

The DNA of Pharmacy Education: CAPE Outcomes and Pharmacogenomics

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I. Introduction

Pharmacogenomics (PGx) is a rapidly evolving area of precision (*i.e.*, personalized) medicine in which a patient's genomic information is used to identify the safest and most effective treatment. While basic pharmacogenomic concepts have developed over the past 50 years, the pace of genomic research accelerated with the completion of the Human Genome Project in 2003.¹ Using the genomic "roadmap" developed by this initiative, researchers and clinicians were able to speed up the process of identifying millions of genetic variants/polymorphisms along the DNA template. Pharmacogenetic studies use these genetic variants/polymorphisms to identify their potential effects on individual patient drug response, disposition, and/or toxicity.

Pharmacists are well positioned to clinically apply pharmacogenetic data to optimize medication efficacy, clinical and safety outcomes, and cost effectiveness.² Given their extensive education and training in pharmacokinetics and pharmacodynamics, assessing pharmacogenetic effects of variability in protein structure and/or function (e.g., enzymes, receptors, transporters and signaling proteins) is a logical next step for pharmacists to optimize pharmacotherapy. Therefore, it is imperative that future pharmacists receive adequate instruction and experience with clinically applied pharmacogenomics to realize the promise of precision medicine in the new paradigm of patient-centered care.³

Four years after the completion of the Human Genome Project, the Food and Drug Administration (FDA) changed the warfarin prescribing information to include clinical evidence that genotype-guided warfarin therapy improved the safety of patients receiving anticoagulants.⁴ The FDA has since developed a website with the labeling changes for over 130 medications that

highlights pharmacogenomic information that impacts drug exposure and clinical response variability, risk for adverse events, genotype-specific dosing, mechanism of drug action, and polymorphic drug target and disposition genes. For certain drugs, pharmacogenetic testing has either been recommended or required prior to prescribing therapy.⁶ Examples include cetuximab, panitumumab, bosutinib, crizotinib, abacavir, and vemurafenib.⁷

Several components are required to fully realize the potential of pharmacogenomics and precision medicine. One component is dissemination of evidence-based recommendations for genotype-guided therapy for specific drug-gene pairs, which is presently facilitated by the Clinical Pharmacogenetics Implementation Consortium (CPIC).⁸ CPIC has established clinical guidelines to assist clinicians with actionable recommendations for patients whose genotype is already known – as opposed to recommending for or against pharmacogenomics testing. These guidelines are widely available online through the Pharmacogenomics Knowledge Base (PharmGKB) website and are available as open-access in the journal *Clinical Pharmacology and Therapeutics*.^{9,10,11} The goal of PharmGKB is to “facilitate the translation of this pharmacogenetics knowledge from the bench to bedside.”^{9,10}

Another essential component is recognition by professional associations of the importance of practice advancement in this area. In April 2015, the American Society of Health-System Pharmacists (ASHP) published a statement on the responsibilities and functions of a pharmacist for implementing pharmacogenomics in the clinical setting.¹² The purpose of this statement was to articulate that growing evidence supports clinical pharmacogenomic testing to promote safe, effective, and cost-effective treatment, and that pharmacists should be accountable for educating patients and healthcare professionals about pharmacogenomic test results, optimizing treatment based on test results, and promoting the use of clinical pharmacogenomic

testing as part of a comprehensive medication safety strategy. The ASHP statement reflects a clear professional practice expectation, which directly influences education of student pharmacists. Since recent survey evidence suggests that pharmacists understand the importance of pharmacogenomics, but a majority lack the confidence and knowledge to implement pharmacogenomics in their current practice setting, there appears to be tremendous opportunity to align educational goals to help close this gap.¹³

A third component is professional training and education at all levels, including undergraduate, postgraduate, and continuing education. For this paper we focus on opportunities and recommendations to ensure future pharmacists are adequately prepared to meet this professional need, and to ensure pharmacogenomics concepts and clinical applications are integrated into the curricula of schools and colleges of pharmacy.^{14,15} Historically, the House of Delegates of the American Association of Colleges of Pharmacy (AACP) has supported education in this area, and passed a resolution in 2008 to encourage pharmacy programs to integrate the advances in biotechnology and personalized medicine into their pharmacy curricula.¹⁶ Subsequently in 2010 and outside of AACP, a survey of pharmacy schools and colleges across the United States suggested that 89% offered genetics or pharmacogenomics in their curriculum; however, concerns were raised about possible educational gaps.¹⁷ These concerns included: (1) perceived lack of core faculty with specific or clinical expertise in pharmacogenomics; (2) challenges for faculty to stay current with new and existing literature, which is increasing at an exponential rate; and (3) the need to find the ‘ideal’ curricular balance while incorporating pharmacogenomics without compromising other important topics.

