



Research Article

## Evaluation Of Knowledge, Attitude and Practice of Adverse Drug Reaction Reporting Among Health Care Professionals at A Tertiary Care Teaching Hospital

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### ABSTRACT

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**Background:** Adverse drug reaction (ADR) reporting is an essential component of pharmacovigilance, but under-reporting remains common among healthcare professionals. Educational interventions may improve awareness and reporting preparedness.

**Methods:** This single-group pre-post interventional questionnaire-based study was conducted among healthcare professionals at a tertiary care teaching hospital. A total of 180 participants were approached, of whom 150 completed paired pre- and post-intervention questionnaires and were included in the final analysis. Knowledge, attitude, practice/exposure, and overall KAP scores regarding ADR reporting were assessed before and after a structured educational intervention.

**Results:** The response rate was 83.3%. The participants included resident doctors 75 (50.0%), nursing staff 46 (30.7%), and faculty doctors/consultants 29 (19.3%). The mean knowledge score increased from  $8.48 \pm 1.95$  to  $13.98 \pm 1.44$ , attitude score from  $4.33 \pm 1.03$  to  $4.76 \pm 0.55$ , and practice/exposure score from  $2.11 \pm 0.72$  to  $2.95 \pm 0.23$ . The overall KAP score improved significantly from  $14.92 \pm 2.76$  to  $21.69 \pm 1.64$  after intervention ( $p < 0.001$ ). Training in ADR reporting increased from 38.0% to 100.0%, and correct identification of VigiBase improved from 42.7% to 94.7%. The most common perceived barrier changed from difficulty in deciding whether an ADR had occurred before intervention (54.0%) to lack of time after intervention (70.7%).

**Conclusion:** The educational intervention significantly improved knowledge, attitude, practice/exposure, and overall KAP scores regarding ADR reporting among healthcare professionals. Regular pharmacovigilance training may help strengthen ADR reporting culture in tertiary care hospitals.

**Keywords:** Adverse drug reaction, Pharmacovigilance, ADR reporting, Healthcare professionals, Educational intervention.

### INTRODUCTION

Adverse drug reactions (ADRs) continue to be a significant and avoidable cause of patient morbidity, hospitalisation, extended hospital stay and health care burden. Lazarou et al. published a landmark meta-analysis that found serious ADRs in 6.7% of hospitalized patients and fatal ADRs in 0.32% [1]. In a similar prospective study of 18,820 patients, Pirmohamed et al. also reported that a significant number of hospital admissions were due to ADRs [2]. These findings underscore the importance of robust pharmacovigilance systems to identify, evaluate, comprehend, and prevent drug-related harm.

Pharmacovigilance is particularly relevant once a drug has been marketed, as many rare, delayed or population-specific adverse effects may not be detected in pre-marketing clinical trials. Onakpoya et al. analysed 462 medicinal products

withdrawn from the market due to ADRs and found that post-marketing reports were frequently the basis for withdrawal, highlighting the need for timely and reliable reporting of ADRs [3]. Spontaneous reporting by health care professionals is one of the most practical ways to detect drug safety signals in real-world settings.

But one of the biggest drawbacks of spontaneous ADR reporting systems is under-reporting. Hazell and Shakir found a median under-reporting rate of 94% in 37 studies in 12 countries [4]. Lopez-Gonzalez et al. identified that under-reporting was highly associated with modifiable knowledge and attitude factors such as ignorance, lethargy, diffidence, indifference, insecurity and complacency [5]. More recently, García-Abeijon et al. validated that knowledge and attitude barriers remain as factors affecting the under-reporting of ADR by healthcare professionals [6]. These results indicate that raising awareness and confidence in ADR reporting could enhance pharmacovigilance practice.

