Int. J. Pharm. Investigation, 2026; 16(3):961-967.
https://www.jpionline.org

Original Article

Unveiling Healthcare Professionals' Insights via Knowledge, Attitude and Practice on Materiovigilance: A Multi-Centric Prospective Interventional Study

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ABSTRACT

Background: Materiovigilance is essential for ensuring safety and efficacy of medical devices by monitoring and reporting adverse events. Despite its importance, healthcare professionals' Knowledge, Attitude, and Practice (KAP) regarding materiovigilance remain underexplored in India. This study evaluates the impact of an educational intervention on the KAP of healthcare professionals in a multi-centric setting. **Materials and Methods:** A prospective, interventional study was conducted among physicians, nurses, and pharmacists in a privately-owned tertiary healthcare facility, a public tertiary care hospital and two primary healthcare centres. A validated questionnaire assessed baseline KAP, followed by an awareness-cum-sensitization program comprising and informational leaflets. Post-intervention assessments were conducted to evaluate improvements. Data were analyzed using SPSS, with a *p*-value below 0.05 indicating statistical significance. **Results:** A total of 256 healthcare professionals participated in the study. Pre-intervention, knowledge was inadequate, with only 49.6% of physicians, 39.0% of nurses, and 46.7% of pharmacists scoring above the adequacy threshold. Attitude toward materiovigilance was positive, yet practice remained suboptimal, with low adverse event reporting. Post-intervention, knowledge scores significantly improved across all groups ($p<0.05$), with 89.9% of physicians, 80.5% of nurses, and 66.7% of pharmacists demonstrating adequate knowledge. Attitude scores also increased, though practice improvements were moderate. **Conclusion:** Educational interventions enhance knowledge and attitude toward materiovigilance, yet practice remains a challenge. Strengthening institutional support, simplifying reporting procedures, and encouraging a supportive reporting culture can increase engagement and compliance, ultimately ensuring better patient safety.

Keywords: Materiovigilance, Adverse Event Reporting, Healthcare Professionals, KAP Study, Medical Device Safety, Intervention.

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Received: 23-02-2026;
Revised: 16-04-2026;
Accepted: 06-05-2026.

INTRODUCTION

Medical devices are essential components of the healthcare system, significantly influencing patient care quality. However, they can also lead to user injuries or unintended adverse effect varying in severity from mild to severe (Bhavsar and Trivedi, 2024). Currently, over a million medical devices exist, ranging from simple items like bandages to complex technologies such as MRI machines and medical software applications (Therapeutic Goods Administration, 2024; Jefferys, 2001). According to the WHO, a medical device refers to any tool, equipment, machine, implant, *in vitro* diagnostic reagent, software, material, or related product intended by the manufacturer for medical applications, whether used independently or together. Worldwide, there are around 7,000 categories of generic medical devices and approximately 2 million unique types (World Health Organization, 2025). Identifying the growing importance of medical devices in healthcare, WHO has introduced an essential diagnostics list, similar to the essential medicines list (Meher *et al.*, 2021). Even though medical devices help patients by making Diagnosis and therapy easier, using them is not risk-free. The usage of medical devices has frequently led to illness and mortality among device users (World Health Organization, 2025; Heneghan *et al.*, 2011). In the past, certain instruments, including breast implants, pacemakers, and hip prostheses, have been recalled due to malfunctions (Meher *et al.*, 2021). With the extensive adoption of medical devices, proper monitoring of these devices and their associated adverse events is essential. Therefore, evaluating and verifying the risks and benefits at every stage of their development and use is crucial (Meher, 2018; Kalaiselvan and Saxena, 2020). Materiovigilance

