

Impact of Educational Intervention on Pharmacovigilance Knowledge, Attitude, and ADR Reporting among Pharmacy Students: An Interventional Study

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ABSTRACT

Aim: To assess the awareness and identify barriers related to pharmacovigilance and ADR reporting among healthcare students, and to evaluate the impact of an educational intervention. **Materials and Methods:** A prospective pre-post interventional study was conducted among 149 pharmacy students at Dr. Moopen's College of Pharmacy, Wayanad, over six months. A validated, structured questionnaire assessing knowledge, attitude, awareness, and perceived barriers was administered before and after a 30-min educational session on pharmacovigilance and ADR reporting. Data were analyzed using SPSS, with statistical significance set at $p < 0.05$ using paired t-test and Wilcoxon signed-rank test. **Results:** A total of 149 students completed the study. Baseline findings showed moderate knowledge and awareness of pharmacovigilance, with notable gaps in ADR reporting procedures. Post-intervention, there was a statistically significant improvement in knowledge scores (mean increased from 7.77 ± 1.77 to 10.01 ± 0.39 ; $p < 0.001$). Awareness of pharmacovigilance systems, including PVPI and ADR reporting processes, improved to 100%. Students' willingness to report ADRs increased from 89.3% to 98.7%. Recognition of reporting barriers also improved significantly. No significant differences were observed in baseline knowledge based on gender or course of study. **Conclusion:** The educational intervention was highly effective in enhancing pharmacovigilance knowledge, awareness, and attitudes among pharmacy students. Integrating structured pharmacovigilance training into academic curricula can reduce reporting barriers and promote active participation in ADR reporting, ultimately contributing to improved patient safety.

Keywords: Adverse Drug Reaction (ADR), Awareness, Educational Intervention, Knowledge, Pharmacovigilance, Pharmacy Students, Reporting Barriers.

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INTRODUCTION

Pharmacovigilance is a vital component of healthcare, focusing on the detection, assessment, and prevention of Adverse Drug Reactions (ADRs). Pharmacy students, as future healthcare professionals, need to be well-prepared to contribute to medication safety. Assessing educational interventions in this area helps determine how effectively students are trained to engage in pharmacovigilance activities. One important dimension of such assessments is 'knowledge'. This involves evaluating students' understanding of pharmacovigilance principles, ADR reporting systems, and regulatory frameworks. A validated questionnaire is often used to measure baseline knowledge and track improvements after targeted educational programs.

Another key aspect is 'attitude'. Students' perceptions, willingness, and motivation to participate in pharmacovigilance activities are crucial for building a culture of safety. Positive attitudes can encourage proactive ADR reporting, while negative or indifferent attitudes may hinder participation. The intervention itself refers to the educational strategies implemented, such as lectures, workshops, case studies, or simulations. These interventions aim to strengthen both knowledge and attitudes, and their effectiveness is typically assessed by comparing pre- and post-intervention responses.

Equally important is identifying reporting barriers. Pharmacy students often face obstacles such as lack of awareness of reporting systems, fear of legal consequences, time constraints, or uncertainty about what qualifies as an ADR. Recognizing these barriers allows educators to design solutions that make reporting easier and more accessible. Finally, the use of a validated questionnaire ensures that the assessment is reliable and accurate. Standardized tools allow consistent measurement across different student groups and institutions, making the findings more robust and comparable.



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The validation process of a pharmacovigilance questionnaire ensures accuracy and reliability through several steps. First, 'content validation' is done by experts to check relevance and clarity of items. Second, 'pilot testing' with a small group identifies ambiguities and practical issues. Third, 'construct validation' uses statistical methods like factor analysis to confirm that questions measure the intended domains.

Finally, 'reliability testing' (e.g., Cronbach's alpha, test-retest) ensures consistency and stability of responses across time.

AIM AND OBJECTIVES

Aim

The aim of this study is to assess the awareness and identify the barriers to pharmacovigilance and Adverse Drug Reaction (ADR) reporting among healthcare students.

