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Proposal for a pharmacogenetics certificate program for pharmacists

“Pharmacist certification in PGx could ensure the appropriate and safe use of PGx testing and optimize the lifetime benefits to patients.”

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The delivery of pharmacogenetic (PGx) testing has expanded outside of the traditional clinical setting to include community pharmacies. While pharmacists have been involved as a liaison between the clinical testing laboratory and ordering clinician, assisting with interpretation or application of results [1–3], the delivery of clinical testing by a community pharmacist marks another step in the expansion of roles and pharmacy services. Many community pharmacies currently offer tuberculosis testing, blood pressure monitoring, and now some have begun to offer PGx testing. Despite their interest in PGx testing, pharmacists have recognized their limited training and lack of knowledge and skills regarding PGx [4–7]. For several years, professional pharmacy organizations have called for enhanced training and curricula in PGx to prepare pharmacists to use and apply PGx testing [8–13]. Some state pharmacy boards require certification or specialized training to perform certain services, but do not yet require it for PGx testing. In this article, we propose the development of a certification program that pharmacists would be required to complete before offering PGx testing. Pharmacist certification in PGx could ensure the appropriate and safe use of PGx testing and optimize the lifetime benefits to patients.

In the USA, training requirements to provide specific pharmacy services are determined and approved by state pharmacy boards. For example, provision of immuni-

zation services requires completion of the pharmacy-based immunization delivery certificate training program, which provides pharmacists the knowledge to administer and implement immunization services [14]. For other services, additional training is recommended; completion of the Medication Therapy Management (MTM) Certificate Training Program is recommended for pharmacists wishing to provide MTM services. This training program provides skills-based training on how to interview a patient, identifying and prioritizing medication-related programs, developing interventions and documenting activities. States may opt to develop their own training programs or approve completion of training programs offered by national pharmacy groups or private vendors to meet the state requirements. For example, New Mexico pharmacists interested in offering tuberculosis testing must complete a training program offered by the state health department [15]. The American Pharmacist Association (APhA), one of the oldest pharmacy associations, has developed certificate or training programs to ensure pharmacists are qualified to perform certain services for immunization delivery, diabetes care, MTM and cardiovascular disease risk management [16].

A recent search (14 October 2015) of the three types of continuing education programs (knowledge, application, practice) approved by the US Accreditation Council for Pharmacy Education (ACPE [17])



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identified 35 home-study or live-study knowledge or application programs in pharmacogenetics offered in the calendar year 2015. However, no educational programs (either home study or live) were available on the practice of pharmacogenetics (or implementation of these tests in practice). Most of the programs were offered by professional organizations, with others offered by academia or commercial groups.

“...the proposed curricula for PGx training for pharmacists should include a combination of knowledge and skills that address the anticipated roles and informational needs.”

Pharmacists perceive a range of roles with respect to the use, delivery and/or application of PGx testing: recommend/provide PGx testing in their practice; provide clinical recommendations about the appropriate use of PGx testing; and make therapy recommendations based on PGx test results [4]. Although they have acknowledged their limited knowledge of this field [6,18] and need for further training to increase their confidence in providing PGx testing [7,19,20], there are few data that specify the content of PGx education for pharmacists. Romagnoli *et al.* [21] categorized 36 informational needs into four broad categories based on pharmacist interviews: background; specific medication and drug–gene details; patient-specific clinical information; and PGx guidance-related information.

Like other required certificate programs, the proposed curricula for PGx training for pharmacists should include a combination of knowledge and skills that address the anticipated roles and informational needs. For example, immunization training programs provide information about administration, dosing and schedules, as well as require demonstration of proper sterile technique in the preparation and administration of injectable and intranasal immunizations. Similar to other pharmacy certificate programs, a certificate in PGx would include two sections described in further detail below: an independent self-study and a live study. **Box 1** outlines the educational objectives for each section, which include all of the competencies for pharmacists defined by the US Genetics/Genomics Competency Center (G2C2), an initiative funded by the US NIH [22], as well as additional skills identified by the UK National Genetics Education and Development Centre in collaboration with the Royal Pharmaceutical Society of Great Britain, and based on our own experiences from our prior studies [23]. We confirmed that the proposed educational objectives are responsive to the anticipated perceived roles of pharmacists. Given the range of professional or private groups that currently develop and offer continuing education programs in pharmacogenetics for pharmacists, we anticipate that

many different groups could develop and offer the proposed certification program. However, the certificate developer is encouraged to partner with PGx experts as instructors or consultants to insure that the content is accurate and current, and to provide credibility to the new program.

