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Impact of pharmacovigilance training on knowledge, attitude, and practice among pharmacy students - A cross sectional study

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Abstract: *Background:* Underreporting of adverse drug reactions (ADRs) remains a major barrier to effective pharmacovigilance (PV) despite global and national efforts to strengthen medication-safety systems. Pharmacy students, as future healthcare professionals, require adequate training to develop the knowledge, attitude, and practice (KAP) essential for competent ADR reporting. *Objectives:* To evaluate the impact of structured pharmacovigilance training on pre- and post-intervention KAP among Bachelor of Pharmacy students. *Methods:* cross-sectional interventional Pre- and Post-test questionnaire based study was conducted among 150 pharmacy students. A validated 15-item KAP questionnaire was administered before and after a structured two hours educational intervention consisting of an interactive lecture and hands-on ADR reporting demonstration. Data were analyzed using paired t-tests, with $p < 0.05$ considered statistically significant. *Results:* Mean knowledge scores increased from 3.61 ± 0.8 to 4.37 ± 0.6 ($p < 0.001$), and practice scores improved from 11.0 ± 2.9 to 17.6 ± 2.3 ($p < 0.001$). Attitude scores showed a modest, non-significant rise from 17.8 ± 1.8 to 18.2 ± 1.6 ($p = 0.12$). Overall KAP scores increased significantly from 32.4 ± 5.2 to 40.2 ± 4.8 ($p < 0.001$). *Conclusion:* Incorporating systematic PV training into undergraduate curricula is essential to strengthen the future pharmacovigilance workforce and improve medication-safety practices.

Keywords: Pharmacovigilance, Adverse Drug Reactions, Pharmacy Students, Educational Intervention.

Introduction

The expanding global pharmaceutical market and the increasing complexity of therapeutic regimens have amplified concerns regarding the safety of medicines, particularly the burden of adverse drug reactions (ADRs), which constitute a major cause of preventable morbidity, mortality, and healthcare expenditure worldwide [1-2]. The World Health Organization defines an ADR as any harmful and unintended response to a drug administered at normal therapeutic dose [3].

Ensuring medication safety therefore depends heavily on robust pharmacovigilance (PV) systems capable of identifying, assessing, and preventing drug-related harm. The cornerstone of these systems is spontaneous ADR reporting, which enables early detection of rare or unexpected reactions that may not be evident during pre-marketing clinical trials [4].

In India, the Pharmacovigilance Programme of India (PvPI), established in 2010, plays a central role in strengthening the national drug-safety architecture. Although the program has significantly expanded ADR monitoring activities, underreporting remains a pervasive challenge [5]. Educational gaps, limited awareness, uncertainty regarding reporting procedures, and lack of confidence among healthcare professionals are consistently identified as major barriers to effective reporting [6]. Given that today's pharmacy students are future dispensers, medication counselors, and pharmacovigilance contributors, early training is imperative to cultivate competent, responsible reporters who can strengthen the national PV framework.

Current evidence highlights considerable variability in baseline knowledge, attitudes, and practices (KAP) toward

pharmacovigilance among pharmacy and other healthcare students. Previous study reported that although over two-thirds of pharmacy students were aware of core pharmacovigilance concepts and expressed positive attitudes toward ADR reporting, gaps persisted in areas such as classification of ADRs, reporting procedures, and practical reporting experience indicating a disconnect between theoretical understanding and operational readiness [7]. Structured training, targeted curriculum integration, and periodic reinforcement were therefore recommended to address these deficits.

Complementing these findings, evidence suggests that organized Pharmacovigilance sensitization sessions substantially improved students' conceptual clarity, procedural confidence, and willingness to participate in ADR reporting. Their interventional study showed significant pre- to post-training improvement across multiple domains of knowledge and attitude among medical and paramedical students was shown affirming the value of early, repeated educational interventions, particularly during formative undergraduate years [8]. These findings collectively highlight the transformative potential of well-structured pharmacovigilance training programs in bridging existing competency gaps.

