

(RESEARCH ARTICLE)



## Knowledge, attitude and practice of materiovigilance among nurses and healthcare technicians in a tertiary care hospital: A questionnaire-based survey

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Open Access Research Journal of Biology and Pharmacy, 2023, 09(01), 038–044

Publication history: Received on 08 August 2023; revised on 16 October 2023; accepted on 19 October 2023

Article DOI: <https://doi.org/10.53022/oarjbp.2023.9.1.0037>

### Abstract

Materiovigilance is “the coordinated system of identification, collection, reporting, and analysis of any untoward occurrences associated with the use of medical devices. This aims to safeguard the well-being of patients by not only preventing the recurrence of these Medical Device Adverse Events but also by taking necessary actions for safety improvements or recalls of such devices. The increasing importance of evaluating the awareness and reporting practices of Medical Device Adverse Events among Indian Healthcare Professionals, the present study was conducted to assess the Knowledge, Attitude, and Practice of Materiovigilance among nurses employed in a tertiary care hospital. This study is questionnaire-based survey which is designed to evaluate the knowledge, attitude and practice of medical professionals. Our study found that nurses and healthcare technicians in a tertiary care hospital possessed adequate knowledge about different facets of Materiovigilance and maintained a positive attitude towards reporting adverse events associated with medical devices. However, we also noted that the translation of this knowledge and attitude into effective practice of reporting Medical Device Adverse Events was lacking within the participants.

**Keywords:** Knowledge; Attitude; Practice; MDAE; Materiovigilance

### 1. Introduction

Medical devices (MDs) have a significant impact on how medicine is practised, and the innovation and diversity of this industry help to improve the efficacy and quality of healthcare. MDs have a key role at diagnosis, prophylaxis, treatment, and controlling of disorders and cover a wide range of items, from straightforward bandages to life-supporting devices like stents [1]. Medical devices have enhanced the care delivery and associated outcome in treating various medical illness. Despite their advantages, the use in patients who are being treated with medical devices could suffer catastrophic side effects [2]. Although reporting adverse events involving medical devices is a crucial first step in post-market surveillance, underreporting of such events is a problem that affects the entire world [3]. There are numerous distinct ethical concerns associated with the supervision of the use of medicinal gadgets in surgical treatments [4]. The occurrence of these incidents highlights the necessity for a properly controlled framework for monitoring medical devices. Materiovigilance is “the coordinated system of identification, collection, reporting, and analysis of any untoward occurrences associated with the use of medical devices” [5]. This aims to safeguard the well-being of patients by not only preventing the recurrence of these Medical Device Adverse Events but also by taking necessary actions for safety improvements or recalls of such devices. As a positive development, in July 2015, the Materiovigilance Program of India (MvPI) was initiated under the supervision of the Indian Health Ministry, with the Indian Pharmacopoeia Commission (IPC) serving as the national coordinating center. Furthermore, the Indian government introduced the Medical Devices Rules 2017 to regulate the safe usage of medical devices within the country. In India, there has been limited exploration of Healthcare Professionals knowledge, attitude, and practice regarding Materiovigilance. The increasing importance of evaluating the awareness and reporting practices of Medical Device Adverse Events among

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Indian Healthcare Professionals, the present study was conducted to assess the Knowledge, Attitude, and Practice of Materiovigilance among nurses employed in a tertiary care hospital [6].

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## **2. Material and methods**

### **2.1. Study design and setting**

This study is questionnaire-based and involves the participation of nurses and healthcare technicians in Vivekanandha Medical Care Hospital (VMCH) which is designed to evaluate the knowledge, attitude and practice of medical professionals and the study was carried out over a period of 1 month.

### **2.2. Study tool**

#### *2.2.1. Questionnaire development*

A 19-item structured questionnaire tool was designed to assess the Knowledge, Attitude, and Practice of healthcare professionals, with all the questions centered around the Materiovigilance domain. The questionnaire's focus was on aspects such as relevant, practicable, understandable, and clear. The questionnaire was distributed among the participants, and their responses were subsequently collected and analysed [7-11].

