Materiovigilance Program Of India (MVPI): Current Need And Status In Country

Dr. Shivani Trivedi*

*Pharmacovigilance Associate, Gmers Medical College, Gandhinagar

Abstract: Background: The term "medical device" includes a broad classification of production ranging from therapeutic medicinal devices with local uses to highly advanced electronic medical equipment and indicative medical devices. These devices vary widely in their production, type and are highly essential for patients' care. Thus, their manufacturing, distribution, and sales must be managed to ensure their quality, safety, and efficacy. They play a major role in to detection, assessment and management and treatment of many different diseases. That being said, the quality of devices can very different and even the perfectly articulated products can fail in clinical practice. Post-market surveillance is therefore essential to ensure the quality and evaluate the safety and performance of medical devices. Despite the importance placed on surveillance of drug safety, the need for better monitoring of medical device-associated adverse events receives less attention. A well-structured vigilance system is the backbone of a robust regulatory framework to ensure the quality and promote the safe use of medical devices. The regulation of medical devices, however, is a complex and constantly evolving area that is often complicated by legal technicalities. Although the regulations may differ from one country to another. [Trivedi S Natl J Integr Res Med, 2022; 13(4): 29-32, Published on Dated: 10/07/2022]

Key Words: Materiovigilance, Materiovigilance Program Of India, Medical Products

Author for correspondence: Dr. Shivani Trivedi, Pharmacovigilance Associate, GMERS Medical College, Gandhinagar - 382012 E-Mail: shivaneetrivedee@gmail.com

Introduction: There has been a wide increase in the use of medical devices thus resulting into the wide range in the number of devices as well. But it also cannot be denied that medical devices are the integral part of healthcare system. They play a key role in to detection, assessment and management and treatment of many different diseases. According to data, there are more than a million devices available now a day's ranging from a simple toothbrush or bandage to high cost surgery equipments[1,2]. And in an after Covid world, the need and dependency of medical devices has only increased.

The world health organization has defined them as, "instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury, investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life, control of conception, disinfection of medical devices providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means[3]."

However, along with all the benefits of medical devices, there have been a few mishaps as well. Some unfortunate incidents have been resulted in calling back of such devices with potential risk factors[4,5]. Thus to avoid such incidents, proper management channel was desperately needed and hence the materiovigilance programme was invented.

Materiovigilance Programme Of India: Materiovigilance programme of India (MvPI) was launched by the Drug Controller General of India at the Indian Pharmacopoeia commission (IPC) in Ghaziabad in 2015. The main purpose of this initiative is to monitor adverse events associated with medical devices in order to generate safety data, create awareness among the various stakeholders, and prescribe best practices for patient safety[6]. Materiovigilance refers to tight monitoring of any unwanted events resulting from the use of medical devices by having a system in place which is made for identifying, collecting, reporting, and measuring undesirable occurrences and reacting directly to them, or

safety corrective actions after their post marketing phase[7,8].

The main goal of this program is to assess medical device-associated adverse events (MDAE), spread awareness among health-care professionals about the importance of MDAE reporting and create independent credible evidence-based safety data of medical devices and to share it among the stakeholders[9].

The IPC functions as the National Coordination Centre (NCC) and Central Drug Standard Control Organization (CDSCO) functions as the regulator of MvPI.

The goal of this program was to initially enrol 10 medical colleges across four parts of India and encourage voluntary reporting, whereas later, it intends to expand the program to all private and public health-care delivery system, develop e-reporting system, and make the reporting mandatory for device manufacturers and health-care providers which is now being fulfilled quite successfully with 174 MDAE centres working across the country as of 2022.

