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# INDIA'S MATERIAL VIGILANCE PLAN: CURRENT STATUS

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## ABSTRACT

India's Materiovigilance Programme (MvPI) plays a pivotal role in ensuring the safety and efficacy of medical devices. Initiated in 2015, MvPI focuses on monitoring adverse events related to healthcare device usage, promoting awareness, and providing evidence-based recommendations for safe usage. The program's unique features include collaboration with medical colleges, an organized reporting structure, and a regulatory framework established in the Medical Device Rules of 2017. This article reviews the history, goals, and current status of MvPI, emphasizing its role in enhancing healthcare device safety in India. The program faces challenges, but ongoing efforts are vital for continued success. The article concludes with considerations for future improvements, emphasizing the need for increased engagement, awareness, and collaboration at various levels to strengthen Materiovigilance in India.

**Keywords: Adverse Event Reporting, Materiovigilance Programme (MvPI), Medical Device Safety, Postmarket surveillance**

## INTRODUCTION

The term "materiovigilance " refers to a system that keeps monitoring out for and prevents any negative things from happening when patients utilise medical equipment. It involves detecting, assessing, understanding, and preventing adverse events stemming from medical devices. Medical devices are essential for patient care, but they can pose potential risks, such as malfunctioning or releasing harmful particles into the bloodstream **[1]**. Materiovigilance is important to ensure

standardised and safe healthcare devices. Initiated in 2015, the MvPI seeks to methodically gather data from the Indian community about the safety of healthcare device usage. Its key functions include monitoring adverse events, promoting awareness among healthcare professionals regarding reporting, assessing the balance between benefits and risks, providing evidence-based recommendations on safety, and communicating its findings to stakeholders and regulatory authorities. The Medical Device Rules of 2017 provided a more comprehensive and specific regulatory framework for these products in the Indian market [2]. Materiovigilance plays a pivotal role in safeguarding patient well-being and addressing the evolving landscape of medical device usage, ultimately contributing to the overall safety and efficacy of healthcare devices in India [3]. Medical devices, ranging from cardiac stents to glucometers and orthopaedic implants, are integral to patient care. However, akin to pharmaceuticals, they pose potential risks, such as ADE malfunction resulting in electrical burns or the release of metal particles into the bloodstream from worn-down hip replacement devices. Some devices have even undergone recalls due to associated risks, emphasising the critical need to ensure standardised and safe healthcare devices [4].

A medical device is something made by companies for different health reasons. It can be tools, machines, or software used on or inside our bodies. These devices help with:

(a) Figuring out, stopping, controlling, treating, or lessening diseases.

(b) Figuring out, controlling, treating, lessening, or fixing injuries, problems, or troubles in our bodies.

(c) learning, changing, or replacing parts of our bodies or how our bodies work.

(d) Trying to make big progress in getting pregnant [2].

## HISTORY OF MATERIOVIGILANCE PROGRAMME OF INDIA

The Drug and Cosmetic Acts of 1940, along with the Rules of 1945, are employed to oversee the safety, quality, and performance of medical devices in India. However, there was a deficiency in India's existing system for consistently monitoring adverse events related to the ongoing use of medical products. Recently, the Govt. of India and the Drugs Technical Advisory Board collaborated to create the Medical Devices Rules of 2017 to govern their import, manufacture, sales, and distribution. It was announced on January 31, 2017, and became effective on January 1. The distinctiveness of MvPI lies in its challenges related to infrastructure and capacity building, as well as its distinctive reporting tools, methods of

