

Personalized Medicine: Concepts, Clinical Applications, Challenges, and Future Perspectives

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ABSTRACT

Personalized Medicine (PM) represents a paradigm shift from the traditional “one-size-fits-all” approach to personalized preventive, diagnostic, and treatment regimens tailored to individual genetic, biological, environmental, and lifestyle characteristics. Breakthroughs in genetics, pharmacogenomics, biomarker discovery, and targeted therapies have significantly improved disease prediction, treatment efficacy, and patient safety in cancer, infectious diseases, and chronic disorders. Focusing on biomarkers, drug delivery techniques, and pharmacogenomic testing, this review examines the fundamental concepts, practical applications, and potential benefits of personalized medicine. It critically evaluates the implementation, ethical, economic, and regulatory challenges associated with real-world adoption. Current regulatory initiatives that encourage innovation and the evolving role of personalized medicine in primary care and disease management are discussed. Finally, the International Consortium for Personalized Medicine (ICPerMed) 2030 vision, emphasising data-driven therapies, informed healthcare professionals, empowered patients, and sustainable healthcare systems, is used to analyse future directions. Considering all aspects, personalized medicine holds immense potential to improve clinical outcomes, minimise adverse drug reactions, and promote a proactive, preventive healthcare paradigm; however, coordinated efforts are required to address societal, legal, and scientific challenges.

Keywords: Biomarkers, ICPerMed, Personalized medicine, Pharmacogenomics, Precision medicine, Targeted therapy.

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AIM AND OBJECTIVES

Aim

The primary aim of this review is to examine the concept, applications, benefits, challenges, and future prospects of personalized medicine, with particular focus on pharmacogenomics, biomarkers, drug delivery techniques, and the ICPerMed 2030 vision (Jameson and Longo, 2015; Hood and Friend, 2011).

Objectives

1. Explain the fundamental concepts and techniques of personalized medicine (Collins and Varmus, 2015).

2. Investigate the application of pharmacogenomics, biomarkers, and genetic information in personalized treatment (Relling and Evans, 2015; Phillips *et al.*, 2001).

3. Demonstrate how personalized medicine is employed in general care, infectious diseases, cancer, and disease management (Weston and Hood, 2004; La Thangue and Kerr, 2011).

4. Evaluate the advantages and clinical impacts of personalized medicine on patient outcomes (Lesko and Schmidt, 2012).

5. Identify unmet needs, challenges, ethical concerns, and legal obstacles associated with implementation (FDA, 2013; EPRS, 2015).

6. Discuss the future prospects of personalized medicine based on global initiatives, especially the ICPerMed 2030 framework (ICPerMed, 2019).



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INTRODUCTION

Personalized medicine is a targeted therapeutic strategy for individual patients or patient groups (Jameson and Longo, 2015; Issa, 2007). It integrates advanced molecular detection techniques with conventional approaches, such as detailed case histories, to deliver accurate, tailored evaluation and treatment (Hood and Friend, 2011). Historically, disease identification relied on clinical signs, which often reflected multiple conditions. Currently, genetic testing allows for far more precise diagnosis by identifying genes associated with specific disease susceptibilities (Collins and Varmus, 2015).

Personalized medicine involves developing pharmaceuticals tailored to individual patients or stratifying patients into subgroups according to predicted response to therapy or susceptibility to disease (Lesko and Schmidt, 2012; Relling and Evans, 2015). This approach relies on technological advances that reveal how an individual's molecular and genetic profile influences disease risk and treatment response (Phillips *et al.*, 2001; Johnson, 2003).

According to the European Parliamentary Research Service (2015), personalized medicine is an “emerging and evolving approach” that utilises molecular and genetic insights to guide disease anticipation, mitigation, detection, and management. The ultimate goal is to provide “the right treatment for the right person at the right time.” Supported by scientific innovations and advanced technologies, this approach has profoundly impacted healthcare delivery (Figure 1) (Topol, 2019).

P4 Systems Medicine

Personalized medicine enables proactive healthcare, emphasizing disease prevention and risk management (Hood and Friend, 2011). The emerging P4 systems medicine framework - predictive, preventive, personalized, and participatory - integrates clinical, genomic, genetic, and epigenetic data to deliver therapies that address molecular and individual patient characteristics (Figure 2) (Weston and Hood, 2004). A key concept of personalized medicine is the development and modification of integrative biomarkers to treat patients rather than merely treating the disease (La Thangue and Kerr, 2011). While personalized medicine terminology is still evolving (e.g., personalized, customized, precision), it offers opportunities to improve pharmacotherapy, enhance clinical trial design, and optimize medication selection and administration for individual patients (Roden *et al.*, 2019).

METHODOLOGY

This article was prepared using a narrative literature review approach to analyse the concepts, clinical applications, challenges, and future perspectives of personalized medicine (Topol, 2019; Schork, 2015).

Scientific literature was retrieved from PubMed, Scopus, and Google Scholar, along with reports and policy documents from the U.S. Food and Drug Administration (FDA), World Health Organization (WHO), European Parliamentary Research Service (EPRS), and the International Consortium for Personalized Medicine (ICPerMed) to incorporate regulatory and global healthcare perspectives (FDA, 2013; WHO, 2018; EPRS, 2015; ICPerMed, 2019).

The literature search employed keywords including “personalized medicine,” “precision medicine,” “pharmacogenomics,” “biomarkers,” “targeted therapy,” “drug delivery systems,” and “ICPerMed,” focusing on publications between 2010 and 2024 (Roden *et al.*, 2019; Relling and Evans, 2015; Ashley, 2016).

The selected literature was analysed using a thematic synthesis approach, enabling critical evaluation of clinical, ethical, and regulatory challenges and future research directions in personalized medicine (Hood and Friend, 2011; Topol, 2019).

