



Original Article

Effectiveness of Educational Intervention on Knowledge, Attitude, and Perception of Pharmacovigilance Process Among Interns an A Tertiary Care Teaching Hospital in Bengaluru

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ABSTRACT

Background: Adverse Drug Reactions (ADRs) have a major impact on public health, imposing economic burden on society and the health care system. Spontaneous reporting of ADRs is essential to safeguard public health and promote rational drug therapy. To overcome under-reporting of ADRs, training interns, who are future practitioners in pharmacovigilance is necessary to ensure spontaneous reporting behaviour among them.

Objective: To assess the effectiveness of educational intervention on knowledge, attitude, and practice of ADR reporting and pharmacovigilance process among Interns in a tertiary care hospital.

Methods: A prospective quasi-experimental study was conducted after obtaining approval from the Institutional Ethics Review Board, among interns using a pre-designed and validated questionnaire on knowledge, attitude, and practice of pharmacovigilance shared through a Google form. The results were statistically analyzed using SPSS v25.

Results: The study included 111 participants, 61 males and 50 females. There was a significant improvement post-intervention in the knowledge and attitude domains regarding ADR, its types, mandatory elements required for reporting ADR, who can report, what, where, and how to report ADR. However, critical practice gap persisted, and the number of participants who observed ADR and who reported remained unchanged. There were concerns about legal issues in reporting ADRs.

Conclusion: Educational interventions have a significant impact on improving healthcare professionals' pharmacovigilance knowledge and attitudes, supporting their implementation as essential components of professional development programs. While education provides the foundation, achieving optimal ADR reporting requires integrated approaches combining training with supportive policies, simplified systems, and institutional culture change.

Keywords: Interns, KAP, Pharmacovigilance, ADR.

INTRODUCTION

Adverse Drug Reactions (ADRs) are unwanted effects of drugs, which impact public health by imposing economic burden on society and the healthcare systems.[1] Monitoring of ADRs is called pharmacovigilance. Pharmacovigilance (PV) is defined by the World Health Organization as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem. [2] It is estimated that only 6%–10% of all ADRs are reported, and under-reporting of ADRs is a major problem.[3] Spontaneous reporting of ADRs is an important method for detecting new safety issues related to drugs. Lack of awareness and training of health professionals regarding the importance of pharmacovigilance and drug safety is probably the main reason for under-reporting.[4]

To improve the reporting rate, it is essential to improve the knowledge, attitude, and practices (KAPs) of health-care professionals regarding ADR reporting and PV. Training and imparting adequate knowledge and skill to medical students,

mainly during their compulsory rotatory internship program, could play a major role in the successful implementation of the PV program. [5] Hence, this study was done to assess knowledge, attitude, and practice of pharmacovigilance among Interns who belong to the clinical section and are the future practitioners in a tertiary care teaching hospital, which would help in planning interventions among this group depending on the results obtained.

Although many studies have been conducted in this regard, very few have analyzed the responses after intervention. By understanding the pre-test and post-test study design, we can assess the effectiveness of interventions and programs, making informed decisions to improve outcomes.

OBJECTIVE(S) OF THE STUDY:

1. To assess the knowledge, attitude, and practice (KAP) of Adverse Drug Reactions reporting and Pharmacovigilance process among Interns in East Point College of Medical Sciences & Research Centre.
2. To assess the effectiveness of educational intervention on knowledge, attitude, and practice of ADR reporting and the Pharmacovigilance process among Interns.

METHODOLOGY: A prospective quasi-experimental study design, which was conducted among 111 Interns of East Point College of Medical Sciences & Research Centre, Bengaluru, using a pre-designed and validated questionnaire on ADR and Pharmacovigilance [4, 6], after obtaining approval from the Institutional Ethics Review Board. The participants were trained batch-wise. Before training, the pre-test survey using Google Forms containing the questionnaires of knowledge, attitude, and perception of students regarding ADR and Pharmacovigilance was shared through QR code. They filled out the forms under the investigator's supervision in a controlled environment. No personal information was collected or stored, and access to data was authorized to the primary investigator only. Students were given 15 minutes to fill out and submit the form. Later, they were given a 60-minute Lecture by the primary investigator on ADR and Pharmacovigilance, and also training on filling the spontaneous ADR reporting form. At the end of the training, a Post-test survey was taken using the same Google form questionnaires, again giving them 15 minutes to fill and submit the completed forms. The pre- and post-test questionnaire was compared among the groups separately. Test scores were analyzed. Effectiveness of intervention was measured as a score of >90% in >95% of the study participants.