Objectives: Materiovigilance programme of India was created with a vision to improve patient safety and welfare of Indian population by monitoring adverse events related to medical devices and thereby reducing the risk associated with use of medical devices. The objectives listed by MvPI are as following[9]:

1. To capture and record suspected medical device adverse events like death or serious deterioration in state of health, serious injuries and disability.
2. To identify and analyze new signal from the reported cases both via active as well as passive surveillance.
3. To analyze the benefit-risk ratio/risk analysis/causality assessment of medical devices.
4. To generate evidence-based information on safety of medical devices and medical generate device alert to regulator/healthcare professional.
5. To support regulatory agencies in the decision-making process on use of medical devices.
6. To communicate the safety information on use of medical devices to various stakeholders with an aim to minimize the risk Mission Safeguard the health of Indian population by ensuring that the benefits of use of medical devices outweigh the risks associated with its use. Vision to improve patient safety and welfare of Indian population by monitoring adverse events related to medical devices and thereby reducing the risk associated with use of medical devices.
7. To emerge as a national centre of excellence for Materiovigilance activities.
8. To collaborate with other national centres for the exchange of information and data management.
9. To create awareness among healthcare professionals about the significance of MDAE reporting.
10. To provide training and consultancy support to other national Materiovigilance centres across the globe.

Documenting And Reporting: Any type of adverse event regarding medical devices can be reported whether they are suspected/known/serious/non serious/ common or rare. Reporting can be done in various formats to MvPI. One of the most common reporting format is the adverse event reporting form that is created by the MvPI.

The form contains all the details regarding the adverse event caused by the medical device, reporter, patient and event. The form is made available from the official website of IPC. Use the Medical Device Adverse Event Reporting Form which is available on the official website of IPC (www.ipc@gov.in) to report any adverse event.

Reporters from MDMC (Medical device monitoring centres) after filling the above mentioned MDAE reporting form can submit it to the coordinator or Research Associate of the respective MDMC. A reporter who is not part of MDMC can submit the filled MDAE reporting form to the nearest MDMC or directly to the National Collaborating Centre.

Reporter can also mail the scanned form at lab.ipc@gov.in and copy to mvpi.ipcindia@gmail.com. IPC having a facility of helpline number 1800-180-3024 to report adverse events associated with medical devices and medicines. A reporter can also call on this number to report MDAEs[9].

Steps Ahead: Drugs Controller General India launched materiovigilance program of India

(MvPI) at Indian Pharmacopeia Commission (IPC), Ghaziabad on July 6, 2015 as the NCC for the Post market vigilance of medical devices.

All the Adverse Drugs Reaction Monitoring Centers (AMCs) under Pharmacovigilance Programme of India (PvPI) have also been entrusted to report adverse events due to the use of medical devices.

Scope Of MvPI Is To: Establish a system for patient safety monitoring that can be used pan country. Explore the benefit-risk ratio of medical devices. To create an evidence-based information on safety of medical devices.

Support CDSCO in the decision-making process on use of medical devices. Communicate the safety information on use of medical devices to various stakeholders to minimise the risk. Emerge as a national centre of excellence for Materiovigilance activities. Collaborate with other healthcare organizations for exchange of information and data management[10,11].

Medical device adverse event monitoring centres (MDAE) are now obliged to organize advance-level training for hospital personnel in their respective region and to continue medical education training in materiovigilance sector to increase awareness about the programme.

Guidance: Programmes for the specialists involved in data accumulation, processing and analysis are arranged systematically to cultivate competency for determining the cause and operating root cause reasoning for adverse occurrences. The trainings are designed by the commission with the help of partner organizations and delivered by staff from the commission, the Central Drugs Standard Control Organization, partner organizations and industry representatives in one-day (basic level) or two-day (advanced level) courses, depending on stakeholder's needs[12].

Conclusion: A recent time has seen quite a big leap in the usage of medical tools. That being the case, the awareness regarding the Materiovigilance program is still not as extensive as it should have been. Materiovigilance programme is built to resolve, scrutinize and lessen the frequency of harmful effects that is caused by the usage of medical devices that were created to help them. And for MvPI to reach to the level of growth that developed countries has seen, it is very important to have a strong root level awareness of the programme to all the health care professionals as well as the public to create a strong bridge of knowledge and its proper use.

That being the reason is why the need of MvPI is at highest currently in the country. All the essential information regarding the procedure guidelines, the detailed process of it, roles and responsibilities of various partners is laid down with great precision in the guidance document of MvPI.

The functional implementation of this program can ensure the protection of the vast majority of the country using the medical devises on a regular basis and can also provide the anticipation of general safety measures to avoid such incidences in the future as well.

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Conflict of interest: None
Funding: None
Cite this Article as: Trivedi S. Materiovigilance Program Of India (MvPI): Current Need And Status In Country. Natl J Integr Res Med 2022; Vol.13(4): 29-32