DOI: 10.5530/ijpi.20260552

(Mv) involves the structured supervision as well as assessment of medical devices to evaluate its effectiveness and safety throughout their lifecycle. It plays a crucial role in post-market surveillance, ensuring patient safety (Selvam *et al.*, 2024). The Drugs Controller General of India initiated the Materiovigilance Program of India (MvPI) at the Indian Pharmacopoeia Commission (IPC), Ghaziabad, on July 6, 2015. This program primarily focuses on monitoring medical device-related adverse events, increasing awareness among healthcare professionals about the importance of reporting such incidents, and generating reliable, evidence-based safety data on medical devices to share with relevant stakeholders (Indian Pharmacopoeia Commission, 2018). The awareness, perception, and implementation (KAP) of materiovigilance among Healthcare Professionals (HCPs) in India remain insufficiently explored despite the establishment of the Materiovigilance Programme of India (MvPI), the underreporting of Medical Device-Related Adverse Events (MDAEs) remains a concern, primarily attributed to insufficient awareness and training among healthcare professionals (Sojitra *et al.*, 2024). Evaluating their understanding and reporting practices of Medical Device-Associated Adverse Events (MDAEs) is essential for strengthening MvPI adoption and addressing the increasing reliance on medical devices (Sivagourounadin *et al.*, 2022).

The need for assessing the KAP of healthcare professionals in materiovigilance is evident to bridge knowledge gaps, promote positive attitudes towards reporting adverse events, and enhance the overall practice of reporting MDAEs for enhanced patient security and healthcare quality.

MATERIALS AND METHODS

A multicentric, prospective, interventional study was based on a KAP questionnaire and was conducted among healthcare providers in a privately-owned tertiary healthcare facility, a public tertiary care hospital, and two primary healthcare centres. The research was commenced after obtaining approval from the "Institutional Ethics Committee" from KLE College of pharmacy, Belagavi. Participation was entirely voluntary and they were also guaranteed of data protection and confidentiality. The study population consists of physicians, nurses, and pharmacists Participants were selected from multiple hospitals and healthcare institutions.

A structured, pre-designed questionnaire was utilized as the primary data collection instrument. The questionnaire was developed by the faculty of the Department of Pharmacy Practice and content-validated by doctors from a private tertiary healthcare facility. A 5-point Likert scale was used to assess the relevance and clarity of each item during the validation process, ensuring that the questionnaire was appropriate and comprehensive for evaluating the knowledge, attitude, and practice related to materiovigilance among healthcare professionals. The internal consistency of the validated KAP questionnaire was assessed using Cronbach's alpha coefficient. The overall reliability of the tool was confirmed through strong internal consistency values across all domains. Specifically, the knowledge section demonstrated a Cronbach's alpha of 0.90, indicating excellent reliability. The attitude section showed a value of 0.70, reflecting acceptable consistency, while the practice section also achieved a high reliability score of 0.90. These results validate the robustness and consistency of the questionnaire in effectively assessing the knowledge, attitude, and practice of healthcare professionals regarding materiovigilance. The tool included sections on demographic information along with questions addressing the participants' Knowledge, Attitude, and Practice (KAP) regarding materiovigilance. It comprised 6 questions on knowledge, 7 questions on attitude, and 7 questions on practice. The validated questionnaire was shared with participants through Google Forms, and informed consent was obtained prior to participation.

After the baseline (pre-intervention) data collection, an educational intervention was administered through the distribution of an informative leaflet. The leaflet provided essential information on materiovigilance, its significance, and procedures for reporting adverse events related to medical devices, aiming to improve awareness and reporting behaviour among healthcare professionals.

A one-month interval was maintained between the pre- and post-intervention assessments to evaluate the impact of the educational intervention on KAP scores.

A structured scoring approach was employed to assess knowledge, assigning grade of 1 for individual correct response and 0 for incorrect ones. Attitude and practice were measured through closed-ended questions with simple "yes" or "no" choices. This evaluation method was implemented for both pre- and post-intervention assessments.

The mean scores for KAP were calculated and analyzed among the groups in both intervention assessments. Participants who scored at or above the mean were considered to have sufficient knowledge, a suitable attitude, and proper practice, whereas those with scores below the mean were classified as having insufficient knowledge, an unsatisfactory attitude, and inadequate practice.

