



MATERIOVIGILANCE PROGRAMME OF INDIA (MvPI): A STEP TOWARDS PATIENT SAFETY FOR MEDICAL DEVICES

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Article Received on 19/10/2016

Article Revised on 09/11/2016

Article Accepted on 30/11/2016

ABSTRACT

Materiovigilance 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. Ministry of Health & Family Welfare, Govt. of India approved and commenced Materiovigilance Programme of India (MvPI) in the country in order to monitor the safety of Medical Devices Associated Adverse Events (MDAEs) in Indian Population. The MvPI launched on 06th July 2015 at Indian pharmacopoeia Commission (IPC), Ghaziabad by the Drugs Controller general India (DCG(I)). All health care professionals, patients/consumers can reports MDAEs to Sree Chitra Tirunal Institute of medical Sciences & technology (SCTIMST), Thiruvananthapuram or National Coordination Centre (NCC) - IPC. The collected and generated safety data will help to give recommendations to Central Drugs Standard Control Organisation (CDSCO) for taking regulatory decisions on safe use of medical devices in Indian Population.

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

INTRODUCTION

Materiovigilance 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 Monitoring the safety of these devices enables dangerous devices to be withdrawn from the market and to eliminate faults in medical devices with the intention to constantly improve the quality of the devices and providing patients and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. Materiovigilance refers only to medical devices whereas pharmacovigilance refers to medicines.

Medical device is defined as any instrument, equipment, material or other article used on its own or jointly,

including software required for it to function correctly, which is intended by the manufacturer to be used on humans for the following purposes:^[1]

- For diagnostic, prevention, control, treating or diminishing an illness.
- For diagnostic, control, treating, for diminishing or compensating an injury or handicap.
- For studying, replacing or modifying part of the anatomy or a physiological process.
- For mastering conception.

Medical devices which covers the market of US\$ 3.1 billion for medical devices; In spite of this India has no system for registering/monitoring the adverse events caused by the medical devices and also to track the safety record of medical devices. We are dependent on the developed countries for the safety data of these

devices.

In order to monitor the safety on the use of medical devices in the country, Ministry of Health & Family Welfare, Govt. of India approved and commenced Materiovigilance Programme of India (MvPI) in the country. The MvPI launched on 06th July 2015 at Indian pharmacopoeia Commission, Ghaziabad by the Drugs Controller general India (DCGI). Indian Pharmacopoeia commission (IPC) is an autonomous institution under Ministry of Health & Family welfare and also functions as National Coordination Centre for the Materiovigilance

Programme of India. Sree Chitra Tirunal Institute of medical Sciences & technology (SCTIMST), Thiruvananthapuram will function as a National Collaborating Centre for MvPI. Technical support for the programme is to be provided by the Division of Healthcare Technology, a proposed WHO collaborating centre for priority medical devices and health technology policy in the National Health Systems Resources Centre.^[2] The diagrammatic representation of the partners of the Materiovigilance Programme of India is mentioned in the figure 1.



Figure 1: Diagrammatic representation of the partners of the Materiovigilance Programme of India.

The MvPI aims to collect the safety data in a systematic manner so that the recommendations and regulatory decisions on safe use of medical devices can be taken based on the data generated in Indian Population. The programme is meant to monitor medical device associated adverse events (MDAEs) and create awareness among healthcare professionals about the importance of MDAEs reporting in India and monitoring the benefit-risk profile of the medical devices. It is also meant to generate independent, evidence based recommendations on the safety of medical devices and further to communicate the findings to all the key stakeholders in the country and the stakeholders of the Pharmacovigilance Programme of India (PvPI). Currently 10 Medical Device Adverse Event Monitoring (MDAEM) Centres has been identified in order to monitor the safety of medical devices across the country. The reporting of adverse events of medical devices is yet to be started from the institutions and the hospitals across the country and further planned to involve district hospitals, medical colleges and corporate hospitals of the country in future. The programme will be along the lines of the existing Pharmacovigilance Programme in the

country.^[3] Accordingly the medical colleges are equipped to collect and disseminate and communicate the finding to all the stake holders of the PvPI in the country.

