



KNOWLEDGE, ATTITUDE AND PRACTICE (KAP) OF MATERIOVIGILANCE AMONG POST-GRADUATES & INTERN IN A TERTIARY CARE HOSPITAL IN NAGPUR: A CROSS-SECTIONAL OBSERVATIONAL STUDY

¹Dr Anjali Date , ²Dr Amit P Date*, ³Dr Nirbhay Kumar,

¹Associate Professor Department of Physiology N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital, Nagpur, Maharashtra

¹Email: date.anjali63@gmail.com

²Associate Professor Department of Pharmacology N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital, Nagpur, Maharashtra

²Email: amit_date9173@yahoo.co.in

³Junior Resident II Department of Pharmacology N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital, Nagpur, Maharashtra

³Email:nirbhays464@gmail.com

***Corresponding ;**Dr Amit P Date
Mail: amit_date9173@yahoo.co.in

Abstract

Materiovigilance is crucial in-patient safety because it observes adverse outcomes concerning medical devices, but underreporting is a significant issue, especially in underdeveloped health care systems. The present study is a cross-sectional observational study that was carried out to determine the knowledge, attitude, and practice (KAP) of materiovigilance among postgraduate residents and medical interns in a tertiary care teaching hospital in Nagpur within the six months. The enrolled participants (n=302) were done so through a validated, self-administered questionnaire of sociodemographic and knowledge, attitude as well as practice domains. The statistical analysis was conducted in SPSS, through descriptive and inferential analysis. The results showed that a low percentage of the participants were well informed of materiovigilance and most of them had moderate to low knowledge especially on Materiovigilance Programme of India and reporting process. Although the overall attitude towards adverse event reporting and patient safety was mainly positive, the reality practice was poor with a substantial difference between the exposure to adverse events related to medical devices and the official reporting. Multivariate analysis revealed that previous training in materiovigilance and sufficient knowledge were significant predictors of good reporting whereas attitude alone failed to have any independent relationship with good reporting practice. The research notes that it is necessary to implement the structured training, curricular inculcation, streamlined reporting strategies, and supportive institutional policies that would reinforce materiovigilance practices and improve patient safety.

Keywords: Materiovigilance, Medical device adverse events, Knowledge attitude and practice, Postgraduate residents, medical interns, Patient safety.

1. Introduction

Medical equipment has turned out to be a crucial part of the contemporary healthcare delivery and has become the dominant factor in the prevention of diseases, their diagnosis, monitoring, treatment, and rehabilitation [1]. These products are simple and low-risk consumables (such as syringes, gloves, catheters) to highly complex, high-risk diagnostic and therapeutic systems (such as ventilators, infusion pumps, dialysis machines, implantable cardiac devices, orthopaedic prostheses and high-level imaging technologies) [2]. The fast-growing medical technology has clearly enhanced clinical practice and patient outcomes but has also brought in emerging new and complicated safety issues concerning the workability, performance, maintenance, and post-marketing of the device [3].

Medical device-related adverse events are also a major and undervalued part of patient safety events across the globe [4]. The world experience indicates that the issues with the devices can be caused by the manufacturing flaws, design constraints, program malfunctions, labelling issues, lack of training, or improper clinical use [5]. The adverse events involving medical devices are reported by regulatory authorities (European Medicines Agency (EMA) and the United States Food and Drug Administration (US FDA), which state that they may lead to severe morbidity, extended hospitalization, further interventions, long-term disability, and even death [6]. Nevertheless, the less systematic adverse event monitoring of medical devices observed in the past as compared to pharmacovigilance of medicines did not stop such risks.

To fill this vital gap in the safety of health, materiovigilance was a new field of study [7]. It is the science and activity that involves the recognition, evaluation, comprehension, and avoidance of the negative events and other issues related to medical equipment's. Materiovigilance goals go beyond reporting, but involve sustained track performance of the devices, early detection of warning signs, preventing recurrence, and supporting evidence-based regulatory and clinical decisions [8]. A good materiovigilance system is hence needed to ensure that the safety of the patient is well preserved and that the overall healthcare delivery is enhanced [9].

One of the most notable aspects of the materiovigilance systems throughout the world is that these systems rely on spontaneous reporting by the medical staff [10]. Medical devices are mostly used by doctors, nurses, interns and other healthcare providers and usually, they are the first to realize anomalies or mistakes caused by the device use in real clinical practices. Therefore, the effectiveness of any materiovigilance program is highly associated with both the awareness and attitude as well as reporting habits of the healthcare professionals [11]. Poor involvement at this stage may seriously undermine post-marketing monitoring and slow down corrective regulatory measures. In India, the medical device sector has been growing very fast and as a result of this growth, the need to rely on the use of advanced medical technologies has emerged, so the Materiovigilance Programme of India (MvPI), based in Ghaziabad, was established in 2015 by the ministry of health and family welfare with the Indian Pharmacopoeia Commission (IPC) serving as the National Coordination Centre [12]. The MvPI is intended to gather, tabulate, examine and interpret medical device and in vitro diagnostic device adverse events in a systemized manner. The program facilitates decision-making in the regulatory sphere allowing safety warnings, recall, software adjustments, and the development of use guidelines [13]. The reporting in MvPI is optional and is promoted with a national system of Medical Device Adverse Event Monitoring Centres (MDMCs).

Although MvPI has been operationalized, a series of studies done in various parts of India have always registered poor reporting of the medical device-related adverse events [14]. According to literature, multifactor contribute to underreporting, and these factors are lack of awareness of what MvPI is and what its goals are, inadequate training on materiovigilance, lack of knowledge of what comprises a reportable adverse event, and lack of knowledge of reporting forms and processes [15]. Also, pragmatic factors like work overload, time and lack of institutional support do not encourage reporting. Attitudinal barriers are also quite important in determining reporting behavior. Although many healthcare professionals are aware of the importance of reporting the cases of adverse events related to the device to ensure patient safety, this positive attitude does not always reflect in the real

practice of reporting [16]. The fear of blame worries about medico-legal consequences, no feedback following reporting, and the belief that action following reporting might not result in any concrete action have been widely mentioned in the literature as the reason not to engage in active participation in materiovigilance programs [17].

