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Original Article

Assessing Knowledge, Attitude and Practice of Materiovigilance among Pharmacy Students in South Kerala: A Cross-Sectional Study

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ABSTRACT

Aim: This cross-sectional study examined the knowledge, attitudes and practices regarding materiovigilance among pharmacy students in Kerala, conducted over 6 months from November 2022 to May 2023, with approval from the institutional ethics committee. **Materials and Methods:** A self-administered questionnaire was created based on previous research, divided into two sections: the 1st collected demographic data and the second contained 15 questions about materiovigilance. The questionnaire was distributed via Google Forms through WhatsApp and LinkedIn. **Results:** The study found that most respondents were aged 18-25, with females making up 67.11% of the sample. In total, 74.58% of respondents identified as female compared to 25.42% male, suggesting that findings may primarily reflect female perspectives. The results revealed that 89. 83% believed medical devices could lead to adverse events and 37% felt reporting this events was necessary. Additionally, 87.29% agreed that healthcare professionals should report such events and 96. 61% acknowledged that doing so enhances patient safety. However, only 21.19% had encountered adverse events and of those, 80.51% had not reported them. Alarmingly, 65.25% were unaware of any reporting forms, indicating a gap in necessary knowledge. Furthermore, 58.47% did not take patient feedback after implanting devices and 80. 51% had not attended workshops on medical devices. **Conclusion:** Most respondents recognized the risks associated with medical devices and the need for reporting. However, barriers such as lack of awareness, inadequate training and limited participation in reporting systems were evident. Many were not familiar with the classification system for medical devices. A significant portion (32.2%) lacked knowledge of existing monitoring programs. The gender disparity in responses may affect interpretations and suggests a need for balanced representation in future studies. In conclusion, while awareness of the importance of reporting adverse events exists among healthcare professionals, major gaps persist in education, engagement and system accessibility. Enhancements in training, awareness and patient feedback collection are crucial to improve materiovigilance practices and ensure patient safety in medical device usage.

Keywords: Adverse events, Materiovigilance, Medical Devices.

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INTRODUCTION

"The Ministry of Health and Family Welfare (MOHFW) of the Government of India approved the Materiovigilance Programme (MvPI) in July 2015 to address potential adverse events stemming from medical devices.[1] Medical devices, as defined by MOHFW, encompass instruments, apparatuses, implements, machines, appliances, implants, *in vitro* reagents or calibrators, software materials and similar items intended for use alone or in combination for diagnosis, prevention, monitoring treatment or alleviation of disease in human beings. As of now 50 Medical Devices Adverse Event Reporting Monitoring Centers (MDMCs) have been established across India in order to aid with materiovigilance: the coordinated system of identifying, collecting, reporting and analysing untoward occurrences associated with medical devices to protect patient health and prevent recurrences."

The fundamental purpose of this program is to monitor and track Medical Device-Associated adverse Events (MDAE), create awareness among healthcare professionals about the importance of MDAE reporting, generate independent credible

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evidence-based safety data on medical devices and share it with stakeholders. The IPC acts as the National Coordination Centre (NCC) and Central Drug Standard Control Organization (CDSCO) functions as the regulator of MvPI (Figure 1). Initially, this program intends to enroll 10 medical colleges across four parts of India and encourage voluntary reporting. In the future, it will expand to include all private and public healthcare delivery systems, develop an e-reporting system and make reporting mandatory for device manufacturers and healthcare providers. The main objectives of MVPI includes,

- To create a nationwide system for patient safety monitoring.
- To analyze the risk-benefit ratio of medical devices uses.
- To generate evidence-based data on the safety of medical devices.
- To support CDSCO in the decision-making process on the use of medical devices.
- To communicate the safety information on the use of medical devices to various stakeholders to minimize the risk.
- To emerge as a national center of excellence for materiovigilance activities.
- To collaborate with other healthcare organizations and international agencies for the exchange of information and data management.[1]

