

A Review on the Integration of Pharmacovigilance and Materiovigilance: A Holistic Strategy for Strengthening Patient Safety

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ABSTRACT

Patient safety hinges on vigilant monitoring of adverse events associated with drugs and medical devices. In India the Indian Pharmacopoeia Commission (IPC) spearheads this responsibility by serving as the National Coordination Centre (NCC) for Pharmacovigilance programme of India (PvPI) and Materiovigilance programme of India (MvPI) under the Ministry of Health and Family Welfare. The Pharmacovigilance programme addresses the adverse events caused by medicines whereas the Materiovigilance programme tracks medical devices associated adverse events. As pharmaceuticals and medical technologies evolve, integrating these vigilance programmes is crucial. This unified approach emphasizes the advantage of an integrated framework through shared infrastructure and reporting mechanism, enhancing surveillance efficiency and facilitating timely detection of safety signals. Despite progress, hurdles such as underreporting, awareness gap, and medico-legal concerns persist. Reinforcing the integrated pharmacovigilance-materiovigilance system through capacity building unified reporting process and platform and stakeholders buy-in is crucial for improving post marketing oversight and ensuring patient safety. This review demonstrates the scope and feasibility of integrating both the programmes, along with emerging opportunities, potential public health outcomes in a unified and cohesive national vigilance ecosystem.

Keywords: Adverse Drug Reaction, Indian Pharmacopoeia Commission, Materiovigilance, Medical Device Adverse Events, Patient Safety, Pharmacovigilance.

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INTRODUCTION

The Indian Pharmacopoeia Commission (IPC) is an autonomous organization run under the Ministry of Health and Family Welfare, Government of India. IPC serves as the National Coordination Centre (NCC). It plays a central role in coordinating the surveillance of medicines and medical devices across India to enhance patient safety by conducting the Pharmacovigilance Programme of India (PvPI) and Materiovigilance Programme of India (MvPI). IPC serves as a key institution in India's mission to ensure the safety of both medicine and medical devices. It coordinates National Surveillance Programmes, monitors and analyses safety data, and works closely with the regulatory bodies to uphold public health (Soni *et al.*, 2014; Meher, 2018).

The integration of Pharmacovigilance and Materiovigilance programmes creates a comprehensive safety net that is more cohesive and effective in safety monitoring. The coordinated management of adverse events associated with medicines and medical devices under a single regulatory framework improves surveillance efficiency, promotes effective utilization of available resources, and strengthens patient safety through integrated post-marketing monitoring.

Most published reviews treat Pharmacovigilance and Materiovigilance as two separate areas of surveillance. In contrast, this review looks at the PvPI and the MvPI together, focusing on how they function within the Indian Pharmacopoeia Commission. It explores how shared infrastructure, reporting systems, training efforts, and regulatory coordination can support a more unified vigilance framework for medicines and medical devices. By examining both programmes side by side, the review offers a broader systems-level view of patient safety, highlights common challenges in post-marketing surveillance, and identifies opportunities to strengthen integrated vigilance practices in India.



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METHODOLOGY

A comprehensive literature search was conducted to identify relevant publications related to pharmacovigilance, materiovigilance, patient safety, and post-marketing surveillance. Electronic databases including PubMed, Google Scholar, Scopus, and official websites of the Indian Pharmacopoeia Commission (IPC), Central Drugs Standard Control Organization (CDSCO), and the World Health Organization (WHO) were searched for articles published up to May 2026. Search terms included "pharmacovigilance," "materiovigilance," "Pharmacovigilance Programme of India," "Materiovigilance Programme of India," "medical device adverse events," "adverse drug reactions," and "patient safety." Relevant peer-reviewed articles, official guidelines, programme reports, and regulatory publications published in English were included. Duplicate records and studies lacking relevance to the scope of this review were excluded.

Functions of IPC

The primary function of IPC is to ensure quality, safety, and efficacy of medical products across the country. It plays a pivotal role in harmonizing efforts among various stakeholders by organising steering committee meetings and working groups. It develops, updates, and disseminates Standard Operating Procedures (SOPs), guidance documents, training manuals, and newsletters to promote standardized vigilance practices across the country (Date *et al.*, 2023). IPC is a member of World Health Organization (WHO) Programme for International Drug Monitoring, India, sends Adverse Drug Reaction (ADR) reports to the Uppsala Monitoring Centre (UMC) in Sweden as a contribution to the global reporting of ADR for databases.

