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Materiovigilance -A Critical Review of Medical Device Safety Monitoring Systems

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ABSTRACT
Materiovigilance represents the systematic surveillance of medical devices post-market to detect, assess, report, and prevent adverse events associated with their use, mirroring the principles of pharmacovigilance but tailored to non-pharmacological interventions. This critical review examines the evolution, frameworks, strengths, limitations, and future directions of medical device safety monitoring systems globally and in emerging contexts like India. Medical device-associated adverse events (MDAEs) range from malfunctions, breakages, infections, and perforations to severe outcomes such as organ injury, surgical interventions, or death. Effective materiovigilance enables timely recalls of defective devices, informs design improvements, evaluates risk-benefit profiles, and alerts stakeholders to counterfeit or substandard products. Globally, established systems such as the U.S. FDA's Medical Device Reporting (MDR), the European Union's Medical Device Regulation (MDR 2017/745), and frameworks in Japan, Australia, and Canada emphasize mandatory reporting, post-market surveillance, risk management and international harmonization through bodies like the International Medical Device Regulators Forum (IMDRF). These systems benefit from robust enforcement, proactive data analysis and integration of advanced technologies including AI and machine learning for signal detection and real-time monitoring.

Key Words: Materiovigilance, Medical Devices, Medical Device Associated Adverse Events

I. 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 Monitoring the safety of these devices enables dangerous devices to be withdrawn from the market and to eliminate faults in medical devices with the intention to constantly improve the quality of the devices and providing patients and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. 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 center for priority medical devices and health technology policy in the National Health Systems Resources Centre**.** The diagrammatic representation of the partners of the Materiovigilance Programme of India is mentioned in the Figure 1[1,2]

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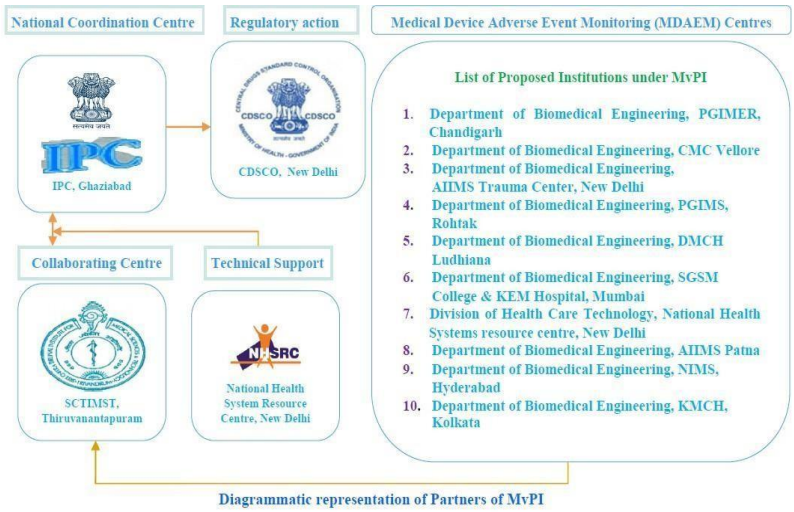

Figure 1: Diagrammatic representation of the partners of the Materiovigilance Programme of India.

Sree Chitra Institute for Medical Sciences and Technology (SCTIMST) operates as National Collaborating Centre. Central Drug Standard Control Organisation‟ (CDSCO) is a regulator of MvPI and Technical support is rendered by National Health System Resource Centre (NHSRC). Twenty-six Medical Device Monitoring Centres (MDMCs)/ Adverse Drug Reaction Monitoring Centres (AMCs) has been setup for checking completeness of a case scrutinizing the MDAE reports and sending reports to NCC. [3] The communication channel of this program is shown as a flow diagram in Figure 2.