STATISTICAL ANALYSIS: Statistical analysis was done after collecting the primary data using MS Excel. Descriptive analysis was carried out by frequency and proportion for categorical variables. Statistical comparison of data between pre- and post-test was made using the Chi-square test and Fisher's exact test in SPSS v25. A value of $P < 0.05$ was considered statistically significant.

RESULTS (n=111 participants)

The study included 111 interns, 61 males and 50 females. Among them, only around 30 (27%) interns could answer that pharmacovigilance means ADR monitoring both in pre- and post-test. The majority of the interns (42%) believed that pharmacovigilance covers only drug-related ADRs, which improved post-test by 69% understanding that pharmacovigilance covers all types of ADRs. After intervention, the majority (>90%) understood the types of ADRs (97%), serious ADR (90%), mandatory elements required to report an ADR (98%), who can report (99%), and also what types of ADRs to be reported (99%). (Table 1, Graph 1)

Their attitude also improved significantly post-intervention. The majority of them understood about the Pharmacovigilance Program of India (PvPI) (95%), ADR monitoring centres (AMCs) (93%), where (96%), and how to report ADR (96%). However, the percentage of interns who observed (23%) and who reported ADRs (14%) remained the same as the pre-test response. (Table 1, Graph 2)

With respect to practice questions (both pre and post-test), mainly many felt that pharmacovigilance is important for patient safety (>95%) and that regular training on ADR reporting is necessary (>90%), also many were concerned about legal issues in reporting ADR (87%), and that majority opined that medicine safety monitoring should be a standard aspect of clinical practice (>95%). (Table 2, Graph 3)

Table 1: Questions on Knowledge & Attitude of Interns on ADR and Pharmacovigilance.

Sl no	Questions	Pre-Test n=111(%)	Post-Test n=111(%)	p Value	
1	Pharmacovigilance means	ADR monitoring	30(27)	32(29)	0.881
		Monitoring of drug plasma levels	8(7)	0	0.007*
		Inspection of the pharma company for good manufacturing practice	10(9)	0	0.001*
		All of the above	63(57)	79(71)	0.025*
2	Pharmacovigilance covers	Drug-related side effects	47(42)	34(31)	0.070
		Blood products-related side effects	2(2)	0	0.498
		Vaccine-related side effects	1(1)	0	1.000
		All	61(55)	77(69)	0.027*

