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Development and Piloting of Patient Education Material on Pharmacogenomic Testing

Louise Limoges
Sarah Lawrence College

DEVELOPMENT AND PILOTING OF PATIENT EDUCATION MATERIAL ON PHARMACOGENOMIC TESTING

Louise M. Limoges

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ABSTRACT

Pharmacogenomic (PGx) testing is increasingly utilized in patient care, with the potential to personalize the use of medication for individual patients. However, many barriers stand in the way of PGx testing becoming standard-of-care, including a lack of resources for patient education. The objective of this study was to develop and pilot a pre-test educational tool for clinical PGx testing and gather patient input. We designed a one-page, printed PEM which was piloted at a genetic counseling clinic in Cincinnati, Ohio. In total, 53 participants read the PEM and provided their feedback through a survey. The survey was designed to collect and assess patient demographics, prior awareness of PGx, effectiveness of and satisfaction with the PEM, and interest in PGx testing. We found little prior awareness of PGx, with 66% of patients reporting no prior knowledge of PGx. Reading the PEM was associated with a statistically significant improvement in self-reported understanding of PGx for patients of all educational backgrounds. In addition, 94% of patients agreed the handout was a helpful educational tool. Finally, 79% of patients expressed potential interest in pursuing PGx testing. Patients reporting use of a prescription medication were more likely to express interest. The findings of this pilot study support that simple, written educational tools could increase patient understanding of PGx in the pre-test context. In addition, in our study, we found that patients had little prior awareness of, but much interest in, PGx testing.

Keywords: pharmacogenomics, pharmacogenomic testing, education

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1 INTRODUCTION

Pharmacogenomics (PGx) is an emerging area of practice which explores how genetic variation influences the body's response to medications. PGx testing has been introduced as a proactive approach to informing risk-benefit analyses for pharmacotherapy in areas such as oncology (Reizine & O'Donnell, 2022) and cardiology (Magavern et al., 2022). PGx-guided prescribing aims to improve treatment efficacy and limit adverse drug reactions (ADRs). The clinical utility of PGx has been advanced by the development and publication of PGx-guided prescribing guidelines by the Clinical Pharmacogenetics Implementation Consortium (CPIC), used globally by a wide variety of institutions (Clinical Pharmacogenetics Implementation Consortium (CPIC), 2024). There are also hundreds of medications approved by the U.S. Food and Drug Administration that now include drug labels containing PGx information.

Multiple studies suggest that the appropriate use of clinical PGx testing could help make pharmacological treatment safer and more effective for many patients. Clinically-significant variation in pharmacogenes is common in the general population. In a large PGx study of 10,077 consented volunteers from the Mayo Clinic Biobank, over 99% of them had at least one clinically actionable PGx variant (Wang et al., 2022). The high prevalence of variation in pharmacogenes has been corroborated by numerous other studies (Chanfreau-Coffinier et al., 2019; McInnes et al., 2021). This is especially important in conjunction with increasing use of prescription medication; studies show that currently more than 70% of physician office visits in the U.S. involve drug therapy (Santo & Kang, 2019). As the consideration of drug-drug interactions has become standard-of-care, PGx proponents argue that drug-gene and drug-drug-gene interactions should also

be assessed (Brixner et al., 2016). Many studies in diverse clinical contexts have shown that PGx testing can reduce ADRs (Swen et al., 2023), healthcare costs (Jarvis et al., 2022), and hospitalizations (David et al., 2021).

While PGx is an emerging area of practice, there are inherent limitations to this type of testing and questions yet unanswered with regards to implementation and utility. For example, many variants in pharmacogenes have limited clinical relevance due to marginal associations with drug outcomes (Chang et al., 2021). Additionally, genetic variation is not the only variable influencing medication response, not all medications have PGx guidelines, and there is a residual risk of ADRs even with PGx-guided prescribing (Wake et al., 2021).

