



# Patient-Centric Pharmacovigilance in India: Innovative Approaches to Adverse Event Reporting and Risk Communication

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## **Abstract**

In India, the traditional pharmacovigilance (PV) model has been predominantly “drug-centric,” relying on spontaneous adverse event reporting by healthcare professionals. However, chronic under-reporting, low public awareness, variable healthcare access, and socio-linguistic diversity limit the effectiveness of conventional systems. To bridge this gap, a shift toward patient-centric pharmacovigilance is emerging, in which patients (and/or caregivers) are active partners in detecting, reporting, and understanding adverse drug reactions (ADRs). This review examines the rationale, challenges, and innovative approaches for implementing patient-centric PV in India, emphasizing digital, community-based, and communication strategies tailored to the Indian context.

We begin by establishing the conceptual underpinnings of patient-centric PV, defining its principles as a move from passive reporting to active partnership and then explore the specific imperatives in India: under-reporting, low health literacy, genetic and phenotypic heterogeneity, polypharmacy, and the use of traditional medicine. The role of the Pharmacovigilance Programme of India (PvPI) in promoting patient engagement is scrutinized. Next, we catalogue and assess innovative reporting strategies: mobile apps (with vernacular options), QR codes, integration with EHRs, AI/NLP mining of unstructured patient narratives (in social media or call transcripts), and leveraging pharmacists and patient support groups as intermediaries in reporting. Strategies to counter under-reporting such as simplified forms, feedback loops, and assurance of confidentiality are also discussed.

In the domain of risk communication, we emphasize culturally appropriate messaging (multilingual, plain language summaries, info graphics), multi-channel dissemination (social media, radio, local campaigns), and two-way feedback mechanisms (helplines, interactive Q&A) to foster informed decision-making. We then critically examine challenges: verifying data quality from patient reports, digital divides, and infrastructure limitations at ADR Monitoring Centers (AMCs), and health/digital literacy constraints. The regulatory landscape current PvPI guidelines, alignment with global best practices, and gaps is analyzed. We conclude with future perspectives: embedding patient input in risk minimization plans, pharmacogenomics-based individualized risk profiling, sustained patient education, and closed feedback loops for continuous improvement.

This review is intended as both a scholarly synthesis and a promotional narrative for elevating patient voice in India’s drug safety systems. It is hoped that by highlighting innovations and pragmatic pathways, stakeholders (regulators, industry, academia, NGOs) will accelerate adoption of patient-centric pharmacovigilance, ultimately strengthening drug safety and patient trust in India.

**Keywords:** Patient-centric pharmacovigilance, Adverse drug reaction (ADR) reporting, Risk communication, Pharmacovigilance Programme of India (PvPI), Mobile health (mHealth) reporting, Artificial intelligence / NLP in PV, Patient support groups, Digital health literacy, Two-way communication, Pharmacogenomics, Under-reporting, EHR integration

## List of Abbreviations

### Abbreviation Full Form

<b>ADR</b>	Adverse Drug Reaction
<b>AEFI</b>	Adverse Event Following Immunization
<b>AI</b>	Artificial Intelligence
<b>ABDM</b>	Ayushman Bharat Digital Mission
<b>AMC</b>	Adverse Drug Reaction Monitoring Centre
<b>CDSCO</b>	Central Drugs Standard Control Organization
<b>CoWIN</b>	COVID Vaccine Intelligence Network
<b>EHR</b>	Electronic Health Record
<b>EMA</b>	European Medicines Agency
<b>FDA</b>	Food and Drug Administration (USA)
<b>GVP</b>	Good Pharmacovigilance Practices
<b>GVSI</b>	Global Vaccine Safety Initiative
<b>HCP</b>	Healthcare Professional
<b>ICH</b>	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
<b>IPC</b>	Indian Pharmacopoeia Commission
<b>ML</b>	Machine Learning
<b>NLP</b>	Natural Language Processing
<b>NHA</b>	National Health Authority
<b>PAG</b>	Patient Advocacy Group
<b>PBRER</b>	Periodic Benefit-Risk Evaluation Report
<b>PSUR</b>	Periodic Safety Update Report
<b>PvPI</b>	Pharmacovigilance Programme of India
<b>PV</b>	Pharmacovigilance
<b>RMP</b>	Risk Management Plan
<b>RWE</b>	Real-World Evidence
<b>WHO-UMC</b>	World Health Organization – Uppsala Monitoring Centre

## 1. Introduction

Pharmacovigilance (PV) is the science and activities associated with the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems plays a critical role in safeguarding public health by ensuring that medicines, once approved, continue to demonstrate acceptable benefit–risk profiles in real-world use. In traditional systems, PV relies heavily on spontaneous reporting by physicians, pharmacists, or other healthcare professionals (HCPs). Yet this “health-care professional–centric” model often underestimates the frequency, severity, or nuance of adverse drug reactions (ADRs), particularly when patients themselves may experience or interpret symptoms differently from clinicians.

In recent years, there has been a growing recognition globally of the need to evolve toward patient-centric pharmacovigilance an approach where patients, caregivers, and consumer communities are engaged as active contributors to drug safety surveillance rather than passive recipients. This shift aligns with broader trends in patient-centered healthcare, shared decision-making, and digital health democratization. Patient-reported

outcomes (PROs) and narratives can capture subtler, subjective, or longer-term adverse effects that might escape detection by HCPs alone, thereby enriching signal detection and enhancing regulatory responsiveness [1, 2, 3].

