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REVIEW ARTICLE

Enhancing patient safety: Materiovigilance and medical device surveillance in India and global perspectives

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ABSTRACT

The post-marketing vigilance system for medical devices in India is not as robust as that for drugs. Materiovigilance, which focuses on monitoring and reporting adverse events associated with medical devices, is an essential aspect of post-marketing surveillance. Various countries, including India, have implemented their own post-marketing surveillance systems in accordance with the World Health Organization's directives. In India, this system is known as the materiovigilance program of India (MvPI). This article aims to evaluate the current status of MvPI, compare it with the systems in developed countries, and propose specific measures to enhance the effectiveness of the program.

Keywords: Materiovigilance, Medical device, Adverse event and post-market surveillance

INTRODUCTION

Materiovigilance refers to the post-market surveillance of medical equipment, which involves a comprehensive system of performance characterization, monitoring, identification, collection, reporting, and analysis of any adverse events associated with the use of medical devices. Unlike pharmacovigilance, which focuses on the post-market surveillance of medications, materiovigilance mainly focuses on the monitoring of medical equipment, including *in-vitro* diagnostics. The medical device market in India is valued at 3.1 billion USD. Nevertheless, for a significant duration, there lacked a robust surveillance system dedicated to monitoring adverse events associated with medical devices.[1] In India medical devices were initially regulated under the Drugs and Cosmetics Act of 1940, along with its accompanying rules from 1945. However, in 2017, a new and separate set of regulations called the Medical Device Rules, 2017, were introduced to specifically govern the medical devices available in the Indian market.[2]

The term "medical device" refers to any instrument, apparatus, machine, implant, material, or physical object employed to aid in the diagnosis, treatment, prevention, or management of ailments, whether in humans or animals.[3] Its primary function is to support individuals and animals in their healthcare needs, encompassing various aspects such as diagnosis, therapy, prevention, and the handling of disabilities. In the year 2010, a significant incident involving a medical device took place, resulting in a renowned manufacturer of medical devices being compelled to recall all their products used for hip replacement from the market. This adverse event prompted the withdrawal of their devices to ensure public safety and address the concerns raised. The presence of these devices posed a significant risk to patients, leading to malfunctions that jeopardized their lives. This dangerous situation arose from the

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release of metallic particles into the bloodstream, necessitating numerous surgeries, particularly when metal implants were utilized.

Apart from this, there have been several instances of significant adverse events documented in India, including a patient who suffered an electrical burn injury due to defibrillator fault.[4] Metal ions were detected in the blood and soft tissue of patients who underwent hip replacement surgery, and tragically, an infant lost his/her life due to overheating in the incubator.[5] Therefore, the development of a surveillance system has become crucial to detect and address any unforeseen, undesirable, and unintended incidents associated with the utilization of medical devices. To mitigate such occurrences, an essential measure needed to be implemented, leading to the launch of the Materiovigilance Programme of India (MvPI) by the Government of India.

Materiovigilance initiative in India

To ensure the safety monitoring of medical devices in India, the Ministry of Health and Family Welfare (MoHFW) has taken measures to regulate this aspect through the Pharmacovigilance Program of India (PvPI). As part of this comprehensive initiative, the Indian government established the Medical Devices Vigilance Program of India (MvPI) in 2013. MvPI serves as a dedicated system for monitoring the safety of medical equipment in collaboration with the government, contributing to enhanced safety surveillance measures.

On July 6, 2015, MvPI was formally established in partnership with the Sri Chitra Thirunal Institute of Medical Sciences and Technology (SCTIMST), Thiruvananthapuram, which serves as the National Coordinating Center (NCC). Over time, the significance and necessity of MvPI have continued to grow.

This is primarily due to malfunctions in various medical devices and the subsequent occurrence of adverse events associated with them. These incidents have resulted in complications for patients and, in more severe cases, even fatalities.

