Precision Pharmacy in India: Pharmacogenomics Meets Digital Health under the Ayushman Bharat Digital Mission

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Abstract

Precision pharmacy synergizes pharmacogenomics and digital health to revolutionize individualized medication management in India. Integration of pharmacogenomics, with a high burden of the country's remarkable genetic diversity and adverse drug reactions (ADR), enables physicians for drug remedies based on patient-specific genetic profiles, which can significantly improve drug efficacy and safety. India's Ayushman Bharat Digital Mission (ABDM) and Digital Personal Data Protection Act (DPDP, 2023) provides digital infrastructure and regulatory framework required to include pharmacogenomics in regular care. This paper reviews global and Indian evidence supporting pharmacogenomics adoption, outlines opportunities and key challenges unique to India. It further highlights the role of artificial intelligence-driven decision support and federated learning models for scalable, privacy-sensitive implementation. Further, a proposed phased roadmap shows how precision pharmacy can be integrated within the ABDM ecosystem by targeting high-impact drug–gene pairs, laboratory capacity expansion, and utilizing digital platforms for clinical decision support. The paper concludes that with with strategic investment, strong infrastructure and patient-focused policies, India has the ability to emerge as a global leader in precision genomics-driven healthcare.

Keywords: Pharmacogenomics, Precision Pharmacy, Digital Health, Ayushman Bharat Digital Mission, Adverse Drug Reactions, Personalized Medicine, Clinical Decision Support.

Introduction

Adverse drug reactions (ADRs) are a constant issue in modern medicine. They make up almost one in ten hospital admissions around the world [1]. In India, where the systems for monitoring drug safety are still developing, ADRs tend to be underreported. However, the evidence suggests that they contribute significantly to drug-related morbidity and mortality [2]. Pharmacogenomics helps us understand how genetic differences affect drug metabolism, transport, and how drugs interact with their targets. It provides a scientific way to prevent ADRs and improve treatment effectiveness [3,4].

Digital health technologies have changed how healthcare is delivered. More healthcare providers are using electronic health records (EHRs), telemedicine, wearable devices, and mobile health apps. These tools enable continuous monitoring, integration of real-world data, and smooth information exchange [5]. The combination of pharmacogenomics (PGx) and digital health infrastructure lays the groundwork for what we call "precision pharmacy." This approach tailors drug selection and dosing to each patient's genetic and contextual information [6].

For India, the potential of precision pharmacy is particularly compelling. The government's Ayushman Bharat Digital Mission (ABDM) seeks to set up health records and registries that work together across the country [7]. At the same time, the Digital Personal Data Protection Act (DPDP, 2023) offers a legal framework for data privacy [8]. Together, these initiatives lay the groundwork for incorporating PGx into everyday prescribing. However, the process is complex and needs careful prioritization based on evidence, strong infrastructure, ethical protections, and policies that focus on equity.

Global Evidence for Pharmacogenomics in Clinical Care

The clinical utility of pharmacogenomics is best illustrated through specific drug–gene interactions. One of the most prominent examples is the relationship between HLA-B15:02 and carbamazepine-induced Stevens–Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), particularly in Asian populations [9]. Implementation of pre-treatment screening in Taiwan and Singapore has nearly eliminated these life-threatening reactions [10]. Similarly, HLA-B57:01 testing has become standard of care before initiating abacavir, preventing hypersensitivity reactions that were once a major barrier to therapy [11].

In cardiovascular medicine, CYP2C19 polymorphisms have been shown to influence clopidogrel metabolism. Patients carrying loss-of-function alleles derive reduced benefit, with higher rates of stent thrombosis and ischemic events [12]. Trials such as TAILOR-PCI have demonstrated improved outcomes with genotype-guided therapy [13], supporting the incorporation of PGx into cardiology practice.

Statin therapy provides another example, where carriers of the SLCO1B1*5 allele are at higher risk of simvastatin-induced myopathy [14]. Incorporating this information into prescribing decisions has been recommended by Clinical Pharmacogenetics Implementation Consortium (CPIC) guidelines [6]. Warfarin pharmacogenetics, long studied, has shown mixed results; the EU-PACT trial demonstrated benefits of genotype-guided dosing [15], while the COAG trial

reported neutral outcomes [16]. These differences underscore the importance of contextual factors such as ancestry and healthcare infrastructure.