data collection, and assessment, setting it apart from drug-related initiatives. Integral to the successful implementation of MvPI is the crucial step of coordinating with other departments and incorporating biomedical engineering departments within hospitals and institutions **[5]**.
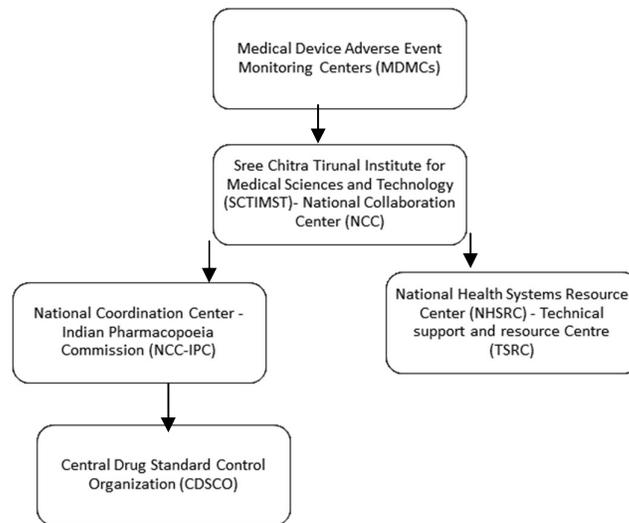


**Figure 1: Organizational structure of MvPI [6]**

By implementing a system that includes detecting, gathering, reporting, and forecasting undesirable events after the device's post-marketing phase or introducing safety measures, medical device owners are closely monitoring any unfavourable outcomes. The MvPI initiative in India, launched on July 6, 2015, the main objective of the Drugs Controller General of India at the Indian Pharmacopoeia Commission in Ghaziabad is to monitor incidents related to healthcare equipment **[3]**. Its goals are to provide independent, reliable safety data on the use of medical instruments for users and to raise awareness among healthcare providers of the need to report MDAE. The IPC and the Central Drug Standard Control Organisation (CDSCO) manage the National Coordination Centre (NCC). This initiative initially targets the enrolment of 10 medical colleges across four regions of India, promoting voluntary reporting. Subsequently, the plan involves extending the programme to encompass all healthcare delivery systems, establishing an e-reporting system, and mandating reporting for both device manufacturers and healthcare providers **[6]**.

## GOALS AND OBJECTIVES OF MVPI IN INDIA

The main objective of the Materiovigilance Programme (MvPI), launched on July 6 by the Ministry of Health and Family Welfare

of the Indian government, is medical device safety in India. The purpose of this programme is to carefully and methodically collect scientifically significant data on negative occurrences associated with medical gadgets, aiding regulatory decisions and recommendations for their safe usage. The project's objectives include assessing the relative risk and utility of medical instruments and educating healthcare professionals on the significance of reporting MDAEs in India. The Indian Pharmacopoeia Commission has served as MvPI's National Coordination Centre (NCC) since 2018. Thiruvananthapuram's Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) serves as the National Collaboration Centre. New Delhi's National Health System Resource Centre (NHSRC) serves as the technical assistance partner. The Central Drugs Standards Control Organisation (CDSCO), based in New Delhi, provides further help, building on its significant expertise as the national regulator. The initiative also aims to establish medical device benefit ratios [1, 2, 7].

The following are MvPI's goals:

1. Ensure the security of healthcare equipment in India.

2. Gather information on MDAE in a methodical manner and analyse it scientifically to help guide recommendations for safe medical product usage and regulatory choices.

3. Educate Indian healthcare providers about the need to report MDAEs.

4. Assess the potential risks associated with medical devices by considering their benefit ratio.

5. Provide unbiased, fact-based advice on the safety of health-care supplies, and make sure that all relevant parties are aware of your findings [10].

Medical equipment safety is monitored and guaranteed by the MvPI, including those applied to maternal and child healthcare. While the specific aims and objectives of MvPI are not explicitly provided in the available search results, the broader initiatives and advancements in maternal and child health in India demonstrate a commitment to enhancing the safety and effectiveness of interventions. India has achieved significant progress in reducing maternal mortality. From 556 per 100,000 live births in 1990 to 130 per 100,000 live births in 2016, the country's mother-death ratio decreased by an amazing 77%. The Indian Government has implemented strategies and programmes to enhance maternal health services, increase access to quality care, and address social determinants of maternal health [8]. Collaborative

endeavours with institutions such as the Bill & Melinda Gates Foundation have been directed towards advancing maternal and child health. This includes a targeted focus on enhancing the quality of intrapartum care, emergency obstetric and newborn care, and antenatal care **[9]**.

## CLASSIFICATION OF MEDICAL DEVICES

The proposed guideline defines key concepts and standards for the categorization of medical devices and in vitro diagnosis healthcare devices (collectively referred to as IVD medical devices).

