Value of a Genomic Wellness Program:

How your organization can offer pharmacogenomic testing to employees

by Amjaad Al-Hussain, MHSA

Employers have established wellness programs to improve employee health with activities such as company-sponsored exercises, weight-loss competitions, educational seminars, tobacco-cessation programs, and health screenings that are designed to help employees improve their overall health.

Recently, some healthcare systems and employers have recognized the value of investing in genomics as a wellness offering to their employees and their families (see **Table 2**). Genomics can potentially improve an individual's future health through prediction, prevention, and tailoring a program to an employee's lifestyle and therapeutic regimen (e.g., recovery from heart surgery with subsequent changes in diet, exercise regimen, and medications). Clinically useful genomic testing results combined with data from tracking devices, healthcare check-ups, diaries, and other inputs would add to a comprehensive record to inform decisions to treat employees with precision medicine (best drug, best dose). This article will explore one of the lower hanging fruits of the genomics world and how employers have incorporated it into their wellness program offerings.

Why Pharmacogenomics?

Healthcare providers believe that pharmacogenomics testing can be most impactful when done pre-emptively (depicted in **Figure 1**). This means prescribing a medication taking account of an individual's unique genetic makeup and how their body may react to those medications. Individuals may no longer need to wait three to six weeks to see if their prescribed antidepressant is effective or wait and see if their pain medication will cause negative side effects.

Making baseline PGx information available at the physician's fingertip (e.g., in the electronic health record) could become a tool to guide the physicians to consider the most efficacious medications and limit the trial and error process of prescribing for their patients. Implementing wide-scale pre-emptive testing is as-yet uncommon in many healthcare systems. Some healthcare systems have the unique ability to offer PGx testing as part of a standard package of service to all employees and families through wellness program partnerships. In the

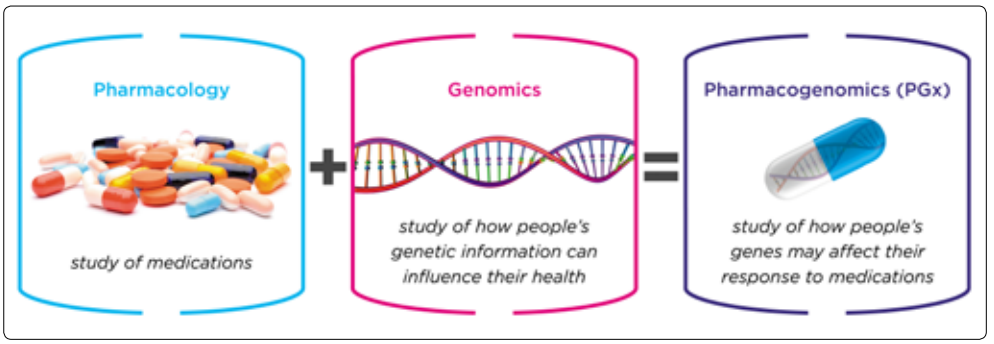

Figure 1: Pharmacogenomics (PGx) is the study of how people's genes may affect their response to prescription medications. PGx test results can help healthcare providers consider which medications may be most effective, which to avoid, and which dosage may be best for that individual.

Table 1: Examples of Corporate Wellness Programs

Program	Company	Website
Caring Health Plan	Geisinger	https://www.geisinger.org/health-plan/members/getting-started https://www.geisinger.org/-/media/OneGeisinger/pdfs/ghs/about-geisinger/news-and-media/annual-reports/87179-Geisinger-AR_2017_final5_spreads.pdf?la=en
Health & Wellness	Kaiser Permanente	https://healthy.kaiserpermanente.org/health-wellness https://healthy.kaiserpermanente.org/static/health/annual_reports/nw_channualreport_2017/

Table 2: Examples of Corporate Partners Programs

Company	Website
AmeriHeatlh	https://www.amerihealth.com/employers/employer_resources/wellness_partners.html http://provcomm.amerihealth.com/ProvComm/ProvComm.nsf/b45c1fdaf8df93f285257936006fc1b3/111374d640b88a0385257fa20042a734!OpenDocument
23andMe (e.g., with Lark Health)	https://mediacenter.23andme.com/press-releases/lark-health-and-23andme-collaborate-to-integrate-genetic-information-in-two-new-health-programs/
Genome Medical	https://www.genomemedical.com/employers/
Newtopia	https://www.newtopia.com/

appendix, we provide recommendations on how to incorporate pre-emptive PGx testing into your employee wellness program.

