



## Precision Medicine: A New Revolution in Healthcare System

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Every human being is different based on genetics, lifestyle, and environmental factors. Novel medical technologies have become more precise owing to molecular information, including genomics, transcriptomics, proteomics, metabolomics, etc. The “omics” technologies have opened up new horizons for healthcare systems, enabling them to prevent and/or diagnose diseases more precisely, as well as to find the most effective treatments with fewer adverse events. Recently, the term ‘precision medicine’ (PM), focusing on molecular-based medicine, has been introduced. PM empowered by “omics” technologies is going to be translated into precision healthcare. In other words, personalized healthcare is developed to improve the safety and efficacy of medical treatments and also to lower healthcare costs. Accordingly, some PM initiatives have been announced in the US and European countries to revolutionize healthcare systems.

In the field of drug discovery, there are concerns about the role of genomics and proteomics in individual response to medicines. Information coming from “omics” such as genomics, proteomics, metabolomics, epigenomics, transcriptomics, and antibodyomics based on molecular characteristics of patients will enable physicians to administer safer and more effective drugs to each individual.

There are different successful experiences of personalized approach about treatment of various diseases. For instance, a prediction model to identify patients with a high risk of initiating statin therapy has been introduced to improve implementation of “omics” in clinical practice. In another study, the impact of computer-generated individualized goals on HbA1c was evaluated. In that study, 150 patients with diabetes were randomized to receive standard care or intervention, inclusive of a computer-generated individualized HbA1c

status and goals. After six months, reduction of HbA1c in the intervention group was significantly more than the control group. The study showed that the effect of computer-generated personalized goals on HbA1c is comparable to hypoglycemic medications. Another study assessed the clinical outcome of a known case of gemcitabine-resistant pancreatic cancer receiving DNA-damaging medications, though personalized tumor graft had been generated from the patient’s own tumor. That study was repeated and applied to tumors resected from 14 more cancer patients. Subsequently, each patient received his/her individualized treatment and astonishingly, a partial remission was observed in some cases.

Although PM was established in accordance with individual factors, its successful implementation depends on the population health, relevant sciences, policies, regulations, and interdisciplinary teamwork. Certain disciplines and approaches such as health economy, ecological view of health, population-based researches and practices, evidence-based medicine, and shared decision-making play crucial roles in precision healthcare. Using such approaches can control “premature translation”, which can increase healthcare costs and potential risks. Moreover, PM needs the support of decision makers to be established in the healthcare system. Of course, an efficient and precise healthcare system depends on equipping the health system with several elements, including risk assessment, family history, and clinical decision support for complex risk, and predictive information. Thus, it requires serious changes in standards, legislation, ethical codes, and investment policies. Also, PM provides an enforcement to impel the health systems to a more active and patient-oriented approach. In addition, this strategy encourages the patients in having a more effective role in their care.

Therefore, PM can revolutionize the healthcare system; however, there are certain limitations and challenges to implement such approaches in the healthcare system, which include (1) policy limitations, (2) lack of basic, translational, and regulatory knowledge, (3) ethical, legal, and social considerations, (4) economic and insurance limitations, and (5) remaining “omics” technologies as a scientific not applied field without full implementation in the health system.

To overcome these challenges, a deliberate relationship among all relevant stakeholders such as researchers, clinicians, health authorities, governments, pharmaceutical companies, sponsors, and insurers is required. Further, resource allocation can take an important part in the development of a perfect personalized healthcare system. Surprisingly, resources are more allocated to basic investigations in comparison with applicable research. Thus, to avoid inappropriate resource allocation, several requirements such as decision-making process, educational needs evaluation, cost-effectiveness assessment, population-based studies, and evaluation of health outcomes are required. On the other hand, health authorities need to be confronted with ethical, economic, legal, and social challenges and try to overcome them using different assessment technologies such as health technology assessments (HTA). Accordingly, HTA and similar instruments are suggested to help health authorities to recognize the real and appropriate needs in the field of personalized healthcare such as “omics” technologies. HTA, as a multidisciplinary process, evaluates the characteristics and impacts of personalized healthcare technology based on medical, social, financial and ethical considerations, in a systematic way. Therefore, HTA assists decision makers to implement an accurate technology in an appropriate manner with a reasonable cost.

