Original Article

Knowledge and Attitude toward Adverse Drug Reaction Reporting among Doctors in a Tertiary Care Hospital in Navi Mumbai

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Abstract

Background and Aim: Adverse reactions to drugs pose risks to healthcare safety and negatively impact quality of life, significantly raising healthcare costs. Aiming to improve healthcare and patient safety, this study was undertaken in a tertiary care center in Navi Mumbai, Maharashtra, to assess medical practitioners' familiarity with and perspectives on adverse drug reaction (ADR) reporting. **Methodology:** Following Institutional Ethics Committee approval, this study was conducted as a cross-sectional survey using a questionnaire from March 2022 to April 2023. The study was performed in a tertiary-level healthcare facility, Kamothe, Navi Mumbai, Maharashtra. Pretested and validated questionnaires were used to collect responses from 200 doctors working in all specialties. **Results:** Only junior residents (19%), senior residents (40%), and faculty (32%) had ever reported an ADR. Only 67% of doctors agreed that all ADRs should be reported. Underreporting was attributed to a lack of knowledge on the reporting process and reporting locations, challenges in identifying ADRs, time constraints, and inadequate awareness of ADR reporting protocols. **Conclusions:** The study indicates a favorable attitude of doctors toward reporting ADRs, yet their knowledge is inadequate, highlighting the importance of thorough pharmacovigilance training and increased awareness among healthcare professionals.

Keywords: Awareness, drug-induced reactions, knowledge and attitude, pharmacovigilance

Introduction

Adverse effects of drugs are a significant concern for the healthcare system, as they contribute to worldwide disease burden and fatalities. The World Health Organization defines adverse drug reactions (ADRs) as a response to a drug that is noxious and unintended, occurring at doses typically used in humans for prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function.[1] ADRs not only put patient safety at risk but also negatively impact patient well-being and lead to a significant rise in healthcare spending.

Studies suggest that ADRs are responsible for 0.2%–24% of hospital admissions, with 1.3% of hospitalized patients experiencing an ADR.[2] In India, the incidence of serious ADRs is 6.7%.[3] These statistics underscore the importance of timely recognition and accurate documentation of ADRs to safeguard patients and to manage healthcare resources efficiently.

Although medications are approved following extensive quality control and clinical trials, unforeseen adverse effects may emerge once a drug is introduced to the broader population.[1,3-7] This highlights the critical importance of ongoing postmarketing surveillance, especially through spontaneous ADR reporting for both new and established medications. While this type of ADR reporting is one of the simplest methods for collecting ADR data, it has notable limitations, such as low reporting rates and the inability to reliably estimate how often ADRs occur. Underreporting delays the identification of safety signals, which can result in harmful drugs remaining in circulation, thereby endangering public health.[8,9]

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India ranks below 1% in reporting ADRs globally, primarily due to underreporting of ADRs.[10] To address this issue, a nationwide pharmacovigilance program has been implemented to ensure drug safety, monitor ADRs, and create awareness of the importance of ADR reporting among health professionals.[11] This program intends to make ADR monitoring centers out of all medical colleges, private hospitals, and autonomous institutes, in cooperation with the World Health Organization–Uppsala Monitoring Centre in Sweden. Active participation of healthcare professionals is sought to strengthen the reporting of ADRs, and it is vital to assess the awareness and perspective of medical practitioners toward the ADR reporting system.

This research primarily seeks to evaluate the awareness and perspective of medical practitioners toward reporting of drug-induced reactions in a Navi Mumbai tertiary care setting as well as identify factors for underreporting of ADRs.

Materials and Methods

Upon receiving approval from the IEC (MGM/DCH/IEC/129/22), this questionnaire-based cross-sectional study was conducted between March 2022 and April 2023 at a tertiary care hospital in Kamothe, Navi Mumbai, Maharashtra.

A structured questionnaire on knowledge and attitudes was developed to record the demographic characteristics of the participating doctors, including age, gender, designation, their knowledge of ADR, attitudes toward reporting, and factors responsible for underreporting of ADR among doctors. The knowledge questionnaire had six items, including a definition of ADR, who can report an ADR, awareness of the regulatory body overseeing ADRs, familiarity with the online ADR reporting portal, the required reporting period for serious adverse events, and knowledge about the existence of a pharmacovigilance committee in the institute. The attitude questionnaire had seven items, assessing participants' attitude of ADR reporting, recognition of the necessity for reporting ADRs, factors required to diagnose an ADR, what type of ADR should be reported, and whether healthcare professionals should receive comprehensive training in pharmacovigilance. This research adopted techniques (as in the pilot study) to ensure the completeness of the data, ensuring record completeness and data conformity. Redundancy assessment was performed to identify and eliminate duplicate or overlapping entries.

