An Overview of Materiovigillence in Medical Device Safety: Regulatory Framework, challenges, and Future Direction

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Abstract—**Materiovigilance focuses on the systematic monitoring of medical devices associated with adverse events, referred to as medical device adverse events (MDAEs). Materiovigilance and pharmacovigilance share a common objective and methodological approach aimed at ensuring patient safety. Through continuous evaluation of safety data, materiovigilance plays a vital role in identifying and facilitating the recall of defective or malfunctioning medical devices. All MDAEs, whether known or unknown, critical or non-critical, frequent or infrequent, or resulting from inadequate or missing specifications must be reported and thoroughly assessed. Materiovigilance contributes to the prevention of device-related complications and failures while enhancing the safety, performance, and design of medical equipment. It also serves to alert healthcare professionals and users to counterfeit or substandard devices. Commonly reported adverse events include device malfunction or breakage, infections at insertion or exit sites, organ damage or perforation, the need for surgical intervention, life cycle related device issues, and, in severe cases, death. Regulatory authorities worldwide have established structured and time-bound reporting systems for MDAEs, such as CDSCO in India Medsafe in New Zealand and MedWatch in the United States. Emphasizing the role of materiovigilance is essential to ensure the safe use of medical devices and to educate healthcare professionals and consumers about reporting mechanisms and appropriate response strategies following device related adverse events.**

Index Terms—**Materiovigillence, Medical device adverse Event, Patient safety, Post Marketing surveillance.**

I. INTRODUCTION

Materiovigilance is the systematic process of identifying, collecting, reporting, and evaluating adverse events associated with the use of medical devices, with the objective of protecting patient health and preventing their recurrence. Although post-marketing surveillance systems for medical devices have been implemented in many countries, they are not yet as advanced or comprehensive as those established for pharmaceuticals. In India, the Materiovigilance Programme of India (MvPI) was launched on 6 July, 2015 by the Indian Pharmacopoeia Commission (IPC). The programme aims to monitor adverse events related to medical devices, generate evidence-based safety data, raise awareness among stakeholders, and recommend best practices and regulatory interventions to enhance patient safety[1].The IPC, in collaboration with the National Health Systems Resource Centre (NHSRC) and the Central Drugs Standard Control Organization (CDSCO), established MvPI to create a nationwide system for the collection, analysis, and dissemination of data related to medical device associated adverse events[2]. Key stakeholders involved in the programme include manufacturers, importers, distributors, healthcare professionals, and patients. The MvPI also provides training and guidance to promote effective reporting practices and to minimize device-related adverse events. With the increasing use of medical devices in clinical practice, concerns regarding their safety and performance have also grown, highlighting the critical importance of a robust materiovigilance system. Similar pharmaceuticals, post marketing surveillance data on medical devices provides critical evidence for evaluating their safety, effectiveness, and overall impact on healthcare delivery [3].

Materiovigillence programme in India

Medical devices in India are regulated under the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules,1945. To streamline the regulation of medical devices, the Government of India, in consultation with the Drug Technical Advisory Board , notified the Medical Devices Rules 2017, which came into effect on January 1, 2018, following their notification on January 31, 2017.The Drug Controller General of India introduced the Materiovigilance Programme of India (MvPI) at the Indian Pharmacopoeia Commission , Ghaziabad, on July 6, 2015. The primary objective of this programme is to educate healthcare professionals about the importance of reporting medical devices associated with adverse events and to promote a culture of patient safety. In addition to adverse event monitoring, the programme emphasizes the benefit–risk assessment of medical devices and the systematic sharing of safety-related information with all relevant stakeholders. The National Coordination Centre for MvPI, located at the Indian Pharmacopoeia Commission, is responsible for collecting, analyzing, and monitoring adverse events associated with medical devices reported across the Indian population. The Sree Chitra Tirunal Institute for Medical Sciences and Technology functions as a National Collaborating Centre under the MvPI framework. The programme is regulated by the Central Drugs Standard Control Organization, while the National Health Systems Resource Centre provides technical support. To facilitate effective reporting and evaluation, Medical Device Adverse Event Monitoring Center have been established. These centers are responsible for reviewing MDAE reports, ensuring case completeness, and forwarding validated data to the NCC [4].

Objective of Materiovigillence Programme of India

1. Develop and implement a nationwide system in India to monitor and report adverse events related to medical devices.
2. Evaluate the causality and benefit–risk profile associated with the use of medical devices.
3. Support regulatory authorities in decision-making processes regarding medical device safety.
4. Provide safety data and issue medical device alerts to regulators and the healthcare system.
5. Communicate safety guidelines for the use of medical devices to various stakeholders to minimize risks.

