Assessing feasibility of delivering pharmacogenetic testing in a community pharmacy setting

Aim: To describe the rationale and design of a study evaluating the delivery of pharmacogenetic (PGx) testing in community pharmacies. **Study rationale:** Pharmacists have expressed interest in offering PGx testing; however, their lack of knowledge and experience, patients' acceptance and feasibility are unknown in this setting. **Study design:** Through a cluster randomized trial, we will assess pharmacist and patient experiences with delivery of PGx testing as a standalone service or integrated into medication therapy management services. **Anticipated results:** We anticipate that PGx testing can be delivered in a community pharmacy setting and accepted and valued by patients. **Conclusion:** This study is expected to provide valuable evidence about the real-world feasibility and acceptance of a community pharmacist-delivered approach of PGx testing.

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Background

The pharmacy practice has greatly evolved, expanding from traditional roles of compounding and dispensation to provision of a range of clinical services including vaccinations, clinical testing (e.g., cholesterol, hemoglobin A1C and glucose) and medication therapy management (MTM) [1,2]. With an estimated 55,000 community pharmacies in the USA, these settings enable more convenient access to health services that were once limited to physicians' office [3]. It is estimated that 56% of all prescriptions are filled at chain pharmacies, 15% at independent pharmacies and 20% through mail order [4]. Several studies have demonstrated that pharmacists' direct involvement in patient care can reduce health costs and improve clinical outcomes [5–7] and that they are a healthcare provider highly trusted by both prescribers and patients [8–10]. Pharmacogenetic (PGx) testing is an emerging tool to identify patients more likely to receive benefit/toxicity from drug therapy. Currently, 168 drugs include PGx information in the drug label (US FDA) [11]. While

the evidence base of PGx testing to improve health outcomes grows, the optimal tools for delivering PGx to healthcare providers are not well delineated.

With the advent of PGx testing, the delivery of these tests could represent the next expansion in pharmacy practice. While pharmacists have been involved in implementation of PGx testing in clinic-based or hospital settings, often as a liaison between the testing laboratory and provider [12–14], the feasibility and impact of community pharmacist-delivered PGx testing have not been explored in depth. As pharmacists have specialized expertise about drug effects and metabolism, and regularly interact with both patients and providers, they occupy a unique position in the healthcare delivery team and may be ideally suited to provide PGx testing. Further, PGx content has been or is currently being incorporated into pharmacy curricula [15–20], more so than training programs of other care providers [21,22], making pharmacists well-suited to provide this service to their customers. Patients often rely on their community

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pharmacist not only to safely dispense medications, but as a source of medical information and other health services (e.g., vaccinations) [23]. Pharmacies already record and reconcile all prescription medications filled by patients in order to avoid dangerous drug–drug interactions and promote adherence. Therefore, the addition of PGx testing in this framework is a natural extension and also provides oversight across different healthcare providers and healthcare systems. Pharmacists have the authority to order and interpret tests under a collaborative practice agreement in more than 30 states [24]. Some commercial laboratories have begun to establish partnerships with community pharmacies to offer PGx testing. Lastly, because PGx test results do not change over time (i.e., they are encoded in our genome) and due to known ‘pleiotropy’ where several drugs are affected by a particular pharmacogene, utilization of PGx testing may shift from a point-of-care service (used at the time of treatment) to a more preventive or pre-emptive model and be included among pharmacy wellness services.

To address patient needs and maximize outcomes of PGx testing, some have proposed that PGx testing be incorporated into MTM [25,26]. MTM is a systematic and coordinated process for comprehensive medication management [27] and is typically conducted by a pharmacist in community pharmacies and ambulatory care settings to address adherence, side effects, duplication of therapies and prevention of drug interactions. Though practices can vary [28], MTM services typically include five core elements: medication therapy review; personal medication record; medication action plan (MAP); intervention and/or referral; and documentation and follow-up [29]. MTM has been effective for some patient populations in reaching clinical goals, increasing compliance with recommended lab monitoring, reducing rehospitalizations and inappropriate prescribing and risk of adverse drug reactions, and improving adherence [6,30–36]. Because of its effectiveness, MTM is a service covered by insurance companies and the Medicare program in the USA [37].

