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Review Article

Tracking Risks, Saving Lives: How India and the U.S. Protect Patients through Materiovigilance

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ABSTRACT

Materiovigilance refers to the system of safety monitoring and performance of medical devices after being placed on the market and involves collecting, analyzing, and responding to reports of malfunctions, adverse events, or other issues related to medical devices used in healthcare settings. Materiovigilance goal is to ensure that medical devices continue to meet safety and effective standards throughout their lifecycle and to take corrective actions when necessary. Key Elements of Materiovigilance are Adverse Event Reporting, Data Collection and Analysis, Regulatory Oversight, Post-Market Surveillance and Risk Management. Materiovigilance helps in Patient Safety, Device Improvement and Regulatory Compliance. Examples of Materiovigilance Activities include adverse reaction Reporting of a cardiac stent, ventilator failure tracking. This review examines how India and the United States monitor medical device safety to protect patient health. In the U.S., the FDA has a strong system that includes the Medical Device Reporting (MDR) and MedWatch programs, which enable quick reporting of safety issues by manufacturers, healthcare providers, and patients. This organized approach allows for fast responses to potential risks, enhancing patient safety. India's system, managed by the "Materiovigilance Programme of India" (MvPI) under the "Central Drugs Standard Control Organization (CDSCO)," is newer and faces challenges such as low awareness and varying compliance among healthcare providers. However, recent initiatives to improve reporting and engage providers show promise.

Keywords: Materiovigilance, Post-marketing surveillance, Patient safety, Global consortium, Adverse events.

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INTRODUCTION

The term "materials" (materialo) designates that the materials used to create a medical device; the word "vigilance" alludes to the great care taken to identify any signs therefore, Materiovigilance (MV) is defined as a coordinated system that detects, gathers, reports, and analyzes performance or unusual variations in a device and responds by recalling devices or implementing Field Safety Corrective Actions (FSCA). Everything that is used to detect or treat diseases in humans falls under the category of "medical device," including any apparatus, software, implants, and *in vitro* reagents. Both intended purpose and usage indications vary among medical devices. There is always a danger associated with using medical devices, one that could lead to misdiagnosis, injury, or even death. By lowering the possibility of unfavorable occurrences connected to the application of medical equipment, post-marketing surveillance is often referred to as MV (Hoda *et al*., 2020). Since all medical technology is inherently dangerous and can cause problems in certain situations, medical device monitoring involves investigating and monitoring events that may be connected to the use of medical devices. This method helps identify adverse events associated with medical devices and, through careful observation, it also makes it easier to remove hazardous products from the market and helps businesses identify and address any underlying issues. In addition to guaranteeing patient and consumer safety, this would raise the caliber of the devices. Countries may differ in their standards and laws, the primary objective of MV include reducing the frequency of incidents, improving patient safety and public health, assessing implications of framework proposed by the "Global Harmonization Task Force (GHTF)" for the Indian medical device vigilance system, boosting equipment productivity and efficiency, and developing a national framework for patient safety assessment. Moreover, a national hub for MV efforts can greatly reduce hazards. To manage data and share information effectively, it is imperative to foster communication with overseas organizations and other healthcare facilities. Like PV, MV is a

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concept and technology that has been incorporated into medical equipment. Because of the rising rates of chronic illnesses including cancer, diabetes, obesity, and stroke, the global demand for medical equipment increased dramatically from 260 billion USD in 2006 to 380 billion USD in 2016 (Deshwal *et al.*, 2020). As a result, practitioners, legislators, regulators, and patients must therefore educate themselves on the quality assurance, safety, effectiveness, and other crucial aspects of each new product that enters the market. Although Medical devices are not dependent on people, it is anticipated that to accomplish any of their main intended effects; they will change the structure and function of both human and animal bodies when they are digested (Meher, 2018). Since the usage of medical devices has grown dramatically, ensuring their efficacy and quality is crucial. Harmonization is a significant endeavor that increases the time required to market this medical equipment while lowering the pricing. Additionally, it aims to restore consumer confidence by enhancing the device's efficacy and security (Lambda Therapeutic Research Ltd., 2019).

