

## Meeting the New AACP Competencies in Genetics and Clinical Pharmacogenomics at the University of Minnesota

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### Abstract

**Objective:** Pharmacogenomics (PGx) is increasingly being used for creating individualized treatments for patient care. Healthcare professionals, especially pharmacists, need to understand how genetic variation impacts the efficacy and toxicity of medications. Due to the breadth and complexity of PGx-related information, it has been challenging to determine what information should be included in pharmacy curricula and how best to educate students. **Methods:** The University of Minnesota College of Pharmacy recently began the process of incorporating into the curriculum expanded competencies for PGx from the American Association of Colleges of Pharmacy (AACP) Pharmacogenomics Special Interest Group (PGx-SIG). We evaluated our curriculum for PGx content, determined what was currently being taught and identified educational gaps. **Results:** A review of our Doctor of Pharmacy curriculum showed substantial PGx content, although it was inconsistently taught throughout the required courses and in some courses absent. We revised the content of existing courses incorporating content that meet most of the PGx-SIG recommended competencies. **Conclusion:** There are and will be major changes in our understanding of the influences of PGx on individualized medical treatment. As our understanding grows, information on PGx in pharmacy curriculums will need to keep pace with these changes. We have begun this process at the University of Minnesota by doing a full review of PGx related information and making appropriate revisions in the pharmacy curriculum.

**Keywords:** pharmacogenomics; pharmacy curricula; competencies

### Introduction

Pharmacogenomics (PGx), has mainly been practiced in academic medical centers and specialty clinics, but is increasingly becoming a part of medical care elsewhere and incorporated into comprehensive medication management.<sup>1,2</sup> Increased utilization and growing evidence that it provides healthcare value has made it critical for healthcare workers, especially pharmacists, to become proficient in the understanding of and application of PGx-related information in the care of patients.<sup>3</sup> PGx education is steadily evolving from boutique and elective content to required material in pharmacy school curricula; however, the level of competency among practicing pharmacists remains low.<sup>4</sup> Postgraduate and workforce education programs have emerged to fill these competency gaps, including certificate programs, Post-Graduate Year 2 (PGY2) PGx residency programs, and fellowships.

The American Association of Colleges of Pharmacy (AACP) Academic Affairs Committee initially developed pharmacist competencies in genomics in 2002,<sup>5</sup> followed by updates in 2017<sup>6</sup> and most recently in 2021.<sup>7</sup> These new and expanded competencies are broadly categorized as 1) Foundational Genetics Concepts, describing the basic science side of

genomics and 2) Clinical Pharmacogenomics, describing patient care application. Additionally, the authors group the Clinical Pharmacogenomics competencies as they relate to Entrustable Professional Activities.<sup>8</sup> Although the 2016 Accreditation Council for Pharmacy Accreditation (ACPE) standards include PGx, the direction is limited and not prescriptive.

Previous reviews have described PGx courses within pharmacy schools, showing a range of approaches to the extent of and how the content is taught.<sup>9</sup> While some schools have a standalone required course with 'Pharmacogenetics' or 'Pharmacogenomics' in the course title, other schools offer it only as an elective, and more than half do not have a PGx focused course.<sup>9</sup> Courses that focus specifically on PGx are necessary to provide deeper understanding of this complex topic as shown by improved self-reported competency among student pharmacists for PGx competencies following an online PGx program.<sup>4</sup>

PGx content has been in our curriculum for over 10 years; however, we had not evaluated it in the context of the updated AACP PGx-SIG pharmacist genomic competencies.<sup>7</sup> Therefore, we undertook a formal and comprehensive evaluation of the genomic content in our Doctor of Pharmacy curriculum. Faculty performed a curriculum assessment, defined gaps relative to the competencies, provided recommendations and implemented these changes in required and elective content to meet these competencies. This paper describes our findings, process and curriculum changes. The primary objective of our curricular change is to create a workforce that can apply current PGx knowledge to patient care, and evaluate, analyze and

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incorporate new data and emerging PGx concepts to future patient care.

### Methods

A PGx Doctor of Pharmacy curriculum committee at the University of Minnesota College of Pharmacy was formed and met weekly for 12 months. The committee was charged to 1) Assume responsibility for envisioning pharmacist competencies and capabilities expected from graduates of our program regarding the application of PGx, and 2) Coordinate efforts to implement the instructional, assessment and practice partnership strategies needed to facilitate learner acquisition of the defined competencies and capabilities. The committee consisted of four faculty members, three with PGx subject matter expertise and one with expertise in primary care practice and comprehensive medication management, as well as a project manager to assist the chair in planning and organizing the work.

