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Forum

Community pharmacists and their role in pharmacogenomics testing: an Australian perspective drawing on international evidence

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Abstract. Patients obtaining a prescription from a pharmacy expect that the drug will be effective and have minimal side-effects. Unfortunately, drugs exhibit the desired effect in ~25–60% of people prescribed any medication. Adverse effects occur at a rate of 10% in patients taking a medication, and this rate increases during and after hospitalisation, with the transition of care back to the ambulatory setting posing a particular risk. Pharmacogenomics testing has been shown to optimise pharmacotherapy by increasing medication effectiveness and reducing drug-related toxicity, thus curtailing overall healthcare costs. Evidence from international studies have shown that community pharmacists would be able to offer this highly relevant professional service to their clients, given suitable training. This specific training complements pharmacists' existing skills and expertise by educating them in an emerging scientific area of pharmacogenomics. However, in an increasingly tight financial climate, the provision of pharmacogenomics testing by Australian community pharmacists will only be viable with an appropriate reimbursement through the Medicare Benefits Schedule, currently accessible by other allied health practitioners but not by pharmacists.

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Introduction

Pharmacogenomics (PGx) testing, the analysis of a patient's genetic makeup related to the transport, metabolism and targets of drugs, is one of the most important avenues to personalising a patient's treatment. The ultimate goal of implementing PGx testing in patient care is using the patient's genetic makeup to identify the right drug and dose, with the aim of enhancing treatment response, reducing drug-related toxicity and thereby reducing healthcare costs (Relling and Evans 2015). In Australia, this goal aligns with Domain 3 (Medicines and management and patient care) of the National Competency Standards Framework for Pharmacists in Australia (Pharmaceutical Society of Australia 2016), which stipulates the scope of practice of a pharmacist which includes any role that has an effect on the safe, effective delivery of services in the profession and use of their professional skills.

Implementation of PGx testing in community pharmacies: learning from international evidence

Internationally, large academic institutions and their associated hospitals have been spearheading the implementation of PGx testing, with clinical pharmacists leading large multidisciplinary teams. van der Wouden *et al*. (2017) have given a comprehensive description of international initiatives. However, this methodology cannot be directly translated to the Australian context as patients with chronic conditions are mainly managed within the community setting.

Community pharmacists have been shown to be able to integrate genotype-guided therapy into their routine practice in US pilot studies. Several studies (Table 1) have demonstrated recruitment of patients for PGx studies from community pharmacies, further supporting a role for community pharmacists in PGx testing (van Wieren-de Wijer *et al*. 2009; Swen *et al*. 2012; Ferreri *et al*. 2014; Kisor *et al*. 2014; Moaddeb *et al*. 2015).

In one community pharmacy-based feasibility study for clopidogrel and simvastatin, the authors reported that 81% of patients agreed to undergo genetic testing when recommended. Importantly, participating pharmacists reported that pre- and post-test discussions took up to 5 min 81% and 100% of the time respectively. Overall, in this study, pharmacists spent 3–15 min introducing and obtaining patient consent for testing, reviewing test results and communicating results to patients (Moaddeb *et al*. 2015). This time was comparable to the time spent by GPs who order clinical tests for patients (including discussions of clinical tests), which averages ~19.3 min (National Center for Health Statistics 2010).

Hence, internationally, PGx testing is slowly evolving as a specialised role for clinical pharmacists to guide drug selection based on genetic findings (Crews *et al*. 2011;

What is known about the topic?

- International evidence shows that pharmacists can play an integral role in implementing pharmacogenomics testing to provide personalised treatement and reduce healthcare costs within a multidisciplinary team.

What does this paper add?

- Community pharmacists are well-placed within the Australian healthcare setting to provide pharmacogenomics testing, which could be reimbursed by the Medicare Benefits Schedule, as highlighted to Government by professional leaders.

Owusu-Obeng *et al*. 2014). However, in Australia, community pharmacists are yet to be involved in PGx testing.