The analysis of knowledge was carried out using a scoring system where a score of 1 was assigned for each correct response, and no points were deducted for incorrect or unanswered questions. The total knowledge score for each participant could range from 0 to 10. To classify the participants' overall knowledge level, the median knowledge score was employed. Those who scored equal to or above the median score were classified as having adequate knowledge, while those with scores below the median were categorized as having inadequate knowledge.

Attitude and Practice were assessed based on the closed-ended questions which can be answered by "Yes or No" and the attitude section was categorized as positive and negative attitude. And the total score for knowledge, attitude, and practice (minimum 0 to maximum 19) was calculated for each participant [12-17].

### **2.3. Study participants**

The study included nurses and healthcare technicians working in different departments of VMCH who voluntarily provided informed consent. Participants who were absent during the questionnaire distribution were excluded from the study.

### **2.4. Data collection**

All participants were provided with an explanation of the study's purpose, and informed consent was obtained from those who were willing to participate in the questionnaire survey. The questionnaire was then distributed to the study participants, and they were given clear instructions on how to fill it out.

### **2.5. Statistical analysis**

All the collected data were entered into a Microsoft Excel spreadsheet and were subsequently analysed using descriptive statistical methods.

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## **3. Results**

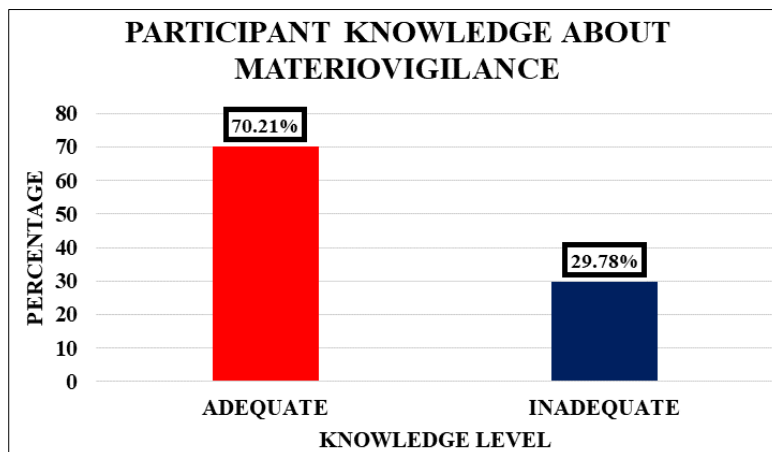
The questionnaire was distributed to 47 respondents of which 32 nurses and 15 healthcare technicians.

### **3.1. Participants knowledge about materiovigilance**

It is evident from the study that (70.21%) were aware about the Materiovigilance program to monitor MDAE. Majority of them know about the reporting of adverse effects caused by medical device and it will enhance patient safety. Only very few members weren't aware about the reporting form prepared by CDSCO for reporting the MDAE.

**Table 1** Participants Knowledge About Materiovigilance

Knowledge level	Number of participants N = 47	Percentage (%)
Adequate	33	70.21
Inadequate	14	29.78



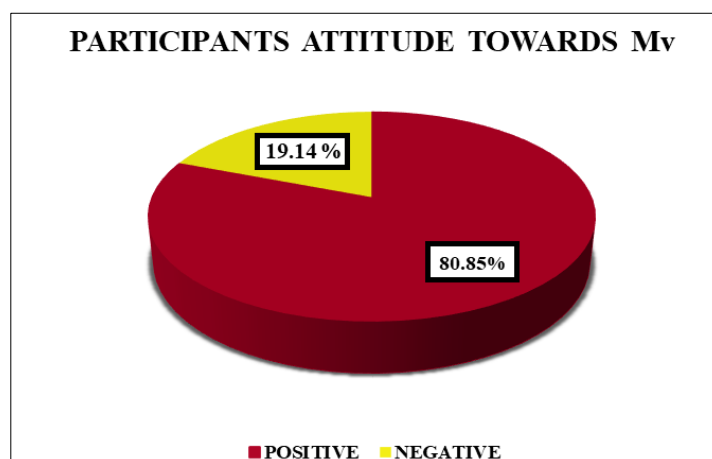
**Figure 1** Participant Knowledge About Materiovigilance

