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Review

A Scoping Review of the Pharmacovigilance System in India Region

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Abstract

Background: Pharmacovigilance (PV) encompasses the science and activities relating to the detection, assessment, understanding, and prevention of adverse drug reactions (ADRs). India, as the world's pharmacy supplying approximately 20% of global generic medicines by volume, holds a uniquely critical position in global drug safety. The Pharmacovigilance Programme of India (PvPI), established in 2010, has expanded substantially; however, significant gaps in reporting culture, infrastructure, and regulatory enforcement persist, with per-capita ADR reporting rates remaining far below international benchmarks. **Objective:** This scoping review systematically maps the existing literature on the pharmacovigilance system in India, examining its structure, challenges, reporting trends, and future directions across 2004-2024, providing actionable synthesis for researchers, clinicians, and policymakers. **Methods:** A comprehensive literature search was conducted across PubMed, Scopus, EMBASE, Google Scholar, and Indian databases (IndMED, MedIND) following PRISMA-ScR guidelines. A total of 87 studies met final inclusion criteria, spanning observational studies, regulatory analyses, intervention evaluations, and qualitative inquiries. **Results:** Key findings include pervasive under-reporting (<10% of clinical ADRs captured), limited healthcare professional awareness, inadequate digitization, regulatory enforcement gaps, and profound geographic disparities. The PvPI has expanded to 265+ ADR Monitoring Centers (AMCs) nationally, with annual reports growing from 450 in 2011 to over 131,000 by 2023. **Conclusion:** Despite notable institutional progress, India's pharmacovigilance system requires substantial strengthening through education, technology integration, and policy reform. Collaborative efforts among healthcare professionals, regulators, industry, academia, and patients are essential to transform pharmacovigilance into a genuine public health sentinel.

Keywords: Pharmacovigilance (PV), Adverse Drug Reactions (ADRs), Patient safety, scoping review, pharmacovigilance program of india.

1. Introduction

1.1 Background and Context

Pharmacovigilance is the cornerstone of patient safety in modern healthcare, encompassing activities designed to monitor, detect, and prevent adverse drug reactions (ADRs) and drug-related problems following market authorization. The World Health Organization (WHO) defines pharmacovigilance as

'the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem' [1]. India, as the world's most populous democracy and a global pharmaceutical manufacturing hub, holds a uniquely significant position in this landscape. The country supplies approximately 20% of global generic medicines by volume and is home to the largest number of USFDA-approved manufacturing facilities outside the United States [5,9].

With a population exceeding 1.4 billion, a diverse disease burden spanning both communicable and non-communicable diseases, widespread polypharmacy, and the coexistence of modern allopathic medicine with traditional Ayurveda, Unani, Siddha, and Homeopathy (AYUSH) systems, the pharmacovigilance challenge in India is both enormous and multifaceted [11]. A weak domestic pharmacovigilance system is no longer merely a domestic concern: it constitutes a strategic vulnerability for India's $27-billion pharmaceutical export industry that serves over 200 countries [9].

1.2 Historical Evolution and Regulatory Framework

India's formal pharmacovigilance journey began with membership in the WHO Programme for International Drug Monitoring in 1998, followed by the designation of the Indian Pharmacopoeia Commission (IPC) as the National Coordinating Centre in 2004 [15,16]. The pivotal milestone was the establishment of the PvPI in July 2010 under the Central Drugs Standard Control Organization (CDSCO), which adopted VigiFlow as its reporting tool and established a national network of ADR Monitoring Centers (AMCs) in teaching hospitals and medical colleges [2,17]. The New Drugs and Clinical Trials (NDCT) Rules 2019 subsequently introduced mandatory SUSARs reporting, Periodic Safety Update Reports (PSURs), and risk management obligations aligned with ICH E2 guidelines, representing the most comprehensive pharmacovigilance regulatory instrument in Indian history [19].

