Implementing a Pharmacist-Led Primary Care Pharmacogenomics Medication Management Service

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Abstract

Background: Pharmacogenomics (PGx) is a tool to guide optimal medication selection. Increased demand for personalized medicine and the growing occurrence of chronic diseases are drivers for pharmacogenomic medication management services. A review of implementation models identified a paucity of models delivering these services utilizing pharmacists in primary care. Lack of standardization of this process remains a barrier to widespread implementation within health systems. *Purpose:* Describe the process of developing an institutional guidance document and applying it to implement a pharmacogenomics medication management service at clinic sites within an integrated health system in the United States. Measure the growth in the number of PGx visits completed. *Method:* A task force of pharmacists reviewed literature, guidelines, and institutional policies to create a comprehensive guidance document. The document included six minimum practice requirements for implementation in the primary care setting, and six additional recommendations. A retrospective chart review of all face to face, phone and eConsult PGx visit types occurring from January 1, 2022 through September 30, 2022 was conducted. *Results:* A pharmacist-led pharmacogenomics medication management service is now offered at all primary care sites within the health system. During the study timeframe, 1378 patients had a PGx visit, resulting in 1939 PGx visits. Of those visits, 1777 (92%) were referred by a primary care provider and 1675 (86.7%) were conducted by a primary care pharmacist. Twenty-nine primary care pharmacists offered the PGX service and 25 (89%) completed at least one visit. Patients were referred by providers from 56 of the 64 (87.5%) primary care departments. *Conclusions:* Developing an institutional process and guidance document for the implementation of a new pharmacist-led pharmacogenomics medication management service at clinic sites within an integrated health system was beneficial in developing and standardizing the workflow. Dissemination of workflow expectations to the primary care providers and pharmacists resulted in adoption of the service.

Keywords: Medication therapy management, pharmacogenomics, primary health care, collaborative practice agreement

INTRODUCTION

Pharmacogenomics (PGx) is a subset of personalized medicine, which is the study or practice of medicine using a person's unique genetic characteristics to make optimal therapy decisions for the prevention, diagnosis, and treatment of disease.[1] A systems approach to implementing PGx testing, including developing clinical decision support tools and integration of lab results within the electronic health record (EHR) has previously been reported.[2-4] Similarly, implementation of single site PGx consult clinics have also been described in various clinical settings.[5,6] However, challenges remain with the widespread adoption of PGx testing and interpretation within primary care settings. A structured review conducted in 2021 identified only a handful of models delivering pharmacogenomic medication management service lines utilizing pharmacists in primary care.[3]

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The purpose of this summary is to describe the process used to standardize the implementation of PGx clinical services at multiple primary care clinic sites across a large health system using integrated ambulatory clinical pharmacists as the key driver. The increase in demand for personalized medicine and the growing incidence of chronic diseases are principle factors that precipitate demand for pharmacogenomics medication management services.[7] The application of pharmacogenomics is projected to limit health care costs and has been shown to prevent adverse drug reactions, which is ranked as the fourth leading cause of death in the United States.[8,9] Studies show greater than 90% of patients have clinically actionable genetic variants, indicating pharmacogenomics could inform treatment decisions.[10,11] The American Society of Health System Pharmacists (ASHP) recognizes the fundamental role pharmacists play in ensuring optimal medication therapy selection based on pharmacogenomic results, and pharmacist involvement in the implementation of pharmacogenomics within primary care has been identified as an underlying factor to success.[3,12]

SETTTING

Mayo Employee and Community Health in Rochester, Minnesota, and Mayo Clinic Health System sites in Minnesota and Wisconsin, encompass 799 primary care providers serving

DOI: https://doi.org/10.24926/iip.v15i2.6178

514,813 paneled patients within 64 departments at 49 clinic locations. A total of 29 primary care pharmacists are embedded within 27 of these clinic sites and provide comprehensive medication management services utilizing a collaborative practice agreement for chronic disease management, comprehensive medication reviews, and transitions of care management. After an institutional decision to require PGx certification for all ambulatory care pharmacists within Mayo Clinic regardless of practice setting, PGx consultation became a new service expectation in 2021 for all pharmacists embedded in primary care departments. However, creating a new service line across a variety of primary care practice sites prompted the need for a standardized approach to the expansion and delivery of these services.