The United States initiated post-market surveillance of medical devices by enacting Section 522 of the Medical Device Modernization Act of the Food and Drug Administration (FDA) of 1970 and FDA also offers a mandatory and voluntary reporting system. The Medical Device Reporting Regulation (21CFR 803) contains mandatory requirements for manufacturers, importers and user agencies to report certain adverse events and problems related to the use of the devices on the FDA Medwatch Form 3500A or FDA equivalent electronic form. The FDA has set a strict schedule for manufacturers and importers of medical devices to report deaths or serious injuries caused by or damage caused by the devices and when the devices have malfunctioned. The device user facility must also notify both the manufacturers and the FDA within the prescribed time frame of any suspected serious injury or death associated with the medical device. It must also submit an annual death or serious injury summary report to the FDA on Form 3419 FDA.[2]

The USFDA also encourages healthcare providers and device users to report any suspected device-related injuries or adverse effects to the FDA via the FDA 3500 form or the MedWatcher mobile app.[3]

Other countries such as Australia, Canada and the European Union enacted legislation for effective medical surveillance. devices.[4,5] In 1993 an initiative was taken to create a Global Harmonization Task Force (GHTF) between the European Union and the United States, Japan, Australia and Canada. The goal of the GHTF was to harmonize the regulatory system for the safety, efficiency and quality of medical devices.[6] In 2011, a new forum, the International Medical Device Regulators Forum (IMDRF), was established to build on the commendable work of the GHTF and accelerate the harmonization and convergence of medical device regulation. Syllabus updation ensures healthcare professionals are equipped with knowledge of materiovigilance, fostering awareness, skill development and research. Artificial intelligence enhances MvPI by enabling automated data collection, advanced analytics, real-time monitoring and efficient reporting. Together, they modernize training and improve surveillance, ensuring robust medical device safety and patient care outcomes

MATERIALS AND METHODS

We conducted this cross-sectional study to assess the knowledge, attitudes and practices of pharmacy students on materiovigilance in Kerala. The six-month study, which ran from November 2022 to May 2023, was approved by the institutional ethical committee. With their permission, a self-administered questionnaire in English was developed for this study based on earlier research conducted by Bikas Ranjan Meher *et al.* at AIIMS, Bhuvaneswar. There were two sections to the questions. While part two consisted of 15 questions about materiovigilance knowledge, attitude and practice, part one contained demographic data such as job and educational status. The prepared survey was sent via LinkedIn and WhatsApp as a Google form.

Inclusion Criteria

1. Educational Qualification**:** Students currently enrolled in undergraduate (B. Pharm), postgraduate (M. Pharm), or Doctor of Pharmacy (Pharm. D) programs in Kerala.
2. Willingness to Participate**:** Students who provided informed consent to participate in the study.
3. Accessibility**:** Participants with access to the internet and able to complete the Google Form survey.
4. Language Proficiency**:** Students who are proficient in English, as the questionnaire was administered in English.

Exclusion Criteria

1. Non-pharmacy Students**:** Individuals not enrolled in pharmacy-related educational programs.
2. Incomplete Responses**:** Participants who submitted incomplete or invalid survey forms.
3. Non-consenting Participants**:** Students who declined to give informed consent.

4. Professionals**:** Pharmacy graduates who were already practicing and not currently students.

Based on the inclusion and exclusion criteria, the adjusted sample size was approximately 87 students. To account for potential non-responses, oversampled by 10-20%, targeting around 96-115 students.

