

**Perspectives on Materiovigilance Among Nurses in a Tertiary Care Hospital: A Cross-Sectional Study****Pradnya Deolekar<sup>1</sup>, Kavitha VD<sup>1</sup>, Sandesh Deolekar<sup>2</sup>, Akash Sinha<sup>1</sup>, Atharva Dahibhate<sup>1</sup>, Prateek DT<sup>1</sup>, Yuvraj Sawant<sup>3</sup>, Nidhi Hrishikesh Vadhavekar<sup>4</sup>, Keshav Agrawal<sup>5</sup>, Arushi Dayal<sup>3</sup>, Jasmit Kaur Puri<sup>6</sup>**<sup>1</sup>Department of Pharmacology, D.Y.Patil Medical College and Hospital, Navi Mumbai<sup>2</sup>Department of General Surgery, D.Y.Patil Medical College and Hospital, Navi Mumbai<sup>3</sup>IIIrd year MBBS student, D.Y.Patil Medical College and Hospital, Navi Mumbai<sup>4</sup>Intern, D.Y.Patil Medical College and Hospital, Navi Mumbai<sup>5</sup>IIInd year MBBS student, D.Y.Patil Medical College and Hospital, Navi Mumbai<sup>6</sup>Final year MBBS Student, D.Y.Patil Medical College and Hospital, Navi Mumbai**Corresponding Author****Kavitha VD**Department of Pharmacology,  
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Attribution 4.0 International License.**ABSTRACT****Objective:** Medical devices are essential in healthcare, but their increasing use has led to a rise in reported adverse effects globally. This study aims to assess nurses' awareness and behavior regarding MDAE reporting, identify training gaps, and improve reporting practices. By evaluating knowledge, attitude, and practice, the study aims to guide targeted interventions to enhance reporting and improve patient safety.**Methods:** A cross-sectional questionnaire-based study was conducted among nurses at a tertiary care teaching hospital from May to July 2023. The final 21-question questionnaire included sections on personal details and consent, knowledge of MV (10 questions), attitude toward MV (5 questions), and practice (5 questions). The survey was distributed via Google Form, and responses were analyzed.**Results:** Of 500 nurses, 419 responded (83.8% response rate), with 75% female and a mean age of  $38.72 \pm 7.1$  years. Most nurses (83-86%) correctly identified medical devices, but knowledge of India's adverse event monitoring program was lower (61-65%), with overall basic knowledge at 73.16%. While 71-80% believed medical devices could cause adverse events and supported reporting (70-78%), only 5% reported MDAEs. Despite 93% receiving training, the reporting rate was low. Senior Nursing Officers had the highest scores in knowledge, attitude, and practice.**Conclusion:** While nurses demonstrated awareness of medical devices and adverse events, the low MDAE reporting rate points to a gap in practice. Despite training, underreporting remains an issue. However, the positive attitude and willingness to participate in Materiovigilance workshops, particularly among Senior Nursing Officers, indicate a proactive approach that, with further reinforcement, could improve MDAE reporting and enhance patient safety.**Keywords:** Adverse reactions, Materiovigilance program of India, Medical devices.**INTRODUCTION**

Medical devices play a vital role in the diagnosis, monitoring, and management of different diseases.<sup>1</sup> A medical device is defined as any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article used for the diagnosis, prevention, treatment, or alleviation of disease.<sup>2</sup> Medical devices can range from simple cotton bandage or syringe to heart pacemakers, coronary stents as well as complex instruments such as magnetic resonance imaging and software application.<sup>3</sup>

Although medical devices benefit the patients by facilitating the diagnosis and management, the use of it is not entirely risk-free. Many times, medical devices use has caused morbidity and mortality in the device users.<sup>4</sup> It becomes essential to assess the risks and benefits during the premarketing development of the device as well as during its use through a robust-reporting mechanism.