Thoughts to Consider for Establishing a Wellness Program

> *Energy and persistence conquer all things.*
>
> – Benjamin Franklin

In 2017, adult consumers in the Washington D.C. and Northern Virginia areas were surveyed for their knowledge and opinions on PGx testing. More than 70% of consumers surveyed were generally not familiar with PGx testing (illustrated in **Figure 2A**). However, after survey participants were introduced to what PGx is, a significant majority of about 80% expressed interest and wanted to learn more (see **Figure 2B**). Only 17% were either unsure if testing was useful or did not want PGx testing. The consumer survey concluded that with the appropriate education and an affordable price, consumers would be very interested in PGx testing.[1]

As most professionals in the field of precision medicine know, there is no nationally recognized "standard" process for genomic testing integration in clinical settings, let alone testing for employees. Genetic test implementation involves a thorough assessment of current operational and clinical workflows before any genetic testing is added to clinical settings. Working closely with front-line staff (the people who know their job best) enables customized workflows that successfully integrate genetic testing without disrupting existing standards and efficiencies.

Implementing PGx testing without a deep understanding of how results can impact clinical care may cause more harm than good. Clinical leadership must be prepared to fully integrate PGx results into clinical care while deeply understanding the benefits and limitations of testing.

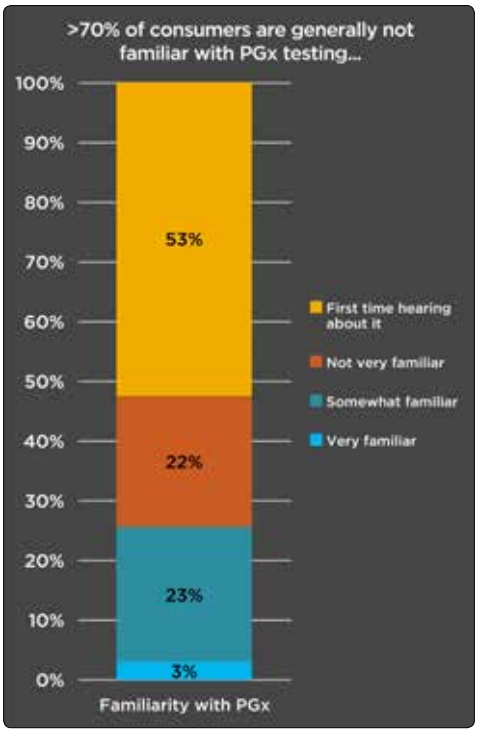

Figure 2A: A 2017 survey asked adult consumers in the Washington D.C. and Northern Virginia areas for about knowledge and opinions on PGx testing. More than 70% of consumers surveyed were generally not familiar with PGx testing.

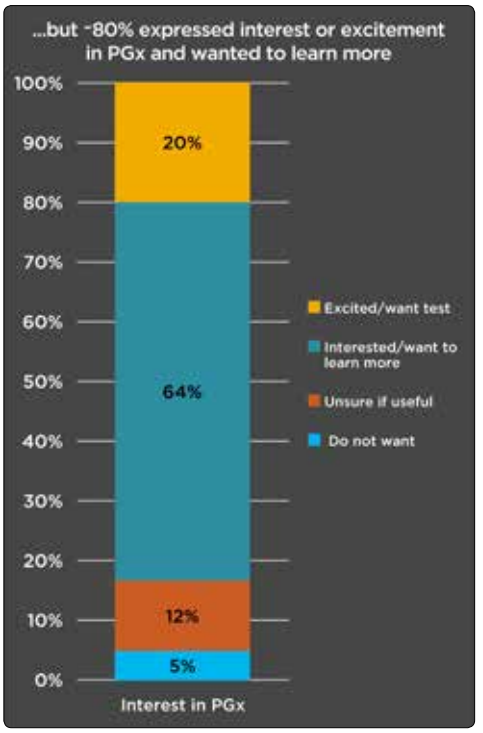

Figure 2B: The same survey showed that the majority of adult consumers in the Washington D.C. and Northern Virginia expressed interest in PGx testing and wanted to learn more once they were introduced to the concept.

For healthcare systems that strongly believe in precision medicine and the power genomics can have on predictive and preventative healthcare, PGx testing for employees is a unique way to demonstrate their commitment and give their clinicians hands-on experience on a wide scale. While many employees will enroll in a PGx testing program, a comprehensive education roll-out that reaches out to all – early to late adopters - is needed to realize the benefits for their future health and the health of their family members. Healthcare system employees who enroll also have the unique opportunity to experience a clinical tool that can benefit their patients which they would now have the opportunity to experience on a personal level.