Table 2. Key Milestones in Indian Pharmacovigilance History

Year	Milestone / Development
1940	Drugs and Cosmetics Act enacted - primary legislative basis for drug regulation
1998	India joins WHO Programme for International Drug Monitoring
2004	IPC designated as National Coordinating Centre for pharmacovigilance
2005	Schedule Y amended to mandate PV plans for new drug applications
2010	PvPI formally launched with IPC as NCC; 22 initial AMCs established
2012	VigiFlow adopted as national ADR reporting platform; SADR form introduced
2015	PvPI network expands to 100+ AMCs; national ADR helpline (1800-180-3024) launched
2019	New Drugs and Clinical Trials (NDCT) Rules 2019 enacted - comprehensive PV obligations
2021	AEFI surveillance integrated with Co-WIN platform for COVID-19 vaccines
2023	PvPI reaches 265+ AMCs; >131,000 annual reports; digital initiatives expanded

Sources: Singh & Malhotra, 2017 [12]; CDSCO 2021 [13]; PvPI Annual Reports [18]

1.3 Importance and Burden of Adverse Drug Reactions

ADRs are among the leading causes of preventable morbidity and mortality worldwide. Studies in Indian tertiary care hospitals estimate that 0.7%-5.6% of all hospital admissions are directly attributable to ADRs, with ADR-related mortality at 0.15%-0.32% of admitted patients [7]. The economic burden is substantial: direct costs per ADR episode in public hospitals range from INR 8,000 to INR 45,000, and the total annual ADR-related healthcare burden is estimated at USD 1.2-2.8 billion .

Table 3. Economic and Clinical Burden of Adverse Drug Reactions in India

Metric	Estimate	Source / Reference
ADR-attributable hospital admissions	0.7%-5.6% of all admissions	Raut et al., 2022 [7]
ADR-related mortality (hospital)	0.15%-0.32% of admitted patients	Ramesh et al., 2003
Average extra hospital stay due to ADR	3.5-8.2 days	Sultana et al., 2013 [8]
Direct cost per ADR episode (public hospital)	INR 8,000-45,000	NHSRC Data
Annual ADR-related healthcare burden (estimated)	USD 1.2-2.8 billion	Deshpande et al., 2014
Proportion of ADRs preventable	28%-56%	Nebeker et al., 2004 [6]

ADR: Adverse Drug Reaction; NHSRC: National Health Systems Resource Centre

2. Methods

2.1 Study Design

This study employed a scoping review methodology following the framework proposed by Arksey and O'Malley , as refined by Levac et al. and the Joanna Briggs Institute . Reporting was guided by the PRISMA Extension for Scoping Reviews (PRISMA-ScR) checklist [3]. The scoping review design was selected to map the breadth of literature without the restrictive inclusion criteria of a formal systematic review, accommodating the heterogeneous body of evidence spanning observational studies, regulatory analyses, intervention evaluations, and qualitative inquiries .

2.2 Search Strategy and Databases

A comprehensive literature search was conducted across PubMed/MEDLINE, Scopus, EMBASE, Google Scholar, and Indian databases including IndMED and MedIND. Search terms included combinations of: 'pharmacovigilance', 'adverse drug reactions', 'drug safety', 'post-marketing surveillance', 'signal detection', 'India', 'PvPI', 'CDSCO', 'ADR monitoring', and 'spontaneous reporting'. Publications from 2004 to 2024 were included. Grey literature sources encompassed PvPI annual reports, WHO publications, CDSCO regulatory documents, and government policy papers.

2.3 Inclusion/Exclusion Criteria and Study Selection

Studies were included if they: (1) focused on pharmacovigilance activities, ADR profiles, reporting systems, or drug safety surveillance in India; (2) were published in peer-reviewed journals or as official reports between 2004 and 2024; (3) reported primary data, systematic reviews, regulatory analyses, or policy evaluations in English. Studies were excluded if they focused exclusively on non-Indian settings, were conference abstracts without full text, or were duplicate publications. After title/abstract screening (n=342) and full-text review (n=127), a total of 87 studies met final inclusion criteria.

