Published in final edited form as:
J Am Coll Clin Pharm. 2019 June ; 2(3): 303–313. doi:10.1002/jac5.1118.

Precision Pharmacotherapy: Integrating Pharmacogenomics into Clinical Pharmacy Practice

J. Kevin Hicks, Pharm.D., Ph.D., **Christina L. Aquilante, Pharm.D., FCCP**, **Henry M. Dunnenberger, Pharm.D.**, **Roseann S. Gammal, Pharm.D.**, **Ryan S. Funk, Pharm.D., Ph.D.**, **Samuel L. Aitken, Pharm.D.**, **David R. Bright, Pharm.D.**, **James C. Coons, Pharm.D., FCCP**, **Kierra M. Dotson, Pharm.D.**, **Christopher T. Elder, Pharm.D.**, **Lindsey T. Groff, B.S.**, **James C. Lee, Pharm.D.**
American College of Clinical Pharmacy

Abstract

Precision pharmacotherapy encompasses the use of therapeutic drug monitoring; evaluation of liver and renal function, genomics, and environmental and lifestyle exposures; and analysis of other unique patient or disease characteristics to guide drug selection and dosing. This paper articulates real-world clinical applications of precision pharmacotherapy, focusing exclusively on the emerging field of clinical pharmacogenomics. This field is evolving rapidly, and clinical pharmacists now play an invaluable role in the clinical implementation, education, and research applications of pharmacogenomics. This paper provides an overview of the evolution of pharmacogenomics in clinical pharmacy practice, together with recommendations on how the American College of Clinical Pharmacy (ACCP) can support the advancement of clinical pharmacogenomics implementation, education, and research. Commonalities among successful clinical pharmacogenomics implementation and education programs are identified, with recommendations for how ACCP can leverage and advance these common themes. Opportunities are also provided to support the research needed to move the practice and application of pharmacogenomics forward.

Keywords

precision pharmacotherapy; personalized medicine; pharmacogenomics; clinical pharmacy; pharmacy practice

Introduction

Pharmacists have long recognized that using unique patient characteristics to guide pharmacotherapy decision-making can improve drug response and mitigate drug-associated

Correspondence: J. Kevin Hicks, Pharm.D., Ph.D., H. Lee Moffitt Cancer Center, 12902 Magnolia Drive, MRC-CANCONT, Tampa, FL 33612, USA, Phone (813) 745-4673, ext. 4668, james.hicks@moffitt.org.

This document was prepared by the 2018 ACCP Clinical Practice Affairs Committee: J. Kevin Hicks, Pharm.D., Ph.D. (Chair); Christina L. Aquilante, Pharm.D., FCCP (Vice Chair); Samuel L. Aitken, Pharm.D., BCIDP, BCPS-AQ ID; David R. Bright, Pharm.D., BCACP; James C. Coons, Pharm.D., FCCP, BCCP; Kierra M. Dotson, Pharm.D., BCPS; Henry M. Dunnenberger, Pharm.D., BCPS; Christopher T. Elder, Pharm.D., BCOP; Ryan S. Funk, Pharm.D., Ph.D.; Roseann S. Gammal, Pharm.D., BCPS; Lindsey T. Groff, B.S.; James C. Lee, Pharm.D., BCACP

risks. Age, weight, and dietary habits were among the first patient-specific characteristics used to individualize pharmacotherapy. As technologies advanced, analytic tools that measured surrogate markers of liver and renal function, together with drug concentrations in biological fluids, were adopted to optimize therapeutic regimens. Cutting-edge genomics technologies are now being integrated into patient care for the selection of targeted therapies and identification of those at increased risk of poor pharmacotherapy outcomes. The term *precision pharmacotherapy* has been coined to refer to the use of genetic, environmental, lifestyle, and other unique patient or disease characteristics to guide drug selection and dosing.[1]

The American College of Clinical Pharmacy (ACCP) charged the 2018 ACCP Clinical Practice Affairs Committee to develop this white paper, which focuses exclusively on the emerging field of clinical pharmacogenomics as one component of precision pharmacotherapy. The recommendations provided in this paper are intended to serve as a guide for ACCP to support clinical pharmacists' efforts to advance clinical pharmacogenomics and precision pharmacotherapy. The ACCP Practice and Research Networks have written a companion paper published in this issue of *JACCP* that provides a broader analysis of the application of precision pharmacotherapy across therapeutic specialties.

Evolution of Pharmacogenomics in Clinical Pharmacy Practice

The concept of genetic variations affecting drug response dates back to at least the 1940s,[2,3] with Friedrich Vogel coining the term *pharmacogenetics* in 1959.[4] Initial research mainly focused on how inherited genetic variations (i.e., germline variations) in a single gene could influence drug response, termed *pharmacogenetics*. After decades of research focused on discovering the genetic variations that influence drug response and the subsequent validation of these findings, evidence became sufficient to warrant the application of pharmacogenetics to clinical practice.[5,6] One of the earliest and most well-known examples of clinical pharmacogenetics is the screening of patients for variations in the thiopurine methyltransferase (TPMT) gene to guide thiopurine (e.g., azathioprine, mercaptopurine, thioguanine) dosing. Clinical data analyses published in the 1990s showed that reducing thiopurine doses in pediatric patients with acute lymphoblastic leukemia who harbored genetic alterations predictive of TPMT intermediate- or poor-metabolizer phenotypes prevented severe, life-threatening myelosuppression.[7,8] Subsequent studies of patients with autoimmune diseases suggested that *TPMT* genotyping could prevent thiopurine-induced toxicities in a cost-effective manner.[9,10] These findings resulted in the integration of *TPMT* genotyping strategies into routine patient care.

Throughout the 2000s, clinical use of other single gene-drug pairs to guide drug selection and dosage increased. Examples included *CYP2C19*-clopidogrel, *CYP2C9*/*VKORC1*-warfarin, *CYP2D6*-opioids, *CYP2D6*-tamoxifen, *DPYD*-fluoropyrimidines, *HLA-B*15:02*-carbamazepine, and *HLA-B*57:01*-abacavir. However, the integration of pharmacogenetics into routine patient care was slow. High genotyping costs, a lack of consensus guidelines for tailoring pharmacotherapy on the basis of genetic test results, and limited options for informing clinicians of genetic test results at the time of drug prescribing (beyond a paper-based laboratory report) made large-scale implementation models impracticable.

