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## Survey of Genetic Counselors and Clinical Geneticists' Use and Attitudes Towards Pharmacogenetic Testing

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### Abstract

Pharmacogenetic (PGx) testing aims to improve therapeutic outcomes through tailoring treatment based on a patient's genetic risk for non-response and/or an adverse event. Given their expertise, geneticists could facilitate the use of PGx testing; however, the preparedness and perceived role of the clinical genetics community is unclear. To assess the attitudes, preparedness, and perceived roles of geneticists in the delivery of PGx testing, we conducted a survey of 1500 randomly selected board-certified genetic counselors and clinical geneticists in the U.S (response rate: 37.8% (n=516)). Twelve percent of genetic counselors and 41% of clinical geneticists indicated that they had ordered or coordinated patient care for PGx testing, a seemingly high proportion at this early stage of adoption. Almost all respondents had some education on pharmacogenetics, though only 28% of counselors and 58% of clinical geneticists indicated they felt well-informed about PGx testing. About half of counselors (52%) and clinical geneticists (46%) felt they would play 'some' role in the delivery of PGx testing; 17% and 19%, respectively, felt that they would play 'no' or 'a little' role. At this early stage of PGx testing, the role of geneticists and genetic counselors is unclear. However, their experience may aid in readying PGx testing and informing delivery strategies into clinical practice.

### Keywords

pharmacogenetic testing; survey; attitudes; clinical uptake

### INTRODUCTION

Drug developers and health professionals have long been aware of the heterogeneity in drug response, often due to a combination of factors associated with disease type, co-morbidities, poly-pharmacy and unique patient characteristics. Several genetic variations associated with adverse responses or likelihood to respond have been identified (1), yielding a new group of clinical tests known as pharmacogenetic (PGx) tests aimed to improve drug treatment outcomes (2,3). The wide range of drugs that now include information in the labels about the

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effects of genetic variation on treatment outcome or risk of adverse response (4) demonstrates the rapid growth of the field and applicability across multiple medical specialties.

Despite advances in pharmacogenetics, the translation of these new tests to clinical practice is variable (5). The slower uptake may be due to unfamiliarity about the appropriate use of these tests, lack of robust evidence of clinical utility or recommendations for test use, concerns about reimbursement, ethical concerns and unfamiliarity with genetic testing in general (6–12). The use of PGx testing is also unclear with respect to issues of informed consent and the storage and portability of test results.

While any prescribing clinician may order a PGx test, the use of PGx testing currently appears to be limited to experts of a particular drug target or disease (5, 13–14). The role of other medical specialists, namely geneticists and pharmacists, is unclear. While clinical genetic laboratorians and researchers may be involved in the development of PGx tests, including the discovery and link to a drug-related phenotype, it is unclear what role geneticists and genetic counselors may play, if any, in the delivery of PGx testing in clinical care. Given their knowledge and experience in the provision, counseling and interpretation of genetic testing for disease diagnosis and prediction, geneticists and genetic counselors would appear to be a valuable resource in guiding the use of these tests, which are based on inherited variants that often have implications for more than one drug and may potentially imply disease risks as well (15).

No research has been conducted to ascertain geneticists and genetic counselors' attitudes and their role regarding the delivery of PGx tests. Therefore, we conducted a survey to assess their experience with and training about PGx testing and views on issues related to the delivery of PGx tests. This includes views on the appropriate roles for geneticists, genetic counselors and other health professionals, informed consent, and reporting results. These data can help identify potential challenges of translating PGx testing into clinical practice as well as suggest professional roles and guidelines to support clinical use of PGx testing.

## MATERIALS AND METHODS

### Survey Development

The survey was developed through a collaborative effort between investigators at Duke University's Institute for Genome Sciences & Policy and the Survey Research Unit at the University of North Carolina, Chapel Hill. The survey questions were based on a literature review, data collected from three groups of health professionals including geneticists and genetic counselors (11), and a legal analysis of managing incidental findings from PGx testing. The reporting of geneticist attitudes towards PGx testing with incidental findings will be published separately.