RESULTS

The most common age groups are 18-20 and 21-25 years. Females dominate across all age groups, but the gender gap narrows slightly in older age groups. Females comprise 67.11% of the total, significantly outnumbering males (32.89%). Females consistently make up the majority across all age groups, with the highest proportion in the 18-20 years group. The Chi-Square test indicates that age and gender are independent, with no significant association between them (p-value>0.05). 88 out of 118 respondents identified as female, which accounts for 74.58% of the total sample.Male Respondents: 30 out of 118 respondents identified as male, making up 25.42% of the total sample. The study results indicate a significant majority of female respondents (74.58%) compared to male respondents (25.42%) (Table 1). This suggests that the opinions and attitudes reflected in the study may predominantly represent female perspectives. The disparity in gender representation could influence the results and interpretations of the study findings, especially in topics related to healthcare and medical devices. It would be prudent to consider gender-based analyses or implications when drawing conclusions from this study.

A significant majority (89.83%) believe that medical devices can cause adverse events, while only 10.17% do not. Among those who believe adverse events can occur, 92.37% feel that reporting such events is necessary, while 7.63% do not. The majority (87.29%) agree that it is the obligation of healthcare professionals to report adverse events related to medical devices. A high percentage (96.61%) believe that reporting adverse events will enhance patient safety, with only 3.39% disagreeing. In clinical practice, 78.81% have not encountered any adverse events, whereas 21.19% have. Among those who encountered adverse events, 80.51% have not participated in reporting them, while 19.49% have. 65.25% have not seen an adverse event reporting form, while 34.75% have. A majority (58.47%) do not take feedback from patients after implanting devices, while 41.53% do. 80.51% have not attended any workshops or continuing medical education focused on medical devices, while 19.49% have. There may be a need for improved training and awareness regarding adverse event reporting among healthcare professionals, especially since a significant number have not attended relevant workshops. Increasing awareness of reporting forms and suggesting feedback mechanisms could help improve safety protocols and patient outcomes. Establishing systems to gather patient feedback after device implantation may enhance reporting and monitoring of adverse events. The study results you provided reflect healthcare professionals' attitudes and experiences regarding the safety and reporting of adverse events associated with medical devices. Here's a detailed interpretation: A substantial majority (89.83%) of respondents believe that medical devices can lead to adverse events, indicating a high level of concern regarding patient safety. Among those who acknowledge the possibility of adverse events, an overwhelming 92.37% feel that it is necessary to report these occurrences. This suggests a strong belief in the need for transparency and accountability in healthcare, highlighting an awareness of the potential consequences adverse events may have on patient safety. The study shows that 87.29% of respondents agree that healthcare professionals have an obligation to report these adverse events (Table 2).

This indicates recognition of the ethical and professional responsibilities placed on healthcare workers to protect patient interests and improve healthcare quality. A significant majority (96.61%) believe that reporting adverse events can enhance patient safety. This reflects an understanding that reporting can lead to better monitoring of device performance, identification of patterns and implementation of improvements in practice. Although 21.19% of respondents have experienced adverse events during their clinical practice, a notable 78.81% have not. This could suggest that while concerns exist, actual experiences of adverse events may be relatively low. However, it is crucial to note that the latter figure doesn't negate the importance of addressing potential risks. Of those who encountered adverse events, a significant majority (80.51%) did not play a role in reporting them. This may point to a gap in reporting practices or systems

Table 1: Age and genderwise classification.

Age Group	Total Count	Female Count	Female Percentage	Male Count	Male Percentage
18-20	44	31	70.45%	13	29.55%
21-25	58	38	65.52%	20	34.48%
26-30	28	19	67.86%	9	32.14%
31-35	12	8	66.67%	4	33.33%
36+	10	6	60.00%	4	40.00%
Total	152	102	67.11%	50	32.89%

Table 2: Knowledge, attitude and practice of materiovigilance.