Objectives

- To assess the level of awareness and knowledge about pharmacovigilance and ADR reporting among healthcare students.
- To identify the common barriers that prevent healthcare students from actively participating in ADR reporting.
- To educate and analyse pharmacovigilance and ADR reporting and its impact.

MATERIALS AND METHODS

This study employed a prospective pre-post interventional design to evaluate the impact of an educational program on pharmacovigilance knowledge, attitude, awareness, and perceived barriers to Adverse Drug Reaction (ADR) reporting among pharmacy students. The study was conducted over a period of six months at the Department of Pharmacy, Dr. Moopen's College of Pharmacy, Meppadi, Wayanad. A total of 149 undergraduate students from BPharm, PharmD, and DPharm programs were recruited using convenience sampling. Students who provided informed consent, attended the educational session, and completed the questionnaire were included, while those with prior formal training in pharmacovigilance or incomplete responses were excluded. Data were collected using a validated, structured, self-administered questionnaire consisting of sections on demographics, knowledge, attitude, awareness, and perceived barriers. The educational intervention included a 30-min structured session using PowerPoint presentations covering pharmacovigilance concepts, ADR reporting procedures, and the Pharmacovigilance Programme of India (PVPI). Baseline data were collected before the intervention, and the same questionnaire was administered immediately after the session. Data were analyzed using SPSS, and statistical significance was

determined using paired *t*-test or Wilcoxon signed-rank test with $p < 0.05$.

RESULTS AND DISCUSSION

A prospective interventional study was conducted at Dr. Moopen's College of Pharmacy to evaluate pharmacy students' knowledge, attitude, awareness, and barriers regarding pharmacovigilance. Validated questionnaires were administered before and after the educational intervention. Pre-intervention results revealed limited understanding of pharmacovigilance concepts and Adverse Drug Reaction (ADR) reporting among many students. Post-intervention assessments showed significant improvements in knowledge, awareness, and attitudes toward ADR monitoring.

Among the 149 participants, an average age of 21.70 ± 2.11 years and a median age of 22 years (IQR: 21-23), showing that most individuals were clustered within a similar age group. The sample was predominantly female, accounting for 134 participants (89.9%), while males made up only 15 (10.1%). The most participants were from the B. Pharm course (104; 69.8%), followed by PharmD (25; 16.8%) and D. Pharm (20; 13.4%).

In the current study, no significant difference was observed in the knowledge levels of male and female students before the intervention, indicating that both groups had a similar baseline understanding. This finding suggested that gender did not influence the initial level of knowledge among participants. It also implied that the observed gaps in knowledge were more likely due to insufficient exposure, education, and training rather than any gender-related factors. These results highlighted the need for structured educational interventions that could equally benefit all students regardless of gender and help improve their understanding of the subject.

The study sample mainly consisted of young participants with a narrow age range, indicating homogeneity. It was predominantly female, with males forming a small minority. Most participants were B. Pharm students, followed by PharmD and D. Pharm. Similar patterns were reported by Sharma *et al.* (2023), who noted a higher representation of young female B. Pharm students in pharmacy-related studies. Overall, the findings reflected a relatively uniform group, which might limit generalizability.

Among the 149 participants, the comparison of pre- and post-intervention results showed a significant improvement in knowledge (Table 1). Awareness of ADR was already universal among the 149 participants before the intervention and remained unchanged afterward. However, improvements were observed in other areas. Those who knew the full form of ADR increased from 131 (87.9%) to 149 (100%). Awareness of ADE increased from 132 (88.6%) to 149 (100%), and knowledge of its full form improved from 133 (89.3%) to 149 (100%). Understanding of the difference between ADE and ADR increased from 115 (77.2%) to 149 (100%), and the number of participants who could correctly

explain the difference rose from 93 (62.4%) to 149 (100%). Overall, the intervention led to a marked improvement in knowledge among the 149 participants, particularly in understanding and differentiating between ADE and ADR, while ADR awareness remained consistently high.