Medical devices can be sorted into distinct risk categories, including

1. Low-risk (Class A)

   Examples: Bolster sutures, alcohol swaps, nasopharyngeal catheters

2. Low to moderate risk (Class B)

   Examples: disinfectants, intravenous catheters, rectal catheters

3. Moderate to high risk (Class C)

   Examples: biliary stents, bone cement, imaging catheters

4. High risk: Class D

   Examples: copper-T, cardiac valve, coronary stent.

The intended use of medical equipment and in-vitro diagnostics equipment, as well as other factors like the application principle, device combination, software that affects device operation, and intended location or purpose, are used to classify them. These principles can be used independently or together. The classification of medical devices should take into account diverse parameters, including invasiveness (body image), non-invasiveness (blood sample), surgical implantation (handling), and devices that contain medicinal products **[11]**.

## CURRENT STATUS OF MVPI IN INDIA

As of January 2024, there has been no update on the status of India's Materiovigilance Programme in recent times. India secured two additional loans of $500 million each from the World Bank in March 2023 to enhance its health sector, including pandemic preparedness and improved health service delivery **[12]**.

In an effort to lower the rates of mother and newborn deaths, the Ministry of Health and Family Welfare, Government of India, published Guidelines for Antenatal Care and Skilled Attendance at Birth by ANM(s) in April 2010. During pregnancy, women receive health care interventions such as vaccines and other medicines through the monitoring of maternal intervention vigilance (MIV) **[13]**. MDSR is a continuous process that involves notifying and evaluating maternal deaths, then interpreting the review findings, responding

to them, and taking steps to prevent future fatalities. The MDSR is designed to help prevent future maternal deaths by learning from past deaths **[14]**.

In general, MvPI has made considerable breakthroughs since its beginning in 2015. Its continuing attempts are concentrated on ensuring the safety and effectiveness of medical equipment.

## DOCUMENTING AND REPORTING ADVERSE EVENTS

- **Who can report MDAEs?**

SCTIMST, or NCC, is designated to collect reports on MDAEs from healthcare professionals and patients. These professionals encompass doctors, pharmacists, dentists, nurses, and biomedical engineers. Moreover, direct

reporting of particular adverse occurrences related to medical devices by authorised producers or importers with CDSCO endorsement is permitted to SCTIMST or NCC in Thiruvananthapuram, Kerala, India **[15, 16, 17]**.

- **What needs to be reported?**

Any kind of disease, whether it be well-known or not, severe or not, uncommon or common, may have its MDAEs reported without taking the causative link into account. The AE report includes details about the incident, medical device risks to patients or users, and any potential risks related to their previous use. Additionally, MDAE reporting forms should include information about possible risks associated with surgical procedures **[15, 16, 17]**.

**Table 1: Timelines for different types of reports [3, 15, 16, 17]**

| Sr. No | Reporter | What should I report? | Where do I report? | When should I report? |
|---|---|---|---|---|
| 1 | The Manufacturer | Demise, breaks down, and severe incidents necessitating remedial measures | FDA | In a period of 30 business days |
| | | unfavourable occurrences needing remedial measures | FDA | In five business days |
| | | Follow-up reports | FDA | Within a month |
| 2 | User facility | Severe harm | FDA or the manufacturer (if unknown) | In ten business days |
| | | Demise | FDA along with manufacturer | In ten business days |
| 3 | Traders | Critical incidents, including demise | Manufacturer with the FDA | In ten business days |

- How and to whom should MDAEs be reported?

All patients in India are free to report side effects connected to medical equipment, irrespective of their risk level or event frequency. Reporting becomes essential in

instances of device malfunction or degradation in characteristics or performance, as well as incorrect labelling or usage instructions. MvPI has devised a two-page form for reporting medical device adverse events, encompassing

comprehensive details about the patient, adverse events, device specifications, regulatory aspects, and the person who reported them. The form can be easily accessed at www.ipc.gov.in, the official web page of the IPC. The patient's signature is needed on the signed form to be sent to MDMC, and the same form has to be forwarded to NCC. The scanned copy of the document can be forwarded to sctismt.ac.in or digitally copied to mvpi.ipcindia@gmail.com. Furthermore, the NCC-PvPi helpline is operational 24/7 at 1800-180-3024, allowing reporters to communicate adverse events. The intricate web of relationships and interrelated aspects among various stakeholders involved in recording and reporting device-related adverse events adds complexity to the process [3].