The Human Genome Project bolstered DNA genotyping and sequencing technologies, resulting in a drastic decline in costs by the mid-to-late 2000s.[11] Affordable Clinical Laboratory Improvement Amendments (CLIA)-certified array-based genomics panels capable of interrogating hundreds of genes and thousands of variants facilitated the expansion of genetic testing into clinical practice. As more genes were tested on a single platform, the term *pharmacogenomics* (i.e., the study of how the genome influences drug response) became more common than *pharmacogenetics* (i.e., the study of how a gene or genes influence drug response). By the early 2010s, several large-scale pharmacogenomics implementation science programs had been launched that used array-based genomics panels to preemptively genotype patients.[12–16] Simultaneously, the Centers for Medicare & Medicaid Services (CMS) started an electronic health record (EHR) incentive program that promoted the adoption of EHR software. EHR software platforms in turn enabled the development of clinical decision support (CDS) tools that communicated important genomics information at the time of drug prescribing and verification.[17–20] The Clinical Pharmacogenetics Implementation Consortium (CPIC; www.cpicpgx.org) was established during this time to provide evidence-based guidelines for optimizing drug therapy on the basis of genetic test results.[6] By the middle 2010s, clinical pharmacist–managed pharmacogenomics clinical services were becoming more widespread, including the establishment of pharmacogenomics ambulatory clinics.[21,22]

In addition to germline variations, precision pharmacotherapy strategies were emerging to identify the genetic mutations driving cancer (i.e., somatic mutations) to guide targeted drug therapy.[23,24] Among the first targeted cancer therapies introduced into clinical practice were trastuzumab for HER2-positive breast cancer and imatinib for *BCR-ABL* positive chronic myeloid leukemia.[25–27] During the 2010s, the number of anticancer drugs targeting specific somatic mutations increased exponentially.[28,29] Clinical trials were introduced that called for patients to receive targeted therapy on the basis of molecular profiling, regardless of histology (i.e., cancer type).[30–32] The 2017 FDA approval of pembrolizumab for any advanced solid tumor with microsatellite instability highlights the paradigm shift of selecting anticancer agents on the basis of molecular alterations instead of histology. Cancer genomics profiling is now emerging as standard of care for numerous cancer types, with CMS recently issuing a national coverage determination for a comprehensive genomics profiling assay as a companion diagnostic for advanced, recurrent, or refractory solid tumors.[33]

Genomics analysis has expanded beyond human germline and somatic genomes to include microbial genomes. Antimicrobial stewardship programs are adopting microbiologic molecular rapid diagnostic tests to identify the presence of bacterial or fungal organisms (e.g., *Staphylococcus* spp., *Klebsiella* spp., *Candida* spp.) and associated antimicrobial resistance genes.[34] These tests are often performed in patients with life-threatening infections who are most likely to benefit from earlier organism identification and institution of targeted therapies. Similarly, viral genotypes are now routinely used to guide antiviral therapy for diseases such as HIV and hepatitis C.

Moreover, numerous publications now provide detailed descriptions of clinical pharmacogenomics implementation models, educational programs, and clinical research methods.[21–24,35–44] A 2015 American Society of Health-System Pharmacists position statement delineated pharmacists' responsibilities and functions in clinical pharmacogenomics.[45] A goal of the present paper is to identify commonalities among successful clinical pharmacogenomics and educational programs and provide recommendations for how ACCP can leverage and advance these common themes. Opportunities for supporting the research needed to move clinical pharmacogenomics forward are also discussed. The following sections on clinical pharmacogenomics implementation, education, and research focus on the inherited (germline) human genome. However, the recommendations can be extrapolated to the entire field of precision pharmacotherapy.

Clinical Pharmacogenomics Implementation Science

The goal of clinical pharmacogenomics implementation science is to improve pharmacotherapy outcomes by seamlessly integrating evidence-based genomics data with other unique patient- and disease-specific characteristics to guide drug selection and dosing. Numerous clinical pharmacogenomics implementation models have been used to integrate genomics information into patient care. Early implementers, primarily at academic health centers, deployed reactive testing (i.e., at the time of drug prescribing) and focused on only one or two gene-drug pairs. These early implementation models typically used pharmacist-managed consultation services to guide gene-based dosing recommendations.[22,35,46–48] Later, implementation models expanded to include preemptive, panel-based approaches that interrogate numerous genes at once.[49] Other examples of implementation models include the establishment of standalone ambulatory pharmacogenomics clinics,[21,22] together with efforts to integrate pharmacogenomics into medication therapy management.[50,51] Irrespective of the implementation model used, five common themes underlying these successful implementation efforts have emerged (Table 1): engaging with key stakeholders, prioritizing gene-drug pairs for implementation, selecting a pharmacogenomics test, establishing EHR infrastructure, and maintaining sustainability.

Engaging with Key Stakeholders

Cultivating strong institutional support, ranging from executive leaders to end users (e.g., physicians, pharmacists, and patients), is essential for implementing pharmacogenomics into patient care. Obtaining institutional support typically involves understanding how a new clinical service will be evaluated and aligning the deliverables with those valued by the institution. Executive leaders, together with other key stakeholders like the department of laboratory medicine, often request a budget impact analysis. This analysis should quantify the resources needed from the stakeholders and summarize the expected costs, benefits, and potential savings.[52] This may involve evaluating the institutions' payer portfolio, patients' interest in and ability to pay for pharmacogenomics testing, and whether implementation will occur in a bundled payment or a fee-for-service environment.

A strategy for obtaining buy-in from physicians and other health care professionals is providing educational programs focused on clinical evidence supporting clinical pharmacogenomics implementation and its benefit to patients. Another common theme among successful implementation programs is collaborating with existing groups (e.g., pharmacy and therapeutics committees) and/or creating a pharmacogenomics oversight committee. Members of an oversight committee may include, but not be limited to, pharmacists, physicians, pathologists, nurses, genetic counselors, clinical informatics personnel, and billing specialists.

Prioritizing Gene-Drug Pairs for Implementation

CPIC guidelines, FDA prescribing information (e.g., boxed warnings), and literature searches can be used to identify drugs with sufficient evidence to warrant clinical pharmacogenomics implementation. A shared characteristic among successful pharmacogenomics implementation programs is understanding the prescribing patterns of drugs with actionable genomics results and which providers are prescribing them. The percentage of patients exposed to a particular drug, the severity of the gene-drug interaction, and the availability of alternative therapies can be used to prioritize implementation efforts. The frequencies of genetic variations that influence drug response can differ by race and ethnicity. Obtaining race and ethnic demographics of patients and calculating the expected frequency of actionable genetic variants within a patient population can also be used to prioritize implementation efforts. Resources such as CPIC or the Pharmacogenomics Knowledgebase (PharmGKB) can provide information about genetic variation frequencies among races and ethnicities.[6,53]

Selecting a Pharmacogenomics Test

The number of genomics variations interrogated and associated interpretations can vary among clinical pharmacogenomics testing platforms.[54] Similar to how race and ethnicity can influence the prioritization of gene-drug pairs for implementation, race and ethnicity influence the selection of a pharmacogenomics testing platform. Pharmacogenomics testing options should be evaluated to determine whether a particular test provides adequate coverage of the variants observed among the patient population of interest. If the CPIC guidelines are used to guide implementation, selecting a reference laboratory that provides interpretations concordant with CPIC should be considered. Other factors to consider when selecting a pharmacogenomics test include turnaround time, sample collection logistics (e.g., blood sample or buccal swab), need for a single gene test or genomics panel, and costs.[55] Certain reference laboratories may provide billing services together with financial assistance programs that are based on a patient’s income.