Sample size estimation

The required sample size (n) was obtained using the standard formula applicable to a finite population:

$$n = (Z^2 \times p \times (1 - P)/e^2)/(1 + [Z^2 \times P \times (1 - P)/(e^2 \times N)])$$

Where: $Z = 1.96$ (for 95% confidence interval), $P = 0.5$ (expected proportion),[12] $e = 0.05$ (margin of error), $N = 400$ (total number of eligible doctors).

This yielded a minimum required sample size of approximately 196. We rounded up and enrolled 200 participants for the study.

Stratified random sampling was performed by dividing eligible doctors into junior residents, senior residents, and faculty strata, which comprised 178, 41, and 108, respectively, and a proportionate number from each stratum in every department was selected using a computer-generated random number table. If a selected doctor declined participation or was unavailable, another doctor from the same stratum and department was randomly chosen as a replacement to maintain randomness and representativeness.

Sample selection criteria

The inclusion criteria were doctors working as junior residents, senior residents, duty medical officers, or faculty (assistant professor, associate professor, professor, or head of department) in clinical departments, including resident doctors from superspecialty disciplines such as traumatology or MCh, who had consented in writing to participate. Participants were excluded if they were interns, doctors who were not prescribers, and those who were on leave at the time of the study.

Scoring criteria for the knowledge questionnaire

For each correct response, participants were given a score of 1 and 0 for incorrect or skipped answers. There were four levels as per the score categorization. Every 0–1 correct answer was assigned a "poor" level, 2–3 score an "average" level, 4–5 score with a "good" level, and with all six questions being correct, the level assigned was "excellent."

A pilot test and validation of the questionnaire were conducted on 20 randomly selected doctors of the institute. The value for Cronbach's alpha for the study was $\alpha = 0.84$. Questions that were unclear or inappropriate were revised based on the pretest results. The finalized self-administered questionnaire was then distributed to the selected doctors. The doctors were made aware of the study's objectives, and any doubts regarding the questionnaire were clarified before completing the questionnaire by the investigator.

Data analysis

Collected data were managed and analyzed in Microsoft Excel and SPSS software, version 23 from IBM Corp., Newyork, USA. Any missing or incomplete data were reviewed, and the extent of incomplete information that was considered to be acceptable was 5% (except for crucial data).

Frequencies and percentages were employed to summarize the data descriptively for attitude-related questions. For the knowledge-based questions, scoring was done with 1 point for each correct response. The overall knowledge level was categorized as poor, average, good, or excellent based on total scores.

Results

Demographic details of the doctors

The demographic information of the participants is summarized in Table 1. Out of 200 participants, the male-to-female doctor ratio was 133:67 [Table 1].

Level of knowledge among the doctors

The highest number of doctors, i.e., 54%, fell into the average-level category, while the lowest number, i.e. only 4%, was in the excellent category. About 12% of doctors were in the poor category, and 30% of doctors demonstrated a good level of knowledge.

On comparison, senior residents exhibited a more advanced understanding than junior residents and faculty. The highest number of doctors – 57% of senior residents, 56% of junior residents, and 52% of faculty – fell into the average level category.

Thus, the overall level of knowledge among doctors regarding ADR and its reporting was average. Based on the scoring criteria, the average score was found to be 3, with a standard deviation = 0.45 [Tables 2 and 3].

Attitude-related questions among doctors on adverse drug reaction reporting

A detailed analysis of the attitude-based questions is provided in Table 4. As per Table 4, 84% of junior residents, 84% of senior residents, and 69% of faculty believed that reporting ADRs was necessary. Only 12% of junior residents, 12% of senior residents, and 11% of faculty had ever received training in ADR reporting.

Importance of adverse drug reaction reporting among doctors

As shown in Table 4, 18% of junior residents, 8% of senior residents, and 19% of faculty believed that ADR reporting was important for calculating the incidence of ADR. In addition, 14%, 12%, and 16% of junior residents, senior residents, and faculty, respectively, had considered it important for identifying predisposing factors. Overall, the highest percentage of doctors, 44%, agreed that ADR reporting was important for identifying drug safety [Table 4].

Factors important for the diagnosis of an adverse drug reaction among doctors

Among all respondents, 37% of junior residents, 28% of senior residents, and 30% of faculty identified the unusualness of the reaction as an important factor. Overall, 38% of doctors responded that new drug involvement was an important factor in diagnosing an ADR [Table 4].

Doctor's opinion on which adverse drug reactions should be reported

In all, 67% of doctors chose the most appropriate option that all ADRs should be reported [Table 4].

Determinants of adverse drug reaction underreporting in the medical profession

A total of 28% of respondents did not know the procedure for reporting, while another 29% of respondents were unsure of the reporting location, and 13% of respondents indicated that identifying the occurrence of an ADR was challenging. The remaining 31% of respondents cited other reasons such as all of the above, time constraints in reporting, and insufficient information on reporting procedure [Figure 1].