Patient safety encompasses the identification, assessment, and reduction of risk linked to medical interventions. While Pharmacovigilance (PV) primarily monitors Adverse Drug Reaction (ADRs), Materiovigilance (MV) focuses on adverse events related to medical devices (MDAEs).

Pharmacovigilance Programme of India

All India Institute of Medical Science (AIIMS), New Delhi, as the National Coordination Centre (NCC) on 14th July 2010 took an initiative to promote the safe and effective use of medicines by monitoring ADRs by launching the PvPI. To enhance its effectiveness the NCC was shifted from AIIMS to the Indian Pharmacopoeia Commission (IPC), Ghaziabad on April 15, 2011. IPC now functions, collects and monitors ADR data provided by the Adverse Drug Reaction Monitoring Centre (AMCs) to improve patient safety and protect public health.

Objectives

- The main goal of this programme is to protect public health by detecting, assessing and minimizing risk from medicines.
- To increase public protection from new drug side effects.
- To check drug efficacy and monitor adverse effects.
- To contribute to assessment of benefit efficiency and risk of medicine.
- To promote rational and safe use of drugs (Soni *et al.*, 2014; Yadav *et al.*, 2021).
- Identify new ADR Signals from reported cases, and communicate safety information to various stakeholders to reduce risk (Yadav *et al.*, 2021; Nimesh *et al.*, 2019).

Overview and Challenges

The evolution of Pharmacovigilance is rooted in a long history of ADRs with the notable incidents highlighting the need for systematic safety monitoring- from early observations in the 18th century to the 1937 sulfonamide formulation in the diethylene glycol that caused kidney failure, chloramphenicol induced aplastic anemia in 1950 and the thalidomide tragedy of 1961. Several medications in the 1980s and 1990s were also found to have severe side effects, fortifying the global push to enhance drug safety systems. In this frame of reference, India joined the WHO ADR Monitoring programme in 1997, and initiated Pharmacovigilance (PV) activities in 1998, operationalizing a strategic nationwide programme by 2009-10 (Soni *et al.*, 2014). Under this framework, the IPC functions as the National Coordination Centre (NCC) for the PvPI under the Ministry of Health and Family Welfare, overseeing a network of Adverse Drug Reaction Monitoring Centre (AMCs) that collect ADR case reports across the country. To make reporting more accessible, PvPI allows consumers, pharmacists, and all healthcare professionals to submit ADR reports through forms available in multiple Indian languages, a toll-free helpline number (1800-180-3024), and a dedicated mobile application (Nimesh *et al.*, 2019).

Despite having this robust unified structure, the programme faces several critical challenges that limit its effectiveness, including poor awareness and engagement among healthcare professionals, widespread underreporting of ADRs, inadequate training and limited incorporation of PV concepts in undergraduate and postgraduate curricula, and sufficient financial and human resources (Soni *et al.*, 2014; Pawar *et al.*, 2022). Additionally, the lack of a reliable unified system for reporting ADRs and prescription errors, a shortage of trained PV associates, and attitudinal issues such as indifference, reluctance and perceived inconvenience among healthcare workers further jeopardize the programme's capacity to ensure optimal drug safety.

Annual number of ADR reports from India

Early efforts to establish an ADR monitoring programme began in 1986 with 12 regional centers, but were unsuccessful. The programme was reintroduced in 1997 with 3 monitoring centers but however, it again failed due to lack of funding and awareness. Over the years India's PV system has evolved, with continuous efforts to monitor and report ADRs (Nimesh, *et al.*, 2019; Suke *et al.*, 2015). There are 1200 AMCs in India which collectively reported total of 1.09 million Individual Case Safety Reports (ICSRs) till 31 March 2026. PvPI has also reported cases of Adverse Events Following Immunization (AEFI) during COVID-19 post vaccination for 2 years, 2021 and 2022.

