ORIGINAL RESEARCH ARTICLE

Factors Affecting the Reporting of Adverse Events Due to Medical Devices Among Doctors: A Qualitative Approach

Anil Sandra[1], Mahesh Kumar D[2*], Princy Louis Palatty[3], Febina MB[4]

[1-4]Department of Pharmacology, Amrita Institute of Medical Sciences and research centre, Amrita Vishwa Vidhyapeetham, Kochi, India

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ABSTRACT

Background: A medical device is any tool or gadget used to diagnose or treat a condition. These devices may be associated with Adverse Medical Device Events (AMDEs), ranging from minor complications to serious morbidity or mortality. Underreporting of AMDEs remains a significant challenge to patient safety and regulatory surveillance. The primary objective of this study was to explore doctors' beliefs and behaviors related to the reporting of Adverse Medical Device Events (AMDEs). Secondary objectives were to identify other individual and organizational factors influencing the reporting of AMDEs.

Methodology: A descriptive qualitative study was conducted using stratified purposive sampling to recruit doctors from a tertiary care hospital. Thematic saturation was attained by semi-structured interviews that lasted ten to fifteen minutes. Interviews were audio-recorded, transcribed verbatim, and analyzed using inductive thematic analysis with QDA Miner Lite. Methodological rigor was ensured through data saturation, reflexive analysis, and adherence to COREQ reporting guidelines. Ethical approval was obtained (08.12.2023), and written informed consent was secured from all participants.

Results: Sixteen doctors were interviewed between December 2023 and February 2024. Analysis revealed two major themes: doctors' knowledge, beliefs, behaviors, and organizational systems and processes. Awareness of AMDE reporting varied across participants, with some demonstrating familiarity with reporting mechanisms while others expressed uncertainty regarding definitions, reporting pathways, and perceived consequences. Beliefs regarding responsibility, fear of blame, time constraints, and lack of institutional support influenced reporting behaviors.

Conclusion: The study demonstrates variability in doctors' awareness and practices related to AMDE reporting, with several individual and systemic barriers contributing to underreporting. These findings highlight the need for targeted training, supportive institutional policies, and strengthened collaboration among clinicians, hospitals, industry, patients, and regulatory authorities to improve AMDE surveillance and patient safety.

Keywords: Materiovigilance, Adverse Events, Doctors, Qualitative, Medical Device

ARTICLE INFO

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***Correspondence:** Mahesh Kumar D (Email: saakethbhagat@gmail.com)

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INTRODUCTION

Any tool, equipment, implant, in vitro diagnostic reagent, or software meant to aid in the diagnosis or treatment of human illnesses is considered a medical device.[1-3] They have a crucial role in the prevention, diagnosis, treatment, and cure of illnesses and aberrant physical conditions.[4] However, like all medical treatments, medical devices carry a certain degree of risk, and adverse events can occur. These events, called Adverse Medical Device Events (AMDEs), can range from minor complications to events that can lead to serious morbidity or mortality in a patient.[5]

AMDEs, particularly those that have the potential to cause serious harm to patients and have significant negative impacts on outcomes, especially for higher-risk devices, have received significant attention in the media and have led to legal action.[3] This has prompted calls for the implementation of strategies that will ensure patient safety while still allowing access to innovative medical technology.[3] US FDA data reveals that a total of 249 devices were recalled from the market between 2005-2012 due to related adverse events/malfunctioning.[6]

Materiovigilance is a systematic approach that involves identifying, collecting, reporting, and analyzing any adverse events related to the use of medical devices.[3] This is aided by post marketing surveillance of medical devices, which is very essential in these situations, as it is an effective way of gathering and analyzing a large amount of data over time to quickly identify devices that are likely to cause adverse events.[1,3] This information can be utilized to improve devices and inform healthcare providers of potential risks, which can help prevent future adverse medical device events.[1] In the absence of a structured system for collecting data, identifying, and sharing information about adverse medical device events, materiovigilance relies heavily on voluntary reports from doctors who have direct experience with device-related issues and may be able to observe patterns in device usage and outcomes.[1,3,7]

In our country, despite having a robust Materiovigilance Program of India (MvPI) functioning since 2015, reporting of AMDE is often found to be on the lower side.[8-10] Qualitative research studies in certain developed nations have shown that factors such as fear of blame, the belief that errors are unavoidable, lack of time, lack of knowledge about reporting, and cultural norms can all impact the willingness of healthcare professionals to report medical errors.[8,11] Furthermore, organizational factors such as a lack of feedback and a functioning reporting process can also affect the rate of reporting.[7] However, comparable qualitative evidence examining these factors in the Indian healthcare context is limited. Understanding the beliefs, behaviors, and contextual influences affecting AMDE reporting among doctors is therefore essential, and this gap formed the basis for conducting the present study among doctors involved in patient care.