Medical device history

Basic medical supplies such as wooden splints to stabilize fractured bones, constructed stretchers to support the sick and makeshift crutches have most likely existed since the dawn of time. There is a wealth of evidence supporting their use from archeological sites and ancient literature. In February 1778, Franz Anton Mesmer landed in Paris, may have utilized the most well-known experimental device of the eighteenth century (Sapkota *et al.*, 2023). "Animal magnetism" is the fundamental power of nature, according to Mesmer, and the source of all wellbeing (Hutt and Hutt II 1984). Mesmer thought that recharging an animal's magnetism could heal the sick. He accomplished this by first connecting patients to specifically magnetized water jars using enormous tubs equipped with iron rods, and then he used magnets. Entire medical elite that comprised the Royal Commission included notable scientists like Benjamin Franklin and Antoine Lavoisier After conducting research, they concluded in 1784 that Mesmer's treatment was unsuccessful. The first medical gadget known to be false was created and sold in the United States by Dr. Elisha Perkins in the late 1700s. Two three-inch-long iron poles and brasses known as "Perkins" Patent Tractors were manufactured by Perkins. He boldly claimed that they could treat any sickness while marketing them all over the world (Teli and Jhawat, 2023). It turned out to be a hoax ten years later. Throughout the 1800s, politicians and the public in the United States focused on passing laws that would have prohibited the falsification and misbranding of medications, food items, but not medical apparatus. In 1916, American Medical Association pamphlet listing solely "cures" for deafness described several ineffective technologies. One of the most popular deception tools at the time was the Abrams "dynamizer" computer. Abrams believed that by injecting a blood sample into the system, he could determine the exact disease the patient had gotten and the exact part of the body where the disease was concentrated. The innovation was shown to be a fraud by the time of Abrams' death in 1924 by Hutt II in 1984. Based on the available evidence, it may be inferred that medical equipment malfunctions and their associated adverse effects have been present for millennia (National Coordination Center MvPI, 2018).

Applications of MV

By developing and strengthening institutional and individual ability to report and resolve device-related adverse effects, health professionals including nurses, physicians, surgeons, and pharmacists can voice concerns about medical devices. This is something that the medical equipment signal generation database information system can help with (Joshi *et al.*, 2021). While creating and nurturing an institutional culture for reporting MDAEs is crucial for preventing them in the future, they can also provide training and education to patients and colleagues to improve their comprehension of the significance of MV in device recalls in the event of a malfunction in application.

- Identification, tracking, reduction, treatment, or prevention of an illness or injury.
- Enhancement in the form and functionality of medical equipment.
- Recording and looking into adverse incidents connected to medical devices.
- Corrective actions will be implemented to prevent future bad events.
- Examination, substitution, alteration, or reinforcement of the skeleton or a physiological mechanism.
- Information obtained for medical reasons by *in vitro* analysis of specimens taken from the human body.
- Maintaining or bolstering life.

Recall of medical devices

Recalls of devices happen for several reasons, including defects in the product or potential consequences for user illness or death (Casal *et al.*, 2013). Devices may be returned to makers or vendors as the primary method in accordance with guidelines established by the GHTF and the Medicine and Healthcare Product Regulatory (MHRA). In addition, these could be changed, renovated, or replaced with new ones, or they might be disassembled as part of a regular device recall. Depending on the device's classification or degree of hazard, the FDA has the right to recall it; the FDA may also provide a justification for these recalls on its website (Dieffaga *et al.*, 2013). The highest risk patients are covered by Class I recall; people with intermediate risk are covered by Class II recalls; and people with low-risk profiles are covered by Class III recalls. Considering the lengthy recall list, the following is a summary of several medical devices

that have been recalled throughout the last ten years and have been presented in Table 1.

Role of Social Media on MV

In addition to providing consumers with instant access to up-to-date knowledge on unfavorable occurrences and rational selection, social media platforms such as LinkedIn, Face book, Twitter, and YouTube also support scientific and health-related breakthroughs and issues (Nagaratnam *et al.*, 2018). They also aid in bringing attention to medical equipment recalls if any faults are found. In the end, this will educate users and practitioners on the latest rules or regulatory measures related to the device. In the end, this will inform users and practitioners about the most recent efforts or laws pertaining to the item. People face the risk of experiencing physical and psychological harm, though, if they rely too much on the information found on social networking sites to satisfy all their information needs. To prevent potential misinformation, it is crucial to carefully assess anything shared on social media and validate its source, since often having little knowledge can be more harmful than having none (Kalaiselvan *et al.*, 2015).

