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Community pharmacists' attitudes towards clinical utility and ethical implications of pharmacogenetic testing

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Abstract

Aim—To examine community pharmacists' attitudes towards pharmacogenetic (PGx) testing, including their views of the clinical utility of PGx and the ethical, social, legal and practical implications of PGx testing.

Methods—A web-based survey administered to 5600 licensed community pharmacists in the states of Ohio and Pennsylvania (USA).

Results—Of 580 respondents, 78% had a Bachelor of Science degree in pharmacy and 58% worked in a chain drug store. Doctors of pharmacy-trained pharmacists had a significantly higher knowledge score than those with a Bachelor of Science in pharmacy (3.2 ± 0.9 vs 2.6 ± 0.6; $p < 0.0001$). All pharmacists had positive attitudes towards PGx and most (87%) felt it would decrease the number of adverse events, and optimize drug dosing. More than half (57%) of pharmacists felt that it was their role to counsel patients regarding PGx information. Many (65%) were concerned that PGx test results may be used to deny health insurance.

Conclusion—Regardless of the type of education, all pharmacists had positive attitudes towards PGx. There is still a concern among pharmacists that PGx test results may be used to deny health insurance and, thus, there is a need to educate pharmacists about legal protections prohibiting certain forms of unfair discrimination based on genotype.

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Ethical conduct of research
The authors state that they have obtained appropriate institutional review board approval or have followed the principles outlined in the Declaration of Helsinki for all human or animal experimental investigations. In addition, for investigations involving human subjects, informed consent has been obtained from the participants involved.

Keywords

community pharmacy; ethics; genetic testing; personalized medicine; pharmacists; pharmacogenetics; pharmacogenomics

Tremendous progress has been made over the last decade in the field of pharmacogenomics, or the study of the genetic basis for variations in drug response. Pharmacogenomics holds the promise of improving drug dosing and preventing harmful adverse drug events. While the US FDA has modified over 100 drug labels to include genetic information, the application of genetic information to the clinical use of drugs or pharmacogenetics (PGx) has been slow to be implemented into patient care [1,101]. One of the major barriers to implementation is the acceptance of PGx tests by healthcare providers.

Pharmacists, as medication experts, routinely interface with patients and providers in providing medication education, selecting and monitoring drug therapy for patients, and ensuring safe and appropriate use of therapies [2]. Pharmacists could therefore play an important role in the integration of genotype-guided drug therapy into routine practice, but they must be knowledgeable about PGx and be willing to communicate PGx information to the patient.

Lack of provider knowledge and confidence in applying genetic information to clinical care has been previously documented, and represents a major barrier to the acceptance of PGx tests in practice [3–7]. The need for enhanced genetics education has been acknowledged by educators since the early 2000s and is included in the core competencies outlined by the National Coalition for Health Professionals Education in Genetics and recommendations from the American Association of Colleges of Pharmacy Academic Affairs committee and the International Society of Pharmacogenomics [7,8,102]. The release of standards and guidelines from the Accreditation Council for Pharmacy Education in 2007 resulted in pharmacogenomics education being integrated into the curricula of most colleges of pharmacy in the USA [9,103].

Since PGx has been a recent addition to pharmacy school curricula, many pharmacy practitioners working in the community setting who have not been exposed to PGx information may encounter patients prescribed medications that require an understanding of PGx principles. For example, carriers of the *HLA-B*57:01* variant are at significant risk of abacavir-induced hypersensitivity reaction and therefore pharmacists should recommend screening for this variant prior to initiation of therapy with abacavir to prevent a serious adverse event [10]. Given the anticipated diffusion of PGx testing into clinical care through Clinical Laboratory Improvement Amendments-certified laboratories and the availability of PGx testing in genomic tests sold directly to consumers, it is important that all pharmacists be prepared to interpret and apply genetic information to the tailoring of medication therapy [104].

