Clinical Relevance of Pharmacogenetic Testing: Clinical vs. Ethical

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“Variability is the law of life and as no two faces are the same, so no two bodies are alike, and no two individuals react alike and behave alike under abnormal conditions which we know as disease.” [1]. The study of pharmacogenetics serves to explain variability in pharmacological response resulting from genetic differences. Pharmacogenetics is based on the observation of phenotypes and investigates variations in genes as they relate to drug metabolism. It allows for better comprehension of pharmacodynamics and pharmacokinetics in order to reduce potentially harmful side effects [1]. The mainstay of pharmacotherapy involves giving the right medication at the right dose to the right patient in order to treat a specific disease state or condition. Personalized medicine is achieved through having a comprehensive understanding of how a drug works, the pathology of the disease state, and drug response within individuals [1]. The idea of individualized medicine has been around for centuries. Notably, the Egyptian Papyrus Ebers contained more than 800 prescriptions, which were used to treat individual patients suffering from various conditions such as asthma and cancer. The goal of individualizing therapy is to reduce the quantity and severity of side effects and toxicities while reaching the desired therapeutic effect for the patient, yielding the most beneficial health outcomes. Pharmacogenetics allows for selection of pharmacological therapy based on a patient’s specific genetic makeup, therefore it has the potential to become an invaluable resource in certain fields of medicine to provide patients with tailored medication therapy.

Studies propose that pharmacogenetic testing is the missing link to better health outcomes. However, evidence also exists that suggest it is of little clinical relevance. Despite this conflicting evidence, the Food and Drug Administration (FDA) has approved more than 100 drugs with pharmacogenetic information included within their labels [2]. There is a multitude of pharmacogenetic tests available to identify genes that may affect drug metabolism. Pharmacogenetic testing remains a topic of controversy with conflicting evidence. The areas of particular interest and controversy include the following: cardiology, oncology, pain management, anti-retroviral, and antidepressant therapies.

Recent developments in the area of pharmacogenetics have raised some ethical issues that are receiving widespread consideration. Some ethical concerns that are discussed in the literature include the sharing and storage of genetic information, changes in professional-patient relationships, regulatory issues, and discrimination and stigmatization of groups and individuals. Some pharmacogenetics tests carry the possibility of revealing additional sensitive information about the patient. A confidentiality concern arises because genetic information is not only personal, but familial at the same time. Using pharmacogenetic testing to help understand the association of genetics and drug response, individuals from particular ethnic communities and well as people with certain disease states could be potentially be open to discrimination or stigmatization. The retention of DNA samples poses the problem that the individual’s genetic information would be stored in computerized databases and could be vulnerable to a violation of privacy. This could potentially lead to discrimination by employers and insurance companies in the event that this information was accessed inappropriately. Pharmacogenetics is also likely to create a more complex doctor-patient encounter. There will be an increased need for genetic knowledge throughout all levels of medical services. All health care providers involved need to be well educated on the subject, therefore it is imperative to develop ways to incorporate the subject into the educational curriculum. Due to the potential ethical concerns pharmacogenetics poses, it will be important to develop appropriate policies and guidelines for its use [3].

Although the implementation of pharmacogenetics into routine practice is not occurring at the rate it was expected to, it is a maturing field that is being integrated into the practice of medicine more each day [2]. The future of pharmacogenetics and its place in clinical practice is still unclear, but there is the potential for individuals to be broadly genotyped and that their genetic information will guide therapy decisions throughout their lifetime [4]. This could potentially lead to clinicians being able to choose the best drug and dose that will result in better outcomes for patients with the least chance for harm based on genotype [4].

Pharmacogenetics is an emerging field that investigates variations in candidate genes that are relevant to drug metabolism and are based on phenotype observations. The identification of these polymorphisms is leading to an increased understanding of variability in pharmacodynamic and pharmacokinetic responses between individuals and potentially opening doors to improved medication efficacy, a reduction in adverse events, and more individualized care. Currently, pharmacogenetic testing has not been fully implemented into clinical practice. There remains a need for additional prospective, randomized, control trials including larger and more racially diverse populations, in order to provide a more complete understanding of how pharmacogenetic information may be applied to clinical situations. As more information becomes available, healthcare providers will also need additional education and training pertaining to the use of pharmacogenetic testing and its potential clinical benefits. At this time pharmacogenetic testing is relevant in clinical practice in select patient specific situations. The future of pharmacogenetic testing has a great potential to provide healthcare providers with the additional information needed to provide optimal individualized care and its utility is expected to increase as more high level evidence becomes available.

References


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