Case examples demonstrating PvPI impact

One of the landmark examples illustrating the impact of PvPI was the life threatening adverse reaction caused by Pioglitazone, an antidiabetic drug. Several signals were generated by different AMCs indicating a potential risk of bladder cancer. Pharmacovigilance data contributed to ongoing benefit-risk evaluation and subsequent regulatory recommendations (Bhushan *et al.*, 2019). Diclofenac, a widely prescribed Non-Steroidal Anti-Inflammatory Drug (NSAID), has been associated with rare but serious hypersensitivity reactions, including anaphylaxis following parenteral administration. Published case reports and pharmacovigilance data have highlighted the importance of prompt recognition and reporting of these adverse reactions, reinforcing the role of post-marketing surveillance in identifying uncommon but clinically significant safety concerns (Sahoo *et al.* 2024; Badyal *et al.*, 2019). PvPI received multiple reports regarding the adverse reactions; this pattern triggered a nationwide safety signal, regulating authorities to take appropriate actions.

Besides drug specific examples, PvPI has also expanded its scope to include the monitoring of AEFI, and MvPI programmes. It has developed a comprehensive network and framework for identifying and mitigating risk associated with drugs and other products which are used in patient care (Pawar *et al.*, 2022).

Materiovigilance Programme of India

The increasing number of reported medical device-associated adverse events highlighted the need for a structured surveillance programme, leading to the establishment of the Materiovigilance Programme of India (MvPI) in collaboration with the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) on 6 July 2015. The programme subsequently became operational under the Indian Pharmacopoeia Commission as the National Coordination Centre. It works by monitoring performance, safety of medical devices used across the country. The framework is designed in such a way that it collects, identifies, reports and analyzes the adverse events related to medical devices (Meher, 2018; Date *et al.*, 2023), (Saifuddin *et al.*, 2022). Through this approach MvPI generates credible and evidence based data, helps

in decision making and robust culture of vigilance to enhance the safety of medical devices.

Objectives

- To develop a comprehensive vigilance system that will assist regulatory authorities in making informed decisions thereby ensuring quality, performance and safe use of medical devices.
- To create a nationwide framework for patient safety.
- To analyse the risk-benefits ratio of medical devices use.
- Tracking and analysing Medical Devices Associated Adverse Events (MDAEs) to improve patient care (Meher, 2018; Saifuddin *et al.*, 2022).

Overview and Challenges

The MvPI operates through a well-defined structural organizational framework to ensure effective monitoring of medical devices safety. The Indian Pharmacopoeia Commission (IPC), Ghaziabad, works as the National Coordination Centre (NCC), overseeing and coordinating all programme activities (Date *et al.*, 2023). The SCTIMST Thiruvananthapuram, functions as the National Collaborating Centre, providing technical support and training in the monitoring of the devices safety and adverse events. Nearly about 630 Medical Device Adverse Events Monitoring Centers (MDMCs), located in medical colleges and hospitals across India are responsible for identifying, collecting and reporting Medical Devices Associated-Adverse Events (MDAEs). The Central Drugs Standard Control Organization (CDSCO) acts as the National Regulatory Authority, formulating policies and regulatory actions based on data and recommendations generated by the MvPI (Date *et al.*, 2023; Saifuddin *et al.*, 2022).

Despite this well-defined structure, MvPI faces several barriers that restrict its impact, including low awareness and limited participation from healthcare professionals, manufacturers and consumers, as well as inadequate data collection and reporting systems (Yadav *et al.*, 2021; Saifuddin *et al.*, 2022; Vikas *et al.*, 2019). Additional challenges to MDAE reporting include fear of repercussions, concerns over professional reputation, and medicolegal consequences, along with the absence of robust, clear guidelines for post-marketing surveillance of medical devices in India (Saifuddin *et al.*, 2022). Although the number of reported MDAEs is gradually increasing, the corresponding recall actions and safety signals generated by the MvPI remain relatively low compared to other countries, underscoring the need for further strengthening of the programme.

Annual reports of MDAEs in India

According to data available through the Indian Pharmacopoeia Commission, the Materiovigilance Programme of India (MvPI) has shown a steady increase in reporting since its inception. The

expanding network of Medical Device Adverse Event Monitoring Centres (MDMCs) and growing awareness among healthcare professionals have contributed to the accumulation of tens of thousands of medical device adverse event reports by March 2026, demonstrating progressive strengthening of device safety surveillance in India.