In India, the imperative for patient-centric PV is compelling. The country's vast demographic, socio-cultural, and geographic diversity introduces multiple challenges in safety monitoring: (i) pervasive under-reporting of ADRs, often due to low awareness or lack of motivation among HCPs; (ii) limited health and digital literacy among large segments of the population; (iii) extensive heterogeneity in genetics, comorbidities, and drug use patterns (including traditional, herbal, and over-the-counter medications) that influence ADR risk; (iv) widespread polypharmacy and use of fixed-dose combinations; and (v) infrastructural constraints in rural or resource-limited settings. Indeed, the Pharmacovigilance Programme of India (PvPI), coordinated by the Indian Pharmacopoeia Commission (IPC) under the aegis of the Central Drugs Standard Control Organization (CDSCO), has struggled to capture adequate adverse event data to support robust signal generation and regulatory action. [4, 5, 6]

By repositioning patients (and caregivers) as empowered partners, India can potentially overcome under-reporting, gather more diverse and context-relevant ADR profiles, build trust in the healthcare system, and accelerate regulatory responsiveness. However, doing so requires innovations in reporting infrastructure, risk communication, regulatory adaptation, and sustained stakeholder engagement. This review aims to (1) define and contextualize patient-centric pharmacovigilance, (2) explore innovative approaches to patient-reported ADR reporting and risk communication in India, (3) analyze implementation barriers and regulatory frameworks, and (4) propose a forward-looking roadmap for sustainable patient-centric PV in India.

In the sections ahead, we discuss (I) the imperative and foundations of patient-centric PV; (II) digital and community-based innovations for ADR reporting; (III) strategies for effective, transparent risk communication; (IV) challenges, regulatory outlook, and future recommendations; concluding with actionable insights and perspectives.

## 2. PRISMA Methodology

### 2.1 Systematic Literature Search, Selection and Eligibility Criteria

This review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines, ensuring transparency, reproducibility, and rigor in evidence identification and synthesis. A structured literature search was conducted across PubMed, Scopus, Embase, Web of Science, and Google Scholar for studies published between January 2015 and September 2025. Additional grey literature, including reports from the Pharmacovigilance Programme of India (PvPI), World Health Organization (WHO-UMC), and Central Drugs Standard Control Organisation (CDSCO), was included to capture national program updates and policy documents.

Search terms combined controlled vocabulary (MeSH) and free-text keywords using Boolean operators: (“pharmacovigilance” OR “drug safety” OR “adverse event reporting”) AND (“patient-centered” OR “patient-centric” OR “community engagement”) AND (“India” OR “South Asia”) AND (“digital health” OR “AI” OR “risk communication”).

- Inclusion Criteria:
  - Articles, reviews, or reports focusing on pharmacovigilance systems in India or LMIC contexts
  - Studies highlighting patient-centric or digital approaches to ADR/AEFI reporting
  - Publications in English between 2015–2025
- Exclusion Criteria:
  - Non-English language articles
  - Editorials, opinions, or conference abstracts without empirical or policy relevance
  - Duplicated datasets or incomplete online sources

## 2.2 Study Screening, Data Extraction and data Synthesis

The initial search identified 438 records. After duplicate removal (n = 86), 352 titles and abstracts were screened. Of these, 137 were excluded and a total of 215 full-text documents were reviewed for eligibility. Following exclusions for non-patient-focused or non-Indian context (n = 29), excluded with other reason (n = 67) and editorials exclusion (n = 23), a final 96 studies/reports/regulatory documents/guidelines were included in this review. Data extraction focused on author, year, region, population, PV intervention type, outcomes, and reported innovations. National policy documents and WHO reports were assessed for relevance, completeness, and temporal validity.

Findings were synthesized thematically across four core domains:

1. Paradigm shift toward patient-centric PV
2. Innovative reporting mechanisms and community inclusion
3. Risk communication and public engagement
4. Regulatory reforms and future pathways

The narrative synthesis integrates empirical evidence, programmatic data, and regulatory perspectives to form a cohesive assessment of India's evolving patient-centric PV ecosystem.