This study did not involve the administration of any investigational product or clinical trial procedures and was therefore not registered with a clinical trial registry. However, it was conducted in accordance with the ethical guidelines outlined by the Institutional Ethics Committee of KLE College of Pharmacy, Belagavi, and adhered to all applicable ethical standards for observational and interventional educational research.

Confounding factors such as years of experience and prior exposure to materiovigilance were not considered in the current

analysis. The focus of this study was to assess the overall impact of the educational intervention on the KAP scores of healthcare professionals as a group.

Statistical Analysis

The compiled data were processed and examined using "IBM SPSS Statistics software (version 20)". Descriptive statistics and percentage analysis were applied to categorical variables, while the chi-square test was used to determine significant differences among the samples. A *p*-value of less than 0.05 was considered statistically significant. Additionally, a comparative analysis before and after intervention data was conducted to evaluate the impact of the intervention.

Sample size calculation was based on previous similar KAP studies in India, with an anticipated moderate effect size and 95% confidence level, yielding a minimum sample of 240 participants. A total of 256 HCPs participated, meeting the required threshold.

RESULTS

In total 256 healthcare professionals enrolled in this study, comprising 129 physicians (50.4%), 82 nurses (32.0%), and 45 pharmacists (17.6%). The majority of participants (47.7%) were below 30 years of age, while 40.6% were in 31- 40 age group, and 11.7% were above 40 years. The gender distribution was nearly equal, including 130 males (50.8%) and 126 females (49.2%). Participants were recruited from a private tertiary healthcare facility, a public tertiary care hospital, and two primary healthcare centres.

Knowledge-based responses indicated limited baseline awareness. Only 67.4% of physicians, 37.8% of nurses, and 53.3% of pharmacists correctly identified the definition of materiovigilance. Post-intervention, these figures rose significantly to 87.6%, 65.9%, and 71.1% respectively, indicating improved conceptual understanding across all groups. Similarly, the percentage of participants correctly identifying the main aim of materiovigilance rose significantly among physicians (from 51.2% to 76.0%) and nurses (from 45.1% to 74.4%) post-intervention (p=0.027). However, understanding of roles in reporting and mechanisms contributing to public health saw only modest, non-significant increases (Table 1).

Attitudinal assessment showed that most participants already held a positive outlook towards materiovigilance. Prior to the intervention, 89.9% of physicians, 79.3% of nurses, and 93.3% of pharmacists believed it should be taught thoroughly to healthcare professionals, which increased post-intervention to 94.6%, 89.0%, and 95.6% respectively. One of the more significant changes was observed in satisfaction with the current Adverse Event (AE) reporting system, particularly among nurses, where satisfaction rose from 30.5% to 56.1% (p=0.001). Confidence in the role of

Table 1: Knowledge-based correct responses from physicians, nurses, and pharmacists regarding materiovigilance, assessed before and after intervention.

Knowledge based questions	"Pre-intervention"			*p*-value	"Post-intervention"			*p*-value
	Physician n (%)	Nurse n (%)	Pharmacist n (%)		Physician n (%)	Nurse n (%)	Pharmacist n (%)	
What is the meaning of materiovigilance?	87 (67.4)	31 (37.8)	21 (53.3)	0.001*	113 (87.6)	54 (65.9)	32 (71.1)	0.001*
Which program in India tracks adverse events related to medical devices?	40 (31.0)	27 (32.9)	17 (37.8)	0.707	87 (67.4)	49 (59.8)	30 (66.7)	0.502
Who is responsible for reporting adverse events in materiovigilance?	49 (38.0)	26 (31.7)	17 (37.8)	0.626	82 (63.6)	54 (65.9)	30 (66.7)	0.907
What is the main aim of materiovigilance?	66 (51.2)	37 (45.1)	17 (37.8)	0.280	98 (76.0)	61 (74.4)	25 (55.6)	0.027*
How does materiovigilance help in protecting public health?	51 (39.5)	29 (35.4)	19 (42.2)	0.720	83 (64.3)	54 (65.9)	30 (66.7)	0.951
What should be done if a medical device has a serious safety problem?	61 (47.3)	35 (42.7)	21 (46.7)	0.799	97 (75.2)	57 (69.5)	27 (60.0)	0.150

AE reporting in improving patient safety also increased slightly across all groups, though not significantly (Table 2).