Materiovigilance Program in India

In India, standards for the safety, quality, and operation of medical equipment were outlined in the 1940 and 1945 Drug and Cosmetic Acts and Rules. In India, there was no suitable mechanism for monitoring adverse events arising from usage of medical equipment for a long period. The Indian government released the Medical Devices Rules, 2017 in cooperation with the "Drugs Technical Advisory Board". Medical equipment imports, manufacturing, distribution, and marketing are governed by these rules as of January 1, 2018 (Kumar *et al.*, 2016). On July 6, 2015, the "Drugs Controller General of India" presented the "Materiovigilance Program of India" (MVPI) at the "Indian Pharmacopeia Commission" (IPC), Ghaziabad. The primary goal of this effort is MDAE. Medical personnel must be made aware of the significance of MDAE reporting in India. They also must produce independent, reliable, and fact-based safety data on medical devices and disseminate it to the right people. The procedure depicted in Figure 1.

To promote the reporting habit, any adverse event arising from medical devices used in India may be recorded, regardless of its severity, likelihood, frequency, or degree of comprehension (Polisena *et al.*, 2015). A medical device's features or performance failing or deteriorating, an incorrect or non-standard test result, the discovery of a design flaw, or incorrect labelling or usage instructions can also be reported. Comprehensive details on the patient, the adverse event, the device, the regulator, and the reporter are all included in the two-page medical device adverse event reporting form created by MVPI (Ronquillo and Zuckerman, 2017). The process of adverse events reporting system in India is depicted in Figure 2. The "IPC's official website, www.ipc.gov.in," offers this form for free. The completed MDAE reporting form will be accepted from the reporter by the National Collaborating Centre, if they are not associated with MDMC, or the nearest MDMC. The documentation and reporting of negative incidents caused by the device, as well as the maintenance of an efficient information flow. Health care service providers were responsible for the role of national cooperating centre and research associate and coordinator at MDMC. As of October 2019, the IPC had received and evaluated about 1931 adverse incidents involving medical devices since

Table 1: Recalled medical devices data in the last 10 years.

Date of recall	Country	Medical device	Reason of recall
January, 2022	USA	Sevofurane vaporizer, Maquet Filling for Flow Family Anesthesia Systems.	Chemical breakdown of sevofurane resulted in inhalation or skin exposure to harmful chemicals, which ultimately irritated the respiratory tract.
October, 2021	USA	Ellume COVID-19 home test.	False-positive test results.
July, 2020	India	Corona virus testing kits	Non-performance reports from Punjab, Rajasthan, and Karnataka.
August, 2020	USA	Alaris system pump module and pump module door assembly replacement kits.	One or more unresponsive keys, leading to delay in infusion and increased risk of harm and even death.
October, 2019	USA	Med fusion® syringe pumps.	Therapy-related malfunctioning alarms related to battery.
July, 2019	USA	Allergen breast implant.	High risk of anaphylactic large cell lymphoma.
2010	India	ASR XL ace tabular hip replacement system.	Repeat surgery due to the release of metallic debris from metal implants into bloodstream.

the MVPI began (Shrestha *et al.*, 2019). Of these, 1277 (66.17%) were considered significant, while the remaining incidents were not. Following the implementation of patient-friendly reporting guidelines and medical device regulations in 2017, the quantity of MDAE reports in India skyrocketed. For a variety of medical devices, Table 2 shows the adverse events that were reported by various organizations, including ADR monitoring centres (70), marketing authorization holders (1439 instances), MDAEs monitoring centres (419 cases), and consumers themselves (3 cases). The recently proposed medical device adverse event legislation in India is still being developed and will be changed over time with more comprehensive suggestions. However, significant regulatory bodies like the USA have created rules for reporting Adverse Events (AEs) related to medical devices (Date *et al.*, 2023). Table 3 compares the reporting requirements for medical devices.

Criteria for Reporting Adverse Events

Adverse Event Reporting System (ADERS) is used to document MDAEs by lowering the frequency of unfavorable events; it is a crucial tool for enhancing patient and medical device user wellness. To prevent or lessen the impact of these recurrences, data is shared, recorded occurrences are assessed, and standards for reporting adverse incidences are observed (Shukla *et al.*, 2020).

