

The Efficiency of Multi-Faceted Educational Intervention on Knowledge, Perceived Behavior, and Practice Skills towards Pharmacovigilance among Undergraduate Pharmacy Students of India

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Abstract

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BACKGROUND: The primary reason for poor adverse drug reaction (ADR) signal detection worldwide is the under-reporting of ADRs by healthcare professionals. Multidisciplinary teams, including pharmacists, may play an essential role in targeting this issue.

AIM: The purpose of the study was to evaluate the impact of a multi-faceted educational intervention (MEI) on the knowledge, perception, and practice skills of pharmacovigilance among undergraduate pharmacy students.

METHODS: A longitudinal, prospective study using a single group before-and-after intervention design was conducted among 100 undergraduate pharmacy students at Togari Veeramallappa Memorial College of Pharmacy, Ballari, India (TVMCP), affiliated to Vijayanagara Institute of Medical Sciences (VIMS), Ballari, India. The questionnaire was structured using previous studies and standardized. It had three groups of questions. Group 1 questions evaluated the knowledge (K1-K8), group 2 tested perceptions (A1-A6), and group 3 tested the practice skills of pharmacovigilance (P1-P5) of the participant. The participants were graded in 3 categories as poor, unsatisfactory, and satisfactory, depending upon the mean score. Matched pairs student t-test and The Wilcoxon Signed rank statistical test was used to assess the impact of the MEI on the participants' knowledge, perception, and practice skills score, along with recording different factors preventing them from being actively involved in the pharmacovigilance program.

RESULTS: The educational intervention improved the pharmacovigilance knowledge, perception, and practice skills scores of our pharmacy students.

CONCLUSION: Our study showed that knowledge, perception, and practice skills scores increased after MEI highlighting the need for regular educational campaigns to healthcare professions.

Introduction

Pharmacovigilance (PV) is the scientific activity related to the monitoring of adverse drug reactions (ADR), including any other drug-related problem [1]. The National Pharmacovigilance Program of India (PvPI) is the governmental authority that directs all activities of ADR detection, their assessment, understanding, and prevention, along with submission of drug safety reports to the World Health Organisation-ADR monitoring center located at Uppsala, Sweden [2]. There are around 60,000–

80,000 different drug brands obtainable in market of India which are frequently irrationally prescribed and mistreated that could be due to deficient medicine safety usages, and lack of robust governing environment [3]. The incorrect prescribing and misuse account for a substantial increase in adverse drug reactions (ADRs), which are the principal reasons for unplanned hospitalization, morbidity, fatality, and raised health-care expenses worldwide [4], [5]. Therefore, for assuring the patient's well-being, this is a call of the hour to recognize ADRs and if practicable prevent them, at a sensible cost.

Spontaneous or voluntary reporting of

suspected ADRs to pharmacovigilance centers by health-care professionals is the cornerstone of pharmacovigilance [6], which requires a multi-disciplinary strategy, wherein different health-care professionals, including medicine, pharmacy, dentistry, and nursing have to make a significant contribution. This preventable characteristic of adverse drug reactions is the motive for contemporary ADR reporting programs, which reinforce the significance of immediate identification and their treatment [7]. Anticipating, recognizing, effective management, and reporting ADRs are also an essential component of rational and unharmed prescribing, that are integrated into discrete steps of the WHO-six-step Guide to Good Prescribing [8].

Indeed, lower reporting of suspected and even confirmed ADRs by all health-care professionals is a massive obstacle in India [9]. Due to limitations of efficient healthcare support in low- and intermediate-income countries like India, due to shorter contact time interval between practitioners and patients, absence of complete data in patients' reports about safety of drugs and also need of time to notify drug-related problems, the performance of reporting the ADRs must be distributed amongst trained health-care professionals including pharmacists and nurses [10] to check underreporting [11]. Community pharmacists are thus in a unique position for monitoring, reporting of ADRs, management of symptoms associated with ADRs due to their easy accessibility for patients. Moreover, by addressing appropriate counseling of medications for the patients, they play the main role in preventing ADRs [12]. Most pharmacy students start the clinical practice soon after graduation, and therefore they dispense and monitor drugs daily. To execute these responsibilities efficiently as one of the sections of the health-care team and to ensure the safe usage of medications, they should obtain at least some standard pharmacovigilance competencies before they certify and commence clinical practice [13]. Based on these considerations, the present research was conducted to evaluate the knowledge, perceived behavior, and practice skills towards pharmacovigilance amongst undergraduate pharmacy students to highlight any existing gaps and result of multifaceted educational intervention on their knowledge, perception, and practice skills for the PV programme.