In part to address such concerns (in pharmacy and other health professional curricula), the National Human Genome Research Institute’s (NHGRI) Genomic Healthcare Branch

developed a free, online website (www.g-2-c-2.org) that includes pharmacogenomics competencies for pharmacists.¹⁸ Fifteen competencies were established by a group of 10 representatives from pharmacy and pharmacy professional organizations including the AACP Pharmacogenomics Special Interest Group. The goal of these competencies was to define the skills that pharmacists need to effectively understand and translate the genotype-related information about a patient. These competencies are divided into four areas: Basic Genetic Concepts, Genetics and Disease, Pharmacogenetics/Pharmacogenomics, and Ethical, Legal and Social Implications (Table 1).¹⁹

Selected educational outcomes outlined in CAPE 2013 underscore the essential competencies for pharmacists in this age of precision medicine, including the student pharmacist's knowledge and abilities as learner (1.1), caregiver (2.1), manager (2.2), promoter (2.3), provider (2.4), problem solver (3.1), educator (3.2), collaborator (3.4), includer (3.5), communicator (3.6), and innovator (4.3). These outcomes comprise necessary knowledge and skills for graduating pharmacists. As such, there is an opportunity to align the CAPE 2013 educational outcomes with these competencies, dovetail these concepts with the 2016 Accreditation Council for Pharmacy Education (ACPE) standards, and provide representative teaching and assessment activities for this content.

II. Pedagogical Considerations

Pharmacogenomics Education in Basic Science Foundations

Pharmacogenomics-related pharmacy education must address the “genetic basis for disease and individual differences in metabolizing enzymes, transporters, and other biochemicals impacting drug disposition and action that underpin the practice of personalized medicine.”²⁰

This can be accomplished through various pedagogies, with an emphasis on linking the science of pharmacogenomics with the application of precision medicine.

Regardless of the curricular structure, the CAPE 2013 outcomes may be applied across pharmacogenomics-related subject matter: basic science/foundation courses, application-based courses, and applied biotechnology laboratory sessions (See Table 2). Basic science foundation courses including biochemistry, molecular biology and human genetics should be considered as prerequisites to pharmacy school (depending on individual pharmacy programs' admissions criteria). These foundation courses are intended to provide an appropriate background for pharmacogenomics content and support the groundwork for application-based courses.

While standalone pharmacogenomics courses have been offered since 2002, most related subject matter is integrated throughout pharmacy curricula.^{17,21} As of 2010, 21.7% and 72.5% of programs included the subject matter as a required standalone course or as a component of other courses, respectively. These percentages have increased since 2005, at which time 9.8% and 46.3% of schools and colleges of pharmacy had standalone courses or incorporated pharmacogenomics into other courses, respectively.²²

Brazeau and Brazeau described a 2-credit hour required standalone course offered to pharmacy students in their third professional year.²¹ This course was offered in response to the identified need in this area. In addition, pharmacy program application data indicated that less than 40% of students received any education in genetics beyond that provided by introductory biology courses.²¹

The pharmacogenomics course addressed the structure and function of genes, allelic variances and allele frequencies among populations, genetic expression (*i.e.*, phenotypes), the

relationship between genetics, pharmacokinetics, pharmacodynamics, and other basic and applied science topics. Clinical applications presented were related to oncology, hematology, cardiology, and psychiatry.²¹ Traditional lecture format was used and incorporated problem-based active learning in-class exercises.

Offering a standalone 2-credit hour course to second year pharmacy students, Farrell *et al.* combined didactic lectures with online resources to cover basic and specialized pharmacogenomics concepts.²³ This course was intended to introduce pharmacogenomics concepts, emphasize the utility of online resources, examine the effects of genetic variation on drug therapy outcomes, and provide clear examples of the clinical applications of pharmacogenomics in the treatment of specific diseases, including infectious diseases, cardiovascular diseases, and cancer.

Didactic lectures provided students with information about online resources including PharmGKB and the National Center for Biotechnology Information (NCBI). Cytochrome P450 2D6 (*CYP2D6*) was used as a model gene for which NCBI resources were used to identify information about the gene and PharmGKB was utilized to identify how *CYP2D6* gene variants affected specific drugs. Students were assigned specific genes and asked to identify three alleles (variant forms of a gene), three drug substrates that would potentially be affected by those alleles, the pharmacogenetic test associated with that gene, and three articles containing information about the gene. Assessment of student performance was based on the students' execution of the requested deliverables.²³

Molecular biology techniques were explained in didactic lectures which covered a number of analytical approaches to detecting gene variation. The students were then given an

exercise to examine a somatic mutation (a non-inherited cell mutation) involving the *KRAS* gene, which is associated with hyporesponsiveness to EGFR inhibitor drugs (e.g., cetuximab). The students were provided with an answer key and self-assessed their capability to identify *KRAS* variants and explain how immunotherapies may fail in certain patients with colorectal cancer.²³ Other exercises included identifying variants in the human immunodeficiency virus that were related to antiretroviral therapy resistance, recognizing genotypes and phenotypes relative to warfarin dosing, identifying appropriate antiplatelet therapy relative to *CYP2C19* genotype.²³ The content and learning activities were for this course were centered on competencies provided at the time by AACP and the National Coalition for Health Profession Education in Genetics (NCHPEG).^{24,25}

Springer *et al.* offered an elective standalone one-semester hour course consisting of seven 2-hour sessions and one 4-hour session covering the basics of pharmacogenomics.²⁶ This course included a review of basic concepts, introduction to the human genome, a review of DNA synthesis, the technology of DNA detection and related technologies, pharmacogenomics as related to pharmacokinetics and pharmacodynamics using a computer simulation program, and genomics-based drug safety, clinical applications of pharmacogenomics, and bioinformatics.²⁶ Assessment of the teaching approach was based on the IDEAS format (Introduction, Design, Evaluation, Assessment, and Summary), using data from pre-course and post-course attitudinal surveys, students' care plans (*i.e.*, observational data), development of educational pamphlets, and a 2-page paper as performance assessments.²³