For early adopters of clinical pharmacogenomics, selecting a pharmacogenomics test has mainly been a well-thought-out process that considers several clinical factors. However, direct-to-consumer (DTC) testing can add a “Wild West” component to pharmacogenomics implementation. The FDA has recently approved DTC tests for cancer risk (i.e., *BRCA1* and *BRCA2*), pharmacogenomics, and certain conditions such as G6PD deficiency, Parkinson disease, and Alzheimer disease. DTC tests allow individuals to purchase pharmacogenomics panel testing, typically for a few hundred dollars. The quality of a DTC test in the context of variant coverage and its associated interpretations may vary among reference laboratories. DTC genomics tests can dramatically affect pharmacies, particularly in community settings where patients typically have easy access to pharmacists.

Establishing EHR Infrastructure

Clinical pharmacogenomics implementation models have focused on EHR infrastructure. EHRs allow genomics data to be incorporated into continuity of care as patients transition between care settings within health care organizations. However, using the EHR for curating and disseminating genomics data remains one of the most challenging steps in implementation. EHR terminologies and standards (e.g., LOINC, SNOMED, HL7, FHIR) are limited to support the discrete transfer of pharmacogenomics results from laboratories to EHRs.[56] Furthermore, genomics information may be relevant throughout a patient's life. For example, a *CYP2D6* result obtained to guide antidepressant selection may be important several years later to guide pain management. Simply scanning a document or entering other nondiscrete pharmacogenomics information into the EHR is insufficient, given that end users, including physicians and clinical pharmacists, may find it almost impossible to retrieve the pharmacogenomics results years later. In addition, non-discrete data may hamper the ability to appropriately manage changes in the clinical application of a genetic result over a patient's lifetime. CDS tools have emerged as the primary means to deliver EHR-integrated genomics data in a meaningful way.

Several groups and organizations have developed methodologies to support the integration of pharmacogenomics data into the EHR, including the CPIC, the Implementing Genomics in Practice study (IGNITE; https://ignite-genomics.org/spark-toolbox), and the Electronic Medical Records and Genomics Network (https://emerge.mc.vanderbilt.edu/ and https://cdskb.org/).[14, 57, 58] Efforts have focused on curating discrete pharmacogenomics data in a patient-centric, time-independent manner to support active and passive CDS.[59] Active CDS tools focus primarily on interruptive "pop-up" alerts that provide clinicians with meaningful information at the point of care (e.g., drug-genotype-specific recommendations).[17] Passive CDS tools include result portals, comments, and interpretations, which reside in the background waiting for the user to access them.[22] Target audience, alert fatigue, practice setting, and clinical importance determine which tools are most appropriate in a given situation. Irrespective of the tools used, it is critical to follow the "CDS Five Rights" (i.e., the right information to the right people through the right channels in the right intervention formats at the right points in workflow) and to engage clinical informatics specialists early in EHR integration and CDS build efforts.[60]

Maintaining Sustainability

Ongoing efforts are needed to sustain the pharmacogenomics clinical services that have been implemented. Continuous provider education, maintenance and further development of CDS tools, and genomics test reimbursement are key considerations for sustainability.[61] Although reimbursement of pharmacogenomics tests may minimize the financial burden for institutions and patients, it often fails to provide significant revenue. In an era of DTC genomics tests and lowered costs of whole exome sequencing, reimbursement models for cognitive services related to reinterpreting data and applying these data to patient care may emerge as key drivers for sustainability.

Transitions from fee-for-service to value-based care also affect the sustainability of pharmacogenomics services. In a value-based care system, reimbursements are bundled into a lump-sum payment for all services performed during an episode of care. Clinical services that do not demonstrate value are less likely to be rewarded through lump-sum reimbursement dollars that support and sustain the service. In a value-based health care model, pharmacogenomics clinical services are unlikely to be sustainable if value propositions such as improved pharmacotherapy outcomes and reduced costs to treat drug-induced toxicities are not met.[52,62] Thus, systematically evaluating operational metrics on a regular basis is essential for demonstrating value and promoting long-term sustainability.

ACCP can help sustain the role of clinical pharmacists in implementing clinical pharmacogenomics. Moreover, ACCP can endorse and promote existing resources such as the CPIC guidelines and implementation tools developed by IGNITE and others. Opportunities also exist to provide educational resources that describe how to perform pharmacogenomics-specific budget impact analyses and evaluate operational metrics to demonstrate clinical value. Recommendations for ACCP support of clinical pharmacogenomics implementation efforts are summarized in Table 2.

Pharmacogenomics Education

Effective clinical pharmacogenomics implementation begins with effective education of students, postgraduate trainees, clinicians, and patients. There is a growing need to expand pharmacogenomics education and share best practices for each of these groups. As the field of pharmacogenomics continues to evolve, educational strategies must evolve in parallel to meet the needs of contemporary clinical pharmacogenomics practices.

Pharmacogenomics Education for Pharmacists

Inclusion of pharmacogenomics principles and clinical application in the pharmacy curricula is stipulated by the Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree,[63] and the North American Pharmacist Licensure Examination includes pharmacogenomics as a required competency.[64] Pharmacogenomics education provided within pharmacy curricula is diverse. Pharmacy programs continue to explore the optimal quantity, delivery, and placement of pharmacogenomics content.[35,65] Pharmacogenomics content may be integrated (i.e., threaded) throughout the required pharmacotherapeutic coursework or offered as a standalone or elective course. More recently, novel approaches such as participatory (i.e., student) genotyping have emerged in the classroom.[43,66] Independent of the format used, case-based examples provide an excellent learning tool, particularly cases that require students to integrate evidence-based genomics data with other unique patient- and disease-specific characteristics to guide drug selection and dosing. Case-based teaching can also be integrated into introductory and advanced pharmacy practice experiences (IPPEs, APPEs). In addition, the Genetics/Genomics Competency Center (G2C2) provides pharmacogenomics competencies for pharmacists, which may serve as a blueprint for developing the educational content in pharmacy curricula.[67]

There is currently much debate regarding postgraduate pharmacogenomics training. One side of the debate is that all postgraduate training should integrate pharmacogenomics to the level pertinent to the generalist clinician. Proponents of this viewpoint argue that pharmacogenomics, much like pharmacokinetics, is a clinical tool relevant to all clinical pharmacists rather than its own specialty area of practice. The other side of the debate is that specialized pharmacogenomics residency and fellowship programs may help train future clinical and research faculty leaders. It can be argued that both viewpoints are correct. For the pharmacy profession to fully embrace precision pharmacotherapy, every pharmacist needs a basic understanding of pharmacogenomics that, at the minimum, encompasses knowledge about the CPIC guidelines and FDA genomics-based dosing recommendations. Integrating pharmacogenomics competencies and training into existing postgraduate year one (PGY1) and PGY2 residency curricula will help ensure that future clinical pharmacists can appropriately interpret and apply pharmacogenomics test results to patient care as they pertain to future clinical pharmacists' areas of practice.

