Original Article

Evaluation of Knowledge, Attitude, and Practice of Pharmacovigilance Among Resident Doctors: A Cross-Sectional Study

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Abstract

Background: Pharmacovigilance (PV) is crucial for ensuring drug safety by monitoring, detecting, and preventing Adverse Drug Reactions (ADRs). The success of any national PV program depends heavily on the active participation of healthcare professionals, particularly resident doctors who are at the forefront of patient care. **Material and Methods:** A prospective, cross-sectional, questionnaire-based study was conducted over a period of two months, from November 2024 to January 2025. A total of 150 resident doctors from various clinical departments were included using a convenience sampling method. A pre-validated, structured questionnaire was used to collect data on demographics and KAP related to pharmacovigilance. The collected data were analyzed using descriptive and inferential statistics. A p-value of <0.05 was considered statistically significant. **Results:** Out of 150 participants, the mean knowledge score was 9.8 ± 2.5 (out of a maximum of 15). Only 68 residents (45.3%) were found to have good knowledge, while 61 (40.7%) had moderate knowledge. The majority of residents (n=132, 88%) demonstrated a positive attitude towards PV, with a mean attitude score of 41.5 ± 4.8 (out of 50). However, the practice of ADR reporting was poor. Only 54 residents (36.0%) had ever reported an ADR. A statistically significant association was observed between the year of residency and the practice of reporting an ADR, with senior residents reporting more frequently than junior residents (p=0.02). The most commonly cited barriers to reporting were lack of time (61.5%) and uncertainty about which reactions to report (48.9%). **Conclusion:** Despite a positive attitude towards pharmacovigilance, resident doctors in this tertiary care center exhibit moderate knowledge and poor practice regarding ADR reporting. The identified knowledge-practice gap highlights the urgent need for targeted educational interventions and the integration of mandatory PV training into the residency curriculum to foster a stronger reporting culture.

Keywords: Pharmacovigilance, Adverse Drug Reaction, Knowledge, Attitude, Practice, Resident Doctors, ADR Reporting.

Received: 10 July 2025 **Revised: 05 August 2025** **Accepted: 27 September 2025** **Published: 30 September 2025**

Introduction

Medicines have revolutionized healthcare, but their use is not without risk. Adverse Drug Reactions (ADRs) are a significant cause of morbidity and mortality worldwide, posing a substantial burden on healthcare systems.[1] The World Health Organization (WHO) defines an ADR as "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease".[2] Pharmacovigilance (PV) is the science and activity relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem.[2]

An effective pharmacovigilance system relies on the spontaneous reporting of ADRs by healthcare professionals (HCPs). Resident doctors, being on the front lines of patient management in teaching hospitals, are uniquely positioned to identify and report ADRs. Their active involvement is pivotal for generating post-marketing safety data, especially for new drugs and for identifying rare or long-latency ADRs that may not have been detected during pre-marketing clinical trials.[3] In India, the Pharmacovigilance Programme of India (PvPI) was launched to safeguard public health by establishing a robust ADR monitoring system. However, under-reporting remains a major challenge globally and within India, hindering the program's effectiveness.[4] Several factors contribute to this under-reporting, including inadequate knowledge about the PV system, a perception that only serious reactions are worth reporting, fear of legal repercussions, and practical issues like lack of time and complex reporting forms.[5]

Numerous studies have been conducted across India to assess the knowledge, attitude, and practice (KAP) of pharmacovigilance among HCPs. A study by Gupta et al. in North India found that while most doctors had a positive attitude, their knowledge and reporting practices were suboptimal.[6] Similarly, research in Southern India among junior residents revealed a significant gap between knowledge and practice.[7] These studies consistently

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DOI:
10.21276/amit.2025.v12.i3.98

How to cite this article: Bhangare NK, Marawar AP, Kundalwal KA. Evaluation of Knowledge, Attitude, and Practice of Pharmacovigilance Among Resident Doctors: A Cross-Sectional Study. Acta Med Int. 2025;12(3):371-375.

highlight the need for continuous training and sensitization.