The clinical uptake of PGx testing is likely to be influenced by a provider's attitude and acceptance of PGx; however, few studies have examined pharmacists' attitudes towards PGx testing [3,11–14]. Importantly, it is unknown how community pharmacists feel about PGx testing and counseling patients about PGx test results. Direct patient access to community pharmacists, as compared with pharmacists working in hospital settings, makes them an ideal healthcare provider in guiding consumers about the appropriate use of their medications, including the application of PGx information to better individualize patient therapy.

Methods

A web-based survey tool was developed by adapting previous surveys on PGx and pharmacists [12,13]. The online survey was field tested by four community pharmacists chosen for convenience who were not involved in the study. The survey included six socio–demographic background questions, five knowledge questions, 11 questions concerning attitudes toward PGx testing, five questions concerning the ethics of PGx testing, two questions regarding counseling of patients and two questions regarding the direct-to-consumer (DTC) genomewide profile testing (e.g., 23andMe [23andMe Inc., CA, USA], Pathway Genomics [Pathway Genomics, CA, USA] and deCODEme [deCODE Genetics, Reykjavik, Iceland]). In addition, an open-ended question was included to solicit comments about PGx.

The study was approved by the University of Pennsylvania Institutional Review Board. An email invitation with a link to the online survey through the web-based survey tool, Survey Monkey (CA, USA), was distributed to 4500 community pharmacists in Ohio. The list of recipients was acquired through the Ohio Board of Pharmacy and sent to those pharmacists that specifically listed community pharmacy (either chain drug store or independent pharmacy) as their area of practice. In addition, 1100 email invitations were sent through the Pennsylvania Pharmacist Association to pharmacists who indicated that they practiced in the community setting. Survey participants were offered the chance to win one of ten US$100 Amazon gift cards as an incentive for completing the survey. Two reminder emails were sent out spaced 2 weeks apart. The survey was distributed in December 2011 and closed in February 2012. Responses originating from the same IP address with the same demographic information were removed from analysis.

Attitude and ethics questions were asked on a Likert scale with 5 = strongly agree, 4 = agree, 3 = neither agree nor disagree, 2 = disagree and 1 = strongly disagree. Knowledge regarding PGx was assessed using true/false questions, as previously published [13], with the option of answering “do not know.” Descriptive statistics were generated for the survey participants as a whole and by type of pharmacy education: Bachelor of Science (BS) versus doctor of pharmacy (PharmD). A knowledge score was derived as the number of knowledge questions answered correctly out of five and compared by type of pharmacy education using a Student’s t-test. Attitudes were compared by type of pharmacy education using Pearson’s χ^2 test. Statistical analyses were performed using STATA version 12.1 (StataCorp LP, TX, USA).

Results

A total of 611 pharmacists began the survey, yielding an 11% response rate, with 580 completing the majority of the questions. The demographics of the participants are listed in Table 1. The majority of respondents received a BS degree in pharmacy and worked in a chain drug store setting. There were significant differences in age and years since graduation based on type of pharmacy education. Survey participants with a PharmD degree were younger and had fewer years since graduation than participants with a BS degree in pharmacy. There were no significant demographic differences between the Ohio and Pennsylvania pharmacists, so the responses were combined for analysis.

We assessed actual knowledge of PGx utilizing five true and false knowledge questions. The questions and responses are shown in Table 2. The average knowledge score for all participants, derived as the number of questions correct out of five, was 2.8 ± 0.5. When comparing pharmacists with a PharmD education versus those with a BS in pharmacy, PharmD-trained pharmacists had a significantly higher knowledge score (3.2 ± 0.9 vs 2.6 ±

0.6; $p < 0.0001$). Pharmacists graduating in the past 10 years also had a higher knowledge score than those graduating >30 years ago (3.1 ± 1.1 vs 2.7 ± 1.2; $p = 0.03$). PharmD-trained pharmacists also reported greater PGx knowledge as determined by self-assessed knowledge (Table 3). Those responding strongly agree and agree to the self-assessed knowledge questions in Table 3 had a significantly higher knowledge score (3.0 ± 1.2 vs 2.6 ± 1.2; $p = 0.002$), indicating that perceived knowledge was a good indicator of actual knowledge.