Case examples demonstrating MvPI impact

Several MDMCs have reported the signals related to cardiac stents regarding their structural failure, coating effects, breakage, device malfunction, post implant complications and incomplete expansion during angioplasty procedures (Mewada *et al.*, 2025). Adverse events related to hip implants were also observed which includes pain, infection, loosening of the implant, fracture, releasing metallic ions into the bloodstream of the patients (Aqil *et al.*, 2020). Malfunctioned infusion pumps resulted in inappropriate flow rate and sudden inaccurate bolus delivery to the patients, with reports highlighting the device failure, software errors, and mechanical faults (Sarvani *et al.*, 2024). Evaluation of such reports supports regulatory review, quality improvement initiatives, and post-marketing surveillance activities. These examples underline the importance of systematic monitoring of medical devices throughout their lifecycle and reinforce the role of MvPI in strengthening patient safety (Date *et al.*, 2023; Saifuddin *et al.*, 2022).

Integration of Pharmacovigilance and Materiovigilance in India

Pharmacovigilance Programme of India (PvPI) was launched to ensure the patient safety by identifying the drugs causing ADRs, but with the upgradation in the technology and enhancement of the device for to ease the patient treatment and management strategies, many devices are causing Adverse Events (AE) in the patient and even to the healthcare professionals. To collate and to identify the AE causing devices Materiovigilance Programme of India (MvPI) was launched under the umbrella of PvPI. This integration allows for the utilization of shared resources, workforce and logistics for both the programmes (Saifuddin *et al.*, 2022).

Goals

The integration of both the programmes in India, primarily through MvPI, aims to create a robust, unified system for monitoring the safety of both drugs and medical devices.

The primary objective is to safeguard the health and well-being of medical device users by preventing the recurrence of adverse events and device malfunction through continuous monitoring, evaluation, and implementation of corrective actions.

To produce independent, reliable and evidence-based-safety data on medical devices, and supporting the Central Drugs Standard

Control Organization (CDSCO) in making informed regulatory and policy decisions (Meher, 2018; Joshi *et al.*, 2021).

The MvPI operates in cooperation with the PvPI, utilizing its firmly set infrastructure to streamline device safety surveillance. Several Adverse Drug Reaction Monitoring Centres (AMCs) under the PvPI network are also engaged in reporting adverse events related to medical devices (Saifuddin *et al.*, 2022). MvPI uses the same helpline number introduced for PvPI to report adverse events related to devices, ensuring a unified and convenient communication channel. This strategic integration of both the programmes under IPC reflects a deliberate move towards a unified vigilance ecosystem. By taking into the use of the existing network of Pharmacovigilance Programme, Materiovigilance Programme magnifies efficiency, fosters comprehensive safety monitoring for all medical devices, and reinforces alignment with international standards (Joshi *et al.*, 2021).

Current landscape of PvPI and MvPI in India

The current status of Pharmacovigilance and Materiovigilance in India reflects a reinforced post marketing surveillance system that is rapidly aligned with global regulatory standards. Both the programmes are in a phase of swift augmentation of reach, reporting capabilities and infrastructure making them the central pillar of India's patient care. Although, PvPI is now an internationally recognized programme while MvPI is emerging as a strong parallel system, with the shared goals- early detection of safety signals, to promote rational use, strengthening of regulatory decision making and prevention of harm and quality control. Sustained investment, focused capacity building, advanced digital reporting systems and enhanced engagement of healthcare professionals will be crucial for further strengthening of both the programmes in future.

Challenges and Opportunities

The integration of both the programmes offers significant challenges with substantial opportunities. Although, both the programmes share a common objective; ensuring patient safety either from drugs or from adverse events associated with medical devices. Challenges in the integration and implementation of both the programmes are the resources and infrastructure disparities. Pharmacovigilance has more capacity and assessment procedures than Materiovigilance. Low priority and awareness for reporting adverse events, remains a major challenge, despite PV programmes being in operation for over decades. A major hurdle for healthcare professionals in reporting an adverse event caused by a medical device is reputational and medico-legal consequences. ADRs caused by drugs are available in public domains with real time awareness while data for MDAE is not available for the public which limits awareness for manufacturers and stakeholders and can delay preventive actions. Opportunities for a unified vigilance ecosystem are that they have the same coordinating center with the decision to utilize optimum

Table 1: Key Challenges and Future Opportunities for the Integrated Pharmacovigilance-Materiovigilance Framework in India.