Table 1: Demographic details of the doctors (*n*=200)

Particulars	Frequency (%)
Gender	
Male	133 (66)
Female	67 (34)
Age distribution (years)	
20–25	58 (29)
26–30	50 (25)
31–35	30 (15)
<35	62 (31)
Professional Status	
JR	100 (50)
SR	25 (12.5)
Faculty	75 (37.5)

JR: Junior resident, SR: Senior resident

Table 2: Level of knowledge among doctors regarding adverse drug reaction and its reporting

Level of knowledge (score)	JR (%)	SR (%)	Faculty (*n*=75) (%)	Overall knowledge level (*n*=100) (%)
Excellent (6)	1	8	5	4
Good (4–5)	29	36	27	30
Average (2–3)	57	56	52	54
Poor (0–1)	13	0	16	12

JR: Junior resident, SR: Senior resident

Discussion

In the present study, doctors had demonstrated an appropriate attitude to report ADRs, though they lacked the necessary knowledge to effectively do so. Spontaneous reporting is crucial for identifying ADRs due to any drug, and doctors are considered frontline workers and future consultants.

The study found that respondents' knowledge of pharmacovigilance and ADR reporting was average, indicating a need for education and sensitization. However, no significant association was observed between doctors' knowledge and their designation or experience. Adhikari *et al*.'s study found

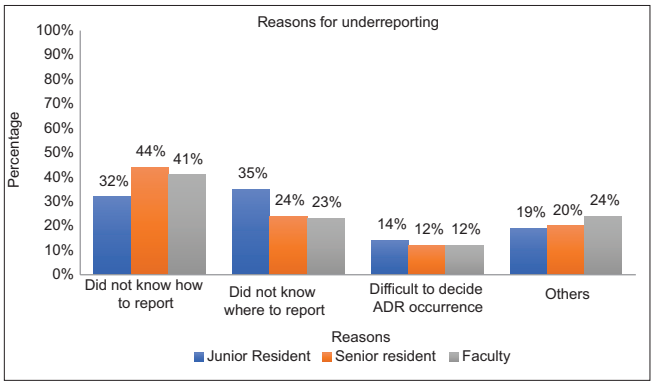

Figure 1: Response of doctors on reasons for under reporting of adverse drug reaction

Table 3: Knowledge of doctors related to adverse drug reaction and its reporting

Assessing knowledge among doctor	JR (*n*=100)		SR (*n*=25)		Faculty (*n*=75)		Total (*n*=200)	
	Correct response (%)	Incorrect response (%)	Correct response (%)	Incorrect response (%)	Correct response (%)	Incorrect response (%)	Correct response, *n* (%)	Incorrect response, *n* (%)
What is an adverse drug reaction?	56	44	64	36	59	41	58	42
Who can report an adverse drug reaction in a hospital?	68	32	64	36	68	32	68	32
Which regulatory body is responsible for monitoring of ADRs in India?	55	45	68	32	56	44	57	43
Which one of the following is the "WHO online database" for reporting ADRs?	34	66	44	56	32	68	35	65
A serious adverse event in India should be reported to the Regulatory body within 14 calendar days	19	81	36	64	23	77	23	77
Is there any Pharmacovigilance Committee in your Institute?	55	45	52	48	49	51	53	47

ADRs: Adverse drug reactions, JR: Junior resident, SR: Senior resident

Table 4: Analysis of attituderelated questions among doctors on adverse drug reaction reporting

Assessing attitude among doctors	JR (*n*=100) (%)	SR (*n*=25) (%)	Faculty (*n*=75) (%)	Total (*n*=200) (%)
Do you think reporting of adverse drug reaction is necessary?	84	84	69	79
Doctors opinion on which ADRs should be reported				
All ADR	64	76	67	67
Serious ADR	20	8	15	16
ADR to new drugs	14	8	13	13
Others	2	8	5	4
Have you ever been trained on how to report ADR?	12	12	11	12
Do you know regarding the existence of a National Pharmacovigilance Program in India?	70	60	55	63
Do you think Pharmacovigilance should be taught in detail to healthcare professionals?	91	88	87	89
Factors important for diagnosis of an ADR				
Unusualness of the reaction	37	28	30	33
New drug involvement	37	40	39	38
Confidence in diagnosis of ADR	18	16	16	17
Other	8	16	15	12
Importance of ADR reporting among doctors				
To calculate incidence	18	8	19	17
Identify predisposing fact	14	12	16	15
Identify safety of drugs	41	64	41	44
Identify unrecognized ADR	27	16	24	24