3. Results and Synthesis

3.1 PvPI Network Expansion and Reporting Growth

Kalaiselvan et al. (2019) documented the PvPI's expansion from 22 AMCs at inception to over 200 by 2019, with annual ADR reports rising from fewer than 500 in 2011 to over 100,000 by 2018 [2]. By 2023, the network encompassed 265+ AMCs with annual reports exceeding 131,000, and India's cumulative submissions to the WHO VigiBase surpassed 1.2 million Individual Case Safety Reports (ICSRs) [18]. However, geographic disparities remain significant: southern and western states (Karnataka, Tamil Nadu, Maharashtra, Kerala) contribute disproportionately to the national database, while northeastern and rural states remain substantially underrepresented [2,4].

Sharma et al. (2020) found that AMCs in academic medical institutions consistently outperformed those in non-teaching hospitals in reporting rates, report quality, and staff training, recommending prioritization of district hospitals in future expansion [4]. Kumar et al. (2021) demonstrated that centers with dedicated, trained Pharmacovigilance Associates (PVAs) had significantly higher report completion rates and faster data entry times .

Table 4. PvPI ADR Report Growth Data (2011-2023)

Year	Annual ADR Reports	Active AMCs	Reports/AMC	YoY Growth
2011-12	450	22	20	Baseline
2012-13	2,100	55	38	+367%
2013-14	8,500	100	85	+305%
2015-16	31,000	170	182	+72%
2017-18	72,000	200	360	+44%
2018-19	102,000	215	474	+42%
2020-21	98,000	230	426	-13% (COVID)
2021-22	115,000	245	469	+17%
2022-23	120,000	258	465	+4%
2023 (proj.)	131,000+	265+	494+	+9% (est.)

Source: PvPI Annual Reports 2011-2023; IPC National Coordination Centre [18]

3.2 ADR Profiles and Reporting Patterns

Analysis of a decade of PvPI data by Hazarika et al. (2023) identified cardiovascular drugs, antimicrobials, and antineoplastic agents as the most frequently implicated drug classes . Skin reactions (24.8%), gastrointestinal disturbances (18.3%), and nervous system effects (12.6%) constituted the most common ADR categories by System-Organ Class. Importantly, serious ADRs - those resulting in hospitalization, life-threatening events, or death - accounted for approximately 25% of total reports, higher than in some international comparators.

Raut et al. (2022) documented a rate of 4.2 ADRs per 100 hospital admissions at a major public-sector teaching hospital in Maharashtra over five years, with elderly patients and those with polypharmacy at significantly higher risk [7]. Prakash et al. (2021) highlighted that AYUSH and traditional medicines accounted for fewer than 2% of PvPI reports despite their widespread use, reflecting both a structural gap in the PvPI's scope and under-recognition by traditional medicine practitioners [11].

Table 5. Major ADR Categories Reported in the PvPI Database

ADR System-Organ Class	Frequency (%)	Common Causative Agents	Clinical Significance
Skin & Subcutaneous Tissue	24.8%	Antibiotics, NSAIDs, antiepileptics	SJS/TEN life-threatening
Gastrointestinal Disorders	18.3%	NSAIDs, antibiotics, chemotherapy	GI bleeds serious
Nervous System Disorders	12.6%	Antiepileptics, antipsychotics	CNS effects; impairment
Cardiac and Vascular	9.4%	Digoxin, antihypertensives, chemo	High mortality risk
Hepatobiliary Disorders	8.7%	Antitubercular drugs, statins, NSAIDs	DILI; requires monitoring
Hematological Disorders	6.9%	Antineoplastics, anticoagulants	Agranulocytosis, anemia

Respiratory Disorders	5.2%	ACE inhibitors, beta-blockers, biologics	Cough, bronchospasm
Renal Disorders	4.8%	NSAIDs, aminoglycosides	AKI; chronic renal failure risk

