

Research Paper

Materiovigilance In The Era Of Patient Safety: A Kap Study Among Healthcare Professionals

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Background: In order to guarantee patient safety, material vigilance plays a crucial role for tracking adverse occurrences associated with medical equipment. Improving reporting and preventing device-related issues require an understanding of the knowledge, attitudes, and practices (KAP) of healthcare workers.

Aim: To evaluate healthcare workers' knowledge, attitudes, and practices related to materiovigilance in a tertiary care hospital.

Methods: Using a validated self-administered questionnaire, a cross-sectional study was carried out among 232 healthcare professionals, including physicians, nurses, and pharmacists. Descriptive statistics were used to examine the data, and the Chi-square test was used to evaluate the relationship between KAP variables and demographic characteristics. Statistical significance was defined as a p-value of less than 0.05.

Results: Among the participants, **25.4%** consistently practiced reporting medical device adverse events, **93.1%** had a favorable attitude toward reporting medical device adverse occurrences, and **32.8%** showed sufficient awareness of materiovigilance. The study's conclusion emphasizes the necessity of ongoing education and training initiatives to improve reporting procedures and knowledge of materiovigilance. Patient safety and device surveillance could be enhanced by fortifying institutional regulations and streamlining reporting processes.

Keywords: Medical Device Safety, Materiovigilance, Healthcare Professionals, Knowledge, Attitude, Practice

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INTRODUCTION:

Materiovigilance envisions close monitoring of any undesirable performance or characteristic fluctuations of a medical device using a system that can identify, collect, report with an estimate of undesirable occurrences, and respond to them with field safety corrective actions or device recall(1). The Ministry of Health and Family Welfare (MoHFW), Government of India, approved the Materiovigilance Programme on July 6, 2015 at the Indian Pharmacopoeia Commission in Ghaziabad. This programme was launched in an attempt to address potential adverse events related to medical devices following a number of horrifying cases involving malfunctioning medical devices, such as infants burned to death due to short circuits in incubators or hip implants causing blood poisoning(2). The quantity, variety, and complexity of medical devices in use have all increased. The medical equipment market in India is worth more than \$1.3

billion. Numerous case reports have brought attention to the sale of a number of dangerous medical gadgets. Over 1.7 million injuries have been reported globally as a result of these dangerous devices, and over 83,000 fatalities have been documented in the past ten years(3). Ultimately, the programme's mission is to protect the Indian population's health by making sure that using medical equipment has more advantages than disadvantages. In order to support regulatory decisions and recommendations on the safe use of medical devices, the Materiovigilance Programme of India (MvPI) collects data on adverse events related to medical devices in a methodical and scientific manner. The program's objectives are to keep an eye on medical device-associated adverse events (MDAE), educate medical personnel about the significance of reporting MDAEs in India, and track the benefit-risk profile of medical devices. Additionally, it is intended to produce independent, evidence-based recommendations about

medical device safety and to share the results with all relevant parties(4).

In clinical, device-dependent departments like ophthalmology, orthopedics, cardiology, anesthesia, surgery, and interventional specialties, where medical devices are used on a daily basis, healthcare professionals' awareness of the Materiovigilance Programme of India is still low. Materiovigilance is rarely highlighted in academic lectures, clinical assignments, postgraduate training, or faculty development programs at medical institutions and corporate hospitals. As a result, both academicians and clinicians have little functional understanding. Device-related adverse events are frequently addressed clinically but never acknowledged as reportable safety data due to the lack of departmental ownership, low visibility of reporting methods, and unstructured inclusion in the curriculum, which further reduces awareness and participation(5).

Due to the intense clinical burden, lack of integration into ordinary processes, fear of blame or medico-legal ramifications, and the belief that reporting is an administrative rather than a clinical role, even in cases when awareness is restricted, it has not been implemented in practice. Unlike other patient safety domains, materiovigilance has not yet developed into a research-driven or teaching priority at academic institutions, hence KAP studies are crucial to consistently highlighting enduring gaps in knowledge, attitude, and practice. In order to guarantee that materiovigilance gets ingrained in both practice and academia, these research offer vital evidence in favor of curriculum integration, specialty-specific sensitization, and institutional policy reinforcement, especially in clinical device-intensive departments (6). In order to consistently evaluate knowledge gaps, attitudes, and practical practices, produce evidence for curriculum inclusion, and direct institutional and policy-level interventions that can normalize materiovigilance in both clinical practice and academia, more research studies—especially KAP studies and department-specific evaluations—are crucial. Hence this study was undertaken with an aim to assess the knowledge, attitude and practice of Materiovigilance among the healthcare professionals that can help demonstrate that the problem lies not only in practice but also in **persistent gaps in knowledge and attitude**, providing evidence that materiovigilance has yet to be effectively internalized by healthcare professionals.

