Materiovigilance: An Indian perspective

Bikash Ranjan Meher

Department of Pharmacology, All Indian Institute of Medical Science, Bhubaneswar, Odisha, India

Abstract

Materiovigilance is the coordinated system of identification, collection, reporting, and analysis of any untoward occurrences associated with the use of medical devices and protection of patient's health by preventing its recurrences. Postmarketing surveillance of medical devices has been initiated in many countries, but it is still not as developed and robust as that of medicines. Materiovigilance program of India was launched on July 6, 2015, at Indian Pharmacopeia Commission with objectives to track the adverse events associated with the use of medical devices, to generate safety data, create awareness among the different stakeholders, and recommend the best practices and interventions to improve the patient's safety.

Keywords: Adverse event, medical device, postmarketing, vigilance

Address for correspondence: Dr. Bikash Ranjan Meher, Department of Pharmacology, All Indian Institute of Medical Science, Bhubaneswar, Odisha, India.
E-mail: bikash1meher@gmail.com

INTRODUCTION

Medical devices have an immensely important role in diagnosis, prevention, and treatment of different diseases.[1,2] Recent stride in scientific innovation has substantially increased the role medical devices in the health-care delivery system. There are more than a million medical devices available ranging from simple low-cost bandage or tongue depressor to high cost and complex devices such as magnetic resonance imaging machine and medical software application.[3,4] The World Health Organization has defined medical device as any "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."[5]

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.[6-8] 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.[9,10]

Access this article online	
Quick Response Code:	**Website:** www.picronline.org
	DOI: 10.4103/picr.PICR_26_18

How to cite this article: Meher BR. Materiovigilance: An Indian perspective. Perspect Clin Res 2018;9:175-8.

Postmarketing surveillance practice of device in other countries

The Unites States pioneered the postmarketing surveillance of medical devices by enacting the Food and Drug Administration (FDA) Modernization Act 1970 under section 522 for medical devices. Subsequently, other countries such as Australia, Canada, and European Union brought out the law for effective surveillance of medical devices.[11,12] In 1993, initiative was taken to establish Global Harmonization Task Force (GHTF) by European Union, USA, Japan, Australia, and Canada. The aim of GHTF was to bring uniformity in regulatory system related to safety, performance, and quality of medical devices.[13] In 2011, a new forum, International Medical Device Regulators Forum (IMDRF) was conceived to build on the commendable work of GHTF and accelerate the medical device regulatory harmonization and convergence.[14]

The UK Medical Devices Agency has both vigilance reporting scheme and the adverse event scheme for the postmarketing surveillance of medical devices. Vigilance reporting scheme is for manufacturers and is mandatory, whereas Adverse Event Scheme is for health-care providers, hospital engineers, and patients and is voluntary. There is prescribed timeline for the manufacturer to report adverse events failing which they are levied penalties. Health-care professionals are obliged to report the adverse event and expected to report it immediately.[4]

In the United States also mandatory and voluntary scheme of reporting is proposed by FDA. Medical Device Reporting regulation (21CFR 803) contains mandatory requirements for manufacturers, importer, and user's facilities to report certain adverse events and problems pertaining to the use of the devices on FDA Med watch form 3500A or on an electronic equivalent to the FDA. FDA has specified the strict timeline for the manufacturers and importers of medical devices to submit reports of death or serious injury occur due to devices and if devices have developed any malfunctions. A device user facility also must report the suspected medical device-related serious injury or death to both manufactures and FDA within the prescribed timeline. It also has to submit the annual summary report of death or serious injury in 3419 FDA form to the FDA.[15]

USFDA encourage the health-care providers and device users to report any suspected device-related injury or adverse effect on FDA 3500 form or using the MedWatcher mobile app to the FDA.[16]

MATERIOVIGILANCE PROGRAM OF INDIA

In 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.[17] 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 [Figure 1]. It was notified on January 31, 2017 and came into force from January 1, 2018.[17]

Materiovigilance refers to close monitoring of any undesirable occurrences resulting from the use of medical devices by means of having a system in place which comprises identifying, collecting, reporting, and estimating undesirable occurrences and reacting to them, or safety corrective actions after their postmarketing phase.[18,19]

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.[20] The IPC functions as the National Coordination Centre (NCC) and Central Drug Standard Control Organization (CDSCO) functions as the regulator of MvPI [Figure 1]. 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.

OBJECTIVES OF MATERIOVIGILANCE PROGRAM OF INDIA

The program was initiated with the objectives to protect the health and ensure the safety of device users and others by reducing the recurrences of adverse events and malfunctions.[20]

- To create a nationwide system for patient safety monitoring
- To analyze the risk–benefit ratio of medical devices uses
- To generate evidence-based data on the safety of medical devices

- To support CDSCO in the decision-making process on the use of medical devices
- To communicate the safety information on the use of medical devices to various stakeholders to minimize the risk
- To emerge as a national center of excellence for materiovigilance activities
- To collaborate with other healthcare organizations and international agencies for the exchange of information and data management.

Documenting and reporting adverse events

All types of adverse events related to medical devices used in India irrespective of whether they are known or unknown, serious or nonserious, frequent or rare can be reported. Along with that any malfunction or deterioration in characteristics or performance of medical device or inaccuracy in labeling or instructions for use can be reported. A reporting format, two pages medical device adverse event reporting form has been prepared by MvPI which contain all information in detail regarding the patient, adverse event, device, regulator, and reporter. This form is freely available on the official website of IPC (www.ipc. gov.in). The duly signed form can be sent to the nearest medical device monitoring center (MDMC) or can be directly sent to the National Collaborating Center (NCC). It can also be scanned and mailed @sctismt.ac.in and copy to mvpi.ipcindia@gmail.com. The reporter can also call the helpline number created by NCC-PvPI (1800-180-3024) and report the adverse event. Documenting and reporting adverse events due to the device and seamless flow of information involves various aspects and interrelationship among different stakeholders.