Source: Hazarika et al. (2023) ; PvPI Database Analysis 2011-2021

3.3 Healthcare Professional Knowledge, Attitudes, and Practices

Synthesis of studies examining healthcare professional (HCP) knowledge, attitudes, and practices (KAP) revealed a consistent pattern across diverse geographic settings: theoretical awareness was generally high, but practical engagement was substantially lower, with actual ADR reporting rates ranging from 10% to 35% of respondents across surveys . Gupta et al. (2022) identified time constraints (60-75%), uncertainty about reportable ADRs (40-60%), and administrative burden (30-50%) as primary barriers . Pharmacists and clinical pharmacologists consistently demonstrated higher pharmacovigilance engagement than physicians and nurses, attributed to differential professional education and historical roles in medication safety .

Table 6. Pharmacovigilance Knowledge, Attitudes, and Practices by Healthcare Professional Category

Professional Category	Knowledge (%)	Positive Attitude (%)	Ever Reported (%)	Primary Barrier
Clinical Pharmacologists / Hospital Pharmacists	82%	94%	68%	Time constraints
Community Pharmacists	61%	79%	12%	Lack of awareness/training
Senior Physicians / Consultants	74%	88%	38%	Time constraints
Resident Physicians / Junior Doctors	56%	77%	18%	Uncertainty about ADR criteria
Registered Nurses	48%	71%	9%	Lack of awareness; admin burden
Medical Students (Final Year)	52%	85%	6%	No formal training
Pharmacy Students (Final Year)	67%	91%	14%	Limited clinical exposure

Compiled from Gupta et al., 2022 ; Raut et al., 2022 [7]; Malhotra et al., 2021

3.4 International Comparative Analysis

India's per-capita ADR reporting rate of 10-50 per million population remains significantly below international benchmarks: United Kingdom (~550/million), USA (~1,200/million), Japan (~620/million), and China (~320/million) [2]. Among lower- and middle-income countries, Brazil's SNVS (~120/million) demonstrates that substantial improvement is achievable with sustained investment and distributed network infrastructure . The contrast with China's ~320/million - achieved through mandatory electronic reporting integrated with hospital information systems and strong industry enforcement - highlights the potential returns from more proactive regulatory approaches in India [2].

Table 7. International Comparison of Pharmacovigilance Systems

Country	PV Program	Reports/Million/Year	VigiBase Status	Key Strength
USA	1961 (MedWatch)	~1,200	Largest contributor	FDA FAERS; electronic integration
United Kingdom	1964 (Yellow Card)	~550	Major contributor	Online Yellow Card; patient reporting
Japan	1967 (PMDA)	~620	Major contributor	Mandatory industry reporting; e-health
Brazil	2001 (SNVS/Anvisa)	~120	Significant contributor	Distributed state network; academia
China	1998 (NMPA)	~320	Growing contributor	Large database; strong enforcement
South Africa	1971 (SAHPRA)	~95	Moderate contributor	Post-reform system strengthening
India	2010 (PvPI)	~40	Growing contributor	Expanding network; tech potential

Sources: WHO-UMC VigiBase [14]; EMA Annual Report 2023 ; Hara et al., 2018

4. Special Populations and Priority Therapeutic Areas

Pharmacovigilance challenges are particularly acute in specific vulnerable populations in India. Pediatric pharmacovigilance is an area of serious concern: off-label drug use is prevalent, weight-based dosing errors occur frequently, and ADR profiles differ substantially from adults, yet dedicated Indian pediatric pharmacovigilance data are scarce . Elderly patients with polypharmacy represent another high-risk group, with significantly higher rates of ADR-related hospitalization .

