

EXPLORING AWARENESS AND UNDERSTANDING OF ADVERSE DRUG REACTIONS AMONG MEDICAL UNDERGRADUATES

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ABSTRACT

Background: Adverse drug reactions (ADRs) are an important cause of medication-related morbidity and may compromise patient safety. Adequate knowledge of ADR recognition, pharmacovigilance and reporting among future medical practitioners is essential. **Objective:** To assess knowledge and awareness regarding ADRs among undergraduate medical students and compare awareness across different academic years. **Materials and Methods:** A cross-sectional questionnaire-based study was conducted among 100 undergraduate medical students, with 25 students each from the first to fourth years. A structured 25-item questionnaire assessed knowledge of ADRs, classification, risk factors, pharmacovigilance, ADR reporting and perceptions regarding patient safety and further training. Descriptive statistics were used, and composite scores were compared across academic years using the Kruskal–Wallis test and between sexes using the Mann–Whitney U test. **Result:** Overall, the mean knowledge and awareness score was 20.81 ± 2.42 out of 25, with 72.0% of students achieving a score of ≥ 20 . Awareness was high regarding Type A and Type B ADRs (93.0%), recognition of mild to life-threatening reactions (92.0%) and drug–drug interactions as potential causes of ADRs (92.0%). Awareness of pharmacovigilance and the Pharmacovigilance Programme of India was 85.0% and 81.0%, respectively. The mean score increased progressively from 19.16 ± 2.27 among first-year students to 22.40 ± 1.80 among fourth-year students ($p < 0.001$). No significant difference was observed between female and male students ($p = 0.963$). Most students supported ADR reporting for patient safety, and 97.0% expressed interest in additional pharmacovigilance training. **Conclusion:** Undergraduate medical students demonstrated favorable ADR knowledge and awareness, with significantly higher scores among senior students. Strengthening practical pharmacovigilance training may further improve ADR recognition and reporting competence.

INTRODUCTION

Medicines play a fundamental role in the prevention, diagnosis and treatment of diseases and have contributed substantially to improvements in health and life expectancy. However, the use of medicines is also associated with the possibility of unintended and harmful effects. Adverse drug reactions (ADRs) are an important cause of morbidity and mortality and represent a significant challenge to safe and effective pharmacotherapy (Jiang et al., 2022). ADRs may result in additional diagnostic investigations, prolonged hospitalization, increased healthcare expenditure, disability and, in severe cases, death

(Patel et al., 2023). Therefore, ensuring the safe use of medicines requires healthcare professionals to possess adequate knowledge regarding the recognition, prevention, management and reporting of ADRs. ADRs may present with considerable variation in their clinical manifestations and severity. They may be predictable and related to the pharmacological properties or dose of a drug, or may occur unpredictably in susceptible individuals (Bellanca et al., 2023). Factors such as age, genetic characteristics, renal and hepatic function, comorbidities, polypharmacy and drug–drug interactions may influence an individual's susceptibility to ADRs (Jose and Abajo, 2024)