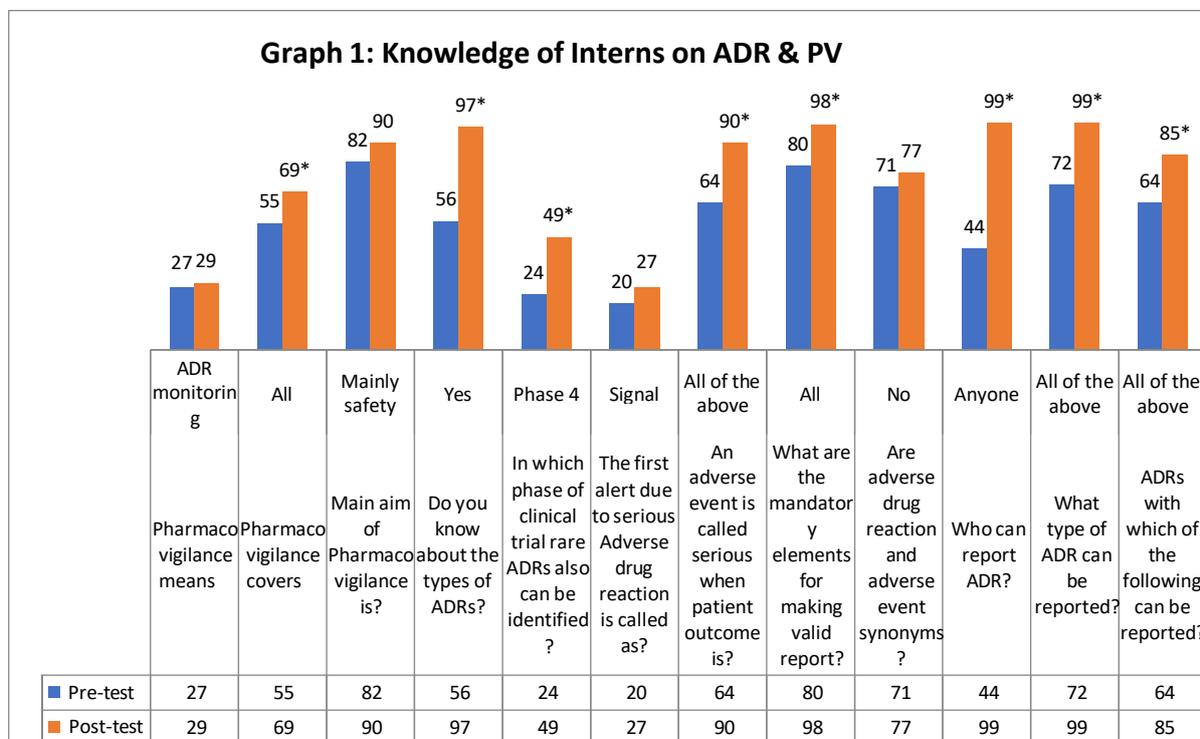
3	The main aim of Pharmacovigilance is?	Mainly safety	91(82)	100(90)	0.081
		Mainly efficacy	20(18)	11(10)	0.081
4	Do you know about the types of ADRs?	Yes	62(56)	108(97)	<0.001*
		No	49(44)	3(3)	<0.001*
5	In which phase of clinical trial can rare ADRs also be identified?	Phase 1	10(9)	10(9)	1.000
		Phase 2	33(30)	20(18)	0.041*
		Phase 3	41(37)	27(24)	0.042*
		Phase 4	27(24)	54(49)	<0.001*
6	The first alert due to a serious Adverse drug reaction is called?	Red alert	50(45)	36(32)	0.054
		Red signal	24(22)	34(31)	0.127
		Signal	22(20)	30(27)	0.205
		Notification	15(14)	11(10)	0.404
7	An adverse event is called serious when the patient's outcome is?	Disability	4(4)	0	0.122
		Life threatening	34(31)	10(9)	<0.001*
		Prolonged hospitalisation	2(2)	1(1)	1.000
		All of the above	71(64)	100(90)	<0.001*
8	What are the mandatory elements for making a valid report?	Identifiable patient and reporter	6(5)	1(1)	0.119
		Identifiable reaction	13(12)	0	<0.001*
		Identifiable drug	3(3)	1(1)	0.622
		All	89(80)	109(98)	<0.001*
9	Are adverse drug reaction and adverse event synonyms?	Yes	32(29)	25(23)	0.282
		No	79(71)	86(77)	0.282
10	Who can report ADR?	Doctors	41(37)	0	<0.001*
		Nurses	3(3)	0	0.247
		Pharmacists	15(14)	1(1)	<0.001*
		Patient	3(3)	0	0.247
		Anyone	49(44)	110(99)	<0.001*
11	What type of ADR can be reported?	Serious ADR	17(15)	0	<0.001*
		Non-serious ADR	2(2)	0	0.498
		Allergic reactions	6(5)	1(1)	0.119
		Rare ADR/unknown ADR	4(4)	0	0.122
		Common/known ADR	2(2)	0	0.498
		All of the above	80(72)	110(99)	<0.001*
12	ADRs with which of the following can be reported?	Allopathic medicine	26(23)	13(12)	0.022*
		Herbal/traditional medicine	2(2)	2(2)	1.000
		Blood products	4(4)	0	0.122
		Biological/medical devices	8(7)	2(2)	0.052
		All of the above	71(64)	94(85)	<0.001*
Attitude					
13	Have you heard about the Pharmacovigilance program of India (PvPI)?	Yes	61(55)	106(95)	<0.001*
		No	50(45)	5(5)	*
14	Are you aware of AMCs (ADR monitoring centres) in India?	Yes	50(45)	103(93)	<0.001*
		No	61(55)	8(7)	*
15	Are you aware of the process of reporting ADR?	Yes	47(42)	107(96)	<0.001*
		No	64(58)	4(4)	*
16	Are you aware of where to report suspected ADR?	Yes	45(41)	107(96)	<0.001*
		No	66(59)	4(4)	*
17	Are you aware of how to report	Yes	35(32)	107(96)	<0.001*

