

COMMENTARY

Pharmacists Leading the Way to Precision Medicine: Updates to the Core Pharmacist Competencies in Genomics

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Genomics is becoming an increasingly important part of health care, and pharmacists are well-positioned to be practice-based leaders in pharmacogenomics and precision medicine. Competencies available through the Genetics/Genomics Competency Center provide a framework for pharmacogenomics instruction in both pharmacy school curricula and continuing education programs. Given the significant advancements in pharmacogenomics over the past decade, the 2019-2020 American Association of Colleges of Pharmacy Pharmacogenomics Special Interest Group updated the pharmacist competencies. The process used a systematic approach which included mapping pharmacogenomics-specific competencies to the entrustable professional activities for pharmacists and seeking consensus from key stakeholders. The result is an expansion to 30 competencies that reflect the contemporary roles pharmacists play in the application of pharmacogenomics in clinical practice. When implemented into curricula, these competencies will ensure that learners are “practice ready” to integrate pharmacogenomics into patient care. Additional postgraduate training is needed for advanced roles in pharmacogenomics implementation, education, and research.

Keywords: pharmacogenomics, pharmacogenetics, pharmacy, education, competencies

INTRODUCTION

Genomics is becoming an increasingly important part of health care, and pharmacists across practice settings have important roles to play. The recently published National Human Genome Research Institute (NHGRI) strategic vision for “improving human health at the Forefront of Genomics” highlights how pharmacists and pharmacy systems can support the implementation of genomics into clinical care.¹ With extensive education and training in pharmacology, including pharmacokinetics and pharmacodynamics, and the optimal use of medications, pharmacists

are the health care professionals best suited to lead efforts to integrate pharmacogenomics into clinical practice, an idea uniformly supported by major professional pharmacy organizations.²⁻⁴

Pharmacogenomics is a rapidly evolving field, and the profession of pharmacy must advance with it to meet the needs of today's patients. One of the many barriers to deploying pharmacogenomics more broadly in the clinic is the lack of adequate education and training for health care professionals, including pharmacists.⁵ The 2016-2017 American Association of Colleges of Pharmacy (AACP) Argus Commission, which is comprised of the past five AACP presidents, recognized the educational needs to support the vision of pharmacists as practice-based leaders in the field, stating that “the most significant threat to pharmacy will be a failure to enrich our curricula and post-graduate education with the adequate intensity of

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attention to the expanding field of pharmacogenomics ...”⁶ Although the 2016 Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree includes “pharmacogenomics/genetics” as foundational content in pharmacy education and “pharmacogenomic considerations” as a key part of evidence-based clinical decision making, further granularity in characterizing how pharmacists can integrate pharmacogenomics into the Pharmacists’ Patient Care Process (PPCP) across the continuum of care is needed.⁷

Established competencies provide a standardized framework for pharmacogenomics instruction, helping educators to design learning objectives and prioritize content delivery. In 2012, the AACP Pharmacogenomics Special Interest Group (SIG) led the effort to update the original 2002 pharmacist competencies in genomics, including pharmacogenomics.^{8,9} The competencies were published in 2016 and disseminated through the NHGRI Genetics/Genomics Competency Center (G2C2) website alongside the genomics-related competency statements for physicians, physician assistants, nurses, and genetic counselors.¹⁰

Since the latest pharmacist competencies in genomics were published, the profession has seen significant progress in the field, including the development of novel pharmacist-led clinical pharmacogenomics services, United States Food and Drug Administration approval of direct-to-consumer pharmacogenomic testing, and expansion of evidence-based pharmacogenomics clinical practice guidelines.¹¹⁻¹⁴ The Academy has also been introduced to the concept of entrustable professional activities (EPAs), which are discrete, essential activities that all pharmacy graduates are expected to perform without direct supervision.¹⁵ As newer areas of practice emerge (eg, clinical pharmacogenomics), mapping the associated core competencies to the EPAs will help define the pharmacist’s role in those areas and provide a standard framework for pharmacy education. To support the vital role of pharmacists in advancing pharmacogenomics-based care, the 2019-2020 AACP Pharmacogenomics SIG leadership launched the effort to update the pharmacist competencies in genomics to reflect the needs of contemporary pharmacy practice and map them to the EPAs.

