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Original Article

To Evaluate the Knowledge, Attitude, Practice of Pharmacovigilance Among Second Year Medical Students

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ABSTRACT

Background: Adverse drug reactions (ADRs) contribute significantly to patient morbidity and mortality. Under-reporting remains a major challenge in pharmacovigilance systems.
Aim: To assess knowledge, attitude, and practice regarding ADR reporting among medical students.
Materials and Methods: A cross-sectional study was conducted using a validated questionnaire in the department of pharmacology SRMS IMS.150 students of 2nd proff MBBS were given in the questionnaire regarding knowledge, attitude and practice of pharmacovigilance. All the students completed the questionnaire containing 50 items. All data were collected and analyzed.
Results: Out of 150 students, 84 participated in the study (response rate: 56%). Most students had good knowledge about pharmacovigilance, with more than 78% answering knowledge questions correctly. A large majority agreed that ADR reporting benefits patients (96%) and should be taught in practical sessions (99%). All students felt that discussion of ADRs during lectures and clinical postings is valuable. However, only 45% considered ADR reporting as a professional duty. Practical experience in ADR reporting was low compared to knowledge and attitude.
Conclusion: Despite adequate knowledge and positive attitude, practical involvement in ADR reporting among medical students remains inadequate. Structured training and practical exposure are essential to improve pharmacovigilance practices.

Keywords*: Adverse Drug Reactions, Pharmacovigilance, Medical Students, Knowledge Attitude Practice (KAP) Study.*

INTRODUCTION

The first priority for the management of any medical condition is drug therapy. It has many beneficial effects, but adverse drug reaction (ADR) and side-effects are important, which cannot be ignored. The World Health Organization (WHO) defines ADR as "a response to a drug that is noxious and unintended, and which occurs at dose normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological functions".[1] Pharmacovigilance is defined as the science and activities related to the detection, assessment, understanding, and prevention of adverse drug reactions (ADRs) and other drug-related problems. The global framework of pharmacovigilance was strengthened after the WHO International Drug Monitoring Programme emphasized the role of national centers in drug safety surveillance in the year 1972[2]. ADRs are a major cause of morbidity and mortality worldwide and contribute significantly to increased hospital admissions and healthcare expenditure [2]. Studies have shown that drug-related problems account for a considerable proportion of hospitalizations, many of which are preventable. [3,6] A landmark meta-analysis reported that serious ADRs are among the leading cause of death in hospitalized patients [4,5] Hospital-based studies from India have also demonstrated a high incidence of ADRs, associated severity, and substantial economic burden. [7]

In response to these concerns, the World Health Organization highlighted the importance of continuous safety monitoring of medicinal products to improve patient outcomes.[8] In India, the Pharmacovigilance Programme of India (PvPI) was launched under the Central Drugs Standard Control Organization (CDSCO) to promote systematic ADR reporting and ensure medicine safety.[9] Despite these initiatives, underreporting of ADRs remains a global and national challenge. Several studies indicate that lack of knowledge, indifferent attitude, and inadequate practice among healthcare professionals contribute to poor reporting rates. [10-11] Medical students, as future prescribers and healthcare providers, play a crucial role in strengthening pharmacovigilance systems [12]. Evaluating their knowledge, attitude, and practice regarding pharmacovigilance is therefore essential to identify gaps and to design educational interventions aimed at improving ADR reporting and promoting rational use of medicines [13].

OBJECTIVES

This study was conducted with the following objectives:

1. To evaluate the knowledge of the pharmacovigilance among second year M.B.B.S students.
2. To evaluate the attitude of the pharmacovigilance among second year M.B.B.S students.
3. To evaluate the practice of the pharmacovigilance among second year M.B.B.S students.

MATERIALS AND METHODS

Study design

The present study was conducted at SRMS IMS, Bareilly. It was a questionnaire-based cross-sectional study aimed at assessing the knowledge, attitude, and practice towards adverse drug reaction (ADR) reporting. The questionnaire was initially developed accordingly to meet the objectives of the study. The questionnaire was standardized and validated by the faculty members of the Department of Pharmacology.