METHODS

In February of 2019, a task force of six pharmacists was assembled and charged with defining the role of PGx in the health system's primary care pharmacist practice and creating a standardized workflow. The task force members were all Ambulatory Care board certified pharmacists practicing in primary care and had a practice interest in PGx. Three of the members had completed a pharmacogenomic certificate, had substantial experience implementing PGx results into practice and had been providing PGx services for approximately 2 years. All task force members were eager to find a way to implement this emerging science into primary care practice.

To clarify the role of PGx in primary care, the task force first reviewed literature, guidelines, and internal institutional policies to identify practice models or guidance that were already established. Primary care pharmacists were polled to determine what guidance would be most beneficial to implement a PGx service. In addition, the task force considered the experience of pharmacists already providing established PGx services and recommendations from specialty PGx pharmacists. The task force conducted a needs assessment to determine key stakeholder needs, which included: identifying which patients could benefit from PGx consult, which PGx labs to order, how to interpret and apply results, pharmacist education and training, and patient cost estimation.

The task force determined that across the health system the unique demands of each practice site created some heterogeneity among primary care pharmacists' practice. In order to standardize PGx services across the health system, while allowing each practitioner to adapt based on individual practice needs, a guidance document was created that identified both rigid practice requirements and more flexible practice recommendations for pharmacists to consider prior to and during PGx service implementation (Table 1).

In July of 2019, the guidance document was shared with health system pharmacists to start the implementation phase. Pharmacists were tasked with using the information to access PGx training resources, establish a mentor if needed, identify stakeholders, and determine PGx service workflow details appropriate to their practice. Examples include how consults would occur (virtual or face to face) and who would be responsible for ordering the consult.

Service implementation included the requirement that primary care pharmacists complete a Pharmacogenomics Certificate Program entitled *Pharmacogenomics For Your Practice Certificate* offered by Mayo Clinic School of Continuous Professional Development prior to offering new PGx services to ensure a baseline level of competency in PGx service delivery. Previous studies have demonstrated that increasing a pharmacist's knowledge of PGx may increase engagement and confidence in their practice.[13,14] The task force determined that only PGx labs with results that were integrated into the EHR were acceptable to ensure PGx results were actionable, as demonstrated in the Sanford Health pharmacogenomics model.[4] Mayo Clinic adopted standardized reporting of PGx test results within the electronic medical record for integrated PGx testing options. This infrastructure incorporated PGx information within the EHR that would serve as the basis for drug-gene interaction alerts and would trigger clinical decision support tools with best practice advisories for significant drug-gene interactions. Reporting included genomic indicators, which signify that genetic test results may have medically actionable disease or drug sensitivity risk. Although beyond the scope of this report, the process of utilizing genomic indicators with decision support is an important consideration for implementing PGx and should not be overlooked.

When evaluating which patients would benefit from referral to a pharmacist for PGx consultation, the task force recommended, at minimum, all PGx results be assessed by the pharmacist for clinically significant drug-gene and drug-drug-gene interactions. High significance drug-gene pairs already triggered interaction alerts within the EHR; however, to avoid alert fatigue, many potentially clinically actionable genomic results do not initiate EHR alerts. Therefore, the task force determined that interpretation by a trained clinician such as a pharmacist was important to identify clinically actionable medication changes or potential drug-drug interactions that may affect the patient's response to a specific medication based on PGx results.

The guidance document reviewed the PGx consultation visit types, including a face-to-face visit with the patient in the clinic, a virtual visit with the patient by video, or a clinical chart review in which no contact between pharmacist and patient occurs (Table 2). The task force recommended an in-person or virtual visit with the patient when consultation with the pharmacist was indicated due to the complexity of the material reviewed, the ability to use a shared decision-making model to apply PGx results to medication management decisions, and the capability of the pharmacist to utilize the collaborative practice

DOI: https://doi.org/10.24926/iip.v15i2.6178

agreement (CPA) to implement medication changes. Virtual visits were recommended for patients unable to physically attend appointments or where travel was not feasible, and chart reviews were offered when a patient was unable to present for a pharmacist visit. While the task force debated ideal approaches to PGx test result management, it was determined that maximizing the already existing CPA would be optimal for implementation of PGx within primary care. Under the current CPA, pharmacists start, stop, or change drug therapy for any condition that the patient has been referred for, and may order appropriate labs, including PGx tests. Since the CPA was already broadly accepted and utilized, it was determined that PGx consults should be ordered by those same collaborating providers and managed by the clinical pharmacists they were familiar with (Figure 1). Individual practice sites determined if and how referrals from outside primary care would be managed, including referrals from specialty providers like psychiatry and patient self-referrals. Regardless of who ordered the PGx test, the task force recommended that providers enter the pharmacist specific PGx consult order at the same time as the PGx lab order so that no PGx results were missed for interpretation by the pharmacist. Additionally, use of the specific PGx consult order allowed for surveillance of PGx visit types and outcomes (Table 2).