Aim of the study: Assessment of the knowledge, perceived behavior, and practice skills toward pharmacovigilance and influence of the multi-faceted educational intervention (MEI) on their knowledge, perception and practice skills for the PV programme among undergraduate pharmacy students of India.

Specific Objectives: 1) To evaluate the knowledge related to Pharmacovigilance among undergraduate pharmacy students; 2) To assess the perceived behavior towards Pharmacovigilance among undergraduate pharmacy students; 3) To

assess practice skills related to Pharmacovigilance among undergraduate pharmacy students; and 4) To determine the efficiency of multi-faceted educational intervention on pharmacy students' knowledge status, perception, and practice skills for ADR reporting requirements by comparing before and after the intervention.

Materials and Methods

Design of the study: A longitudinal, prospective study using a single group was conducted from February 2016 through May 2016 in form of before and after multi-faceted educational intervention design measuring the achievement of respondents after training session to evaluate the intervention's outcome [14].

The Study Setting: The study was carried at Togari Veeramallappa Memorial College of Pharmacy (TVMCP), Ballari affiliated to Vijayanagara Institute of Medical Sciences (VIMS), Ballari, Karnataka. The students have regular clinical postings at the hospital of VIMS. The ethical permission from Institutional Review Board of the institution was obtained before the start of the study.

Sample selection criteria

Inclusion criteria: The non-probability convenience sample of the undergraduate pharmacy students which were studying pre-final and final year of B. Pharmacy, Pharm. D (Doctor of Pharmacy) and final year D. pharm. at Togari Veeramallappa Memorial College of Pharmacy, Ballari (TVMCP) who gave their informed consent were included in our study.

Exclusion criteria: Participants who do not give their consent were not included in the study.

Sample size calculation: The sample size for the study was calculated after going through a selection of literature on various studies about pharmacovigilance and their perceptions [15]. Using G*power sample size calculator with a power of 80% and 5% α -error, a sample size of 100 subjects was required for detecting an effect size of 0.25 between pairs indicating a 25% frequency difference.

Study Tool Development

The data was collected using a validated questionnaire. Detailed review of relevant literature was done to develop the instrument according to its purpose and all constructs of interest [16], [17], [18]. The questionnaire was examined for its face and content validity by two independent faculty members

from the college of pharmacy regarding the relevance, clarity, conciseness of the items, and ease of understanding of the questions. However, a pilot study was carried out in 20 students of the first year of pharmacy students determining the reliability of the questionnaire and, if required, further simplification of the language and validation of the tool was done. It composed of four parts: Section I comprised demographic information. Section II related to eight knowledge assessment questions designed with multiple-choice options, Section III, focused on perceptive behavior, and their attitudes and section IV consisted of an evaluation of the practical skills for ADR reporting. A score of one was credited to the right answer and zero score to the wrong answer. Lastly, the causes that hinder them from active participation in the pharmacovigilance program were too recorded. The participants were graded in 3 categories as poor, unsatisfactory and satisfactory depending upon the mean score as shown in Table 1.

Table 1: Knowledge, perception, and practice skills of the pharmacovigilance score range

Parameter	Poor	Unsatisfactory	Satisfactory	Max score
Knowledge	1-2	3-4	5-8	8
Perception	1-2	3	4-6	6
Practice skills	1-2	3	4-5	5

Data collection and Multifaceted educational intervention

The study was carried from February 2016 through May 2016 among 100 undergraduate pharmacy students studying pre-final and final year of B. Pharmacy, Pharm. D (Doctor of Pharmacy), and final year D. pharm. at Togari Veeramallappa Memorial College of Pharmacy, Ballari. Pagotto C et al., first suggested the applied multi-faceted educational interventional (MEI) model. Briefly, the MEI involved four different sessions, each lasting one hour [19]. During the first session, the structured questionnaire was used to obtain baseline information about the students' knowledge, perception, and practice skills associated with pharmacovigilance and therefore called the pre-educational evaluation. It was followed by second and third sessions involving a lecture on pharmacovigilance concepts and its importance and a practical class on how to accurately fill up ADR reports and the distribution of educational material to the participating students. The post-educational assessment was carried out in the final session. The participators were requested to fill out the same questionnaire, which they finished at the time of the first session to facilitate an evaluation of the effectiveness of the interference on their knowledge, perception, and practice skills of pharmacovigilance.