Materiovigilance is defined as the activities involving detection, collection, assessment, reporting, and prevention of any undesirable occurrences, resulting from the use of medical devices by a well-co-ordinated surveillance system. Materiovigilance Program of India (MvPI) was launched in India on July 6, 2015 to create the awareness among the health care professionals about the importance of medical device-associated adverse events (MDAE) reporting and generate independent credible evidence-based safety data of medical devices.<sup>5,6</sup> Although the program was launched

nearly 7 years ago, we found very few studies regarding the knowledge, attitude and practice of medical professionals toward Materiovigilance and factors influencing these behaviours; hence, we undertook this study.

## MATERIALS AND METHODS

This questionnaire-based cross-sectional study was conducted among nurses at a tertiary care teaching hospital from May to July 2023, following approval from the Institutional Ethics Committee (IEC BH reference No.: 2023/113). The final questionnaire consisted of 21 questions across four sections: personal details and consent, knowledge of MV (10 questions), attitude toward MV (5 questions), and practice (5 questions). The questionnaire was distributed via Google Forms through email or messaging apps, and responses were collected and analyzed. Knowledge was assessed using a scoring system, with 1 point for correct answers and no penalty for wrong answers. The mean knowledge score was calculated and compared between groups. Attitude and practice were assessed using closed-ended "yes or no" questions. Nurses from various departments of D Y Patil Medical College, Navi Mumbai, who provided written informed consent, were included in the study.

**Statistical analysis:** All the data were entered into the Microsoft Excel sheet. The data is expressed in numbers and percentages. Continuous data were expressed as mean  $\pm$  standard deviation, and categorical data was represented in proportions. Categorical data was analysed using Chi square test and comparison on scores between groups was done using Kruskal-Wallis test. A p value of  $<0.05$  was considered to be statistically significant.

## RESULTS

**Demographic characteristics** Four hundred and nineteen (419) nurses responded out of 500 contacted, providing a response rate of 83.8%. Majority of the study participants were females ( $n = 315$ , 75%) and the mean age was  $38.72 \pm 7.1$  years. About 58% ( $n = 243$ ) of them were nursing officers (NO) with a work experience of  $<10$  years, 22% ( $n=93$ ) were senior Nursing officer (SNO), and 20% ( $n= 83$ ) were assistant nursing superintendents (ANS) with a work experience of 10–20 years and more than 20 years respectively.

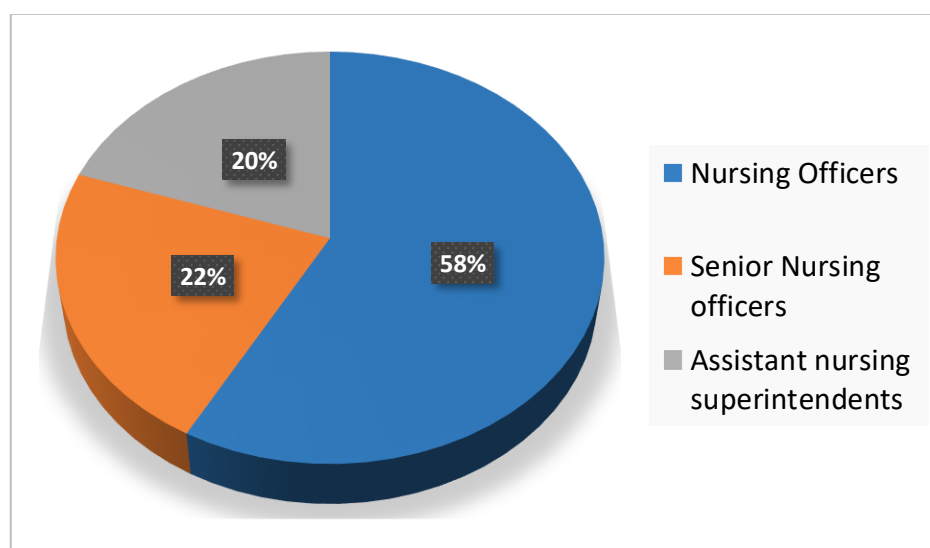


Fig. 1: Description of the study sample

**Table 1: Summary of Nurses' knowledge about Materiovigilance**

Item No.	Knowledge based questions	Response	Nursing Officers [NO] 58% (n = 243)	Senior Nursing Officers [SNO] 22% (n=93)	Assistant nursing superintendents (ANS) 20% (n= 83)	P value
1.	What do you think is an example of medical device?	Correct	203 (83.53)	80 (86.02)	71 (85.54)	0.817
		Incorrect	40 (16.46)	13 (13.97)	12 (14.45)	
2.	What is the basis of classifying medical	Correct	176 (72.42)	72 (77.41)	62 (74.69)	0.898