KAP studies are popular tools that have been utilized to assess the interaction of healthcare professionals with safety and regulatory initiatives, such as pharmacovigilance and materiovigilance [18]. The current knowledge about KAP based evidence on materiovigilance shows that even though awareness and attitude towards patient safety is usually positive, there is a low level of practical involvement in reporting. One of the consistent results of studies is the difference between the percentage of healthcare professionals who are involved in an adverse event associated with medical devices and the significantly lower percentage of all such cases that are reported formally with the help of the existing channels [19].

Postgraduate residents and medical interns might be considered a highly vulnerable but poorly investigated group in terms of materiovigilance. These practitioners in the early career have a strong engagement in patient care, they often use and check medical devices, and they are the first to notice malfunctions or adverse events with medical devices [20]. It is however indicated in literature that they usually get a little formal training on regulatory science, patient safety systems and adverse reporting mechanisms. Their excessive clinical workload, lack of autonomy, and ambiguity on the issue of reporting may also add to low reporting rates [21].

Comparative analysis has revealed that pharmacovigilance awareness, as well as reporting, is comparatively well-established among the medical professionals compared to materiovigilance [22]. This is mostly because the pharmacovigilance is included in the undergraduate and postgraduate medical programs, but materiovigilance is not well covered. Some of the authors have stressed that reporting behavior can be greatly enhanced by incorporating materiovigilance education in the medical training programs and by holding regular sensitization workshops [23].

Materiovigilance practices are also affected by the institutional culture and support systems. Hospitals that have a non-punitive reporting culture, routinely train their staff, and simplify the reporting system, especially via electronic systems, have indicated high participation in adverse event reporting [24]. The implementation of materiovigilance, through the inclusion of this practice into hospital quality assurance, risk management, and patient safety frameworks, has been suggested as a sustainable way of enhancing post-marketing surveillance of medical devices [25].

Although there is an increasing appreciation of the role of materiovigilance as an essential element of patient safety in healthcare literature [26], the central concern in the literature is the scarcity of literature that specifically addresses postgraduates and interns in the Indian healthcare context [27]. Since medical device utilization has been growing significantly in the tertiary care hospitals and that junior clinicians play a significant role in clinical decisions and use of devices, it is evident that the knowledge, attitude and practice of junior clinicians in materiovigilance should be evaluated [28].

In this respect, the current cross-sectional observational research was conducted at a tertiary care teaching hospital in Nagpur to determine the level of knowledge, attitude, and practice of Materiovigilance among postgraduates and interns. The proposed study will produce evidence that can be used to develop specific educational interventions, institutional policies, and national strategies to improve the Materiovigilance Programme of India and promote patient safety by identifying the existing gaps and determinants of reporting behavior.

Objectives

- To assess the knowledge, attitude, and practice (KAP) of materiovigilance among postgraduates and interns in a tertiary care hospital in Nagpur.
- To evaluate awareness of the Materiovigilance Programme of India (MvPI) and medical device adverse event reporting.
- To identify reporting practices and barriers related to materiovigilance.

- To determine factors associated with effective materiovigilance practice.

2. Materials and Methods

2.1 Study Design and Setting

It was a six-month cross-sectional observational study in the form of a tertiary care teaching hospital located in Nagpur, Maharashtra, India (January 2024 to June 2024). The school has a high number of patients, and has sophisticated diagnostic and therapeutic medical equipment, which is why it is the right location to determine materiovigilance awareness and practice.

2.2 Study Population

The population of the study was composed of postgraduate residents and medical interns who were actively engaged in clinical practice in the different departments such as Medicine, Surgery, Pediatrics, Obstetrics and gynecology, Orthopedics, Anaesthesiology and allied specialties.

❖ Inclusion Criteria

- Postgraduate residents (MD/MS/DNB) from clinical departments
- Medical interns undergoing compulsory rotatory internship
- Those participants who were willing to sign written informed consent

❖ Exclusion Criteria

- Nursing personnel and faculty members.
- Those on long leave during the study.
- Questionnaires that are not filled completely.

2.3 Sample Size Calculation

Sample size was calculated using the formula:

$$n = \frac{Z^2 \times p \times q}{d^2}$$

Where:

- $Z = 1.96$ (95% confidence level)
- $p = 50\%$ (*this is the assumed prevalence of adequate knowledge, based on past KAP research of materiovigilance*)
- $q = 100 - p$
- $d = 5\%$ allowable error

The minimum sample size calculated was 384. Based on the feasibility and non-response, 320 individuals were contacted where 302 of them responded to the questionnaires and were used in final analysis.

2.4 Sampling Technique

The convenience method of sampling was used. Participants were recruited one after the other through consecutive departmental academic sessions and duty hours until the required sample size was attained.

2.5 Study Tool (Questionnaire)

The data were obtained through administering self-administered questionnaire that was pre-validated and structured according to the extensive examination of published literature and guidelines of Materiovigilance Programme of India (MvPI).

The questionnaire was based on the past published KAP research in materiovigilance and pharmacovigilance and adjusted to the Indian healthcare setting. The content validity was determined through the review of experts, pharmacologists and clinicians engaged in patient safety programs. Pilot study was carried out on 30 respondents, and their responses were not to be analyzed in the end. The internal consistency of the questionnaire was acceptable (Cronbach's $\alpha = 0.82$).

2.6 Questionnaire Structure

Section A: Sociodemographic Details

Age, gender, designation (postgraduate/intern) and department, years of clinical experience and previous exposure or training in materiovigilance were included.