DISCUSSION

The expert group leading the effort to update pharmacist competencies in genomics included seven experienced pharmacogenomics educators and implementers who are current leaders in the AACP Pharmacogenomics SIG or pharmacogenomics experts who authored the previous

competencies. The process was conducted in 2020 and included garnering support from key stakeholders, including representatives from NHGRI and AACP; critically analyzing the existing genomics-related competencies for pharmacists and other health care providers; developing a revised framework for pharmacist competencies in genomics; conducting a gap analysis of pharmacogenomics-specific competencies relative to the EPAs; systematically reviewing, editing, and adding competency statements to achieve expert consensus; seeking input and approval of the revised statements from leaders/content experts of continuing education programs offered by national pharmacy organizations; and seeking input and approval of the revised statements from the AACP Pharmacogenomics SIG membership. Revising the competency statements was an iterative process that occurred over several months to achieve consensus.

The AACP Executive Vice President and CEO, as well as leadership of the NHGRI Inter-Society Coordinating Committee for Practitioner Education in Genomics, expressed strong support for the project from the beginning. The expert working group first reviewed and compared genomics competencies across professions with a particular focus on pharmacogenomics-related competencies. All experts agreed that the EPAs provided a logical framework from which to build the pharmacogenomics-related competency statements for pharmacists. From there, the prior competencies were mapped back to specific EPAs. Foundational genetics concepts emerged as its own category to capture relevant but non-pharmacogenomics-related, competencies. Based on the gaps identified through the EPA mapping exercise, additional genomics competencies were created, discussed, and modified iteratively by the expert group through regular meetings occurring over a six-month period. Thus, the EPA framework was a major driver for the final number of competencies. To ensure broader stakeholder input, the draft competencies were disseminated to the AACP Pharmacogenomics SIG membership through the AACP Connect discussion board with an open comment period. The feedback received was used to further refine the competency statements. All members of the expert working group agreed with the final version.

The previous 15 genomics competency statements were originally divided into four categories: Basic Genetic Concepts (n = 4), Genetics and Disease (n = 3), Pharmacogenetics/ Pharmacogenomics (n = 3), and Ethical, Legal, and Social Implications (ELSI) (n = 5). The new competencies (Table 1) are organized into just two categories: Foundational Genetics Concepts (n = 6) and Clinical Pharmacogenomics (n = 24), with the latter mapped to the