There were no differences in attitudes towards PGx by education type, so we reported the overall responses (Table 4). The overwhelming majority of pharmacists agreed that PGx testing would be associated with perceived benefits such as decreased adverse events, optimized drug dosing and improved efficacy. The majority of respondents agreed that part of a pharmacist's role should include counseling patients regarding PGx information and viewed it as a natural extension of medication counseling they already provided. However, 68% indicated that they did not have the tools accessible to them in the pharmacy to assist in PGx counseling. We also asked about the best way to communicate to patients about PGx and 91% agreed that one-on-one counseling would be the most desired method of communication.

There were no differences regarding the ethics of PGx testing by education type, so we reported the overall responses (Table 5). Pharmacists seemed comfortable utilizing PGx information to determine a patient's drug therapy and unconcerned about submitting their own DNA for PGx testing. There was still concern that PGx test results may be used to deny healthcare coverage.

We asked pharmacists about their exposure to DTC genomewide profile testing through two questions:

- What is your experience with DTC genome-wide profile testing?
- Has a patient ever discussed their results from DTC genomewide testing with you?

The majority of pharmacists (61%) were unaware of DTC genomic testing and only 1% had ever had a patient discuss their results from DTC testing with them.

Discussion

Pharmacists will likely be expected to apply results from PGx tests to optimizing drug therapy, regardless of their practice environment [15]. The focus of this study was to assess pharmacists' knowledge of and attitudes towards the application of PGx in the community practice setting. Since community pharmacists interface at the point of medication dispensing, they have a unique opportunity to apply PGx information to the tailoring of medication regimens. Indeed, there are efforts underway to assess the feasibility of providing PGx testing in a community pharmacy in North Carolina using clopidogrel as an example [16].

Few studies have assessed community pharmacists' attitudes toward PGx [12,14,17]. We found that, regardless of education type, most pharmacists hold positive attitudes towards the perceived benefits of PGx, and 57% agreed that part of their role should include counseling patients regarding PGx information, primarily through one-on-one counseling with a pharmacist. In 2003, Sansgiry and Kulkarni reported on pharmacists' perception of their roles following the completion of the Human Genome Project in a survey of 377 community pharmacists in Houston, TX (USA) [14]. Most pharmacists agreed that genetic information would identify patients who would respond to drug therapy and that pharmacists would spend more time counseling patients regarding PGx information. Agreement

regarding the role of pharmacists in providing PGx information was echoed in the study by McCullough *et al.*, where 67% of their survey respondents agreed that pharmacists should be able to provide information regarding PGx testing [12]. Although their study was conducted in a large academic healthcare system, 22% of the respondents practiced in community healthcare settings. In a more recent study of 284 pharmacists in Quebec (Canada), where 60% of respondents practiced in the community setting, 96% of pharmacists indicated that they would be willing to recommend the use of a PGx test to their patients if the test could predict drug efficacy [17]. Together, these studies suggest that there is great interest in PGx among community pharmacists' and a willingness to counsel patients regarding PGx test results.

Consistent with previous studies assessing pharmacists confidence and knowledge about PGx [12–14,17], less than one-fifth of respondents in our survey agreed that they felt competent in their knowledge about PGx. In the present study, we measured both actual and perceived knowledge, and ascertained that there was consistency between the two. Not surprisingly, those with a PharmD education scored better on both the actual and perceived knowledge questions, since PharmD-educated pharmacists had fewer years since graduation and the Accreditation Council for Pharmacy Education requirements regarding education about PGx did not go into effect until 2007. Thus, the type of education (PharmD vs BS) may actually serve as a surrogate for time since graduation. Knowledge scores measured in our study were lower than in the study by Roederer *et al.*, with a lower percentage of participants correctly answering the PGx knowledge questions [13]. Our study contained more BS-trained pharmacists and had a higher proportion of distant graduates from pharmacy school. The pharmacy practice setting for the participants was not reported in the Roederer study, but their sample did contain respondents who were faculty members or educators, and these demographic differences likely explain the difference in PGx knowledge. In a recent survey of US physicians by Stanek and colleagues, 98% of physicians believed that genetics may influence a patient's response to drug therapy; however, only 10% felt that they were adequately informed about PGx [18]. Physicians who felt adequately informed were twice as likely to have ordered or plan on ordering (within the next 6 months) a PGx test. Therefore, training and education of all healthcare providers will play an important role in accelerating the use of PGx in clinical practice. Clinical guidelines and recommendations such as those published by the Clinical Pharmacogenetics Implementation Consortium [19,105] and Translational Pharmacogenomics Program [20] will provide important resources for evidence-based application of PGx and will address the lack of information providers feel that they have when ordering PGx tests.