Section B: Knowledge Domain (10 items)

Assessed awareness regarding:

- Definition and scope of Materiovigilance
- Objectives of the Materiovigilance Programme of India
- Types of reportable medical device adverse events
- Reporting forms and reporting center
- Regulatory authority responsible for materiovigilance

Each correct answer was awarded **1 mark**, while incorrect or “don’t know” responses scored **0**. Maximum score: **10**

Section C: Attitude Domain (8 items)

Assessed perceptions regarding:

- Importance of reporting medical device adverse events
- Professional responsibility of healthcare professionals
- Impact of reporting on patient safety
- Willingness to report in future

Responses were recorded on a **5-point Likert scale** (1 = strongly disagree to 5 = strongly agree). Maximum score: **40**

Section D: Practice Domain (6 items)

Assessed:

- Encounter with medical device adverse events
- Previous reporting experience
- Awareness of reporting procedures
- Perceived barriers to reporting

Practice was categorized as **good** or **poor** based on prior reporting behavior and procedural awareness.

2.7 Scoring and Categorization

• Knowledge:

- Poor (<4)
- Moderate (4–6)
- Good (≥ 7)

• Attitude:

- Negative (<24)
- Positive (≥ 24)

• Practice:

- Good practice: Reported at least one medical device adverse event or aware of reporting procedure
- Poor practice: Never reported and unaware of reporting mechanism

2.8 Data Collection Procedure

The participants were informed about the objectives of the study after getting ethical clearance. Informed consent was obtained by providing written consent. The questionnaires were handed

over, and the responses were collected anonymously to minimize the social desirability bias. The subjects had ample time to do the questionnaire.

2.9 Statistical Analysis

The data have been inputted into Microsoft Excel 2019 and analyzed with the help of SPSS 26.0 (IBM Corp., Armonk, NY, USA).

- Categorical variables were indicated in terms of frequency and percentage.
- Continuous variables were summarized as **mean $\pm$ standard deviation**
- Association Demographic variables were measured against KAP scores by Chi-square test
- Independent t-test was used to carry out the comparison between postgraduates and interns
- Variables that had $p < 0.20$ in the univariate analysis were included in multivariate logistic regression to predict good reporting practice
- A p-value < 0.05 was considered statistically significant

2.10 Ethical Considerations

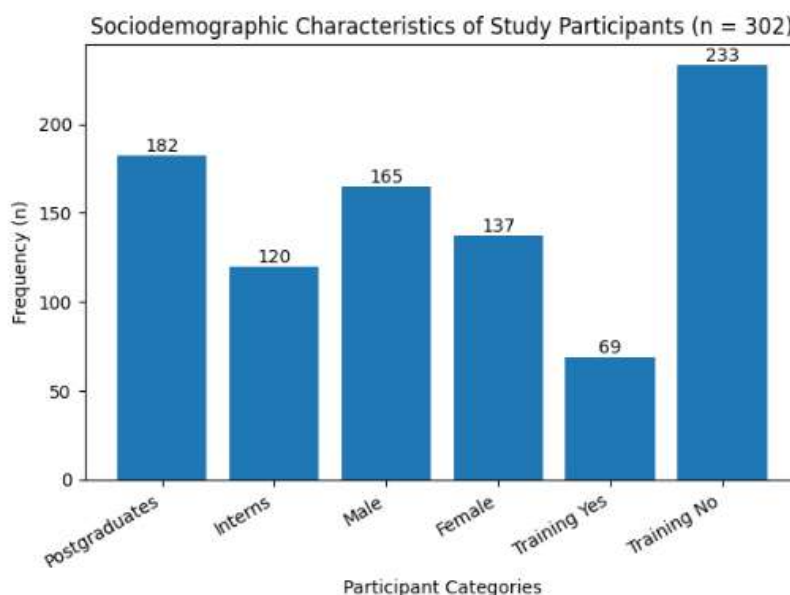
The Institutional Ethics Committee of the tertiary care hospital. All participants had been informed by written means. There was a high level of confidentiality and anonymity and the participation was voluntary.

3. Results

Table 1. Sociodemographic Characteristics of Study Participants (n = 302)

Variable	Category	Frequency (n)	Percentage (%)
Designation	Postgraduate residents	182	60.3
	Medical interns	120	39.7
Gender	Male	165	54.6
	Female	137	45.4
Mean age (years)	—	26.8 $\pm$ 2.4	—
Prior training in materiovigilance	Yes	69	22.8
	No	233	77.2

The table 1 presents sociodemographic traits of the 302 participants who were enrolled in the research, which gives some background knowledge about the people participating in the study. Most of the respondents were postgraduate residents (60.3%), with 39.7 % being made up of medical interns, which would mean that the sample size is better represented by more clinicians with a relatively higher degree of clinical exposure and responsibility in patient care. This distribution suits the assessment of a materiovigilance practice because postgraduates are more likely to be engaged in the utilization, surveillance, and troubleshooting of medical devices. The gender distribution was displayed almost in an equal proportion, or 54.6 % and 45.4 %, respectively, which reduced the possible gender-related bias in the research results. The average age of participants was 26.8 $\pm$ 2.4 years old, and, therefore, it can be noted that the sample is mainly composed of young professionals in the field of healthcare, which is especially important when evaluating awareness and training opportunities in regulatory and patient safety initiatives. It is interesting to note that only 22.8 percent of the respondents claimed to have received previous training in materiovigilance and an impressive 77.2 percent had no formal exposure. This observation underscores a major gap in structured training and sensitization, and thus, this aspect might affect future knowledge, attitude, and practice on medical device adverse event reporting.



Graph 1: Sociodemographic characteristics of study participants

Graph 1 represents the sociodemographic features of the 302 participants of the study as far as the designation, gender, and previous training on the topic of materiovigilance is concerned. The study group of postgraduate residents formed a higher percentage of the study population than interns, which means that a greater number of clinicians, who are more involved in clinical work, are represented. The gender was relatively even, with a minor percentage imbalance, whereby, there were more male participants than female participants. One of the strongest results of the graph is the significant deficit in training in the field of materiovigilance: the number of individuals who received no previous training was significantly larger than the number of those who received training. This pictorial example indicates a substantial deficiency regarding formal materiovigilance education among novice healthcare workers, which could be the reason behind the poor awareness and ineffective reporting attitudes found in the experiment.