	devices in different categories?	Incorrect	67 (27.57)	21 (22.58)	21 (25.30)	
3.	Which of the following medical device belongs to class I?	Correct	186 (76.54)	76 (81.72)	65 (78.31)	0.589
		Incorrect	57 (23.45)	17 (18.27)	18 (21.68)	
4.	Which of the following medical device belongs to class III?	Correct	174 (71.60)	70 (75.26)	59 (71.08)	0.767
		Incorrect	69 (28.39)	23 (24.73)	24 (28.91)	
5.	India's current program for monitoring adverse events caused by medical devices is	Correct	151 (62.13)	61 (65.59)	51 (61.44)	0.810
		Incorrect	92 (37.86)	32 (34.40)	32 (38.55)	
6.	Who can report a medical device induced adverse effect?	Correct	191 (78.60)	77 (82.79)	73 (87.95)	0.155
		Incorrect	52 (21.39)	16 (17.20)	10 (12.04)	
7.	..... is the National Co-ordination centre for India's current program for monitoring adverse events caused by medical devices	Correct	153 (62.96)	63 (67.74)	51 (61.44)	0.638
		Incorrect	90 (37.03)	30 (32.25)	32 (38.55)	
8.	Which of the following event need not be reported?	Correct	154 (63.37)	65 (69.89)	63 (75.90)	0.917
		Incorrect	89 (36.62)	28 (30.10)	20 (24.09)	
9.	What is the reporting system available in India to report Medical device-induced adverse events (MDAEs)?	Correct	148 (60.90)	60 (64.51)	53 (63.85)	0.786
		Incorrect	95 (39.09)	33 (35.48)	30 (36.14)	
10.	Is it mandatory to have MV unit in every medical college?	Correct	206 (83.53)	87 (75.26)	61 (73.49)	0.001
		Incorrect	37 (15.22)	06 (6.45)	22 (26.50)	

The Chi-square test shows no significant differences in knowledge across most questions ( $p > 0.05$ ), except for the MV unit question ( $p = 0.001$ ), where nursing officers performed better. This indicates a notable knowledge gap on this topic. Table 1 highlights the knowledge of NO, SNO, and ANS regarding medical devices and safety programs. Most respondents correctly identified examples of medical devices (83.53% of NO, 86.02% of SNO, and 85.54% of ANS) and understood the classification of medical devices. However, knowledge was lower regarding India's monitoring program for adverse events, with only 62.13% of NO, 65.59% of SNO, and 61.44% of ANS answering correctly. Awareness of the National Coordination Centre and the reporting system was also limited. Overall, while basic knowledge is about 73.16% ( $n = 307$ ) there is a need for improvement in understanding reporting processes and national programs.

**Table 2: Summary of Nurses' Attitude towards Materiovigilance:**

Item No.	Attitude based questions	Response	Nursing Officers [NO] 58% (n = 243)	Senior Nursing Officers [SNO] 22% (n=93)	Assistant nursing superintendents (ANS) 20% (n= 83)	P Value
1.	Do you think medical devices can cause adverse events?	1	179 (73.66)	74 (79.56)	59 (71.08)	0.3954
		2	64 (26.33)	19 (20.43)	24 (28.91)	
2.	Do you think it is necessary to report adverse events caused by medical device usage?	1	171 (70.37)	73 (78.49)	62 (74.69)	0.3011
		2	72 (29.62)	20 (21.50)	21 (25.30)	
3.	Do you think reporting of adverse event will enhance patient safety?	1	173 (71.19)	71 (76.34)	61 (73.49)	0.6036
		2	70 (28.80)	22 (23.65)	22 (26.50)	
4.	Are you willing to report a medical device-induced	1	195 (80.24)	75 (80.64)	65 (78.31)	0.9138
		2	48 (19.75)	18 (19.35)	18 (21.68)	

	adverse event if you come across one?					
5.	Are you willing to attend workshops or training sessions related to Materiovigilance?	1	201 (82.71)	79 (84.94)	69 (83.13)	0.8858
		2	42 (17.28)	14 (15.05)	14 (16.86)	

1: Yes, 2: NO.

