



Original Article

Knowledge, Practice and Attitude of Materiovigilance among the health care professionals in a Tertiary Care Teaching Hospital- A cross sectional observational study

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Received: 21-12-2025

Accepted: 13-01-2026

Available online: 22-01-2026

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ABSTRACT

Background: Materiovigilance Programme of India (MvPI) is functioning in India since 2015 and its primary objective is to increase awareness among Health care professionals regarding the importance of report Medical Device Adverse Events (MDAE). However MDAE are being severely under reported, in this context this study aims to evaluate the Knowledge, Attitude and Practices of HCP's so that regulatory authorities can implement strategies to foster reporting culture in HCP's.

Objective: To assess knowledge, practice and Attitude of Materiovigilance among health care professionals in a tertiary care hospital.

Methodology: A self-designed questionnaire, as a google form was distributed among HCP's working in JJM Medical College and data obtained was analysed and presented in terms of percentages.

Results: Out of 100 HCP's recruited for the study, majority of them had adequate knowledge of materiovigilance (82%) and most of them had optimistic and responsible attitude towards reporting MDAE. However, their reporting practices were not satisfactory.

Conclusion: From the findings of the present study there is an impending need for structured training programmes, hands on workshops to fill up all the gaps in knowledge of HCP's. To establish a foundation for their knowledge, incorporation of materiovigilance in curriculum can be considered. In future further studies to assess the barriers which hinder MDAE reporting can be considered, accordingly strategies can be implemented from the regulatory authorities.

Keywords: MvPI, HCP, Materiovigilance, Knowledge.

INTRODUCTION

Medical devices constitute an integral and fundamental component of modern healthcare, playing a crucial role in the diagnosis, monitoring, and treatment of wide array of medical conditions. They encompass an extensive range of products, from simple tools like bandages and syringes to advanced technologies such as heart pacemakers, coronary stents, magnetic resonance imaging machines, and healthcare software applications. The multifaceted functional capabilities of these devices have revolutionised clinical practice by enhancing diagnostic accuracy, optimizing therapeutic interventions and improving overall patient outcomes.^[1,2]

Despite the considerable benefits of medical devices in patient care, their use is accompanied by potential risks. In several instances medical devices were recalled either due to manufacturing defects or because of the morbidity and mortality observed among users.^[3-5] Therefore, it is essential to systematically evaluate and assess risks and benefits associated with medical devices throughout their development and clinical use. This objective necessitates establishment of a comprehensive monitoring and surveillance system to identify adverse events associated with the use of medical devices and prevent such events in future.^[6,7]

“Vigilance” refers to the act or state of keeping a close eye out for potential threats or problem. Materiovigilance refers to the close observation of any unfavourable changes in a medical device’s performance or characteristics. This is done by a system that can detect, gather, report, and estimate unfavourable occurrences and respond to them with field safety corrective actions or device recalls, during the postmarketing phase of a medical device. The Materiovigilance Program of India (MvPI) was initiated by the Ministry of Health and Family Welfare at Indian Pharmacopoeia Commission, Ghaziabad, Uttar Pradesh, India on July 6th 2015, and it aimed to enhance awareness and safety monitoring of medical devices in our country.^[8]

The Materiovigilance Programme of India (MvPI) was established to improve awareness among healthcare professionals (HCPs) regarding the importance of reporting medical device adverse events (MDAEs). The programme aims to promote a culture of safety and encourage systematic reporting, thereby contributing to evidence-based data on medical devices. Spontaneous reporting of MDAEs by healthcare providers and other stakeholders constitutes the foundation of an effective medical device surveillance system ^[9].

Despite the recognized importance of materiovigilance, studies from several countries have reported inadequate knowledge, attitudes, and practices related to MDAE reporting among HCPs ^[10,11,12]. Further more evidence regarding the awareness and perceptions of medical professionals towards materiovigilance in India remains limited. In this context, the present study was conducted to assess the knowledge, attitudes, and reporting practices of HCPs concerning medical device adverse event.

OBJECTIVE

To assess knowledge, practice and Attitude of Materiovigilance among health care professionals in a tertiary care hospital.

MATERIAL AND METHODS

Study design

This was a questionnaire-based cross-sectional observational study conducted among Health care professionals of Bapuji and CG hospital attached to JJM Medical College, Davanagere, Karnataka, which is a MDAE monitoring center under MvPI.

Ethical considerations

The study was conducted after getting approval from the Institutional Ethical Committee of JJM Medical College, Davanagere.

Study criteria

Inclusion Criteria: Health care professionals working in Bapuji Hospital willing to participate in the study.

Exclusion Criteria: Health care professionals not willing to participate in the study.