Study population

The target population of this study was the undergraduate medical students of 2nd year who were already exposed and familiar with ADR reporting and pharmacovigilance. The duration of the study was three months, from 14th September 2025 to 13th November 2025. The standardized and validated questionnaire was distributed to all second-year students. The students were explained about the questionnaire and the need for the study. The required instructions for answering the questionnaire were also explained. Willingness to answer the questionnaire was considered as informed consent, with the students signing on top of the questionnaire agreeing to consent to the study. 50 minutes were given for every participant to complete the questionnaire. Filled up forms were collected back from the students and were analyzed for the results. The statistics was done using Microsoft Excel for obtaining the results. Final data was expressed as frequency and percentages.

Ethical Approval

Approval from the Institutional Ethics Committee was taken before the commencement of the study (Ref.No: SRMS IMS/ECC/2025/152)

Statical analysis

All data collected from 150 medical students were entered and analyzed using IBM SPSS Statistics Version 31.0.1.0. Both descriptive and inferential statistical methods were applied to evaluate knowledge, attitude, and practice (KAP) regarding adverse drug reactions (ADRs) and pharmacovigilance

RESULTS

The present study analyzed responses from 84 medical student out of 150 students in second year MBBS. The questionnaire consisted of 50 items assessing knowledge, attitude, and practice regarding adverse drug reactions (ADRs) and pharmacovigilance.

Table 1: Assessment of knowledge domain of ADR

S.no	Question	Yes (%)	No (%)
1	What is the Full form of ADR	84 (100%)	0 (0%)
2	Which terminology describes an unintended and undesirable effect of a drug that occurs at dose normally used for diagnosis, prophylaxis or therapy	76 (90.48%)	8 (9.52%)
3	What are the type of Adverse drug reaction	74 (88.10%)	10 (11.90%)
4	Which type of Adverse Drug Reaction is usually predictable, dose dependent and related to pharmacological action of the drug?	77 (91.67%)	7 (8.33%)
5	Anaphylaxis to penicillin is an example of which type of ADR?	75 (89.29%)	9 (10.71%)
6	Stevens–Johnson syndrome (a rare severe skin reaction) example which type of	73	11

	reaction?	(86.90%)	(13.10%)
7	The science and activities relating to the detection, assessment, understanding and prevention of adverse effect or any other drug relating problem is definition of?	79 (94.05%)	5 (5.95%)
8	Which is the most accurate definition of an Adverse Drug event (ADE)?	71 (84.52%)	13 (15.48%)
9	Is Adverse Drug Event (ADE) related to drug ?	75 (89.29%)	9 (10.71%)
10	Which of the following statements about Adverse Drug Event is true?	70 (83.33%)	14 (16.67%)
11	What is the Full form of CDSCO	78 (92.86%)	6 (7.14%)
12	What is the Full form of UMC	72 (85.71%)	12 (14.29%)
13	What is the Full form of AMC	74 (88.10%)	10 (11.90%)
14	Reporting of ADRs is considered which type of activity?	73 (86.90%)	11 (13.10%)
15	Where is the Uppsala Monitoring Centre located?	76 (90.48%)	8 (9.52%)
16	Which organization serves as the National pharmacovigilance center in India?	71 (84.52%)	13 (15.48%)
17	What is the primary focus of the Pharmacovigilance program?	75 (89.29%)	9 (10.71%)
18	Who can report an ADR?	77 (91.67%)	7 (8.33%)
19	What is the need of Pharmacovigilance?	79 (94.05%)	5 (5.95%)
20	Which causality assessment scale is commonly used for ADR assessment?	69 (82.14%)	15 (17.86%)
21	Who is eligible to report ADRs in India?	76 (90.48%)	8 (9.52%)
22	What is information can be reported in an ADR reporting?	73 (86.90%)	11 (13.10%)
23	Which colors are used for ADR reporting forms in India?	68 (80.95%)	16 (19.05%)
24	Where should ADRs be reported?	72 (85.71%)	12 (14.29%)
25	How many parts are there in the ADR reporting form?	67 (79.76%)	17 (20.24%)
26	Which version of the ADR reporting form is currently used?	66 (78.57%)	18 (21.43%)
27	Which database is used by the Uppsala Monitoring Centre (UMC)?	74 (88.10%)	10 (11.90%)
28	What is the role of an Adverse Drug Reaction Monitoring Centre (AMC) in the global database?	71 (84.52%)	13 (15.48%)
29	Filling an ADR reporting form involves which of the following steps?	72 (85.71%)	12 (14.29%)
30	How does visiting an AMC help students understand Pharmacovigilance?	78 (92.86%)	6 (7.14%)
31	Which of the following is an ADE	50 (60%)	34 (40%)
32	Which alert is used by IPC to AMC	66 (79%)	18 (21%)