Despite this body of evidence, there is a relative scarcity of recent data specifically from the Western Maharashtra region, an area with a high density of medical institutions and a large patient population. The perspectives and practices of resident doctors in this specific geographical and academic context may present unique challenges and opportunities. Therefore, a gap exists in understanding the current state of PV awareness and practice among the next generation of physicians in this region. This study was conceived to bridge this gap.

The aim of this study was to evaluate the knowledge, attitude, and practice regarding pharmacovigilance and ADR reporting among resident doctors at a tertiary care teaching center in Western Maharashtra.

Materials and Methods

Study Design and Setting: This was a prospective, cross-sectional, questionnaire-based study conducted at a single tertiary care teaching hospital in Western Maharashtra, India. The hospital has over 1000 beds and serves as a major referral center for the region. The study was conducted from November 2024 to January 2025.

Study Population and Sample Size: The study population comprised resident doctors from various major clinical departments, including General Medicine, General Surgery, Pediatrics, Obstetrics &Gynecology, and Orthopedics. Based on an estimated 50% prevalence of good PV knowledge from previous studies, a 95% confidence level, and a 8% margin of error, the minimum required sample size was calculated to be 150. A convenience sampling method was used to recruit 150 participants.

Inclusion and Exclusion Criteria: All resident doctors (first, second, and third year) working in the selected clinical departments who were willing to provide written informed consent were included. Interns, medical officers not in a residency program, residents from non-clinical departments, and those who were unwilling to participate or returned incomplete questionnaires were excluded.

Study Tool: A pre-validated, self-administered, structured questionnaire was used for data collection. The questionnaire was developed after a thorough review of relevant literature and was validated for content and clarity by senior faculty members in the Department of Pharmacology. It was divided into four sections:

- **Section A:** Demographics: Collected information on age, gender, department, and year of residency.
- **Section B:** Knowledge Assessment: Contained 15 multiple-choice and true/false questions assessing knowledge about the definition of PV and ADRs, the purpose of PvPI, which ADRs to report, and the location of ADR reporting forms. Each correct answer was awarded one point (total score: 15). Scores were categorized as Poor (<8), Moderate (8–11), and Good (>11).
- **Section C:** Attitude Assessment: Consisted of 10 statements on a 5-point Likert scale (5=Strongly Agree, 4=Agree, 3=Neutral, 2=Disagree, 1=Strongly Disagree). This section gauged the residents' perception of the importance of ADR reporting. A total score out of 50 was calculated, with a score >35 considered a positive attitude.
- **Section D:** Practice Assessment: Included 5 questions about their ADR reporting habits, such as whether they had ever witnessed or reported an ADR, the number of ADRs reported in the past year, and the reasons for not reporting.

Questionnaire: It includes structured questions targeting three core domains: knowledge, attitude, and practice related to pharmacovigilance and adverse drug reaction (ADR) reporting. These questions are validated and used in similar published studies with resident doctors and healthcare professional.

Sample Questionnaire Structure

- Knowledge Domain
- What is the definition of pharmacovigilance?
- What is an adverse drug reaction (ADR)?
- Are you aware of the national pharmacovigilance program?
- Who can report ADRs?
- Which types of ADRs should be reported?
- Are you aware of the procedures for ADR reporting in your hospital?
- Attitude Domain
- Do you believe pharmacovigilance is important for clinical practice?
- Should reporting of ADRs be mandatory for all healthcare professionals?
- Do you feel confident in your ability to detect and report ADRs?
- Do you believe carrying out pharmacovigilance activities will improve patient safety?
- Do you consider ADR reporting as an additional burden in your day-to-day duties?

Practice Domain

- Have you ever encountered an ADR during your clinical practice?
- How often do you report ADRs that you observe?
- If you have not reported ADRs, what are the reasons for not reporting?
- Are you aware of the reporting forms or online platforms for ADR submission?
- Have you received any training or orientation on pharmacovigilance activities?