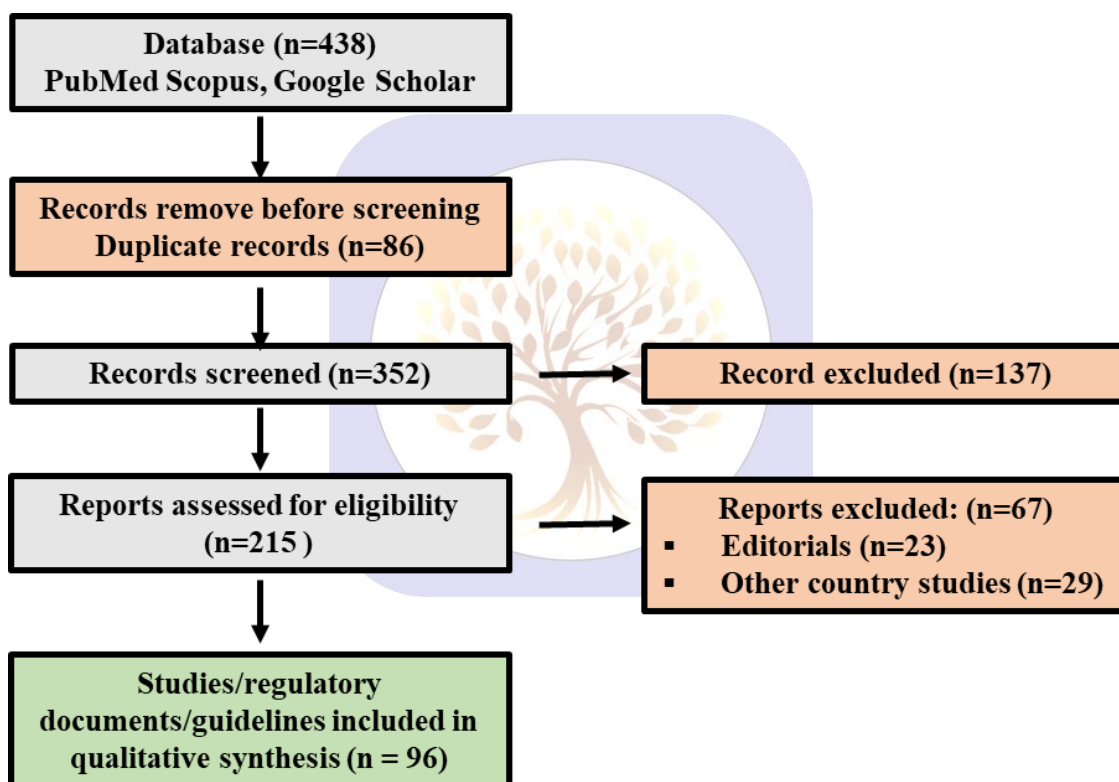


Figure 1: PRISMA Methodology

## 3. Shifting the Paradigm: The Imperative for Patient-Centric Pharmacovigilance in India

### 3.1. Definition and Core Principles of Patient-Centric Pharmacovigilance

Pharmacovigilance (PV) has conventionally been designed as a regulatory and clinician-driven framework, emphasizing the collection and analysis of adverse drug reactions (ADRs) reported by healthcare professionals (HCPs) after marketing authorization. In contrast, patient-centric pharmacovigilance (PC-PV) repositions the patient as an *active contributor* and *decision partner* in drug safety monitoring. It embraces the philosophy of participatory medicine where individuals are not mere data sources but stakeholders whose experiences, perceptions, and feedback directly inform pharmacovigilance strategies [2, 3].

The core principles of PC-PV include [4, 5, 6]:

- **Active engagement;** Encouraging direct patient and caregiver participation in ADR detection, reporting, and follow-up.
- **Transparency and shared decision-making:** fostering open communication of safety information in patient-friendly formats.
- **Accessibility and inclusivity:** Ensuring reporting systems accommodate linguistic, digital, and literacy diversity.
- **Bidirectional information flow:** Enabling continuous feedback from regulators and HCPs to patients about reported events and safety actions.
- **Empowerment through education:** Improving health literacy so that patients recognize, interpret, and report suspected ADRs appropriately.

This paradigm shift from *passive surveillance* to *active partnership* enhances the scope of pharmacovigilance beyond regulatory compliance toward a culture of shared responsibility and trust between the healthcare system and its users [7, 8].

### 3.2. The Indian Context and Rationale

#### A. Addressing Under-Reporting and Low Health Literacy

India reports one of the lowest ADR reporting rates globally, with an estimated <1% of actual ADRs being captured through formal systems [9, 10]. Factors contributing to chronic under-reporting include time constraints among clinicians, lack of feedback mechanisms, fear of legal consequences, and limited awareness among both HCPs and the public [11]. **Error! Reference source not found.** According to PvPI annual data (2023), only a small fraction of reports originates from patients or consumers despite established channels such as consumer forms and helplines [12].

Furthermore, health literacy remains uneven across India's population. Approximately 73% of adults are literate, but only about 15–20% demonstrate adequate *health* literacy the ability to comprehend and act on medical information [13]. This disparity severely limits spontaneous ADR reporting and comprehension of drug risks, particularly in rural and semi-urban areas.

#### B. Importance of Capturing ADRs in a Heterogeneous Population

India's population is characterized by vast genetic diversity, variations in metabolism (e.g., CYP450 polymorphisms), co-morbid conditions, and polypharmacy, especially in elderly patients [14]. Additionally, extensive use of Ayurvedic, Siddha, Unani, and herbal remedies alongside allopathic medicines introduces complex interactions rarely captured in traditional PV databases [15]. Such heterogeneity underscores the necessity for direct patient input to detect region- or genotype-specific ADR patterns that might otherwise be missed in conventional systems [16].

#### C. Role of the Pharmacovigilance Programme of India (PvPI)

The Pharmacovigilance Programme of India (PvPI), initiated in 2010 under the Indian Pharmacopoeia Commission (IPC) and coordinated by the Central Drugs Standard Control Organisation (CDSCO), remains the central hub for national ADR monitoring [17]. PvPI oversees over 600 ADR Monitoring Centres (AMCs) across the country and has progressively incorporated patient-centric initiatives [18]:

- Consumer Reporting Forms in English and vernacular languages;
- A toll-free helpline (1800-180-3024) for patient ADR reporting;
- The ADR PvPI Mobile App for real-time submissions;
- Outreach through community pharmacies and Patient Safety Week campaigns.