Self-study

Based on the G2C2 competencies, the proposed self-study could be divided into mini-modules per each of the four main content sections: basic genetic concepts; genetics and disease; pharmacogenetics and pharmacogenomics; and ethical, legal and social implications. Learners must demonstrate proficiency of the subject area by attaining a minimum score of 70%. We also suggest two additional components to complement the overview of the field in the section on pharmacogenetics and pharmacogenomics. First, an overview of the range of testing platforms/technology should be presented with discussion of the benefits and limitations of different assays. Pharmacists are not likely to have the training/knowledge to understand the differences in testing platforms and how that may impact the type of results returned and test limitations. Second, specific applications should be presented to illustrate when testing may be indicated, the potential outcomes of testing and how the test results would be applied to inform medication selection or dosing. In addition, particularly for community/ambulatory pharmacists, a separate optional module should be developed to provide guidance about how to set up a viable business model to offer PGx testing that would address key issues such as reimbursement, training, documentation and staffing needs.

Live study

Pharmacists will need to develop specific skills to effectively and appropriately provide PGx testing to patients. The second part of the certification program, the live study component, will enable learners to learn and practice these skills. Specifically, pharmacists should be proficient in discussing PGx testing with patients, specimen collection, report interpretation and application and communication of test results to patients. Learners will be divided into small groups for a role-playing activity to practice discussing PGx testing with patients, obtaining informed consent (as is sometimes required by the laboratory), specimen collection, test result interpretation based on actual PGx test reports, utilization of evidence-based guidelines to make clinical decisions and communicating test results. The role-playing will allow learners an opportunity to not only learn about a range of PGx applications in their practice settings,

Box 1. Proposed elements of a pharmacogenetic certificate**Self-study – Self-study post test (estimated time to complete: 6 h)****Passing score of ≥70% required**

- To recognize and appreciate the role of behavioral, social and environmental factors (lifestyle, socioeconomic factors, pollutants, among others) to modify or influence genetics in the manifestation of disease
- To identify drug- and disease-associated genetic variations that facilitate development of prevention and treatment strategies and appreciate there are differences in testing methodologies and are aware of the need to explore these differences in drug literature evaluation
- To use family history in assessing predisposition to disease and selection of drug treatment
- To understand the role of genetic factors in maintaining health and preventing disease
- To assess the difference between clinical diagnosis of disease and identification of genetic predisposition to disease (genetic variation is not strictly correlated with disease manifestation)
- To appreciate that pharmacogenomic testing may also reveal certain genetic disease predispositions (e.g., the *Apo E4* polymorphism)
- To understand the influence (or lack thereof) of ethnicity in genetic polymorphisms and associations of polymorphisms with drug response
- To understand the potential physical and/or psychosocial benefits, limitations and risk of genomic/ pharmacogenomic information for individuals, family members and communities, especially with genomic/ pharmacogenomic tests that may relate to predisposition to disease
- To understand the increased liability that accompanies access to detailed genomic patient information and maintain confidentiality and security
- To appreciate the cost, cost–effectiveness and reimbursement by insurers relevant to genomic or pharmacogenomic tests and test interpretation for patients and populations
- To identify the need to refer a patient to a genetic specialist or genetic counselor

Live study (estimated time to complete: 3 h)

- To learn of and demonstrate proficiency in different types of sample collection practices for PGx testing, review of safety procedures for handling biospecimens and proper mailing[†]
- To gain experience through group-based activities and role-playing about reviewing PGx test reports and demonstrate the following knowledge/skill-based competencies[†]
- To gain experience through group-based activities and role-playing on patient communication about PGx testing and test results and counseling[†]
- To demonstrate understanding of basic genetic/genomic concepts and nomenclature
- To demonstrate an understanding of how genetic variation in a large number of proteins influences pharmacokinetics and pharmacodynamics related to pharmacologic effect and drug response
- To utilize evidence-based guidelines that synthesize information relevant to genomic/PGx tests and selection of drug therapy (e.g., Clinical Pharmacogenomics Implementation Consortium)
- To adopt a culturally sensitive and ethical approach to patient counseling regarding PGx test results
- To maintain proper documentation of test results in electronic patient record[†]
- To learn about different business models to integrate in their practice sites[†].
- To learn about strategies to engage with local practitioners to discuss the delivery of PGx prior to implementation[†]

CE 2 years after the completion of course (estimated time to complete: 2 CE h)

- A refresher course to update knowledge about new tests, technologies, reimbursement and clinical decision support tools.

[†]Non-Genetics/Genomics Competency Center recommendations.

