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MATERIOVIGILANCE: CONCEPT AND EMERGING PERSPECTIVE FOR PATIENT'S SAFETY IN INDIA

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ABSTRACT

There has been an escalation in the number, diversity, and complexity of medical devices. Regulation of these devices has also advanced due to the requirement of better regulatory perspective induced due to elevation in the number of adverse events associated with medical devices. All over the globe, various measures are undertaken to provide better safety to the patients along with attempts to improve the standard of medical devices. Materiovigilance is the study and follow-up of occurrences that arise as a result from the usage of the medical equipment. It not only manages adverse events (AE) but also creates harmonization among countries. Ministry of Health & Family Welfare, Govt. of India approved and commenced Materiovigilance Programme of India (MvPI) in the country inorder to monitor the safety of Medical Devices Associated Adverse Events (MDAEs) in Indian Population. TheMvPI launched on 06th July 2015 at Indian pharmacopoeia Commission (IPC), Ghaziabad by the Drugs Controller general India (DCG(I).

KEYWORDS: Materiovigilance Programme of India (MvPI), Medical Devices Associated Adverse Events (MDAEs), Medical Device Adverse Event Monitoring (MDAEM), Adverse Drug Reaction (ADRs).

INTRODUCTION

Materio vigilance is the study and follow up of incidents that might result from the use of medical devices. It enables to identify the adverse events associated with the use of medical devices as all the devices may have certain degree of risk and can cause some problems under specific circumstances. Monitoring the safety of these devices enables dangerous devices to be with drawn from the market and to eliminate faults in medical devices with the intention to

constantly improve the quality of the devices and providing patients and consumers with increased safety. Materio vigilance refers only to medical devices whereas pharmacovigilance refers to medicines.

Although the use of medical devices benefits the patients immensely, they also carry significant potential risks. There are multiple instances where the device was recalled either due to defect or because of the significant morbidity and mortality it caused in the users. Therefore, it is imperative to assess and ascertain the risks and benefits associated with the device at all stages of its development and uses. This can be achieved by a robust monitoring mechanism which at present is followed only in few countries.

The potential risk and benefit of all medical devices must be assessed across all stages of the product life cycle. Thus, the risk-management systems, which include pre-market (pre-approval studies) and post-market surveillance, improved the protection of health. The manufacturer must perform the conformity assessment, but this not always guarantee the patient safety.[9] The large number of recall reports proves that the pre-market review process cannot identify all possible malfunctions of all different medical devices currently on the world- market.

Medical device rule in india: Devices are different than drugs

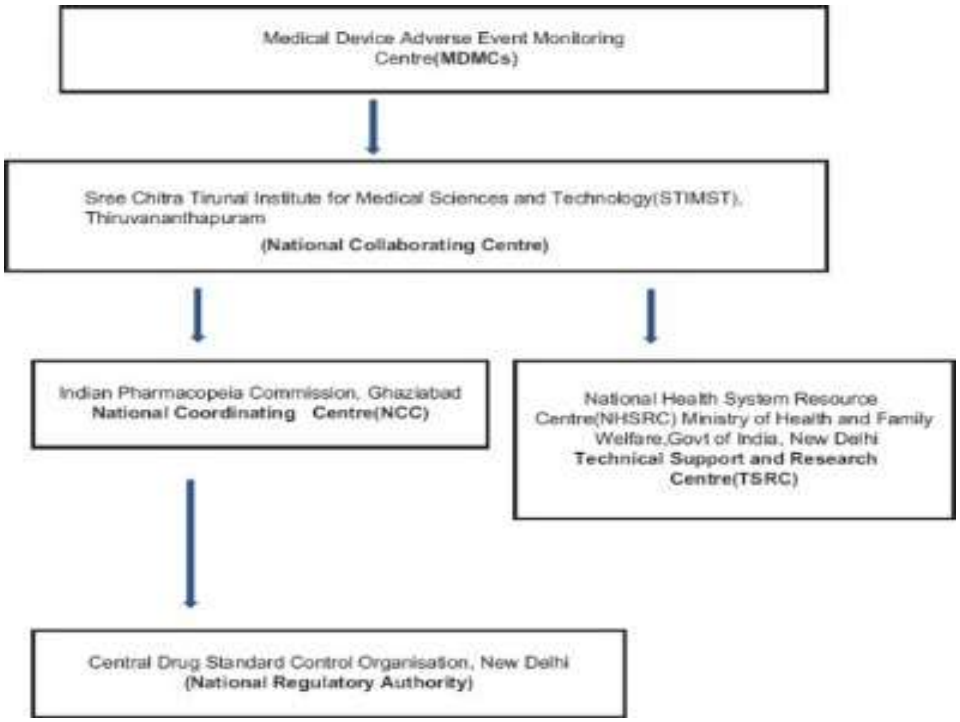
Under the Drug and Cosmetic Act, 1940, medical devices were regulated as drugs (pharmaceutical products) in India prior to the introduction of the Medical Device Rules 2017 which came into force on 1 January 2018. Hence, the differentiation between medical devices and pharmaceutical products was needed. The central drug standard control organization (CDSCO) categorized devices from time to time and displayed them on their official website. The classification list provided by Medical Device Rule 2017 mentioned in [Table 1].