Despite these advances, PvPI's uptake of direct patient reports remains modest (<5% of total reports in 2023) [19]. Institutional integration and sustained digital engagement are still evolving, emphasizing the need for a more structured patient-centric approach.

### 3.3. Benefits of Patient-Reported Data

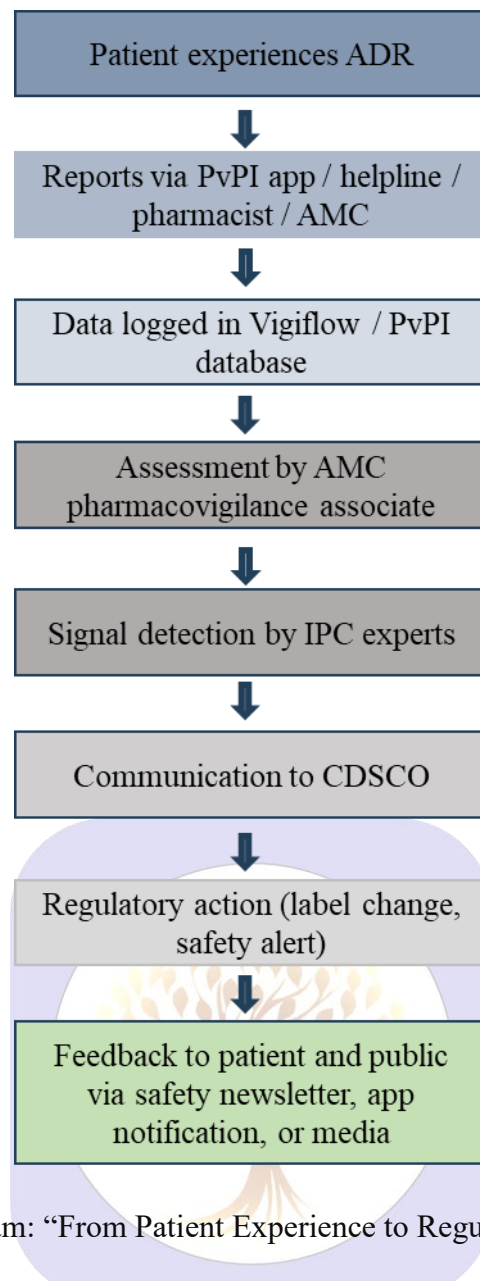
Engaging patients directly in pharmacovigilance offers numerous advantages that strengthen the national safety architecture [20, 21, 22, 23]:

**Table 1: Comparative Dimensions of Traditional and Patient-Centric Pharmacovigilance and Their Impact on Drug Safety**

Dimension	Traditional PV (HCP-centric)	Patient-Centric PV (PC-PV)	Key Impact
Data Source	Reports from clinicians, hospitals	Reports from patients, caregivers, pharmacists	Broader real-world dataset
Nature of Information	Clinical, diagnostic focus	Subjective symptoms, lifestyle context, temporal associations	Richer contextual detail
Reporting Timeliness	Often delayed	Near-real-time via apps/social media	Early signal detection
Representation	Limited to clinical settings	Inclusive of community and home-care experiences	Wider population coverage
Patient Awareness	Minimal	Empowered through feedback and education	Increased trust and transparency
Regulatory Utility	Quantitative signal strength	Qualitative insight into patient experience	Improved causality assessment

Direct patient reporting complements HCP data by enhancing *signal sensitivity* and enabling early detection of unknown or rare ADRs [24]. Studies from Europe and Japan demonstrate that integrating patient-reported data improves the robustness of signal detection algorithms and enriches regulatory decision-making [25, 26]. In India, patient-driven inputs could be particularly transformative, considering the country's demographic scale and variability of drug usage patterns.

Moreover, patient participation fosters public trust in regulatory institutions. When individuals perceive that their experiences lead to tangible safety actions (e.g., label changes, warnings, or recalls), they are more likely to adhere to therapies and participate in future reporting [27].



**Figure 2:** Conceptual Flow Diagram: “From Patient Experience to Regulatory Action”

#### 4. Innovative Digital and Community-Based Approaches to Adverse Event Reporting

The evolution of pharmacovigilance in India increasingly depends on innovative technological and social solutions that extend beyond hospital settings into the digital and community sphere. In recent years, the convergence of mobile technology, artificial intelligence (AI), social media analytics, and community empowerment has created new avenues to engage patients, caregivers, and allied healthcare providers as active contributors to adverse drug reaction (ADR) surveillance. India’s Digital Health Mission, coupled with the Pharmacovigilance Programme of India (PvPI), offers an unprecedented opportunity to integrate these approaches for more responsive and inclusive pharmacovigilance.

##### 4.1. Digital Transformation in Reporting

###### A. Mobile-Based Applications and Vernacular Design

The introduction of PvPI’s mobile application marked a significant milestone in democratizing ADR reporting. Available on Android and iOS platforms, the app allows both healthcare professionals and consumers to report ADRs directly to PvPI. Recent iterations include vernacular language options, improving accessibility among non-English-speaking populations [28, 29].

Mobile-based systems reduce barriers such as form complexity and physical access to health facilities. Reports are transmitted instantly to the Vigiflow database, ensuring near real-time surveillance. The inclusion of QR code–linked ADR forms on medicine packages (piloted in 2024 by IPC) further simplifies reporting and links pharmacovigilance with post-marketing traceability [30].

