

Improving Pharmacovigilance Knowledge among Nursing and Pharmacy Students through a Structured Educational Module

Dr. Yogalakshmi S¹, Prof. Raja M²

¹Professor, Anurag University, Hyderabad

²PhD Scholar, Apollo College of Nursing, Chennai.

Professor, Billroth College of Nursing, Chennai

Affiliated to The Tamil Nadu Dr. MGR Medical University, Chennai.

Corresponding author: Dr Yogalakshmi S

Abstract

Background: Pharmacovigilance education is essential for preparing nursing and pharmacy students to recognize, document, and report suspected adverse drug reactions (ADRs). This study evaluated the effectiveness of a structured instructional module on pharmacovigilance knowledge among undergraduate nursing and pharmacy students. **Methods:** A pre-experimental, two-group pretest–posttest design was conducted among 195 students, comprising 108 nursing and 87 pharmacy students, in Hyderabad. Participants completed a 10-item knowledge questionnaire before and after receiving the structured educational module. Descriptive statistics, chi-square tests, independent-samples *t* tests, and paired-samples *t* tests were used for analysis. **Results:** Baseline knowledge was comparable between nursing and pharmacy students, with mean scores of 5.58 ± 1.75 and 5.99 ± 1.51 , respectively ($p > 0.05$). Following the intervention, mean knowledge increased to 7.43 ± 1.55 among nursing students and 8.63 ± 1.01 among pharmacy students. The posttest difference between groups was statistically significant ($t = 6.26, p = 0.001$). Knowledge gains were 18.5% and 26.4%, respectively. **Conclusion:** The structured instructional module effectively improved pharmacovigilance knowledge in both groups, with greater posttest achievement among pharmacy students. Integrating pharmacovigilance training into undergraduate curricula may strengthen future ADR recognition and reporting practices.

Keywords: Pharmacovigilance; Adverse drug reactions; Nursing students; Pharmacy students; Educational intervention; Medication safety

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1. Introduction

Pharmacovigilance is the science and activities concerned with the detection, assessment, understanding and prevention of adverse effects and other medicine-related problems. It is an essential component of patient safety because adverse drug reactions (ADRs) may cause avoidable morbidity, hospitalisation, prolonged treatment, disability and death. Effective pharmacovigilance depends on the timely recognition, clinical assessment, documentation and reporting of suspected ADRs. However, underreporting remains a major limitation of spontaneous reporting systems, resulting in incomplete estimates of drug-related harm and delayed identification of safety signals. Spontaneous ADR reporting therefore remains an important post-marketing surveillance approach, particularly for detecting uncommon, serious or previously unrecognised reactions. A systematic review reported substantial and widespread underreporting of ADRs, highlighting the need for improved education, simplified reporting procedures and greater participation of nurses and pharmacists [1].

Nurses and pharmacists occupy important positions in pharmacovigilance. Nurses administer medicines and maintain close, continuous contact with patients, placing them in a favourable position to observe temporal changes, unexpected symptoms and treatment-related reactions. Pharmacists contribute medication expertise through prescription review, dispensing, patient counselling, identification of drug-related problems and monitoring of medicine safety. Consequently, both professional groups have responsibilities extending beyond medication administration or dispensing to include recognition, documentation and reporting of suspected ADRs. These competencies should be developed during undergraduate education, before students assume independent clinical responsibilities. Future nurses and pharmacists must therefore understand that a suspected reaction does not require definitive proof of causality before reporting [2][3].

Evidence indicates that healthcare students frequently demonstrate positive attitudes towards ADR reporting but inadequate knowledge and practical preparedness. Students may be unfamiliar

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with reporting procedures, the location of reporting forms, the role of pharmacovigilance centres, the appropriate reporting channels, regulatory systems and timelines for serious or unexpected reactions. A review of undergraduate pharmacovigilance education found that many students felt inadequately prepared, despite encountering ADRs during clinical training; most did not know where or how to report them. Similarly, comparative research among healthcare students has shown differences between professional groups, with pharmacy students generally demonstrating greater exposure to pharmacovigilance education than other students. These gaps may contribute to future underreporting and weaken the development of a patient-safety culture [4].

