INNOVATIVE CANADIAN PHARMACOGENETIC SCREENING INITIATIVE IN COMMUNITY PHARMACIES: A SUMMARY

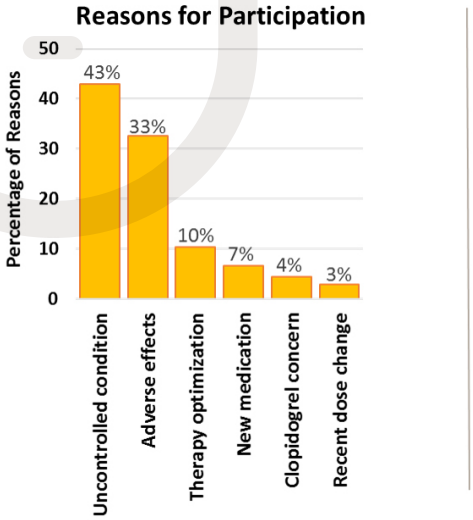
Introduction

By personalizing medicine, the field of pharmacogenetics (PGx) can significantly improve the safety and efficacy of medications, helping patients achieve better health outcomes and reducing their cost of care and recovery times. However, broad implementation of PGx has been slow due to limited clinical adoption and lack of reimbursement. To facilitate the deployment of PGx in Canada, we developed Pillcheck™, a personalized medication optimization service. Pillcheck is powered by our proprietary bioinformatics and data-sharing platform.

In Q4 2015, a practice study on Pillcheck was launched by 2 community pharmacies to evaluate the impact of Pillcheck on medication management. Before launch, all pharmacists participated in an education program on PGx developed by us. The online component of this training program is now offered by the Ontario Pharmacists Association (OPA) to pharmacists provincewide:
www.opatoday.com/224130

Methods

One hundred patients participated in the study. Patients prescribed 3 or more medications and/or recently prescribed a medication for which safety or efficacy is significantly influenced by genetics (e.g. clopidogrel, antidepressants, or opioids) were invited to participate in the study (Figure 1A). Reasons for participation were: symptoms not resolved by prescribed medications; adverse side effects of prescribed medications; and personalization of therapy (Figure 1B). Mean age of patients participating in the study was 56.5 years; 38% were male; 62% were female. Patients met with a PGx-trained pharmacist who educated them about Pillcheck, reviewed their medications, and obtained their consent for the Pillcheck test. Cheek swab samples were collected by patients and mailed to the Pillcheck laboratory for genotyping.



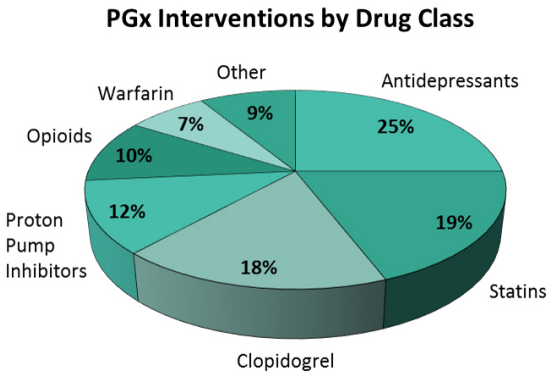
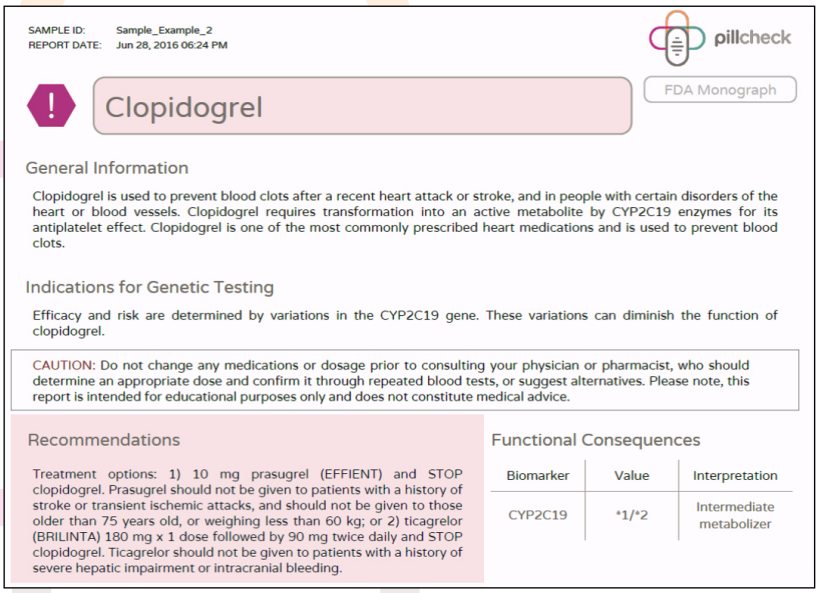