6. Collaborate with other national healthcare organizations to exchange data and related information [4].

Class1	Class 2	Class 3	Class 4
• (Low risk) • Eg.Nasopharyngeal Catheter, Surgical dressing	• (Low Moderate • risk) • Eg.Arterial catheter,cervical Drain	• (Moderate Risk) • Eg.Cerebrospinal Catheter,Colonic Stents	• (High Risk) • Eg.Drug Eluting Stents,Heart valves

Fig.1 Classification of Medical Device in India [4]

Fig.2Vision, Aim, and objective of the materiovigilance programme of India [5]

Fig.3Application of Materiovigillence [6]

Stakeholders In MVPI

All professionals, including employees of SCTIMST NHSRC, IPC, and other similar organizations. Officials from the Medical Device Monitoring Center. CDSCO employees and advisors. Everyone who makes healthcare policy, but especially those who deal with medical device policy. Hospital technology managers work with physicians, nurses, biomedical engineers, pharmacists, and clinical engineers. CDSCO recommends medical device makers. innovators and medical Technologist [7-9].

Roles and Responsibilities of units of Materiovigillence Programme in India

Medical Device Monitoring Centers (MDMCs) are responsible for collecting and assessing the completeness of medical device associated adverse event (MDAE) reports, analyzing failure modes, establishing causality, and submitting consolidated monthly reports to the National Collaborating Centre (NCC) in accordance with standard operating procedures (SOPs). In line with the Mvpi guidelines, medical colleges across India have been designated as MDMCs. Maharashtra, for example, hosts 13 of the 174 active MDMCs participating in the program. These centers are required to submit case reports for review and analysis. The NCC compiles and analyzes adverse event reports from MDMCs, conducts signal detection, and communicates the findings to the National Collaborating Centre. In addition, MDMCs regularly conduct training sessions, awareness campaigns, and workshops on materiovigilance in different regions of the country. The Indian Pharmacopoeia Commission (IPC), functioning as the NCC for MvPI, is primarily responsible for coordinating all program activities, including convening steering committee and working group meetings. Its responsibilities also include identifying newly established MDMCs nationwide, preparing and distributing training manuals, newsletters, guidance materials, and SOPs. Furthermore, the NCC consolidates data obtained from the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) and provides recommendations to the Central Drugs Standard Control Organization (CDSCO). The Drug Controller General of India (DCGI)–CDSCO formulates regulatory decisions based on these recommendations and communicates them to all relevant stakeholders. Additionally, as the national regulator, CDSCO participates in international forums, including the International Medical Device Regulators Forum (IMDRF), for the exchange of post-marketing safety data. The National Health Systems Resource Centre (NHSRC), under the Ministry of Health and Family Welfare, Government of India, provides technical support to the NCC. This includes assistance in the preparation of SOPs, training manuals, newsletters, and guidance documents, as well as support in identifying and establishing new MDMCs across the country [10].

Medical device adverse event monitoring Centres

As of 2025, 639 Medical Device Adverse Event Monitoring Centres have been established nationwide, reflecting the significant strengthening of India's materiovigilance infrastructure and regulatory oversight [11].

Medical Device Adverse Event Reporting Form [12]

Integration of Artificial intelligence in medical device Post market Monitoring

AI greatly enhances postmarket surveillance by increasing the ability to track, evaluate, and react to information about the efficacy and safety of products aftertheyare put on the market .Artificial intelligence can efficiently analyze vast amounts of data from multiple sources, such as social media, electronic health records, adverse event reports, and other types of realworld evidenece by employing advanced machine learning algorithms.This feature makes it possible to spot patterns and trends that might point to new safety issues or efficacy challenges that would be challenging for people to spot right away.Additionally, AI systems have the capacity to continuously learn and adapt, improving their accuracy and forecasting abilities over time.Manufacturers and regulatory bodies can more efficiently distribute their resources..By evaluating and classifyingpossible hazards based on the severity and likelihood of unfavorable outcomes, manufacturers and reulatory bodies can more efficiently deploy their resources.Additionally, by generating usefu insights and visual representations, AI can improve communication and decisionmaking process.This helps stakeholders'lower risks and perform timely solutions.In conclusion,the effectiveness and efficiency of monitoring operations are increased when artificial intelligence (AI) is includedinto postmarket surveillance.Additionally, by enabling a proactve approach to risk management throughout the product lifetime, it supports improved patient outcomes and safety[13].

Fig.4 Steps of post marketing surveillance [13]

Innovations in Materiovigilance

Materiovigilance plays a critical role in ensuring patient safety, maintaining the security of medical devices, and monitoring their performance. It involves systematic collection, assessment, and reporting of adverse events associated with medical devices. Recent advancements in materiovigilance have substantially enhanced patient safety, particularly

through the implementation of improved monitoring methodologies. To further strengthen patient protection, materiovigilance systems are increasingly incorporating machine learning and artificial intelligence. These technologies facilitate the identification of patterns and correlations, enable the prediction of potential adverse outcomes, and support the efficient analysis of large datasets generated from medical devices. Such real-time analytical capabilities allow for timely interventions, thereby minimizing the risk of serious harm. Consequently, regulatory authorities are better equipped to ensure the safety of medical devices and to mitigate associated risks [14].