Proposed elements are based on the Genetics/Genomics Competency Center [22] recommendations and new educational objectives derived from the recommendations of the National Genetics Education and Development Centre in collaboration with the Royal Pharmaceutical Society of Great Britain [24] and on our experiences in our translational studies on PGx testing.

CE: Continuing education; PGx: Pharmacogenetic

but offer constructive feedback for the different components of delivering PGx testing. Also, discussion of business models to integrate PGx testing in community pharmacy settings will be reviewed. Upon completion of the live study, each participant would receive a certificate valid for 2 years. After 2 years, to maintain their certification status, pharmacists would need to complete a 2-h continuing education refresher

course to update their knowledge about new tests, technologies, reimbursement, new clinical decision support tools and skills including patient communication and results interpretation. For updates on new publications, US FDA label changes and guidelines, pharmacists will be referred to the comprehensive and regularly updated PharmGKB website [25], supported by the US NIH and other resources. Participant

suggestions for topics for future continuing education modules will also be solicited to insure that the modules are addressing pharmacists' knowledge and skills needs.

Given the reported limited knowledge of pharmacists about pharmacogenetics [18], this proposed format for a certification may require more intense initial self-study. A report of an ACPE program demonstrated some improvement in pharmacists' knowledge of PGx, but still a relatively low knowledge level following the completion of the program (precourse score: 46%; postcourse score: 53%) [19]. Therefore, it may be necessary to expand the introductory home-study modules with more detailed optional modules about the history of PGx, understanding genetic variation, clinical PGx evidence and drug-gene interactions. However, this does not address the need for skill-based learning of PGx for pharmacists, which is essential for the appropriate delivery of PGx testing. The increasing content of PGx in pharmacy school curricula and training programs [26] should help increase scores and reduce the need for an intensive certification program over time.

In order to successfully offer PGx testing in community pharmacies, interprofessional collaboration will be important [5], particularly with laboratory professionals and ordering providers (both specialists and general practitioners). While other clinical providers have expressed support for a collaborative relationship with pharmacists, more effort is needed to define the roles of pharmacists as a provider of clinical services, which may then lead to greater acceptance by other providers

as a member of the clinical team [27–31]. Thus, one of the topics in the certificate program is engagement with local practitioners to discuss the delivery of PGx testing prior to implementation. Engagement with laboratory medicine providers could also be helpful with the interpretation of test results. As many physicians have acknowledged their limited knowledge of PGx, the pharmacist may serve as a resource about PGx testing until physician familiarity about testing increases.

In conclusion, certificate programs are intended to provide pharmacy professionals with the knowledge and skill sets to improve or expand their current practice for new technologies or applications. The current lack of a training program for PGx may stifle pharmacists' likelihood to offer testing and use test results to inform medication decisions. Such a program as proposed here will help pharmacists acquire the needed knowledge and skills to appropriately offer and utilize PGx testing.

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References

- Gerrald KR, Dixon DL, Barnette DJ, Williams VG. Evaluation of a pharmacist-managed lipid clinic that uses point-of-care lipid testing. *J. Clin. Lipidol.* 4(2), 120–125 (2010).
- Jarab AS, Alqudah SG, Mukattash TL, Shattat G, Al-Qirim T. Randomized controlled trial of clinical pharmacy management of patients with Type 2 diabetes in an outpatient diabetes clinic in Jordan. *J. Manag. Care Pharm.* 18(7), 516–526 (2012).
- Ziman ME, Bui HT, Smith CS *et al.* The pharmacists' role in improving guideline compliance for thyroid function testing in patients with heart failure. *J. Pharm. Pract.* 25(2), 195–200 (2012).
- McCullough KB, Formea CM, Berg KD *et al.* Assessment of the pharmacogenomics educational needs of pharmacists. *Am. J. Pharm. Educ.* 75(3), 51 (2011).
- Owusu-Obeng A, Weitzel KW, Hatton RC *et al.* Emerging roles for pharmacists in clinical implementation of pharmacogenomics. *Pharmacotherapy* 34(10), 1102–1112 (2014).
- Tuteja S, Haynes K, Zayac C, Sprague JE, Bernhardt B, Pyeritz R. Community pharmacists' attitudes towards clinical utility and ethical implications of pharmacogenetic testing. *Pers. Med.* 10(8) doi: 10.2217/pme.13.85 (2013).
- De Denus S, Letarte N, Hurlimann T *et al.* An evaluation of pharmacists' expectations towards pharmacogenomics. *Pharmacogenomics* 14(2), 165–175 (2013).
- Accreditation Council for Pharmacy Education. Accreditation standards and guidelines for the Professional Program in Pharmacy leading to the Doctor of Pharmacy Degree. www.acpe-accredit.org
- Anderson C, Bates I, Beck D *et al.* The WHO UNESCO FIP Pharmacy Education Taskforce. *Hum. Resour. Health* 7, 45 (2009).
- Gurwitz D, Lunshof JE, Dedoussis G *et al.* Pharmacogenomics education: International Society of Pharmacogenomics recommendations for medical, pharmaceutical, and health schools deans of education. *Pharmacogenomics J.* 5(4), 221–225 (2005).
- Cavallari LH, Overholser BR, Anderson D *et al.* Recommended basic science foundation necessary to prepare pharmacists to manage personalized pharmacotherapy. *Pharmacotherapy* 30(6), 626 (2010).

