroads within clinical pharmacogenomics. While pharmacists are being recognized as leaders in clinical pharmacogenomics, both within and outside of pharmacy, individual pharmacists consistently report being underprepared to assume practice-based responsibilities in pharmacogenomics, pointing to significant clinical and educational gaps within the profession.

There is an urgent need for the profession to address these gaps through development and dissemination of educational and clinical practice models that can equip practicing pharmacists, new graduates, and students with the knowledge and skills needed to integrate pharmacogenomic data into individualized medication therapy choices in the current patient care paradigm. An essential step in meeting this need is the development of current, practice-based pharmacogenomic educational competencies. Pharmacist competencies for pharmacogenomics were last updated in 2002.[14] In a manner similar to that employed by other health care professionals to systematically address pharmacogenomics, the creation of practice-based pharmacogenomic competencies fulfills a need to identify the core areas of knowledge, skill, and attitudes required for pharmacist proficiency in this area.[15,16] Moving forward, the maintenance and widespread dissemination of such competencies will be essential to create a dynamic professional “blueprint” that can be used to standardize and improve education and practice expectations for pharmacists in clinical pharmacogenomics.[17-19] Further, leading this competency development and revision process from within the profession allows the unique perspective and background of pharmacists to consistently be at the forefront of revised pharmacogenomics competencies.[14,15]

Employing a Systematic Process to Update Pharmacist Competencies

In 2011, the National Institutes of Health (NIH) National Human Genome Research Institute (NHGRI) invited pharmacy education stakeholders, including representatives from 11 national pharmacy organizations, other medical associations, government agencies, and colleges and schools of pharmacy, to participate in such a process to explore needs for pharmacist education in the era of genomics.[15] This meeting resulted in plans to address perceived gaps in pharmacist education around pharmacogenomics, including the need for developing updated pharmacist competencies in pharmacogenomics and increasing pharmacy contributions to established educational and practice-based resources in this area, such as NHGRI's Genetics and Genomics Competency Center (G2C2, www.g-2-c-2.org).[16]

As with the 2002 competencies, the American Association of Colleges of Pharmacy (AACP) Pharmacogenetics/Pharmacogenomics Special Interest Group (SIG) was charged to lead this process. In 2012, a SIG subcommittee analyzed the needs for pharmacist competencies and assembled an updated competencies inventory, which included the need for increased coverage of the clinical applications of genomics to MTM.

Based on the desired outcome that, “pharmacy graduates should possess competent knowledge and skills to seek coordination and collaboration of care with an interdisciplinary team of health professionals when assessing genetic information,” the AACP SIG led a systematic process to revise the existing competencies. This process was conducted from 2012 to 2013 and included 1) searching the medical literature to identify, review, and critically analyze existing competency statements in genomics or pharmacogenomics for health care providers; [14,17-19] 2) examining existing health care professional competencies to develop a revised framework for pharmacists in the area of genomics;[19] 3) seeking consensus from a professional panel composed of nine pharmacy organizations to gain approval of the competencies; and 4) seeking approval of the larger AACP SIG body. These steps were successfully carried out with unanimous approval from the pharmacy organizations in July 2012 and final approval by the AACP SIG in July 2013. Table 1 summarizes the competencies provides real-world examples of pharmacist activities and clinical responsibilities when these competencies are put into practice.

Applying a Competency-Based Approach to Meet Current Professional Needs

Although this revision and the future maintenance of pharmacogenomics competencies are important steps towards creating a much-needed framework for education, dissemination and adoption of these competencies will be required to meet the significant educational and practice-based needs in this area. These needs span multiple settings and target audiences, including both student pharmacists and practitioners.

For student pharmacists, the need for a competency-based approach to teaching pharmacogenomics is underscored by recent changes to ACPE Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree, which *require* colleges/schools of pharmacy to teach pharmacogenomics in their curricula beginning with the 2016-2017 academic year.[20] In spite of this requirement, few resources exist to support faculty in teaching clinical pharmacogenomics and there are a limited number of clinical faculty who have received formal training in pharmacogenomics. To meet these needs, a number of individual schools and colleges of pharmacy have developed shared curricular or train-the-trainer approaches, such as the PharmGenEd[21-24], Manchester University certificate training program,[25] University of Pittsburgh's Test2Learn program™[26], and University of Florida (UF) Health Personalized Medicine Program graduate and certificate courses in pharmacogenomics.[27]

For pharmacists, professional competencies can be used to demonstrate a knowledge foundation for practice needs in pharmacogenomics. Although program content and individual emphasis on the current competency areas varies, a systematic approach to educating practitioners has been adopted by many institutions, including St. Jude Children's Research Hospital, Vanderbilt University, Mayo Clinic, and the UF Health Personalized Medicine Program.[28-31] Pharmacy and medical associations have led national efforts to meet practitioner needs in this area, including APhA, ASHP, and the American Medical Association. These programs extend to the state level, with for example, the Indiana Pharmacists Alliance and Manchester University now offering a certificate training program centered on the revised competencies. Increasing numbers of post-graduate specialized residency training programs also provide practice-based opportunities for pharmacists to develop further specialized knowledge and skills in pharmacogenomics or to focus on a specific therapeutic area (e.g., oncology).

