Making pharmacogenetic testing a reality in a community pharmacy

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Abstract

Objective: To provide information for community pharmacies considering implementation of a pharmacogenetic testing service.

Setting: A single community pharmacy from a regional chain.

Practice description: Community pharmacists at the study site routinely provide pharmacy services including medication therapy management, immunizations, point-of-care testing, blood pressure monitoring, and diabetes education. The pharmacy is a training site for post-graduate year 1 and 2 community-pharmacy residents and for introductory and advanced pharmacy practice experience students.

Practice innovation: Implementation of a pharmacogenetics testing service in a community pharmacy.

Main outcome measures: Feasibility of offering a pharmacogenetics testing service in a community pharmacy.

Results: Study investigators identified several internal and external barriers to the community pharmacy when initiating a pharmacogenetics service. This article shares experiences of the study team and solutions to the identified barriers.

Conclusion: Community pharmacies interested in providing pharmacogenetic testing can overcome barriers by identifying practice partners and planning appropriately.

Keywords: Community pharmacy services, community pharmacy, pharmacogenetics, pharmacogenomics, medication therapy management, clinical pharmacy service.
In 2011, the American Pharmacists Association released a white paper describing the importance and practicality of integrating pharmacogenetics or genomics in the medication therapy management (MTM) process to optimize pharmacotherapy for patients. Although controversial, the discussion is fueled by the availability of genetic tests through prescriber-ordered clinical laboratory tests or direct-to-consumer (DTC) tests. At one time, patients had the potential for access to DTC genetic tests through two routes: purchasing from online companies or through a community pharmacy. As part of the online access, the company sends the patient a kit for sample collection, the patient returns the sample, and the lab returns the results with a limited, and often inaccurate, interpretation of the results. The inaccuracies of the information provided by these companies was highlighted in a 2010 statement from the U.S. Government Accountability Office. In 2010, the U.S. Food and Drug Administration (FDA) deemed it illegal to sell health-oriented DTC genetic tests in community pharmacies. Despite the decision by the FDA, consumer demand for pharmacogenetic testing is growing, and the interpretation of results by pharmacists or prescribers regarding pharmacogenetic tests may soon become a part of routine clinical practice.

At a Glance

Synopsis: The increasing need to apply pharmacogenetic information to patient prescriptions was addressed in a new service described in this experience article. The authors helped to establish a pharmacogenetic testing service in a community pharmacy, in a collaboration between physician, pharmacist, and genetic testing service. The complications described here involved legal, financial, and medical practice questions, all of which would need to be considered by anyone interested in implementing a similar service. The article discusses the barriers that were encountered to such implementation with suggested ways to address those barriers.

Analysis: In an attempt to avoid the adverse effects of drugs, or to ensure their efficacy, there is a growing capacity to connect individual differences in biochemistry causing these differences directly with personal genetic variations. More than 100 drugs now carry FDA pharmacogenetic information on the label, and this labeling trend will certainly grow. The application of such knowledge can be critical to a patient’s health, an application that requires testing and interpretation relative to medication. Pharmacists are the logical information nexus to bring together information on patient health, medications being taken or considered, and potential genetic interaction with those medications. The experience described here is a leading edge for what may reasonably become common in pharmacy practice.

The more reliable tests are offered by lab companies that analyze samples pursuant to a prescriber’s order. This requirement is intended to ensure proper follow-up and the availability of counseling as necessary. As patient interest heightens and the available information trickles into clinical decision making, pharmacogenetics will become increasingly relevant to community pharmacists.

Background

Pharmacogenetics is currently mentioned in the drug package insert of more than one hundred drugs. Few primary care practitioners use the pharmacogenetic information contained in package inserts to order those pharmacogenetic tests that influence prescribing, even though we know that one in four prescription drugs dispensed is metabolized by polymorphic pathways. Given this information, not many studies have investigated whether prospective pharmacogenetic testing influences a therapeutic regimen. Furthermore, no studies in the United States evaluating prospective pharmacogenetic testing by pharmacists in a community pharmacy currently exist.

Community pharmacists are integral to patient care through MTM. Because of the relationships they have with patients, pharmacists are poised to assume the role of obtaining samples and providing clinical pharmacy services in response to pharmacogenetic test results. In fact, it is a natural extension of the MTM rubric for pharmacists to include the results of pharmacogenetic tests or the recommendation to test. Similar to other clinical pharmacy services, such as point-of-care tests for lipid management, the process for establishing a service to offer pharmacogenetic testing in a community pharmacy requires thoughtful consideration of the viability of a new service (Figure 1a). The objective of this experience paper is to provide information for community pharmacies to use when considering offering a pharmacogenetic testing service.