Given the rapidly evolving and interdisciplinary nature of personalized medicine, a flexible narrative approach was considered more suitable than a rigid systematic design.

Operational Framework of Personalized Medicine

Genetic Data

Analyzing an individual's genetic makeup helps determine how their genes affect health, disease susceptibility, and response to treatments. This may involve genetic testing to identify mutations that influence drug metabolism or increase the risk of specific diseases (Relling and Evans, 2015; Phillips *et al.*, 2001).

Customised Treatment Programs

Using genetic data alongside lifestyle and environmental factors, physicians can develop personalized treatment plans that are more effective and safer than standard therapies (Lesko and Schmidt, 2012; Ashley, 2016).

Preventive Techniques

Personalized medicine sets tailored preventive measures based on each individual's risk factors. Healthcare providers can recommend strategies to reduce the likelihood of disease onset by understanding genetic predispositions and lifestyle influences (EPRS, 2015; Hood and Friend, 2011).

Screening and Monitoring

Personalized medicine often requires continuous monitoring of a patient's health and response to therapy. This may include regular genetic testing, biomarker tracking, or other diagnostic methods to evaluate drug efficacy and adjust treatments as needed (Roden *et al.*, 2019).

The integration of digital health technologies and wearable biosensors enables continuous patient monitoring and

real-time data collection, supporting proactive intervention and personalized disease management (Spinelli *et al.*, 2025; Ravichandran and Ramachandran, 2025).

To enhance screening and monitoring in personalized medicine, additional data types beyond genomics are crucial:

Longitudinal Multi-Omics

Serial proteomics (e.g., liquid biopsies for circulating tumor DNA) and metabolomics (e.g., drug metabolite profiles) track real-time treatment response and resistance emergence, enabling dynamic dosing adjustments.

Real-World Data (RWD) from electronic health records, wearables (continuous glucose, heart rate variability), and patient-reported outcomes captures lifestyle, adherence, and adverse events outside trial settings, refining predictive algorithms.

Epigenetic and Microbiome Profiling

DNA methylation patterns and gut microbiome composition influence drug metabolism (e.g., irinotecan toxicity) and efficacy, guiding pre-treatment stratification.

Pharmacogenomic Panels expanded to include rare variants and polygenic scores for drug transporters (e.g., SLCO1B1) and metabolizing enzymes (e.g., CYP2D6), integrated with clinical decision support systems.

Digital Twins and AI using aggregated multi-modal data simulate patient-specific drug trajectories, flagging non-response or toxicity before clinical onset (Figure 3).

Role of Drug Delivery Systems in Personalized Medicine

The effectiveness of a drug depends not only on its properties but also on its ability to reach the intended target in the body without degradation or unintended interactions. Drug delivery systems play a crucial role in ensuring that therapeutic agents reach their designated sites in effective concentrations (Lesko and Schmidt, 2012).

Advances in molecular biology, bioinformatics, and high-throughput screening have improved drug design, though challenges remain in optimising drug deliverability *in vivo*. Personalized delivery strategies allow medications to be administered safely and effectively according to individual patient characteristics, thereby maximising therapeutic outcomes (Weston and Hood, 2004; Ashley, 2016).

Emerging technologies such as artificial intelligence-enabled drug delivery systems, predictive modeling, and three-dimensional (3D) printed formulations are further enhancing dosing precision and patient-specific therapeutic optimization (Panchpuri *et al.*, 2025).

Unmet Needs and Barriers in Personalized Medicine

The pharmaceutical industry is evolving rapidly, driven largely by biotechnology. Since the introduction of recombinant human insulin, biotechnology has accelerated medical innovation, including the development of genetic and regenerative therapies (Lesko and Schmidt, 2012; Weston and Hood, 2004).

Biotechnology not only provides novel drugs but also reshapes drug development, enabling customized treatment approaches. When implemented effectively, personalized therapies can reduce long-term healthcare costs and improve productivity (Ashley, 2016).

However, personalized medicine remains challenging to achieve in practice due to financial, educational, and infrastructural barriers. Incentives for development, affordability, and widespread access remain major obstacles in many regions (ICPerMed, 2017; Phillips *et al.*, 2001).

Factors Influencing Personalized Medicine

Several factors impact the success of personalized medicine:

Polypharmacy in Elderly Patients

Patients over 65 may be prescribed numerous medications simultaneously, requiring delivery strategies that manage drug-drug interactions effectively (Lesko and Schmidt, 2012; Johnson, 2003).

Chronic Conditions

Most drugs are tested in patients with a single chronic condition, whereas many patients have multiple comorbidities, affecting treatment efficacy (Relling and Evans, 2015).

Technological Advancement

Improvements in drug delivery systems and technology can accelerate personalized therapy implementation (Weston and Hood, 2004; Ashley, 2016).

Applications of Personalized Medicine

Early detection of disease through enhanced surveillance allows for timely interventions (La Thangue and Kerr, 2011).

Prevention of adverse drug reactions by avoiding generic “one-size-fits-all” prescriptions (Phillips *et al.*, 2001).

Improved treatment efficacy by tailoring drugs and dosages to individual genetic profiles (Relling and Evans, 2015).

Recommendation of preventive measures for high-risk individuals (EPRS, 2015).

Genetic testing, such as BRCA analysis, enables early detection and preventive interventions for hereditary cancers (King *et al.*, 2003).

In oncology, personalized medicine identifies tumour-specific mutations to select targeted therapies with fewer side effects than standard chemotherapy (Slamon *et al.*, 2001; Lynch *et al.*, 2004).

