Published in final edited form as:
Pharmacogenomics. 2013 June ; 14(8): 957–968. doi:10.2217/pgs.13.76.

The Clinical Delivery of Pharmacogenetic Testing Services: A Proposed Partnership between Genetic Counselors and Pharmacists

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Abstract

One of the basic questions in the early uses of pharmacogenetic (PGx) testing revolves around the clinical delivery of testing. Because multiple health professionals may play a role in the delivery of PGx testing, various clinical delivery models have begun to be studied. We propose that a partnership between genetic counselors and pharmacists can assist clinicians in the delivery of comprehensive PGx services. Based on their expert knowledge of pharmacokinetics and pharmacodynamics, pharmacists can facilitate the appropriate application of PGx test results to adjust medication use as warranted and act as a liaison to the healthcare team recommending changes in medication based on test results and patient input. Genetic counselors are well-trained in genetics as well as risk communication and counseling methodology, but have limited knowledge of pharmaceuticals. The complementary knowledge and skill set supports the partnership between genetic counselors and pharmacists to provide effective PGx testing services.

Keywords

Pharmacogenetic testing; delivery models; team-based care

Introduction

Drug response may be improved through adjustment of drug selection and dosing based on information from a patient's genotype regarding efficacy and risk of adverse events [1]. Over the past decade, a number of pharmacogenetic (PGx) tests have become clinically available and many drug package inserts in the U.S. and Europe [201] have been revised to include information about PGx variants and testing [2–4]. Despite the expanded knowledge of the role of genetic variants in drug response and the development of clinical tests, the delivery model of PGx testing is uncertain. Some have advocated for pre-emptive testing [5, 6] instead of testing on an as-needed basis (point-of-care). The delivery of PGx testing encompasses not just the ordering of tests, but consideration of the appropriateness of testing, alternative drug and pharmacovigilance options, turnaround time, and patient interest [7]. Additionally, pre-test counseling and/or post-test counseling may be warranted.

Regardless of the mode of delivery, it is unlikely that a single health professional can provide effective clinical care across the delivery spectrum of PGx testing. However, some of the uncertainty surrounding the use of PGx testing, not only regarding when testing is ordered but the evidence supporting the use of testing, has translated into uncertainty about

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which health professionals should be involved. Recent surveys of healthcare professionals reveal some discrepancy regarding which health professional would best be suited to order PGx testing and communicate results to patients[8]. A U.K. study reported that patients do not appear to have a preference about which health provider(s) should deliver PGx testing, but are more concerned that the information about the test and results are accurate [9] and be communicated in an understandable manner from trained healthcare professionals [10]. Some have speculated that the practice of personalized medicine will likely benefit from a multi-disciplinary approach [11].

Genetic counselors and/or pharmacists can play an important role in delivering PGx testing by informing and assisting physicians and patients in the use and interpretation of PGx information. Specifically, genetic counselors can play an important role informing and assisting physicians in the interpretation and communication of PGx information [12, 13] and addressing PGx testing in the context of disease susceptibility. In contrast, pharmacists can provide therapeutic support, serving as an educational resource and advising on drug selection, dose adjustment, and drug monitoring based on the PGx results and other clinical factors. The combined and complementary knowledge and skill set of genetic counselors and pharmacists would enable the comprehensive delivery of services essential to the appropriate use of PGx testing. Thus, we propose a new partnership between these two groups of professionals in the delivery of comprehensive services for PGx testing. Since these groups have not previously worked closely together, establishing this relationship will require developing an infrastructure to promote the effective delivery of services to ensure the safe and appropriate use of PGx testing.

To illustrate the delivery of a PGx test through the proposed genetic counselor-pharmacist partnership, the following clinical scenario will be used for discussion purposes: Patient X presents with a family history of cardiovascular disease, high BMI, triglycerides and cholesterol. The patient has unsuccessfully attempted diet and exercise regimens to reduce weight, triglycerides, and cholesterol. Given the wide variability in treatment response to lipid-lowering medications and potential adverse effects, her physician recommends *ApoE* and *SLCO1B1* testing to help inform selection of a safe and effective statin medication [14, 15]. The results show that the patient has the genotype ApoE3/ApoE4. As the *ApoE* gene is also predictive of onset of Alzheimer disease [16, 17], these results reveal the patient has an increased risk for the disease.