Future Goals to improve genomics integration:

- Demonstrate clinical utility of pre-emptive PGx testing in primary care settings, as well as specialty areas. Showcase the cost effectiveness of pre-emptive PGx testing and support the case for broader PGx reimbursement. These demonstrations will be critical to expanding health insurance coverage and making PGx testing available to more communities.
- Create evidence-based decision support tools for providers to document medication

management decisions and automate data analysis reporting on PGx test result utility.

- Work with professionals: Many resources and partners are available to introduce a genetic testing program. An in-house genetic testing program is not needed to offer genetic testing as part of an employer's wellness program. One should not set up a genetic testing program just for employees. Partnering with a healthcare system that has an operating genetic testing program or a third-party laboratory would be a good starting point.
- Implement discrete data recommendations for PGx test results into electronic medical records so providers have immediate access to their patients' genetic test results. Many health systems have been limited to uploading PGx results as PDF files which are less accessible and difficult for clinicians to find.
- Deploy a patient portal and medication search function for mobile devices that is compatible with your electronic medical system. This tool would make it more practical for patients to use while visiting other healthcare providers and pharmacists.

Employers offering PGx testing to employees can only offer free or discounted genetic testing as part of their employee wellness program. A comprehensive employee wellness program is necessary to enhance a workforce's overall health and wellness. Pre-emptive genetic testing alone will not be effective in improving health and wellness nor will it solely have a positive impact on controlling health care costs. In the appendix, "A Brief Guide to PGx Implementation for Healthcare Systems and Employers," we review the components needed for PGx implementation for healthcare systems and employers, including brief summaries of employers who have offered PGx testing to their employees. JoPM

Amjaad Al-Hussain, MHSA is a is a genomics integration expert who specializes in helping health care systems implement precision medicine programs. Amjaad helped lead product development of genomic services and test integration at Inova Health System. Amjaad is passionate about health care management and spends her evenings mentoring future leaders and teaching at Georgetown University as adjunct faculty. Amjaad holds a master's degree in Health Systems Administration from Georgetown University. She was honored with the Excellence in Health Administration Award from the College of Health and Human Services at George Mason University. In her free time, Amjaad loves to cook and plan her next travel adventure. She believes food is one of the best ways to learn about different cultures. Everybody eats and food is an entry point to empathy. Her self-published Yemeni cookbook, *Sifratna*, was featured in the Washington Post, Middle East Eye, Washingtonian Magazine, Northern Virginia Magazine, and more.

References

1. Survey commissioned by Inova Health System and conducted by L.E.K. Consulting in 2017.

A Brief Guide to PGx Implementation for Healthcare Systems and Employers

by **Amjaad Al-Hussain, MHSA**

To establish an employee wellness program, start by identifying a group of leaders that will be held accountable for drafting a Wellness Program Plan and charging a team with executing the plan and maintaining metrics. The plan will serve several purposes but perhaps most important are determining the scope and resources needed, conveyed goals and how they relate to the organization's mission and vision, estimated costs (dollars and people), and a cost-benefit analysis to the organization leadership team.

An organization's wellness program should work towards engaging employees and partnering with leadership to make wellness a core part of the organization's internal activities. Once the employee wellness program is well recognized internally and has a sustainable infrastructure for support services and special programs, leadership may then want to consider enhancing the program's offerings with discounted or free genetic testing for employees.

Points to Include for Setting Up and Launching a Genetic Testing Program

I. Leadership Buy-In

For advocates of wellness programs, leadership buy-in is a critical aspect to success. Like many other investments, a genomics program will likely not be profitable to an organization in its early stages. Consider presenting published cost-benefit analyses from programs elsewhere and how the program aligns with the organization's mission, vision, and values. Partnerships with the clinical leadership team is key in developing a strategy for your program. This first stage may take the longest, but it can make or break your implementation's success as you need momentum to help overcome inevitable challenges.

II. Community and Employee Awareness of the Promise of Pre-emptive Testing

Most people do not know what PGx testing is

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but, when explained, the overwhelming majority sees the value. Furthermore, organizations are more likely to participate if testing is accessible or the price point is affordable. Healthcare is typically reactive – patients seek care, remedies, and solutions at the time when they experience poor health. Shifting to a pre-emptive approach to healthcare services will not be intuitive to most and people may have a hard time comprehending why they should pay now for something they may not need anytime soon. Explain the facts, benefits, and limitations of PGx testing in plain language. One should work closely with physician leaders to strategize on educating participants.

