Original Article

# Adverse Drug Reporting and Determinants of Under-reporting among Doctors of a Tertiary Care Hospital: A Survey on Knowledge, Attitude and Practice

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## Abstract

**Background:** Adverse drug reaction reporting is a core pharmacovigilance activity, yet spontaneous reporting systems remain limited by under-reporting among healthcare professionals. Understanding doctors' knowledge, attitude, practice, and perceived barriers is essential for strengthening institutional drug-safety systems. The objective is to assess knowledge, attitude, and practice regarding adverse drug reaction reporting among doctors of a tertiary care hospital and to identify determinants of under-reporting. **Material and Methods:** This hospital-based analytical cross-sectional survey was conducted among 150 doctors at Gayatri Vidya Parishad Institute of Healthcare and Medical Technology, Visakhapatnam, from March 01, 2026 to March 31, 2026. Data were collected using a structured questionnaire covering demographic characteristics, pharmacovigilance knowledge, attitude, reporting practice, and barriers. Descriptive statistics, Chi-square test, and multivariable logistic regression were used for analysis. **Results:** The mean age of participants was 31.8 ± 7.2 years, and males constituted 56.0%. Previous pharmacovigilance training was reported by 41.3%. Adequate knowledge was observed in 45.3%, whereas 80.7% showed a positive attitude. Although 72.0% had encountered suspected adverse drug reactions, only 32.7% had ever reported one. Among doctors who encountered adverse drug reactions, 67.6% had not reported them. Major reasons for under-reporting were uncertainty about causality, workload, lack of awareness about reporting procedure, non-availability of forms, and lack of training. Independent determinants of under-reporting were absence of pharmacovigilance training, unawareness of the nearest monitoring centre, workload, and uncertainty about causality. **Conclusion:** Doctors demonstrated favourable attitudes toward adverse drug reaction reporting, but reporting practice remained low. Regular training, simplified reporting pathways, visible reporting forms, and feedback-based institutional pharmacovigilance systems are required to reduce under-reporting.

**Keywords:** Adverse drug reaction; Pharmacovigilance; Under-reporting; Knowledge; Attitude; Practice; Doctors; Tertiary care hospital.

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## Introduction

Adverse drug reactions (ADRs) represent an important and preventable component of medication-related harm. They contribute to morbidity, hospital admission, prolonged hospital stay, additional treatment costs, and avoidable mortality. The diagnosis of ADRs is often complex because clinical manifestations overlap with disease progression, comorbid illness, drug interactions, and patient-related susceptibility factors.[1] Prospective and meta-analytic evidence has shown that ADRs constitute a relevant burden among hospitalized patients and remain a continuing patient-safety concern in both developed and developing health systems.[2,3] In clinical practice, early recognition and timely reporting of suspected ADRs provide the foundation for safer prescribing, rational therapeutics, and regulatory decision-making.

Pharmacovigilance is concerned with detecting, assessing, understanding, and preventing adverse effects or other drug-related problems after medicines enter routine use. Spontaneous reporting is one of the most widely used pharmacovigilance methods because it captures suspected reactions from real-world clinical settings and supports early signal generation. However, its usefulness depends on the active participation of prescribers and other healthcare professionals. Under-reporting is recognized as the major limitation of spontaneous reporting systems, with systematic reviews showing that only a small fraction of suspected ADRs are reported to monitoring authorities.[4,5] The problem becomes more relevant in busy hospital environments, where doctors encounter ADRs but do not always document or submit reports.

Previous studies from India have shown a repeated gap between awareness of pharmacovigilance and actual ADR reporting

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practice. Doctors, residents, and other healthcare professionals usually express a favourable attitude toward reporting, but the proportion who have ever submitted an ADR report remains low.[6-10] A systematic review and meta-analysis of Indian studies found substantial gaps in knowledge, attitude, and practice, particularly in the practical aspects of where and how to report ADRs.[11] Similar findings have been reported in international studies, where lack of training, poor awareness of reporting pathways, limited feedback, and low confidence in causality assessment were associated with poor reporting behaviour.[12,13]

The determinants of under-reporting are multidimensional. Knowledge-related barriers include poor understanding of the national pharmacovigilance programme, uncertainty about the types of ADRs that require reporting, and lack of familiarity with reporting forms. Attitude-related barriers include complacency, fear of legal consequences, and the belief that a single report will not make a difference. Practice-related barriers include workload, limited time, non-availability of forms, and absence of institutional feedback. Recent reviews indicate that knowledge and attitude continue to be modifiable determinants of reporting behaviour among healthcare professionals.[5,14] Therefore, institution-specific surveys are useful for identifying local gaps and designing targeted interventions.