The primary objective of this study was to explore doctors' beliefs and behaviors related to the reporting of Adverse Medical Device Events (AMDEs). Secondary objectives were to identify other individual and organizational factors influencing the reporting of AMDEs.

METHODOLOGY

A descriptive qualitative approach centered around gathering direct experiences from the participants was used for the study. The study was conducted in a tertiary care hospital over a three-month period (December 2023 to February 2024).

Physicians from departments that often employ medical devices, such as cardiology, oncology, cardiovascular and thoracic surgery, general surgery, and orthopedics, who were willing to give written informed consent, met the inclusion criteria for our study. Junior residents or physicians who were not actively involved in device-based therapies, as well as those who refused to have their interviews recorded, were excluded from our study.

Stratified purposive sampling was employed to include physicians from diverse specialties and with differing levels of clinical experience, to maximize variation in perspectives. As is customary in qualitative research, data collection and analysis occurred concurrently, and sampling continued until thematic saturation was achieved. Saturation was assessed during data analysis, and was considered achieved after consecutive interviews failed to yield novel codes or subthemes. Two additional interviews were conducted to confirm saturation.

Following Institutional Ethics Committee (IEC) approval (ECASM-AIMS-2023-572 dated 08/12/2023), participants were approached individually and provided with the study information sheet and consent form. After obtaining informed consent from all participants, interviews were scheduled at each participant's convenience and conducted in their office chambers to ensure comfort and privacy. Interviews lasted around 10-15 minutes, reflecting the demanding clinical schedules of participating doctors. To maximize depth within the limited interview duration, a semi-structured interview guide was used, adapted from a previously published qualitative study by Gagliardi AR et al.[12] and contextualized to the present setting. The guide comprised open-ended questions exploring participants' experiences with adverse medical device events (AMDEs), awareness of reporting mechanisms, and individual- and organizational-level factors influencing reporting behavior.

Despite the brief interview, the critical event interview approach prepared participants to address AMDE reporting by asking them to explain a recent AMDE that had captured their attention during their clinical practice. They were then asked if and how

they report AMDEs in any way to any system or organization. They were also asked to list the factors that likely influence their reporting of AMDEs, including organizational or environmental factors like policies or procedures in their department, hospital, or region, as well as individual healthcare professional factors like attitude and knowledge.

All interviews were audio-recorded with permission and later transcribed verbatim using Microsoft Office tools. Audio recordings were stored on password-protected department computers accessible only to the research team. Transcripts were anonymized by removing identifying information and assigning unique participant codes. Both audio files and transcripts were securely stored and will be retained in accordance with institutional data protection policies.

Data collected were analysed using an inductive thematic analysis approach. Interview transcripts were managed and coded using QDA Miner Lite software. Analysis began with open coding, which was carried out independently by the primary investigator through careful reading and re-reading of transcripts to identify meaningful units of data. Codes were continuously compared across transcripts and refined through an iterative process.

Following initial coding, similar and related codes were examined and merged, leading to the development of subthemes. These subthemes were subsequently reviewed and organised into broader overarching themes through repeated discussions among members of the research team. This process allowed for consolidation of findings while ensuring that the themes remained grounded in the data. Illustrative participant quotations were selected and organised under the relevant themes to support interpretation of findings. The reporting of results adhered to the Consolidated Criteria for Reporting Qualitative Research (COREQ) guidelines.