The recently constituted national level committee is currently, therefore, also looking into aspects related to doing causality assessment. This is difficult in medical devices as it requires inputs in biomedical engineering unlike in medicines where the mechanism is different for reporting of Adverse Drug Reaction (ADRs).^[4] Till date, 22 types of medical devices which were regulated as drugs. Subsequent to the establishment of definitions for medical devices, a risk based classification system would be established. The risk based classification would enable rigorous regulations for complex devices and easier procedure for safe to use medical devices.

Based on these reports, a decision will be taken on whether any change is required in the labelling of the devices, or whether a recall or a ban on the product is called for.

Reporting of Medical Device associated Adverse Events (MDAEs)

What to Report

All types of suspected Medical Device associated Adverse Events (MDAEs) can be reported whether they are serious or non serious, known and unknown, frequent or rare regardless of an established causal relationship. Any Adverse events related with the use of medical devices can be reported. Incident description, Details of adverse event including description of device (deficiency or malfunction), clarification of hazards associated with device and the associated risk of patient, user or person, any possible risk to patient associated with previous use can be provided in the MDAEs reporting form.^[5]

Where to Report MDAEs

The Healthcare professionals (clinicians, dentists,

pharmacists, nurses) and patient/consumers can report MDAEs to SCTIMST or NCC. Duly filled Medical Device Adverse Event Reporting Form can be send to Sree Chitra Tirunal Institute of Medical Science and Technology (SCTIMST), National Collaboration Centre-Materiovigilance Programme of India, Biomedical Technology Wing, Poojappura, Thrivananthapuram-695012, Kerala, India Or Can directly email the duly filled form to mvpi@sctimst.ac.in.

How to Report MDAEs

Medical Device Adverse Event Reporting Form [Figure 2] can be downloaded from the website of IPC (www.ipc.gov.in) to report adverse event associated with medical devices. MDAEs can also be reported via PvPI helpline number (1800 180 3024) on weekdays from 9:00 am to 5:30 pm.^[6]

 MEDICAL DEVICE ADVERSE EVENT REPORTING FORM Materiovigilance Programme of India								
FOR MDMC/NCC USE ONLY								
Type of report: Initial ☐ Follow-up ☐				Report No. _____				
A. PATIENT DETAILS								
1. Patient Hospital ID _____				3. Age at time of Event or Date of Birth _____				
2. Sex: M ☐ F ☐				4. Weight (Kg) _____				
B. EVENT DETAILS								
1. Event description-								
Reason for the Event(Tick) a) Electrical ☐ b) Mechanical ☐ c) Electronic ☐ d) Biocompatibility ☐ e) Clinical application error ☐								
2. Severity of the event (Yes ☐ No ☐) If yes please specify following								
☐ Death (____/____/____) ☐ cause congenital-anomaly ☐ Life threatening ☐ Required intervention to prevent death or impairment of body function ☐ Hospitalization/Prolonged impairment/damage ☐ Disability ☐ Other (specify)_____								
3. Date of event - (dd/mm/yyyy)								
4. Location of the event- OPD ☐ IPD ☐ Others (Please specify)_____								
5. Device category: (A) Therapeutic ☐ Diagnostics ☐ Both ☐ (B) Implantable device ☐ Non Implantable device ☐								
(C). Single use device ☐ Reusable device ☐ Reuse of manufacture marked single use device ☐								
6. Date-								
Last preventive maintenance				Last calibration				
7. Location of device after the incident:								
Place of use ☐ Place of reporter ☐ Place of Manufacture/vendor ☐ With patient or end user ☐								
8. Is device in use after incident Yes ☐ No ☐								
9. (A) Is same model device available in organisation? Yes ☐ No ☐ If yes, Quantity_____								
(B) Organization - Healthcare facility ☐ Manufacturer ☐								
C. MEDICAL DEVICE(S) DETAIL								
Name of Medical Device (1)	Manufacturer (2)	Brand Name (3)	Model No. (4)	Serial No. (5)	Batch No./ Lot No. (6)	Catalogue No. (for instruments only)	Date of installation/ implantation/ explanation (8)	List of Accessories (9)
10. Actions taken immediately after incident				11. A Whether other medical devices were being used at same time with above device for therapeutic or diagnostic service? If yes, please specify..... 11 B. Any history of adverse event(s) from device with same serial/model/catalogue number. If yes please specify.....				