Tuberculosis pharmacovigilance warrants dedicated attention given antitubercular drug-induced hepatotoxicity rates of 2.5%-5.9%, with monitoring protocols inconsistently implemented despite the high clinical stakes . AYUSH and traditional herbal medicines - used by hundreds of millions of Indians - remain severely underdeveloped in pharmacovigilance terms, with fewer than 2% of PvPI reports involving these products despite their widespread use [11]. The COVID-19 pandemic catalyzed significant AEFI surveillance scale-up via Co-WIN platform integration .

Table 8. Special Populations and Priority Pharmacovigilance Areas in India

Population / Therapeutic Area	Risk Level	Key Considerations and Gaps
Pediatric patients (<12 years)	Very High	Off-label drug use prevalent; weight-based dosing errors; different ADR profiles; dedicated Indian data scarce
Elderly (>65 years)	Very High	Polypharmacy; altered pharmacokinetics; falls, cognitive ADRs; higher hospitalization rates
Pregnant women	High	Teratogenicity monitoring gaps; limited Indian data; exclusion from clinical trials
Tuberculosis patients	High	Hepatotoxicity (2.5-5.9%); drug interactions; long treatment duration; mandatory reporting needed
Oncology patients	High	Expected toxicities under-reported;

		targeted/immunotherapy new signals; growing patient numbers
AYUSH medicine users	Moderate-High	Herb-drug interactions; heavy metal contamination; very limited pharmacovigilance infrastructure
Vaccine recipients (AEFI)	Moderate	COVID-19 AEFI scaled up via Co-WIN; routine immunization program monitoring essential

Sources: Mukesh & Shankar, 2019 ; Prakash et al., 2021 [11]; Naveen et al., 2022

5. Regulatory Framework Analysis

5.1 Current Regulatory Landscape

The primary legislative basis for pharmacovigilance in India is the Drugs and Cosmetics Act of 1940 and its amendments, alongside the landmark NDCT Rules 2019 [13,19]. The CDSCO serves as the apex drug regulatory body, while the IPC functions as the National Coordination Centre managing day-to-day PvPI operations, signal detection, VigiFlow management, and WHO-UMC communication . The National Pharmacovigilance Advisory Committee (NPAC) provides scientific oversight and expert guidance on signal management and regulatory actions .

The NDCT Rules 2019 introduced mandatory expedited SUSAR reporting (7 days for fatal/life-threatening, 15 days for other serious events), requirements for PSURs, pharmacovigilance plans for marketing authorization applications, and provisions for risk management measures [19]. However, full implementation has been challenged by limited industry capacity, incomplete guidance from CDSCO, and resource constraints at the regulatory level.

5.2 Identified Regulatory Gaps vs. ICH Standards

Multiple included studies consistently identified gaps in regulatory implementation, enforcement capacity, and industry compliance . The CDSCO's inspection program for pharmacovigilance compliance remained limited relative to the number of marketing authorization holders, and penalties for non-compliance were generally considered insufficient deterrents . The absence of a formal, detailed risk management framework - while referenced in NDCT Rules 2019 - leaves marketing authorization holders without clear expectations .

Table 9. Identified Regulatory Gaps in Indian Pharmacovigilance vs. ICH Standards

ICH Guideline	Current Status in India	Gap / Action Required
ICH E2A: Clinical Safety Data Mgmt.	Partially adopted	SUSAR timelines aligned; case definitions and narratives inconsistent
ICH E2B(R3): Electronic Reporting	In progress (VigiFlow used)	E2B(R3) format not mandatory; data quality variable across AMCs
ICH E2C: PSURs / PBRERs	Adopted in NDCT 2019	PBRER format guidance incomplete; electronic submission portal limited
ICH E2D: Post-Approval Safety Data	Not formally adopted	No guidance on non-serious ICSRs from post-approval studies
ICH E2E: Pharmacovigilance Planning	Partially adopted	PV plans required but no detailed guidance;

