

ASHP Statement on the Pharmacist's Role in Clinical Pharmacogenomics

Position

The American Society of Health-System Pharmacists (ASHP) believes that pharmacogenomic testing can improve medication-related outcomes across the continuum of care in all health-system practice settings. These improvements include reduction in suboptimal clinical outcomes, decreased cost of treatment, better medication adherence, more appropriate selection of therapeutic agents, decreased length of treatment, and enhanced patient safety.¹⁻³ Because of their distinct knowledge, skills, and abilities, pharmacists are uniquely positioned to lead inter-professional efforts to develop processes for ordering pharmacogenomic tests and for reporting and interpreting test results. They are also uniquely qualified to lead efforts to guide optimal drug selection and drug dosing based on those results. Pharmacists therefore have a fundamental responsibility to ensure that pharmacogenomic testing is performed when needed and that the results are used to optimize medication therapy.¹ Pursuant to this leadership role, pharmacists share accountability with other hospital and health-system leaders, such as physicians, laboratory professionals, and genetic counselors, for the ongoing implementation and application of pharmacogenomics across the continuum of care. Because test results will have implications throughout a patient's lifetime, all pharmacists should have a basic understanding of pharmacogenomics in order to provide appropriate patient-care recommendations. Some advanced pharmacist functions in applying clinical pharmacogenomics may require specialized education, training, or experience. ASHP encourages pharmacist education on the use of pharmacogenomics and advocates inclusion of pharmacogenomics and its application to the therapeutic decision-making process in college of pharmacy curricula and Board of Pharmacy Specialties certification programs.

Background

Clinical pharmacogenomics uses genetic information to guide optimal drug selection and drug dosing for patients to maximize therapeutic effects, improve outcomes, and minimize toxicity.² Pharmacogenomic testing can be performed reactively or preemptively. Reactive testing generally occurs when a patient is experiencing adverse effects unexplained by dose or drug-drug or drug-disease interactions, or when the use of a high-risk drug is anticipated and the patient's genotype is obtained in anticipation of starting therapy. In contrast, preemptive testing occurs when patients are screened for multiple pharmacogenomic variants prior to developing an indication for specific pharmacotherapy.

Application of pharmacogenomic information requires an understanding of how genetic variations impact the pharmacokinetic and pharmacodynamic properties of a drug in specific diseases and patient populations, as well as an understanding of molecular pathways. The influence of factors such as age, sex, diet, pathophysiologic conditions, and current medication use, as well as their relationship to

genetic variability, must also be understood. As awareness of individual genetic variation grows due to improved access to lower-cost testing and availability of evidence-based consensus guidelines in pharmacogenomics,⁴ the development of patient-individualized therapeutic regimens should include an assessment of patients' pharmacogenomic profiles in addition to allergy and adverse reaction history, drug interactions, dietary and lifestyle factors, patterns of adherence, and other therapeutic drug-monitoring parameters.⁵ The FDA provides a list of drugs for which pharmacogenomic markers are included in the drug labeling,⁶ and the Clinical Pharmacogenetics Implementation Consortium (CPIC) has published ASHP-endorsed therapeutic guidelines for multiple drug-gene pairs.^{7,8}

The pharmacist's patient-care functions include appropriate and cost-conscious medication selection and monitoring, which now increasingly include pharmacogenomic profile assessment. The purpose of this statement is to describe pharmacists' responsibilities and accountabilities in the field of pharmacogenomics.

Pharmacists' Responsibilities

Pharmacists' responsibilities for pharmacogenomics include promoting the optimal use and timing of pharmacogenomic tests; interpreting clinical pharmacogenomic test results; and educating other pharmacists, fellow health care professionals, patients, and the public about the field of pharmacogenomics. The following are responsibilities that should be part of any clinical pharmacogenomics service:

- Advocating for the rational and routine use of pharmacogenomic testing.
- Providing test result interpretation and clinical guidance for return of results to providers and patients in collaboration with other health care professionals (e.g., physicians, laboratory professionals, and genetic counselors).
- Optimizing medication therapy based on pharmacogenomic test results.
- Educating and providing information on the clinical application of pharmacogenomics to health professionals, patients, and members of the public.
- Supporting and participating in research, consortia, and networks that guide and accelerate the application of pharmacogenomics to clinical practice.