Additionally, despite the availability of clinical PGx gene panels, there are crucial challenges to our ability to implement PGx testing. Many healthcare providers (HCPs) have limited knowledge of PGx and low confidence in their ability to use PGx test results effectively. A recent survey-based study found that, without specialized PGx education, only 18.5% of primary care providers and 18.1% of specialists felt comfortable ordering PGx testing (Preys et al., 2023). A recent survey of HCPs in Canada identified lack of HCP knowledge and clinical guidelines as major barriers to PGx implementation (Hayashi & Bousman, 2022). Furthermore, there is contradictory evidence on the impact of PGx on disparities in healthcare (Martin et al., 2017). Despite these limitations, PGx testing is being used in clinical practice today and its popularity is expected to increase.

Though patient education is vital to patient engagement and the successful implementation of clinical PGx testing, there are no consensus guidelines on PGx pre-test counseling (Zierhut et al., 2017). Lack of patient knowledge about PGx is considered

a major barrier to clinical implementation (Qureshi et al., 2022) and patient education in this area is expected to be a challenge, considering the complexity and novelty of PGx information. Patients' desire for shared decision-making was evident in the findings of a focus group study on attitudes and perceptions of PGx (Lee et al., 2017). Studies exploring pre-test education on PGx have demonstrated the positive impact of education on attitudes towards testing and perceived patient control (Sloat et al., 2022). In addition, a 2022 study concluded that education on testing would be a motivating factor for willingness to pursue PGx testing (Bagautdinova et al., 2022).

The PGx literature contains little on how patients should be informed about the logistics, benefits, limitations, and risks of PGx testing. Much of the existing literature has been collated in a scoping review, identifying critical themes for PGx counseling (Allen et al., 2022). An exploration of the practices of four PGx clinics during pre-test counseling appointments was also published recently (Wake et al., 2021). However, these publications, in their discussion, reinforce the importance of further research on PGx literacy needs and development of appropriate patient education materials (PEMs).

The aim of this study was to develop and pilot a pre-test educational tool for clinical PGx testing. The PEM was designed to help supplement traditional education, provided verbally by an HCP. Accessible reading materials provide the opportunity for people with all levels of health literacy to gain knowledge and confidence in their care. In addition, a recent meta-analysis provided evidence that both patients and HCPs view handouts as helpful educational tools for PGx (Veilleux et al., 2020). For all of these reasons, a printed PEM was selected as the prototype for this study. It was the goal of this pilot study to gather participant feedback to improve the PEM for future use. Specifically, the aims of

this research were to (1) investigate the utility of a one-page, printed PEM on clinical PGx testing and (2) explore public awareness of and interest in PGx.

2 METHODS

2.1 Development of the PEM

The multidisciplinary research team, including genetic counselors, a pharmacist, a precision medicine expert, and a genetic counseling student, developed and refined the PEM. The goal of the PEM was to serve as an introduction to both PGx testing and the process for testing at the Christ Hospital Health Network. The Christ Hospital Health Network was selected as the site for this study due to their Precision Health program, which includes offering clinical PGx testing to patients. The PEM was designed to complement traditional HCP counseling on PGx, with the goal of reducing HCP educational burden.

The final PEM was a one-page handout, consisting of four panels (**Supplementary Information, Figure 1**). Each panel included information in a question-and-answer format, a format which was well-received in another study piloting a PEM on PGx testing for warfarin (Barajas et al., 2015). The panels gave background information on PGx, explained how individuals could access PGx testing at the Christ Hospital Health Network, and listed testing benefits and limitations. In creating the PEM, the authors used published literature on PGx education and existing PGx PEMs to guide content selection and wording (Allen et al., 2022; Asiedu et al., 2020; Bagautdinova et al., 2022; Wake et al., 2021). The completed handout was reviewed by HCPs with experience offering PGx testing.

The PEM prioritized readability to optimize comprehension, in accordance with guidelines from the Centers for Disease Control and Prevention (CDC) which suggest that educational materials be created at no higher than a sixth-grade reading level (Centers for Disease Control and Prevention (CDC), 2010). A readability analysis for the PEM was conducted using the Hemingway editor, a free Internet resource which calculates readability using the Automated Readability Index. Best practices outlined in the CDC Clear Communication Index, Patient Education Materials Assessment Tool, and the Suitability Assessment of Materials were also incorporated to maximize comprehension. Adult-learning theory principles were also considered. For example, since adult learners have been shown to prioritize the immediate use of knowledge (Merriam, 2001), a step-by-step explanation of how to access PGx testing was included.