Genetic Counselors & Delivery of PGx Testing

Little research has been conducted involving genetic counselors' delivery of pharmacogenetics services. The concept of 'pharmacogenetic counseling' was discussed in 2003 during an advisory committee to the U.S. Food and Drug Administration (FDA) [202]. Specifically, the idea was raised in a discussion about the need to communicate to patients 'incidental' information that would inevitably be a part of the test result. In subsequent years, genetic counselors have continued to be named as a potential provider of [18, 19] and educator for PGx testing services [20]. In a U.S. survey of genetic counselors, 52 percent of respondents believed that genetic counseling would be necessary for PGx testing [21] . Generally, though, genetic specialists, including genetic counselors, appear to perceive a limited role for themselves in pharmacogenetics [10, 12, 13, 21]. The perception of a limited role is due in part to the belief that PGx testing does not carry the same implications for patients as traditional genetic tests and would be routinely delivered as part of general care; thus, PGx testing would not require the same type of counseling offered for other genetics tests [10, 12]. Opinions of other health professionals about the need for genetic counseling for PGx testing have been conflicting. Hoop et al.[22] reported that some early-adopter psychiatrists believed that pre- and post- test counseling for PGx testing was very important, some indicating that there is currently not enough counseling to facilitate decision-making

regarding testing [22]. Others in this same group believed that counseling is unnecessary [22]. Differences of opinion may be due to the expanding use of PGx testing over the period that these opinions were gathered, differences in health care systems, and greater understanding about PGx and counselors' possible roles [12].

One of the primary goals of genetic counseling is to empower patients through education and facilitate autonomous decision-making through pre-test counseling [23]. Promoting informed decision-making about PGx testing could be an important role for genetic counselors in some cases [12, 24]. In a German study of patient and professional attitudes about PGx testing, about 40% of patients admitted they may not completely understand the scope and consequences of PGx testing [25]; this finding supports the need for pre-test education and counseling. However, the decision-making period may necessarily be abrupt since patients will likely need to decide about testing at the time of treatment. If a patient is considering testing in a non-urgent care situation (i.e., no immediate treatment required, regular check-up), counselors could provide support and education about the risks and benefits of testing to facilitate informed decision-making.

In post-test counseling, counselors can primarily assist in communicating test results. Given the importance of a PGx test result for a patient's lifetime, it is essential that patients clearly understand the result and recognize the importance of sharing it with other treating clinicians [19, 26]. In addition, as with disease susceptibility testing, other factors may contribute to drug response and therefore, patients need to understand that the results are not absolute. Involvement of a genetic counselor would also be beneficial when discussing PGx results that yield incidental findings such as disease risks [12, 21, 27] or discussing familial implications of test results. Use of genome-wide testing technologies such as whole genome or exome sequencing will likely reveal all types of information including PGx information, and necessitate involvement of a genetic counselor [24, 28, 29].

Although many genetics professionals do not believe that PGx would warrant the same amount of counseling as other genetic tests [10, 12], genetic counselors' services in the delivery of PGx testing may more closely align with the education or teaching model of genetic counseling [23]. The teaching model describes the role of the counselor as providing information and correcting misinformation and misperceptions. This type of counseling may be described as "one size fits all" and can be beneficial when dealing with a high volume of patients across all medical specialties and even direct-to-consumer [23]. This type of service is exemplified by one U.S. laboratory's experience in the introduction of the PGx test HLA-B*5701 for the HIV drug abacavir [30]. When the test result was sent back to the ordering physician, a genetic counselor would place a follow-up call to provide a "patient-specific interpretation," considering the patient's ethnicity and discussing treatment management plans [30].

In summary, genetics professionals, including counselors, anticipate that their primary role will be to assist health professionals on the use and interpretation of PGx testing [12, 13, 30]. As a result, their primary contact will likely be with practitioners rather than the patients. This vision fits well into our proposed pharmacist-genetic counselor delivery model. To a lesser extent, limited in large part by accessibility, genetic counselor services may fit into a clinical pathway where patients are seen first by their general practitioner and then potentially referred to a counselor for post-test counseling [12]. Thus, we envision at least three primary roles of genetic counselors via a clinical pathway in the delivery of PGx testing (Table): 1) facilitate patient understanding of genetics; 2) discuss implications of testing for other family members; and 3) discuss incidental findings. Counselors could facilitate patient understanding of the genetic component of testing and results that a general practitioner may not understand or have sufficient time to address. In particular, patients