Educational interventions have been found to be effective in enhancing pharmacovigilance knowledge and ADR reporting behaviour. In a systematic review of interventions to improve ADR reporting, Li et al. reported that educational and electronic interventions were both effective, and that multifaceted interventions were more effective than single interventions [7]. Paudyal et al. also found that face-to-face educational interventions led to an increase in the quality and quantity of ADR reporting [8]. Ganesan et al. showed that there was a significant increase in knowledge, attitude and practice after an educational intervention in an Indian tertiary care setting, and that the reporting of ADR doubled after the intervention [9]. Shrestha et al. also found that structured training of healthcare professionals led to similar improvements in pharmacovigilance knowledge and attitude [10].

Doctors and nurses are key players in the success of pharmacovigilance programs as they are often the first to suspect, identify, and document ADRs. The present study was designed as a single group pre-post interventional questionnaire-based study among resident doctors, faculty doctors/consultants and nursing staff to determine the baseline knowledge, attitude and practice/exposure towards ADR reporting and to evaluate the impact of an educational intervention on pharmacovigilance awareness. Hence, the present study was conducted to assess the knowledge, attitude and practice/exposure of healthcare professionals towards ADR reporting in a tertiary care teaching hospital and to determine the effect of an educational intervention on pharmacovigilance awareness.

## **AIM**

To evaluate knowledge, attitude, and practice/exposure regarding adverse drug reaction reporting among healthcare professionals at a tertiary care teaching hospital and to assess the effect of an educational intervention on pharmacovigilance awareness.

## **OBJECTIVES**

### **Primary objectives**

1. To assess baseline knowledge, attitude, and practice/exposure regarding pharmacovigilance and adverse drug reaction reporting among healthcare professionals.
2. To evaluate the impact of an educational intervention on knowledge, attitude, practice/exposure, and overall KAP scores related to adverse drug reaction reporting.

### **Secondary objectives**

1. To assess item-wise changes in correct or favourable responses related to pharmacovigilance and adverse drug reaction reporting after the educational intervention.
2. To identify perceived factors discouraging adverse drug reaction reporting among healthcare professionals.

## **MATERIALS AND METHODS**

### **Study design and setting**

This was a single-group pre-post interventional questionnaire-based study conducted in the Department of Medicine in collaboration with the Department of Pharmacology at Guru Gobind Singh Medical College and Hospital, Faridkot, Punjab, India. The study was conducted over a period of six months.

### **Study population**

The study population included healthcare professionals involved in patient care, including resident doctors, faculty doctors/consultants, and nursing staff working in clinical departments of the tertiary care teaching hospital.

### **Sample size and sampling technique**

A total of 180 healthcare professionals were approached and invited to participate in the study. Of these, 150 participants submitted complete paired pre- and post-intervention questionnaires and were included in the final analysis, giving a response rate of 83.3%.

The sample size was calculated using the formula:

$$n = Z^2 p (1-p) / d^2$$

where  $Z = 1.96$  at 95% confidence level,  $p = 50\%$  because the expected prevalence of adequate pharmacovigilance awareness was not known, and  $d = 7.5\%$  absolute precision. Probability proportional to size sampling was used to ensure representation of different categories of healthcare professionals.

### **Inclusion criteria**

Healthcare professionals were included if they fulfilled the following criteria:

1. Resident doctors, faculty doctors/consultants, or nursing staff working in clinical departments.
2. Involved in patient care during the study period.
3. Willing to participate in the study.
4. Submitted a complete pre-intervention KAP questionnaire.
5. Attended the educational intervention.
6. Submitted a complete post-intervention KAP questionnaire.

### **Exclusion criteria**

Participants were excluded if they fulfilled any of the following criteria:

1. Healthcare professionals not willing to participate.
2. Participants who submitted incomplete pre-intervention questionnaires.
3. Participants who did not attend the educational intervention.
4. Participants who failed to submit the post-intervention questionnaire.
5. Participants with incomplete post-intervention responses that prevented paired pre-post analysis.

### **Study tool**

Data were collected using a predesigned structured KAP questionnaire on pharmacovigilance and adverse drug reaction reporting. The questionnaire included 22 questions on knowledge, attitude, practice/exposure, and perceived barriers to ADR reporting.

