RESEARCH

Assessing Learners' Attitudes Towards Pharmacogenomics Using Their Own Pharmacogenomics Testing Results

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Objective. Pharmacogenomics within personalized medicine is becoming a key tool to elucidate inter-individual variation in therapeutic drug regimen management and its clinical implementation may soon be an integral part of pharmacy and clinical practice. This study proposes an innovative active learning activity using several interactive processes to increase learners' competencies and confidence in pharmacogenomics for future practice.
Methods. Student pharmacists at the Medical College of Wisconsin (MCW) participated in a combination of standard lectures, active engagement, patient care laboratory training along with voluntary personal pharmacogenomics testing. Participants were surveyed before and after these activities about their attitudes towards utilization of pharmacogenomics in current and future practice.
Results. Students learning outcomes, competencies and attitude towards pharmacogenomics have shifted in a very positive manner from a relatively neutral perception to more confidence.
Conclusion. This study has demonstrated that an innovative teaching structure including individual pharmacogenomics assays was beneficial to student pharmacists and has improved their knowledge, interest, confidence and comfort in learning and utilizing pharmacogenomics in their education and future pharmacy practice.
Keywords: active learning, learning outcome, perception, pharmacogenomics, survey

INTRODUCTION

Pharmacists are in a unique position to provide education and counseling on precision medicine and specifically pharmacogenomics. This has been recognized by the accreditation standards of the Accreditation Council for Pharmacy Education (ACPE), as shown in its Professional Competencies and Outcome Expectations for Doctor of Pharmacy (PharmD) Programs, in that students should be exposed to "Pharmacogenomics/genetics: 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."[1] Considering this emerging area, and the need for pharmacy graduates to be competent in precision medicine and pharmacogenomics, it is important to incorporate this material as part of contemporary pharmacy curricula. Recognizing this, the Medical College of Wisconsin (MCW) School of Pharmacy developed a required course, "Principles of Drug Actions and Pharmacogenomics" in the three-year Doctor of Pharmacy (PharmD) curriculum from its inception in 2015. Additionally, the topic of pharmacogenomics is included as a curricular thread in the PharmD program. We developed a study that uses interactive and innovative approaches to teaching precision medicine and pharmacogenomics to first year pharmacy students to validate our hypothesis that including this pertinent teaching material will increase students' performance, skills and competencies related to pharmacogenomics.

Pharmacy educators are striving to engage students within the classroom using a variety of teaching styles to foster an interactive learning environment while ultimately gaining an appreciation for the impact knowledge has on their understanding and application in a therapeutic area.[2,3] In particular, we designed an intervention to allow students to be active participants in their own learning, leading to a greater understanding and retention of the material by letting students, for a temporary time, to make a transition from a student-learner to a patient-learner. Importantly, this active learning intervention was intended to produce a cadre of pharmacy graduates ready to enter practice with a differentiated and needed job skill set, in pharmacogenomics.

Our study goals and objectives were: 1) assess pharmacy students understanding of pharmacogenomics prior to engagement in a required course using an attitudinal survey, 2) complete a voluntary individual student pharmacogenomics assay, 3) analyze and discuss results of a pharmacogenomics assay, 4) understand the course and relate learning to their own

genetic status using lecture material and in-class activities, and 5) perform a post intervention attitudinal survey to assess pharmacy student learning of pharmacogenomics to determine attitudinal changes from baseline, that were measured individually as well as in the aggregate.

METHODS

Participants were given a pre-survey at the beginning of the course to assess their baseline knowledge and attitude towards pharmacogenomics and their role as a future healthcare provider in assisting patients in this area. Upon completion of the course, students completed a post-assessment to determine attitudinal changes from baseline, measured individually as well as in the aggregate. To further enhance learning, students volunteered for an individual pharmacogenomics assay. They were able to use their personal results to better understand the course material relating it to their own genetic status and understand the importance of the tenants of precision medicine and pharmacogenomics.