The responses from NO, SNO, and ANS in Table 2 show a positive attitude towards medical device-induced adverse events and Materiovigilance. Most respondents believe that medical devices can cause adverse events and agree that reporting such events is necessary. A majority also feel that reporting enhances patient safety, although 23-29% do not share this view. Furthermore, most are willing to report adverse events and attend workshops on Materiovigilance. The table's P values, all above 0.05, indicate no statistically significant differences in the attitudes of NO, SNO, and ANS. Responses to questions about medical devices causing adverse events, the need to report them, and willingness to attend workshops show similar views across the groups, suggesting consistent attitudes toward these issues.

**Table 3: Summary of Nurses' Practice about Materiovigilance:**

Item No.	Practice based questions	Response	Nursing Officers [NO] 58% (n = 243)	Senior Nursing Officers [SNO] 22% (n=93)	Assistant nursing superintendents (ANS) 20% (n= 83)	P value
1.	Have you come across any adverse event caused due to medical device during your practice?	1	112 (46.09)	67 (72.04)	03 (3.61)	0.00001
		2	131(53.90)	26 (27.95)	80 (96.38)	
2.	If yes, Have you reported it?	1	09 (3.70)	07 (7.52)	03 (3.61)	0.00001
		2	103 (42.38)	60 (64.51)	00 (0)	
3.	Have you been trained on how to report a medical device induced adverse event?	1	233 (95.88)	87 (93.54)	79 (95.18)	0.667574
		2	10 (4.11)	06 (6.45)	04 (4.81)	
4.	Have you seen the medical device adverse event reporting form prepared by CDSCO?	1	201(82.71)	79 (84.94)	38 (45.78)	0.00001
		2	42 (17.28)	14 (15.05)	45 (54.21)	
5.	Have you attended any workshop/CME focused on safety of medical device?	1	223 (91.76)	88 (94.62)	75 (90.36)	0.549267
		2	20 (8.23)	05 (5.37)	08 (9.63)	

1: Yes, 2: NO.

Table 3 shows the practice-based experiences of NO, SNO, and ANS with medical device-induced adverse events. While 46% have encountered such events, only 4% reported them. Despite over 93% receiving training, reporting remains low. Most have seen the reporting form, though familiarity is significantly lower among ANS (45.78%) compared to NO (82.71%) and SNO (84.94%). Over 90% have attended workshops or CMEs on device safety. The table highlights significant differences between the groups in encountering and reporting events, as well as familiarity with the CDSCO form (P-value = 0.00001), but no differences in training (P-value = 0.667574) or workshop attendance (P-value = 0.549267).

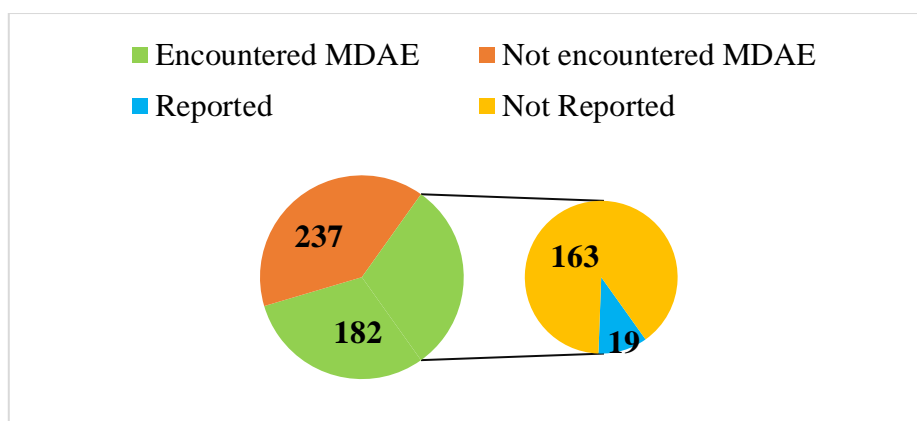


Figure 1: Pie diagram showing practice of reporting of an encountered adverse event (n=419)