In conclusion, the advancements in precision healthcare using “omics” technologies will revolutionize PM-based health care. PM revolution depends on a close collaboration of stakeholders to re-organize health infrastructures. HTA and other similar tools could help decision makers to find and implement the right PM technology, at the right time, for the right patient. Therefore, the decision process should be performed in accordance with a “case by case” rather than a “one-size-fits-all” method. Additionally, patient's privacy, science promotion, and resource allocation should be balanced. Furthermore, evidence-based personalized healthcare tries to reduce the uncertainties in prevention, diagnosis, and treatment using a shared decision-making method involving both health professionals and patients. Finally, besides the power of data, evidence for desired test or technology, availability of guidelines, cost-effectiveness and HTAs by independent organizations, and patient's interest as well as insurance coverage has a pivotal role in the widespread implementation of PM.

#### More details in:

*A pilot clinical study of treatment guided by personalized tumorgrafts in patients with advanced cancer.* M Hidalgo *et al.* 2011. *Mol Cancer Ther*, Vol. 10, No. 8: pp. 1311-1316.

*A population perspective on how personalized medicine can improve health.* MJ Khoury *et al.* 2012. *Am J Prev Med*, Vol. 42, No. 6: pp. 639- 645.

*An economic perspective on personalized medicine.* S Jakka and M Rossbach 2013. *HUGO J*, Vol. 7, No. 1: doi: 10.1186/1877-6566-7-11.

*Environmental toxicants, incidence of degenerative diseases, and therapies from the epigenetic point of view.* M Hodjat *et al.* 2017. *Arch Toxicol*. doi: 10.1007/s00204-017-1979-9. [Epub ahead of print].

*Challenges in the development and reimbursement of personalized medicine—payer and manufacturer perspectives and implications for health economics and outcomes research: a report of the ISPOR personalized medicine special interest group.* E Faulkner *et al.* 2012. *Value Health*, Vol. 15, No. 8: pp. 1162-1171.

*Impact of computer-generated personalized goals on HbA1c.* CS Levetan 2002. *Diabetes Care*, Vol. 25, No. 1: pp. 2-8.

*Making personalized health care even more personalized: insights from activities of the IOM genomics roundtable.* SP David *et al.* 2015. *Ann Fam Med*, Vol. 13, No. 4: pp. 373-380.

*Personalizing health care: feasibility and future implications.* B Godman *et al.* 2013. *BMC Med*, Vol. 11, No. 1: pp. 179.

*Personalized medicine and access to health care: potential for inequitable access?* KA McClellan *et al.* 2013. *Eur J Hum Genet*, Vol. 21, No. 2: pp. 143-147.

*Personalized health care: from theory to practice.* R. Snyderman 2012. *Biotechnol J*, Vol. 7, No. 8: pp. 973-979.

*Personalised health care, the need for reassessment. A HTA perspective far beyond cost-effectiveness.* I Utiérrez-Ibarluzea 2012. *Ital J Public Health*, Vol. 9, No. 4: e8653.1-e8653.9.

*Personalized medicine: part 1: evolution and development into theranostics.* FR Vogenberg *et al.* 2010. *P T*, Vol. 35, No. 10, pp: 560-76.

*Personalized medicine: a confluence of traditional and contemporary medicine.* S Jafari *et al.* 2014. *Altern Ther Health Med*, Vol. 20, No. 5: pp. 31-40.

*Preemptive genotyping for personalized medicine: design of the right drug, right dose, right time—using genomic data to individualize treatment protocol.* SJ Bielinski *et al.* 2014. *Mayo Clin Proc*, Vol. 89, No. 1: pp: 25-33.

*Personalized Medicine in Europe.* E Nimmesgern *et al.* 2017. *Clin Transl Sci*, Vol. 10, No. 2: pp: 61-63.

*The economic value of personalized medicine tests: what we know and what we need to know.* KA Phillips *et al.* 2014. *Genet Med*, Vol. 16, No. 3, pp: 251-257.

*The role of patient engagement in personalized healthcare.* S Daack-Hirsch and CA Campbell 2014. *Personal Med*, Vol. 11, No. 1: pp. 1-4.

*Why is personalized medicine relevant to public health?* S. Boccia 2014. *Oxford Univ Press*, Vol. 24, No. 3: pp. 349-350.