First year professional PharmD students (Class of 2022) were given an anonymous Qualtrics online (Qualtrics, Provo, UT) pre-survey prior to taking the "Principles of Drug Actions and Pharmacogenomics" and "Patient Care Laboratory III" courses (January to March 2020). These courses cover broad ranges of lectures and practices including basic pharmacology, medicinal chemistry, pharmacokinetics, principle of pharmacogenomics, applications to Pharmacokinetics and Pharmacodynamics, CPIC (Clinical Pharmacogenetics Implementation Consortium) guidelines, ethics, and patients counseling training. Genetic and molecular biology basic science foundational knowledge was provided during their first quarter (July to September 2019).

Following the completion of the requisite material on pharmacogenomics and before final exams occurred, students were again asked to complete a post-evaluation survey that was identical to the pre-survey to assess any measurable changes in their attitudes and understanding of pharmacogenomics. Students were provided a consent form that included a detailed description of the purpose, goals and objectives of the study. Pre and post surveys consisted of 27 questions grouped in four categories as follow: 1) assessment of students' knowledge of pharmacogenomics testing, 2) usage of the information to counsel patients and other healthcare providers, 3) application to future clinical pharmacy practices, and 4) their comfort with the practice of adapting medication regimens and counselling based on genetic information, and their future professional development. The survey questions are validated survey questions from the University of Maryland School of Medicine (45%),[4] from a recent article in AJPE (18%)[5] and with additional questions by the authors. Answers were paired from the pre- and post-survey using anonymous codes. The scoring was performed according to the Likert 5-point scoring. Each choice was assigned a value from 1 to 5, and data were merged into two groups for percentage calculations: answers 1 and 2 vs. answers 3, 4, and 5. The mean of answers along with standard deviation were also calculated for each question and compared. Lastly, our data has a minimal number of selections by students of the choice neutral (value of 3 by 0-17% of students on average) allowing thus the utilization of the Likert scale with minimal bias and errors. Student learning outcome and examinations scores were extracted from ExamSoft (Examsoft Worldwide, Inc., Dallas, TX).

As an additional benefit, all first year professional PharmD students were offered the opportunity to voluntarily participate in a pharmacogenomics assay performed on their saliva specimens. All samples were retained in a locked area, and only handled by the investigators until the assays were run by RPRD Diagnostics (Milwaukee, WI). Genomic DNA from saliva was extracted and amplified by multiplex PCR and the PCR products from each student's amplified DNA were pooled, purified, fragmented, labeled, and hybridized to the PharmacoScan Array per the manufacturer's recommendations (ThermoFisher Scientific, Waltham, MA). Arrays were then stained with a fluorescent antibody and scanned on the GeneTitan Multi-Channel Instrument. The data were analyzed using the Axiom Analysis Suite 3.1 (ThermoFisher Scientific). Analysis was performed using the commercially released allele translation table (version R6). Pharmacogenomics data and other relevant demographic data were harvested and anonymously stored. A total of 45 (100%) students were enrolled and 39 (89%) agreed to the personal genetic testing. The declining six students received mock personal genetic test results to augment their learning in the course.

This study was approved by the MCW-IRB (IRB#PRO35789) and all participants gave informed consent. According to the study's IRB, genetic data collected from the "pharmacogenomics assay" was maintained by RPRD Diagnostics, and the primary investigators had no direct access to student-specific laboratory results following current laws on privacy and confidentiality. Students were then provided their pharmacogenomics report (or a "virtual" copy of one if they did not consent to a pharmacogenomics assay) for analysis and in class discussions.

Statistical analyses were performed by R-software (version 4.0.0) using the RStudio platform (version 1.2.5042). All individual questions used a paired Wilcoxon signed-rank test to generate p-values and significance was set at a p-value under .05.

RESULTS

The student cohort shows a mainly young mean at 25 years of age, mostly female (60%) and mostly Caucasian (60%). Most students have a bachelor's degree (82%) and retail pharmacy experience (52%). All 45 students (100%) participated in the surveys and an overwhelming majority (89%, n=39) voluntarily participated in the personal pharmacogenomics testing.