Using these responsibilities as a guide, ASHP has developed the following recommendations for pharmacists' functions in pharmacogenomics.

Pharmacists' Functions

A pharmacist's functions in clinical pharmacogenomics will vary, depending on education, training, experience, and the needs of the practice setting. All pharmacists should have a basic understanding of pharmacogenomics in order to pro-

vide patient care that incorporates pharmacogenomic recommendations. Elements of a basic understanding of pharmacogenomics should enable pharmacists to perform the following functions:

- Recommending or scheduling pharmacogenomic testing to aid in the process of drug and dosage selection.
- Designing a patient-specific drug and dosage regimen based on the patient's pharmacogenomic profile that also considers the pharmacokinetic and pharmacodynamic properties of the drug. These factors should be combined in the regimen design along with other pertinent patient-specific factors such as comorbidities, other drug therapy, demographics, and laboratory data to optimize patient outcomes.
- Educating patients, pharmacists, and other health care professionals about pharmacogenomic principles and appropriate indications for clinical pharmacogenomic testing, including the cost-effective use of pharmacogenomic testing.⁹
- Communicating pharmacogenomic-specific drug therapy recommendations to the health care team, including documentation of interpretation of results in the patient's health record.¹⁰

Pharmacists with specialized education, training, or experience in pharmacogenomics should also assume the following additional functions:

- Developing pharmacogenomic-specific clinical decision support tools in electronic health record systems that guide prescribers on the appropriate use and dosing of medicines based on a patient's pharmacogenomic profile.¹¹⁻¹³
- Developing a process, including patient-specific educational materials, to explain to patients the importance and significance of their pharmacogenomic test results, not only in the short term but also over the patient's lifetime.
- Developing institutional guidelines and processes for implementation of a clinical pharmacogenomic service.
- Establishing a process for communicating patient-specific results, including documentation of the results in the patient's health record.
- Establishing a mechanism for revisable reporting (re-interpretation of findings based on evolving science) over the course of the patient's care with the institution and beyond.
- Developing processes to document improved patient outcomes and economic benefits resulting from clinical pharmacogenomics.
- Serving as an expert consultant on a clinical pharmacogenomics service.
- Contributing to the evaluation and implementation of clinical pharmacogenomic testing as an integral part of medication therapy.
- Promoting collaborative relationships with other health care professionals and departments involved in drug therapy to encourage the development and appropriate use of pharmacogenomic principles in patient care.

- Applying collaborative drug therapy management principles to a clinical pharmacogenomics service, including advocating for the reimbursement of pharmacogenomic tests and pharmacist interpretation by health insurance plans.
- Developing and planning pharmacogenomic-specific advanced training opportunities for pharmacists and other health care professionals.
- Actively contributing to the body of knowledge in pharmacogenomics by publishing articles on the topic in the biomedical literature.
- Designing and conducting pharmacogenomic research.

Conclusion

ASHP believes that pharmacists have a responsibility to take a prominent role in the clinical application of pharmacogenomics. This emerging science should be spearheaded in many institutions by pharmacists to promote safe, effective, and cost-efficient medication practices.