The National Health Systems Resource Centre (NHSRC), operating as a technical support and resource center under the MoHFW in the Government of India, plays a crucial role in supporting MvPI. During the inauguration of the program, the Deputy Controller General (DCG) emphasized the pivotal role of the PvPI in ensuring patient safety. The DCG highlighted the significance of monitoring medical devices as an equally important aspect, alongside drugs, to safeguard the well-being of patients.

Since 2018, the Indian Pharmacopoeia Commission (IPC) has been functioning as the NCC for the MvPI, in addition to its role as the NCC for the PvPI. This strategic decision was essential to effectively utilize available resources, workforce, and logistical support for both programs. Recognizing the unique challenges posed by infrastructure and capacity development in MvPI compared to pharmacovigilance for drugs, it is important to acknowledge that reporting tools, data collection methods, and assessment procedures differ in nature.

To ensure the successful implementation of MvPI, integration with the biomedical engineering departments at hospitals and other institutions, along with efficient departmental coordination, must be emphasized. Consequently, the principal Medical device adverse event monitoring centers (MDMCs) have been categorized as institutions with a biomedical/clinical engineering department (BMED). Other departments closely related to BMED are also given priority. Given the critical role engineering technology plays in the design and production of medical devices, the participation of BMED is essential for the effectiveness of MvPI.

MATERIALS AND METHODS

The objective of the MvPI is to:

1. Developing a nationwide strategy to ensure patient safety.
2. Assessing the ratio of benefits to risks associated with a medical device.
3. Generating evidence-based information about medical equipment connected to negative outcomes.
4. Assisting the Central Drugs Standard Control Organization (CDSCO) with decision-making regarding the regulation of medical devices within the country.

5. Sharing safety-related information with different stakeholders in the industry.
6. Engaging in partnerships with fellow healthcare organizations and global agencies to foster information sharing and streamline data management.

At present, there are 174 medical device monitoring centers (MDMCs) available throughout India as part of MvPI to report the adverse events associated with the use of medical devices, purely on voluntary basis.[6] Regular training is provided to PvPI and MvPI stakeholders to improve their reporting skills using various reporting tools. The NCC collaborates actively with stakeholders to cultivate a culture of reporting adverse events related to medical devices. By prioritizing patient safety, our professional and ethical responsibility is emphasized through education and advocacy, fostering awareness regarding the importance of reporting adverse events.

According to the Medical Devices Rules of 2017, it is required that the Marketing Authorization Holder submits all adverse events related to medical devices to the Central Licensing Authority, which is commonly known as CDSCO. At the same time, they also provide MvPI with a copy of any unfavorable incidents. MvPI conducts an initial evaluation of these reported adverse events and carries out a root cause analysis to determine whether there are any temporal links between the reported adverse event and malfunction of the medical device. If any significant findings are reached, NCCMvPI sends reports to CDSCO. Furthermore, NCC-MvPI releases medical device alerts to all MDMCs for ongoing monitoring of suspected medical devices. In addition, NCCMvPI raises awareness among the general public regarding medical device safety and encourages them to report any adverse events caused by household medical devices.

Centers in India's meteriovigilance program

Since the inception of the MvPI program, over 7000 reports have been submitted to the IPC through MvPI. The MDMCs have the responsibility of accurately identifying, collecting, and reporting any suspected or confirmed MDAEs, which are categorized into five groups: Not related, unlikely, possible, probable, and causal relationship, respectively. MDMCs are required to submit their reported cases to NCC-IPC on a monthly basis for review and analysis. It is expected that any MDAE, once identified, should be reported within 5 working days. Furthermore, a timeframe of 30 calendar days is provided to report the event after conducting a thorough assessment of its root cause.[7]

The MvPI database is under the exclusive custody of the IPC. NCC is entrusted with the responsibility of coordinating with all MDMCs in India and effectively communicating all relevant matters to the CDSCO. Furthermore, they cooperate with international agencies and extend financial aid to SCTIMST, the NHSRC, and MDMCs. The SCTIMST serves as the National Collaboration Center, offering assistance with all technical matters, while the NHSRC functions as a technical support partner within the program. The SCTIMST provides technical support and expertise in the development of standard operating procedures, guidance documents, newsletters, training manuals, and more. In addition, it communicates all relevant issues to the CDSCO, the national regulatory authority responsible for ensuring safety. The CDSCO takes necessary actions based on the recommendations provided by the NCC-MvPI. Figure 1 illustrates the organizational structure of MvPI.