Consequently, recognition of potential risk factors is an important component of rational and safe drug therapy. The occurrence of an ADR does not necessarily indicate inappropriate prescribing or medication error. ADRs may occur despite appropriate selection and administration of a medicine (Nouri et al., 2024). Distinguishing ADRs from medication errors, disease-related manifestations and other adverse events is therefore important for appropriate clinical assessment. Healthcare professionals need to obtain a comprehensive medication history, recognize temporal associations between drug exposure and symptoms, consider alternative explanations and initiate appropriate management when an ADR is suspected (Jha & Gaikwad, 2025). An important limitation in ensuring medication safety is that not all ADRs can be identified before a medicine is introduced into routine clinical practice. Clinical trials are conducted under controlled conditions and may involve relatively limited numbers of participants, making it difficult to identify uncommon, delayed or population-specific adverse effects (Spahn et al., 2025). Continuous monitoring of medicines after their introduction into clinical use is therefore essential. Pharmacovigilance refers to the science and activities concerned with the detection, assessment, understanding and prevention of adverse effects or other medicine-related problems (Gande, 2026). It provides an important mechanism for identifying potential safety signals and generating evidence that can support regulatory action, clinical decision-making and safer use of medicines. Spontaneous ADR reporting is an important component of pharmacovigilance systems. However, under-reporting of suspected ADRs remains a recognized challenge worldwide (Maisela, 2025). Failure to recognize an ADR, uncertainty regarding causality, inadequate knowledge of reporting procedures, lack of awareness of reporting systems, time constraints and concerns regarding professional or legal consequences have been identified as potential barriers to reporting. Consequently, improving healthcare professionals' knowledge and attitudes toward pharmacovigilance is considered an important strategy for strengthening medication safety. In India, pharmacovigilance activities are supported through the Pharmacovigilance Programme of India (PvPI), which aims to monitor the safety of medicines and strengthen ADR reporting and assessment (Tripathi et al., 2026). The effectiveness of such a system depends substantially on the participation of healthcare professionals who encounter suspected ADRs during routine patient care. Doctors, pharmacists, nurses and other healthcare workers therefore have an important role in recognizing and reporting suspected reactions (Khan et al., 2023). Undergraduate medical education provides an important opportunity to establish the foundations of safe prescribing and pharmacovigilance practice. Medical students acquire knowledge of pharmacodynamics,

pharmacokinetics, therapeutic uses, contraindications, drug interactions and adverse effects during their pharmacology training. Developing an appropriate understanding of ADRs during undergraduate training may therefore contribute to safer prescribing and improved recognition of medication-related problems after graduation. However, knowledge of ADRs encompasses more than familiarity with definitions and drug-related adverse effects. Medical students should also understand the classification and clinical significance of ADRs, recognize patient-related risk factors, identify potentially important drug interactions, understand pharmacovigilance principles and become familiar with appropriate ADR reporting mechanisms. The transition from theoretical pharmacology to practical application is particularly important because future physicians will be responsible for prescribing medicines and monitoring patients for therapeutic response and adverse effects.

Importantly, knowledge and awareness alone may not guarantee appropriate reporting behaviour. Studies among healthcare professionals have demonstrated that positive attitudes toward pharmacovigilance may coexist with inadequate practical reporting practices (Khan et al., 2023; Tripathi et al., 2025). This highlights the need for educational strategies that move beyond theoretical instruction and provide students with opportunities to apply pharmacovigilance concepts in clinically relevant situations. Case-based teaching, simulated ADR reporting, practical demonstrations and integration of pharmacovigilance into clinical postings may provide useful approaches for strengthening these competencies (Haque et al., 2026, Raj et al., 2025). Assessing ADR-related knowledge and awareness among undergraduate medical students is therefore relevant for identifying educational needs and strengthening medication-safety competencies before students enter independent clinical practice. A structured assessment across different academic years can provide insight into the areas of ADR knowledge that are well understood as well as those requiring further reinforcement. Against this background, the present study was undertaken to explore the awareness and understanding of adverse drug reactions among undergraduate medical students. The study focuses on fundamental ADR knowledge, pharmacovigilance awareness, ADR reporting, perceptions regarding patient safety and the perceived need for further pharmacovigilance education.

MATERIALS AND METHODS

Study design and setting: A cross-sectional questionnaire-based study was designed to assess knowledge and awareness regarding adverse drug reactions among undergraduate medical students. The study included students from the first, second,

third and fourth years of undergraduate medical education.

Study population and sample size: A total of 100 undergraduate medical students were included, with 25 students from each academic year. The study population comprised 55/60 female and 45/40 male students as per the respective dataset used for analysis. Students from all four academic years were included to permit comparison of ADR-related knowledge according to academic progression.

Study instrument: Data were collected using a structured 25-item questionnaire developed to assess different domains of ADR knowledge and awareness.

Data collection and analysis: Responses were entered into Microsoft Excel and checked for completeness and consistency before analysis. Descriptive statistics were used to summarize participant characteristics and individual questionnaire responses. Categorical variables were expressed as frequencies and percentages. A composite positive-response score was generated for the 25 questionnaire items, with a positive response coded as 1 and other responses coded as 0, giving a maximum possible score of 25. The composite scores were summarized using mean $\pm$ standard deviation, median and range. The Kruskal–Wallis test was used to compare composite scores across the four

academic years, while the chi-square test was used to compare categorical proportions. A p-value of <0.05 was considered statistically significant.