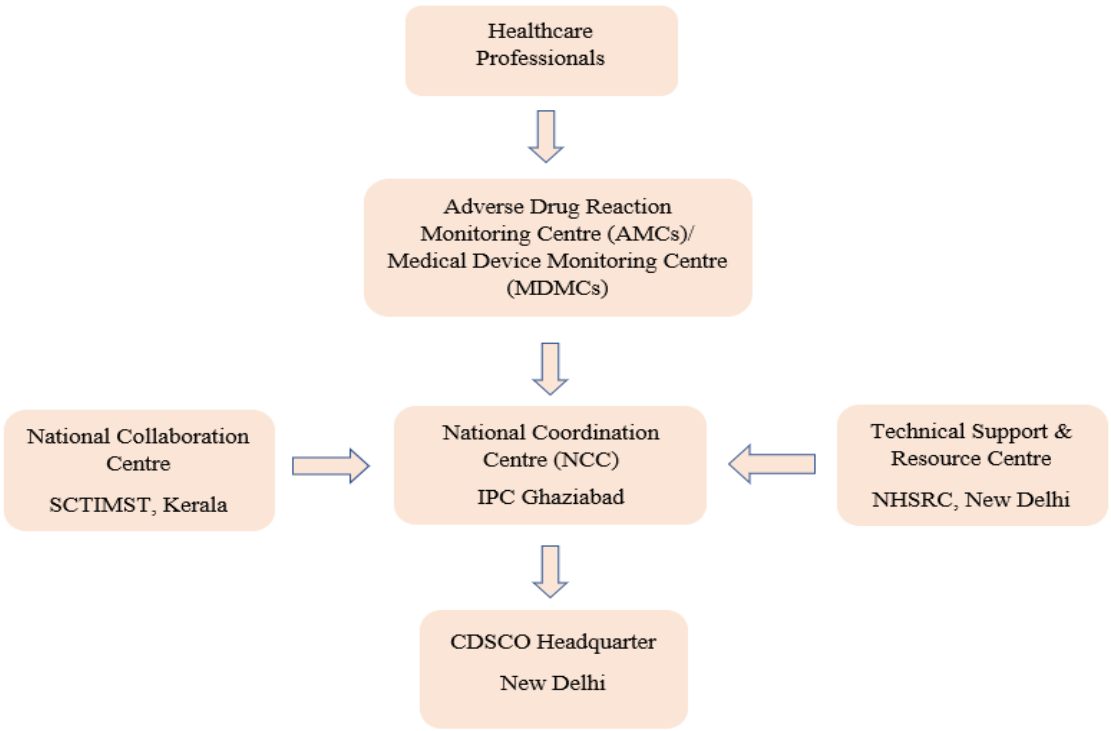

Figure 2 Communication Channel of MvPI [4]

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II. OBJECTIVES OF MATERIOVIGILANCE PROGRAMME [3]

1) Establish and implement nation wise system for the vigilance in India on medical device associated adverse events.
2) Analyze causality assessment/ benefit-risk ratio of medical device.
3) Aid decision-making process of regulatory agencies.
4) Generate safety information and medical device alarm to regulator/healthcare experts.
5) Convey safety information on medical device use to different stakeholders to limit hazard.
6) Work together with other national healthcare organizations for trade of data management and other information.
7) Develop as national center for Materiovigilance activities.

Adverse Event Reporting
MDAE are recorded through adverse event reporting system. It is an important tool to improve well-being of patients and medical device users by reducing occurrence of adverse events. Recorded incidents are evaluated and information is disseminated to avoid or mitigate the outcome of such repetitions.

Classification of adverse event on basis of severity
Adverse events are classified into three categories on the basis of severity- Death of patient or device user, Serious injury including life-threatening disease, congenital abnormality/ irreversible impairment, permanent destruction of a body function and Near Miss Event. [3,4]

REPORTING CRITERIA FOR ADVERSE EVENTS NOTICED

When manufacturer becomes aware of an adverse event related with their device – Manufacturers initiate root cause of failure and intimate IPC-NCC once they become aware of event. IPC-NCC would send this information to the research associate located at nearest MDMC.