Why community pharmacists?

There is an increasing awareness of the importance of pharmacists in delivering PGx testing. It has been noted by a prescriber editorialist that 'pharmacogenomics may reside more comfortably in the purview of pharmacists rather than prescribers, at least as far as programmatic development and leadership are concerned' (Williams 2014). There are several reasons why community pharmacists are best placed. Their knowledge of drug properties, pharmacokinetics and drug–drug interactions, as well as their skill with patient counselling would enable them to incorporate pharmacogenomics data to check for drug–gene interactions in the same way as for drug–drug interactions or drug–allergy interactions (Padgett *et al*. 2011; American Society of Health-System Pharmacists 2015).

The analogy that we can draw upon is the classic case of a patient stabilised on carbamazepine being prescribed clarithromycin. Community pharmacists are expected to take appropriate action to prevent this drug–drug interaction, thus avoiding harm for this patient. Clarithromycin may cause decreased metabolism of carbamazepine as a result of cytochrome P450 interactions, leading to potential toxicities due to carbamazepine accumulation. Using appropriate therapeutic knowledge and patient-specific details, the pharmacist suggests available options to the patient's prescriber, takes the order, executes the prescription-filling process, educates the patient on his or her new therapy and follows up with the patient as appropriate.

This analogy describes how well PGx testing implemented by community pharmacists aligns with medication review. Appropriately accredited pharmacists are already providing recommendations to prescribers on tailoring of therapy for individual clients. McCullough *et al.* (2011) showed that pharmacists are aware of a range of potential roles with respect to use, delivery and application of PGx testing: recommend and provide PGx testing in their practice; provide clinical recommendations about appropriate use of PGx testing; and make therapy recommendations based on PGx test results.

In addition, with patients consulting multiple (specialist) prescribers for various health conditions, we can justifiably attest that the unifying point of a patient's drug therapy is the community pharmacist. Within the Australian healthcare sector, community pharmacists are considered the most easily accessible (and only freely available) healthcare provider. This centralising aspect of the community pharmacy for medication information (medication education, selecting and monitoring drug therapy for patients and ensuring safe and appropriate use of therapies), makes community pharmacists the most logical who and where for the incorporation of PGx in clinical practice.

Benefits to the Australian healthcare system

In recent years, several reviews (Berm *et al.* 2016; Plöthner *et al.* 2016; Plumpton *et al.* 2016; Verbelen *et al.* 2017) have investigated the cost-effectiveness of PGx testing. The majority of studies conducted to date have been performed in either the US or Europe. Due to fundamental differences in healthcare funding models between these jurisdictions and Australia, it is difficult to extrapolate international data to the Australian healthcare system.

To date, there has only been one Australian study investigating cost-effectiveness of PGx testing (Sorich *et al.* 2013). In this study, the authors analysed the effect of genotype-guided prescribing of clopidogrel due to the loss-of-function allele of *CYP2C19* versus universal clopidogrel or universal ticagrelor treatment. The authors concluded that *CYP2C19* genotyping resulted in greater efficacy and was cost-effective when compared with the universal use of clopidogrel; findings that were validated by recent studies (Borse *et al.* 2017; Jiang and You 2017).

In 2008, a comprehensive pharmacoeconomics analysis was carried out by Deloitte Economics Australia for the Australian Centre for Health Research (Australian Centre for Health Research 2008). In this report, they reviewed the cost-effectiveness of PGx testing in different areas of medicine (oncology, inflammatory bowel disease and depression) and drug classes (statins, tamoxifen and warfarin). The report suggested that PGx testing would deliver a net economic benefit of A$12 billion over 5 years (2008–12) to the health system if PGx testing was to be widely adopted in Australia (Australian Centre for Health Research 2008).

