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Guest Editorial

Current Limitations and Challenges of Precision Drugs

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Introduction

While precision medicine is an excellent approach to treating diseases, only a few early-phase candidates make it to full approval. For example, in oncology, patients often develop resistance to single-agent targeted drugs. Making precision medicine realistic requires a multi-layered strategy that bridges cutting-edge molecular science with practical healthcare delivery, data integration, and policy reform.

Background

Precision medicine focuses on matching medical treatments to individual genetic, genomic, or molecular characteristics of disease targets, not on a drug providing treatment to the entire population [1]. It does it by targeting well-defined molecular targets or biomarkers through matching the drug's mechanism of action.

In oncology, targeted therapies using monoclonal antibodies such as trastuzumab (for HER2-positive breast cancer), imatinib (for chronic myeloid leukemia), and osimertinib (for NSCLC) have radically transformed survival rates in previously fatal or hard-to-treat cancers [2]. However, while the global access to precision medicine is expanding as a major international health priority, significant geographical and economic disparities remain [3]. My previous publications on precision drugs [4-6] explored the gap between the concept of precision medicine and the reality of current drug development.

On May 22, 2026, the World Health Assembly (World Health Organization (WHO)) endorsed a landmark resolution (EB158) to make precision medicine a global health priority [7].

The Global Strategy is to guide context-appropriate implementation, particularly in low- and middle-income countries. Initiatives like the international precision health commission led by the Karolinska Institute and sponsored testing programs (such as SOPHiA DDM™) aim to expand next-generation sequencing (NGS) and data-sharing frameworks [8,9]. However, a number of core obstacles must be addressed to implement this strategy:

- Most genomic data and advanced diagnostics are concentrated in high-income nations (such as the United States and parts of Europe), leaving racial minorities and low-income populations underrepresented [10].
- Many regions face technical complexity, high costs for next-generation sequencing, a lack of standardized workflows, limited provider education, and fragmented regulatory frameworks [10].
- It is of concern that costly precision interventions could divert resources away from proven, low-tech population-level health measures if not carefully balanced [10].

To address this, Artificial Intelligence (AI) tools are increasingly used to accelerate patient workups [11], optimize clinical trials, and streamline biomarker analysis including harmonizing data storage and cloud access across international research labs and vendors, establishing biopharmaceutical partnerships, subsidized or sponsored, for genomic testing programs to bypass local cost barriers in underserved markets. The need for optimizing clinical trials has been recognized [12-14].

I argued previously [4-6] that:

- True precision drugs must act exclusively on specific molecular targets tied directly to a disease without causing adverse effects on healthy parts of the body.
- Drugs currently labeled as targeted or approved by agencies like the FDA are often not selective enough. Most act on general disease markers rather than unique, disease-driving mechanisms.
- Traditional site-specific drug delivery systems (such as nanoparticle encapsulation of chemotherapies) improve drug concentration at a site, but they often fail to meet the broader requirements of true precision medicine (accounting for individual genetics, environment, and lifestyle).

Concluding that a new paradigm was needed, I suggested that future drug development required better mapping of individual genetic variability, improved sequencing accuracy, and a shift from broad-distribution models to rationally designed molecules that target disease initiation sites.

Current limitations and challenges

While precision medicine is an excellent approach to treating diseases, only a few early-phase candidates make it to full approval. For example, in oncology, patients often develop resistance to single-agent targeted drugs [15]. Making precision medicine realistic requires a multi-layered strategy that bridges cutting-edge molecular science with practical healthcare delivery, data integration, and policy reform [16-19].

To this end, the following strategies have been proposed:

- Combine multi-omics data (genomics, proteomics, metabolomics) and real-time environmental data (exposomes) with electronic health records (EHRs) using artificial intelligence and machine learning to process complex patient profiles [17].
- Adopting adaptive trial designs, early enrichment strategies, and robust subgroup/biomarker identification.
- Transition genome sequencing and pharmacogenomic testing from exceptional or high-cost add-ons to standard clinical practice—similar to checking for drug allergies before writing a prescription.
- Shift health economic and payment models from reactive, volume-based care to value-based frameworks that align diagnostic and drug reimbursement with actual patient outcomes.
- Standardized evidence frameworks: Apply structured evidence strategy frameworks PPD Precision Medicine Evidence Strategy Guide to connect scientific development directly with regulatory and market access decisions from the earliest stages.
- Point-of-care and accessible tools: Build rapid, accessible point-of-care tests and clinical decision support tools that embed seamlessly into everyday clinician workflows without adding administrative burden.

The core arguments have been presented as follows [20]:

- **Definition of precision drugs:** True precision drugs must act exclusively on specific molecular targets tied directly to a disease without causing adverse effects on healthy parts of the body.

- **Limitations of current "targeted" therapies:** Drugs currently labeled as targeted or approved by agencies like the FDA are often not selective enough. Most act on general disease markers rather than unique, disease-driving mechanisms.
- **Role of drug delivery:** Traditional site-specific drug delivery systems (such as nanoparticle encapsulation of chemotherapies) improve drug concentration at a site, but they often fail to meet the broader requirements of true precision medicine (accounting for individual genetics, environment, and lifestyle).
- **New paradigm needed:** Future drug development requires better mapping of individual genetic variability, improved sequencing accuracy, and a shift from broad-distribution models to rationally designed molecules that target disease initiation sites.

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