

**COMMUNITY PHARMACY IMPLEMENTATION OF PHARMACOGENETIC TESTING FOR MENTAL
HEALTH**

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Abstract

Pharmacogenomics has the potential to improve outcomes related to mental health medications by reducing adverse drug events and increasing drug efficacy through selection and dosing based on a patient's genetic makeup. Community pharmacists are uniquely positioned to provide this innovative care to patients, as accessible members of the healthcare team. While evidence-based guidelines exist for the use of several mental health medications based on a patient's pharmacogenetic makeup, little guidance exists for applying a pharmacogenetic testing service in a community pharmacy setting. The goal of this project was to determine the feasibility of implementation of a community pharmacy-based pharmacogenomic testing service, and to identify the barriers that exist to providing this service to patients. In an eight-month implementation project, a total of thirteen patients were provided pharmacogenetic testing services and test interpretation as a part of a medication therapy management appointment. Referrals were generated by creating partnerships with mental health providers in the community. A total of 26 drug therapy problems were identified. Significant barriers to implementation and sustainability were identified throughout the data collection period. Though pharmacogenetic testing may be beneficial to patient care, current payment models do not make it a sustainable service for the community pharmacy setting.

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Introduction

Pharmacogenetics is a rapidly expanding field, and our understanding of the relationship between variation in a patient's genome and their response to therapy is improving every year. Pharmacogenetics has the potential to improve patient outcomes, through eliminating and reducing avoidable adverse drug events and by increasing medication efficacy through the selection and appropriate dosing of drugs. It may also increase patient adherence to therapeutic regimens by allowing the selection of medications that a patient is more likely to tolerate.¹⁻² It does this by examining the variation in drug transport, metabolism, and pharmacodynamic targets based on a patient's genetic make-up, and applying this information to known pharmacokinetic and pharmacodynamic properties of drugs. As the cost of genetic sequencing decreases, the cost-barrier for patients also decreases. There has been an increase in the number of patients that are looking for healthcare providers that are comfortable ordering and interpreting these test results for them, which has been evidenced by increasing number of inquiries about these services at Goodrich Pharmacy. Several health systems within Minnesota provide genetic testing, however, patient access is limited to those receiving care within the healthcare system. A state-wide survey of pharmacists-in-charge found that 63% of respondents did not have a pharmacogenetic testing program in their health system.³

OneOme's pharmacogenetic test looks at a variety of proteins involved in the metabolism of, and response to, medications. More than 100 medications contain pharmacogenetic information in the package insert, and many of these are included in the OneOme report.⁴ Current pharmacogenetics-based guidelines include those published by the Clinical Pharmacogenetics Implementation Consortium (CPIC), the Royal Dutch Association for the Advancement of Pharmacy - Pharmacogenetics Working Group (DPWG), and the Canadian Pharmacogenomics Network for Drug Safety (CPNDS). However, evidence-based guidelines for applying the results of pharmacogenetic tests to patient care exist for a much smaller number of medications. To interpret and apply these results to patient care, a strong knowledge of pharmacokinetics and pharmacodynamics is essential.

Antidepressants and anxiolytics are two classes of medications that are heavily utilized in the community setting in which evidence-based guidelines are available for adjusting therapy based on

patients' pharmacogenetic profiles.⁵⁻⁶ Applying the results of pharmacogenetic testing to medications for mental health may be beneficial for a variety of reasons. According to the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) study, only one-third of patients with major depressive disorder will respond to a first line medication for depression, and after several trials with different antidepressants, one-third of patients will not achieve remission from their acute depression episode.⁷ Patients that are newly started on medications for depression or anxiety may benefit from using testing to guide therapy decisions to reduce the risk of medication failure. Patients with a long history of these conditions may also benefit from understanding how their genetic makeup may have contributed to multiple failed medications. Medication dosing guided by pharmacogenetic test results may also reduce the incidence of adverse effects.²

There have been many studies examining the implementation of pharmacogenetic services within health systems, clinics, and hospitals.⁸⁻¹² Pharmacogenomics clinics have been successfully implemented within already-established clinic settings with pharmacist-led services.⁸ However, literature regarding implementation in a community pharmacy setting is scarce, particularly in regards to mental health medications. Available studies in the community setting have focused primarily on clopidogrel and CYP2C19 polymorphisms.^{5,13-14} Other studies in community pharmacies have provided pharmacogenetics as an additional service outside of normal MTM delivery. Surveys revealed that community pharmacists ordering these results spent less than five minutes on pre-test counseling, and approximately one minute calling patients to deliver test results.¹¹ Comprehensive medication review and education did not accompany testing in these cases. The implementation of such a service as part of the delivery of medication therapy management services for mental health medications in a small chain of independent pharmacies has not been studied.

