Section: Miscellaneous

Original Research Article

A CROSS-SECTIONAL STUDY ON PERCEPTIONS OF PHARMACOVIGILANCE AMONG UNDERGRADUATE MEDICAL STUDENTS FROM NORTHERN INDIA

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ABSTRACT

Background: Spontaneous reporting of adverse drug reactions (ADRs) constitutes the cornerstone of the pharmacovigilance program. However, underreporting by healthcare professionals remains a significant challenge. The objective is to evaluate the knowledge, attitude, and practice of pharmacovigilance among undergraduate medical students in relation to adverse drug reaction reporting and to compare findings across different academic years.
Materials and Methods: A cross-sectional study was conducted at a tertiary care teaching institute in Haryana. A total of 772 undergraduate MBBS students participated, comprising 210 students from 1st Professional, 194 from 2nd Professional, 196 from 3rd Professional (Part-I), and 172 from 3rd Professional (Part-II). A validated questionnaire containing 21 questions was administered.
Results: The mean knowledge score across all years ranged from 4.60 to 5.71 out of a maximum of 10. Mean attitude scores ranged from 4.37 to 5.19 out of 7. Mean practice scores ranged from 1.43 to 1.71 out of 4, with statistically significant differences observed (P=0.0319). Students demonstrated significantly better attitude scores compared to knowledge and practice. Second and 3rd Professional (Part-II) students showed superior knowledge scores regarding pharmacovigilance definition and mandatory reporting.
Conclusion: Undergraduate medical students exhibited average knowledge and positive attitude toward pharmacovigilance but demonstrated poor practice regarding adverse drug reaction reporting. The findings underscore the critical need for integration of comprehensive pharmacovigilance training and ADR reporting skills into the undergraduate medical curriculum to enhance future physician participation in drug safety monitoring.
Keywords: Pharmacovigilance, Adverse drug reactions, Undergraduate medical students, Drug safety.

INTRODUCTION

According to the World Health Organization (WHO), an ADR is defined as "a response to a drug that is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function".[1] Adverse drug reactions contribute substantially to morbidity and mortality globally, emerging as one of the leading causes of preventable hospital admissions and deaths.[2] Beyond the clinical burden, ADRs impose considerable economic implications on healthcare systems through increased hospital stays, additional diagnostic investigations, and therapeutic interventions.[3]

Despite these initiatives and increased emphasis on pharmacovigilance, the problem of underreporting of ADRs persists as a critical challenge. Research indicates that only 6-10% of all ADR cases are reported to the relevant authorities.[4,5] This substantial underreporting gap significantly undermines the effectiveness of pharmacovigilance programs and compromises patient safety surveillance. Several factors contribute to this phenomenon, including inadequate knowledge and

practical skills regarding ADR identification and reporting mechanisms among healthcare professionals, absence of a robust and active ADR monitoring system, and the lack of a well-established reporting culture within the medical community.[6]

Medical students represent a crucial target population for pharmacovigilance education, as they are future healthcare providers who will shape drug safety practices. Evidence suggests that medical students, if provided with adequate knowledge and practical skills during their undergraduate training, could substantially contribute to strengthening ADR monitoring and reporting mechanisms.[7,8] Limited studies have specifically assessed the knowledge, attitude, and practice of pharmacovigilance among undergraduate medical students in India.[9,10] Therefore, this study was undertaken to assess the knowledge, attitude, and practice of pharmacovigilance among undergraduate MBBS students at a tertiary care teaching hospital in northern India and to compare these parameters across different professional years.

MATERIALS AND METHODS

This was a cross-sectional, questionnaire-based observational study conducted at a tertiary care teaching institute and medical college in Haryana, northern India. The study was conducted among undergraduate MBBS students undergoing clinical postings and practical training. The total sample comprised 772 students, stratified as follows: 1st Professional MBBS: 210 students, 2nd Professional MBBS: 194 students, 3rd Professional MBBS Part-I: 196 students and 3rd Professional MBBS Part-II: 172 students

Students were selected based on their active enrollment in clinical postings and willingness to participate in the study. Written informed consent was obtained from all participants prior to data collection. Students absent during the study period or unwilling to provide informed consent were excluded from the study.

A structured, self-administered questionnaire was developed based on extensive literature review of previous studies assessing pharmacovigilance KAP.[11,12] The questionnaire was pretested with a small pilot group of medical students to ensure clarity, comprehension, and relevance. Based on pilot feedback, modifications were made to enhance the questionnaire's applicability and readability. The final questionnaire comprised 21 questions distributed across three domains: Knowledge Domain (10 questions), Attitude Domain (7 questions), Practice Domain (4 questions).