An elective online course offered by Bova and colleagues provided an introduction to pharmacogenomics and precision (personalized) medicine.²⁷ The course covered three major topic areas including genome science, ethical and legal issues, and the current utility of DNA

data in precision medicine. During the 15-week semester course, students were involved in weekly online blog posts discussions where they would respond or comment on the topic posted by the instructor.²⁷ The students were assessed through weekly online quizzes and through completion of a 2-page paper that addressed “three things I learned” about pharmacogenomics and precision medicine. The students picked three topics to present based on categories of disease risk, drug response, privacy, or “other”, e.g., DNA testing, drug-drug-gene interactions. An evaluative pre- and post-course survey assessed student knowledgebase, showing an increase following the weblog-based course.²⁷

Pharmacogenomics Exercises in the Laboratory

Laboratory or “hands-on” exercises immerse students in the analytical process – from acquisition of the genetic sample from patients, to analyzing raw genetic data, and ultimately to translating the genetic information into clinical recommendations. Several institutions have used such exercises to raise students’ awareness of pharmacogenomics applications. The CAPE competency statement (1.1.4) is addressed by the examples below (see Table 3).

As of 2010, only 2.9% of pharmacy programs included a required laboratory exercise as a component of pharmacogenomics education. Elective laboratory courses have also been offered in an effort to connect the science and application of pharmacogenomics. Evidence indicates that pharmacogenomics-based laboratory exercises provide valuable experiences for students.^{15,28}

Knoell *et al.* presented a pharmacogenomics laboratory, which included an angiotensin converting enzyme (*ACE*) genotyping exercise with student volunteers supplying buccal swab DNA samples.²⁸ The *ACE* genotyping data were assimilated into didactic lectures throughout the elective course to demonstrate pharmacogenomics applications to students. The

pharmacogenomics data were presented in the setting of genetic counseling with the information being presented to 115 students.²⁸ The genotyping exercise was aimed at improving comprehension of pharmacogenomic principles that apply to precision medicine in patient care. A large majority of students agreed or strongly agreed that first-hand genotyping experience was valuable in relating pharmacogenomics to practice.

Drawing on second-year pharmacy student knowledge in biochemistry, foundational medicinal chemistry, and pharmacology, Krynetskiy *et al.* introduced a genotyping exercise in a section of a pharmaceuticals course.¹⁵ The section included material to introduce the concepts of genetics related to drug metabolism, human genetics and genetic variability. The material included examples of polymorphic drug-metabolizing enzymes which influenced pharmacologic response. Students completed single nucleotide polymorphism (SNP) analysis of the N-acetyltransferase 2 (*NAT2*). This class of 150 students performed the work during two three-hour laboratory periods and one one-hour discussion period. The goal of the exercise was to “demonstrate to the students the universal character of genetic variability in genes coding for drug-metabolizing enzymes and the importance of genetic analysis for practical pharmacotherapy.” A post laboratory survey indicated that almost 89% of the students acknowledged the experience showed “why pharmacogenetics is so important”.¹⁵

A pilot laboratory exercise was included in a biochemistry course for third-year students in a “zero-six” pharmacy program. The exercise included 24 students performing a self-cheek swab to test for the *1 and *2 forms of the *CYP2C19* gene relative to antiplatelet drug selection. After collection of their sample, students stabilized the DNA. The students were given instructions on sample preparation and learned the polymerase chain reaction protocol and gel electrophoresis procedure. The results of the genotyping were presented as images of gels and a

reference gel image was utilized for students to compare their results with.²⁹ Students then applied the CPIC guidelines for the clopidogrel-*CYP2C19* drug-gene interaction to make a “clinical decision” relative to antiplatelet drug selection.²⁹ An evaluative post-exercise survey completed by 23 of the 24 students indicated that the exercise had value in the Doctor of Pharmacy program. The positive experience of the pilot resulted in adoption of the exercise as a required component of the curriculum.

Farrell *et al.* designed a genomics-based laboratory exercise to have students (n = 78) apply a polymerase chain reaction protocol and high-resolution melting DNA analysis.³⁰ The analysis was used with colorectal cancer cells in the determination of somatic mutation biomarkers in oncology. The students utilized the marker to guide cancer treatment for a patient with colorectal cancer who had similar tumor genomics. The intent of this exercise was for students to assimilate and grasp the scientific basis of genomic mutations, recognize DNA mutations in a colorectal tumor, evaluate if certain tumor markers were specific drug targets, and apply the appropriate tumor-genome related pharmacotherapy.³⁰ Pre-exercise and post-exercise surveys were utilized to document students’ understanding of pharmacogenomics. Post-exercise survey scores were higher relative to the two survey statements of understanding tumor growth as a consequence of somatic mutations and understanding how somatic mutations impacted drug response. Students also rated the effectiveness of the laboratory using a survey instrument, with each of five evaluation statements being rated as at least 4 out of 5 on a five-point scale. Here with 1 representing “completely disagree”, while a value of 5 represented “completely agree”. Finally, questions from the laboratory exercise were included in a practice integrated laboratory final exam, with almost 80% of students showing they had an understanding of the applications of pharmacotherapy in cancer based on PGx.³⁰

Strategies for Teaching Patient Care Skills in Pharmacogenomics

As health care providers and pharmacotherapy experts, practicing pharmacists across a broad spectrum of patient care settings are uniquely positioned to educate providers and patients about PGx testing applications and develop efficient clinical implementation strategies.³¹⁻³⁵

Through these activities, pharmacists have a tremendous opportunity to lead precision medicine in clinical practice as the ‘canary’ for the anticipated genomic medicine age. Likewise, pharmacy educators are faced with a tremendous responsibility to equip future pharmacists with the clinical knowledge and skills needed to realize these opportunities.