METHODOLOGY:

This was an observational, cross-sectional, and questionnaire(KAP) based study, conducted among the healthcare professionals in a tertiary care hospital in Chennai, India, from October 2025 to December 2025. The study was initiated only after getting the approval from the Institutional Ethics Committee. A structured self-administered Google form-based questionnaire in the English language was prepared and validated by the subject expertise.

The questionnaire comprised of four sections. The first section comprised of briefing on the study; the second section was about the informed consent to take part in the study. The third section contained questions about the professional details of study participants. The last section contained a questionnaire with a total of 15 questions.

There was a total of five multiple-choice questions related to the knowledge aspect of materiovigilance. Knowledge of the study participants was assessed using a scoring system, where a score of “1” was assigned for each correct answer and a score of “0” for each incorrect answer. Moreover, there were a total of 10 questions related to attitude and practice aspect of materiovigilance with 5 questions in each. The 5 questions in attitude were with 5-point Likert scale with choices of “Strongly agree,” “Agree,” “Disagree,” and “Strongly disagree.” The 5 questions on practice were close ended and the participants has to select from “Yes” or “No” options. The sample size was calculated using the formula $n = 4pq/d^2$ for estimation of a proportion, where p is the expected prevalence, $q = 1 - p$, and d is the absolute precision. Based on previous study among healthcare professionals reporting approximately 50% awareness of materiovigilance, p was taken as 0.5. With a precision of $\pm 6.7\%$, the calculated minimum sample size was approximately 220(7)

The questionnaire was distributed to the study participants through a digital web link using social media platforms for a period of two months and their responses were collected.

Data were entered into the Microsoft Excel sheet. Statistical Package for the Social Sciences software, version 20.0 was used to carry out the statistical analysis. Categorical data were presented as numbers and percentages, while continuous data were presented as mean \pm standard deviation. Chi-square tests and Mann–Whitney U was used to assess the difference between two groups.

RESULTS: The study included a total of 232 participants. After giving the consent to participate in this study, professional details of the details was

collected. The participants from various cadres like students from allied health sciences, undergraduates of medicine, CRMIs, junior residents, post graduates, senior residents, assistant professors, associate professors, professors and HODs of various departments in the centre participated in this study. Majority of the response was from CRMIs which included 48 of 232.(20.69%). Years of experience varied from 7 months to 13 years where 52 participants had experience of 3 years(22.42%) .With respect to type of health care setting, which included teaching hospital , Government, Private, Primary care where most of them worked in Private sectors (69.1%) and Government sectors (23%).

With respect to Knowledge about 41.4% of participants are aware that a medical device-related adverse event includes any undesirable experience associated with device use. With regard to field safety corrective action (FSCA) 43.1% gave the correct option. Knowledge on under-reporting of medical device adverse events 41.1% of the participants gave the correct option. Around 37.9% is aware of the regulatory body in India that oversees medical device regulation. About 38.8% gave right response with respect to safety signal in Materiovigilance (Table 1).

from reporting device-related adverse events 40.5% gave a neutral response. This result points to a significant degree of ambiguity or ambivalence among medical professionals about the part medico-legal concerns play in deterring the reporting of adverse occurrences associated to devices. The fact that 40.5% of respondents selected a neutral response may suggest that many are either unclear about the legal ramifications, have little firsthand knowledge of medico-legal consequences, or believe that these concerns have little bearing on their reporting behavior. It could also indicate a lack of unambiguous agreement or disagreement with the statement due to uneven knowledge of reporting requirements and legal protections. This neutrality draws attention to a possible communication and education gap about medico-legal matters, reporting requirements, and protections for medical professionals. Reducing uncertainty and encouraging more consistent reporting of adverse events could be achieved by addressing this through focused training, explicit institutional policies, and assurances on legal rights. Regarding training in materiovigilance, 53.1% felt that it should be included in medical education. Furthermore, 34.5% feel that reporting minor or non-serious device related issues is

