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PRECISION MEDICINE: WHAT MAY BE THE BEST TREATMENT FOR AN INDIVIDUAL??

Abdul Rasheed Razia [*1], R. V. Ramanarayan Reddy [2] and G. Venkatraman [3]

Department of Pharmacology [1], Melmaruvathur Adhiparasakthi Institute of Medical Sciences and Research, Melmaruvathur - 603319, Tamil Nadu, India.
Department of Pharmacology [2], Annai Gowri Medical College and Hospital, Tirupati - 517584, Andhra Pradesh, India.
Department of Orthopaedics [3], Vels Medical College & Hospital, Tiruvallur – 601102, Tamil Nadu, India.

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Correspondence to Author:
Dr. Abdul Rasheed Razia

Assistant Professor,
Department of Pharmacology,
Melmaruvathur Adhiparasakthi Institute of Medical Sciences and Research, Melmaruvathur - 603319, Tamil Nadu, India.

E-mail: dr.raziaar@gmail.com

ABSTRACT: Extraordinary advances in clinical pharmacology transforms the current state of healthcare into the era of precision medicine where; clinical practice takes individual variability into account. It has been boosted by genetics and typically considered to be driven in an individual by a single genetic variant. Often the mechanisms generating the full clinical phenotype from such a perceived single cause are incompletely understood. Health care under precision medicine will become a more integrated, dynamic system, in which patients will participate actively in shared decision-making. There is a need for more comprehensive evaluation and a more rigorous framework, to explain clinical presentation and clinical responses to precision treatment.

INTRODUCTION:

Background: Precision medicine is an approach to healthcare that aims to identify the most effective treatment for an individual by considering their unique biological, genetic, environmental, and lifestyle factors rather than using a "one-size-fits-all" method. This article aims to provide a more comprehensive view on precision medicine as a process [1].

History: Humans with the same gene defect can develop different phenotypic diseases, a single disorder may be caused by varied genetic defects. Therefore the predictive power of genetics alone regards the cause of a disease.

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Hence, there was a need for newer technologies and ideas in medicine [2]. Sir William Osler said "It is much more important to know what sort of a patient has disease than what sort of a disease a patient has". This inter-individual variation should impact decisions about the optimal way to treat, monitor, or prevent a disease for an individual. Hence, Individualizing patient treatment is a core objective of the medical field [3].

Priorities for Precision Medicine – A National Research Agenda: In 2015, President Barack Obama initiated PM - a bold new research effort to revolutionize how to improve health and treat disease. The mission was to enable a new era of medicine through research, technology, and policies that empower patients, researchers, and providers to work together toward development of individualized care [4]. Over a period of 10 years, more than one million participants contributed data obtained from sequencing, electronic medical

records, self-reported information, and digital health technologies [5]. These data were analysed to drive both a completely novel scientific agenda for understanding of disease pathogenesis, as well as an agenda for data driven precision health care for all individuals. These were expected to impact health and decisions across the lifespan and to enhance the already emergent examples of precision health care being used, from reproductive counselling and prenatal testing at conception to healthy aging and molecular autopsies at death.

Precision Medicine- Development in India: The Indian Genome Variation Database (IGVdb), launched in 2003, compiled a comprehensive repository of genetic variation data, including both reported and novel single nucleotide polymorphisms (SNPs) and genetic repeats. The database was developed using samples from approximately 15,000 individuals across diverse populations in India, covering over 1,000 genes. It played a crucial role in understanding population-specific genetic diversity and laid the foundation for future genomic research in the country. In 2019, the Government of India introduced the DNA Technology (Use and Application) Regulation Bill, focusing on the establishment of regulatory frame work and data protection measures to safeguard genetic information.

The same year marked the launch of the National Digital Health Mission (NDHM), to promote the use of clinical decision support systems among healthcare professionals, thereby enhancing the quality, efficiency, and accessibility of healthcare services across the country. The Genome India Project initiated in 2020, involved the collection and analysis of 10,000 genetic samples from individuals representing various regions and ethnic groups in India. The primary goal is to develop a comprehensive reference genome that accurately reflects the genetic diversity of the Indian population. Such a resource is expected to significantly contribute to personalized medicine, disease prediction, and the development of targeted therapies [6-8].

Hence, India has progressed over the past decade in the field of PM. However, to make it routine into clinical and public health decision making, we have long way to go in terms of availability of meaningful data, clinician and public health specialist who understands the application of complex data, also awareness and acceptance of PM by society [9].

What Is Precision Medicine?: The National Research Council's Toward Precision Medicine adopted the definition of precision medicine from the President's Council of Advisors on Science and Technology in 2008 as: "The tailoring of medical treatment to the individual characteristics of each patient to classify individuals into subpopulations that differ in their susceptibility to a particular disease or their response to a specific treatment" [10].