The knowledge section contained 13 questions, with multiple scored sub-items, and a maximum knowledge score of 16. The attitude section contained items that measured participants' attitudes towards ADR reporting as a professional duty, the need for ADR monitoring centres, the need for ADR reporting, pharmacovigilance teaching and responsibility of healthcare professionals in ADR reporting, with a maximum attitude score of 5. The practice/exposure section contained three items pertaining to reading about ADR prevention, experiencing ADRs in clinical practice, and training in ADR reporting, with a maximum practice/exposure score of 3.

One item measured the perceived factor that most often deters ADR reporting. This item was analysed separately as a categorical variable and was not added to the total KAP score as it was a perceived barrier and not a correct or incorrect answer.

The highest possible KAP score was 24.

### **Scoring method**

Each correct answer for knowledge-based questions was awarded 1 point and each incorrect answer was awarded 0 points. The country-specific ADR reporting system matching item was scored as follows: ADR Reporting Form—India, Yellow Card—United Kingdom, Blue Card—Australia, and Green Card—Scotland.

Favourable or appropriate answers to attitude items were coded as 1, unfavourable answers as 0. For practice/exposure items, a score of 1 was given for appropriate responses that showed relevant exposure or training, and a score of 0 was given for other responses.

Unanswered or missing item-level responses, where present, were treated as incorrect for score calculation. The domain scores were obtained by adding the individual item scores. The overall KAP score was calculated by adding the knowledge, attitude, and practice/exposure scores.

### **Study procedure**

Before administering the questionnaire, participants were briefed about the purpose of the study. The participation was voluntary and the confidentiality of the responses was respected. Eligible participants completed the pre-intervention KAP questionnaire and returned it.

After baseline assessment an educational intervention was carried out to enhance the awareness of pharmacovigilance and ADR reporting. The intervention consisted of a structured interactive teaching session on the definition and importance of pharmacovigilance, classification and recognition of ADRs, seriousness and severity of ADRs, causality assessment, national and international ADR reporting systems, ADR reporting timelines, ADR reporting forms, and the role of healthcare professionals in patient safety.

The practical part of the intervention involved demonstration of the documentation and reporting of a suspected ADR using the standard ADR reporting form. All suspected ADRs, including mild, serious, known, unknown, preventable and non-preventable ADRs were encouraged to be reported.

The same participants were given the post-intervention KAP questionnaire after the educational intervention. Only those participants who had both pre and post intervention responses were included in the final analysis.

### Outcome measures

The main outcome measures were the difference in knowledge, attitude, practice/exposure and overall KAP scores following the educational intervention. Domain-wise score changes were considered the primary inferential outcomes.

Secondary outcome measures were item-wise changes in correct or favourable responses and change in the distribution of perceived factors discouraging ADR reporting. Item-wise analyses were considered exploratory.

### Statistical analysis

Data was entered in MS Excel and analysed in SPSS version 24. Categorical variables were presented as frequency and percentage, n (%). Continuous variables were presented as mean  $\pm$  standard deviation.

Since the same participants completed both pre- and post-intervention questionnaires, paired statistical tests were used. Responses were dichotomised as correct/incorrect, favourable/unfavourable, or appropriate/inappropriate and item-wise paired categorical comparisons were made using McNemar's test. The Stuart-Maxwell or marginal homogeneity test was used to compare the paired multi-category distribution of perceived factors discouraging ADR reporting.

Paired t-test was used to compare pre and post intervention domain scores. A p value  $<0.05$  was considered statistically significant.

## RESULTS

Of the 180 questionnaires distributed, 150 complete paired pre- and post-intervention questionnaires were available for final analysis, giving a response rate of 83.3%. The study population comprised 75 resident doctors (50.0%), 46 nursing staff (30.7%), and 29 faculty doctors/consultants (19.3%) (Table 1).