Table 2. Distribution of Knowledge Scores on Materiovigilance

Knowledge Level	Score Range	Frequency (n)	Percentage (%)
Poor	< 4	116	38.4
Moderate	4–6	135	44.7
Good	≥ 7	51	16.9
Total	—	302	100

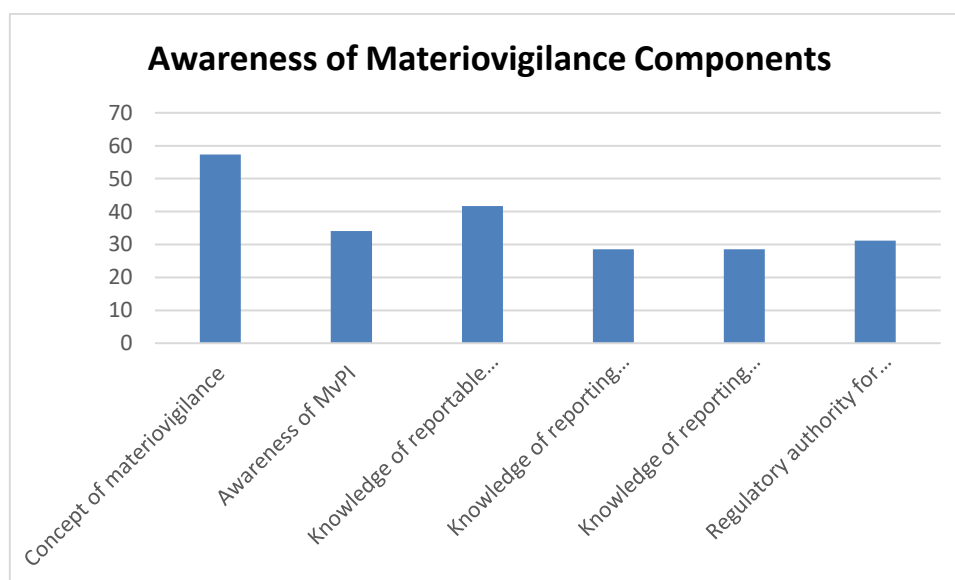
Table 2 demonstrates the proportion of scores on materiovigilance knowledge among 302 study subjects. Another significant percentage of the respondents exhibited low levels of knowledge with 38.4% of respondents having a score lower than 4, which shows lack of awareness in major concepts, reporting and regulatory issues of materiovigilance. The moderate category of respondents (44.7 %) was the greatest number that was observed, and it indicated some level of knowledge but significant gaps in comprehensive knowledge needed to report adverse events of medical devices. Notably, the rating of good knowledge was reached by only 16.9% of respondents (≥ 7), which indicates the general lack in the depth of knowledge about the topic of materiovigilance in the respondent postgraduate residents and interns. This distribution explains that accurate awareness is only basic to moderate among almost half of the participants whereas, a considerable percentage of the respondents do not know enough to know and report adverse events involving medical devices. The small percentage of participants who knew well enough is the key

reason to implement organized educational activities, periodic trainings, and introduce materiovigilance to medical programs to enhance the level of knowledge and promote the use of proper reporting practices.

Table 3. Awareness of Specific Materiovigilance Components

Knowledge Item	Correct Response (%)
Concept of materiovigilance	57.3
Awareness of MvPI	34.1
Knowledge of reportable device adverse events	41.7
Knowledge of reporting forms	28.5
Knowledge of reporting centers	28.5
Regulatory authority for materiovigilance	31.2

The level of awareness among the participants of the study of the components of the materiovigilance is informed in table 3. The basic concept of materiovigilance was known to slightly over half of the respondents (57.3%), which means that the general awareness about the term is quite high. Awareness however dropped significantly on the evaluation of more specific and operational aspects. The recognition of the Materiovigilance Programme of India (MvPI) was identified to have been low at only 34.1% of participants, with little awareness of the national framework on which the monitoring of medical device adverse events is done. The awareness about reportable medical device adverse events existed in 41.7 percent of the respondents, which implies that there was confusion to cure what should be reported. The knowledge of the reporting forms and reporting centers was particularly low, with only 28.5% of the participants giving the answer correctly to each of them, which presents a significant gap in the procedures. In addition, only 31.2% of them identified the regulatory body in charge of materiovigilance. All in all, the results indicate a distinct spectrum of awareness, the ability to understand general concepts better than the knowledge of practical and regulatory issues that are the key to an efficient reporting, and the direct necessity to undergo specific training of MvPI procedures and reporting mechanisms.



Graph 2: Awareness of Materiovigilance Components

The data on the graph 2 has the percentage of the correct answers concerning different elements of the materiovigilance of the participants. There was also a larger familiarity with the term since the proportion of respondents who correctly answered the basic concept of materiovigilance had a percentage of over half. Nonetheless, the level of awareness about the Materiovigilance

Programme of India (MvPI) was significantly lower which is an expression of the lack of awareness of the national reporting framework. The levels of knowledge about the adverse events with reportable medical devices were rated at moderate, and knowledge about reporting forms and reporting procedure were comparatively low, with less than one-third of participants answering the question correctly. Likewise, there was poor awareness on the regulatory authority that is involved in materiovigilance. Overall, the graph shows that the awareness based on conceptual knowledge of the reporting mechanisms and institutional processes decreases significantly, and it is necessary to pay special attention to their training.