The PGx guidance document included information for pharmacists preparing for PGx visits, reviewing results with the patient, standardizing documentation of the visit, addressing no shows or cancellations, and scheduling follow-up visits. When discussing the PGx test with the patient, the task force identified several educational topics to highlight, including potential benefits and limitations of PGx testing, estimated cost, time to obtain results, and how the results would be reviewed. In addition to reviewing the traditional components of a comprehensive medication review (i.e., appropriateness, efficacy, safety, and convenience of all medications), the task force identified specific PGx topics the pharmacist should review to prepare for a pharmacogenomics medication management visit. The typical components of a comprehensive medication review would still be conducted as time allowed, but the task force noted that follow-up visits may be required to achieve this. The task force required all pharmacogenomics consultation visits be documented in the health record using standardized PGx note templates that were designed to ensure pharmacist assessment of PGx results were documented in a standardized manner across multiple sites and addressed any safety concerns related to PGx results.

Upon completion and final adoption of the PGx guidance document, the task force and pharmacy department leadership implemented the PGx services in all primary care locations within the Mayo Employee and Community Health in Rochester, Minnesota, and Mayo Clinic Health System in Minnesota and Wisconsin.

In mid-late 2020, a series of educational sessions were provided to clinical pharmacists expected to deliver the pharmacist-led PGx service, and informational meetings were conducted with primary care department leadership and providers to introduce the new service.

A retrospective chart review of all face to face, phone and eConsult PGx visit types occurring from January 1, 2022 through September 30, 2022 was conducted using reporting functionality from the EHR. PGx visits conducted via video were excluded due to inability to capture data from EHR. The review was deemed exempt by the Institutional Review Board. Visits were excluded if they were completed outside the participating Mayo Clinic sites.

RESULTS

As depicted in Figure 2, 1777 (92%) visits were referred by a primary care provider with the remaining 8% referred by specialty providers, such as psychiatrists. A primary care pharmacist completed 1675 (86.7%) visits, with the remainder completed by specialty pharmacists outside of primary care. A total of 1378 patients had a pharmacist-led pharmacogenomics visit during the specified time frame, resulting in 1939 completed PGx visits, including initial and follow-up visits. A total of 25 of the 29 (86%) primary care pharmacists completed at least one PGx visit in the specified time frame. These patients were referred by providers from 56 of the 64 (87.5%) primary care departments. Figure 3 depicts pharmacogenomics participation among primary care providers and pharmacists. The number of PGx visits completed per quarter are shown in Figure 4.

DISCUSSION

The growth of the pharmacist led PGx service in primary care was clearly demonstrated within this integrated health system. The use of recommendations and requirements in the guidance document helped pharmacists make optimal decisions for their practice, which allowed for more flexibility and autonomy. This may have improved acceptance of the standardized workflow and dissemination of the service throughout primary care practices. The use of an existing CPA allowed for efficient use of the pharmacist team in delivering the PGx service.

There are limitations to the applicability of this workflow process and implementation guideline. Although completion of a didactic pharmacogenomics certificate program was mandated, individual pharmacists had varying degrees of clinical experience and confidence in their ability to provide PGx services even after completing the program. This could have impacted implementation of the service at each site. Alternatively, some pharmacists provided a robust PGx service prior to the creation of the implementation guideline. The task force recognized this dichotomy and developed the workflow to include both requirements and recommendations, which

DOI: https://doi.org/10.24926/iip.v15i2.6178

allowed for flexibility within the well-established primary care PGx practices.

The availability within each pharmacist's patient care schedule differed for each site, which may have affected their ability to promote this new service. The data collected regarding implementation of PGx services, specifically the number of PGx visits conducted by primary care pharmacists, are likely underrepresented due to several limitations. The PGx visit type does not include video visits, which are utilized by a growing number of patients. Another potential for error was that any incorrectly ordered consults may have been omitted from the report. A common example was a provider not using the PGx consult and instead ordering a general pharmacy consult for review of PGx results. Pharmacists leading these visits could correct the visit type prior to conducting the PGx visit, however, potentially increasing the validity of the number of visits reported.