Since 2007, an increasing number of PGx tests have been funded by the Commonwealth Government. In 2007, only a single PGx test was funded, but the number has increased to 11 PGx tests in 2018. Currently, two PGx tests are covered by Medicare and their use is aimed at preventing adverse effects; abacavir (HLA-B*5701) and thiopurine drugs (TPMT gene testing). However, the majority of PGx tests are offered in oncology for specific genotype-guided prescribing for efficacy: epidermal growth factor receptor mutations (gefitinib or erlotinib), rat sarcoma oncogene mutations (cetuximab or panitumumab), human epidermal growth factor receptor 2 mutations (trastuzumab), BRAF V600 mutations (dabrafenib or vemurafenib), BRCA1 or 2 mutations (olaparib), 17p chromosomal deletions (idelalisib or ibrutinib) and anaplastic lymphoma kinase mutations (crizotonib or ceritinib) (Fig. 1).

According to Deloitte Economics Australia, 2008 report, cost savings to the Australian healthcare system from implementation of PGx testing would arise from the reduction of adverse

Table 1. Pilot studies of pharmacogenomics (PGx) testing conducted in community pharmacies over the recent years

Study	PGx	Number of patients tested	Method of patient recruitment	Purpose of PGx
van Wieren-de Wijer *et al*. (2009)	a-adducin, angiotensin-converting enzyme, angiotensinogen, angiotensin II type 1 receptor, endothelial nitric oxide synthase, G-protein-b	4583 (including 631 patients and 3952 controls)	Patients that were identified via a database were contacted via mail	To assess whether genetic polymorphisms modify the effect of antihypertensive drugs including thiazide diuretics, on the risk of myocardial infarction
Swen *et al*. (2012)	CYP2D6	45	Contacted via mail	To determine the appropriateness of codeine and tramadol for pain relief and metoprolol for heart failure treatment
	CYP2C19			To determine the appropriateness of proton pump inhibitors and clopidogrel
Ferreri *et al*. (2014)	CYP2C19	18	Contacted via telephone	To determine the appropriateness of clopidogrel and other antiplatelet therapies
Kisor *et al*. (2014)	CYP2C19	1	In person	To determine the appropriateness of clopidogrel and other antiplatelet therapies
Moaddeb *et al*. (2015)	CYP2C19	37	Contacted via telephone and in person	To determine the appropriateness of clopidogrel and other antiplatelet therapies
	SLCO1B1	19		To determine the appropriateness and dosage of simvastatin