Pharmacogenomics data were analyzed and the laboratory report provides three sets of data: 1) Actionable results with phenotype and gene activity for genes with CPIC guidelines, 2) Phenotype and gene activity for genes with known pharmacogenetic functions, but without CPIC guideline, and 3) Genotype calls for additional possibly pharmacogenetically relevant genes. Students were provided their personal data and given two weeks to review and understand their pharmacogenomics makeup. Our genetic testing was 100% focused on pharmacogenomics relevant genes (mostly drug metabolism genes). Indeed, we have analyzed sensitive genetic data that might raise anxiety or concerns from students (predisposition to disease, hidden diseases, family data and so forth) and no complaint has been submitted nor observed.

They were asked to select few markers of interest for discussion based on their and/or their relatives' medication history. All students' data were appropriately clustered to trigger active discussions in small groups of students in the course. Within each cluster, at least one major genetic polymorphism was identified that was later selected as a subject of discussion in small groups of four-six students and in whole class activities using CPIC guidelines and PharmGKB data. For example, CYP3A5 normal metabolizers (24% heterozygotes and 4.4% homozygotes) discussed tacrolimus dosing, CYP2C9 poor metabolizers (9%) analyzed warfarin dosing, CYP2C19 (24.4%) rapid metabolizers focused on clopidogrel susceptibility, and SLC01B1 decreased function (30%) analyzed the risk of rhabdomyolysis with statins. Other genetic variations and students' personal data were also discussed in both lecture classroom and in the additional Patient Care Laboratory course, that focuses on pharmacy practice counselling training. Specifically, one member of the class volunteered a personal family history related to heart disease and non-response to clopidogrel following surgery. Our genetic analysis showed that the student was a CYP2C19 poor metabolizer, thus can explain the inefficacy of clopidogrel. Furthermore, another student discussed their complicated response to an antidepressant that might be related to their CYP2D6 metabolism status.

Before joining the School of Pharmacy, students had not taken any pharmacogenomics course. They did take a basic science course in molecular biology and genetics during their first session in the PharmD program. Their first contact with pharmacogenomics started in the third session and was selected for this study. Therefore, we decided to assess their understanding of basic pharmacogenomics and the role of pharmacists using eight validated survey questions.[4] First, they were asked about their understanding of the risks associated with pharmacogenomics, 55.3% of students have little or no grasp of this concept before the course (pre-survey) and activities, this percentage dropped to 6.7% after completion of the course (post-survey) (Table 1). Similarly, the second question evaluated their knowledge about potential benefits of pharmacogenomics, and their understanding increased from 62% to 94%. Furthermore, for the following set of questions relating to testing and test results interpretation in a clinical pharmacy setting, their comprehension has increased from an overall average of 32% to 97% (Table 1). All responses were statically significant from pre-to-post survey administration (p<.001).

The next set of questions investigated students' confidence in conducting different aspects of pharmacogenomics consulting (Table 2). In terms of student's confidence in consulting patients, 77.8% students had little or no confidence in their ability to consult patients in the pre-survey and after the completion of the courses, this percentage dropped to 4.4% in the post-survey. Concerning the confidence to discuss results with physicians and other prescribers, student confidence increased from 22.2% to 97.8%. The last question assessed student confidence on the possibility of modifying a patient's medications based on pharmacogenomics test results. The perception jumped from 20% to 89%. Here too, all responses were statically significant from pre-to-post survey administration (p<.001).

The next group of questions assessed usefulness of pharmacogenomics testing (Table 3). The first question explored students' feeling about pharmacogenomics testing in the clinical setting. Their usefulness feeling increased non-significantly from 93% to 100%. The second question assessed their feeling about pharmacogenomics testing in the pharmacy setting. This increased from 84.4% to 100%, but also in a non-significant way.

Lastly, students answered questions on their attitude towards pharmacogenomics test results to the pharmacist's care of patients and the improvement was also non-significant as it increased from 88.9% to 100%. These results show that students were aware of the importance of genetic testing in disease and polymorphism diagnostics before participating in the course, mainly resulting from their introductory lectures in genetics and molecular biology early in the program thus explaining the absence of significance.