A binary scoring system was employed where each correct answer or positive response was assigned 1 point, and incorrect, unattempted, or negative responses were assigned 0 points. The maximum possible scores were: Knowledge domain: 10 points, Attitude domain: 7 points, Practice domain: 4 points and Total KAP score: 21 points.

Performance categories were classified as follows: Poor performance: <50% of maximum possible score, Average performance: 50-69% of maximum possible score and Good performance: ≥70% of maximum possible score.

After obtaining approval from the Institutional Ethics Committee, the questionnaire was distributed to eligible students during their regular class sessions and clinical posting periods. Students were informed about the purpose and objectives of the study. Each student was given 25 minutes to complete the questionnaire. Research staff remained available to clarify any ambiguities or doubts regarding the questions.

Data were compiled and entered in Microsoft Excel spreadsheet (Microsoft Corporation, USA) and subsequently analyzed using SPSS version 19.0 (IBM Corporation, USA). Descriptive statistical analysis was performed to calculate frequencies, percentages, and mean scores with standard deviations. Comparison of mean scores across different professional years was conducted using one-way analysis of variance (ANOVA). Chi-square test (χ^2) was employed to assess the statistical significance of differences in categorical variables across groups. A P-value of <0.05 was considered statistically significant throughout the analysis.

RESULTS

Among the 772 undergraduate medical students enrolled in the study, complete data were available from all participants (100% response rate). The distribution of participants across professional years was as follows: 1st Professional MBBS (n=210, 27.2%), 2nd Professional MBBS (n=194, 25.1%), 3rd Professional MBBS Part-I (n=196, 25.4%), and 3rd Professional MBBS Part-II (n=172, 22.3%).

Students were evaluated on 10 knowledge-based questions encompassing various aspects of pharmacovigilance and ADR reporting. The performance of students across different professional years is presented in [Table 1].

When asked to define ADR according to WHO criteria, 61.67-80% of students across all professional years responded correctly, with statistically significant differences observed ($\chi^2 = 4.603$, $P < 0.05$). Most students (73.33-80%) understood the distinction between adverse drug events and ADRs, though this difference was not statistically significant across groups ($P > 0.05$). [Table 1]

Students' attitudes toward pharmacovigilance and ADR reporting were assessed through seven questions, and results are presented in [Table 2]. An overwhelming majority of students (93.33-98.33%) across all professional years recognized the necessity of ADR reporting and rejected the notion that it is a waste of time ($P > 0.05$). Similarly, 83.33-90% of students acknowledged the mutual benefits of ADR

reporting for both patients and healthcare providers, with no significant difference across groups (P > 0.05).

Regarding curriculum integration, 85-91.67% of students across all professional years felt that ADR reporting should be included in pharmacology practical sessions, indicating strong consensus regarding the importance of hands-on training (P > 0.05). However, when specifically asked about ADR reporting being a professional obligation of all healthcare workers, only 13.33-38.33% of students agreed (χ^2 = 27.531, P < 0.0001). Notably, 2nd Professional and 3rd Professional (Part-II) students demonstrated significantly higher awareness of this professional responsibility (38.33%) compared to their junior colleagues (13.33-20%). [Table 2]

Table 1: Response of students to knowledge-based questions

Knowledge-Based Questions	1st Prof (n=210)	2nd Prof (n=194)	3rd Prof P-I (n=196)	3rd Prof P-II (n=172)	P-value
Define ADR	130 (61.67%)	155 (80.00%)	121 (61.67%)	138 (80.00%)	<0.05
Are adverse drug event and ADR same?	168 (80.00%)	146 (75.00%)	144 (73.33%)	129 (75.00%)	>0.05
Who can report ADR?	133 (63.33%)	142 (73.33%)	131 (66.67%)	126 (73.33%)	>0.05
Is ADR reporting mandatory?	21 (10.00%)	52 (26.67%)	20 (10.00%)	46 (26.67%)	<0.05
What is pharmacovigilance?	105 (50.00%)	133 (68.33%)	72 (36.67%)	118 (68.33%)	<0.05
Which method is commonly used for causality assessment of ADR?	80 (38.33%)	84 (43.33%)	56 (28.33%)	75 (43.33%)	>0.05
What does PvPI stand for?	143 (68.33%)	133 (68.33%)	137 (70.00%)	118 (68.33%)	>0.05
Where is national pharmacovigilance center in India located?	88 (41.67%)	107 (55.00%)	111 (56.67%)	95 (55.00%)	>0.05
Expand the acronym CDSCO	59 (28.33%)	65 (33.33%)	62 (31.67%)	57 (33.33%)	>0.05
Where is UMC located?	119 (56.67%)	84 (43.33%)	75 (38.33%)	75 (43.33%)	>0.05

Abbreviations: ADR = Adverse drug reaction; PvPI = Pharmacovigilance Programme of India; CDSCO = Central Drugs Standard Control Organization; UMC = Uppsala Monitoring Centre