- 12 American Society of Health-System Pharmacists. ASHP formulary management policy position (Pharmacogenomics – 1104). www.ashp.org
- 13 American Association of Colleges of Pharmacy. Final report of the 2007–2008 Bylaws and Policy Development Committee. *Am. J. Pharm. Educ.* 72(Suppl.), S16 (2008).
- 14 American Pharmacists Association. APha announces special offerings of the pharmacy-based immunization delivery certificate training program. www.pharmacist.com
- 15 Jakeman B, Gross B, Fortune D, Babb S, Tinker D, Bachyrycz A. Evaluation of a pharmacist-performed tuberculosis testing initiative in New Mexico. *J. Am. Pharm. Assoc.* (2003) 55(3), 307–312 (2015).
- 16 American Pharmacists Association. APhA training programs. www.pharmacist.com
- 17 ACPE. www.acpe-accredit.org
- 18 Alexander KM, Divine HS, Hanna CR, Gokun Y, Freeman PR. Implementation of personalized medicine services in community pharmacies: perceptions of independent community pharmacists. *J. Am. Pharm. Assoc.* (2003) 54(5), 510–517 (2014).
- 19 Formea CM, Nicholson WT, Mccullough KB *et al.* Development and evaluation of a pharmacogenomics educational program for pharmacists. *Am. J. Pharm. Educ.* 77(1), 10 (2013).
- 20 Roederer M, Van Riper M, Valgus J, Knaff G, Mcleod H. Knowledge, attitudes and education of pharmacists regarding pharmacogenetic testing. *Per. Med.* 9(1), 19–27 (2012).
- 21 Romagnoli KM, Boyce RD, Empey PE, Adams S, Hochheiser H. Bringing clinical pharmacogenomics information to pharmacists: a qualitative study of information needs and resource requirements. *Int. J. Med. Inform.* 86, 54–61 (2016).
- 22 G2c2. Pharmacist competency map. <http://g-2-c-2.org>
- 23 Haga SB, Moaddeb J, Mills R, Patel M, Kraus W, Allen Lapointe NM. Incorporation of pharmacogenetic testing into medication therapy management. *Pharmacogenomics* 16(17), 1931–1941 (2015).
- 24 Newton R, Lithgow J, Po ALW, Bennett C, Farndon P. How will pharmacogenetics impact on pharmacy practice? Pharmacists' views and educational priorities. NJS National Genetics Education and Development Centre, Birmingham, England, UK (2007). www.geneticseducation.nhs.uk
- 25 PharmGKB. www.pharmgkb.org
- 26 Drozda K, Labinov Y, Jiang R *et al.* A pharmacogenetics service experience for pharmacy students, residents, and fellows. *Am. J. Pharm. Educ.* 77(8), 175 (2013).
- 27 Alkhateeb FM, Unni E, Latif D, Shawaqfeh MS, Al-Rousan RM. Physician attitudes toward collaborative agreements with pharmacists and their expectations of community pharmacists' responsibilities in West Virginia. *J. Am. Pharm. Assoc.* (2003) 49(6), 797–800 (2009).
- 28 Bryant L, Coster G, McCormick R. General practitioner perceptions of clinical medication reviews undertaken by community pharmacists. *J. Prim. Health Care* 2(3), 225–233 (2010).
- 29 Halvorsen KH, Stensland P, Granas AG. A qualitative study of physicians' and nurses' experiences of multidisciplinary collaboration with pharmacists participating at case conferences. *Int. J. Pharm. Pract.* 19(5), 350–357 (2011).
- 30 Hatah E, Braund R, Duffull S, Tordoff J. General practitioners' perceptions of pharmacists' new services in New Zealand. *Int. J. Clin. Pharm.* 34(2), 364–373 (2012).
- 31 Kucukarslan S, Lai S, Dong Y, Al-Bassam N, Kim K. Physician beliefs and attitudes toward collaboration with community pharmacists. *Res. Social. Adm. Pharm.* 7(3), 224–232 (2011).