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Advancing pharmacogenomics as a component of precision medicine: How, where and who?

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Introduction

Pharmacogenomics is an important element of precision medicine. Advances in pharmacogenomics implementation have been made but significant barriers remain, including evidence, reimbursement, and clinician knowledge, among others. Widespread adoption of pharmacogenomics requires overcoming these barriers, a clinician champion group, which we propose will be pharmacists, and an easily accessible setting, which may be the community pharmacy. Whatever the path, it must be evidence-driven and pharmacogenomics must improve drug-related outcomes to become a standard of care.

President Obama's announcement of the Precision Medicine Initiative in his 2015 State of the Union address presents tremendous opportunities for the clinical pharmacology community. Precision medicine is centered on tailoring a person's care to their individual characteristics, and within drug therapy, precision medicine aligns nicely with the work of many clinical pharmacologists, whether in academia, industry, Food and Drug Administration, or practice. An important component of precision medicine is the use of genetic information to guide drug therapy decisions, or pharmacogenomics.

Pharmacogenomics can be broadly divided into two categories, use of germline variation to individualize drug treatment, and use of somatic variation to guide cancer therapy. The latter is making solid in-roads into patient care as hematologists and oncologists increasingly embrace this strategy. Additionally, most recently approved cancer treatments use a genetically-targeted approach. Herein we focus on use of germline variation to guide drug therapy decisions, which also include cancer treatments.

Clinical implementation of pharmacogenomics has seen significant advances in recent years, and multiple academic medical centers have embraced this approach (1,2), with approximately 7% of U.S. hospitals offering pharmacogenomic testing.(3) Progress in this area has been steady, but not without challenges, ranging from issues surrounding evidence, reimbursement, integration into the electronic health record, to education/knowledge of clinicians, among others.(1,2) The NIH-supported IGNITE Network (Implementing Genomics in Practice, http://ignite-genomics.org/) seeks to advance methods for effective

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and sustainable genomic medicine implementation into clinical practice, including outside the traditional academic medical center. Our experience to date is that implementation in private practice settings is challenging, and requires a local champion who will push the agenda within their institution. This leads to questions about how long it will take pharmacogenomics to be a routine part of care, and the keys to getting there.

Several elements seem fundamental to pharmacogenomics becoming part of mainstream care. There needs to be continued building of evidence that genetic associations with drug dose, response or toxicity are predictable in the clinical setting and improve patient-related outcomes in some way. The Clinical Pharmacogenetics Implementation Consortium (CPIC) guidelines, which are published in this journal, serve a critical role in evidence evaluation and provision of clear guidelines for implementing pharmacogenomics into clinical practice. CPIC and society guidelines will be important for continued advancement of the field. There must also be a cost-effective manner for generating and using genetic information. Substantial evidence supports a pre-emptive approach with generation of large amounts of data, for use over a lifetime, as the most logical strategy, providing a cost-effective means of generating data available for clinical use “as needed.”(1,2) At present this is primarily accomplished through chip-based approaches with pharmacogenetic “single nucleotide polymorphisms (SNPs)” or genome-wide SNP data, but in the future will likely arise through targeted sequencing or whole genome sequence data. However, current reimbursement patterns do not facilitate rapid movement toward this approach, leading to “one gene at a time” being tested, which is both unnecessarily expensive and typically delays availability of the data. Until generation of larger amounts of data can be supported by the healthcare system, and there is a mechanism for storing data in a manner that provides access across a patient’s care providers, wide-scale implementation of pharmacogenomics will remain challenged.

Clinician knowledge and comfort level with pharmacogenomic data is also a substantial barrier, thus educational programs and resources to support widespread adoption of precision medicine are critical. Although healthcare professionals identify the potential value of pharmacogenomic data, many feel unprepared to routinely apply it in practice. Indeed, the educational knowledge gap between science and clinical practice is often cited as one of the most significant barriers to routine clinical use of pharmacogenomic data.