Educational strategies such as classroom teaching, structured modules, workshops, case-based learning, practical completion of ADR forms and e-learning have been used to improve pharmacovigilance knowledge and reporting competence. Evidence suggests that educational interventions can increase ADR reporting, with workshops showing particularly favourable effects. In an Indian study involving nursing and pharmacy students, a structured educational module significantly improved knowledge of pharmacovigilance, although attitudes were already positive at baseline. Nevertheless, evidence from Indian undergraduate settings directly comparing nursing and pharmacy students exposed to the same structured instructional module remains limited. Although both groups participate in medication safety, their curricula provide different emphases: nursing education focuses strongly on medication administration and bedside observation, whereas pharmacy education emphasises medicines, therapeutics, and drug-related problem assessment [5].

Therefore, this study aimed to evaluate the effectiveness of a structured instructional module on pharmacovigilance knowledge among nursing and pharmacy students and to compare pretest and posttest knowledge between the two groups.

Significance and Need for the Study

This study is significant because it focuses on undergraduate nursing and pharmacy students, who represent the future frontline workforce in medication safety. Providing pharmacovigilance education before graduation may help students develop the knowledge, confidence, and professional responsibility required to recognise, document and report suspected ADRs during clinical practice. Early preparation may also promote a positive reporting culture and reduce

barriers such as uncertainty about reporting procedures, lack of awareness of pharmacovigilance centres and misunderstanding of the information required in an ADR report.

Aim of the study

The aim of this study is to evaluate the effectiveness of a structured instructional module on pharmacovigilance knowledge among undergraduate nursing and pharmacy students and to compare the difference between their pretest and posttest knowledge scores.

2. Methodology

Research Approach

Research approach is the most significant part of any research. The appropriate choice of the research approach depends on the purpose of the research study which is undertaken. According to Polit and Beck [6], an evaluative research is an extremely applied form of research and involves finding out how well a programme, the practice or policy is working. Its goal is to evaluate the success of the programme. In this study, Pre Experimental approach

Research Design

A research design is the most important methodological design that a researcher works in conducting a research study.[7] In this study Pre Experimental approach : Two group pre test post test design

Independent variable:

The independent variable for this study is Education module

Dependent variable:

The dependent variable for this study will be awareness, Attitude and Barrier. The study will be conducted in college of nursing and Pharmacy college at Hyderabad

Sample size calculation

Sample size was calculated using 20% difference of knowledge score (36.66% to 56.66%) between medical and nursing students , power of the study 80% ($\beta = 20\%$) , confidence of result 95%(type 1 error $\alpha = 5\%$) and with 10% dropout rate final sample size is 104 per group.

$$\begin{aligned}n &= \frac{[P1 (100-P1) + P2 ((100 - P2)]}{(P1-P2)^2} (Z_{\alpha} + Z_{\beta})^2 \\P1 &= 36.66\% \quad P2 = 57.66 \% \\ \alpha &= 1.96(\text{allowable error } 5\%) \\ \beta &= 0.84(\text{power of the study } 80\%) \\ d &= 20\%(\text{knowledge difference }) \\ n &= \frac{[36.67 \times 63.33] + (56.67 \times 43.33)}{20^2} (1.96 + 0.84)^2 \\ &= (2322.31+2455.51)/(7.84)/400= 94 \text{ per group} \\ &\text{With 10\% dropout rate, final sample size was 104 per group}\end{aligned}$$

Ethical considerations

Content validity will be obtained from the experts in the field of Nursing, Pharmacologist, Language and Biostatistician.

The modifications and suggestions given by the experts will be incorporated in the final tool.

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Ethical approval will be obtained from the Institutional Ethics Committee, Neelima college of nursing and Pharmacy college. Anurag University. Setting permission will be obtained from the concerned authorities.