When manufacturer becomes aware of a device related adverse occurrence-The manufacturers promptly notify the IPC-NCC and investigate to determine the root cause of the event. IPC-NCC would forward this information to the research associate at the closest MDMC.

When healthcare providers detect an incident, they notify the research associate at "MDMC" so that the committee can investigate further. The group comprises experts such as biomedical/clinical engineers, MDMC research associates, medical practitioners, and device technicians.

Reported Unwanted Reactions to Medical Devices

The literature currently in publication indicates that healthcare professionals report adverse medical device reactions at a comparatively low incidence. Medication safety may be enhanced by having a better understanding of the difficulties and incentives associated with patient reporting. To increase the effectiveness of MDAE administration, the speed of MDAE response, and the effectiveness of multiparty collaboration between medical facilities, dealers, and physicians, numerous issues still need to be resolved (Sanjana *et al.*, 2016). All personnel are free to report Adverse Medical Events (MDAEs), albeit there are fewer reported cases in India than there are in all the research that are currently available. Therefore, it is critical to discuss the motivations behind, and difficulties faced by medical personnel in disclosing these incidents so that appropriate safety and quality measures may be implemented to stop them. Based on the material that is currently accessible, this review provides insight into the many reporting problems that healthcare practitioners encounter (Pandey and Imran, 2020). Year wise number of reports are given in Table 4 and the data shown in Figures 3 and 4. Table 5 compiles the variations in adverse event reporting connected to "medical devices" between US and India.

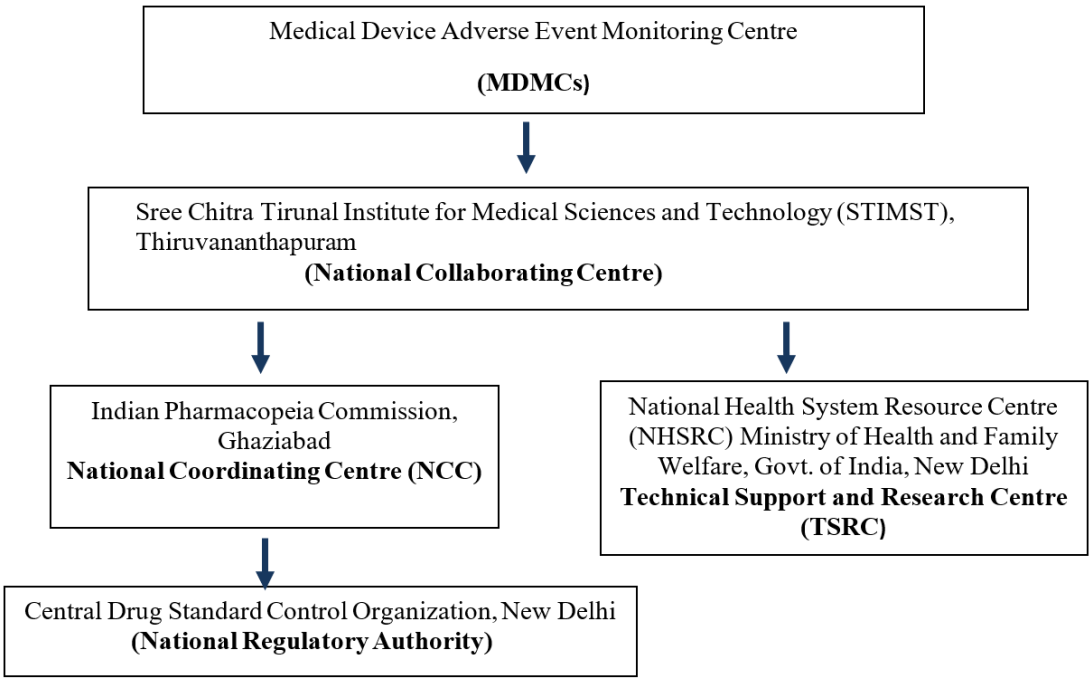

Figure 1: Organizational structure of MV program in India.