Enhancing Patient Safety Through Enhanced Monitoring

By identifying trends and anomalies within large volumes of data generated from medical devices, electronic health records, and other real-world data sources, materiovigilance systems that incorporate artificial intelligence and machine learning have significantly improved patient safety. These technologies enable real-time analysis of data from medical devices, allowing for the early detection of device malfunctions and potential safety risks. This proactive approach enhances patient protection by facilitating rapid intervention and timely corrective actions in the event of adverse incidents. Furthermore, predictive analytics and advanced algorithms can identify patient-specific patterns and risk characteristics. The integration of advanced analytical methods and diverse data sources enhances diagnostic accuracy, improves signal detection, supports personalized treatment strategies, and strengthens materiovigilance decision-making, ultimately leading to improved patient outcomes [14].

Recent Regulatory Advances in Materiovigilance

To promote consistency and convergence in national medical device regulatory frameworks, the United States, Canada, Japan, Europe, and Australia established the Global Harmonization Task Force in 1992. Since the early 1980s, the regulatory landscape for medical devices has evolved substantially, making regulatory harmonization increasingly important to reduce barriers, streamline approval processes, and facilitate timely access to high quality, safe, and effective medical devices. Recent advancements in materiovigilance, particularly those incorporating artificial intelligence and machine learning, have further strengthened regulatory oversight and decision-making processes. These technologies enhance monitoring capabilities, improve patient safety, and enable large data analysis for the early detection of safety signals and potential risks. In this context, regulatory agencies such as the U.S. Food and Drug Administration are actively exploring the use of AI and machine learning to improve the identification, evaluation, and management of safety concerns associated with medical devices [14].

Materiovigilance practice in Dentistry

In dentistry, materiovigilance refers to the systematic monitoring, evaluation, and reporting of adverse events associated with the use of dental materials and devices. These events may include infections, allergic reactions, device malfunctions, breakages, and other unforeseen complications occurring during clinical use. Numerous dental products including toothbrushes, orthodontic appliances, implant instruments, prefabricated arch wires, milled crown materials, impression materials, porcelain glaze sprays, and craniomaxillofacial distraction systems have been recalled globally due to safety concerns. The increasing availability of counterfeit and non-CE marked dental products through online platforms further elevates risks to patient safety. These incidents underscore inconsistencies in regulatory enforcement and highlight the urgent need for standardized international guidelines to ensure patient protection across dental care systems. Globally, approaches to dental materiovigilance vary; while some countries rely primarily on manufacturers and regulatory authorities for post-marketing surveillance, others actively involve healthcare professionals and patients in adverse event reporting. Nevertheless, challenges such as underreporting and limited awareness persist, emphasizing the need for improved collaboration, education, and harmonized reporting frameworks. Despite the critical importance of materiovigilance in dentistry, this field remains underrepresented in broader discussions on medical device safety [15].

Enhancing Materiovigilance in Dentistry: Through Effective reporting and Risk control

In dentistry, materiovigilance refers to the systematic monitoring, assessment, and reporting of adverse events associated with dental devices, including

malfunctions, breakages, infections, allergic reactions, and other unexpected outcomes during clinical use. To ensure comprehensive safety oversight, all suspected medical device associated adverse events, regardless of their severity, frequency, or established causality, should be documented. Active reporting by dental healthcare professionals is essential, as it enhances risk awareness and contributes to overall patient safety. Patient confidentiality is strictly maintained, and reports are treated with full discretion. Serious incidents are thoroughly investigated to assess the device's role, considering factors such as timing, accuracy, and potential contributory elements. These evaluations facilitate the identification of safety signals and provide critical information for regulatory actions, including product recalls, safety alerts, updates to user manuals, and the development of training programs. Ultimately, data from materiovigilance systems support targeted educational initiatives and strengthen benefit risk assessments, promoting the safe and effective use of dental devices across healthcare settings [15].

