

ORIGINAL RESEARCH

Impact assessment of pharmacovigilance-related educational intervention on nursing students' knowledge, attitude and practice: A pre-post study

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ABSTRACT

Objective: This study evaluated the impact of a pharmacovigilance education module for nursing students.

Methods: In this prospective, pre-post interventional study, the 2nd year diploma in Nursing students (n = 38) were the 'test' group (who received intervention), and the 1st and 3rd year students were the control group (n = 78); total n = 116. Knowledge Attitude Practice (KAP) responses were taken at baseline (0 day), 30 days, 90 days and 180 days from both the groups. Improvements in the KAP scores following the intervention was analyzed using Wilcoxon signed rank test at alpha = .05, and the feedback was obtained using a 'Likert scale' having 20 questions; maximum possible score was 100.

Results: The median (IQR) overall baseline scores of knowledge were 11 (10-12), the attitude/practice scores were 22 (20.25-22.00) and the total scores was 32.5 (31-34); the maximum possible score was 40. Almost all (n = 113; 97.4%) of them felt adverse drug reactions reporting was necessary and were interested in learning about adverse drug reactions. The baseline KAP scores were significantly higher among the second- and third-year students compared to the first year ($p < .001$). Upon intervention, a significant improvement was seen in knowledge scores between the baseline and first follow-up ($p = .018$) and between second and third follow-up ($p = .001$) in the test group. The median (IQR) feedback score was 85 (80.7-88.2).

Conclusions: Students had better attitude/practice scores, but a poor knowledge score at baseline. This study confirmed the feasibility of conducting a pharmacovigilance module for nursing students in Nepal.

Key Words: Nepal, Nursing students, Pharmacovigilance education

1. INTRODUCTION

The scope of pharmacovigilance has widened these days and is associated with the detection, assessment, understanding and prevention of drug related problems.^[1] Pharmacovigilance programs have played a major role in early detection of Adverse Drug Reactions (ADRs) and has led to the with-

drawal of several harmful drugs from the market.^[2] Ensuring safe use of medicines is a teamwork involving members from all levels of the healthcare system. Knowledge of the healthcare professionals about medicines safety is important for better patient care and safe use of medicines. The information obtained about medicines during the premarketing trials

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are incomplete and hence spontaneous reporting of ADRs by healthcare professionals is essential.^[3]

Nurses are an important member of the healthcare team who administer medications, monitor them and provide drug information to the patients at the bedside. In institutional setting nurses play an important role in pharmacovigilance. Nurses record signs and symptoms of the patients and play an increasingly important role in detection of suspected ADRs.^[4] A Swedish study highlighted that ADR reporting by nurses could improve the overall safety of medicines.^[5] Nurses can even teach the patient and the patients' attendants the signs and symptoms that should be reported immediately versus those that can be postponed until the next visit unless it is troubling.^[6]

In order to possess knowledge and competence on pharmacovigilance, nurses should be trained on the subject. There can be on the job training and participation in continuing nursing education programs. It is also important that they are taught the fundamentals of pharmacovigilance and drug safety during their diploma, undergraduate and postgraduate courses. Unfortunately, there is limited information about teaching in this area and the pharmacology that is being taught is largely limited towards studying the effects of drugs in the body with less coverage on safety issues.^[7]

The nursing practitioners of Manipal Teaching Hospital (MTH) often ask drug information queries to the Drug Information Center (DIC) attached to the regional pharmacovigilance center. A previous research assessing drug information services provided by the DIC revealed 7.1% of the queries related to drug safety were asked by the nurses of MTH.^[8] The DIC in the past has developed drug information leaflets for the nursing practitioners regarding the storage conditions of medicines, dosage administration schedule and infusion rates for antimicrobials. The present research assessed the baseline knowledge, attitude and practice (KAP) of diploma nursing (a three-year nursing course that prepares a candidate who could provide nursing care either at community or institutional level) students regarding ADRs and pharmacovigilance, and evaluated the impact of an educational intervention in terms of their KAP score improvements and sessions feedback.