### Survey Pre-testing

To evaluate understandability and the ability of respondents to complete the questions as intended, a panel of clinical geneticists and genetic counselors pre-tested the survey through an online evaluation noting confusing questions and ambiguous terms and reporting confidence in answering questions accurately. The resulting survey was comprised of 7 major parts, totaling 101 questions: 1) demographics; 2) background information on clinical practice; 3) knowledge of PGx testing and preferred educational sources; 4) experience with PGx testing; 5) attitudes towards determining clinical value of a PGx test; 6) provider preferences and practices with incidental risk information revealed by a PGx test; and 7) provider preferences, actions, decisions and obligations regarding PGx testing with and

without incidental information. The majority of questions used a 5-point Likert scale to assess levels of likelihood, interest or, agreement with certain statements.

### Sampling methods

A total of 1,500 names were randomly selected from the population of genetic counselors (n=1,946) and clinical geneticists (n=1,053) obtained from the American Board of Genetic Counselors and the American Board of Medical Genetics, respectively (750 per group). The only available information on the frames were names, addresses, and phone numbers. The samples were stratified by census regions to ensure representation from the midwest, northeast, south and west. The lists were compared to delete duplicate listings of individuals with membership in both groups. Our response rates, 45.2% for counselors and 31.2% for clinicians, were calculated based on standards set by the American Association for Public Opinion Research. An overall response rate of 37.8% was achieved for a total of 516 completed surveys, 846 non-responses, and 138 ineligible (e.g., retired, no longer practicing).

### Data Collection

The survey was conducted from June 15 to October 31, 2010. The mode of data collection included an online web survey, mail questionnaire, or fax (if requested). A mailed letter of support from the President of the National Society of Genetic Counselors (E. Kearney) or the Executive Director of the American College of Medical Genetics (M. Watson) was sent with the invitation along with the URL for the online survey. Approximately two weeks later, the survey instrument was sent with a postage-paid return envelope and instructions on how to access the survey website to those who did not complete the online survey in the first request. If an email address was available, we followed up by email instead. All communications were personalized and included a unique access code for purposes of follow-up and logging into the online survey. This study was approved by the Institutional Review Boards at Duke University Medical Center and the University of North Carolina, Chapel Hill. Survey respondents were eligible to enter a drawing for an Apple iPad and received a \$25 Amazon gift card.

### Data Analysis

Sample weights were produced as the inverse of stratum-specific sampling rates and then adjusted for differential non-response in the sample based on census region response rates. It was not possible, however, to post-stratify the sample based on demographic characteristics of the population such as race, age or gender because we did not have access to such data. Therefore, we were not able to correct for any demographic differences and potential biases that might exist. The following estimates were weighted and a 95% confidence bound was provided where applicable. Cochran-Mantel-Haenszel (CMH) Chi-square tests were conducted, adjusting for gender and race when comparing the two groups (genetic counselors and clinical geneticists) on a binary response. All analyses were conducted in SUDAAN (Version 10.0, 2008; Research Triangle Institute International, Research Triangle Park, NC) and accommodated a single-stage without replacement sample design among a finite population.

## RESULTS

### Respondent Characteristics

A total of 516 complete eligible responses were received. Overall, respondents were 76% female ( $\pm 2.72\%$ ) and self-identified as White (90%) ( $\pm 2.37\%$ ). Fifty-eight percent were board-certified in genetic counseling; 43% were board-certified in clinical genetics. There

was a significant difference in year of graduation with more than half (53%) of genetic counselors receiving their Master's degree after 2000, compared to 64% of clinical geneticists who received their medical degree before 1991 ( $\chi^2 = 62.07$ ,  $p < 0.0001$ ). (See Table 1)