Reflexivity was addressed by documenting the interviewer's academic background, training, and assumptions prior to data collection. The interviews were conducted by a final-year postgraduate student who had received prior training in qualitative research methods. The interviewer had no supervisory, evaluative, or hierarchical relationship with the participants, thereby minimizing potential power imbalance. Regular discussions with senior faculty members of the research team were undertaken throughout data collection and analysis to reflect on emerging interpretations, reduce individual bias, and enhance analytical rigor.

RESULTS

Sixteen doctors/consultants from different medical and surgical specialties were interviewed, using a semi structure interview guide, during the study period (Dec 2023 to Feb 2024) and their characteristics are given below in Table 1.

Quotes/remarks are examined here under the various themes that were derived after data analysis and dissimilar opinions are also expressed accordingly (Figure 1). Themes and subthemes summarized in Table 2.

Theme 1: Knowledge, beliefs, and behavior of doctors

This theme reflects doctors' understanding of Adverse Medical Device Events (AMDEs), their beliefs about the importance and consequences of reporting, and their actual reporting practices. Participants demonstrated varying levels of knowledge about AMDEs and available reporting mechanisms.

Table 1: The table summarizes participant characteristics, including unique participant identifiers, gender, specialty or subspecialty, professional designation, and total years of clinical experience after completion of postgraduate training

Participant	Gender	Specialty/Subspecialty	Designation	Years of experience
P1	Male	Cardiology	Professor	More than 8 years
P2	Female	Cardiology	Associate professor	Less than 8 years
P3	Male	Oncology	Professor	More than 8 years
P4	Male	Oncology	Assistant professor	Less than 8 years
P5	Male	General surgery	Assistant professor	Less than 8 years
P6	Male	Orthopedics	Assistant professor	Less than 8 years
P7	Male	General surgery	Assistant professor	Less than 8 years
P8	Male	Cardiovascular thoracic surgery	Associate professor	Less than 8 years
P9	Male	General surgery	Assistant professor	Less than 8 years
P10	Male	Orthopedics	Assistant professor	Less than 8 years
P11	Male	Orthopedics	Associate professor	Less than 8 years
P12	Male	General surgery	Additional professor	More than 8 years
P13	Male	Orthopedics	Professor	More than 8 years
P14	Male	Cardiovascular thoracic surgery	Professor	More than 8 years
P15	Male	Cardiovascular thoracic surgery	Assistant professor	Less than 8 years
P16	Male	Orthopedics	Assistant professor	Less than 8 years

