


# Patients' Perspectives on Psychiatric Pharmacogenetic Testing

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## Key words

Pharmacogenetics, Pharmacogenomics, Patient, Psychiatry

received 10.12.2019

revised 18.03.2020

accepted 11.05.2020

published online 24.06.2020

## Bibliography

Pharmacopsychiatry 2020; 53: 256–261

DOI 10.1055/a-1183-5029

ISSN 0176-3679

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Supporting Information (Appendix) for this article is available online at <https://doi.org/10.1055/a-1183-5029>

## ABSTRACT

**Introduction** There is growing interest to adopt pharmacogenetic (PGx) testing in psychiatric medicine, despite mixed views regarding its clinical utility. Nevertheless, providers are utilizing PGx testing among patients with mental health disorders. This study sought to assess genotyped patients' perspectives and experiences with psychiatric PGx testing.

**Methods** Individual semi-structured interviews were conducted among patients with depression who had undergone psychiatric PGx testing. The audio-recorded interviews were transcribed and analyzed inductively and deductively for salient themes.

**Results** Twenty patients (100% Caucasian, 60% female, mean age  $39 \pm 18$  years) were interviewed. The majority of the PGx tests were provider-initiated for patients who failed multiple pharmacotherapies (50%) and/or had medication intolerances (45%). Patients' pre-testing expectations ranged from hopefulness to indifference to skepticism. Their post-testing experiences varied from optimism to disappointment, with the perceived value of the test influenced by the results and cost of the test.

**Discussion** Genotyped patients had mixed perspectives, expectations, and experiences with psychiatric PGx testing. Their perceived value of the test was influenced by the test outcomes and its cost.

## Introduction

Major depressive disorder is a disabling mood disorder with a lifetime prevalence of 17% in the United States [1]. Despite the armamentarium of antidepressants available, the treatment of major depressive disorder remains unsatisfactory with less than 50% of patients responding to initial treatment and only a third achieving remission [2–4]. This poor treatment response can be attributed to factors such as the inherent delay in the onset of antidepressant

effects, the wide interpatient variability in treatment response, and adverse drug effects.

Antidepressant selection has historically involved a trial-and-error approach. Since the discovery of genetic associations in antidepressant response, there has been an impetus to incorporate pharmacogenetics (PGx) in the selection of psychiatric treatment [5–8]. The Clinical Pharmacogenetics Implementation Consortium (CPIC) and Dutch Pharmacogenetics Working Group (DPWG) have pub-

lished evidence-based PGx guidelines for *CYP2D6* and *CYP2C19* genotypes for selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants [9–12]. In addition, the International Society of Psychiatric Genetics (ISPG) issued a genetic testing statement that described PGx testing as a decision-support tool to assist in good clinical care and that PGx results supplemented other factors to guide treatment decisions [13]. The ISPG also suggested that genetic testing might benefit patients who had inadequate treatment responses or experienced adverse drug reactions. The society also stated that psychiatric PGx implementation should at least include *CYP2D6*, *CYP2C19*, *HLA-A*, and *HLA-B* genetic testing.

The opportunity to use PGx has spurred the commercial development of many psychiatric PGx tests marketed directly to providers [5]. Many of these tests include *CYP2D6* and *CYP2C19* genes on their panel, in addition to other genes of varying evidence to provide a combinatorial gene testing approach [14]. These companies often use proprietary algorithms that incorporate different genes to make a therapeutic recommendation in the form of a PGx-based decision-support tool. The clinical utility of these commercial psychiatric PGx tests carrying genes of varying evidence remains unclear [15]. Nevertheless, patients show a growing interest in psychiatric PGx testing [16]. Previous studies have reported the perspectives of non-genotyped patients toward PGx testing in general, but to date, no study has reported patients' perspectives and experiences with psychiatric PGx post-testing [17–21]. This study sought to assess genotyped patients' knowledge, attitudes, perceptions, and experiences toward psychiatric PGx testing.

## Methods

### Study participants and setting

The study was conducted at the Helen and Arthur E. Johnson Depression Center, University of Colorado Anschutz Medical Campus. Participants had to be at least 18 years of age with a diagnosis of major depressive disorder or bipolar disorder with depressive symptoms and had undergone commercial psychiatric PGx testing in the 7 years before the study began. The Depression Center is an outpatient clinic with 8 psychiatry providers (7 psychiatrists and 1 psychiatric mental health nurse practitioner). The study purposely interviewed at least 1 genotyped patient under the care of each provider to obtain a fair representation of patient views. Patients were recruited for the study, with the interviews conducted until data saturation was reached and additional interviews did not yield new knowledge. This study was approved by the Colorado Multiple Institutional Review Board with all participants providing written, informed consent.