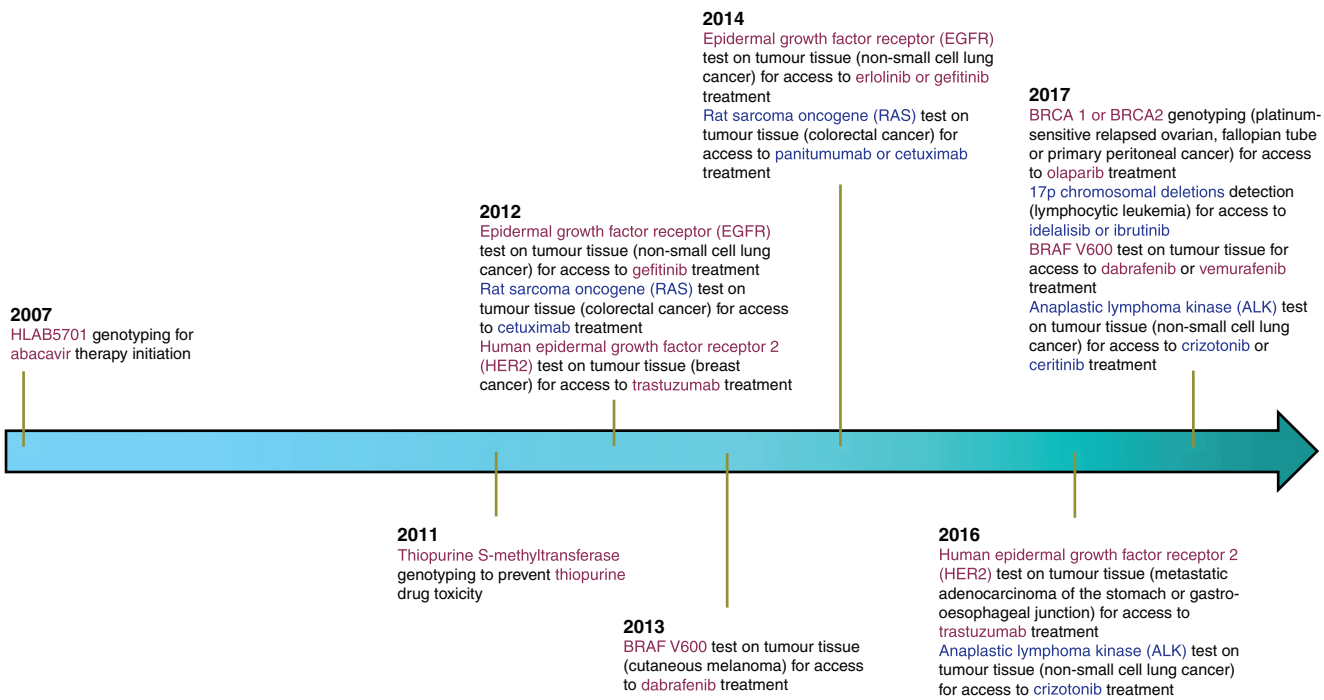

Fig. 1. Timeline of pharmacogenomics (PGx) tests funded by the Commonwealth Government from 2007 until 2017 (Australian Centre for Health Research 2008).

drug reactions (ADRs), reduction in medicine wastage and improvements in quality and effectiveness of care (Australian Centre for Health Research 2008).

Avoided adverse drug reactions

It was estimated in this report that ADRs in 2003–04 were costing on average A$14 027 per hospital admission. The authors then indexed this cost by three per cent to 2018 and estimated that if these ADRs (between 38 000 and 76 000) could all be avoided using PGx technologies, the potential benefits from the avoided costs of ADRs would be between A$1.0 billion and A$1.6 billion in 2018.

Avoided wastage

Pharmocogenomics-guided therapy can aid doctors in avoiding current 'trial and error' methods of prescribing. The authors reported that in 2006–07, 168.5 million Pharmaceutical Benefits Schedule scripts were filled at an average price of A$32 to the government and A$6.50 to the patient. If ~20 per cent of all scripts are new scripts, and between 5 and 10 per cent of half of all dispensed scripts will be either unsafe or ineffective, the potential benefits of avoided wastage would be between A$53 million and A$105 million (one per cent of total PBS spending) by 2018. Over a 5-year period, this could add a further A$360 million to A$720 million in additional benefits, bringing the total net potential benefit to Australia from reduced healthcare costs (avoided adverse events and avoided wasted medicine expenditure) to between A$2.5 billion and A$6.2 billion.

Improvements in quality and effectiveness of care

In addition, PGx testing would enhance the effectiveness of prescribing and the quality of care, by enabling doctors to target the right dose for a patient. In addition to cost savings from avoided ADRs and avoided wastage (as described above), Australian quality of life would improve, leading to lower utilisation of healthcare resources.

Additionally, unlike current disease management and monitoring services provided by community pharmacists, PGx testing needs to be performed only once. Hence, it is comparatively cheaper than other re-occurring monitoring costs such as regular blood glucose and blood pressure monitoring. Once the patient's unique global metabolism phenotypes have been established, it is simply a matter of the pharmacist integrating this information into the mandatory medication checking process, whenever the client comes to the pharmacy with a prescription for a new drug.