ADRs: Adverse drug reactions, JR: Junior resident, SR: Senior resident

average knowledge levels among doctors, with junior residents having the highest level, compared to senior residents and faculty. No association was found between knowledge level and professional status.[11]

In our study, knowledge about the definition of an ADR and the reporting of an ADR by healthcare professionals was comparable to the findings from Pimpalkhute *et al*.'s study, which showed that 35% of respondents correctly knew who can report an ADR, while Shetti *et al*.'s study found that 96.5% of doctors knew who can report an ADR.[13,14] Observations on the reporting of ADRs by doctors were quite less in our study relative to the study carried out by Desai *et al*., in which 97% of doctors considered reporting as necessary. Similar results were obtained in a study conducted by Gupta *et al*., where the rate was 89%.[3,15] In this study, a very small percentage of the doctors received training on ADR reporting. However, the findings from studies conducted by Datta and Sengupta depicted a rate of 84% doctors who had received training on ADR reporting.[16,17] This highlights the need for basic workplace training regarding ADR reporting among doctors.

The findings showed that the importance of ADR reporting according to the doctors was to monitor the safety profile of the drug and measure ADR frequency. Similar results were cited in a study performed by Upadhyaya *et al*. Almost 67%

of the participants in our study were of the view that all the ADRs should be reported. Analogous results were obtained in a study undertaken by Desai *et al*., where the rate was 56%; however, another study performed by Shetti *et al*. reported 94% of the doctors agreeing to the fact that it is essential to report ADRs. In contrast to our study, in a study performed by Gupta *et al*., 98% of respondents were of the view that ADRs to new drugs should be reported.[3,9,14,15] A few of the respondents were unsure where to submit reports, and a minimal number of doctors found it difficult to determine if ADR had occurred. Some of them also lacked time, awareness, and information on reporting procedures. Similar findings were observed in a study conducted by Upadhyaya *et al*.,[2] where the results showed, 44.55% and 47.52% did not know how to report and where to report an ADR. 53.7% responses were of the view that managing patients was more important than reporting ADRs. Thus, it is imperative to include what, when, and how the ADRs should be reported during the training of the doctors or healthcare professionals.

In the study conducted by Gupta *et al*., the most frequently cited reasons for underreporting were insufficient time to complete ADR reports (23.8%) and uncertainty about whether an ADR had actually occurred (22.8%), which was similar to our result.[15] The organization should encourage spontaneous adverse event reporting among healthcare professionals through ongoing discussions on regular case-based ADRs. This shall be observed and carried out by clinical pharmacologists during the outpatient department hours as well as by taking regular inpatient department rounds.

According to the study, the level of knowledge among doctors was average, but their attitude toward reporting of ADR was good. Thus, provision of training for doctors is recommended to raise their competence to improve their level of knowledge and improve spontaneous documentation of ADRs in the hospital.

Some of the recommendations to improve ADR reporting among the doctors as suggested by the doctors themselves are as follows: First, integration of ADR reporting into the undergraduate and postgraduate curriculum. Secondly, education on ADR reporting through case-based learning in all health science programs like pharmacy, medicine and allied sciences. By discussing case studies of patients who had experienced ADRs, students can learn how to identify, report, and manage ADRs. Third, establishing a network of doctors from each department and forming a committee for monitoring the ADRs. The pharmacology department shall be acting as the core department to guide and educate on the reporting process through regular online/e-mail updates on the safety of drugs. By implementing these educational interventions, medical students and doctors can develop a better understanding of the relevance of ADR reporting and its influence on safeguarding patients. This will aid them in their professional practice as consultants or community specialists.

Limitations

Research for this study was conducted within a single tertiary hospital setting, in a small sample, thereby restricting the applicability of the findings to other settings. In addition, self-reported questionnaire design was potentially prone to response bias. Subsequent studies involving larger, multicentric samples and objective assessments are recommended.

Conclusion

The results of the study suggest that most hospital doctors show a constructive approach to ADR reporting, but have limited knowledge about it. While they understand the importance of ADR monitoring, few have communicated an ADR to the pharmacovigilance center. The majority of doctors believe that it is necessary to report ADR and emphasize the need for detailed pharmacovigilance training. Therefore, there is a need to raise awareness and promote ADR reporting among healthcare professionals.

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Ethical consideration

Ethical Approval has been taken from Institutional Ethics Committee for Biomedical and Health Research, (MGM/DCH/IEC/29/22; dated: 24.08.2022), MGM Medical College, Kamothe, MGMIHS, Navi Mumbai, Maharashtra, India.

Author's contribution statement

Conceptualization, Methodology done by first and corresponding author, Review, Data collection and Editing done by corresponding author and second author and Statistical Analysis and draft writing done by fourth author.

Data availability statement

Data is available with Corresponding Author and will be given on reasonable request.

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Conflicts of interest

There are no conflicts of interest.

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