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Editorial

Materiovigilance: Its impact on patient's safety

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According to World Health Organization (WHO), a medical device is defined as any instrument, apparatus, machine, appliance, reagent or implant in-vitro or calibrator, software, material or other related article, intended by the manufacturer to be used, alone or in combination, for human beings for the diagnosis, prevention, and treatment of diseases. Medical devices can be classified into (i) Low risk (Class A); (ii) Low moderate risk (Class B); (iii) Moderate high risk (Class C) and (iv) High risk (Class D) based on their risk parameters. All medical devices have been associated with adverse effects which can cause harm to the patient. To avoid sub-standard and incompatible devices, flooded in Indian market, it is of utmost priority to have a vigilance system in place to record feedback from patients and users. Medical device related adverse events is a universal health concern and various countries had come forward to establish regulatory mechanisms for the vigilant monitoring of the manufacturing and use of such medical devices.

Materiovigilance is the close monitoring of any undesirable performance or characteristics fluctuations of a medical device by means of a system which is capable of identifying, collecting, reporting and reacting to them with field safety corrective actions or device recall during post - marketing phase of a Medical Device. Materiovigilance Programme of India (MvPI) was started in 2015 by the Govt. of India at Indian Pharmacopeia Commission (IPC) as National coordinating centre. Sree Chitra Tirunal Institute of clinical Sciences and development (SCTIMST), Thiruvananthapuram functions as National Collaborating Centre for MvPI, National Health System Resource Centre (NHSRC), New Delhi, provides the technical support and CDSCO (Central Drugs Standards Control Organization), New Delhi functions as Regulatory body.[1–4]

Objectives of MvPI

1. To develop a well-organised vigilance system that will help in regulatory decisions to ensure the quality and safe use of medical devices.
2. To create a system for vigilance of medical device adverse event reporting at a national level, that will create a MDAEs database, help in signal detection and/or other regulatory decisions.
3. To determine the benefit-risk analysis of reported MDAEs and to perform the causality assessment of the same.
4. To generate and communicate medical device alerts to the regulator/healthcare facilities as well as to the

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hospitals.

5. To sensitise and raised awareness among healthcare professionals all over India towards the significance of MvPI and reporting of MDAEs.
6. To provide technical and consultancy support to other countries who are interested to develop medical device vigilance system in their country.

Reporting of MDAE is the communication of an event to those who can make a contribution towards a meaningful outcome. It is indeed the moral responsibility of the healthcare professional to report any adverse events associated with use of medical devices in order to ensure and safeguard the health of Indian population. All healthcare professionals (HCPs), biomedical engineers, hospital technology managers, pharmacists, nurses and technicians can report (MDAEs) to Medical Devices Adverse Event Reporting Centre (MDMC) or NCC-MvPI. Moreover, anyone with direct/indirect knowledge of Medical Devices Adverse Event can report MDAE. Pharmaceutical companies can also send adverse events specific to their product to NCC. In order to promote the reporting culture in India, MvPI encourages the reporting of all known or unknown, serious or non-serious, frequent or rare MDAEs. A standard MDAE form available at ww w.ipc.gov.in website for reporting MDAEs. The IPC where necessary investigates, consult subject experts, disseminates information and/or oversees corrective actions (e.g. safety alerts, product or labelling changes), exchanges information with other regulatory agencies.[4,5]

At present, there is not much awareness of MvPI and its reporting among HCPs. This is the area which needs to be developed further. MvPI should be incorporated in medical and paramedical curriculum. Regular awareness programmes should be organised to sensitize the HCPs and to increase the reporting of MDAEs in order to ensure patient safety.

Conflict of Interest

None.

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