### Interview guide development and data collection

Semi-structured individual interviews were conducted to assess patients' knowledge, attitudes, perceptions, and experiences with psychiatric PGx testing. An interview guide was initially developed based on literature review and the research question [22–24]. The guide was then pilot tested among 5 healthcare professionals and students. The interview guide (**Appendix A**) was used for all patients, with interview questions modified based on patients' responses. The guide consisted of 8 questions covering the following areas: patients'

knowledge of PGx; patients' pre-test expectations of PGx; and patients' post-testing experiences and treatment outcomes. The interviews were conducted by 2 study investigators (YML, IL). They were audio-recorded and transcribed by Mile High Transcripts (Denver, Colorado, USA) with patient identifiers redacted.

### Data analysis

The transcribed interviews were uploaded in Dedoose (Los Angeles, California, USA), a secure, web-based application for qualitative research that was used to analyze and manage the data. The data were analyzed using deductive and inductive approaches. Specific codes were developed based on the interview questions and agreed upon by 2 investigators. These codes were then applied to the deductive portion of the analysis. The inductive analysis allowed de novo codes to emerge from the data with new themes identified based on these codes. In the initial open coding phase, 2 investigators (YML, EL) analyzed the transcripts independently to identify key codes and then discussed the codes until consensus was achieved. In the second data analysis phase, a third investigator (IL) reviewed the codes for patterns and themes to identify key concepts and aggregated codes that shared common themes. These main themes and subthemes were then discussed with the entire study team until consensus was reached regarding the final themes and subthemes.

## Results

### Participant characteristics

A total of 20 patients (100 % Caucasians, 60 % female, mean age  $39 \pm 18$  years old) were enrolled, with demographic and clinical information shown in ► **Table 1**. The primary mental health disorder was major depressive disorder ( $n = 14$ , 70 %) followed by bipolar disorder with depressive symptoms ( $n = 6$ , 30 %). Thirteen patients (65 %) had co-morbid psychiatric conditions with anxiety disorder ( $n = 12$ , 92 %) being predominant, followed by schizophrenia ( $n = 1$ , 8 %). On average, patients' self-reported time between the PGx test and study interview date was 13.7 months (range 6 months to 2 years).

### Qualitative analysis of the interviews

An analysis of the interview transcripts revealed 4 main themes: 1) reasons for PGx testing, 2) patients' knowledge of PGx, 3) patients' perceptions and expectations pre-testing, and 4) patients' post-test perception of the value of psychiatric PGx testing, with subthemes 4a) psychiatric PGx test outcomes, and 4b) cost of the test.

### Reasons for PGx testing

The majority (95 %) of the psychiatric PGx tests were initiated by providers, while 1 treatment-naïve patient requested the test preemptively, saying: *"So it was my first time considering getting on a medication for depression and my parents and me were just, in general, opposed to the idea of being on a medication for anything and so we wanted to be sure that if there was anything that we could do to make a better decision because we know that some medications work and some don't and the doctor mentioned the possibility of 'You try this and if it doesn't work, we'll switch to another one'. And so we didn't*

► **Table 1** Patient demographic and clinical information.

No.	Age (years)	Gender	Ethnicity	Primary mental health disorder	Co-morbid psychiatric condition	Reason for psychiatric PGx testing			
						Pre-emptive PGx testing	History of medication intolerances	History of failing ≥ 1 psychiatric medication	Co-pay involved
1	23	M	Caucasian	MDD	–		X		Yes
2	40	M	Caucasian	MDD	–		X		Yes
3	51	F	Caucasian	MDD	–		X		Yes
4	69	F	Caucasian	BPD with DS	GAD		X		No
5	68	F	Caucasian	MDD	GAD		X		No
6	21	M	Caucasian	MDD	GAD	X			Yes
7	30	M	Caucasian	MDD	SAD		X		No
8	29	M	Caucasian	BPD with DS	GAD			X	No
9	22	M	Caucasian	MDD	GAD		X		No
10	47	F	Caucasian	MDD	–		X		No
11	36	F	Caucasian	MDD	–			X	Yes
12	29	M	Caucasian	BPD with DS	–			X	Yes
13	31	F	Caucasian	BPD with DS	Schizophrenia			X	No
14	25	M	Caucasian	BPD with DS	GAD		X		No
15	26	F	Caucasian	MDD	GAD			X	Yes
16	50	F	Caucasian	MDD	GAD, SAD			X	Yes
17	43	F	Caucasian	MDD	GAD			X	Yes
18	71	F	Caucasian	MDD	–			X	No
19	75	F	Caucasian	MDD	GAD			X	No
20	67	F	Caucasian	BPD with DS	GAD			X	No