Investing in specialized postgraduate training programs is essential to address growing needs in the emerging field of clinical pharmacogenomics. Implementing a sophisticated clinical pharmacogenomics service requires expertise across genomics, pharmacology, therapeutics, clinical informatics, and, in many instances, unique legal and ethical issues (e.g., identification and reporting of incidental genomics findings). It is unlikely that a PGY1 or non-pharmacogenomics PGY2 residency can effectively teach all aspects of clinical pharmacogenomics and its successful implementation, particularly given that use of clinical pharmacogenomics in clinical practice is not yet widespread. In addition, faculty members with specialized training in pharmacogenomics can be valuable resources for other faculty and preceptors teaching student pharmacists, both in the classroom and as part of IPPEs and APPEs. By incorporating pharmacogenomics into student and residency curricula, together with further developing specialized postgraduate training programs, the pharmacy profession will have the basic knowledge to embrace precision pharmacotherapy and the needed leaders to advance clinical pharmacogenomics implementation, education, and research.

Given the rapid developments in clinical pharmacogenomics, many practicing clinical pharmacists may feel inadequately prepared to integrate pharmacogenomics into their practice settings.[68] Different strategies exist to enhance a practicing clinical pharmacist's knowledge and skills in pharmacogenomics, such as traditional continuing pharmacy education (CPE) programs, institution-specific training programs, online resources, and certificate programs.[35] The number of hours that a clinical pharmacist must devote to these resources can vary depending on the scope of the training and the educational needs of the individual. Certificate programs, also known as certificate training programs or advanced training programs, have recently emerged and are offered by several professional associations and educational institutions,[69,70] including ACCP with its Precision Medicine: Applied Pharmacogenomics Certificate Program (https://www.accp.com/PGx). Although the available certificate programs vary considerably in design and scope, they generally offer more comprehensive application- or practice-based clinical pharmacogenomics content than other resources.

Pharmacogenomics Education for Patients and Other Health Care Professionals

Educating patients about pharmacogenomics testing, what the test results mean, and the lifelong implications of such testing should be considered an essential function of clinical pharmacists providing precision pharmacotherapy. Although patients find value in pharmacogenomics testing, there are potential concerns related to privacy, cost, and the psychological consequences of testing. Clinical pharmacists should play a key role in patient education initiatives in person, by telephone, or through telemedicine counseling to explain pharmacogenomics test results to patients. Additional tools to provide patient education may include web-based educational videos, letters/pamphlets, and integrated patient portals.[71,72] As testing for pharmacogenomics and other germline variants begins to overlap and the focus of testing moves beyond pharmacokinetic genes, clinical pharmacists should collaborate with genetic counselors to enable a broader scope of genomics education. For example, discussions regarding risk of disease and associated family implications for *BRCA1/2* testing should be conducted by a genetic counselor, and discussions about opportunities for targeted therapy (i.e., PARP inhibitors) should be conducted by a clinical pharmacist.[73]

The primary methods of delivering education for health care providers have been institution-specific online or live modules (including grand rounds), point-of-care CDS tools, and continuing education programs. Online modules and CDS tools often provide links to other educational resources (e.g., PharmGKB, CPIC, and G2C2).[74] Various models, including physician ground rounds and web-based continuing education modules, have shown positive outcomes related to pharmacogenomics education.[75,76] However, inherent barriers such as provider time constraints and learner attitudes, together with financial and personnel resources, necessitate a multimodal approach to delivering education. Combining the use of point-of-prescribing resources embedded in the EHR with ongoing live educational opportunities provides clinicians with multiple points of exposure to support and reinforce pharmacogenomics education.[77]

All clinical pharmacists should possess a basic and functional knowledge of pharmacogenomics to adequately support clinical pharmacogenomics at their practice sites. ACCP can support educational needs through continued advocacy for the inclusion of pharmacogenomics education in pharmacy curricula and continued development of clinical pharmacist–oriented educational resources (e.g., CPE and certificate programs). Providing up-to-date patient education and clinician educational resources will further support the pharmacogenomics educational role of clinical pharmacists. A summary of recommendations for how ACCP can support pharmacogenomics education initiatives is provided in Table 2.

Clinical Pharmacogenomics Research

Value

Pharmacogenomics implementation models have mainly focused on integrating genomics data into patient care, with limited resources available to measure outcomes. Thus, data are limited to establish whether current pharmacogenomics implementation efforts unequivocally improve patient outcomes and do so in a cost-effective manner. This issue highlights both a critical need and an excellent research opportunity to evaluate the value of pharmacogenomics-based interventions in patient care.[44]

Determining the value of a pharmacogenomics test is complex and includes variables such as cost of the test itself, cost and effectiveness of alternative treatment, frequency of variant alleles, prevalence of adverse drug reactions, scope of the evaluation (e.g., single gene-drug evaluation vs. panel testing that may affect future outcomes), and evidence of the clinical effectiveness of pharmacogenetics testing.[78] As preemptive testing becomes more common and less expensive, the cost-effectiveness of testing is hypothesized to become more favorable.[78] However, this hypothesis does not settle debates in the field – the major one being what constitutes "high-quality" evidence of clinical effectiveness. In particular, randomized controlled trials (RCTs) remain the gold standard for clinical research and are often relied on to show the benefit of an intervention; however, conducting RCTs to evaluate the benefit of clinical pharmacogenomics is expensive and logistically complex. RCTs require large patient cohorts to capture rare variants/phenotypes and have ethical considerations.[79] Therefore, innovative trial designs are critical for future clinical pharmacogenomics research efforts and will likely include the use of pragmatic studies, quality improvement projects, well-designed retrospective studies, and meta-analyses. A multitude of evidence, rather than a single RCT, will likely be needed to demonstrate the value of clinical pharmacogenomics.[80] Such evidence will also be essential in expanding reimbursement models and advancing the roles and responsibilities of clinical pharmacists in pharmacogenomics.