2.2 Survey development

An anonymous survey (**Supplementary Information, Table 1**) was designed to measure the effectiveness and impact of the PEM. For two questions, participants were asked to reflect on their knowledge of PGx before reading the PEM. Participants were also asked six questions assessing the handout and their interest in PGx. Most responses were measured using 3- or 4-point Likert scales. There were two free-response questions inviting participants to share suggestions for the PEM. Participants were also asked about demographics and their current use of prescription medications.

2.3 Data collection

This study was conducted at the genetic counseling clinic associated with the Christ Hospital Health Network in Cincinnati, Ohio (hereafter referred to as the CHHN clinic). The CHHN clinic offers prenatal, cancer, and cardiac genetic counseling to adult patients. This study was approved by the Christ Hospital Health Network Institutional Review Board (IRB #: 23-083), which assessed it as low-risk and granted an informed consent waiver.

Between mid-October 2023 and early November 2023, all patients seeking in-person genetic counseling at the CHHN clinic were offered the opportunity to take part in the study, except in those cases where it was deemed inappropriate by the genetic counselor because of time constraints, significant psychosocial issues related to their reasons for counseling, or other concerns.

Following their genetic counseling session, participants who elected to take part in the study were handed a printed version of the PEM and the survey. Participants read the PEM and completed the survey in the clinic's waiting room. Written survey responses were transferred to a REDCap database hosted at the Christ Hospital Health Network. Participant responses were excluded from the analysis if the participant selected "no" to the survey question "did you read the 1-page handout?" (only one survey was excluded from the analysis based on this exclusion criterion).

2.4 Data analysis

Data were presented as percentage for categorical variables. Comparisons of the Likert-scale data of self-reported understanding of PGx before and after reading the PEM

were treated as interval data. Numerical values were assigned to each of the Likert responses (none – 0 to excellent – 3). An unpaired, parametric t-test was used to compare participant understanding before and after reading the PEM. The value of $p < 0.05$ was used to determine statistical significance. All data were graphed and analyzed using GraphPad Prism software V10.1.1.

3 RESULTS

3.1 Participants

Genetic counselors at the CHHN clinic approached 57 patients for participation in the study. A total of 53 individuals completed the majority of the survey (response rate 93%). Most respondents identified as women (77.4%) over the age of 30 (88.7%) and as non-Hispanic White (84.9%). Participants varied in terms of their highest level of educational attainment and current number of prescription medications, as summarized in **Table 1**.

Table 1. Self-reported demographics of survey respondents (*n*=53).

Characteristic		***n***	**(%)**
Gender			
	Man	12	(22.6)
	Woman	41	(77.4)
Age (years)			
	18-30	6	(11.3)
	31-50	22	(41.5)
	51+	25	(47.2)
Race/ethnicity			
	Asian	1	(1.9)
	Black or African American	3	(5.7)
	Hispanic or Latino	3	(5.7)
	White non-Hispanic	45	(84.9)

	Another race/ethnicity not listed	1	(1.9)
Highest level of educational attainment			
	High school/GED	8	(15.1)
	Vocational/technical/associates degree	15	(28.3)
	Four-year college degree	15	(28.3)
	Graduate or professional school	15	(28.3)
Current number of prescription medications			
	0	15	(28.3)
	1-4	21	(39.6)
	5+	17	(32.1)

GED: General Educational Diploma.

3.2 Prior awareness of PGx

Prior knowledge of PGx among participants was evaluated. The majority of respondents (66%) reported they had never heard of PGx or PGx testing previously. A smaller proportion of respondents (22.7%) reported prior awareness of PGx, while 11.3% were unsure or had limited awareness (**Figure 1**).

