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Review Article

Emerging Horizons in Materiovigilance: Global Innovations and Regulatory Advances

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ABSTRACT

Materiovigilance, the science and activities relating to the detection, assessment, understanding, and prevention of adverse events associated with medical devices, has undergone rapid evolution in recent years. Global and national regulatory authorities, including the Materiovigilance Programme of India (MvPI), have introduced significant reforms to strengthen post-market surveillance. Recent updates include the mandatory establishment of Medical Device Adverse Event Committees (MDAECs) in healthcare institutions, revised reporting forms by the Central Drugs Standard Control Organization (CDSCO), and alignment of device standards with the National Medical Device Policy 2023. Alongside these policy changes, there has been a surge in capacity-building initiatives, such as regional training programmes, awareness workshops, and the inclusion of materiovigilance concepts in professional development curricula. Technological advancements—particularly in artificial intelligence, machine learning, Bayesian signal detection, blockchain, wearable devices, and automated label-extraction tools—are enhancing data accuracy, traceability, and predictive safety monitoring. However, challenges such as under-reporting, limited awareness, fragmented data systems, and ethical considerations in AI integration persist. Knowledge, attitudes, and practice (KAP) surveys among healthcare professionals reveal moderate awareness but low reporting rates, highlighting the urgent need for structured training and mandatory reporting mechanisms. This review consolidates recent regulatory, technological, and educational advancements in materiovigilance, critically examines existing barriers, and outlines future directions for building robust, integrated, and proactive device safety monitoring systems. These developments collectively indicate a paradigm shift toward patient-centric and technology-enabled materiovigilance, promising enhanced medical device safety and improved healthcare outcomes.

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INTRODUCTION

Materiovigilance—the systematic monitoring, evaluation, and prevention of adverse events or product-related problems associated with medical devices—has emerged as a critical component of healthcare safety systems. In India, this discipline has seen accelerated growth through the Materiovigilance Programme of India (MvPI), established in 2015 by the Indian Pharmacopoeia Commission (IPC) under the Ministry of Health & Family Welfare. The programme aims to create a robust national framework for post-market surveillance, ensuring that any malfunction, deterioration in performance, or design-related defect in a medical device is identified, reported, and addressed promptly to safeguard patient health. Over the past few years, MvPI has undergone significant strengthening through the introduction of revised adverse event reporting forms, the mandatory constitution of Medical Device Adverse Event Committees (MDAECs) in healthcare institutions, and alignment with global regulatory practices. Simultaneously, advances in technology—including artificial intelligence, Bayesian analytics, blockchain-based traceability systems, and wearable device integration—are revolutionizing data collection, signal detection, and real-time safety monitoring. [1-3]. Complementing these regulatory and technological strides are capacity-building initiatives such as nationwide training programmes, workshops for healthcare professionals, and structured inclusion of materiovigilance concepts in medical and nursing curricula. Furthermore, emerging research trends in India and globally are providing deeper insights into reporting behaviours, barriers to compliance, and the potential of predictive safety analytics. Collectively, these developments reflect a paradigm shift from reactive incident management to proactive, technology-enabled, and patient-centred materiovigilance systems, strengthening healthcare delivery and patient trust. [4-6]

1. Regulatory and Policy Enhancements

The regulatory landscape for materiovigilance in India has undergone substantial strengthening in recent years, with multiple policy interventions designed to improve post-market surveillance, harmonise standards with global best practices, and support industry compliance.

India's Strengthened Reporting Mandates

A series of regulatory directives have been introduced to ensure greater accountability and systematic reporting of medical device-related adverse events:

- ***Mandatory Adverse Event Reporting by License Holders (May 15, 2024):***

The Ministry of Health & Family Welfare issued a notification requiring all licensed medical device manufacturers, importers, and distributors to establish robust adverse event reporting systems under the Materiovigilance Programme of India (MvPI). This move aims to improve post-market safety surveillance, ensure early detection of device-related hazards, and promote timely corrective actions.

- ***Revised Adverse Event Reporting Form (October 8, 2024):***

The Central Drugs Standard Control Organization (CDSCO) introduced version 1.2 of the Medical Device Adverse Event Reporting Form. This revision incorporated enhanced anonymity provisions to protect the identity of reporters, simplified data entry fields for ease of use, and introduced clearer categorisation of adverse events. These modifications were designed to

encourage broader participation from healthcare professionals, institutions, and device users.

