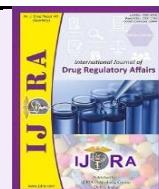


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Research Article

Consumer Reporting in Materiovigilance: Awareness, Attitudes & Barriers to Action

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Abstract

Background: Materiovigilance is an essential component of patient safety, involving the monitoring, identification, reporting, and analysis of adverse events associated with medical devices. Consumer reporting plays a crucial role in detecting faulty medical devices early. However, underreporting remains a significant challenge, often due to a lack of awareness or perceived barriers in the reporting process.

Aims: This study aims to assess consumer awareness, attitudes, and barriers to reporting adverse events related to medical devices under the Materiovigilance Programme of India (MvPI).

Materials & Methods: A cross-sectional study was conducted at Jawaharlal Nehru Medical College & Hospital, Aligarh Muslim University. Consumers were provided with a structured questionnaire in various OPDs and IPDs. Out of 102 screened participants, 76 were selected after obtaining verbal informed consent. Data were collected on awareness, attitudes, and reporting practices and analyzed using descriptive statistics.

Results: The study revealed a significant lack of awareness, with only 12 out of 76 participants aware of Materiovigilance. While 49 participants acknowledged the importance of reporting faulty medical devices, 27 expressed hesitancy. Among 39 participants who encountered medical device issues, only 9 reported them. The primary barriers to reporting included a lack of knowledge (n=37) and doubts regarding the impact of reporting (n=22).

Discussion: The findings highlight a pressing need for improved public awareness and simplified reporting mechanisms. Unreported faulty medical devices may continue circulating, increasing risks to patient safety. Overcoming these barriers requires targeted educational initiatives, streamlined reporting channels, and greater consumer engagement.

Conclusion: Enhancing consumer participation in Materiovigilance through awareness programs and social media outreach can significantly improve reporting rates. Addressing existing barriers will contribute to a more effective surveillance system, ensuring the safe use of medical devices and reducing adverse health outcomes.

Keywords: Materiovigilance, consumer reporting, patient safety, medical device surveillance, healthcare awareness, MvPI

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1. Introduction

Materiovigilance is an activity that has a combined system of performance characterization, monitoring, identifying, collecting, reporting, and analysing any untoward occurrence caused by medical devices. (1) Consumer reporting is crucial in this activity, as it aids in the early detection of faulty devices, contributing to improved patient safety. (2) Underreporting remains a significant challenge, as many consumers experience issues but do not report them, often due to a lack of awareness or perceived

complexity in the reporting process. (3) As the use of medical devices continues to rise globally, the need for an effective surveillance system to track and mitigate potential risks has become increasingly crucial. In India, the Materiovigilance Programme of India (MvPI) was established to enhance post-market surveillance and improve patient safety by monitoring device-related adverse events. (1) Consumer reporting is a key component of Materiovigilance, as it enables the early detection of defective or malfunctioning medical devices. Unlike healthcare professionals, who are trained to

recognize and report adverse events, consumers often serve as the first point of contact when a device issue arises. Their experiences provide critical real-world data that can contribute to identifying safety concerns and initiating corrective actions, such as recalls, safety alerts, and design modifications. Without consumer participation, many faulty devices may remain in circulation, posing potential risks to patient health and well-being. (2)

2. Materials and Methods

2.1 Objective:

To assess consumer awareness, attitudes, and barriers to reporting faulty medical devices under MvPI.

A cross-sectional study was conducted using a structured questionnaire to assess consumer awareness, attitudes, and barriers to reporting adverse events related to medical devices in various OPDs and IPDs at Jawaharlal Nehru Medical College & Hospital, Aligarh Muslim University.