M: male; F: female; BPD with DS: bipolar disorder with depressive symptoms; MDD: major depressive disorder; GAD: generalized anxiety disorder; SAD: social anxiety disorder.

want—I didn't want to have to try multiple things so I wanted to make the best decision possible" (Participant 6). The 2 main reasons providers ordered the test were for patients' history of medication failures (50 %) and medication intolerances (45 %). One patient cited: "The past 2 years I have been trying a lot of different psych meds to get my bipolar under control. Haven't had a lot of success, and thought (the test) would be beneficial" (Participant 2). Another patient commented: "I have had side effects, uncomfortable side effects. And then when we did the test, we found out why (I) probably had those reactions" (Participant 7).

### Patients' knowledge of PGx

The majority of the genotyped patients (95 %) could describe the PGx test, with 1 patient citing: "So basically they take your genes and look at them and compare it to different medications and look for different genomes, genes, patterns, or whatever to see which medications they think will work best for you and which medications they don't think will work for you" (Participant 6); 1 exception was a patient who replied: "I don't even know what that means" (Participant 19).

### Patients' perceptions and expectations pre-testing

Patients' pre-testing expectations ranged from hopefulness to indifference to skepticism. The majority of the patients were hopeful that the test would identify the right psychiatric medication for them, with 1 saying: "I was hopeful that it would be able to find something that would actually work because I had, up to that point, I hadn't had any good experiences with trying to find a drug. I didn't think they

would ever work. So, maybe hopeful that there might be something that we could find" (Participant 7).

One patient who felt indifferent toward the PGx test and did not have high hopes stated: "I wasn't so sure that anything was going to help. But I figured it couldn't hurt I guess. Like, okay it's not painful. Go for it. But I don't think I had high hopes particularly" (Participant 3). Another patient who also felt indifferent said: "I expected it to help (the provider) have an idea; give her a better idea of good medications to prescribe for me" (Participant 11). Some patients were skeptical about the psychiatric PGx test with one of them stating: "I don't know, I've always been kind of skeptical about medication. ... I expected hopefully that things I would take would have reduced side effects or maybe higher or lower dosage or something like that" (Participant 1).

### Patients' post-test perception of the value of psychiatric PGx testing

#### Psychiatric PGx Test Outcomes

Post-testing, the perceived value of the test was influenced by the PGx test outcomes, the severity of patients' psychiatric condition, and whether the results validated patients' past medication experiences. Sixteen patients (80 %) had their psychiatric medications changed based on their psychiatric PGx results. Among these patients, 56 % reported the medication change led to an improvement of their psychiatric condition, with 1 patient stating: "It helped (the provider) decide on a new—I think it was an SNRI that we chose. ... And that actually was helpful for quite some time. For a good, I would

say, good 18 months, it was probably kind of pretty useful. So that was good" (Participant 3). One patient wished the test was done earlier saying: "Wish this test had existed 20 years ago ... because I could have saved all that time and energy struggling through med change" (Participant 16). However, 2 patients felt indifferent about the test outcomes and thought it was a tool to guide the provider with medication selection: "The doctor read the things I shouldn't be taking. And then she prescribed the things... I think it helped her... I don't know that there was a lot for me to read. I think she just really kinda took over when it came back" (Participant 19).

Some patients felt that the test was not helpful as it did not give clear guidance for selecting a medication nor did it provide helpful answers to make any medication changes. The commercial PGx test that the majority of the patients used conveyed the medication recommendations using different colored bins that indicated the level of gene-drug interaction. Drugs in the green bin had no gene-drug interaction; drugs in the yellow bin had moderate gene-drug interaction; and drugs in the red bin had severe gene-drug interaction. One patient said: "Because there wasn't clear evidence to me, pointing to selection of drug ... I don't think that it-that's what made the critical difference. I think it was my therapist that made the critical difference" (Participant 4). Another patient cited: "It's all green and so they were like well that means everything works. I don't think we did anything with the results.... It doesn't eliminate anything.... It didn't provide any help" (Participant 13).

There were instances where the PGx results contradicted patients' past medication experiences, with 1 patient citing: "They said green about a drug that I had stopped years past that didn't work. So I think that was the thing, like one of the greens was like no, that's not a green" (Participant 12). In this case, the PGx result showed a severe gene-drug interaction for 1 drug that had been working well for the patient: "We were like okay, this drug that seems to be working is red so we didn't say we're going to stop it, you know? I think that we recognized that this was a very fallible test.... I think the ones that were red, like I liked that drug, I feel like this drug is working for me" (Participant 12).