**Table 1. Distribution of study participants**

Participant category	n (%)
Resident doctors	75 (50.0)
Nursing staff	46 (30.7)
Faculty doctors/consultants	29 (19.3)
<b>Total</b>	<b>150 (100.0)</b>

### Knowledge regarding pharmacovigilance and ADR reporting

Baseline knowledge regarding pharmacovigilance was variable. Participants showed relatively good baseline awareness of post-marketing surveillance, regulatory agencies, and major risk factors for ADRs. However, lower baseline awareness was observed for ADR reporting timelines, regional pharmacovigilance centres, VigiBase, causality assessment, and international ADR reporting systems.

Following the educational intervention, significant improvement was observed in most knowledge items. Marked gains were seen in knowledge of the definition and purpose of pharmacovigilance, the 14-calendar-day reporting timeline for serious adverse events, ADR causality assessment, regional pharmacovigilance centres, VigiBase, and country-specific ADR reporting systems. Detailed item-wise changes are shown in Table 2.

**Table 2. Change in knowledge regarding pharmacovigilance and ADR reporting before and after educational intervention**

Knowledge item, correct response	Pre-intervention n/N (%)	Post-intervention n/N (%)	Test statistic	p value
Correct definition of pharmacovigilance	92/150 (61.3)	141/150 (94.0)	$\chi^2 = 39.361$	$<0.001$
Purpose of pharmacovigilance: drug safety	80/150 (53.3)	144/150 (96.0)	$\chi^2 = 55.351$	$<0.001$
PMS studies used to monitor ADRs after drug launch	137/150 (91.3)	149/150 (99.3)	$\chi^2 = 10.286$	0.001
Serious adverse event should be reported within 14 calendar days	24/150 (16.0)	99/150 (66.0)	$\chi^2 = 67.771$	$<0.001$
International ADR monitoring centre located in Sweden	95/150 (63.3)	141/150 (94.0)	$\chi^2 = 39.185$	$<0.001$

US FDA involved in drug safety issues in USA	136/150 (90.7)	143/150 (95.3)	$\chi^2 = 2.333$	0.127
Renal failure as a major risk factor for ADRs	120/150 (80.0)	147/150 (98.0)	$\chi^2 = 22.091$	<0.001
CDSCO responsible for ADR monitoring in India	128/150 (85.3)	150/150 (100.0)	$\chi^2 = 22.000$	<0.001
Naranjo algorithm used for causality assessment	86/150 (57.3)	130/150 (86.7)	$\chi^2 = 29.333$	<0.001
ADR reporting form correctly matched with India	95/150 (63.3)	149/150 (99.3)	$\chi^2 = 54.000$	<0.001
Yellow Card system correctly matched with United Kingdom	29/150 (19.3)	111/150 (74.0)	$\chi^2 = 73.087$	<0.001
Blue Card system correctly matched with Australia	16/150 (10.7)	99/150 (66.0)	$\chi^2 = 72.516$	<0.001
Green Card system correctly matched with Scotland	31/150 (20.7)	95/150 (63.3)	$\chi^2 = 47.628$	<0.001
Regional pharmacovigilance centre correctly identified	24/150 (16.0)	117/150 (78.0)	$\chi^2 = 82.371$	<0.001
VigiBase identified as WHO online ADR database	64/150 (42.7)	142/150 (94.7)	$\chi^2 = 72.429$	<0.001
Rare ADRs identified during phase IV clinical trials	115/150 (76.7)	140/150 (93.3)	$\chi^2 = 15.244$	<0.001

Values are presented as n/N (%). McNemar's test was used for paired item-wise comparisons after dichotomising responses as correct or incorrect.

### Attitude towards ADR reporting

Participants showed a favourable attitude towards ADR reporting at baseline, with further improvement after the educational intervention. Improvement was observed in the proportion of participants considering ADR reporting a professional obligation, supporting the establishment of ADR monitoring centres in every hospital, favouring detailed teaching of pharmacovigilance, and recognising that all healthcare professionals are responsible for ADR reporting. The proportion considering ADR reporting necessary was already high at baseline and did not change significantly after intervention. Detailed attitude-related findings are presented in Table 3.