Indian Post marketing Surveillance Approach

An Indian regulatory organization is gradually catching up to international regulatory agencies in post-marketing monitoring. Although the annual number of reported adverse events has increased from 40 in 2015 to 897 in 2019, they remain lower than those in other countries in terms of cumulative number and other safety considerations like recall. This highlights the significant advancements MVPI has made in terms of data collection, processing of adverse events, and signal generation for recall action (Dhamini *et al.*, 2021). It is necessary to encourage greater participation from private hospitals, assisted living facilities, and labs. Furthermore, the MVPI-generated data is not publicly accessible, which hinders manufacturers' and stakeholders' ability to take immediate corrective action in the event of an adverse occurrence.

Materiovigilance In United States

In the United States, the FDA employs a comprehensive materiovigilance framework to ensure the safety and efficacy of medical devices. Central to this system are the Medical Device Reporting (MDR) protocol and the MedWatch program, which facilitates the systematic reporting and analysis of adverse events by manufacturers, healthcare professionals, and patients. This robust reporting infrastructure enables the FDA to detect potential safety concerns, analyze trends, and implement timely regulatory interventions as necessary. By fostering active stakeholder engagement and promoting a culture of transparency, the FDA's materiovigilance efforts significantly enhance patient protection and maintain the integrity of the medical device ecosystem. The following pathways involving in the regulatory framework,

PMA (Pre-Market Approval) Pathway

When evaluating the safety and efficacy of Class-3 medical devices, the FDA employs the most scientific and regulatory evaluation procedure. Class 3 devices either exhibit extreme harm or disease or sustain well-being (Rani and Singh, 2018). To guarantee the safety and efficacy of Class-3 medical equipment, the FDA argues that broad and specific regulations are insufficient due to the high degree of risk involved. According to section 515 of the FD&C Act, a post-marketing approval application must be submitted for these devices to be authorized for marketing ("U.S. Food and Drug Administration 2019a"). Therefore, if a PMA is not available, a 510K form must be submitted to the FDA to commercialize a device in the US.

PMN (Pre-Market Notification) Pathway

This strategy was developed to regulate both class I and a small percentage of class II medical devices. As per the provisions of Title 21 and Section 807 the Code of Federal Regulation, the manufacturer of a device seeking clearance through this method

Table 2: Adverse events associated with medical device.

Sl. No.	Medical Device	No of reported MDAEs
1	Cardiac stents	926
2	Intrauterine contraceptive devices	226
3	Orthopedic implants	179
4	Catheters	76
5	Intravenous cannulae	75
6	Other Devices	449

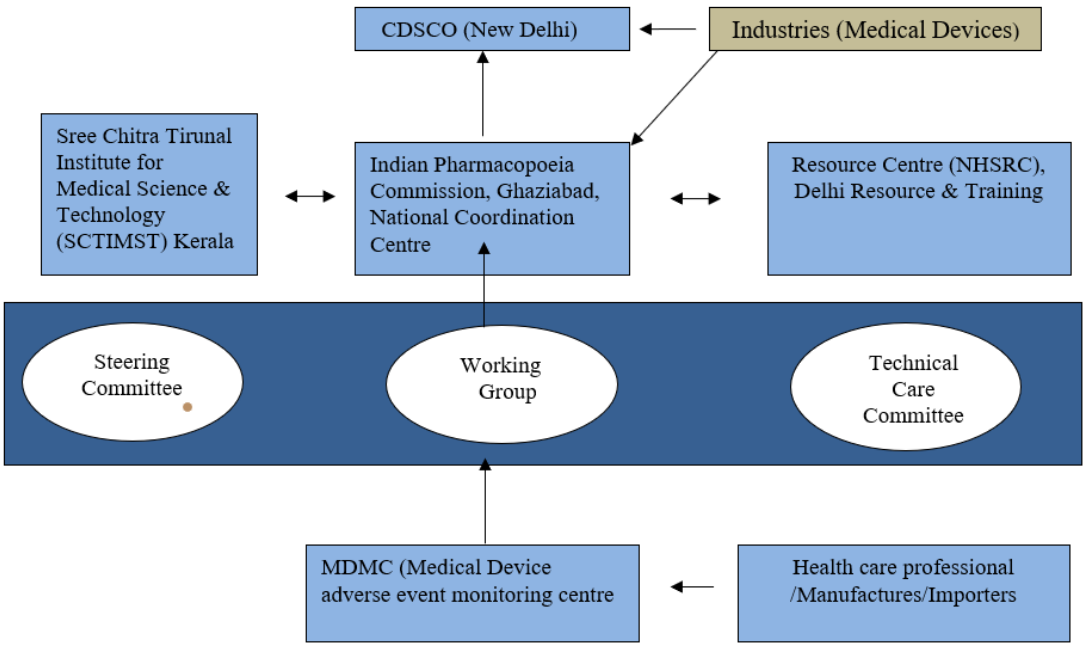

Figure 2: Process of adverse events reporting related to medical devices.

