Personalized Medicine - Scientific and Commercial Aspects

Description: The aim of personalized medicine or individualized treatment is to match the right drug to the right patient and, in some cases, even to design the appropriate treatment for a patient according to his/her genotype. This report describes the latest concepts of development of personalized medicine based on pharmacogenomics, pharmacogenetics, pharmacoproteomics, and metabolomics. Basic technologies of molecular diagnostics play an important role, particularly those for single nucleotide polymorphism (SNP) genotyping. Biomarkers play an important role in personalized medicine. Diagnosis is integrated with therapy for selection of treatment as well for monitoring the results. There is emphasis on early detection and prevention of disease in modern medicine. Biochip/microarray technologies and next generation sequencing are also important. The concept of personalized medicine described in this report remains the best way to integrate new technologies such as nanobiotechnology for improving healthcare. Finally bioinformatics is needed to analyze the immense amount of data generated by various technologies.

Pharmacogenetics, the study of influence of genetic factors on drug action and metabolism, is used for predicting adverse reactions of drugs. Several enzymes are involved in drug metabolism of which the most important ones are those belonging to the family of cytochrome P450. The knowledge of the effects of polymorphisms of genes for the enzymes is applied in drug discovery and development as well as in clinical use of drugs. Cost-effective methods for genotyping are being developed and it would be desirable to include this information in the patient's record for the guidance of the physician to individualize the treatment. Pharmacogenomics, a term that overlaps with pharmacogenetics but is distinct, deals with the application of genomics to drug discovery and development. It involves the mechanism of action of drugs on cells as revealed by gene expression patterns. Pharmacoproteomics is an important contribution to personalized medicine as it is a more functional representation of patient-to-patient variation than that provided by genotyping. A 'pharmacometabonomic' approach to personalizing drug treatment is also described.

Biological therapies such as those which use patient's own cells are considered to be personalized medicines. Vaccines are prepared from individual patient's tumor cells. Individualized therapeutic strategies using monoclonal bodies can be directed at specific genetic and immunologic targets. Ex vivo gene therapy involves the genetic modification of the patient's cells in vitro, prior to reimplantation of these cells in the patient's body.

Various technologies are integrated to develop personalized therapies for specific therapeutic areas described in the report. Examples of this are genotyping for drug resistance in HIV infection, personalized therapy of cancer, antipsychotics for schizophrenia, antidepressant therapy, antihypertensive therapy and personalized approach to neurological disorders. Although genotyping is not yet a part of clinically accepted routine, it is expected to have this status by the year 2020.

Several players are involved in the development of personalized therapy. Pharmaceutical and biotechnology companies have taken a leading role in this venture in keeping with their future role as healthcare enterprises rather than mere developers of technologies and manufacturers of medicines.

Ethical issues are involved in the development of personalized medicine mainly in the area of genetic testing. These along with social issues and consideration of race in the development of personalized medicine are discussed. Regulatory issues are discussed mainly with reference to the FDA guidelines on pharmacogenomics.

Increase in efficacy and safety of treatment by individualizing it has benefits in financial terms. Information is presented to show that personalized medicine will be cost-effective in healthcare systems. For the pharmaceutical companies, segmentation of the market may not leave room for conventional blockbusters but smaller and exclusive markets for personalized medicines would be profitable. Marketing opportunities for such a system are described with market estimates from 2016-2026.

Profiles of 320 companies involved in developing technologies for personalized medicines, along with 584 collaborations are included in the part II of the report. Finally the bibliography contains over 750 selected publications cited in the report. The report is supplemented by 80 tables and 38 figures.
This report includes information on the following areas:

- Basic aspects of personalized medicine
- Role of molecular diagnostics
- Pharmacogenetics
- Pharmacogenomics
- Pharmacoproteomics
- Personalized biological therapies
- Personalized non-pharmacological therapies
- Personalized medicine in major therapeutic areas
- Personalized Therapy of Cancer
- Development of personalized medicine
- Ethical, Legal and Regulatory Aspects of Personalized Medicine
- Commercial aspects of personalized medicine
- Companies involved in the development of personalized medicine

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