The European Union's Horizon 2020 Advisory Group defines PM as the ''characterization of individuals' phenotypes and genotypes (e.g., molecular profiling, medical imaging and 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'' [11].

Examples of Precision Medicine:

- Warfarin can cause a potentially life-threatening side effect if taken incorrectly, naturally occurring genetic variation in both the VKORC1 and CYP2C9 genes leads to interindividual (pharmacodynamic and pharmacokinetic) variation in responses to warfarin. The US Food and Drug Administration therefore recommended that warfarin dose has to be tailored according to the specific genetic variants in the VKORC1 and CYP2C9 genes.[12]

- Another classic example is primaquine (PQ), which is used to control endemic malaria. However, military doctors found that some soldiers treated with PQ for malaria suffered from Acute HemolyticAnemia (AHA). It was later shown that people with AHA had variants in the G6PD gene after PQ administration. Current clinical practice for PQ therefore requires genotyping of individual patients to see if they have significant variants in the G6PD gene [13].

- Imatinib, a great illustration of a PM used to treat chronic myelogenous leukemia (CML).

Tyrosine kinase is boosted by the fusion of two genomic regions: the breakpoint cluster region (bcr) and the Abelson proto-oncogene (abl). This fusion event, also known as the "Philadelphia chromosome" or "bcr-abl fusion," contribute to the development of CML. But not every CML patient has malignancies that include the bcr-abl fusion mutation. As a result, imatinib is usually restricted to CML patients who have experienced this fusion event [14].

The Conceptual Distinction between Personalized and Precision Medicine: Personalized medicine refers to an approach to patients that considers their genetic make-up but with attention to their preferences, beliefs, attitudes, knowledge and social context, whereas precision medicine describes a health care delivery model that relies heavily on data, analytics, and information [18].

Personalized medicine also, involves the use of technologies to seriously acquire and assess an individual's own data for only their own treatment. For example, this may involve the use of artificial intelligence (AI) to both design a drug combination based on a patient's own biopsy in cancer treatment, a tumor biopsy may reveal specific genetic mutations responsible for uncontrolled cell growth. AI tools can identify targeted therapies or drug combinations that inhibit these mutations. If the patient shows partial response or adverse effects, the treatment is iteratively refined adjusting doses or substituting drugs until the most effective and tolerable regimen is achieved [19].

Challenges in Precision Medicine: PM approaches and genetic testing may lead to intervention, which could be harmful to individuals if the underlying tests are not sufficiently verified. A case report highlights the limitations of personalized medicine (PM) when genetic data are interpreted in isolation from clinical findings. Following sudden cardiac death in a young individual, cascade genetic screening of family members identified a variant associated with Long QT syndrome. On the basis of this molecular finding alone, an asymptomatic first-degree relative underwent prophylactic implantation of an Implantable cardioverter-defibrillator (ICD). Such intervention, in the absence of phenotypic confirmation, represents a deviation from evidence-based clinical practice. The predictive value of genetic variants is variable, particularly in conditions with incomplete penetrance and variable expressivity, where genotype does not necessarily correspond to clinical manifestation. Consequently, reliance solely on genotypic data may lead to overestimation of disease risk and inappropriate clinical decision-making. Comprehensive clinical evaluation, including assessment with an Electrocardiogram (ECG), is essential to establish or exclude the diagnosis prior to initiating invasive interventions. Integration of genotypic and phenotypic data is therefore critical for accurate risk stratification and therapeutic planning.

This case underscores the necessity for rigorous validation of PM approaches, standardized guidelines for the interpretation of genetic variants, and enhanced clinician competency in genomic medicine to minimize the risks of overdiagnosis, overtreatment, and iatrogenic harm [21].

The focus of future work should be to emphasize the potential of PM not only for individuals, but increasingly for the general population - what has been called "precision public health". Initial efforts toward accurate public health are underway, but much more work remains to develop a solid evidence base for use [22].

CONCLUSION: PM has increasingly contributed to improved screening, diagnostic precision, and targeted therapeutic interventions across a wide range of diseases. Despite these advances, the successful integration of PM into routine clinical practice requires progress beyond technology-centric innovation. Effective implementation depends on the development of supportive healthcare frameworks, interdisciplinary (bioinformatics, data science, and biomedical engineering) education and the integration of clinical training to interpret complex molecular data which can be applied in clinical decision-making.

Furthermore, the adoption of PM is influenced by several economic and operational factors, including cost-effectiveness, variability in willingness-to-pay thresholds, and the requirement for specialized infrastructure and resources. Traditional health

technology assessment models may not fully capture the individualized and long-term benefits of PM interventions. Therefore, revised evaluation approaches are needed to adequately assess their value. A balanced integration of technological innovation, clinical expertise, and economic considerations is crucial to ensure the safe, effective, and sustainable implementation of personalized medicine in healthcare systems.

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