- Role of health-care service providers
- Role of manufactures
- Role of research associate and coordinator at MDMC
- The responsibility of National Collaborating Centre
- The responsibility of National Coordinating Centre(NCC)
- The responsibility of technical support and research center (TSRC)
- The responsibility of CDSCO.

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

There is an upsurge in the use of medical devices in recent years. Despite that, there are not adequate measures to protect the patients from the untoward occurrences
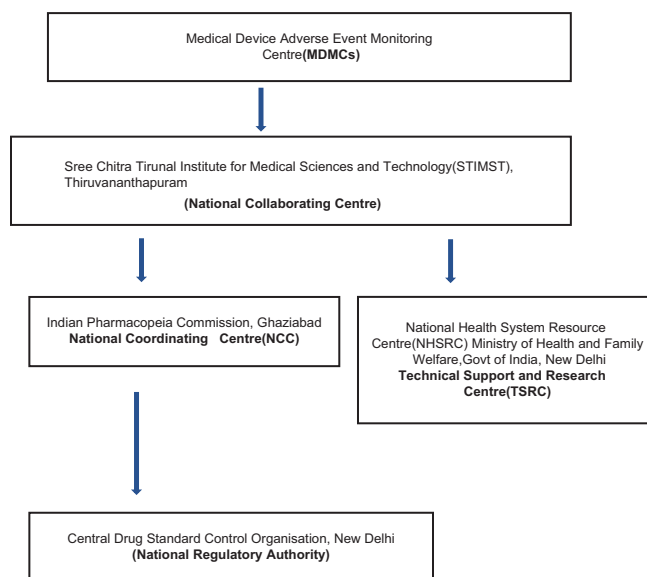

Figure 1: Organisational structure of materiovigilance program of India

associated with the use of medical devices. Materiovigilance program is meant to analyze, scrutinize, and prevent the recurrence of harmful effects occurs due to use of medical devices. MvPI is a good initiative to ensure the safety of medical devices among the device users in India. The guidance document of MvPI has laid down the policy guidelines, procedures, and enunciated the role and responsibilities of different stakeholders to enable safety data collection in a systematic manner. It is expected that effective implementation of this program will safeguard the safety of device users substantially by preventing the recurrence of adverse effects and reducing the risk associated with the use of medical devices.

Financial support and sponsorship
Nill.

Conflicts of interest
There are no conflicts of interest.

REFERENCES

1. Johnson JA. FDA Regulation of Medical Devices. CRS Report for Congress Prepared for Members and Committees of Congress; 25 June, 2012. Available from: http://www.fas.org/sgp/crs/misc/R42130.pdf. [Last accessed on 2017 Dec 10].
2. Gupta SK. Medical Device regulations: A current perspective. J Young Pharm 2016;8:6-11.
3. Available from: http://www.tga.gov.au/what-medical-device. [Last accessed on 2017 Dec 20].
4. Jefferys DB. The regulation of medical devices and the role of the medical devices agency. Br J Clin Pharmacol 2001;52:229-35.
5. Available from: http://www.who.int/medical_devices/full_deffinition/en/. [Last accessed on 2017 Dec 10].
6. Heneghan C, Thompson M, Billingsley M, Cohen D. Medical-device recalls in the UK and the device-regulation process: Retrospective review of safety notices and alerts. BMJ Open 2011;1:e000155.
7. Hauser RG. Here we go again – Another failure of postmarketing device surveillance. N Engl J Med 2012;366:873-5.
8. McGee RG, Webster AC, Rogerson TE, Craig JC. Medical device regulation in Australia: Safe and effective? Med J Aust 2012;196:256-60.
9. Higson GR. Medical Device Safety: The Regulation of Medical Devices for Public Health. London: IOP Publishing; 2002.
10. Mirel S,Colobatiu L,Fasniuc E,Boboia A,Gherman C,Mirel V, et al. Materiovigilance and medical devices. In: Vlad S, Ciupa R, editors. International Conference on Advancements of Medicine and Health Care through Technology, IFMBE Proceedings. Vol. 44. Cluj-Napoca, Romania: Springer, Cham; 2014.
11. Available from: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm268141.pdf. [Last accessed on 2017 Dec 12].
12. Gupta P, Janodia MD, Jagadish PC, Udupa N. Medical device vigilance systems: India, US, UK, and Australia. Med Devices (Auckl) 2010;3:67-79.
13. Available from: http://www.who.int/medical_devices/collaborations/force/en/. [Last accessed on 2017 Dec 20].
14. Available from: http://www.imdrf.org/. [Last accessed on 2017 Dec 12].
15. Available from: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm. [Last accessed on 2017 Dec 18].
16. Available from: https://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm. [Last accessed on 2017 Dec 22].
17. Available from: http://www.cdsco.nic.in/writereaddata/Classification%20wise%20list%20of%20MD%20and%20IVDs17.pdf. [Last accessed on 2017 Dec 20].
18. Radhadevi N, Balamuralidhara V, Pramod Kumar TM, Ravi V. Regulatory guidelines for medical devices in India: An overview. Asian J Pharm 2012;6:10-7.
19. 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.
20. Available from: http://www.Users/Aiims%2044/Desktop/materiovigilance/materiovigilance%20programme%20of%20india.pdf. [Last accessed on 2017 Dec 26].