Some patients found the PGx test valuable as it explained their previous failed treatments or medication intolerances, even though the results were not used to improve their treatment. These patients had a history of uncontrolled psychiatric disorders characterized by multiple hospitalizations or being refractory to treatment. They perceived the psychiatric PGx test to be another tool to help clinicians choose a medication for them. One patient cited: "I don't think we did anything with the results. I think we kind of just looked at it and moved on. We didn't use it to make.... We were like well, it doesn't eliminate anything so let's keep going. So for me personally we didn't really use it because it didn't provide any help. [Interviewer: Would you say it's worth doing the test?] I would 100%, yes. I was in such a place trying to find medications ... anything that could have helped, we would have done.... We were in such a place that we were desperate for answers" (Participant 13).

### Cost of the test

The cost of the test also influenced patients' perceived value of the psychiatric PGx test. In over half of the cases (55%), the test was fully covered by patients' insurance. The rest of the patients (45%) had a co-pay, which varied from \$75.00 to \$600.00. Some patients

felt that the test would be worth doing if the cost was lower or it was covered by their insurance, with 1 patient stating: "If insurance does begin to cover it or maybe if what you have to pay out of pocket is less than \$200, I would call it worthwhile" (Participant 15). Another patient cited: "I mean just depression affects a wide range of people and I'm sure a lot of them are, maybe even at poverty level, there's no way they're going to pay that. So I think if you could make the test cheaper or if insurance would cover it I think it's worth taking. But it's not worth \$300 or \$400" (Participant 10). One patient found the cost of the test too expensive and stated: "I am not sure I would've taken the test if the insurance didn't cover it.... Just because as I said financially things are very tight, and I don't have money to spend on certain things" (Participant 19). Another patient felt that the benefit of the test would outweigh its cost in patients who failed multiple medications, saying: "If you've like been through a bunch of drugs and you haven't found something that works it would probably be beneficial.... If you're like trying to weigh the cost of spending 6 more months going through a bunch of drugs ... I think it would definitely be worth it. ...if you're like trying your first drug, like I don't think it would be like worth it to spend right away ... unless it's like totally covered by insurance" (Participant 8).

## Discussion

To our knowledge, this is the first study that evaluated genotyped patients' knowledge, attitudes, perspectives, and experiences with commercial psychiatric PGx testing. The main reasons providers ordered the psychiatric PGx test were patients' history of medication failures and/or medication intolerances. Most patients were knowledgeable about PGx since their provider educated them about it prior to testing. Patients' pre-test expectations varied from hopefulness to indifference to skepticism, with the majority being hopeful that the PGx test would help find the right medication/dose faster. Post-testing, patients' perceived value of PGx testing was influenced by the test outcomes and cost of the test.

Patients with mental health disorders showed an interest in psychiatric PGx testing despite having mixed views toward it pre-testing. Although the majority of the PGx tests were initiated by psychiatric providers, patients were receptive to psychiatric PGx testing due to their history of medication failures and/or medication intolerances, with the exception of 1 treatment-naïve patient who wanted the test done preemptively to avoid wasting time with trial-in-error prescribing. This receptiveness toward PGx testing was seen in another study conducted among patients without mental health disorders, where patients expressed with certainty that there was an association between genetics and drug treatment [25]. These data are similar to a survey of patients' post-testing perspectives of PGx in a general medicine clinic [18]. The survey found that 73.2% of patients reported feeling more confident that the medications prescribed by their providers post-PGx testing would not cause side effects and would be more efficacious. In addition, these results are supported by a survey of the public's opinion toward PGx testing, which found that most U.S. adults were interested in PGx testing to assist with drug selection, medication dosing, and prediction of medication side effects [17]. The presence of skepticism pre-testing was similarly found among non-genotyped patients in another study that contrasted the views of pa-

tients who had or had not been genotyped [26]. The genotyped cohort reported a better understanding of PGx with greater receptiveness to its use by their provider. In contrast, our study of genotyped patients' views toward psychiatric PGx testing found some patients who were skeptical about the ability of PGx testing to predict drug response, including 1 patient who was even skeptical about his psychiatric medications in general. This illustrates that patients' prior experiences with their psychiatric medications may influence their expectations of psychiatric PGx testing.