Though pharmacy practice, precision medicine, and PGx nicely dovetail as concepts, critical educational gaps in clinical knowledge and skills remain to be addressed for present and future student pharmacists.³⁶⁻³⁸ Recently, professional practice societies such as ASHP, the American College of Clinical Pharmacy (ACCP), the American Pharmacists Association (APhA), the National Community Pharmacists Association (NCPA), and the National Association of Chain Drug Stores (NACDS) have begun to address these gaps broadly across multiple practice settings and disciplines to provide pharmacists with resources needed to optimize patient care.^{12,39} In addition, the NIH-supported Genetics and Genomics Competency Center (G2C2) has largely supplanted previous work by NCHPEG in publishing core competencies for healthcare professionals (*e.g.*, pharmacists, physicians, genetic counselors, and nurses) to provide a framework for continuing healthcare education and interprofessional development. Hopefully, these competencies, which involve knowledge, skills, and attitudes, will result in healthcare practitioners integrating genomics into their daily practice (www.g-2-c-2.org).¹⁹

While many of the foundational science concepts of pharmacogenomics can be taught and assessed in the traditional classroom lecture or laboratory setting, the knowledge and skills needed to apply these principles to complex patient care scenarios require applications-based didactic and experiential learning activities that actively engage the student. For example, pharmacist competencies for PGx specify that learners should be able to apply foundational knowledge to analyze evidence-based guidelines and develop patient care recommendations that incorporate ethical, legal, social, and cost implications of pharmacogenomic testing.¹⁹ The ASHP statement on the pharmacist's role in clinical PGx builds on this foundation and states that all pharmacists should be able to perform basic functions in clinical PGx, including recommending PGx testing, designing a drug-therapy regimen that is informed by PGx data, and communicating PGx-specific drug therapy recommendations to the health care team.⁴⁰ These competencies and functions align closely with CAPE outcomes 2.1 (patient-centered care); 3.1 (problem solving); 3.4 (interprofessional collaboration); 3.5 (cultural sensitivity); and 3.6 (communication) (see Table 4).

Comprehensive medication management - including precision medicine - is clearly the future of pharmacy practice. It is imperative that student pharmacists of today – and tomorrow – understand how to apply pharmacogenomic data to optimize therapeutic outcomes. In the future, patients will be able to enter most acute or ambulatory care practice settings and either present known pharmacogenomic test results or readily obtain testing to identify relevant polymorphisms. This information will then be seamlessly integrated into electronic health records to inform clinicians in real-time of critical drug-gene interactions that will assist with tailoring a precise therapy regimen for any given patient.

To equip students with the knowledge and skills needed to realize this vision, we propose three overarching educational strategies to optimize clinical pharmacogenomics education for student pharmacists across didactic and experiential settings:

- (1) Emphasize on patient-centered care in concert with a robust electronic health record to optimize individual health as well health of targeted populations;
- (2) Enhance problem-solving and communication skills to prepare graduates to serve as strong advocates for patients within an interprofessional clinical collaboration; and
- (3) Enhance professional development through structured leadership experiences (*e.g.*, embedded within a clinical implementation strategy) and exposure to national and international best practices for precision medicine.

To optimally educate student pharmacists in clinical pharmacogenomics, the concept of patient-centered care must be self-evident, meaning that for most students a change in thinking (*i.e.*, from two-dimensional to three-dimensional) will be required. Precision medicine applies to both individual patient case management approaches and population-based approaches. For example, a common clinical scenario incorporating precision medicine or pharmacogenomic applications may involve a patient presenting with acute coronary syndrome (ACS) who requires dual antiplatelet therapy. In this scenario, the student pharmacist would be well positioned to recommend pharmacogenetic testing (*i.e.*, *CYP2C19* genotyping), assess the results, and either recommend or institute appropriate therapy for the patient. As with teaching other pharmacotherapy concepts in the classroom setting, teaching strategies for clinical pharmacogenomics should be comprised largely of active-learning, engaging, applications-based, activities that incorporate real-life clinical patient case scenarios (Appendix A). These

activities should incorporate close alignment with and integration into real-world patient care scenarios and the electronic health record (*e.g.*, clinical decision support and informatics), require patient and interprofessional communication and education, and provide opportunities for problem solving and leadership development when possible. In addition, as with other pharmacotherapy and skills-based concepts, assessment strategies for clinical pharmacogenomic activities should incorporate active assessment of students' communication and problem-solving skills (Appendix B).

Within the experiential environment, immersing student pharmacists into a 'learning' health system that efficiently uses electronic health records and clinical decision support tools is paramount, and aligns with practice advancement principles highlighted by national and international experts. Finally, given the importance of monitoring and applying emerging medical literature in this field, didactic and experiential educational strategies in clinical pharmacogenomics should include activities that incorporate analysis and interpretation of pharmacogenomics medical literature (*e.g.*, participation in pharmacogenomics journal clubs, use of pharmacogenomics databases [*i.e.*, PharmGKB, application of CPIC guidelines]).