Global scenario of post-marketing surveillance

The United States (US), Canada, Japan, Australia, United Kingdom, Europe, Saudi Arabia, Thailand, Brazil, Singapore Ireland, Algeria, and India have established their own surveillance systems to actively and passively monitor MDAEs. The US has established a globally renowned regulatory body known as the Food and Drug Administration (FDA) to oversee and monitor the safety and efficacy of food, pharmaceuticals, vaccines, and medical devices on a global scale. A proposal has also been put forward in the US for a system of reporting that combines both mandatory and voluntary participation. Countries like the United Kingdom possess their own adverse event

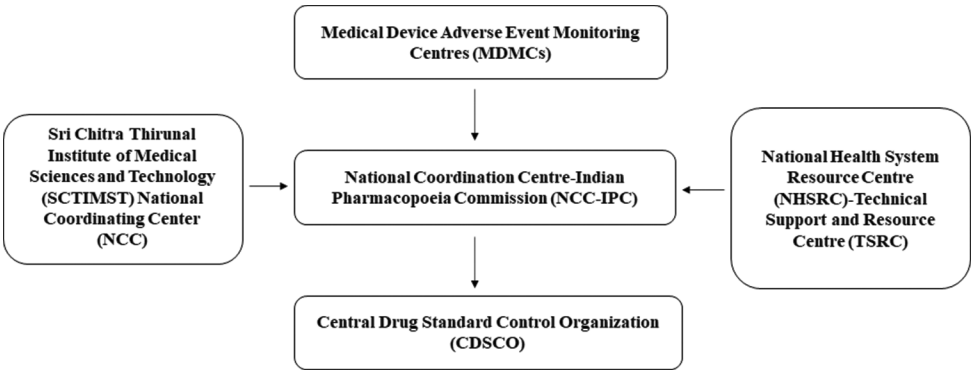

Figure 1: Organizational structure of MvPI in India

databases and monitoring systems, along with reporting schemes.[8] The approval systems and databases for medical devices in the aforementioned countries are listed in Table 1.

In the US of America, the introduction of medical devices into the market requires authorization and approval from the FDA. This stringent process ensures that the devices are both effective and safe for use. Oversight of the global relabeling, manufacturing, export, and import of medical devices is the responsibility of the Center for Device and Radiological Health, an integral division of the FDA.[9]

In Europe, the approach to handling complaints related to medical devices from manufacturers varies. The National Competency Authority (NCA) directly handles these complaints. However, it is mandatory for general practitioners, doctors, and nurses to report incidents to both the manufacturer and the NCA. Manufacturers are required to promptly submit an initial report of any significant adverse event within 2 calendar days.

If a manufacturer identifies a potential connection between a medical device and a fatality or any health-related issue, they must conduct a thorough assessment, which should be completed within 10 days. Non-serious miscellaneous incidents can be reported within a timeframe of 30 calendar days.[10]

In Japan, the oversight of medical devices is entrusted to the Pharmaceutical and Medical Device Agency (PMDA), which operates within a defined framework of guidelines and regulations. These regulations cover various aspects, such as certification, quality assurance, and licensing of medical devices, including those produced domestically in Japan.[11]

