ENVIRONMENTAL SCAN

Understanding the needs of healthcare providers in Pharmacogenomic (PGx) program implementation

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Overview

Pharmacogenomics (PGx) has great potential to enhance patient care across medical specialties by optimizing of drug dose and choice according to an individual's genetic make-up to increase treatment efficacy and lower the risk of serious adverse events. Despite accumulating evidence of the importance of PGx to successful pharmacological treatment, the rate of adoption of PGx testing in clinical settings has been uneven.¹

The Providence Genomics team is working to expand the uptake of PGx testing across the Providence footprint. In partnership with the Center for Outcomes Research and Education (CORE), the Providence Genomics team developed an environmental scan with the goal of identifying actionable ways to make genomic medicine work for patients and providers. The aim of this report is to collect and synthesize current evidence through an environmental scan, informational interviews with key Providence stakeholders, and a short survey with participants attending a Providence Ambulatory Clinical Pharmacy Council meeting, on the current state of PGx in and outside of Providence, equity considerations to ensure that PGx adequately meets all patients' needs and effective approaches for engaging healthcare providers in genomic medicine to drive the adoption of PGx at Providence.

The following research questions were used to guide the environmental scan, informational interviews and the survey.

- Which healthcare providers current use PGx? What are differences in PGx uptake and perceptions by specialty?
- What are the barriers/facilitators for engaging healthcare providers in PGx?
- What is known about supporting primary care providers (PCPs) engagement in PGx?

Methods

Our approach for answering the research questions was three-fold. The first half of the report summarizes the results and themes from informational interviews we conducted with nine subject matter experts within the Providence Health system, which covered topic areas that aligned with our primary research questions. A short survey was also administered based on a convenience sample of participants attending the Providence Ambulatory Clinical Pharmacy Council meeting in July 2024. We then conducted a structured environmental scan of peer reviewed published research and publicly available reports through April 2024. Summaries and themes from the environmental scan are included in the second part of the report. Additional detailed Methods are found in the <u>Appendix</u>.

Key Findings and Highlights

Providence stakeholders expressed a wide range of knowledge, interests, and buy-in around integrating PGx into routine care. Many anticipated that PGx would be the standard of care for many specialties in the coming years. The literature review

supported this perspective, which underscored providers positive perceptions in PGx's potential for supporting patient care.

- Providers across different specialties reported similar barriers to PGx uptake lack of related knowledge and skills, questions of clinical utility, the need for clinical decision support tools, and potential concerns for patients. In particular, the lack of reimbursement and the need for the clinical integration of PGx testing infrastructure were highlighted as key to encouraging PGx uptake. Ensuring adequate reimbursement will help ensure that PGx is available for all patients.
- PGx will likely require contributions from multiple healthcare provider types such as pharmacists, medical assistants, and nurses, in addition to the prescribing provider. Effective implementation of PGx will require coordination across these provider types, clear descriptions of roles and responsibilities, and consistent communication across the care team. There may also be value in engaging these other provider types early in the implementation process to ensure sufficient support and buy-in for PGx across the care team.
- Given the general gap in knowledge for many providers around PGx, encouraging PGx will require additional training and education for providers. Understanding the value and efficiency PGx can offer along with strategies for communicating with patients about PGx were highlighted as key topic areas. And, because this is a rapidly evolving area of medicine, training and education will likely need to be ongoing to align with updates to PGx guidelines.
- Finding opportunities to engage providers in the process of implementation and building momentum for PGx uptake may be helpful for advancing implementation at Providence. Interviewees talked about the importance of providers feeling like they are part of the process of bringing tools and innovation into practice – and not feeling like they "have" to do something.

Key Takeaways from Informational Interviews with Providence System Stakeholders

Informational interviews with stakeholders across different specialties and roles in the Providence system revealed a wide range of interest, knowledge, awareness, experience, and buy-in around PGx testing. For example, few pharmacists surveyed for the environmental scan had ever ordered a PGx test (Figure 1). Even so, many stakeholders commented that they thought PGx would be the standard of care in the coming years.