Perhaps the most compelling evidence for pharmacogenomics in routine care comes from the PREPARE trial, a multicentre European study demonstrating that pre-emptive multi-gene PGx testing significantly reduced ADRs compared to standard care. This evidence base, along with initiatives like the eMERGE Network in the US [17] and U-PGx in Europe [18], provides a strong rationale for large-scale implementation. Table 1 summarizes key drug–gene pairs, highlighting the clinical outcomes, supporting evidence, and the contrasting implementation status in India compared to global practice.

Drug	Gene	Clinical Outcome	Evidence (Trial/Guideline)	Implementation Status (India/Global)
Carbamazepine	HLA-B*15:02	Prevents Stevens Johnson Syndrome / Toxic Epidermal Necrolysis	NEJM 2011 (Chen et al.); CPIC guideline	Global: Standard in Taiwan, Singapore India: high allele prevalence, limited testing
Abacavir	HLA-B*57:01	Prevents hypersensitivity reaction	NEJM 2008 (Mallal et al.); standard of care	Global: Standard of care India: rare testing in HIV centers
Clopidogrel	CYP2C19	Improves antiplatelet efficacy; reduces stent thrombosis	NEJM 2009 (Mega et al.); TAILOR-PCI 2020; CPIC 2022	Global: Used selectively in cardiology India: not routine despite common polymorphisms
Simvastatin	SLCO1B1	Reduces risk of simvastatin-induced myopathy	CPIC guideline 2022 (Ramsey et al.)	Global: CPIC-recommended India: not adopted
Warfarin	CYP2C9 / VKORC1	Optimizes anticoagulation dosing; reduces bleeding risk	EU-PACT 2013 (positive), COAG 2013 (neutral)	Global: Mixed adoption India: minimal use in clinical practice

Table 1. Clinically Significant Drug–Gene Pairs: Evidence, Outcomes, and Implementation in India vs. Global Context

The Indian Context: Opportunities and Challenges

India presents a complex but promising landscape for precision pharmacy. The country faces a high burden of ADRs, many of which are genetically predictable. HLA-B*15:02 prevalence is

notable among Indian populations, particularly in southern states, making carbamazepine-induced SJS/TEN a major preventable cause of morbidity [19]. CYP2C19 polymorphisms, also common in South Asians, may reduce clopidogrel efficacy, posing challenges for cardiovascular disease management [20].

Despite these needs, pharmacogenomics adoption in India has been limited. Testing facilities are concentrated in metropolitan centers, and costs remain prohibitive for most patients. Moreover, PGx has yet to be incorporated into routine medical curricula, leaving clinicians ill-prepared to interpret genetic results. Policy frameworks supporting clinical PGx remain underdeveloped compared to the EU and US [21].

Nevertheless, India has unique opportunities. The ABDM provides the backbone for interoperable health records [7]. Telemedicine platforms such as eSanjeevani, adopted rapidly during COVID-19, could enable delivery of PGx-informed consultations [20]. India's genetic diversity also offers a powerful resource for building ancestry-specific pharmacogenomic databases with global relevance.

Digital Infrastructure and Clinical Decision Support

The successful integration of pharmacogenomics into care depends on digital infrastructure. In high-income countries, Health Level 7–Fast Healthcare Interoperability Resources (HL7 FHIR) standards and Clinical decision support (CDS) Hooks have enabled the embedding of genomic data into EHRs, allowing drug–gene interactions to trigger real-time prescribing alerts [21,22].

In India, the ABDM provides a nascent but promising foundation. Health IDs can permanently link PGx results to individuals, ensuring reusability across care episodes [23]. Health information exchanges can support portability of results, while registries of providers can facilitate referrals to PGx-capable facilities [7].

CDS tools must be carefully designed. Poorly designed alerts risk contributing to fatigue and reduced clinician trust [24]. Effective CDS should be concise, context-specific, and actionable, integrating seamlessly into existing workflows. Pharmacists, as medication experts, are ideally placed to interpret results and support prescribers in translating them into clinical decisions. Figure 1 illustrates the proposed workflow of precision pharmacy in India which begins with the patient undergoing genetic testing, followed by integration of results into the ABDM-enabled EHR system, where clinical decision support tools guide prescribers and pharmacists toward optimized treatment decisions.