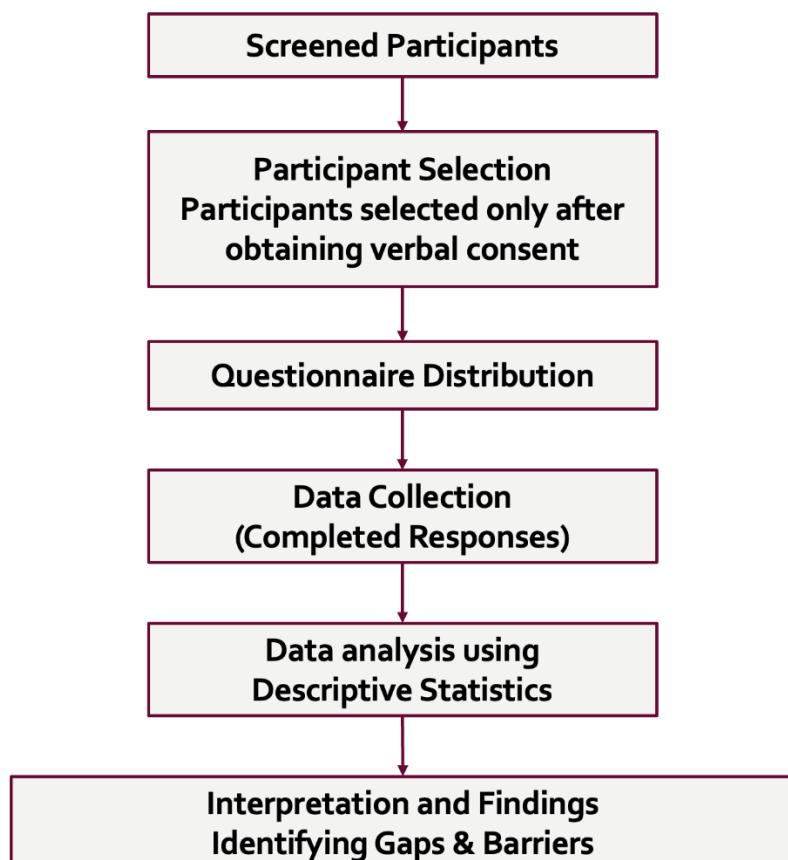


Figure 1. Conduct of the study

2.2 Study tool: Questionnaire

A 20-item structured questionnaire (both in English and Hindi) was developed by the faculties of the Department of Pharmacology (Check Supplementary material for complete form). The questionnaire comprised 20 questions about Materiovigilance under 5 domains [consumer demographics (Question no: 1–5), awareness and attitude (Question no: 6–9), attitude towards reporting (Question no: 10–13), experience with reporting (Question no: 14–18), suggestions for improvement (Question no: 19–20)].

3. Results

A total of **102 participants** were screened out of which **76 were selected** and provided with printed questionnaires to record their response.

Our study revealed a significant lack of awareness about Materiovigilance among consumers, with only 12 out of 76 participants aware of it. While most believed reporting is important, 27 participants felt hesitant to report. 39 participants came across issues with medical devices,

either by themselves or in their surroundings, yet only 9 reported them. The primary barriers include lack of knowledge (n=37) and doubts about impact (n=22) (Figure 2).

4. Discussion

Despite its significance, **underreporting remains a major challenge in Materiovigilance**. Many consumers encounter issues with medical devices but fail to report them. Several factors contribute to this underreporting, including a lack of awareness about the reporting process, uncertainty about whom to report to, and the misconception that individual complaints will not lead to meaningful change. Additionally, the perceived complexity of reporting mechanisms can discourage consumers from participating. Studies have shown that inadequate knowledge about Materiovigilance and the role of the MvPI significantly hinder consumer engagement. (3) Unreported faulty medical devices remain in circulation, posing risks to patient safety. Without consumer reports, harmful devices continue to be used,

potentially leading to serious health consequences. A single report can trigger investigations, recalls, and safety improvements, preventing future adverse events.

A study on the implementation of adverse event reporting for medical devices in India revealed that a majority of consumers were unaware of Materiovigilance initiatives

and reporting channels. (3) Even among those who recognized the importance of reporting, many hesitated due to doubts about whether their reports would be taken seriously or lead to action. These findings underscore the necessity of enhancing public awareness and simplifying the reporting process to encourage more active consumer participation.