We feel strongly that educational and professional development programs built on a standardized competency-based framework will be most effective in advancing clinical practice and strengthening the potential pool of pharmacy faculty members, clinicians, and preceptors trained to provide education in this unique scientific area. To support and streamline such efforts, educators and practitioners can rely on existing resources for pharmacogenomics education (Table 2). For example, many pharmacogenomics teaching materials are available within NHGRI's G2C2 website. All materials indexed by G2C2 undergo pharmacist peer review and program content is mapped to the current pharmacogenomics competencies. Increasing awareness of these types of resources can assist large-scale competency-based educational efforts.

Moving from Competence to Clinical Implementation

To achieve the vision of pharmacists as leaders within pharmacogenomics, however, it is essential that pharmacists' education, training, and professional development extend beyond merely demonstrating competency. Many barriers to implementation and adoption of clinical pharmacogenomics lie beyond the classroom within professional practice. Although practice-based resources such as CPIC guidelines provide much-needed guidance for clinical decisions, there is a continued need to equip pharmacists to lead the development and implementation of viable and sustainable clinical pharmacogenomics practice models.[4,5] Examples of such practice models that incorporate the pharmacist as the clinical pharmacogenomics expert are emerging across all practice settings, but most quickly in the community pharmacy and health-system environments.

There are a number of published reports that provide examples of pharmacist-driven pharmacogenomics services in the community pharmacy. O'Connor and colleagues evaluated the implementation of pharmacogenomics services in community pharmacy and showed that these services could be a component of MTM.[32] As in other pharmacist-led patient care services, reimbursement for the pharmacist's time to interpret and counsel patients about pharmacogenomic test results remains a challenge. However, studies have shown that prescribers value the pharmacist's input and are receptive to pharmacist recommendations.[32-35] Practice models for pharmacogenomic testing in the community pharmacy are beginning nationwide implementation into mainstream pharmacy establishments with community pharmacists performing buccal swab testing, receiving test results, interpreting the results and communicating the results to prescribers.[36,37]

Various examples of clinical pharmacogenomics practice models are available from the health-system perspective, including pharmacist-led consult-based services to interpret and apply pharmacogenomic test results in oncology, cardiology, pain management, and other areas.[2,29] While some of these models use a “reactive” approach with interpretation and guidance provided after a pharmacogenomic test is resulted, others illustrate a “preemptive” array-based approach to pharmacogenomics. In a preemptive testing model, multiple genes are tested and systematically included in the electronic health record to prospectively inform medication choices.[28,29] Moving forward, progression of the science that has provided for a substantial decrease in the cost of the array-based chips will continue to drive the use of the technology and exponentially increase the availability of genomic data within health systems. Having many patients with pharmacogenomic data will necessitate increased adoption of a systematic and preemptive approach, much like a need for renal dosing when serum creatinine is routinely tested and reported.

Pharmacists are carving out significant leadership roles within these practice models and pharmacogenomics represents an important niche and emerging practice-based specialty for our profession. In addition to the need for a standardized, competency-based approach to pharmacogenomics education, efforts that support identification and dissemination of best practice models for integrating clinical pharmacogenomics into standard practice and health information technology systems will continue to be essential.[28-30,32]

Conclusion

The profession of pharmacy is faced with significant educational, practice-based, and implementation challenges within clinical pharmacogenomics. Adoption and maintenance of current practice-based competencies for pharmacogenomics provides a defined and standardized framework to measure the knowledge, skills, and attitudes of students and practitioners. This competency framework can also serve as a launch pad for the continued growth of educational and practice-based resources for students and practitioners alike. Scientific evaluation and dissemination of clinical practice models in pharmacogenomics will serve to normalize the use of these data to optimize medication therapy and stimulate the rapid uptake of clinical and technology systems to allow safe, effective and broad use of this pharmacogenomics within pharmacist-directed patient care.