Methods

Study location

Goodrich Pharmacy is an independent community pharmacy in the northwest suburbs of the Twin Cities. There are five locations, and the majority of these pharmacies are located within primary care clinics. A partnership was established with a variety of mental health providers to generate patient referrals, including Arden Woods Psychological Services, the Minnesota Clinic of Health and Wellness, and several local practitioners with private practices. The Minnesota-based company OneOme was utilized for testing services. The service was based out of the Anoka location, and entailed a patient consultation with a pharmacist which was designed to be similar to already-established comprehensive medication management services at this location. A collaborative practice agreement was signed by a local healthcare provider, in this case a certified physician's assistant, to order pharmacogenetic testing. This project was evaluated and did not meet criteria for human subject research according to the University of Minnesota Institutional Review Board.

Patient recruitment and selection

Patients were referred by licensed individuals providing mental health services and included psychologists and prescribers from Arden Woods Psychological Services, the Minnesota Clinic of Health and Wellness, and several local practitioners with private practices. Handouts regarding frequently asked questions about pharmacogenetic testing were developed by the pharmacist for providers to give to patient at the time of the referral (see Appendix A). Patients were also able to request pharmacogenetic testing independently of a prescriber. To be eligible for testing, all patients were at least 18 years of age and were taking medications for depression or anxiety, or were newly diagnosed with anxiety or depression. Patients were excluded if they were less than 18 years of age, or if consent to test could not be gathered from the patient or a legal guardian. Legal guardians were required to provide a copy of the court order appointing guardianship in addition to signing consent forms.

Service delivery

The length and style of participation varied depending on the needs of the patient. All patients required at least two visits; one for the initial consultation and testing, and one for follow-up. The initial consultation included a comprehensive medication review of the patient's current medications and chronic conditions; including gathering information on current mental health medications and previous medication trials. Patients also received face-to-face education by a pharmacist about pharmacogenetic testing, its role in medication management, the types of information generated by testing, the cost of testing, and were shown a sample test report. A buccal swab was performed by the patient at the end of this encounter. The pharmacist assisted the patient in completing test requisition forms and sent the swab to OneOme for processing.

All patients had at least one follow-up consultation to discuss the results of their pharmacogenetic testing and recommendations regarding drug therapy based on pharmacogenetics, which occurred face-to-face, or via phone. All patients received a personalized summary letter written by the pharmacy resident with recommendations for changes to their medication therapy. Recommendations were also delivered to the referring provider via US Mail and fax. If drug therapy problems were identified for health conditions not managed by the referring provider, a letter with recommendations was sent to the patient's primary care provider. If changes were recommended, the pharmacist followed-up with the patient and prescriber as appropriate to determine if the prescriber responded to changes.

Goodrich Pharmacy contracts with MTM Express for their electronic documentation system. MTM Express is not integrate with other dispensing software at the pharmacy, and is utilized solely to document all MTM encounters that occur in the community pharmacy setting. A patient profile was created for each patient within MTM Express following the initial consultation, including demographic information, a complete medication list, and allergies. A complete SOAP note was documented and entered into the record for every encounter, using the Pharmacy Quality Alliance Medication Therapy Problem Categories Framework to report drug therapy problems.¹

Billing for the pharmacist consultation was managed entirely by the pharmacy resident at Goodrich Pharmacy. The resident billed insurance plans for the delivery of medication therapy management to eligible patients. This included all Health Partners patients, and a subset of Blue Cross

Blue Shield patients. For the initial consult, the first 15 minutes were billed for \$65, and subsequent 15 minutes were billed for \$35 each. At the follow-up visit, the first 15 minutes were billed for \$40, and subsequent 15 minutes were billed for \$35 each. Cash-paying patients were asked to pay a \$50 deposit at the time of the first pharmacy visit, and were sent invoices for the remaining balance using the same billing codes submitted to insurance. OneOme billed the patient directly for the cost of the test after first submitting a claim to insurance. If insurance rejected the claim, the patient was charged a fee based on income. Patients earning more than \$100,000 annually were charged \$349 and patients earning less than \$100,000 received a \$100 subsidy from OneOme to reduce the cost of testing to \$249.

Data collection

Data collection included the number and type of drug therapy problems identified per patient. The referral source, patient insurance-type, pharmacist time per visit, and reimbursement (insurance and direct payments by patients) was also documented for each visit. Total pharmacist time and reimbursement per hour was calculated. Pharmacist time outside of patient visits, including meeting with potential referral sources, requesting records, and evaluating test results, was not recorded.

Results

At the end of the data collection period, thirteen patients had an initial pharmacist consultation for pharmacogenetic testing and were swabbed for the pharmacogenetic test for mental health conditions. Twelve of those patients returned for the follow-up appointment to receive test interpretation and an explanation of results. Seven patients were referred by Arden Woods Psychological Services, two had independently sought out pharmacogenetic testing for their mental health medications, one was referred by the Minnesota Clinic of Health and Wellness, and three were referred by a private practitioner. The testing company, OneOme, was responsible for billing patients for this test directly. The patient that did not return for follow-up elected not to pay for the pharmacogenetic test after the sample was collected, and did not pay for the initial consultation with the pharmacist.