must demonstrate that the device substantially resembles the predicate device and this approach is faster and less expensive than the Pre-Market Approval (PMA) route because it does not need the submission of clinical data (Gupta, 2016). Because of its effectiveness, it is now known as the "fast track approval process" and "substantial equivalence" refers to a close likeness in key features rather than the requirement that the new device be exactly the same as the predicate equipment. Really, all it means is that the "intended use" and "technical attributes" of a new gadget must match those of the preceding device.

Humanitarian Device Exemption (HDE) pathway

According to the 1984 Orphan Drug Act (ODA), a condition is rare if fewer than 200,000 people in the US are affected by it. Of the 7,000 rare diseases known to exist in the United States, only a small percentage have approved therapies. Because rare diseases only impact a limited number of people, meeting the FDA's safety and assurance standards can be challenging. A new regulatory framework for goods intended for use in unusual medical diseases was established by the Safe Medical Device Act, which was enacted by the US Congress in response to this issue.

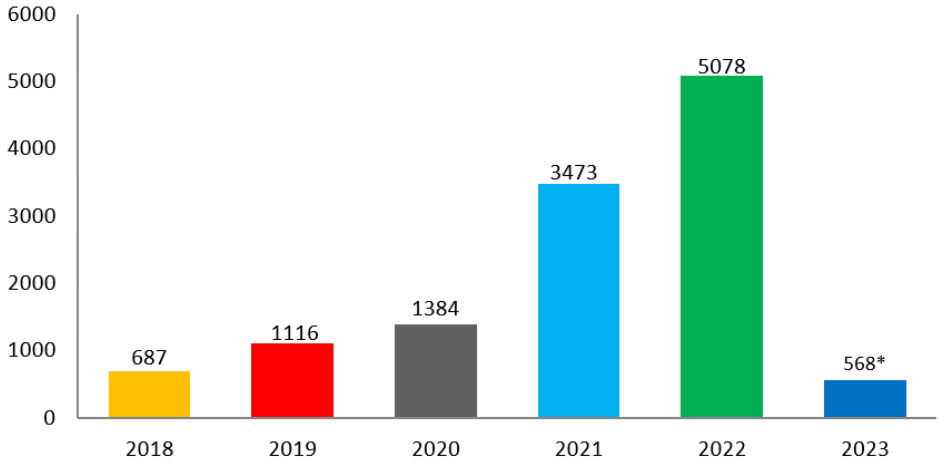

Figure 3: Year-wise medical device adverse events reporting trend.

Table 3: Comparison of reporting guideline for medical device in USA and India.

	India	USA
Device tracking	Medical devices are required to feature lot/ batch numbers on their label.	Device tracking is done as post marketing surveillance activity. Certain implantable devices are subjected to tracking. Manufacturer is required to produce information within 3 or 10 days depending upon the position of a device.
Adverse event reporting	Adverse event can be reported by the manufacturer, importer, and distributer.	Manufacturers and importers are required to report serious injury/ death within 30 days of its discovery as per Medical Device Reporting (MDR) regulations by FDA. Manufacturers are required to report malfunctions less than 30-day time.
Timeline of reporting	Immediate reporting as soon as possible.	30-days to report death, serious injuries, and malfunctions. 5-days to report an event designated by FDA or that requires remedial action to prevent an unreasonable risk. 10-days to report death and serious injuries by user facilities. Summary reports on quarterly basis.
How to report	A reporting format has been prepared by MVPI.	Form 3500A or an electronic equivalent. Form 3419 for reporting annual user facility report.
Penalties	A device's, which is not compliant to regulations, individual manufacturing, sale or selling to buyers' preconception is eligible for fine extending to five lakhs Rupees or imprisonment which may extend to one year or both.	FDA can order a product recall, seize product as well as refuse import of products in violation of FFDCA. If necessitated FDA can have courts issue injunction or prosecute law violating company individuals.