Ambulatory clinical pharmacists' experiences with PGx					
Have heard of PGx	75.0				
Have recommended PGx testing	25.0				
Have ordered a PGx test	12.5				
A patient has come to me with PGx test results	37.5				

Because PGx testing is not routinely used in patient care currently, providers will need additional training and education to be able offer PGx to their patients. Interviewees highlighted increased understanding of how PGx can support patient care and make things more efficient for providers as a key message that should be communicated in provider education. In addition, interviewees thought that offering specific talking points to providers to engage with patients around PGx in a way that is meaning would

also be helpful. For example, talking points might include "What's the chance of picking the right medication without the test?" and "What's the chance of picking the right medication with the test?" Auxiliary staff like medical assistants will likely support PGx testing in practice and should be included in opportunities for education and engagement on the topic.

Surveyed pharmacists identified webinars, online modules, grand rounds, conference or symposium, and case conferences as effective methods for informing clinicians on PGx.

- Incorporating PGx testing into primary care may have unique challenges. PCPs are already managing highly complex decision-making processes around medication selections. It may be challenging to add PGx into a primary care visit because of the short amount of time providers have with patients in a typical visit. Building a support team of medical assistants, pharmacists, and/or other providers may facilitate PGx testing in the primary care setting.
- Pharmacists may be well poised to support the scaling of PGx testing at Providence. Pharmacists' background knowledge and training, areas of interests, and potentially lower patient panels puts them in a good position to play a primary role in supporting healthcare teams offer PGx testing.
- Providers will likely rely on multiple members of the care team to facilitate PGx testing including pharmacists and medical assistants. There should be coordination across the care team so that patients receive consistent, reinforcing communication around the PGx testing recommendations. Patients need to feel like they are getting the

recommendation from a trusted provider and that their care team is on the same page. It can be challenging to get the recommendation from one provider and a differing opinion (or no indication) from another.

- Reimbursement and insurance coverage for PGx testing is important for uptake. Stakeholders reiterated that providers do not want to stick patients with medical bills for a high-cost test. Furthermore, insufficient insurance coverage limits the ability to make PGx testing available to *all* patients. Even so, a few interviewees have found that some patients are asking for PGx testing or are willing to pay out-of-pocket if they have not yet found the right medication treatment for their condition.
- Across interviews, stakeholders emphasized the importance of making PGx testing easy, doable, and relevant to patient care. Again, providers need to understand how this will improve patient care while also being something relatively easy and straightforward for them to do. Integration of PGx clinical decision support tools, test ordering, and test results into EPIC will facilitate the feasibility of PGx uptake.



Percent of surveyed pharmacists who ranked these factors as the top three barriers to PGx.

Providers want to be a part of the process of bringing tools and innovation into practice – they do not want to feel like they "have" to do something. Finding ways to engage providers early in the implementation process to help envision and build out the program can help facilitate uptake and buy-in. Identifying champion-leaders to identify key stakeholders and initiate engagement can also be a facilitator in starting new programs.

Key Findings from Literature

Differences in PGx uptake by provider specialty

PRIMARY CARE

Primary care is a key specialty to engage in the implementation of PGx programs. Most prescribing happens in primary care, and evidence from recent research suggest that over 60% of patients within the primary care setting are prescribed a medication with a PGx recommendation.^{2,3} Even so, the lack of adequate skills and knowledge, clinical evidence to support PGx testing, decision support tools to aid interpreting results, clarity of professional roles and responsibilities between primary care clinicians, cost effectiveness, leadership to develop policy and guidance for PGx prescribing, and reimbursement supports have been perceived as barriers for the low clinical uptake of PGx testing among PCPs.^{1,4–12} That said,

provider education on PGx has been shown to positively improve PCPs perspectives of PGx utility relative to other specialty types.¹³

PHARMACY

Pharmacists are well-positioned to support the clinical uptake of PGx testing, make PGx-based prescribing recommendations, and educate patients and other healthcare professionals about how to interpret the results of PGx tests. ^{14,15} Many pharmacists feel motivated to incorporate more PGx testing into their practice because they believe that the use of PGx will become more widespread in the future and feel they will be expected to play a leadership role in its growth.^{15,16} Despite this, pharmacists have raised concerns with cost of the service, lack of time, gaps in their knowledge, process complexity, high patient loads, and fitting PGx testing into their existing workflows.^{15,17–19} Other barriers cited include low patient engagement and motivation, patients' concerns regarding consent, privacy, and the ownership of their genetic information, lack of formal PGx training among pharmacists and lack of confidence in interpretation and dissemination of results.^{15,16,20}