Challenges in Advancing Materiovigilance in Dentistry

The implementation of materiovigilance programs in dentistry faces challenges like those encountered in pharmacovigilance, particularly in encouraging active participation from both practitioners and patients. Reporting adverse events is often perceived as burdensome, and many stakeholders remain uncertain about when, how, and why to report. The lack of mandatory reporting requirements further impedes the integration of materiovigilance into routine clinical practice. Additionally, negative perceptions among some practitioners who may associate reporting with admitting clinical errors can discourage transparency and open communication. Another major challenge is the shortage of trained personnel and the absence of robust reporting infrastructure. One potential solution is for regulatory authorities to require that all dental devices include package inserts and a Summary of Product Characteristics (SPC), which would enhance awareness and standardize reporting procedures. As dentistry increasingly adopts digital workflows, 3D printed implants, and bioactive materials, ensuring patient safety amid rapid technological innovation becomes more complex. Existing post-market surveillance systems may not be agile enough to address the unique risks associated with these emerging technologies. Therefore, adapting materiovigilance frameworks to support innovation while protecting public health is a critical global priority.[15]

Importance of Materiovigilance in Orthopedics

With a population of 1.4 billion and millions of orthopedic surgeries performed annually, India presents a unique opportunity for advancing materiovigilance. By analyzing extensive data on patient outcomes and implant performance, India can identify trends, detect potential issues, and improve the quality and design of orthopedic implants. This approach has the potential to position India as a global leader in medical device optimization, promoting safer, more effective orthopedic treatments and fostering innovation. Orthopedic surgery is distinct due to the frequent use of implants that remain in the body for extended periods. Devices such as external fixators, screws, plates, and joint replacements are continuously exposed to biomechanical stress, making them susceptible to wear, tear, and, in rare cases, failure. Effective materiovigilance ensures the early detection of such issues, enhancing patient safety and improving long-term surgical outcomes.

The inherent complexity of orthopedic implants introduces several potential risks:

1. Mechanical failures: Implants may experience wear, breakage, or loosening, particularly in joint replacements where components are subjected to high mechanical loads.
2. Material degradation: Corrosion or deterioration of implant materials, such as metal-on-metal components, can cause local tissue damage or systemic complications, including metallosis.
3. Biocompatibility issues: Some devices can trigger adverse immune responses, leading to inflammation or, in rare cases, implant rejection.
4. Surgical and human factors: Improper implantation techniques or intraoperative errors can compromise device functionality and patient outcomes [16].

The role of social media in Materiovigillence

Social media platforms such as LinkedIn, Facebook, Twitter(X), and YouTube play an important role in disseminating timely and accurate information regarding the rational selection of medical devices and the reporting of adverse events. These platforms also

contribute to the promotion of scientific advancements and emerging issues in healthcare. When device-related defects are identified, social media can facilitate the rapid communication of safety alerts and product recalls. As a result, healthcare professionals and users may remain informed about recent regulatory updates and related development. However, excessive dependence on information obtained from social networking platforms may expose individuals to potential physical and psychological risks. Misinformation or unverified content can be more harmful than the absence of information. Therefore, it is essential to critically evaluate published content and verify its sources before applying such information in clinical practice or healthcare decision-making.[17].

Responsibilities of Healthcare Professionals in Medical Device Incident Reporting

Healthcare professionals have a significant responsibility in identifying and reporting problems associated with medical devices. Enhancing the ability of both individuals and healthcare institutions to recognize and report harmful effects related to these devices is essential. Surgeons, physicians, nurses, and pharmacists all play an important role in this process. The use of database information systems that generate safety signals for medical devices can further support effective monitoring and reporting. Moreover, healthcare professionals can educate and train their colleagues and patients about the importance of medical device vigilance (MDV), especially in the context of device recalls. The ultimate goal is to establish and promote a strong institutional culture that encourages the reporting of medical device adverse events, which can contribute to improving device safety and preventing similar events in the future.[17].

II. FUTURE DIRECTIONS

The Materiovigilance Programme of India (MvPI) seeks to enhance patient and healthcare professional safety by minimizing the recurrence of adverse events related to medical devices. Vigilant monitoring of medical devices is as critical as pharmacovigilance in ensuring patient safety, as widely used devices can occasionally lead to serious complications if not properly monitored. MvPI raises awareness of adverse event reporting among patients, healthcare providers, and other stakeholders, fostering a proactive reporting culture and encouraging timely documentation of device-related incidents. It enables oversight of manufacturers, regardless of their engagement with safety concerns, and supports research on device-related adverse outcomes as a valuable public health tool. A long-term goal is to make reporting of device-related adverse events mandatory for manufacturers, strengthening patient safety and regulatory compliance. Additionally, MvPI collaborates with international regulatory agencies such as the FDA and European Medicines Agency to adopt best practices, standardize reporting systems, and facilitate global data sharing. The programme provides training and capacity-building initiatives for healthcare professionals to improve detection, documentation, and reporting of device-related adverse events. By maintaining a centralized database and analyzing trends, MvPI helps identify high-risk devices, issue safety alerts, guide regulatory interventions, and inform policy decisions. Through these measures, MvPI not only safeguards patients but also contributes to the global effort to improve the quality, reliability, and safety of medical devices in clinical practice.

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