Table 4. Attitude Towards Materiovigilance

Attitude Statement	Agree / Strongly Agree (%)
Reporting is a professional responsibility	86.4
Reporting improves patient safety	82.1
Willing to report in future	77.6
Concerned about medico-legal consequences	36.9
Discouraged due to lack of feedback	48.7

Overall Attitude Score

Attitude Category	Score	Frequency (n)	Percentage (%)
Positive	≥ 24	241	79.8
Negative	< 24	61	20.2

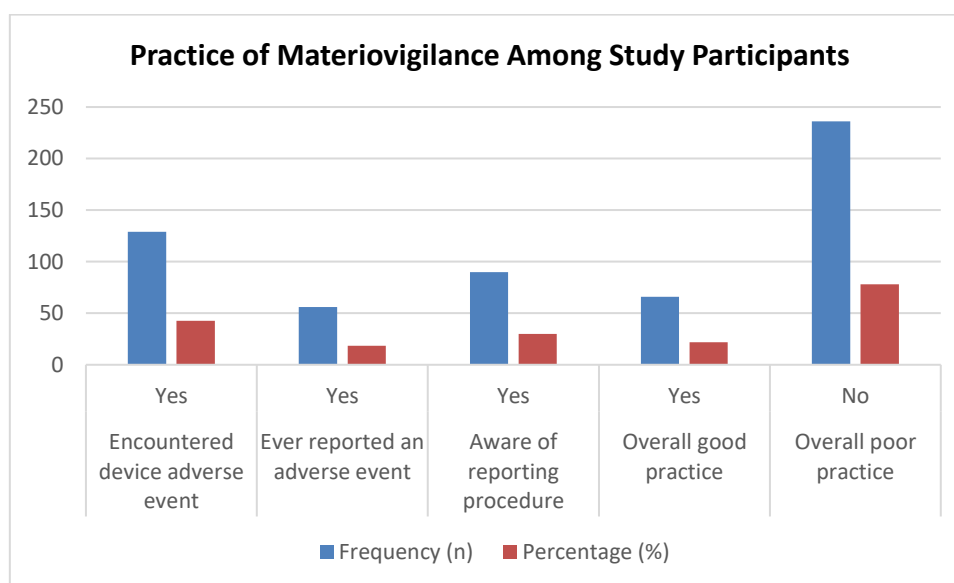
Table 4 shows the attitude of postgraduate residents and medical interns towards materiovigilance and medical device adverse event reporting. A large majority of respondents reported a positive perception as 86.4% believed that it is a professional role of reporting adverse events associated with medical equipment and 82.1% of them considered it useful in safeguarding patients. Furthermore, 77.6% of the respondents were willing to report the adverse events in future, which shows that there is a favorable attitude to taking part in the materiovigilance activities, in general. Although there was such a positive attitude there were clear concerns that were found. Over one-third (36.9 %) of the participants expressed concern about medico-legal consequences, but almost half (48.7 %) of the participants were discouraged by the absence of feedback post-reporting, which also demonstrates that there are still enduring barriers to attitudinal and systemic attitudes. General attitude scoring showed that 79.8 percent of the respondents showed positive attitude (score ≥ 24) with 20.2 percent of the participants showing a negative attitude. These results indicate that despite the rather favourable attitudes in terms of materiovigilance, there are still issues connected to the feedback and legal aspect to be taken into consideration, to turn positive attitudes into the regular reporting behavior.

Table 5. Practice of Materiovigilance Among Participants

Practice Variable	Response	Frequency (n)	Percentage (%)
Encountered device adverse event	Yes	129	42.7
Ever reported an adverse event	Yes	56	18.5
Aware of reporting procedure	Yes	90	29.8
Overall good practice	Yes	66	21.9
Overall poor practice	No	236	78.1

Table 5 presents the real practice of materiovigilance by the study participants and shows that there is a significant disparity between the exposure, awareness and reporting practice. Though 42.7 percent of the hospitals interviewed had experienced a medical device adverse event in their clinical practice, only 18.5 % reported that they had ever reported the event having experienced it,

which is high underreporting. The respondents were only found to be aware of the reporting procedure in 29.8 percent, which indicates the possibility of little procedural knowledge and poor knowledge of the reporting system. According to the predetermined criteria (21.9 % of respondents were practicing materiovigilance well, and a huge percentage of 78.1 percent was grouped as practicing poorly). These results indicate that there is a strong disparity in clinical exposure to adverse events and the reality of reporting behavior. Regarding the frequent experience of medical device related problems even though most respondents did not have adequate procedural awareness as well as did not engage in active reporting, there was ample evidence to implement structured training, streamlined reporting systems and enhanced institutional support to enhance materiovigilance practices.



Graph 3: Practice of Materiovigilance Among Study Participants

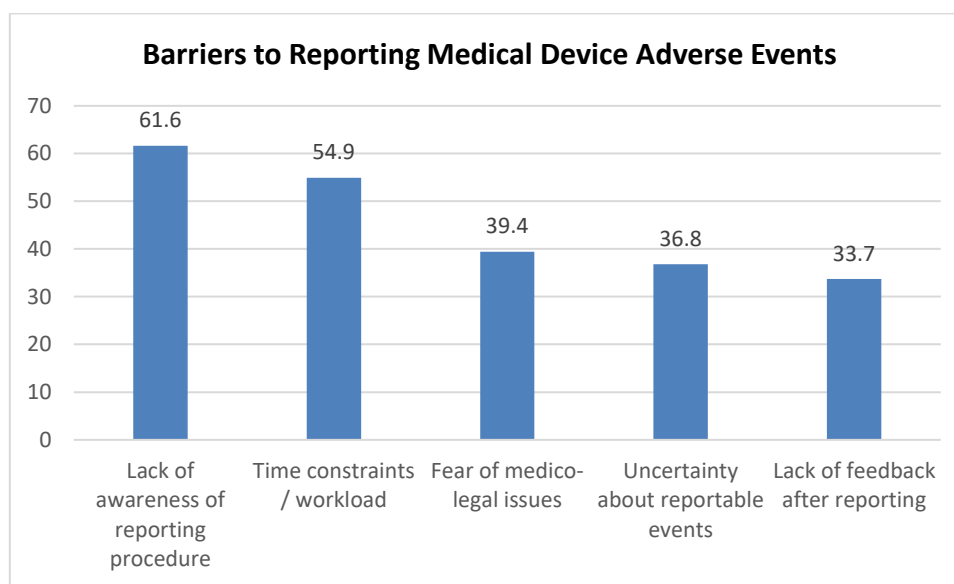
The graph 3 demonstrates the practice-related facets of materiovigilance by the participants of the study, which appeared in the form of frequency and percentage. Although a significant number of the participants said they had experienced medical device-related adverse events, a substantially limited number of the participants had experienced such events, which is a major underreporting. Participants did not have much knowledge on the reporting process as fewer than a third were conversant with the process. As a result, only a minority practiced overall good materiovigilance and majority were classified as poor as indicated by the high frequency in this category. Such a gap between clinical exposure, awareness and actual reporting behavior highlights a large gap in the application of materiovigilance and call upon the need to train better, with better reporting arteries and better institutional enforcement to improve reporting behavior.