	suspected ADR?	No	76(68)	4(4)	*
18	Have you observed any ADR in a patient in your career?	Yes	26(23)	26(23)	1.000
		No	85(77)	85(77)	
19	Have you ever reported an ADR?	Yes	16(14)	16(14)	1.000
		No	95(86)	95(86)	
20	Do you instruct your patients regularly on ADRs while prescribing medicines?	Yes	43(39)	59(53)	0.031*
		No	41(37)	30(27)	0.113
		Sometimes	27(24)	22(20)	0.418
21	Do you expect a reply for ADR reporting?	Yes	71(64)	84(76)	0.057
		No	16(14)	16(14)	1.000
		Sometimes	24(22)	11(10)	0.017*

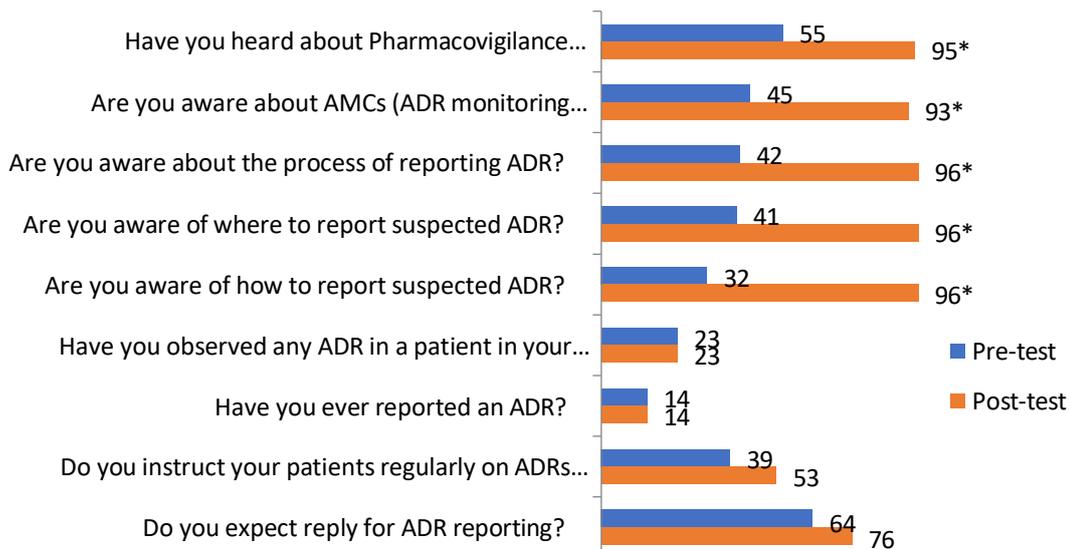
Table 2: Questions on Practice of Interns on Pharmacovigilance

