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EDITORIAL

The personalized medicine challenge: shifting to population health through real-world data

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Personalized medicine (PM) is an initiative aimed at optimizing a person's health through targeted, precise care. The field of precision health has rapidly blossomed, fed by the fertile, data-rich healthcare environment and the hype surrounding artificial intelligence (AI) and big data analytics (BDA). The ability to sequence and analyze large amounts of omics data (e.g., genomics, proteomics), enhanced by AI algorithms, has encouraged the growth of targeted therapies (Jameson and Longo 2015). Enormous databases are now fed by real-world data (RWD), automatically generated healthcare data based on records of routine medical encounters. These databases inform analyses from drug discovery to disease relapse prediction (Mc Cord et al. 2018).

But PM has its limits. Right now, it is mostly sustained by sequencing data, but it is not sufficient to focus on the genetic markup of pathogenesis only. RWD includes environmental and societal determinants of health that enrich the assessment of health outcomes. Though some PM projects have demonstrated its potential (Jiang et al. 2017), others have ended in disappointment [IBM's Watson (Davenport 2018)]. Analyses based on AI or machine learning algorithms are of uncertain benefit. Many AI and machine learning researchers depend on the ability of their products to "learn" to recognize patterns after being trained on large datasets. Low quality data, including misclassification and formatting issues, may derail these efforts, especially in healthcare where data acquisition is burdensome, collected data are often unstructured and text-heavy, and rules about collecting and maintaining data may lag behind practice. Even when current PM analyses are accurate and trustworthy enough to complement evidence generated in clinical trials, the decision to collect large amounts of specific data (e.g., on tumor receptors and their sensitivity to oncological treatments) instead of extracting general inferences from RWD and then deriving specific hypothesis from them, might be limiting and unsustainable in the long run.

Instead, we could drive the field through inductive reasoning based on population-wide data and develop theories to improve individualized medicine. We could strengthen the RWD infrastructure and use population health outcomes to develop research hypothesis applicable at the individual level instead of focusing on improving the outcomes of sparse diseases and directing hypothesis-testing in such direction. For example, an electronic health record add-on, the Stanford Green Button (Longhurst et al. 2014), can query many clinical charts and screen for elements the physician stipulates. When physicians care for patients with characteristics not widely represented in clinical trials, they can use the Green Button to search for other patients with similar characteristics and recommend a course of treatment based on their combined records. We should create large RWD networks and use this vast information to answer PM questions, not the other way around.

Using RWD also lowers the risk that PM will fall into the health disparity trap. PM is driven by monetary forces such as the research agenda of pharmaceutical companies, rather than research needs, but this bias could be reduced by strengthening the population precision medicine infrastructure and leveraging RWD. In such a scenario, point-of-care trials, virtual trials, or other study designs of more pragmatic nature can be implemented in healthcare systems and more likely be initiated by investigators rather than sponsors. This could foster the typically neglected research questions such as those of behavioral health, gynecology and rehabilitation; and favor underrepresented populations like minorities, penurious communities and women. If there are social and physiological differences among such populations, systematically testing interventions in privileged populations would aggravate the

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imbalance of representation in the evidence synthesis environment. When, for example, interventions (e.g., drugs) are tested mostly on white male participants, health disparities can develop because women and other ethnic groups are underrepresented. If an oncology clinical study uses only genomics data to personalize treatment, the data the study gathers may only be pertinent to patients or patient groups with similar genetic markup.

It is time that we shift our focus to personalized population medicine and integrate elements other than omics into personalized health, including social, environmental, and behavioral causal factors of disease development. RWD can help us answer many public health questions, but researchers must do more than improve costly treatments, such as improving chemotherapeutics, and revert to preventing diseases, by identifying determinants of cancer that can be prevented. As the hype for PM continues its course, I trust that some of its enthusiasm and advancements will transfer to the precision population health field, where truly substantial and sustainable impact can transpire. RWD will be the disruptor and democratizer of the public health and clinical research fields, but only through the collaboration of all stakeholder and the inclusion of patient's needs in the dialogue.

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