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Original Article

A STUDY ON ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE (KAP) OF ADR MONITORING AND REPORTING AMONG CRMI CONDUCTED IN A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Objective: Adverse drug reactions (ADRs) are a significant cause of morbidity and mortality worldwide, yet underreporting is a persistent challenge. Compulsory Rotating Medical Interns (CRMI) are frontline healthcare providers whose contribution to pharmacovigilance is critical. The aim of this study was to assess the knowledge, attitude and practice (KAP) for ADR monitoring and reporting among CRMI students and to identify barriers and strategies for improvement.

Methods: This was a cross-sectional descriptive study conducted at a tertiary care teaching hospital in the month of September 2025 among CRMI students. A structured and validated KAP questionnaire was distributed electronically, after obtaining informed consent, and used to collect data on knowledge (10 items), attitude (6 items), and practice (6 items). Data was entered on Microsoft excel and statistical analysis was performed using Python. Descriptive and inferential tests were used to explore associations.

Results: A total of 90 interns responded to this study, with equal gender distribution. Interns scored>80% in knowledge domain,>4 in attitude domain and>60% in practice domain. Female interns had higher knowledge (p=0.023) and higher knowledge was significantly correlated with ADR reporting (p=0.021). While most interns had moderate knowledge and positive attitudes toward ADR reporting, actual reporting practices were poor.

Conclusion: Although interns recognized the importance of ADR reporting, their practice remains suboptimal. Common barriers included lack of awareness of reporting systems, uncertainty regarding causality and fear of consequences. Structured pharmacovigilance training and institutional support mechanisms are essential to bridge the knowledge–practice gap.

Keywords: Adverse drug reaction, Attitude, Knowledge, Pharmacovigilance, Practice

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INTRODUCTION

Adverse drug reactions (ADRs) are a significant cause of morbidity and mortality worldwide and represent a major public health concern. 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 humans for prophylaxis, diagnosis, or therapy of disease, or for modification of physiological function" [1]. According to estimates, ADRs are one of the main causes of iatrogenic damage and may be responsible for as much as 5–10% of hospital admissions worldwide [2]. Pharmacovigilance has become more and more important in India because of the country's high disease burden, genetic variety, and vast population, all of which lead to intricate medication use patterns. In order to improve the system for ADR reporting and monitoring, the Ministry of Health and Family Welfare launched the Pharmacovigilance Programme of India (PvPI) in 2010 [3]. Even with these efforts, underreporting is still a problem; research shows that only a small percentage of ADRs are reported [4].

Identification and reporting of adverse drug reactions (ADRs) are crucial tasks for medical professionals, especially physicians. Due to their position at the nexus of professional practice and undergraduate education, Compulsory Rotating Medical Interns (CRMI) are an essential group for establishing pharmacovigilance practices early in their careers. A durable pharmacovigilance system must be built by ensuring that this group has the necessary expertise, cultivate a positive attitude and follow proper reporting procedures [5]. Medical students and interns have gaps in their knowledge and practice regarding ADR monitoring, according to a number of research done in India and around the world. Although many participants agree that pharmacovigilance is important, obstacles like ignorance, inadequate training, and ambiguity about reporting protocols make it difficult for them to participate effectively [6, 7].

In order to find gaps and guide initiatives to improve pharmacovigilance training in medical curricula, a thorough evaluation of CRMI's knowledge, attitude, and practice (KAP) regarding ADR reporting is required. Therefore, this study was conducted to evaluate CRMI's knowledge, attitude and practice regarding ADR monitoring and reporting at a teaching hospital that provides tertiary care. The secondary objectives were to identify barriers perceived by CRMI in ADR reporting, to explore the association between demographic variables and KAP levels; and to provide recommendations for strengthening pharmacovigilance training.

MATERIALS AND METHODS

This was a descriptive cross-sectional study to find the knowledge, attitude and practice on ADR reporting among CRMI students using preformed questionnaires by the Department of Pharmacology, Government Villupuram Medical College, in the month of September 2025. All interns who had completed at least one month of clinical rotation and were willing to participate in the study were included. Interns who were not willing to participate or those who were not present during data collection were excluded. Ethical approval was obtained from the Institutional Ethics Committee. Informed consent was taken from each participant. Confidentiality and anonymity were maintained.