We also evaluated community pharmacists' attitudes towards the ethical implications of genetic testing. Attitudes towards the ethics surrounding PGx were not different by education type. The majority of pharmacists were concerned that insurance companies may use PGx test results to deny healthcare coverage. While the Genetic Information Nondiscrimination Act (GINA) was signed into law by President George W Bush on May 21, 2008 [106], there seems to be a lack of understanding of protections afforded by GINA. GINA prohibits discrimination by health insurance companies and employers based on genetic information, including genetic test results of patients and the relatives of patients. Under GINA, genetic information cannot be considered a pre-existing condition and group and individual health insurers cannot use genetic information to set eligibility or premium amounts [107]. Future surveys regarding provider attitudes towards PGx conducted in the USA should include a question regarding the awareness of GINA, which may help clarify concerns surrounding denial of healthcare coverage. In addition, future training of pharmacists should include a focus on ethical issues, as these concerns will affect the uptake of genetic tests into clinical practice.

We also asked pharmacists about their exposure to DTC genomewide profiling. DTC testing can provide information about a person's genetic risk of development of dozens of common polygenic diseases, in addition to variants that affect drug response [21]. Although 40% of pharmacists were aware of DTC genetic testing, only five (1%) pharmacists had ever had a patient discuss results from DTC testing with them. DTC testing is available to consumers for purchase from the internet; however, interest by the consumer is probably limited at this time due to the cost, which currently ranges from US$99 to US$2000 [108–110]. However, as the cost of these tests is expected to decrease in the future, we can speculate that more patients who chose testing may need help interpreting and applying the results.

Limitations

We acknowledge several limitations of our study, including a small sample size and low response rate. For the Pennsylvania cohort, we invited members of the Pennsylvania Pharmacists Association, which may have biased the participant type to those that are more actively engaged in issues concerning the practice of pharmacy, meaning that it is not representative of the attitudes of all community pharmacists practicing in Pennsylvania. For the Ohio cohort, we invited all licensed pharmacists in the state of Ohio who indicated that they practiced in a community setting. The demographics of the survey completers were similar to the demographics of all community pharmacists in Ohio, except that our survey participants contained a higher proportion of community pharmacists with a PharmD degree (22 vs 13%; $p < 0.001$). Although a small portion of our survey respondents did not work in community pharmacies (16%), this is the largest survey focusing specifically on community pharmacists that has assessed knowledge and attitudes towards PGx testing. Our response rate (11%) was similar to other large surveys assessing knowledge and attitudes among pharmacists in North Carolina (8%) and Quebec (7%) [13,17]. There is a risk of response bias with a survey of this type. Pharmacists who took the time to participate in the study may have already had a positive attitude towards the clinical utility of PGx. Therefore, future studies of this type should focus on methods to ensure higher response rates. In addition, we did not specifically ask about previous PGx or genetics training in our study, as this may directly impact provider attitudes and knowledge about PGx [18].

Conclusion

Community pharmacists responding to this survey generally had a positive attitude towards PGx testing and seemed willing to counsel patients regarding PGx test results, but needed more training in this area. There is still a concern among pharmacists that PGx test results may be used to deny healthcare coverage and thus there is a need to educate healthcare professionals about privacy and legal issues surrounding genetic testing.

Future perspective

Community pharmacists play an important role in counseling patients about the appropriate use of their medications and will probably have the technology available to incorporate PGx information to better individualize patient therapy. Most pharmacists, regardless of type of pharmacy education, have a positive view of the role PGx will play in improving medication outcomes. The majority of pharmacists are still concerned that PGx test results may be used to deny healthcare coverage. Additional efforts must be paid to educating community pharmacists to increase their knowledge of PGx and provide tools in the pharmacy to assist with counseling patients regarding PGx test results. When developing resources to educate community pharmacists about PGx, it is important to include information concerning the ethical implications regarding PGx testing, emphasizing legal protections prohibiting discrimination based on genetic test results.