1. Responsibilities of healthcare service providers

2. Responsibilities of manufacturers

3. Responsibilities of research associates and coordinators at MDMC

4. Duties of the National Collaborating Centre

5. Duties of the National Coordinating Centre (NCC)

6. Duties of the Technical Support and Research Centre (TSRC)

7. Duties of CDSCO (Central Drugs Standard Control Organisation) [3, 15, 16, 17]



**Figure 2: MDAEs Medical Device Adverse Event Reporting Form**

## DIFFERENT CENTERS UNDER MVPI

There are now 150 MDMCs nationally reporting medical device-related adverse events (MDAEs), up from the original 10 at the beginning. Since the inception of the programme, there has been an uptick in the reporting rate. The total reports submitted to IPC through MvPI exceed a certain number. All suspected or proven MDAEs are categorised into five types by MDMCs: not related, implausible, plausible, probable, and causal relationship. MDMCs are required to submit their reported cases to NCCIPC for monthly evaluation and analysis. Within five business days of identification and thirty calendar days after root cause determination, an MDAE must be reported [18]. IPC is solely responsible for maintaining the MvPI database. NCC coordinates with all MDMCs in India, addressing any related issues directly with CDSCO. They work together with global organisations and finance MDMCs, NHSCs, and SCTIMSTs. Technical support for the programme is provided by NHSRC, a technical support partner, and is managed by the National Collaboration Centre (SCTIMST). The company contributes to the creation of newsletters, instruction papers, training manuals, standard operating procedures, and other materials through its technical support. All the concerns are forwarded to CDSCO, which is a safety regulatory body overseeing the entire country. It must follow the recommendations of the NCC MvPI and take all necessary actions [19].

## DIFFERENT MVPI PROGRAMME CENTRE LOCATED ACCROSS INDIA

The MvPI programme has a network of participating centres across India. The participating centres are responsible for collecting and reporting data on MDAEs. The following is a list of the MvPI participating centres:

1. Ghaziabad's Indian Pharmacopoeia Commission (IPC)
2. Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh
3. All India Institute of Medical Sciences (AIIMS), New Delhi
4. The Bengaluru-based National Institute of Mental Health and Neurosciences (NIMHANS)
5. Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Thiruvananthapuram
6. Christian Medical College (CMC), Vellore
7. SGPGIMS, Lucknow, is the Sanjay Gandhi Postgraduate Institute of Medical Sciences.
8. Shah G.S. Medical College and KEM Hospital, Mumbai

9. King George's Medical University (KGMU), Lucknow
10. The Institute of Postgraduate Medical Education and Research (IPGMER), located in Kolkata
11. Government Medical College, located in Nagpur **[20]**.

## GLOBAL POSTMARKETING SURVEILLANCE APPROACHES

The MDAEs in the US, Canada, Australia, Japan, the UK, and Europe are monitored by each nation's active and passive monitoring systems. American food, medicine, and vaccine regulation is overseen by the world-renowned FDA. The US has suggested a mandatory and voluntary reporting system. The United Kingdom and other nations have their own databases and monitoring and reporting systems for adverse events **[21]**. To ensure safe and effective use, medical devices in the United States must be approved by the FDA before they can be sold. The Device and Radiological Health Centre at the FDA oversees the global processes of medical device relabeling, manufacturing, export, and import. In Europe, the National Competent Authority (NCA) manages all complaints related to medical devices, and incidents must be reported to manufacturers by general practitioners, doctors, and nurses **[22]**. It is necessary for manufacturers to report a preliminary adverse event within two days. If a manufacturer detects any relationship between a healthcare device and mortality or health difficulties, the review must be done within 10 days **[23]**. Medical device monitoring is done in Japan by the Pharmaceutical and Medical Device Agency, and in Australia, the manufacturer is required to submit all device information to the Therapeutic Goods Administration (TGA) for evaluation or approval. Health Canada also controls the licencing of devices, both new and modified. During the premarketing stage, the regulatory body confirms that all essential requirements for obtaining permits are met **[24]**.

