The Canadian Path from Discovery to Implementation of Personalized Medicine Approaches

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Keywords
Canada · Implementation · Personalized medicine

Abstract
Personalized (or precision) medicine approaches are currently being introduced in healthcare delivery following the development of new technologies and of novel ways to integrate and analyze various data sources. This editorial describes the efforts invested since 2012 by the Canadian Institutes of Health Research (CIHR) to foster the development and implementation of personalized medicine in Canada. Success stories from past investments as well as future developments are presented from a Canadian perspective.

In 2016, the Canadian Institutes of Health Research (CIHR) launched the Personalized Health (PH) Initiative, with the goal of driving evidence-based implementation of PH that will identify solutions that can contribute to more cost-effective and sustainable healthcare for the benefit of patients and the population. Building on the CIHR’s Personalized Medicine (PM) Initiative and the Health Innovation Initiative, both launched in 2012, this new PH Initiative aims to integrate the perspectives of policy makers, health technology assessments, healthcare providers, regulators, researchers, and patients. This is especially important in Canada, where the delivery of healthcare falls under provincial and territorial jurisdiction, in a domain where innovation requires national and international coordination and data sharing.
The impacts and the demonstration of the value of PH approaches are still in their infancy, and many people are concerned that PH will lead mostly to expensive new drugs that could jeopardize the healthcare system and increase inequities. However, examples of successful cost-effective implementation of PH in Canada are emerging, in part through projects funded by the 2012 Large-Scale Applied Research Projects Competition-Genomics and Health, launched by the CIHR and Genome Canada, in collaboration with numerous partners. One such example is ICHANGE, which identified recurrent driver mutations of high-grade astrocytomas in children and then developed a genetic test that is now part of the WHO recommendations and used in standard clinical care, allowing clinicians to select the appropriate therapeutic approach, which differs from the standard first-line therapy, which is ineffective for these astrocytomas (http://ichangeconsortium.mcgill.ca). A second example, the Care4Rare rare diseases project, provided diagnoses to over 1,000 patients, developed the expertise needed to set up clinical whole-exome/genome sequencing, and has assembled data on the cost of rare diseases to the healthcare system (http://care4rare.ca). Finally, the PEGASUS project demonstrated that using noninvasive prenatal testing as a second-tier test would be cost neutral to the Québec healthcare system, and would result in fewer pregnancies being terminated in comparison to more invasive procedures used presently (http://pegasus-pegase.ca). This group is now collaborating with a working group on noninvasive prenatal testing from the Québec Ministry of Health to promote its adoption.

The new Canadian PH Initiative will support projects that can assess the value of PM in a publicly funded healthcare system, aiming to support more of these “Canadian success stories.” Its initial investments include catalyst and team grants. The catalysts focus on the real-world application of PH with supporting grants in three specific areas: development of novel e-health apps, development of predictive analytic models, and mining of existing databases to identify sex-drug-gene interactions. These catalysts will feed into a second team grant program, while the first team grants, in partnership with Genome Canada, are designed to increase the number of success stories and assess the value of PM approaches for patients and the society by specifically addressing the health economics of PH approaches and how they affect patient outcomes.

To maximize progress in this area, Canada is a partner in numerous international efforts. For instance, in 2011, an international need for physical standardization in the cancer imaging field was identified. To address this gap, the CIHR partnered with the National Cancer Institute (NCI) of the National Institutes of Health (NIH) and Genome British Columbia (BC) to launch the “Quantitative Imaging for Evaluation of Responses to Cancer Therapies Initiative” funding opportunity, which allowed for the creation and integration of two Canadian nodes into the NCI Quantitative Imaging Network (QIN) (https://imaging.cancer.gov/informatics/qin.htm) to improve the role of quantitative imaging for clinical decision-making in oncology. Rare diseases are another area that has benefited greatly from international cooperation, and Canada has had important roles in the International Rare Diseases Research Consortium (http://www.irdirc.org), the ERA-Net E-Rare consortium that funds international collaborative projects (http://www.erare.eu), and the Matchmaker Exchange, which has developed tools for international phenotypic and genotypic data exchange (http://www.matchmaker-exchange.org).

The European Union and the UK are valued partners in the development and implementation of PH approaches, as they share with Canada many of the opportunities and challenges in healthcare delivery. The new PH Initiative will further strengthen partnerships between Canada and Europe in this area. It is in this spirit that the CIHR joined the CSA PerMed project in 2014 to contribute to the development of the Strategic Research & Innovation Agenda, which served as the starting point for the development of the ICPeMed Action plan. Canada’s ongoing participation in ICPeMed and the developing ERA-Net PerMed – meant to support
ICPerMed objectives – is ensuring that these links are maintained. In addition, Canadian expertise in sex- and gender-based analysis, a key aspect of the PH Initiative, will also be added through our involvement in the ERA-Net GenderNet. Finally, Canada is looking forward to working closely with European partners to ensure that existing resources for data sharing and harmonization are maximized, and that common approaches compatible with and within various jurisdictions are developed and implemented.

**Disclosure Statement**

The authors have no conflicts of interest to disclose.