On the other hand, a population-based approach can also be emphasized in the educational process. In the classroom, this may involve a student-led project to develop a business and/or clinical practice plan for an ideal clinical pharmacogenomics implementation in various practice settings. This exercise would require students to consider clinical, financial, laboratory, administrative, and other feasibility components of developing and implementing a new clinical service. In the experiential setting, this may involve asking student pharmacists to design and implement a clinical pathway for *CYP2C19* genotyping for all patients at risk for ACS.

Problem-solving skills remain arguably the most critical to developing student pharmacists into future clinical experts. Current experiential practice settings offer an unprecedented opportunity for student pharmacists and their preceptors to engage in precision medicine in practice and in interprofessional collaboration. Since the majority of practice settings have not yet clinically implemented pharmacogenomic testing, there are myriad opportunities to design pilot programs, educate other health care providers, and even engage in targeted pharmacogenetic testing in order to optimize pharmacotherapy regimens and outcomes. This fundamental paradigm shift must occur to realize significant gains in the broader scheme of health care delivery, and as such, precision medicine and pharmacogenomics provides a clear starting point.

Finally, introducing the concept of leadership and professional development to student pharmacists in the classroom and during their practice experiences is critical, and perhaps largely unrealized. As an emerging field, pharmacogenomics is a tremendous use case that can effectively combine development of clinical practice skills and clinical leadership skills. Arguably we strive to train student pharmacists to be practice leaders, and an environment where evidence and best practices are still emerging (as is the case with precision medicine) may provide an ideal place for incubating these skills. Involving student pharmacists in meetings with clinical and administrative stakeholders is an excellent example, as is charging them to develop and implement testing pathways for a specific drug-gene pair as part of an overarching clinical strategy. We must not forget that the profession of pharmacy needs a constant succession plan, and using pharmacogenomics as an example in experiential training is a tremendous opportunity.

III. Assessment: Means to Assess Pharmacogenomics Education across the Curriculum

Assessment of pharmacy student acquisition of knowledge and competencies as they progress through their curriculum is extremely important and must be done carefully to gain a true measure of student abilities. Assessments are done for courses and for the entire curriculum. A full discussion of assessment is beyond the scope of this article, but for a comprehensive discussion of assessment in relation to evaluating CAPE outcomes, the reader is directed to the paper written by Fulford, Souza, et al.⁴⁰

This section will explore examples of a number of published assessments used in a variety of pharmacogenomics courses from different pharmacy programs. These examples will be categorized for use in the courses discussed in this paper: basic science/foundational courses, hands on lab-based courses and in application based courses. Suggestions as to the level of Bloom's Taxonomy that the example assessments can evaluate will be provided.⁴¹ When provided in the literature, information regarding the CAPE outcomes the assessments were designed to evaluate are included as well. If information was not provided regarding the CAPE outcomes the assessment was designed to address, the authors of this article have provided some suggestions of which CAPE outcomes these assessment tools could evaluate.

General Pharmacogenomic Assessment Strategies

Quizzes and exams are summative forms of assessment. Their use in pharmacogenomics curriculum is not unique, but is worth mentioning as they are important means of measuring student mastery of all the material that contributes to pharmacogenomics. They may be used in all three types of courses discussed in this paper where pharmacogenomics is taught. Many

examples are found throughout the literature discussing how pharmacogenomics content is presented and evaluated. The level of Bloom's Taxonomy that has been reached by the students assessed using quizzes and exams are only limited by the questions asked by the instructor. Pharmacogenomic information lends itself to being taught throughout all levels of Bloom's. Given the sophistication needed for clinical application of the material, it should be assessed when possible at the higher Bloom's level in students. Most of the CAPE outcomes with the exception of those in Domain 4 can be assessed using quizzes and exams, depending on how the instructors wish to write their assessment questions.

Brazeau and Brazeau described a 2-credit hour required standalone course offered to pharmacy students in their third professional year.²¹ This course was a blend of basic science/foundational knowledge with application,. Learning was assessed through examinations, in-class exercises, and a writing exercise. This writing exercise is discussed in more detail below. Examinations were composed entirely of short answer or essay questions.²¹ The students also had in class assignments that were short answer. Brazeau and Brazeau stated that student evaluations of the course indicated students did not see the relevancy of being assessed using this written format, but a great majority of the students do see the relevancy of the course to their future practice. As stated by the authors, the outcomes for the course were based on the American Society of Human Genetics guidelines for medical school core curriculum in genetics.

Based on the lecture topics covered in the course taught by Brazeau and Brazeau, many of the CAPE Outcomes could be assessed using this course as a model. It could be suggested that the following CAPE Outcomes were addressed in this course: Learner (1.1), Caregiver (2.1), and Problem Solver (3.1).

The use of interactive audience response systems (e.g., clickers), can be an effective assessment tool. Clickers engage students in active learning and can be used to gather formative assessment data on students' understanding of the material presented in real time. Data from an organized review of the literature on the use of clickers in health care education found that clickers are an effective formative assessment tool as well as provide information to the instructor that allows them to revise their teaching plan to ensure students meet the learning objectives.⁴² Clickers can be used during lecture in any course, including those on pharmacogenomics taught in basic science/foundational courses or application based courses. If lecturing is a component of lab-based courses, clickers could be used in this type of course as well. Depending on the topic being covered, clickers could be used to assess student attainment of many of the CAPE outcomes. Outcomes in the Personal and Professional Development domain (Domain 4) are probably not as well suited to the use of clickers. Courses focusing on Domain 1- Foundational Knowledge would be well suited for student assessment at least in part by the use of clickers.