Data analysis

The data was interpreted using the statistical software JMP®, Version 12, SAS Institute Inc., Cary,

NC, 1989-2019. Descriptive statistics were conducted to estimate the KAP score of the participant and between sexes. Matched pairs student-t-test and the Wilcoxon Signed rank statistical test was applied to assess the influence of the MEI on the participants' knowledge, perception, and practice skills score. The statistical significance was fixed at a p-value of 0.05 and a 95% confidence interval.

Results

Figures 1 show descriptive statistics indicating the pre and post-intervention knowledge, perception and practice skills score of pharmacovigilance among study participants where the respondents are graded in 3 categories as poor, unsatisfactory, and satisfactory depending upon the mean score.

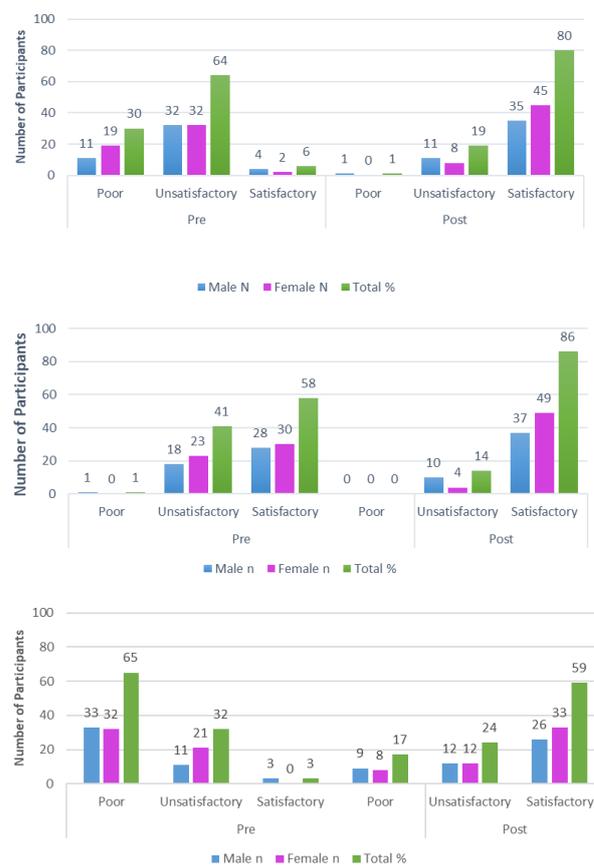


Figure 1: Comparison of pre and post-intervention knowledge score of pharmacovigilance among students (top); Comparison of pre and post-intervention perception score of pharmacovigilance among students (middle); Comparison of pre and post-intervention Practice skills score of pharmacovigilance among students (bottom)

Figure 2 and Table 2 depicts the effect of educational intervention as Matched Pairs Difference of knowledge post-intervention score-knowledge pre-intervention score that is statistically significant with a p-value of < 0.0001*, that is confirmed with Wilcoxon-

Signed Rank statistical test in Table 3.

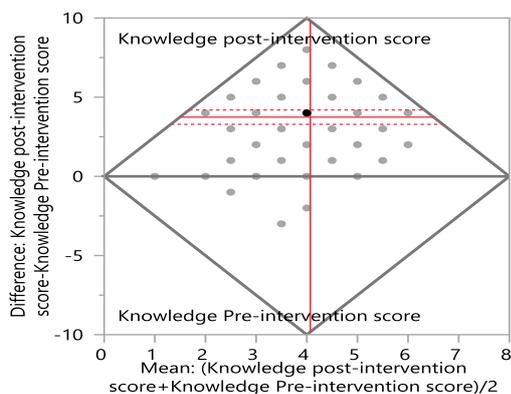


Figure 2: Matched Pairs Difference: Knowledge post-intervention score-Knowledge Pre-intervention score

Figure 3 and Table 4 depicts the impact of educational intervention as Matched Pairs Difference test of perception post-intervention score-knowledge pre-intervention score that is statistically significant with a p-value of < 0.0001*, that is confirmed with Wilcoxon-Signed Rank statistical test in Table 3.