2. METHODS

2.1 Study type and design

A prospective, pre-post interventional study was carried out among students and the KAP scores before and after intervention was evaluated and compared. This design was adopted to quantify the actual impact of the educational intervention on the students' KAP. The 2nd year nursing students

were recruited as the test group and the 1st and 3rd year students were recruited as the control group. These groups were selected purposively because none of them had pharmacovigilance in their course and hence all were considered neutral or naïve for the study purpose. The study was conducted for six months. Approval was taken from the Hospital Ethics Committee and Principal of the College.

2.2 Study population and sampling procedure

The study subjects included the diploma nursing students from a nursing school in western Nepal. This school was selected since they were in western Nepal and the researchers had easier access to and understanding about them. All the 1st, 2nd and 3rd year nursing students of the Manipal School of Nursing (MSON), Pokhara were enrolled. MSON runs a three-year diploma in nursing program affiliated with the Council of Technical Education and Vocational Training (CTEVT), Nepal. All students willing to participate in the training modules were included in the study. A verbal consent was taken from the students prior to inclusion. The students who were not present during the first session were excluded from the study as the baseline response was collected during the first session.

2.3 Study tools

2.3.1 Knowledge, attitude and practice questionnaire

The questionnaire had twenty questions (eight questions on knowledge: question numbered 1, 2, 3, 7, 12, 13, 14, 18 and twelve questions on attitude/practice: question numbered 4, 5, 6, 8, 9, 10, 11, 15, 16, 17, 19, and 20). Face validity was carried out by circulating the questionnaire among physicians and professors in pharmacy who have experience in pharmacovigilance. Modifications were made based on their suggestions. Then the questionnaire was pretested by administering it to eleven nursing students covering all the three years of study and a reliability measure was calculated. The final Cronbach's alpha value of the revised questionnaire was 0.61. This questionnaire was a modified version used in previous researches.^[9,10]

2.3.2 Feedback questionnaire for the nursing students

Feedback from the students on the education module was obtained using a Likert-type scale questionnaire with twenty questions. This was a standard feedback questionnaire developed by the regional pharmacovigilance center and has been used in other researches.^[11,12] The questions focused on exploring student feedback regarding the education sessions.

2.4 Modality of operation

The baseline KAP of the students was taken prior to the intervention from both the control and the test group. The

researchers developed training modules for the intervention based on their expertise gained during previous education modules on pharmacovigilance and related topics for pharmacy and medical students.^[11–13] There were a total of three training sessions over a duration of 3 months. Only the students from the test group received the intervention and no intervention was provided for the control group. However, there is a possibility that few of the students across control and test groups shared the information obtained during the training sessions. The details are mentioned below.

Session I: The main objective of this session was to introduce nursing students to terminologies used in pharmacovigilance, introduce the concept of pharmacovigilance and its status in Nepal. The facilitators for the session were pharmacists from the regional pharmacovigilance center trained in pharmacovigilance. The session was divided into three parts:

Part I: It included a brief introduction about the objectives of the training program. Participants were introduced to the term ‘clinical trials’ and ‘pharmacovigilance’. Following this, a brief overview of the pharmacovigilance program in Nepal was discussed and participants were provided with a guide “Pharmacovigilance in Nepal: a guide for healthcare professionals” that was developed by the research team and reviewed by experts;^[14] Time was given for them to go through the book during the session.

Part II: Students were divided into six groups. Each group was asked to write a one-page article (about 500 words) about the ‘pharmacovigilance program in Nepal’ on a blank paper and the paper was collected.

Part III: Distribution of educational materials: The students were provided with copies of the booklet ‘Pharmacovigilance in Nepal: a guide for healthcare professionals’ published by the regional pharmacovigilance center and other articles and materials related to drug safety.

Session II: During this session, the nursing students were introduced to the ADR reporting form and its components. The session proceeded as detailed below:

Part I: Facilitators briefed the students regarding how they can report ADR to the pharmacovigilance center. They also mentioned the components of the ADR reporting form.

Part II: The students were divided into six groups and each group was asked to design an ADR reporting form for the hospital setting. The students developed and submitted the forms to the facilitator.