**Table 3. Change in attitude towards ADR reporting before and after educational intervention**

Attitude item, favourable/correct response	Pre-intervention n/N (%)	Post-intervention n/N (%)	Test statistic	p value
ADR reporting is a professional obligation	117/150 (78.0)	135/150 (90.0)	$\chi^2 = 8.100$	0.004
ADR monitoring centre should be established in every hospital	120/150 (80.0)	138/150 (92.0)	$\chi^2 = 9.000$	0.003
ADR reporting is necessary	139/150 (92.7)	144/150 (96.0)	$\chi^2 = 1.471$	0.225
Pharmacovigilance should be taught in detail to healthcare professionals	142/150 (94.7)	150/150 (100.0)	$\chi^2 = 8.000$	0.005
All healthcare professionals are responsible for ADR reporting	132/150 (88.0)	147/150 (98.0)	$\chi^2 = 10.714$	0.001

Values are presented as n/N (%). McNemar's test was used for paired item-wise comparisons after dichotomising responses as favourable/correct or otherwise.

### Practice and exposure related to ADR reporting

Practice- and exposure-related responses improved after the educational intervention. Reading about ADR prevention and training in ADR reporting increased substantially after intervention. Most participants had already encountered ADRs in clinical practice at baseline, and this remained unchanged after intervention. Detailed findings are shown in Table 4.

**Table 4. Change in practice and exposure related to ADR reporting**

Practice/exposure item	Pre-intervention n/N (%)	Post-intervention n/N (%)	Test statistic	p value
Had read an article on prevention of ADRs	115/150 (76.7)	148/150 (98.7)	$\chi^2 = 29.432$	<0.001
Had ever come across an ADR	144/150 (96.0)	144/150 (96.0)	—	—
Had been trained on how to report ADRs	57/150 (38.0)	150/150 (100.0)	$\chi^2 = 93.000$	<0.001

Values are presented as n/N (%). McNemar's test was used for paired binary responses. For "had ever come across an ADR," no pre-post change was observed.

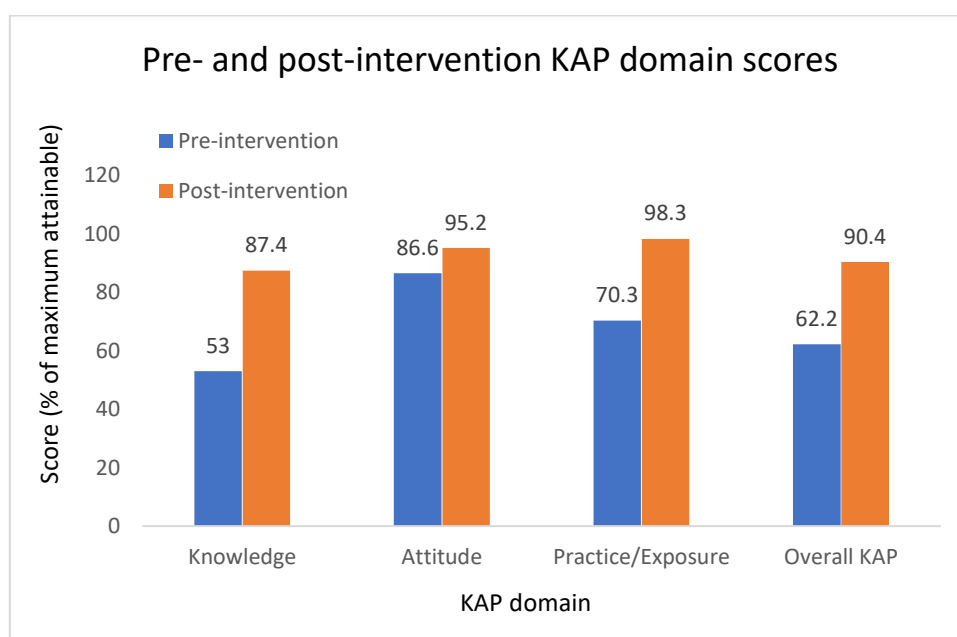
### Overall KAP score

The educational intervention resulted in significant improvement in knowledge, attitude, practice/exposure, and overall KAP scores. The largest absolute improvement was observed in the knowledge domain. The overall KAP score increased from  $14.92 \pm 2.76$  before intervention to  $21.69 \pm 1.64$  after intervention ( $p < 0.001$ ). Domain-wise score changes are summarised in Table 5 and illustrated in Figure 1.