However, usability studies show that app adoption remains limited outside urban areas due to digital illiteracy and connectivity issues [31]. Integration with existing health platforms like the CoWIN app, Ayushman Bharat Digital Mission (ABDM) health ID system, or eHospital networks could ensure broader coverage and reduce duplication of effort.

## **B. Integration with Electronic Health Records (EHRs)**

EHR-based pharmacovigilance represents a transformative step in data automation. Linking patient clinical data with ADR monitoring systems allows semi-automated detection of safety signals based on abnormal laboratory values, prescriptions, and diagnosis patterns [32].

Pilot programs in India such as the AIIMS–PvPI collaboration on digital ADR flagging within EHRs (2023) demonstrated improved detection rates for drug-induced liver injury and hematologic toxicity [33]. Integrating EHRs with Vigibase, WHO’s global ICSR repository, could enhance global signal sharing and reduce latency between event occurrence and regulatory action [34].

## **C. Artificial Intelligence (AI) and Natural Language Processing (NLP)**

India’s large volume of unstructured, patient-generated data such as posts on social media, health forums, and call-center transcripts presents a vast untapped reservoir for pharmacovigilance.

AI and NLP algorithms can mine this unstructured text to identify emerging drug-safety concerns [35]. For instance, machine-learning classifiers trained on Hindi and English Twitter data achieved >85% accuracy in detecting ADR mentions linked to antibiotics and COVID-19 vaccines [36]. The IPC–IIT Delhi AI collaboration (2024) is exploring hybrid NLP models for ADR extraction from vernacular languages [37].

A major advantage of AI-based systems is their scalability, allowing continuous monitoring of real-world experiences. Nevertheless, these tools require validation to minimize false positives and misclassification, ensuring alignment with regulatory data quality standards [38, 39].

### **4.2. Strengthening the Reporting Network**

#### **A. Empowering Non-Physician Healthcare Professionals**

Pharmacists and nurses constitute vital yet underutilized intermediaries in pharmacovigilance. With over 800,000 community pharmacists across India, their frequent contact with patients positions them ideally to identify, document, and report ADRs [40].

PvPI’s 2023–2024 “Pharmacist ADR Reporter Initiative” resulted in a 20% increase in regional reporting rates [41]. Nurses in hospital wards similarly serve as frontline observers of ADRs and can be empowered through structured training modules on detection and online submission [42].

This decentralization of responsibility mitigates physician overload, fosters community ownership, and enhances the representativeness of safety data.

#### **B. Patient Support Groups (PSGs) and Advocacy Networks**

**Patient support groups (PSGs)** especially for chronic conditions such as diabetes, oncology, and autoimmune disorders serve as powerful platforms for awareness generation and peer-assisted ADR reporting [43]. In India, patient associations such as the Diabetes Self-Care Forum and Cancer Care India Network collaborate with PvPI to promote ADR awareness workshops and integrate online reporting widgets on their websites [44].

By embedding pharmacovigilance within patient advocacy, these groups enhance participation, address stigma, and foster long-term adherence to treatment while improving data capture quality.

### 4.3. Strategies for Overcoming Under-Reporting

#### A. Simplifying Reporting Forms and Reducing Cognitive Load

Research suggests that even minor reductions in form complexity can double reporting rates [45]. PvPI's simplified ADR Consumer Form (Form Med-6) available in 10 regional languages allows intuitive submission of key data points (drug, symptom, onset date, and outcome) without requiring clinical interpretation [46]. Digital interfaces should incorporate auto-fill features, drop-down drug lists, and voice-based input options, particularly for elderly or low-literacy users [47].

#### B. Ensuring Data Privacy and Confidentiality

Patient reluctance to share sensitive health information remains a barrier to spontaneous reporting. India's Digital Personal Data Protection Act (DPDP Act) 2023 mandates strict privacy controls, which PvPI and health apps must comply with [48]. Secure encryption, anonymization, and transparent privacy policies are critical for patient confidence in digital platforms [49].

#### C. Providing Feedback and Acknowledgement

Timely acknowledgment of patient contributions significantly improves ongoing participation [50]. PvPI's mobile app currently sends automated confirmation messages upon submission, but expanded personalized follow-up such as notification of outcome analysis or safety alerts could strengthen engagement [51]. The UK MHRA Yellow Card Scheme, which publicly recognizes frequent reporters, has been cited as a best practice India could emulate [52].

**Table 2: Traditional vs. Digitally Enhanced Pharmacovigilance in India**

Aspect	Traditional Reporting	PvPI	Digital / Community-Based PV	Impact
<b>Reporter</b>	Healthcare professional		Patient, caregiver, pharmacist, nurse	Broadened participation
<b>Submission Mode</b>	Paper forms via AMCs		Mobile app, QR codes, online portal	Faster, decentralized
<b>Data Capture</b>	Structured, clinical		Structured + unstructured (AI-mined)	Enhanced context
<b>Feedback</b>	Limited or delayed		Instant confirmation, app updates	Improved engagement
<b>Language Accessibility</b>	Primarily English		Multilingual (vernacular)	Inclusion of diverse populations
<b>Signal Detection</b>	Manual		Automated + AI-assisted	Faster detection
<b>Coverage</b>	Hospital-centric		Nationwide community reach	Higher representativeness

## 5. Effective and Transparent Risk Communication Strategies

Risk communication is a cornerstone of patient-centric pharmacovigilance (PV). It ensures that patients are not merely passive recipients of drug safety information but are informed, empowered, and engaged in the decision-making process. In India's context characterized by vast linguistic diversity, health literacy disparities, and heterogeneous media access an effective and transparent risk communication strategy must be tailored, multimodal, and participatory [45, 46].

