

# Assessment of Knowledge, Attitude, and Practice Toward Materiovigilance Among the Health Care Workers in Mumbai: A Questionnaire-Based Study

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## Abstract

**Introduction:** Materiovigilance is an organized method for locating, obtaining, recording, and evaluating any unfavorable occurrences associated with medical devices to protect a patient's health by preventing recurrences. Recent advancements in science and technology have led to a significant expansion in the role of medical devices in the healthcare delivery system. This questionnaire-based cross-sectional study was conducted among physicians and nurses in a teaching hospital that offers tertiary care and is part of the MvPIMDAE reporting system.

**Case report:** Among the participants, the worst performers were junior nurses, with 66.7% unaware of the term materiovigilance itself, and the best performers were professors, at 73.5%. Participants self-rated their knowledge, and 31.0% considered it average regarding the subject. However, only 53% of respondents were aware of MvPI systems in their institution, and 60.5% were aware of the reporting process.

**Conclusion:** This study shows that our tertiary care teaching institute's medical practitioners lack sufficient materiovigilance knowledge. A campaign of ongoing materiovigilance awareness among healthcare practitioners and nurses, however, would enhance their understanding and inspire them to report MDAEs.

**Keywords:** Materiovigilance, healthcare, awareness, questionnaire.

## Introduction

Materiovigilance is a systematic approach to identifying, gathering, documenting, and analyzing any adverse events related to the use of medical devices and safeguarding patients' health by avoiding recurrences [1]. The importance of medical devices in the healthcare delivery system has significantly expanded due to recent advances in science and technology. More than a million medical gadgets are on the market, ranging in price from inexpensive bandages and tongue depressors to expensive, sophisticated equipment like magnetic resonance imaging machines and medical software [2].

According to the World Health Organization [3], a medical

device is any instrument, apparatus, machine, appliance, implant, reagent for in vitro use, software, material, or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purposes as shown in Table 1. One does not achieve its primary intended action by pharmacological, immunological, or metabolic means in or on the human body but which may be assisted in its intended function by such means.

"In Vitro Diagnostic (IVD) medical device" means a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring, or compatibility purposes [3].

Medical device-associated adverse events (MDAEs) have alarmingly increased globally as a result of the widespread usage of medical devices in the healthcare industry [4,5]. The Materiovigilance Programme of India (MvPI) was formally introduced in July 2015 under the auspices of the Indian Health Ministry. The IPC served as the national coordinating center

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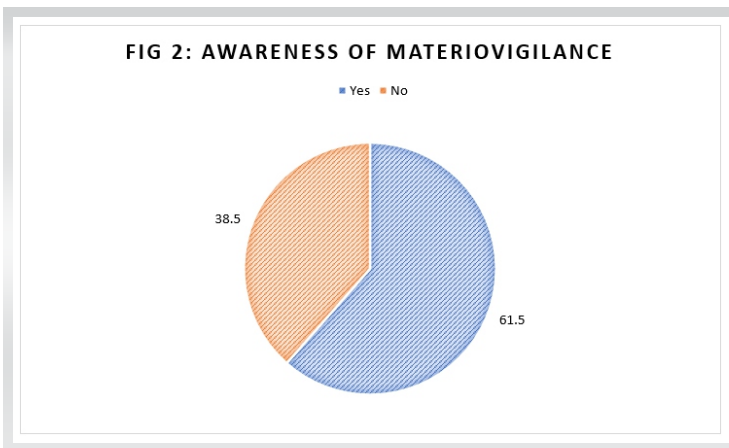
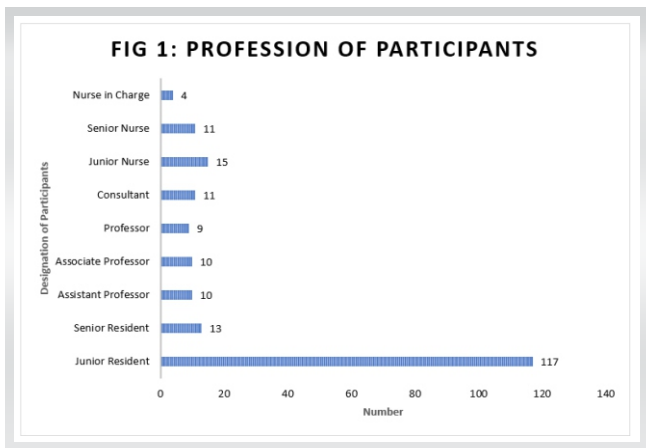
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for this initiative. In addition, the Indian government released the Medical Devices Rules 2017 to control the nation’s safe use of medical devices. From July 2015 to October 2019, the IPC received about 1931 reports of MDAEs [6]. The essential component of the medical device surveillance system’s effective operation is the spontaneous reporting of MDAEs by stakeholders and healthcare providers (HCPs) [7]. Research conducted in various nations revealed that HCPs had inadequate understanding, dispositions, and practices regarding MDAE reporting [8,9]. The knowledge, attitude, and practice (KAP) of HCPs in India with regard to materiovigilance has not been thoroughly investigated. It is crucial to evaluate the knowledge and use of MDAE reporting among Indian HCPs in light of the introduction of MvPI and the growing usage of medical devices. Hence, we have conducted this study to assess the knowledge, attitude, and practice toward Materiovigilance among the health care workers in Navi Mumbai.