Figure 1. Workflow of Precision Pharmacy

Ethical, Legal, and Equity Considerations

The collection, storage, and use of genomic data raise profound ethical and legal challenges. The DPDP Act provides a framework for consent-driven, accountable use of sensitive data [8]. This aligns India with international frameworks such as General Data Protection Regulation (GDPR) in Europe. However, operationalizing these protections in fragmented healthcare settings remains challenging. The DPDP Act aligns with the European Union's GDPR in recognizing genetic data as sensitive, but important differences remain in enforcement strength, healthcare-specific provisions, and data portability rights (Table 2).

Aspect	India (DPDP Act, 2023)	Europe (GDPR, 2016)
Consent	Consent-based, with some exemptions for government functions; consent managers introduced	Strict consent with explicit opt-in; strong limits on exceptions
Enforcement	Enforcement via Data Protection Board; powers still evolving, penalties lower than GDPR	Independent supervisory authorities with significant powers; heavy penalties (up to 4% global turnover)
Data Portability	Basic right to access and correct data; portability provisions less detailed than GDPR	Explicit and strong right to data portability, including machine-readable formats
Healthcare-specific Protections	No explicit healthcare-specific provisions; applies generally to all sensitive personal data	Explicit recognition of health/genetic data as special category requiring additional safeguards

Right to be Forgotten	Recognized, but mechanisms and scope less defined than GDPR	Clearly defined and enforceable right; organizations must erase data upon request
Cross-border Data Transfer	Permitted if recipient country ensures comparable safeguards; rules still under formulation	Permitted only with adequate safeguards (adequacy decisions, standard contractual clauses, etc.)

Table 2: Comparison of DPDP Act (India) vs. GDPR (EU)

Equity is particularly important. Without safeguards, pharmacogenomics risks becoming accessible only to affluent urban populations. Currently, PGx testing services in India are concentrated in private labs in metropolitan areas. To promote equity, testing must be subsidized or covered under public insurance schemes like Ayushman Bharat. Public laboratories, supported by Indian Council of Medical Research (ICMR) and National Accreditation Board for Testing and Calibration Laboratories (NABL), should be developed for wider access [23, 25].

Educational initiatives are also critical. Clinicians need training to interpret PGx results, and patients require genomic literacy to consent meaningfully and avoid misuse. Without these efforts, mistrust and inequities could undermine implementation.

Roadmap for India

India's journey toward precision pharmacy must be phased. Early pilots should target high-impact drug–gene pairs, such as HLA-B*15:02–carbamazepine and CYP2C19–clopidogrel [18,26]. These pilots could be launched in tertiary centers with established PGx capacity and integrated into Pharmacovigilance Programme of India (PvPI) reporting.

Parallel investments must be made in laboratory capacity, ensuring accuracy, affordability, and quality through NABL accreditation and ICMR oversight [25]. Integration with ABDM should be pursued simultaneously, embedding PGx into digital workflows. Pharmacists should be central actors in this ecosystem, guiding prescribers and counseling patients.

Policy incentives will sustain adoption. Insurance coverage for PGx testing, research funding, and alignment with PvPI will drive uptake. International collaborations such as eMERGE [18] and U-PGx [19] offer models for scaling, while India's participation could add valuable diversity to global pharmacogenomic knowledge. As illustrated in Figure 2, India's phased roadmap for precision pharmacy progresses from early pilots targeting high-impact gene–drug pairs to medium-term digital integration and long-term adoption of advanced technologies such as AI-driven decision support.