Data collection procedure

Pre Experimental group was selected: one in nursing college and other group was selected from pharmacy college. Formal permission obtained from the concerned college authority. The study was conducted over 2 months period. Pretest assessment of awareness, Attitude and Barriers will be done for both the groups. Educational module will be taught. At the end both the group will be assessed for post test

3. Results

3.1 Participant characteristics

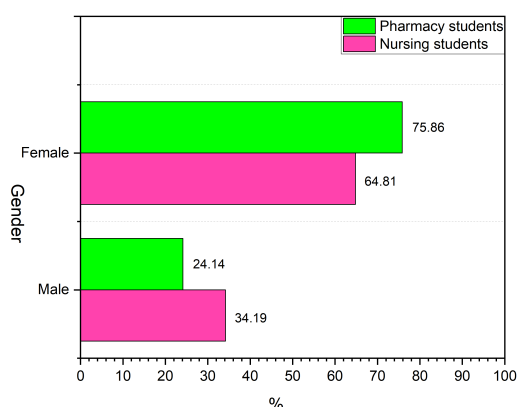


Fig. 1 Gender of participants

Table 1 Demographic characteristics of nursing and pharmacy students

		Group				Chi-square test
		Nursing students(n =108)		Pharmacy students(87)		
				n	%	
1.Gen der	Male	38	35.19 %	21	24.14 %	$\chi^2=2.79$ p=0.10 (NS)DF= 1
	Female	70	64.81 %	66	75.86 %	
2. Age group	18-19 yrs	15	13.89 %	13	14.94 %	$\chi^2=3.99$ p=0.14
	19-20 yrs	71	65.74 %	46	52.87 %	

>20 yrs	22	20.37 %	28	32.18 %	(NS)DF= 2
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$p>0.05$ not significant NS= Not significant DF= Degrees of Freedom

The table shows the distribution of demographic variables among nursing students (n=108) and pharmacy students (n=87). Regarding gender, the majority of participants in both groups were females, with 64.81% among nursing students and 75.86% among pharmacy students, while males constituted 35.19% and 24.14% respectively. The chi-square test revealed no statistically significant difference between the two groups in terms of gender ($\chi^2 = 2.79$, $p = 0.10$, DF = 1). With respect to age distribution, most nursing students (65.74%) and pharmacy students (52.87%) belonged to the 19–20 years age group. Students aged 18–19 years constituted 13.89% of nursing and 14.94% of pharmacy students, whereas those above 20 years accounted for 20.37% and 32.18% respectively. The chi-square test indicated that there was no significant difference in age distribution between the two groups ($\chi^2 = 3.99$, $p = 0.14$, DF = 2). Overall, the findings suggest that both groups were comparable in terms of demographic characteristics, as no statistically significant differences were observed.

3.2 Baseline pharmacovigilance knowledge

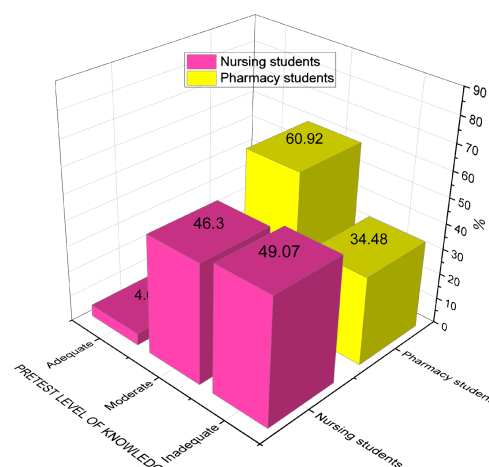


Fig. 2 Pretest level of knowledge among participants

Table 2 Distribution of pretest knowledge levels among nursing and pharmacy students

Level of score	Nursing students		Pharmacy students		Chi square test
	n	%	n	%	
Inadequate	53	49.07 %	30	34.48 %	

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Moderate	50	46.30 %	53	60.92 %	$\chi^2=4.36$ $P=0.11$ (NS)
Adequate	5	4.63%	4	4.60%	
Total	108	100.00%	87	100.00%	

***very high significance at $p<0.001$

Table no.2 shows the pre-test level of knowledge score among students. Considering pretest, among Nursing students 49.70% of them are having inadequate level of knowledge score, 46.30% of them are having moderate level of knowledge score, and 4.63% of them are having adequate level of score. Among Pharmacy students 34.48% of them are having inadequate level of knowledge score, 60.92% of them are having moderate level of knowledge score, and 4.60% of them are having adequate level of score. There is no significant difference between Nursing students and Pharmacy students level of knowledge score. It was calculated using chi-square test.