The current study showed that the educational program significantly enhanced the basic knowledge of students ($n = 149$) regarding Adverse Drug Reactions (ADRs) and Adverse Drug Events (ADEs). Prior to the intervention, many students had only a partial understanding, particularly in distinguishing between ADR and ADE. After the intervention, nearly all participants were able to answer correctly, indicating a clear improvement in their comprehension.

These findings were consistent with the study by Gupta *et al.* (2023), which reported limited ADR awareness and insufficient depth of knowledge among participants. In contrast to Gupta

et al. (2023), the present study demonstrated that a structured educational intervention could effectively bridge these knowledge gaps and substantially improve both awareness and understanding of ADR and ADE concepts.

The data showed a significant improvement in pharmacovigilance awareness among 149 students after the educational intervention. Before the intervention, awareness levels were moderate to low for most variables. While a high percentage of students (96.6%) already knew the full form of PVPI, knowledge about other aspects such as awareness of PVPI (67.8%), location of the NCC (61.7%), and the responsible organisation (45.0%) was comparatively lower.

After the intervention, all students (100%) answered correctly for every variable, indicating complete awareness. This indicates that the educational program was highly effective in enhancing students' understanding of pharmacovigilance concepts.

Table 1: Knowledge Questions (Correct vs Incorrect) Before and After Intervention ($n = 149$).

Variable	Before Correct n (%)	After Correct n (%)	p -value
Heard about ADR	149 (100%)	149 (100%)	—
ADR Full Form	131 (87.9%)	149 (100%)	<0.001
Heard about ADE	132 (88.6%)	149 (100%)	<0.001
ADE Full Form	133 (89.3%)	149 (100%)	<0.001
Know ADR/ADE Difference	115 (77.2%)	149 (100%)	<0.001
Correct Difference Statement	93 (62.4%)	149 (100%)	<0.001
Awareness Variables Before and After Intervention ($n = 149$)			
PVPI Full Form	144 (96.6%)	149 (100%)	<0.001
Aware of PVPI	101 (67.8%)	149 (100%)	<0.001
NCC Location	92 (61.7%)	149 (100%)	<0.001
Responsible Organisation	67 (45.0%)	149 (100%)	<0.001
ADR Reporting Knowledge Before and After Intervention ($n = 149$)			
Variable	Before Correct n (%)	After Correct n (%)	p -value
Who Can Report ADR	103 (69.1%)	143 (96.0%)	<0.001
Where to Report ADR	118 (79.2%)	149 (100%)	<0.001
ADR Form Name	92 (61.7%)	144 (96.6%)	<0.001
ADR Form Colour	65 (43.6%)	138 (92.6%)	<0.001
ADR Reporting Method	52 (34.9%)	138 (92.6%)	<0.001
ADR Reporting Timeframe	68 (45.6%)	102 (68.5%)	<0.001
Experience Variables Before and After Intervention ($n = 149$)			
Variable	Before n (%)	After n (%)	p -value
Familiar with ADR Form	76 (51.0%)	132 (88.6%)	<0.001
ADR Form Available	84 (56.4%)	148 (99.3%)	<0.001
Reporting Barrier	45 (30.2%)	106 (71.1%)	<0.001
Willingness to Report ADR	133 (89.3%)	147 (98.7%)	0.004

Table 2: Knowledge Score Comparison Before and After Intervention (n = 149).

Measure	Before	After	p-value
Mean $\pm$ SD	7.77 $\pm$ 1.77	10.01 $\pm$ 0.39	<0.001
Median (Q1-Q3)	8 (7-9)	10 (10-10)	<0.001

Paired *t*-test: $t = -15.70$; Wilcoxon signed-rank test: $p < 0.001$ Mean Difference: -2.23; 95% CI: -2.52 to -1.95.

