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Review

The Recent Trends and Development of Pharmacovigilance in India

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Abstract:
Introduction: Pharmacovigilance (PV) is essential for monitoring, detecting, and preventing adverse drug reactions (ADRs) to ensure drug safety. In India, PV has progressed from a fragmented system in the late 1980s to the structured Pharmacovigilance Programme of India (PvPI) under the Indian Pharmacopoeia Commission (IPC). This review evaluates the evolution, current status, and challenges of PV in India, focusing on ADR reporting, regulatory frameworks, and technological integration**. Methods:** We reviewed published literature, regulatory documents, and PvPI reports to assess ADR reporting trends, stakeholder roles, and emerging technologies in Indian PV. Key areas analyzed included healthcare professional participation, public involvement, and implementation of artificial intelligence (AI), natural language processing (NLP), and Bayesian signal detection methods. The impact of pharmacogenomics and multimodal ADR detection was also examined. **Results:** India currently contributes approximately 3% of global ADR reports to VigiBase, showing improved reporting over time. Despite growth, under-reporting persists due to limited awareness, inadequate training, and weak integration of PV into healthcare curricula. Pharmacists play a pivotal role in strengthening ADR reporting, though public participation remains low. AI, NLP, and Bayesian methods have improved signal detection efficiency. The COVID-19 pandemic highlighted the need for robust PV systems to monitor repurposed and investigational drugs. Regional disparities and limited digital infrastructure continue to hinder progress. **Conclusion:** India has made significant strides in pharmacovigilance, yet challenges in awareness, education, and digital integration remain. Strengthening regulatory policies, expanding PV education, and adopting advanced technologies are critical to enhance drug safety monitoring and promote rational medicine use across the country.

Keywords: Pharmacovigilance, Adverse Drug Reactions (ADRs), PvPI, Drug Safety, Artificial Intelligence, Signal Detection, VigiBase, Healthcare Professionals, Pharmacogenomics, COVID-19, ADR Reporting, India

INTRODUCTION

Evolution and Challenges of PV in India

This research highlights the journey on the Pharmacovigilance Programme of India (PVPI). It

discuss the transition from fragmented system on 1986 to a robust national framework managed by an Indian Pharmacopoeia Commission (IPC). The core focus are on the importance of monitoring Adverse Drug Reactions (ADRs) to ensure patient safety in one of the world's largest drug-consuming nations.

MDDC: Statistical Tools for Signal Detection

This technical paper introduces the Modified Detecting Deviating Cells (MDDC) algorithm, implemented on R and Python. Unlike traditional methods that look at drug-event pairs in isolation, MDDC identifies complex patterns in spontaneous reporting systems (like FAERS), helping researchers find hidden safety signals more efficiently.

Historical Milestones of PV in India

This article provides a chronological timeline of drug safety in India, starting from the 1980s. It emphasizes how India joined the WHO Programme for International Drug Monitoring in 1997 and details the roles of the CDSCO and NCC in regulating current practices.

Broadening the Scope: MATERIOVIGILANCE & AYUSH

Focusing on the 1983–2022 period, this review expands the definition of PV to include MATERIOVIGILANCE (medical device safety) and the monitoring of AYUSH (Ayurveda, Yoga, Unani, Siddha, and Homoeopathy) drugs. It advocates for a multidisciplinary approach to drug safety.

AI and NLP in Mining Adverse Reactions

This paper addresses the "reporting gap" by using Natural Language Processing (NLP) to mine ADRs from unstructured data, such as social media posts and clinical notes. It introduces state-of-the-art Named Entity Recognition (NER) models that outperform previous benchmarks in identifying drug-related harm.

Implementation Challenges in Modern India

While acknowledging the growth of the PVPI, this article analyzes the persistent hurdles in the Indian context, such as under-reporting by healthcare professionals, lack of public awareness, and the need for better integration of PV into medical curricula.