Initially, the committee developed a vision statement to describe the expectations regarding PGx for each student. Next, to determine and understand what was already taught in the curriculum, the committee evaluated the curriculum for PGx content by reviewing syllabi, surveying the faculty, and one on one meetings with course directors. The PGx content was then mapped to the new AACP core pharmacist competencies in Foundational Genetics Concepts and Clinical Pharmacogenomics.<sup>7</sup> Competencies that were not addressed in our curriculum were identified as gaps. The committee proposed PGx content to course directors and facilitated its incorporation by identifying faculty that could teach or implement these changes. Changes proposed to the curriculum began in the Fall semester of 2021.

### Results

The committee developed the following vision statement and was a guide for subsequent steps: "Every University of Minnesota pharmacy student will self-identify competence within pharmacogenomics and upon graduation apply precision medicine as a standard of care. Students' educational experience will be uniquely enhanced by the precision medicine clinical practice and research conducted within the college and statewide. Graduates will have an appreciation for the future scope and impact of precision medicine in improving medication outcomes and health."

A review of the PGx material within the curriculum identified substantial PGx content sporadically taught throughout required courses and in some cases absent. Basic PGx concepts, principles and foundational PGx resources (e.g., PharmGKB, CPIC, PharmVar) were clearly identified in the curriculum. For some content the level of PGx education was extensive and in-depth, while in other cases superficial or not included. Students received basic genetics, PGx relevant drug metabolism and pharmacokinetic content in their first year through the

Integrative Biochemistry and Pharmacology courses. Second year PGx content was primarily topics in the Cardiovascular Pharmacotherapy course with mentions in other Pharmacotherapy courses. Third year PGx content was found in the Oncology Pharmacotherapy course and included both germline PGx and personalized therapy directed towards somatic mutations. The majority of PGx content meeting the competencies was found in the elective course, *Pharmacogenomics: Genetic Basis for Variability in Drug Response*, which contained in-depth content related to pediatrics, psychiatry, HLA and adverse events, ethical, legal, and social issues, laboratory testing, genetic counseling, implementation topics, and additional cardiovascular and oncology content. Another elective course offered in the third year, Applied Psych Pharmacotherapy, contained several hours of PGx-oriented cases and content. The review found that PGx content was lacking in the Pharmaceutical Care Skills labs, a key educational component in the PharmD curriculum. Fourth year Advanced Pharmacy Practice Experience (APPE) PGx rotations were limited with only one regularly offered PGx-specific rotation and others offered sporadically.<sup>10</sup>

Following the curriculum review the committee determined that 18 of the 30 (4/6 from Foundational Genetics and 14/24 Clinical Pharmacogenomics) competencies were being met in the current curriculum and curricular changes were necessary. (**Table 1**) The committee identified the areas where PGx content was needed, and in collaboration with the Curriculum Committee and course directors, proposed modifications which included the relocation, addition and removal of PGx content. It was then determined that these changes were feasible and met the AACP PGx SIG competencies. (**Table 1**) Two competencies (CP-22 and CP-24) were not adopted as they were deemed by the committee to be beyond the expectations of a pharmacy student graduate.

The updated PGx curriculum is shown in **Table 2**. Notably, substantial content previously taught in the elective course was integrated into the third year by replacing lectures in the required Topics in Pharmacotherapy course, subsequently renamed Topics in Pharmacotherapy and Pharmacogenomics. This shift created space in the elective course for new precision medicine topics such as disease genetics and ancestry, which was then renamed Advanced Pharmacogenomics and Precision Medicine. Special attention was also given to incorporate PGx content into Pharmaceutical Care Skills labs, as they occur nearly every semester and offered unique opportunities to coordinate with and build upon PGx material taught in Pharmacotherapy courses around the same timeframe. Lastly, the committee also identified three additional APPE rotation sites that will afford students the opportunity to gain practical experience in both patient care and non-patient care PGx electives. Following these revisions our curriculum now meets 28 of the 30 (6/6 Foundation Genetics, 22/24 Clinical

Pharmacogenomics) of the AACP PGx-SIG competencies. (Table 1)

### Discussion

The evidence for drug/gene pairs and the implementation of broad PGx testing has increased dramatically in the last decade, requiring pharmacy school curricula to adjust their PGx offerings to meet this need. As the number of commercial companies offering PGx testing increases, in addition to numerous health systems implementations, new pharmacy graduates will increasingly be expected to know how to order and interpret this testing as well as understand where and how it can be applied. Therefore, the University of Minnesota College of Pharmacy underwent an evaluation and revision of its PGx content to meet the competencies proposed by the AACP PGx-SIG. A formal team successfully identified gaps, proposed changes, gained faculty buy-in and implemented changes.

The pharmacist competencies<sup>7</sup> recently published by provide a strong framework for the type of knowledge pharmacy graduates should have in foundational genetics and clinical PGx. Updates were needed as the original competencies proposed by the AACP Academic Affairs Committee occurred at least twenty years ago, and expectations of graduates since that time have changed.