Session III: The objective of the session was to familiarize the students about ADRs and pharmacovigilance. The session had the following parts:

Part I: Theoretical aspects related to ADRs and pharmacovigilance: The students were presented with some theoretical aspects which included the basic terminologies involved, types of ADRs, and predisposing factors for ADRs.

Part II: Importance of nurses in ADR monitoring: The importance of nurses in pharmacovigilance was discussed. The various strategies that nurses could follow like appropriate dosing, and early detection of ADRs were discussed.

Part III: Briefing about the functioning of the regional pharmacovigilance center: The students were briefed about the operational aspects of the regional pharmacovigilance center and the various procedures performed by the center (see Figure 1).

Simultaneously, the KAP was collected at baseline (day 0), 30 days, 90 days and 180 days, from both the test group as well as control group students. The feedback responses were obtained after completing all the three sessions from the test group students who received the training (on day 90).

2.5 Data source

The completed KAP questionnaires and the feedback forms were the data sources. Each correct/positive response in the KAP questionnaires were given a score of 2 and the wrong/negative responses were given a score of 1 (Section 2.3.1). The attitude and practice domain were clubbed together while scoring because the evaluation period was short and hence the impact on practice could not be influenced significantly within this time period. For the feedback questionnaires, the scoring given as 1 (strongly disagree), 2 (disagree), 3 (neutral), 4 (agree) and 5 (strongly agree). The minimum possible KAP scores for an individual was ‘20’ and the maximum was ‘40’. Similarly, the maximum score of the individual questions can be 5 and thus, the maximum total score for a participant was 100.

2.6 Data analysis

The completed KAP questionnaires and feedback forms were analyzed as per the research objectives. Statistical Package for Social Sciences (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.) was used to carry out the analysis. The normality of distribution of the variables was tested using the Kolmogorov Smirnov test. The data was not normally distributed. The median (IQR) of the total score was compared among different subgroups of respondents. Mann Whitney U and Kruskal-Wallis tests were used for comparing the scores of the groups Wilcoxon Signed Ranks test was used to compare the median (IQR) KAP scores before and after intervention at $\alpha = .05$.

