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ADVANCES IN PHARMACY PRACTICE

The Innovative Canadian Pharmacogenomic Screening Initiative in Community Pharmacy (ICANPIC) study

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ABSTRACT

Objectives: The safety and efficacy of medications can vary significantly between patients as a result of genetic variability. As genomic screening technologies become more widely available, pharmacists are ideally suited to use such tools to optimize medication therapy management. The objective of this study was to evaluate the feasibility of implementing personalized medication services into community pharmacy practice and to assess the number of drug therapy problems identified as a result of pharmacogenomic screening.

Setting: The study was conducted in 2 busy urban community pharmacies, operating under the brand Shoppers Drug Mart, in Toronto, Ontario.

Practice innovation: Pharmacists offered pharmacogenomic screening as part of their professional services program. Eligible patients received a buccal swab followed by DNA analysis with the use of Pillcheck. Pillcheck is a genotyping assay that translates genomic data and generates a personalized evidence-based report that provides insight into patients' inherited drug metabolic profile. After receiving the report, pharmacists invited patients back to the clinic for interpretation of the results. Clinically significant drug therapy problems were identified and recommendations for medication optimization forwarded to the primary care physician.

Results: One hundred patients were enrolled in the study. Average age was 56.7 years, and patients were taking a mean of 4.9 chronic medications. Pharmacists cited the most common reasons for testing as ineffective therapy (43.0%), to address an adverse reaction (32.6%), and to guide initiation of therapy (10.4%). An average of 1.3 drug therapy problems directly related to pharmacogenomic testing were identified per patient. Pharmacist recommendations included change in therapy (60.3%), dose adjustment (13.2%), discontinuation of a drug (4.4%), and increased monitoring (22.1%).

Conclusion: These results highlight the readiness of community pharmacists to adopt pharmacogenomic screening into practice and their ability to leverage this novel technology to positively affect medication therapy management. Community pharmacists are ideally suited to both offer personalized medication services and interpret genomic results.

The field of pharmacogenomics (PGx) was established in the 1950s, but physicians and pharmacists had long been aware of the subtle differences in drug response between patients.[1] Interpatient variability in drug response can result in lack of efficacy, intolerance, or even serious adverse reactions (ADRs). Severe ADRs are the fourth leading cause of morbidity and mortality in the developed world.[2] In Canada alone, an estimated 200,000 severe ADRs occur annually, with 5%-10% being fatal.[3] One-fourth of general admissions to Canadian hospitals are drug related, and 70% of those are thought to be preventable.[4] These ADR costs the health care system a staggering $17 billion each year.[3] Similarly in the United States, more than 2 million serious ADRs cause more than 100,000 deaths annually, exceeding the fatality rates of pulmonary disease, diabetes, or acquired immunodeficiency syndrome.[4,5]

It is routine for physicians and pharmacists to consider factors such as age, body mass, renal function, and drug interactions in an attempt to avoid unintentional drug consequences. Nonetheless, genetic factors alone can account for

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Key Points

Background:

- The safety and efficacy of medications can vary significantly between patients as a result of genetic variability.
- Clinical PGx research has made significant progress in defining which genetic variations are important for influencing inter-patient variability in drug response.
- Recently, the technology for PGx testing has been made available to practitioners in frontline clinical settings.
- Pharmacist's expertise in pharmacology and pharmacokinetics make them ideally suited to champion implementation and interpretation of this novel technology into clinical practice in order to best optimize patient therapy.

Findings:

- Pharmacists cited the most common reasons for PGx testing as ineffective therapy (43.0%), to address an adverse reaction (32.6%), and to guide initiation of therapy (10.4%).
- Medications most frequently implicated in triggering PGx screening included antidepressants (33.9%), statins (22.1%), clopidogrel (12.6%), and proton pump inhibitors (12.6%).
- The types of interventions that resulted from PGx testing included change in therapy (60.3%), dose adjustment (13.2%), discontinuation of a drug (4.4%), and increased monitoring (22.1%).
- Community pharmacists have the confidence and capability to successfully implement PGx screening services into clinical practice, identify patients that are likely to benefit from such testing, and apply the results to optimize medication therapy management.