PSYCHIATRY

Like providers from other specialties, psychiatrists maintain positive perceptions of PGx but adoption into routine practice remains suboptimal. ^{21,22} Commonly reported barriers include lack of PGx education, uncertainty on the clinical utility of PGx testing or how it would improve their practice, requesting tests, lack of timeliness in getting test results, the interpretation of test results, cost-effectiveness, managing patients' expectations and ethical issues.^{23–28} More receptive mental health providers have identified the potential advantages of PGx, such as improved treatment for patients with multiple co-morbid conditions or those that have been difficult to treat or have had poor responses to medication. These improvements may support patient buy-in around the use of medication to treat depression and help overcome patient resistance or concerns around medication and possible side effects.²⁸

CARDIOLOGY

Similar to other specialties, cardiologists are also interested in pharmacogenomic testing being incorporated into diagnostic cardiovascular genetic tests, especially given that many actionable pharmacogenomic genes are implicated in cardiovascular medication response variability.^{29–31} However, lack of genetics education, discomfort with the logistics of test ordering, lack of evidence, uncertainty about the clinical utility and difficulty choosing an appropriate test, high costs, limited access to genetics services, and lack of clarity on integrating genetic information into clinical tools were considered major barriers hindering the uptake of PGx testing.^{13,29,31–34} Privacy protections and data sharing protocols were also crucial considerations especially when embedding research-based tests into clinical care.³⁰ The potential for misuse and genetic discrimination, and the ability of providers to effectively explain test results and for patients to understand those results were other barriers cited in utilizing pharmacogenomic technology.³⁵ Overall, cardiovascular specialists felt that they would consider adopting PGx if they were

provided additional education, ongoing support, and evidence supporting the clinical utility of PGx testing in cardiovascular medicine.^{13,29,31,36}

ONCOLOGY.

Oncologists also perceived value in PGx but reported similar barriers to utilization described by providers in other specialties, including cost, lack of consistent recommendations across guidelines, limited knowledge among providers, test accuracy, clear testing benefits, and genomic information confidentiality among consumers.^{37–42} A qualitative study of cancer clinicians raised concerns about using race and/or ethnicity as a surrogate for genetic information during clinical decision-making about drug choice and drug risk.⁴³

Facilitators and barriers for engaging healthcare providers in PGx

Facilitators	
Provider attitudes	• In general, healthcare providers believe that PGx testing can support patient care in terms of informing drug selection and dosage to improve treatment efficacy, reduce side effects, and help avoid adverse effects. ^{4,13,33,44-46}
Having a supportive care team	• Several studies point to the need for additional care team support to facilitate the uptake of PGx, especially in primary care (e.g., a PCP working in partnership with a pharmacist). For this to work, implementers should work to ensure clear roles and responsibilities between members of the care team. PGx engagement might also benefit from access to PGx experts that providers could consult when needed to help guide decision making. ^{4,45,47}
Barriers	
Provider knowledge of PGx	• Many studies highlight the lack of PGx knowledge, skills, and education as a primary barrier to scaling PGx uptake. Most providers did not receive PGx education as a part of their training. In data collected from surveys and interviews, providers express uncertainty around interpreting PGx test results and recommendations. ^{4,16,44–47}
The caregiving environmental context & resources	• Several aspects of PGx testing infrastructure have been identified as challenging. This includes the process for ordering tests, long wait time to receive results, and the accessibility of test results. Results reports can be difficult to interpret, are often not standardized, and not well-integrated into EMRs. Questions also remain around what genes and variants should be included on PGx panels. ^{4,45,48}
	• Another barrier frequently identified around PGx uptake centers on clinical utility . Part of this is related to the evidence base supporting PGx. Providers point to the lack of randomized control trials and conflicting recommendations from national guidelines bodies as limiting factors. There is also concern with navigating how PGx recommendations may conflict with other clinical factors. ^{4,16,48}
	• Reimbursement is a significant barrier for PGx. Overall, although the coverage and payments for PGx testing ranges by insurance company and gene-drug pair, reimbursement remains suboptimal. ^{16,46,49}
Meeting patient needs	• Ensuring that PGx adequately serves patients is another commonly cited barrier by providers. Concerns arise around privacy, discrimination, and potential risks of psychological distress. Costs and lack of insurance coverage for testing is also a common concern. Costs concerns contribute to the worry that increased availability of PGx testing may exacerbate health inequities. ^{4,16,44,45,47,50}