When healthcare service- provider notice an event or incident– The information's will be passed to the research associate at MDMC and further root cause analysis of event is carried out by committee. Experts like biomedical/clinical engineers, research associate at MDMC, healthcare professional and technician handling device are part of the committee. [4]

Non-reportable Incident
1) If side effect associated with medical devices are predictable by the manufacturer's labelling, documented with proper risk assessment in the device master record and are clinically well known.
2) When the shelf-life of medical device exceeds as specified by manufacture at time of use by patient/end-user.
3) When deficiency is observed by the end user before the use of medical device.
4) When the root cause of incident is patient's pre-existing condition. [3,5]

CLASSIFICATION

Medical devices vary widely in their design, function, duration of use, and degree of invasiveness. Because not all devices pose the same level of risk to patients, regulatory authorities classify medical devices based on the potential risk associated with their use. This system is known as risk-based classification. The World Health Organization (WHO) recommends this approach, and it has been adopted by many regulatory agencies, including:

- CDSCO (India) under the Medical Devices Rules, 2017
- European Union (EU MDR 2017/745)
- US FDA
- Global Harmonization Task Force (GHTF) / IMDRF

According to this system, medical devices are classified into four categories: Class A, Class B, Class C, and Class D, where Class A represents the lowest risk and Class D the highest risk.

Class I – Low Risk Medical Devices
Class I medical devices are low-risk devices that have minimal contact with the human body and are unlikely to cause harm if they malfunction.

➢ **Characteristics**
- Non-invasive or minimally invasive
- Short-term or external use
- Do not support or sustain life

Class II – Low to Moderate Risk Medical Devices
Class II devices present a low to moderate risk and may be invasive for a short duration.

➢ **Characteristics**
- Short-term invasive device
- Used for diagnosis or temporary treatment.
- Failure may cause minor to moderate injury, but not life-threatening

Class III – Moderate to High-Risk Medical Devices

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Class III devices are moderate to high-risk medical devices that are often long-term invasive or implantable and may support or sustain life.

➢ **Characteristics**

- Long-term use inside the body
- Implantable or surgically invasive
- Failure can result in serious health deterioration or disability

Class IV – High Risk Medical Devices

Class IV devices are high-risk, life-supporting or life-sustaining medical devices.

These devices are critical for patient's survival.

➢ **Characteristics**

- Implantable and life-saving devices
- Used in critical medical conditions
- Failure can lead to death or irreversible harm

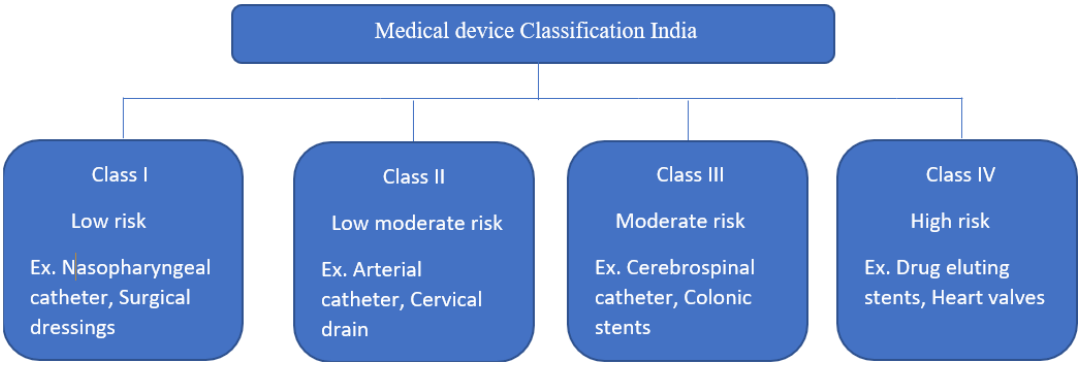

Figure 3. Medical Device Classification India [6,7]

III. MEDICAL DEVICES

DEFIBRILLATOR

Defibrillators are essential medical devices designed to restore a normal heartbeat by delivering an electric charge or current to the heart. They are primarily used in cases of sudden cardiac arrest where the heart's rhythm becomes irregular or stops entirely, such as in ventricular fibrillation or pulseless ventricular tachycardia. These devices can be life-saving when applied promptly often in combination with cardiopulmonary resuscitation (CPR).[8]

SPHYGMOMANOMETER

The sphygmomanometer is a fundamental medical device used to measure arterial blood pressure non-invasively. It consists of an inflatable cuff, a pressure gauge, and an inflation mechanism, providing readings in millimeters of mercury (mmHg) for systolic and diastolic pressures. This instrument plays a critical role in diagnosing hypertension, monitoring cardiovascular health, and guiding therapeutic interventions, making it indispensable in both clinical and home settings [9]

PATIENT MONITOR

Patient monitors are critical medical devices used in hospitals and clinical settings to continuously track and display a patient's vital signs. These systems measure parameters such as electrocardiogram (ECG), respiration rate, blood pressure, blood oxygen saturation (Spo_2), pulse rate, and body temperature. By providing real-time data, patient monitors enable healthcare professionals to detect changes in a patient's condition promptly, facilitating timely interventions in areas like intensive care units (ICUs), operating rooms and emergency departments. This technology has become

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indispensable for ensuring patient safety and improving outcomes in both acute and chronic care scenarios.