Despite these encouraging results, literature specifically focusing on pharmacy students key stakeholders in medication safety remains limited [9]. Pharmacy students receive foundational training in drug mechanisms, dispensing, and patient counseling, making them ideally positioned to contribute meaningfully to pharmacovigilance systems. However, without systematic exposure to ADR reporting pathways, documentation tools, and national frameworks such as PvPI, their engagement remains suboptimal.

Evaluating the impact of organized PV training on their KAP is therefore essential to guide curriculum reforms and strengthen India's pharmacovigilance workforce pipeline. Hence, the present study aims to assess the impact of structured pharmacovigilance training on the knowledge, attitude, and practice of pharmacy students. By generating evidence on training-related improvements, this study seeks to inform academic policymakers, support competency-based curriculum development, and contribute to national efforts to improve ADR reporting and medication safety.

Material and Methods

This cross sectional (KAP) questionnaire based intervention study was conducted among Bachelor of Pharmacy students of Deccan School of Pharmacy at the Deccan College of Medical Sciences, Hyderabad, over a three-month period from September 2025 to November 2025. The objective was to assess the impact of a structured educational intervention on knowledge, attitude, and practice (KAP) regarding pharmacovigilance (PV) and adverse drug reaction (ADR) reporting.

Ethical approval for the study was obtained from the Institutional Ethics Committee prior to data collection. A total of 150 students participated voluntarily after obtaining informed consent. Participation was anonymous, and confidentiality was ensured throughout the study. The people who completed the questionnaire within the stipulated time were included in the study, whereas those with incomplete questionnaires were excluded.

The study was designed as a 30 minute pre-test and 30 minute post-test questionnaire-based survey. A validated, semi-structured questionnaire comprising both closed-ended and Likert-scale questions was used to assess three domains knowledge, attitude, and practice related to pharmacovigilance and ADR reporting.

The knowledge section contained five multiple-choice questions evaluating understanding of basic PV concepts, ADR definitions, and reporting systems. The attitude section included five statements rated on a five-point Likert scale (strongly agree to strongly disagree), assessing perceptions toward the importance of PV, reporting responsibilities, and inclusion in the academic curriculum. The practice section evaluated self-reported behaviors, confidence, and intentions to engage in ADR reporting through five practical questions.

The educational intervention included an interactive lecture sessions and a demonstration of ADR reporting procedures, followed by hands on training within institutional and national PV frameworks both for one hour. The sessions covered the objectives of pharmacovigilance, reporting mechanisms through the Indian Pharmacopoeia Commission (IPC), and the global coordination role of the World Health Organization (WHO). The post-test was administered immediately after each session using the same questionnaire to evaluate changes in KAP levels.

Responses were coded and entered into Microsoft Excel and analyzed using R Language. Descriptive statistics were used to summarize demographic data as frequencies and percentages. Knowledge, attitude, and practice scores were expressed as mean ± standard deviation (SD). Pre- and post-test comparisons were performed using paired t-tests, and a p-value of <0.05 was considered statistically significant.

Results

The majority of participants were aged between 21–25 years (68.0%), followed by those below 20 years (26.7%), with a mean age in the early twenties. Most respondents were females (88.0%). Nearly half of the participants were in the 4th year of study (46.7%), and 18.6% were interns. Prior pharmacovigilance (PV) training had been received by 40.0% of the students, while 60.0% had no previous exposure (Table 1).

Table-1: Demographic characteristics of study participants

Variable	Category	Frequency (n)	(%)
Age	< 20 years	40	26.7
	21–25 years	102	68.0
	26–30 years	8	5.3
Gender	Male	18	12.0
	Female	132	88.0
Year of study	1st year	10	6.7
	2nd year	20	13.3
	3rd year	22	14.7
	4th year	70	46.7
	Interns	28	18.6
Prior PV training	Yes	60	40.0
	No	90	60.0

Knowledge regarding pharmacovigilance showed marked improvement following the training. Awareness about the main purpose of pharmacovigilance, i.e., detecting, assessing and preventing adverse drug reactions (ADRs), increased from 97.3% to 100%. Correct identification of an ADR definition rose from 96.0% to 100%. Knowledge of the global coordinating body improved from 44.7% identifying WHO pre-test to 73.3% post-test, while recognition of the Indian Pharmacopoeia Commission as the national center increased substantially from 35.3% to 70.0%. Understanding that all healthcare professionals can report ADRs also rose from 88.0% to 93.3% (Table 2).