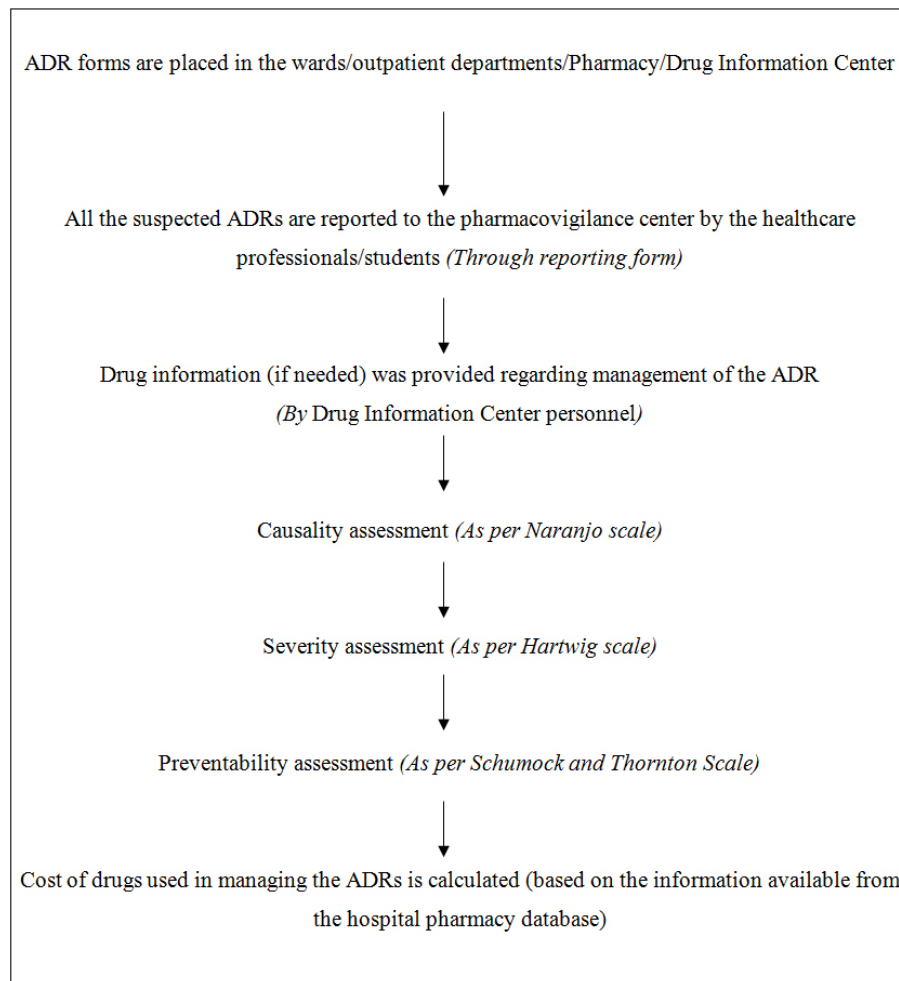


Figure 1. Functioning of the Regional Pharmacovigilance Center

3. RESULTS

A total of 116 nursing students were available on the initial day and all of them participated in the study; 78 (67.2%) were in the control group and the remaining 38 (32.8%) in the test group.

3.1 Demographic details of the nursing students

Among the total 116 nursing students, majority (93.1%) were aged below 20 years and originated from urban areas (82.8%). The demographic details of the nursing students are listed in Table 1.

3.2 Baseline knowledge, attitude and practice scores of the nursing students

The median (IQR) overall baseline knowledge score was 11 (10-12), the attitude/practice scores were 22 (20.25-22.00) and the total scores was 32.5 (31-34). The maximum possible score was 40.

Table 1. The demographic details of the nursing students (n = 116)

Demographic parameters		Frequency	Percentage (%)
Gender	Female	116	100.0
	Male	0	0.0
Age (in years)	15-20	108	93.1
	21-25	6	5.2
	Not available	2	1.7
Method of financing	Self-financing	80	69.0
	Scholarship	5	4.3
	Not available	31	26.7
Native place	Urban	96	82.8
	Rural	18	15.5
	Not available	2	1.7
Year of study	1 st year	41	35.3
	2 nd year*	38	32.8
	3 rd year	37	31.9

*= test group purposively selected keeping in mind that none of the students were taught about pharmacovigilance

3.3 Response to the knowledge questions by the nursing students

A high number (n = 88; 75.9%) of the students knew the method of preventing type-1 hypersensitivity reactions. How-

ever, only a few (n = 20; 17.2%) knew the year during which the pharmacovigilance activities in the country were first established. The students’ response to the knowledge related questions are listed in Table 2.

Table 2. Response to knowledge questions by nursing students (n =116)

Questions	Number of students providing the correct answer	Percentage (%)
One of the following drugs is known to cause anaphylaxis reactions	62	53.4
The system reported to be commonly affected by adverse drug reactions is	40	34.5
“Type I hypersensitivity” reactions can be prevented by one of the following methods	88	75.9
The regional pharmacovigilance center in western Nepal is located at	42	36.2
In Nepal, the pharmacovigilance activities started in the year	22	19.0
The National Pharmacovigilance Center in Nepal is located at	20	17.2
One of the following is the agency in Unites States of America involved in drug safety issues	12	10.3
Which one of the following classes of drugs is known to cause more severe adverse drug reactions?	60	51.7

3.4 Response to the attitude/practice questions by the nursing students

In general, students had a positive attitude/practice towards drug safety. Almost all (n = 113; 97.4%) of them felt ADR

reporting was necessary and were interested in learning about ADRs. The response to the attitude/practice questions are listed in Table 3.