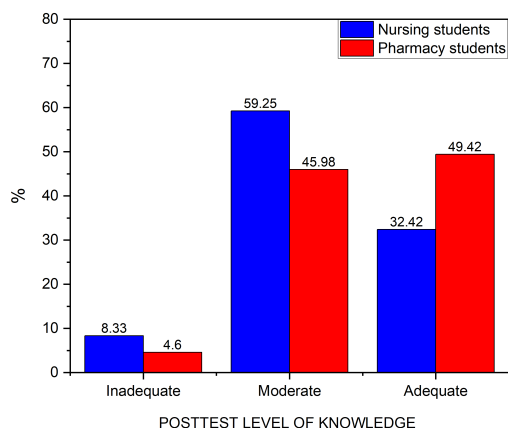


Fig. 3 Posttest level of knowledge among participants

Table 3: Comparison of posttest level of knowledge score

Level of score	Nursing students		Pharmacy students		Chi square test
	n	%	n	%	
Inadequate	9	8.33%	4	4.60%	$\chi^2=6.09$ $P=0.05$ *(S)
Moderate	64	59.25 %	40	45.98 %	
Adequate	35	32.42 %	43	49.42 %	

Total	108	100.00%	87	100.00%
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***very high significance at $p<0.001$

Table no.3 shows the post-test level of knowledge score among students

Considering pretest, among Nursing students 8.33% of them are having inadequate level of knowledge score, 59.25% of them are having moderate level of knowledge score, and 32.41% of them are having adequate level of score. Among Pharmacy students 4.60% of them are having inadequate level of knowledge score, 45.98% of them are having moderate level of knowledge score, and 49.42% of them are having adequate level of score. There is no significant difference between Nursing students and Pharmacy students level of knowledge score. It was calculated using chi-square test.

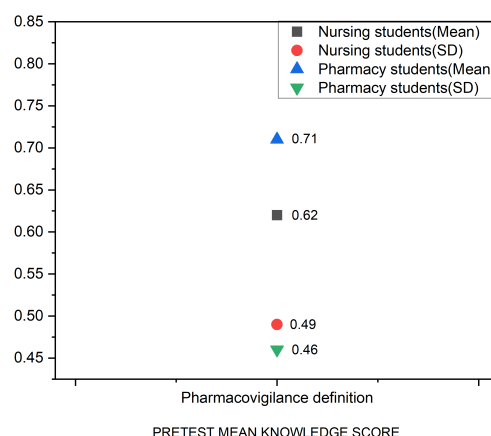


Fig. 4 Mean and standard deviation of Pharmacovigilance definition among participants

Table 4 : Each statementwise pretest mean knowledge score

	Group				Mean difference	Student independent t-test
	Nursing students		Pharmacy students			
	Mean	SD	Mean	SD		
1. Pharmacovigilance definition	.62	.49	.71	.46	0.09	t=1.35 p=0.18 (NS)

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2. In which year was The Pharmacovigilance Programme of India (PvPI) started?	.70	.46	.78	.42	0.08	t=1.22 p=0.22(NS)
3. Primary purpose of pharmacovigilance	.69	.46	.77	.42	0.08	t=1.18 p=0.24(NS)
4. How many centres in India in 2025 (approximate projection)?	.30	.46	.32	.47	0.02	t=0.38 p=0.70(NS)
5. How many centres in Hyderabad in 2025 (approximate)?	.20	.40	.22	.42	0.02	t=0.25 p=0.80(NS)
6. Who benefits from ADR reporting?	.69	.47	.66	.48	0.03	t=0.44 p=0.65(NS)
7. Components of ADR reporting form	.72	.45	.79	.41	0.07	t=1.14 p=0.25(NS)
8. Serious adverse event reporting timeline	.27	.45	.28	.45	0.01	t=0.71 p=0.48(NS)
9. In India, which regulatory body is responsible for monitoring ADRs?	.74	.44	.78	.42	0.04	t=1.23 p=0.22(NS)