Pharmacogenomic testing informs medication selection and dosage adjustments to minimise risks and improve outcomes (Weinshilboum and Wang, 2017; Caudle *et al.*, 2014).

In infectious diseases, including HIV and hepatitis C, genetic tests guide effective antiviral therapy based on host genetics, mutations, and resistance profiles (Figure 4) (Roden *et al.*, 2019).

Advantages of Personalized Medicine

Reduced healthcare costs through targeted therapies (Lesko and Schmidt, 2012).

Improved treatment success due to better-matched interventions (Ashley, 2016).

Focus on disease prevention rather than solely treatment (Hood and Friend, 2011).

Lower risk of serious adverse effects (Phillips *et al.*, 2001).

Earlier disease interventions compared to traditional approaches (Collins and Varmus, 2015).

Accurate diagnosis through genetic and molecular profiling (Relling and Evans, 2015).

Personalized treatment reduces risk of resistance or negative reactions (Weinshilboum and Wang, 2017).

Preventive care strategies are tailored to individual risk factors, including lifestyle and genetics (Topol, 2019).

Expectations Versus Real-World Implementation

Public perception of personalized medicine can be influenced by exaggerated claims regarding “completely customised” therapies (Schorck, 2015). While these promises may be aspirational, actual clinical implementation often lags behind. Differences between political, commercial, and scientific expectations versus real-world adoption highlight the need for careful evaluation of efficacy, safety, and clinical utility (FDA, 2013; ICPeMed, 2019).

Real-world evidence from clinical databases and patient registries is increasingly used to validate personalized treatment strategies beyond controlled clinical trial environments (Nguyen *et al.*, 2024).

Core Principles of Personalized Medicine

Personalized medicine uses individual characteristics to guide disease prevention, diagnosis, and treatment (Jameson and Longo, 2015).

Detailed diagnostic information is required, obtained through immunohistology, biochemical assays, molecular diagnostics, or next-generation sequencing (Relling and Evans, 2015).

Multiple technologies, including small molecules, biologics, and Advanced Therapy Medicinal Products (ATMPs), are used (Lesko and Schmidt, 2012).

Individualised therapies include gene therapy, ATMPs, and modified T-cell therapies (Ashley, 2016).

Targeted approaches may vary among individuals with the same disease (La Thangue and Kerr, 2011).

Targeted therapies focus on molecular pathways or specific mutations; for example, in oncology, they inhibit tumour growth, induce apoptosis, prevent metastasis, and modulate immune responses (Slamon *et al.*, 2001; Lynch *et al.*, 2004).

Clinical and Healthcare Benefits of Personalized Medicine

Reduced adverse events

By targeting individuals less likely to experience side effects, PM improves patient safety (Phillips *et al.*, 2001).

Enhanced survival rates

Therapies targeting disease-specific molecular mechanisms improve outcomes and reduce recurrence (Topol, 2019).

Preventive health

Genetic testing and early risk assessment enable proactive disease prevention (Hood and Friend, 2011).

Improved efficacy

Treatments tailored to patient responsiveness increase therapeutic benefits (Relling and Evans, 2015).

Patient-centred care

Personalized interventions consider genetic makeup, lifestyle, and disease characteristics, improving quality of life (Ashley, 2016).

Cost-effectiveness

Although upfront diagnostics may be expensive, long-term healthcare costs are reduced through fewer hospitalisations, complications, and ineffective treatments (Lesko and Schmidt, 2012).

Empowered patients

Patients can make informed decisions regarding their healthcare by understanding their genetic risks and available therapies (ICPeMed, 2019).

Research advancement

Data from personalized medicine guides future research, drug development, and targeted therapy design (Topol, 2015).

Role of Personalized Medicine in Disease Management

Studies have demonstrated improved outcomes in cancer care, particularly for Non-Small Cell Lung Cancer (NSCLC). Traditional cytotoxic therapies have been supplemented by treatments targeting specific genetic mutations, improving symptom-free survival and reducing physical and psychological burdens (Mok *et al.*, 2009; Garraway *et al.*, 2013).

Targeting the PD-1/PD-L1 pathway with monoclonal antibodies exemplifies precision oncology, allowing therapies to be tailored to tumour-specific characteristics and immune system interactions (Rosenberg *et al.*, 2016; Caudle *et al.*, 2014).

Impact of Personalized Medicine on Patient Outcomes

Personalized medicine improves patient outcomes through three main strategies:

- **Prevention:** Educating patients on environmental and genetic risks to prevent disease (EPRS, 2015).
- **Diagnosis:** Identifying molecular causes of diseases for targeted intervention (Relling and Evans, 2015).
- **Treatment:** Delivering therapies tailored to individual biological mechanisms, ensuring safety and efficacy (Phillips *et al.*, 2001).

Recent evidence demonstrates that personalized medicine is translating into significant, measurable improvements in patient outcomes across multiple disease areas.

Oncology

In metastatic breast cancer, comprehensive genomic profiling leading to molecularly targeted therapy resulted in a progression-free survival benefit for one-third of patients, with 44% receiving a personalized recommendation. For end-stage, treatment-refractory cancer patients, those receiving targeted therapy had a median overall survival of 15 months compared to just 5-6 months for those who did not. In advanced melanoma, personalized ctDNA monitoring showed that patients achieving ctDNA clearance at 6 months had a 2-year progression-free survival of 89% versus 30% in ctDNA-positive patients. A Czech national study found that cancer patients with high tumor mutation burden (≥ 15 muts/Mb) receiving checkpoint inhibitors had significantly longer progression-free survival (23.4 vs. 3.5 months).

Psychiatry

A meta-analysis of pharmacogenomic testing in major depressive disorder (3,532 patients) found that genetically-guided prescribing improved response rates by 30% and remission rates by 41% compared to unguided care.