Building a bridge across this educational gap, though, has been challenging for educators, and the need for clinician-friendly educational resources and practice-based tools is becoming paramount to the translation of this science to practice. Resources such as CPIC guidelines, NIH’s Genetics/Genomic Competency Center (http://g-2-c-2.org//) and Global Genetics and Genomics Community (http://g-3-c.org/enhttp://g-3-c.org), provide practical tools that can be used to engage learners, and illustrate clinical applications of precision medicine. NIH’s IGNITE Network is examining the effectiveness of educational strategies alongside its implementation research initiatives. Additional research is needed to identify ideal educational strategies and resources to enable clinicians to routinely translate the science underpinning precision medicine to the care of their patients.

Early trends in the movement of pharmacogenomics into routine clinical care involve novel, multidisciplinary models to help address these challenges. While initial clinical pharmacogenomics implementations were most commonly, and appropriately, undertaken in specialized, inpatient settings within academic or tertiary medical centers, there is increasing interest and uptake of pharmacogenomics in outpatient settings, particularly community pharmacies. The unifying point of a patient's drug therapy is the community pharmacy, and this raises critical questions about what role community-based pharmacists will play in facilitating widespread adoption of pharmacogenomics. Community pharmacists are considered the most easily accessible healthcare provider, and this, along with the centralizing aspect of the community pharmacy for medication information, makes the community pharmacist and the community pharmacy seem like a logical who and where for advancing use of pharmacogenomics in clinical practice. Although comprehensive medication management services are not yet widespread in community pharmacies, practitioners in this setting have demonstrated their ability to improve a variety of patient outcomes, including decreased cardiovascular event rates and emergency department visits (4); lower 30-day hospital readmission rates in heart failure (5); and improved self-care and adherence in diabetes (6), among others. Additionally, pharmacists in community pharmacy and other outpatient settings are increasingly seeking, and being granted, the right and ability to be compensated by third-party insurers for these services through provider status and other models, including for pharmacogenomics services.(7) However, most community pharmacists are not trained in pharmacogenomics, so educational strategies for advancing their knowledge in this area are critical. Pilot studies of pharmacogenomic implementations have been conducted in regional chain (8) and independent community pharmacies (9), and pharmacogenomic testing is now offered in national chain drug stores, including Rite-Aid and CVS. Although it is encouraging to see the broad patient and provider interest in pharmacogenomics in the community pharmacy, there has to be an appropriate balance between a sustainable business model and evidence-based approaches that improve the patient's medication-related care. Caution against rapid growth that may be driven by the financial interests of the pharmacy or commercial laboratory, but lacks the requisite clinical evidence is warranted. While there is some movement in this area, much work remains to be done to make pharmacogenomics in the community pharmacy setting a reality that meaningfully impacts patient care.

Whether it is in the community setting, or elsewhere, it is also clear that meeting the potential for pharmacogenomics as a piece of precision medicine requires individuals to advance the cause. Pharmacists (based in the community or elsewhere) may be best positioned to be the major health professional champions who help lead the multidisciplinary team needed to advance clinical use of pharmacogenomics. Indeed, there is already evidence that pharmacists are advancing clinical implementation in significant ways, with the development of collaborative practice models that incorporate the pharmacist as a stakeholder and clinician.(10) CPIC is organized and led by pharmacists, and among the last ten CPIC guidelines, seven have been first authored by pharmacists, with a third of the overall authorship on those guidelines being pharmacists. Lead authors on many of the papers describing pharmacogenomics implementations are pharmacists and the Pharmacogenetics Interest Group of the IGNITE network has a preponderance of leadership

by pharmacists. This is not to say that physicians and other healthcare professionals have not and will not play critical roles, but it seems that the pharmacists will be key in facilitating widespread use of pharmacogenomics over time.

Widespread adoption of well-documented care approaches, e.g. aspirin use post-myocardial infarction, can take up to two decades. Will use of pharmacogenomic data become part of routine care, and if so what is needed for it to happen sooner than twenty years? We have noted many barriers to widespread adoption, which include evidence, reimbursement models, informatics challenges, clinical knowledge gaps, and others. These must all be addressed, but it will also take an "army of champions." Those champions may increasingly be patients, who are taking larger, more active roles in their healthcare decisions, but we also project that pharmacists, and potentially community-based pharmacists, represent the likely healthcare provider champions who will move pharmacogenomics outside the walls of academia. Substantial work needs to be done, and changes in our healthcare system may be required to make this a reality.

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