The final set of questions investigated students' comfort about their future readiness in pharmacogenomics prescription, analysis and counseling (Table 4). This set was the largest in our survey and included 13 questions exploring all aspects of pharmacy practice and future specialization in the area of pharmacogenomics. All but two questions of the 13 questions saw significant improvement from around 30% to over 90% (p<.001). However, the overall evaluation scores for the two questions in the pre-survey were very high and the improvement only slightly increased in the post-survey. These

two questions were: #13- "Pharmacogenomics is a useful tool that pharmacists and medical professionals can use to optimize medication efficacy and/or prevent adverse events," and #12- "Post-graduation, I intend to read up on pharmacogenomics especially on how it influences my practice and/or specialty." These results show that students were aware of the need of pharmacogenomics before participating in the course and most students in this cohort have plans to further their education in pharmacogenomics after graduation. Although with less statistical significance, their intentions in these areas have been reinforced after completing the course.

To assess objective data, in opposition to the subjective results of the survey, we compared student learning outcome (SLO) data from quizzes and exams using ExamSoft for this cohort of students in comparison to the previous two cohorts in the School of Pharmacy (Class of 2020 and 2021) that did not participate in this new activity in the course. The previous two cohorts did have the identical two-course sequence, material covered and instructor of record. The Class of 2022's SLO and overall course grades, although not statistically significant, show a trend to improvement (Grades: 79% ± 7.62% for 2020 class (n = 43), 79% ± 7.61% for 2021 class (n = 51), 82% ± 7.71% for 2022 class (n = 45); p = .08).

Students (n=6) that declined to participate in the pharmacogenomics testing, still received a mock report for analysis in the same conditions as the whole cohort. We then assessed their aggregate performance compared to the rest of the class and saw a significant improvement but to a lesser extent than the participating students (53% improvement versus 60.8% in the participating group; p = .036). However, because of the small size, these data need to be expanded and reanalyzed in future participating classes, assuming future likelihood of non-consenting students remains about the same.

DISCUSSION

Pharmacogenomics and personalized medicine have been a subject of interest for pharmaceutical and medical educators for over a decade. Several health science universities started implementing clinical pharmacogenomics with some success despite major investments.[6] Indeed, many studies have shown that medical and pharmacy students are not certain about including pharmacogenomics in their future practices despite having some knowledge.[4,5,6]

To facilitate this issue, we decided to start an innovative approach to teaching pharmacogenomics using several interactive courses and patient care laboratory training. Our study combined the benefit of a flipped classroom, active learning, standard lecture, patient care laboratory, and personal genetic data to increase student competencies in pharmacogenomics and personalized medicine. The flipped classroom focuses on critical thinking, independent active learning and engaged discussions among students and with teachers. This has previously been shown to increase learning outcome and competencies.[7] Similar studies were performed in elective courses or in post graduate programs (e.g., MS degree, post-graduate residency) with only a portion of the class.[3,8,9] In contrast, our study used an entire PharmD class of students participating in major required courses. By selecting the whole class in a required course, we have minimized potential biases and overestimations resulting from using only highly motivated students that opted for an elective course and who may already have strong feelings about this area of interest as performed by these studies.

Expanding pharmacogenomics education, using competency-based, knowledge-based or other students and course learning objectives, has been explored to improve patient care using therapeutic regimen optimization based on genetic makeup. Furthermore, several published studies have not assessed competency,[8,10] whereas our current study tried to implement several learning processes including personal genetic testing to simulate a real-life scenario of patient care competencies. Our data delivers strong evidence that the combination of several activities improves student's confidence and comfort towards implementing personalized medicine approach to their training and future practice. This improvement has clearly increased by the addition of personalized analysis of their own genetic status relative to pharmacogenomics as shown by the shifts in responses from the pre-survey to the post-survey exploration. The opportunity for students to voluntarily highlight personal anecdotes related to gene-drug parings, has value in bringing the relevance to the clinical utility of pharmacogenomics. With respect to assessment, participant examination performance compared to the previous cohorts of students that did not have this activity but had all other content delivered in the same way, also improved.