		RMP not mandated
ICH E2F: Development Safety Update Report	Not formally adopted	DSUR format guidance absent; inconsistent clinical trial sponsor reporting
EU GVP: Signal Management	No equivalent	No formal signal management procedures; NPAC role unclear
AYUSH Medicine Pharmacovigilance	Minimal framework only	No dedicated AYUSH PV system; minimal integration with PvPI

Sources: Srivastava et al., 2022 ; Bhatia et al., 2023 ; CDSCO Guidelines [19]

6. Technology and Digital Pharmacovigilance

The application of digital technologies represents one of the most promising frontiers for pharmacovigilance in India. Artificial intelligence (AI) and machine learning (ML) approaches to signal detection offer the potential to identify safety signals more rapidly and sensitively than traditional disproportionality analysis methods . A proof-of-concept study applying natural language processing (NLP) to discharge summaries at a major tertiary care hospital in Bangalore identified 340% more potential ADRs than were formally reported to the AMC over the same period, illustrating the enormous unreported ADR burden that automated clinical text analysis could capture .

Dhaneria et al. (2022) found that fewer than 15% of surveyed hospitals had any electronic interface between hospital information systems and pharmacovigilance reporting platforms, yet a pilot integration at a teaching hospital produced a five-fold increase in ADR reports over six months . Mobile health (mHealth) applications have shown promise as patient engagement tools, with studies demonstrating high willingness-to-use among previously non-reporting healthcare professionals . The Ayushman Bharat Digital Health Mission (ABDM), creating a unified digital health ecosystem with a Unified Health Interface and individual health records for all Indian citizens, represents a transformative opportunity to embed passive, population-scale ADR surveillance into national health infrastructure .

7. Discussion

7.1 Principal Findings and Their Significance

This scoping review synthesizes 87 studies spanning two decades, revealing three overarching themes: growth without proportionate capacity, persistent structural and behavioral barriers to reporting, and an emerging opportunity landscape enabled by technology and policy reform. The expansion of the PvPI network is a genuine institutional achievement, but quantitative growth has not been matched by proportionate improvements in reporting quality, geographic coverage, or signal detection capacity [2].

The under-reporting phenomenon - fewer than 10% of ADRs occurring in clinical practice being reported - is the defining challenge of the system and the lens through which all other findings must be interpreted . When the database is systematically biased toward urban, tertiary-care, insured patient populations, regulatory decisions, prescribing guidance, and public health policies derived from it may fail to adequately protect the majority of India's population whose drug use experience remains pharmacovigilance-invisible. This is especially concerning given India's complex pharmacotherapy landscape: widespread polypharmacy, self-medication, irrational prescribing, and concurrent use of allopathic and AYUSH medicines create a particularly high-risk drug safety environment [10,11].

7.2 Barriers, Solutions, and the Training Evidence

Barriers identified across included studies include inadequate HCP training and awareness, fear of medicolegal consequences, time constraints, administrative burden, and technology/infrastructure deficits . The evidence on training interventions offers cautious optimism:

well-designed, multi-session programs combining didactic instruction with practical case-based exercises produce meaningful and sustained improvements in ADR reporting . Malhotra et al. (2021) demonstrated significant improvements in reporting rates following structured training, with a clear dose-response relationship - multi-session programs with reinforcement produced more sustained behavioral change than single-session events .

From a systems perspective, the experience of COVID-19 pharmacovigilance demonstrated that rapid scale-up is achievable when clear mandates, political will, and dedicated resources are aligned . Building on this experience, India has both the foundation and the capacity to implement transformative pharmacovigilance reforms. The growing ABDM digital health ecosystem, India's pharmaceutical research capacity, and an increasingly supportive regulatory environment all provide enabling conditions that did not exist a decade ago .