### Training & Experience with PGx Testing

Ninety percent of genetic counselors indicated that they had some education relating to pharmacogenetics: 36% ( $\pm 5.10$ ) indicated that they had learned about pharmacogenetics through graduate school courses and 53% ( $\pm 5.29\%$ ) had learned about pharmacogenetics from the literature, seminars, professional meetings, or representatives of testing laboratories. In comparison, 96% of clinical geneticists indicated that they had some education regarding pharmacogenetics, with 18% ( $\pm 4.43\%$ ) learning about pharmacogenetics in medical school and 78% ( $\pm 4.80\%$ ) beyond medical school. Year of graduation was positively associated with learning about PGx through graduate coursework ( $\chi^2 = 24.12$ ,  $p < 0.001$ ).

Twenty-eight percent ( $\pm 4.63\%$ ) of genetic counselors indicated that they strongly or somewhat strongly agreed that they felt well-informed about PGx testing compared to 58% ( $\pm 5.80$ ) of clinical geneticists. Overall, there was a significant association between feeling well-informed and having PGx-related coursework ( $\chi^2 = 24.11$ ,  $p < 0.0001$ ). However, there was no significant association found between year of graduation and likelihood of feeling well-informed about PGx testing (genetic counselors: ( $\chi^2 = 1.49$ ,  $p = 0.2044$ ; clinical geneticists:  $\chi^2 = 0.75$ ,  $p = 0.5618$ ). Fifty-nine percent of clinical geneticists indicated that they would feel or felt comfortable ordering a PGx test, which was strongly associated with feeling well-informed about PGx testing ( $\chi^2 = 20.53$ ,  $p < 0.0001$ ). Similarly, 42% ( $\pm 5.23\%$ ) of genetic counselors indicated that they would feel or felt comfortable counseling a patient about PGx testing, which was strongly associated with feeling well-informed ( $\chi^2 = 54.15$ ,  $p < 0.0001$ ).

Regarding actual practices in ordering or coordinating patient care for PGx testing, 12% ( $\pm 3.53$ ) of genetic counselors indicated that they had ordered or coordinated patient care for PGx testing 1–10 times per year. For clinical geneticists, 35% ( $\pm 5.68$ ) had ordered PGx testing 1–10 times per year and 6% ( $\pm 2.86$ ) more than 10 times per year. Respondents who had graduated prior to 1991 were more likely to order PGx tests than those who had graduated after 2000 ( $\chi^2 = 3.73$ ,  $p = 0.0058$ ) as were those who felt well-informed compared to those who did not feel well-informed ( $\chi^2 = 7.08$ ,  $p < 0.0001$ ).

### Perceived Roles in Delivery of PGx Testing

About half of genetic counselors (52%  $\pm 5.44\%$ ) and clinical geneticists (46%;  $\pm 5.98\%$ ) felt they would play 'some' part in the delivery of PGx testing; 17% ( $\pm 4.06\%$ ) and 19% ( $\pm 4.78\%$ ), respectively, felt that they would play no role or 'a little' role. When asked which health professional or group should have primary responsibility for various steps in the delivery of PGx testing, more than half of genetic counselors and clinical geneticists believed that a disease specialist had primary responsibility to inform the patient about the availability of PGx testing, discuss the PGx test results with the patient, and determine how the PGx test result should inform drug selection and/or dosing (Table 2). Both genetic counselors (45.2%) and clinical geneticists (49.5%) believed that a record of the patient's PGx test results should be maintained through the primary care practitioner. However, a substantial proportion of genetic counselors (40.5%) and clinical geneticists (39.6%) indicated that they should have a primary role in discussing PGx results with the patient.