Ethical considerations: Ethical approval was waived by the Institutional Ethics Committee as the study was a non-interventional, questionnaire-based survey involving no more than minimal risk to participants. The study did not involve any clinical intervention, administration of drugs, collection of biological specimens or access to sensitive personal health information. The questionnaire was anonymous and did not collect personally identifiable information. Participation was voluntary, and privacy and confidentiality of participants were maintained throughout the study.

RESULTS

A total of 100 undergraduate medical students were included in the analysis, with an equal representation of students across the four academic years. Twenty-five students each were included from the first, second, third and fourth years. The study population consisted of 60 female students (60.0%) and 40 male students (40.0%). Within each academic year, 15 females and 10 males were represented. [Table 1]

Table 1: Distribution of study participants according to academic year and sex

Academic year	Female, n (%)	Male, n (%)	Total, n (%)
First year	15 (60.0)	10 (40.0)	25 (25.0)
Second year	15 (60.0)	10 (40.0)	25 (25.0)
Third year	15 (60.0)	10 (40.0)	25 (25.0)
Fourth year	15 (60.0)	10 (40.0)	25 (25.0)
Total	60 (60.0)	40 (40.0)	100 (100.0)

Overall, the students demonstrated a favourable level of awareness regarding adverse drug reactions. Eighty-four students (84.0%) reported that they had heard of the term ADR, while 87.0% indicated that they understood the difference between an ADR and a medication error. Awareness that ADRs can occur even when medicines are used correctly was reported by 79.0% of students. A high proportion of participants (92.0%) recognized that ADRs can vary from mild reactions to life-threatening events (Table 2). Knowledge of ADR classification was also relatively high. Awareness of Type A and Type B ADRs was reported by 93.0% of students, while 79.0% indicated that they could identify common

examples of Type A ADRs. Eighty-five percent recognized allergic drug reactions as ADRs. Similarly, 79.0% were aware that ADRs may be dose-related or dose-independent. Students demonstrated good awareness of factors that can influence the occurrence of ADRs. Eighty-three percent recognized that patient-related factors, including age and organ function, can influence ADR risk. Awareness of drug–drug interactions as a potential cause of ADRs was particularly high, with 92.0% of students responding positively. Furthermore, 86.0% understood the importance of obtaining an appropriate medication history when evaluating a suspected ADR.

Table 2: Knowledge and awareness regarding adverse drug reactions

Knowledge/awareness domain	Positive response, n (%)
Heard of adverse drug reactions	84 (84.0)
Understands difference between ADR and medication error	87 (87.0)
Aware ADRs may occur despite correct drug use	79 (79.0)
Aware of ADR classification	83 (83.0)
Recognizes that ADRs may be mild or life-threatening	92 (92.0)
Aware of Type A and Type B ADRs	93 (93.0)
Can identify common Type A ADRs	79 (79.0)
Recognizes allergic reactions as ADRs	85 (85.0)
Aware of dose-related/dose-independent ADRs	79 (79.0)
Recognizes patient factors affecting ADR risk	83 (83.0)
Aware of drug–drug interactions causing ADRs	92 (92.0)

Understands importance of medication history	86 (86.0)
Aware of pharmacovigilance	85 (85.0)
Knows purpose of ADR reporting	80 (80.0)
Aware of ADR reporting mechanisms in India	79 (79.0)
Aware of PvPI	81 (81.0)

Awareness of pharmacovigilance was present in 85.0% of participants. Eighty percent understood the purpose of ADR reporting, while 79.0% were aware of mechanisms for reporting suspected ADRs in India. Awareness of the Pharmacovigilance Programme of India (PvPI) was reported by 81.0% of students. The attitude toward ADR reporting was predominantly positive. Seventy-six students (76.0%) stated that they would report a suspected ADR encountered during clinical training, while 23.0% selected “Maybe.” Only one student (1.0%)

gave a negative response. Similarly, 81.0% agreed that ADR reporting contributes to patient safety (Table 3). The students also expressed a favorable attitude toward strengthening pharmacovigilance education. Ninety-seven students (97.0%) expressed interest in receiving additional training in pharmacovigilance and ADR reporting. Case-based teaching was considered useful by 85.0% of participants, while 93.0% considered awareness of ADRs to be an essential competency for medical graduates.