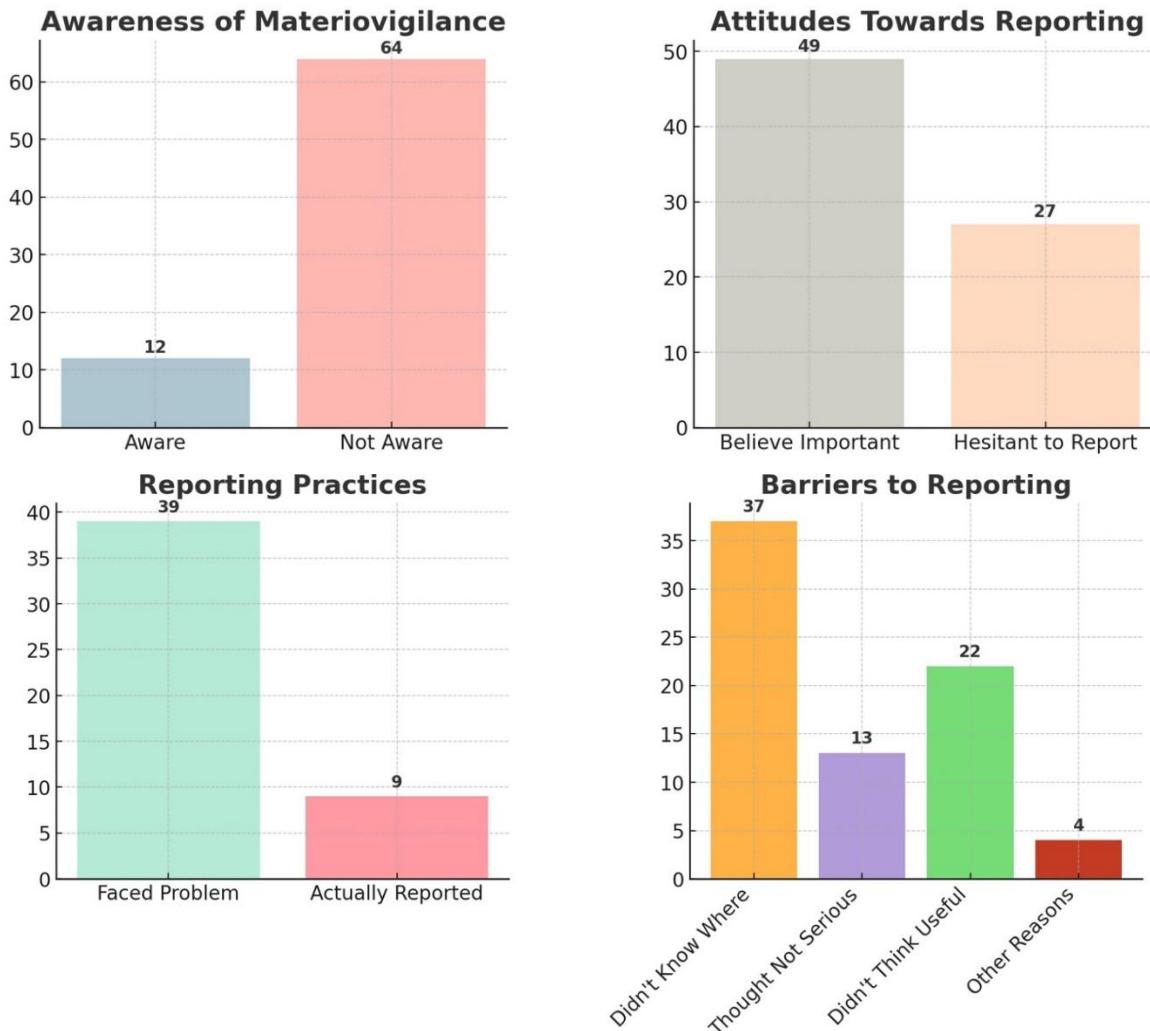


Figure 2. Materiovigilance Awareness, Reporting Attitudes and Practices, and Barriers to Reporting: Analysis of Reporting Practices and Challenges

To address these challenges, several strategies can be employed:

- **Public Awareness Campaigns:** Governments and healthcare organizations should actively promote Materiovigilance through educational initiatives, social media, and public health programs. Increasing awareness about the MvPI and its objectives can empower consumers to report adverse events more confidently.
- **Simplified Reporting Mechanisms:** Lengthy or complicated reporting procedures deter consumers from engaging with Materiovigilance systems.
- **Integration with Healthcare Providers:** Encouraging healthcare professionals to educate patients about medical device safety and the importance of reporting adverse events can

bridge the gap between consumers and the Materiovigilance system.

- **Feedback and Transparency:** Providing updates on reported cases and demonstrating how consumer reports contribute to improved device safety can enhance trust and encourage future participation.

The Materiovigilance Programme of India serves as a crucial framework for ensuring the safety of medical devices, but its success depends heavily on consumer involvement. By increasing awareness, simplifying reporting mechanisms, and fostering a culture of patient safety, underreporting can be significantly reduced. Addressing barriers to reporting is essential for improving the detection of faulty medical devices and preventing adverse health consequences. A robust Materiovigilance system that actively involves consumers will contribute to a safer healthcare environment for all.