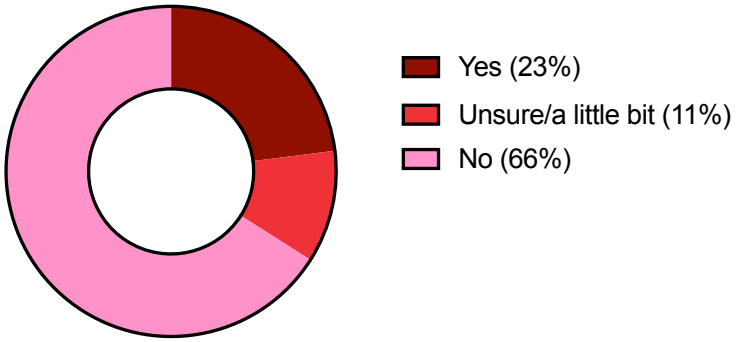

Figure 1. Self-reported awareness of PGx or PGx testing prior to their genetic counseling visit. Participants (*n*=53) were asked whether they had ever heard of PGx or PGx testing by selecting “yes”, “unsure/a little bit”, or “no”. PGx: pharmacogenomics.

Having at least one active prescription medication was positively associated with prior awareness of PGx. Of those who reported zero current prescription medications,

only 6.7% had prior awareness of PGx, compared to 28.9% of those with at least one current prescription.

3.3 Understanding of PGx

The PEM was effective in increasing respondents' self-reported understanding of PGx testing. Prior to reading the PEM, 50.9% of respondents reported no understanding of PGx and a further 20.8% of respondents described their understanding of PGx as "limited". After reading the PEM, all participants described themselves as having at least a limited understanding of PGx. Most described their understanding as good (64.2%) and there was a 12.9-fold increase in those describing their understanding as "excellent" (**Figure 2**).

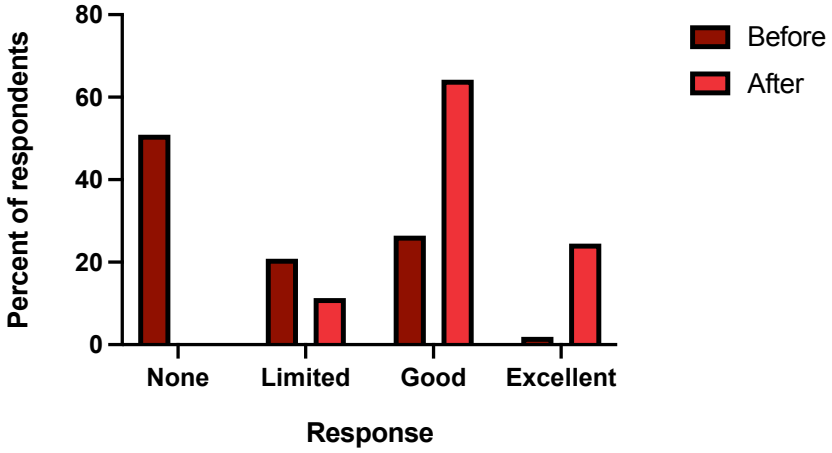

Figure 2. Self-reported understanding of PGx testing before and after reading the PEM. Participants (*n*=53) were asked to rate their understanding on a four-point scale, from none (no understanding) to excellent. PEM: patient education material; PGx: pharmacogenomics.

Overall, there was a statistically significant increase in self-reported understanding of PGx testing after participants read the PEM ($p<0.001$). The increase in self-reported understanding remained significant for both groups after stratifying by level of educational

attainment (high school/GED or vocational/technical/associates degree vs. four-year college degree or graduate/professional school).

3.4 Satisfaction with the PEM

The majority of respondents either agreed (71.2%) or strongly agreed (23.1%) that the PEM was an appropriate tool to educate them on PGx (**Figure 3**).