Knowledge Related Questions	Correct Response (n)	Incorrect Response (n)	p-value	Significance
1. A medical device-related adverse event includes	96	136	0.009	Statistically significant
2. A field safety corrective action (FSCA) refers to:	100	132	0.036	Statistically significant
3. Under-reporting of medical device adverse events results in:	96	136	0.009	Statistically significant
4. Which regulatory body in India ultimately oversees medical device regulation?	88	144	<0.001	Highly significant
5. A safety signal in Materiovigilance refers to:	90	142	<0.001	Highly significant

Table 1: Knowledge Related Questions

Attitude regarding reporting adverse events related to medical devices can improve patient safety and surgical outcomes, 55.2% of participants strongly agreed. About 59.9% feel that training and awareness programs can improve MDAE reporting practices. Whereas with focus to fear of medico-legal consequences discourages healthcare professionals

unnecessary. The vast majority of participants disagreed (34.5%) or strongly disagreed (27.2%) with the statement, indicating that the majority of healthcare professionals acknowledge the significance of reporting minor issues in patient safety and device surveillance and do not see them as needless (Table 2).

Attitude related questions	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	P VALUE	SIGNIFICANCE
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6.Do you believe that reporting adverse events related to medical devices can improve patient safety and surgical outcomes	1	0	15	88	128	< 0.0001	Significant
7.Do you feel that training and awareness programs can improve MDAE reporting practices?	0	0	14	79	139	< 0.0001	Significant
8.Do you think that fear of medico-legal consequences discourages healthcare professionals from reporting device-related adverse events?	0	5	94	83	50	< 0.0001	Significant
9.Do you agree that training in materiovigilance should be included in medical education?	5	3	18	83	123	< 0.0001	Significant
10.Do you feel that reporting minor or non-serious device related issues is unnecessary?	63	80	23	30	36	< 0.0001	Significant

Table2: Attitude related questions

With regard to practice ,84.5% had encountered a medical device-related adverse event in your practice. And 70.3% document and communicate device related malfunctions within your institution. About 25.4% reported a medical device adverse event to MDMC(Medical Device Adverse Event Monitoring

Centre). Around 99.1% routinely check calibration, maintenance records, and expiry dates of the equipments and consumables before use. Only 32.8% received any formal training or workshop on materiovigilance or medical device adverse event reporting (Table 3).

Practice related questions	YES	NO	P VALUE	SIGNIFICANCE
11. Have you ever encountered a medical device-related adverse event in your practice?	196	36	< 0.0001	Significant
12. Do you document and communicate device related malfunctions within your institution?	163	69	< 0.0001	Significant
13. Have you ever reported a medical device adverse event to MDMC(Medical Device Adverse Event Monitoring Centre)?	59	173	< 0.0001	Significant
14. Do you routinely check calibration, maintenance records, and expiry dates of the equipments and consumables before use?	230	2	< 0.0001	Significant

15. Have you received any formal training or workshop on materiovigilance or medical device adverse event reporting ?	76	156	< 0.0001	Significant
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Table 3: Practice related questions

Statistical Analysis: The Chi-square test was used to evaluate the relationship between formal training in materiovigilance and reporting of medical device adverse events (MDAEs) to the Materiovigilance Programme of India (MDMC).

Only 4 (2.6%) of the participants without training had reported an unpleasant occurrence, compared to 55 (72.4%) of those who had attended workshops or received formal training on materiovigilance. A highly significant correlation between formal training and reporting of MDAEs was found using the Chi-square test ($\chi^2 = 127.65$, $df = 1$, $p < 0.001$), suggesting that healthcare personnel with formal training were much more likely than those without to record adverse occurrences.