5. Supplementary Material (2)

5.1 English Questionnaire used (Front and Back):

<div style="text-align: center;">  <p>Materiovigilance Consumer Reporting Experience Questionnaire</p>  </div> <p>Section 1: Demographics</p> <p>1. Age: _____</p> <p>2. Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other</p> <p>3. Education level: <input type="checkbox"/> No formal education <input type="checkbox"/> Primary <input type="checkbox"/> Secondary <input type="checkbox"/> Graduate <input type="checkbox"/> Postgraduate</p> <p>4. Have you ever used a medical device? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>5. If yes, what type of medical device? (e.g., BP monitor, glucometer, implants) _____</p> <p>Section 2: Awareness & Knowledge</p> <p>6. Have you heard of Materiovigilance (Medical Device Safety Monitoring)? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>7. Do you know where to report a faulty or harmful medical device? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>8. Are you aware of the Materiovigilance Programme of India (MvPI)? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>9. Have you seen any campaigns or advertisements promoting medical device safety reporting? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Section 3: Attitude Towards Reporting</p> <p>10. Do you think reporting defective medical devices is important? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>11. Do you believe your report can help improve medical device safety? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>12. Would you feel comfortable reporting an issue with a medical device? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>13. What would stop you from reporting a problem? (Check all that apply)</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;"><input type="checkbox"/> Lack of knowledge about where to report</td> <td style="width: 50%;"><input type="checkbox"/> Fear of consequences</td> </tr> <tr> <td><input type="checkbox"/> Belief that reporting won't make a difference</td> <td><input type="checkbox"/> Lack of time</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Other (please specify): _____</td> </tr> </table>	<input type="checkbox"/> Lack of knowledge about where to report	<input type="checkbox"/> Fear of consequences	<input type="checkbox"/> Belief that reporting won't make a difference	<input type="checkbox"/> Lack of time	<input type="checkbox"/> Other (please specify): _____		<p>Section 4: Experience with Reporting</p> <p>14. Have you or a family member ever faced a problem with a medical device? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>15. If yes, did you report it? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>16. If no, why didn't you report it? (Check all that apply)</p> <p><input type="checkbox"/> Didn't know where/how to report <input type="checkbox"/> Thought it was not serious <input type="checkbox"/> Didn't think it would be useful <input type="checkbox"/> Other (please specify): _____</p> <p>17. If you reported, where did you report it? <input type="checkbox"/> Hospital staff <input type="checkbox"/> Manufacturer <input type="checkbox"/> Government website <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other: _____</p> <p>18. Was the issue resolved after reporting? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know</p> <p>Section 5: Suggestions for Improvement</p> <p>19. Would you like to receive more information on how to report faulty medical devices? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>20. How can the process of reporting medical device problems be made easier? _____ _____ _____</p>
<input type="checkbox"/> Lack of knowledge about where to report	<input type="checkbox"/> Fear of consequences						
<input type="checkbox"/> Belief that reporting won't make a difference	<input type="checkbox"/> Lack of time						
<input type="checkbox"/> Other (please specify): _____							