An important limitation of the current competencies is that they can realistically only highlight the baseline educational and practice needs in pharmacogenomics as identified today. In a rapidly emerging area of patient care such as genomic medicine, the knowledge and skills required for pharmacists to be leaders in pharmacogenomics will continue to see significant changes and growth in coming years. Continued resource investment for maintaining the competencies and developing professional curricula and practice models that reflect the constant advances in pharmacogenomic discoveries will be necessary for ongoing effective translation of genomic science into clinical care with pharmacists as a prepared and essential member of the healthcare team.

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Table 1

Pharmacist Competencies in Pharmacogenomics and Sample Clinical Practice Activities

	Competency Domain and Pharmacist-Specific Knowledge	Example Pharmacist Activity or Responsibility
Basic Genetic Concepts		
1	To demonstrate an understanding of the basic genetic/genomic concepts and nomenclature.	• Translate genotype data into phenotypical categories to develop clinical recommendations to optimize medication use for patient care • Educate patients and health care providers about family history, genomic risk, and pharmacogenomic test results as they relate to health behaviors • Interpret and document drug response-related family history information (e.g., in electronic health records and family history software programs)
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.	
Genetics and Disease		
1	To understand the role of genetic factors in maintaining health and preventing disease.	• Educate patients and health care providers about genetics, complex disease risk assessment, and recommended screening for early detection and diagnosis. • Educate healthcare providers and others about the potential use of and strategies for handling incidental findings with pharmacogenomic test results.
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).	
Pharmacogenetics/Pharmacogenomics		
1	To demonstrate an understanding of how genetic variation in a large number of proteins (e.g. drug transporters, metabolizing enzymes, receptor targets) influence pharmacokinetics and pharmacodynamics related to pharmacologic effect and drug response.	• Recommend drug therapy changes that integrate pharmacogenomic, pharmacokinetic, and pharmacodynamic data to optimize patient care. • Educate health care providers on the influence of genetic variance on pharmacokinetics-based dosing regimens. • Educate patients and health care providers on the influence of ethnicity on pharmacogenomic recommendations • Apply pharmacogenomic drug dosing guidelines in practice and guide healthcare providers on their appropriate use and interpretation.
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. CPIC).	
Ethical, Legal, and Social Implications		
1	To understand the potential physical and/or psychosocial benefits, limitations and risk of pharmacogenetic/	• Serve as a resource for institutions and providers regarding best practices for interpreting and returning incidental findings with pharmacogenomic and genomic testing.

Competency Domain and Pharmacist-Specific Knowledge		Example Pharmacist Activity or Responsibility
	pharmacogenomic information for individuals, family members and communities, especially with pharmacogenetic/ pharmacogenomic tests that may relate to predisposition to disease.	• Educate patients and health care providers about privacy and other potential concerns with pharmacogenomic and genomic data.
2	To understand the increased liability that accompanies access to detailed genomic patient information and maintain the confidentiality and security.	
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 reimbursement by insurers relevant to genomic or pharmacogenomic tests, for patients and populations.	
5	Identifying when to refer a patient to a genetic specialist or genetic counselor.	

Table 2

Educational and Practice-Based Resources for Pharmacogenomics

Evaluation of Genomic Applications in Practice and Prevention	http://www.egappreviews.org/default.htm	Primarily focused on genomic medicine implementation; evidence reports for a limited number of pharmacogenomic gene-drug pairs
Genetics/Genomics Competency Center	http://g-2-c-2.org	Categorized educational resources in generics/genomics and pharmacogenomics for healthcare educators and clinicians
Global Genetics and Genomics Community	http://g-3-c.org/en	Online learning portal, including interactive cases demonstrating the link between genetics and genomics and health
National Human Genome Research Institute	http://www.genome.gov	Information for health care professionals and patients on genetics and pharmacogenomics, including terminology, videos, and illustrations
PharmGKB (PharmacogenomicsKnowledgeBase)	http://www.pharmgkb.org/	Database of research findings about the impact of genetic variation on drug response for clinicians; links to other subspecialty society guideline recommendations (e.g., Dutch Pharmacogenomics Working Group); the Clinical Pharmacogenomics Implementation Consortium (http://www.pharmgkb.org/page/cpic) provides free peer-reviewed guidelines with supplemental information and updates
Clinical Pharmacogenetics Implementation Consortium (CPIC) Guidelines	https://www.pharmgkb.org/page/cpic and https://www.cpicpgx.org	Standardized guidelines generated by a complete evidence based review of the literature that provide actionable prescribing decisions from

		genetic laboratory results.
Dutch Pharmacogenomics Working Group	https://www.pharmgkb.org/page/dpwg	Comprised of clinicians and scientists working to develop pharmacogenetics-based therapeutic recommendations.
PharmGenEd	https://pharmacogenomics.ucsd.edu/	Educational materials (including recorded lectures and handouts) focused on clinical applications of pharmacogenomics for health care students and practitioners.