Emerging Applications

A multi-ancestry genome-wide study identified the first genetic variant (SLC39A10) associated with buprenorphine treatment response for opioid use disorder, opening pathways for personalized addiction medicine.

Collectively, these findings confirm that biomarker-guided treatment selection and molecular monitoring significantly enhance survival, response rates, and remission across therapeutic areas, though further validation in randomized trials remains needed

Key benefits include:

- Targeted treatments selected based on genetic, environmental, and behavioural factors (Ashley, 2016).
- Reduced adverse reactions due to consideration of individual variations (Weinshilboum and Wang, 2017).
- Enhanced patient outcomes, including improved disease management, survival rates, and quality of life (Topol, 2019).
- Early diagnosis and preventive interventions through genetic and advanced diagnostic testing (La Thangue and Kerr, 2011).
- Personalized dosages to optimise efficacy and reduce under- or overdosing (Relling and Evans, 2015).
- Cost-effectiveness by minimising unnecessary treatments and hospitalisation (Lesko and Schmidt, 2012).

Biomarkers in Personalized Medicine

Critics argue that personalized medicine is merely a rebranding of scientific research, yet biomarkers, such as blood cholesterol and vital signs, have proven essential for clinical diagnosis and treatment (Strimbu and Tavel, 2010; Diamandis, 2010).

Biomarkers guide therapeutic decisions, indicating which patients should receive specific interventions and when. Modern regulatory approvals increasingly depend on biomarker-based approaches, reflecting their central role in personalized medicine (Sawyers, 2008; La Thangue and Kerr, 2011).

Recent real-world studies demonstrate that pharmacogenomic biomarkers, including CYP2D6 and related gene-drug associations, improve treatment efficacy and reduce adverse drug reactions across diverse clinical settings (Rodriguez *et al.*, 2025).

Evolution and Future Potential of Personalized Medicine

Personalized medicine is increasingly recognised as central to future healthcare. By considering genetic, lifestyle, and environmental factors, it optimises preventive strategies,

treatment efficacy, and patient outcomes (Topol, 2019; Schork, 2015).

Technological advances in genomics, proteomics, and data analytics are expected to expand personalized medicine's role in routine care (Weston and Hood, 2004). Ethical, regulatory, and access challenges remain, but personalized medicine promises more effective, proactive, and preventive healthcare delivery (FDA, 2013; ICPeMed, 2019).

Ultimately, integrating individual genetic profiles into medical records from birth could enable highly tailored treatment plans throughout life, maximising efficacy and minimising adverse effects (Hood and Friend, 2011).

Personalized Medicine in Primary Care: Potential and Limitations

Genetic applications in primary care can improve the prevention and treatment of cancers, cardiovascular disease, anaemia, and other conditions (Ashley *et al.*, 2012). Pharmacogenetics reveals how genetic variations influence drug responses, enabling tailored prescriptions and dosing (Evans and Relling, 2004).

However, challenges exist, including patient acceptance, cost-effectiveness, and integration into public health systems. For instance, non-responders to certain therapies may require alternative strategies, and cost-effectiveness modelling is essential to justify personalized interventions over standard care (Phillips *et al.*, 2018).

Challenges, Limitations, and Research Gaps in Personalized Medicine

In routine clinical practice, the implementation of personalized medicine remains constrained by cost, infrastructure, data integration, and patient acceptance, particularly in primary care settings (Ashley *et al.*, 2024).

While scientific advances are promising, practical implementation in diverse healthcare settings remains uneven and multifaceted. Despite substantial scientific progress, translating personalized medicine into everyday clinical practice remains complex, particularly when economic, ethical, and infrastructural constraints are considered.

- **Privacy and Data Security:** Maintaining confidentiality of sensitive genetic information is essential to retain patient trust (ICPeMed, 2019).
- **Cost:** Development of personalized therapies involves expensive diagnostics, sequencing, and targeted medications, potentially limiting access (Lesko and Schmidt, 2012).
- **Ethical Considerations:** Issues include equitable resource allocation, discrimination risks, and informed consent for genetic testing (Topol, 2019).

Personalized medicine, while promising, raises several critical ethical considerations that warrant careful attention.

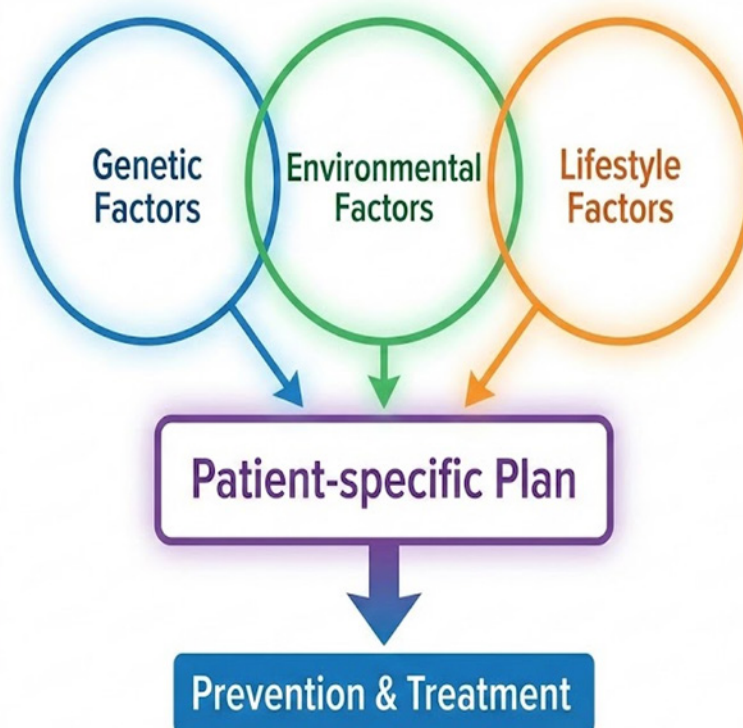


Figure 1: Patient-specific factors influencing prevention and treatment decisions.