**Materials and Methods**

This cross-sectional questionnaire-based study was carried out among medical professionals and paramedical workers, such as nurses in a tertiary care teaching hospital from Navi Mumbai, which is a registered MDAE reporting system under MvPI. The Institutional Ethics Committee gave its approval to the study protocol. The pre-validated questionnaire was administered through the Google link and ran for three months, from November 2023 to January 2024. The questionnaire contains 30 questions in sections for demographic information knowledge, attitude, and practices about materiovigilance, including an invitation paragraph and various questions.

**Statistical methods**

The data collected were entered in a Microsoft Excel sheet and analyzed using descriptive and inferential statistics, using the Statistical Package for the Social Sciences (SPSS version 21.0).

**Results**

**Participant demographics**

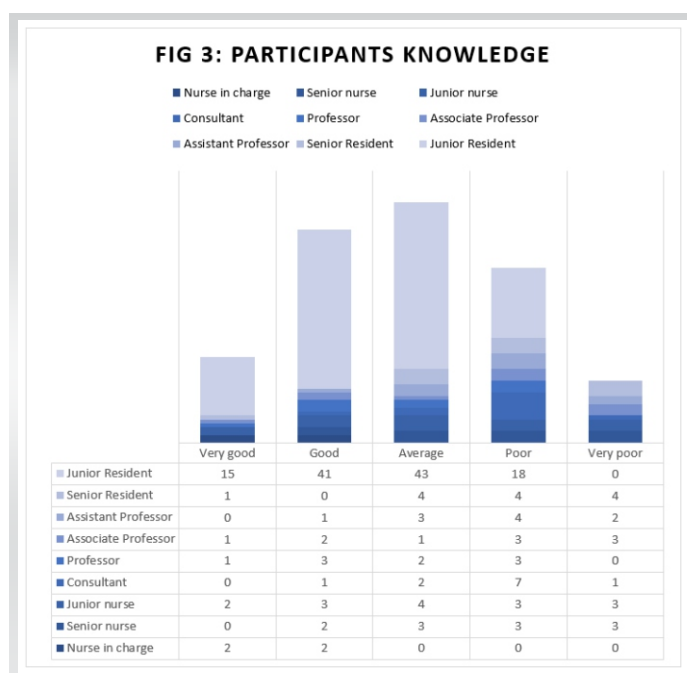
The total number of study participants was 200, and the mean age of the participants was 30.2 years, with male participants being more common (64.2%). The majority of participants were junior residents (Fig. 1), indicating the study’s reach to the population making first contact with patients. Gender did not show significant variation among the options chosen by the participants.