- ***Formation of Medical Device Adverse Event Committees (MDAECs) (July 13, 2025):***

The National Medical Commission (NMC) directed all healthcare institutions to establish an MDAEC, register it with the IPC by July 31, 2025, and publish the committee details on their official websites. This committee-based model decentralises materiovigilance, enabling faster on-site evaluation of adverse events and streamlined reporting to the national database. [7-8]

Regulatory Capacity and Industry Support

Beyond strengthening reporting mandates, significant efforts are being made to expand regulatory capacity and foster industry readiness:

- *Standard Development for Critical Devices:*

The Bureau of Indian Standards (BIS) is actively developing and updating standards for over 214 critical medical devices and assistive technologies. This initiative ensures alignment with the National Medical Device Policy 2023 and international regulatory frameworks such as ISO standards, thereby facilitating both domestic safety compliance and global market access for Indian-manufactured devices.

- ***Strategic Financial Support for the Medical Device Sector:***

The Government of India launched a ₹500 crore strategic scheme aimed at enhancing domestic manufacturing capacity, supporting skill development programmes, upgrading infrastructure for device testing and calibration, and funding clinical evaluation studies. This investment is expected to create a strong ecosystem for innovation, quality assurance, and materiovigilance integration at every stage of the device lifecycle (Figure 1). [9-10]

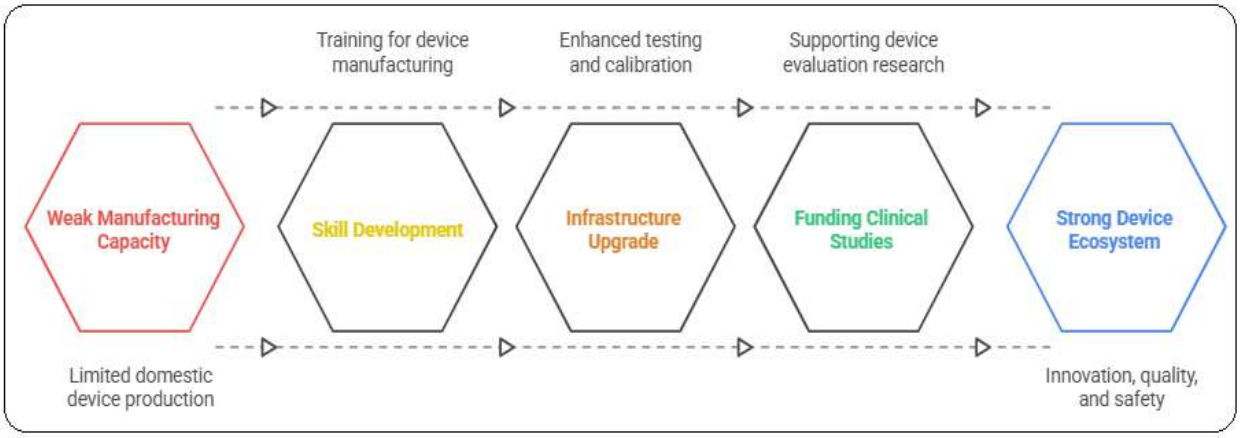

Figure 1: Strengthening India's Medical Device System

2. Training, Awareness & Capacity Building

Capacity building is a cornerstone of effective materiovigilance, ensuring that healthcare professionals, manufacturers, and regulators have the necessary skills, awareness, and resources to identify, evaluate, and report medical device–related adverse events. Recognising that under-reporting often stems from a lack of awareness or inadequate training, the Indian Pharmacopoeia Commission (IPC)—the National Coordination Centre for the Materiovigilance Programme of India (MvPI)—has intensified its outreach and education efforts in recent years (Table 1).

Nationwide Regional Training Programmes

In 2024–2025, multiple regional capacity-building workshops were conducted to improve understanding and adoption of materiovigilance practices:

North-East Region Focus: Dedicated training sessions were held in the North-Eastern states, targeting both public and private healthcare institutions. These sessions addressed challenges specific to resource-limited and geographically remote areas, ensuring inclusivity in national surveillance efforts.