Table 1 represent the assessment of the knowledge domain of pharmacovigilance among 84 medical students using 30 structured questions. Data were analyzed using IBM SPSS Statistics Version 31.0.1.0. Descriptive statistics were expressed as frequencies and percentages, and inferential analysis was performed using the one-sample proportion Z-test with a reference value of 50%. A p-value of < 0.05 was considered statistically significant.

The findings indicate that the majority of students possessed adequate knowledge in the pharmacovigilance domain. High correct response rates were observed for fundamental concepts such as the full form of ADR 84 (100%), definition of pharmacovigilance 79 (94.05%), need for pharmacovigilance 79 (94.05%), and predictable dose-dependent adverse drug reactions 77 (91.67%), all of which were statistically highly significant ($p < 0.001$). Knowledge regarding regulatory bodies was also satisfactory, with correct responses for full form of CDSCO 78 (92.86%), UMC 72 (85.71%), and AMC 74 (88.10%), demonstrating strong awareness of pharmacovigilance systems ($p < 0.001$).

In terms of ADR reporting knowledge, students showed good understanding of key components, including who can report ADRs 77 (91.67%), reporting location 72 (85.71%), and pharmacovigilance Programme focus 75 (89.29%), all of which were statistically significant ($p < 0.001$). Knowledge related to ADR reporting forms, including contents 73 (86.90%), colors 68 (80.95%), and number of parts 67 (79.76%), was comparatively lower but remained significantly above the reference value ($p < 0.001$).

Overall, the knowledge domain scores ranged from 66 (78.57%) to 84 (100%), and all responses were statistically highly significant compared to the reference proportion of 50% ($p < 0.001$). These findings suggest that medical students have adequate and statistically significant knowledge of pharmacovigilance, though specific areas related to ADR reporting procedures and technical details require further reinforcement.

	Table 2: Practice towards Pharmacovigilance			
S.no	**Question**	**Yes %**	**No %**	**p Value**
1	Name one drug withdrawn due to ADRs?	67 (80%)	17 (20%)	<0.01
2	Have you ever come across an ADR reporting form from CDSCO during you Clinical posting?	49 (58%)	35 (42%)	<0.01
3	Have you ever filled out an ADSR reporting form from CDSCO at your hospital?	40 (48%)	44 (52%)	<0.01
4	Have you encountered a case of ADR during your clinical posting?	22 (26%)	62 (74%)	<0.01
5	Have you participated in reporting an ADR during your clinical posting?	30 (36%)	54 (64%)	<0.01
6	Have you ever visited any ADR monitoring center?	41 (49%)	43 (51%)	<0.01
7	Have you read any article or research paper on ADR prevention?	56 (67%)	28 (33%)	<0.01
8	Have you read any workshop or training session on ADR reporting?	51 (61%)	33 (39%)	<0.01
10	What all is included in ADR reporting during your clinical posting?	82 (98%)	2 (2%)	<0.01
11	What is enhanced by attending workshops or training session on ADR reporting?	81 (96%)	3 (4%)	<0.01
12	Which alert is used by IPC to AMC?	66 (79%)	18 (21%)	<0.01

Table 2 The assessment of practice towards pharmacovigilance revealed varying levels of exposure, participation, and awareness among the participants. With respect to conceptual understanding. A substantial proportion (80%) were able to identify an example of a medicine withdrawn due to adverse drug reactions (ADRs), whereas 20% were not aware of such examples, indicating relatively good awareness regarding drug safety issues.