### 3.2. Participants attitude towards materiovigilance

A significant majority, accounting for 80.85% of the participants, expressed agreement with the idea that reporting Medical Device Adverse Events (MDAEs) is a professional obligation and can significantly benefit patient care. This indicates a highly positive attitude towards MDAE reporting. Conversely, only a small minority, comprising 19.14%, held a negative attitude towards MDAE reporting.

**Table 2** Participants Attitude towards Materiovigilance

Category of attitude	Number of participants n = 47	Percentage (%)
Positive	38	80.85
Negative	9	19.14



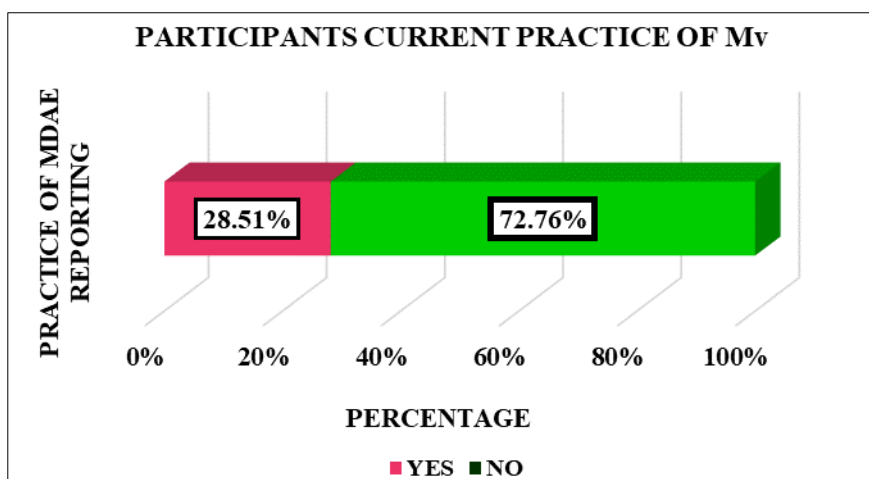
**Figure 2** Participants Attitude towards Materiovigilance

### 3.3. Participants current practice of MV

Around 72.16% of them weren't encountered occurrence any adverse events due to medical devices during their practice and haven't attended any workshops or seminars focused on the safety of medical devices. Very few (28.51%) were monitored for any untoward events from patients after the implanting of devices. Overall, the poor practice of medical device adverse event reporting was observed among all the nurses and healthcare technicians.

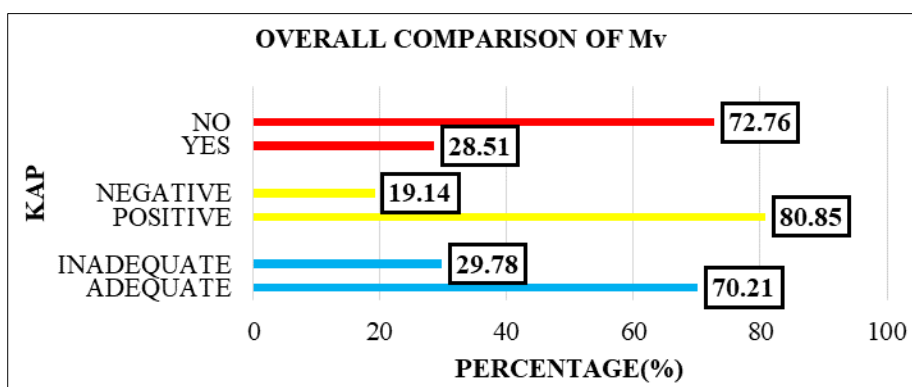
**Table 3** Participants current practice of Mv