By analyzing and discussing their own pharmacogenomic results in relation to different medication susceptibilities and counselling each other, these activities have increased their interest and level of confidence into incorporating personalized medicine into their future practice. Similar results were also observed in other studies,[10,11] although they used other active learning approaches. In agreement with several studies,[2,3,9] competencies and learning outcomes related to pharmacogenomics have seen the greatest improvement or shift into agreement for almost all surveyed questions in each of the four groups of questions seen. Six students that declined to participate in the genetic testing, were provided a mock report and participated similarly to the other students. Their survey data were relatively similar than the rest of the class suggesting that both active and passive participation had an impact on students' perception on incorporating pharmacogenomics in their learning but using genetic data.

Questions related to the use of CPIC evidence-based guidelines have also seen the best improvement in the response from students between the pre- and post-survey, as students' confidence in conducting pharmacogenomics consulting

improved dramatically. Moreover, the last set of questions clearly demonstrated that students were aware of the importance of pharmacogenomics in the future of pharmacy practice as shown by their answers in the pre-survey even though they had not yet taken the required course. This awareness has been further imprinted after participating in the study as shown by their results in the post-survey. Indeed, as our results indicate, our pharmacy students at the Medical College of Wisconsin School of Pharmacy are highly considering utilizing of pharmacogenomics testing to alter and optimize patients' therapies as well as counselling and educating them in respect of the laws covering confidentiality and ethics. Given the demographics of our pharmacy student are comparable to others in pharmacy education (2019 PharmCAS data report), one might anticipate similar results, if provided similar instruction, instructional delivery and intervention with students using their own pharmacogenomics testing results.

By comparing assessment and comfort data with previous years, it was shown that adding different active learning strategies alongside with this laboratory exercise might be needed to increase learning and retention. Moreover, in agreement with recent publications,[5,8] our study provides a foundation that introducing pharmacogenomics in a learned centric model, may have an enormous impact on students' readiness to use pharmacogenomics in personalized medicine in clinical practice. Based on these findings, we are planning to expand these active learning activities on pharmacogenomics to all future pharmacy students and to medical students of MCW. We too plan to keep surveying student pharmacists to assess the evolution of their attitude and perception of pharmacogenomics counselling throughout the PharmD curriculum.

LIMITATIONS

Given the nature of the pre- and post-surveys administered to students, there is the possibility of response-shift bias, that may result in inaccurate pretest ratings. An attempt to reduce response shift bias is to ask subjects to give a renewed judgment of their pre-program level of functioning following the post-test. Unfortunately, a "retrospective-pretest" following the post-survey was not performed in this study.

CONCLUSION

Our study supports a combination of didactic lectures, practice laboratory counseling activities, and group discussions, coupled with student-specific personal pharmacogenomics testing, to improve learning, interest, confidence and comfort of students learning pharmacogenomics. An innovative teaching structure including pharmacogenomics assay will help prepare future pharmacists with the skills, competencies and confidence to implement a personalized medicine practice with the emerging area of pharmacogenomics.

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Table 1. Student' Understanding of Basic Pharmacogenomics and Role of the Pharmacist in Personalized Medicine

Survey question	Pre-Survey Mean (SD)	Post-Survey Mean (SD)
The risks of pharmacogenomic testing	2.56 (1.18)	3.78 (0.82)
The benefits of pharmacogenomic testing	2.91 (1.16)	4.13 (0.73)
How to interpret pharmacogenomic testing results	1.76 (0.80)	3.73 (0.75)
How pharmacogenomic test results are used in clinical practice	2.4 (0.99)	3.89 (0.72)
The purpose of preemptive pharmacogenomic testing	2.37 (1.07)	4.07 (0.73)
The purpose of reactive pharmacogenomic testing	2.16 (1.13)	3.98 (0.72)
The role of pharmacists in collecting patient samples/specimens for pharmacogenomic testing	2.2 (1.12)	3.87 (0.84)
The role of pharmacists in interpreting pharmacogenomic testing results	2.11 (0.96)	4.04 (0.74)

Survey questions were evaluated using a 5-point Likert scale: 1 = no understanding, 2 = little understanding, 3 = average understanding, 4 = above average understanding, and 5 = thorough understanding.
All individual questions used a paired Wilcoxon signed-rank test to generate p-values.
All results are significant at a $p<.001$.
SD: Standard deviation.