Table-2: Comparison of knowledge responses before and after pharmacovigilance training

Knowledge	Response	Pre-test n(%)	Post-test n(%)
What is the main purpose of Pharmacovigilance?	To detect, assess, and prevent ADRs	146 (97.3)	150 (100.0)
	To promote drug sales	2 (1.3)	0 (0.0)
	To monitor drug prices	1 (0.7)	0 (0.0)
	To conduct clinical trials	1 (0.7)	0 (0.0)
Which of the following defines an Adverse Drug Reaction (ADR)?	Harmful or unintended response to a drug at normal doses	144 (96.0)	150 (100.0)
	Overdose effect	5 (3.3)	0 (0.0)
	Drug dependence	1 (0.7)	0 (0.0)
Which organization coordinates Pharmacovigilance globally?	WHO	67 (44.7)	110 (73.3)
	FDA	10 (6.7)	4 (2.7)
	CDSCO	71 (47.3)	35 (23.3)
	EMA	2 (1.3)	1 (0.7)

Knowledge	Response	Pre-test n(%)	Post-test n(%)
National Pharmacovigilance Centre in India?	Indian Pharmacopoeia Commission (IPC)	53 (35.3)	105 (70.0)
	National Pharmacovigilance Centre (NPC)	90 (60.0)	40 (26.7)
	DCGI	5 (3.3)	3 (2.0)
	CDL	2 (1.3)	2 (1.3)
Which professionals can report an ADR?	All of the above	132 (88.0)	140 (93.3)
	Any healthcare professional	10 (6.7)	6 (4.0)
	Only pharmacists	6 (4.0)	3 (2.0)
	Only doctors	2 (1.3)	1 (0.7)

Attitudes toward pharmacovigilance were generally positive both before and after training, with further enhancement post-intervention. The belief that ADR reporting is a professional responsibility rose slightly from 73.3% to 78.0%. The perception that pharmacovigilance ensures patient safety increased from 82.7% to 91.3%. A consistently high proportion supported including pharmacovigilance in the medical curriculum (58.0% pre-test and 67.3% post-test strongly agreed). The willingness to participate in pharmacovigilance programs also showed a marginal rise from 56.0% to 59.3% (Table 3).

Table-3: Comparison of attitude responses before and after pharmacovigilance training

Attitude	Response	Pre-test n(%)	Post-test n(%)
Reporting ADRs is a professional responsibility of healthcare workers	Strongly agree	110 (73.3)	117 (78.0)
	Agree	32 (21.3)	28 (18.7)
	Neutral	1 (0.7)	0 (0.0)
	Disagree	5 (3.3)	5 (3.3)
	Strongly disagree	2 (1.3)	0 (0.0)
Pharmacovigilance helps in ensuring patient safety	Strongly agree	124 (82.7)	137 (91.3)
	Agree	25 (16.7)	13 (8.7)
	Neutral	1 (0.7)	0 (0.0)
	Disagree	0 (0.0)	0 (0.0)
	Strongly disagree	0 (0.0)	0 (0.0)
I believe ADR reporting don't add unnecessary workload	Strongly agree	76 (50.7)	73 (48.7)
	Agree	62 (41.3)	61 (40.7)
	Neutral	6 (4.0)	6 (4.0)
	Disagree	2 (1.3)	7 (4.7)
	Strongly disagree	4 (2.7)	3 (2.0)
I am willing to participate in Pharmacovigilance programs in the future	Strongly agree	84 (56.0)	89 (59.3)
	Agree	47 (31.3)	52 (34.7)
	Neutral	18 (12.0)	8 (5.3)
	Disagree	1 (0.7)	1 (0.7)
	Strongly disagree	0 (0.0)	0 (0.0)
Educational programs on Pharmacovigilance should be included in the curriculum	Strongly agree	87 (58.0)	101 (67.3)
	Agree	58 (38.7)	48 (32.0)
	Neutral	3 (2.0)	1 (0.7)
	Disagree	1 (0.7)	0 (0.0)
	Strongly disagree	1 (0.7)	0 (0.0)