The present study was conducted to assess knowledge, attitude, and practice regarding adverse drug reaction reporting among doctors working in a tertiary care hospital. The study also aimed to estimate the extent of under-reporting among doctors who encountered suspected ADRs and to identify determinants associated with under-reporting, including previous pharmacovigilance training, awareness of the nearest ADR monitoring centre, workload, uncertainty about causality, and fear of legal consequences.

## Materials and Methods

**Study design:** This hospital-based analytical cross-sectional survey assessed knowledge, attitude, practice, and determinants of under-reporting of adverse drug reactions among doctors. Exposure variables, KAP domains, and perceived barriers were measured once during the study period; hence, the design was suitable for estimating reporting gaps without assigning temporal causality.

**Study setting and study period:** The study was carried out at Gayatri Vidya Parishad Institute of Healthcare and Medical Technology, Maridi Valley, Marikavalasa Village, Madhurawada, Visakhapatnam, Andhra Pradesh, India. The institution is a tertiary care teaching hospital providing clinical services and medical training. Data collection was done from March 01, 2026 to March 31, 2026.

**Study population and eligibility criteria:** The study population included doctors working in clinical and allied clinical departments. Interns, junior residents, senior residents, and faculty members available during data collection and willing to participate were included. Doctors who declined consent, were on long leave, or submitted questionnaires with missing primary outcome data were excluded.

**Sample size and sampling technique:** Sample size was calculated using $n = Z^2p(1-p)/d^2$, with p = 32% for ADR reporting practice from earlier KAP literature,[9,13] Z = 1.96, and precision of 8%. The calculated sample was 131; after adding allowance for incomplete responses, it was rounded to 150. Consecutive sampling was used until the required sample was reached.

**Study tool and variables:** Data were collected using a structured, pretested questionnaire adapted from earlier pharmacovigilance studies.[6-13] It included demographic details, professional category, experience, previous training, knowledge items, attitude items, practice items, and barriers. The dependent outcome was under-reporting, defined as not reporting a suspected ADR among doctors who had encountered one. Independent variables included training, awareness of the nearest monitoring centre, workload, uncertainty about causality, and fear of legal consequences.

**Data collection procedure and bias control:** The study was conducted through approach of participants at academic sessions and duty hours in the department. The purpose of the instrument was explained, consent was obtained and the questionnaire was anonymous to minimize social desirability bias. Items were straightforward, there was a pre test before the survey and there was some checking of the completeness of the responses.

**Statistical analysis:** Data tabulated in Microsoft Excel and analysed with the help of Micro Computers with statistical software. Continuous variables were presented as mean and SD. The categorical variables were presented as frequency and percentage. Categorical variables were compared using a chi-square or Fisher's exact test. Independent determinants for under-reaching were identified by multivariable logistic regression. Odds Ratios with 95% CI were computed and $p<0.05$ was deemed to be statistically significant.

**Ethical considerations:** The Institutional Ethics Committee, Gayatri Vidya Parishad Institute of Healthcare and Medical Technology, Visakhapatnam, gave the approval. It was voluntary, written informed consent was given and confidentiality was kept.

## Results

A total of 150 doctors participated in the study. The mean age of the participants was 31.8 ± 7.2 years, and the mean duration of clinical experience was 5.6 ± 4.8 years. Males constituted 84 participants (56.0%), while females accounted for 66 participants (44.0%). Junior residents formed the largest professional group, followed by interns, senior residents, and faculty members. Previous formal training or sensitization on pharmacovigilance was reported by 62 doctors (41.3%) [Table 1].