III. Provider Awareness and Education

PGx testing is here, and it is here to stay despite regulatory hurdles the industry is facing. Like most organizational and technology-based changes, organizations and individuals will naturally resist. With proper education, evidence-based guidance, and physician advocate leadership, organizations can effectively educate and train providers about PGx testing, how PGx testing can potentially improve patient outcomes, and how to utilize this type of testing in their everyday practice. Consider identifying areas in which small-scale pilots can be implemented most readily. Primary care, behavioral health, and surgical services are a great place to start because of the evidence available for prescriptions applicable to those patient populations. Since PGx testing is not as affordable as flu shots, individuals are less likely to spend money when they have not experienced the benefits. Better success may be had by engaging clinical teams to help with patient outreach as opposed to traditional direct marketing and/or advertising.

IV. System Integration/Partnering with a Healthcare System

Employers who are not part of a health system should consider partnering with one that is invested in precision medicine or has successfully implemented a PGx program (see examples in **Tables 1 and 2**). Also consider whether this potential partner has in-house genetic testing capabilities, bundled genetic counseling services and other clinical and implementation support and expertise.

Healthcare systems are traditionally not well equipped to quickly adapt and adopt new technologies due to rigid systems that require security clearances and interoperability streamlining. Many groups – e.g., patient registration, billing, medical records, and others - are unprepared for how genetic testing would be included in their validation processes.

An implementation team should identify a group of executive sponsors and advocates across leadership levels and departments. These sponsors and advocates should meet periodically and tackle operational and regulatory hurdles. They will serve as your engine and will be key to engaging other stakeholders critical to the program's success. Over time, consider involving the following departments: patient billing, human resources, employee wellness (if separate from human resources), IT and/or your medical record team, physician advocates from several key service-lines, genetic counselors, legal, communications, compliance, and quality.

> *"PGx testing is here, and it is here to stay despite regulatory hurdles the industry is facing"*

V. Electronic Medical Records and Clinical Testing

Employee access to his/her PGx results in one's electronic medical record is critical to the program's success. Additional medical record integration features such as embedded best practice advisories (pop-ups) or PGx result alerts (similar to allergy banners) can be differentiating investments.

These features can efficiently display providers with the information they need to make informed clinical decisions. Patients should also have easy access to their results via their patient portal on various platforms (e.g., smartphone) should they need to share with providers outside the system or pharmacists.

Your physician and PGx implementation team should offer the option of the highest standards PGx test available. For example, an FDA approved test is not necessarily clinically useful for providers. A PGx testing program must include a validated clinical test that is ordered by a physician, provide genetic counseling resources, and is transparent about the evidence behind each PGx drug included in the report of the test. Not all medications have sufficient PGx evidence. If the PGx test is not classified as a "clinical test", it likely won't be added to the medical record.

VI. Genetic Counseling and Pharmacy Consults

Genetic testing results are not always easy to interpret. Employees, patients, and their families must understand that their PGx results are intended for their physician's use and how it can guide their care. Medications should never be changed without a physician's guidance. Despite training and education, providers should still have regular access to genetic counselors and pharmacy consults – many service providers are available (e.g., InformedDNA). Depending on the volume, consider setting up a medication management consult service for both providers and patients. Genetic counseling may be needed pre- and post-testing to prepare an employee about possible outcomes and to deliver results in appropriate context.

VII. Payment Method(s)

Depending on how the PGx tests will be offered, you will need to consider how employees will pay for their tests. The most critical questions at this stage include:

- Should payment be collected before or after testing?
- Will the employer cover the cost of the test, or will they provide a discount?
- Will that discount be extended to dependents and other family members?
- Does our current payment system accept credit cards at the point of service?
- How will we process requests to cover testing for individuals who want to use their flexible spending account (FSA) or healthcare savings account (HSA)?
- Can the benefit be deducted directly from the employee's paycheck?
- Will the price include counseling and updated reports?

VIII. Patient and Provider Testimonials

Collecting a series of testimonials will help engage your audiences and make pre-emptive PGx testing more relatable. Because PGx testing is still foreign to many, sharing success stories will be important. Do not use these testimonials as sales videos. The intent is to educate your audience on what PGx is and what they can realistically expect from this test. Work closely with your physician advocates and genetic counselors to accurately convey your key messages. Use case-studies and examples from your pilot program(s) to showcase your organization's investment.