Practices related to pharmacovigilance demonstrated remarkable improvement after training. Knowledge of where and how to report ADRs increased from 30.0% to 88.0%. The proportion of participants who felt "very confident" in identifying and reporting ADRs rose from 12.0% to 60.0%. Those who stated they would "always" report ADRs increased from 14.0% to 56.0%, and those willing to participate in pharmacovigilance activities rose sharply from 26.0% to 66.0%. Likewise, the frequency of discussing ADRs with peers improved from 18.0% to 54.0% post-training (Table 4).

Table-4: Comparison of practice responses before and after pharmacovigilance training

Practice	Response	Pre-test n(%)	Post-test n(%)
Do you know how and where to report an Adverse Drug Reaction (ADR) in your institution or hospital?	Yes	45 (30.0)	132 (88.0)
	No	105 (70.0)	18 (12.0)
How confident are you in identifying and reporting an ADR after this training?	Very confident	18 (12.0)	90 (60.0)
	Somewhat confident	42 (28.0)	45 (30.0)
	Neutral	48 (32.0)	10 (6.7)
	Not confident	42 (28.0)	5 (3.3)
How often do you plan to report ADRs you may encounter in the future?	Always	21 (14.0)	84 (56.0)
	Often	36 (24.0)	45 (30.0)
	Sometimes	63 (42.0)	16 (10.7)
	Rarely	21 (14.0)	4 (2.7)
	Never	9 (6.0)	1 (0.7)
How often do you intend to discuss ADRs or Pharmacovigilance with your peers or teachers after this session?	Frequently	27 (18.0)	81 (54.0)
	Occasionally	60 (40.0)	51 (34.0)
	Rarely	45 (30.0)	15 (10.0)
	Never	18 (12.0)	3 (2.0)
Would you be willing to participate in Pharmacovigilance activities or reporting programs in your institution?	Definitely yes	39 (26.0)	99 (66.0)
	Probably yes	57 (38.0)	39 (26.0)
	Not sure	33 (22.0)	8 (5.3)
	Probably no	15 (10.0)	3 (2.0)
	Definitely no	6 (4.0)	1 (0.7)

A comparison of overall KAP scores showed significant post-training improvement. The mean knowledge score increased from 3.61 ± 0.8 to 4.37 ± 0.6 ($p < 0.001$), and the mean practice score rose from 11.0 ± 2.9 to 17.6 ± 2.3 ($p < 0.001$). Although attitude scores showed a modest rise from 17.8 ± 1.8 to 18.2 ± 1.6, the change was not statistically significant ($p = 0.12$). The total KAP mean score improved significantly from 32.4 ± 5.2 to 40.2 ± 4.8 ($p < 0.001$), indicating the overall effectiveness of the educational intervention (Table 5).

Table-5: Comparison of pre- and post-test KAP domain scores among participants

Domain	Max Score	Pre-test (Mean ± SD)	Post-test (Mean ± SD)	p-value
Knowledge	5	3.61 ± 0.8	4.37 ± 0.6	<0.001
Attitude	25	17.8 ± 1.8	18.2 ± 1.6	0.12
Practice	20	11.0 ± 2.9	17.6 ± 2.3	<0.001
Total KAP	50	32.4 ± 5.2	40.2 ± 4.8	<0.001

Discussion

The present study demonstrated a significant overall improvement in knowledge, attitude, and practice (KAP) following structured pharmacovigilance training, with total KAP scores rising from 32.4 ± 5.2 to 40.2 ± 4.8 ($p < 0.001$). These findings align with the educational-intervention model described by Reddy VL et al [10], who also reported marked post-training increases in knowledge and attitude levels among South Indian pharmacy students, confirming the effectiveness of targeted instructional modules in strengthening core pharmacovigilance competencies. In the present study, knowledge about the purpose of pharmacovigilance and ADR definition reached 100% post-training, while awareness of the WHO's global coordinating role improved from 44.7% to 73.3%, and identification of the Indian Pharmacopoeia Commission as the national center rose from 35.3% to 70%.