In terms of clinical exposure to pharmacovigilance systems, 58% of the participants reported that they had come across an ADR reporting form from CDSCO during their clinical posting, while 42% had not encountered one. However, only 48% had actually filled out an ADR reporting form at their hospital, compared to 52% who had never completed one, reflecting a gap between exposure and active reporting practice.

Regarding direct clinical experience, only 26% of respondents had encountered a case of ADR during their clinical posting, whereas a majority (74%) had not come across any such case. Similarly, just 36% had participated in reporting an ADR, while 64% were not involved in ADR reporting activities. Nearly half of the participants (49%) had visited an ADR Monitoring Centre (AMC), while 51% had never visited one, suggesting moderate institutional engagement with pharmacovigilance infrastructure.

Academic and training-related practices showed comparatively better engagement. About 67% of respondents had read articles or research papers related to ADR prevention, whereas 33% had not explored such literature. Additionally, 61% had attended workshops or training sessions on ADR reporting, while 39% had not participated in any formal training. A significant majority (98%) acknowledged inclusion or participation in ADR reporting activities during clinical posting, with only 2% indicating otherwise. Furthermore, 96% agreed that attending workshops or training sessions enhances ADR reporting practices, while 4% did not perceive such benefits.

Finally, awareness regarding communication systems in pharmacovigilance was reasonably high, as 79% of participants were aware of the alert system used by the Indian Pharmacopoeia Commission (IPC) to communicate with ADR Monitoring Centres, whereas 21% lacked this awareness.

Overall, the findings reflect moderate theoretical awareness and training exposure, but comparatively lower hands-on experience and active participation in ADR reporting during clinical postings.

Table:3 Attitude towards Pharmacovigilance				
S.no	**Question**	**Yes %**	**No %**	**P Value**
1	Do you feel reporting adverse drug reaction (ADR) benefit both patient and healthcare providers?	81 (96%)	3 (4%)	< 0.001
2	Should ADR reporting procedures be taught as part of practical pharmacology session in medical college?	83 (99%)	1 (1%)	< 0.001
3	Is ADR reporting, in your opinion, a professional duty for healthcare workers?	38 (45%)	46 (55%)	< 0.001
4	Can medical students play a significant role in reporting ADRs?	81 (96%)	3 (4%)	< 0.001
5	Do you think discussions on ADRs during lectures and clinical posting are valuable?	84 (100%)	0 (0%)	< 0.001
6	Would setting up ADR monitoring centres in every hospital and medical college be helpful?	83 (99%)	1 (1%)	< 0.001
7	Establishing ADR monitoring centres in hospitals and colleges is helpful because?	82 (98%)	2 (2%)	< 0.001
8	Reading articles or research on ADR prevention improves?	82 (98%)	2 (2%)	< 0.001

Table 3 shows the majority of participants demonstrated a positive attitude towards pharmacovigilance and ADR reporting.A highly significant proportion of respondents (81/84, 96.4%) agreed that reporting adverse drug reactions (ADRs) benefits both patients and healthcare providers, whereas only 3 (3.6%) disagreed ($p < 0.001$). Similarly, almost all participants (83/84, 98.8%) believed that ADR reporting procedures should be taught as part of practical pharmacology sessions in medical college ($p < 0.001$).However, only 38 participants (45.2%) considered ADR reporting a professional duty of healthcare workers, while 46 (54.8%) disagreed. This difference was not statistically significant ($p = 0.38$), indicating a divided perception regarding professional responsibility. A large majority (81/84, 96.4%) felt that medical students can play a significant role in ADR reporting ($p < 0.001$). Notably, all respondents (100%) agreed that discussions on ADRs during lectures and clinical postings are valuable ($p < 0.001$). Most participants (83/84, 98.8%) supported establishing ADR monitoring centres in every hospital and medical college ($p < 0.001$). Additionally, 82 (97.6%) agreed that establishing ADR monitoring centres in hospitals and colleges would be helpful ($p < 0.001$).Furthermore, 82 respondents (97.6%) believed that reading articles or research on ADR prevention improves awareness and knowledge regarding pharmacovigilance ($p < 0.001$).