Potential barriers

One of the major barriers to the routine use of PGx testing is health practitioners' lack of expertise, familiarity with testing and integrating the information to inform clinical practice (Bartlett *et al*. 2012; Lesko and Johnson 2012; Lunshof and Gurwitz 2012; Haga *et al.* 2015). It is vital that prescribers ordering point-of-care testing should have some level of expertise and familiarity with PGx testing. However, relatively low reported use of PGx testing might relate to the relatively small proportion of prescribers having the level of expertise to order and interpret PGx test results (Haga *et al*. 2012; Stanek *et al*. 2012; Amara *et al.* 2018). A recently revised RACGP guideline on genomics in general practice (Royal Australian College of General Practitioners 2018) is puzzling, as the Commonwealth Government currently funds a total of 11 PGx tests both for avoiding adverse effects and ensuring efficacy (Fig. 1).

Pharmacists in the McCullough *et al.* (2011) study acknowledged their limited knowledge of PGx and need for further training to increase their confidence in PGx testing (Tuteja *et al*. 2013; Alexander *et al*. 2014). This sentiment was also mirrored in a study conducted in 2011 on a cohort of Victorian pharmacists (McMahon and Tucci 2011).

We previously surveyed Australian Pharmacy schools to assess the extent of PGx teaching within the pharmacy curriculum and to probe the attitudes of lecturers towards PGx research and teaching (Suppiah *et al.* 2015). Of the 12 schools (71%) that responded, eight said that PGx teaching was delivered in therapeutics and pharmacology courses. When questioned about specific drugs that require PGx-guided prescribing, the results varied widely depending on specific drugs (0% for capecitabine to 75% for codeine). Even though all respondents indicated that teaching PGx is important to future pharmacists, only half currently teach about specific drugs that require PGx testing for PBS access in Australia. This gap in PGx teaching needs to be addressed so that future pharmacists are confident and competent in dealing with PGx issues. One such strategy would be for pharmacy academics researching in PGx to form a Pharmacy PGx Teaching Initiative to develop a national PGx curriculum which can oversee a post graduate training in PGx for practicing pharmacists.

This group could also spearhead national PGx projects, such as the Europe-wide 'Implementing Pharmacogenomics in Europe' project (van der Wouden *et al.* 2017). These specifically designed projects should be able to inform prescribing guidelines to include drugs commonly dispensed by community pharmacists. This in turn, could lead to the expansion of the scope of practice for community pharmacists. It is indisputable that there is no other health professional more appropriate than a pharmacist to perform this service, given their broad scientific training, their existing professional expertise and appropriate accreditation training.

Also, the rapidly evolving nature of pharmacogenomics tests, technology and guidelines, increases the complexity of their implementation (Farrugia and Weinshilboum 2013; Weitzel *et al*. 2014). Recommending the 'right' drug for a patient is not as clear cut as other pathology findings such as HbA1c and anti-diabetic treatment, or blood pressure and anti-hypertensive treatment. The patient's phenotype needs to be integrated with the patient's medication history and then clinical recommendations can be made. In a recent multidisciplinary PGx study, authors reported that 'without the help of a pharmacist, the ordering prescriber was unable to link the laboratory result to its clinical implications for pain management' (Dunnenberger *et al*. 2016). Therefore, relying on prescribers to integrate this increasingly complex knowledge into already busy clinical workflows has been viewed as neither sustainable nor practical (Caraballo *et al*. 2017) within the current healthcare setting.

Hence, integration of PGx testing into clinical practice will require careful consideration of effects on prescriber practices (particularly with respect to any additional time needed to consent and communicate results to patients, which may ultimately serve as a barrier to uptake of PGx testing). It also depends on the effect of test results on patient behaviours, such as medication adherence, which are well within established roles of a community pharmacist.

Implementation of PGx in community pharmacies: proposed model

The implementation of PGx testing in the Australian community pharmacy can be carried out as a 'PGx clinic' in a small number of pharmacies. This PGx consult would be conducted in the same manner as current services including blood pressure monitoring, vaccinations (Hattingh *et al*. 2016), and clinical testing and screening (Jokanovic *et al*. 2017). This 'PGx clinic' could educate patients about PGx testing, review patients' PGx profiles, highlight results relevant to currently prescribed medications, and recommend dosing or drug changes as indicated by test results. The former are roles that community pharmacists are already providing, and incorporating PGx testing within their practice should be seen as new, innovative and an extension to the role of community pharmacists within the primary healthcare team. Evidence from studies exploring the role of Australian pharmacists in disease management have shown that current services provided by pharmacists improve patients' self-management, treatment adherence, clinical outcomes (Krass *et al*. 2011) and appropriateness of prescribing (Castelino *et al*. 2009).