When bringing a product to the market in Australia, the sponsor is obligated to meet the requirement of submitting thorough documentation to the Therapeutic Goods Administration (TGA) concerning medical devices. These records encompass details such as the batch number, ingredient information, and a properly stored sample of the potentially harmful substance. This submission serves as an official record that the TGA must retain for duration of up to 5 years.[12]

Health Canada, the regulatory body in Canada, holds the responsibility of supervising and guaranteeing the safety and appropriateness of medical devices. Their duties encompass conducting inspections, evaluations, and investigations throughout the entire process of introducing and marketing these devices

Table 1: Medical device regulatory bodies in India and other countries

S. No.	Country	Medical device regulatory authority/database
1.	India	CDSCO
2.	USA	FDA MAUDE
3.	Japan	PMDA
4.	United Kingdom	MHRA
5.	Australia	TGA
6.	Europe	EMA
7.	Saudi Arabia	MoH SFDA
8.	Algeria	MOHP
9.	Thailand	MDCD TFDA
10.	Ireland	HPRA
11.	Singapore	HSA
12.	Brazil	
13.	Canada	

CDSCO: Central Drugs Standard Control Organization, FDA MAUDE: Food and Drug Administration MAUDE, PMDA: Pharmaceutical and Medical Device Agency, TGA: Therapeutic Goods Administration, MoH SFDA: Ministry of Health Saudi Food and Drug Authority, MOHP: Ministry of Health and Population, MDCD TFDA: Medical Device Control Division of the Thai Food and Drug Administration, HSA: Health Science Authority, HPRA: Health Products Regulatory Authority, EMA: European Medicines Agency, MHRA: Medicines and Healthcare Products Regulatory Agency.

to ensure adherence to regulations. Furthermore, Health Canada governs the licensing procedure for both new devices and modifications to existing ones. During the premarketing stage, this regulatory authority ensures that all the essential requirements for obtaining a license are met with the utmost scrutiny.

Saudi Arabia has established the Saudi Food and Drug Authority (SFDA) with two main objectives. First, the SFDA is responsible for diligently monitoring the safety of medical devices and assessing their potential impact on public health. Second, it ensures the utmost precision and safety of medical and diagnostic devices, regardless of whether they are imported or locally manufactured.

In Algeria, the regulation of medical devices is overseen by the directorate of pharmacy – direction de la pharmacy et du medicament within the Ministry of Health and Population (MOHP). The MOHP's approval is required for the registration of medical devices intended for sale in Algeria. It is important to note that all documentation submitted to Algerian regulators must be translated into either French or Arabic. The regulation of medical devices in Algeria is carried out by the directorate of pharmacy and the National Laboratory for the Control of Pharmaceutical Products, both operating under the supervision of the MOHP. The registration documents must be submitted to both entities for review.

Thailand's Medical Device Control Division of the Thai Food and Drug Administration (TFDA) is responsible for regulating all medical devices in the country. The TFDA serves as the regulatory body overseeing medical device regulation in Thailand. To showcase or market a device in Thailand, it must meet the requirements set by the TFDA based on its risk classification.

To market medical devices in Ireland, manufacturers must obtain a CE marking, which signifies compliance with European Union regulations. This certification enables the device to be marketed across any EU member state. Once a device is successfully registered in Ireland or any other EU country, it can be freely marketed throughout the entire EU territory.

Singapore's Health Science Authority requires the registration of all medical devices, whether they are manufactured locally or imported before they can be distributed. However, Class A low-risk medical devices are exempt from the registration process. The Medical Device Information and Communication System provides an online platform, facilitating the registration and related transactions, including renewals and change notifications.

In Brazil, the Brazilian Health and Regulatory Agency (ANVISA) mandates that any foreign medical device company without a physical presence in Brazil must designate a Brazilian Registration Holder to market their product in the country. ANVISA has established compliance requirements similar to those developed in the European Union and offers two primary pathways for device approval: Cadastro (Low risk) and Registro (High risk). Both Cadastro and Registro require formal registration and approval from ANVISA, although Cadastro is a simpler and quicker process. In addition, certain medical devices require Brazilian Good Manufacturing Practice certification.