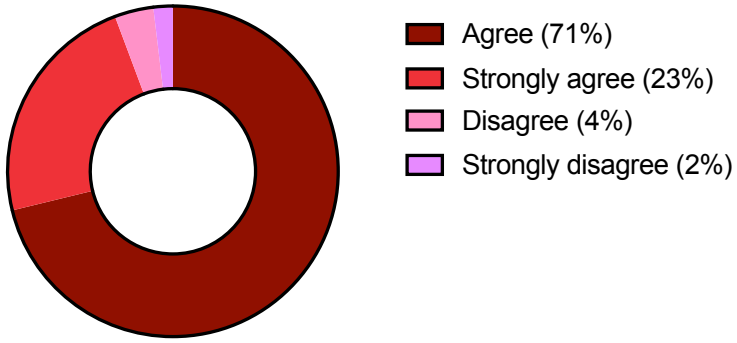

Figure 3. Self-reported satisfaction with the PEM as an educational tool. Participants (*n*=52) were asked to rate whether they found the PEM to be a good way for them to learn about PGx testing on a 4-point scale, from strongly agree to strongly disagree. PEM: patient education material; PGx: pharmacogenomics.

Self-reported satisfaction with the PEM remained high across all levels of educational attainment. For example, 95.5% of those reporting high school/GED or vocational/technical/associates degree agreed or strongly agreed that the PEM was a good tool for education about PGx, as did 93.3% of those with a four-year college or graduate/professional degree. In addition, the vast majority of respondents (90.6%) reported understanding everything included on the PEM.

3.5 Interest in PGx and further PGx education

When asked about their personal interest in pursuing PGx testing, 44.2% reported they were interested and 34.6% reported they might be interested in the future. There were 11 respondents (21.2%) who reported no interest in clinical PGx testing (**Figure 4**).

Figure 4. Self-reported personal interest in pursuing PGx testing. Participants (*n*=52) were asked whether they were interested, whether they may be interested in the future, or whether they were not interested in pursuing PGx testing. PGx: pharmacogenomics.

Having at least one active prescription medication was positively associated with an interest in clinical PGx testing. Of the participants reporting zero current prescription medications, only 13.3% expressed an interest in PGx testing, compared to 56.8% of participants using at least one prescription medication.

When asked which of a list of potential educational media they thought would be helpful for getting more information on PGx, those most frequently endorsed were discussions with HCPs (60.4%), educational videos (50.9%), and websites (47.2%). Of note, only 10 respondents (18.9%) indicated an interest in a longer PEM (brochure) (**Figure 5**).

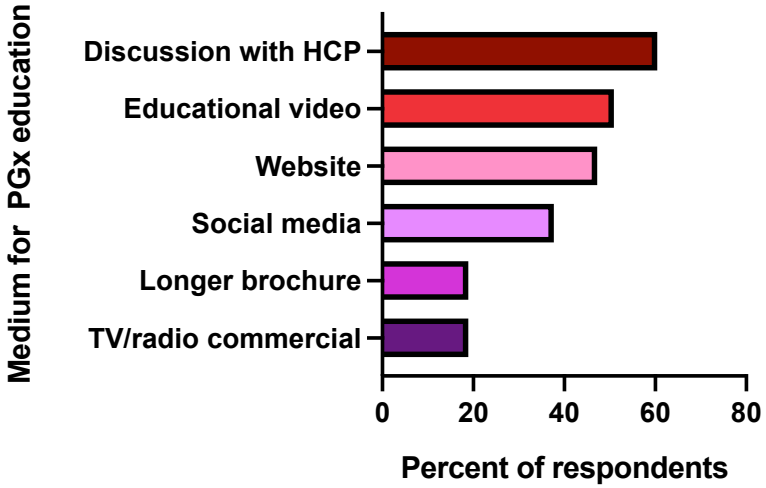

Figure 5. Participants (*n*=53) were asked to select other format(s) they felt would be helpful to educate people about PGx testing. HCP: healthcare provider; PGx: pharmacogenomics; TV: television.

In the nine responses to an open-ended question asking participants what else they would like to know about PGx, two themes emerged. Four participants reported being interested in average cost and available insurance coverage for testing. Additionally, three participants wanted more information about who would benefit the most from testing (i.e. asking for which medications the testing would be informative).

4 DISCUSSION

Patient education on PGx will be critical to its successful implementation into mainstream clinical practice. This study sought to gather feedback from a sample of genetic counseling patients on a PEM designed for pre-test education on PGx. Participants were also asked about their awareness of and interest in this type of testing. Overall, there was little prior awareness of PGx and a high level of interest in PGx testing. A single-page, printed PEM was seen as a helpful educational tool and significantly increased patient understanding of PGx for patients with varying levels of educational

attainment. These data suggest that the use of a simple PEM may assist HCPs in educating their patients about PGx.