Table 1: Device classification as per medical device rule 2017.

Device risk class	Type of risk	examples
Class A	Low-risk	Bolster suture, Alcohol swaps, Nasopharyngeal catheter
Class B	Low-moderate	Disinfectants, Intravenous catheter, Rectal catheter
Class C	Moderate-high	Biliary stents, Bone cement, Imaging catheter
Class D	High	Coronary stent, Heart valve, Copper-T

Materiovigilance program of india

India, safety, quality, and performance of medical devices are regulated as per Drug and Cosmetic Acts, 1940 and Rules, 1945. India did not have a proper system to monitor the adverse events associated with uses of medical devices for a long period of time. To regulate the import, manufacture, sales, and distribution of medical devices, Government of India in consultation with Drugs technical advisory board has recently brought out Medical Devices Rules, 2017. It was notified on January 31, 2017 and came into force from January 1, 2018.



Drugs Controller General India launched materiovigilance program of India (MvPI) at Indian Pharmacopeia Commission (IPC), Ghaziabad on July 6, 2015. The fundamental aim of this program is to monitor medical device-associated adverse events (MDAE), create awareness among health-care professionals about the importance of MDAE reporting and generate independent credible evidence-based safety data of medical devices and to share it with the stakeholders. 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 is to initially enroll 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.

Applications of MvPI

Prime Applications of MvPI

1. To fabricate a structure for patient safety supervising.
2. Injuries & impediments prevention.
3. To generate evidence-based statistics on medical device safety
4. To aid CDSCO in the authoritative operations on medical device utilization and share conclusive reports with different stakeholders.
5. To come into view as national centre of eminence for materiovigilance schemes.
6. To put into effect restorative steps in order to inhibit possible adverse events in future.

Stakeholders of MvPI

1. All professionals including staff at IPC, SCTIMST NHSRC and all such institutions.
2. Medical device Monitoring Centre Officials.
3. CDSCO advisers & staff.
4. All Healthcare Policy makers, specifically the ones concerned with Medical Device Policy.
5. Clinicians, clinical engineers, biomedical engineers, pharmacists, nurse in conjunction with hospital technology managers.
6. Medical device manufacturers advised by CDSCO.
7. Medical Technologists & Innovators.
8. Importers & Traders dealing in medical devices are also eligible to report specifically about their own products.

Reporting system of the medical device-associated adverse events

Who can report MDAEs?

MDAEs can be reported to SCTIMST or NCC by healthcare professionals (physicians, pharmacists, dentists, nurses, biomedical engineers) and patients. Additionally, CDSCO recognized medical device manufacturers or importer trader can also report AEs specific for their device directly to SCTIMST or NCC, Thiruvananthapuram, Kerala, India.

What to report?

All types of MDAEs (known or unknown, serious or non-serious, rare, or frequent) regardless of established causal relationship can be reported. Details of AE include incident description, medical device description, and associated risk with a medical device to patient/user, any possible risk associated with previous use can be documented in MDAEs reporting form**.**

How and Whom to Report MDAEs?