It should be noted that the PGx accreditation standards required by ACPE are not the same as the PGx pharmacist competencies. While the PGx SIG competencies number 30 in total, accreditation standards related to PGx are limited, mentioned in the Pharmaceutical and Clinical Sciences sections. Nevertheless, it is the responsibility of educators to consider the changing landscape of our dynamic profession. As PGx testing becomes more widespread and readily available it will be expected from both patients and employers that pharmacy graduates are able to understand and interpret PGx testing.

One challenge currently faced by pharmacy schools is how to include emerging topics into already full curriculums. Decisions of what to remove to incorporate new content are difficult. We were able to incorporate PGx without increasing educational hours in the curriculum by removing older content and thoughtful incorporation of PGx into existing topics, lectures and labs. A standalone course dedicated to PGx is an appealing approach to incorporate competencies, although this may not be feasible for all schools. While more logistically challenging, threading PGx material throughout each year of the curriculum, beginning with foundational content and ultimately working up to how to apply PGx results to patients, may be more beneficial to students as they have more touch points with PGx rather than receiving a large amount all at once. An additional challenge is identifying partnerships to create new APPE rotation sites with a focus on PGx for students. Due to the relatively few preceptors practicing in PGx on a full-time basis

with limited capacity to take students, as well as multiple schools of pharmacy competing for these rotations, creating new opportunities for students to gain practical experience should be a priority.

Two competencies were determined to be outside of the expectations for graduating pharmacy students, and were not adopted by the committee. These competencies were: 1) CP-22: Oversee pharmacy operations that integrate PGx for an assigned work shift, and 2) CP-24: Create a written plan for continuous professional development in clinical PGx. While these competencies are important for pharmacists working in certain areas, they are not necessary for all graduates.

An additional piece of this work is student learning of PGx and programmatic evaluation. As the changes described herein are relatively recent, we are also working with education experts to better understand student comprehension of PGx content. Furthermore, the amount of PGx information available is changing rapidly, thus it is expected that this information will need to be continuously updated and ultimately be integrated further into pharmacotherapy courses as PGx testing becomes standard of care. Due to the changing nature of PGx information included within curriculums there exists a need for regular reviews to keep up with current evidence and recommendations. Curricular evaluations should also anticipate the ongoing evolution of this field and consider how PGx content fits into other areas of precision medicine, including gene therapy.

### Conclusion

In summary, we have created a working group of faculty members who teach PGx content either as a main focus or as part of their lectures in their courses. A major aim of this group is to ensure that the curriculum remains up to date with major advances in PGx through ongoing monitoring of PGx and modifying our curriculum as needed. Moreover, we are currently assessing our students on their understanding of PGx content, which will allow us to make sure students are incorporating PGx information into their understanding of the profession of Pharmacy.

**Disclaimer:** The statements, opinions, and data contained in all publications are those of the authors.

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**Table 1. PGx AACP Pharmacist Competencies Met Before and After Revisions to the PharmD Curriculum**

	<b>Proposed PGx Competencies from the AACP PGx SIG</b>	Met Before (Yes/No) Class of 2022	Met After (Yes/No) Class of 2025
	<b>Foundational Genetics Concepts (FG)</b>		
FG-1	Explain basic genetics concepts using appropriate nomenclature.	Yes	Yes
FG-2	Recognize the combined impact of genetic, behavioral, social, and environmental factors in the manifestation of disease and drug response.	Yes	Yes
FG-3	Identify drug- and disease-associated genetic variations that facilitate development of prevention, diagnostic, and treatment strategies.	No	Yes (elective)
FG-4	Differentiate between the clinical diagnosis of disease informed by genetics and the identification of genetic predisposition to disease.	No	Yes
FG-5	Assess differences in genetic testing technologies, including sequencing and genotyping.	Yes	Yes
FG-6	Recognize the legal protections against discrimination based on genetic test results.	Yes	Yes
	<b>Clinical Pharmacogenomics (CP)</b>		
CP-1	Identify pharmacogenomic test results that are relevant to a patient's care.	Yes	Yes
CP-2	Interpret pharmacogenomic test results, including translating genotype to phenotype to drug therapy recommendation.	Yes	Yes
CP-3	Determine the impact of genetic variation on pharmacokinetics and/or pharmacodynamics.	Yes	Yes
CP-4	Identify medication-related problems that may be related to genetic variability, even when a pharmacogenomic test has not been done.	Yes	Yes
CP-5	Recognize disease implications of pharmacogenomic test results and refer the patient to a genetics-trained healthcare provider when necessary.	No	Yes (elective)
CP-6	Use family history to assess predisposition to disease and drug response.	Yes	Yes
CP-7	Assess the quality and source of existing pharmacogenomic test results.	No	Yes
CP-8	Distinguish between actionable and non-actionable pharmacogenomic test results using high-quality, evidence-based pharmacogenomics databases and clinical guidelines.	Yes	Yes
CP-9	Integrate pharmacogenomic test results with other clinical variables to optimize medication therapy.	No	Yes
CP-10	Recommend pharmacogenomic testing when appropriate.	Yes	Yes
CP-11	Consider the cost, cost-effectiveness, and reimbursement issues relevant to pharmacogenomic tests and services.	No	Yes
CP-12	Implement a pharmacogenomics-guided care plan in collaboration with the patient, caregivers, and other health professionals.	Yes (APPE)	Yes (APPE)
CP-13	Document pharmacogenomic test results in the electronic health record.	Yes (APPE)	Yes
CP-14	Follow-up and monitor a pharmacogenomics-guided care plan.	Yes (APPE)	Yes (APPE)

