REVIEW article

From one-size-fits-all to tailor-made: The emergence of personalized medicine in clinical practice

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Abstract: A significant departure from the conventional one-size-fits-all approach is represented by personalized medicine, which is the customization of medical care to each patient's unique traits. This review thoroughly examines the past, present, and future developments of personalized medicine. We examine its fundamental pillars-genomics, pharmacogenomics, and biomarker discovery-and describe their clinical uses in rare illnesses, oncology, cardiology, and psychiatry. The importance of enabling technologies, such as artificial intelligence, big data analytics, and next-generation sequencing, is emphasized. It also discusses the major obstacles to wider adoption, including the need for physician education, regulatory and reimbursement barriers, health fairness and access, and data privacy and security. A more dynamic, predictive, and participative approach to medicine is being made possible by the convergence of wearable technology, digital health technologies, and multi-omics data. Even if science and technology have advanced remarkably, to fully realize PM's promise and guarantee that it benefits all facets of society, concurrent breakthroughs in ethical frameworks, health policy, and interdisciplinary collaboration are required.

Introduction

The need for customization: For several years, the majority of medical practice has been based on a population-average paradigm, in which treatment and diagnostic plans are created for the "normal" patient. Although this strategy is crucial for improving public health, it often produces inconsistent results, with some patients experiencing treatment failure and others experiencing adverse drug reactions (ADRs) [1, 2]. According to estimates, ADRs are a major source of morbidity and mortality, indicating a systemic inefficiency in therapeutic intervention [3-5]. This variety gives rise to the concept of personalized medicine, which aims to categorize diseases into distinct groups based on underlying molecular mechanisms and unique patient profiles that encompass genetic, environmental, and lifestyle factors [6]. An important turning point was the Human Genome Project's completion in 2003, which produced the fundamental map for comprehending the role of genetics in health and illness [7]. To provide the appropriate treatment to the right patient at the right time, personalized medicine (PM) is an integrative model that uses a variety of data streams to inform risk assessment, prevention, diagnosis, prognostication, and treatment selection [8, 9].

Foundational pillars of personalized medicine

Genomics and next-generation sequencing (NGS): Genomics is PM's main technical engine. The capacity to quickly decode a person's genome, exome, or transcriptome has been transformed with the development of

affordable, high-throughput NGS [10]. These days, whole-exome sequencing (WES) and whole-genome sequencing (WGS) are utilized to profile malignancies and diagnose uncommon Mendelian illnesses [11]. For diseases including hereditary breast and ovarian cancer (BRCA1/2 genes) and familial hypercholesterolemia, the discovery of pathogenic variants, single-nucleotide polymorphisms (SNPs), and copy number variations (CNVs) enables the clarification of disease aetiology and risk prediction [12].

Pharmacogenomics (PGx): A key component of PM is pharmacogenomics, which examines how genetic differences affect a person's reaction to medications. By anticipating genetic predispositions, it seeks to maximize medication efficacy and reduce toxicity [13, 14]. Testing for HLA-B *5701* before prescribing abacavir to prevent severe hypersensitivity responses in HIV patients and for HLA-B *1502* in Asian populations before carbamazepine use to prevent Stevens-Johnson syndrome are two important examples that are now considered standard of care [15]. Similarly, DPYD testing identifies patients at risk of severe toxicity from fluoropyrimidine chemotherapy, and CYP2C19 genotyping directs antiplatelet medication (clopidogrel) in cardiology [16].

Biomarker discovery and validation: PM relies heavily on biomarkers, which are quantifiable indications of biological processes. They may be physiologic, radiographic, histologic, or molecular [17]. Biomarkers such as HER2 amplification for breast cancer treatment, EGFR mutations for tyrosine kinase inhibitors in lung cancer, and PD-L1 expression for immunotherapy eligibility are paradigmatic in oncology [18]. Liquid biopsies, which identify circulating tumour DNA (ctDNA), are a non-invasive breakthrough for monitoring cancer, identifying developing resistance mutations, and detecting minimal residual disease [19].