Prior awareness of PGx was poor, with most respondents reporting they had never heard of PGx or PGx testing. This was not surprising, given that previous research has found little awareness of PGx in the general population (Veilleux et al., 2020). The lack of awareness aligns with the fact that PGx testing is not currently considered standard of care for most indications. There is limited research on the current uptake of PGx testing in North America. A U.S. study found that less than 1% of people, within a sample of 11 million insured patients, had PGx testing completed between 2013 and 2017 (Anderson et al., 2020). However, the landscape is rapidly changing, with availability of direct-to-consumer PGx testing and several states implementing statewide PGx initiatives (Bishop et al., 2021; Patel et al., 2021). Our findings, which suggest that the changes have not led to significant increases in patient familiarity with PGx for our study population, lend support to the importance of accessible patient engagement and education, a conclusion also reached by previous research (Allen et al., 2022; Wake et al., 2021).

Our survey found that people taking at least one prescription medication were more likely to have some awareness of PGx. This may suggest that people currently on medications are more likely to receive this information from their HCPs or conduct their own research. This would be an interesting area for further study.

In the small group surveyed by this study, interest in PGx was high, with 78.8% of the sample expressing an interest in PGx testing now or in the future. Our findings are in alignment with previous research, which have documented a high level of patient interest (Allen et al., 2022). Those on prescription medication reported the highest levels of

interest. This may be useful information for HCPs when deciding which patients to prioritize for PGx counseling, especially considering that guidelines are lacking in regard to which patients should be tested (Wake et al., 2021).

This pilot study demonstrated the potential utility of a printed PEM for PGx education, with high levels of self-reported satisfaction with the tool and a significant boost in self-reported understanding. Satisfaction and educational benefit were high across all levels of self-reported educational attainment. Patient input while developing PEMs is critical to their optimization.

The content of the PEM was selected by considering key information for PGx pre-test counseling, as summarized by Wake and colleagues (Wake et al., 2021). In addition, a statement was added to differentiate PGx from genomic testing for disease/disease susceptibility, as this has been identified as a common misconception (Allen et al., 2022; Wake et al., 2021). Participants seemed happy with the length of the PEM, with only two participants reporting they did not finish reading it. In addition, less than 20% of respondents indicated an interest in a longer PEM. This suggests that the one-page length for the PEM was appropriate for the majority of individuals.

The PEM was written at a sixth-grade reading level, as recommended by the CDC. It is critical that PEMs are accessible to the general public, considering that appropriate patient education has been associated with significant improvements in patients' physical and psychological outcomes (Simonsmeier et al., 2022). The majority of respondents expressed satisfaction with the PEM and reported they understood all the included information.

Previous literature has gathered patient feedback on PEMs for PGx; however, these studies have mainly focused on specific disease areas (Barajas et al., 2015; Giuse et al., 2016; Sloat et al., 2022) or PGx results materials (Haga et al., 2014; Olson et al., 2017). Putting our study in the context of previous work on general, pre-test written PEMs on PGx (Asiedu et al., 2020; Mills & Haga, 2018), we conclude that limiting the use of medical terminology can be a viable approach for introductory material. In the study by Asiedu and colleagues, most participants expressed that medical jargon such as ‘phenotype’ and ‘metabolizers’ were too complex (Asiedu et al., 2020). In contrast, work by Mills and Haga had diverging opinions on the use of medical terminology, and the authors concluded that use of medical terminology with a corresponding glossary of terms might be an appropriate approach (Mills & Haga, 2018).

In this study, medical jargon (other than ‘pharmacogenomic’) was avoided, and the PEM was well appraised by the majority of respondents. Since the PEM, as in other studies, was not designed to convey all pre-test PGx information and was meant to complement traditional counseling by an HCP, we concluded that the written introduction should be brief and easy to read. In our study, the majority of respondents indicated that a discussion with their HCP would be their ideal way to learn about PGx. Thus, another possible hybrid approach would be that HCPs describe the more complex information about PGx in their verbal counseling, while providing a simple printed PEM to remind patients of critical points.