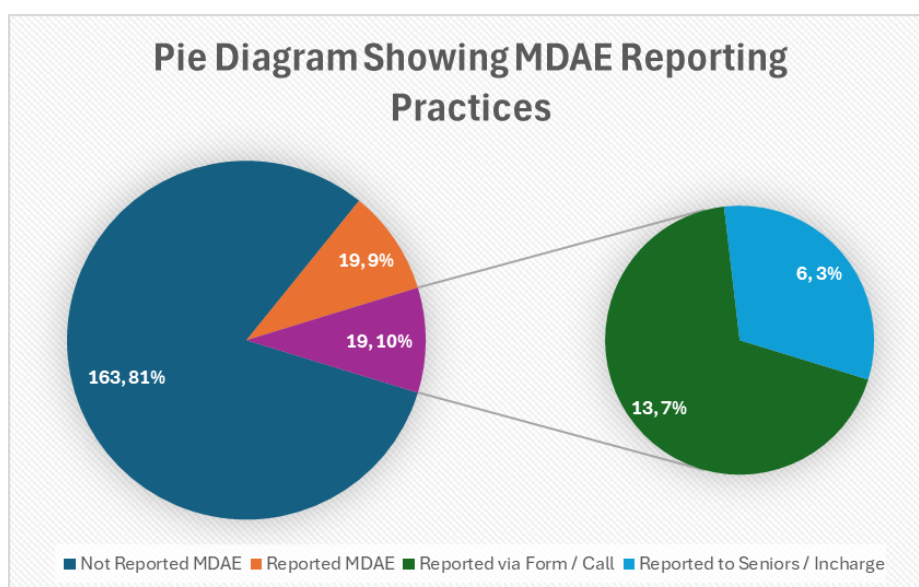
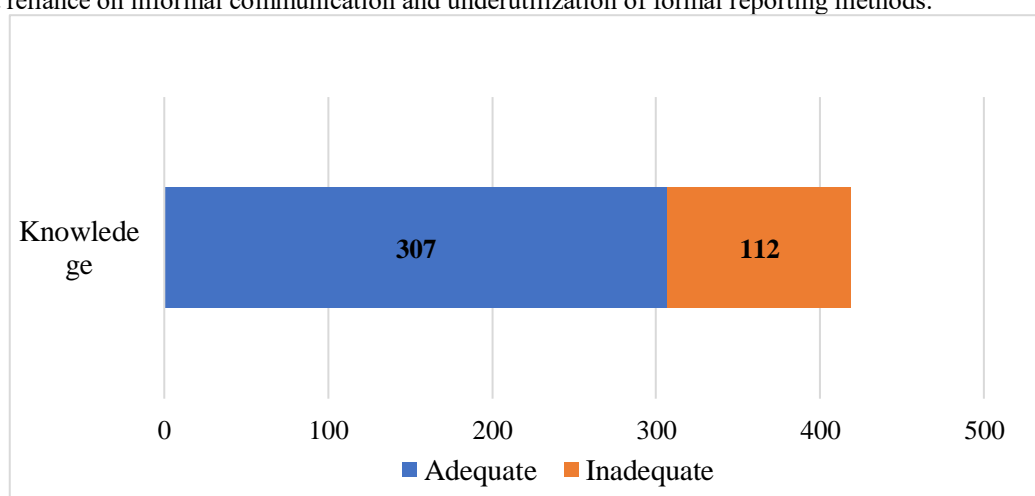


Fig no. 2 summarises that out of 182 MDAE cases encountered, only 19 (4.53%) were reported. Of these, 13 cases (3.10%) were reported through formal channels, such as using a form or making a call, indicating limited adherence to proper reporting systems. Meanwhile, 6 cases (1.43%) were reported informally to seniors or in-charge personnel, reflecting a reliance on informal communication and underutilization of formal reporting methods.