**Table 5. Change in KAP domain scores before and after educational intervention**

Score domain	Maximum score	Pre-intervention mean $\pm$ SD	Post-intervention mean $\pm$ SD	Test statistic	p value
Knowledge score	16	$8.48 \pm 1.95$	$13.98 \pm 1.44$	$t(149) = 27.385$	$<0.001$
Attitude score	5	$4.33 \pm 1.03$	$4.76 \pm 0.55$	$t(149) = 4.415$	$<0.001$
Practice/exposure score	3	$2.11 \pm 0.72$	$2.95 \pm 0.23$	$t(149) = 14.026$	$<0.001$
Overall KAP score	24	$14.92 \pm 2.76$	$21.69 \pm 1.64$	$t(149) = 25.805$	$<0.001$

Values are presented as mean  $\pm$  SD. Paired t-test was used for pre- and post-intervention score comparisons.



**Figure 1.** Pre- and post-intervention KAP domain scores expressed as percentage of the maximum attainable score.

### Factors discouraging ADR reporting

The distribution of perceived barriers to ADR reporting changed significantly after the intervention. Before intervention, the most common barrier was difficulty in deciding whether an ADR had occurred. After intervention, lack of time to report ADRs became the predominant barrier, while difficulty in identifying ADRs and non-remuneration became less frequently reported. The distribution of perceived barriers is shown in Table 6 and Figure 2.

**Table 6. Factors discouraging ADR reporting before and after educational intervention**

Factor discouraging ADR reporting	Pre-intervention n/N (%)	Post-intervention n/N (%)
Difficulty in deciding whether an ADR had occurred	81/150 (54.0)	27/150 (18.0)
Lack of time to report ADRs	34/150 (22.7)	106/150 (70.7)
Non-remuneration for reporting	21/150 (14.0)	7/150 (4.7)
A single unreported case may not affect the ADR database	14/150 (9.3)	10/150 (6.7)
<b>Overall distributional change</b>		$\chi^2 = 54.883; p < 0.001$

Values are presented as n/N (%). Stuart-Maxwell/marginal homogeneity test was used to compare the paired multi-category barrier distribution before and after intervention.

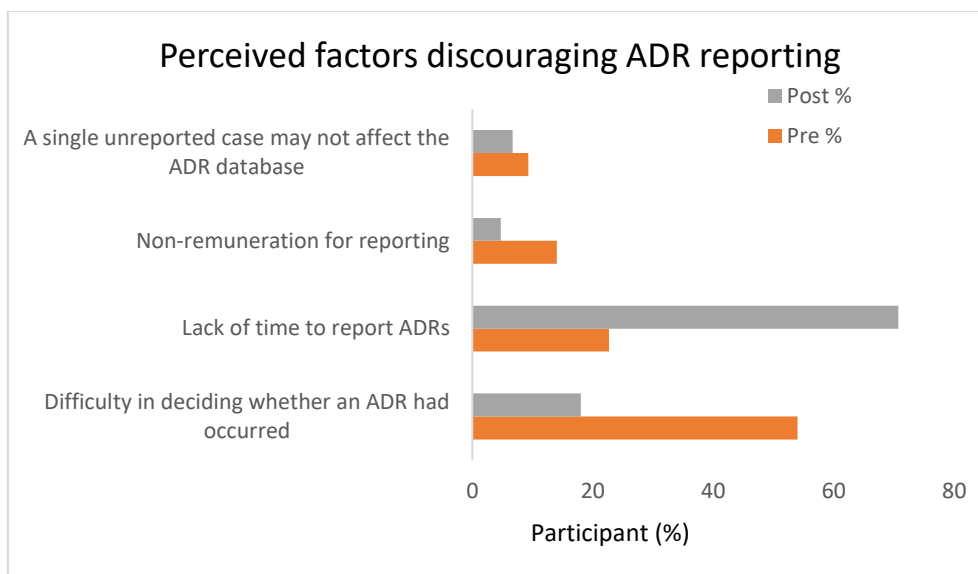


Figure 2. Perceived factors discouraging ADR reporting before and after educational intervention.

