

ASHP Statement on the Pharmacist's Role in Clinical Pharmacogenomics

Position

The American Society of Health-System Pharmacists (ASHP) believes pharmacogenomic testing can improve medication-related outcomes across the continuum of care in all health-system practice settings. These improvements include improved clinical outcomes, decreased side effects, lower cost of treatment, increased medication adherence, more appropriate selection of therapeutic agents, decreased length of treatment, and enhanced patient safety.¹⁻⁴ Because of their distinct knowledge, skills, and abilities, pharmacists are uniquely positioned to lead interprofessional efforts to develop processes for ordering pharmacogenomic tests and for reporting and interpreting test results. Pharmacists are also singularly qualified to lead efforts to guide optimal drug selection and drug dosing and provide patient as well as provider education based on those results. Pharmacists therefore have a fundamental responsibility to ensure that pharmacogenomic testing is performed when needed and the results are utilized to optimize medication therapy.¹ Pursuant to this leadership role, pharmacists share accountability with other 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 serve as advocates for preemptive and reactive testing and have a basic understanding of pharmacogenomics in order to provide appropriate patient-care recommendations. ASHP therefore encourages pharmacist education on the use of pharmacogenomics and advocates inclusion of pharmacogenomics and its application to the therapeutic decision-making process in student and resident training, continuing education offerings, and Board of Pharmacy Specialties certification processes. Some advanced pharmacist functions in applying clinical pharmacogenomics may require specialized education, training, or experience.

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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.³ Although early applications of pharmacogenomics were in the oncology and cardiology realms, the use of pharmacogenomic data has expanded to other across therapeutic areas, for example psychiatry, neurology, and infectious diseases.⁵⁻⁸

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 drug that is affected by pharmacogenomic variations is anticipated. In contrast, preemptive testing occurs when patients are genotyped prior to developing an indication for specific pharmacotherapy; usually multiple pharmacogenomic genes are assessed at the same time. Preemptive testing yields the highest value and quality of care for the patient by preventing undesirable drug responses such as toxicity or therapeutic failure.⁹

Application of pharmacogenomic information requires an understanding of how genetic variations impact the pharmacokinetic and pharmacodynamic properties of a drug and prevent the occurrence of adverse drug events. The combined influence of factors such as age, sex, race, ethnicity, diet, pathophysiologic conditions, and current medication use, as well as their relationship to genetic variability, must also be understood. The development of patient-individualized therapeutic regimens should therefore include an assessment of the patient's pharmacogenomic profile in addition to their allergy and adverse reaction history, drug interactions, dietary and lifestyle factors, patterns of adherence, and other therapeutic drug-monitoring parameters.¹⁰ There are more than a dozen comprehensive, ASHP-endorsed therapeutic guidelines from the Clinical Pharmacogenetics Implementation Consortium (CPIC) to guide pharmacotherapy decisions when pharmacogenomic information is available.¹¹⁻¹³ From a regulatory perspective, the FDA also provides a list of drugs for which pharmacogenomic markers are included in the drug labeling¹⁴ as well as a table of pharmacogenomics associations.¹⁵ Pharmacogenomic information is emerging in other sources, such as specialty guidelines and widely used drug information resources, so

pharmacists should consult a variety of evidence-based resources in therapeutic decision-making.

The pharmacist's patient-care responsibilities include education as well as 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 clinical pharmacogenomics.

Pharmacists' Responsibilities

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

- Advocating for the rational and ethical use of pharmacogenomics testing as part of routine patient care.¹⁶
- Ordering pharmacogenomics tests, when appropriate, and providing test result interpretation and clinical guidance for the return of pharmacogenomic results to providers and patients in collaboration with other healthcare professionals.
- Optimizing medication therapy based on pharmacogenomic test results.
- Providing information and educating healthcare professionals, patients, and members of the public on the evidence-based, clinical application of pharmacogenomics.
- Supporting and participating in research, consortia, and networks that guide and accelerate the application of pharmacogenomics in clinical practice.
- Facilitating the seamless integration of pharmacogenomics in the electronic health record (EHR) with clinical decision support.
- Promoting EHR interoperability and portability of patient-specific pharmacogenomic test results across health systems and to pharmacies.^{17,18}

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

Pharmacists' Roles

All pharmacists should have a basic understanding of pharmacogenomics to provide patient care incorporating pharmacogenomic recommendations regarding medication response.

Elements of a basic understanding of pharmacogenomics should enable pharmacists to perform the following responsibilities:

- Recommending or ordering preemptive or reactive pharmacogenomic testing to aid in the process of drug and dosage selection.
- Designing patient-specific drug and dosage regimens based on a person's pharmacogenomic profile and other pertinent factors, such as the pharmacokinetic and pharmacodynamic properties of the drug, drug-drug and drug-gene interactions, comorbidities, patient demographics, and laboratory data to optimize patient outcomes.
- Educating healthcare professionals about pharmacogenomic principles and appropriate indications for cost-effective pharmacogenomic testing.¹⁹
- Communicating pharmacogenomics-based drug therapy recommendations to the healthcare team, including documentation of and interpretation of results in the patient's health record.^{17, 18, 20}
- Providing resources and education that empower patients to make informed healthcare decisions about undergoing pharmacogenomic testing and understanding their test results.²¹
- Ensuring pharmacogenomic test results are handled in an ethical manner and that patients are provided access to their genetic data when applicable.