with limited health literacy may benefit from additional discussion with a counselor. It is particularly important for patients to clearly understand their PGx test results so that they will share them with different providers in the future that may be prescribing medications to avoid redundant testing and inform therapeutic decision-making without delay. Genetic counselors may also discuss the implications of PGx test results for other family members. For example, a patient found to have a variant in *CYP2D6* associated with ultra-rapid metabolizer phenotype may consider having their child tested or more closely monitored if codeine is used for pain management. A number of cases have been reported of children dying after the use of codeine [31, 32]. Additionally, counselors could discuss incidental findings when a PGx variant is also linked to the onset or risk of disease. For example, the *ApoeE* gene is associated with not only statin efficacy but also with the risk of Alzheimer disease. Likewise, if a physician inquires about the appropriateness of the *ApoE* testing for statin treatment, a genetic counselor could inform him/her of the potential risks associated with this test related to the Alzheimer disease risk and perhaps advise use of a different PGx test that does not reveal incidental disease risk (e.g., *SLCO1B1*). Discussion of such incidental findings would be a particularly important role for genetic counselors in the clinical scenario presented.

Pharmacists & Delivery of PGx Testing

Pharmacists are widely anticipated to play a role in the delivery of PGx testing [18, 33–39]. Pharmacists are trained to assure the safety of drug therapy by assessing potential adverse drug interactions when a new drug is prescribed and by providing information about appropriate substitutions for patients with drug allergies and concomitant medications that should be avoided. Pharmacists are in a unique position to play a role in the delivery of PGx testing, serving as a medical liaison between the patient and the provider. Specifically, the pharmacist can consult with providers on behalf of the patient about PGx test results and advise on drug regimens based on PGx test results and other clinical factors to improve health outcomes [40]. Since medications are prescribed by most medical specialties, pharmacists have experience in interacting with all types of health providers and settings. In the U.S., pharmacists are involved in the delivery of increasingly more services [41] and the addition of PGx testing appears to be a natural extension of pharmacy practice. Pharmacists can serve as part of the medical home team, collaborating with physicians to perform medication-related assessments, involved in test ordering, monitoring and adjusting therapies to improve overall patient care [42]. Although they cannot order testing on their own by law, pharmacists may order PGx testing under a collaborative pharmacy practice agreement [43]. On a national scale, pharmacists are involved in the delivery of PGx testing for select medications through some pharmacy benefits management programs in the U.S., notably CVS Caremark and Medco [44,203].

A few surveys have been conducted on pharmacist attitudes toward PGx testing and their potential role. McCullough et al.[45] reported that 31% of pharmacist respondents' believed they should recommend PGx testing within their clinical practice (58% neutral). More than half of respondents (53%) felt that providers should be asking pharmacists for recommendations on appropriate use of PGx testing. Seventy four percent agreed that pharmacists should make therapy recommendations based on results. Similarly, Roederer et al.[46] reported favorable attitudes of pharmacists in North Carolina (USA) toward PGx testing, as well as an interest in learning more about PGx testing.

Early visions of roles for pharmacists in PGx included three areas: 1) research and evaluation, 2) teaching, and 3) clinical integration of PGx test results [47]. Later, El-Ibiary et al.[48] suggested that pharmacists could potentially work in slightly different areas described as research, clinical valuation and/or implementation and education of PGx testing. In 2010, the National Academy of Clinical Biochemistry recommended that

pharmacists serve as an intermediary between laboratories and physicians to assist with test interpretation [49]. There are a number of services and projects exploring the anticipated role of pharmacists in the delivery of PGx testing. In 2005, St Jude's Children Hospital in Nashville, TN (USA) implemented a Clinical PGx service [50] in which clinical pharmacists review test results and provide a written consultation including recommendations for changes to therapy. The provision of PGx testing in a community pharmacy setting is also being explored as a delivery model [51, 52]. Swen et al. [53] demonstrated the feasibility of pharmacy-initiated PGx testing for primary care practice polypharmacy patients in the Netherlands. Consideration of PGx testing by the treating physician or pharmacist may be triggered by reporting of adverse drug reports, as was demonstrated in a Dutch feasibility study [54]. Additionally, we are investigating a clinical pharmacy intervention in primary care practice for the delivery of PGx testing [NCT01600846].