The Mann–Whitney U test was used to compare knowledge scores between trained and untrained groups. However, statistical comparison was not possible because there was no variation in the knowledge ratings. Materiovigilance attitude 87.0% of study participants believe it is their responsibility to report MDAE. Additionally, they discovered that a more thorough introduction to the topic is required (85.5%). Despite the fact that 42.5% of individuals have experienced MDAE, the majority of participants—82.5%—have never reported any MDAE. Additionally, participants discovered that a lack of accountability for the operation of medical equipment would result from the absence of MvPI (Fig. 4).

Additionally, most participants (72.0%) agreed that MDAE enhances patient safety. More education and training is needed, according to about half of the respondents (45%). Materiovigilance practices Additionally, 79.5% of participants knew that manufacturers, paramedical personnel, practitioners, and consumers can report MDAE. However, just 53% of respondents knew that their institution had MvPI systems, and only 60.5% knew about the reporting procedure.

These findings are impacted by the fact that over half of the participants, or 57.5%, had never experienced an MDAE. Additionally, the majority of responders were

young residents and nurses, therefore their years of experience in the field was limited. Factors affecting MDAE reporting It was seen from the write-in responses that the majority of participants understood the necessity of MDAE but were ignorant of its procedure. More sessions centered on the reporting system's mechanism were desired by the participants.

DISCUSSION:

This interventional cross-sectional study was conducted over two months in a tertiary care hospital. The current study identified factors impacting the reporting of medical device adverse events (MDAEs) and assessed healthcare professionals' knowledge, attitudes, and practices regarding materiovigilance. Actual reporting procedures were found to be insufficient, despite the fact that understanding of the significance of device surveillance was very satisfactory. Significant underreporting was evident in the current investigation, as only 59 out of 232 patients (25.4%) had ever reported an MDAE to the Medical Device Adverse Event Monitoring Center (MDMC). Recent studies conducted in India have shown similar low reporting rates, highlighting a persisting gap in the Materiovigilance Programme of India's implementation (8).

One important factor impacting reporting behavior was found to be formal training. Just 2.6% (4/156) of untrained participants reported an MDAE, compared to 72.4% (55/76) of participants who had attended seminars or had formal instruction in materiovigilance. This robust correlation emphasizes how important structured training programs are for improving reporting procedures. Similar results were reported by Sharma et al., who found that skilled healthcare personnel had far greater reporting rates than their untrained colleagues (9).

The majority of participants had favorable opinions about the significance of MDAE reporting despite low reporting rates, and they all agreed that reporting enhances surgical results and patient safety. This discrepancy between positive sentiments and subpar reporting practices points to the existence of behavioral and systemic hurdles, such as a lack of institutional support, ignorance of reporting procedures, and fear of medico-legal repercussions. Previous KAP research

among Indian healthcare workers have found similar obstacles (10).

One prominent issue among respondents was fear of medico-legal ramifications, which may be a factor in their unwillingness to disclose bad events associated to devices. Previous research has also emphasized the necessity for a non-punitive reporting culture by highlighting fear of blame and legal ramifications as significant barriers to vigilance reporting (11). Reporting compliance may be enhanced by addressing these issues with policy support and confidentiality assurance. Prior research using composite or weighted scoring systems has shown stronger associations with reporting behavior and improved knowledge level discriminating (12). To properly reflect differences in knowledge and competence, future research should take into account more sophisticated grading methods.

Overall, the study's conclusions are consistent with recent research in India and support the necessity of ongoing training initiatives, integrating materiovigilance into undergraduate and graduate programs, and bolstering institutional reporting systems. These steps are crucial for enhancing reporting procedures and guaranteeing patient safety through efficient medical device post-marketing surveillance.

CONCLUSION:

The majority of healthcare workers have a positive attitude and a reasonable awareness on the idea of materiovigilance, acknowledging the significance of identifying and reporting adverse medical device incidents. Despite experiencing or acknowledging such events in clinical settings, a considerable percentage of respondents reported low levels of reporting of medical device-associated adverse events, indicating that there are still significant gaps in actual practice. This gap between knowledge/attitude and practical reporting highlights enduring obstacles that prevent the Materiovigilance Programme of India (MvPI) from being implemented effectively, such as a lack of formal training, a lack of familiarity with reporting procedures, and underutilization of reporting forms. These results underline the ongoing need for focused educational initiatives, frequent training sessions, and institutional assistance to improve materiovigilance culture and encourage spontaneous reporting in Indian healthcare settings.

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