Legal Framework for Employee Genetic Testing

This section is not intended to provide legal advice, but rather to offer suggestions for which regulations play a major role in the implementation of genetic testing programs and should be reviewed with the help of an organization's legal team.

I. Overview Rules Around Incentivizing Employees

To ensure federal compliance, an employer can only offer free or discounted PGx testing to its employees as part of its employee wellness program. The program must be administered according to federal rules permitting employer-sponsored wellness programs that seek to improve employee health or prevent disease, including the Americans with Disabilities Act of 1990, the Genetic Information Nondiscrimination Act (GINA) of 2008, the Equal Employment Opportunity Commission (EEOC), and the Health Insurance Portability and Accountability Act (HIPAA). All employees must have equal access to the same offered benefit.

Testing must be consented to and voluntary for employees and families. An employer cannot incentivize employees to purchase or utilize genetic testing. Employees cannot be penalized for not partaking in the offered benefit. An employer must consult with their legal and compliance teams to determine what type of outreach or internal communications are appropriate for educating your employees on the benefits availability.

II. Liability, Privacy, Data Security

If the genetic test is a clinical test with clinical results, the results must be included in the individual's medical record.

HIPAA prohibits employees from electronically accessing medical records for any family members (including minor children), coworkers or others unless they are involved in the patient's care based on their position or unless access is necessary to complete their job duties. Policies such as these would apply to the offered genetic testing.

Like all other medical testing, PGx and other genetic testing results are confidential. Employers – including HR, the employee's manager or supervisor – must not have access to any medical information of their staff including genetic testing. Medical information that identifies an individual can never be used to make decisions regarding their employment. Participating employees must complete GINA, HIPAA and EEOC compliant authorization forms for testing, and voluntarily provide their DNA sample.

All medical information obtained through testing must be maintained separately from personnel records and information stored electronically and should be encrypted. Individuals cannot be discriminated against in their employment because of the information provided as part of participating in their employer's wellness program and genetic testing, nor may they be subjected to retaliation if they choose not to participate.

> *"To ensure federal compliance, an employer can only offer free or discounted PGx testing to its employees as part of its employee wellness program"*

III. Insurance, Reimbursement, FSA/HSA

Most insurance companies do not offer reimbursement for PGX panels that cover many genes and multiple prescription medications. There is limited coverage for single-drug single-gene PGx testing contingent on the patient's diagnoses.

Forward-thinking insurance companies have launched pilots to assess how PGx testing can potentially help them control costs for their highly utilizing patients and may consider expanding PGx programs through strategic partnerships.

As part of your employee offering, consider ways in which employees can use their flexible spending account (FSA) or healthcare saving accounts (HSA) to pay for PGx testing if your organization can only offer a discount.

Examples of Employers Who Have Offered Pharmacogenomics Testing to Employees

I. Community Healthcare System with Hospitals & Outpatient Clinics

As part of the health system's precision medicine program, their in-house genomics laboratory offered genetic testing to patients and the community. Employees were eligible to purchase a discounted PGx test through their organization's employee wellness program. The program was voluntary and employees were not incentivized nor penalized if they did not participate.

Employees purchased a discounted PGx test voucher that they could then redeem at their organization's PGx Clinic. At the clinic, employees or their family members would see a genetic counselor prior to authorizing the test and getting tested. The test was then ordered by the clinic's providers or by the individual's referring physician. Test results were uploaded into the patient's electronic medical record for their ordering provider to review and for future clinical use. Best practice advisories (pop-ups) were built to alert providers whenever a medication on the ordered PGx test was prescribed. The pop-up would link to the full test report. Patients also received a copy of their results to share with their out-of-network providers and community pharmacists.

II. Information Technology Company

A precision medicine program with free PGx testing was launched by an Information Technology Company to its U.S. based employees with support by its leadership. Their goal was to enable associates to recognize genetically based health risks so they could take steps to remain healthy, which would be of great value to both employee and their employer. Leadership also believed that this important information can help a provider arrive at the right diagnosis and best treatment faster.

The program is being managed by a third party, which offers a platform to deliver testing results into clinical workflows. Employees who choose to participate in the voluntary program receive a testing kit which they use to swab their own mouth. After analysis and physician review, participants receive their results through a patient portal shared with their healthcare providers. JPM

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