## Important Factors Regarding Use of PGx Testing

We asked respondents to indicate the importance of 13 potential test characteristics or related factors regarding the clinical use of a PGx test to predict an adverse drug reaction (Table 3). For four of the factors, more than half of respondents considered them to be important with respect to clinical use of the test to predict an adverse drug reaction: severity of the drug reaction, prevalence of the drug reaction, predictive value of the test, and availability of guidelines for test use/interpretation. There was a statistically significant difference in the proportion of genetic counselors (35%  $\pm$  5.08%) and clinical geneticists (44%  $\pm$  5.90%) who felt that the prevalence of the genetic variant was a very important factor ( $p=0.0179$ ). A significantly greater proportion of genetic counselors (64.0%  $\pm$  5.12%) versus clinical geneticists (53.1%  $\pm$  5.90) felt that availability of practice guidelines for test use and interpretation was a very important factor ( $p=0.0062$ ).

For PGx tests to predict drug response, more than half of genetic counselors and clinical geneticists indicated five of 13 factors were important: prevalence of non-response to the drug, predictive value of the test, urgency of treatment, severity of condition being treated, and availability of guidelines for test use/interpretation. The perceived importance for several factors significantly varied between the two groups including urgency of treatment ( $p=0.0363$ ), inclusion of information about the test on the drug label ( $p=0.0324$ ), and availability of an alternative drug ( $p=0.0002$ ).

**Informed Consent and Counseling**—Fifty-two percent ( $\pm$  6.13%) of genetic counselors and 54% ( $\pm$  6.25%) of clinical geneticists believed that genetic counseling would be necessary. In addition, the majority of genetic counselors (67%;  $\pm$  5.68) indicated that written informed consent should be obtained prior to PGx testing, though significantly fewer clinical geneticists (39%  $\pm$  5.98%) agreed that it should ( $\chi^2 = 11.44$ ,  $p = 0.0008$ ).

**Reporting & Storage of PGx test results**—When asked about their preference for the reporting format, most genetic counselors (98.7%  $\pm$  1.18%) and clinical geneticists (96.0%  $\pm$  2.27) agreed that the test report should contain both test result (e.g., genotype) and phenotype regarding drug safety or efficacy.

Regarding the storage of PGx test results, significantly more clinical geneticists (80.2%  $\pm$  4.76%) than genetic counselors (73.2%  $\pm$  4.68%) strongly agreed that PGx test results should be stored in a patient's medical record ( $p=0.036$ ). A smaller proportion of genetic counselors (58.8%  $\pm$  5.17%) and clinical geneticists (62.6%  $\pm$  5.72%) strongly agreed that results should be stored in a patient's *pharmacy* record. Clinical geneticists were significantly more likely to indicate that PGx test results should be stored in *both* a patient's medical and pharmacy record (70.5%  $\pm$  5.41% vs. 60.3%  $\pm$  5.10%) ( $p=0.0089$ ). Most genetic counselors (81.8%  $\pm$  4.06%) and clinical geneticists (78.9%  $\pm$  4.82%) also strongly agreed that patients should keep a copy of PGx test results to aid prescribing by different treating physicians.

## DISCUSSION

Although use of PGx testing is not yet widespread, consideration of the role of specialists at this early stage will help facilitate the transition to broader use and minimization of potential harms. Geneticists already play some role in overseeing the development and performance of PGx testing as laboratory directors, but their role with respect to clinical delivery and counseling remains to be explored. We find that geneticists and genetic counselors appear unclear about their role at this early stage of test use. About half believe that they will play some part in the delivery of PGx testing, with 40% of respondents believing they should have a primary role in discussing PGx test results with patients.

We found 12% of genetic counselors and 41% of clinical geneticists indicated that they had ordered or coordinated patient care for PGx testing, a seemingly high proportion at this early stage of adoption. Further study of the types of tests ordered by geneticists may clarify whether their experience was a result of referrals or the incorporation of new testing for patients traditionally treated by geneticists. High use of PGx testing by other medical specialists has been reported (12–14), suggesting their comfort in ordering PGx testing without involvement of a geneticist or genetic counselor.