Table 6. Barriers to Reporting Medical Device Adverse Events

Reported Barrier	Frequency (%)
Lack of awareness of reporting procedure	61.6
Time constraints / workload	54.9
Fear of medico-legal issues	39.4
Uncertainty about reportable events	36.8
Lack of feedback after reporting	33.7

Table 6 indicates the key obstacles that the participants felt about reporting adverse events associated with medical devices. The least frequently cited hindrance was unawareness of the reporting process (61.6%), which implies that they did not know where and how to report such

events. It was then succeeded by time constraints and workload (54.9%), as the postgraduate residents and interns had to encounter severe clinical duties. Medico-legal consequences related concerns were reported by 39.4 percent of participants which is an indication of fear of being blamed or facing legal consequences as a deterrence towards reporting. Also, 36.8 % of respondents indicated that they were unsure of what a reportable event was and this showed that there was ambiguity in the determination of eligible adverse events. The most common was a lack of feedback following the reporting (33.7 %), which might help decrease future motivation to report. All in all, these results reveal that knowledge-related and system-level barriers are enormous obstacles to successful practice of materiovigilance, and therefore it is necessary to have clear guidelines, frequent training, favourable institutional policies and efficient feedback system to enhance reporting practices.



Graph 4: Barriers to Reporting Medical Device Adverse Events

The graph 4 illustrates the major obstacles to reporting adverse events related to the use of medical devices. The most common one was the lack of awareness of the reporting procedure (61.6%), which meant the inadequate knowledge of the reporting mechanisms. This was then succeeded by time constraint and workload (54.9%), which indicated the heavy clinical condition of postgraduate residents and interns. Medico-legal concern (39.4 %) became also a major consideration, fearing active reporting. Further, the inability to know what a reportable event (36.8 %) is demonstrates an insufficiency of knowledge in practice. There is also the issue of no feedback after reporting (33.7 %) that discourages reporting. Generally, the results illustrate that knowledge-related barriers, as well as systemic ones, have a significant negative impact on the successful practice of materiovigilance.

Table 7. Association Between Designation and Knowledge Level

Designation	Poor n (%)	Moderate n (%)	Good n (%)	p-value
Postgraduates	54 (29.7)	86 (47.3)	42 (23.0)	< 0.01
Interns	62 (51.7)	49 (40.8)	9 (7.5)	
Total	116	135	51	

Table 7 shows the relation between the level of knowledge and the professional designation on materiovigilance among the study participants. Much a higher share of postgraduate residents had moderate to good knowledge than interns. Out of the postgraduates, 23.0% of them scored good knowledge whereas only 7.5% of interns were in the good category. Conversely, interns (51.7%)

had poorer knowledge as opposed to postgraduates (29.7%). The perceived difference in the distribution of knowledge in both groups was determined to be significant ($p < 0.01$). This result implies that postgraduate residents on account of a larger clinical exposure and experience are more aware of the concepts of materiovigilance than are interns. Nevertheless, the proportion of postgraduates who possess good knowledge is rather low as well, which can also indicate knowledge gaps even among the more experienced trainees. All in all, the findings demonstrate that to achieve the desired homogeneity in the level of knowledge among all categories of trainees, there should be early-unit-based education on materiovigilance throughout the internship period, as well as the maintenance of the same into the postgraduate period.

Table 8. Multivariate Logistic Regression Analysis for Predictors of Good Practice

Predictor Variable	Adjusted OR	95% CI	p-value
Prior materiovigilance training	3.21	1.78–5.79	< 0.001
Good knowledge score	2.47	1.32–4.61	0.004
Positive attitude	1.18	0.68–2.03	0.54

Table 8 shows the outcome of the multivariate logistic regression analysis that product factors linked with good materiovigilance practice among the research participants. Prior training in materiovigilance turned out to be the best independent predictor of good practice, and participants who had undergone training were 3.21 times more likely to display appropriate reporting behaviour than those who had not (Adjusted OR = 3.21; 95% CI: 1.785.79; $p < 0.001$). On the same note, those who scored good on knowledge had 2.47 times higher chances of engaging in good materiovigilance practice (Adjusted OR = 2.47; 95% CI: 1.32 4.61; $p = 0.004$) which highlights the importance of sufficient knowledge in turning awareness into practice. Contrastingly, whereas positive attitude towards materiovigilance, this component was readily shared among the participants, and it was not independently correlated with good practice (Adjusted OR = 1.18; 95% CI: 0.68203; $p = 0.54$). Such results indicate that positive mindset plays a significant role, but organized training and quality knowledge are the crucial factors of the effective reporting behaviour in materiovigilance.

4. Discussion

The current research indicates that there are significant knowledge gaps around materiovigilance among the postgraduate residents and medical interns, only a small percentage of them exhibited good knowledge. The observation is in line with the conclusion of various Indian studies, which have continued to record low awareness levels of medical device vigilance systems. According to Mulchandani et al. (2019) [29], less than a quarter of medical workers had sufficient knowledge of both the Materiovigilance Programme of India (MvPI) and the reporting systems. On the same note, Sharma et al. (2021) [19] have identified that despite the familiarity of clinicians with the term of materiovigilance, the awareness about specific reportable adverse events and the form of reporting, as well as governmental bodies, was limited. Similar shortcomings have been reported by international studies of developing healthcare environments, including those by Zhao et al. (2022) [30] and show that medical device vigilance is underdeveloped in comparison with pharmacovigilance on an international scale.