## DISCUSSION

The current study is a single group pre-post interventional study involving 150 healthcare professionals (resident doctors, nursing staff and faculty doctors/consultants) who filled paired questionnaires. The educational intervention led to significant improvement in all KAP domains. The overall KAP score increased from  $14.92 \pm 2.76$  to  $21.69 \pm 1.64$  out of 24, while the knowledge score improved from  $8.48 \pm 1.95$  to  $13.98 \pm 1.44$ , both with  $p < 0.001$ . There was also a significant increase in attitude and practice/exposure scores. The item-wise analysis showed that there was significant improvement in the awareness of timelines for reporting serious adverse events, regional pharmacovigilance centres, VigiBase, causality assessment and international ADR reporting systems. The results indicate that a structured educational intervention can have a substantial impact on improving pharmacovigilance awareness among healthcare professionals.

The attitude-practice gap found in our study is similar to the previous Indian KAP studies. Desai et al. found that while 97.3% of prescribers felt that reporting of ADR was important, only 15% had reported an ADR, suggesting that positive attitude does not necessarily lead to reporting [11]. In a similar study, Kaur et al., at Guru Gobind Singh Medical College and Hospital, Faridkot, found that the KAP of healthcare professionals was low and increased after intervention [12]. Bisht et al. also reported that doctors who attended pharmacovigilance CME had higher awareness of PvPI and the regional ADR monitoring centre, but the practice of ADR reporting was still poor [13]. These findings are similar to our baseline finding that while the majority of participants had experienced ADRs in clinical practice, only 38.0% had been trained in reporting ADRs.

The improvement seen in the current study is similar to that seen in the cluster randomized trial by Figueiras et al., which assessed 6,451 physicians in Portugal and reported a 90.19 report increase per 1000 physician-years after a one-hour educational outreach intervention. The relative risk of reporting in the intervention group was 10.23 compared to the control group, and the greatest effect was seen in the first four months after training [14]. Likewise, our study demonstrated that a targeted educational session resulted in a significant increase in pharmacovigilance knowledge and reporting readiness, especially in areas with low baseline knowledge.

Herdeiro et al. also demonstrated that the educational intervention with pharmacists was effective. The intervention group consisted of 342 pharmacists and the control group consisted of 1,091 pharmacists. After the intervention, the number of ADR reports rose by 275.63 reports per 1000 pharmacist-years, with an adjusted relative risk of 5.87. There was also a significant rise in the number of serious ADRs and new-drug-related ADRs reported [15]. While our study assessed KAP improvement and not actual reporting rate, the complete improvement in training exposure from 38.0% to 100.0% indicates that similar educational strategies may be effective in changing awareness into reporting behaviour if sustained over time.

The current findings are also similar to those of Pham et al., who conducted a comparative intervention study of 388 healthcare workers in Vietnam. After multifaceted interventions, they reported adequate knowledge increased from 73.5% to 99.2%, favourable attitude from 70.6% to 91.8%, and appropriate practice from 81.4% to 97.2%. Spontaneous ADR reports increased by 31% within three months [16]. In our study, the percentage of maximum attainable score for knowledge, attitude and practice/exposure increased from 53.0% to 87.4%, 86.6% to 95.2% and 70.3% to 98.3%, respectively. This is a similar trend to the improvement seen in mixed healthcare worker populations after structured pharmacovigilance training.