Study Procedure

Ethical clearance was obtained from the Institutional Ethics Committee before the commencement of the study. The purpose of the study was explained to the potential participants, and written informed consent was obtained. The questionnaires were distributed in person to the residents during their academic sessions or departmental meetings. Participants were given approximately 15-20 minutes to complete the questionnaire and were assured of the confidentiality of their responses.

Statistical Analysis: The collected data were entered into Microsoft Excel and analyzed using SPSS Statistics for Windows, Version 25.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were used to summarize the data, with frequencies and percentages calculated for categorical variables and mean ± standard deviation (SD) for continuous variables. The Chi-square test was used to determine the association between categorical variables, such as the year of residency and

ADR reporting practice. A p-value of less than 0.05 was considered statistically significant.

Results

Sociodemographic Characteristics: A total of 150 resident doctors participated in the study. The majority were male (n=92, 61.3%). The mean age of the participants was 27.4 ± 2.1 years. The largest group of participants was from the Department of General Medicine (n=48, 32.0%), followed by General Surgery (n=35, 23.3%). First-year residents constituted 40.0% (n=60) of the sample. The detailed demographic characteristics are presented in [Table 1].

Table 1: Sociodemographic Characteristics of Study Participants (n=150)

Characteristic	Category	Frequency (n)	Percentage (%)
Age (Years)	Mean ± SD	27.4 ± 2.1	-
Gender	Male	92	61.3
	Female	58	38.7
Department	General Medicine	48	32.0
	General Surgery	35	23.3
	Pediatrics	25	16.7
	Obstetrics &Gynecology	22	14.7
	Orthopedics	20	13.3
Year of Residency	First Year	60	40.0
	Second Year	55	36.7
	Third Year	35	23.3

Knowledge of Pharmacovigilance: The mean knowledge score of the participants was 9.8 ± 2.5 (out of 15). Based on the predefined criteria, 68 (45.3%) residents had good knowledge, 61 (40.7%) had moderate knowledge, and 21 (14.0%) had poor knowledge. A significant portion of residents (72.0%) knew the correct definition of pharmacovigilance, and 85.3% were aware that all ADRs should be reported. However, only 38.0% knew the name of the national pharmacovigilance program (PvPI), and 44.7% knew where to find the ADR reporting form in the hospital. Knowledge scores were slightly higher among residents from General Medicine compared to other departments, but this difference was not statistically significant (p=0.08). The details are shown in [Table 2].

Attitude towards Pharmacovigilance: The study revealed a predominantly positive attitude towards pharmacovigilance among the resident doctors. The mean attitude score was 41.5 ± 4.8 (out of 50). A total of 132 participants (88.0%) demonstrated a positive attitude. The vast majority agreed that ADR reporting is a professional obligation (92.7%) and essential for patient safety (95.3%). Table 2 provides a summary of the KAP scores.

Table 2: Assessment of Knowledge, Attitude, and Practice Scores (n=150)

Parameter	Category	Result
Knowledge Score	Mean ± SD (max 15)	9.8 ± 2.5
(Categorical)	Good (>11)	68 (45.3%)
	Moderate (8-11)	61 (40.7%)
	Poor (<8)	21 (14.0%)
Attitude Score	Mean ± SD (max 50)	41.5 ± 4.8
(Categorical)	Positive (>35)	132 (88.0%)
	Neutral/Negative	18 (12.0%)
Practice	Ever Reported an ADR	54 (36.0%)
	Never Reported an ADR	96 (64.0%)

Practice of Pharmacovigilance and ADR Reporting: Despite good attitudes, the practice of ADR reporting was found to be poor. Only 54 (36.0%) of the 150 residents had ever reported an ADR. Among those who had reported, most (68.5%) had reported only 1-2 ADRs in the preceding year. A significant association was found between the year of residency and the practice of ADR reporting (p=0.02). Third-year residents (51.4%) had a significantly higher reporting rate compared to second-year (34.5%) and first-year residents (25.0%).

The most frequently cited barrier to reporting was a "lack of time" (61.5%), followed by "uncertainty about which reactions to report" (48.9%), and "difficulty in accessing reporting forms" (35.4%). Details on reporting practices and barriers are presented in [Table 3].