Setting and practice description

The practice setting is a single pharmacy that is part of a regional chain known for providing clinical services. All community pharmacists at the study site routinely provide pharmacy services including MTM, immunizations, point-of-care testing, blood pressure monitoring, and diabetes education. The pharmacy fills approximately 1800 prescriptions weekly and has three full time pharmacists at the store. The pharmacy is also a training site for postgraduate year 1 and 2 community pharmacy residents and for introductory and advanced pharmacy practice experience students. Two of the pharmacists at this location provided the pharmacogenetic service to patients.

Practice innovation

Recognizing the future of pharmacogenetics and the role it may play in health care, Kerr Drug, a regional pharmacy chain, Laboratory Corporation of America, a national lab testing company, and the Eshelman School of Pharmacy at the University of North Carolina at Chapel Hill are collaborating to test the practicality of a pharmacogenetics testing service in a community pharmacy. Developing this collaboration was important to
establish this new service and to test feasibility for pharmacogenetics. We decided to conduct pharmacogenetic testing for CYP2C19 using clopidogrel as the example. A complete description of the research methods has been published.12

Main outcome measures
The core questions and outcomes for the study address issues that any pharmacy or chain of pharmacies would likely address in considering initiation of a new service: questions of feasibility, the ability to obtain reimbursement for the clinical service, and the level of satisfaction of patients and prescribers. While we were planning the study to investigate these issues, several unexpected barriers arose. The objectives of this manuscript are to discuss the barriers and solutions we identified to make a pharmacogenetic testing service practical in the real world of community practice and to discuss barriers and solutions for practitioners considering research in this area.

Results

Barriers and solutions

■ How will the pharmacist order the lab test?

Barrier: Because most insurance companies do not recognize pharmacists as health care providers, lab companies, in turn, do not allow pharmacists to order or receive the lab results for patients. Furthermore, individual state regulations are inconsistent regarding the legality of pharmacist-ordered lab tests.

Solution: The Pharmacy Practice Act in North Carolina defines the opportunity for pharmacists to serve as a provider extender, or Clinical Pharmacist Practitioner (CPP). Similar to a nurse practitioner or a physician assistant, a CPP can order lab tests under collaborative practice agreement. In order to achieve CPP designation, pharmacists in this study were required, according to NC requirements, to submit an application, including a protocol mutually developed with their supervising physician, to the North Carolina Board of Pharmacy and Board of Medicine. Once approval was granted by both Boards, study pharmacists were able to order the pharmacogenetic tests under their expanded scope of practice as CPPs.

In order for this service to be replicated in other states or sites, a similar provider status arrangement would need to be made to order the test. Alternatively, an agreement with individual prescribers could be obtained where the prescriber orders a lab test and he or she would share the result with the pharmacist for interpretation. Although this solution still presents a communication barrier, it may be feasible in the absence of pharmacist-ordered lab tests. As the regulatory landscape differs from state to state, pharmacists interested in ordering and interpreting pharmacogenetic data as an extension of their current practice need to be fully abreast of the state pharmacy rules and statutes under which they practice.

■ How will the pharmacist receive the lab results?

Barrier: The next barrier was pharmacist receipt of testing results. The turnaround time to receive lab results was seven business days. Although the pharmacists involved were able to resolve the issue of ordering the test through a collaborative practice agreement with the supervising physician, also a coin-

Figure 1 Clinical pharmacy service implementation: Lipids and pharmacogenetics.
vestigator, a precedent did not exist for a pharmacist to receive a copy of the test results from the lab company.

**Solution:** An online account for the pharmacogenetics research team was created with the lab company to ensure that all CPP-ordered lab results were delivered and accessible only to study personnel. This account was created using the supervising physician's Drug Enforcement Administration number as part of the CPP protocol. Pharmacists in other states may be able to order lab tests without prescriber approval or may need to set up agreements with a physician and the lab company.

- How will the results be documented with the prescriber?
- **Barrier:** Medical record and prescription documentation proved to be a concern. These systems, while both electronic, do not have the capacity to merge data, so the need to establish clear lines of communication and documentation was imperative. The documentation for the medical record was sent to the prescriber in a similar way to other pharmacist–provider communication.

**Solution:** Pharmacists communicated with prescribers via a 1- to 2-page fax that outlined the recommendation, the patient’s genetic test result, and the lab company result sheet. Confirmation of receipt was requested, and lack of confirmation triggered a fax within 3 working days. The faxed information was intended to be integrated into the patient medical record at the prescriber’s office.

- How will the results be documented within the pharmacy?
- **Solution:** Integration into the pharmacy dispensing record presented multiple challenges, as the operating software did not have an input for pharmacogenetic data to be automatically reviewed or manually reviewed by the pharmacist. This deficiency meant that, although the lab information could be reviewed for the study drug, the information could not inform clinical decision making during the process of dispensing other medications affected by the same polymorphic pathway.