The *p*-values for all variables are less than 0.001, which indicates that the improvement observed is statistically highly significant. The current study demonstrated a notable improvement in awareness about pharmacovigilance system, such as the Pharmacovigilance Program of India (PVPI), National Coordination Center (NCC) and responsible authorities, also improved a lot after the intervention, initially many students were not fully aware of the system, but after the educational session, awareness increased to almost all the participants. Rehan *et al.* (2012) also founded that awareness about the pharmacovigilance programs is often low among healthcare professionals. current study showed that simple awareness program can make a big difference in improving their knowledge.

The findings of this study demonstrate a significant enhancement in ADR reporting knowledge among participants following the educational intervention. Before the intervention, awareness about who can report ADRs was moderate (69.1%), but it increased markedly to 96.0% after the session, Knowledge regarding where to report ADRs also showed considerable improvement, rising from 79.2% to 100%, which means all participants became aware of the correct reporting centers. Similarly, understanding of the ADR form name increased from 61.7% to 96.6%, reflecting better familiarity with the reporting format. A notable rise was observed in identifying the ADR form colour, which improved from 43.6% before the intervention to 92.6% after. the same way, knowledge about ADR reporting methods improved substantially from 34.9% to 92.6%.

Although knowledge about the ADR reporting timeframe improved from 45.6% to 68.5%.

The current study showed significant improvement in ADR reporting knowledge among pharmacy students became more aware of who can report ADR's, where to report them and how to report them the biggest improvement was seen in understanding the reporting methods and forms however, knowledge about the corrent time frame for reporting ADR's was still slightly lower compared with other area similarly Desai *et al.*, founded that structured educational interventions significantly improved awareness and practical knowledge of ADR reporting

Among the 149 participants, familiarity with the ADR reporting form increased from 76 to 132 after the intervention, indicating improved awareness of the reporting system. Awareness of the availability of the ADR form also rose from 84 to 148, showing that more participants became informed about where and how to access it. Understanding of reporting barriers improved from

Table 3: Knowledge Level Distribution Before and After Intervention.

Before Intervention		
Level	Frequency	Percentage
Poor (0-4)	10	6.7%
Moderate (5-8)	85	57.0%
Good (9-12)	54	36.2%
After Intervention		
Level	Frequency	Percentage
Poor	0	0%
Moderate	0	0%
Good	149	100%

McNemar test: $p < 0.001$.

45 to 106 participants, reflecting a better recognition of the challenges involved in ADR reporting. In addition, willingness to report ADRs increased from 133 to 147 participants, suggesting a positive change in participants' attitude and readiness toward ADR reporting practices.

The current study also evaluated students' experience and behavior toward ADR reporting. After the intervention, a greater number of students were familiar with ADR reporting forms and were aware of their availability. Their willingness to report ADRs also improved. In addition, more students became aware of the barriers associated with ADR reporting, indicating that they had developed a more practical and realistic understanding of the reporting process.

The study identified several barriers that hindered ADR reporting among participants. The most commonly reported barriers included lack of knowledge regarding the ADR reporting process, uncertainty in identifying ADRs, lack of time, insufficient training, concerns about the accuracy of the report, and unawareness of the reporting authority or reporting forms. These findings were in line with Kumar *et al.* (2024), who reported that limited awareness, inadequate training, and lack of familiarity with reporting systems were key barriers to ADR reporting. The results of the current study supported these findings and further showed that structured educational interventions could enhance students' attitude, awareness, and confidence in ADR reporting.