Data collection and Analysis

A structured questionnaire was developed by the faculties of the Department of Pharmacology. The questionnaire consists of 2 parts. Section I comprised demographic data of Health care professionals (age, gender, and Category in profession), and section II comprised questions about materiovigilance under 3 domains [knowledge, practice and Attitude]. An expert panel validated the questionnaire's validity in terms of content, highlighting the questions' relevance, clarity, and simplicity of usage. Questionnaire was pretested in a small group of 10 members later it was distributed among 100 health care professionals encompassing consultants, post graduates, interns and nurses. Google Forms were used to manage the survey questionnaire as it was user-friendly. The collected data was analysed and expressed in terms of percentages and graphs.

RESULTS

A total of 100 health care professionals participated in the study and they were chosen with due consideration so as to include multifaceted categories of health care professionals to provide broad spectrum understanding and perspective of the topic. Among 100 participants number of males (58) were slightly high compared to females (42). The table below shows age wise distribution of participants.

Table 1

Age group in years	Number
20- 30	37
31 – 40	26
41 – 50	34
51- 60	3

The study included 36 nurses, 20 interns, 30 post graduates and 14 consultants. Pie chart below depicts the distribution of participants by category in profession.

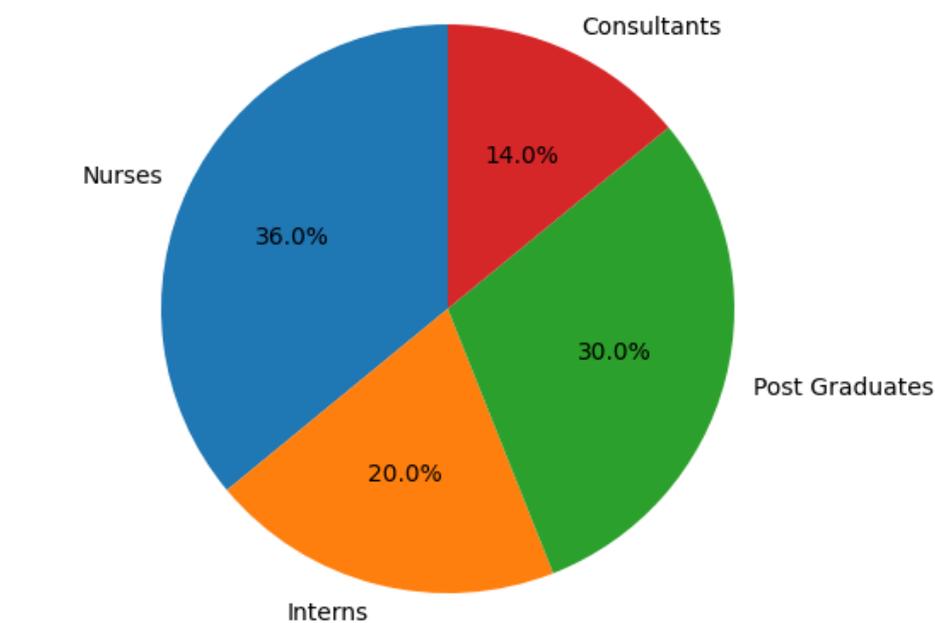


Figure 1

Knowledge:

In our study most of the participants (82%) were aware of the concept of materiovigilance and that there is an ADR reporting system to medical devices in India (77%). However, only a few of the participants had knowledge about the information required to report ADR to medical devices like, risk wise category of devices (11%), who all can report (22%) and the various ways to report (18%).

Attitude:

When we look at the attitude domain of the participants, out of 100 participants most of the health care professionals are of the opinion that reporting ADR to medical devices is necessary (94%) and many of them also agreed that reporting ADR to medical devices can enhance patient safety (97%), but majority of them were not confident that they are prepared to document an ADR to medical device (72%) in addition they feel they need training to know more about materiovigilance (86%). Very few are of the opinion that reporting can be extra burden on HCP's.

Practice:

There was a large difference observed between the attitude of participants and their practice. Less than half of them have noticed ADR to medical devices (39%) but only two consultants had reported an MDAE at our center. More than half of the participants had attended training programme in materiovigilance (68%) and the same were familiar with the MDAE reporting form. Only a handful of participants had taken part in a discussion on usage of medical device.

Table 2

Responses of the participants in Knowledge, Attitude and Practice domains

Domain	Questions	Responses	
		Yes	No
Knowledge	K 1. Do you know the meaning of Materiovigilance?	82	18
	K 2. Do you know that there exists a system to report ADR to medical devices?	77	23
	K 3. Do you know how medical devices are classified?	11	89
	K 4. Do you know who can report ADR to medical devices?	22	78
	K 5. Do you know the various ways to report ADR?	18	82
Attitude	A 1. Do you feel reporting to ADR to medical devices is necessary?	94	6
	A 2. Do you feel reporting ADR to medical devices may enhance patient safety?	97	3
	A 3. Are you prepared enough to document any ADR to medical devices?	72	28