Practice of mdae reporting	Score	Percentage (%)
Yes	67	28.51
No	171	72.76



**Figure 3** Participants current practice of Mv

### 3.4. Over-all knowledge, attitude, practice of materiovigilance among nurses and healthcare technicians



**Figure 4** Over-all Knowledge, Attitude, Practice Of Materiovigilance Among Nurses And Healthcare Technicians

## 4. Discussion

Medical devices have been integral to patient treatment for many years. However, the concept of reporting Medical Device Adverse Events (MDAEs) is relatively new in India, and there is limited information available in the public domain regarding the awareness and attitudes of medical professionals towards Materiovigilance. Despite some shortcomings in practice, the study revealed that there is adequate knowledge and a positive attitude towards MDAE reporting among the participants [18].

A significant number of participants were unaware of the current Materiovigilance Program of India (MvPI), initiated by the Indian government to monitor MDAEs. Additionally, many were uncertain about where to report MDAEs. This lack of awareness may be attributed to the fact that, unlike pharmacovigilance, Materiovigilance has yet to gain widespread attention among medical professionals. This aligns with the findings of a similar study conducted in Romania, indicating that MDAE reporting tends to be underreported in various countries.

In our study, it shows that a significant portion (70.21%) of the participants were informed about the Materiovigilance program, which is designed to oversee and manage adverse events caused by medical devices. Most of these individuals also understand that reporting such adverse events involving medical devices contributes to improving patient safety. Only a small minority of respondents were not familiar with the reporting form created by CDSCO for documenting adverse events associated with medical devices.

Pane et al. [19] have suggested that the variation in reporting practices can be attributed to several factors, including poorly defined regulatory guidelines for medical device surveillance, inadequate reporting mechanisms, and the absence of comprehensive global or national databases for collecting and analysing adverse events associated with medical devices.

In this study, the majority of respondents (80.85%) expressed agreement with the idea that reporting Medical Device Adverse Events (MDAEs) is a professional responsibility, recognizing its potential benefits for patient care. These individuals demonstrated a strong positive attitude toward MDAE reporting. Conversely, a small minority (19.14%) held a negative perspective on the matter of reporting MDAEs.

Kurien et al. [20] conducted a study that revealed a similar positive attitude towards reporting adverse events associated with medical devices. However, Gagliardi et al. reported contrasting findings, where medical professionals viewed reporting adverse events related to medical devices as unnecessary and pointless. Additionally, they did not consider it their responsibility to report such events.

In our study, approximately 72.16% of the participants did not experience any adverse events linked to medical devices during their professional practice, and they had not participated in workshops or seminars specifically addressing medical device safety. Only a small minority (28.51%) had been involved in monitoring patients for any adverse events following the implantation of devices. In general, there was a noticeable lack of adherence to proper Medical Device Adverse Event (MDAE) reporting practices among all the nurses and healthcare technicians surveyed.

The individuals in our study have very poor practices for reporting adverse events. Many of them did not report any adverse events or participate in any training programs related to reporting adverse occurrences. This can be the result of inadequate reporting procedures and awareness.

In a study conducted by Gagliardi et al. [21], medical professionals identified various barriers to the practice of Materiovigilance. These included factors such as the absence of a suitable reporting system and an environment that is not conducive to reporting.

In a study conducted by Nirmalya Manna et al. [22], they assessed the knowledge, attitude, and practice of Materiovigilance among staff nurses in a medical college setting. The study concluded that there was a deficiency in the translation of supportive knowledge and a supportive attitude into actual practice when it came to reporting Medical Device Adverse Events (MDAEs). As a result, the study recommended conducting various training programs such as workshops and Continuing Medical Education (CME) sessions, suggesting that these interventions could be beneficial in improving MDAE reporting practices among staff nurses.