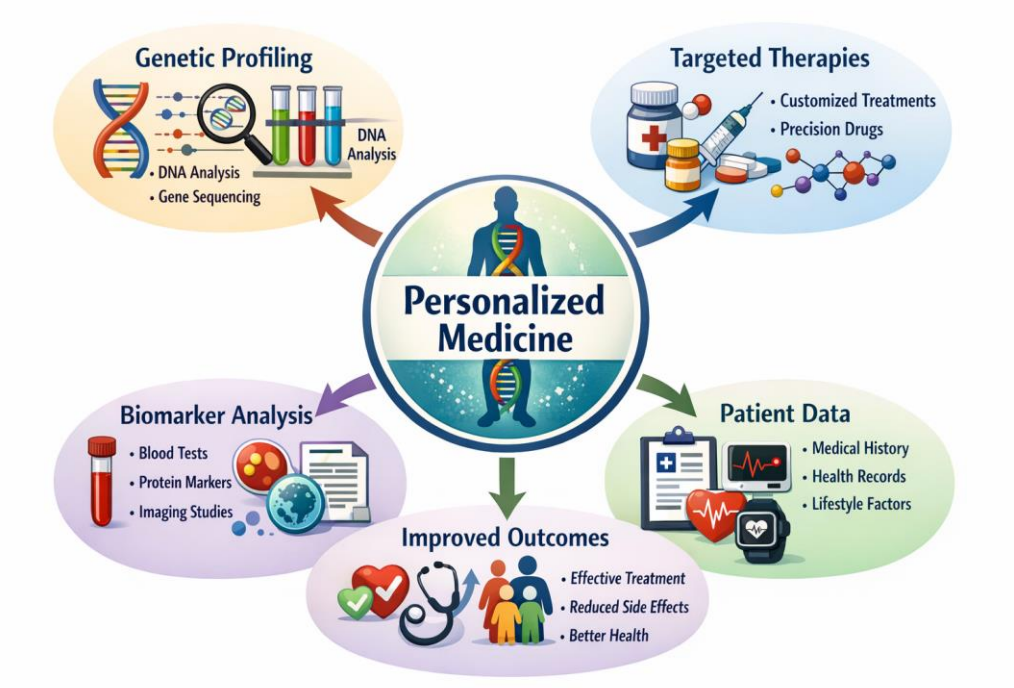

Figure 1: Foundational pillars of personalized medicine

Clinical implementations in various specialties

Oncology: The vanguard of PM, the most developed area of PM is oncology, which has been completely transformed by molecular stratification. These days, driver mutations are used to categorize cancers instead of just the tissue of origin [20]. For certain patient populations, treatments that target certain pathways - such as BRAF inhibitors for melanoma and ALK inhibitors for lung cancer - have improved results [21]. To match patients to targeted medicines or clinical trials, thorough genomic sequencing of malignancies using NGS panels is becoming standard practice [22]. Biomarkers such microsatellite instability (MSI) status and tumour mutational burden (TMB) also influence the effectiveness of immunotherapy [23].

Cardiology and cardiovascular risk: PM is revolutionizing the treatment of cardiovascular disease. To enable focused primary prevention, polygenic risk scores (PRS), which combine the impacts of numerous genetic variations, are being improved to estimate a person's lifetime risk of atrial fibrillation or coronary artery disease [24]. Early diagnosis and family screening are made easier by genetic testing for channelopathies (long QT syndrome) and familial cardiomyopathies (hypertrophic cardiomyopathy) [25]. Despite its complexity, PGx for clopidogrel and warfarin is still the subject of ongoing implementation research [26].

Psychiatry and neurology: There is a great deal of variation in mental health conditions. To inform treatment choices, PM methods look for biological subgroups. Research on genetic indicators (CYP2D6 for antidepressant metabolism), neuroimaging biomarkers, and EEG patterns to predict response to antidepressants or antipsychotics is still in its infancy [27]. In neurology, PM plays a crucial role in monogenic illnesses such as spinal muscular atrophy (SMA), where specific SMN1 genotypes are targeted by Nusinersen and gene therapy [28]. To enable early, pre-symptomatic intervention in at-risk patients, research on Alzheimer's disease is increasingly concentrated on biomarkers such as tau and amyloid-beta [29-31].