Pharmacogenomics Assessment Strategies in Basic Science Foundations

Students in basic science/foundational courses in PGx could be expected to read, comprehend, and apply the information in a pharmacogenomics primary research article. One method for assessing student understanding of scientific PGx papers was published by Brazeau and Brazeau in their description of their pharmacogenomics course mentioned above.²¹ During the course, faculty had students choose a current primary research paper on pharmacogenomics to read and summarize using language their student colleagues could comprehend. This exercise was accepted by the students as being relevant to the course outcomes and has had increasing student acceptance as an assessment method. This exercise could assess students at the level of

analysis in the Bloom's Taxonomy, as they would have been required to distill what they read into a simpler format. This type of exercise could be used to assess several CAPE outcomes. The following outcomes could be assessed using this example: Learner (1.1), Educator (3.2) and Communicator (3.6).

Pharmacogenomics Assessment Strategies in the Laboratory

There are several examples in the pharmacy education literature of assessments that have been used to measure how well students reached curricular outcomes in laboratory based courses where pharmacogenomics is taught. The assessments were various writing exercises that focused on some aspects of scientific writing. In the course created by Krynetskiy, et al, as mentioned above, in which a lab component was inserted into a required pharmaceutics course, students were assessed using scientific writing. Students genotyped DNA for a drug-metabolizing enzyme using saliva samples obtained from their classmates during the lab class time¹⁵ The students determined allele frequencies from the class sample and discussed clinical implications of specific genotypes. Student ability to carry out these lab procedures was assessed by having the students write a lab report of the lab activities, including their calculated quantitation of the isolated DNA, identify the genotypes present in the class, and calculate the allele frequency in the class. Students in the course reported that the lab enhanced their understanding of the materials taught in the didactic portion of the course and helped them identify the potential of pharmacogenomics in practice. Many of the CAPE Outcomes could be measured using this type of exercise, including Learner (1.1), Caregiver (2.1), Problem Solver (3.1), and Communicator (3.6).

O'Brien and his colleagues published a similar example of incorporating lab based exercises into a pharmacogenomics course.⁴³ The exercises were developed for undergraduate pre-pharmacy and pre-medicine students to prepare them for entry into clinical programs. This two semester long course included several diverse activities, one of which included a genetics based lab activity in the second semester. Students were given a chance to volunteer to participate in a study where anonymous buccal swabs and their demographic information were obtained from the students that decided to participate. The collected genomic samples were genotyped for *CYP2C9* and *CYP2D6* variants. Students were given the anonymized results of all the sample genotypes along with the demographic data and were asked to write a paper about the data on the topic of their choice. Faculty felt that this activity greatly increased student comprehension of the basic pharmacogenomic outcomes being taught and also increased student enthusiasm for the topic. The faculty developed outcomes for the course based on the Core Competencies in Genetics Essential for All Health-Care Professionals from NCHPEG.²⁵ This example of an assessment could be used to evaluate student attainment of the current CAPE outcomes Learner (1.1), Educator (3.2) and Communicator (3.6), as well as others depending on the topic each student chose to address.

Pharmacogenomic Assessment Strategies in Application-based Courses

As described above, Knoell also incorporated a genotyping analysis into an application based PGx course in a manner similar to that published by O'Brien. However, this laboratory-based exercise was used in the course as an opportunity for students to take part in a mock patient genetic counseling session.²⁸ In this exercise, student volunteers provided DNA samples that were genotyped for an insertion/deletion variant of the angiotensin converting enzyme (*ACE*) gene. The anonymized genotyping results were presented to the class and used in a

simulated patient counseling session. This counseling session involved having the students experience consenting patients to a study or procedure, obtaining a DNA swab, interpreting the genotyping results, and creating a patient action plan that was dependent on the genotype of the mock patient. A large majority of the students stated in course evaluations that this exercise helped them understand course content. CAPE outcomes Learner (1.1), Educator (3.2) and Communicator (3.6), Caregiver (2.1), and Problem Solver (3.1) could all be addressed with this exercise.

Application-based courses in pharmacogenomics can take place in classroom settings or in clinics themselves. Drozda et al. published their work in providing students with an opportunity to use their pharmacogenomics knowledge in an anticoagulation clinic setting in an experiential course.⁴⁴ Students were involved in the pharmacy's genotyping service to determine first warfarin doses for patients or were involved in pharmacogenomics research efforts that involved patients in the clinic as well. Students involved in either aspect of the anticoagulation service (patient care or the research) were assessed for their mastery of the objectives of the experience using an outcomes learning checklist developed by the faculty. This course was teaching the students at the higher levels of Bloom's taxonomy. As stated by the authors, the course outcomes were based on the AACP proposed competencies in pharmacogenomics and the core competencies for health-care professionals proposed by the National Coalition for Health Professional Education in Genetics.^{25,45} This experiential opportunity created by Drozda and colleagues for students in the anticoagulation clinic can be mapped to almost all the CAPE Outcomes and is an excellent model of the level of breadth and depth to which pharmacy students can be taught to understand and apply pharmacogenomics in patient care. At the least, the following CAPE Outcomes could be assessed in this course: 1.1 (Learner), 2.1 (Caregiver),

2.3 (Promoter), 2.4 (Provider), 3.1 (Problem Solver), 3.2 (Educator), 3.4 (Collaborator), 3.6 (Communicator), and 4.4 (Professional).