Table 3: Attitudes and perceptions regarding ADR reporting and education

Statement	Positive response, n (%)
Would report a suspected ADR during clinical training	76 (76.0)
Consider ADR reporting important for patient safety	81 (81.0)
Feel adequately prepared to recognize common ADRs	76 (76.0)
Consider undergraduate pharmacology teaching sufficient	82 (82.0)
Believe case-based teaching would improve ADR recognition	85 (85.0)
Interested in additional pharmacovigilance training	97 (97.0)
Consider ADR awareness an essential graduate competency	93 (93.0)

Statistical Analysis: For the purpose of quantitative analysis, a composite positive-response score was calculated from the 25 questionnaire items, with a positive “Yes” response coded as 1 and other responses coded as 0. The maximum possible score was 25. The overall mean score was 20.81 ± 2.42 , with a median of 21 and a range of 13–25. Seventy-

two students (72.0%) obtained a score of at least 20/25. A progressive increase in mean scores was observed with increasing academic year. The mean score increased from 19.16 ± 2.27 in first-year students to 22.40 ± 1.80 among fourth-year students (Table 4).

Table 4: Distribution of ADR knowledge/awareness scores according to academic year

Academic year	n	Mean $\pm$ SD	Median	Range	Score ≥ 20 , n (%)
First year	25	19.16 ± 2.27	19	15–23	12 (48.0)
Second year	25	20.48 ± 2.38	21	13–24	17 (68.0)
Third year	25	21.20 ± 2.08	21	17–25	20 (80.0)
Fourth year	25	22.40 ± 1.80	23	19–25	23 (92.0)
Overall	100	20.81 ± 2.42	21	13–25	72 (72.0)

The difference in composite scores across the four academic years was statistically significant using the Kruskal–Wallis test ($H=23.81$, $df=3$, $p<0.001$). The proportion of students achieving a score $\geq 20/25$ also increased significantly across academic years.

Female students had a mean score of 20.83 ± 2.36 compared with 20.78 ± 2.54 among male students. The difference between sexes was not statistically significant (Mann–Whitney $U=1207.0$, $p=0.963$).

Table 5: Comparison of ADR knowledge/awareness scores by sex

Sex	n	Mean $\pm$ SD	Median	Score ≥ 20 , n (%)
Female	60	20.83 ± 2.36	21	43 (71.7)
Male	40	20.78 ± 2.54	21	29 (72.5)
Total	100	20.81 ± 2.42	21	72 (72.0)

Overall, the findings demonstrated a predominantly favourable level of ADR awareness and positive attitudes toward pharmacovigilance. The significant increase in knowledge scores across academic years suggests greater awareness among senior students, whereas no significant difference was observed according to sex (Table 5).

DISCUSSION

Adverse drug reactions (ADRs) are an important component of medication-related morbidity and represent a major concern in clinical practice and pharmacovigilance. Early recognition, appropriate management and timely reporting of suspected ADRs are essential for improving medication safety. The present study assessed the knowledge and awareness