Rare and undiagnosed diseases: For individuals with uncommon illnesses, who frequently endure a diagnostic journey, NGS-based PM has proved revolutionary. A considerable percentage of these individuals receive a diagnosis from WES and WGS, which eliminates diagnostic uncertainty, permits reproductive planning, and occasionally directs management even in the absence of a specific therapy [32].

Enabling technologies and data science

Big data analytics and artificial intelligence (AI): Advanced computational techniques are required due to the volume of data created by wearable devices, electronic health records (EHRs), and omics technologies. Pattern recognition, disease onset prediction, patient stratification, and the identification of new biomarkers from complex datasets are all made possible by AI and machine learning (ML) algorithms [33]. When it comes to evaluating medical photos for early cancer identification and grading, deep learning models are performing better than people [34, 35]. To improve patient profiles, natural language processing (NLP) aids in the extraction of unstructured clinical data from electronic health records [36].

Digital health and wearables: The field of personalized medicine is moving from the molecular to the digital sphere. A dynamic picture of a person's physiology in real-time is provided by continuous data streams from wearable devices that track heart rate, physical activity, sleep, and glucose levels [37]. This creates a feedback loop for managing chronic diseases and early detection of decompensation by enabling remote patient monitoring and customized lifestyle treatments [38, 39].

Multi-omics integration: Integrative multi-omics, which combines genomes with transcriptomics, proteomics, metabolomics, and microbiomics to produce a thorough systems-level understanding of a person's health, is the way of the future [40]. This method can find new therapeutic targets that a single-omics layer would overlook and highlight the functional effects of genetic variations [41].

Implementation difficulties and obstacles

Implications for ethics, law, and society (ELSI): PM poses important queries regarding ownership, permission, and data privacy. Genomic information can be individually identified and has consequences for the individual as well as their family members [42]. To preserve public confidence, strong cybersecurity standards and transparent governance guidelines are crucial [43]. Despite being lessened by the US regulations, such as the Genetic Information Non-discrimination Act (GINA), the possibility of genetic discrimination is still a worry worldwide [44].

Health equity and the genomic divide: PM has a significant danger of making already-existing health inequities worse. Variant databases and polygenic risk scores that perform poorly in other ancestral groups

have resulted from the majority of genomic research being done in people of European ancestry [45]. A significant ethical and practical problem is ensuring fair access to costly genetic technology and targeted medicines, as well as diverse representation in research [30, 46].

Obstacles in regulation and reimbursement: Companion diagnostics and biomarker-driven medicine approvals have been made possible by regulatory bodies such as the FDA and EMA [47]. Regulations, however, frequently fall behind the rate of technical advancement. Reimbursement is a recurring obstacle; before covering genetic tests or targeted medicines, payers frequently need strict proof of clinical benefit and cost-effectiveness, creating a valley of death between discovery and acceptance [48].

Healthcare infrastructure and education: Healthcare IT systems must be significantly upgraded for data integration and interpretation in order to implement PM [49]. Most importantly, there is a lack of qualified bioinformaticians and genetic counsellors, as well as a broad knowledge gap among practicing doctors [50]. For widespread use, genomic medicine must be integrated into nursing and medical curricula, and decision-support systems must be developed for Electronic Health records [51].

The future path: P4 medicine: predictive, preventive, participatory, and personalized

The P4 medicine - predictive, preventative, personalized, and participatory - is becoming the new PM vision [52]. This model makes use of longitudinal data to forecast health hazards prior to the onset of symptoms, allowing for really preventive measures. By co-managing their data and choices with their healthcare team, the patient takes an active and knowledgeable role in their health journey [53]. Deep molecular profiling combined with wearable real-time data will allow for dynamic, just-in-time treatments that will transition from static treatment to ongoing health optimization [54].

Conclusion: From a theoretical idea to a practical reality, PM has drastically changed the landscape of diagnosis and treatment, especially in oncology. Deep insights into disease mechanisms and heterogeneity are being produced by its genomics foundation, which is driven by NGS and AI. But getting from the bench to the patient's bedside presents a number of difficult issues in the areas of ethics, equity, economics, and education. The ability of all of us to create a patient-centred, sustainable, and equitable ecosystem that converts these developments into better health outcomes for all populations will ultimately define PM's success rather than just its technological prowess. A new era of precision health is being ushered in by a paradigm change from population-based to individual-focused, from reactive to proactive.

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