Figure 2: The P4 medicine framework highlights the transition toward predictive, preventive, personalized, and participatory healthcare to improve patient outcomes and disease management.

Privacy and Data Security

Genomic and multi-omic data are uniquely identifiable and sensitive. Unlike passwords, genetic information cannot be changed if breached. There are concerns about re-identification from de-identified databases, unauthorized access by employers or insurers (despite GINA protections in the U.S., gaps remain for life, disability, and long-term care insurance), and potential misuse by law enforcement or third parties.

Informed Consent

Traditional consent models struggle with the breadth of genomic data. Whole-genome sequencing may reveal incidental findings (e.g., predisposition to Huntington's disease) that the patient did not wish to know. Consent must be dynamic, allowing individuals to opt in or out of receiving secondary findings, and to decide on data sharing for future research-challenging when data utility evolves over time.

Equity and Access

Personalized medicine risks exacerbating health disparities. Genomic databases are predominantly Eurocentric, leading to poorer test performance and fewer targeted therapies for non-European ancestry groups. Additionally, high costs of biomarker testing and matched therapies (e.g., CAR-T cells)

may be inaccessible to underinsured or low-income populations, creating a two-tiered system where only the affluent benefit.

Psychosocial and Family Impact

Genetic results are not solely individual. A high-risk variant discovered in one person automatically informs biological relatives of their potential risk, raising questions about the duty to warn family members versus the proband's right to confidentiality. Furthermore, predictive testing for untreatable conditions can cause anxiety, stigmatization, or fatalism.

Clinical Integration and Oversight

Direct-to-consumer genetic tests often lack clinical validation, leading to unnecessary interventions or false reassurance. There is also the risk of "therapeutic misconception"-patients overestimating benefits from targeted therapies based on hope rather than evidence.

Addressing these considerations requires robust governance, diverse research cohorts, transparent consent protocols, and policies ensuring equitable access, so that personalized medicine advances ethically as well as scientifically.

Recent discussions emphasise the ethical, legal, and social implications of genomic data use, including consent frameworks, data governance, and equitable access to personalized therapies (Martinez and Singh, 2024).

- **Regulatory Barriers:** Balancing innovation with safety and efficacy presents challenges for regulatory agencies (FDA, 2013).
- **Multidisciplinary Collaboration:** Effective PM requires coordination among clinicians, researchers, policymakers, and technologists (Hood and Friend, 2011).
- **Health Disparities:** Unequal access may exacerbate existing healthcare inequalities (EPRS, 2015).
- **Data Analysis:** Integrating vast genetic, clinical, and environmental datasets demands advanced computational methods (Topol, 2019).
- **Patient Engagement:** Educating patients on personalized medicine empowers informed healthcare decisions (ICPerMed, 2019).

Collectively, these challenges highlight the complexity of translating scientific innovation into safe, effective, and equitable patient care. Addressing these challenges is critical to realizing the

full potential of personalized medicine across diverse populations (Schork, 2015).

Regulatory and Implementation Considerations in Personalized Medicine

Effective PM implementation requires risk-based, transparent, and predictable regulatory frameworks (FDA, 2013):

- **Reimbursement Policies:** Reflect the clinical value of personalized interventions to encourage adoption (ICPerMed, 2017).
- **Healthcare Professional Education:** Training is crucial for proper integration of PM into clinical practice (Hood and Friend, 2011).
- **Streamlined Approvals:** Facilitating rapid authorisation of innovative therapies (FDA, 2013).
- **Research Support:** Government funding promotes continued innovation (ICPerMed, 2017).
- **Health Infrastructure:** Modernised data systems enable effective personalized care delivery (Topol, 2019).