**Table 2: Timelines for different types of reports [24]**

| Country | Database or regulating body for medical devices |
|---|---|
| USA | MAUDE FDA |
| JAPAN | PMDA |
| UK | MHRA |
| AUSTRALIA | TGA |
| EUROPE | EMA |
| INDIA | CDSCO |

## INDIAN POSTMARKETING SURVEILLANCE APPROACH

The rate at which the Indian regulatory agency (MvPI) is doing post-marketing surveillance is increasing and is now faster than that of international regulators. In spite of a yearly increase in the total number of recorded adverse events—which increased

from 40 occurrences in 2015 to 897 in 2019 [25]—these numbers are still far behind those of other countries in terms of both the total number and many safety-related factors, such as product recalls. By contrast, the Australian regulatory agency (TGA) received 5348 adverse event reports in 2017 and 2018, while the USFDA recalled 30 medical devices in 2017 and 32 in 2018 for various reasons. Based on the assessment of these instances, 27 goods were recalled, and 41 danger advisories were given to customers [26]. During the 2018–2019 era, TGA identified 5874 adverse occurrences and issued 5129 signals, resulting in 55 product recalls and 68 cases of safety risks [27]. During this period, Health Canada additionally reported an increase in recalls. Conversely, the Medical Device Adverse

Event Reporting System (MvPI) exhibited limited recall measures or safety alerts associated with reported adverse events throughout the same time. It is noted that MvPI possesses a considerable advantage in data collection, adverse event processing, and signal creation for recall actions. However, the scope of data gathering is constrained to recognised medical schools, hospitals, autonomous institutions, and importers, demanding expanded cooperation from private hospitals, nursing homes, and labs. Additionally, the restricted accessibility of MvPI data in the public domain prevents manufacturers and stakeholders from rapidly recognising unfavourable occurrences and delays remedial efforts [28].

**Table 3: A list of medical device recalls throughout the last 10 years [29]**

| SR. NO | DATE OF RECALL | COUNTRY | MEDICAL DEVICE | PURPOSE OF RECALL |
|---|---|---|---|---|
| 1. | August 2020 | United States | Alaris PC unit 8015 | The recall of the product was announced because of the possibility for systems to incorrectly reflect the syringe size or type. Such inaccuracies could result in delays in infusion or over-infusion, posing a significant risk of severe adverse events and potentially leading to fatal outcomes. |
| 2. | July of 2020 | Europe and the UK | COVID-19 testing kits | Spain sent back 9000 testing kits to China due to the inadequacies observed in the testing capabilities of these kits. |
| 3. | 2020 | India | COVID-19 testing kits | Only COVID-19 antibody kit tests were purchased from ICMR by Indian businesses. Punjab, Rajasthan, and Karnataka submitted several concerns about the kits ineffectiveness. |
| 4. | February 2020 | U.S.A | kits for switching out the Alaris system module and pump module door assemblies | The lack of responsiveness in the device could result in delayed infusions, posing a significant risk to high-risk populations. Interruptions or delays in infusion could potentially lead to patient fatalities. There have been 976 reports about this problem as of right now; however, no cases of injuries or deaths have been documented. |
| 5. | 2020 | USA | Pumps for medical infusion | Some Medfusion 3500 and 4000 versions of the software were recalled due to a software issue that might have resulted in the patient receiving too much or too little fluid. Using the impacted |