anywhere from 20% to 95% of the variability in drug response, yet they often go unrecognized.[6] In recent years, clinical PGx research has made significant progress in defining which genetic variations are important for influencing interpatient variability in drug response. For example, a substudy of the CHARM (Candesartan in Heart Failure—Assessment of Mortality and Morbidity) trial examined the association between cytochrome P450 2C19 (CYP2C19) genetic variants and clinical outcomes in Chinese clopidogrel-treated patients with minor stroke or transient ischemic event.[7] The study demonstrated that patients who were not carriers of the CYP2C19 loss-of-function alleles had a reduced risk of new stroke. Despite the study's retrospective nature and Asian patient population, the findings support a role of CYP2C19 genotyping in improving efficacy of clopidogrel. Evidence-based consensus guidelines for multiple drug–gene pairs have been developed and are promoted by the Clinical Pharmacogenetic Implementation Consortium (CPIC).[8] The U.S. Food and Drug Administration (FDA) has also begun incorporating PGx information into certain product monographs, and Health Canada has developed a framework for voluntary PGx data submission in drug development.[9,10]

Despite these advances, there is still much debate over the applicability and clinical significance of PGx testing in practice. Historically, clinicians have no easy way to screen or assess patients for these differences. It was not until recently that the technology for PGx testing was made available to practitioners in front-line clinical settings. In Canada, commercial tests are available through several providers, including Pillcheck, Biogeniq, and Genexys. This availability, in combination with the pharmacist's expertise in pharmacology and pharmacokinetics, make them ideally suited to champion implementation of this novel technology to best optimize patient therapy. In 2011, St. Jude Children's Research Hospital developed and implemented a pharmacist-managed clinical PGx service, demonstrating pharmacists' readiness in providing PGx consult services.[11] The American Society of Health-System Pharmacists has also recently published a position statement on the pharmacist's role in clinical PGx and challenged pharmacists to take the lead in this area.[12] In response to these efforts and goals, we set out to be the first to evaluate the feasibility of implementing personalized medication services into community practice and to quantify the type of drug therapy problems identified by pharmacists as a result of PGx screening.

Setting

The study was designed as open-label, nonrandomized, and observational. Institutional Review Board approval was obtained before initiation. Two busy urban community pharmacies, operating under the brand Shoppers Drug Mart, in Toronto, Ontario, offered PGx screening clinics as part of their professional services program. Each pharmacy was adequately staffed to balance dispensing responsibilities with clinical pharmacy activities. Adjustments to pharmacy labor were not made to accommodate the study protocol.

Practice innovation

Participating pharmacists received structured comprehensive training in PGx. Training consisted of a combination of didactic classroom sessions, online learning modules, and small-group interactive sessions, which allowed pharmacists to review clinical cases and discuss therapeutic interventions with consulting medical geneticists.

Pharmacists then facilitated voluntary subject enrollment among patients taking medications whose response was known to be affected by genetic variability and whom they thought would benefit from screening. Rationale for testing included the patient reporting ineffective therapy, to address an adverse reaction, or to guide initiation of therapy. Other inclusion criteria included age 18 years or older and ability to provide informed consent. Exclusion criteria included liver transplant; possible opioid dependency; or a diagnosis of schizophrenia, bipolar disorder, or dementia. Geneyouin provided PGx tests at no cost to the study pharmacies.

Eligible patients received a buccal swab with the use of DNA Genotek's cheek swab kit OCR-100. Deidentified barcoded samples were then sent by regular mail to the Clinical Laboratory Improvement Amendments–certified Arctic

Table 1
Geneyouin's Pillcheck v2.0 custom genotyping panel: Clinically relevant variants associated with drug response

Gene	Variant(s)
CYP1A2	*1C, *1F, *1K, *7, *11
CYP2C9	*2, *3, *4, *5, *6, *8, *11, *12, *13, *15, *25
CYP2C19	*2, *3, *4, *4B,*5, *6 *7, *8, *17
CYP2D6	*2, *3, *4, *4A, *4K, *4M, *6, *6C, *7, *8, *9, *10, *12, *15, *17, *19, *20, *29, *34, *39,*41, *64, *65, *68A, *69, *70, *91
CYP3A4	*2, *17, *22
CYP3A5	*2, *3,*7
OPRM1	118A>G
SLCO1B1	*5
VKORC1	1639G>A