Among the 149 participants, the results showed a statistically significant improvement in knowledge scores after the intervention (Table 2). The mean score increased from 7.77 $\pm$ 1.77 before the intervention to 10.01 $\pm$ 0.39 after the intervention ($p < 0.001$), indicating a substantial gain in overall knowledge. The median

score also improved from 8 (Q1-Q3: 7-9) to 10 (Q1-Q3: 10-10), suggesting that most participants achieved near-maximum scores with reduced variation after the intervention. Both the paired *t*-test ($t = -15.70, p < 0.001$) and the Wilcoxon signed-rank test ($p < 0.001$) confirmed that this improvement was statistically significant. The mean difference of -2.23, with a 95% confidence interval of -2.52 to -1.95, further indicated a consistent and meaningful increase in knowledge following the intervention. Overall, the findings demonstrated that the educational program was highly effective in improving knowledge among the 149 participants.

The current study showed a clear overall improvement in knowledge scores among the students ($n = 149$). The average score increased significantly after the intervention, with all participants achieving a “good” level of knowledge, demonstrating the effectiveness of the educational program. In comparison, Khan *et al.* (2023) reported that healthcare professionals often had only moderate knowledge in the absence of formal training. These findings highlighted the importance of continuous education and training in pharmacovigilance to strengthen knowledge and improve understanding of ADR-related concepts.

Among the 149 participants, the distribution of knowledge levels showed a marked improvement after the intervention (Table 3). Before the intervention, 10 participants (6.7%) had poor knowledge, 85 (57.0%) had moderate knowledge, and 54 (36.2%) had good knowledge. After the intervention, all participants (149, 100%) achieved a good level of knowledge, with no participants remaining in the poor or moderate categories.

The change in knowledge levels was statistically significant, as indicated by the McNemar test ($p < 0.001$). These findings demonstrated a clear shift from lower to higher knowledge categories, confirming the effectiveness of the educational intervention in improving the overall knowledge level of the participants.

The current study, participants initially showed a range of knowledge levels, from poor to good. However, after the educational intervention, all 149 participants achieved a good level of knowledge, indicating a complete improvement across the

group. This reflected not only an increase in overall knowledge but also a uniform distribution of knowledge among participants.

These findings were in line with Sharma *et al.* (2023), who reported variability in ADR awareness and knowledge among participants at baseline. In contrast, the current study demonstrated that a structured educational intervention could effectively minimize such differences and ensure consistently high knowledge levels among all participants.

The comparison of baseline knowledge scores between male and female participants showed that in female a slightly higher mean score (7.79 ± 1.78) than males (7.60 ± 1.68), the median scores will be identical in both groups [8 (7-9)] (Table 4). The *p*-value (0.701) obtained from the Mann-Whitney U test indicates that this difference is not statistically significant. This suggests that there is no meaningful association between gender and baseline knowledge levels in the study population, and both male and female participants had a similar level of knowledge prior to the intervention.

The present study showed that there was no significant difference in baseline knowledge scores between male and female participants. Indicating that gender did not influence the initial level of understanding. This finding is supported by a study by Rajiah *et al.* (2016), which also reported no significant gender-based differences in pharmacovigilance knowledge among pharmacy students.

The baseline knowledge scores among students from B. Pharm, PharmD, and DPharm courses were found to be quite similar, with only minor variations in mean and median values. The mean scores were 7.82 ± 1.75 for B. Pharm students, 7.65 ± 1.89 for PharmD students and 7.65 ± 1.62 for D. Pharm students although BPharm students showed a slightly higher mean score compared to the other groups. However, the median scores were almost identical across all courses, indicating a consistent level of knowledge distribution among the groups.

The *p*-value (0.356) obtained from ANOVA/Kruskal-Wallis test was not statistically significant, suggesting that there is no meaningful difference in baseline knowledge levels among students of different pharmacy courses before the intervention.

Table 4: Baseline Knowledge Score by Gender.