Implementation

As the field of clinical pharmacogenomics continues to evolve, there is a corresponding need for well-designed research studies that systematically assess implementation-related outcomes.[81] Examples include acceptability, adoption, appropriateness, cost, coverage (penetration), feasibility, fidelity, and sustainability of an intervention or program.[82] Implementation metrics such as these are often crucial for ongoing institutional support of a clinical pharmacogenomics program. Along the same lines, there is an increased need for rigorous qualitative research studies to evaluate patient and provider perspectives about the clinical usefulness of pharmacogenomics testing.[83] To overcome current health care disparities, future clinical pharmacogenomics research studies should include more diverse patient populations (e.g., minorities, children, patients of low socioeconomic status) to ensure that all patients benefit from pharmacogenomics.[44] At the same time, assessments of how to most effectively deliver pharmacogenomics test results at the point of care and provide patient and provider education are also fruitful research directions. Clinical pharmacists are well positioned to lead and participate in these endeavors.[84]

The current era of precision medicine extends beyond genomics and seeks to integrate patient health data with genomics, epigenomics, transcriptomics, proteomics, and metabolomics data to improve the prevention and treatment of disease. Integration of various omics-based platforms, coined "panomics," holds the promise of future biomarker discovery.[85] Clinical pharmacists and pharmacologists will play a critical role in researching and applying panomic approaches to understand patient factors that contribute to variability in drug response. As new and clinically meaningful biomarkers are adopted in clinical practice (e.g., PD-L1 expression and tumor mutation burden status for immunotherapy treatment opportunities),[86] clinical pharmacists will have to remain nimble and adapt their practice models to incorporate these discoveries.

There remains a critical need for outcomes-based research to establish value and evaluate clinical pharmacogenomics implementation, with a future need for sophisticated models that can integrate panomics into patient care. Innovative study designs will be needed, together with funding mechanisms to support these initiatives. ACCP can help support these efforts by providing grant funding and training resources for clinical pharmacogenomics–based research as described in Table 2.

The Promising Future of Precision Pharmacotherapy

Application of pharmacogenomics to clinical practice has already yielded success by avoiding untoward drug effects and improving efficacy. Continued refinement of implementation models is needed that allows for the integration of genomics, other biomarkers, and unique patient and disease characteristics into precision pharmacotherapy strategies. In the near future, epigenomics, transcriptomics, proteomics, and metabolomics information will likely be integrated into precision pharmacotherapy implementation models. These advances will require sophisticated EHR and clinical informatics solutions. Outcome studies will be warranted to further understand how precision pharmacotherapy implementation efforts influence health outcomes and costs. As technologies quickly advance, pharmacist education will be of upmost importance, with the need for innovative methods to support clinical pharmacists' efforts to educate other health professionals and patients on complex precision pharmacotherapy topics. These continued efforts will conceivably translate to greatly improved pharmacotherapy outcomes that are cost-effective.

Conclusion

The field of pharmacogenomics and precision pharmacotherapy is evolving rapidly. Clinical pharmacists can play an instrumental role in pharmacogenomics efforts ranging from leading clinical pharmacogenomics implementation to stewarding the prudent use of pharmacogenomics data across the spectrum of care. Clinical pharmacists have the potential to sustain leadership in pharmacogenomics implementation, education, and research efforts. ACCP is well positioned to advance clinical pharmacist knowledge/skill development in pharmacogenomics and the broader field of precision pharmacotherapy. The recommendations provided herein are intended to serve as a guide for ACCP to support clinical pharmacogenomics implementation, education, and research as an essential component of precision pharmacotherapy.

Acknowledgements

We thank Dr. Brandon Bookstaver for serving as the liaison to the ACCP Board of Regents and Dr. Jill Kolesar for serving as an ad hoc member of the committee. We also thank the ACCP Board of Regents and the 2018 Task Force on Precision Medicine (Drs. Larissa Cavallari, Vicki Ellingrod, William Evans, Julie Johnson, Angela Kashuba, and Howard McLeod) for providing critical input.

Financial Disclosure

J. Kevin Hicks is supported by NCI P30CA076292, ASHP Research and Education Foundation, and OneOme and serves as an academic associate for Quest Diagnostics; Henry M. Dunnenberger is a paid consultant for Admera Health and Veritas Genetics; Ryan S. Funk is supported by KL2TR002367; David R. Bright is supported by RxGenomix; James C. Coons is supported by the National Association of Chain Drug Stores and United Therapeutics.

References

1. Bishop JR, Ellingrod VL. Precision pharmacotherapy enables precision medicine. Pharmacotherapy 2017;9:985–7.
2. Haldane JBS. Disease and evolution. Ric Sci Suppl 1949;19:68–76.
3. Sawin PB, Glick D. Atropinesterase, a genetically determined enzyme in the rabbit. Proc Natl Acad Sci U S A 1943;2:55–9.
4. Vogel F Moderne problem der humangenetik. Ergeb Inn Med U Kinderheik 1959;12:52–125.
5. Relling MV, Evans WE. Pharmacogenomics in the clinic. Nature 2015;7573:343–50.
6. Relling MV, Klein TE. CPIC: Clinical Pharmacogenetics Implementation Consortium of the Pharmacogenomics Research Network. Clin Pharmacol Ther 2011;3:464–7.
7. Evans WE, Horner M, Chu YQ, Kalwinsky D, Roberts WM. Altered mercaptopurine metabolism, toxic effects, and dosage requirement in a thiopurine methyltransferase-deficient child with acute lymphocytic leukemia. J Pediatr 1991;6:985–9.
8. Relling MV, Hancock ML, Rivera GK, et al. Mercaptopurine therapy intolerance and heterozygosity at the thiopurine *S*-methyltransferase gene locus. J Natl Cancer Inst 1999;23:2001–8.
9. Dubinsky MC, Reyes E, Ofman J, Chiou CF, Wade S, Sandborn WJ. A cost-effectiveness analysis of alternative disease management strategies in patients with Crohn's disease treated with azathioprine or 6-mercaptopurine. Am J Gastroenterol 2005;10:2239–47.
10. Marra CA, Esdaile JM, Anis AH. Practical pharmacogenetics: the cost effectiveness of screening for thiopurine s-methyltransferase polymorphisms in patients with rheumatological conditions treated with azathioprine. J Rheumatol 2002;12:2507–12.
11. National Human Genome Research Institute (NHGRI). DNA sequencing costs: data from the NHGRI Genome Sequencing Program (GSP). Available from https://www.genome.gov/sequencingcostsdata/. Accessed July 2018.
12. Bielinski SJ, Olson JE, Pathak J, et al. Preemptive genotyping for personalized medicine: design of the right drug, right dose, right time – using genomic data to individualize treatment protocol. Mayo Clin Proc 2014;1:25–33.
13. Fernandez CA, Smith C, Yang W, et al. Concordance of DMET plus genotyping results with those of orthogonal genotyping methods. Clin Pharmacol Ther 2012;3:360–5.
14. Gottesman O, Scott SA, Ellis SB, et al. The CLIPMERGE PGx program: clinical implementation of personalized medicine through electronic health records and genomics-pharmacogenomics. Clin Pharmacol Ther 2013;2:214–7.
15. Johnson JA, Burkley BM, Langaee TY, Clare-Salzler MJ, Klein TE, Altman RB. Implementing personalized medicine: development of a cost-effective customized pharmacogenetics genotyping array. Clin Pharmacol Ther 2012;4:437–9.
16. Oetjens MT, Denny JC, Ritchie MD, et al. Assessment of a pharmacogenomic marker panel in a polypharmacy population identified from electronic medical records. Pharmacogenomics 2013;7:735–44.