In terms of practice, baseline behaviours revealed very limited engagement. Only 11.6% of physicians, 17.1% of nurses, and 8.9% of pharmacists had received training on medical device-related AE reporting. After the intervention, these figures rose to 51.9%, 42.7%, and 37.8% respectively, reflecting improved preparedness. Reporting of actual adverse events improved slightly in all groups but was not statistically significant. However, familiarity with the medical device AE reporting form increased significantly among pharmacists, from 42.2% to 77.8% (p=0.020). Additionally, the proportion of participants with a designated protocol or time for reporting increased notably, especially among pharmacists (from 31.1% to 57.8%, p=0.032) (Table 3).

A summary of adequacy levels in knowledge, attitude, and practice is presented in Table 4. Pre-intervention, only 49.6% of physicians, 39.0% of nurses, and 46.7% of pharmacists had adequate knowledge. Post-intervention, knowledge adequacy rose significantly to 89.9%, 80.5%, and 66.7%, respectively (p=0.001). Attitudinal improvement was evident, with appropriate attitudes

Table 2: Attitude-based responses from physicians, nurses, and pharmacists regarding materiovigilance, assessed before and after intervention.

Attitude based questions	Pre-intervention			*p*-value	Post-intervention			*p*-value
	Physician n (%)	Nurse n (%)	Pharmacist n (%)		Physician n (%)	Nurse n (%)	Pharmacist n (%)	
Do you think Materiovigilance Should be thoroughly taught to healthcare professionals?	116 (89.9)	65 (79.3)	42 (93.3)	0.031*	122 (94.6)	73 (89.0)	43 (95.6)	0.232
Do you think it is essential to report all medical device-related adverse events, regardless of their severity?	67 (51.9)	48 (58.5)	35 (77.8)	0.010*	95 (73.6)	65 (79.3)	39 (86.7)	0.180
Are you confident that reporting adverse events helps in enhancing patient safety?	87 (67.4)	50 (61.0)	28 (62.2)	0.596	102 (79.1)	63 (76.8)	36 (80.0)	0.896
Do you consider reporting adverse events to be an unnecessary task?	22 (17.1))	24(29.3)	14 (31.1)	0.051	10 (7.8)	13 (15.9)	7 (15.6)	0.138
Do you believe that regular training on materiovigilance is necessary for healthcare professionals?	111 (86.0)	61(74.4)	40 (88.9)	0.045*	120 (93.0)	72 (87.8)	42 (93.3)	0.396
Are you satisfied with the current adverse event reporting system in your workplace?	38 (29.5)	25 (30.5)	14 (31.1)	0.974	38 (29.5)	46 (56.1)	18 (40.0)	0.001*
Do you think it is important to establish MDAE reporting canter in every hospital?	112 (86.8)	61 (74.4)	38 (84.4)	0.064	119 (92.2)	73 (89.0)	42 (93.3)	0.631

Table 3: Practice-based responses from physicians, nurses, and pharmacists regarding materiovigilance, assessed before and after intervention.