Hospital-Based Workshops: Major healthcare institutions, including Apollo Hospital, New Delhi, and centres in Coimbatore, hosted on-site materiovigilance training. These programmes combined lectures, hands-on demonstrations of adverse event reporting, and case-study-based learning to bridge theory and practice.

Customised Stakeholder Sessions: Separate modules were developed for clinicians, nurses, biomedical engineers, and medical device manufacturers, recognising the differing roles and responsibilities in the reporting chain.

Professional Development Initiatives

Beyond institutional workshops, the IPC has created additional platforms to foster sustained engagement and professional growth:

Internship Opportunities: Structured internships under MvPI have been offered to pharmacy, medical, nursing, and biomedical engineering students. These placements provide exposure to real-world adverse event data management, regulatory documentation, and national surveillance operations.

Expert Committee Memberships: Invitations to join subject expert committees have been extended to experienced professionals in clinical medicine, biomedical engineering, and device manufacturing. This approach not only builds a multidisciplinary review capacity but also encourages stakeholder ownership of the materiovigilance process.

Impact and Future Needs

These initiatives have significantly improved awareness levels among healthcare professionals and created a pipeline of trained personnel capable of contributing to device safety surveillance. However, periodic refresher courses, e-learning modules, and integration of materiovigilance into undergraduate and postgraduate curricula are needed to maintain momentum and embed a culture of proactive reporting across the healthcare ecosystem. [11-14]

Table 1: Training, Awareness & Capacity Building

Category	Initiative	Description	Target Audience	Impact
Nationwide Regional Training Programmes	**North-East Region Focus**	Dedicated sessions in resource-limited and geographically remote areas to address regional challenges and promote inclusivity in national surveillance.	Public and private healthcare institutions in North-Eastern states	Expanded coverage and inclusion in materiovigilance network

	Hospital-Based Workshops	On-site training at Apollo Hospital, New Delhi, and centres in Coimbatore, combining lectures, live demonstrations, and case studies.	Clinicians, nurses, biomedical engineers	Improved practical skills in adverse event identification and reporting
	Customised Stakeholder Sessions	Tailored modules designed for specific professional groups based on roles in reporting chain.	Clinicians, nurses, biomedical engineers, manufacturers	Enhanced role-specific competencies and reporting efficiency
Professional Development Initiatives	**Internship Opportunities**	Structured internships offering exposure to real-world data management, regulatory processes, and national surveillance operations.	Pharmacy, medical, nursing, and biomedical engineering students	Built a pipeline of trained future workforce for materiovigilance
	Expert Committee Memberships	Invitations to join MvPI subject expert committees for multidisciplinary review and decision-making.	Experienced professionals in medicine, biomedical engineering, device manufacturing	Increased stakeholder engagement and expert-driven safety assessment
Impact & Future Needs	–	Awareness significantly improved; created skilled personnel for device safety monitoring. Need for refresher courses, e-learning, and curricular integration for sustainability.	All stakeholders	Sustained culture of proactive reporting

3. Knowledge, Attitudes, and Practices (KAP) in India

Understanding the knowledge, attitudes, and practices (KAP) of healthcare professionals toward materiovigilance is crucial for identifying barriers to effective adverse event reporting and designing targeted interventions. Several cross-sectional surveys conducted in India over the past few years have shed light on the current status among key professional groups.

Knowledge Levels

Studies involving postgraduate medical students, nursing students, and interns indicate moderate awareness of materiovigilance, with knowledge levels ranging from 40% to 74% depending on the cohort and institution. Participants were generally familiar with the basic definition of materiovigilance and the role of the Materiovigilance Programme of India (MvPI), but detailed understanding of reporting mechanisms, timelines, and regulatory requirements was often lacking. Awareness of specific reporting forms (e.g., Medical Device Adverse Event Reporting Form) and online submission portals was particularly low.

Attitudes

Despite these knowledge gaps, attitudes toward materiovigilance were overwhelmingly positive.

A large proportion of respondents agreed that adverse event reporting is essential for patient safety, that materiovigilance should be part of routine clinical practice, and that it should be mandated for all healthcare providers. Many expressed willingness to report device-related problems if clear procedures, training, and institutional support were available. This suggests a strong potential for culture change if appropriate systemic and educational interventions are implemented.