References

1. Swen JJ, Nijenhuis M, de Boer A, et al. Pharmacogenetics: from bench to byte—an update of guidelines. *Clin Pharmacol Ther*. 2011; 89(5):662–73.
2. Manolio TA, Chisholm RL, Ozenberger B, et al. Implementing genomic medicine in the clinic: the future is now. *Genet Med*. 2013; 15(4):258–67.
3. Wu AC, Fuhlbrigge AL. Economic evaluation of pharmacogenetic tests. *Clin Pharmacol Ther*. 2008; 84(2):272–4.
4. Relling MV, Klein TE. CPIC: Clinical Pharmacogenetics Implementation Consortium of the Pharmacogenomics Research Network. *Clin Pharmacol Ther*. 2011; 89(3):464–7.
5. ASHP policy position 1104: Pharmacogenomics. In: Hawkins B, ed. Best practices for hospital and health-system pharmacy: positions and guidance documents of ASHP. 2013–2014 ed. Bethesda, MD: American Society of Health-System Pharmacists; 2013:162. <http://www.ashp.org/DocLibrary/BestPractices/FormularyPositions.aspx> (accessed 2014 Jun 19).
6. Table of Pharmacogenomic Biomarkers in Drug Labeling. <http://www.fda.gov/drugs/scienceresearch/researchareas/pharmacogenetics/ucm083378.htm> (accessed 2014 Jun 19).
7. Clinical Pharmacogenetics Implementation Consortium [CPIC]. Drug-Gene Pairs. www.pharmgkb.org/page/cpicGeneDrugPairs (accessed 2014 Jun 19).
8. American Society of Health-System Pharmacists. Endorsed Documents. <http://www.ashp.org/menu/PracticePolicy/PolicyPositionsGuidelinesBestPractices/BrowsebyDocumentType/EndorsedDocuments.aspx> (accessed 2014 Jun 19).
9. Feero WG, Kuo GM, Jenkins JR, et al. Pharmacist education in the era of genomic medicine. *J Am Pharm Assoc*. 2012; 52:e113–e121.
10. Hicks JK, Crews KR, Hoffman JM, et al. A clinician-driven automated system for integration of pharma-

- cogenetic interpretations into an electronic medical record. *Clin Pharmacol Ther.* 2012; 92(5):563–6.
11. Welch BM, Kawamoto K. Clinical decision support for genetically guided personalized medicine: a systematic review. *J Am Med Inform Assoc.* 2013; 20(2):388–400.
 12. Pulley JM, et al. Operational implementation of prospective genotyping for personalized medicine: the design of the Vanderbilt PREDICT project. *Clin Pharmacol Ther.* 2012; 92(1):87–95.
 13. Bell GC, Crews KR, Wilkinson MR, et al. Development and use of active clinical decision support for preemptive pharmacogenomics. *J Am Med Inform Assoc.* 2013. DOI: 10.1136/annals-2013-001993 [Epub ahead of print].

Developed through the ASHP Section of Clinical Specialists and Scientists Section Advisory Group on Emerging Sciences, and approved by the ASHP Board of Directors on April 10, 2014, and by the ASHP House of Delegates on June 1, 2014.

Cyrine-Eliana Haidar, Pharm.D., BCPS, BCOP; James M. Hoffman, Pharm.D., M.S., BCPS; and Samuel G. Johnson, Pharm.D.,

FCCP, BCPS (AQ-Cardiology) are gratefully acknowledged for drafting this statement. Mary V. Relling, Pharm.D., and Kristine R. Crews, Pharm.D., BCPS, are gratefully acknowledged for their review of and contributions to the statement.

The following individuals are gratefully acknowledged for reviewing this statement (review does not imply endorsement): Manju T. Beier, Pharm.D., CGP; Gillian C. Bell, Pharm.D.; Larisa H. Cavallari, Pharm.D., BCPS; J. Kevin Hicks, Pharm.D., Ph.D.; Shannon Manzi, Pharm.D.; Darius Mason, Pharm.D., BCPS; Teresa Vo, Pharm.D.; and Kristin Weitzel, Pharm.D., CDE, FAPhA.

Copyright © 2015, American Society of Health-System Pharmacists, Inc. All rights reserved.

The bibliographic citation for this document is as follows: American Society of Health-System Pharmacists. ASHP statement on the pharmacist's role in clinical pharmacogenomics. *Am J Health-Syst Pharm.* 2015; 72:579–81.