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Executive summary

Background

- Community pharmacists will be required to apply pharmacogenetics (PGx) knowledge to tailoring of medication; however, their attitudes towards PGx are not well established.

Methods

- A web-based survey of community pharmacists from Ohio (USA) and Pennsylvania (USA) was conducted to ascertain pharmacists' knowledge and attitudes towards PGx.

Results

- Community pharmacists with a doctor of pharmacy degree reported greater PGx knowledge than pharmacists with a bachelor's degree, as determined by both measured and self-assessed knowledge.
- Although the response rate was low (11%), the study revealed that, regardless of education type, most community pharmacists held positive views about the clinical utility of PGx. Community pharmacists felt that PGx testing would:
  - Optimize drug dosing;
  - Improve drug efficacy;
  - Decrease the number of adverse events.
- Most community pharmacists felt it was the pharmacist's role to counsel patients regarding PGx test results.
- However, community pharmacists will require further training in the area of PGx.
- Additionally, most community pharmacies are not equipped with the necessary resources to provide counseling regarding PGx.
- Further education is required regarding the ethics of PGx testing.
- Community pharmacists were comfortable having pharmacogenetic information used to determine a patient's drug therapy, and even comfortable submitting their own DNA for PGx testing.
- There is concern among most community pharmacists that insurance companies may use pharmacogenetic test results to deny healthcare coverage.
- One area of educational emphasis for community pharmacists in the future should focus on further explaining legal protections prohibiting discrimination based on genetic test results.

Table 1

Demographics of survey participants (n = 580).

Characteristics	Total; n (%)†	BS-trained; n (%)	PharmD-trained; n (%)
Gender*			
Male	297 (52)	252 (56)	45 (35)
Female	272 (47)	191 (43)	81 (64)
Unknown	5 (1)	4 (1)	1 (0.8)
Age category*			
20–30	56 (10)	2 (0.4)	54 (43)
31–40	126 (22)	73 (16)	53 (42)
41–50	156 (27)	144 (32)	12 (9)
51–60	145 (25)	140 (31)	5 (4)
61+	90 (16)	88 (20)	2 (2)
Unknown	4 (0.7)	3 (0.7)	1 (0.8)
Years since graduation*			
0–4	11 (2)	0	11 (9)
5–9	91 (16)	7 (2)	84 (66)
10–19	132 (23)	112 (25)	20 (16)
20–29	135 (23)	129 (28)	6 (5)
≥30	211 (36)	205 (45)	6 (5)
Primary work setting*			
Chain drug store	347 (58)	268 (59)	71 (56)
Independent pharmacy	153 (26)	124 (27)	22 (17)
Community hospital	21 (4)	12 (3)	9 (7)
Other	74 (12)	49 (11)	25 (20)
Primary role*			
Staff pharmacist	298 (50)	225 (50)	64 (50)
Pharmacist in charge	205 (34)	174 (39)	26 (20)
Manager	29 (5)	21 (5)	8 (6)
Clinical pharmacist	28 (5)	5 (1)	21 (17)
Other	36 (6)	28 (6)	8 (6)

BS-trained pharmacists n = 453 (78%).

PharmD-trained pharmacists n = 127 (22%).

*$p < 0.01$, comparing BS- versus PharmD-trained pharmacists.

†Not every participant answered every question, so not all add up to 580.

BS: Bachelor of Science; PharmD: Doctor of Pharmacy.

Table 2

Questions assessing pharmacogenomics knowledge[†].