The combination of differing comfort levels, education, and relationships with patients may have attributed to several differences in responses observed between genetic counselors and clinical geneticists. For example, almost twice as many counselors indicated that written informed consent was necessary for PGx testing compared to clinical geneticists. This difference in opinion may be attributed to counselors' training, which emphasizes exploration of psychosocial issues as well as facilitation of informed decision-making (16). Support of written informed consent might also reflect a recognition that geneticists are not likely to be involved in the delivery of PGx testing and it could help assure that non-genetics professionals discuss pertinent issues with patients. The relatively large proportion of respondents supportive of written informed consent, however, contrasts with previous reports that consent is not routinely obtained for PGx testing (17, 18), though other data suggests that clinicians would seek to obtain consent (19). The perceived importance of informed consent as well as counseling for PGx testing among geneticists, particularly counselors, may also reflect current practices with disease-based testing.

This is the first study to explore the views and attitudes of geneticists and genetic counselors regarding PGx testing, however, some limitations should be noted. Although the sample was randomly drawn from the population of board-certified genetic counselors and clinical geneticists, those familiar with PGx testing may have been more likely to respond to the survey, resulting in response bias and limiting the generalizability of the findings. We were not able to correct for any demographic differences and potential biases that might exist. In addition, responses to hypothetical clinical scenarios may not account for complexities in actual clinical practice and the differences in practice between genetic counselors and clinical geneticists (e.g., with respect to test ordering).

At this early stage, the clinical integration of PGx testing will likely benefit from a collaborative approach to facilitate the safe and appropriate use of PGx testing. Specifically, geneticists may serve as a useful resource to prescribing clinicians, providing expertise on test characteristics and interpretation of results, as many clinicians may have little knowledge about pharmacogenetics or genetics in general. However, with respect to actual delivery of testing, the time-sensitive nature of drug treatment would seem to preclude pre-testing consultation with geneticists. The prescribing physician and/or primary care clinician would appear to be the optimal place for integration of PGx testing to maximize both immediate and long-term benefits of testing over a patient's lifetime. Another possibility would be pharmacists as they also advise on drug-drug interactions and related issues to optimize drug response and minimize risk of adverse effects. Future studies should assess the need for and feasibility of consulting genetic specialists in the delivery of PGx testing in various clinical specialties and testing scenarios.

While interpretation and communication may be well within the expertise of geneticists, the reporting, storage and management of pharmacogenetic information is not limited to geneticists and warrants broad consideration to inform practice guidelines. This is particularly germane as testing platforms have moved away from single gene-based testing to panel testing and eventually to whole genome sequencing, resulting in the generation of more prevalent and complex information. Thus, consultation with geneticists on genome

analysis or interpretation may increase until general clinician knowledge increases and/or new tools are developed to aid in patient genome queries.

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**Table 1**

Demographic characteristics of survey respondents expressed as weighted percentages (standard errors in parentheses).

Demographic Characteristics	Genetic Counselors (n=295)	Clinical Geneticists (n=218)	Combined (n=516)
	Weighted % (SE)	Weighted % (SE)	Weighted % (SE)
<b>Female</b>	97 (0.93)	48 (3.02)	76 (1.39)
<b>Race</b>			
White	90 (1.61)	84 (2.22)	88 (1.32)
Non-White			
Black/African-American	1 (0.45)	2 (0.96)	1 (0.48)
Asian	4 (1.06)	6 (1.5)	5 (0.88)
Other	5 (1.19)	7 (1.58)	6 (0.96)
<b>Hispanic</b>	2 (0.81)	4 (1.18)	3 (0.69)
<b>Year of Graduation (from genetic counseling program or medical school)</b>			
Before 1980	1 (0.64)	29 (2.71)	13 (1.22)
1981–1990	12 (1.74)	35 (2.86)	22 (1.58)
1991–2000	34 (2.57)	26 (2.61)	30 (1.85)
After 2000	53 (2.69)	10 (1.83)	35 (1.73)
<b>Primary Practice Location</b>			
Community-based or hospital-affiliated	6 (1.29)	5 (1.39)	6 (0.95)
Hospital-based	18 (2.07)	8 (1.63)	14 (1.37)
Academic Medical Center	54 (2.69)	69 (2.72)	60 (1.93)
Private practice	8 (1.50)	7 (1.56)	8 (1.09)
Private testing laboratory	5 (1.15)	1 (0.57)	4 (0.70)
Government	1 (0.71)	2 (0.70)	2 (0.47)
HMO	1 (0.65)	2 (0.87)	2 (0.52)

**Table 2**

Perceived healthcare provider roles in delivery of PGx testing (percentage).