Similar upward trends were seen in Tamilselvan et al[7], where 66.6% - 78.6% of students already exhibited good baseline knowledge, reflecting curriculum inclusion but not structured reinforcement. Priya et al [11] likewise found favorable knowledge levels among students across Tamil Nadu and Kerala, though gaps persisted regarding ADR identification. In contrast, Etminani Isfahani et al [12] observed only 30.9% awareness of the national PV center in Iran and over 60% deficit in professional knowledge, highlighting that structured training similar to the present intervention is essential to bridge such deficits. Siddiqua et al. [13] also reported variation in knowledge across academic levels, with senior students scoring higher, again supporting the benefit of curricular reinforcement.

Attitude indicators in the present study were already positive but showed further strengthening post-intervention, with agreement that pharmacovigilance ensures patient safety increasing from 82.7% to 91.3% and endorsement of PV curriculum inclusion rising from 58% to 67.3%. Comparable positive attitudes were also documented by Tamilselvan et al. [7] (79.46% positive attitudes) and Priya et al [11] who reported high support for ADR reporting as a professional obligation. Reddy KV et al [14] found nearly all students (98%) believed ADR reporting enhances patient safety, aligning closely with the present findings, although their study revealed minimal translation into practice. Siddiqua et al [13] similarly observed strong attitudes across levels, particularly regarding the necessity of ADR monitoring centers. This convergence indicates a consistently favorable attitude across regions, with training contributing to further refinement.

Practice scores in the present study showed the greatest improvement, from 11.0 ± 2.9 to 17.6 ± 2.3 ($p < 0.001$), with knowledge of reporting pathways increasing from 30% to 88% and confidence in identifying ADRs rising from 12% to 60%. Such gains contrast sharply with earlier cross-sectional studies: Etminani Isfahani et al [12] found that although 63% had encountered ADRs, only 4% had ever reported one. Tamilselvan et al [7] reported only 44.6% had reported an ADR. Priya et al [11] noted that 41.8% struggled even to determine whether an event was an ADR and Reddy KV et al [14] documented only 8% actual reporting despite strong theoretical understanding. Siddiqua et al [13] further confirmed uniformly low practical skills across training levels. These comparisons emphasize that structured hands-on training as delivered in the present study produces significantly superior improvements in practical competency compared to curriculum-based or theory-only instruction.

The predominance of female participants (88%) and representation from senior academic years in the present study are consistent with prior studies, which also demonstrated higher engagement among later-year or female cohorts. This demographic consistency strengthens the external validity and comparability of the present findings. The present study's intervention produced stronger improvements across all variables knowledge, attitude, and especially practice than most existing cross-sectional studies. While earlier studies consistently reported good knowledge and positive attitudes but poor real-world practice, the present structured training conclusively demonstrated that targeted educational interventions could close the long-

standing "knowledge-practice gap" in pharmacovigilance.

Conclusion

The present study demonstrates that a structured pharmacovigilance training program significantly enhances students' knowledge, attitude, and practice toward adverse drug reaction reporting, as reflected by the marked rise in overall KAP scores from pre- to post-intervention. The training effectively strengthened core conceptual understanding, improved recognition of national and global pharmacovigilance systems, and substantially increased students' confidence and willingness to identify and report ADRs. Although attitudinal improvement was modest, the sharp gains in knowledge and especially in practical competencies highlight the value of experiential, skill-based learning in bridging the long-standing gap between awareness and actual reporting behaviour. These findings underscore the need to integrate structured pharmacovigilance training into undergraduate health-science curricula to cultivate a more vigilant, responsible, and reporting-oriented future healthcare workforce.

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