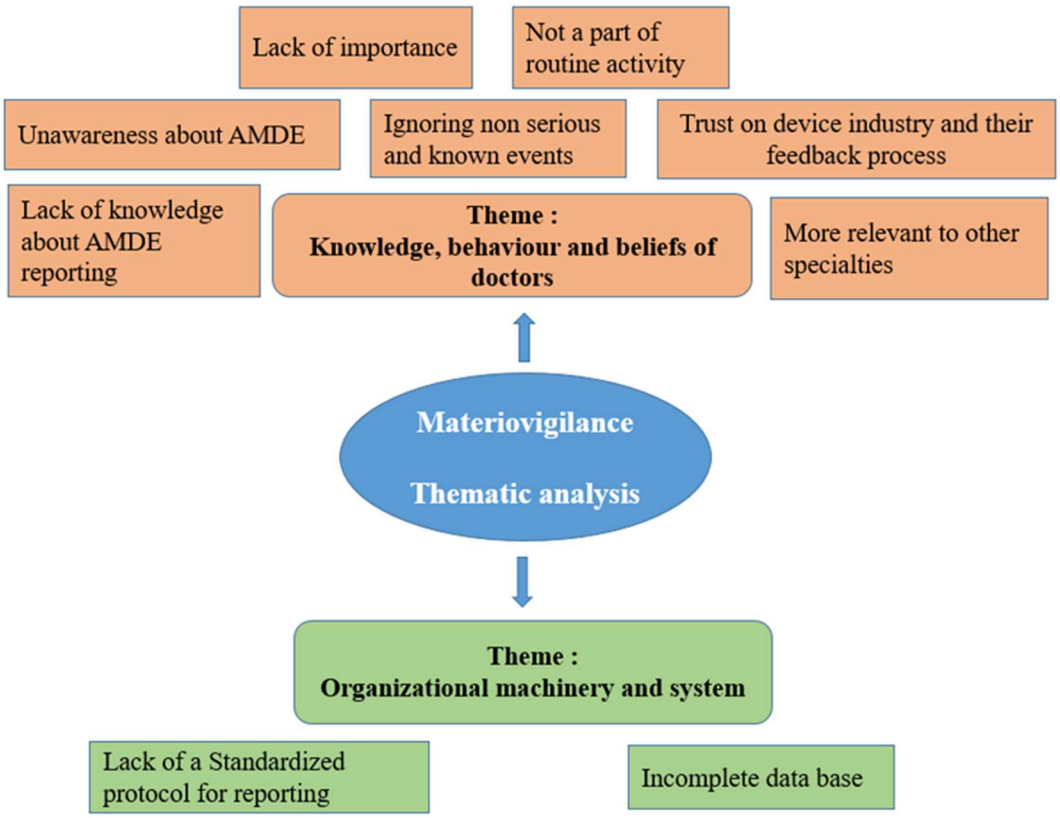

Figure 1: The themes and subthemes derived from the qualitative data

Subtheme: Unawareness about AMDE

Some of the respondents were unaware of what constitutes an AMDE. Several clinicians demonstrated uncertainty about how AMDEs are defined and whether certain device-related occurrences should be classified as reportable events, particularly when no immediate patient harm was evident.

"If the flow rate that is set in an infusion pump doesn't work as predicted, would that amount to AMDE? If the increased rate of infusion leads to oral mucositis, can that be labelled as an AMDE?" (P4 with less than 8 years of clinical experience)

Subtheme: Lack of knowledge about AMDE reporting

Both the surgeons and physicians were unaware about the existence of a system of reporting within the organization. While some clinicians acknowledged that device-related adverse events should be reported, they lacked clarity regarding reporting pathways, responsible authorities, or available institutional and national reporting mechanisms.

"Actually, there is one thing we are not aware of and that is the pathway to report. I am really not aware of any centralized reporting. Something I don't think the physicians are generally aware of." (P1 with more than 8 years of clinical experience)

But a differing viewpoint was also shared by few clinicians who were aware of the existence of a robust system of AMDE reporting.

"We have a staff here, Mr X, doing his thesis on materiovigilance and he keeps us updated about adverse events due to devices. We are reporting these things and, we have gotten biomedical team reporting the same." (P13 with more than 8 years of experience)

Subtheme: Lack of importance

Some participants were of the view that reporting adverse medical device events was not a priority in routine clinical practice. Events perceived as minor, expected, or without immediate adverse outcomes were often regarded as insufficiently important to warrant formal reporting.

"It is a grey area where the focus has not been given much. Even papers and conferences can come on this because there have been a lot of adverse events happening. I think the surgeons are lagging and maybe at the surgical society levels, we should realize the importance of discussing the reporting of such events". (P12 with more than 8 years of experience)

Subtheme: Ignoring non serious and known events

Many participants considered the reporting of known and non-serious AMDEs as non-imperative. Events that were considered expected complications or part of routine device use were often regarded as not warranting formal documentation.

"I know, we as a clinician may also not be very proactive in reporting adverse events, especially the non-serious ones. May be because of lack of time or

may be assuming that it might not affect patient care." (P13 with more than 8 years of experience)

Subtheme: Not a part of routine activity

Majority of the clinicians considered that AMDE reporting is still sub optimal as it is still not considered as part of day-to-day patient care.

"It's not really the lack of time as some people say. The problem is we never have that habit of doing these things. Once it becomes a habit and once, we start doing it as part of our routine clinical practice, it will cease to remain an issue". (P13 with more than 8 years of experience).

"It's not that we are hesitant to report but we are just not used to report". (P1 with more than 8 years of experience)

Subtheme: More relevant to other specialties

Some of the participants considered that adverse events related to devices are rarer and of a non- serious nature in their specialties in comparison to certain other specialties of medical profession. Participants reported lower perceived relevance of materiovigilance to their own practice and greater attribution of responsibility to other specialties.