5.2 Hindi Questionnaire used (Front and Back):

<div style="text-align: center;">  <p>मेडिकल उपकरणों की सुरक्षा पर उपभोक्ता रिपोर्टिंग अनुभव प्रश्नावली</p> <p>JNMO 35 YEARS OF ADR REPORTING 1988 - 2023</p> <p>भाग 1: व्यक्तिगत जानकारी</p> <p>1. आयु: _____</p> <p>2. लिंग: <input type="checkbox"/> पुरुष <input type="checkbox"/> महिला <input type="checkbox"/> अन्य</p> <p>3. शिक्षा स्तर: <input type="checkbox"/> कोई औपचारिक शिक्षा नहीं <input type="checkbox"/> प्राथमिक <input type="checkbox"/> माध्यमिक <input type="checkbox"/> स्नातक <input type="checkbox"/> स्नातकोत्तर</p> <p>4. क्या आपने कभी किसी मेडिकल उपकरण का उपयोग किया है? <input type="checkbox"/> हाँ <input type="checkbox"/> नहीं</p> <p>5. यदि हाँ, तो किस प्रकार का उपकरण? (जैसे - बीपी मॉनिटर, ब्लूकोमीटर, इम्प्लांट) _____</p> <p>भाग 2: जागरूकता और ज्ञान</p> <p>6. क्या आपने कभी 'मेटरियोविजिलेंस' (मेडिकल उपकरण सुरक्षा निगरानी) के बारे में सुना है? <input type="checkbox"/> हाँ <input type="checkbox"/> नहीं</p> <p>7. क्या आपको पता है कि किसी खराब या हानिकारक मेडिकल उपकरण की शिकायत कहाँ करनी चाहिए? <input type="checkbox"/> हाँ <input type="checkbox"/> नहीं</p> <p>8. क्या आपको 'मेटरियोविजिलेंस प्रोग्राम ऑफ इंडिया' (MvPI) की जानकारी है? <input type="checkbox"/> हाँ <input type="checkbox"/> नहीं</p> <p>9. क्या आपने कभी मेडिकल उपकरण सुरक्षा से जुड़ा कोई प्रचार अभियान या विज्ञापन देखा है? <input type="checkbox"/> हाँ <input type="checkbox"/> नहीं</p> <p>भाग 3: रिपोर्टिंग को लेकर आपका दृष्टिकोण</p> <p>10. क्या आपको लगता है कि खराब मेडिकल उपकरणों की रिपोर्टिंग महत्वपूर्ण है? <input type="checkbox"/> हाँ <input type="checkbox"/> नहीं</p> <p>11. क्या आपको विश्वास है कि आपकी रिपोर्टिंग से मेडिकल उपकरणों की सुरक्षा में सुधार हो सकता है? <input type="checkbox"/> हाँ <input type="checkbox"/> नहीं</p> <p>12. क्या आप किसी खराब मेडिकल उपकरण की समस्या को रिपोर्ट करने में सहज महसूस करेंगे? <input type="checkbox"/> हाँ <input type="checkbox"/> नहीं</p> </div>	<p>13. आपको रिपोर्टिंग से क्या रोक सकता है? (सभी उपयुक्त विकल्प चुनें)</p> <p><input type="checkbox"/> यह नहीं पता कि शिकायत कहाँ करनी है <input type="checkbox"/> रिपोर्ट करने के बाद किसी प्रेशानी का डर</p> <p><input type="checkbox"/> ऐसा लगता है कि रिपोर्टिंग से कोई फ़र्क नहीं पड़ेगा <input type="checkbox"/> समय की कमी</p> <p><input type="checkbox"/> अन्य (कृपया लिखें): _____</p> <p>भाग 4: रिपोर्टिंग का अनुभव</p> <p>14. क्या आपको या आपके परिवार के किसी सदस्य को कभी किसी मेडिकल उपकरण से समस्या हुई है? <input type="checkbox"/> हाँ <input type="checkbox"/> नहीं</p> <p>15. यदि हाँ, तो क्या आपने इस समस्या की रिपोर्ट की थी? <input type="checkbox"/> हाँ <input type="checkbox"/> नहीं</p> <p>16. यदि नहीं, तो रिपोर्ट क्यों नहीं की? (सभी उपयुक्त विकल्प चुनें)</p> <p><input type="checkbox"/> नहीं पता था कि रिपोर्ट कहाँ और कैसे करें <input type="checkbox"/> समस्या गंभीर नहीं लगी</p> <p><input type="checkbox"/> लगा कि रिपोर्ट करने से कोई लाभ नहीं होगा</p> <p><input type="checkbox"/> अन्य (कृपया लिखें): _____</p> <p>17. यदि आपने रिपोर्ट की थी, तो कहाँ की थी?</p> <p>18. क्या रिपोर्टिंग के बाद समस्या हल हुई? <input type="checkbox"/> हाँ <input type="checkbox"/> नहीं <input type="checkbox"/> जानकारी नहीं</p> <p>भाग 5: सुधार के सुझाव</p> <p>19. क्या आप मेडिकल उपकरण रिपोर्टिंग की प्रक्रिया के बारे में अधिक जानकारी प्राप्त करना चाहेंगे? <input type="checkbox"/> हाँ <input type="checkbox"/> नहीं</p> <p>20. आपके अनुसार, मेडिकल उपकरण से जुड़ी समस्याओं की रिपोर्टिंग को और आसान कैसे बनाया जा सकता है?</p> <p>_____</p> <p>_____</p> <p>_____</p>
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6. Conclusion

Consumers should be encouraged to report any medical device issues through Materiovigilance Programme of India (MvPI), as every consumer's voice plays a crucial role in ensuring medical device safety. They should also be informed about the importance of following MvPI on social media for updates on medical device safety and awareness campaigns. By actively participating, consumers can contribute to creating a safer healthcare environment for everyone.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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