PULSE OXIMETER

Pulse oximeters are essential medical devices widely recognized as providing the "fifth vital sign" by offering a quick, non-invasive method to measure oxygen saturation in the blood. These devices shine light through tissue typically a fingertip to determine the percentage of hemoglobin saturated with oxygen, known as SpO2. In clinical settings, they help monitor patients during anesthesia, surgery and in critical care ensuring timely detection of hypoxemia. With the rise of home healthcare, consumer versions have become popular for tracking respiratory health especially in conditions like COVID-19 or chronic obstructive pulmonary disease (COPD). [10]

IV. REPORTING OF MEDICAL DEVICES 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.[11]

Who and why to report?

Healthcare clinicians, hospital technology managers, medical device manufacturer, nurses, pharmacists, technicians, clinical engineers and biomedical engineers can account medical device adverse events „(MDAEs)" and hence, safeguard public health.

Where and how to report?

Healthcare professionals (clinicians, dentists, pharmacists, nurses) and patients/consumers can report MDAEs to SCTIMST or NCC. Duly filled Medical Device Adverse Event Reporting Form can be sent to Sree Chitra Tirunal Institute of Medical Science and Technology (SCTIMST), National Collaboration Centre Materiovigilance program of India, Biomedical Technology Wing, Poojappura, Thrivananthapuram695012, Kerala, India Or Can directly email the duly filled form to mvpi@sctimst.ac.in. .[12] Medical Device Adverse Event Reporting Form [Figure 2] can be downloaded from the website of IPC (www.ipc.gov.in) to report adverse events associated with medical devices. MDAEs can also be reported via the PvPI helpline number (1800 180 3024) on weekdays from 9:00 am to 5:30 pm.[13]

Details to be filled in the form

Dully filled form can be sent to Indian Pharmacopoeial Commission or can be reported by sending e-mail to mvpi.ipcindia@gmail.com. Adverse event can also be reported by calling on Helpline no. 1800-180-3024.

General Information

Reporting Date, Type of Report
Reporter Reference for MDMC- Location, Month-Year, Centre, and case no.

Reporter Details

Type of reporters-
Manufacturer/Distributor/Importer /Healthcare professional/Patient/Others
Name, Address, Contact Number and Email id of reporter

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Device Category

1) Medical device- Invasive, non-invasive, implantable, non-implantable, sterile, non-sterile, personal use or single use device
2) In Vitro Diagnostics (IVD)- Kits, reagents, calibrator, control material, IVD electronic reader or other
Medical equipment/ machines- therapeutic, diagnostic, assistive, imaging, invasive or non-invasive

Device Information

1) Name of Device / brand name
2) Manufacturer/ importer/ distributor address and name
3) manufacturer/ importer license number
4)Model no., Batch no. and Serial no.
5)Version of software
6) UDI no. if applicable
7) Installation date
8)Year of manufacturing
9) Expiration date
10) Is device regulated in India or not
11) Nomenclature code if applicable; Global Medical Device Nomenclature (GMDN)/ Unique medical device nomenclature (UMDN)

Event Description

1) Date of event
2) Implant/ Explant date
3) Event Location-Manufacture/Distribution premise/ Home/ Hospital
4) Serious event- Death(date)/ Life threatening/ Disability/ Hospitalisation/ congenital defect or Non-serious event
5) Detailed description of event

Information Outcome and Patient History

1) hospital id
2) Name, Age, Weight and gender
3) Patient outcomes- recovery date / not yet recovered / death report