Factors	Levels	Frequency	Cumulative Sum	Percent (%)	Cumulative Sum (%)
Do you think medical devices can cause adverse events in the patient?	No	12	12	10.17%	10.17%
	Yes	106	118	89.83%	100%
If yes, do you think reporting of any adverse events associated with the medical device is necessary?	No	9	9	7.63%	7.63%
	Yes	109	118	92.37%	100%
Do you agree it is the obligation of healthcare professional to report adverse events due to medical device?	No	15	15	12.71%	12.71%
	Yes	103	118	87.29%	100%
Do you think reporting of adverse event will enhance patient 1?	No	4	4	3.39%	3.39%
	Yes	114	118	96.61%	100%
Have you ever encountered any adverse events due to medical device during your clinical practice?	No	93	93	78.81%	78.81%
	Yes	25	118	21.19%	100%
If yes, have you ever played any role in reporting of it?	No	95	95	80.51%	80.51%
	Yes	23	118	19.49%	100%
Have you seen medical device adverse events reporting form?	No	77	77	65.25%	65.25%
	Yes	41	118	34.75%	100%
Do you take any feedback for any untoward events from patients after implanting the device?	No	69	69	58.47%	58.47%
	Yes	49	118	41.53%	100%
Have you ever attended any workshop or CME focused on 1 of medical device?	No	95	95	80.51%	80.51%
	Yes	23	118	19.49%	100%

within healthcare institutions, indicating that there is room for improvement in encouraging and facilitating the reporting process. The finding that 65.25% are unaware of adverse event reporting forms. A majority (58.47%) do not take feedback from patients post-implantation, which signals an opportunity for healthcare professionals to enhance communication and monitoring practices related to medical devices. The fact that 80.51% have not attended relevant workshops or Continuing Medical Education (CME) programs focused on medical devices could indicate a lack of ongoing education on this topic. Improving access to such educational opportunities may bridge knowledge gaps and improve practices related to device safety and reporting.

The results suggest an overarching recognition of the potential risks associated with medical devices and a strong belief in the importance of reporting adverse events. However, gaps in awareness, educational engagement and active participation in reporting adverse events indicate areas for improvement within healthcare settings. Addressing these gaps through enhanced training, better reporting systems and a culture of feedback could significantly improve patient safety and healthcare outcomes related to medical device use. Healthcare institutions might consider implementing strategies tailored to increase awareness, education and encourage feedback to ensure continuous safety monitoring and improvement in medical device usage. A large majority of respondents recognize that medical devices can cause adverse events. This is important because understanding that devices can cause harm is the first step in identifying and addressing safety concerns in clinical practice. Most respondents agree on the necessity of reporting adverse events, which aligns with best practices in materiovigilance. Reporting adverse events is crucial for tracking the safety of medical devices and identifying potential risks.

A strong majority of respondents believe it is a healthcare professional's duty to report adverse events. This is important because materiovigilance relies on healthcare professionals to provide data on device-related issues, ensuring that regulatory agencies can act accordingly. The vast majority of respondents recognize the importance of reporting in improving patient safety. This indicates that healthcare professionals are generally supportive of materiovigilance systems and understand how reporting can help mitigate risks. While a smaller proportion of respondents have directly encountered adverse events, it suggests that such events are not uncommon. It also highlights the importance of reporting systems for capturing those incidents that do occur. While some respondents have encountered adverse events, few have actively participated in reporting them. This indicates a gap in reporting and suggests that there may be

barriers preventing healthcare professionals from engaging with materiovigilance practices.

A large proportion of healthcare professionals have not seen an adverse event reporting form. This could be a potential barrier to reporting, as familiarity with the form is essential for initiating the reporting process. Less than half of the respondents actively take feedback from patients after implanting a device. This suggests a potential area for improvement in materiovigilance practices. Gathering feedback is essential for identifying adverse events early. A low percentage of healthcare professionals have attended workshops or Continuing Medical Education (CME) sessions focused on medical devices. This may be a contributing factor to the lack of awareness about materiovigilance practices and the importance of reporting adverse events. While a majority is aware of the ongoing program for monitoring medical device safety, there is still a significant portion (32.2%) who either does not know about or are unaware of the relevant programs. This indicates that greater outreach and education are needed to ensure that all healthcare professionals are aware of the available materiovigilance systems. Most respondents are aware of the classification system used in India for medical devices, but a smaller number are familiar with all the categories. This classification is important for monitoring device safety, as the regulatory requirements can vary depending on the category. There is reasonable awareness of where to report adverse events, with most respondents knowing at least one reporting avenue.