The present research revealed that postgraduate residents showed a much higher level of knowledge than interns, which are in line with previous findings reported by Kumar et al. (2020) [9]. These authors explained the increased level of knowledge among the residents by the more frequent clinical exposure and the use of medical devices by the residents. Nevertheless, in line with the results of Alsohime et al. (2019) [31], the rate of good knowledge among postgraduates was not that high, which can be explained by the fact that only clinical experience does not guarantee the required level of knowledge of materiovigilance. This strengthens the role of the structured educational interventions as opposed to the incorporation of experiential learning.

Although there was a lack of knowledge, the attitudes toward materiovigilance in the current research were mostly positive as a significant majority of the subjects identified the adverse events reporting as a professional duty and the valuable measure of patient safety. Indian studies the international ones (Alatawi et al., 2017) [32] have also reported similar positive attitudes. These results indicate that patient safety principles awareness is effectively enshrined in healthcare professionals. Nonetheless, a positive attitude, as is always mentioned in the literature, does not always result in effective reporting practice.

The difference between adverse events exposure and real reporting identified in this study replicates the results of various past studies. Even though a large percentage of the participants had experienced some adverse events related to devices, few of them had reported them. Sakthibalan et al. (2024) [33] found similar underreporting in an Indian tertiary care. It is also supported by international evidence, who observed that the reporting of adverse events associated with medical devices is significantly lower than adverse drug reaction reporting, despite the well-established healthcare systems. All these results imply that underreporting is a systemic problem and not an institutional one.

The obstacles to reporting found in the current research are in line with the previously reported ones. Three components that have been noted repeatedly to be major deterrents include lack of awareness on procedures of reporting, heavy workload, time constraint, medico-legal issues and absence of feedback. pointed out that uncertainty about the event that should be reported and the fear of being taken to court is a huge deterrent to reporting. Aboufour et al. (2022) [34] also mentioned that lack of feedback after reporting lowers the motivation to take part again, a result that is closely similar to the present study.

The major observation in this research is that previous training in materiovigilance and good knowledge were among the most important predictors of good reporting practice, whereas the attitude alone was not. Interventional studies by Tantia et al. (2023) [35] substantiate this observation significantly since the studies have shown a significant improvement in reporting behavior after structured training programs. WHO reports have also made similar conclusions and argued that materiovigilance should be integrated into curriculums. In general, the current study supports the current body of knowledge and highlights that the strengthening of the practice of materiovigilance involves the need to have structured education, procurement of procedural clarity, and institutional support to improve patient safety.

5. Conclusion

This study demonstrates that although postgraduate residents and medical interns generally possess a favorable disposition towards materiovigilance and acknowledge the importance of reporting adverse events related to medical devices for patient safety, their knowledge and actual reporting practices are significantly deficient. A significant disparity exists between bad events connected to medical devices and their reporting, primarily due to inadequate awareness of the Materiovigilance Programme of India, lack procedural understanding, excessive workload, and medico-legal complications. The results indicate that prior training and adequate knowledge are the primary factors influencing effective reporting practices, but attitude alone cannot facilitate meaningful participation. The findings need the prompt implementation of structured training programs, the integration of materiovigilance into the curriculum, the simplification of reporting processes, and the establishment of institutional rules that facilitate adverse event reporting and enhance patient safety in tertiary care units.

References

1. World Health Organization. WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices.

2. Tau N, Shepshelovich D. Assessment of data sources that support US Food and Drug Administration medical devices safety communications. *JAMA internal medicine*. 2020 Nov 1;180(11):1420-6.
3. Vozikis A, Cooper DN, Mitropoulou C, Kambouris ME, Brand A, Dolzan V, Fortina P, Innocenti F, Lee MT, Leyens L, Macek Jr M. Test pricing and reimbursement in genomic medicine: towards a general strategy. *Public Health Genomics*. 2017 Jan 3;19(6):352-63.
4. Maisel WH. Medical device regulation: an introduction for the practicing physician. *Annals of internal medicine*. 2004 Feb 17;140(4):296-302.
5. Dhruva SS, Redberg RF. Medical device regulation: time to improve evidence and transparency. *JAMA*. 2018;320(12):1211-1212.
6. Kramer DB, Xu S, Kesselheim AS. Regulation of medical devices in the United States and European Union. In *The ethical challenges of emerging medical technologies* 2020 Sep 10 (pp. 41-48). Routledge.
7. Date AP, Date AA, Siddiqui RA, Shende TR, Salankar HV, Quazi SH, Sonwane PG. Materiovigilance programme of India: A step towards patient safety. *Int J Basic Clin Pharmacol*. 2023 Jul;12(4):621-5.
8. Grover M, Sharma M, Shukla VK, Chawla R, Nayak SR, Sharma N. Regulatory Framework for Emergency Approval of Medical Devices in India. *Research Journal of Pharmacy and Technology*. 2025 Oct 1;18(10):5054-60.
9. Kumar P, Kalaiselvan V, Kaur I, Thota P, Singh GN. Materiovigilance programme of India (MVPI): A step towards patient safety for medical devices. *Eur J Biomed Pharm Sci*. 2016 Nov;12(7):497-501.
10. Rashid M, Hashmi S, Ali MS, Alkhalaf IS, Fadhel AF, Aljohani SA, Abdullah Barayan AW, Akhtar N, Yezdani U. KAP Survey on Adverse Drug Reaction Reporting and Risk Management Among Pharmacist, Nurse, Dentist and General Practitioners in Saudi Arabia. *Journal of Namibian Studies*. 2023 Apr 1;37.
11. Rani S, Singh K. Materiovigilance: An emerging discipline.
12. Mukhopadhyay S, Abraham SE, Holla B, Ramakrishna KK, Gopalakrishna KL, Soman A, Chikkanna UC, Bharath MM, Bhargav H, Varambally S, Gangadhar BN. Heavy metals in Indian traditional systems of medicine: a systematic scoping review and recommendations for integrative medicine practice. *The Journal of Alternative and Complementary Medicine*. 2021 Nov 1;27(11):915-29.
13. Alsohime F, Temsah MH, Hasan G, Al-Eyadhy A, Gulman S, Issa H, Alsohime O. Reporting adverse events related to medical devices: A single center experience from a tertiary academic hospital. *PloS one*. 2019 Oct 24;14(10):e0224233.
14. Golder S, Wright K, Rodgers M. Failure or success of search strategies to identify adverse effects of medical devices: a feasibility study using a systematic review. *Systematic Reviews*. 2014 Oct 13;3(1):113.
15. Wang JF, Wu CL, Tsai YT, Weng SJ, Hsu YC. The Effects of safety climate on psychosocial factors: An empirical study in healthcare workplaces. *Journal of Patient Safety*. 2022 Mar 1;18(2):e528-33.
16. Mohanan PV, editor. *Artificial Intelligence and Biological Sciences*. CRC Press, Taylor & Francis Group; 2025 Jun 17.
17. Zhang CQ, Li X, He L, Xu B, Wu Y, He J, Wang W, Lu Z. Critical Care, Critical Gaps: Assessment of Burnout and Behavioral Profiles of ICU Healthcare Workers in China-A Multicenter Cross-Sectional Study. *Frontiers in Public Health*. 2025 Jun 26; 13:1617081.
18. Samar A, Sahana GN, Deepak P, Nagaral JV, Saranyaa M. Assessment of knowledge, attitude, and practice of materiovigilance among interns in a tertiary care institute: A cross-sectional study. *National Journal of Physiology, Pharmacy and Pharmacology*. 2024;14(7):1301-3.