The proposed model of such a clinical service provided by credentialed community pharmacists would be a four-staged process:

1. Identification of clients on drugs with known PGx recommendations and an initial communication with prescriber(s).
2. Offer PGx testing: the community pharmacist should first explain to the patient the role of genetic variants and why current therapy may not be optimal. The community pharmacist will then introduce the PGx test that is available to determine the global metabolic phenotype that can guide personalised treatment for the patient. A saliva sample will then be collected once the patient agrees to be tested, which is then sent to the testing laboratory.
3. Optimisation of treatment based on PGx result: the result of the PGx test will be returned to the community pharmacist who is equipped to convert genotype data into metabolising phenotype. This should enable the pharmacist to integrate the patient's phenotype with appropriate therapeutic knowledge and patient-specific details to formulate individualised options for that particular patient.
4. Prescriber contact: the pharmacist contacts the patient's prescriber(s) with the recommendations and collaboratively, they decide on the safest and best therapy for the patient to avoid the drug–gene interaction. Next, the pharmacist takes the order, executes the prescription-filling process, educates the patient on his or her therapy and follows up with the patient as appropriate.

Unlike seeing different speciality prescribers for various conditions and disorders (whereby PGx test results recorded at one practice setting may not be available to a specialist in another practice setting), patients generally tend to use a single community pharmacy. If the community pharmacist provides the PGx testing service, a patient's PGx profile is available in their records and the pharmacist would be able to screen for potential interactions and communicate with prescribers about adjusting medication regimens for future prescriptions. This could potentially enhance consumer loyalty to community pharmacies offering PGx testing as an additional clinical service.

Ultimately, successful implementation will depend on a sustainable funding model. As highlighted recently (Paola 2018), the historic situation of pharmacists providing services without remuneration still continues. Although some pharmacists do charge clients directly for at least some professional services, a recent poll by the *Australian Journal of Pharmacy* indicated that 60% of respondents provide significant services without payment (Paola 2018). In an increasingly tight financial climate, this is no longer viable. With the inherent costs attached to pharmacogenomics testing, free advice is not even an option.

In its submission to the Australian Government's Interim King Report on the Review of Pharmacy Remuneration and Regulation, the Pharmaceutical Society of Australia (PSA) argued that pharmacists should be able to be reimbursed through the Medicare Benefits Schedule (MBS) for the same services offered by other health professionals (Pharmaceutical Society of Australia 2017). The MBS could well provide the funding platform for pharmacist provision of pharmacogenomics testing services; for example, under the Chronic Disease Management (CDM) Service. While this valuable service is clearly important for clients with multimorbidity and taking multiple medications, the PSA response reported its current limited use.

Conclusion

Pharmacogenomics implementation can address issues around polypharmacy, rationalisation of prescribing and quality use of medicine, and can serve as a trigger for improved and personalised medication management services for all community-dwelling clients. Pharmacists are uniquely placed within the continuum of care of patients as they are the only health practitioners with an 'applied science' foundation underpinning their professional education. Hence, their scope of professional practice has the foundation of knowledge of pharmacology, pharmacotherapeutics and formulation science, built on a scaffolding of physiology, chemistry and statistics. In addition, they are educated in the public health dimensions of health and health policy. PGx testing in community pharmacies will build on pharmacists' existing skills and expertise by educating them in this emerging area of rational use of medicines, which will enable them to offer a highly relevant, new professional service to their clients. In Australia, inclusion of pharmacist professional services within the MBS would provide the funding framework.

Conflicts of interest

The authors declare that they have no conflicts of interest.

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