Test ordering and physician consultation would not be the only potential roles for pharmacists in the delivery of PGx testing. Pharmacists may also be expected to provide medication-related information to patients. In the U.S., most states require pharmacists to provide some type of "counseling" to patients dispensed prescription medications [55]. This type of pharmacist counseling corresponds to the education/teaching model of genetic counselors [23] mentioned previously, whereby pharmacists provide information in writing and/or orally about the intended use of the prescribed drug, dosage and administration schedule, common side effects, and potential drug interactions among other things.

A more intensive type of pharmacist counseling is known as medication therapy management (MTM). Typically provided to high-risk patients and independent of medication dispensing, MTM services include a comprehensive review of a patient's current and past medication history and development of a medication-related action plan [56–58]. By focusing on the patient's complete medication therapy regimen, the pharmacist can assess various factors potentially causing medication-related problems. While MTM programs have received high patient satisfaction reports [59, 60], improvement in health outcomes and cost-savings are inconsistent [61–67]. PGx test results could become a routine part of MTM services to assess risks for potential adverse effects and need for medication therapy changes based on a patient's genetic make-up [68].

The delivery of PGx testing by pharmacists could also be modeled after therapeutic drug monitoring services [69] such as anticoagulation or diabetes clinics For example, warfarin is one of the most commonly prescribed medications for prophylaxis and treatment of thromboembolic disorders and embolic complications arising from atrial fibrillation or cardiac valve replacement. In the 1980's, anticoagulation clinics were established to provide patient education, adjust warfarin dosage to maintain therapeutic benefit, and monitor patients for hemorrhagic and thromboembolic complications. As these clinics are often directed by pharmacists, a patient's *CYP2C9/VKORC1* genotype could be added to the other clinical biomarkers considered in determining the optimal initial dose.

Team-based Delivery Approach

Genetic counselors and pharmacists have marked strengths and weaknesses in providing pharmacogenetic services. Genetic counselors' can facilitate informed decision-making and patient understanding of PGx test results; however, their lack of knowledge regarding pharmacokinetics and pharmacodynamics may hinder aiding patients and clinicians to understand how to use those results [12, 37]. The probabilistic nature of PGx test results, not unlike other genetic test results, will necessitate careful communication to ensure patient comprehension [9], a skill genetic counselors are especially trained to do. In contrast, although pharmacists obviously have a much better understanding of drugs and how PGx

test results could be used to inform risk of adverse drug reactions and treatment options, their knowledge of genetics and communicating genetic results to patients is limited.

Therefore, since neither genetic counselors nor pharmacists are trained to fully provide the spectrum of services associated with the delivery of PGx testing, a partnership delivery model may provide the optimal delivery of these tests [18]. As described in more detail in each of the respective sections above and shown in the Table, genetic counselors would provide support regarding disease susceptibility, familial interpretation, and other issues specific to genetic testing, while pharmacists would provide support in test interpretation and guidance about drug dosing and selection. Both genetic counselors and pharmacists would primarily advise the general practitioner, the latter being the primary contact for patients. For example, *CYP2C9/VKORC1* testing may only involve the pharmacist, whereas the *ApoE* test would likely involve both a genetic counselors and pharmacist.

This team-based PGx consultation model could be implemented through a combination of approaches, including electronically (e.g., providing pharmacist/genetic counselor notes to physician in electronic medical record or with laboratory test results), by phone (e.g., counseling of patients and physician consultation), and/or in-person. The service could be associated with a reference testing laboratory, through a hospital's pharmacy or genetics department, through a patient-centered medical home model [70–73], or through a private contracting service.[71, 72] Organizational infrastructures would need to be established to enable implementation of new services such as pharmacogenetic testing [74].

The implementation of such a consultation service may face several barriers. Notably, the major obstacles appear to be the adequate preparation of pharmacists and genetic counselors to provide effective pharmacogenetic testing services, availability of a workforce to do so, patient and physician preferences, test readiness, and reimbursement issues.

Barrier #1: Preparing Counselors & Pharmacists to Deliver PGx Testing Services—Reported pharmacist knowledge of PGx testing varies from good to poor, often associated with year of graduation and degree (PharmD vs. BSc)[45, 46, 48, 75]. For example, Kadafour et al. [75] reported that more than 40% of respondents to a survey of anticoagulation providers in the U.S. were uncertain about the clinical utility of PGx testing for warfarin use. Thus, before pharmacists can advise either patients or health professionals about the use of pharmacogenetic testing, they will need to be knowledgeable about genetics and pharmacogenetics [76, 77]. Recently, an evaluation of outpatient pharmacists' knowledge of pharmacogenomics after a continuing education program showed that while knowledge scores increased slightly, there is still a need for greater educational efforts [78].