Of the thirteen patients, five had private insurance that would pay for the consultation with the pharmacist, though reimbursement rates differed. Patients that did not have medication therapy management coverage under their insurance plan received a subsidy using grant funding that was acquired several months into the data collection period to reduce the cost of the pharmacist consultation. The Incentive Grant was provided by the American Pharmacists Association Foundation for residents to implement or support an existing innovative patient care service within their pharmacy practice. All patients had medical insurance. Seven were privately insured, three were Medicare-eligible, and three had state-subsidized insurance (Table 1). The maximum out of pocket cost for the patients in this cohort was \$459. This patient did not have MTM services as a covered benefit, and were responsible for paying the full \$249 cost of the pharmacogenetic test. Grant funding was used to subsidize the \$65 charge for the initial 15 minutes of the first appointment (CPT 99605).

An average of two drug therapy problems were identified per patient (range 0 to 7). Options for future medication therapy for mental health was provided to all thirteen patients. Safety-related drug therapy problems were the most frequent (10 of 26). Indication and efficacy were represented evenly (7 of 26). Convenience-related drug therapy problems accounted for 2 of 26 total drug therapy problems (Table 2). Of the 26 drug therapy problems identified, 10 were related to medications for conditions other than mental health, and included medications such as antihypertensives, vaccinations, and supplements.

Time outside of the patient appointment was not tracked. This burden was substantial, as all patient visits were documented in the electronic health record and pharmacogenetic tests were reviewed. Appointments accounted for 17 hours of pharmacist time and were equally split between initial and follow-up appointments. Had all patients returned for follow-up, the amount of time spent educating about pharmacogenetic results would have exceeded the time spent in initial appointments. This does not mirror traditional MTM scheduling at Goodrich Pharmacy, where initial visits are scheduled for 60 minutes, and follow-up appointments are 30 minutes. It is not surprising, however, given the complexity of pharmacogenetic testing results, and the time required to adequately convey this information to patients. A total of \$2835 was charged for the pharmacist consultation, and \$2503.87 of payments were collected, for a total reimbursement rate of 88.3% of expected. However, \$990 of this payment (39.5%) was provided by grant funding, including additional allocation of funds toward one patient account where the patient did not have the pharmacist consultation covered by insurance and refused to pay.

Discussion

Barriers to the implementation and sustainability of a pharmacogenetic testing service in a community pharmacy setting are substantial. Poor insurance coverage of pharmacist consultation and medication therapy management leads to high out-of-pocket costs for many patients for delivery of testing services and interpretation. This poor coverage is surprising given that the benefits of medication therapy management are well known. Additionally, insurance coverage of pharmacogenetic testing is limited. Patients with Medicare and state-subsidized health plans do not receive a charge for testing, however private insurance generally does not cover the cost of testing. This places a unique burden on patients with private or no health insurance. Together, these costs provide a considerable burden for many patients who wish to receive pharmacogenetic testing. Additionally, the inconsistency of coverage between and within plans increases burden for pharmacists who must contact payors to see if patient visits are billable to the plan. Had grant funding not been awarded several months into the data collection period, patient participation may have been reduced.

There are additional challenges to implementing a testing and interpretation service. First, pharmacists on staff may have varying levels of comfort interpreting test results. The University of Minnesota College of Pharmacy offers *Pharmacogenetics: Genetic Basis for Variability in Drug Response* as an elective course, and many pharmacy students may not be exposed to this material. The Accreditation Council for Pharmacy Education (ACPE) has included pharmacogenomics/genetics among the required elements of the didactic Doctor of Pharmacy curriculum, however, it is not guaranteed that this will translate to pharmacists that feel comfortable providing this kind of care.¹⁵ Further complicating this is the fact that evidence-based guidelines do not exist for all medications included in the pharmacogenetic test report, which requires pharmacists to use their clinical judgment in providing recommendations to patients.

Finally, limitations with the electronic health record and online portal for accessing the pharmacogenetic test results result in further barriers to implementation. The online provider portal is provider-specific, rather than institution specific. Providers who must maintain access to OneOme at a new job site will have access to the records of patients at previous institutions, unless they make

arrangements with the testing company. Additionally, there is limited integration of patient results into electronic health records. Test results are provided to patients on paper. Patients without internet access must retain paper copies. Test results may be delivered to the patient's prescriber by the patient at a visit, or may be faxed or mailed to the provider by the pharmacist. However, these results are usually scanned into the medical record in a portable document format (PDF), which is not searchable and is not included with other lab results. As a result, providers may not be aware that the patient has completed pharmacogenetic testing and may have actionable recommendations based on their results. Concerns over liability and uncertain benefit to patients may cause providers who are unfamiliar with pharmacogenetics to be hesitant to refer patients for testing.