Multimodal ADE Detection (Text & Images)

This innovative study suggests that text alone isn't enough to identify ADRs. It introduces the MMADE dataset, which combines textual descriptions with visual cues (like images of rashes or infections) to help AI models "see" and "read" adverse reactions simultaneously.

The Fundamentals of Drug Safety

Serving as a foundational review, this article defines the core pillars of PV: detection, assessment, understanding, and prevention. It traces the global necessity of PV back to historical tragedies like the SULFANILAMIDE elixir disaster, emphasizing that drug safety is a lifelong commitment for any pharmaceutical product.

Pharmacovigilance in the Era of COVID-19

Summary Introduction: This article discusses the critical role of pharmacovigilance during the COVID-19 pandemic, particularly concerning the safety monitoring of repurposed and investigational drugs. It highlights the increased risk of unknown short-term and long-term adverse drug reactions (ADRs) and the challenges in causality assessment due to complex clinical presentations and concomitant drug use.

Bayesian Approaches to Signal Detection

Summary Introduction: This paper addresses the challenge of inferring adverse events (AEs) from Spontaneous Reporting Systems (SRS) databases. It introduces novel, scalable empirical Bayes methods designed to simultaneously detect potential signals and estimate their relevance while overcoming the computational and parametric limitations of existing models.[10]

Revival of the Pharmacovigilance Programme of India (PVPI)

Summary Introduction: Adverse drug reactions (ADRs) are cited as the fourth leading cause of morbidity globally. This review outlines the implementation of the Pharmacovigilance Programme of India (PVPI) as the national authority, coordinated by the Indian Pharmacopoeia Commission (IPC), to safeguard community health through a structured reporting system.

ADR Reporting Patterns in North India

Summary Introduction: Focusing on a regional pharmacovigilance Centre in North India, this study emphasizes that while ADRs are a major contributor to the healthcare burden, they are largely preventable. The article describes a retrospective observational study aimed at identifying reporting

patterns to alert healthcare providers and protect future patients.

General Overview and Background of Pharmacovigilance

Summary Introduction: This paper provides a broad overview of the evolution of pharmacovigilance, tracing its roots to 1950s drug safety concerns like the chloramphenicol crisis. It elaborates on the system's importance in the pharmaceutical industry and its growth into a specialized medical field essential for drug safety.

ADR Monitoring and Reporting in India

Summary Introduction: This article examines the current state of the ADR monitoring system in India, highlighting the role of the Central Drugs Standard Control Organization (CDSCO). It details the operational structure of over 200 monitoring centres and the use of standardized reporting forms available in multiple languages to encourage professional and public participation.

Safety Profile of Rituximab in Southern India

Summary Introduction: This original research presents a seven-year retrospective analysis of the safety profile of Rituximab, conducted at a regional training centre in Southern India. The study aims to contribute specific safety data to the broader national pharmacovigilance efforts managed by the IPC.

Grouped Summarization for Cancer Pharmacovigilance

Summary Introduction: Addressing the complexity of cancer treatments, this paper introduces the "GASCADE" framework for summarizing ADRs reported by cancer patients. It highlights a gap in existing research which often focuses on general diseases, and presents a new dataset (MCADRS) to improve drug-related decision-making in oncology.

Role and Genomics in Indian Pharmacovigilance

Summary Introduction: This overview defines pharmacovigilance as a key pillar of the healthcare system for monitoring drug interactions and effects. It introduces the growing importance of pharmacogenetics and pharmacogenomics in understanding how variations in the human genome affect drug susceptibility and safety.

Perspectives and Prospects of PV in India

Summary Introduction: As India becomes a global destination for clinical trials, this article argues that robust regulations and post-approval vigilance are more critical than ever. It summarizes the methodologies used in the current system and provides a critical overview of the challenges and future prospects for pharmacovigilance in the Indian context.