Table 3. Response to attitude/practice questions by the nursing students (n = 116)

Questions	Number of students answering yes/positive response	Percentage (%)
Do you think knowing more about adverse drug reactions is relevant to you?	111	95.7
In the future will you be interested in carrying out research activities in pharmacovigilance?	91	78.4
Have you ever come across someone experiencing an adverse drug reaction?	29	25.0
Do you think Nepal should be actively involved in Pharmacovigilance activities?	105	90.5
Are you interested in learning more about adverse drug reactions?	113	97.4
Do you think that many patients in Nepal suffer from adverse drug reactions?	78	67.2
The healthcare professional responsible for reporting adverse drug reaction in a hospital is	67	57.8
Do you think reporting adverse drug reaction is necessary?	113	97.4
Do you think reporting adverse drug reaction should be made mandatory?	86	74.1
Do you think the curriculum of nurses should include adverse drug reactions?	111	95.7
Do you think that herbal drugs are free from adverse drug reactions?	91	78.4
The responsibility of ensuring drug safety belongs to whom?	85	73.3

3.5 Baseline knowledge, attitude and practice scores among various subgroups of nursing students

Baseline KAP scores was compared among different subgroups of respondents. The baseline KAP scores was sig-

nificantly higher among the second- and third-year students compared to the first year (*p* < .001). Further details are listed in Table 4.

Table 4. Baseline KAP scores among different subgroups of nursing students (n = 116)

Demographic parameters		Median (IQR)	p value
Age (in years)	15-20 (n = 108)	32.5 (31-34)	.204
	21-25 (n = 6)	34 (31-36)	
Method of financing	Self-financing (n = 80)	33 (31-34)	.110
	Scholarship (n = 5)	30 (27.5-31.5)	
Native place	Urban (n = 96)	33 (31-34)	.742
	Rural (n = 18)	32.5 (32-33)	
Year of study	I year (n = 41)	31 (30-32)	< .001***
	II year (n = 38)*	33 (31-35)	
	III year (n = 37)	33 (33-35)	

*= test group; *** Kruskal Wallis test at = .05; The total number may not add up to 116 for some parameters due to missing values; The maximum possible score was 40.

3.6 Knowledge, attitude and practice outcomes among nursing students before and after the educational intervention

Following the intervention, there was a significant improvement in knowledge scores between the baseline and first follow-up ($p = .018$) and between second and third follow-up ($p = .001$) in the test group. There was also an improvement in the attitude/practice scores between the first and second follow-up ($p = .008$); day 30 and day 90 and second and third follow-up ($p = .025$); day 90 and day 180. This led to an improvement in the total KAP scores between the baseline and first follow-up ($p = .002$) and the second and third follow-up

($p = .001$).

In the control group, an improvement was seen between the baseline and first follow-up in the knowledge ($p = .008$) and the total scores ($p = .021$). Further details are listed in Table 5.

3.7 Feedback about the educational intervention from the nursing students

The feedback of the students on the module (see Table 6) was obtained by noting their agreement with a set of 20 questions using a Likert type scale. The median (IQR) feedback scores was 85 (80.7-88.2).

Table 5. KAP scores among nursing students at baseline, first, second and third follow up

Groups	Variables	Scores [Median (IQR)]				p value*
		Baseline	1 st Follow up	2 nd Follow up	3 rd Follow up	
Control (n = 78)	Knowledge	11 (10-12)	11 (10-12)	11 (10-12)	11 (10-12)	.008; B-IF .541; I-III .371; II-III
	Attitude /Practice	22 (21-22)	22 (20-23)	22 (21-23)	22 (21-23)	.598; B-IF .327; I-III .503; II-III
	Total	32 (30.75-33.25)	33 (31-34)	32 (31-34)	34 (31-35)	.021; B-IF .636; I-III .250; II-III
Test (n = 38)	Knowledge	12 (11-12)	13 (11.75-13.00)	12 (12-13)	13 (12-14)	.018; B-IF .900; I-III .001; II-III
	Attitude/Practice	21 (20-22)	22 (21-23)	23 (21-23)	23 (22-23)	.008; B-IF .654; I-III .025; II-III
	Total	33 (31-35)	34 (33-36)	34.5 (33-36)	36 (34-37)	.002; B-IF .645; I-III .001; II-III

*Wilcoxon Signed Ranks test at = .05; B = Baseline; IF = I follow up; IIF = II follow up; IIIF = III follow up.