4.1 Study limitations

This study has several limitations. Firstly, the sample was limited in size and mostly composed of non-Hispanic White women, over the age of 30 and living in Ohio, and thus the findings from the survey may not be applicable to other populations. We did not ask respondents whether they had PGx testing in the past (one participant disclosed they had), which would presumably affect both understanding of and interest in PGx. Additionally, participants read the PEM and completed the survey after having a genetic counseling session. It is possible that their understanding and interest in genetics may have been higher than that of the general population. Also, the PEM was not piloted in the clinical context which it was ultimately intended to be used (during pre-test counseling for PGx), thus, these findings should be seen as preliminary.

4.2 Future directions

Based on participant feedback from this study, we would advise adding information about the maximum out-of-pocket cost for PGx testing to the PEM. One excellent area for further exploration would be an assessment of the PEM, with this additional information, and in conjunction with verbal PGx counseling from an ordering provider, for clinical utility. If found to be effective in this setting, the PEM could be easily implemented into PGx counseling at the Christ Hospital Health Network and adapted for use elsewhere.

5 CONCLUSIONS

Patient education and engagement will be critical for the implementation of PGx testing into routine clinical practice. Our participants reported limited prior awareness of

PGx, but a high level of interest in pursuing PGx testing. This pilot study indicated that a simple, one-page printed PEM improved participant understanding of PGx. This is suggestive of the potential utility of written educational tools to accompany HCP counseling when consenting patients for PGx testing.