In recent years, changes to pharmacy curricula have been recommended and/or implemented to prepare pharmacists to appropriately use laboratory diagnostics [46, 79–82]. Licensed or registered pharmacists in the U.S. and U.K. require advanced specialty training (PharmD and MPharm, respectively). In the U.S., prior to 2000, individuals with a Bachelor's degree from an accredited school of pharmacy could also obtain a pharmacist licensee. In the U.S., several groups have recommended inclusion of PGx educational requirements as a component of pharmacy curriculum including the Accreditation Council for Pharmacy Education [204], the American Society of Health-System Pharmacists [205], the American College of Clinical Pharmacy [83], and the American Association of Colleges of Pharmacy [84]. In the UK, the Royal Pharmaceutical Society has recognized the importance of promoting pharmacist knowledge of genetics and pharmacogenetics to adequately prepare them to provide PGx testing [74]. Pharmacy educators appear to have heeded calls for increased PGx education, and the profession is leading medical education in this area [37]. In 2010, 92% of pharmacy schools and 89% clinical degree or doctor of pharmacy programs

incorporated PGx education compared to 39% of schools surveyed in 2005 [85, 86]. In addition, the availability of continuing education programs on pharmacogenetics will help update practicing pharmacists about these new tools [47].

Completion of Masters-level specialty training programs is required in the U.S. and U.K. to be eligible for genetic counselor licensure or registration, respectively. In contrast to pharmacists, professional organizations of medical geneticists and genetic counselors have not formally recommended changes to the educational curricula specific to pharmacogenetics nor recognized the role of genetic specialists in the delivery of PGx testing. This may be due to the fact that 'new' educational material is not warranted for genetic specialists to appropriately deliver PGx testing (i.e., current training deemed sufficient to provide PGx testing services). Haga et al.[21] reported that 90 percent of genetic counselors had had some education relating to pharmacogenetics, though more than half indicated that they learned about pharmacogenetics outside of their training programs (literature, seminars, professional meetings, or testing laboratory representatives). Overall, promoting patient understanding about the meaning and significance of the test result for patients and their family members are within the current realm of standard genetic counseling practice; counselors would only need additional education about the genetics of drug response in order to provide counseling specific for PGx testing.

Cross-training of genetic counselors and pharmacists would help develop better understanding of the fundamental concepts in each respective field. In the U.S., of 120 schools of pharmacy, 13 have a genetic counseling program at the same institution, permitting convenient access and exchange of information. Additionally, many genetic counseling programs have established relationships with other institutions to enable students to complete clinical rotations required of the program. Thus, it may be feasible to coordinate genetic counselor training with pharmacy programs at other institutions. In addition to didactic learning, interactive group analysis and co-clinical training would enable each group to develop greater appreciation for the respective expertise and how the professions could work together to provide comprehensive care regarding PGx testing. It may even be possible to develop a dual-training program for individuals interested in becoming board-certified as a genetic counselor and pharmacist.

A sound understanding of the evidence for clinical validity and utility will be needed for accurate interpretation and application of PGx test results. We anticipate that the pharmacist or genetic counselor will interact with the medical director of the testing laboratory to gather information about the test characteristics such as sensitivity, specificity and predictive value. For example, many PGx studies have been performed on populations of European descent, and test characteristics may be less certain for other populations. While counselors or pharmacists should possess a good understanding of issues that could affect test interpretation, we would not expect them to possess the knowledge and skills to review original literature to make these assessments on their own.