Sample size of 90 was estimated using a 95% confidence interval and expected prevalence of adequate knowledge from previous studies (~50%). Convenience sampling was applied. A structured, validated KAP questionnaire was used, consisting of 8 knowledge

questions, 6 attitude items (Likert scale), and 6 practice-related questions and open-ended questions. The questionnaire was validated for content by subject experts and was distributed electronically (Google Form). Data were entered into Microsoft Excel and analysed using Python (pandas, SciPy, and stats models packages). Descriptive statistics were presented as frequencies, percentages, means, and standard deviations. Maximum score for knowledge items was 8, for attitude items was 5 while practice responses were summarised as frequencies and percentages. Independent t-test was used to compare mean knowledge scores across gender. Spearman correlation was applied to examine associations between knowledge, attitude, and practice (ADR reporting). Binary logistic regression was used to identify predictors of ADR reporting. Significance was set at $p<0.05$.

RESULTS

In the present study, most of the interns were in the age group of 21-23 y (91.11%, n = 82/90). Males were nearly equal to females (48.88%, n = 44/90). In the knowledge domain, more than 80% of the responses were correct (table 1). In the attitude domain, mean scores were more than 4 (table 2). In the practice domain, mean of responses was 64.42% (table 3).

Table 1: Responses of interns to items in knowledge domain

S. No.	Knowledge item	Correct responses (n)	Correct responses (%)
1	Which regulatory authority in India is responsible for monitoring ADRs?	78	86.7
2	The National Coordinating Centre (NCC) for PvPI is located at:	51	56.7
3	Who can report an ADR?	85	94.4
4	Which is the highest centre for reporting ADR?	69	76.7
5	What is the World Health Organization's (WHO) definition of an Adverse Drug Reaction (ADR)?	73	81.1
6	What is the primary objective of pharmacovigilance?	80	88.9
7	What is the primary purpose of spontaneous ADR reporting?	77	85.6
8	What is causality assessment in the context of ADR reporting?	73	81.1

Table 2: Responses of interns to items in Attitude domain

S. No.	Attitude items	Mean score (Mean±SD)
1	I believe that reporting every observed ADR, no matter how minor, is a professional obligation	4.36±0.61
2	I feel that ADR reporting is a time-consuming and tedious process that distracts from patient care.	2.78±1.09
3	I am confident in my ability to recognize an ADR and determine if it should be reported.	4.13±0.60
4	ADR reporting is a collective responsibility of all healthcare professionals, not just a designated few.	4.33±0.69
5	Pharmacovigilance is an essential part of improving drug safety in my country.	4.50±0.60

Table 3: Responses of interns to items in practice domain

S. No.	Practice item	Frequency (n)	Percentage (%)
1	Encountered suspected ADR during clinical rotations	28	31.1
2	Ever reported a suspected ADR	56	62.2
3	Know where/how to submit ADR in institution	75	83.3
4	Aware of PvPI yellow form	73	81.1

Female interns showed a statistically significant higher score in knowledge domain ($t = -2.32$, $p = 0.023$). Higher knowledge score was positively correlated with ADR reporting by Spearman correlation (rho = 0.242, $p = 0.021$). But there was no correlation between knowledge and attitude (rho = -0.077, $p = 0.470$) and between attitude and ADR reporting (rho = 0.165, $p = 0.120$).

DISCUSSION

The present study assessed the knowledge, attitude and practice regarding adverse drug reaction (ADR) monitoring and reporting among Interns (CRMI) at a tertiary care teaching hospital. The findings reveal that while most respondents demonstrated adequate knowledge and positive attitudes, there remains a considerable gap in actual reporting practices, reflecting trends reported both in India and globally.