Table 2: Matched Pairs Difference: Knowledge post-intervention score-Knowledge Pre-intervention score

Knowledge post-intervention score	5.94	t-Ratio	16.33071
Knowledge Pre-intervention score	2.2	DF	99
Mean Difference	3.74	Prob > t	< 0.0001*
Std Error	0.22902	Prob > t	< 0.0001*
Upper 95%	4.19442	Prob < t	1.0000
Lower 95%	3.28558		
N	100		

Figure 4 and Table 5 depicts the Matched Pairs Difference test of practice skills post-intervention score- practice skills pre-intervention score that is statistically significant with a p-value of < 0.0001* and confirmed with non-parametric Wilcoxon-Signed Rank statistical test in Table 3.

Table 3: Wilcoxon Signed-Rank of the parameters

	Knowledge post-score-Knowledge pre score	Perception post-score-Perception pre Score	Practice skills post score-Practice skills pre Score
Test Statistic S	2435.50	1469.00	2045.00
Prob > S	< 0.0001*	< 0.0001*	< 0.0001*
Prob < S	1.0000	1.0000	1.0000

Discussion

India contributed more than 1,00,000 Individual Case Safety Reports (ICSRs) in the Vigibase which is World Health Organisation (WHO)-Uppsala Monitoring Centre's global drug safety database. Between the period April 2011 and March 2016, the National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI) received a total of 1,81,656 reports from different

sources, like registered ADR monitoring centres (AMCs), Non-AMC and via Toll-free helpline number [20]. However, the contribution from India towards ADR reporting is below 1%, which highlights the existent gaps in the progress of the PV program. With regard to the source of reports, during period between April 2015 – March 2016, a total of 63,970 reports received nationally, the physicians (56%) were a prominent source, followed by the other health-care professionals (19%). The pharmacists comprised only 13% of reporters followed by consumers or other non-healthcare professionals (12%) [20].

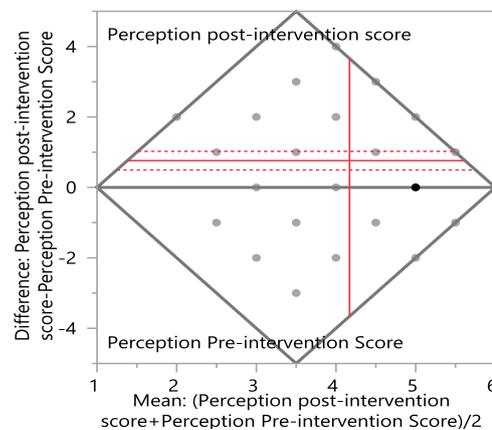


Figure 3: Matched Pairs Difference of Perception post-intervention score-Perception Pre-intervention Score

Certainly, recognizing the significance of reporting the ADRs, it is recommended that health-care professionals prioritize timely reporting of ADRs to decrease ADR related problems. A systematic review proposes that inter-professional collaborations enhance benefits to health-care assistance and improve patient outcomes [21]. Thus, in this study, we estimated the knowledge, perception, and practice skills of pharmacovigilance amongst undergraduate students of pharmacy.

Table 4: Matched Pairs Difference of Perception post-intervention score-Perception Pre-intervention Score

Perception Post-intervention score	4.55	t-Ratio	5.696118
Perception Pre-intervention Score	3.79	DF	99
Mean Difference	0.76	Prob > t	< 0.0001*
Std Error	0.13342	Prob > t	< 0.0001*
Upper 95%	1.02474	Prob < t	1.0000
Lower 95%	0.49526		
N	100		

The mean knowledge score of our study participants before the educational intervention was 2.2. About 30% and 64% of participants' knowledge towards PV was found to be poor and unsatisfactory, respectively, as shown in Figure 1. About 59% of participants were unaware of the term pharmacovigilance, and only 22% knew the definition of PV. Comparable findings were seen in previous studies, where most utmost health-care professionals reported poor knowledge regarding pharmacovigilance [22], [23], [24].