Table 1. Core Pharmacist Competencies in Genomics

Foundational Genetics Concepts (FG)	
FG-1	Explain basic genetics concepts using appropriate nomenclature.
FG-2	Recognize the combined impact of genetic, behavioral, social, and environmental factors in the manifestation of disease and drug response.
FG-3	Identify drug- and disease-associated genetic variations that facilitate development of prevention, diagnostic, and treatment strategies.
FG-4	Differentiate between the clinical diagnosis of disease informed by genetics and the identification of genetic predisposition to disease.
FG-5	Assess differences in genetic testing technologies, including sequencing and genotyping.
FG-6	Recognize the legal protections against discrimination based on genetic test results.
Clinical Pharmacogenomics (CP)	
<i>EPA Domain: Patient Care Provider</i>	
CP-1	Identify pharmacogenomic test results that are relevant to a patient's care.
CP-2	Interpret pharmacogenomic test results, including translating genotype to phenotype to drug therapy recommendation.
CP-3	Determine the impact of genetic variation on pharmacokinetics and/or pharmacodynamics.
CP-4	Identify medication-related problems that may be related to genetic variability, even when a pharmacogenomic test has not been done.
CP-5	Recognize disease implications of pharmacogenomic test results and refer the patient to a genetics-trained healthcare provider when necessary.
CP-6	Use family history to assess predisposition to disease and drug response.
CP-7	Assess the quality and source of existing pharmacogenomic test results.
CP-8	Distinguish between actionable and non-actionable pharmacogenomic test results using high-quality, evidence-based pharmacogenomics databases and clinical guidelines.
CP-9	Integrate pharmacogenomic test results with other clinical variables to optimize medication therapy.
CP-10	Recommend pharmacogenomic testing when appropriate.
CP-11	Consider the cost, cost-effectiveness, and reimbursement issues relevant to pharmacogenomic tests and services.
CP-12	Implement a pharmacogenomics-guided care plan in collaboration with the patient, caregivers, and other health professionals.
CP-13	Document pharmacogenomic test results in the electronic health record.
CP-14	Follow-up and monitor a pharmacogenomics-guided care plan.
<i>EPA Domain: Interprofessional Team Member</i>	
CP-15	Collaborate as a member of an interprofessional team as the pharmacogenomics expert.
<i>EPA Domain: Population Health Promoter</i>	
CP-16	Identify patient populations that may be most likely to benefit from pharmacogenomic testing.
CP-17	Identify genetic variations that predispose patients to adverse drug reactions and modify therapy accordingly to mitigate the risk.
CP-18	Recognize the differences in pharmacogenomic allele frequencies among ancestry groups to guide appropriate test selection and maximize the appropriate use of medications in a population.
<i>EPA Domain: Information Master</i>	
CP-19	Educate patients and professional colleagues on the benefits and limitations of pharmacogenomics to optimize drug therapy.
CP-20	Use a culturally sensitive approach that considers potential ethical concerns when counseling patients about pharmacogenomic test results.
CP-21	Use evidence-based resources and pharmacogenomics information to advance patient care.

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Table 1. (Continued)

EPA Domain: Practice Manager

- CP-22 Oversee pharmacy operations that integrate pharmacogenomics for an assigned work shift.
- CP-23 Fulfill a medication order considering the clinical implications of pharmacogenomics.

EPA Domain: Self-Developer

- CP-24 Create a written plan for continuous professional development in clinical pharmacogenomics.

established EPAs for pharmacy practice (Appendix 1).¹⁵ Competencies specific to the retired categories of Genetics and Disease and ELSI were reviewed, modified, and integrated into the two new sections as appropriate. The final result is an expansion to 30 total competency statements that are more specific to the contemporary roles pharmacists play in the application of genomic medicine, particularly pharmacogenomics, in clinical practice.

The Foundational Genetics Concepts competencies encompass basic genetics principles/nomenclature, the genetics of disease, genetic testing technologies, and legal protections against genetic discrimination. Although pharmacogenomics is the subset of genomic medicine most within the pharmacist’s purview, pharmacists must also have a working knowledge of core genetics concepts to understand the broader context of how pharmacogenomics intersects with other areas of medical genetics. This idea has persisted since the development of the original 2002 competencies.⁸

A key difference between the most recent competencies and the new ones presented herein is the organization and depth of the pharmacogenomics-related statements. Previously, pharmacogenomics-specific competencies were located in multiple sections; now, they are grouped together in a single section. The rationale for this change is multifold. First, organizing comprehensive competency statements in clinical pharmacogenomics for pharmacists will help further delineate the pharmacist’s role as a practice-based leader in the field. The genomics-related competencies for most non-pharmacist health care providers (eg, physician assistants, nurses, and genetic counselors) do not include specific statements pertaining to pharmacogenomics; however, the physician competencies include some general pharmacogenomics-focused statements.¹⁰ Further, a major change included integrating the previous pharmacogenomics competencies into the existing EPA framework and using the established EPA domains and core statements to address any gaps in pharmacogenomics-specific competencies. This resulted in an expansion of pharmacogenomics-specific competency statements from three to 24. There is only one EPA without a corresponding pharmacogenomics competency