Practices

The practice component showed the most significant gap. Only 6–22% of respondents had ever filed a medical device adverse event report, reflecting both under-reporting and systemic barriers. Common reasons cited for non-reporting included lack of awareness about where and how to report, time constraints, uncertainty about whether the event qualified for reporting, and absence of institutional mandates. Furthermore, training coverage remains low (<30%), and most participants reported never having attended a dedicated materiovigilance workshop.

Implications for Policy and Training

The findings indicate that while baseline awareness exists and attitudes are favourable, the transition from knowledge to consistent reporting practice is hindered by training gaps, absence of standard operating procedures in institutions, and limited integration of materiovigilance into medical and nursing curricula. Addressing these issues through regular educational interventions, mandatory reporting policies, and simplified reporting tools could significantly strengthen the national materiovigilance system. [15-18]

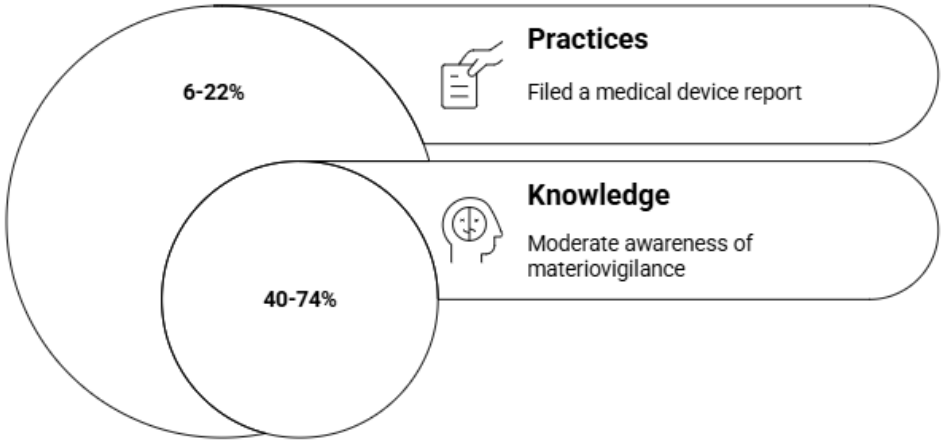

Figure 2: Healthcare Professional's Engagement with Materiovigilance in India

4. Technological Innovations and Research Trends

The integration of advanced technologies into materiovigilance is revolutionising how adverse events related to medical devices are detected, reported, and analysed. Recent research trends point towards a shift from passive, retrospective monitoring to real-time, predictive, and data-driven surveillance systems.

Advanced Analytics & Machine Learning

Bayesian Signal Detection:

Cutting-edge Bayesian statistical models are increasingly being employed in pharmacovigilance and are now finding

applications in materiovigilance. These models enable scalable and flexible detection of safety signals, allowing for both strength estimation and dynamic threshold adjustment. This approach improves sensitivity in identifying emerging device-related risks while reducing false positives, making post-market safety monitoring more reliable and efficient.

Ontology-Based Semantic Clustering:

Natural language processing (NLP) techniques and ontology-based semantic similarity measures are being used to cluster related medical terms in adverse event datasets. By grouping similar terms and harmonising terminology, these tools enhance early detection of safety signals and facilitate better trend analysis in device safety workflows, particularly when integrating heterogeneous datasets from multiple reporting sources.

Automated Reporting & Label Extraction Tools

PVLens and Similar Platforms:

Automation in materiovigilance reporting has been boosted by AI-driven tools such as PVLens, which can automatically extract, classify, and code adverse event labels from structured medical and regulatory documents. With demonstrated accuracy levels of F1 ≈ 0.88, these systems support real-time signal monitoring, reduce manual workload, and standardise data for downstream analytics.

Integration Trends: AI, Blockchain, and Wearables

Artificial Intelligence & Machine Learning: AI models are being developed to predict device failures before they occur, based on historical performance data and real-time usage metrics from connected devices.

Blockchain for Data Traceability: Blockchain technology is emerging as a secure method for recording adverse event data, ensuring tamper-proof traceability and enabling seamless multi-stakeholder access to verified safety records.