Practice based questions	Pre-intervention			*p*-value	Post-intervention			*p*-value
	Physician n (%)	Nurse n (%)	Pharmacist n (%)		Physician n (%)	Nurse n (%)	Pharmacist n (%)	
Have you ever received training on reporting adverse events associated with medical devices?	15 (11.6)	14 (17.1)	4 (8.9)	0.350	67 (51.9)	35 (42.7)	17 (37.8)	0.184
Have you ever reported a medical device-associated adverse event?	21 (16.3)	15 (18.3)	6 (13.3)	0.769	47 (36.4)	28 (34.1)	18 (40.0)	0.806
Do you record medical device-associated adverse event in patient records?	24 (18.6)	16 (19.5)	8 (17.8)	0.970	24 (18.6)	25 (30.5)	14 (31.1)	0.080
Do you report adverse events even if they do not result in patient harm?	26 (20.2)	17 (20.7)	13 (28.9)	0.454	52 (40.3)	31 (37.8)	25 (55.6)	0.127
Have you ever come across the medical device adverse event reporting form?	46 (35.7)	27 (32.9)	19 (42.2)	0.577	89 (69.0)	45 (54.9)	35 (77.8)	0.020*
Do you believe that reporting adverse events is part of your professional responsibility?	118 (91.5)	65 (79.3)	36 (80.0)	0.025*	123 (95.3)	72 (87.8)	42 (93.3)	0.123
Do you have a designated time or protocol for reviewing and reporting adverse events?	29 (22.5)	22 (26.8)	14 (31.1)	0.486	47 (36.4)	39 (47.6)	26 (57.8)	0.032*

rising to 79.1% in physicians, 75.6% in nurses, and 64.4% in pharmacists, although the change was not statistically significant (p=0.146). In terms of practice, pharmacists showed the greatest improvement, increasing from 35.6% to 64.4%, contributing to an overall significant difference across groups (p=0.022) (Table 4).

In summary, the educational intervention had a significant impact on improving knowledge and practice among healthcare professionals. While attitudes were generally positive at baseline and showed limited statistical change, key improvements in awareness, procedural knowledge, and actual reporting behaviours suggest the intervention's practical value in enhancing materiovigilance participation (Tables 1-4).

DISCUSSION

This study highlights significant gaps in the Knowledge, Attitude, and Practice (KAP) of Healthcare Professionals (HCPs) concerning materiovigilance and the reporting of Medical Device-Associated Adverse Events (MDAEs). Despite participants demonstrating adequate knowledge and a generally positive attitude, these strengths did not translate into effective reporting practices. This disconnect underscores the ongoing

Table 4: Level of adequacy in knowledge, attitude, and practice from physicians, nurses, and pharmacists regarding materiovigilance.

		Pre-intervention			Post-intervention		
		Groups			Groups		
		Physician *n (%)*	Nurse *n (%)*	Pharmacist *n (%)*	Physician *n (%)*	Nurse *n (%)*	Pharmacist *n (%)*
Knowledge	Adequate	64 (49.6)	32 (39.0)	21 (46.7)	116 (89.9)	66 (80.5)	30 (66.7)
	Inadequate	65 (50.40)	50 (61.0)	24 (53.3)	13 (10.1)	16 (19.5)	15 (33.3)
Attitude	Appropriate	70 (54.3)	50 (61.0)	20 (44.4)	102 (79.1)	62 (75.6)	29 (64.4)
	Inappropriate	59 (45.7)	32 (39.0)	25 (55.6)	27 (20.9)	20 (24.4)	16 (35.6)
Practice	Appropriate	44 (34.1)	28 (34.1)	16 (35.6)	56 (43.4)	33 (40.2)	29 (64.4)
	Inappropriate	85 (65.9)	54 (65.9)	29 (64.4)	73 (56.6)	49 (59.8)	16 (35.6)

issue of underreporting, even after the implementation of the Materiovigilance Programme of India (MvPI).

Findings from this study are consistent with those of prior research. For instance, while many nursing professionals reported being aware of MvPI, actual reporting behaviour remained minimal (Selvam *et al.*, 2024). This suggests that awareness alone is insufficient to drive meaningful engagement with the reporting system. Similarly, in the current study, although a majority of respondents acknowledged the importance of materiovigilance, only a small fraction had reported an MDAE.