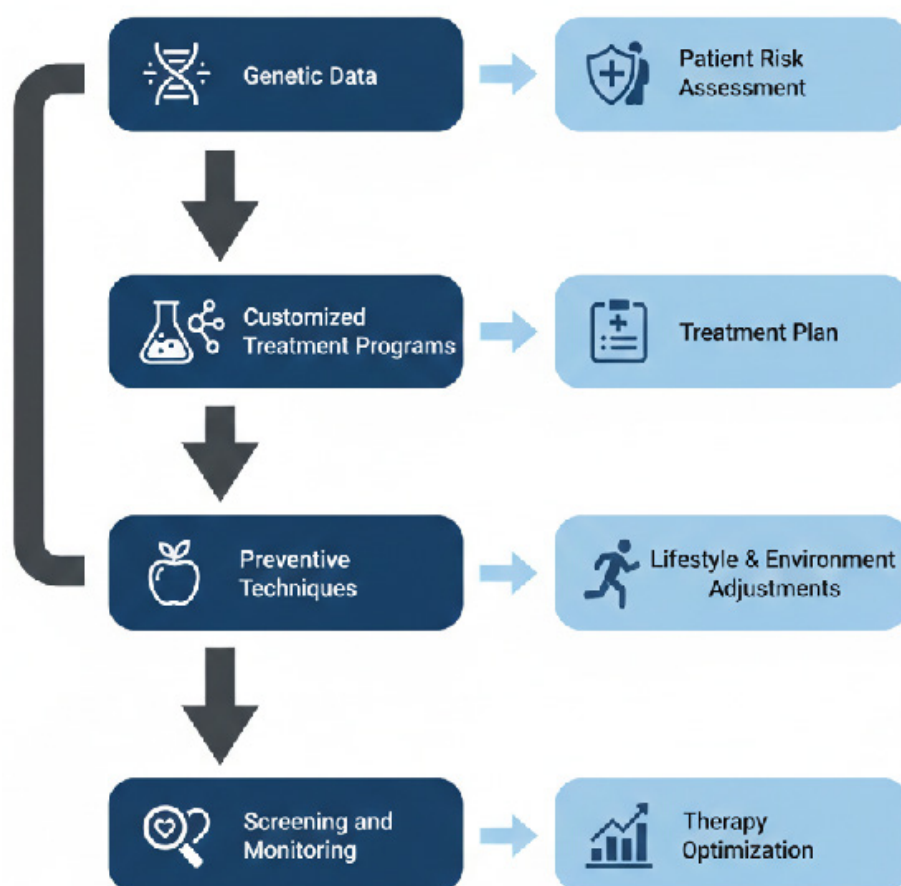


Figure 3: Practical workflow from genetic data to therapy optimisation.

Application Area	Example / Technique	Clinical Benefit
 Oncology	Tumor-specific mutations (BRCA, EGFR)	Targeted therapy, reduced side effects
 Pharmacogenomics	Genetic testing for drug metabolism	Optimized dosage, reduced ADRs
 Infectious Diseases	HIV/HCV genotyping	Effective antiviral therapy
 Preventive Care	Lifestyle + genetic risk analysis	Early intervention and disease prevention

Figure 4: Highlights therapeutic and preventive benefits across clinical domains.

Future Perspectives in Personalized Medicine: ICPeMed 2030 Vision

As personalized medicine continues to evolve, strategic frameworks like ICPeMed play an increasingly important role in guiding its long-term integration into healthcare systems.

Despite persistent challenges, emerging international initiatives suggest that strategic frameworks such as ICPeMed can meaningfully guide the equitable implementation of personalized medicine. By 2030, ICPeMed envisions full integration of personalized medicine into healthcare systems, guided by five principles (ICPeMed, 2019):

- **Empowered Citizens:** Patients actively engage in healthcare decisions and control their health data.
- **Informed Health Providers:** Clinicians use personalized data safely and effectively.
- **Optimized Healthcare Systems:** Resources are allocated fairly, and data flows safely.
- **Information-Driven Care:** Integration of biomarkers, multi-omics data, and EHRs for precise diagnosis and therapy.
- **Economic Value and Innovation:** Balance investment with societal benefit while supporting new business models, telemedicine, and workforce development.

Recent international roadmaps highlight the importance of regulatory harmonization, reimbursement strategies, and

workforce training to support the sustainable and equitable adoption of personalized medicine (Beccia *et al.*, 2025).

Five pillars guide the implementation for equitable, data-driven healthcare by 2030.

Transversal pillars - data and technology, inter-sectoral collaboration, healthcare system updates, and literacy/education - support these goals, promoting preventive strategies, improved patient outcomes, cost-effectiveness, and equitable PM implementation (Topol, 2019; ICPeMed, 2019). These transversal elements collectively support the strategic goals of ICPeMed, ensuring that personalized medicine can be implemented efficiently, equitably, and sustainably across diverse healthcare systems.

DISCUSSION

This review highlights that while Personalized Medicine (PM) has transitioned from a conceptual framework to clinical reality-particularly in oncology, infectious diseases, and pharmacogenomics-its widespread implementation remains hindered by multifaceted barriers. The integration of biomarkers, genetic profiling, and advanced drug delivery systems has undeniably improved treatment efficacy and reduced adverse drug reactions. However, the authors critically note a persistent gap between scientific promise and real-world adoption. Key challenges include high diagnostic costs, data privacy concerns, regulatory fragmentation, and the need for multidisciplinary collaboration. The ICPeMed 2030 vision offers a strategic roadmap, emphasising empowered patients, informed providers,

and data-driven care. Nevertheless, without addressing health disparities, workforce training gaps, and equitable reimbursement policies, PM risks exacerbating existing inequalities. The discussion underscores that technological innovation alone is insufficient; sustainable progress requires parallel advances in ethical frameworks, healthcare infrastructure, and patient engagement to ensure PM becomes a standard of care rather than a niche offering.

CONCLUSION

Taken together, recent advances demonstrate that personalized medicine is transitioning from a conceptual innovation to a practical component of modern healthcare systems. From a clinical and policy standpoint, the success of personalized medicine depends not only on technological innovation but also on equitable access, feasibility, and integration into routine care.

By tailoring preventive, diagnostic, and therapeutic strategies to individual genetic and molecular profiles, personalized medicine is reshaping modern healthcare (Jameson and Longo, 2015; Hood and Friend, 2011). Pharmacogenomics, biomarkers, and targeted therapies enhance treatment efficacy, reduce adverse effects, and improve outcomes across multiple disease categories (Relling and Evans, 2015; Ashley, 2016).

Challenges remain, including costs, ethical concerns, data privacy, regulatory complexity, and workforce training (FDA, 2013; ICPeMed, 2019). Multidisciplinary collaboration, robust regulation, technological innovation, and patient engagement are essential for continued growth (Topol, 2019; Schork, 2015).

The ICPeMed 2030 framework provides a roadmap for integrating personalized medicine into healthcare systems, promoting data-driven care, patient empowerment, and sustainable, preventative healthcare. Addressing current challenges while fostering innovation will ensure personalized medicine reaches its full potential (ICPeMed, 2019).

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The schematic figures included in this review were created by the authors using Gemini AI (Google) as a visualization tool. These figures are conceptual in nature and are based on the authors' scientific understanding of personalized medicine. No data or results were generated by the AI.