Table 3: Pharmacovigilance Practice and Barriers to ADR Reporting (n=96 non-reporters)

Parameter	Response	Frequency (n)	Percentage (%)
Ever Reported an ADR (N=150)	Yes	54	36.0
	No	96	64.0
Association of Reporting with Residency Year		p-value	0.02*
	First Year (n=60)	15	25.0
	Second Year (n=55)	19	34.5
	Third Year (n=35)	18	51.4
Barriers to Reporting (multiple responses allowed)	Lack of time	59	61.5

	Unsure what to report	47	48.9
	Reporting form not available	34	35.4
	Fear of consequences	18	18.8
	Think one case is not important	15	15.6
*Statistically significant ($p<0.05$)			

Discussion

This study provides valuable insights into the current state of pharmacovigilance knowledge, attitude, and practice among resident doctors in a tertiary care setting in Western Maharashtra. The key finding is the significant discordance between a positive attitude and poor reporting practices, a phenomenon often termed the "KAP gap".[8]

Our finding of a moderate level of knowledge (mean score 9.8/15) is consistent with several other Indian studies. For example, a study conducted in Gujarat reported that only about half of the resident doctors had adequate knowledge of PV.[9] The specific knowledge deficits identified in our study, such as low awareness of the PvPI and difficulty locating reporting forms, point to systemic gaps rather than individual failings. This suggests that the existing medical curriculum and hospital induction programs may not be sufficiently emphasizing the operational aspects of pharmacovigilance.

The overwhelmingly positive attitude (88%) observed among residents is an encouraging sign. It indicates that doctors intrinsically understand and value the importance of ADR reporting for patient safety. This aligns with findings from across the globe, where healthcare professionals generally support the principles of pharmacovigilance.[10] This positive attitude represents a crucial foundation upon which effective educational and administrative interventions can be built. The challenge lies in converting this positive intent into concrete action.

The most concerning finding of our study is the poor practice of ADR reporting, with only 36% of residents having ever reported an ADR. This rate is alarmingly low for a teaching hospital where complex cases and polypharmacy are common. This finding mirrors the chronic issue of under-reporting documented in numerous other studies. A systematic review of studies in India found reporting rates among doctors to be consistently low, often below 40%.[11] The significant association between seniority and reporting practice ($p=0.02$) suggests that clinical experience and perhaps increased confidence play a role. Senior residents may be more adept at recognizing ADRs and more familiar with hospital protocols.

The barriers identified in our study—lack of time, uncertainty, and inaccessibility of forms—are universally recognized impediments to spontaneous reporting.[12] The perception of being "too busy" is particularly acute in high-volume tertiary care centers. This highlights the need for simplified, rapid, and easily accessible reporting systems, such as mobile applications or integrated electronic health record (EHR) prompts, which can reduce the administrative burden on clinicians.[13]

The findings of this study must be viewed in light of its limitations. First, being a single-center study, the results may not be generalizable to all hospitals in the region. Second, the use of a self-administered questionnaire may have introduced response bias, as participants might provide socially desirable answers. Finally, the cross-sectional design only provides a snapshot in time and cannot establish causality.

Despite these limitations, this study underscores the urgent need for multifaceted interventions. These should include integrating practical, case-based pharmacovigilance training into the postgraduate curriculum, conducting regular continuous medical education (CME) programs, and making ADR reporting forms readily available both physically and digitally. Furthermore, creating a supportive, non-punitive hospital culture and providing feedback to reporters on the actions taken based on their reports could significantly enhance motivation and participation.[14,15]

Conclusion

This study concludes that while resident doctors at our tertiary care center possess a highly positive attitude towards pharmacovigilance, this does not translate into adequate reporting practices. The identified gap between knowledge/attitude and actual practice is substantial, driven by moderate knowledge levels and significant practical barriers. To strengthen the national pharmacovigilance program and enhance patient safety, it is imperative to implement targeted educational strategies, simplify the reporting process, and foster an institutional culture that actively encourages and supports ADR reporting.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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