There are endless possibilities for assessing student achievement of the CAPE Outcomes pertinent to the parts of pharmacy school curriculum that focuses on PGx. As this topic is multi-disciplinary, is in depth, and is constantly progressing, faculty ability to assess student understanding and ability to clinically apply patient genotypes, accurate assessment of students in this area is critical. The assessments presented here are excellent examples of assessments of pharmacogenomics that have been presented in the literature. Many of these assessments provide flexibility to assess students at all levels of Bloom's taxonomy and also to assess many of the CAPE outcomes in one assessment effort.

IV. Conclusion

As engaged members of the AACP PGx SIG, we issue the above recommendations to Deans and Faculty of not only all Schools and Colleges of Pharmacy, but also to Schools and Colleges in all Health Professions. This call to action is specifically to incorporate pharmacogenomics in the core teaching curricula of clinical pharmacy practice without further delay. Taking this step now is vital for ensuring successful implementation of precision medicine into pharmacy practice in the near future, in pace with the emergence of the latest genomic technology and resources, for the benefit of the individual patient and society at large. If we, as an educational collaborative, fail to take this step soon, pharmacy education may become a bottleneck in the road to implementing precision medicine. Education for the next generation is a prime community task concerning all disciplines of knowledge. Wherever pharmacy is

concerned, this task is also an asset for the present generation, as our current students will be charged to care of our generation as it ages.

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Appendix A: Sample Clinical Pharmacogenetics Patient Case 1

HPI: TK is a 43 year old man presenting to your pharmacogenomics clinic as a new patient with complaints of pain all over. He had a motor vehicle accident in 1993 and has had chronic pain since then. His primary care physician prescribed Percocet[®] which helped, but he was referred for additional evaluation of pain and pharmacogenomics. Pt reports using one tablet of Percocet[®] (5-325 mg) three to four times daily and he has not tried any other therapies.

PMH: anxiety, back pain, depression, COPD, arthritis

Current medication(s):

Proair[®] (albuterol) 108 mcg/act 1 puff every 6 hours as needed

Duloxetine 60 mg daily

Gabapentin 100 mg daily

Nicoderm[®] CQ 21 mg 1 patch every 24 hours

Ondansetron every 8 hours as needed

Relevant pain medication history:

Norco[®] 5-325 mg 1-2 tabs every 4-6 hours as needed for ~1 month (provides some relief)

Dilaudid[®] 4 mg 1 tablet every 4 hours as needed for ~ 3 months (did not help)

Percocet[®] 5-325 every 4 hours as needed intermittently (provides some relief)

Tramadol 50 mg every 6 hours as needed (tried for 2 months, patient reports it does not help)

Drug allergies/intolerances: NSAID (shortness of breath)

Cyclobenzaprine (leg spasm)

Methocarbamol (does not help)

Seroquel[®] (seizures)

Tramadol (does not help)

Bupropion (stick to stomach)

Morphine (chest pain)

Pharmacogenetic test results:

CYP2D6 *4/*5 (poor metabolizer phenotype; absent *CYP2D6* enzyme activity)

CYP2D6 interacting drugs:

Duloxetine (moderate *CYP2D6* inhibitor)

1. List TK's potential drug-therapy problem(s).
2. Identify drugs in TK's regimen that are affected by *CYP2D6* genotype and provide the level of evidence (according to PharmGKB) for each of these drug-gene associations.
3. How does TK's *CYP2D6* poor metabolizer status affect your assessment of his drug therapy problems?
4. Provide a drug-therapy recommendation for TK's pain management that incorporates his *CYP2D6* genotype status. This recommendation should include drug, dose, rationale, and references for genotype-based drug therapy recommendations.
5. List key educational points that you would include for the patient and the physician when explaining this drug therapy change.

Appendix A: Sample Clinical Pharmacogenetics Patient Case 2

HPI: SN is a 67 year old female presenting to your pharmacogenomics clinic as a new patient with a diagnosis of major depressive disorder. SN has had the feeling of worthlessness and has no will to perform any typical daily tasks. Her physician asks for input as they would like to start SN on the tricyclic antidepressant amitriptyline. There is a family history of depression and other psychiatric illnesses.

PMH: hypertension, seasonal allergies, mild social anxiety

Current medication(s):

Hydrochlorothiazide 25 mg daily

Cetirizine 10 mg daily as needed

Propranolol 10 mg twice a day

Drug allergies/intolerances:

Metoprolol (does not help)

Pharmacogenetic test results:

CYP2C19 *1/*2 (intermediate metabolizer phenotype; reduced CYP2C19 enzyme activity)

CYP2D6 *1/*2Xn (ultrarapid metabolizer phenotype; increased CYP2D6 enzyme activity)

1. List SN's potential drug-therapy problem(s).

2. Identify drugs in SN's regimen that are affected by CYP2D6 genotype and provide the level of evidence (according to PharmGKB) for each of these drug-gene associations.
3. How does SN's CYP2C19 intermediate metabolizer status and CYP2D6 ultrarapid metabolizer status affect your assessment of her proposed drug therapy problems?
4. Provide a drug-therapy recommendation for SN's depression management that incorporates her CYP2C19 and CYP2D6 genotype status. This recommendation should include drug, dose, rationale, and references for genotype-based drug therapy recommendations.
5. List key educational points that you would include for the patient and the physician when explaining this drug therapy recommendation.