D.REGULATORY DETAILS			E. REPORTER DETAILS of MvPI CENTRE
Manufacturer name: Regulator in Country of origin: Regulatory status in origin country:	Entity legally representing the Manufacture: Country:	Notified Body name in: (I) Country of Manufacturing: (II) In India:	Name and Professional Address:_____ Pin:_____ 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: nhsrc.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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DATA MANAGEMENT SIGNAL DETECTION

There is a striking difference in signal detection as practiced in drugs and as suggested for devices. The reason: most pharmaceutical products have a single or at the most a dual Active Pharmaceutical Ingredient (API). A single device could, however, have hundreds of components, each working on a distinct technological pathway. Signal detection in medical devices could make root-cause analysis more elaborate.[14] Signal detection involves identifying patterns of adverse events associated with a particular device that warrant further investigation.

A medical device safety signal may arise from:

- a previously unrecognized safety issue
- a change in frequency or severity of a known safety issue
- identification of a new at-risk group
- use of a device other than one intended by the manufacturer

Based on the completed root cause analysis report, events/incidents would be classified as per above mentioned signals or classification of signals after discussion in core technical committee of MvPI. Signals would be used as markers for trend analysis. As soon as a safety signal has been detected, it is assessed to determine the nature, magnitude and significance of the concern and the impact on the overall benefit-risk profile of the device. The complete analysis of the signals detected has to be initiated after getting enough adverse events reports.[15]

CHALLENGES IN MATERIOGIVILANCE

As in the case of Pharmacovigilance programs, Materiovigilance also faces similar challenges to getting implemented up to the practitioners and consumer's level. The consumers and practitioners generally perceive reporting as tedious and lack awareness on the significance and procedures of reporting (e.g., what, how, where and when to report the incidents). In addition, the lack of stringent regulatory mechanisms to make the reporting mandatory makes its implementation challenging in real practice settings. The practitioners' negative perception of MDAEs reporting as if these are being directed at reporting their mistakes has also become a significant barrier. Moreover, a lack of trained reporters and conducive facilities are also hindering the successful implementation of Materiovigilance.[16] Regulatory authority's initiation in affixing the mandatory package inserts and summary product characteristics (SPC) of the devices may help tackle some hindrances implementing Materiovigilance. Underreporting of Adverse Events is one of the most common issues. Many healthcare professionals, patients, and manufacturers fail to report incidents due to lack of awareness, fear of blame or medicolegal consequences, perception that the event is minor, or belief that reporting won't lead to change.[17] Lack of awareness and inadequate training healthcare professionals often have limited knowledge about what constitutes a reportable event, how to report it or the importance of materiovigilance. Training programs are insufficient leading to low participation and gaps in knowledge, attitude, and practice (KAP. This affects timely data gathering analysis and real-time monitoring.[18]

V. CONCLUSION

Materiovigilance plays a pivotal role in ensuring the safety, performance and effectiveness of medical devices throughout their life cycle. With the rapid advancement and increasing dependence on medical devices in modern healthcare, the potential risks associated with device malfunction, misuse or design limitations cannot be overlooked. This review highlights that unlike medicines, medical devices often interact mechanically or electronically with the human body making continuous post-market surveillance essential to prevent serious adverse events and protect patient safety. The establishment of structured materiovigilance systems across the globe including robust frameworks in the United States, European Union and other developed regions has significantly improved the detection, reporting, and management of medical device–related adverse events. In India, the introduction of the Materiovigilance Programme of India (MvPI) marked an important milestone toward strengthening medical device safety monitoring. Although commendable progress has been made, challenges such as underreporting, limited awareness among healthcare professionals, lack of mandatory reporting mechanisms, and data integration gaps still hinder its full potential. It also emphasizes that effective materiovigilance is a shared responsibility involving regulators, manufacturers, healthcare professionals, and patients. Training, awareness programs, and simplified reporting systems are crucial to enhance active participation and data quality. Furthermore, emerging digital innovations such as artificial intelligence, real-time data analytics, and integrated health information systems offer promising opportunities to improve signal detection, risk

assessment, and regulatory decision-making.