Figure 1. Patients were screened by pharmacists for enrollment in the study based on chief complaints involving medications, for which safety and efficacy are significantly influenced by genetics. Pharmacists' rationale for enrolment of patients in the study. Patients could be enrolled for more than one reason.

Patients first received a standard MedsCheck review of their prescribed medications (the status quo method in pharmacies) in order to identify Drug Therapy Problems (DTPs) caused by drug-drug interactions. In the same session, Pillcheck was introduced and a cheek swab kit was provided to the patients, who submitted their samples. After the pharmacists received their patients' Pillcheck reports, they performed a second medication review, taking into consideration drug-gene interactions. When warranted, pharmacists issued Pharmaceutical Opinion Letters to attending physicians to inform treatment.



SAMPLE ID: Sample_Example_2
REPORT DATE: Jun 28, 2016 06:24 PM

pillcheck

Clopidogrel

FDA Monograph

General Information

Clopidogrel is used to prevent blood clots after a recent heart attack or stroke, and in people with certain disorders of the heart or blood vessels. Clopidogrel requires transformation into an active metabolite by CYP2C19 enzymes for its antiplatelet effect. Clopidogrel is one of the most commonly prescribed heart medications and is used to prevent blood clots.

Indications for Genetic Testing

Efficacy and risk are determined by variations in the CYP2C19 gene. These variations can diminish the function of clopidogrel.

CAUTION: Do not change any medications or dosage prior to consulting your physician or pharmacist, who should determine an appropriate dose and confirm it through repeated blood tests, or suggest alternatives. Please note, this report is intended for educational purposes only and does not constitute medical advice.

Recommendations

Treatment options: 1) 10 mg prasugrel (EFFIENT) and STOP clopidogrel. Prasugrel should not be given to patients with a history of stroke or transient ischemic attacks, and should not be given to those older than 75 years old, or weighing less than 60 kg; or 2) ticagrelor (BRILINTA) 180 mg x 1 dose followed by 90 mg twice daily and STOP clopidogrel. Ticagrelor should not be given to patients with a history of severe hepatic impairment or intracranial bleeding.

Functional Consequences

Biomarker	Value	Interpretation
CYP2C19	*1/*2	Intermediate metabolizer

Figure 2. Pillcheck uses genomic data to generate a personalized report that provides insight into a patient's inherited metabolic profile. This report shows a patient who is an intermediate metabolizer of the prodrug clopidogrel as a result of having CYP2C19 *2/*17 alleles. A drug switch is recommended due to reduced activation of the prodrug to active metabolite. This recommendation is provided in the Clinical Pharmacogenetics Implementation Consortium (CPIC) guidelines.
After patients received their Pillcheck report and Pharmaceutical Opinion Letter, they were asked to complete a survey about their experience.

Results

In the 100 patients studied, MedsCheck reviews identified 56 DTPs (0.56 per patient). The addition of a Pillcheck review increased identified DTPs by 119, resulting in 175 identified DTPs (1.75 per patient).

Pharmacists' recommendations consisted of drug switches in 60% of cases, drug dose modification in 13% of cases, discontinuation of medication in 4% of cases, and continued monitoring in 22% of cases. Antidepressants, statins, and clopidogrel, a commonly prescribed antiplatelet, (Figure 3) were the most frequent classes of medications subjected to Pillcheck-based intervention.