Table 2: Response of Students to Attitude-Based Questions

Attitude-Based Questions	1st Prof (n=210)	2nd Prof (n=194)	3rd Prof P-I (n=196)	3rd Prof P-II (n=172)	P-value
Is ADR reporting necessary or waste of time?	200 (95.00%)	181 (93.33%)	193 (98.33%)	161 (93.33%)	>0.05
Does ADR reporting benefit both patients and doctors?	185 (88.33%)	175 (90.00%)	163 (83.33%)	155 (90.00%)	>0.05
Should ADR reporting be included under Pharmacology practical?	178 (85.00%)	175 (90.00%)	180 (91.67%)	155 (90.00%)	>0.05
Is ADR reporting a part of professional obligation?	28 (13.33%)	74 (38.33%)	39 (20.00%)	66 (38.33%)	<0.0001
Could medical students play a role in ADR reporting?	116 (55.00%)	110 (56.67%)	95 (48.33%)	97 (56.67%)	>0.05
Discussion on ADR during clinical posting relevant?	21 (10.00%)	74 (38.33%)	36 (18.33%)	66 (38.33%)	<0.0001
Is collecting box at clinical departments helpful?	168 (80.00%)	165 (85.00%)	167 (85.00%)	146 (85.00%)	>0.05

Abbreviations: ADR = Adverse drug reaction

Four questions assessed the practical aspects of pharmacovigilance and ADR reporting among students. Results are presented in [Table 3]. Regarding exposure to ADR reporting forms, 53.33-61.67% of students across all professional years reported having seen the CDSCO ADR reporting form, with no statistically significant differences (P > 0.05). This indicates that approximately half the student population lacks familiarity with the official reporting documentation.

When asked about encountering actual cases of ADRs during clinical ward postings, 63.33-85% of students reported such exposure (χ^2 = 19.406, P = 0.0002). Notably, senior students (1st Professional and 3rd Professional Part-I) reported higher frequency of ADR exposure (80-85%) compared to 2nd Professional and 3rd Professional (Part-II) students (63.33%), suggesting variations in clinical exposure or case complexity across different posting schedules. [Table 3]

Table 3: Response of Students to Practice-Based Questions

Practice-Based Questions	1st Prof (n=210)	2nd Prof (n=194)	3rd Prof P-I (n=196)	3rd Prof P-II (n=172)	P-value
Have you seen an adverse drug reporting form by CDSCO?	130 (61.67%)	116 (60.00%)	105 (53.33%)	103 (60.00%)	>0.05
Have you ever seen a case of ADR during ward posting?	168 (80.00%)	123 (63.33%)	167 (85.00%)	109 (63.33%)	<0.001
Have you ever played any role in reporting ADR?	38 (18.33%)	19 (10.00%)	10 (5.00%)	17 (10.00%)	>0.05
Have you ever visited any ADR monitoring center?	7 (3.33%)	29 (15.00%)	20 (10.00%)	26 (15.00%)	>0.05

Abbreviations: ADR = Adverse drug reaction; CDSCO = Central Drugs Standard Control Organization

Mean scores across the three domains and statistical analysis are presented in [Table 4] and corresponding figures. Practice scores (maximum 4) ranged from 1.43±1.17 to 1.71±0.76, representing the most concerning domain. Despite the differences in knowledge and attitude, practice scores remained uniformly low across all professional years (F = 2.95, P = 0.0319). This indicates that even senior students have not translated their theoretical knowledge and positive attitudes into concrete practice regarding ADR reporting. [Table 4]

Table 4: Comparison of Mean KAP Scores

Domain	1st Prof (n=210)	2nd Prof (n=194)	3rd Prof P-I (n=196)	3rd Prof P-II (n=172)	P-value
Knowledge (Maximum=10)	4.74±1.51	5.71±1.71	4.60±1.73	5.63±1.88	P<0.0001*
Attitude (Maximum=7)	4.37±0.74	5.16±1.37	4.48±1.02	5.19±1.39	P<0.0001*
Practice (Maximum=4)	1.71±0.76	1.43±1.17	1.52±0.71	1.51±1.23	P=0.0319*

*Denotes statistical significance (ANOVA test)

DISCUSSION

Pharmacovigilance represents an integral and essential component of comprehensive healthcare delivery systems worldwide. Its primary function is the early detection and prevention of adverse drug reactions associated with medicinal products. Spontaneous reporting of ADRs by healthcare professionals constitutes the backbone of any functional pharmacovigilance program. However, numerous studies have documented substantial underreporting of ADRs across various healthcare settings, which remains a significant concern for public health authorities and drug regulatory agencies.[8,9]

While considerable research has evaluated the knowledge, attitude, and practice of pharmacovigilance among practicing healthcare professionals including physicians, nurses, and pharmacists, limited data exist regarding undergraduate medical students' perspectives and competencies in this critical domain.[10] As the future generation of healthcare providers, medical students represent a strategic target population for implementing pharmacovigilance education and fostering a culture of ADR reporting. This study addresses this gap by comprehensively assessing KAP of pharmacovigilance among 772 undergraduate MBBS students across different professional years at a tertiary care teaching institution in northern India.