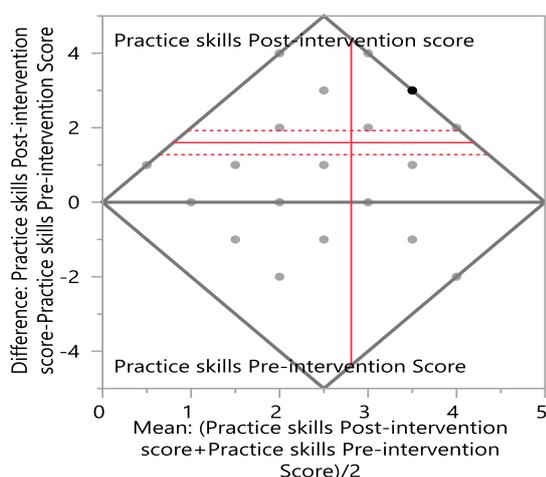


Figure 4: Matched Pairs Difference of PV Practice skills Post-intervention score-Practice skills Pre-intervention Score

Table 6 shows responses to several knowledge related questions given pre-intervention and post-intervention. Their knowledge had improved significantly after educational intervention with raise to mean knowledge score of 5.94 out of maximum 8 (< 0.001).

Table 5: Matched Pairs Difference of PV Practice skills Post-intervention score-Practice skills Pre-intervention Score

Practice skills Post-intervention score	3.61	t-Ratio	9.835285
Practice skills Pre-intervention Score	2.01	DF	99
Mean Difference	1.6	Prob > t	< .0001*
Std Error	0.16268	Prob > t	< .0001*
Upper 95%	1.92279	Prob < t	1.0000
Lower 95%	1.27721		
N	100		

The mean perception score before the educational intervention was found to be 3.79. About 58% of participants' perception score towards PV reporting was satisfactory. Therefore it showed a positive opinion towards the engagement of reporting ADRs pre-educational session, as shown in Figure 2.

Table 6: Knowledge related responses of pharmacovigilance from study participants

Question	Correct response	Pharmacy students	
		Pre-intervention %	Post-intervention %
Do you know the term "Pharmacovigilance"?	Yes	41%	95%
Pharmacovigilance is defined as	Activity of detection, assessment, understanding, and prevention of ADRs	22%	71%
The aim of pharmacovigilance is to assess	Safety over efficacy	70%	76%
Pharmacovigilance include	Drug, blood, herbal, vaccines, and medical devices related ADRs reporting	26%	70%
The Pharmacovigilance Program of India was officially launched in the year	2010	23%	69%
The international center for ADR monitoring is located in	Sweden	17%	76%
Which of the following is the "WHO online databases" for reporting ADRs?	Vigibase	14%	65%
There are how many ADR Monitoring Centres in India?	179	7%	72%

This was similar with the study of J. Jose et al which exhibited a good attitude of pharmacists for ADR reporting by good total median attitude score and by the research conducted in Saudi Arabia [25], [26].

Most of our respondents considered that reporting of ADRs is necessary (91%) and 81% were of positive impression about having ADR monitoring centre in every hospital before intervention as depicted in Table 7. The educational session resulted in additional significant improvement in health-care perception with raise to a mean perception score of 4.55 out of maximum 6. (< 0.001). A majority agreed (68%) that non-medical person is allowed to report ADR.

Table 7: Attitude related responses of pharmacovigilance from study participants

Questions	Correct Answer	Pre-intervention %	Post-intervention %
Your view about establishing an ADR monitoring center in each hospital?	Need to be in all hospitals	81%	82%
Do you believe reporting of ADRs is necessary?	Yes	91%	97%
Do you think pharmacovigilance (PV) should be explained in detail to healthcare professionals?	Yes	87%	93%
Have you come across tutorial sessions in specifically about PV?	Yes	27%	79%
Have you come across any article on prevention of ADRs?	Yes	40%	48%
The non-medical person can report ADR to nearby healthcare professional?	Yes	42%	68%

The mean practice skills score before the educational intervention was found to be 2.01, and the majority were on the poor scale. Only 13% were aware of the most common causality assessment scale, Naranjo scale, for ADRs. This finding is similar to the research of Rajiah K et al., [27] and Gamil Q. Othman et al., [28]. A large number of participants did not know how to diagnose augmented ADRs. Table 8 shows answers to various practice skills related questions given pre and post-intervention. The educational intervention produced a significant increase in their practice skills with raise to mean practice skills score to 3.61 out of maximum 5 (< 0.001).