Clinical Applications of Genomic Medicine Grading Rubric

DATE: _____

Student Name: _____

Grading Scale: 5 (strongly agree) 4 (agree) 3 (neutral) 2 (disagree) 1 (strongly disagree)

Criteria: Score Notes

PATIENT PRESENTATION/ASSESSMENT

Included appropriate discussion of the patient's disease states		
Included appropriate discussion of the patient's current drug therapy		
Included appropriate interpretation of patient's genotype results		
Summarized clinical implications of patient's genotype results		
Assessment demonstrated student's understanding of the subject matter		
Assessment was clearly communicated		

PATIENT PLAN

Plan reflects patient's genotype results		
Plan considers patient's other disease states and/or drug therapy		
Plan includes appropriate suggestions for drug therapy/other changes		
Plan is supported by evidence-based reasoning		

Score /50

Table 1: Core Competencies for Pharmacists in Genomics and Pharmacogenomics^{(18)*}

Basic Genetic Concepts
<ul style="list-style-type: none"> • B1) To demonstrate an understanding of the basic genetic/genomic concepts and nomenclature. • B2) To recognize and appreciate the role of behavioral, social, and environmental factors (lifestyle, socioeconomic factors, pollutants, etc.) that modify or influence genetics in the manifestation of disease. • B3) To identify drug and disease associated genetic variations that facilitate development of prevention, diagnostic and treatment strategies and appreciate there are differences in testing methodologies and are aware of the need to explore these differences in drug literature evaluation. • B4) To use family history (minimum of three generations) in assessing predisposition to disease and selection of drug treatment.
Genetics And Disease
<ul style="list-style-type: none"> • G1) To understand (describe) the role of genetic factors in maintaining health and preventing disease. • G2) 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). • G3) To appreciate (demonstrate) that pharmacogenomic testing may also reveal certain genetic disease predispositions (e.g. the Apo E4 polymorphism).
Pharmacogenetics/Pharmacogenomics
<ul style="list-style-type: none"> • P1) To demonstrate an understanding of how genetic variation in a large number of proteins, including drug transporters, drug metabolizing enzymes, direct protein targets of drugs, and other proteins (e.g. signal transduction proteins) influence pharmacokinetics and pharmacodynamics related to pharmacologic effect and drug response. • P2) To understand (identify) the influence (or lack thereof) of ethnicity in genetic polymorphisms and associations of polymorphisms with drug response. • P3) Recognize the availability of evidence based guidelines that synthesize information relevant to genomic/pharmacogenomic tests and selection of drug therapy (e.g. Clinical Pharmacogenetics Implementation Consortium).
Ethical, Legal And Social Implications (ELSI)
<ul style="list-style-type: none"> • E1) To understand (differentiate) the potential physical and/or psychosocial benefits, limitations and risk of genomic/pharmacogenomic information for individuals, family members and communities, especially with genomic/pharmacogenomic tests that may relate to predisposition to disease. • E2) To understand (explain) the increased liability that accompanies access to detailed genomic patient information and maintain confidentiality and security. • E3) To adopt a culturally sensitive and ethical approach to patient counseling regarding genomic/pharmacogenomic test results. • E4) To appreciate (identify) the cost, cost-effectiveness, and reimbursement by insurers relevant to genomic or pharmacogenomic tests and test interpretation, for patients and populations. • E5) To identify the need to refer a patient to a genetic specialist or genetic counselor.

*The competencies established by pharmacy and pharmacy organization representatives were not stated as strict objectives relative to a given taxonomy. To provide a measurable objective, terms are provided (parenthetically) for specific competencies.

Table 2: Basic Science Foundation Courses

CAPE Outcomes	Competencies (G2C2)
Learner (1.1)	B1, B2, B3, B4, G1, G2, G3, P1, P2, E1, E4
Caregiver (2.1)	B2, B3, P3
Manager (2.2)	B3, G1, P1
Promoter (2.3)	G1
Provider (2.4)	E1
Problem Solver (3.1)	B3, B4, G1, P3
Educator (3.2)	B3, P3
Collaborator (3.4)	B3, P3
Includer (3.5)	G2, G3, P2
Communicator (3.6)	B3, P3

Table 3: Practical Laboratory Experiences

CAPE Outcomes	Competencies
Learner (1.1)	B1, B3, B4, P1, P2
Caregiver (2.1)	B3
Manager (2.2)	P1
Problem Solver (3.1)	B3, B4
Educator (3.2)	B3
Collaborator (3.4)	B3
Includer (3.5)	P2
Communicator (3.6)	B3

Table 4: Clinical Application-based Courses

CAPE Outcomes	Competencies
Learner (1.1)	B4, P1, P2, E1, E2
Caregiver (2.1)	P3, E3, E4, E5
Manager (2.2)	P1
Provider (2.4)	E1
Problem Solver (3.1)	B4, P3, E4, E5
Educator (3.2)	P3
Collaborator (3.4)	P3, E4
Includer (3.5)	P2, E3
Communicator (3.6)	P3, E3, E4
Innovator (4.3)	E4