**Table 1: Baseline characteristics of study participants (n=150)**

| Variable | Frequency | Percentage |
|---|---|---|
| Age group | | |
| 23-30 years | 78 | 52.0 |
| 31-40 years | 46 | 30.7 |
| >40 years | 26 | 17.3 |

| | | |
|---|---|---|
| Sex | | |
| Male | 84 | 56.0 |
| Female | 66 | 44.0 |
| Professional category | | |
| Interns | 40 | 26.7 |
| Junior residents | 55 | 36.7 |
| Senior residents | 30 | 20.0 |
| Faculty members | 25 | 16.7 |
| Clinical experience | | |
| <2 years | 44 | 29.3 |
| 2-5 years | 51 | 34.0 |
| >5 years | 55 | 36.7 |
| Previous pharmacovigilance training | 62 | 41.3 |

Regarding knowledge, 128 doctors (85.3%) had heard about pharmacovigilance, and 116 (77.3%) were aware that doctors can report ADRs. However, only 72 participants (48.0%) knew the nearest ADR monitoring centre. Overall, adequate knowledge was observed in 68 participants (45.3%). A positive attitude was found in 121 doctors (80.7%), while only 49 doctors (32.7%) had ever reported an ADR [Table 2].

**Table 2: Knowledge, attitude, and practice regarding ADR reporting among doctors (n=150)**

| KAP item | Frequency | Percentage |
|---|---|---|
| Knowledge-related items | | |
| Heard about pharmacovigilance | 128 | 85.3 |
| Aware that doctors can report ADRs | 116 | 77.3 |
| Aware of national pharmacovigilance programme | 95 | 63.3 |
| Knew that suspected ADRs can be reported | 89 | 59.3 |
| Aware of standard ADR reporting form | 86 | 57.3 |
| Knew nearest ADR monitoring centre | 72 | 48.0 |
| Adequate overall knowledge | 68 | 45.3 |
| Attitude-related items | | |
| ADR reporting improves patient safety | 140 | 93.3 |
| ADR reporting is important in clinical practice | 137 | 91.3 |
| Reporting ADRs is a professional responsibility | 126 | 84.0 |
| Supports regular pharmacovigilance training | 132 | 88.0 |
| Positive overall attitude | 121 | 80.7 |
| Practice-related items | | |
| Encountered suspected ADRs in clinical practice | 108 | 72.0 |
| Ever reported an ADR | 49 | 32.7 |
| Reported ADR during previous 12 months | 35 | 23.3 |
| Maintained ADR documentation in case records | 61 | 40.7 |
| Received feedback after ADR reporting | 18 | 12.0 |

Among the 108 doctors who had encountered suspected ADRs, 73 (67.6%) had not reported them. The common reasons for under-reporting were uncertainty about causality (58.7%), lack of time or workload pressure (52.0%), lack of awareness about the reporting procedure (46.7%), non-availability of reporting forms (38.7%), and lack of training (37.3%) [Table 3].

**Table 3: Reported reasons for under-reporting of ADRs among doctors (n=150)**

| Reason for under-reporting | Frequency | Percentage |
|---|---|---|
| Uncertainty about causality | 88 | 58.7 |
| Lack of time/workload | 78 | 52.0 |
| Lack of awareness about reporting procedure | 70 | 46.7 |
| Non-availability of reporting forms | 58 | 38.7 |
| Lack of training | 56 | 37.3 |
| Fear of legal consequences | 42 | 28.0 |
| Belief that only serious ADRs should be reported | 39 | 26.0 |
| Did not know where to submit the report | 36 | 24.0 |
| Felt that one report would not make a difference | 31 | 20.7 |

Under-reporting was significantly higher among doctors without previous pharmacovigilance training compared with those who had received training (82.8% versus 50.0%; p = 0.001). It was also significantly associated with lack of awareness of the nearest ADR monitoring centre, lack of time or workload, and uncertainty about causality. On multivariable logistic regression, absence of pharmacovigilance training, lack of awareness of the nearest monitoring centre, workload, and uncertainty about causality remained independent determinants of under-reporting [Table 4].

**Table 4: Determinants of under-reporting among doctors who encountered ADRs (n=108)**

| Determinant | Under-reporting n/N (%) | Adjusted OR | 95% CI | p-value |
|---|---|---|---|---|
| No previous pharmacovigilance training | 48/58 (82.8) | 3.42 | 1.42-8.25 | 0.006 |
| Previous pharmacovigilance training | 25/50 (50.0) | Reference | - | - |
| Unaware of nearest ADR monitoring centre | 43/51 (84.3) | 3.18 | 1.26-8.03 | 0.014 |
| Aware of nearest ADR monitoring centre | 30/57 (52.6) | Reference | - | - |
| Lack of time/workload | 45/55 (81.8) | 2.87 | 1.16-7.08 | 0.023 |
| No lack of time/workload | 28/53 (52.8) | Reference | - | - |
| Uncertainty about causality | 49/63 (77.8) | 2.41 | 1.01-5.77 | 0.048 |
| No uncertainty about causality | 24/45 (53.3) | Reference | - | - |
| Fear of legal consequences | 26/33 (78.8) | 1.54 | 0.56-4.24 | 0.405 |

Overall, the study showed that doctors had a favourable attitude toward ADR reporting, but actual reporting practice was low. The main determinants of under-reporting were inadequate pharmacovigilance training, poor awareness of reporting channels, clinical workload, and uncertainty in causality assessment.