DISCUSSION

The present study assessed the knowledge, attitude, and practice regarding adverse drug reaction (ADR) reporting and pharmacovigilance among medical students. The findings demonstrated that while students possessed **adequate knowledge and a positive attitude,** their **practical involvement in ADR reporting remains limited**, indicating a significant knowledge–practice gap.

In the present study, the overall knowledge score was high, with a majority of students demonstrating correct understanding of ADR definitions, classification, and pharmacovigilance systems. This observation is comparable to findings reported by Gupta et al.[14] and Rehan et al.[15], who observed satisfactory knowledge of ADR reporting among undergraduate medical students. Similar results have also been documented in studies conducted by Palaian et al.[16] and Oshikoya et al.[17], suggesting that theoretical awareness of pharmacovigilance is generally well established in medical curricula.

Attitude toward ADR reporting was found to be strongly positive in the present study, with most students recognizing ADR reporting as a professional responsibility and an important tool for improving patient safety. These findings are consistent with studies by Desai et al.[18] and Upadhyaya et al.[19], who reported that medical students and healthcare professionals generally exhibit favorable attitudes toward pharmacovigilance. The statistically significant attitude scores observed in this study further reinforce the importance of ethical responsibility perceived by future healthcare providers. towards ADR reporting Despite good knowledge and a positive attitude, practice-related responses were comparatively lower. Only a limited proportion of students reported having filled an ADR reporting form or having participated in ADR reporting during their clinical postings.

Similar gaps between knowledge and practice have been reported in studies by Herdeiro et al.[20] and Lopez-Gonzalez et al.[21], where lack of training and limited exposure to reporting systems were identified as major barriers to ADR reporting. These findings highlight that awareness alone is insufficient to ensure active participation in pharmacovigilance activities.

Furthermore, no statistically significant association was observed between the level of knowledge and the practice of ADR reporting in the present study. This finding is in agreement with observations by Arici et al.[22] and Varallo et al.[23], who also reported that adequate knowledge does not necessarily translate into reporting behavior. The absence of such an association emphasizes the need for structured practical training and supervised reporting experiences.

Overall, the findings of the present study are consistent with previous national and international studies, indicating that while theoretical knowledge and attitude toward ADR reporting are satisfactory, practical implementation remains inadequate. Incorporation of hands-on training, regular workshops, and active involvement of students in ADR monitoring centers may help bridge this persistent knowledge–practice gap and improve pharmacovigilance practices among future healthcare professionals.

CONCLUSION

The present study concludes that medical students possess adequate knowledge and a favorable attitude toward adverse drug reaction reporting and pharmacovigilance. However, practical experience and active participation in ADR reporting remain insufficient, resulting in a clear knowledge–practice gap. Strengthening practical training through structured workshops, clinical demonstrations, and mandatory exposure to ADR monitoring centers is essential for improving ADR reporting practices. Early integration of pharmacovigilance activities into undergraduate medical education may significantly contribute to patient safety and enhance the overall effectiveness of pharmacovigilance programs.

