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Personalized Medicine: A Reality or A Dream?

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Inter-individual variability in drug response is common and can often pose problems that can turn out to be serious. This variability can originate from both patient's characteristics (age, genetic and environmental factors) and disease's etiology and pathophysiology. Based on patient's unique genetic and non genetic characteristics, personalized medicine is a rapidly advancing field that aimsto optimize medical care. For many years, clinical pharmacology aimed atdosage individualization of compounds with low therapeutic index. Since the establishment of the Human Genome Project, Pharmacogenomics emerged as a promising area thatwill allow health care providers to tailor each individual's therapy based on his/her inherited characteristics.

According to some scientists, the concept of personalized medicine is close to becoming a reality. The Human Genome Project as well as the rapid development of genome analysis techniques led to the application of new predictive tools (biomarkers) in personalized prescription. Additionally, the evolution of Pharmacogenomics guided the identification of multigene effects and targets for new DNA tests. As extensive research has been performed on the role of Single Nucleotide Polymorphisms (SNPs) and several potentially powerful tools (next-generation sequencing techniques that facilitate rapid whole genome sequencing, new versatile methods for SNP and copy number identification, etc.) have been developed, the integration of research findingsinto clinical practice has been promoted [1]. Indeed, the contribution of pharmacogenomics to the achievement of personalized medicine shows a various degree of diffusion in many clinical conditions [1,2]. Some biomarkers have already been approved for clinical application by USA FDA and in some fields (such as cardiovascular disease, oncology etc.), pharmacogenetic tests are being used in choosing and/or dosing a specific compound. At present, pharmacogenomics can even be applied in com¬plex diseases that are characterized by pheno¬typic and genetic variability and can also be used during drug development as it is significantly important to consider inter-individual variability in drug response at an early stage during drug development.

According to the rest of the scientific world, personalized prescription remains a dream. Even if several newly discovered SNPs contributed to the optimization of the use of various compounds and USA FDA has already approved some pharmacogenetic tests, being able to predict individual's drug response based on genetic information remains a challenge. Several scientific and ethico-legal issues should be solved before further integration of pharmacogenomics into clinical workflow and several barriers with regard to education, accessibility and economic issues should be overwhelmed [2-4]. For instance, pharmacogenetic tests usually evaluate one or a few genes and although this approach can turn out to be successful for some drugs, it may miss important contribution of other gene variants. For most compounds, multiple genetic and non genetic factors will modify drug action and pharmacogenomic studies should employ a genome-wide approach. However, even if the impact of genotype on drug response turns out to be significant, there is still considerable controversy on whether dosage adjustment based on genetic information can improve therapeutic efficacy and/or prevent adverse events to an extent of clinical importance.

Additionally, more clinical data that relate genotype to clinical outcome are deemed necessary as some populations (African-Americans, Hispanics, etc.) are currently under-represented in most pharmacogenomic studies, thus the presence of possible variants in these groups is underestimated. The evaluation of DNA tests is another cumbersome issue as no universally acceptable approach for the evaluation of DNA tests exist. Besides, it is somehow difficult to determine if DNA tests should be considered as a research finding with a degree of uncertainty, or if they are sufficient enough to be used in clinical practice. The development of decision-making algorithms based on DNA testing results remains difficult as the concept of risk and probability applies to both medical practice and pharmacogenomic testing. Economic barriers such as covering the cost of pharmacogenetic testing and ethical issues regarding the use of the genomic information do actually exist. As pharmacogenomics investigates genetic differences among individuals, it has to deal with issues related to genetic discrim¬ination, stigmatization and privacy. Education of the commu¬nity and the health care providers with regard the use of pharmacogenetic testing must also constitute a high priority. Clinicians do not generally feel confident in providing this kind of service to their patients mainly due to lack of training and knowledge.

In conclusion, despite the promising evidence towards an extensive integration of pharmacogenomics in clinical practice, a number of barriers should be overcome for the design of 'real world' personalized medicine. Besides, genetic tests provide new tools for safer and more effective healthcare but they do not really change the primary goal of traditional medicine.

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