A systematic review and meta-analysis by Cervantes-Arellano et al. further supports these findings. They found that educational interventions were effective in improving the reporting of ADR by healthcare professionals with a pooled odds ratio of 4.74. Interventions using workshops were even more effective with an odds ratio of 6.26 [17]. The present study used an interactive teaching session with practical demonstration of ADR documentation and reporting, which may explain the substantial post-intervention improvement in several technical knowledge items such as reporting timelines, VigiBase, regional centres and causality assessment.

Tabali et al. have also shown that educational strategies have an impact on the quality of ADR reporting. In their primary care intervention study, the proportion of complete ADR reports increased from 80.3% to 90.7% and the agreement in causality assessment increased from  $\kappa = 0.15$  to  $\kappa = 0.43$  after training [18]. This is relevant to our study because there was an increase in the awareness of the Naranjo algorithm from 57.3% to 86.7% after the intervention. Understanding of causality assessment can help to move from suspecting to systematically documenting and reporting ADRs by healthcare professionals.

The present study also showed that attitude towards ADR reporting was already positive, with 92.7% of the respondents saying that ADR reporting was necessary and 94.7% saying that detailed teaching of pharmacovigilance was necessary. However, there were still significant gaps between knowledge and practice/exposure. This attitude-practice gap has been reported in other studies. Gidey et al. found that the attitude of health care professionals in Ethiopia was generally positive towards ADR reporting, but knowledge and practice were still low [19]. In another study, Khan et al. conducted a survey of 412 healthcare professionals, where 71.1% had positive attitude and 92.5% had poor practice, 13.1% had reported an ADR and 60.4% had never received pharmacovigilance training [20]. These findings confirm our preliminary finding that although there was high clinical exposure to ADRs, only 38.0% of participants had been trained in reporting ADRs.

The perceived barriers in our study were altered following intervention. The most common barrier before training was lack of clarity whether an ADR had occurred (54.0%). This was reduced to 18.0% after intervention, with lack of time becoming the most common barrier (70.7%). Similar barriers have been reported in previous Indian studies. Desai et al. found that lack of information on where to report, lack of knowledge on how to report, and lack of access to ADR reporting forms were major reasons for under-reporting [11]. Kaur et al. also found that lack of time, lack of confidence and lack of awareness of ADR reporting systems were important discouraging factors among healthcare professionals [12]. Bisht et al. found that lack of awareness of the reporting centre was an important barrier among doctors who were not exposed to CME, while lack of time was an important barrier in both CME and non-CME groups [13]. These observations corroborate our finding that knowledge barriers can be reduced with educational intervention, while workflow barriers may remain.

Johansson et al. found that written information letters had no significant impact on the number of ADR reports, but did have an impact on the quality of the reports, with high quality reports being more common in the intervention units than in the control units [21]. This implies that system-level supports such as simplified reporting forms, electronic access to reporting, departmental reminders, and feedback to reporters should be provided in addition to education. Desai et al. also suggested that the ADR reporting forms should be readily available, the reporting process should be simplified, feedback should be given and the base of reporters should be expanded to include nurses, pharmacists and other health care professionals [11]. These measures are especially pertinent to our study, as time was the most common post-intervention barrier.

These findings suggest that education should be complemented by system-level support, including simplified reporting forms, electronic access to reporting, departmental reminders, and feedback to reporters. Such measures are particularly relevant in the present study, where lack of time emerged as the leading post-intervention barrier.

### **Strengths and limitations**

The strengths of this study are the paired pre-post design, the representation of various categories of healthcare professionals, and the evaluation of domain-wise scores and item-wise changes. It was, however, a single centre study without a control group, and the post-intervention assessment was for short-term KAP improvement, not for long-term retention or actual ADR reporting rates.

### **CONCLUSION**

The educational intervention significantly improved knowledge, attitude, practice/exposure, and overall KAP scores regarding ADR reporting among healthcare professionals. However, lack of time emerged as the major post-intervention barrier, indicating that awareness-building alone may not be sufficient. Regular pharmacovigilance training, practical demonstration of ADR reporting, simplified reporting pathways, and system-level support may help strengthen the culture of ADR reporting in tertiary care hospitals.

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