"Our device related safety issues are mostly at the departmental level rather than at a huge peer group level. You'll find it in cardiology where such things are probably discussed at a higher peer group level. They are probably more vigilant as their devices can lead to life threatening events. Not so, here"(P4 with less than 8 years of clinical experience)

Subtheme: Trust on device industry and their feedback process

Some of the clinicians relied heavily on the feedback system existing in medical devices industry, especially those involved in manufacturing high risk equipment. Some clinicians were of the opinion that notifying the company directly was sufficient for addressing adverse events and formal reporting through institutional or national materiovigilance systems was viewed as less immediately necessary.

"Till date, in my practice I have come to know about adverse events from the manufacturer. And the manufacturer picks up the problem and takes it further till a solution is obtained. The sales representative and the company are in constant touch with the operator. And they are available over phone 24 by 7. They don't try to shy away from what we say and when the operator says that we have a problem, they are ready to chip in and help us."(P1 with more than 8 years of clinical experience)

Some respondents also had complete confidence in the various steps leading to the availability of a particular device in the market.

"Suppose a product is there, it must go through a lot of trials and then come forward. So, the events which are happening, it's usually not life-threatening events as fatal events get declared by the time they go through the trial". (P14 with more than 8 years of clinical experience)

Theme 2: Organizational machinery and system

Participants described how the availability, clarity, and functionality of institutional reporting systems, along with feedback mechanisms and administrative support, influenced their willingness and ability to report device-related adverse events. Inadequate or poorly defined systems were perceived as barriers to consistent reporting.

Subtheme: Lack of a standardized protocol for reporting

Majority of the respondents opined that a proper functioning system of reporting should be in place and its existence should be informed to all the stake holders.

"As per the hospital system, we are having a reporting system for needle stick injury, but not for biomedical machines and I think we should have a committee entrusted with the preparation and implementation of a standard protocol for reporting adverse events." (P13 with more than 8 years of clinical experience)

"We don't know that there is a systematic way of reporting. When an event arises, we panic and call the sales representative and the technician. Is there any other method to approach the problem?" (P1 with more than 8 years of experience)

Table 2: Table summarizes the themes and subthemes derived from the qualitative data

Themes	Subthemes
Knowledge, beliefs, and behavior of doctors	Unawareness about AMDE
	Lack of knowledge about AMDE reporting
	Lack of importance
	Ignoring non serious and known events
	Not a part of routine activity
	More relevant to other specialties
	Trust on device industry and their feedback process
Organizational machinery and system	Lack of a standardized protocol for reporting
	Incomplete data base

Subtheme: Incomplete data base

Some of the participants underscored the importance of having a data base at the central level which would make alerting the recipient of a malfunctioning medical device a lot easier.

"It so happened once that a particular batch of pacemakers manufactured by a company had a problem as certain complaints were raised from other parts of the country. The company alerted us and with much difficulty we were able to inform the recipients of that equipment. Maintenance of a proper data base at the central level would facilitate AMDE reporting and surveillance". (P1 with more than 8 years of experience)

Discussion

Our study was aimed at examining the various factors that influence AMDE reporting among specialist doctors by conducting a one-on-one interview. Sixteen participants were interviewed during the study period, which was almost identical to the number of doctors that participated in similar qualitative studies where sample size usually tend to be smaller in number because of the phenomenon of saturation.

In the present study, AMDE reporting by specialist doctors was influenced by multiple interacting factors. A prominent barrier identified was limited awareness and lack of clarity regarding what constitutes an adverse medical device event, as well as insufficient knowledge about existing reporting systems at both the institutional and national levels. Similar observations have been reported in studies from other settings, including questionnaire-based investigations, indicating that inadequate awareness is a common challenge in AMDE reporting.[7,8,10] These findings emphasize the need for structured awareness initiatives, such as regular training programs and continuing medical education sessions, implemented at both institutional and national levels to improve reporting practices.[11] Such informative and frequent orientation programs could be one of the reasons for certain studies in western countries not considering lack of awareness as one of the primary reasons for under reporting of AMDEs.[12-14]

While some of our clinicians considered that the reporting of AMDEs have never been given due importance in patient care, some were also of the opinion that only the non-serious events were often neglected, due to time and human resource constraints, as reflected by their commitment in finding out the root cause of fatal events related to medical devices. These findings were in line with certain study results published elsewhere in the world indicating that doctors are generally hesitant in compromising patient safety but may refrain themselves from reporting certain adverse events with the conviction that such kind of incidents hardly affects the quality of patient care.[12,14]