Medical Laboratories, Grand Rapids, MI, for DNA analysis with the use of Pillcheck. Pillcheck is Geneyouin's proprietary genotyping assay performed with the use of Agena's Massarray system. It detects mutations associated with altered gene activity. These include variations in 10 genes and copy variants (Table 1) responsible for drug transport and metabolism of more than 100 commonly prescribed medications.[13] After genomic data translation, a personalized evidence-based report deriving recommendations from the CPIC guidelines (https://www.pharmgkb.org/view/dosing-guidelines.do) and FDA drug labels is generated. This report provides insight into the patient's inherited drug metabolic profile. Pillcheck software is a platform-agnostic technology that automatically annotates genetic data derived from any genotyping and sequencing instrument and provides patient-specific, evidence-based recommendations for drug prescribing. It also seamlessly integrates probabilistic phasing of multiple markers for diplotype determination, which is required for accurate assessment of the functional impact of different polymorphisms. The report provides categorization of metabolic status into 4 major classes (poor, intermediate, extensive, or ultrafast metabolizer) and flags medications that may cause significant drug reactions or reduced clinical efficacy at standard starting doses.

The CYP450 genes are variation rich, with some variations being of low frequency, often represented by single occurrence of the minor allele in sample sets. The occurrences of these low-frequency allelic variants differ depending on the ethnicity of the population studied; therefore the false-negative rate of Pillcheck would be specific to the cytochrome gene and ethnicity and is expected to be in the range of 1%-2%.[12]

Reports were delivered to the pharmacist via a secure file-sharing portal within 2 weeks. On receiving the report, pharmacists invited patients back to the clinic for interpretation of their results. Based on the pharmacist's professional judgment and the patient's chief complaint, clinically significant drug therapy problems were identified and recommendations for medication optimization forwarded to the primary care physician. Each patients was also provided with a copy of their report.

Table 2
Summary of patient demographics and rationale for pharmacogenomic testing

Number of patients	100
Lost to follow-up	4
Failed test	1
Mean age (y)	56.7
Female (%)	62
Mean number of chronic medications	4.9
Mean number of Pillcheck medications	2.0
Reason for enrollment, n (%)	
Uncontrolled condition on triggering medication	58 (43.0)
Experiencing adverse effects on triggering medication	44 (32.6)
Testing to determine optimal medication option	14 (10.4)
New medication was initiated	9 (6.7)
Concern about clopidogrel activation	6 (4.4)
Recent dose change	4 (3.0)
Medications triggering pharmacogenomic testing, n (%)	
Clopidogrel	16 (12.6)
Statin	28 (22.1)
Antidepressant	43 (33.9)
Opioid	10 (7.9)
Warfarin	9 (7.1)
Proton pump inhibitor	16 (12.6)
Other[a]	5 (3.9)

[a] Medications classified as "other" included benzodiazepines, cycloxygenase-2 selective inhibitors, beta-blockers, and nonsteroidal anti-inflammatory drugs.

Evaluation

A total of 100 patients were enrolled in the study. Four patients were lost to follow-up, and 1 patient experienced a failed test owing to poor sample collection. Table 2 summarizes patient demographics and rationale for testing, including the drug classes responsible for triggering pharmacist-directed screening. Average age was 56.7 years, with women representing 62.0% of the sample. Patients were taking a mean of 4.9 chronic medications and 2.0 Pillcheck medications. Pharmacists cited the most common reasons for testing as ineffective therapy (43.0%), to address an adverse reaction (32.6%), and to guide initiation of therapy (10.4%). Medications most frequently implicated in triggering PGx screening included antidepressants (33.9%), statins (22.1%), clopidogrel (12.6%), and proton pump inhibitors (12.6%).

Pharmacists identified a total of 175 drug therapy problems, representing an average of 1.8 per patient (Table 3). Of these, 119 (1.3 per patient) resulted directly from pharmacist interpretation of the PGx tests, although 56 (0.6 per patient) were unrelated to PGx screening and were identified by pharmacists during the medication review process.