*Panchal YN et al* [23], assessed that the knowledge, attitude, and practice of Materiovigilance among medical surgeons in Gujarat. Out of 156 participants, only a small number were aware of India's current program for monitoring adverse events during their medical practice. However, the majority of the participants expressed willingness to report Medical Device Adverse Events (MDAEs). The study's conclusion highlighted the need for various educational interventions and training programs to encourage and promote the reporting of adverse events induced by medical devices.

In our study by overall comparison, the participants in the study exhibited a deficiency in their ability to effectively apply their knowledge and change their attitudes towards reporting adverse events associated with medical devices into practical actions. Therefore, it is imperative to organize additional clinical workshops, seminars, and training sessions for healthcare professionals (HCPs) to promote a culture of increased reporting of adverse events linked to medical devices.

## 5. Conclusion

Our study found that nurses and healthcare technicians in a tertiary care hospital possessed adequate knowledge about different facets of Materiovigilance and maintained a positive attitude towards reporting adverse events associated with medical devices. However, we also noted that the translation of this knowledge and attitude into effective practice of reporting Medical Device Adverse Events was lacking within the participants. Therefore, there is a crucial need for additional clinical workshops, seminars, and training sessions aimed at healthcare professionals to foster a stronger reporting culture regarding adverse events linked to medical devices. This will help bridge the gap between knowledge and actual practice, ensuring better patient safety and Materiovigilance implementation.

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## Compliance with ethical standards

### *Acknowledgments*

We are very grateful to acknowledge our Principal Dr. G. Murugananthan, M. Pharm., Ph.D., and Dr. P. Sharmila Nirojini, HOD, Department of Pharmacy Practice of Swamy Vivekanandha College of Pharmacy for their Valuable suggestions and guidance for this review.

### *Disclosure of conflict of interest*

No conflict of interest to be disclosed.

### *Statement of informed consent*

Informed consent was obtained from all individual participants included in the study.

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## References

- [1] Neugebauer EA, Rath A, Antoine SL, Eikermann M, Seidel D, Koenen C, Jacobs E, Pieper D, Laville M, Pitel S, Martinho C. Specific barriers to the conduct of randomised clinical trials on medical devices. *Trials*. 2017 Dec, 18(1):1-0.
- [2] Gao X, Wen Q, Duan X, Jin W, Tang X, Zhong L, Xia S, Feng H, Zhong D. A hazard analysis of class I recalls of infusion pumps. *JMIR Human Factors*. 2019 May 3, 6(2):e10366.
- [3] Choi SJ, Nam KC, Choi S, Kim JK, Lee YK, Kwon BS. The establishment of the Korean medical device safety information monitoring center: reviewing ten years of experience. *Health Policy*. 2021 Jul 1, 125(7):941-6.
- [4] Muskens IS, Gupta S, Hulsbergen A, Moojen WA, Broekman ML. Introduction of novel medical devices in surgery: ethical challenges of current oversight and regulation. *Journal of the American College of Surgeons*. 2017 Oct 1, 225(4):558-65.
- [5] Sun J, Pan J, Jin Y, Zhang Q, Lv Y, Feng J. Establishment of a medical device adverse event management system for hospitals. *BMC Health Services Research*. 2022 Dec, 22(1):1-9.
- [6] Dhamini M, Jawahar N, Vignesh M. Materiovigilance programme of India-An overview. *Research Journal of Pharmacy and Technology*. 2021, 14(2):1137-41.
- [7] Kalaiselvan V, Tripathi SK, Prakash J. Materiovigilance programme of India: A scheme to assure cardiovascular devices safety surveillance. *Indian Heart J*. 2020, 72:316–8
- [8] Polisena J, Gagliardi A, Clifford T. How can we improve the recognition, reporting and resolution of medical device-related incidents in hospitals? A qualitative study of physicians and registered nurses *BMC Health Serv Res*. 2015, 15:220.
- [9] Sivagourounadin K, Rajendran P, Ravichandran M. Knowledge, attitude, and practice of Materiovigilance among nurses at a tertiary care hospital in South India: A cross-sectional study. *Journal of Pharmacy & BioAllied Sciences*. 2022 Jul, 14(3):162.
- [10] Abhima MB, Thomas TM, Philip S, Gopinath G. Knowledge, Attitude and Practices of Materiovigilance Among The Medical Professionals In A Tertiary Care Centre: A Cross-Sectional Study. *Int J Acad Med Pharm*. 2023, 5(4):1100-3.