Questions assessing knowledge	Correct answer	Answering 'correct'; n (%)	Answering 'incorrect'; n (%)	Answering 'do not know'; n (%)
Subtle differences in a person's genome can have a major impact on how the person responds to medications	True	539 (93)	0 (0)	41 (7)
Genetic determinants of drug response change over a person's lifetime	False	155 (27)	234 (40)	191 (33)
Genetic variations can account for as much as 95% of the variability in a drug disposition and effects	True	305 (53)	48 (8)	227 (39)
The package insert for warfarin includes a warning about altered metabolism in individuals who have specific genetic variants	True	268 (46)	37 (6)	275 (47)
Pharmacogenetic diagnostic testing is currently available for most medications	False	331 (57)	28 (5)	221 (38)

[†]Knowledge questions adapted from [13].

Table 3

Self-assessed knowledge by type of pharmacy education[†‡].

Statements	Education type	Agree; n (%)	Neutral; n (%)	Disagree; n (%)
I believe I am competent to discuss pharmacogenetic information with other healthcare providers (e.g., physicians, nurses and physician assistants)	BS	67 (15)	81 (19)	287 (66)
	PharmD	23 (19)	25 (21)	73 (60)
I can identify medications for which pharmacogenetic testing is recommended[*]	BS	49 (11)	88 (20)	298 (68)
	PharmD	36 (30)	20 (17)	65 (54)
My pharmacy training has prepared me to discuss pharmacogenetic information with patients[**]	BS	40 (9)	80 (18)	315 (72)
	PharmD	21 (17)	26 (21)	74 (61)

[*] $p < 0.001$, comparing BS- versus PharmD-trained pharmacists.

[**] $p = 0.06$, comparing BS- versus PharmD-trained pharmacists.

[†] Strongly agree/agree collapsed into one category; strongly disagree/disagree collapsed into one category.

[‡] Not every participant answered every question, so not all add up to 580.

BS: Bachelor of Science; PharmD: Doctor of Pharmacy.

Table 4

Attitudes towards pharmacogenetic testing[†‡].

Statements	Agree; n (%)	Neutral; n (%)	Disagree; n (%)
Pharmacogenetic testing will help to decrease the number of adverse events patients experience due to their drug therapy	483 (87)	60 (11)	13 (2)
Pharmacogenetic testing will help to optimize drug dosing	482 (87)	67 (12)	7 (1)
Pharmacogenetic testing will help to improve drug efficacy	478 (86)	72 (13)	6 (1)
Pharmacogenetics is relevant to my practice setting	246 (44)	198 (36)	112 (20)
Learning more about pharmacogenetic testing would be a top priority for my immediate educational needs	285 (51)	202 (36)	69 (12)
Part of a pharmacist's role should include counseling patients regarding pharmacogenetic information	319 (57)	200 (36)	37 (7)
I have the ability to access pharmacogenetic information in my pharmacy to help me with patient counseling	70 (12)	109 (20)	377 (68)
The best way for pharmacists to be aware of drug–gene interactions is through computerized alerts, similar to the way drug–drug interactions are flagged today	409 (74)	111 (20)	36 (6)
Counseling patients regarding pharmacogenetic test results would be a natural extension of medication counseling I currently provide in my pharmacy	394 (75)	102 (19)	31 (6)

[†]Strongly agree/agree collapsed into one category; strongly disagree/disagree collapsed into one category.

[‡]Not every participant answered every question, so not all add up to 580.

Table 5

Questions regarding ethics of pharmacogenetic testing[†‡].

Statements	Agree; n (%)	Neutral; n (%)	Disagree; n (%)
I would be comfortable with having pharmacogenetic information used to determine a patient's drug therapy	397 (73)	115 (21)	33 (6)
Counseling patients regarding pharmacogenetic test results is more sensitive than medication counseling	309 (57)	133 (24)	103 (19)
I am concerned that pharmacogenetic test results may be accessed by unauthorized persons	145 (27)	184 (34)	216 (40)
I am concerned that insurance companies may use pharmacogenetic test results to deny healthcare coverage	353 (65)	135 (25)	57 (10)
I would be concerned about submitting a DNA sample to analyze my own pharmacogenetic profile	132 (24)	165 (30)	248 (46)

[†]Strongly agree/agree collapsed into one category; strongly disagree/disagree collapsed into one category.

[‡]Not every participant answered every question, so not all add up to 580.