Patients' post-test experiences with psychiatric PGx test outcomes ranged from beneficial to having no clear prescribing direction based on the PGx report to receiving PGx recommendations that conflicted with patients' prior medication experiences. Nevertheless, a few patients with a history of difficult-to-control psychiatric disorders found the test helpful even though the results were not used to make clinical decisions. Some patients who had hoped to find a medication that would work best for them were disappointed when the results were not useful to make treatment decisions. This should not be surprising because various factors contribute toward the treatment outcomes. Firstly, many commercial psychiatric PGx tests have included genes of varying clinical evidence on their test panel; hence providers might not see a consistent correlation between the PGx recommendations and treatment outcomes [15]. There is currently no consensus regarding which genes to include in the test panel as highlighted by the ISPG statement, hence the selection of a psychiatric PGx test should be done with caution [13, 27]. This is further demonstrated by the findings of Bousman et al. who tested the same group of patients with treatment-resistant depression using 4 different commercial PGx tests [14]. These 4 companies used different genetic combinations in addition to *CYP2C19* and *CYP2D6* genes that were present across all the test panels, and came up with different PGx recommendations for the same patient. Secondly, not all the genes that predict psychiatric treatment response have been identified. Thirdly, PGx testing is a clinical decision tool that providers use in addition to other factors to guide medication selection. As such, providers will need to manage patients' expectations toward psychiatric PGx testing during their pre-test discussion. The pre-test discussion can include educating patients that PGx evidence varies among the genes tested. Genes such as those associated with *CYP2C19* and *CYP2D6* drug metabolism have stronger evidence with PGx guidelines available; the limitations of PGx testing; and how PGx results are utilized in context with patients' medication history, medication intolerances, and other factors to derive the final prescribing decision. Since not all providers who order PGx testing are familiar with PGx evidence, the ISPG recommends providers educate themselves or consult an expert prior to ordering a PGx test and use PGx resources available to assist in their interpretation and use of the PGx results [13].

In our study, the commercial PGx test used among patients presented the results in a traffic light system (green/yellow/red) that indicated the level of drug-gene interaction. This color reporting system could be misleading to patients as some patients perceived "green bin" medications to mean the medications should work, when it actually meant there was no reported drug-gene interaction based on the genes tested. Similarly, some patients perceived "red bin" medications as being ineffective and should not be used.

However, in this case it meant that there was greater drug-gene interaction or that the medication dose may need to be adjusted. This finding highlights the need for providers to educate patients in the proper way to interpret their PGx results.

Patients' perceived value of psychiatric PGx testing was also influenced by the cost of the test. Several study patients expressed that the PGx test would be valuable if it was more affordable or covered by their health insurance. This finding is similar to a study by Mukherjee et al. where patients with cardiac conditions were willing to pay a mean of \$56.30 for PGx testing [19]. In a study by Lemke et al, the majority of the patients in a general medicine clinic thought that a reasonable price for a PGx test would be less than \$200 [18]. Some insurance companies have recently come on board to cover PGx testing. An example is United HealthCare Services that announced they would cover PGx multigene panel testing for patients with a diagnosis of major depressive disorder or anxiety who have failed at least 1 prior medication to treat their condition [28]. Medicare also covers 1 commercial PGx test and a proposed local coverage determination for PGx testing in psychiatric and neurologic conditions comment period recently ended (<https://cpicpgx.org/proposed-palmetto-lcd-for-pgx-testing/>). As more insurance companies start covering psychiatric PGx testing, it is expected to gain more widespread adoption.

Our study had a few limitations. First, there may be a recall bias among patients who had their psychiatric PGx testing performed earlier, with patients having difficulty remembering the details of their pre-testing expectations. However, most of the study patients could recall their PGx test experiences and post-test outcomes. Another limitation was that we used a convenience sample of patients who came in for their appointment during the study period; hence this may not represent the opinions of all the genotyped patients. This was taken into account as the study interviewed patients until thematic saturation was reached and no new themes emerged. Previous studies have reported privacy of results as one of the concerns patients had about PGx testing [29, 30]. This theme did not arise in our study, nor was it specifically probed. Future studies on psychiatric PGx testing could explore the issue of privacy in more depth. Another study limitation was that the commercial PGx test used in our study presented patients' PGx results using a traffic light system. Patients could have different post-test perceptions and interpretation of their PGx results if another PGx test presented their results in a different format. Finally, our study was conducted at a depression center where patients were cared for by psychiatric providers, and most of these patients tended to be more treatment resistant. Hence, these findings may not be generalizable to patients in the primary care setting who may be at the early stages of their depression treatment and are managed by primary care providers.

In conclusion, this study highlighted genotyped patients' perspectives, expectations, and experiences with psychiatric PGx testing. In particular, genotyped patients' perceived value of psychiatric PGx testing was influenced by the test outcomes and the cost of the test.

## Conflict of Interest

The authors declare that they have no conflict of interest.

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