Types of interventions that resulted from PGx testing included change in therapy (60.3%), dose adjustment (13.2%), discontinuation of a drug (4.4%), and increased monitoring (22.1%). The medications most commonly requiring intervention included antidepressants (25.0%), statins (19.1%), and clopidogrel (17.6%; Table 3). Examples of interventions unrelated to PGx testing included drug interactions with over-the-counter supplements, suboptimal agents for secondary prevention, and medication non-adherence. Overall physician acceptance rate of interventions was 59.0%. PGx-identified interventions were accepted at a higher frequency than non−Pgx-related interventions: 63.2% and 51.4% respectively.

Practice implications

The present study is the first to show that community pharmacists have the confidence and capability to successfully implement PGx screening services into clinical practice,

Table 3
Frequency and classification of drug therapy problems and pharmacist interventions

	n (%)
Drug therapy problem (DTP)	
Total DTPs	175
PGx-detected DTPs	119 (68.0)
Non–PGx-detected DTPs	56 (32.0)
Interventions[a]	
Total pharmacist interventions sent to physician	105
Pgx-detected interventions	68 (64.8)
Non–Pgx-detected interventions	37 (35.2)
Types of PGx interventions	
Increase monitoring	15 (22.1)
Change in therapy	41 (60.3)
Dose adjustment	9 (13.2)
Drug discontinuation	3 (4.4)
PGx interventions by drug class	
Clopidogrel	12 (17.6)
Statin	13 (19.1)
Antidepressant	17 (25.0)
Opioid	7 (10.3)
Warfarin	5 (7.4)
Proton pump inhibitor	8 (11.8)
Other[b]	6 (8.8)
Physician DTP acceptance rate	
Overall	62 (59.0)
PGx-based interventions	43 (63.2)
Non–PGx-based interventions	19 (51.4)

Abbreviation used: PGx, pharmacogenetics.

[a] Interventions require direct pharmacist collaboration with a physician to implement a change in therapy. These differ from drug therapy problems in that pharmacists in Ontario, given their expanded scope of practice, are able to resolve many drug therapy problems without involving the physician.

[b] Medications classified as "other" included benzodiazepines, cycloxygenase-2 selective inhibitors, beta-blockers, and nonsteroidal antiinflammatory drugs.

identify patients that are likely to benefit from such testing, and apply the results to optimize medication therapy management. Pharmacists cited the most common reasons for testing as ineffective therapy (43.0%), to address an adverse reaction (32.6%), and to guide initiation of therapy (10.4%). An average of 1.8 drug therapy problems were identified per patient, of which 68% were attributed directly to PGx testing. Of interest, an average of 0.6 drug therapy problems per patient were unrelated to PGx testing but were identified during the course of the patient interview. This highlights the importance of pharmacist-patient interaction during the medication review process.

The high detection rate of drug therapy problems directly related to PGx testing speaks to the ability of community pharmacists to appropriately triage and identify patients that would benefit from screening. Moreover, pharmacists were able to enroll patients across a wide array of therapeutic areas, with no single disease state or drug class dominating. Medications most commonly involved in triggering PGx testing included antidepressants (33.9%), statins (22.1%), clopidogrel (12.6%), and proton pump inhibitors (12.6%). This finding is significant, because earlier studies have focused testing exclusively on a single therapeutic area. The present study was able to expand on this because Pillcheck's proprietary genotyping assay assesses variations in 10 genes responsible for drug transport and metabolism for more than 100 commonly prescribed medications.[12] If pharmacies are to successfully and sustainably integrate PGx screening into their clinical programs, it is instrumental that they be able to offer and promote the service to a broad group of patients.

Similarly, the frequency of pharmacists' interventions were equally distributed across the spectrum of drug classes, with no single drug class being over-represented. The medications having the highest number of interventions included antidepressants (25.0%), statins (19.1%), and clopidogrel (17.6%). That being said, these drug categories also had a relatively higher number of patients enrolled in the study. Interestingly, an examination of intervention rate as a function of the number of patients in each drug class revealed that clopidogrel (75.0%), opioids (70.0%), and warfarin (55.6%) had a higher intervention rate than proton pump inhibitors (50.0%), statins (46.4%), and antidepressants (39.5%). Although this trend was observed in a relatively small sample size, it may be indicative of patient populations that would receive increased benefit from PGx testing.