However, more efforts are needed to ensure that all healthcare professionals are fully aware of the reporting mechanisms available. While most healthcare professionals acknowledge the potential for adverse events related to medical devices, there is room for improvement in their knowledge of reporting systems and regulatory programs in place to monitor such events. Awareness of the materiovigilance system is not universal and many professionals may not know where or how to report adverse events effectively. Despite recognizing the importance of reporting and patient safety, many healthcare professionals have not actively participated in reporting adverse events, suggesting barriers such as lack of knowledge, training, or accessibility to reporting systems. The relatively low attendance in workshops or CMEs on medical devices and adverse event reporting suggests that there may be a need for more targeted education to engage healthcare professionals in materiovigilance activities. Increase awareness and training about materiovigilance practices and adverse event reporting systems can be achieved through more workshops, CMEs and hands-on training. Improve accessibility to reporting forms and ensure that healthcare professionals know where and how to report adverse events. Strengthen engagement with the existing monitoring programs in India to ensure that healthcare professionals are aware of and actively participate in post-market surveillance of medical devices.

DISCUSSION

The study results highlight several key insights into healthcare professionals' attitudes, awareness and practices concerning adverse events associated with medical devices. Overall, while the study reflects a high level of recognition about the potential for harm from medical devices, it also points to notable gaps in knowledge, reporting practices and professional engagement with materiovigilance systems.

A significant majority (89.83%) of respondents acknowledge that medical devices can cause adverse events. This reflects a strong understanding of the risks associated with medical device use and suggests that healthcare professionals are generally aware of the potential for harm. However, the relatively small group (10.17%) who do not believe that devices can cause adverse events could indicate a need for further education on the topic, as even experienced professionals may underestimate certain risks.

Among those who acknowledge the risk of adverse events, 92.37% agree that it is necessary to report any such occurrences. This aligns with the core principles of materiovigilance, where adverse event reporting is critical to monitoring device safety, identifying emerging risks and enhancing patient care. These figures suggest a broad recognition of the importance of transparent reporting to improve patient outcomes and safety. However, the 7.63% of respondents who do not see the necessity of reporting indicate that there may be lingering misconceptions or practical barriers to reporting.

A strong majority (87.29%) of respondents agree that it is the professional obligation of healthcare providers to report adverse events. This is crucial as materiovigilance depends heavily on healthcare professionals to provide data on device-related issues, which can inform regulatory bodies and helps implement corrective actions. However, the remaining 12.71% who disagree may reflect a gap in understanding the ethical and legal responsibilities involved in reporting adverse events, underscoring a need for stronger institutional emphasis on this duty.

An overwhelming 96.61% of respondents believe that reporting adverse events will enhance patient safety, reflecting a strong understanding of the broader benefits of post-market surveillance in identifying device-related issues. This also suggests a high level of support for materiovigilance systems, as these mechanisms are designed to proactively address safety concerns and improve outcomes by making data on adverse events publicly available. However, the fact that a small percentage (3.39%) disagrees indicates that more could be done to explain the direct impact of reporting on patient outcomes and device safety.

Despite the high awareness of adverse event risks, only 21.19% of respondents have encountered adverse events in their clinical practice. This could suggest that adverse events, while a significant

concern, may be relatively uncommon. However, it is crucial not to overlook the risks, as the data also show that 80.51% of those who encountered adverse events did not participate in reporting them. This points to a significant gap in engagement with materiovigilance practices. Factors contributing to this gap could include lack of familiarity with reporting forms, unclear reporting pathways, or a lack of institutional support for reporting.