10. To which international body does India send its ADR reports?	.65	.48	.68	.47	0.03	t=0.97 p=0.33(NS)
PRETEST TOTAL	5.58	1.75	5.99	1.51	0.41	t=1.71 p=0.09(NS)

The pretest comparison of knowledge scores shows that both nursing and pharmacy students had similar baseline knowledge regarding pharmacovigilance and ADR reporting. Although pharmacy students had slightly higher mean scores in most statements, the differences were not statistically significant ($p > 0.05$).

Both groups demonstrated moderate knowledge, with lower scores observed in specific areas such as the number of pharmacovigilance centers and reporting timelines. The overall pretest mean knowledge score was marginally higher among pharmacy students (5.99 ± 1.51) compared to nursing students (5.58 ± 1.75), but this difference was not statistically significant ($t = 1.71, p = 0.09$). Overall, both groups had comparable baseline knowledge before the intervention.

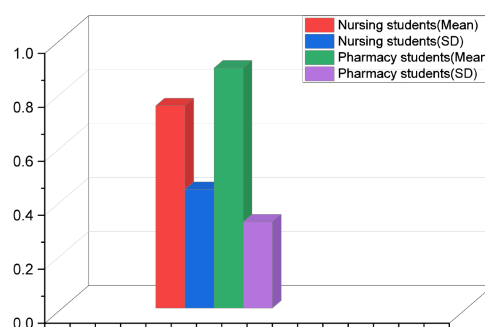


Fig. 5 Mean and standard deviation for ‘the year was The Pharmacovigilance Programme of India (PvPI) started?’

Table 5: Each statementwise posttest mean knowledge score

knowledge score						Mean differ ence	Student independ ent t-test
Group							
Nursin g student s			Pharm acy student s				
M ea n	S D		M ea n	S D			

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1. Pharmacovigilance definition	.73	.45	.90	.31	0.17	t=2.94 p=0.01* *(S)
2. In which year was The Pharmacovigilance Programme of India (PvPI) started?	.75	.44	.89	.32	0.14	t=2.41 p=0.04* (S)
3. Primary purpose of pharmacovigilance	.76	.43	.84	.37	0.08	t=1.37 p=0.24(NS)
4. How many centres in India in 2025 (approximate projection)?	.63	.49	.79	.41	0.16	t=2.51 p=0.04* (S)
5. How many centres in Hyderabad in 2025 (approximate)?	.69	.46	.85	.36	0.16	t=2.58 p=0.01* *(S)
6. Who benefits from ADR reporting?	.91	.29	.95	.21	0.04	t=1.25 p=0.65(NS)
7. Components of ADR reporting form	.79	.41	.89	.32	0.10	t=1.82 p=0.07(NS)
8. Serious adverse event reporting timeline	.63	.49	.79	.41	0.16	t=2.51 p=0.02* (S)

9. In India, which regulatory body is responsible for monitoring ADRs?	.75	.44	.89	.32	0.14	t=2.41 p=0.02* (S)
10. To which international body does India send its ADR reports?	.79	.41	.85	.36	0.06	t=1.13 p=0.25(NS)
Posttest TOTAL	7.43	1.55	8.63	1.01	1.20	t=6.26 p=0.001 *** (S)

The posttest comparison of knowledge scores shows that pharmacy students achieved higher mean scores than nursing students across most statements. Statistically significant differences were observed in several areas, including pharmacovigilance definition, year of initiation, number of centers, reporting timelines, and regulatory authority ($p < 0.05$).

However, no significant differences were found in certain aspects such as the primary purpose of pharmacovigilance, beneficiaries of ADR reporting, components of the reporting form, and international reporting body.