The impact of these barriers may be substantial, given the scarcity of pharmacogenetic testing services in community pharmacies in Minnesota. However, the discovery of drug therapy problems and guidance for future medication therapy indicates that the service may be beneficial to patients. As reimbursement models change, these services may become more viable as part of medication therapy management delivery in the community pharmacy setting.

How our pharmacogenomics service works

The process is simple, noninvasive, and provides important information about your body's ability to respond to certain drugs.



1 Call us

Contact Goodrich Pharmacy (763-421-5540) to set up an appointment.



2 Come see us for testing

Come into the store to get your cheek swabbed with a Q-tip.



3 We send it to be analyzed

Goodrich sends it to the lab to be analyzed.



4 We set up your appointment

We receive your full DNA analysis within 7-10 days and call you to set up an appointment to review your results.



5 You come in for your review

Come in for your pharmacogenomics and medication review.



Goodrich Pharmacy
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Pharmacogenetic Testing with Goodrich Pharmacy

601 Jacob Lane, Anoka, MN 55303

763-421-5540



What is pharmacogenetic testing?

Every person is different. Differences in DNA can affect how your medication works. This test looks at your DNA to predict how you might respond to certain medications. This test can help your provider choose the safest and most effective medication for you. This test is not designed to provide ancestry or heritage information.

How does this benefit you?

This test helps your health care providers choose medications that might work better for you based on your DNA. It can help you avoid medications that may not work for you and help you avoid medications that may cause side effects. They may also be able to choose a better dose of the medication for you due to your specific genes.

Who makes the test? What does the test measure?

The company is called OneOme. The test looks at specific genes in your DNA and reports differences in the way your body responds to medications.

How do I get this test?

Your provider can refer you to Goodrich Pharmacy for an appointment to discuss your medications and to get tested. A pharmacist at Goodrich Pharmacy will contact you to set up an appointment. Please bring all of your medications with you to your appointment with the pharmacist. You will review all of your medications with the pharmacist before getting the test.

How does the test work?

A pharmacist will help you collect a DNA sample using a cotton swab on the inside of your cheek. This is sent to the company for processing, which takes about a week. Once finished, OneOme makes the results available to you and the pharmacist online. The pharmacist will gather information about your current medications, and medications that you have tried in the past. You and the pharmacist will meet to discuss the results and how they affect your medications.

How much does it cost?

If you have Medicare, Medicaid, or a state health plan, the test is free. If you have private insurance and earn more than \$100,000 per year, you will pay \$349. If you earn less than \$100,000 per year, you will pay \$249. The testing company will contact you directly about paying for the test.

You will have at least two appointments with a pharmacist to discuss your medications, collect your sample, and to discuss your results. This will cost up to \$170 per appointment depending on your insurance coverage. Please bring your insurance card with you to Goodrich.

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Tables

Table 1. Patient insurance, visit length, and charges.

<i>Patient</i>	<i>Insurance type</i>	<i>MTM covered service?</i>	<i>Initial visit length (minutes)</i>	<i>Initial charge</i>	<i>Initial payment</i>	<i>Follow-up length (minutes)</i>	<i>Follow-up charge</i>	<i>Follow-up payment</i>
1	Commercial	Yes	45	135	129.86	60	145	135.28
2	Medicare	No	60	170	170	0	0	0
3	Commercial	No	15	65	50	15	45	60
4	Medicare	Yes	60	170	125	45	110	50
5	Commercial	Yes	45	135	129.86	45	110	102.81
6	PMAP	Yes	30	100	97.39	45	110	102.81
7	Commerical	No	45	135	135	60	145	145
8	Commercial	No	45	135	135	60	145	145
9	Medicare	No	45	135	135	45	110	110
10	Commerical	No	15	65	65	45	110	110
11	PMAP	No	45	135	135	45	110	0
12	PMAP	No	15	65	65	15	40	40
13	Commerical	Yes	45	135	129.86	30	75	70.34
<i>Total</i>			510	\$1580.00	\$1501.97	510	\$1255.00	\$1071.24

Table 2. Medication therapy problems identified.

<i>Medication Related Needs</i>	<i>Medication Therapy Problem Category</i>	<i>Frequency</i>
<i>Indication</i>	Unnecessary medication therapy	5
	Needs additional medication therapy	2
<i>Effectiveness</i>	Ineffective medication	5
	Dose too low	2
	Needs additional monitoring	0
<i>Safety</i>	Adverse medication event	8
	Dose too high	2
	Needs additional monitoring	0
<i>Adherence</i>	Adherence	1
	Cost	1