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Pharmacogenomics in practice: a review and implementation guide

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Considerable efforts have been exerted to implement Pharmacogenomics (PGx), the study of interindividual variations in DNA sequence related to drug response, into routine clinical practice. In this article, we first briefly describe PGx and its role in improving treatment outcomes. We then propose an approach to initiate clinical PGx in the hospital setting. One should first evaluate the available PGx evidence, review the most relevant drugs, and narrow down to the most actionable drug-gene pairs and related variant alleles. This is done based on data curated and evaluated by experts such as the pharmacogenomics knowledge implementation (PharmGKB) and the Clinical Pharmacogenetics Implementation Consortium (CPIC), as well as drug regulatory authorities such as the US Food and Drug Administration (FDA) and European Medicinal Agency (EMA). The next step is to differentiate reactive point of care from preemptive testing and decide on the genotyping strategy being a candidate or panel testing, each of which has its pros and cons; then work out the best way to interpret and report PGx test results with the option of integration into electronic health records and clinical decision support systems. After test authorization or testing requirements by the government or drug regulators, putting the plan into action involves several stakeholders, with the hospital leadership supporting the process and communicating with payers, the pharmacy and therapeutics committee leading the process in collaboration with the hospital laboratory and information technology department, and healthcare providers (HCPs) ordering the test, understanding the results, making the appropriate therapeutic decisions, and explaining them to the patient. We conclude by recommending some strategies to further advance the implementation of PGx in practice, such as the need to educate HCPs and patients, and to push for more tests' reimbursement. We also guide the reader to available PGx resources and examples of PGx implementation programs and initiatives.

KEYWORDS

guidelines, implementation, pharmacogenomics, practice, pharmacogenetics

1 Introduction

Interindividual variability in drug response is driven by several extrinsic and intrinsic factors, with genetic variations being increasingly recognized among these factors that lead to changes in the activity or availability of drug-metabolizing enzymes (DMEs), receptors, channels, and other proteins involved in drug pharmacokinetics (PK) and pharmacodynamics (PD) (Thummel and Lin, 2014). Consequently, the term

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