Study rationale

Given the lack of evidence regarding the feasibility of delivering PGx testing in a community pharmacy setting, this study will explore patient interest and the feasibility of community pharmacist-delivered PGx testing. Specifically, we will compare two pharmacist delivery strategies: a standalone PGx test or PGx testing with MTM. Many patients may not have experienced the delivery of clinical testing in a community pharmacy, and further, are likely to be unfamiliar with PGx testing [38]. Thus, this study will consider both patient acceptance rates and perceived value, satisfaction and

comprehension of test result in addition to pharmacist factors that may impact feasibility of delivery in this setting. We hypothesize that patients will be satisfied with receiving PGx testing through the community pharmacy and will perceive PGx testing as beneficial. Further, we hypothesize that adherence will be greater for patients who undergo PGx testing than the controls who do not have testing. We anticipate that patients in the combined MTM/PGx arm will have improved comprehension compared with those in the PGx-only group. For the pharmacists, we expect that delivering PGx testing will require additional time with or without MTM that may pose challenges in including PGx testing in the pharmacy’s practice. To our knowledge, this is the first study of its kind to compare delivery models of PGx testing in a community pharmacy setting. Provision of PGx testing through pharmacies could expand patient accessibility, and our study will provide valuable data on the feasibility of pharmacies as an alternative site.

Study populations

Approximately 20 pharmacists working in an independent community pharmacy setting in North Carolina will be enrolled in this cluster randomized trial. Pharmacist participants will first be recruited from membership of the Community Pharmacist Pharmacogenetics Network; if necessary, recruitment will be expanded to all community pharmacists in North Carolina.

Patients of the participating pharmacists will be eligible to participate in the study. Patient participants must be 18 years or older, able to consent to testing on their own and have a new or existing prescription (<1 year active) for a drug listed in Table 1 to be eligible to participate. Patients who have had PGx testing for one of the genes in Table 1 or had an MTM within the past 12 months will be ineligible. For comparison of refill outcome data, contemporary controls matched for age, gender and prescription will be identified from the existing patient populations at the participating pharmacies.

Study design

The study aims to compare the effect of PGx testing as a standalone service to PGx testing with MTM through a cluster randomized trial (Figure 1). Community pharmacies will be randomized to provide PGx testing only or PGx testing with MTM. Outcome measures will include patient comprehension, acceptance and satisfaction, impact on medication adherence and drug or dosing adjustments. A 2:1 matched pharmacy population will be used as the control arm. The study outcomes will be evaluated through pharmacist and

Table 1. Drug and gene pairs eligible for testing.			
Drug	Gene	CPIC guidelines [†]	FDA label
Aripiprazole	<i>CYP2D6</i>	No	Yes
Carisoprodol	<i>CYP2C19</i>	No	Yes
Celecoxib	<i>CYP2C9</i>	No	Yes
Citalopram	<i>CYP2C19</i>	Yes [39]	Yes
Clopidogrel	<i>CYP2C19</i>	Yes [40]	Yes
Metoprolol	<i>CYP2D6</i>	No	Yes
Nortriptyline	<i>CYP2D6</i>	Yes [41]	Yes
Paroxetine	<i>CYP2D6</i>	Yes [39]	Yes
Simvastatin	<i>SLC01B1</i>	Yes [42]	No
Warfarin	<i>CYP2C9/VKORC1</i>	Yes [43]	Yes
[†] Grade 1a CPIC guidelines. CPIC: Clinical Pharmacogenetics Implementation Consortium.			

patient surveys, logs of patient–pharmacist interactions and follow-up interviews with pharmacists. The study protocol has been approved by the Institutional Review Board of the Duke University Health System (Pro00068552) and registered in ClinicalTrials.gov (NCT02937545).

Pharmacist education

All participating community pharmacists in the study will be required to complete an in-person training session (Accreditation Council for Pharmacy Education [ACPE] continuing education credits provided). Those pharmacists randomized to the PGx and MTM arm will attend a second training session on PGx and MTM. The learning objectives of the first ACPE presentation include genetic processes and terminology, history of PGx, PGx case studies, overview of recommendations and clinical guidelines from the FDA, and relevant ethical, legal and social issues. The second ACPE presentation will be for the pharmacists randomized to the MTM + PGx arm and include the elements of MTM, development of medication action plans (MAPs) and incorporation of PGx testing into an MTM session.