Barrier #2: Limited Genetic Counselor Workforce—The number of genetic tests has prodigiously increased due to the rapid identification of disease genes through genome-wide association studies and whole genome sequencing, as well as PGx tests, companion diagnostics and tests for disease prognosis or recurrence. As a result, the demand for genetics services may soon exceed the ability of the limited number of practicing genetics specialists to supply those services. Therefore, it may not be possible for all patients that undergo PGx testing to be seen by genetics professionals [19, 87, 88] and genetic counselors themselves have recognized that they may not be able to meet the anticipated increase for services required if PGx testing becomes widely adopted [12]. In the U.S., there are more than 3,000 board-certified genetic counselors [206]. In contrast, there are almost 275,000

practicing pharmacists in the U.S. [207]. In addition, genetic counselors typically specialize in prenatal, pediatric, or cancer care, while a substantially smaller number specialize in areas such as genomic medicine, personal genomics, and pharmacogenetics [208]. The current practice settings for genetic counselors may pose a barrier to their broader involvement in the delivery of PGx testing.

To address potential challenges due to workforce shortages, changes to curricula of training programs to reflect use of new tests for different purposes and by different clinical specialties may expand the diversity of practice settings (such as general care) for genetic counselors. In the interim, the development and implementation of a method of triage to ensure that patients in greatest need for genetic services, such as those manifesting symptoms of anxiety, are scheduled to be seen immediately [12]. Alternatively, given that counseling for PGx testing is anticipated to adopt the teaching model and the non-directive counseling approach will not typically be necessary, other health professions such as genetic nurses could assist in providing information to inform decision-making and help patients understand test results[89–91], thereby limiting the time required of genetic counselors to interact directly with patients. Given the development of new modes of healthcare delivery (e.g., phone, Internet), the absence of an onsite counselor may no longer be considered a limitation to access.

Barrier #3: Patient & Professional Preferences—Overall, surveys of patients and the general public in the U.S. and abroad have shown strong support for PGx testing [25, 92, 93] . However, patients' preferences about which health professional should be involved in the delivery of these tests is varied. Patients have expressed a preference in receiving PGx testing services from a trusted and familiar provider [10]. Although pharmacists are among the top-rated health professionals with respect to honesty and ethical standards [209], data on patient attitudes are conflicting regarding their comfort in receiving PGx information or testing from pharmacists. An Australian qualitative study reported that physicians and pharmacists were likely to be the primary sources of information for patients about pharmacogenetic testing [94]. However, in 2005, a series of workshops in the UK reported that participants were against the delivery of PGx tests by pharmacists due to their perceived inability to provide expert guidance regarding the use of such tests [95]. Similarly, a more recent British survey reported that patients as well as health professionals did not want a pharmacist to explain a PGx test result [9]. In a survey of a sample of the U.S. general public, Haga et al.[96] reported that 74 percent of respondents were comfortable sharing results with their pharmacist, though this was a significantly smaller proportion compared to those comfortable with sharing test results among physicians involved in their care. A survey of primary care physicians reported little recognition of a role for pharmacists in the delivery of PGx testing [8]. Attitudes about pharmacist counseling are reported to be variable, due in part to the uncertain role of pharmacists and customer expectations [97]. Additionally, it is difficult to generalize patient and practitioner perspectives based on current literature as data are derived from various countries, which have different training and practice for pharmacists.

To our knowledge, little data are available about public preferences for a genetic specialist to be involved in the delivery of PGx services. Rogausch et al.[25] reported that eight percent of asthma patients would want a genetic specialist to communicate PGx test results to them (compared to 80 percent who would want their general practitioner to report the results). A survey of a sample of U.S. primary care physicians found that 14 percent believed that genetic specialists should have primary responsibility for communicating test results to patients [8].

Barrier #4: Test Readiness—Ikediobi et al. [98] identified three major challenges to the translation of PGx testing: incomplete knowledge of the impact of PGx variants, the availability of alternative biomarkers or methods of monitoring toxicity, and the lack of an infrastructure to interpret, communicate, and apply PGx test results in therapeutic decision-making. Although a number of PGx tests are clinically available, there is substantial debate about the clinical utility of these tests [99–101], including the ApoE test for statins [102]. Some of the underlying genetic associations demonstrating clinical validity may be confounded due to lack of standardization of phenotypes [103–105]. The unclear clinical use of some tests may present liability issues for current and future clinical treatment [106–108].

This uncertainty presents an additional challenge for pharmacists and genetic counselors to first understand the benefits and limitations, and clinical evidence of these tests and conveying this information to health providers and/or patients. The same test may have different levels of acceptance and perceived benefit depending on the drug it may be ordered for as exemplified by the varying uses of TPMT testing for leukemia treatment by oncologists or treatment of inflammatory bowel disease by gastroenterologists [109] Given this dynamic field, professional consultation is even more critical to insure understanding of the test.