| | | | | medical equipment may cause serious health issues and, in the worst situations, even end in death. |
|---|---|---|---|---|
| 6. | 2020 | Japan | Abenomask | The recall of 7870 faulty masks was prompted by customer complaints regarding issues such as stains, insects, and mold. |
| 7. | July 2019 | USA | Breast implants from Allergan | The FDA study found 573 additional cases, with 33 reported fatalities. In these instances, 481 people diagnosed with Allergan breast implants were discovered. Additionally, 12–13 fatalities were observed in individuals diagnosed with BIA-ALCL who had Allergan breast implants during the diagnosis of BIA-ALCL. |
| 8. | 2019 | USA | The Giraffe incubator and Omni beds | GE Health launched a recall of these incubators owing to a design defect beside the panel that kept them in an upright posture and was unable to be properly shut. This constituted a problem since if a newborn approached the bedside panel, it might possibly fall open, resulting in the possibility of the infant falling. |
| 9. | 2018 | China | Fake rabies vaccination | Chinese used fogging to falsify papers and violate immunity rules. |
| 10 | 2010 | India | Metal-on-metal acetabular hip replacement device, ASR XL | Because of the metallic particles that were released into the bloodstream in this episode, the patients required a second procedure, typically noted in instances involving metal implants. Additionally, patients had issues with the wear and tear of prosthetic ball and socket components produced by friction between them. |

## PENALTIES FOR FAILURE OF DEVICE

Over $600 million has been paid to doctors or their clinics by the top 10 medical device firms in the US for services including consultations, testing, travel costs, and entertainment. The necessity for medicine and equipment vendors to record payments to physicians necessitates this financial disclosure. Since 2017, the top four providers of spinal cord stimulation have committed a total of over $22 million to create regulations that benefit the whole sector. Businesses that paid for tests that were purportedly safe and effective and promoted items for unauthorised uses have been hit with hefty penalties. In order to resolve fraud charges and legal difficulties claiming its involvement in a scheme to deliver bribes to hospitals and physicians, the Olympus Corporation of America consented to give up $623.2 million in a 2016 lawsuit settlement. In a settlement agreement, Medtronic Inc. agreed to spend $2.8 million in order to settle the government's allegations that it caused harm to patients and cheated public healthcare systems by providing financial incentives to physicians, effectively converting them into salesmen for expensive operations. If concerns about defective medical equipment are not addressed, they are often recalled. According to GHTF guidelines and MHRA, a "recall" is a field safety corrective action (FSRA) that aims to reduce the possibility of patient harm. A list of medical equipment

that malfunctioned and had to be recalled has been made public by the FDA [30].

## FUTURE CONSIDERATIONS / WAY FORWARD

To establish an effective Materiovigilance Programme of India (MvPI), it is crucial to enhance engagement at the grassroots level. Raising awareness about MvPI among healthcare professionals and the general public is imperative. Challenges associated with reporting Medical Device Adverse Events (MDAE) include a lack of knowledge about reporting systems, unclear guidelines on what to report, and concerns about reputational and medicolegal repercussions. To ensure comprehensive foundational training, updating academic curricula across healthcare and paramedical courses to include MvPI is essential. Encouraging MDAE reporting during internships and postgraduate programmes is vital. Making MvPI a prerequisite for doctors to renew their licenses, as suggested by the Medical Council of India, will further solidify the commitment to reporting. Working together with hospitals and medical facilities will promote an MDAE reporting culture. It should be common procedure to create an implant register at the hospital level and to regularly record device information on patient outpatient department cards. Recognising the importance of clinicians' suspicion levels correlating with adverse events related to medical devices is warranted. The National Certification Board for Hospitals and Healthcare Providers (NABH) now includes pharmacovigilance, and MvPI inclusion is recommended as a requirement for NABH certification [18].

## CONCLUSION

The Materiovigilance Programme (MvPI) in India employs an innovative strategy to guarantee the security and calibre of medical equipment. MvPI was founded in 2015 with the specific goal of addressing patient concerns by placing a strong emphasis on international compliance, quality control, and safety. The programme's objectives are to provide evidence-based recommendations, increase healthcare workers' understanding, and methodically collect safety data. Its comprehensive approach is shown by the fact that it includes adverse event reporting, worldwide post-marketing surveillance technique comparison, and medical device categorization. Even though MvPI has proven successful, going forward, it will be crucial to emphasise the value of more involvement, awareness, and cooperation in order to foster a reporting environment that is more productive. MvPI is essential to giving patient safety and healthcare equipment security first priority in India.

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