**Solution:** An ideal resolution, outside of redesign of the pharmacy software, was not found. However, a temporary solution was proposed for a pharmacogenetic testing service when launched outside of the study. Pharmacogenetic data can be entered as a message that would make this information available to the pharmacist during the drug utilization review process at each dispensing. Pharmacists can also enter a message in this field stating the patient had been offered the test so they will not inadvertently receive the test again. Though the addition of multiple messages is far from ideal, this solution would provide the dispensing pharmacist with the requisite information. The documentation component related to pharmacogenetic test results will likely improve as the field become more integrated into patient care.13-15

- How will the results be interpreted?
- **Barrier:** Interpretation of the results from pharmacogenetic testing involved pairing pharmacists’ knowledge of drug metabolism with the relevance of test results. Assessment of the literature was vital in generating an algorithm for evaluating results and generating appropriate responses.

**Solution:** Access to and expertise in reviewing the literature was available through the partnership with a large research institution. Pharmacists routinely draw on their knowledge, drug information databases, and the package insert when reviewing drug–drug interactions. Similarly, much of the information related to pharmacogenetic testing is available in the package insert, drug information databases for many drugs, and evolving evidence-based guidelines.16

- How will the pharmacy obtain reimbursement for the lab test?
- **Barrier:** Reimbursement for the lab test was a concern, as the testing is expensive, and coverage across health insurance plans varies greatly. Furthermore, no mechanism currently exists for a community pharmacist in North Carolina to bill for a lab test.

**Solution:** The solution reached for this study was that the lab company would provide the lab test at no cost to the community pharmacy. Free testing from a clinical reference laboratory is not feasible outside of the study environment, so alternatives must be explored. Another option was requiring the patient to pay out-of-pocket and then request reimbursement from their insurance carrier. This option was eliminated by the study team, as they anticipated that it would seriously decrease patient interest in the service and would require the establishment of a billing subdepartment, which would not be cost effective. In other scenarios, the lab company is also able to work with insurance companies to take charge of billing outside of study scenarios, which frees the pharmacist from needing to be involved with this process. Such freedom from billing does not preclude patient questions related to insurance billing, however. Pharmacists involved in this solution would likely need to be familiar with the lab billing procedures and general insurance coverage policies pertinent to pharmacogenetic lab billing.

- How will the pharmacy obtain reimbursement for clinical services to interpret the genetic tests as they relate to MTM?
- **Barrier:** Several mechanisms existed for billing for cognitive services at the outset of this project. First, patients can pay out-of-pocket on a per minute, per half hour, or per service basis.17 As the out-of-pocket expense was perceived to be a barrier to enrollment, alternative options were pursued. Billing platforms such as MirixaPro and Outcomes Pharmaceutical Health Care may be useful for billing claims of this nature and are beneficial in their ease of incorporation if the pharmacy is already using these platforms to deliver MTM services. However, the focused area of this service and the limited billing processes with current systems decreased the viability of the considered options.

**Solution:** The solution to this problem was found in working through the existing billing service contracted by the pharmacy to process third party claims for administration of vaccines. A mock national drug code number was created for ease of billing at the store, and the claim was sent to the intermediary for adjudication. A formalized template was developed for the pharmacy to use with each submission. The process was streamlined with other services offered and the template allowed the process to fit nicely into normal daily activities. This solution decreased the amount of time the pharmacist...
spent on administrative duties related to reimbursement. In the future, contracts with insurers might be negotiated to further smooth pharmacist reimbursement for cognitive services.

- Will patients be interested in this type of service?
  **Barrier**: Patient interest in this type of service was a concern, so extensive consideration was given to selecting the community pharmacy.
  **Solution**: Kerr Drug in Chapel Hill, North Carolina, was selected because the patient population is accustomed to pharmacist-driven services. Generally, these patients are well informed regarding health care topics, are highly educated, and openly communicate with pharmacists and pharmacy support staff. Patients have come to expect innovative clinical services from this community pharmacy. Space for testing and counseling was not an issue because the location was already equipped with multiple private rooms to speak with patients. Because of the sensitive nature of communicating pharmacogenetic information, a private space should be a top consideration for pharmacists interested in offering this new clinical service. With the space and processes for handling clinical matters already in place, it was a natural extension of current pharmacist-driven services to implement a pharmacogenetic testing study at Kerr Drug in Chapel Hill. Pharmacies considering this service must seriously consider conducting a needs assessment because patient populations with different demographics than ours may have different needs for this type of service. Figure 1a offers basic considerations to think about prior to implementation.