MDAEs can be reported to MAMCs by using the MDAE reporting form which is available on the official website of IPC (www.ipc.gov.in). Research associates from MDMCs then submit this duly filled form to NCC via email on mvpi@sctimst.ac.in. Alternatively, NCC-PvPI toll-free helpline no. 1800-180-3024 can also be used for MDAEs reporting. All the reported cases at NCC are finally reviewed and assessed and forwarded to WHO-Uppsala Monitoring Centre (WHO-UMC).

Reporting of MDAEs to NCC-MvPI IPC

Since the inception of MvPI, the IPC received and evaluated more than 1931 AEs involving medical devices till October 2019. Out of which 1277 (66.17%) were serious and rest were non-serious. Reporting of MDAEs in India significantly increased post-2017, after the introduction of medical device rules and friendly reporting procedures. These AEs were reported by various authorities such as marketing authorization holders (1439 cases), MDAEs monitoring centers (419 cases), ADRs monitoring centers (70), and by consumers itself (3 cases).

Role and Responsibilities of different units of materiovigilance program of india

MDMC collect and review the completeness of MDAE, analyze failure mode effect, assess causality as per the standard operating procedures (SOP), and send the monthly consolidated report to National collaborating centre. As per the guidance documents of MvPI 10 medical colleges in different parts of the country has been identified as MDMC. The National collaborating centre receives the adverse event report from MDMC and collates, analyze and perform signal detection and communicate the outcome to National coordinating centre(NCC). It is also involved in conducting awareness program, training, and the workshop on materiovigilance periodically at various zones of the country. At present, Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Thiruvananthapuram, functions as National collaborating centre. The main responsibility of Indian Pharmacopoeia Commission which functions as MvPI-NCC is to coordinates with all stakeholders of the program by convening steering committee and working group meetings. The other responsibility of it is to recognize new MDMCs across the country. It also prepares and disseminates SOP, guidance documents, training manual, and newsletter. It formulates the data received from SCTIMST and recommend to the CDSCO for appropriate action. DGCI-CDSCO formulates the regulatory decisions and communicates to the different

stakeholders. As regulator, it is also incumbent upon CDSCO to join IMDRF and other international forums for exchange of postmarketing safety information. National Health System Resource Centre Ministry of Health and Family Welfare, Government of India, New Delhi, functions as TSRC. It provides technical support to NCC and National Coordination Centre for the preparation of SOP, guidance documents, newsletters, and training manuals. It also helps in identifying new MDMC**.**

CONCLUSION

The MvPI is still in the infancy stage in India and is growing firmly which will surely play a critical role in preventing MDAEs amongst the Indian population. However, in countries with established regulation, precise device tracking and devising proper penalties in conjunction with firm reporting guideline and limiting forgeries have persuaded manufacturers to develop quality devices. Medical device regulation plays a vital role in ensuring efficacy, safety, and performance of the device so that it is made accessible in the marketplace for refining community health. A safer and effective device will automatically lift the faith and confidence of customers over the device. The comprehension of regulatory reforms in India will prove to be critical in various company's attempts to penetrate the Indian medical market.

REFERENCES

1. Joshi D, Sharma I, Gupta S, Singh TG, Dhiman S, Prashar A, Gulati M, Kumar B, Vishwas S, Chellappan DK, Gupta G. A global comparison of implementation and effectiveness of materiovigilance program: overview of regulations. Environmental Science and Pollution Research, 2021; 1: 1-22.
2. Meher BR. Materiovigilance: an Indian perspective. Perspectives in clinical research, 2018; 9(4): 175.
3. Hoda F, Verma R, Arshad M, Siddiqui AN, Khan MA, Akhtar M, Najmi AK. Materiovigilance: concept, structure and emerging perspective for patient's safety in India. Drug Research, 2020; 70(09): 429-36.
4. Kumar P, Kalaiselvan V, Kaur I, Thota P, Singh GN. Materiovigilance programme of India (MVPI): A step towards patient safety for medical devices. Eur J Biomed Pharm Sci, 2016; 12: 497-501.
5. Mirel S, Colobatiu L, Fasniuc E, Boboia A, Gherman C, Mirel V, Muresan D. Materiovigilance and medical devices. InInternational Conference on Advancements of

Medicine and Health Care through Technology; 5th–7th June 2014, Cluj-Napoca, Romania: MEDITECH, 2014; 2014: 101-106. Springer International Publishing.