Some participants were of the opinion that insufficient reporting will continue to remain a bottleneck unless reporting becomes a habit and part of the daily practice of the specialist doctor. This was also echoed in few other studies where an increased sense of responsibility and self- realization were believed to play a key role in the reporting of adverse events.[11,12]

In our study, certain specialist doctors, like medical oncologists, also neglected AMDE reporting because of their belief that it has got lesser incidence and are mostly of a non-serious nature in their practice. This was also suggested in a study by Gagliardi AR et al.[12]

Senior clinicians of our study, especially those involved in using high risk instruments emphasized the positive impact that device manufacturing industries play in materiovigilance and categorically appreciated their commitment in rectifying errors. Certain observations from the study by Everhart AO et al.[13] contrast these findings. One reason for this discordance could be the punitive nature involved in the former study which focused on the publication of adverse events that would have deterred the companies from playing a pro-active role in vigilance.

Findings from this study indicate that limitations in the availability and functionality of formal reporting systems act as a significant barrier to effective AMDE reporting. Participants described uncertainty regarding reporting pathways and the absence of a streamlined process, which appeared to reduce engagement with materiovigilance activities. Comparable system-level challenges have been documented by Meher BR et al.[11] and Raghav MV et al.[15] suggesting that organizational infrastructure plays a critical role in shaping reporting practices. Together, these observations point toward the need for policy-driven reforms that strengthen reporting mechanisms and facilitate their consistent implementation across all levels of healthcare delivery.

In our study, some senior participants emphasized that maintaining comprehensive patient data registries at both organizational and national levels could help prevent catastrophic harm to recipients of malfunctioning medical devices. This perspective aligns with the observations of Vidi VD et al.[16] who highlighted the importance of establishing such registries, particularly for selected high-risk devices, despite acknowledging the additional costs associated with developing and maintaining these databases.

Strengths and Limitations

Using a descriptive qualitative method, this study offers important insights into the factors influencing specialist physicians' reporting of Adverse Medical Device Events (AMDEs). The inclusion of specialists from both medical and surgical disciplines through stratified purposive sampling ensured a wide range of perspectives. The use of semi-structured interviews based on the critical incident technique en-

hanced the depth and authenticity of the data, while concurrent data collection and analysis until thematic saturation strengthened the credibility of the findings.

When evaluating the results, it is important to take into account the many limitations of this study. The results may not be as applicable to other healthcare settings because it was a single-center study carried out at a tertiary care hospital with a very small sample size of sixteen people. Although thematic saturation was achieved, the short duration of interviews (10-15 minutes) may have constrained deeper exploration of participants' experiences, perceptions, and contextual influences related to AMDE reporting. In addition, as with all qualitative studies, the potential for interviewer bias cannot be entirely excluded; however, the use of a semi-structured interview guide and inductive analysis aimed to minimize this risk. The study also focused exclusively on specialist doctors and did not include other key stakeholders such as nurses, pharmacists, technicians, biomedical engineers, or patients, whose perspectives are integral to a comprehensive understanding of AMDE reporting within the healthcare system. Despite these limitations, the study provides valuable insights into existing gaps and identifies opportunities for strengthening materiovigilance practices in similar clinical settings.

Conclusion

The study demonstrated variability in doctors' awareness and engagement with Adverse Medical Device Event (AMDE) reporting, with some clinicians being knowledgeable and proactive, while others faced uncertainties that contributed to underreporting. Participants perceived that reporting is more likely to improve when it becomes an integral part of routine clinical practice. Strengthening AMDE reporting in India requires periodic awareness sessions and targeted CME programs, along with the constitution and effective functioning of institutional materiovigilance committees to streamline reporting and feedback. These findings contribute to ongoing national efforts under the Materiovigilance Program of India by highlighting context-specific opportunities for policy, institutional, and educational interventions, despite the study's single-center scope.

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Availability of Data: Data generated during this study available from corresponding author upon reasonable request.

Declaration of Non-use of Generative AI Tools: This article was prepared without the use of generative AI tools for content creation, analysis, or data generation. All findings and interpretations are based solely on the authors' independent work and expertise.

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