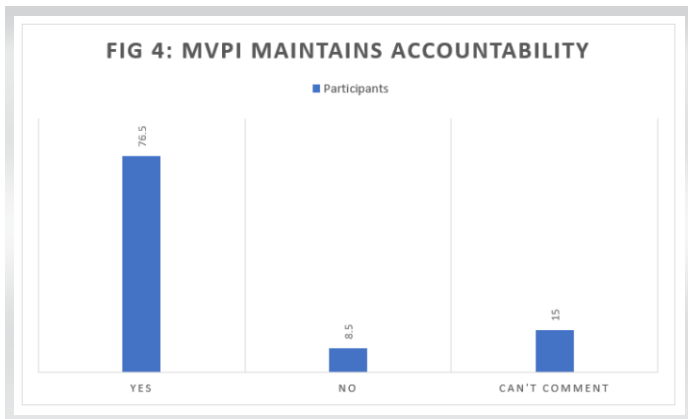
**Knowledge about materiovigilance**

As shown in Fig. 2, 61.5 % of participants were aware of the term materiovigilance.

As shown in Fig. 3, it was observed that 73.5%. Of the professors know materiovigilance.

Participants on self-rating their knowledge have shown that 31.0% consider it average regarding the subject (Fig. 3). Majority of participants, 79% were aware the benefit of materiovigilance spread to doctors, hospitals, patients, and





manufacturers. About half of the participants 57.0% were aware of CDSCO (Central Drug Standard Control Organization). Most participants were also able to positively identify that the role of MvPI is not to persecute the individuals reporting the adverse reactions to medical devices (25.0%) hence showing a positive trend in feeling safe to report such events.

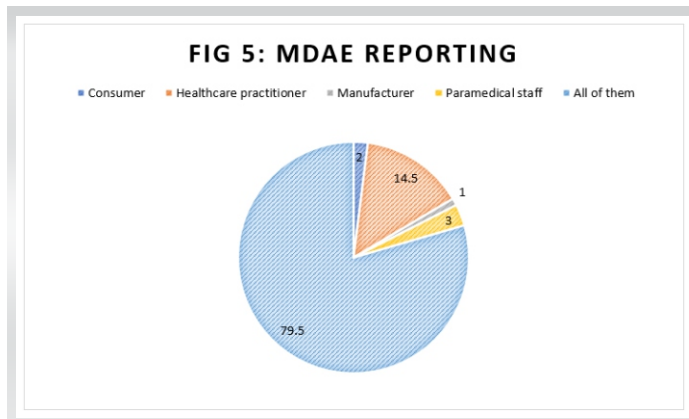
#### Attitude toward materiovigilance

Out of the study respondents, 87.0% consider reporting MDAE their duty. They also found that a more detailed orientation of the subject is needed (85.5%). Most of the participants, however, 82.5%, have never reported any MDAE, even though 42.5% of the participants have encountered MDAE.

Participants also found that the absence of MvPI would lead to a lack of accountability for the functioning of medical devices (Fig. 4). The majority of the participants (72.0%) were also in agreement that MDAE improves patient safety. About half of the respondents (45%) think there's a need for more education and training.

#### Practices of materiovigilance

Participants (79.5%) were also aware that MDAE can be reported by consumers, healthcare practitioners, manufacturers, and paramedical staff (Fig. 5). However, only 53% of respondents were aware of MvPI systems in their institution, and 60.5% were aware of the reporting process. More than half of the participants, 57.5% had never encountered any MDAE, and most of the respondents were



junior residents and nurses hence, the number of years they have been in the field is low, affecting these results.

#### Factors influencing reporting of MDAE

Among the write-in answers, it was noted that most participants were aware of the need for MDAE but lacked the knowledge regarding the process of the same. Participants wanted more programs focused on the mechanism of the reporting system.