The finding that 65.25% of healthcare professionals have not seen an adverse event reporting form is troubling. Familiarity with these forms is essential for enabling prompt and effective reporting. This highlights a key barrier to materiovigilance efforts: without accessible and well-known reporting mechanisms, even professionals who wish to report adverse events may not have the resources or information to do so. Addressing this issue could involve making reporting forms more readily available, simplifying the process and increasing the visibility of these forms in clinical settings.

A relatively high percentage (58.47%) of respondents do not take feedback from patients after implanting devices, while 41.53% do. This suggests a missed opportunity to monitor adverse events proactively. Gathering feedback from patients after device implantation is a valuable tool for detecting untoward events that may not immediately manifest but could affect patient safety over time. It also encourages ongoing communication between healthcare providers and patients, reinforcing patient-centered care. Greater emphasis on feedback mechanisms could help close this gap in monitoring device safety.

The data reveal that 80.51% of respondents have not attended workshops or Continuing Medical Education (CME) programs focused on medical devices. This suggests a significant gap in ongoing education and professional development regarding medical device safety and materiovigilance. While healthcare professionals may receive initial training during their formal education, continuous professional development is essential to keep them informed about the latest safety protocols, regulatory guidelines and the importance of reporting adverse events. Increasing access to relevant CMEs, workshops and educational materials could help bridge this gap and enhance healthcare professionals' ability to participate in materiovigilance effectively.

Although most respondents are aware of the ongoing programs in India for monitoring adverse events related to medical devices, a significant portion (32.2%) is either unaware or unsure about the relevant programs. This indicates that there is room for improvement in disseminating information about materiovigilance programs and their processes. Awareness campaigns, training sessions and informational resources could help increase engagement with these monitoring systems, ensuring that all healthcare professionals are aware of where and how to report adverse events.

A large proportion of respondents (75.42%) are aware of the classification system used in India for medical devices, but fewer are familiar with all the categories. This reflects a need for greater clarity and education on the classification of medical devices and how this relates to risk management. The regulatory requirements for different device categories vary and understanding this system is crucial for effective monitoring and reporting.

The study results are skewed towards female respondents, with 74.58% identifying as female compared to 25.42% male respondents. This gender imbalance could influence the results and interpretations, especially in healthcare fields where certain trends or concerns may vary by gender. Future research may benefit from ensuring a more balanced gender representation to gain a more comprehensive understanding of healthcare professionals' attitudes and behaviors.

CONCLUSION

While healthcare professionals generally understand the importance of adverse event reporting and the risks associated with medical devices, the study identifies several key areas for improvement in materiovigilance practices: The low attendance in relevant workshops and CMEs suggests a need for continuous education on the importance of materiovigilance and the reporting process. Healthcare institutions should prioritize training programs that focus on adverse event reporting, safety monitoring and device classification. A significant number of professionals are not familiar with reporting forms or pathways. Ensuring that reporting forms are easily accessible, well-publicized and simple to complete could encourage more healthcare professionals to engage with the reporting process. Implementing systematic processes for collecting patient feedback after medical device implantation could improve early detection of adverse events and enhance the effectiveness of materiovigilance efforts. Greater outreach is needed to increase awareness of existing programs for monitoring adverse events related to medical devices. This can be achieved through informational sessions, online resources and collaborations with regulatory bodies. By addressing these gaps, healthcare systems can strengthen their materiovigilance efforts, improve patient safety and ensure that medical devices perform as intended in real-world clinical settings. These improvements will lead to a more robust framework for monitoring and mitigating the risks associated with medical device use.

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ETHICAL CLEARENCE

The study was initiated after obtaining approval from the Institutional Research Committee. The participant were approached and given information about the study and those volunteered were included as participants.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest

ABBREVIATIONS

CME: Continuous Medical Education; **MDAE:** Medical device-associated adverse events; **NCC:** National Coordination Centre; **CDSCO:** Central Drug Standard Control Organization; **MvPI:** Materiovigilance programme of India; **GHTF:** Global Harmonization Task Force.

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