Critical Review of ADR Monitoring in India

Summary Introduction: This article provides a comprehensive evaluation of the "way forward" for drug safety in India. It links pre-marketing clinical data with post-marketing surveillance and emphasizes the collaboration between the National Pharmacovigilance Centre and the Uppsala Monitoring Centre (UMC) in Sweden to ensure patient safety through a worldwide monitoring network.

The Process of Pharmacovigilance in India

Summary Introduction: This review explores the fundamental need for pharmacovigilance in a country with one of the world's largest pharmaceutical industries. It details the process of voluntary reporting of Adverse Drug Reactions (ADRs) and discusses how PV helps in assessing the benefit-risk profile of increasingly potent drugs used by the Indian population.

Trends in ADR Reporting (BIOSPECIA REVIEW)

Summary Introduction: Highlighting the rapid growth of the Pharmacovigilance Programme of India (PvPI), this article examines the shift toward digital reporting and the impact of the COVID-19 pandemic on safety monitoring. It addresses persistent issues like regional reporting disparities and the necessity for more patient-centric digital tools to combat under-reporting.

National Coordination Centre (NCC) Updates (PVPI Newsletter)

Summary Introduction: This official publication from the Indian Pharmacopoeia Commission (IPC) serves as a reporting update on national initiatives, such as "National Pharmacovigilance Week." It emphasizes the "Reporting Culture for Patient Safety" and provides insights into new online portals (ADRMS) designed to streamline consumer and professional ADR reporting.[22]

Beginning, Status, and Recent Progress of PVPI

Summary Introduction: This research traces the history of India's formal drug safety journey, starting

years after the WHO's international monitoring program began. It provides a detailed account of how the PVPI has fortified its reach across the country and the specific regulatory steps taken to strengthen capacity building in recent years.

Present Status and Future Perspectives

Summary Introduction: This article offers a broad look at the current infrastructure of drug safety while looking ahead to future requirements. It discusses the integration of pharmacovigilance into veterinary sciences and the critical need for increased awareness among healthcare professionals and students to improve the quality of safety data.

Recent Developments and Future Perspectives of PVPI

Summary Introduction: This paper focuses on the metrics of success for the PVPI, noting that India's contribution to the global safety database has reached 3%. It discusses the use of helpline facilities to assist reporting and the emphasis on documenting adverse reactions to herbal products to ensure a holistic approach to drug safety.

METHODOLOGY

1.Study Design

The present study adopts a qualitative, descriptive, and analytical research design based on a systematic literature review. The objective is to evaluate the evolution, current practices, technological advancements, and challenges of pharmacovigilance in India.

2. Data Sources

The study is based entirely on secondary data collected from credible and peer-reviewed sources. These include:

Scientific databases such as PubMed, Google Scholar, and ScienceDirect

Review articles, original research papers, and case studies

Government and regulatory publications related to the Pharmacovigilance Programme of India

Reports from organizations like Central Drugs Standard Control Organization and WHO

3.Search Strategy

A systematic search was conducted using relevant keywords such as:

Pharmacovigilance in India

Adverse Drug Reactions (ADRs)

PvPI and ADR reporting

Artificial Intelligence in pharmacovigilance

Signal detection methods (Bayesian, MDDC)

Boolean operators (AND, OR) were used to refine the search and ensure relevance.

4.Inclusion and Exclusion Criteria

Inclusion Criteria

- Articles published between 2015 and 2025
- Studies focusing on pharmacovigilance practices in India
- Research covering ADR reporting, regulatory frameworks, and digital advancements
- Both review articles and original research studies

Exclusion Criteria

- Studies not related to the Indian context
- Articles with incomplete or insufficient data
- Non-English publications
- Duplicate or outdated studies

5.Data Collection Procedure

A total of 25 relevant research articles were selected after screening titles, abstracts, and full texts. Key information was extracted and organized into thematic categories such as:

Evolution and regulatory framework

ADR reporting patterns

Technological advancements

Challenges and future perspectives

6.Data Analysis

The collected data were analyzed using a thematic analysis approach. The findings from different studies were compared and synthesized to identify:

Common trends

Research gaps

Emerging technologies

Key challenges in implementation

7.Tools and Techniques

The study utilized:

Comparative literature analysis

Evaluation of statistical models (e.g., Bayesian methods, MDDC algorithm)

Review of digital pharmacovigilance tools such as Vigiflow and ADR reporting systems

8.Limitations of the Study

The study is limited to secondary data sources

Possibility of publication bias

Limited access to some full-text articles

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RESULTS

Growth of Pharmacovigilance in India

The study shows that pharmacovigilance in India has developed significantly over time. Earlier, drug safety monitoring was unorganized and limited to small research activities. However, with the introduction of the **Pharmacovigilance Programme of India (PVPI)**, the system became more structured and effective. The role of the **Indian Pharmacopoeia Commission (IPC)** has been crucial in coordinating and improving drug safety monitoring across the country.

2. Improvement in ADR Reporting

The number of Adverse Drug Reaction (ADR) reports has increased over the years due to better awareness and the establishment of ADR Monitoring Centres. Digital platforms have also made reporting easier. However, compared to global standards, reporting in India is still quite low, contributing only a small percentage to international databases.

3. Major Challenges Identified

Despite improvements, several challenges still exist:

- ADRs are still under-reported in many cases
- Healthcare professionals often lack awareness or proper training
- Many patients are not aware that they can report side effects
- Rural areas face infrastructure and accessibility issues
- Pharmacovigilance is not strongly included in academic education

These issues reduce the overall effectiveness of the system.

4. Role of Healthcare Professionals

Doctors, pharmacists, and nurses play a key role in reporting ADRs. Among them, pharmacists have shown a strong contribution in identifying and reporting drug reactions. However, due to workload, lack of time, and limited training, many healthcare professionals do not report ADRs regularly.

5. Impact of New Technologies

One of the most important findings is the growing use of technology in pharmacovigilance. Tools such as:

- Artificial Intelligence (AI)
- Natural Language Processing (NLP)
- Machine Learning models

are helping in identifying hidden drug reactions from large datasets like medical records and social media. Advanced statistical methods such as MDDC and Bayesian models have improved the accuracy of detecting safety signals.

6. Effect of COVID-19 Pandemic

The COVID-19 pandemic had a mixed impact on pharmacovigilance. On one hand, it increased the need for drug safety monitoring due to the use of new and repurposed medicines. On the other hand, it made ADR reporting more difficult because healthcare systems were overloaded.

7. Expansion of Pharmacovigilance Scope

Pharmacovigilance in India is no longer limited to medicines only. It now includes:

- Monitoring of medical devices (MATERIOVIGILANCE)
- Safety of traditional systems like AYUSH
- Study of genetic factors affecting drug response (pharmacogenomics)
- This shows that PV is becoming more comprehensive and patient-focused.

8. Regulatory System Performance

Organizations like the **Central Drugs Standard Control Organization (CDSCO)** have played an important role in strengthening drug safety regulations. However, the implementation of these policies is not uniform across all regions.

9. Digital and Awareness Initiatives

New initiatives such as online ADR reporting systems, mobile apps, and national awareness campaigns have improved participation. Still, these tools need to reach more people, especially in rural and remote areas.

10. Overall Findings

Overall, the study shows that India has made good progress in building a pharmacovigilance system. However, problems like under-reporting, lack of awareness, and limited infrastructure continue to affect its efficiency. The use of modern technologies and better education can help overcome these issues in the future.