## Discussion

The present study demonstrated a clear knowledge-practice gap in ADR reporting among doctors working in a tertiary care hospital. While the majority had heard of pharmacovigilance and knew that the reporting of adverse drug reactions was an important patient safety activity, less than half reported having a good knowledge of pharmacovigilance overall, and one third had previously submitted an ADR report. This fits in with the findings of previous studies conducted in India and elsewhere, that awareness and favourable attitude did not result in regular reporting practice.[6-13] The discovery suggests that pharmacovigilance does not solely need to be based on the theoretical awareness of the reporting forms, reporting channels, causality assessment and institutional follow-up.

It is encouraging that the attitude of the students in present study is observed as positive. Over 80 percent of doctors concurred with reporting to be beneficial for patient safety, whilst the majority also backed regular pharmacovigilance training. Such positive attitudes were reported in previous studies in India involving prescribers, post-graduates and healthcare professionals.[6-10] But the low reporting rate indicates that attitude is not enough. A significant cohort in the Indian pharmacovigilance study population reported never having reported an ADR in spite of recognizing the importance of reporting in the meta-analysis data presented.[11] The gap suggests a shift from awareness-based teaching to reporting on behaviour, in hospitals.

The actual level of under-reporting was quite significant. Of those doctors who had seen suspected ADRs, 67.6% did not report them. Spontaneous reporting systems are generally considered to be the main disadvantage under-reporting in the different setting.[4,5] Causality was the most common barrier in the current study. This is a widely held belief that physicians have to report only certain "proven" reactions. Pharmacovigilance systems can be set up to accept the suspected reactions and causality can be evaluated afterwards with structured methods. Therefore, repeated training on what, when and how to report can be used to enhance reporting confidence.

Lack of time or workload was another important determinant. Because of the crowded clinical setting, the completion of paper-based reports is less likely, particularly if the report forms are not readily available. Several reasons have been mentioned in the past as barriers: workload, lethargy, lack of information on forms and lack of familiarity with procedures.[5,6,14] Operational burden can be minimised by simple interventions like reporting forms on the one page, reporting links via QR Code, ADR boxes at the ward level, pharmacology department support and reminders at regular intervals. It is also necessary to provide feedback following the reporting; this helps reinforce the value of individual reports and encourages continued reporting.

None of the following factors were found to be associated with under-reporting in multivariable analysis: uncertainty of causality, workload, or lack of awareness of the nearest ADR monitoring centre, and absence of pharmacovigilance training. These determinants can be acted upon at institutional level. Continued induction training for interns and residents, refresher training for faculty, making monitoring centre information visible and reporting on ADRs in clinical audit meeting can help build up reporting culture. The results clearly demonstrate the need for a structured institutional pharmacovigilance programme based on education, streamlined reporting process and monitoring through feedback.

**Limitations:** There were some limitations to this study. It has been performed only in one tertiary care hospital so cannot be generalized to others. The questionnaire-based design was dependent on self-reported responses and recall. Anonymity was used to reduce but not eliminate social desirability bias. Cross-sectional design quantified associations at a single point in time, and were not used for establishing temporal relationships. No verification was done between ADR reporting and hospital pharmacovigilance records.

## Conclusion

This study revealed a favorable attitude of the doctors towards reporting ADR, yet practice was low. While the majority of participants were aware of the significance of pharmacovigilance, many participants did not have a practical understanding of the reporting procedures and access to Monitoring-centres. The factors of under-reporting were independently associated with not having been trained in pharmacovigilance previously, not knowing where to access an ADR monitoring centre, workload, and uncertainty about causality. The findings highlight the importance of re repeating hands-on training, clear reporting formats, reporting visibility and frequent feedback from the pharmacovigilance unit. These steps can facilitate better reporting of ADR, safer usage of prescription medicines in tertiary care hospitals and foster a more

robust institutional culture of medicine safety.

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## Conflicts of interest
There are no conflicts of interest.

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