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D. REGULATORY DETAILS			E. REPORTER DETAILS of MvPI CENTRE
Manufacturer name:	Entity legally representing the Manufacture:	Notified Body name in:	Name and Professional Address: _____
Regulator in Country of origin:	Country:	(I) Country of Manufacturing:	Pin: _____
Regulatory status in origin country:		(II) In India:	E-mail _____
			Tel. No. (with STD code) _____
			Designation: _____
			Signature: _____
			Date of this report ____dd/mm/yyyy
F. Causality Assessment Details			Completed ☐ In Progress ☐ Awaited ☐
Additional Information:			
Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the adverse event.			

 **National Collaborating centre-Materiovigilance Programme of India.**

Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) under the Department of Science & Technology, Government of India. Biomedical Technology Wing, Poojappura, Thrivananthapuram 695012, Kerala. Phone: 91- 471 – 2340411, Fax: 91- 471 -2341814, Email: head-bmtw@sctimst.ac.in.

 **National Coordination Centre-Materiovigilance Programme of India.**

Indian Pharmacopoeia Commission (IPC), Ministry of Health and Family Welfare, Government of India, Sector-23, Rajnagar, Ghaziabad-20002, Tel.: 0120-2783400, 2783401, and 2783392, FAX: 0120-2783311, Email: ipclab@vsnl.net, pvpi.ipcindia@gmail.com

 **Technical support and Resource Centre- Materiovigilance Programme of India.**

National Health System Resource Centre (NHSRC), NIHFW campus Baba Gangnath marg, Munirka, New Delhi-110067, Phones: 011 26108982 / 83 / 84 / 92 /93, Fax: 011-26108994 Email: nhsr.india@gmail.com.

Where to report

- Duly filled Medical Device Adverse Event Reporting Form can be send to Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), National Collaboration Centre-Materiovigilance Programme of India), Biomedical Technology Wing, Poojappura, Thrivananthapuram 695012, Kerala, India.
- Or Can directly email theduly filled form to mvpi@sctimst.ac.in.
- Call on Helpline no. 1800 180 3024 to report Adverse event.

Event description Details of adverse event including description of device (deficiency or malfunction), clarification of hazards associated with device and the associated risk of patient, user or person any possible risk to patient associated with previous use.

Additional Information Other relevant information related to treatment should be provided.

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Figure 2: Medical device Adverse Event reporting form.

Whom to Report MDAEs

After filling the MDAEs reporting form it can be directly submitted to NCC or SCTIMST. In case if the report is submitted directly to SCTIMST, these reports are confirmed and validated by healthcare professionals, following the entry of the case report into Vigiflow and sent to NCC for further assessment. After receiving the case report at NCC, All the cases finally reviewed and assessed at NCC and committed to WHO-Uppsala Monitoring Centre (WHO-UMC).

The submission of the MDAEs report does not have any legal implication on the reporters. The confidentiality of the patient's is strictly maintained and protected to the fullest extent. The submission of a report does not constitute an admission that the medical personnel or the manufacturer or the product caused or contributed to the event or reaction.

Therefore, healthcare providers are encouraged to report MDAEs for better understanding of the risk associated

with the use of medical devices and to safeguard the health of the Indian population.

ACKNOWLEDGEMENT

The authors are thankful to the Indian Pharmacopoeia Commission, National Coordination Centre-Pharmacovigilance Programme of India for providing all the support.

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