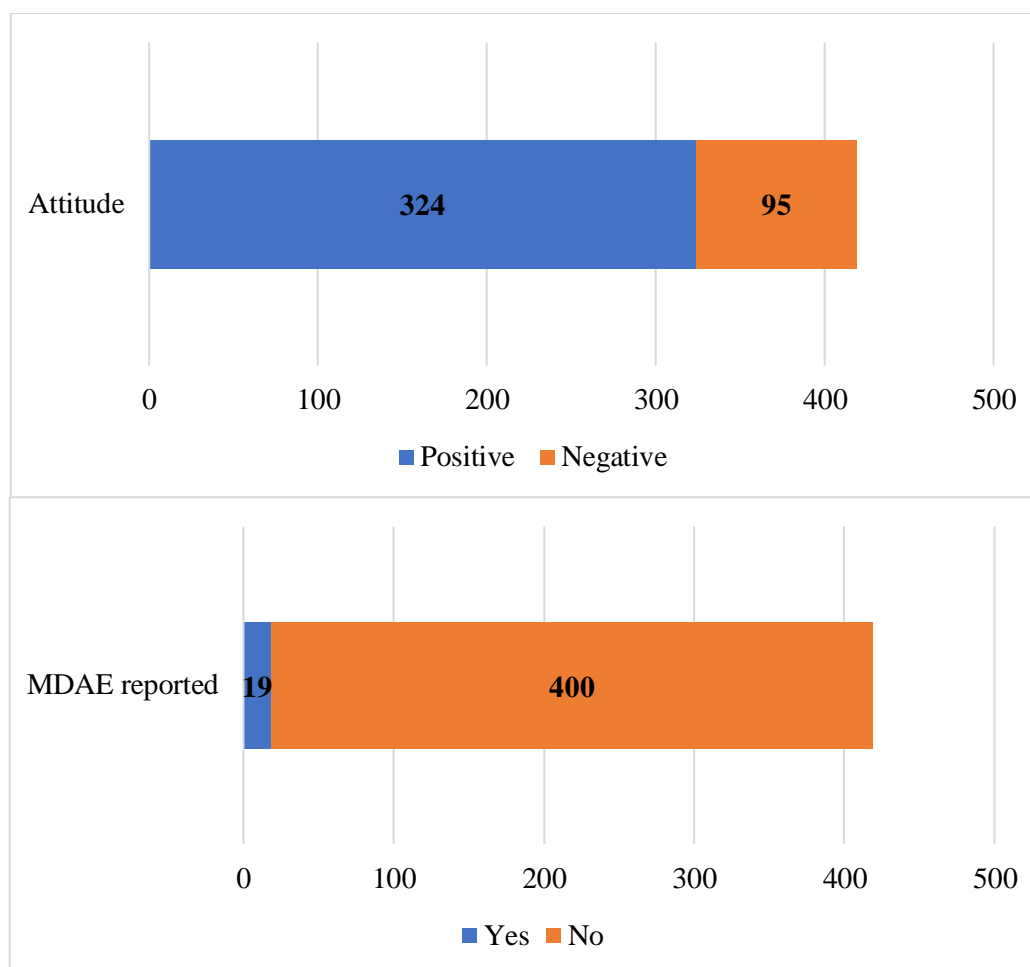


Fig:3. Overall knowledge, attitude, and practice of materiovigilance among nurses ( $n = 419$ ).

The graph shows that out of 419 individuals, 307 (73%) have adequate knowledge, while 112 (27%) have inadequate knowledge. This clear distinction highlights that the majority possess sufficient knowledge, emphasizing a potential gap that exists in the remaining population with inadequate knowledge. The graph effectively demonstrates this disparity, suggesting a need for targeted interventions or educational efforts to bridge this gap.

The graph illustrates the attitude distribution of 419 individuals, with 324 (77%) exhibiting a positive attitude and 95 (23%) showing a negative attitude. This highlights that the majority have a positive outlook, while a smaller portion demonstrates a negative attitude, reflecting an overall favorable sentiment within the group.

The graph shows that out of 419 individuals, only 19 (5%) reported MDAE, while a significant majority of 400 (95%) did not report any MDAE. This highlights a low rate of MDAE reporting, indicating that the vast majority of individuals did not experience or report such events.