- [11] Meher BR, Padhy BM, Srinivasan A, Mohanty RR. Awareness, attitude, and practice of Materiovigilance among medical professionals at a tertiary care institute of national importance: A cross-sectional study. *Perspectives in Clinical Research*. 2022 Apr, 13(2):94
- [12] Panchal YN, Vyas BM, Suthar KM, Shah KN. A study of assessing knowledge, attitude, and practice of materiovigilance among medical surgeons of Gujarat. *National Journal of Physiology, Pharmacy and Pharmacology*. 2022, 12(11):1792-7.
- [13] Manna N, Mazumdar SD, Panchanan P, Das S. A study of assessing knowledge, attitude, and practice of materiovigilance among staff nurses in Medical College and Hospital, Kolkata. *National Journal of Physiology, Pharmacy and Pharmacology*. 2023, 13(7):1584-90.
- [14] Maisel WH. Medical device regulation: An introduction for the practicing physician. *Ann Intern Med*. 2004, 140:296-302.
- [15] Thomas AN, Galvin I. Patient safety incidents associated with equipment in critical care: A review of reports to the UK National Patient Safety Agency. *Anaesthesia*. 2008, 63:1193-7.
- [16] Mohamed M, Bouafia N, Bannour W, Hellali R, Nawel Z, Asma A, et al. Medical device-vigilance in Tunisian Center Est University hospital: Knowledge, attitudes and practices of medical staff. *Antimicrob Resist Infect Control*. 2015, 4:269.
- [17] Aida K. Knowledge, attitudes and practices of dentists on medical devices: Study in the region of Dakar, Senegal *Sci J Public Health*. 2016, 4:396-400
- [18] Alsohime F, Temsah MH, Hasan G, Al-Eyadhy A, Gulman S, Issa H, et al Reporting adverse events related to medical devices: A single center experience from a tertiary academic hospital *PLoS One*. 2019, 14:e0224233.
- [19] Pane J, Coloma PM, Verhamme KM, Sturkenboom MC, Rebollo I. Evaluating the safety profile of non-active implantable medical devices compared with medicines. *Drug Saf*. 2017, 40:37-47.
- [20] Kurien S, Satapathy S, Gupta SK, Arya SK, Sharma DK. Study of reporting system for adverse events related to common medical devices at a tertiary care public sector hospital in India. *World Acad Sci Eng Technol Int J Health Med Eng*. 2014, 8:448-53
- [21] Gagliardi AR, Ducey A, Lehoux P, Turgeon T, Ross S, Trbovich P, et al. Determinants of reporting adverse medical device events: qualitative interviews with physicians about higher-risk implantable devices. *BMJ Qual Saf*. 2018, 27:190-8.
- [22] Manna N, Das S, Rahaman SS, Singh J. Knowledge, attitude, and practice on prevention of novel coronavirus infection among patients attending general out patient department in a medical college of Eastern India. *National Journal of Physiology, Pharmacy and Pharmacology*. 2022 Jan 6, 12(6):828-.
- [23] Panchal YN, Vyas BM, Suthar KM, Shah KN. A study of assessing knowledge, attitude, and practice of Materiovigilance among medical surgeons of Gujarat. *National Journal of Physiology, Pharmacy and Pharmacology*. 2022, 12(11):1792-7.