Supporting Engagement in PGx

While the body of evidence supporting the clinical utility of some PGx tests has grown, the implementation of PGx into clinical practice has been relatively slow, often due to the barriers described above. Even so, a number of studies have highlighted some of the following factors as key recommendations for PGx implementation into clinical practice:

- Employ an implementation framework. The Implementing GeNomic In pracTicE (IGNITE) network advocates for the use of an implementation structure such as the consolidated framework for implementation research to guide PGx program development.⁵¹
- Cultivate institutional support. Institutional buy-in is critical for promoting PGx uptake. Establishing a collaborative, multidisciplinary work group often including geneticists,

Provider knowledge is one of the most commonly cited barriers to implementing PGx. As such, any PGx implementation effort should include a comprehensive education and training package relevant to all involved providers.

- To be effective, PGx education outreach must be multimodal, multidisciplinary and recurring.⁵¹
- Active learning approaches such as a case-based methods for delivering educational content have been highlighted as effective for improving PGx knowledge and practice.⁵³

Finally, a study that tracked provider attitudes during a five-year implementation of a PGx program found a robust adoption of PGx testing despite persistent concerns around the lack of PGx knowledge. It may be that 'learning by doing,' or experiential learning, is a key pathway to close the long-

genetic counselors, informaticists, pharmacists, and physicians to navigate challenges and support decision-making can be helpful to gain acceptance and improve standardization.⁵¹

- Start small. A number of PGx implementation papers recommend starting with a small number of gene-drug pairs and gradually building more comprehensive services over time.⁵²
- **Build an adaptable system.** PGx programs should be prepared to refine and modify tests as new evidence emerges.⁵²
- **Provide clinical support**. To help minimize errors and maximize efficiency, providers need support both in the form of clinical decision support systems as well as from multidisciplinary care teams. Primary care physicians frequently report the belief that pharmacists should play a major role in the implementation of PGx programs.^{51,52}
- Engaging patients. Providing adequate patient education and communication can help promote uptake and help ensure that PGx services do not exacerbate health inequalities. Patients prefer receiving results in ordinary language, as a face-to-face appointment, tailored to current medications, and with simplified visual content.⁵¹
- **Track progress over time**. Identifying and tracking key indicators will support continuous quality improvement and help ensure maximum patient benefit. Commonly reported outcomes include volume of patients and number of actionable genotypes identified. Other

outcomes have included number of alerts, changes in ordering, provider satisfaction and cost–effectiveness.^{51,52}

Conclusion & Recommendations

Conclusion

Pharmacogenomics (PGx) has great potential to enhance patient care across medical specialties by optimizing drug dose and choice according to an individual's genetic make-up to increase treatment efficacy and lower the risk of serious adverse events. Although PGx uptake has been slow and is not yet commonly used at Providence, many providers remain optimistic about the promise of precision medicine support in enhancing patient care.

While providers identified several barriers to PGx implementation; making PGx testing easy, doable, and relevant to patient care were identified as key facilitators for advancing PGx practice. Strategies for making PGx more accessible to providers include clinical integration of PGx testing processes, ongoing opportunities for training and education on PGx for providers, supporting the coordination of multi-provider care teams, and advocating for increased reimbursement. Despite these challenges, the Providence Genomics team has already adopted several strategies for PGx implementation highlighted in literature.

Recommendations

Though the PGx programs at Providence are still in early stages, interviews with key informants suggests an anticipated momentum for the program in coming years. The following are recommendations for support PGx implementation at Providence:

- 1. Continue to build institutional support and buy-in. The wide spectrum of interest in and knowledge about PGx by patients, providers, and administrators suggests that the Genomics team will need to continue to engage a broad constituency to move this work forward. Findings from the scan suggests that multiple members of the care team may be involved in PGx workflows. As such, opportunities to educate a variety of providers on PGx and engage them in decision-making around PGx programming will be key to developing provider buy-in across provider types. At the same time, patients will need education and clear guidance to successfully participate in PGx and leverage the benefits of PGx testing.
- 2. Track progress over time. Understanding the experience and impact of PGx testing at Providence will be important for supporting the growth of the program over time. Determining key measures prior to implementation will support program monitoring and enable the team to adjust processes as needed in early stages. Over time, these measures can also be used to help demonstrate the impact and value of PGX testing for Providence providers and patients. Finally, tracking these data over time may also help ensure that promise of PGX testing equitably reaches all patients.