Multiple barriers may contribute to this disparity between knowledge and practice. Concerns about legal implications, confusion regarding reporting procedures, and lack of institutional support have all been identified as deterrents in previous literature (Meher *et al.*, 2021; Kaur *et al.*, 2024). These findings are mirrored in the present study, indicating that such challenges persist across various healthcare settings.

Institutional infrastructure and continuous professional development play a crucial role in enhancing reporting practices. Studies conducted in facilities with established MDAE monitoring centres and routine training programs have shown improved adherence to materiovigilance protocols and higher reporting rates (Meher, 2018; Sojitra *et al.*, 2024). These results underscore the value of systematic training and robust institutional backing.

Simplifying the reporting process and establishing clear policy guidelines are also essential. The current study, consistent with earlier research, advocates for streamlined procedures and transparent regulatory frameworks to facilitate reporting (Jefferys, 2001; Modi *et al.*, 2023). Additionally, implementing effective feedback mechanisms could help reinforce the value of reporting by showing how submitted data contributes to patient safety improvements.

Targeted educational interventions have proven effective in enhancing HCPs' understanding and participation in pharmacovigilance and materiovigilance activities. Studies have documented significant improvements following structured training, emphasizing the importance of integrating such initiatives into routine professional development (Panneerselvam *et al.*, 2021).

A consistent theme across this and previous studies is that simply establishing a national program like MvPI is not sufficient. Success depends on fostering a culture of active participation, institutional encouragement, and providing a non-punitive environment that supports transparent and proactive reporting.

In summary, while HCPs in this study displayed a sound foundational understanding and a positive disposition toward materiovigilance, there remains a critical need to bridge the gap between knowledge and practice. Addressing the identified barriers through ongoing education, streamlined systems, legal protection, and institutional reinforcement is essential to strengthen materiovigilance efforts and ensure safer healthcare delivery.

CONCLUSION

This study highlights the positive impact of educational interventions on improving the knowledge and attitude of healthcare professionals toward materiovigilance. While significant gains were observed in knowledge and attitude across all professional groups, the improvement in actual reporting practices remained moderate. These findings emphasize the need for continuous training, simplified reporting mechanisms, and institutional support to encourage active participation in materiovigilance. Strengthening regulatory frameworks and fostering a culture of non-punitive reporting could further enhance compliance and ensure better monitoring of medical device-associated adverse events, ultimately improving Patient well-being.

ACKNOWLEDGEMENT

We sincerely thank KLE College of Pharmacy, Belagavi, and KLE Academy of Higher Education and Research (KAHER) for their support. We extend our gratitude to the Human Institutional Ethics Committee for approval and oversight. We appreciate

the contributions of healthcare professionals, including physicians, nurses, and pharmacists, as well as the Government (BIMS) hospital and primary healthcare centres in Belagavi that facilitated data collection and intervention. Special thanks to faculty members of Department of Pharmacy Practice, KLE College of Pharmacy, Belagavi, for their guidance in questionnaire validation and statistical analysis.

ABBREVIATIONS

KAP: Knowledge, Attitude; and Practice; **Mv:** Materiovigilance; **MvPI:** Materiovigilance Program of India; **IPC:** Indian Pharmacopoeia Commission; **HCPs:** Healthcare Professionals; **MDAEs:** Medical Device-Associated Adverse Events; **WHO:** World Health Organization; **SPSS:** Statistical Package for the Social Sciences.

CONFLICT OF INTEREST

The authors declare no conflicts of interest regarding this research, authorship, and publication.

ETHICAL APPROVAL

This study was approved by the Human Institutional Ethics Committee of KLE College of Pharmacy, Belagavi (Ref No. KLECOPBGMEC/DO17-2024). Participant confidentiality was strictly maintained.

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Cite this article: Mahabasha S, Wali S, Reddy MS. Unveiling Healthcare Professionals' Insights via Knowledge, Attitude and Practice on Materiovigilance: A Multi-Centric Prospective Interventional Study. Int. J. Pharm. Investigation. 2026;16(3):961-7.