Finally, pharmacists demonstrated that in addition to being able to interpret PGx test results, they were also able to intervene appropriately when required. Pharmacist recommendations included change in therapy (60.3%), dose adjustment (13.2%), discontinuation of a drug (4.4%), and increased monitoring (22.1%). This was supported by the exceptionally high prescriber acceptance rate (63.2%) for the PGx-based recommendations. That rate of acceptance was even higher than for the non–PGx-based interventions that were identified during the course of medication review (51.4%) and may indicate the positive effect that pharmacists can have using PGx in a community setting. In comparison, typical intervention studies have documented prescriber acceptance rates anywhere from 42% to 60%.[14-16] One anecdote is that prescribers appeared to welcome recommendations, with many seemingly excited to discuss the results with the pharmacists. No prescriber outright rejected the PGx recommendation. Pharmacists reported that for those interventions that were not accepted, it seemed that either they could not reach the physician or the prescriber lacked a general understanding of PGx principles and had concerns about their applicability to practice. It also appeared that specialists embraced the technology more frequently than general practitioners.

Discussion

Individual variation in drug response owing to genetic factors is a commonly observed phenomenon in the practice of both medicine and pharmacy. Such variation in patient response can result in failure to benefit from a drug or the development of adverse drug reactions, factors that may contribute to patient non-adherence. Over the past decade, clinical PGx research has made significant progress in defining the genetic variations that are important contributors to interpatient variability. This has led to the development of evidence-based consensus therapeutic guidelines for use by clinicians. More recently, after years of uncertainty over the value of personalized medicine, studies have begun to show the utility of incorporating PGx testing into routine patient care. Nonetheless, most experience has been limited to PGx implementation in primary care hospital settings, and many barriers to this integration have been reported, including lack of knowledge and skills among primary care physicians, lack of

time and access to resources, and challenges with interpreting results.[17,18]

With the continued expansion in the scope of pharmacy practice and the growing number of services provided by community pharmacists, it may be appropriate for PGx testing to be considered in that practice setting. Pharmacists already have extensive training in pharmacology and pharmacokinetics. In addition, they routinely screen for adverse drug reactions and poor clinical response to drug therapy. A survey of 101 independent U.S. community pharmacists evaluated their interest in implementing personalized medicine services, perceived readiness to provide such services, and perceived barriers to implementation.[19] It also gauged the pharmacists' self-reported knowledge of PGx principles. The investigators determined that the majority of independent community pharmacists are interested in incorporating personalized medicine services into their practices, but that they require further education before this is possible. The survey suggested that future initiatives should focus on the development of comprehensive continuing education programs to further train pharmacists for the provision of these services. In an attempt to address this confidence gap, the National Human Genome Research Institute of the National Institutes of Health has explored the current status of pharmacist genomic education and barriers and facilitators to enhanced education, and has outlined important next steps to ensure that pharmacists are prepared to provide PGx consultation services.[20]

Notwithstanding these calls for further education, implementation experience in community pharmacy remains extremely limited. A small 2014 study sought to determine the practical and economic viability of providing PGx testing in a single U.S. community pharmacy.[21] The investigators were able to provide PGx testing for only a single gene (CYP2C19) to 18 patients receiving therapy with clopidogrel. Although the study was lacking in both size and scope, the authors concluded that a PGx service can be an extension of medication therapy management services in a community pharmacy. They determined that prescribers were receptive to having community pharmacists conduct PGx testing but that reimbursement remained a challenge.