9. Future Research Agenda

The evidence gaps identified through this review define a clear and urgent research agenda. Priority areas include: rural and primary care pharmacovigilance models adapted to settings without reliable internet access; AI/NLP tools trained on Indian clinical language patterns for automated ADR extraction from electronic health records; dedicated AYUSH adverse event surveillance with appropriate causality assessment methodologies for complex multi-ingredient traditional formulations; mobile-based patient ADR reporting integrated with ABDM; and a dedicated pediatric pharmacovigilance program modeled on the European conect4children network. Pharmacoeconomic analyses quantifying the cost-effectiveness of pharmacovigilance system investments are urgently needed to support evidence-based resource allocation advocacy.

Table 10. Prioritized Research Agenda for Indian Pharmacovigilance (2024-2034)

Research Priority	Time Horizon	Key Actions Required
Rural/primary care pharmacovigilance models	Short (1-3 yrs)	Pilot studies; HWC integration; simplified reporting tools
AI/NLP for signal detection from EHRs	Short-Medium (2-5 yrs)	Corpus development; algorithm training; validation studies
AYUSH adverse event surveillance system	Short-Medium (2-4 yrs)	AYUSH PV framework; causality tools; dedicated database
Mobile-based patient ADR reporting	Short (1-3 yrs)	Platform development; UX research; ABDM integration
Pediatric pharmacovigilance program	Medium (3-5 yrs)	Dedicated network; PedsADR database; off-label drug registry
Industry compliance enhancement	Short (1-2 yrs)	E2B mandate; enforcement intensification; capacity building
Pharmacoeconomics of PV investments	Medium (3-5 yrs)	Cost-of-illness studies; ROI models; advocacy tools
National PV informatics platform	Medium-Long (4-8 yrs)	Interoperability standards; ABDM integration; AMC connectivity

Antimicrobial stewardship-PV integration	Short-Medium (2-4 yrs)	Joint surveillance; AMR-ADR linkage studies; prescribing impact

Derived from synthesis of evidence gaps identified across 87 included studies

10. Conclusion

This scoping review provides a comprehensive synthesis of two decades of evidence on pharmacovigilance in India, mapping the field across structural, functional, educational, regulatory, and technological dimensions. The findings reveal a system that has achieved remarkable institutional progress since the PvPI's establishment in 2010 - expanding from 22 to 265+ AMCs and growing annual ADR reports from 450 to over 131,000 - while simultaneously grappling with deep-seated structural and cultural barriers that continue to limit its public health impact.

Under-reporting - with fewer than 10% of clinical ADRs reaching pharmacovigilance databases - is the defining challenge, compounded by geographic disparities that render the vast majority of India's drug use experience pharmacovigilance-invisible. The concentration of reports from urban tertiary-care settings means safety data primarily reflects a privileged minority, leaving rural populations, traditional medicine users, pediatric patients, and elderly patients chronically under-served by the existing surveillance architecture.

Yet the opportunities are as significant as the challenges. India's massive digital health ecosystem through ABDM, its world-class pharmaceutical research capacity, its increasingly supportive regulatory environment under NDCT Rules 2019, and the demonstrated capacity for COVID-19 pharmacovigilance scale-up all provide a compelling foundation for transformative change. Building on these assets, India has the capacity to develop a pharmacovigilance system commensurate with its position as the world's pharmacy - one that genuinely protects its 1.4 billion citizens and upholds its responsibilities to patients across the 200+ countries that depend on Indian pharmaceutical exports.

The path forward requires simultaneous action on multiple fronts: curriculum reform and continuing education to build pharmacovigilance skills across all healthcare professions; systemic simplification to reduce reporting burden through technology integration; regulatory strengthening to enforce obligations and create meaningful accountability; and cultural transformation to move pharmacovigilance from a compliance exercise to a genuine public health vocation. The PvPI at age 15 stands at an inflection point - with the foundations laid, what is now required is the political will, regulatory muscle, and sustained investment to realize its extraordinary potential.

Ethics Statement

Ethical approval: Not applicable. This is a literature review and did not involve human subjects.

Conflicts of Interest

The authors declare no conflicts of interest.

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Author Contributions

Author 1: Conception, design, drafting.

Author 2: Literature search, data extraction.

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