Sl no	Questions		Pre-Test n=111(%)	Post-Test n=111(%)	p Value
22	Have you seen a spontaneous suspected ADR reporting form from CDSCO?	Yes	19(17)	105(95)	<0.001*
		No	92(83)	6(5)	
23	Do you think awareness/ training on ADR reporting is necessary?	Yes	102(92)	107(96)	0.153
		No	9(8)	4(4)	
24	Is Pharmacovigilance beneficial to the patient?	Yes	105(95)	111(100)	0.029*
		No	6(5)	0	
25	Are you concerned about legal issues as you think about reporting ADRs?	Yes	97(87)	97(87)	1.000
		No	14(13)	14(13)	
26	Do you think Medicine safety monitoring should be a standard aspect of clinical practice?	Yes	105(95)	109(98)	0.280
		No	6(5)	2(2)	

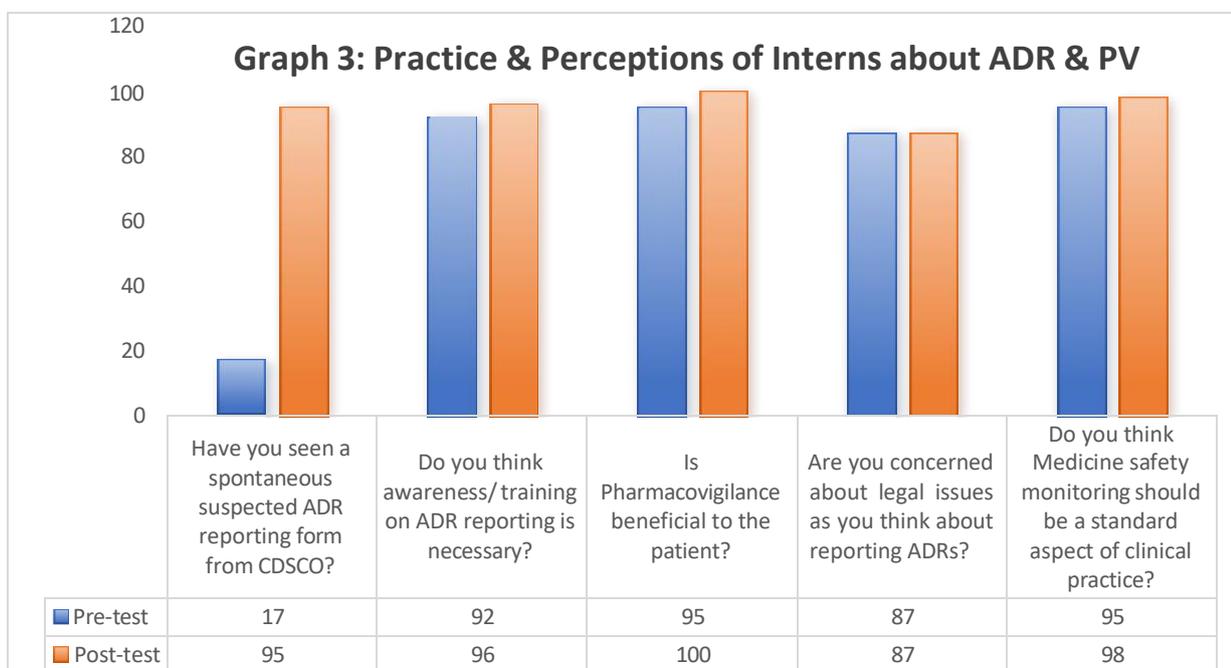
*Indicates statistically significant



Graph 2: Attitude of Interns on ADR & PV



Graph 3: Practice & Perceptions of Interns about ADR & PV



DISCUSSION

This study evaluated the effectiveness of educational intervention on pharmacovigilance knowledge, attitude, and practice among 111 healthcare interns through a pre-post intervention design. The findings demonstrate significant improvements in knowledge and attitude domains, while highlighting persistent challenges in translating these gains into practice behaviors.

Knowledge Improvements

Our baseline assessment revealed substantial knowledge gaps, with only 57% of participants correctly identifying the comprehensive scope of pharmacovigilance. Post-intervention improvements were notable across multiple domains: awareness of ADR types increased from 56% to 97%, understanding of Phase 4 trials for rare ADR identification improved from 24% to 49%, and comprehension of mandatory reporting elements increased from 80% to 98%. These findings align with similar educational interventions in South India, where knowledge, attitude, and practice of healthcare professionals improved following structured training (8).