Timely communication and lack of physician knowledge appeared to be the biggest barriers encountered by pharmacists. This is supported by a survey of Mayo clinic physicians, which revealed that 52% did not expect or did not know whether they would use PGx information in prescribing, and only 30% said that PGx alerts changed prescribing at least once.[22] In addition, a nationwide survey of U.S. physicians found that only 10.3% were adequately informed about PGx testing and only 29.0% had received any education in the field.[23] Additional barriers included integration into workflow and reimbursement. The average time spent with each patient during the initial appointment was 25 minutes and anywhere from 10 to 50 minutes for follow-up appointments, depending on the complexity of the patient case. It would be difficult to provide this time commitment in a traditional community pharmacy setting that focuses primarily on dispensing. Nonetheless, in a study of 30 cardiology outpatients who were offered pharmacist medication management alone or in conjunction with PGx testing, the duration of initial and follow-up consultations were similar between the groups.[24] In our experience, significant changes to the workflow model would be required to be able to provide a PGx consultation service sustainably. Until the profession is fully prepared to embrace wide-scale adoption of PGx services into practice, an interim solution may include offering the sale of genomic kits in pharmacies and having the consultation conducted by specially trained pharmacists at regional sites of excellence or directly through the genomics companies themselves. Other strategies may include focused screening of certain clinically relevant genes in various ethnic populations. These changes are unlikely to occur until a structured reimbursement model becomes available. In the present study, Geneyouin provided genotyping tests at no cost to study pharmacies. As a result, billing and reimbursement considerations were not a main focus of the project. A survey of U.S. independent community pharmacists identified the lack of reimbursement as the primary major barrier to implementing PGx services into practice. Currently, U.S. Medicare Part B recognizes the value of PGx testing and is willing to reimburse the costs, provided that a copay exists. Selected private insurers may also offer reimbursement, although coverage varies broadly from patient to patient.[23,25] Consequently, the cash reimbursement model may be preferable because no partnership with government or private payers is required. However, a major challenge involves setting a suitable cash price that reflects costs of initial testing, consultation, and potential integration of patient-specific genetic information into pharmacy files.[24] Other barriers include affordability of the service, pharmacist time, and workflow limitations.[19,26,27]

A small number of Canadian private payers have begun to provide coverage for PGx consultation services as part of patients' extended or flex benefit plans. A study currently in progress in British Columbia is investigating the economic viability of offering PGx testing in community pharmacies and assessing public willingness to pay for the service.[28] An informal survey of the patients enrolled in the present study found that patients felt that they benefited from genomic testing, valued the interaction with the pharmacist, and would be willing to pay a mean copay of $121 (range $10 to $500) for the service.

Other commercial tests available in Canada include Biogeniq and Genexys. Pillcheck assesses PGx compatibility with more than 100 prescription medications across 18 different pharmaceutical classes.[13] In comparison, Biogeniq's Pharmaprofile includes about 50 medications across 6 pharmaceutical classes.[29] 23andme is an American-based genomics company. Their reports include analysis of 11 genetic risk factors for various health conditions and genetic variants linked to 43 recessive conditions and 41 non–health-related traits (e.g., alcohol flush reaction, caffeine metabolism, height), and assesses an individual's drug response on the basis of their genetic profile for only 12 prescription medications.[30] Common medications in these 3 commercial tests include anticancer drugs (5-FU, azathioprine, mercaptopurine, thioguanine, tamoxifen), cardiovascular drugs (clopidogrel, simvastatin, warfarin), and CYP2C19-mediated proton pump inhibitors (omeprazole, lansoprazole, pantoprazole). Given that our focus was on large-scale PGx service expansion, we required a PGx service that would be able to assess genetic variability in a large number of medications across various drug classes.

Several limitations of this study should be noted. First, study data were collected at 2 community pharmacies in Toronto that have extensive experience with implementing enhanced clinical programs into practice. These findings may not generally represent the experience of most community pharmacists, necessitating additional studies in a broader array of practice settings to more formally assess acceptance. Second, the custom genotyping panel used may not detect all DNA variations that can result in altered gene activity. Only specified genetic variations present in whites and major ethnic minority groups are tested by Pillcheck. The ethnicities of study participants were not captured during the data collection process. This differs from genetic sequencing, which can identify both known and novel variations. That being said, the increased cost and time required for analysis by sequencing does not translate well for widespread use in the community. Furthermore, functional consequences of novel variations are typically not understood, limiting ability for clinical interpretation.

Conclusion

The results of this novel study highlight the readiness of community pharmacists to adopt PGx screening into practice and their ability to leverage this technology to positively affect medication therapy management. The findings suggest that community pharmacists are ideally suited to offer both personalized medication services and interpretation of PGx results on a broad scale.

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