**Table 4: Comparison of knowledge, attitude, and practice scores of materiovigilance among different categories of nurses**

Scores	Nursing Officers [NO] 58% (n = 243)	Senior Nursing Officers [SNO] 22% (n=93)	Assistant nursing superintendents (ANS) 20% (n= 83)	P Value
Knowledge, median (IQR)	5 (2)	5 (1)	4 (1)	0.418
Attitude, median (IQR)	7 (2)	8 (2)	7(3)	0.489
Practice, median (IQR)	1 (1)	2 (1)	1 (1)	0.107
Total Score, median (IQR)	13 (4)	15 (4)	12 (5)	0.586

\* $P < 0.05$  was considered statistically significant and calculated by the Kruskal-Wallis test. IQR: Interquartile range

Table 4 compares the knowledge, attitude, and practice scores of Materiovigilance among NO, SNO, and ANS. Senior Nursing Officers had the highest scores in all areas—knowledge (5, IQR 1), attitude (8, IQR 2), and practice (2, IQR 1)—indicating better performance and consistency. Nursing Officers showed moderate variability (total score 13, IQR 4), while Assistant Nursing Superintendents had the lowest scores, especially in practice (1, IQR 1), with a total score of 12 (IQR 5), reflecting greater variability. Smaller IQRs indicate more consistency, while larger IQRs suggest more variation.

While Senior Nursing Officers had the highest scores, on comparing the scores of all 3 groups it was found that there is no statistically significant difference between them.[P value 0.586]

**Table 5: Factors Influencing Medical Device-Associated Adverse Events Reporting**

Factors Influencing MDAE Reporting	Number of Nurses, n (419%)
<b>Encouraging factors:</b>	
Holding seminars and educational sessions on Materiovigilance within the institution	291 (69.45)
Offering specialized training programs on Materiovigilance at the workplace	189 (45.10)
Convenient and prompt access to MDAE reporting forms	159 (37.94)
Encouraging positive interaction and teamwork among healthcare personnel	197(47.01)
<b>Discouraging factors:-</b>	
Lack of guidance on what to enter and how to submit MDAE reports	192 (45.82)
Concerns about the legal procedures involved in reporting adverse events	196(46.77)
Lack of access to MDAE reporting forms when required	111 (26.49)
Reporting could increase the workload burden	115 (27.44)

Table 5. reveals that 69.45% of nurses are motivated to report MDAEs when educational sessions are conducted, and 45.10% are influenced by specialized Materiovigilance training. Easy access to reporting forms encourages 37.94%, while 47.01% value teamwork in reporting. However, 45.82% are discouraged by a lack of guidance, 46.77% by legal concerns, 26.49% by unavailability of forms, and 27.44% by increased workload. This highlights both the facilitators and barriers affecting MDAE reporting among nurses.

## DISCUSSION

Medical devices play a crucial role in patient care, but like pharmaceutical products, they carry potential risks when used or implemented. Therefore, the vigilant monitoring of medical devices for adverse events, coupled with prompt reporting, is essential for ensuring their safety. Materiovigilance, the practice of monitoring and reporting adverse events related to medical devices, is a key aspect of medical device safety surveillance. Despite its importance, under-reporting of such events remains a significant challenge. While numerous studies have assessed the knowledge, attitudes, and practices (KAP) of healthcare professionals in pharmacovigilance, there is a notable lack of KAP studies focused on materiovigilance. Recognizing this gap, we conducted this study among nurses to better understand their perspectives on materiovigilance.

The response rate observed in this study was 83.8%, which is notably higher than that reported by Meher et al.<sup>7</sup> (76%), but lower than the rate reported by Sivagourounadin et al.<sup>8</sup> (95.2%) and manna et al.<sup>9</sup> (98.69%).

In the present study, as per Fig.3. 73.16% (n = 307) of participants demonstrated an adequate level of knowledge regarding various aspects of materiovigilance. This percentage is higher than the values reported by Sivagourounadin et al.<sup>8</sup> (65.7%) and Mann et al.<sup>9</sup> (44.9%). Additionally, the majority of participants (79.73%, n = 239) in our study had a positive attitude toward MDAE reporting. A similar trend was observed in the study by Sivagourounadin et al.<sup>8</sup> (80.5%), though it was lower than the 88.10% reported by Mann et al.<sup>9</sup> and Mohamed et al.<sup>10</sup>

**According to Fig 3**, the high response rate, coupled with participants' adequate knowledge and positive attitude toward materiovigilance, highlights their active involvement and sense of responsibility as key stakeholders in the Materiovigilance Programme of India (MvPI).