This section explores approaches that (A) tailor communication for diverse audiences, (B) utilize multiple dissemination channels, and (C) institutionalize two-way communication mechanisms to ensure feedback and trust-building.

### 5.1. Tailoring Communication for Diverse Audiences

#### A. Multilingual and Culturally Sensitive Messaging

India's multilingual fabric (22 official languages, hundreds of dialects) demands risk communication that transcends language barriers [47]. PvPI and allied institutions have recognized this through vernacular ADR reporting forms and patient information leaflets in regional languages [48]. Translating technical safety content into simple, culturally contextual narratives enhances comprehension and participation.

- Regional language campaigns (e.g., Hindi, Tamil, Bengali, Marathi, Assamese) help rural populations grasp ADR symptoms and reporting methods.
- Cultural adaptation for example, linking the concept of “drug safety” with traditional beliefs about wellness improves message acceptance.
- Community influencers and local health volunteers (ASHAs, Anganwadi workers) act as interpreters of pharmacovigilance messages at the grassroots level [49].

#### B. Simplifying Complex Safety Information

Most Indian patients encounter drug information through package inserts or hospital leaflets that are overly technical. Simplified, plain-language summaries and infographics transform abstract pharmacovigilance data into accessible knowledge [50, 51].

For instance:

- Replace “hepatotoxicity” with “may harm your liver watch for yellowing eyes or dark urine.”
- Use colour-coded alert symbols (green = safe, yellow = monitor, red = caution) for risk categories.
- Employ short-form videos and illustrated leaflets for those with limited literacy.

A 2023 PvPI-WHO pilot project demonstrated that visual risk cards improved recall of ADR symptoms among diabetic patients by > 60 % compared with text-only materials [51, 52].

### 5.2. Multi-Channel Dissemination of Safety Alerts

Given India's digital divide, risk communication must integrate digital and traditional channels to ensure reach and redundancy [53].

#### I. Digital Platforms

The PvPI mobile app, official CDSCO/PvPI websites, and e-ADR portals are now pivotal tools for instant dissemination of safety updates [54, 55].

- Push notifications for new safety alerts via mobile apps keep patients informed in real time.
- Social media campaigns (Twitter/X, Facebook, YouTube) enable broad reach; for instance, the IPC's “Safe Medicine Use” hashtag series has generated significant engagement since 2022 [56].

- Interactive webinars and short video explainers in vernacular languages can demystify complex regulatory communications such as black-box warnings or product recalls.

## II. Traditional Media and Community Outreach

While digital methods dominate urban communication, traditional media remains crucial for rural populations [57]:

- Radio programmes, community health camps, and local newspapers remain trusted sources of health information.
- Television advertisements under the *Jan Aushadhi* or *Ayushman Bharat* banners can include brief drug safety tips.
- Pharmacovigilance awareness weeks organized by AMCs engage both patients and healthcare professionals through poster exhibitions and interactive sessions [58, 59].

### 5.3. Two-Way Communication and Feedback Mechanisms

True transparency in pharmacovigilance emerges when communication becomes bi-directional patients not only receive information but also provide input [60, 61].

#### I. Helplines and Interactive Portals

The PvPI toll-free helpline (1800-180-3024) serves as a live channel where patients can report ADRs or clarify safety concerns [62]. Integration of chatbot-based assistance within the PvPI app could further enable 24×7 interaction in multiple languages.

#### II. Online Q&A and Community Forums

Moderated Q&A sessions or web-based communities hosted by IPC and medical college's foster open discussion. Monitoring patient queries also helps regulators identify emerging misinformation or public anxiety [63].

#### III. Closing the Feedback Loop

A hallmark of patient-centric PV is providing acknowledgement and outcome feedback after reporting [64]. Timely confirmation ("Your ADR report was received and is being reviewed") validates patient participation. Studies indicate that respondents are 3× more likely to re-report ADRs if they receive personalized feedback [65].

