



Original Article

Barriers and Predictors of Adverse Drug Reaction Reporting Among Early-Career Healthcare Professionals: A Cross-Sectional Study

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Received: 20-05-2026

Accepted: 10-06-2026

Available online: 16-06-2026

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Medical and Pharmaceutical Research

ABSTRACT

Background: Pharmacovigilance is a critical component of post-marketing drug safety surveillance. In India, underreporting of adverse drug reactions (ADRs) remains a major challenge. The aim of this study was to assess health care professionals' knowledge, attitudes and practices (KAP) regarding ADR reporting, specifically the psychological barriers and technology-based motivators for reporting ADRs.

Methods: This study used a cross-sectional design and included 250 doctors and interns at a tertiary care teaching centre. The study expands on conventional KAP assessments by examining institutional barriers, including awareness of digital ADR reporting (such as Vigiflow) and fear of legal consequences. The data were analysed using multiple regression to identify predictors of reporting.

Results: The participants demonstrated a moderate level of knowledge on average (mean \pm SD: 5.4 ± 2.1), but there was a substantial gap between practice and attitude. While 84.8% of study participants expressed a need for ADR reporting, only 25% reported ADRs. The major barriers to ADR reporting, as cited by 60% of health care professionals, were a lack of clear operational mechanisms and fear of medicolegal consequences, which were cited by 45% of participants and were the most important psychological barrier to ADR reporting. Participants who had received prior pharmacovigilance training were almost four times more likely to report ADRs (OR = 3.76, p-value < 0.001). In addition, fear of perceived legal risk significantly reduced the likelihood of reporting. (OR = 0.47, p-value = 0.012).

Conclusion: The vast gap between high attitudinal willingness and low reporting is attributed to a lack of clarity in processes and fear of legal consequences. Bridging the existing attitude-practice gap will require targeted interventions. Those changes will include incorporating pragmatic pharmacovigilance training into intern training, developing safe reporting settings, and establishing two-way feedback systems to create a culture of proactive drug safety.

Keywords: Pharmacovigilance, Adverse Drug Reaction, Interns, Doctors, Drug Safety, India.

INTRODUCTION

An integral part of healthcare is pharmacovigilance, which ensures consumer safety regarding drugs and monitors adverse reactions after they are introduced into the market. Several drugs and fixed-dose combinations have been withdrawn from the Indian market because of safety concerns. This issue is compounded by the inadequate documentation on the adverse drug reactions (ADRs) of drugs, particularly with respect to the irrational over-the-counter drug usage.¹

In the last decade, the most withdrawn drug classes globally were analgesics (NSAIDs) (28%), antidiabetic drugs (14.28%), anti-obesity drugs (14.28%), antihistamines (14.28%), and antibiotics (7.14%). The main safety concerns for these market withdrawals were severe cardiovascular events and hepatotoxicity, which were responsible for 57.14 and 14.28% of the cases, respectively.² ADRs account for 5% of all hospital admissions, and because of the number of ADRs, hospital systems

incur high costs. In 1994, ADRs were documented to be the cause of approximately 106,000 deaths among hospitalised patients in the United States and were among the top reasons for the early termination of drug treatments.^{3,4}

As outlined by Edwards et al., ADRs describe reactions as "appreciably harmful or unpleasant reactions which arise from an intervention linked to the use of a medicinal product which predicts a hazard from the future administration and thus warrants the intervention, a specific treatment, modification of the dosage schedule, or the complete withdrawal of the medicinal product."⁵ As a means of addressing such risks, the National Pharmacovigilance Program (NPP), which is part of the Pharmacovigilance Programme of India (PvPI), is an active ADR monitor to protect the health of the public.⁶ The challenges remain, and despite the existing infrastructure, India continues to struggle with fully embracing the reporting systems due to reporting cultures, differences in clinical practices, and, most notably, the underreporting by clinicians.⁷ The origin of underreporting is often attributed to the primary education of healthcare workers.⁸ Thus, this study attempts to assess the knowledge, attitude, and perception (KAP) of future and current prescribers, namely, medical interns and resident doctors, with respect to the area of study on the safety of drugs and reporting at a tertiary health care centre.

METHODOLOGY

2.1. Study Design and Setting

A hospital-based cross-sectional, questionnaire-based survey was conducted over a one-month period. This study's target population included doctors and interns. Incomplete forms and those who refused to provide informed consent were excluded from the analysis.

2.2. Data Collection and Analysis

Data collection involved a self-administered, validated questionnaire with sections covering participants' demographics, knowledge, awareness, and attitudes toward the study variables. Ethical approval was obtained from the Institutional Ethics Committee. Based on previous pharmacoepidemiologic studies, the sample size was 250 participants, and convenience sampling of eligible participants was done. Participants provided their consent, and data were collected through Google Forms. The data were analysed, and independent predictors of pharmacovigilance knowledge and practice were identified using descriptive statistics and multivariable logistic regression. In the logistic regression analysis, we made ADR reporting practice (ever reported ADRs: yes/no) the dependent variable. The independent variables were professional category, previous training in pharmacovigilance, knowledge score, and fear of legal consequences.