The overall posttest mean knowledge score was significantly higher among pharmacy students (8.63 ± 1.01) compared to nursing students (7.43 ± 1.55) ($t = 6.26$, $p = 0.001$), indicating that pharmacy students demonstrated significantly greater knowledge after the intervention.

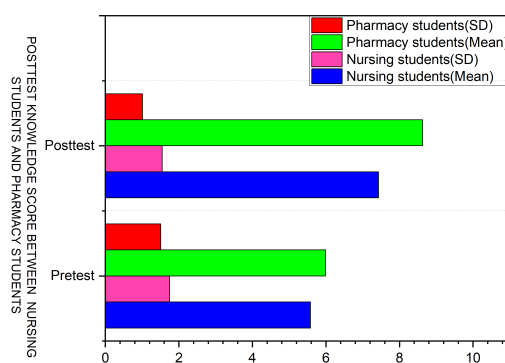


Fig. 6 Post test and pretest knowledge score

Table 6: Comparison of posttest knowledge score between nursing students and pharmacy students score

No. of patients	Nursing students		Pharmacy students		Mean Difference	Student's independent t-test
	Mean	SD	Mean	SD		
Pretest	5.58	1.75	5.99	1.91	0.41	t=1.57 P=0.12 DF=193, not significant
Posttest	7.43	1.55	8.63	1.01	1.20	t=6.26 P=0.001 *** DF=193, Significant

In pretest, Nursing students are having 5.58 knowledge score and in Pharmacy students, they are having 5.99 knowledge score, so the mean difference is 0.41 score, this difference is small and it is not statistically significant score. Statistical significance was calculated using student independent t-test. In posttest, Nursing students are having 7.43 knowledge score and in control, they are having 8.63 knowledge score, so the mean difference is 1.20 score, this difference is large and it is statistically significant score. Statistical significance was calculated using student independent t-test.

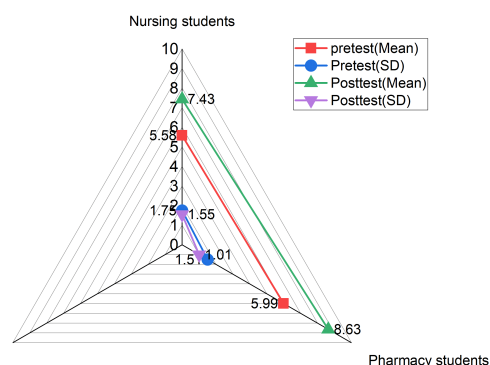


Fig. 7 Pretest and posttest mean knowledge score

Table 7: Comparison of pretest and posttest mean knowledge score

Group	Pretest		Posttest		Mean Difference	Student's paired t-test
	Mean	SD	Mean	SD		
Nursing students	5.58	1.75	7.43	1.55	1.85	t=6.91 P=0.001 *** DF=107, Significant
Pharmacy students	5.99	1.91	8.63	1.01	2.64	t=9.62 P=0.007 DF=86, not Significant

Above table compares the knowledge score between posttest1 and posttest 2. Considering Nursing students group, in pretest they are having 5.58 knowledge score and in posttest they are having 7.43 knowledge score, so the mean difference is 1.85 score, this difference is large and it is statistically significant score. Statistical significance was calculated by using student's paired 't' test.

Considering Pharmacy students group, in pretest they are having 5.99 knowledge score and in posttest they are having 8.63 knowledge score, so the mean difference is 2.64 score, this difference is large and it is statistically significant score. Statistical significance was calculated by using student's paired 't' test.