There is strong consensus on the risks associated with medical devices and the importance of Materiovigilance education, reflecting a positive attitude toward patient safety and professional development. The agreement on the need for ADR monitoring centers in hospitals shows a proactive approach to safety, aligned with broader healthcare studies advocating for enhanced safety frameworks (Meher BR et al., Attri LK et al.). Table 2 further highlights these attitudes, emphasizing the need for improved safety systems and education. Additionally, while most nurses had a positive attitude toward MDAE reporting, 27.21% believed only serious events should be reported, underscoring the need for small group discussions and ongoing training to encourage reporting all MDAEs for better patient safety.<sup>12</sup>

In the current study, although 43.43% (n = 182) of nurses had encountered MDAEs in patients during their professional practice, only 4.53% (n = 19) reported these events. This result is lower than the findings observed in previous studies by Sivagourounadin et al., Alsohime et al.<sup>13</sup> but is consistent with the findings of Mann et al.<sup>9</sup>

As shown in Fig. 2, of the 4.53% of participants who reported an MDAE, 3.10% used formal methods, like submitting a form or making a call, while only 1.43% reported it to seniors. These findings align with Mann et al., who also noted a preference for formal reporting channels. While healthcare professionals recognize safety practices, actual engagement in



training and reporting is limited. Similar studies, including those by Shaik R et al.<sup>14</sup> and Kalaiselvan V et al.,<sup>15</sup> highlight barriers like time constraints, resource limitations, and lack of institutional support, which hinder practical participation. In our study, we identified key barriers to MDAE reporting, including uncertainty among healthcare professionals about the reporting process and concerns over legal repercussions, which contribute to underreporting. These challenges emphasize the need for targeted interventions, such as workshops and training, to boost awareness and encourage consistent reporting. It is also important to assess the effectiveness of these initiatives through regular evaluations of MDAE reports submitted to monitoring centers.<sup>16</sup>

The higher total KAP scores among Senior Nursing Officers (SNOs) compared to other participants can be attributed to several factors. With more years of experience, SNOs are likely to have encountered more MDAEs, providing them with valuable firsthand experience. Their increased responsibilities in patient care also require heightened vigilance about potential adverse events. Furthermore, SNOs are instrumental in implementing safety measures and preventing MDAEs, which enhances their awareness and practice. Table 4 highlights these differences in KAP scores across different groups. To enhance MDAE reporting, several strategies can be implemented. In addition to posting informative materials at nursing stations, digital reminders via mobile apps or notifications could provide real-time guidance. Sensitizing healthcare professionals (HCPs) to the availability of MDAE reporting forms on the IPC website<sup>17</sup> would streamline the process. Interactive training modules or e-learning platforms can engage HCPs, while peer-led discussions and mentorship programs can foster a reporting culture. Additionally, integrating materiovigilance into the undergraduate curriculum would promote patient safety and vigilance among future healthcare providers.

## CONCLUSIONS

This study revealed that nurses at a tertiary care teaching hospital had a strong understanding of materiovigilance and demonstrated a positive attitude toward MDAE reporting. However, there was a noticeable gap in applying this knowledge and attitude to actual MDAE reporting practices. To address these gaps and the factors influencing MDAE reporting, it is important to implement periodic workshops and training sessions for healthcare professionals to encourage more consistent and spontaneous MDAE reporting.

## Limitations of study

**Single-Center Study:** The study was conducted at a single teaching hospital in Maharashtra, which may restrict the generalizability of the results to other healthcare institutions or regions with different demographic and professional characteristics.

**Cross-Sectional Design:** The use of a cross-sectional design captures data at a single point in time, making it unable to assess changes in knowledge, attitudes, or practices over time, or to measure the impact of interventions such as training sessions.

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