A pharmacist ‘toolkit’ will also be dispensed to each participating pharmacist and its use will be reviewed as part of the first ACPE presentation. The components of the toolkit were developed to facilitate both pre-PGx testing and post-testing phases. Various components of the toolkit have been used in other studies [44,45]. An initial version of these components has been reviewed by pharmacists and revised accordingly [46]. We will gather additional feedback from pharmacists and patients before commencement of this study (Duke University Health System Pro00069061) and recommended use of the toolkit components will be described in the training session.

PGx testing (both arms)

A panel of five genes will be ordered for each eligible patient in this study: *CYP2D6*, *CYP2C19*, *CYP2C9*, *SLC01B1* and *VKORC1* (Table 1). Genotyping of multiple markers within each of these genes will be performed. A saliva sample for DNA extraction will be collected from patients in the pharmacy who consented to testing and after physician authorization has been obtained. Samples will be express shipped to the Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory, Pathway Genomics® (CA, USA), for testing. The test results will be returned to the prescribing provider and the pharmacist. Testing will be provided at no cost to the patient. We recognize that covering the costs of testing may artificially increase use of testing. However, given the uneven coverage of testing in the USA by public and private insurers [47], the study population would be potentially biased to those patients with insurance coverage or able to afford testing expenses out-of-pocket without enabling all eligible patients’ access to testing.

MTM + PGx testing arm

Two MTM sessions will be performed by a licensed pharmacist in the MTM + PGx study arm. MTM #1 will be conducted in-person and MTM #2 will be conducted in-person or by phone. The five core elements of a standard MTM will be included: medication therapy review, a personal medication record, an MAP, intervention and referral, and documentation and follow-up [29]. The first MTM session will include a review of the patient’s medications, the medical history, most recent lab values if available/known and medication history. The information will be recorded in a standardized MTM form. At the completion of the session, the pharmacist will discuss PGx testing, including the

Figure 1. Flowchart of study protocol.

MAP: Medication action plan; MTM: Medication therapy management; PGx: Pharmacogenetic.

purpose of testing, description of test, test limitations and anticipated outcomes [48].

The follow-up MTM session will be conducted either in-person or by phone as deemed appropriate by the pharmacist and convenient for the patient. The pharmacist will review the information provided in the previous session and discuss possible medication changes, the PGx test results and its significance to current treatments, and strategies to improve adherence. The pharmacist will also describe how the results may be important for future medications if the patient is taking another medication impacted by the same PGx gene and there is strong evidence regarding dose adjustment/drug selection based on genotype, recommendations for additional drug or dosing changes may be made. Patients will be provided a copy of the MAP and a wallet card of their PGx results. The pharmacist will contact the prescribing physician with recommendations based on the results and send a copy of the MAP. All final treatment decisions will be made by the physician.

PGx testing only arm

Prior to testing, the pharmacist will discuss PGx testing with the patient, including the purpose of testing, description of test, test limitations and anticipated outcomes, using any of the toolkit resources as desired/needed. When testing is completed, the pharmacist will review the PGx results and the participant's medication history to determine if drug or dosage adjustments should be considered based on the test results. Results may be provided to the patient on the PGx wallet card or patient summary test report provided in the toolkit. If the patient is taking another medication impacted by the same PGx gene and there is strong evidence regarding dose adjustment/drug selection based on genotype, recommendations for additional drug or dosing changes may be made. All patients will be notified of their result by the pharmacist; we will encourage pharmacists to notify patients of 'normal' results as well since this may impact patient's confidence in the safety or efficacy of their medication and affect adherence. The pharmacist will also con-

tact the participant's provider if changes are recommended. In the event that MTM is clinically indicated for a patient who undergoes PGx testing in this arm, pharmacists should provide the service and we would exclude these patients from the study.