17. Bell GC, Crews KR, Wilkinson MR, et al. Development and use of active clinical decision support for preemptive pharmacogenomics. J Am Med Inform Assoc 2014;21:e1:e93–9. [PubMed: 23978487]
18. Hicks JK, Crews KR, Hoffman JM, et al. A clinician-driven automated system for integration of pharmacogenetic interpretations into an electronic medical record. Clin Pharmacol Ther 2012;5:563–6.
19. O'Donnell PH, Bush A, Spitz J, et al. The 1200 patients project: creating a new medical model system for clinical implementation of pharmacogenomics. Clin Pharmacol Ther 2012;4:446–9.
20. Peterson JF, Bowton E, Field JR, et al. Electronic health record design and implementation for pharmacogenomics: a local perspective. Genet Med 2013;10:833–41.
21. Dunnenberger HM, Biszewski M, Bell GC, et al. Implementation of a multidisciplinary pharmacogenomics clinic in a community health system. Am J Health Syst Pharm 2016;23:1956–66.
22. Hicks JK, Stowe D, Willner MA, et al. Implementation of clinical pharmacogenomics within a large health system: from electronic health record decision support to consultation services. Pharmacotherapy 2016;8:940–8.
23. Knepper TC, Bell GC, Hicks JK, et al. Key lessons learned from Moffitt's molecular tumor board: the Clinical Genomics Action Committee experience. Oncologist 2017;2:144–51.
24. Walko C, Kiel PJ, Kolesar J. Precision medicine in oncology: new practice models and roles for oncology pharmacists. Am J Health Syst Pharm 2016;23:1935–42.
25. Druker BJ, Talpaz M, Resta DJ, et al. Efficacy and safety of a specific inhibitor of the BCR-ABL tyrosine kinase in chronic myeloid leukemia. N Engl J Med 2001;14:1031–7.
26. O'Brien SG, Guilhot F, Larson RA, et al. Imatinib compared with interferon and low-dose cytarabine for newly diagnosed chronic-phase chronic myeloid leukemia. N Engl J Med 2003;11:994–1004.
27. Slamon DJ, Leyland-Jones B, Shak S, et al. Use of chemotherapy plus a monoclonal antibody against HER2 for metastatic breast cancer that overexpresses HER2. N Engl J Med 2001;11:783–92.
28. Vela CM, Knepper TC, Gillis NK, Walko CM, McLeod HL, Hicks JK. Quantitation of targetable somatic mutations among patients evaluated by a personalized medicine clinical service: considerations for off-label drug use. Pharmacotherapy 2017;9:1043–51.
29. U.S. Food and Drug Administeration (FDA). Table of pharmacogenomic biomarkers in drug labeling. Available from https://www.fda.gov/Drugs/ScienceResearch/ucm572698.htm. Accessed July 2018.
30. McNeil C NCI-MATCH launch highlights new trial design in precision-medicine era. J Natl Cancer Inst 2015;107(7).
31. Mullard A NCI-MATCH trial pushes cancer umbrella trial paradigm. Nat Rev Drug Discov 2015;8:513–5.
32. Von Hoff DD, Stephenson JJ Jr, Rosen P, et al. Pilot study using molecular profiling of patients' tumors to find potential targets and select treatments for their refractory cancers. J Clin Oncol 2010;33:4877–83.
33. CMS.gov. Decision memo for next generation sequencing (NGS) for Medicare beneficiaries with advanced cancer (CAG-00450N). Available from https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=290&DocID=CAG-00450N&bc=AAAAAAAAQAAA& Accessed July 2018.
34. Bauer KA, Perez KK, Forrest GN, Goff DA. Review of rapid diagnostic tests used by antimicrobial stewardship programs. Clin Infect Dis 2014;59(suppl 3):S134–45. [PubMed: 25261540]
35. Cavallari LH, Lee CR, Duarte JD, et al. Implementation of inpatient models of pharmacogenetics programs. Am J Health Syst Pharm 2016;23:1944–54.
36. Formea CM, Nicholson WT, Vitek CR. An inter-professional approach to personalized medicine education: one institution's experience. Per Med 2015;2:129–38.
37. Goldspiel BR, Flegel WA, DiPatrizio G, et al. Integrating pharmacogenetic information and clinical decision support into the electronic health record. J Am Med Inform Assoc 2014;3:522–8.