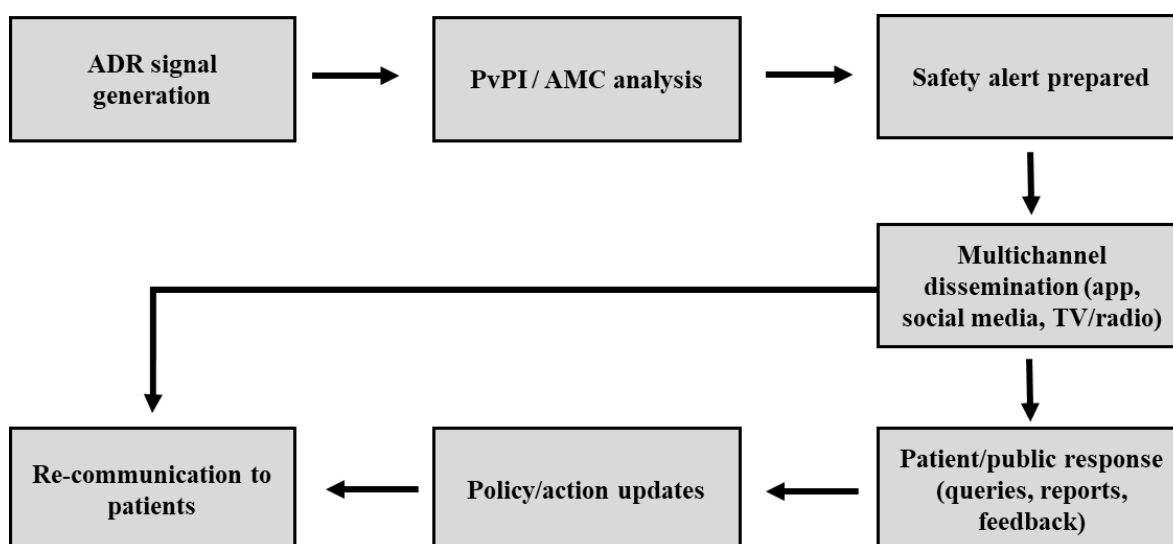


Figure 3. Two-Way Risk Communication Model in Patient-Centric Pharmacovigilance

## 6. Challenges, Regulatory Outlook, and Future Directions

### 6.1 Persistent Challenges in India's Pharmacovigilance Ecosystem

Despite commendable progress, India's pharmacovigilance (PV) ecosystem continues to face systemic limitations that hinder its evolution toward a truly patient-centric model. Persistent issues include under-reporting, fragmented databases, and infrastructure constraints across states and institutions [66, 67, 68]. Studies indicate that less than 10% of adverse drug reactions (ADRs) are reported in India, compared to 50–70% in developed regions [69, 70].

Low patient awareness, fear of legal implications, and a lack of motivation among healthcare professionals (HCPs) remain the leading causes of under-reporting [71]. Furthermore, the disjointed data systems between the Pharmacovigilance Programme of India (PvPI), the CoWIN portal, and state-level Adverse Event Following Immunization (AEFI) committees impede interoperability and real-time analytics [72, 73].

Additionally, the shortage of trained pharmacovigilance officers, particularly in rural Adverse Drug Reaction Monitoring Centers (AMCs), contributes to inconsistent data quality [74, 75]. Infrastructure inequality such as limited internet access and inadequate digital literacy exacerbates disparities in patient engagement and timely ADR reporting [39, 76].

**Table 3: Key Operational Challenges Impacting Pharmacovigilance Functionality in India.**

Challenge Category	Specific Issues	Impact on PV Functionality
Under-reporting of ADRs	Low awareness, lack of incentives	Delayed signal detection
Fragmented Data Systems	Disconnected PvPI, AEFI, and EHR sources	Poor interoperability
Resource Constraints	Limited trained personnel in rural AMCs	Data inconsistency
Ethical/Regulatory Barriers	Lengthy data-sharing approvals	Reduced innovation
Infrastructure Gaps	Unequal digital access	Rural exclusion

### 6.2 Regulatory Outlook: India and the Global Harmonization Trajectory

The Central Drugs Standard Control Organization (CDSCO) and Indian Pharmacopoeia Commission (IPC) have initiated reforms to align national PV practices with global standards such as ICH E2E and EMA GVP modules [72, 77]. However, challenges persist in harmonizing India's multi-tiered regulatory structure with evolving international frameworks.

The Good Pharmacovigilance Practices (GVP) guidelines, released in draft form in 2022 by CDSCO, are India's most direct step toward structured, patient-inclusive pharmacovigilance [78]. Moreover, the integration of PvPI and AEFI networks, alongside partnerships with WHO-UMC and GVSI, enhances India's participation in global signal management [79, 80].

**Table 4: Comparative Overview of Key Pharmacovigilance Regulatory Initiatives: India and Global Alignment**

Regulatory Initiative	Indian Implementation	Global Comparator / Alignment
<b>Good Pharmacovigilance Practices (GVP)</b>	CDSCO draft aligned with Schedule Y	Mirrors EMA GVP Modules I–XVI
<b>Signal Management Framework</b>	Embedded within PvPI and AEFI review	WHO-UMC model
<b>Digital ADR Reporting</b>	ADRPvPI app, CoWIN linkage	FDA MedWatch / EudraVigilance
<b>PSURs and PBRERs</b>	Mandatory under Rule 122E	ICH E2C (R2)
<b>Transparency</b>	Limited dashboards	Real-time EU/US systems

The WHO Global Benchmarking Tool (GBT) 2023 assessment ranked India’s pharmacovigilance maturity as “Level 3” indicating an established yet improvable system [81]. Further harmonization with ICH E2D and FDA FAERS could enable more dynamic safety data exchange [82, 83].

### 6.3 Leveraging Real-World Evidence (RWE) and Artificial Intelligence

Emerging technologies are redefining pharmacovigilance worldwide, and India is well-positioned to harness AI-driven surveillance and RWE analytics [84, 85]. The IPC has piloted AI/NLP-based ADR extraction tools capable of scanning patient feedback from social media, electronic health records (EHRs), and hospital call centers [86].

These innovations, combined with the Ayushman Bharat Digital Mission (ABDM), can generate vast real-world datasets to supplement traditional reporting [87, 88]. Furthermore, blockchain-based systems are being explored for ensuring traceability and authenticity of PV records, reducing data tampering risks [89].