CP-15	Collaborate as a member of an interprofessional team as the pharmacogenomics expert.	Yes (APPE)	Yes (APPE)
CP-16	Identify patient populations that may be most likely to benefit from pharmacogenomic testing.	Yes (APPE)	Yes
CP-17	Identify genetic variations that predispose patients to adverse drug reactions and modify therapy accordingly to mitigate the risk.	Yes (APPE)	Yes
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.	Yes (APPE)	Yes
CP-19	Educate patients and professional colleagues on the benefits and limitations of pharmacogenomics to optimize drug therapy.	No	Yes
CP-20	Use a culturally-sensitive approach that considers potential ethical concerns when counseling patients about pharmacogenomic test results.	No	Yes (elective)
CP-21	Use evidence-based resources and pharmacogenomics information to advance patient care.	Yes	Yes
CP-22	Oversee pharmacy operations that integrate pharmacogenomics for an assigned work shift.	No	No
CP-23	Fulfill a medication order considering the clinical implications of pharmacogenomics.	No	Yes
CP-24	Create a written plan for continuous professional development in clinical pharmacogenomics.	No	No

Table 2. Updated Curriculum Meeting AACP Pharmacist Genomic Competencies

Year	Semester	Course	PGx Content presented in course	Competency presented in Course
PDI	Fall	Becoming a Pharmacist	PGx basics lecture, Overview of Student PGx Testing Opportunity	CP-1
		Integrative Biochemistry	Foundational molecular genetics	FG-1; FG-3; CP-6
		Pharmaceutical Care Skills Lab I	Direct to Consumer Testing activity	CP-1; CP-11
	Spring	Pharmacology	PGx foundations and effects on PK, ADRs and cases	FG-2; FG-3; CP-1; CP-2; CP-3; CP-9; CP-17; CP-18
		Med Agents	Drug metabolism principles and genetic effects	FG-1
		Pharmaceutical Care Skills Lab II	PGx testing in Point of Care Testing activity	CP-1
PDII	Fall	Pharmaceutical Care Skills Lab III	Codeine PGx case	CP-1; CP-3; CP-4; CP-9; CP-23
		Cardiovascular Pharmacotherapy	PGx of statins/clopidogrel	CP-1; CP-17; CP-18; CP-21
	Spring	Pharmaceutical Care Skills Lab IV	PGx of warfarin	CP-1; CP-4; CP-9
PDIII	Fall	Topics in Pharmacotherapy and Pharmacogenomics	Foundational PGx concepts, PGx in children, Oncology PGx, Cardiology PGx, Psychiatry PGx	FG-1; FG-2; FG-3; FG-5; CP-1; CP-2; CP-3; CP-8; CP-9; CP-10; CP-16; CP-17; CP-18; CP-21; CP-23
		Infectious Disease	Abacavir/HLA testing, voriconazole/CYP2C19	CP-1
		<b>ELECTIVE:</b> Applied Psych Pharmacotherapy	PGx patient case/Work up	CP-1; CP-2; CP-3; CP-21; CP-23
	Spring	Outcomes	Psychiatry PGx case	CP-1; CP-2; CP-3; CP-23
		Oncology Pharmacotherapy	1 hour precision medicine	CP-1; CP-2; CP-3; CP-21
		<b>ELECTIVE:</b> Advanced Pharmacogenomics and Precision Medicine	Extensive focus on pharmacogenomic concepts, specific disease states, and precision medicine concepts	FG-2; FG-3; FG-4; FG-5; FG-6; CP-1; CP-2; CP-3; CP-5; CP-6; CP-7; CP-8; CP-9; CP-10; CP-11; CP-16; CP-17; CP-18; CP-19; CP-20; CP-21; CP-23
PDIV experiential	APPE	PGx APPE	Practical experiences of PGx through PGx consult services, education, and research	CP-12; CP-13; CP-14; CP-15; CP-23