ABBREVIATIONS

PM: Personalized Medicine; **ICPeMed:** International Consortium for Personalized Medicine; **P4 Medicine:** Predictive, Preventive, Personalized, and Participatory Medicine; **EHR:** Electronic Health Records; **ASO:** Antisense Oligonucleotide; **ATMP:** Advanced Therapy Medicinal Product; **FDA:** Food and Drug Administration; **NHS:** National Health Service; **NSCLC:** Non-Small Cell Lung Cancer; **BRCA:** Breast Cancer Gene; **DNA:**

Deoxyribonucleic Acid; **RNA:** Ribonucleic Acid; **HIV:** Human Immunodeficiency Virus; **WHO:** World Health Organization; **EU:** European Union; **EPRS:** European Parliamentary Research Service; **PD-1:** Programmed Cell Death Protein-1; **PD-L1:** Programmed Death-Ligand 1.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHORS CONTRIBUTION

Gorinkala Bhargavi Sudeeshna: Conceptualization; Methodology; Literature search and data curation; Writing - original draft preparation; Visualization; Writing- review and editing. **K.T. Sunil Kumar:** Validation; Formal analysis; Investigation; Resources; Supervision; Writing - review and editing. **Sudarshan Rao Nagineni:** Conceptualization; Project administration; Supervision; Funding acquisition (none); Corresponding author responsibilities; Critical revision of the manuscript for important intellectual content; Final approval of the version to be published.

REFERENCES

- Ashley, E. A. (2016). Towards precision medicine. *Nature Reviews Genetics*, 17(9), 507-522. <https://doi.org/10.1038/nrg.2016.86>
- Ashley, E. A., et al. (2024). Precision medicine-Are we there yet? *Journal of Personalized Medicine*, 14(4), 418. <https://doi.org/10.3390/jpm14040418>
- Ashley, E. A., Hershberger, R. E., Caleshu, C., et al. (2012). Genetics and cardiovascular disease. *Circulation Research*, 110(10), 1378-1393. <https://doi.org/10.1161/CIRCRESA.111.262352>
- Beccia, M., et al. (2025). A roadmap for personalized medicine: Findings from the IC2PeMed project. *Frontiers in Medicine*, 12, 1572921. <https://doi.org/10.3389/fmed.2025.1572921>
- Caudle, K. E., Klein, T. E., Hoffman, J. M., et al. (2014). Incorporation of pharmacogenomics into routine clinical practice. *Clinical Pharmacology & Therapeutics*, 95(4), 388-395. <https://doi.org/10.1038/clpt.2013.246>
- Collins, F. S., & Varmus, H. (2015). A new initiative on precision medicine. *New England Journal of Medicine*, 372(9), 793-795. <https://doi.org/10.1056/NEJMp1500523>
- Crews, K. R., Hicks, J. K., Pui, C. H., Relling, M. V., & Evans, W. E. (2012). Pharmacogenomics and individualized medicine. *Clinical Pharmacology & Therapeutics*, 92(4), 467-475. <https://doi.org/10.1038/clpt.2012.120>
- Diamandis, E. P. (2010). Cancer biomarkers: Can we turn recent failures into success? *Journal of the National Cancer Institute*, 102(19), 1462-1467. <https://doi.org/10.1093/jnci/djq306>
- European Parliamentary Research Service. (2015). Personalized medicine: The right treatment for the right person at the right time. European Parliament. [https://www.europarl.europa.eu/thinktank/en/document/EPRS_IDA\(2015\)554213https://www.europarl.europa.eu/thinktank/en/document/EPRS_IDA\(2015\)554213](https://www.europarl.europa.eu/thinktank/en/document/EPRS_IDA(2015)554213https://www.europarl.europa.eu/thinktank/en/document/EPRS_IDA(2015)554213)
- Evans, W. E., & Relling, M. V. (2004). Moving towards individualized medicine with pharmacogenomics. *Nature*, 429(6990), 464-468. <https://doi.org/10.1038/nature02626>
- Garraway, L. A., Verweij, J., & Ballman, K. V. (2013). Precision oncology: An overview. *Journal of Clinical Oncology*, 31(15), 1803-1805. <https://doi.org/10.1200/JCO.2013.49.4799>
- Hamburg, M. A., & Collins, F. S. (2010). The path to personalized medicine. *New England Journal of Medicine*, 363(4), 301-304. <https://doi.org/10.1056/NEJMp1006304>
- Hood, L., & Friend, S. H. (2011). Predictive, personalized, preventive, participatory (P4) cancer medicine. *Nature Reviews Clinical Oncology*, 8(3), 184-187. <https://doi.org/10.1038/nrclinonc.2010.227>
- International Consortium for Personalized Medicine. (2017). Action plan 2017-2021. <https://www.icpermed.eu>
- International Consortium for Personalized Medicine. (2019). Vision 2030: Preparing Europe for leading personalized medicine. <https://www.icpermed.eu>
- Issa, A. M. (2007). Personalized medicine and the practice of medicine in the 21st century. *McGill Journal of Medicine*, 10(1), 53-57.