Most concerning is the alarming gap in students' awareness about the mandatory nature of ADR reporting. Only 10-26.67% of students recognized this as a regulatory requirement, with junior students significantly less aware than seniors. This inadequacy represents a critical knowledge deficit with direct implications for future practice. Knowledge of mandatory reporting establishes the professional and legal imperative for ADR reporting and transforms it from a voluntary, discretionary activity to a professional obligation.[13]

Approximately 28-43% of students could identify appropriate causality assessment methods for ADRs. This limited knowledge compromises students' ability to systematically evaluate drug-disease causality, an essential skill for recognizing and reporting genuine ADRs. Poor performance on causality assessment questions reflects the common gap between theoretical knowledge and practical application highlighted in pharmacovigilance literature.[14]

Regarding institutional knowledge, fewer than 60% of students correctly identified the location of the National Pharmacovigilance Center or could expand relevant acronyms such as CDSCO and UMC. This institutional ignorance likely translates into inability to direct ADR reports to appropriate channels and reflects inadequate integration of pharmacovigilance infrastructure education within the medical curriculum.[15]

A positive finding emerged in the attitude domain, where students consistently demonstrated favorable views toward ADR reporting and pharmacovigilance. An overwhelming 93.33-98.33% of students recognized the necessity of ADR reporting and viewed it as a meaningful clinical activity rather than a waste of time. Similarly, 83.33-90% acknowledged the mutual benefits of reporting for both patients and healthcare providers. These highly positive attitudinal responses indicate that students do not resist or dismiss pharmacovigilance but rather appreciate its importance.

Furthermore, 85-91.67% of students supported integration of ADR reporting education within pharmacology practical sessions, demonstrating enthusiasm for hands-on training in this domain. This consensus regarding curriculum integration represents an important advocacy point for implementing pharmacovigilance education reforms. However, attitudinal assessment revealed concerning gaps. Only 13.33-38.33% of students recognized ADR reporting as a professional obligation of all healthcare workers, with significant variation across professional years. This deficiency in perceiving pharmacovigilance as a fundamental professional responsibility may partially explain the practice gaps despite positive attitudes toward the activity itself. Viewing ADR reporting as optional rather than obligatory substantially diminishes the likelihood of consistent reporting behavior.[16]

The most sobering findings emerged in the practice domain, revealing a substantial theory-practice gap. Although 63.33-85% of students had encountered

actual ADRs during clinical ward postings, only 5-18.33% reported any participation in ADR reporting. This marked discordance between exposure and action represents a critical failure point in the pharmacovigilance system.

The overall pattern of low practice scores uniformly across all professional years, despite variable knowledge and attitude scores, suggests that factors beyond knowledge and attitudes constrain ADR reporting behavior. These may include institutional infrastructure limitations, lack of explicit encouragement from senior physicians, absence of structured reporting protocols accessible to students, and perceived occupational constraints.

A consistent pattern emerged in this study where 2nd Professional and 3rd Professional (Part-II) students demonstrated superior performance in both knowledge and attitude domains compared to junior colleagues. This progressive improvement likely reflects cumulative curricular exposure, advancing clinical experience, and maturation of professional consciousness as students progress through their medical training.

However, this positive trajectory does not extend meaningfully to the practice domain, where scores remained uniformly low regardless of professional year. This finding suggests that advancing academic year and expanded theoretical knowledge do not automatically translate into ADR reporting behavior, indicating that structural and environmental factors significantly constrain practice independent of student preparedness.

Limitations

This study was conducted at a single tertiary care institution in northern India, which may limit the generalizability of findings to other geographic regions or institutional contexts. Cross-sectional design restricts our ability to establish causal relationships or follow changes over time. Students may have responded with social desirability bias to attitudinal and practice questions. The questionnaire approach relies on self-reported data rather than objective assessment of actual reporting behavior.

CONCLUSION

This study reveals that knowledge deficits and practice gaps persist despite favorable attitudes, highlighting the need for systematic educational interventions and curricular modifications. The findings underscore an urgent and imperative need to strengthen pharmacovigilance education within undergraduate medical training. Integration of comprehensive pharmacovigilance modules, practical ADR reporting experience, and faculty mentorship throughout the clinical curriculum represents an evidence-based strategy for developing competent physicians who will champion drug safety in their future professional careers.

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