RESULTS

Post-marketing surveillance approach in India

Post-marketing surveillance conducted by the regulatory authority of India (MvPI) is steadily gaining momentum as it aligns itself with international regulatory bodies. Despite a continuous increase in the overall number of reported adverse events, they remain comparatively lower than those observed in other countries. In India, between July 2015 and October 2019, a comprehensive total of 1,931 adverse events were officially reported. Among these events, 1,277 were categorized as serious, while 654 were considered non-serious. All events were reported by the following members: Marketing authorization holders 1439 events, medical device adverse event (MDAE) surveillance centers 419 events, adverse drug reaction surveillance centers 70 events, and consumers three events. Table 2 presents the occurrence of adverse events linked to medical devices as reported to the Indian Pharmacopeial Commission.[13]

In 2017, a total of 30 medical devices were recalled by the US Food and Drug Administration

Table 2: The reporting of medical device-related adverse events to the Indian Pharmacopeial Commission

S. No.	Name of the associated device	No. of adverse events
1.	Cardiac stents	926
2.	Intrauterine contraceptive devices	226
3.	Orthopedic implants	179
4.	Intravenous cannula	75
5.	Catheters	76
6.	Other devices	449

(USFDA), followed by an additional 32 recalls in 2018. These recalls were initiated due to various reasons.[14] During the period of 2017–2018, the TGA, Australia's official regulatory body, recorded a notable quantity of adverse event reports. Specifically, they documented a total of 5348 cases. After conducting a thorough review of these incidents, TGA recalled 27 products and issued 41 hazard alerts to ensure public safety.[15] Moving forward to 2018–2019, TGA received 5874 adverse event reports and identified 5129 signals, leading to the recall of 55 products and the issuance of 68 hazard alerts. In addition, Health Canada also experienced a higher number of recalls during this same period. However, during this specific time frame, the recall action based on reported adverse events was five in India.[16]
The significance of MvPI lies in its significant advancements in data collection, adverse event processing, signal generation, and recall actions. However, it is important to note that data collection is presently confined to recognized medical colleges and hospitals, autonomous institutes, as well as importers. Promoting increased participation of private hospitals, nursing homes, and laboratories is crucial. In addition, it is essential to make the data generated by MvPI accessible to the public. This will enable manufacturers and stakeholders to have real-time awareness of adverse events and facilitate prompt corrective actions.[17,18]
India currently does not possess explicit guidelines for the MvPI comparable to the comprehensive protocols established by the European Union and the US for their post-marketing surveillance programs, specifically focusing on ensuring the safety of medical devices. The development of signal detection tools and guidelines should be prioritized while ensuring the validation of causality assessment. While MvPI may seem sturdy in paper, there is a lack of transparency in regard to the annual performance report of MvPI and monitoring centers, specifically regarding the collection and submission of data, as it remains unpublished. The information regarding reported adverse events and the corresponding actions taken is not publicly available. Furthermore, several devices remain unlisted despite being required to be notified.
In the US, the leading 10 major medical device companies have disbursed over $600 million to medical practitioners and clinics, recognizing the importance for pharmaceutical and medical equipment manufacturers to fulfill their financial obligations.
In 2016, Olympus Corporation of America found itself liable to pay approximately $623.2 million in legal fines following a court case that accused them of engaging in bribery with doctors and hospital personnel. Similarly, Medtronic Inc. was compelled to offer $2.8 million in restitution to a patient amidst allegations of doctors receiving bribes within the healthcare system. These doctors purportedly received monthly bonuses to employ defective and malfunctioning medical equipment, leading to exorbitant expenses for patients seeking treatment.[19]