	PCP			Disease Specialist			Geneticist/CGC			Laboratory		
	CGC	MD	p-value <sup>†</sup>	CGC	MD	p-value <sup>†</sup>	CGC	MD	p-value <sup>†</sup>	CGC	MD	p-value <sup>†</sup>
Inform patient about PGx testing	25.78	34.24	<b>0.0264</b>	72.05	60.04	<b>0.0036</b>	0.73	4.18	<b>0.0088</b>	0.00	0.00	--
Determine which PGx variants are included in test	1.97	0.54	0.1278	26.28	29.84	0.3491	17.85	23.61	0.0886	40.89	25.67	<b>0.0001</b>
Discuss PGx test results with patient	11.24	14.95	0.1901	48.26	45.50	0.5047	40.50	39.55	0.8140	0.00	0.00	--
Maintain record of patient's PGx results	45.16	49.50	0.3074	40.58	29.37	<b>0.0053</b>	8.04	12.65	0.0789	3.09	4.53	0.3843
Determine how PGx result affects drug selection/dosing	9.96	9.26	0.7778	62.31	69.25	0.0787	0.75	1.44	0.4394	3.39	1.98	0.2992

<sup>†</sup>Based on Cochran-Mantel-Haenszel tests controlling for gender and race.

CGC=certified genetic counselor; MD = clinical geneticist.

Perceived Importance of characteristic of test, condition treated, and adverse event regarding use of pharmacogenetic testing (percentage of responses for 'very important').

**Table 3**

	PGx testing to predict likelihood of an adverse event (Q26)			PGx testing to predict likelihood of drug efficacy (Q27)		
	Genetic Counselors	Clinical Geneticists	P-value <sup>†</sup>	Genetic Counselors	Clinical Geneticists	P-value <sup>†</sup>
Severity of drug reaction	91.32%	86.70%	0.0742	--	--	--
Urgency of treatment	--	--		64.82%	56.48%	<b>0.0363</b>
Prevalence of drug reaction (or non-response)	54.29%	60.43%	0.1273	55.80%	58.33%	0.5296
Predictive value of test	78.88%	74.94%	0.2529	75.84%	78.80%	0.3851
Availability of other clinical tests to monitor toxicity (or drug response)	29.81%	32.25%	0.5186	34.47%	35.50%	0.7918
Severity of condition being treated	34.11%	41.07%	0.0787	52.72%	57.14%	0.2739
Prevalence of genetic variant	34.71%	44.15%	<b>0.0179</b>	38.03%	41.80%	0.3427
Inclusion of PGx testing info on drug label	28.72%	21.24%	<b>0.0329</b>	26.53%	19.22%	<b>0.0324</b>
Availability of guidelines for test use/interpretation	64.04%	53.10%	<b>0.0062</b>	57.14%	51.34%	0.1522
Insurance reimbursement of test	33.72%	37.58%	0.3212	29.83%	31.50%	0.6548
Cost of drug	16.87%	14.84%	0.4919	24.58%	20.64%	0.2458
Cost of test	22.46%	27.20%	0.1781	27.81%	31.07%	0.3811
Turnaround time for test results	32.33%	38.34%	0.1221	35.51%	38.12%	0.5067
Availability of alternate drug	47.15%	31.71%	<b>0.0001</b>	51.02%	36.26%	<b>0.0002</b>

<sup>†</sup> Based on Cochran-Mantel –Haenszel tests controlling for gender and race.