of ADRs among undergraduate medical students from the first to fourth years of medical education. Overall, the participants demonstrated a favourable level of awareness, with a mean positive-response score of 20.81 ± 2.42 out of 25, and 72.0% of students achieving a score of ≥ 20 . A progressive increase in the composite score was observed with academic progression, from 19.16 ± 2.27 among first-year students to 22.40 ± 1.80 among fourth-year students, and this difference was statistically significant ($p < 0.001$). The overall level of ADR awareness in the present study was encouraging. A large proportion of students had heard of ADRs (84.0%), understood the distinction between an ADR and a medication error (87.0%), and recognized that ADRs may range from mild to life-threatening reactions (92.0%). Awareness of Type A and Type B ADRs was particularly high, with 93.0% of students responding positively. These findings suggest that the fundamental conceptual understanding of ADRs was well established among the participants. Adequate knowledge of these concepts is important because medical graduates are expected to recognize suspected drug-related events during clinical practice and contribute to appropriate reporting and patient safety. The findings of the present study were consistent with the study reported by Rauniyar et al. (2021) among third-year undergraduate medical students at BP Koirala Institute of Health Sciences. In their study, only 49.30% of students were familiar with ADRs associated with a particular drug, 40.85% were familiar with ADRs associated with a new product, and 39.44% were familiar with serious or life-threatening ADRs. Furthermore, uncertainty regarding how to report an ADR was identified as the most common barrier, reported by 83.12% of participants. In comparison, 92.0% of students in the present study recognized that ADRs can range from mild to life-threatening reactions (Rauniyar et al., 2021). This difference may be related to variations in the study setting, academic exposure, questionnaire design, participant characteristics and the specific domains used to assess ADR knowledge. Similarly, Yadav et al. (2026) reported that approximately 65% of undergraduate medical students had adequate knowledge regarding ADRs and pharmacovigilance, while 68% were aware of pharmacovigilance and 60% were aware of the Pharmacovigilance Programme of India (PvPI) (Yadav et al., 2026). The authors also observed an improvement in knowledge with increasing academic year. In the present study, awareness of pharmacovigilance and PvPI was higher, at 85.0% and 81.0%, respectively. Although the present findings appear more favourable, direct numerical comparisons should be interpreted cautiously because the questionnaire structure, scoring system and study populations differed between the studies. Awareness of pharmacovigilance is particularly important because effective ADR monitoring depends on recognition of suspected reactions and familiarity with reporting mechanisms. In the present

study, 80.0% of students were aware of the purpose of ADR reporting, while 79.0% were aware of ADR reporting mechanisms in India. Awareness of PvPI was reported by 81.0% of participants. These findings indicate that most students had at least a basic understanding of the pharmacovigilance system. However, awareness of a reporting system does not necessarily imply competence in using the system or actual reporting behaviour. The favourable attitude toward ADR reporting observed in the present study is another important finding. Seventy-six percent of participants stated that they would report a suspected ADR encountered during clinical training, while 81.0% considered ADR reporting important for patient safety. In addition, 93.0% considered ADR awareness an essential competency for medical graduates. These observations are consistent with findings reported by Yadav et al. (2026), where 92% of undergraduate medical students considered ADR reporting a professional responsibility, 88% expressed willingness to report ADRs in future clinical practice and 85% believed that ADR reporting was important for patient safety. The similarity between these findings suggests that undergraduate medical students generally recognize the professional importance of pharmacovigilance. A high level of ADR awareness has also been reported by Raikar et al. (2024), who found that 98% of medical participants had knowledge of ADRs, 70% were aware of pharmacovigilance and 97% recognized the importance of ADR reporting (Raikar et al., 2024). These findings support the favourable perception of ADR reporting observed in the present study. However, their findings also demonstrate that general awareness does not necessarily translate into knowledge of practical reporting resources. This distinction is relevant because the present study assessed willingness and perceived awareness rather than actual reporting practices. One of the most important findings of the present study was the significant improvement in ADR knowledge and awareness with increasing academic year. The mean score increased from 19.16 among first-year students to 22.40 among fourth-year students, while the proportion achieving a score of ≥ 20 increased from 48.0% to 92.0%. The difference across academic years was statistically significant ($p < 0.001$). This pattern suggests that continued exposure to pharmacology and clinical education may contribute to improved understanding of ADRs. This finding is consistent with Yadav et al. (2026), who reported progressive improvement in knowledge and awareness with increasing academic year. Similarly, Sidhu et al. (2023) found that final-year students demonstrated stronger responses regarding ADR classification, filing of ADR reports, national reporting centres and the initial steps involved in ADR monitoring. Their study also demonstrated that students in different academic years performed better in different domains of ADR knowledge (Sidhu et al., 2023). These findings suggest that ADR knowledge may develop progressively throughout

undergraduate medical education, with different components of pharmacovigilance being reinforced at different stages of training.