Table 2. Students' Confidence in Conducting Different Aspects of Pharmacogenomics Consulting

Survey question	Pre-Survey Mean (SD)	Post-Survey Mean (SD)
How confident would you feel explaining pharmacogenomic test results to a patient?	1.76 (0.91)	3.8 (0.69)
How confident would you feel discussing pharmacogenomic test results with physicians and other prescribers?	1.69 (1)	3.76 (0.68)
How confident would you feel modifying a patient's medications (that may include changing a medication) based on pharmacogenomic test results?	1.86 (0.86)	3.6 (0.69)

Survey questions were evaluated using a 5-point Likert scale: 1= extremely not confident, 2 = not confident, 3 = neutral, 4 = confident, and 5 = extremely confident.
All individual questions used a paired Wilcoxon signed-rank test to generate p-values.
All results are significant at the $p<.001$.
SD: Standard deviation.

Table 3: Students' Perception of Usefulness of Pharmacogenomics Testing

Survey question	Pre-Survey Mean (SD)	Post-Survey Mean (SD)
In general, how useful do you feel pharmacogenomic testing will be in the clinical setting?	4.04 (1.3)	4.51 (0.73)
In general, how useful do you feel pharmacogenomic testing will be in the pharmacy setting?	3.8 (1.44)	4.4 (0.75)
In general, how useful do you feel pharmacogenomic test results are to the pharmacist's care of patients?	3.8 (1.47)	4.53 (0.73)

Survey questions were evaluated using a 5-point Likert scale: 1 = extremely not useful, 2 = not useful, 3 = neutral, 4 = useful, and 5 = extremely useful.
All individual questions used a paired Wilcoxon signed-rank test to generate p-values.
All results were not significant.
SD: Standard deviation.

Table 4: Students' Comfort About Their Future Readiness in Pharmacogenomics Prescription, Analysis and Counseling

Survey question	Pre-Survey Mean (SD)	Post-Survey Mean (SD)
I would feel comfortable ordering pharmacogenomic testing	2.84 (1.21)	3.71 (0.59) **
I would feel comfortable explaining the process of pharmacogenomic testing to patients	2.38 (1.05)	3.96 (0.60) **
I would feel comfortable discussing pharmacogenomic test results with patients	2.24 (1.05)	3.96 (0.64) **
I believe that pharmacogenomic testing is critical for determining appropriate healthcare	3.29 (1.14)	4.02 (0.66) **
I would feel comfortable discussing genetics in general with patients	2.91 (0.98)	3.91 (0.68) **
I believe that pharmacogenomic testing is critical for determining appropriate medication selection and regimens (dose and frequency) in patients	3.44 (1.14)	3.91 (0.63) *
I would feel comfortable discussing pharmacogenomic test results with physicians and other prescribers	2.29 (0.99)	3.82 (0.65) **
I would feel comfortable modifying a patient's medications (that may include changing a medication) based on pharmacogenomic test results	2.27 (1.12)	3.80 (0.69) **
Pharmacogenomics is an integral part of the pharmacy profession	3.36 (1.05)	4.00 (0.71) **
Pharmacogenomics may be an integral part of my practice as a pharmacist	3.49 (1.01)	4.02 (0.75) **
I may encounter pharmacogenomics-related questions during my practice as a pharmacist	3.61 (0.87)	4.00 (0.60) *
Post-graduation, I intend to read up on pharmacogenomics especially on how it influences my practice and/or specialty	3.58 (0.97)	3.93 (0.65)
Pharmacogenomics is a useful tool that pharmacists and medical professionals can use to optimize medication efficacy and/or prevent adverse events	3.77 (0.93)	4.09 (0.63)

Survey questions were evaluated using a 5-point Likert scale: 1 = strongly disagree, 2 = disagree, 3 = neither disagree or agree, 4 = agree, and 5 = strongly agree.
All individual questions used a paired Wilcoxon signed-rank test to generate p-values.
** $p<.001$.
* $p<.05$.
SD: Standard deviation.