19. Sharma S, Mohler J, Mahajan SD, Schwartz SA, Bruggemann L, Aalinkel R. Microbial biofilm: a review on formation, infection, antibiotic resistance, control measures, and innovative treatment. *Microorganisms*. 2023 Jun 19;11(6):1614.
20. Patel BD, Tannarana IA, Gadhwal KH, Shah A, Gor A, Mehta A, Gandhi T. A Cross-Sectional Knowledge, Attitude, Practice Survey of Healthcare Professionals on Materiovigilance. *Attitude, Practice Survey of Healthcare Professionals on Materiovigilance*.
21. Kumah A. Adverse event reporting and patient safety: the role of a just culture. *Frontiers in Health Services*. 2025 Aug 20; 5:1581516.
22. Sodhi R, Kapoor T, Vatsyayan V, Seth I, Chandra H, Gill N, Singh M, Pal A, Mannan S. Adverse Drug Reactions in Tuberculosis Treatment: Incidence, Reporting and Outcomes; Insights from a Mixed-Methods study across eight Indian cities. *medRxiv*. 2025:2025-11.
23. Chilukuri G, Westerman ST. Healthcare Workers' Perceptions of Patient Safety Culture in United States Hospitals: A Systematic Review and Meta-Analysis. *International Journal of Medical Students*. 2024 Dec 17;12(4):422-36.
24. Mira JJ, Lorenzo S, Carrillo I, Ferrús LE, Silvestre C, Astier P, Iglesias-Alonso F, Maderuelo JA, Pérez-Pérez PA, Torijano ML, Zavala E. Lessons learned for reducing the negative impact of adverse events on patients, health professionals and healthcare organizations. *International Journal for Quality in Health Care*. 2017 Aug 1;29(4):450-60.
25. World Health Organization. Patient safety incident reporting and learning systems: technical report and guidance.
26. Saini A. Digital transformation in hospital administration: A literature review on adoption and impact of smart healthcare technologies.
27. Dhaiban S, Chandran S, Sajini A. Clinical translation of human iPSC technologies: advances, safety concerns, and future directions. *Frontiers in Cell and Developmental Biology*. 2025 Sep 22;13:1627149.
28. World Health Organization. Regulatory considerations on artificial intelligence for health. World Health Organization; 2023 Oct 19.
29. Mulchandani R, Kakkar AK. Reporting of adverse drug reactions in India: A review of the current scenario, obstacles and possible solutions. *International Journal of Risk & Safety in Medicine*. 2019 Feb;30(1):33-44.
30. Zhao X, Shi C, Zhao L. Nurses' intentions, awareness and barriers in reporting adverse events: A cross-sectional survey in tertiary hospitals in China. *Risk management and healthcare policy*. 2022 Jan 1:1987-97.
31. Alsohime F, Temsah MH, Hasan G, Al-Eyadhy A, Gulman S, Issa H, Alsohime O. Reporting adverse events related to medical devices: A single center experience from a tertiary academic hospital. *PloS one*. 2019 Oct 24;14(10):e0224233.
32. Alatawi YM, Hansen RA. Empirical estimation of under-reporting in the US Food and Drug Administration adverse event reporting system (FAERS). *Expert opinion on drug safety*. 2017 Jul 3;16(7):761-7.
33. Sakthibalan M, Adhimoolam M, Indumathi C. Knowledge, attitudes and practices of Materiovigilance among physicians in a rural tertiary care teaching hospital in Puducherry-a cross sectional study. *Journal of Applied Pharmaceutical Research*. 2024 Feb 29;12(1):10-5.
34. Aboufour MA, Subbarayalu AV. Perceptions of patient safety culture among healthcare professionals in Ministry of Health hospitals in Eastern Province of Saudi Arabia. *Informatics in Medicine Unlocked*. 2022 Jan 1;28:100858.
35. Tantia R, Atray M, Agrawal A. Awareness and outlook of health-care professionals regarding materiovigilance in a tertiary care teaching hospital in South Rajasthan. *National Journal of Physiology, Pharmacy and Pharmacology*. 2023 Jan 2;13(1):37-.