MEDICAL DEVICES REPORTING REQUIREMENTS

In accordance with 21 CFR Part 803, importers, manufacturers, and device users must disclose to the FDA any product concerns, including adverse device outcomes. Table 6 enlists the types of reporting of MV and their timeframe (Raju *et al.*, 2023).

Manufacturers

They must report to the FDA, if they find that a device has caused death or serious harm. Additionally, they must report to the authorities any information they find indicating that a serious injury or death was caused by the device collision or that it was a significant contributing factor.

Importers

They must notify the FDA or the device manufacturer if they find evidence of a fatality or serious injury brought on by one of the devices. Importers, on the other hand, are only obligated to notify producers of any defective devices.

Device user Facilities

Hospitals, assisted living institutions, outpatient diagnostic centers, and surgical centers are a few examples of the types of facilities that use devices. These patient facilities should be designed to notify the FDA or the maker of the medical device of any adverse occurrences involving the device. Consumer facilities are required to contact the FDA if the manufacturer of the medical equipment is unknown. If the manufacturer is known, they will be notified of any serious incidents involving the device's use. Consumer facilities can voluntarily use Med Watch Form FDA 3500, a component of the adverse event reporting program ("U.S. Food and Drug Administration 2020d"), to report a malfunctioning device to the FDA, even if it is not mandatory (Saifuddin *et al.*, 2022).

Penalties for malfunctioning

Since it is essential for pharmaceutical and medical equipment manufacturers to pay the obligations, the top ten large medical device companies in the US have paid about $600 million to medical professionals and their facilities. Olympus Corporation of America was had to pay more than $623.2 million in 2016 to resolve a lawsuit alleging that the business had bought off all hospital staff members and doctors. A different business, Medtronic Inc., was contracted to compensate a patient $2.8 million because the healthcare system was paying doctors bribes to utilize defective and malfunctioning medical equipment, which drove up the cost of treatment (Kramer *et al.*, 2013).

CASE STUDIES ON MV

Johnsonand Johnson faulty hip implant

Johnson and Johnson's DePuy ASR hip implants, launched in 2005, quickly faced issues due to their metal-on-metal design, leading to complications like device loosening, severe pain, and toxic metal ions in patients' bloodstreams. The implants showed high failure rates, with many patients needing revision surgeries. J&J recalled the product in 2010, acknowledging the high failure risk, but over 93,000 patients had already been implanted globally. The company faced thousands of lawsuits and, in 2013, agreed to a $2.5 billion settlement for affected patients in the U.S. The case highlighted regulatory, ethical, and quality concerns in medical device manufacturing (Chauhan *et al.*, 2019).

Table 4: Number of reports recorded in monitoring centers.

Year	No. of MDMCs	No. of Reports
SCTIMST, Kerala		
2015-2017	10	347
IPC National Coordination Centre		
2018	10	687
2019	36	1116
2020	50	3473
2021	150	5078
2022	293	5078

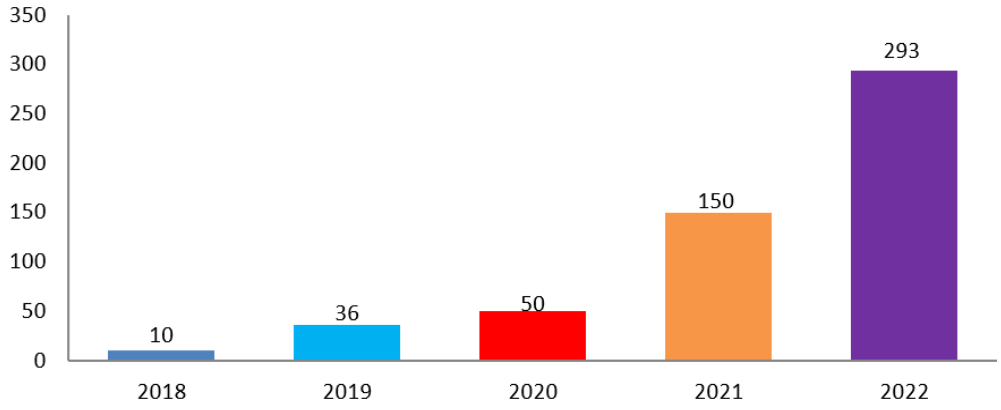

Figure 4: Year wise MDMCS centers across India.