CONCLUSION

The development of an internal guidance document established expectations and standardized the workflow of pharmacist led PGx medication management services in primary care within an integrated health care system. Dissemination of the workflow expectations to the primary care provider teams and pharmacists resulted in robust adoption of the service across individual clinic sites. Further research is needed to determine if adoption of a standardized workflow improves medication outcomes.

Acknowledgements: We thank Bob Hoel, PharmD for his contributions to guideline development.

Funding: None

Conflicts of Interests: None

Treatment of Human Subjects: IRB exemption granted

Disclaimer: The statements, opinions, and data contained in all publications are those of the authors.

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Table 1: Pharmacogenomics Implementation Requirements and Recommendations

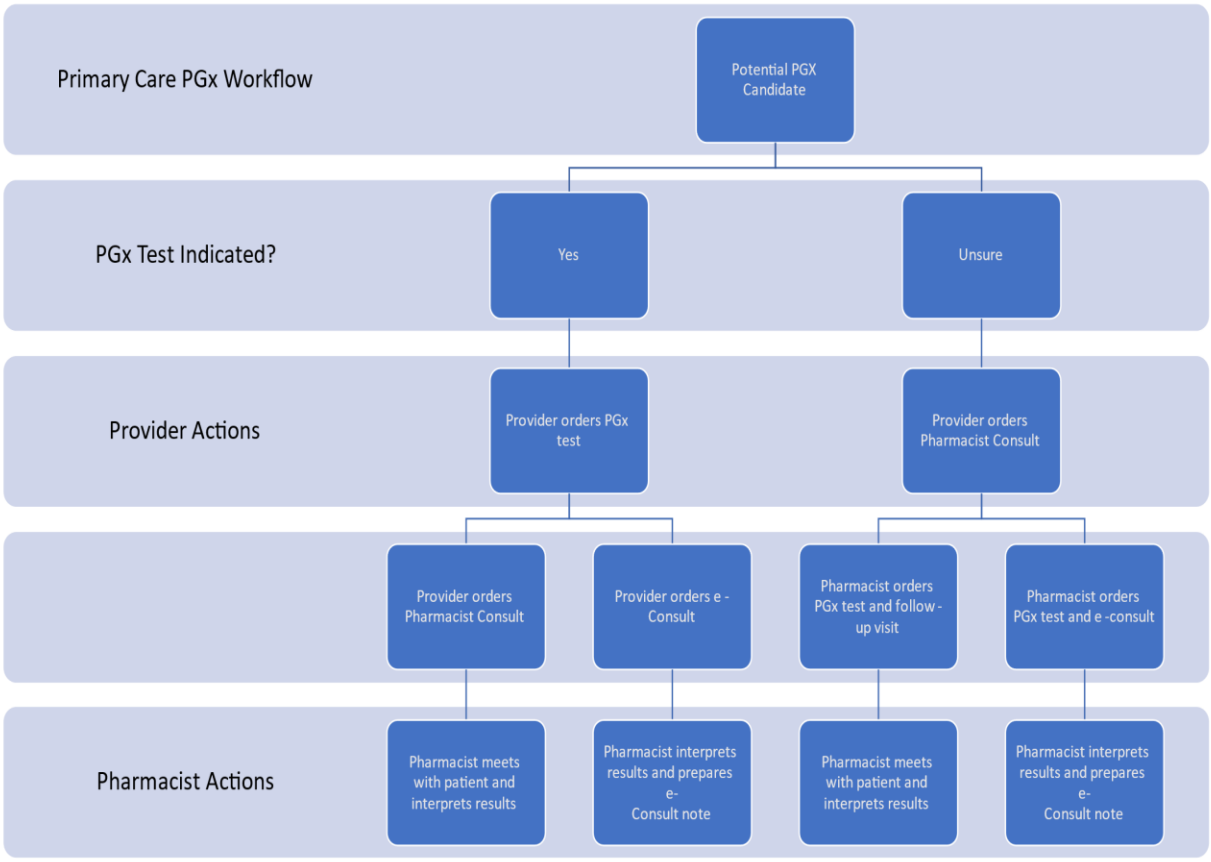
Topic	Requirement	Recommendation
Education / Training	Complete PGx Certificate Course	Identify skilled PGx pharmacist as a mentor
Lab Orders	Order only PGx panels integrated into EHR	
Primary Care Pharmacist Consultation	All primary care pharmacists must offer PGx interpretation consultation services	At minimum, all PGx results should be assessed by a pharmacist for drug-gene interactions and chart review documented.
Specialty Consultation	Expert advice from PGx Specialist Pharmacists shall be sought for patients with liver transplant, allogenic stem cell transplant, and for immunosuppressed patients with blood transfusion within past 6 weeks	Expert advice from PGx Specialist Pharmacists may be sought for pregnant patients and those with severe liver impairment
Pharmacist Consultation Orders	Pharmacist PGx consult order is needed for all initial PGx result interpretation EHR messages are not appropriate for initial PGx interpretation.	60-minute face to face or video visits with patients are preferred Pharmacist PGx consult should be ordered at the same time as PGx test (scheduled 2 weeks after sample collection)
Documentation	Standardized note templates are used for all PGx consultations	
Handling patient no-shows		If visit preparation identified potential safety concerns and patient is unable to be promptly rescheduled, recommend completing an abbreviated chart review focusing on addressing those medication safety concerns and share with provider