A related issue regarding test readiness is the best time to test a patient [19]. Typically, a clinician would order a PGx test as medically needed, when a patient required treatment. However, waiting for the test result would delay treatment, requiring the clinician to weigh the benefits and risks of treatment without the test results. To avoid this problem, some have advocated for ‘preemptive’ testing where PGx testing would be performed in advance of treatment [5, 6]. Some are advocating use of whole genome analysis (including PGx variants) to enable a completely personalized approach to healthcare over the course of an individual’s lifetime [110]. With this model, review of PGx results may not be conducted until it is known which drug the patient needs. At that time, a pharmacist or genetic counselor could be consulted.

Barrier #5: Reimbursement—Another major barrier in implementing the pharmacist/counseling PGx service is the issue of reimbursement. In the U.S., the majority of genetic counselors are not typically reimbursed for services provided because they are not licensed and therefore, must practice alongside a physician. However, new billing procedures now enable counselors to bill for their services; preliminary evidence suggest that this change has increased access to genetic services [111, 112]. Many genetic counselors believe that licensure would provide the recognition and allow counselors to provide services independently [113]. As licensure must be provided by the state of practice, legislation is being considered in some states to grant counselors licensure. Pharmacist-provided therapeutic drug monitoring services at anticoagulation clinics are reimbursable. It is uncertain whether pharmacists are currently being reimbursed for PGx testing and evaluation services if provided, however MTM services are reimbursable through most insurances and thus, counseling for PGx testing may be provided as part of this service.

Compounding the problem of reimbursement for clinical PGx consultations is the issue of reimbursement for the actual test [114]. Current coverage determination policies for PGx tests vary widely in the U.S. and Europe [115, 116, 210]. Payers consider a range of factors to determine whether or not to reimburse for a specific test including data comparing the new PGx tests to standard of care, predictive value and cost offsets [117, 118]. Coverage decisions will continue to change as new data become available, public awareness increases and testing costs decrease.

Conclusion

Professional and public acceptance of PGx testing will depend in great part on 1) the availability of strong evidence to support the use of PGx testing and 2) and the delivery of testing by trusted and respected experts. A partnership between genetic counselors and pharmacists will enable provision of comprehensive services for both patients and clinicians, providing education about the appropriate use (or not) of testing based on current evidence. Given their current dual role, pharmacists can pave the way toward greater acceptance on the part of both patients and physicians [36]. Likewise, genetic counselors can promote effective communication strategies and ensure understanding of test results, critical for ensuring the long-term utility of PGx testing over the patient's lifetime. Due to some of the barriers described above, we anticipate the involvement of the proposed pharmacist/genetic counselor model to be initially limited until the evidence for PGx testing is more robust to support widespread use and greater professional awareness is attained.

Acknowledgments

This work was supported by funding from the U.S. National Institutes of Health 5R01-GM081416-05. We thank Dr. Jivan Moaddeb, PharmD for discussions and contributions to an earlier draft of the manuscript.

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Executive Summary

- The clinical delivery model of pharmacogenetic (PGx) testing is unclear at this time as well as the evidence to support use of some PGx tests.
- The appropriate use of PGx testing may require multiple steps including pre-test counseling, consideration of the appropriateness of testing, alternative drug and pharmacovigilance options, turnaround time, patient interest and post-test counseling.
- We propose that a partnership between genetic counselors and pharmacists to assist clinicians in the delivery of comprehensive PGx services. The complementary knowledge and skill set supports the partnership between genetic counselors and pharmacists to provide comprehensive PGx testing services.

Table 1

	Genetic Counselors	Pharmacists
Skills		
Patient education	✓	✓
Provider education	✓	✓
Promoting informed decision-making	✓	
Extensive knowledge of genetics	✓	
Extensive knowledge of pharmaceuticals		✓
Communicating genetic testing results	✓	
Roles		
Communicate incidental information revealed by PGx.result	✓	
Discuss familial implications of PGx results	✓	
Facilitate decision-making (pre-testing counseling)	✓	✓
Communicate test results to patient	✓	✓
Assist providers with interpreting PGx results	✓	✓
Provide therapeutic recommendations to providers		✓
Provide therapeutic recommendations to patients/conduct therapeutic drug monitoring or MTM		✓
Advise on appropriateness of testing	✓	✓
Test ordering/recommendation		✓