Table 1: Zonal Distribution of ADR Monitoring Centres in India

Zone	States/UTs Covered

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North	Delhi, Punjab, Haryana, Uttarakhand
South	Tamil Nadu, Kerela, Telangana, Andra Pradesh
East	Bihar, Jharkhand, West Bengal, Assam
West	Maharastha, Gujrat, Goa, Rajasthan
Central	Uttar Pradesh, Madhya Pradesh, Chhattisgarh

Table 2: List of ADR Monitoring Centres – North & Central Zone

ADR Monitoring Centre	State/UT	Zone
All India Institute of Medical Sciences	Delhi	North
Post Graduate Institute of Medical Education and Research	Chandigarh	North
King George's Medical University	Uttar Pradesh	Central
Gandhi Medical College	Madhya Pradesh	Central

DISCUSSION

The present study highlights the significant progress of pharmacovigilance in India over the past few decades. The establishment of the Pharmacovigilance Programme of India (PvPI) and ADR Monitoring Centres (AMCs) has strengthened the reporting and monitoring of Adverse Drug Reactions (ADRs). Digital platforms such as VigiFlow have improved data collection and reporting efficiency.

However, challenges such as under-reporting of ADRs, limited awareness among healthcare professionals, insufficient pharmacovigilance education, and low patient participation continue to affect the effectiveness of the system. Recent technological advancements, including Artificial Intelligence (AI), Natural Language Processing (NLP), Bayesian methods, and the MDDC algorithm, have enhanced signal detection and drug safety monitoring.

The COVID-19 pandemic further emphasized the importance of a strong pharmacovigilance system for monitoring the safety of medicines and vaccines. The expansion of pharmacovigilance to include AYUSH products, medical devices, and pharmacogenomics reflects the growing scope of drug safety surveillance in India.

Overall, India has developed a robust pharmacovigilance framework, but continuous efforts in awareness, training, digital innovation, and regulatory strengthening are required to improve patient safety and ensure the rational use of medicines.

CONCLUSION

Pharmacovigilance in India has undergone a significant transformation from a fragmented and limited system in the 1980s to a structured and nationally coordinated program under the Pharmacovigilance Programme of India (PvPI), managed by the Indian Pharmacopoeia Commission. This progress reflects India's growing commitment to ensuring drug safety and protecting public health in a country with a vast and diverse population.

The findings of this study indicate that while considerable improvements have been made in Adverse Drug Reaction (ADR) reporting, system organization, and regulatory frameworks under the Central Drugs Standard Control Organization, challenges such as under-reporting, limited awareness, inadequate training, and regional disparities continue to hinder the full effectiveness of pharmacovigilance practices. The low participation of both healthcare professionals and patients remains a critical barrier that needs focused intervention.

Importantly, the integration of modern technologies—including Artificial Intelligence (AI), Natural Language Processing (NLP), and advanced statistical models—has emerged as a transformative force in pharmacovigilance. These innovations have enhanced the capability to detect hidden safety signals, analyse large datasets, and improve the overall efficiency of drug safety monitoring systems. Additionally, the expansion of

pharmacovigilance into areas such as MATERIOVIGILANCE, AYUSH systems, and pharmacogenomics highlights a shift toward a more comprehensive and patient-centred approach.

However, the study also underscores that technological advancement alone is insufficient without parallel improvements in education, awareness, and infrastructure. Strengthening pharmacovigilance education in medical and pharmacy curricula, promoting a culture of routine ADR reporting, and increasing public engagement are essential for long-term sustainability. Furthermore, better implementation of regulatory policies across all regions, especially rural areas, is necessary to ensure uniformity in drug safety practices.

In conclusion, although India has established a robust foundation for pharmacovigilance, continuous efforts are required to bridge existing gaps. A collaborative approach involving regulatory authorities, healthcare professionals, researchers, and patients—supported by digital innovation and policy reinforcement—will be crucial in advancing pharmacovigilance to global standards and ensuring the rational and safe use of medicines across the count.

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- Dr. Pratyush Purkayastha, Conception, design, drafting.

AUTHOR 2-Gaurav Kumar, Literature search, data extraction.

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