Wearable Device Integration: Continuous data streams from wearable medical devices offer real-time insights into device performance and patient health parameters, enabling faster detection of anomalies and automated triggering of safety alerts. Despite these promising advances, infrastructure limitations, interoperability issues, and ethical concerns around AI implementation—particularly in patient privacy, algorithm transparency, and informed consent—remain significant challenges. Future research is expected to focus on building robust, ethically soun-d frameworks to enable safe and effective deployment of these technologies in materiovigilance. [19-22]

5. Current Challenges & Future Directions

While materiovigilance in India and globally has made significant progress in recent years, several barriers continue to hinder the full potential of post market safety surveillance systems. Addressing these challenges, while leveraging emerging opportunities, will be critical to achieving a robust, proactive, and technology enabled device safety framework.

Barriers

Persistent Under Reporting:

Despite improvements in regulatory infrastructure, under reporting remains one of the most significant obstacles. Many healthcare professionals are unaware of the exact process for submitting reports or are uncertain about which events qualify for reporting. The absence of

mandatory reporting requirements for all professional groups further exacerbates this gap.

Data Quality, Integration, and Infrastructure Gaps:

Current adverse event reporting systems often suffer from incomplete, inconsistent, or non standardised data. Limited interoperability between hospital information systems, regulatory databases, and manufacturer records impedes real time analysis and trend detection.

Ethical and Legal Concerns in AI Adoption:

As artificial intelligence becomes increasingly integrated into materiovigilance, there is a pressing need for clear ethical frameworks to ensure patient privacy, data protection, algorithm transparency, and compliance with consent requirements. Without such safeguards, public trust in technology driven surveillance may be undermined.

Opportunities

Capacity Building and Education:

Expanding structured training programmes for healthcare providers, biomedical engineers, and manufacturers—along with integrating materiovigilance into medical, nursing, and allied health curricula—can create a culture of proactive reporting and device safety awareness.

Strengthened Regulatory Compliance:

Introducing mandatory adverse event reporting across all healthcare facilities, coupled with simplified online submission processes and clear guidelines for anonymous reporting, can significantly increase reporting rates.

Technology Driven Innovations:

Research into AI driven risk prediction models, enhanced post market performance monitoring tools, and the use of wearables and blockchain can enable predictive analytics, tamper proof traceability, and near real time safety alerts. These innovations could transform materiovigilance from a reactive process into a preventive and predictive safety system.

The Way Forward

To advance materiovigilance, a multi-pronged strategy is needed—combining policy enforcement, technological innovation, and human capacity development. Collaborative efforts between regulators, industry, academia, and healthcare providers will be essential to build an integrated, interoperable, and ethically sound surveillance ecosystem that safeguards patient health while fostering innovation in medical technology. [23-26]

Table 2: Novel Updates in Materiovigilance

Area	Key Developments
Regulation	New CDSCO circulars, reporting forms, MDAEC mandates
Training	Regional workshops, internships, expert calls
KAP	Awareness moderate; reporting rare; need education
Tech & Research	Bayesian signal detection; clustering tools; PVLens; AI, blockchain, wearables
Challenges	Under-reporting, infrastructure gaps, ethical concerns
Future Focus	Education, mandatory reporting, AI deployments, policy-tech integration

CONCLUSION

Materiovigilance is steadily transitioning from a conceptual framework into a robust, operational practice both in India and across the globe. This evolution is being driven by a synergistic combination of regulatory reform, technological

innovation, and targeted training initiatives. In India, the Materiovigilance Programme of India (MvPI) has played a central role in formalising adverse event reporting systems, standardising procedures, and fostering multi-stakeholder engagement. Globally, parallel developments in the European Union, the United States, and other regions are contributing to a shared vision of comprehensive medical device safety monitoring.

However, despite these advancements, persistent challenges—including under-reporting by healthcare professionals, fragmented data systems, limited interoperability between reporting platforms, and technological adoption barriers—continue to limit the efficiency and responsiveness of surveillance networks. Furthermore, the integration of advanced technologies into materiovigilance is often hampered by infrastructure gaps, workforce capacity constraints, and ethical concerns around data privacy and transparency. Encouragingly, there is growing momentum toward building integrated, proactive, and technology-driven materiovigilance systems. Strategic investments in artificial intelligence (AI) for predictive analytics, blockchain for secure and tamper-proof data sharing, and real-time data infrastructure for continuous device performance monitoring are paving the way for a next-generation safety ecosystem. When coupled with structured capacity-building programmes, mandatory reporting mandates, and stronger regulatory frameworks, these innovations have the potential to significantly elevate patient safety standards, ensure timely risk mitigation, and foster a culture of accountability and trust in medical device use worldwide.