In conclusion, strengthening materiovigilance systems through regulatory harmonization, technological integration, mandatory reporting, and continuous education is essential for minimizing device-related risks and improving patient outcomes. A proactive, transparent, and collaborative materiovigilance framework will not only enhance public trust but also support the safe and effective use of medical devices in an increasingly technology-driven healthcare environment

REFERENCES

[1]. Gupta, R., & Menon, V. (2025). Establishment and operational framework of the Materiovigilance Programme of India (MvPI): Roles of IPC, SCTIMST, and MoHFW. Indian Journal of Medical Device Vigilance, 11(1), 22– 36.

[2]. Rao, S., & Sharma, P. (2025). National coordination and technical support in materiovigilance: Insights from the Materiovigilance Programme of India. Journal of Healthcare Technology and Safety, 13(1), 44–58.

[3]. Guidance Document: Materiovigilance Programme of India (version 1.1) [Internet]. IPC;2009 [cited 2019 Sept 9]. Available from:

[4]. http://www.ipc.gov.in/news-highlights/574-guidance-document-materiovigilance-programme-of-india-version-1-1.html

[5]. Rani SD, Singh KD. Materiovigilance: An Emerging Discipline. Int J Sci Res. 2018 June;7(6):15–6.

[6]. . Chauhan P, Zarreen A, Iqubal Mk. Current Status of Materiovigilance Globally-an Utter Overview with Clinical Case Perusal. Int J Pharm Pharm Sci. 2019;11(10):1–8.

[7]. CDSCO. Medical Device Rule [Internet]. Ministry of Health & Family Welfare Government of India; 2017 [cited 2019 Sept 2]. Available from: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzMzNg==

[8]. CDSCO. Classification of Newly Notified Medical Devices to be updated with Classification list of Medical Devices and IVDs, Drug Controller General (India) [Internet] India: CDSCO; 2019 [cited 2019 Jul 12]. Available from:

[9]. https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDM5Ng==

[10]. Smith, J., & Lee, M. (2025). Defibrillators in cardiac arrest management: mechanisms, applications, and impacts on survival. Journal of Cardiovascular Emergency Medicine, 18(2), 115–129.

[11]. O'Brien, E., Pickering, T., & Asmar, R. (2003). The Sphygmomanometer: Blood Pressure Measurement and Devices. Journal of Hypertension, 21(5), 951–958.

[12]. Tanaka, H., & Peterson, R. (2025). Historical development, clinical significance, and global adoption of pulse oximetry in modern healthcare. Journal of Clinical Monitoring and Biomedical Instrumentation, 19(1), 41–58.

[13]. Sharma, P., & Gupta, R. (2025). Guidelines for reporting medical device-associated adverse events: Documentation, risk assessment, and regulatory considerations. Journal of Medical Device Vigilance and Patient Safety, 12(1), 33–45.

[14]. Kumar, S., & Iyer, N. (2025). Reporting mechanisms and guidelines for medical device-associated adverse events in India: Roles of healthcare professionals and consumers. Indian Journal of Medical Device Vigilance, 8(2), 56–64.

[15]. Rao, V., & Menon, A. (2025). Medical device adverse event reporting through Indian Pharmacopoeia Commission and PvPI: Guidelines and practical approaches. Journal of Pharmacovigilance and Medical Device Safety, 10(1), 41–50.

[16]. Kaur, S., & Menon, V. (2025). Signal detection, root-cause analysis, and risk assessment in medical device vigilance. Journal of Medical Device Safety and Regulatory Science, 13(2), 88–102.

[17]. Patel, R., & Sharma, L. (2025). Barriers and challenges in implementing materiovigilance programs: Awareness, perception, and reporting hurdles among healthcare professionals and consumers. Indian Journal of Medical Device Vigilance, 10(2), 67–80.

[18]. Chopra, V., & Iyer, N. (2025). Regulatory interventions and strategies to address underreporting of medical device adverse events in materiovigilance programs. Journal of Medical Device Regulation and Safety, 11(3), 122–136.

[19]. Rao, P., & Mehta, S. (2025). Knowledge, attitude, and practice gaps, and infrastructural

challenges in implementing materiovigilance programs in developing countries. International Journal of Medical Device Safety and Education, 9(2), 88–101.

[20]. Kumar, A., & Joshi, R. (2025). Role of materiovigilance in enhancing patient safety and medical device performance monitoring. Journal of Healthcare Technology and Safety, 14(1), 55–67.