	A 4. Do you feel it is extra burden on HCPs to report MDAE?	19	81
	A 5. Do you feel you require training to know about materiovigilance?	86	14
Practice	P 1. Did you come across ADR to medical devices in your hospital?	39	61
	P 2. Have you reported ADR to medical devices from your hospital?	2	98
	P 3. Have you participated in training programmes in materiovigilance?	68	32
	P 4. Are you familiar with the MDAE reporting form created by NCC?	68	32
	P 5. Have you ever been a part of the discussion on proper usage of any medical device?	9	91

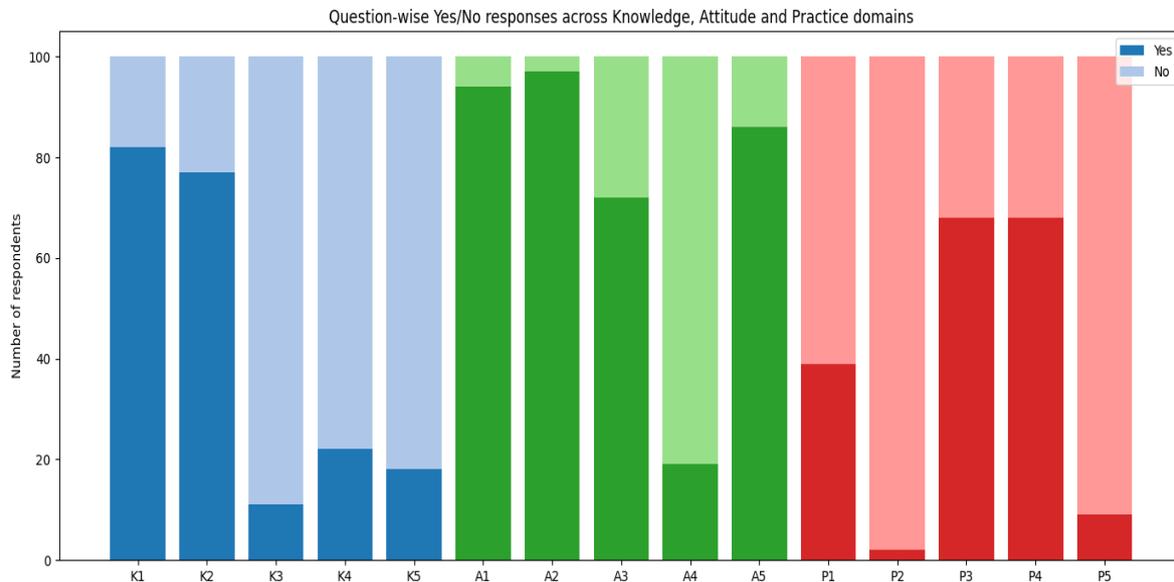


Figure 2

Bar chart representation of responses of the participants in Knowledge, Attitude and Practice domains

DISCUSSION

A comprehensive and well organised surveillance system is the cornerstone to monitor ADR to medical devices. Such a system can enhance patient safety and help maintain quality in health care system. [12-14]. One of the key objectives of MvPI is to raise awareness among HCP's on the importance of MDAE reporting. [15].

There are relatively few KAP studies done on materiovigilance compared to the number of studies on pharmacovigilance. [16] Therefore, the present study aims to analyse the recent data on knowledge, attitude and existing practices related to materiovigilance among HCP's.

In the present study, participants had limited knowledge about materiovigilance. Most Participants in our study were aware of the concept of materiovigilance and the existing system to monitor ADR to devices, which is similar to the study done by Sivagourounadin K et al. [15] whereas, in study done by Panchal YN et al., and Meher BR et al., a relatively lesser percentage of responders knew about the name of the programme [15,17,18].

The participants have shown optimistic and responsible attitude towards reporting ADR to medical devices. Most of the participants acknowledge that reporting ADR to medical devices is necessary and reporting would enhance patient safety. They don't feel that reporting is an extra burden on HCP'S but it is their responsibility to use devices safely in patients. Our results in attitude domain are consistent with study conducted by Kurien et al. [19]

More than half of participants had attended a training programme at institution level so they are familiar with MDAE reporting form, however there was severe under reporting even though many participants encountered MDAE during their clinical practice. This is consistent with the findings from previous studies conducted by Meher and Panchal et al. [17,18]

In the present study important categories of all the health care professionals were included, so the results give us a broader perspective on the topic. but the sample size was less. So, in future we require more multicentric, large scale studies on HCP'S so that results can be generalised and effective strategies can be implemented for safe use of medical devices.

CONCLUSION

From the findings of the present study there is an impending need for structured training programmes, hands on workshops to fill up all the gaps in knowledge of HCP's who are the primary point of contact between patients and medical devices. In addition impact of the training programmes should be evaluated periodically. To lay a strong base for their knowledge, incorporation of materiovigilance in curriculum can be considered. Their optimistic and responsible attitude shows their commitment towards patient safety. From further studies barriers for effective reporting can be evaluated, accordingly strategies can be implemented from the regulatory authorities.

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