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Appendix

Methods

Our approach to answering the research questions was three-fold. Our first approach included conducting informational interviews with PGx interested parties within the Providence Health system. The Providence Genomics team provided a list of potential interested stakeholders and included providers from a wide range of medical specialties. The CORE/Genomics team worked on prioritizing outreach to include representation from across different specialties (oncology, cardiology, primary care, psychiatry, pharmacy). Recruitment emails were sent out by a CORE staff member to prioritized stakeholders. Once recruited, interviews were conducted over Microsoft Teams and lasted 15-30 minutes. A brief discussion guide was developed for the interviews and included questions that aligned with our primary research questions on how the providers used PGx, barriers and facilitators for PGx usage and supports that would be needed to make it more widely usable. Notes taken during the interviews were summarized and thematically analyzed for inclusion into the report.

We also conducted an unstructured review of peer reviewed published research and publicly available reports through April 2024. Summaries and themes from the environmental scan on provider usage of PGx by specialties, barriers and facilitators are included in the report.

A short survey was also administered based on a convenience sample of participants attending the Providence Ambulatory Clinical Pharmacists Council meeting in July 2024. Questions in the survey aligned with our primary research questions and included pharmacists' usage and perceptions of PGx, barriers and facilitators to use and supports they would need to make usage more widely acceptable. The survey was administered via MS Forms, and the 8 responses obtained were analyzed descriptively. Appendix Table 1: Pharmacists' experience with PGx use and instruction and interest in involvement in implementation of PGx at Providence

	Yes (n=8)	No (n=8)
Experience with PGx		
Have heard of PGx before	75%	25%
A patient has come to them with their PGx results at some point in their practice	37.5%	62.5%
Have recommended a PGx test at some point in their practice	25%	75%
Ordered a PGx test at some point in their practice	12.5%	87.5%
Experience with PGx instruction		
Continuing medical education	100%	
Included in graduate medical education	75%	25%
Included in post-graduate medical education (e.g. residency/Master's program)	37.5%	62.5%
Interested in being involved in the implementation of PGx at Providence	50%	50%

Appendix Table 2: Barriers to applying PGx to clinical therapeutics as reported by the pharmacists

	1 st Choice (n=7)	2 nd Choice (n=7)	3 rd Choice (n=7)	4 th Choice (n=7)	5 th Choice (n=7)	6 th Choice (n=7)	7 th Choice (n=7)	8 th Choice (n=7)	9 th Choice (n=7)	10 th Choice (n=7)
Difficulties in accessing PGx testing in the workplace High cost or insurance coverage of PGx testing	28.6%	42.9%			14.3%		14.3%			
	14.3%	28.6%		14.3%	28.6%	14.3%				
Lack of actionable guidelines for drug selection	14.3%	14.3%	14.3%	14.3%	42.9%					
Difficulty in interpreting genotyping results		14.3%	42.9%	14.3%			14.3%	14.3%		
Lack of PGx education for healthcare providers	14.3%			28.6%		14.3%	28.6%	14.3%		
Lack of clinical PGx experts in the workplace	14.3%		28.6%			14.3%		28.6%	14.3%	
Lack of evidence of the clinical utility of PGx	14.3%		14.3%	14.3%		14.3%	14.3%		14.3%	14.3%
Lack of patient's education					14.3%	42.9%		14.3%	14.3%	14.3%
Long turnaround time for PGx testing								28.6%	28.6%	42.9%
Ethical considerations				14.3%					14.3%	71.4%

Appendix Table 3: Perspective on effective methods to educate clinicians about PGx testing					
	Count (n=8)	% responses			
Grand rounds or other types of in-house seminars	2	25%			
Online module	2	25%			
Webinar	2	25%			
Conference or symposium (half or full day)	1	12.5%			
Case conference	1	12.5%			

Appendix Table 3: Perspective on effective methods to educate clinicians about PGx testing

Appendix Table 4: About the pharmacists

	Count (n=8)	% responses
Practice specialty		
Primary care	5	62.5%
Other	3	37.5%
Geography of practice setting		
Suburban	4	50%
Urban	3	37.5%
Rural	1	12.5%
Work setting		
Outpatient	8	100%
Average number of patients seen each		
day		
None	5	62.5%
1-9	2	25%
21+	1	12.5%