RESULTS

3.1. Demographic Characteristics

The survey was completed by 250 participants, representing a 92.6% completion rate (250 out of 270). The demographic data exhibited a female majority (58.0%, n=145) with a mean age of 26.3±4.7 years. The largest professional category comprised doctors (72.8%, n=182), followed by interns (27.2%, n=68). The great majority of the cohort (78.0%, n=195) reported no formal prior training in pharmacovigilance (Table 1).

Table 1. Demographic Characteristics

Variable	Frequency (n)	Percentage (%)
Female	145	58.0
Male	105	42.0
Interns	68	27.2
Doctors	182	72.8
Prior Pharmacovigilance Training	55	22.0
No Prior Training	195	78.0

3.2. Comprehensive Knowledge Assessment

Although participants demonstrated moderate baseline knowledge of pharmacovigilance (mean score 5.4 ± 2.1 out of 10), there was a substantial gap between their attitudes and actual reporting practices. The specific awareness questionnaire showed that 82.0% of respondents could define the term pharmacovigilance, whilst practical knowledge of the reporting procedure was limited. Of the sampled respondents, 65.0% (n=162) reported having observed an ADR in patients; however, they didn't know it could be reported at all. Most interns (78%) reported difficulty recognising ADRs in routine clinical practice. Very few of the respondents, 30.0% (n=75), knew about the ADR reporting suspected case form of the Central Drugs Standard Control Organisation (CDSCO), and 28.0% (n=70) knew about the reporting site Vigiflow. Moreover, only 22.0% of the sampled respondents knew that patients could report ADRs, were able to complete a report, and therefore, had the reporting form (Table 2).

Table 2. Knowledge Regarding Pharmacovigilance

Knowledge Item	n	Percentage (%)
Defined pharmacovigilance correctly	205	82.0
Aware of the CDSCO ADR reporting form	75	30.0

Aware of Vigiflow	70	28.0
Knew patients can report ADRs	55	22.0
Encountered an ADR in practice	162	65.0

3.3. Attitude and Perceptions

While the observed knowledge gaps were significant, the mean attitude score was positive at 32.6 ± 5.3 (max 40). An overwhelming 92.0% of the cohort stated that physicians should receive some form of training on ADR reporting, and 88.0% stated that reporting should be considered an IT-enabled national initiative. Moreover, 84.8% expressed that ADR reporting is necessary. Another notable finding was that an overwhelming 95% of the cohort believed that ADR under-reporting is a problem within their institution or clinical practice. Nonetheless, only 25% (n=62) of participants reported an ADR. (Table 3).

Table 3. Attitudes Towards ADR Reporting

Attitude Statement	Agree n (%)
Physicians should receive training	230 (92.0)
ADR reporting should be a national initiative	220 (88.0)
ADR reporting is necessary	212 (84.8)
Underreporting is a major problem	238 (95.0)
Reported ADR	62 (25%)

3.4. Systemic Barriers and Motivators

Regarding the determinants of underreporting, the participants cited several barriers to ADR reporting. Uncertainty regarding reporting procedures emerged as one of the frequently cited barriers to ADR reporting, with 60.0% of participants noting it. Fear of professional liability was another commonly reported barrier, with 45.0% of participants worrying that reporting an ADR could lead to legal action against them. An additional 30.0% described ADR reporting as "time-consuming and futile." To this end, 75.0% of participants expressed that direct feedback about their reports from the ADR monitoring centres would incentivise them to report ADRs in the future. About 80.0% expressed the need for mandatory training (Table 4).

Table 4. Barriers and Motivators

Factor	n (%)
Lack of clear operational mechanisms	150 (60.0)
Fear of legal consequences	112 (45.0)
Reporting is time-consuming/futile	75 (30.0)
Feedback would motivate reporting	188 (75.0)
Need for mandatory training	200 (80.0)

3.5. Logistic Regression: Predictors of Reporting Practices

A multivariable logistic regression analysis was conducted to identify independent predictors of ADR reporting practice. Compared with doctors, interns had higher odds of reporting ADRs (OR = 2.45, 95% CI: 1.78–3.39, $p < 0.001$). Respondents who had received prior pharmacovigilance training were almost four times more likely to report ADRs than those who were not trained (OR = 3.76, 95% CI: 2.53–5.58, $p < 0.001$). ADR reporting was also positively influenced by having adequate baseline knowledge of pharmacovigilance (knowledge score ≥ 6) (OR = 3.14, 95% CI: 1.60–6.15, $p = 0.001$). Participants who viewed legal consequences as a barrier to reporting ADRs were less likely to report ADRs (OR = 0.47, 95% CI: 0.26–0.85, $p = 0.012$) (Figure 1).