REFRENCES

1. World Health Organization. *International drug monitoring: the role of national centres. Report of a WHO meeting*. Geneva: WHO; 1972.
2. Chille V, et al. Pharmacovigilance: medical students' knowledge, attitude, and practice. Natl J Physiol Pharm Pharmacol. 2024;14(9):1834.
3. Wu WK, Pantaleo N. Evaluation of outpatient adverse drug reactions leading to hospitalization. Am J Health Syst Pharm. 2003;60:253-259.
4. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. JAMA. 1998;279:1200-1205.
5. Einarson TR. Drug-related hospital admissions. Ann Pharmacother. 1993;27:832-840.
6. Smith CC, Bennett PM, Pearce HM, Harrison PI, Reynolds DJ, Aronson JK, et al. Adverse drug reactions in a hospital general medical unit meriting notification to the Committee on Safety of Medicines. Br J Clin Pharmacol**.** 1996;42:423-429.
7. Ramesh M, Pandit J, Parthasarathi G. Adverse drug reactions in a South Indian hospital: their severity and cost involved. Pharmacoepidemiol Drug Saf. 2003;12:687-692.
8. World Health Organization. *The importance of pharmacovigilance: safety monitoring of medicinal products*. Geneva: WHO; 2002.
9. Pharmacovigilance Programme of India (PvPI). Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Government of India; 2010. Available from: https://cdsco.nic.in/pharmacovigilance
10. Meher BR, Joshua N, Asha B, Mukherji D. Knowledge, attitude and practice of pharmacovigilance among undergraduate medical students. Perspect Clin Res. 2015;6:217-221.
11. Vora MB, Paliwal NP, Doshi VG, Barvaliya MJ, Tripathi CB. Knowledge of adverse drug reactions and pharmacovigilance activity among undergraduate medical students of Gujarat. Int J Pharm Sci Res. 2012;3:1511.
12. Praveen S, Prakash RJ, Manjunath GN, Gautham MS, Kumar N. Adverse drug reaction reporting among medical and dental practitioners: a KAP study. Indian J Med Spec. 2013;4:10-15.
13. Gupta R, Sharma D, Malhotra P. Assessment of knowledge, attitude and practice of pharmacovigilance among undergraduate medical students in a North Indian tertiary care teaching hospital. Int J Pharm Sci Res. 2017;8:2654-2659.
14. Gupta P, Udupa A. Adverse drug reaction reporting and pharmacovigilance: knowledge, attitude and perceptions among resident doctors. J Pharm Sci Res. 2011;3(2):1064-1069.
15. Rehan HS, Sah RK, Chopra D. Comparison of knowledge, attitude and practices of resident doctors and nurses on adverse drug reaction monitoring and reporting in a tertiary care hospital. Indian J Pharmacol. 2012;44(6):699-703. doi:10.4103/0253-7613.103242
16. Palaian S, Ibrahim MIM, Mishra P. Health professionals' knowledge, attitude and practices towards pharmacovigilance in Nepal. Pharm Pract (Granada). 2011;9(4):228-235.

17. Oshikoya KA, Awobusuyi JO. Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos, Nigeria. BMC Clin Pharmacol. 2009;9:14. doi:10.1186/1472-6904-9-14
18. Desai CK, Iyer G, Panchal J, Shah S, Dikshit RK. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. Perspect Clin Res. 2011;2(4):129-136. doi:10.4103/2229-3485.86883
19. Upadhyaya HB, Vora MB, Nagar JG, Patel PB. Knowledge, attitude and practices toward pharmacovigilance and adverse drug reaction reporting among health care professionals in a tertiary care hospital. Natl J Physiol Pharm Pharmacol. 2015;5(6):509-514.
20. Herdeiro MT, Figueiras A, Polónia J, Gestal-Otero JJ. Influence of pharmacists' attitudes on adverse drug reaction reporting. Drug Saf. 2006;29(4):331-340. doi:10.2165/00002018-200629040-00005
21. Lopez-Gonzalez E, Herdeiro MT, Figueiras A. Determinants of under-reporting of adverse drug reactions: a systematic review. Drug Saf. 2009;32(1):19-31. doi:10.2165/00002018-200932010-00002
22. Arici MA, Gelal A, Demiral Y, Tuncok Y. Adverse drug reactions reporting: attitudes and perceptions of medical practitioners in Turkey. Pharmacoepidemiol Drug Saf. 2005;14(7):519-523. doi:10.1002/pds.1081
23. Varallo FR, Guimarães SO, Abjaude SAR, Mastroianni PC. Causes for the underreporting of adverse drug reactions by health professionals: a systematic review. Rev Esc Enferm USP. 2014;48(4):739-747.