DISCUSSION

For the MvPI to thrive, the engagement at the grassroots level needs to be enhanced. To achieve this, there is a need to increase awareness among healthcare professionals and the general public about the MvPI. To establish a strong foundation, it is crucial to update the academic curricula of healthcare and paramedical courses to include MvPI (MDAE Investigation). In addition, during internship and postgraduate programs, it is important to foster the practice of reporting MDAEs. By incorporating MvPI into the curricula and instilling the reporting of MDAEs during these training phases, a solid foundation can be built for aspiring professionals in the healthcare and paramedical fields.
At present, in an endeavor to lessen India's reliance on imported medical devices and enhance capacity building, two programs, namely "M. Tech in

Clinical Engineering" and "Ph.D. in Biomedical Devices and Technology," have been initiated through collaboration between three esteemed institutions: IIT Madras, CMC Vellore, and SCTIMST Trivandrum. These institutions possess distinct strengths and cutting-edge facilities, which combine to provide a robust foundation for these programs. One distinguishing aspect of these courses is the inclusion of a clinical attachment that provides students with extensive exposure to the clinical environment. This invaluable experience guarantees that by the conclusion of the course, students will possess the ability to interact proficiently with clinicians, as well as other medical and paramedical personnel in the hospital. This interaction fosters the identification of unaddressed clinical requirements, ultimately inspiring further research endeavors aimed at advancing innovative indigenous health-care technology.

The projected value of the medical device industry is set to reach US$50 billion by 2025. To meet the growing demand for skilled professional's proficient in handling medical instruments, the National Institute of Pharmaceutical Education and Research (NIPER) has taken a proactive step by introducing an M. Tech program focused on medical devices. This program is being offered at NIPER's campuses in Guwahati, Mohali, Hyderabad, and Ahmedabad.

Furthermore, the IPC provides an internship opportunity tailored for students, spanning from 3 months to 1 year. This program is meticulously designed to enable students to participate in both short-term and long-term projects, with the ultimate goal of enhancing their comprehension and acknowledging the importance of MDAEs. At the hospital level, it is imperative for the Medical Council of India to enforce the mandatory inclusion of the MvPI as a requirement for all doctors to renew their licenses. At present, only pharmacovigilance is integrated into the National Accreditation Board for Hospitals and Healthcare Providers (NABH) standards. Therefore, it is recommended that the incorporation of MvPI into the fulfillment criteria of NABH should also be proposed.

The MvPI is a significant initiative established by the Government of India to ensure the post-market surveillance and safety monitoring of medical devices. Recognizing the need for a dedicated system to monitor adverse events associated with medical equipment, the MvPI was launched in collaboration with the SCTIMST in 2015. The program aims to assess the benefits and risks of medical devices, generate evidence-based information, assist regulatory decision-making, share safety-related information, and foster partnerships with healthcare organizations and global agencies.

Since its establishment, the MvPI has made substantial progress in India. It has set up MDMCs throughout the country, and over 7000 reports have been submitted, highlighting the importance of reporting adverse events. The program follows a comprehensive reporting and evaluation process, conducting root cause analyses and sharing reports with the CDSCO. Regular training is provided to stakeholders to improve reporting skills, and awareness among the general public is raised regarding medical device safety.

The global scenario of post-market surveillance reveals that several countries, including the US, Canada, Japan, Australia, and Europe, have established their own surveillance systems for monitoring adverse events associated with medical devices. Each country has its regulatory authority and reporting schemes to ensure the safety and efficacy of medical devices.

CONCLUSION

From this study, the MvPI is a crucial step in ensuring the safety of medical devices in India. By actively monitoring and reporting adverse events, the program contributes to patient safety and the overall improvement of healthcare quality. Continued efforts in strengthening the program, fostering collaborations, and promoting awareness will further enhance the effectiveness of materiovigilance in India and contribute to global efforts in post-market surveillance of medical devices.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare. All authors have seen and agree with the contents of the manuscript and there is no financial

interest to report. We certify that the submission is original work and is not under review at any other publication.

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