The improvement among senior students may be related to increasing exposure to clinical pharmacology, clinical postings, prescribing practices and patient-care environments. As students' progress through medical education, pharmacological concepts are increasingly connected with clinical decision-making and medication safety. Clinical exposure may therefore provide opportunities for students to relate theoretical knowledge to practical recognition of adverse effects. Nevertheless, greater clinical exposure does not necessarily eliminate specific knowledge gaps. This is illustrated by the findings of Dhanani et al. (2024) among postgraduate medical students. Their study reported an overall knowledge level of 53.04% regarding monitoring and reporting of ADRs, with particularly low knowledge regarding examples of Type A ADRs (35.20%) (Dhanani et al., 2024). Despite this relatively limited knowledge, participants demonstrated favourable attitudes toward pharmacovigilance training, and 64.80% routinely counselled patients regarding potential medication side effects. These findings suggest that clinical seniority alone may not ensure adequate pharmacovigilance competence and that structured reinforcement remains necessary even at postgraduate levels. The present study found no significant difference in ADR knowledge scores between female and male students. Female students had a mean score of 20.83 ± 2.36 , compared with 20.78 ± 2.54 among male students ($p=0.963$). Similarly, the proportion achieving a score of ≥ 20 was almost identical between females and males. This suggests that academic progression may have had a greater influence on ADR knowledge than sex in the present study. The finding also supports the importance of curriculum-based educational exposure rather than demographic characteristics in developing pharmacovigilance knowledge.

Another notable finding was the high level of interest in additional pharmacovigilance education. Ninety-seven percent of participants expressed interest in receiving additional training on ADRs and pharmacovigilance. This finding is consistent with Rauniyar et al. (2021), who reported that 94.81% of third-year medical students recommended education and training as a strategy for improving ADR reporting. Similarly, Sidhu et al. (2023) emphasized the need for continued reinforcement and updating of ADR-related knowledge among undergraduate medical students. The consistent demand for further education across different student populations suggests that pharmacovigilance should be reinforced throughout undergraduate medical education rather than being restricted to theoretical pharmacology teaching. The distinction between knowledge, attitude and actual reporting practice is particularly important. Although the present study demonstrated favourable knowledge and willingness

to report ADRs, these findings should not be interpreted as evidence of adequate real-world reporting practices. Khan et al. (2023), in a multicentre study among healthcare professionals, reported that although 71.1% of participants demonstrated positive attitudes toward pharmacovigilance, 92.5% had poor reporting practices and only 13.1% had actually reported an ADR. Furthermore, 60.4% had never received pharmacovigilance training (Khan et al., 2023). These findings highlight a potential knowledge–practice gap, in which positive attitudes do not necessarily translate into actual ADR reporting. This knowledge–practice gap has important implications for undergraduate medical education. Pharmacology curricula could incorporate practical approaches to pharmacovigilance, including case-based learning, simulated ADR reporting, interpretation of suspected ADR scenarios and demonstrations of the actual reporting process. Students could also be exposed to pharmacovigilance activities during clinical postings, allowing them to understand how suspected ADRs are identified, documented, assessed and reported. Such approaches may help translate theoretical knowledge into practical competence. The high level of interest in additional training observed in the present study provides an opportunity for curriculum-based interventions. Short workshops, case discussions, simulation exercises and practical demonstrations of ADR reporting could be integrated into undergraduate pharmacology and clinical teaching. Raikar et al. (2024) emphasized the potential value of simulation-based training to strengthen confidence and practical skills related to pharmacovigilance and ADR reporting. Similarly, Dhanani et al. (2024) highlighted the importance of continuous educational interventions to improve knowledge and promote an ADR reporting culture among medical trainees.

CONCLUSION

The present study demonstrated a predominantly favourable level of knowledge and awareness regarding ADRs among undergraduate medical students. Awareness was particularly high regarding ADR severity, classification, pharmacovigilance and the importance of ADR reporting. A significant improvement in knowledge scores was observed with increasing academic year, whereas no significant difference was identified between male and female students. However, evidence from previous studies indicates that theoretical knowledge and positive attitudes may not necessarily translate into actual reporting practices. Therefore, undergraduate medical education should move beyond theoretical awareness and incorporate practical pharmacovigilance training, case-based learning and simulated ADR reporting exercises. Such interventions may help bridge the gap between

knowledge and practice and contribute to safer prescribing and improved patient care.

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