Collaborative initiatives involving start-ups, academia, and WHO Collaborating Centers will be key to building AI validation sandboxes and ethical oversight frameworks [90, 91].

### 6.4 Building Trust and Transparency: Patient as a Data Partner

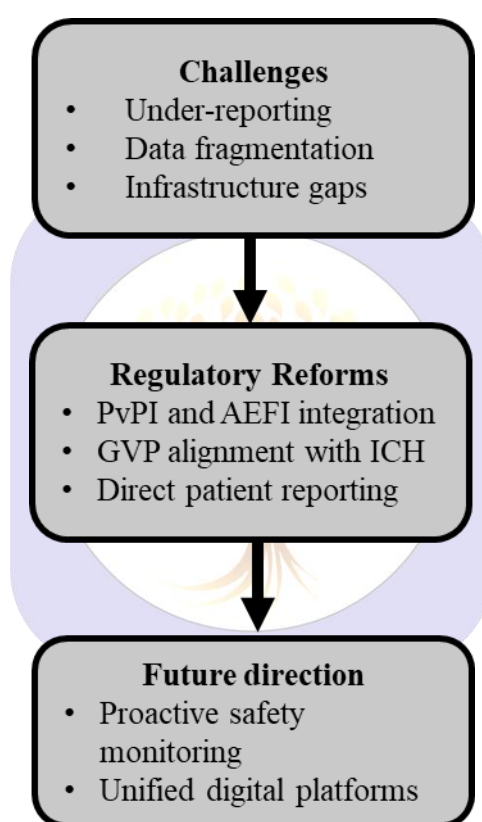
A sustainable patient-centric PV system depends on mutual trust, transparency, and accountability [92]. Citizen dashboards for anonymized ADR trends, acknowledgment mechanisms for each report, and vernacular-language communication enhance patient participation and confidence [93, 94].

PvPI’s inclusion of patient advocacy groups (PAGs) in signal review committees marks a transformative step toward shared governance. Embedding feedback loops and risk communication in both digital and offline channels ensures equitable patient inclusion [95, 96].

**Table 5: Future Directions: Toward a Resilient and Learning PV System**

Strategic Focus Area	Future Direction / Goal
Digital Integration	Unified PV data lake integrating PvPI, AEFI, and RWE
AI & Predictive Analytics	Machine learning–based risk monitoring
Community Partnerships	Leveraging ASHAs and pharmacists as PV ambassadors
Global Collaboration	Data exchange with WHO-UMC, ICH, and GVSI
Policy Evolution	Integration of PV within National Health Mission

Ultimately, India’s future in pharmacovigilance lies in developing a learning health system one that continuously refines clinical decisions through feedback from patients, providers, and AI-driven data insights [86, 95, 96].

**Figure 4: Challenges, Regulatory Outlook, and Future Pathways of Patient-Centric Pharmacovigilance in India**

## 7. Conclusion

India’s journey toward patient-centric pharmacovigilance (PV) represents a paradigm shift from passive regulatory compliance to proactive patient partnership. Over the past decade, the Pharmacovigilance Programme of India (PvPI), Central Drugs Standard Control Organization (CDSCO), and allied institutions have progressively strengthened ADR reporting frameworks, digital infrastructures, and public communication systems. However, persistent challenges including under-reporting, variable data quality, limited health literacy, and infrastructure disparities continue to constrain full patient engagement.

The review highlights that meaningful PV advancement requires integration of digital tools, community networks, and transparent communication. Mobile applications, AI-enabled analytics, vernacular risk messaging, and pharmacist- or nurse-led community outreach can together transform ADR reporting from a top-down regulatory task into a shared social responsibility. Likewise, developing two-way feedback

mechanisms, culturally contextual communication, and multi-channel dissemination will bridge the trust gap between patients and regulatory agencies.

Ultimately, India's PV evolution must be guided by the principle that *patients are data partners, not data points*. A learning, patient-inclusive pharmacovigilance ecosystem supported by ethical AI, real-world evidence (RWE), and transparent regulatory oversight will ensure that every report contributes to safer therapies and stronger public confidence in the healthcare system.

## 8. Future Perspective

Looking ahead, India stands poised to emerge as a global leader in patient-centric PV by operationalizing three strategic imperatives:

- **Digital Integration and Interoperability:** Building a unified national PV data lake integrating PvPI, AEFI, EHR, and ABDM datasets will enable continuous signal detection and predictive safety modelling.
- **AI-Driven Proactive Safety Monitoring:** Deploying validated AI/NLP tools, blockchain verification, and automated dashboards will make ADR surveillance predictive rather than reactive.
- **Empowered Communities and Inclusive Governance:** Involving patient advocacy groups, ASHAs, pharmacists, and nursing professionals as co-owners of safety reporting networks will expand reach to rural and under-represented populations.
- **Global Harmonization and Data Ethics:** Continuous alignment with WHO-UMC, ICH, EMA, and FDA frameworks paired with transparent data-use ethics will strengthen India's credibility in global regulatory science.

By 2030, a digitally mature, ethically governed, and patient-inclusive PV system can transform India from a regional participant to a benchmarking hub for pharmacovigilance innovation, where technology and empathy coexist to advance public health protection.

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