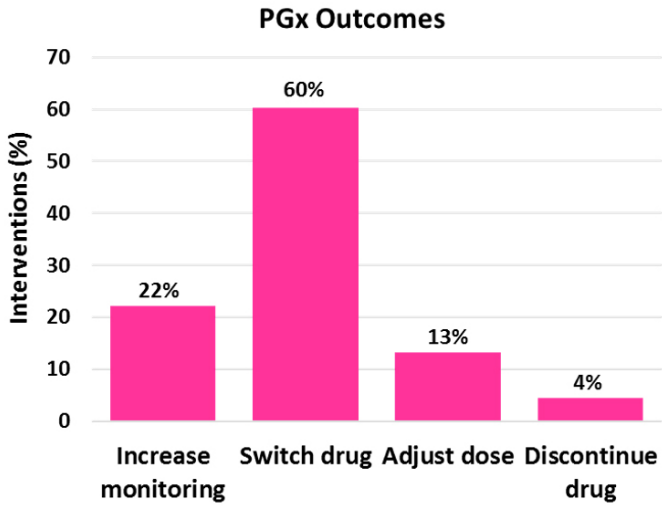


Figure 3. Medication classification of pharmacogenetic (PGx)-related interventions recommended by pharmacists based on Pillcheck reports.

37 Pillcheck users completed a voluntary follow-up survey at the pharmacies. Almost all users rated the service they received as “very valuable” or “valuable”. All users were willing to recommend Pillcheck to their friends or family members. By developing a stronger relationship with their pharmacist, Pillcheck users are more likely to become loyal customers of the pharmacy. A representative sample of patient testimonials is included below:

- “I feel I have better control over what medications to take -- better effectiveness”
- “... I think that OHIP should cover the cost since it promotes effective health care…”
- “The information provided through the study and consultation with Peter [a pharmacist] was extremely valuable”
- “Based on the finding and recommendation I will be scheduling an appointment with my family physician”

Pillcheck is covered by some private health plans, can be claimed for reimbursement through Health Spending Accounts (HSA), and is an eligible medical expense for income tax deduction. An informal survey of patients enrolled in the study suggests that they are willing to co-pay a mean of $121 (range $10-$500) for the service.

Training Effectiveness

A survey of the 16 pharmacists who participated in Pillcheck's PGx training program, before and after training, demonstrated the impact of the program. After their PGx training, the majority of pharmacists (77%) believed that Pillcheck should be a part of their practice, while before training only 31% thought so. 85% became confident in their PGx therapeutic knowledge, compared to 69% before training, and 100% of the participating pharmacists felt comfortable explaining the concept of PGx to patients, compared to 77% before training[1].

Overall Conclusions

Both patients and pharmacists provided very positive feedback regarding their overall experience in using Pillcheck. The expertise, environmental setting, and retailing capacity of pharmacists make them ideally suited to provide PGx screening. With Pillcheck's comprehensive PGx training program, the utilization of Pillcheck shows great promise in the community pharmacy setting.

As described by the pharmacies' owner and lead investigator, Adjunct Assistant Professor John Papastergiou, "these results highlight the readiness of pharmacists to adopt PGx screening into practice and their ability to leverage this novel technology to positively impact medication management." [2]

This study won first prize at the prestigious International Pharmaceutical Federation (FIP) World Congress of Pharmacy and Pharmaceutical Sciences, 2016.

References

1. Papastergiou J *et al.* Implementation of pharmacogenomic services in community pharmacies: Perceptions of community pharmacists after a comprehensive training program *CPJ*. 2016. Accepted as abstract.

2. Papastergiou J. Guest Column: Personalized medicine and pharmacogenomic screening – The future is here. *Pharmacy U*. 2016. http://pharmacyu.ca/2016/08/03/guest-column-personalized-medicine-and-pharmacogenomic-screening-the-future-is-here.