(“ensure that patients have been immunized against vaccine-preventable diseases”); all others have one or more corresponding competency statements associated with them. The additional specificity of the new pharmacogenomics competencies provides the detail needed to guide educational initiatives and can be directly used as specific learning objectives across pharmacy curricula. Relevant ELSI topics were weaved throughout, as the experts agreed that these issues should reflect an integrative process of care rather than be viewed as separate issues. These include legal protections against discrimination based on genetic test results (Table 1, FG-6), disease implications of pharmacogenomic test results (Table 1, CP-5), cost/reimbursement considerations (Table 1, CP-11), benefits and limitations of testing (Table 1, CP-19), and a culturally sensitive approach to counseling patients about their results (Table 1, CP-20). In general, ELSI considerations for pharmacogenomics tend not to be as extensive as those pertaining to genetic testing for disease risk.¹⁶

As the medication experts, pharmacists have a fundamental responsibility to understand the contributions of all factors that influence medication response, including genetics. Just as pharmacokinetics was once a specialty area of pharmacy practice and is now an expected area of competency for all pharmacists, pharmacogenomics must also make the same transition as the profession evolves. These competencies provide a blueprint for integrating and expanding genomics/pharmacogenomics educational content in PharmD program curricula as well as for continuing education programs geared towards practicing pharmacists.

Pharmacogenomics is relevant for all aspects of the PPCP, from collecting pharmacogenomic data to following up and monitoring a pharmacogenomics-guided care plan. From a patient safety perspective, pharmacogenomics is an important tool that pharmacists can leverage to decrease the risk of, or outright prevent, serious adverse drug reactions. With increasing access to pharmacogenomic testing (eg, via expanding clinical pharmacogenomics services, large-scale research programs, such as the All of Us research program, and direct-to-consumer

genetic tests), pharmacists must be ready to meet the needs of patients and other health care providers with respect to pharmacogenomic test interpretation and application to practice as part of comprehensive medication management. Pharmacists should be the primary health care provider that others turn to for guidance on recommending pharmacogenomic testing to aid in drug selection and dosing; designing medication regimens based on pharmacogenomics and other patient-specific data; and educating patients and clinicians about pharmacogenomics principles and the clinical implications of test results.

Just as the core EPAs provide a clear and comprehensive description of a pharmacist's work, the new pharmacogenomics competencies that map back to those core EPAs illustrate the specific skills that all pharmacists need to possess to provide pharmacogenomics-based care. What it means to be a "practice-ready" pharmacist in the era of genomic medicine must include the interpretation and application of pharmacogenomic test results to patient care. In addition, the mapping process establishes clinical pharmacogenomics as integral to the pharmacist's work, which makes it distinct from other health care professionals' roles. While pharmacists are the logical leaders in pharmacogenomics, other health care professionals also support the clinical implementation of pharmacogenomics. For example, collaborations between pharmacists and genetic counselors have been proposed to communicate the benefits and limitations of genetic testing, familial implications of genetic test results, and the clinical significance of secondary (eg, disease-related) findings, while the pharmacist provides the medication-related knowledge and understanding of how genetics may be integrated with other clinical factors to inform pharmacotherapy decision-making.¹⁷

Despite the call for increased pharmacogenomics education and training for all pharmacists, there is still a need for some pharmacists to specialize in pharmacogenomics to lead implementation, education, and research efforts. This may require additional residency, fellowship, or graduate school training to achieve advanced competencies.^{18,19} Furthermore, certain specialty areas of practice with advanced applications of genomics (eg, oncology) may also necessitate additional competencies that are beyond the scope of this project. The competencies presented in this report were written to ensure a baseline level of genomics/pharmacogenomics literacy for all pharmacists to provide solid foundation of knowledge and skills for contemporary clinical practice. Integrating these new competencies into curricula will require pharmacogenomics-trained faculty to provide both didactic and experiential learning opportunities for students.^{5,20} The updated competencies are disseminated to pharmacy educators through AACP and to the general public via the G2C2 website.¹⁰

CONCLUSION

Clearly defined pharmacist competencies in genomics that are refined as genomic medicine matures are essential to advance pharmacy education and practice in pharmacogenomics and precision medicine. Pharmacists are the health care professionals best suited to lead collaborative, interprofessional teams in the provision of pharmacogenomics-based care across practice settings and therapeutic areas. The competencies described in this report serve as a blueprint for clinical pharmacogenomics instruction as part of pharmacy school curricula and continuing education programs for practicing pharmacists. When implemented into pharmacy school curricula, these competencies will ensure that graduates are "practice-ready" to integrate pharmacogenomics into patient care. Additional postgraduate training is needed for advanced roles in pharmacogenomics implementation, education, and research.