Gender	Mean $\pm$ SD	Median (Q1-Q3)	<i>p</i> -value
Male	7.60 ± 1.68	8 (7-9)	0.701
Female	7.79 ± 1.78	8 (7-9)	0.701
Baseline Knowledge Score by Course			
Course	Mean $\pm$ SD	Median (Q1-Q3)	<i>p</i> -value
BPharm	7.82 ± 1.75	8 (7-9)	0.356
PharmD	7.56 ± 1.89	8 (6-9)	
D. Pharm	7.65 ± 1.62	8 (7-9)	

The current study showed that baseline knowledge scores were comparable among BPharm, PharmD, and DPharm students, with no statistically significant difference. This suggests that students across different pharmacy courses possessed a similar level of foundational understanding of pharmacovigilance before any educational intervention. The slight variation in mean scores may be attributed to differences in curriculum exposure or clinical training; however, these differences were not strong enough to influence overall knowledge significantly. However, Palaian *et al.* (2021) reported that pharmacy students had relatively uniform baseline knowledge levels before intervention.

CONCLUSION

This study demonstrated that structured educational interventions can substantially enhance pharmacy students' competencies in Pharmacovigilance (PV). Before the program, students showed moderate to high awareness of Adverse Drug Reactions (ADRs), but gaps remained in understanding Adverse Drug Events (ADEs), differentiating ADEs from ADRs, and navigating the ADR reporting process. Following the intervention, significant improvements were observed in all areas, including comprehension of ADR and ADE definitions, the ability to distinguish between them, and awareness of national PV systems such as the Pharmacovigilance Programme of India (PVPI) and the National Coordination Centre (NCC), as well as the organizations responsible for overseeing PV activities.

The program also greatly enhanced knowledge of ADR reporting procedures. Students' understanding of who can report ADRs, where to submit reports, the ADR form name and color, reporting methods, and timelines improved considerably. Awareness of the availability of reporting forms and the barriers to reporting increased, while willingness to actively report ADRs also rose, indicating a positive shift in attitudes and readiness to engage in PV activities.

Overall, the findings highlight that integrating targeted PV education into pharmacy curricula effectively equips students with the knowledge, skills, and confidence required to promote patient safety. By addressing knowledge gaps, improving awareness, and reducing barriers, such educational initiatives foster a proactive culture of ADR reporting, which is essential for strengthening pharmacovigilance systems and supporting safer healthcare delivery.

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ABBREVIATIONS

ADR: Adverse Drug Reaction; **ADE:** Adverse Drug Event; **PVPI:** Pharmacovigilance Programme of India; **NCC:** National Coordination Centre; **PV:** Pharmacovigilance; **SPSS:** Statistical Package for the Social Sciences; **IQR:** Interquartile Range; **BPharm:** Bachelor of Pharmacy; **PharmD:** Doctor of Pharmacy; **DPharm:** Diploma in Pharmacy; **SD:** Standard Deviation; **CI:** Confidence Interval; **ANOVA:** Analysis of Variance.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ETHICAL STATEMENT

Ethical approval was not required for this questionnaire-based KAP study in accordance with institutional guidelines; nevertheless, informed consent was obtained from all participants prior to their participation in the study.

AUTHOR CONTRIBUTIONS

LJT conceptualized the study. APK, FNK, R, and RH collected the data, analyzed the data and drafted the manuscript. LMP gave permission to conduct the study. All authors reviewed and approved the final version.

SUMMARY

This study assessed the efficacy of an educational intervention on pharmacovigilance knowledge, awareness, attitudes, and perceived obstacles to Adverse Drug Reaction (ADR) reporting among pharmacy students. This study was a prospective pre-post interventional study involving 149 students at Dr. Moopen's college of pharmacy. It employed a validated questionnaire administered prior to and following a structured 30-minute educational session. The preliminary findings indicated that, despite a general awareness of adverse drug reactions, students exhibited a limited understanding of Adverse Drug Events (ADEs), the distinctions between ADRs and ADEs, and the operational mechanisms of pharmacovigilance systems and reporting protocols. Specifically, there was a lack of familiarity with critical components such as the Pharmacovigilance Programme of India (PVPI), the National Coordination Centre (NCC), the procedures for ADR reporting, and the appropriate circumstances for initiating such reports.

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