- Jameson, J. L., & Longo, D. L. (2015). Precision medicine-Personalized, problematic, and promising. *New England Journal of Medicine*, 372(23), 2229-2234. <https://doi.org/10.1056/NEJMs1503104>
- Johnson, J. A. (2003). Pharmacogenetics: Potential for individualized drug therapy through genetics. *Trends in Genetics*, 19(11), 660-666. <https://doi.org/10.1016/j.tig.2003.08.006>
- King, M. C., Marks, J. H., & Mandell, J. B. (2003). Breast and ovarian cancer risks due to inherited mutations in BRCA1 and BRCA2. *Science*, 302(5645), 643-646. <https://doi.org/10.1126/science.1088759>
- La Thangue, N. B., & Kerr, D. J. (2011). Predictive biomarkers: A paradigm shift towards personalized cancer medicine. *Nature Reviews Clinical Oncology*, 8(10), 587-596. <http://doi.org/10.1038/nrclinonc.2011.121>
- Lesko, L. J., & Schmidt, S. (2012). Individualization of drug therapy: History, present state, and opportunities for the future. *Clinical Pharmacology & Therapeutics*, 92(4), 458-466. <https://doi.org/10.1038/clpt.2012.113>
- Lynch, T. J., Bell, D. W., Sordella, R., et al. (2004). Activating mutations in the EGFR underlying responsiveness of non-small cell lung cancer to gefitinib. *New England Journal of Medicine*, 350(21), 2129-2139. <https://doi.org/10.1056/NEJMoa040938>
- Martinez, J., & Singh, R. (2024). Reframing ELSI considerations for the era of precision health. *Journal of Law and the Biosciences*, 11(1), 1s4012. <https://doi.org/10.1093/jlb/lsad012>
- Mok, T. S., Wu, Y. L., Thongprasert, S., et al. (2009). Gefitinib or carboplatin-paclitaxel in pulmonary adenocarcinoma. *New England Journal of Medicine*, 361(10), 947-957. <http://doi.org/10.1056/NEJMoa0810699>
- National Health Service. (2020). Genomic medicine service. NHS England. <https://www.england.nhs.uk/genomics/>
- Nguyen, P., et al. (2024). Real-world evidence complements randomized trials to accelerate precision medicine adoption. *Clinical Pharmacology & Therapeutics*, 115(2), 245-256. <https://doi.org/10.1002/cpt.3245>
- Panchpuri, M., Painuli, R., & Kumar, C. (2025). Artificial intelligence in smart drug delivery systems: A step toward personalized medicine. *RSC Pharmaceutics*, 2(5), 882-914. <https://doi.org/10.1039/D5PM00089K>
- Phillips, K. A., Deverka, P. A., Hooker, G. W., & Douglas, M. P. (2018). Genetic test availability and spending: Where are we now? *Nature Biotechnology*, 36(10), 899-902. <https://doi.org/10.1038/nbt.4267>
- Phillips, K. A., Veenstra, D. L., Oren, E., Lee, J. K., & Sadee, W. (2001). Pharmacogenomics and adverse drug reactions. *JAMA*, 286(18), 2270-2279. <https://doi.org/10.1001/jama.286.18.2270>
- Ravichandran, S., & Ramachandran, K. (2025). A comprehensive review of wearable devices for non-invasive biosensing. *TrAC Trends in Analytical Chemistry*, 193, 118425. <https://doi.org/10.1016/j.trac.2025.118425>
- Relling, M. V., & Evans, W. E. (2015). Pharmacogenomics in the clinic. *Nature*, 526(7573), 343-350. <https://doi.org/10.1038/nature15817>
- Roden, D. M., McLeod, H. L., Relling, M. V., et al. (2019). Pharmacogenomics. *The Lancet*, 394(10197), 521-532. [https://doi.org/10.1016/S0140-6736\(19\)31276-0](https://doi.org/10.1016/S0140-6736(19)31276-0)
- Rodriguez, A., et al. (2025). A systematic review of real-world evidence on the clinical relevance of CYP2D6 biomarker testing. *Journal of Pharmacy & Pharmaceutical Sciences*, 28(4), 112-125. <https://doi.org/10.18433/J3X38K>
- Rosenberg, J. E., et al. (2016). PD-1/PD-L1 pathway inhibition. *Journal of Clinical Oncology*, 34(15), 1800-1807. <https://doi.org/10.1200/JCO.2015.64.5636>
- Sawyers, C. L. (2008). The cancer biomarker problem. *Nature*, 452(7187), 548-552. <http://doi.org/10.1038/nature06913>
- Schork, N. J. (2015). Personalized medicine: Time for one-person trials. *Nature*, 520(7549), 609-611. <https://doi.org/10.1038/520609a>
- Slamon, D. J., Leyland-Jones, B., Shak, S., et al. (2001). Use of chemotherapy plus a monoclonal antibody against HER2 for metastatic breast cancer. *New England Journal of Medicine*, 344(11), 783-792. <https://doi.org/10.1056/NEJM200103153441101>
- Spinelli, J. C., Suleski, B. J., Wright, D. E., et al. (2025). Wearable microfluidic biosensors with haptic feedback for continuous monitoring of hydration biomarkers in workers. *npj Digital Medicine*, 8(1), 76. <https://doi.org/10.1038/s41746-025-01466-9>
- Strimbu, K., & Tavel, J. A. (2010). What are biomarkers? *Current Opinion in HIV and AIDS*, 5(6), 463-466. <https://doi.org/10.1097/COH.0b013e32833ed177>
- Topol, E. J. (2015). The patient will see you now. Basic Books, New York, NY.
- Topol, E. J. (2019). High-performance medicine: The convergence of human and artificial intelligence. *Nature Medicine*, 25(1), 44-56. <https://doi.org/10.1038/s41591-018-0300-7>
- U.S. Food and Drug Administration. (2013). Paving the way for personalized medicine: FDA's role in a new era of medical product development. <https://www.fda.gov/media/86328/download>
- Weinshilboum, R., & Wang, L. (2017). Pharmacogenomics: Precision medicine and drug response. *Mayo Clinic Proceedings*, 92(11), 1711-1722. <https://doi.org/10.1016/j.mayocp.2017.08.007>
- World Health Organization. (2018). WHO guidelines on ethical issues in public health surveillance. <https://www.who.int/publications>

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