Over 80% of the participants in the current survey correctly identified the regulatory bodies and the main goals of pharmacovigilance. These results are consistent with previous findings by HS Rehan et al., who noted that medical students had a high understanding of pharmacovigilance concepts [5]. The relevance of including pharmacovigilance education throughout undergraduate training is highlighted by the high levels of knowledge among interns, which can be ascribed to their early clinical experiences and recent academic exposure. However, there are still unanswered questions in areas like causality assessment and the location of the National Coordinating Centre for Pharmacovigilance Program of India (PvPI), where the accurate response rate was lower. Similar gaps have been documented in studies by SK Gupta et al. and SA Khan, who reported that although students were aware of ADR reporting concepts, their understanding of operational mechanisms and causality evaluation was limited [6, 7]. This underscores the need for structured, hands-on pharmacovigilance training to move beyond theoretical knowledge.

With high mean scores for statements such as "ADR reporting is a collective responsibility of all healthcare professionals" and "Pharmacovigilance is an essential part of improving drug safety," the attitude evaluation indicated a generally positive stance towards ADR reporting. These results were in line with earlier studies that showed medical students and interns generally view reporting adverse drug reactions as a professional obligation [5–7]. Interestingly, the statement "ADR reporting is time-consuming and tedious" had a middling mean score, suggesting that although students appreciate ADR reporting, they still see practical difficulties with it. In a similar vein, research by L. Hazell and SA. Shakir found that procedural complexity, workload and ambiguity were common deterrents [4]. This implies that compliance may be improved by streamlining reporting processes and incorporating reporting into regular healthcare practices.

Even with a positive mindset and good understanding, real reporting methods were still not at their best. Less than one-third of participants said they had come across ADRs throughout their rotations, and only 62.2% said they had ever filed an ADR report. Pharmacovigilance literature has extensively documented this knowledge-practice gap, which continues to be one of the main obstacles to efficient ADR reporting systems [2, 4, 6].

The possible reasons for this gap can be absence of practical instruction in ADR submission and documentation, uncertainty about reporting thresholds and causality evaluation and also concern about administrative or legal repercussions [5-7]. Remarkably, most interns (83.3%) were aware of the PvPI yellow form and knew where to report adverse drug reactions. This indicated a latent readiness to participate, which can be leveraged through targeted interventions such as workshops, simulation exercises and real-time mentorship during ward postings.

Knowledge and ADR reporting habits were found to be positively correlated in a statistically significant way, supporting the notion that knowledge can improve reporting behaviour. Similar to the tendency seen in some previous studies, female interns showed significantly higher knowledge ratings than males ($p = 0.023$), which may be related to gender variations in risk perception or involvement with pharmacology training [6]. However, there was no discernible correlation between attitude and reporting, indicating that without supportive surroundings and enabling systems, favourable attitudes might not translate into actual practice. This discovery was consistent with the research by SA Khan and SK Gupta, who identified procedural and structural impediments as key factors contributing to underreporting [6, 7].

It is recommended that Pharmacovigilance education must go beyond didactic lectures to fill in these gaps by including: sessions for developing practical skills in ADR reporting and detection, ADR reporting be incorporated into clinical logbooks and evaluations, provision of institutional support systems (such as feedback loops, accessible forms and ADR help centres) and by consistent reinforcement via workshops, CMEs and online resources. In other contexts, it has been demonstrated that such comprehensive approaches greatly increase ADR reporting rates and data quality [2, 4, 6].

Limitations in this study was that self-reported data, convenience sampling and single-institution setting could generate response biases. Multicentric designs, longitudinal follow-up and intervention-based evaluations should all be used in future studies.

CONCLUSION

The present study highlighted that CRMI students possess adequate knowledge and positive attitudes toward ADR reporting, but their actual reporting practices remain insufficient. Targeted training, simplified procedures and institutional support are essential to bridge this knowledge–practice gap and strengthen the pharmacovigilance system. By empowering medical interns early in their careers, health systems can enhance drug safety monitoring and reduce preventable ADR-related morbidity and mortality.

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AUTHORS CONTRIBUTIONS

LR conceptualized the study, collected data and prepared manuscript. UMC edited manuscript and analyzed data. RG analyzed data and accepted manuscript.

CONFLICT OF INTERESTS

Declared none

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