- How will providers respond to this service?
  **Barrier**: Prescriber communication and response to this service is crucial to its success. The pharmacists understood the importance of prescriber reception to the service—strong opposition from local prescribers would decrease its feasibility; support from the medical community would improve the likelihood that the service would be sustainable.
  **Solution**: The pharmacy prepared a press release related to the launch of the pharmacogenetics testing service to increase local visibility of the service. Pharmacogenetic testing is a natural extension of pharmacy services because it is tantamount to the rational use of drugs. This type of testing is not very different from other pharmacist-provided testing to select or monitor drug therapy (Figure 1b). In order to obtain prescriber feedback, the fax informing prescribers of patient results from the service requested a signature and referred any questions or comments to the research team. After completion of the study, increased face-to-face marketing may be needed to increase prescriber awareness of the service outside the study environment.

**Practice partners**
This project would not have been successful without establishing relationships with collaborators. Each collaborator filled a vital role and brought important resources, expertise, and experience that should be considered when establishing a pharmacogenetic service (Figure 2). The partners involved in the creation of the pharmacogenetic service are described below.

**Lab partner**
Partnering with a lab company with pharmacogenetic testing experience, fast turnaround for sample analysis, and a network of couriers meant that the sample collection at the pharmacy could be scheduled any day convenient to the patient. Additionally, results analysis and subsequent recommendations to prescribers could occur in a timely fashion. Pharmacies wishing to initiate pharmacogenetic testing would likely have access to a lab testing company either by courier or mail order.

**Pharmacy partner**
The pharmacy within which this clinical service was offered is known for providing innovative clinical services in the community setting. Patients of this pharmacy expect novel services in the pharmacy. Support for the start-up phase of this project from all levels of the company was vital in moving the project forward. Finally, the physical space in the pharmacy was generous and flexible enough to allow for this service to be offered in a private office. Pharmacies that do not have private physical space allocated to clinical services would need to devise private screening areas, possibly by reallocation of space.

**Billing partner**
Compensation for cognitive services was possible through a partnership with a billing company. This company was already a contractual partner of the pharmacy for billing insurance for immunization services; a similar billing mechanism was created for billing for cognitive services delivered by the pharmacist related to pharmacogenetic medication counseling. The billing was done electronically out-of-house, which allowed the clinical service to run smoothly with patients. If a similar agreement is not feasible for other community pharmacies, compensation could be obtained through cash payment similar to billing for point-of-care testing or MTM services, or paper claims could be filed. These potential solutions present the obvious problems of patient willingness to pay and timeliness required for both filling out forms and long turnaround time for reimbursement to be processed by third party payers.

**Institutional partner**
The final partner in this project was a large research institution. This institution was vital in the development of a protocol for pharmacogenetic testing and providing resources such as recent references from the literature from which to draw information for clinical decision making. The research team was able to draw on the genetic expertise at the research institution, facilitate connections with the supervising physician, and use previous experience of other researchers to generate the CPP agreement. As pharmacogenetics is a new and quickly evolving field, this partner was essential in ensuring that the patients received optimal care. Pharmacies without access to a research institution could implement pharmacogenetic testing services with a focus on information available in package inserts, drug information databases, and evidence-based guidelines (e.g., Clinical Pharmacogenetics Implementation Consortium). A research institution partner...
Conclusion
The authors have presented their experience with barriers to offering pharmacogenetic testing in a community pharmacy, site-specific solutions to these barriers, and proposed remedies for a broader audience. As is evidenced in the increasingly common reports related to DTC genetic testing, this burgeoning area of science is likely one that will need to be integrated into routine practice. As community pharmacists have frequent interactions with a broad patient population, the application of pharmacogenetics can logically find a home in this arena. Working through barriers and solving problems will be commonplace as this development occurs. We encourage further open communication related to experience in the field.

Broader application
The number of drugs whose package inserts reference pharmacogenetics is growing.6,7 Patient interest in genetic testing is also evident, but problems exist with DTC options for genetic testing.2,3 The American Pharmacists Association suggests the need to integrate pharmacogenetics into MTM.1 Because community pharmacists routinely offer MTM and have a high level of contact with patients, it may be beneficial for pharmacogenetics testing to be offered by a community pharmacist. No studies of community pharmacy–offered pharmacogenetic testing in the United States have been published to date; therefore community pharmacists interested in offering such a service may need guidance regarding how to initiate their plan. This paper offers insight into barriers we encountered when initiating a pharmacogenetics testing service in a community pharmacy. Our discussion also explains solutions to these barriers and delineates partners to be considered in the establishment of the service. Future studies may explore the integration of pharmacogenetics testing with other clinical pharmacy services in community practice or expand upon partnerships needed to make such a service successful.

References