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

- Developing institutional guidelines and processes for or leading the use and implementation of a clinical pharmacogenomic program.
- Applying collaborative drug therapy management principles to a clinical pharmacogenomics program, including advocating for the reimbursement of testing and pharmacist interpretation by health insurance plans.

- Serving as a subject matter expert for clinical pharmacogenomics. Pharmacists who practice in the oncology setting should also incorporate results of tumor genomics (somatic variations) to personalize and optimize pharmacotherapy. Pharmacists typically have leadership roles on institutional tumor boards in this practice setting.
- Contributing to the evaluation and implementation of clinical pharmacogenomics testing as an integral part of medication therapy.
- Promoting collaborative relationships with healthcare professionals and key departments within the institution to encourage the development and appropriate use of pharmacogenomic principles in patient care.
- Advocating for the use of standardized pharmacogenomic nomenclature, including the use of standardized terms from the Systematized Nomenclature of Medicine Clinical Terms (SNOMED-CT) and Logical Observation Identifiers Names and Codes (LOINC) in EHRs.^{22,23}
- Developing pharmacogenomic-specific clinical decision support tools in EHR systems that guide prescribers on the appropriate use and dosing of medicines based on a patient's pharmacogenomic profile.²⁴⁻²⁶
- Encouraging EHR vendors to assist in the seamless integration of pharmacogenomics in the EHR and promote interoperability and portability of pharmacogenomic data.
- Developing and planning pharmacogenomic-specific advanced training opportunities for pharmacists and other healthcare professionals.
- Establishing processes for communicating patient-specific results with healthcare professionals, including documentation of results in the patient's health record and informing healthcare providers outside of the institution whose care would be impacted by the results.
- Developing a process for return of results to patients, including patient-specific educational materials explaining the importance and lifelong significance of their pharmacogenomic test results.
- Developing processes to document patient outcomes and economic benefits as a result of pharmacogenomic testing.

- Establishing a process for reinterpretation and updating of pharmacogenomics test results based on the emergence of new findings.
- Designing and conducting pharmacogenomic research.
- Actively contributing to the body of knowledge in pharmacogenomics by publishing articles on the topic in the biomedical literature.

Future Directions

As pharmacogenomic testing continues to evolve, genotyping will likely be performed using next-generation sequencing (NGS) technologies, and more patients will get tested for a larger number of variants.²⁷ Pharmacists will need to have a basic understanding of NGS, including its limitations and how to address variants of unknown significance.²⁸ The roles of pharmacists must therefore expand and evolve as well, including but not limited to include the following:

- Routinely utilizing a patient's pharmacogenomic test results as standard practice within comprehensive medication management workflows.
- Working closely with other medical specialties (e.g., close collaboration with medical geneticists or genetic counselors) to provide pharmacogenomics expertise and return of results to patients when broad testing (e.g., whole-genome sequencing) is ordered.
- Assessment of the economic value of clinical pharmacogenomics and pharmacogenomic test reimbursement policies. Payer policies are maturing and are expected to expand as further evidence is generated. The unique expertise of pharmacists will be essential in the development of these best practices policies.²⁹⁻³¹
- Data interoperability and sharing of pharmacogenomic test results with other healthcare institutions, including community pharmacies, will be a critical factor to enable continuing use of the information over a patient's lifetime.
- For pharmacists who practice in the oncology setting, aiding in the replication of the successful principles of germline pharmacogenomics integration in the EHR to somatic variations will help optimize medication therapy.

Conclusion

ASHP believes all pharmacists have a responsibility to take a prominent role in the rational, ethical use and clinical application of pharmacogenomics. Clinical pharmacogenomics initiatives should be spearheaded by pharmacists to promote safe, effective, and cost-efficient medication use. Pharmacists should also lead the efforts of patient and interprofessional pharmacogenomic education.

Authors

Cyrine-Eliana Haidar, PharmD, BCPS, BCOP

St. Jude Children's Research Hospital
Memphis, TN

Natasha Petry, PharmD, MPH, BCACP

North Dakota State University
Sanford Health
Fargo, ND

Carolyn Oxencis, PharmD, BCOP

Medical College of Wisconsin
Milwaukee, WI

Janine S. Douglas, PharmD, BCPS

The University of Texas MD Anderson Cancer Center
Houston, TX

James M. Hoffman, PharmD, MS

St. Jude Children's Research Hospital
Memphis, TN

Address correspondence to Bruce Hawkins (standards@ashp.org).

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Disclosures

The authors have declared no potential conflicts of interest.

Additional information

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