The dramatic improvement in awareness of ADR types (41%) suggests that healthcare professionals are highly receptive to structured pharmacovigilance education. Similar patterns have been observed internationally, with studies showing significant knowledge improvements following educational interventions (9, 10). The complete elimination of specific

misconceptions, such as the belief that pharmacovigilance only involves drug plasma level monitoring, demonstrates the effectiveness of targeted educational content in correcting fundamental knowledge gaps.

Attitude Domain Transformation

The most striking improvement was observed in awareness of the Pharmacovigilance Programme of India (PvPI), increasing from 55% to 95%. Similarly, awareness of ADR Monitoring Centres improved from 45% to 93%, and knowledge of reporting processes increased from 42% to 96%. These improvements are crucial as systematic reviews indicate that 24.8%–73.33% of healthcare professionals globally are unaware of their National Pharmacovigilance Centers (11).

Patient counseling practices showed modest improvement (39% to 53%), though this remains sub-optimal and requires additional emphasis in training programs. The expectation for feedback on ADR reporting increased from 64% to 76%, indicating improved understanding of pharmacovigilance as a systematic process requiring bidirectional communication.

Practice Domain Challenges

Despite significant knowledge and attitude improvements, critical practice gaps persisted. The percentage of participants who had observed ADRs (23%) and those who had reported ADRs (14%) remained unchanged. This knowledge-practice gap reflects a global phenomenon consistently observed in pharmacovigilance literature (12, 13). A Turkish study found that while healthcare professionals developed positive attitudes toward pharmacovigilance, only 40.5% of those encountering ADRs actually reported them (14).

The persistent concern about legal issues (87%) suggests that educational interventions must specifically address professional liability concerns. Time constraints, workload pressures, and competing priorities represent systemic barriers that educational interventions alone cannot address (15).

Our findings are consistent with international studies demonstrating educational intervention effectiveness. A Jordanian study reported knowledge score improvements of 67.9% following educational workshops (16), while a Nepal-based cancer hospital study showed significant attitude improvements from 1.80 ± 0.932 to 3.61 ± 0.556 post-intervention (10). However, the universal challenge of translating improved knowledge into practice behaviors suggests that educational interventions, while necessary, are insufficient alone.

Meta-analyses indicate that educational interventions increase ADR reporting by approximately fourfold (17), yet under-reporting remains a global challenge. The most frequently cited barriers include lack of awareness regarding what, when, and how to report, time constraints, and unavailability of reporting forms (11,18).

Implications and Recommendations

Our results support implementing structured pharmacovigilance education as a fundamental component of healthcare professional development. The significant improvements across knowledge and attitude domains provide evidence for the value of targeted training initiatives. However, addressing the knowledge-practice gap requires comprehensive approaches combining education with system-level interventions.

Recommendations include: (1) integrating pharmacovigilance training into clinical curricula and continuing education programs; (2) addressing systemic barriers through simplified reporting systems and electronic health record integration; (3) implementing institutional policies supporting ADR reporting; and (4) providing regular feedback to reporters to reinforce the value of pharmacovigilance activities.

Study Limitations

The pre-post design without a control group limits causal attribution, and immediate post-testing does not assess knowledge retention. The focus on interns may limit generalizability to experienced healthcare professionals. Future research should examine long-term knowledge retention, behavior change sustainability, and the effectiveness of combined educational and system-level interventions.

CONCLUSION

Educational interventions significantly improve healthcare professionals' pharmacovigilance knowledge and attitudes, supporting their implementation as essential components of professional development programs. However, the persistent knowledge-practice gap highlights the need for comprehensive strategies addressing both educational and systemic barriers to effective pharmacovigilance practice. While education provides the foundation, achieving optimal ADR reporting requires integrated approaches combining training with supportive policies, simplified systems, and institutional culture change.

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