38. Hoffman JM, Haidar CE, Wilkinson MR, et al. PG4KDS: a model for the clinical implementation of pre-emptive pharmacogenetics. Am J Med Genet C Semin Med Genet 2014;1:45–55.
39. Manzi SF, Fusaro VA, Chadwick L, et al. Creating a scalable clinical pharmacogenomics service with automated interpretation and medical record result integration – experience from a pediatric tertiary care facility. J Am Med Inform Assoc 2017;1:74–80.
40. Nutescu EA, Drozda K, Bress AP, et al. Feasibility of implementing a comprehensive warfarin pharmacogenetics service. Pharmacotherapy 2013;11:1156–64.
41. Timbrook TT, Morton JB, McConeghy KW, Caffrey AR, Mylonakis E, LaPlante KL. The effect of molecular rapid diagnostic testing on clinical outcomes in bloodstream infections: a systematic review and meta-analysis. Clin Infect Dis 2017;1:15–23.
42. Weitzel KW, Elsey AR, Langaee TY, et al. Clinical pharmacogenetics implementation: approaches, successes, and challenges. Am J Med Genet C Semin Med Genet 2014;1:56–67.
43. Weitzel KW, McDonough CW, Elsey AR, Burkley B, Cavallari LH, Johnson JA. Effects of using personal genotype data on student learning and attitudes in a pharmacogenomics course. Am J Pharm Educ 2016;7:122.
44. Volpi S, Bult CJ, Chisholm RL, et al. Research directions in the clinical implementation of pharmacogenomics: an overview of US programs and projects. Clin Pharmacol Ther 2018;5:778–86.
45. ASHP statement on the pharmacist's role in clinical pharmacogenomics. Am J Health Syst Pharm 2015;7:579–81.
46. Crews KR, Cross SJ, McCormick JN, et al. Development and implementation of a pharmacist-managed clinical pharmacogenetics service. Am J Health Syst Pharm 2011;2:143–50.
47. Cavallari LH, Weitzel KW, Elsey AR, et al. Institutional profile: University of Florida Health Personalized Medicine Program. Pharmacogenomics 2017;5:421–6.
48. Fusaro VA, Brownstein C, Wolf W, et al. Development of a scalable pharmacogenomic clinical decision support service. AMIA Jt Summits Transl Sci Proc 2013;60.
49. Dunnenberger HM, Crews KR, Hoffman JM, et al. Preemptive clinical pharmacogenetics implementation: current programs in five US medical centers. Annu Rev Pharmacol Toxicol 2015;55:89–106. [PubMed: 25292429]
50. Haga SB, Moaddeb J, Mills R, Patel M, Kraus W, Allen LaPointe NM. Incorporation of pharmacogenetic testing into medication therapy management. Pharmacogenomics 2015;17:1931–41.
51. Reiss SM. Integrating pharmacogenomics into pharmacy practice via medication therapy management. J Am Pharm Assoc (2003) 2011;6:e64–74.
52. Mason NT, Bell GC, Quilitz RE, Greene JN, McLeod HL. Budget impact analysis of CYP2C19-guided voriconazole prophylaxis in AML. J Antimicrob Chemother 2015;11:3124–6.
53. Thorn CF, Klein TE, Altman RB. Pharmacogenomics and bioinformatics: PharmGKB. Pharmacogenomics 2010;4:501–5.
54. Caudle KE, Keeling NJ, Klein TE, Whirl-Carrillo M, Pratt VM, Hoffman JM. Standardization can accelerate the adoption of pharmacogenomics: current status and the path forward. Pharmacogenomics 2018;19:847–60. [PubMed: 29914287]
55. Vo TT, Bell GC, Owusu Obeng A, Hicks JK, Dunnenberger HM. Pharmacogenomics implementation: considerations for selecting a reference laboratory. Pharmacotherapy 2017;9:1014–22.
56. Caudle KE, Dunnenberger HM, Freimuth RR, et al. Standardizing terms for clinical pharmacogenetic test results: consensus terms from the Clinical Pharmacogenetics Implementation Consortium (CPIC). Genet Med 2017;2:215–23.
57. Cavallari LH, Beitelshees AL, Blake KV, et al.; IGNITE Pharmacogenetics Working Group. An opportunity for building evidence with pharmacogenetic implementation in a real-world setting. Clin Transl Sci 2017;3:143–6.
58. Gottesman O, Kuivaniemi H, Tromp G, et al. The Electronic Medical Records and Genomics (eMERGE) Network: past, present, and future. Genet Med 2013;10:761–71.

59. Hicks JK, Dunnenberger HM, Gumpper KF, Haidar CE, Hoffman JM. Integrating pharmacogenomics into electronic health records with clinical decision support. Am J Health Syst Pharm 2016;23:1967–76.

60. Osheroff J, Teich J, Levick D, et al. Improving Outcomes with Clinical Decision Support: An Implementer's Guide, 2nd ed. Chicago: HIMSS Publishing, 2012.

61. Levy KD, Blake K, Fletcher-Hoppe C, et al. Opportunities to implement a sustainable genomic medicine program: lessons learned from the IGNITE Network. Genet Med 2019;21:743–7. [PubMed: 29997387]

62. Brixner D, Biltaji E, Bress A, et al. The effect of pharmacogenetic profiling with a clinical decision support tool on healthcare resource utilization and estimated costs in the elderly exposed to polypharmacy. J Med Econ 2016;3:213–28.

63. Lee JA, Lee CR, Reed BN, et al. Implementation and evaluation of a *CYP2C19* genotype-guided antiplatelet therapy algorithm in high-risk coronary artery disease patients. Pharmacogenomics 2015;4:303–13.

64. Pezalla EJ. Payer view of personalized medicine. Am J Health Syst Pharm 2016;23:2007–12.

65. Rao US, Mayhew SL, Rao PS. Strategies for implementation of an effective pharmacogenomics program in pharmacy education. Pharmacogenomics 2015;8:905–11.

66. Adams SM, Anderson KB, Coons JC, et al. Advancing pharmacogenomics education in the core PharmD curriculum through student personal genomic testing. Am J Pharm Educ 2016;1:3.

67. Roederer MW, Kuo GM, Kisor DF, et al. Pharmacogenomics competencies in pharmacy practice: A blueprint for change. J Am Pharm Assoc (2003) 2017;1:120–5.

68. McCullough KB, Formea CM, Berg KD, et al. Assessment of the pharmacogenomics educational needs of pharmacists. Am J Pharm Educ 2011;3:51.

69. Haga SB, Moaddeb J. Proposal for a pharmacogenetics certificate program for pharmacists. Pharmacogenomics 2016;6:535–9.

70. Kisor DF, Bright DR, Chen J, Smith TR. Academic and professional pharmacy education: a pharmacogenomics certificate training program. Per Med 2015;6:563–73.

71. Mills R, Ensinger M, Callanan N, Haga SB. Development and initial assessment of a patient education video about pharmacogenetics. J Pers Med 2017;2.

72. Rosenman MB, Decker B, Levy KD, Holmes AM, Pratt VM, Eadon MT. Lessons learned when introducing pharmacogenomic panel testing into clinical practice. Value Health 2017;1:54–9.

73. Zierhut HA, Campbell CA, Mitchell AG, Lemke AA, Mills R, Bishop JR. Collaborative counseling considerations for pharmacogenomic tests. Pharmacotherapy 2017;9:990–9.

74. Giri J, Curry TB, Formea CM, Nicholson WT, Rohrer Vitek CR. Education and knowledge in pharmacogenomics: still a challenge? Clin Pharmacol Ther 2018;5:752–5.

75. Dodson C Oncology nurses' knowledge of pharmacogenomics before and after implementation of an education module. Oncol Nurs Forum 2018;5:575–80.

76. Luzum JA, Luzum MJ. Physicians' attitudes toward pharmacogenetic testing before and after pharmacogenetic education. Per Med 2016;2:119–27.

77. Rohrer Vitek CR, Abul-Husn NS, Connolly JJ, et al. Healthcare provider education to support integration of pharmacogenomics in practice: the eMERGE Network experience. Pharmacogenomics 2017;10:1013–25.

78. Hughes DA. Economics of pharmacogenetic-guided treatments: underwhelming or overstated? Clin Pharmacol Ther 2018;5:749–51.

79. Frueh FW. Back to the future: why randomized controlled trials cannot be the answer to pharmacogenomics and personalized medicine. Pharmacogenomics 2009;7:1077–81.