Pharmacist surveys

Participating pharmacists will be invited to complete two surveys. First, a baseline survey will be administered to all pharmacists prior to participation in the educational training. The baseline survey will assess previous knowledge of and experience with PGx testing, comfort with integrating PGx testing into pharmacy practice, comfort discussing PGx testing with patients and experience with patient education and MTM (Box 1). Pharmacist and pharmacy practice data to be collected include number of years in practice, other pharmacy services offered and estimated time to complete each service. At the completion of the study, pharmacists will be invited to complete another survey to re-evaluate their knowledge of PGx testing, comfort with integrating PGx testing into pharmacy practice and comfort in discussing PGx testing with patients. We will ask about the likelihood and the operational feasibility of adding PGx testing to their pharmacy services following conclusion of the trial. Specifically, we will ask about major barriers to implementation including potential impact of adding this service on other currently offered services, costs and staffing.

Prior to the study launch, the survey questions will be reviewed by a group of pharmacists not affiliated with the study to assess comprehension and completeness of answer choices and revised accordingly.

Pharmacist interviews

To complement the survey data and gather more in-depth information about pharmacists' experience in delivering PGx testing, perceived value of testing, consumer interest and likelihood of adding PGx testing as a permanent service, we will conduct semi-structured interviews with a subset of pharmacists at the end of the study. An interview guide will be used to ensure consistency of interviews. We will aim to interview approximately 20 pharmacists (10/study arm) or until we observe that no further new data are being gathered (saturation of themes).

Pharmacist patient log

To aid in determining the burden of delivering PGx testing in a pharmacy setting, pharmacists will be required to keep a record of patient and provider interactions, including the reason for each interaction, time spent and mode of interaction (phone, in-person). Pharmacy adherence data will be recorded for 6 months after test results are communicated. Two measures of adherence based on data from the pharmacy will be generated: the proportion of days covered (# of days with drug on-hand/# of days in the specified time

Box 1. Outline of proposed survey content for pharmacists and patients.

Pharmacists

Baseline survey (prestudy: prior to training)

- Background (pharmacist)
- Background (pharmacy)
- Experience with PGx testing
- Knowledge/awareness of PGx testing
- Experience with patient education and MTM

Follow-up survey (poststudy)

- Re-evaluate knowledge of PGx testing
- Comfort with providing PGx testing in pharmacy practice
- Likelihood of adding PGx testing to their pharmacy services/perceived barriers to implementation

Patients

Baseline survey (following consent for PGx testing)

- Demographics
- Health literacy screening/perceived knowledge of genetics & drug response
- Medication beliefs/behaviors (BMQ)

Follow-up survey (following communication of test results)

- Comprehension of test results and significance to treatment
- Satisfaction with delivery of PGx testing in community pharmacy
- Likelihood to have PGx testing again in community pharmacy/perceived benefits/value of PGx testing
- Sharing of test results with other health professionals
- Medication beliefs/behaviors (BMQ)

BMQ: Brief medication questionnaire; MTM: Medication therapy management; PGx: Pharmacogenetic.

interval) ($\times 100$) [49–51]; and medication possession ratio (# of days of medication supplied within the refill interval/# of days in refill interval).

Patient surveys. Two patient surveys will be administered, one prior to testing & the second, after test results have been reported

The baseline survey aims to collect demographic patient data, prior knowledge about PGx and general medication-taking behaviors and beliefs (the Beliefs in Medicines Questionnaire [52]). The goals of the follow-up survey are to obtain data on patient comprehension of the test result, satisfaction with the testing experience offered in a pharmacy setting, including use/provision of patient materials, perceived value of testing, patient-reported medication-taking behaviors and information sharing.

Analysis

For each pharmacist and patient survey question, responses will be summarized using descriptive statistics. Both univariate and multivariate analyses will be conducted for hypothesis testing regarding patient comprehension of results, patient satisfaction, perceived patient value, patient adherence and pharmacy burden. Because the trial uses a cluster design, the analysis will use logistic mixed effects regressions by including treatments as the fixed effect of interest and clusters as random effect. We will first test if the random effect is significant or not. If not, then we will use regular logistic regression to perform the analysis; if significant, we will continue using mixed effect logistic model. A secondary analysis will be performed in which the comprehension outcome is not collapsed into ‘correctly identifying the presence of any variant versus no variants’, but will include correctly indicating the result for each gene (e.g., slow/fast metabolism vs average). In this case, a logistic random effects model will also be applied with pharmacist and patient as random effects. If a sufficient number of patients are enrolled per drug, a stratified data analysis by drug will be performed to detect any differences regarding comprehension, adherence or satisfaction. Sensitivity analyses will be performed to examine the impact of reported changes in comprehension, as individuals who drop out could potentially be less likely to change behaviors. The results of complete case and imputed analyses will be reported. The type of missing data will be examined to understand whether they are missing at random or not. If they are, then the assumption will be that the imputed analyses provide the better estimate of the treatment differences. If the decision is that one cannot say that the data were missing at random, then both results will be presented with accompanying text

describing the potential biases in both sets of results, the level and type of missingness seen, as well as the limitations of interpretations if a significant number of observations were missing.

