COMMENTARY

Personalized Medicine in Europe

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INTRODUCTION

Personalized medicine is a promising new concept for dealing with challenges of health and health systems. With the launch of the International Consortium for Personalised Medicine, which brings together health research funders and policy-making organizations, European countries aim to coordinate research and health policy to advance the implementation of personalized medicine.

COMMENTARY

Scientific breakthroughs bring new opportunities to address disease and improve health outcomes for many communities in many parts of the world. Frequently, however, these advances come at an increased cost, and some communities do not benefit from the improvements in healthcare and health outcomes. Furthermore, many medicines do not effectively treat some patients or are even harmful, as illustrated by the finding that over 6% of acute hospital admissions are caused by serious adverse reactions to medicines. In addition, our population is aging and chronic diseases are becoming more prevalent. These challenges put an increasing pressure on health systems.

Personalized medicine has emerged as a concept to help address these challenges with strategies for prevention, diagnosis, and treatment tailor-made for individuals or groups of individuals. The aim is to make sure that patients receive the specific interventions that work best for them and that time and money is not wasted on trial and error. Initiatives in personalized medicine have been launched in many parts of the world. Perhaps best known is the precision medicine initiative launched by US President Obama in his State of the Union address in January 2015.

In Europe, efforts are under way to implement personalized medicine, as recognized in the conclusions of the Council of the European Union at its meeting on 7 December 2015.

Box 1

The term used in Europe is personalised medicine:

"Personalised medicine refers to a medical model using characterization of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention."

Other terms that are used by the global community are "precision medicine," "stratified medicine," "individualized medicine," "genomic medicine," "pharmacogenomics," and "P4 medicine" (for personalized, predictive, preventive, and participatory).

It is important to note that personalized medicine not only concerns pharmaceuticals (medicines). A better understanding of biological mechanisms and environmental interactions that govern health and disease will have an impact on the entire healthcare continuum, from health research to patient care. The move towards personalized medicine can be seen as an evolutionary rather than revolutionary process. Although some personalized medicine approaches have already been put into practice in Europe, we are still at an early stage of implementation. A significant paradigm shift will need to take place in medical research and healthcare for this innovative approach to be fully exploited.

At the EU level, reflections on personalized medicine started in 2010 with a series of workshops on different research areas that can contribute to this new model of practicing medicine. The results of the workshops fed into the conference “Perspectives in Personalised Medicine” organized in 2011 by the European Commission.

A report on “Use of ‘-omics’ technologies in the development of personalised medicine” was published in 2013 as a first European policy document in the field. It provided an overview of progress in personalized medicine, with a specific focus on “-omics” technologies, as well as a discussion of the opportunities and challenges this new approach presents for healthcare systems in Europe.

In the second half of 2015, under the Luxembourg presidency of the European Union, health ministers held a wide-ranging discussion on how to advance personalized medicine and adopted Council conclusions on “personalised medicine for patients.” In this document, which contains a total of 24 invitations for action, Member States are encouraged to foster education, training, and continuing professional development for health professionals and to exchange best practices. Member States and the European Commission are invited to jointly promote the interoperability of electronic health records and to develop common principles on data collection. Furthermore, the European Commission...
is asked to continue to support research on personalized medicine.

In parallel, a number of initiatives have been undertaken in EU Member States to define the framework for personalized medicine. For example, in the UK the Academy of Medical Sciences has carried out a series of workshops and conferences and has published reports on stratified medicine. The German Academy of Sciences Leopoldina has published a report on individualized medicine and the German Ministry for Education and Research issued an Action Plan for Individualized Medicine. The French National Alliance for Life Sciences and Health, AVIESAN, has recently issued its Genomic Medicine 2025 plan, as commissioned by French Prime Minister Valls. The efforts in Estonia, France, and Scotland to implement personalized medicine in healthcare were presented at the Personalised Medicine Conference 2016 held in Brussels on 1–2 June 2016 (see also below).

Building on earlier investments in “omics” and biotechnology research through the EU funding programs, research on personalized medicine has been supported since the EU’s 7th Framework Programme for Research and Technological Development, which started in 2007. The support has been expanded under the current program Horizon 2020. In these two programs alone a total of over 3 billion € has already been invested in research supporting different aspects of personalized medicine. Information about future funding opportunities for personalized medicine at the EU level can be found on the Research Participant Portal.

Research funding at the EU level represents only ~10% of total investment in biomedical research in Europe. Accordingly, an important aspect of the EU funding is to complement investments made by EU Member States. For this emerging area of health research and innovation, coordination of actions between the EU Member States is needed.