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To determine the effectiveness of Instructional Module on knowledge by comparing the pre test and post test score of knowledge between Nursing and pharmacy Students

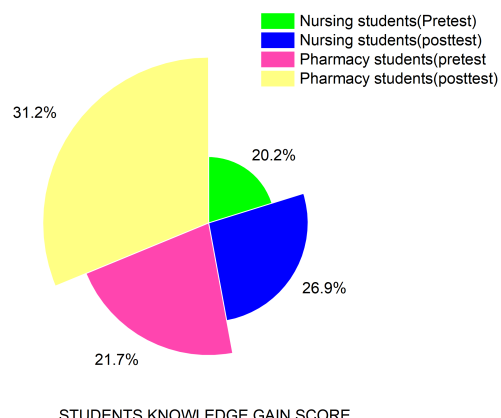


Fig. 8 Students knowledge gain score
Table 8: Effectiveness of instructional module and students knowledge gain score

		Max know ledge score	Mean know ledge score	% of know ledge score	Perce ntage of know ledge gain score
Nursi ng stude nts	Pre test	10	5.58	55.80 %	18.50 %
	Pos test	10	7.43	74.30 %	
Phar macy stude nts	Pre test	10	5.99	59.90 %	26.40 %
	Pos test	10	8.63	86.30 %	

Above table shows the effectiveness of instructional module and students knowledge gain score.

On an average, in Nursing students, in posttest after having intervention, students are gained 18.50% knowledge score. On an average, in Pharmacy students, in posttest after having intervention, students are gain 26.40% knowledge score .

4. Discussion

This study demonstrates that a structured instructional module improved pharmacovigilance knowledge among both nursing and pharmacy students. Baseline scores were comparable

between groups, indicating similar initial educational exposure. Before the intervention, 49.07% of nursing students and 34.48% of pharmacy students had inadequate knowledge, while only approximately 5% in each group demonstrated adequate knowledge. These findings are consistent with evidence that healthcare students often have positive attitudes towards pharmacovigilance but insufficient knowledge of adverse drug reaction (ADR) recognition, reporting procedures, regulatory systems and reporting timelines. The marked improvement in nursing students' mean score from 5.58 to 7.43 and pharmacy students' score from 5.99 to 8.63 suggests that focused, curriculum-based instruction can address important knowledge deficits [1][8].

Pharmacy students achieved a significantly higher post-test score than nursing students, with a mean difference of 1.20 points. This may reflect greater curricular exposure to pharmacology, therapeutics and medication-related problem assessment. Nevertheless, the improvement observed in nursing students is clinically important because nurses maintain continuous contact with patients and are well positioned to identify suspected ADRs. Similar improvement after pharmacovigilance education among nursing and pharmacy students has been reported in India.

The greatest gains involved knowledge of the Pharmacovigilance Programme of India, reporting timelines, the number of monitoring centres and the responsible regulatory authority. These findings indicate that the module successfully addressed practical and system-related gaps rather than merely reinforcing definitions. However, the pretest–posttest design, absence of a control group and short follow-up limit causal inference and assessment of long-term retention. Future studies should use validated instruments, multicentre randomized designs and follow-up measurement of actual ADR-reporting behaviour. Interactive workshops, case-based exercises, repeated reinforcement and practical completion of reporting forms may further translate knowledge into sustained reporting practice [9] [10].

Conclusion

This pretest–posttest study demonstrates that a structured instructional module significantly improved pharmacovigilance knowledge among undergraduate nursing and pharmacy students. Both groups began with comparable, predominantly inadequate-to-moderate baseline knowledge, but showed substantial gains after the

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intervention. Nursing students' mean knowledge score increased from 5.58 to 7.43 (18.5% gain), while pharmacy students improved from 5.99 to 8.63 (26.4% gain). Pharmacy students achieved significantly higher post-test scores than nursing students, likely reflecting greater curricular emphasis on pharmacology and therapeutics. These findings support the integration of dedicated pharmacovigilance education into undergraduate nursing and pharmacy curricula to strengthen future ADR recognition and reporting practices. However, the single-centre, non-randomized design and short follow-up limit generalizability and assessment of long-term retention or actual reporting behaviour. Future research should employ multicentre randomized controlled designs with validated instruments, longer follow-up, and objective measures of ADR reporting to determine whether knowledge gains translate into sustained improvements in medication safety practice.

Conflict of Interest: The authors certify that they have no involvement in any organization or entity with any financial or non-financial interest in the subject matter or materials discussed in this paper.

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