Table 5: Comparison of medical device vigilance in India and USA.

Parameters	CDSCO (India)	FDA (US)
Definition of medical devices	Include device proposed for "internal" or "external" use in the „diagnosis", „treatment", „mitigation" or „prevention" of disease or disorder in human beings or animals, mechanical contraceptives, disinfectants, insecticides, materials used for *in vitro* diagnosis, „surgical dressings" and „surgical bandages"	Include all instrument, implement, apparatus, machine, *in vitro* reagent, implant, and some software that considered as medical devices.
'Medical device' Classification	4 Classes: Class I, Class II, Class III, Class IV	Three Classes: I, II and II
Basis of Classification	Risk based	Level of control and marketing requirements
Post marketing surveillance of medical device	Started in 2015 under III, Programmed of India.	Started in 1990 under Safe Medical Device Act.
Who can report adverse events	Manufacturers, Healthcare professionals, pharmacists, nurses, hospital technology managers, biomedical engineers.	Manufacturer, importer, device user facility, patient, healthcare professionals, consumers.
Criteria for reporting	Device malfunction, serious injury, death.	Death, serious injury.
Non- reportable event	Side effects related to medical device are expected by manufacturer's labeling, exceeded shelf- life of device; root cause of event is patient's pre-existing condition, and deficiency found in medical device before using it.	Manufacturer can request Remedial Action Exemption (RAE) if information received is erroneous When device is manufactured by other manufacturer.

Table 6: Various types of reporting and their timeframes.

Sl. No.	Reporter	What to report?	Where to report?	When to report?
1	Manufacturer	Death, malfunctions along with serious cases Adverse events requiring curative actions Follow-up reports	FDA FDA FDA	Within 30 working days Within 5 working days Within 1 month
2	User facility	Serious injury Death	Manufacturer or FDA (if unknown) FDA along with manufacturer	Within 10 working days Within 10 working days
3	Importers	Serious cases as well as death	Manufacturer along with FDA	Within 10 working days

Premature depletion of battery in some Medtronic pacemakers

Medtronic faced issues with certain pacemaker models due to premature battery depletion caused by a lithium deposit formation, a phenomenon known as "lithium cluster bridging." This problem could lead to sudden battery failure, putting patients at risk of serious health complications or death. Identified in some models in 2016, the issue prompted a Class I recall by the FDA, affecting around 350,000 pacemakers worldwide. Medtronic recommended regular device checks and programming alerts for low battery warnings to prevent harm. The case underscored the need for proactive device monitoring and ongoing communication between medical device companies, healthcare providers, and patients.

CONCLUSION

In summary, the material vigilance practices in the US and India are compared, highlighting significant distinctions in terms of guaranteeing the safety of medical devices. The FDA's Medical Device Reporting (MDR) system and MedWatch program enable prompt and transparent reporting of adverse events, enabling prompt regulatory responses that improve patient safety. The United States benefits from a well-established framework. On the other hand, India's Materiovigilance Programme (MvPI)

is still developing and has issues with healthcare professionals' uneven compliance and lack of awareness. Recent efforts, however, indicate that its system could be strengthened. India's materiovigilance efforts can be strengthened by adopting aspects of the U.S. strategy, such as better digital reporting and stronger engagement of healthcare providers. International standards for medical device and patient safety could be further raised through cooperative exchanges between the two nations.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

MV: Materiovigilance; **PV:** Pharmacovigilance; **FSCA:** Field Safety Corrective Actions; **GHTF:** Global Harmonization Task Force; **CFDA:** Food and Drug Administration China; **MHLW:** Ministry of Health and Labor Welfare; **TGA:** Therapeutic Goods Administration; **MDAE:** Medical Device Adverse Events; **SCTIMST:** Sree Chitra Tirunal Institute of Medical Science and Technology; **AE:** Adverse Events; **MHRA:** Medicine and Healthcare Product Regulatory; **IPC:** Indian Pharmacopeia; **NCC:** National Coordinating Centre; **MDMC:** Medical Device Monitoring Centre; **PMA:** Post Marketing Approval; **HDE:** Humanitarian Device Exemptions; **PMN:** Pre-Market Notification; **NJRR:** National Joint Replacement Registration.

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