80. Cavallari LH, Lee CR, Beitelshees AL, et al. Multisite investigation of outcomes with implementation of CYP2C19 genotype-guided antiplatelet therapy after percutaneous coronary intervention. JACC Cardiovasc Interv 2018;2:181–91.

81. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health 2011;2:65–76.

82. Peters DH, Adam T, Alonge O, Agyepong IA, Tran N. Implementation research: what it is and how to do it. BMJ 2013;347:f6753. [PubMed: 24259324]

83. Curry LA, Nembhard IM, Bradley EH. Qualitative and mixed methods provide unique contributions to outcomes research. Circulation 2009;10:1442–52.

84. Owusu-Obeng A, Weitzel KW, Hatton RC, et al. Emerging roles for pharmacists in clinical implementation of pharmacogenomics. Pharmacotherapy 2014;10:1102–12.

85. Sandhu C, Qureshi A, Emili A. Panomics for precision medicine. Trends Mol Med 2018;1:85–101.

86. Skoulidis F, Goldberg ME, Greenawalt DM, et al. STK11/LKB1 mutations and PD-1 inhibitor resistance in *KRAS*-mutant lung adenocarcinoma. Cancer Discov 2018;7:822–35.

Table 1.

Key Components of CPIC Initiatives

Engaging with Key Stakeholders	Prioritizing Gene-Drug Pairs for Implementation	Selecting a Pharmacogenomics Test	Establishing EHR Infrastructure	Maintaining Sustainability
Identify and engage multidisciplinary institutional champions and stakeholders	Review clinical evidence and select gene-drug pairs with sufficiently strong evidence that warrants clinical implementation	Determine whether a single gene or multigene panel test is most appropriate for the gene-drug pair(s) selected for implementation	Identify methods for discretely curating pharmacogenomics data in the EHR	Develop continuing education for clinicians and patients to sustain ongoing pharmacogenomics efforts
Determine the value proposition of the pharmacogenomics initiative for the institution	Evaluate drug-prescribing frequencies and which providers are prescribing the drugs of interest	Engage with the laboratory medicine department to determine whether genetic testing should be performed internally or specimens sent to a reference laboratory	Collaborate with clinical informatics teams to develop CDS tools that alert clinicians of important genomics information	Maintain and further develop CDS tools to support ongoing pharmacogenomics efforts
Identify potential barriers to implementing clinical pharmacogenomics and formulate solutions	Evaluate the demographics of the patient population and calculate the expected frequencies of actionable genetic variants	Evaluate the demographics of the patient population to determine whether a genetic test provides appropriate coverage, given the expected variant frequencies	Obtain provider input on clinical recommendations found in CDS tools	Perform systematic evaluations of operational metrics and deliverables to demonstrate value
Organize a formal precision medicine or pharmacogenomics oversight committee			Obtain provider input on CDS workflows, including when to use active vs. passive CDS	Integrate pharmacogenomics into institution-specific quality improvement projects
Engage with pharmacy leadership to integrate pharmacogenomics into existing clinical pharmacist services	Align gene-drug pair selection with institutional deliverables and patient care goals	Formulate billing and reimbursement matrices, including the need for a reference laboratory that provides billing services	Establish standard operating procedures for evaluating, maintaining, and updating CDS tools	Communicate findings of value assessments to key stakeholders and institutional leadership
Engage other institutional groups and task forces (e.g., anticoagulation task force, CDS committee, risk management)		Select a test that is suitable for workflow logistics, including turnaround time and specimen type (e.g., blood or buccal swab)		
		Verify that a selected laboratory has appropriate state and federal certification/licensure		

CDS = clinical decision support; CPIC = Clinical Pharmacogenetics Implementation Consortium; EHR = electronic health record.

Table 2.

Recommendations for ACCP Support of Clinical Pharmacists' Efforts to Advance Clinical Pharmacogenomics

Clinical Pharmacogenomics Implementation Science
• Curate and disseminate pharmacogenomics implementation science education resources
- Endorse the CPIC guidelines together with publicizing new or updated guidelines
- Create a resource page on the ACCP website that summarizes pertinent resources and provides links to implementation guides and templates (e.g., IGNITE and CPIC resources)
- Provide webinars from content experts related to implementation strategies (e.g., budget impact analysis, engaging key stakeholders), clinical informatics, and quantitation of operational metrics
• Promote and support the development of short "sabbaticals" or traineeships at sites implementing pharmacogenomics clinical services to provide hands-on training
• Engage with other professional organizations to advocate the clinical pharmacist's role in providing pharmacogenomics services
- For gene-drug pairs with strong evidence warranting implementation, jointly advocate reimbursement of pharmacogenomics testing
- Advocate reimbursement of medication optimization that includes cognitive services for interpreting and applying pharmacogenomics results
Clinical Pharmacogenomics Education
• Support the inclusion of pharmacogenomics education in pharmacy curricula (e.g., didactic and experiential courses) and residency training programs
• Foster the development of pharmacogenomics specialty postgraduate training programs
• Develop and disseminate pharmacist-oriented education resources
- Update the 2016 ACCP Pharmacotherapy Didactic Curriculum Toolkit (https://www.accp.com/docs/positions/misc/AM_Pharm_Toolkit_2016_revised.pdf) to include "pharmacogenomics considerations" as a tier 1[a] topic for each disorder that highlights actionable gene-drug pairs
- Offer a variety of knowledge-, application-, and practice-based CPE programs, including certificate programs
- Update the text of ACCP's *Pharmacogenomics: Applications to Patient Care*, when warranted, and consider developing an abbreviated version of the book for home study, knowledge-based CPE credit
• Create and disseminate patient education and other health care professional–oriented education resources
- Build a resource page on the ACCP website that summarizes pertinent resources and provides links to patient-oriented pharmacogenomics education (e.g., IGNITE)
- Create a resource page on the ACCP website that summarizes pertinent resources and provides links to health care professional–oriented pharmacogenomics education (e.g., IGNITE, G2C2)
• Engage with other organizations to promote interdisciplinary education models (e.g., NIH/NHGRI Inter-Society Coordinating Committee for Practitioner Education in Genomics)
Clinical Pharmacogenomics Research
• Advocate research funding and provide grant opportunities for clinical pharmacogenomics research
• Recruit mentors and mentees interested in clinical pharmacogenomics research to participate in ACCP's MeRIT and FIT programs
• Support the development of pharmacogenomics-related practice-based research and network studies

[a]Tier 1 = Students receive education and training on this topic to prepare them to provide collaborative, patient-centered care upon graduation and licensure.

CPE = continuing pharmacy education; FIT = Focused Investigator Training; G2C2 = Genetics/Genomics Competency Center; IGNITE = Implementing Genomics in Practice; MeRIT = Mentored Research Investigator Training; NHGRI = National Human Genome Research Institute; NIH = National Institutes of Health.