#### Discussion

Medical experts have been employing medical devices for patient benefit for years. Since few studies currently exist on medical professionals' materiovigilance awareness and the concept of reporting MDAE is still in its infancy in India, the purpose of this study was to assess the base knowledge attitude and practices observed by healthcare professionals working in a tertiary care teaching institute.

The study participants, who are nursing professionals, possessed limited information regarding materiovigilance. Most of them were unaware that the Ministry of Health and Family Welfare (MoHFW) of the Government of India had launched the MvPI to track the MDAE. Similarly, most of them had no notion of where to file a report for an MDAE. It could be because, in contrast to pharmacovigilance [10], materiovigilance has not yet received significant attention from medical specialists. A functioning reporting system and a lack of awareness could be the reason of this.

Previous studies have demonstrated that medical professionals have identified some barriers to the efficient execution of materiovigilance, including the absence of a favorable workplace and an inadequate reporting mechanism [11, 12].

Underreporting or non-reporting of MDAE is rather common. The Food and Drug Administration has shared information indicating that only 0.5 percent of adverse events associated with the medical device are reported [13]. Materiovigilance is a tiny and relatively recent field. In India, only a few hospitals have signed up for the MvPI. One major worry is the ignorance of materiovigilance. Adverse events involving medical devices place a significant strain on the global healthcare system [14].

Table 1: Purpose for materiovigilance
• Diagnosis, prevention, monitoring, treatment, or alleviation of disease
• Diagnosis, monitoring, treatment, alleviation of or compensation for an injury
• Investigation, replacement, modification, or support of the anatomy or of a physiological process
• Supporting or sustaining life
• Control of conception
• Disinfection of medical devices
• Providing information by means of in vitro examination of specimens derived from the human body

Social media platforms such as LinkedIn, Facebook, Twitter, and YouTube facilitate the dissemination of timely and accurate information to users regarding rational selection and undesirable events. They also serve to promote discoveries and issues pertaining to science and health [15,16]. If any flaws are discovered, they also help spread the word about recalls of medical devices. In the end, this will inform practitioners and users on the most recent regulations or activities pertaining to the item. However, users risk physical and mental harm if they rely too much on information shared on social networking platforms for all of their information needs. Therefore, it is crucial to critically analyze material published on social media and verify its source to prevent potential disinformation, as misinformation can often be worse than no information at all [15].

Materiovigilance is a small and relatively recent field. In India, only a few hospitals have signed up for the MvPI. One major worry is the ignorance of materiovigilance. Adverse events involving medical devices significantly strain the global healthcare system [14]. An extensive awareness- and sensitization-raising program would be necessary for gathering trustworthy data from diligent, frequent reporting and from motivated healthcare providers to collect MDAEs. Training sessions impart knowledge on materiovigilance and assign participants the responsibility of encouraging their peers to report MDAEs to advance the reporting culture.

According to a study, postgraduate medical students' attitudes

about reporting medical events were undoubtedly influenced by their early exposure to the medical education curriculum [17].

### Conclusion

This study shows that our tertiary care teaching institute's medical practitioners lack sufficient materiovigilance knowledge. A campaign of ongoing materiovigilance awareness among healthcare practitioners and nurses, however, would be beneficial in enhancing their understanding and inspiring them to report MDAEs with great zeal. It is comforting to see how enthusiastic they were, in very aware of the need for materiovigilance, and show interest in continuing their learning in the subject. We can also infer that initiatives like workshops, training courses, and continuous medical education could improve the reporting culture among the participants. This study was conducted in one institution in a limited sample size and does not represent the state of knowledge, attitude, and practice regarding materiovigilance in the rest of India. Larger studies with a follow after more training in the subject would help improve the integration of MvPI in day-to-day practice of all healthcare practitioners and nurses.

**Declaration of patient consent:** The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the Journal. The patient understands that his name and initials will not be published, and due efforts will be made to conceal his identity, but anonymity cannot be guaranteed.

**Conflict of Interest:** NIL; **Source of Support:** NIL

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