DOI: https://doi.org/10.24926/iip.v15i2.6178

Table 2: Visit Types

Description	Type	Length (minutes)	Delivery
Pharmacy – Medication Therapy Management Consult (Clinic)	Initial Consult - Individualized Medicine (Pharmacogenomics)	60	Face to face Video
Pharmacy, Pharmacogenomics eConsult	eConsult	60	Electronic to Clinician
Pharmacy – Medication Therapy Management Office Visit (Clinic)	Return Visit - Individualized Medicine (Pharmacogenomics)	30 or 60	Face to face Video Phone

Figure 1: Pharmacogenomic Workflow in Primary Care



DOI: https://doi.org/10.24926/iip.v15i2.6178

Figure 2: Number of PGx Visits from 1/1/22 to 9/30/23

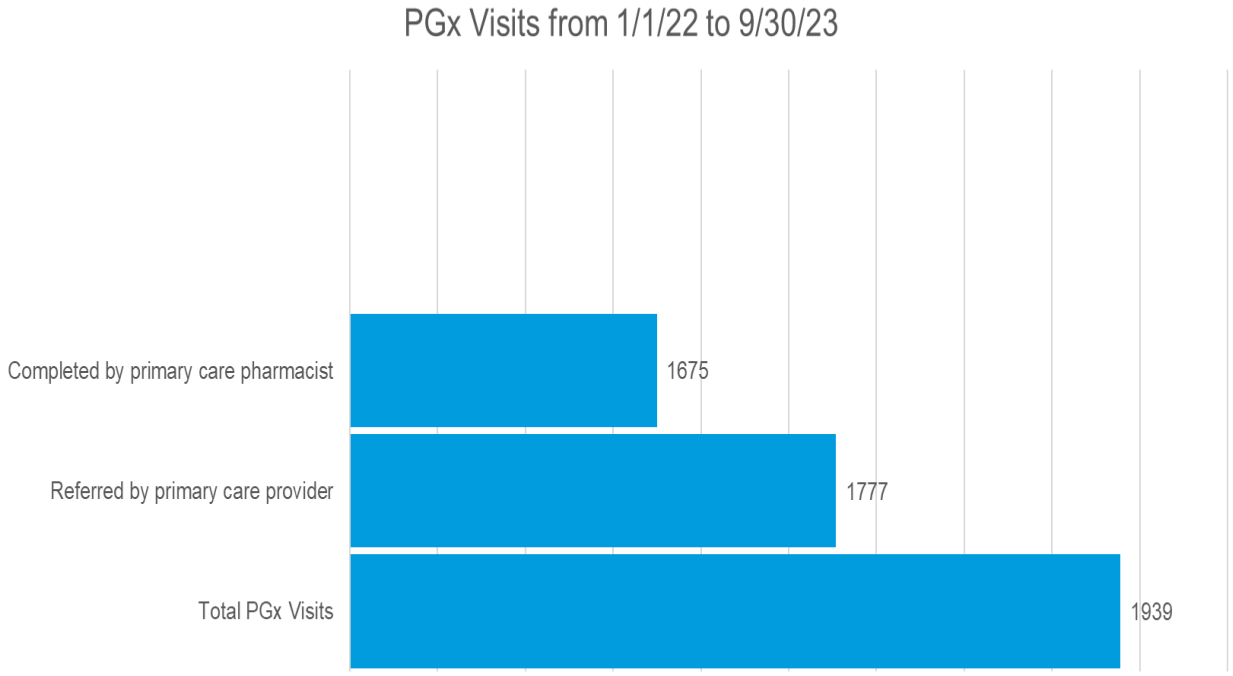
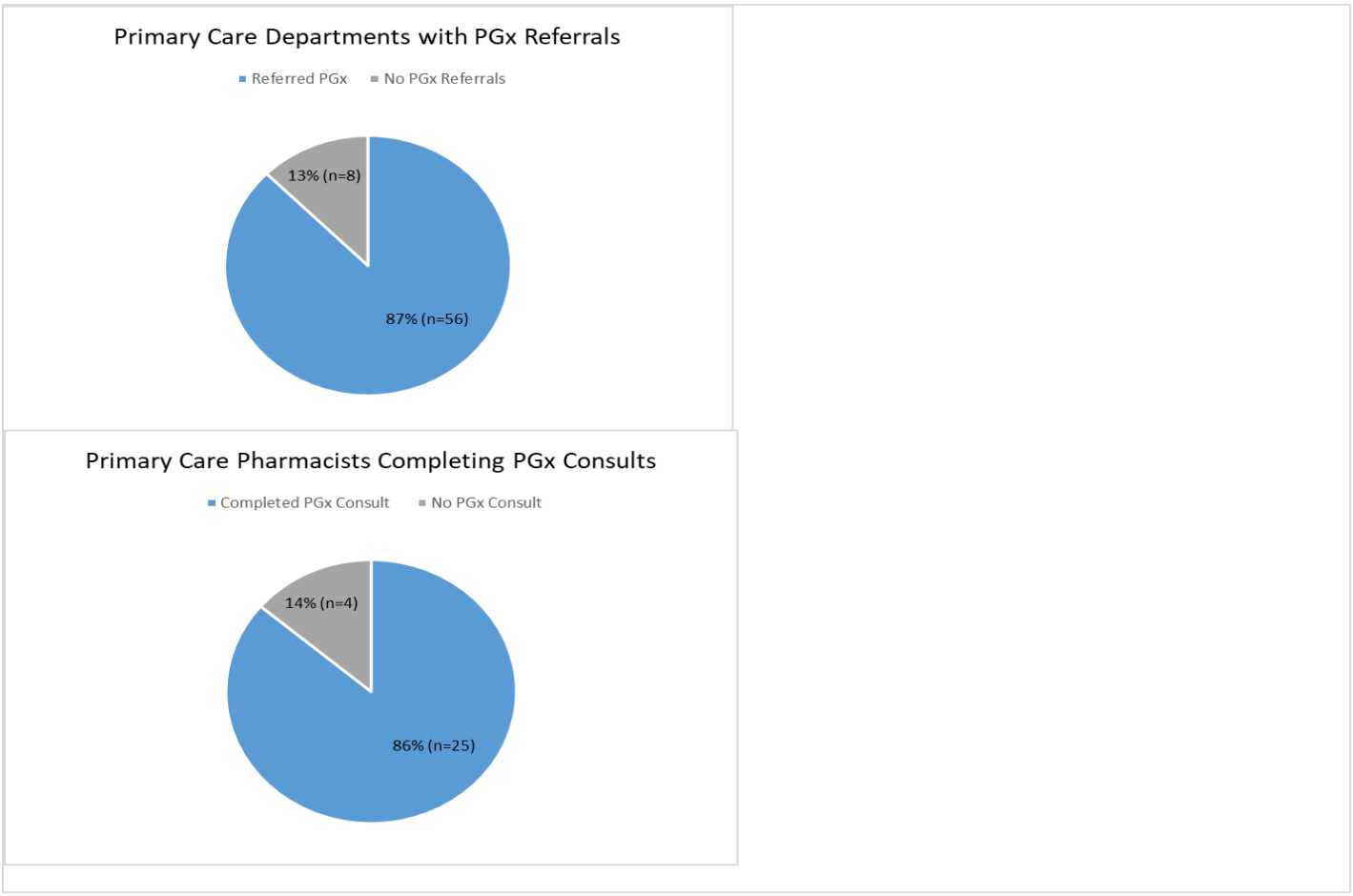


Figure 3: PGx Participation in Primary Care



DOI: https://doi.org/10.24926/iip.v15i2.6178

Figure 4: Number of PGx visits completed over time (quarterly by year)