Table 8: Practice related responses of pharmacovigilance from study participants

Question	Correct Response	Pre-intervention %	Post-intervention %
Which of the method is ordinarily implied by pharmaceutical corporations for PV of novel drugs after they are released in the market?	Post-marketing surveillance studies	54%	70%
ADR reporting can be done by	All are correct (Doctors, Nurses, Pharmacists)	24%	69%
Augmented drug reaction is	Dose-dependent, common in occurrence, rarely fatal	44%	75%
Which scale is most commonly used to determine the causality of an ADR?	Naranjo algorithm	13%	73%
Elements which are mandatory to report, and suspected medicinal products?	All (Identifiable patient, reporter, and suspected medicinal products)	66%	74%

Prior studies reported comparable findings showing that coaching health-care professionals regarding pharmacovigilance presented with a beneficial impact on their knowledge, perception, and practice scores (p -value < 0.001) [29], [30]. Another study carried out in India revealed that consultants who attended continuous medical education (CME) of PV determined better information of the ADRs reporting method than those who did not participate [31]. Accordingly, pharmacy students stressed the need for preparing them about PV, ADRs, and how to tackle the reporting process.

Before the educational session, the factors discouraging students from taking part in pharmacovigilance were asked. The more significant number of participants said that they are concerned about patient confidentiality, a lack of knowledge on the procedure of reporting, and difficulty in diagnosing ADR as depicted in Figure 5.

These determinants should be approached and efficiently answered during training programs. Furthermore, several obstacles found in the research carried amongst pharmacists of Canada and Kingdom of Saudi Arabia, that restrict from reporting ADR included untold address, reporting form unavailable, no knowledge how to communicate (41.7%) and doubt towards the causal relationship between ADR and the drug (30.1%) [25], [32].

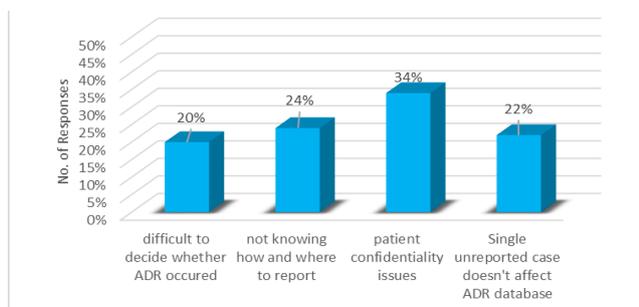


Figure 5: Factors affecting participation in PV program

Our findings contribute a reason to enhance educational campaigns and awareness of pharmacovigilance to improve ADR reporting. Pharmacovigilance should be part of the educational program for undergraduate medical, nursing, pharmacy curriculum and other health-care related to secure well-prepared graduates in future practice. They should be familiarized with the ADR reporting and the ways for determining the causality and the severity of ADRs by postings in the pharmacovigilance centres during studies.

Frequently, the pharmacist is in a unique position and plays more essential roles that include many pharmaceutical care aspects, such as evading medication errors and ADRs, promoting better Quality of Life (QoL), financial outcomes, and patient well-being. Varallo FR et al., study indicated that using MEIs with multidisciplinary teams including

pharmacists for pharmacovigilance revealed a remarkable rise exceeding 100% in the absolute number of reports of drug-induced issues, increase in the prevalence of medication error reporting and increased the relevance of ADE reports [33]. It highlighted the importance of adopting a multidisciplinary perspective of approach for the importance of pharmacovigilance in adding to patient safety. Pharmacist participation, therefore, can considerably help overcome of underreporting of ADRs [34].

Other measures would be providing incentives to promote the reports on ADRs. As 'lack of financial incentives' and lack of time are also the reasons for the lower reporting of ADRs by health-care professionals [35]. The simplification of the ADR reporting process might assist healthcare professionals in reporting ADRs. Importantly, the accomplishing of the online ADR reporting system is also recommended. NCC-PvPI have developed a superior version of the Android mobile app "ADR PvPI" on Sept 29, 2017, which is an enabler for all healthcare professionals and consumers to report ADRs instantly [36].

In conclusion, the multi-faceted educational intervention significantly improved the knowledge, perceptive behavior, and practice skills scores of pharmacovigilance of our Indian pharmacy students. Pharmacovigilance can withstand only with the regular spontaneous ADR reporting by different health-care professionals, including pharmacists, which depends on their satisfactory knowledge about PV and their compliance with reporting. Therefore, regular Continued Medical Education (CME), workshops, conferences, post-training reminders like sending e-mails, SMS alerts should be conducted to facilitate the culture of reporting and creating awareness among pharmacists.

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