Challenges	Future Opportunities
Underreporting of Adverse Drug Reactions (ADRs) and Medical Device Adverse Events (MDAEs) continues to limit the completeness of safety data.	Promote a strong reporting culture through continuous awareness programmes, regular training, and active participation of healthcare professionals, manufacturers, and patients.
Variations in awareness and reporting practices across hospitals and healthcare institutions affect the consistency of surveillance activities.	Standardize reporting procedures through uniform guidelines, structured educational programmes, and competency-based training across all monitoring centres.
Materiovigilance infrastructure is still developing and has fewer monitoring centres compared with the well-established pharmacovigilance network.	Expand the number of Medical Device Adverse Event Monitoring Centres (MDMCs) and strengthen collaboration with existing Adverse Drug Reaction Monitoring Centres (AMCs) to optimize available resources.
Limited digital integration between reporting systems may delay data collection, analysis, and signal detection.	Develop integrated electronic reporting platforms that enable real-time reporting, automated signal detection, and seamless data sharing between PvPI and MvPI.
Fear of legal implications, professional liability, and reputational concerns discourages spontaneous reporting of adverse events.	Foster a non-punitive reporting environment by emphasizing patient safety, confidentiality, and the educational value of reporting adverse events.
Collaboration among healthcare institutions, regulatory authorities, manufacturers, and academia remains inconsistent.	Strengthen multidisciplinary collaboration through coordinated research, regular stakeholder meetings, and information exchange to improve regulatory decision-making.
Limited public awareness restricts direct reporting by patients and caregivers.	Increase public engagement through awareness campaigns, mobile applications, and simplified consumer reporting mechanisms.
Continuous technological advancements introduce increasingly complex medicines and medical devices that require specialized surveillance approaches.	Incorporate advanced data analytics, artificial intelligence-assisted signal detection, and integrated risk management strategies to enhance post-marketing surveillance.

resources, workforce and logistics. Combined PV-MV committee can include pharmacists, clinicians, nurses, quality managers and can ensure routine case review and quicker safety assessment in coordination with regulatory agencies. Strong regulatory alignment and harmonization, along with unified training programmes for healthcare professionals according to international standards would improve India's global regulatory credibility and encourage collaboration between manufacturers, regulators and hospitals.

The challenges discussed above highlight the need for a more coordinated and sustainable approach to integrated vigilance in India. At the same time, they present opportunities to strengthen the existing framework through policy reforms, technological innovation, capacity building, and greater stakeholder engagement. A concise overview of the major challenges and corresponding future opportunities for the integrated Pharmacovigilance Programme of India (PvPI) and Materiovigilance Programme of India (MvPI) is presented in Table 1.

CONCLUSION

The coordinated implementation of the Pharmacovigilance Programme of India (PvPI) and the Materiovigilance Programme of India (MvPI) under the Indian Pharmacopoeia Commission

(IPC) has significantly strengthened India's post-marketing surveillance system. Together, these programmes enhance patient safety by monitoring Adverse Drug Reactions (ADRs) and Medical Device Adverse Events (MDAEs), enabling timely safety signal detection and evidence-based regulatory decisions. Although challenges such as underreporting, limited awareness, and inadequate training persist, continued investment in digital reporting, capacity building, and stakeholder engagement will further strengthen the national vigilance framework and promote the safe use of medicines and medical devices across India.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

ADR: Adverse Drug Reaction; **AE:** Adverse Event; **AEFI:** Adverse Event Following Immunization; **AMC:** Adverse Drug Reaction Monitoring Centre; **CDSCO:** Central Drugs Standard Control Organization; **DCGI:** Drug Controller General of India; **ICSR:** Individual Case Safety Report; **IPC:** Indian Pharmacopoeia Commission; **MDAE:** Medical Device Adverse Event; **MDMC:** Medical Device Adverse Event Monitoring Centre; **MvPI:** Materiovigilance Programme of India; **NCC:** National Coordination Centre; **NSAID:** Non-Steroidal Anti-Inflammatory Drug; **PvPI:** Pharmacovigilance Programme of India; **SCTIMST:** Sree Chitra Tirunal Institute for Medical Sciences and Technology; **SOP:** Standard Operating Procedure; **UMC:** Uppsala Monitoring Centre; **WHO:** World Health Organization.

AUTHOR CONTRIBUTIONS

Ashay Gupta: Conceptualization, literature search, manuscript drafting, data interpretation, and final manuscript preparation; **Anuja Jha:** Study supervision, review, and manuscript editing; **Pooja Reddy:** Conceptual guidance, critical review, and validation of scientific content; **Mohammad Rafi:** Literature review and manuscript editing; **Jitendra Patidar:** Scientific review, proofreading, and literature review.

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