In order to put this coordination into practice, the EU funded the “PerMed” project, in which representatives from EU Member States and countries associated to the EU research framework program, together with various other stakeholders, have developed a European strategy framework for personalized medicine. This resulted in a publication in June 2015 entitled “Shaping Europe’s vision for personalised medicine.”

The PerMed agenda defines five challenges to advance personalized medicine:

**Box 2**
- Challenge 1 – Developing Awareness and Empowerment
- Challenge 2 – Integrating Big Data and ICT Solutions
- Challenge 3 – Translating Basic to Clinical Research and Beyond
- Challenge 4 – Bringing Innovation to the Market
- Challenge 5 – Shaping Sustainable Healthcare

**The international consortium for personalised medicine**

Health policy-making organizations and health research funders from across Europe have recently come together to set up an initiative called the International Consortium for Personalised Medicine, or “IC PerMed.” The European Commission supports this initiative by funding a coordination action called “IC PerMed Secretariat.”

IC PerMed is a voluntary, EU Member States-led collaboration between funders of health research, research policy makers, and health policy makers. It is steered by an executive committee of representatives from each participating organization. As of November 2016, the members of IC PerMed come from 24 different countries, including Canada as an international partner.

The secretariat for the initiative is run by a consortium coordinated by the project management agency DLR (“Projekträger DLR”), working for the German Education and Research Ministry, in partnership with the Spanish Health Research Institute Carlos III, the Italian Health Ministry, and the French National Research Agency (“Agence Nationale de la Recherche”). It started operating on 1 November 2016.

The member organizations of IC PerMed will work to:

**Box 3**
- Establish Europe as a global leader in personalized medicine research;
- Support the personalized medicine science base through a coordinated approach to research;
- Provide evidence to demonstrate the benefit of personalized medicine to citizens and healthcare systems;
- Pave the way for personalized medicine approaches for citizens.

IC PerMed will focus on fostering and coordinating research and innovation actions to deliver on its mission statement (Box 3). This work is built around the five PerMed challenges, each led by one or several members. Participants from other IC PerMed member organizations and nominated scientific experts contribute to the work of the challenge groups. This included the definition of the program for the Personalised Medicine Conference 2016 held in Brussels on 1–2 June. The conference provided a forum for discussing the challenges to be addressed by IC PerMed. The conference report has recently been published.

The conference discussions are being followed up by working on a roadmap that translates the challenges of the PerMed agenda into actionable items: examples could be a health research funder launching a call for proposals or a health policy maker implementing a new approach to a particular aspect of healthcare. A priority list of actionable items to begin in the near future is being put together through an iterative process. After adoption by the executive committee, the priority list will be published by IC PerMed. The roadmap itself is conceived as a living document with periodic revisions.

With the secretariat just having been set up, the first chair elected, and the imminent publication of the priority list, it is timely to look at tools for implementing the suggested actions. The EU research and innovation program Horizon 2020 will continue to play its part in supporting the
development of personalized medicine by funding collaborative research projects. Indeed, in the process for the development of the work programs 2018–2020 the advisory group to the health, demographic change, and wellbeing societal challenge of Horizon 2020 has highlighted personalized medicine as a key aspect to be addressed in the program. Over the coming year this strategic orientation will be translated into call topics to be published by the European Commission.

Opportunities for European health research funders to come together to launch joint calls for proposals will also likely emerge in the coming years in the context of IC PerMed. IC PerMed has decided that each member needs to report on its contribution to the initiative on a yearly basis. Thereby, the progress of IC PerMed and how it delivers on implementing the roadmap can be effectively measured.

Much progress has been made on advancing personalized medicine research and innovation but, so far, translation of results into benefit for patients and transformed healthcare has been limited. In our opinion, the time is ripe for a meaningful demonstration of the potential of personalized medicine approaches, not only to improve existing treatment options and better define the patients who will benefit from particular drugs, but also to underpin prevention strategies and population health measures that can lead to healthier lives of everybody in Europe.

All this will require the transformation of healthcare systems to make them much better at generating, storing, and processing health-related information, in order to inform appropriate action. The way we generate health information needs to be standardized and radically improved. Today, all too often, test results are not fully reproducible or the results are not transferred correctly into the healthcare records. Detailed clinical phenotyping is not reproducible and we need standardized ontologies. We will also need new tools to analyze more rapidly the large amount of information that becomes available in a healthcare system organized around personalized medicine. And finally, the health information which is available needs to be accessible to the individual and authorized healthcare professionals. This will require linking electronic healthcare records with other relevant information in a manner compatible with strict protection of data safety, integrity, and confidentiality. In parallel, we need to continue to invest in research and innovation to advance our understanding of the basis of health and disease and how to treat disease.

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