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SUPPLEMENTARY INFORMATION

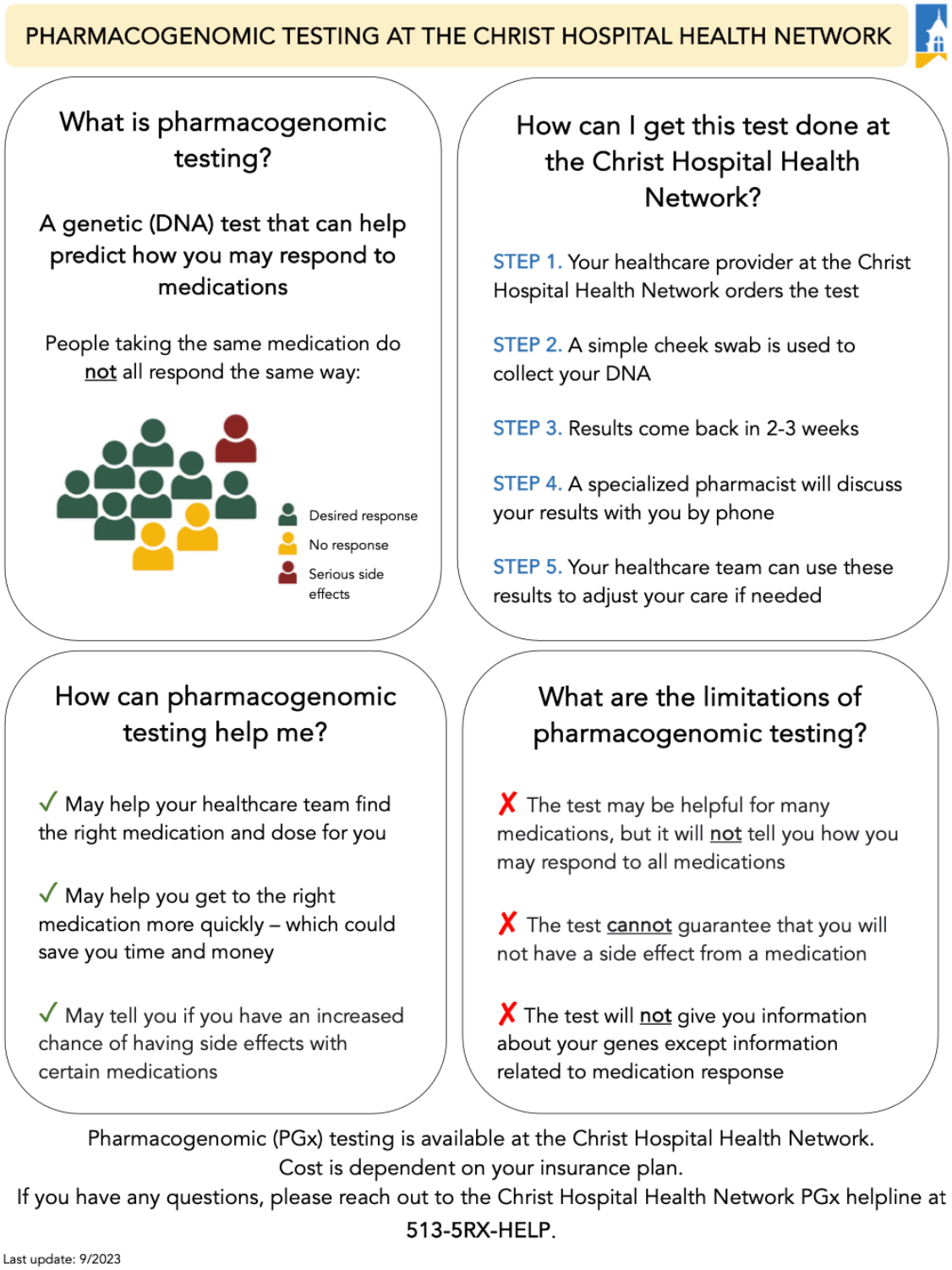

Figure 1. Snapshot of the patient education material that was piloted in this study.

Table 1. Questions and answer options from the participant-facing survey utilized in this study.

Question	Answer options
What is your gender identity? (Select all that apply)	□ Woman □ Man □ Non-binary □ Another gender identity not listed □ Prefer not to answer
What is your age?	□ 18-30 □ 31-50 □ 51+
Which race or ethnicity best describes you? (Select all that apply)	□ American Indian or Alaska Native □ Asian □ Black or African American □ Hispanic or Latino □ Native Hawaiian or Other Pacific Islander □ White non-Hispanic □ Another race/ethnicity not listed
What is the highest level of education that you have completed?	□ Did not complete high school □ High school/GED □ Vocational/technical/associates degree □ Four-year college degree □ Graduate or professional school □ Prefer not to answer
How many prescription medications are you currently taking?	□ 0 □ 1-4 □ 5+ □ Prefer not to answer
Prior to this genetic counseling visit, had you ever heard of pharmacogenomics or pharmacogenomic testing?	□ No □ Unsure/a little bit □ Yes
Did you read the 1-page handout?	□ No □ Part of it □ Yes
If you answered ‘no’ or ‘part of it’ above, which of the following reasons best explains why you did <u>not</u> finish reading the handout?	□ The handout was too long □ The handout was too confusing □ I was not interested in the handout □ I already know about pharmacogenomics □ Other Other: _____
Please rate your level of understanding of pharmacogenomic testing <u>before</u> reading the handout.	□ None □ Limited □ Good □ Excellent
Please rate your level of understanding of pharmacogenomic testing <u>after</u> reading the handout.	□ None □ Limited □ Good □ Excellent

How much do you agree with the following statement? This handout was a good way for me to learn about pharmacogenomic testing.	□ Strongly disagree □ Disagree □ Agree □ Strongly agree
Did you find the handout clear?	□ No, I found it confusing □ I understood some of it □ Yes, I understood everything
If you selected 'No I found it confusing' or 'I understood some of it', do you have any suggestions for how the handout could be easier to understand?	[Free space for response]
What is your level of personal interest in going for pharmacogenomic testing?	□ I am not interested in going for pharmacogenomic testing □ I may be interested in going for pharmacogenomic testing in the future □ I am interested in going for pharmacogenomic testing
What questions do you still have about pharmacogenomic testing that you think should be addressed on the handout?	[Free space for response]
What other formats do you think would be helpful to educate people about pharmacogenomic testing at the Christ Hospital Health Network? (Select all that apply)	□ Educational video □ Website □ Longer brochure □ Discussion with my healthcare provider □ TV/radio commercial □ Social media Other: _____