Discussion

As with any novel medical innovation, the effective translation of new clinical tools such as PGx testing will be substantially influenced by the local environment or context, in which they will be used. Decisions regarding use of new innovations are influenced by both patient and health provider factors such as attitudes, understanding, interest, perceived value and cost [53]. In this study, we propose to compare two delivery approaches through a cluster randomized study design: PGx testing delivered as a standalone service and PGx testing delivered as part of an MTM service in community pharmacy settings. Given the presumed novelty of PGx testing to patients and the unfamiliar delivery model of pharmacist-delivered testing, this study will provide new data about patient acceptance, comprehension as well as pharmacy feasibility. To our knowledge, only one other pilot study of a PGx testing-only service has been conducted [54]. Thus, this would be the first study to comprehensively assess the delivery of PGx testing in actual community pharmacy setting, providing a more realistic assessment of patient response and pharmacy barriers/facilitators to offer PGx testing as a routine service. Pharmacists have expressed interest in delivering PGx testing [55], but educational and feasibility concerns must be addressed. Several factors may impact the delivery of PGx testing in a pharmacy setting, including pharmacy workflow demands, provider responsiveness to pharmacist requests to approve the test and other health system factors.

In parallel, we will assess patient acceptance of this delivery model and perceived value and understanding of testing. For many patients, this may represent their first experience receiving a clinical test in a pharmacy setting. Many patients may be more willing to be tested since there is no cost, but studies have indicated patients’ willingness to pay for genetic tests, particularly for older patients, with higher income and perceived clinical and personal utility [56–59]. A supplemental study to the proposed survey, such as a focus group study, may be of value to gather additional feedback from patients.

Conclusion

With the widespread expansion of precision medicine across clinical practice, new educational and delivery models must be explored to enable broad availability and access, patient engagement and integrated care.

We aim to evaluate delivery models for PGx testing implemented in the community pharmacy setting, a care setting that has not been extensively explored thus far. We anticipate that our study will help provide insight about potential barriers to the use of PGx testing and effective approaches to overcome these barriers in the pharmacy setting. Using data gathered from this study, we hope to inform decisions regarding delivery models for PGx testing and increase the appropriate utilization of PGx in community pharmacy settings. In conclusion, we anticipate the study will yield a rich dataset of interest to many stakeholders in precision medicine and healthcare delivery.

Future perspective

The potential widespread benefits of PGx testing will likely require facilitating access to testing through multiple clinical settings combined with appropriate patient and provider education and decision-making

tools. Potentially, all patients can undergo a one-time broad PGx test with the results accessible to both prescribing providers and pharmacists. With expanded clinical services provided in the pharmacy setting, this may enable greater patient access to testing and an opportunity to partner with pharmacists to identify potential medication issues through an MTM. Thus, pharmacists can play a key role in expanding patient access and education for PGx testing.

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Executive summary

- A number of delivery models are being explored to integrate pharmacogenetic (PGx) testing in various clinical practice settings.

Study rationale

- Community pharmacies may be an optimal location for providing PGx testing services as community pharmacies are more easily accessible than other practice settings, and pharmacists have the necessary skills and knowledge to provide these services.

Study design

- We aim to assess the feasibility and patient satisfaction with providing PGx testing within the community pharmacy setting alone or in combination with medication therapy management.

Conclusion

- This study will provide preliminary evidence regarding the feasibility of providing PGx services within a community pharmacy setting, and will assess patient acceptance of the service and its effect on adherence.

Future perspective

- As benefits of PGx testing become more widespread and its utilization increases, settings like community pharmacies may be considered for providing PGx services. Community pharmacists can play a key role in expanding patient access and education for PGx testing.

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