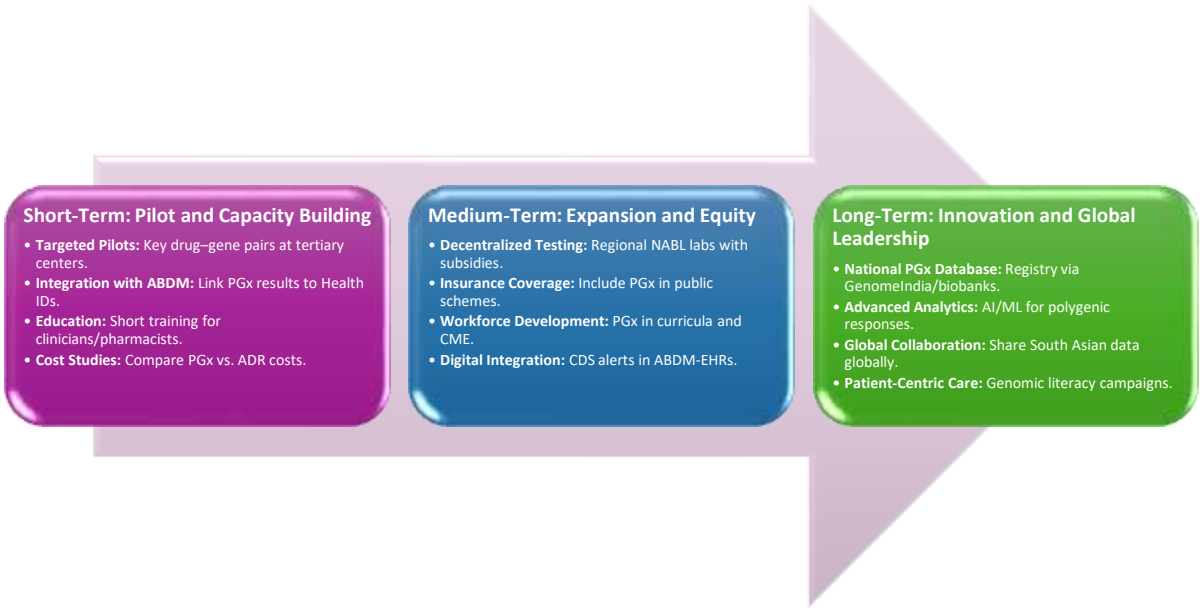

Figure 2. Phased Roadmap for India (Short, Medium, Long Term)

Future Directions

The future of precision pharmacy extends beyond single-gene testing. Polygenic risk scores offer nuanced predictions of drug response in complex conditions like diabetes and depression [18,19]. Artificial intelligence and machine learning can integrate genomic, clinical, and digital health data to generate predictive models.

Federated learning could allow model development without sharing sensitive data, a particularly relevant approach for India's fragmented system [25]. The concept of digital twins which are virtual replicas of patients simulating drug responses is an exciting but experimental frontier (Fig. 3) [26]. Programs such as All of Us in the US [27] and India's growing biobank initiatives may eventually enable such innovations.

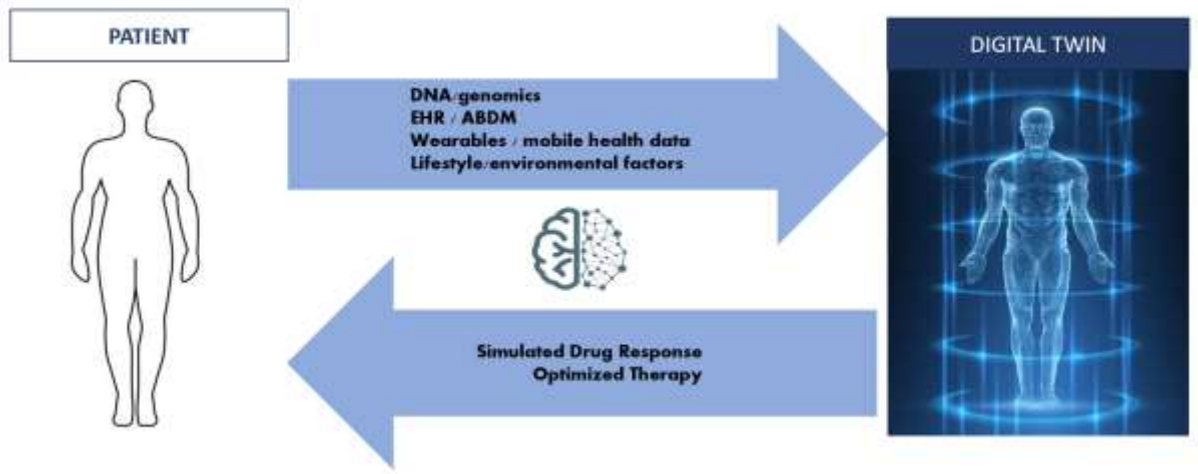

Figure 3. Concept of a Digital Twin in Precision Pharmacy

Conclusion

India is at a crossroads in precision pharmacy. While the evidence for pharmacogenomics is robust, integration into Indian practice is limited. The concurrent development of ABDM and the DPDP Act provides a unique opportunity to embed PGx into a rapidly expanding digital ecosystem. With careful prioritization, investment in infrastructure, pharmacist-led implementation, and strong governance, India can reduce ADRs, improve outcomes, and position itself as a global leader in pharmacogenomics-informed healthcare.

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