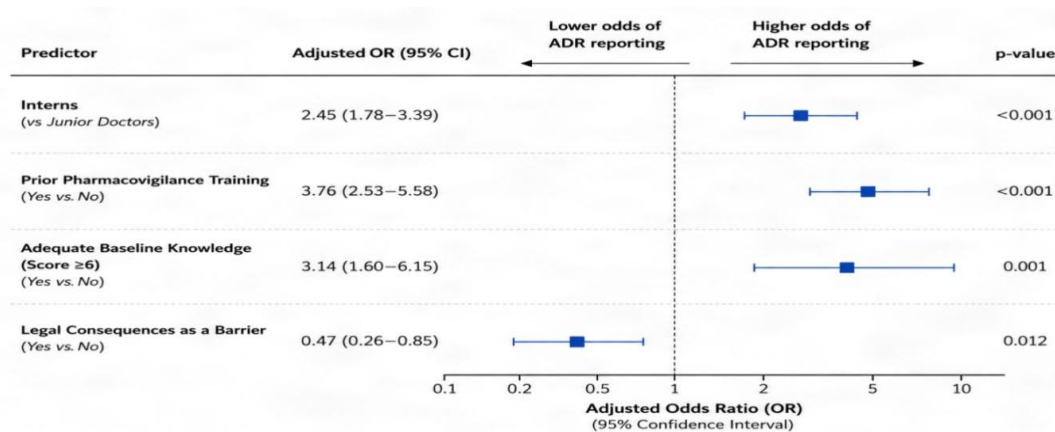


Figure 1. Forest Plot of Independent Predictors of Adverse Drug Reaction (ADR) Reporting Practice

DISCUSSION

This cross-sectional research study, conducted at a tertiary care teaching hospital in India, analyses the knowledge, attitudes, and practices of current and future healthcare professionals towards pharmacovigilance, and the study shows that there is a generally positive attitude towards the importance of pharmacovigilance; however, there is a significant deficiency in operational knowledge regarding the practical components of reporting. A lack of awareness about the PvPI (30%) and the Vigiflow reporting database (28%) is concerning; however, the lack of awareness seems to reflect the current situation in research conducted by Kamtane & Jayawardhani and Meher et al., where clinical cohorts have demonstrated a deficit in knowledge regarding these forms.^{11,12} It has been shown that despite the establishment of the PvPI, national initiatives have faced persistent challenges in raising early awareness among frontline health care professionals.¹³

The significant difference in attitudes (85%) of those surveyed stated that reporting should be mandatory, compared with practices in which only 25% have reported, even though 65% reiterated that they have seen an ADR, indicates a substantial implementation gap. A lack of awareness of the procedures (60%) and medicolegal uncertainty (45%) emerged as the most frequently reported barriers. Lack of ability to confirm an adverse drug reaction was yet another concern. Desai et al. and Lopez-Gonzalez et al. identified apprehensions of legal repercussions as an important barrier to spontaneous ADR reporting.^{14,15}

Multivariate analysis shows that concern regarding litigation lowers the odds of reporting (OR = 0.47, p-value = 0.012). The failure of the feedback loop is epitomised by the 30% of those surveyed who perceive ADR reporting as time-consuming and yielding no results. In fact, 75% of respondents said they would be motivated to report if they received bidirectional feedback.

We found that the odds of interns reporting ADRs were higher than those of doctors (OR = 2.45, p < 0.001). One possible explanation is greater recent exposure to pharmacovigilance teaching among interns. Because interns have only recently completed their core pharmacology education, the active pharmacovigilance protocols emphasised during their curriculum are more readily put into practice, a transition similarly highlighted in recent evaluations of medical interns.^{16,17} Although pharmacovigilance is acknowledged as clinically important, ADRs are often underreported by doctors due to heavy clinical workloads, lack of specific training, and unfamiliarity with institutional reporting protocols, as highlighted by Desai et al. and Tandon et al.^{13,14} There are marked discrepancies between knowledge and reporting behaviour of health professionals in this study. Although awareness of the importance of ADR reporting was high, actual knowledge of reporting mechanisms remained inadequate. Lack of awareness of reporting procedures and fear of legal consequences emerged as important barriers to reporting.

CONCLUSION

A gap exists between the willingness to report adverse drug reactions (ADR) and the actual reporting of ADRs. This pronounced mismatch requires a re-evaluation of how pharmacovigilance is incorporated into medical education and hospital policy. Thus, the aim of hospital policy must go beyond improving passive knowledge and address the specific psychological and functional requirements of the target group. There is a need for capacity development of medical interns to enhance their skills and operational understanding of the PvPI and the completion of the CDSCO ADR forms.

Tertiary care hospitals must create non-punitive, legally safe reporting systems that help reduce the fear of legal consequences. Providing ADR drop boxes or secure portals can help protect prescribers and communicate reporting policies during orientation, thereby helping to differentiate ADR reporting from medical negligence. These will help foster a safe and psychologically rewarding clinical environment. To overcome the tendency to think reporting is "time-consuming and pointless," feedback loops must be established within ADR Monitoring Centres (AMCs) with a system to acknowledge reports. Clinicians should receive notification of the report, including information on its impact on medication safety and other audits. Future studies may explore the role of digital health technologies and artificial intelligence-assisted reporting tools in reducing reporting burden and improving pharmacovigilance practices.

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