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Appendix 1. Pharmacist competencies in clinical pharmacogenomics mapped to the core entrustable professional activities (EPAs) for pharmacy practice.

EPA Domain	EPA Core Statements	Clinical Pharmacogenomics Competencies
Patient Care Provider	<p>Collect information to identify a patient's medication-related problems and health-related needs.</p> <p>Analyze information to determine the effects of medication therapy, identify medication-related problems, and prioritize health-related needs.</p> <p>Establish patient-centered goals and create a care plan for a patient in collaboration with the</p>	<ol style="list-style-type: none"> 1. Identify pharmacogenomic test results that are relevant to a patient's care. 2. Interpret pharmacogenomic test results, including translating genotype to phenotype to drug therapy recommendation. 3. Determine the impact of genetic variation on pharmacokinetics and/or pharmacodynamics. 4. Identify medication-related problems that may be related to genetic variability, even when a pharmacogenomic test has not been done. 5. Recognize disease implications of pharmacogenomic test results and refer the patient to a genetics-trained healthcare provider when necessary. 6. Use family history to assess predisposition to disease and drug response. 7. Assess the quality and source of existing pharmacogenomic test results. 8. Distinguish between actionable and non-actionable pharmacogenomic test results using high-quality, evidence-based pharmacogenomics databases and clinical guidelines. 9. Integrate pharmacogenomic test results with other clinical variables to optimize medication therapy.

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Appendix 1. (Continued)

EPA Domain	EPA Core Statements	Clinical Pharmacogenomics Competencies
Interprofessional Team Member Population Health Promoter	patient, caregiver(s), and other health professionals that is evidence-based and cost-effective.	10. Recommend pharmacogenomic testing when appropriate. 11. Consider the cost, cost-effectiveness, and reimbursement issues relevant to pharmacogenomic tests and services.
	Implement a care plan in collaboration with the patient, caregivers, and other health professionals.	12. Implement a pharmacogenomics-guided care plan in collaboration with the patient, caregivers, and other health professionals. 13. Document pharmacogenomic test results in the electronic health record.
	Follow-up and monitor a care plan.	14. Follow-up and monitor a pharmacogenomics-guided care plan.
	Collaborate as a member of an interprofessional team.	15. Collaborate as a member of an interprofessional team as the pharmacogenomics expert.
	Identify patients at risk for prevalent diseases in a population.	16. Identify patient populations that may be most likely to benefit from pharmacogenomic testing.
Information Master	Minimize adverse drug events and medication errors.	17. Identify genetic variants that predispose patients to adverse drug reactions and modify therapy accordingly to mitigate the risk.
	Maximize the appropriate use of medications in a population.	18. Recognize the differences in pharmacogenomic allele frequencies among ancestry groups to guide appropriate test selection and maximize the appropriate use of medications in a population.
	Ensure that patients have been immunized against vaccine-preventable diseases.	Not applicable
Practice Manager	Educate patients and professional colleagues regarding the appropriate use of medications.	19. Educate patients and professional colleagues on the benefits and limitations of pharmacogenomics to optimize drug therapy. 20. Use a culturally sensitive approach that considers potential ethical concerns when counseling patients about pharmacogenomic test results.
	Use evidence-based information to advance patient care.	21. Use evidence-based resources and pharmacogenomics information to advance patient care.
Self-developer	Oversee the pharmacy operations for an assigned work shift.	22. Oversee pharmacy operations that integrate pharmacogenomics for an assigned work shift.
	Fulfill a medication order.	23. Fulfill a medication order considering the clinical implications of pharmacogenomics.
	Create a written plan for continuous professional development.	24. Create a written plan for continuous professional development in clinical pharmacogenomics.