REFERENCES

1. Meher BR. Materiovigilance: An Indian perspective. Perspect Clin Res. 2018;9(4):175–8.
2. Deshwal M, Nagpal M, Dhingra GA, Aggarwal G. An updated review on Materiovigilance for safe use of medical devices. Int J Drug Reg Affairs. 2020;8(4):5–13.
3. Kumar S, Chaturvedi S, Paswan SK, Singh H. Materiovigilance Programme of India: Global Perspective and Comparison. In: Futuristic Trends in Pharmacy & Nursing. IIP Series. 2024:70–85.
4. Mishra HP, Loriya K, Shah N, Grover S, Mishra SS. Leveraging artificial intelligence to revolutionize medical device safety. INNOSC Theranostics and Pharmacological Sci. 2025;[6204].
5. "Top 5 health laws and policy updates – 15 July 2025." Lexology. 2025 Jul 15.
6. Indian Pharmacopoeia Commission. E-Newsletter Vol 7 Issue 1. 2025.
7. IPC. Materiovigilance Programme of India (MvPI): Resource Material. 2024.
8. CDSCO. Medical Device Adverse Event Reporting Form (MDAE form). [Internet]. 2018. appliedclinicaltrialsonline.com
9. Kokolanski V, Trajkovikj-Jolevska S, et al. Comparative analysis of materiovigilance systems: Macedonia, USA, EU, Japan and China. Arch Public Health. 2019;11(1):20.
10. Sapkota B, Palaian S, Shrestha S, Ibrahim MIM. Materiovigilance in perspective: global healthcare implementation. Ther Innov Regul Sci. 2023;57(4):886–898.
11. Shaik T, Tao X, Higgins N, et al. Remote patient monitoring using artificial intelligence: current state, applications, and challenges. arXiv. 2023.
12. Rehman A, Abbas S, Khan MA, et al. A secure healthcare 5.0 system based on blockchain

entangled with federated learning. arXiv. 2022.
13. Srivastava G, Dwivedi AD, Singh R. Automated remote patient monitoring: data sharing and privacy using blockchain. arXiv. 2018.
14. Kale AU, et al. AI as a Medical Device Adverse Event Reporting in … protocol. JMIR Res Protoc. 2024;13:e48156.
15. Venkateswarlu B, Gowrishankar S. Materiovigilance Programme of India: a review. Perspect Clin Res. 2019;10(3):108.
16. Saifuddin PK, Tandon M, Kalaiselvan V, Suroy B, Pattanshetti V, Prakash A, Medhi B. MvPI current status and recommendations. Indian J Pharmacol. 2022;54(3):221–225.
17. Applied Clinical Trials Online. New regulations for medical devices in India. Applied Clin Trial. 2019.
18. IPC Official. MvPI guidance documents & adverse event forms. IPC website. 2025. ipc.gov.in
19. FDA. Medical Device Reporting (MDR), 21 CFR 803. US FDA. 2021.
20. European Commission. Medical Device Regulation (MDR) 2017/745. EC. 2021.
21. IPC. 34th Skill Development Programme brochure. 2024. ipc.gov.in
22. Jain R, et al. Medical device adverse event committee mandates by NMC. Lexology summary. 2025.
23. Kalaiselvan V. Training programmes by MvPI in North-East hospitals. IPC newsletter. 2025. ipc.gov.in
24. Meher BR. Need for integration of materiovigilance in medical curricula. Perspect Clin Res. 2018;9(4):175–8.
25. Deshwal M, et al. MvPI case studies: faulty hip implants & battery depletion. Int J Drug Reg Affairs. 2020;8(4):5–13.
26. Sapkota B, et al. Ethical frameworks for AI and blockchain in materiovigilance. Ther Innov Regul Sci. 2023;57(4):886–898.

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