Table 6. Feedback of the nursing students on the pharmacovigilance sessions (n = 38)

Statements	Median (IQR) Scores
1. The sessions made me aware of the concept of pharmacovigilance.	4 (4-5)
2. Pharmacovigilance is very much essential to developing countries like Nepal.	5 (5-5)
3. Adverse drug reactions are one of the major causes for death in the world.	4 (3-5)
4. Herbal drugs also carry equal risk of causing ADRs as that of modern medicines.	4 (3-5)
5. Pharmacovigilance program in Nepal is successful.	3 (3-3)
6. The ADR reporting form should be in a single page.	4 (4 -5)
7. Pharmacovigilance should be made mandatory in Nepal.	5 (4-5)
8. Pharmacovigilance should be incorporated in the curriculum of doctors, pharmacists and nurses.	4 (4-5)
9. The pharmaceutical industry should report adverse drug reactions.	5 (5-5)
10. This session may be useful for me in my job.	5 (4-5)
11. Hospital drug and therapeutics committee should be a part of the pharmacovigilance program.	5 (4-5)
12. Causality assessment is an important step in pharmacovigilance.	4 (4-4)
13. Severity assessment is not an important step in pharmacovigilance.*	4 (3-5)
14. A good number of adverse drug reactions can be prevented if appropriate measures are taken.	5 (4-5)
15. Patients should not be allowed to report adverse drug reactions.*	5 (5-5)
16. Dosage adjustment is an important strategy to prevent the occurrence of ADRs.	5 (4-5)
17. The session was informative and interesting.	4 (4-5)
18. The facilitators performed their roles effectively.	4 (4-5)
19. I would like to pursue my career in pharmacovigilance.	4 (3-4)
20. I would welcome similar sessions in the future.	4 (4-5)

Note. The score ranged from a minimum of 1 to a maximum of 5; * Questions 13 and 15 were worded negatively and hence were scored reversely while calculating the scores.

4. DISCUSSION

Nurses are an important member of the healthcare team and have a very important role to play in pharmacovigilance daily.^[15] A considerable percentage of ADRs occur in the hospital setting. A good percentage of hospitalized patients experience at least one ADRs during their hospital stay.^[16-18] During the hospital stay, the nurse plays an important role in patient care. Baseline evaluation of the nursing students revealed that they had a poor knowledge regarding ADRs and pharmacovigilance. Only one third (36.2%) of the nursing students knew the location of the regional pharmacovigilance center in western Nepal. Similarly, only 19% of them knew the starting year of the pharmacovigilance activities in Nepal and only 17.2% knew the location of the national pharmacovigilance center in Nepal. A study from the neighboring country Bhutan found nurses to possess poorer knowledge on ADR reporting than clinical doctors and pharmacists.^[19] Hence, these findings suggest the need for education for nurses that could probably be delivered during their educational courses.

In the present research authors provided education to the nursing students and evaluated the impact in terms of KAP as well obtained students' feedback about the sessions. The

knowledge scores improved following the sessions. In a study from Iran, two clinical pharmacists delivered an educational module for nurses on pharmacovigilance. The education module was delivered using either 'didactic lecture' or 'brainstorming workshop'. Immediately after the module, the nurses' knowledge was significantly higher in the lecture group; however, the knowledge score dropped during follow-up at 3 months. The study revealed educational interventions could improve nurses' knowledge; however, the knowledge is better sustained following sessions using interactive techniques rather than didactic lectures.^[20] In the present study, the nursing students were provided with an education module that used a combination of lectures as well as activity based interactive sessions. Thus, the present research findings are unique in nature. The importance of curriculum changes for nurses in relation with pharmacovigilance has been recognized by a Turkish research group who recommended the need for pharmacovigilance training in their undergraduate and graduate education programs so as to improve knowledge about, and to promote ADR reporting.^[21] Another Italian study found nurses to possess good observational skill for adverse event but a low ability to detect ADRs suggesting a theoretical knowledge on drugs and ADR.^[22] In

order to enhance their knowledge about ADRs nurses should be provided with adequate pharmacology teaching in their curriculum.

In contrast to the knowledge scores, the nursing students had a high attitude/practice score. They felt that knowing more about ADRs is relevant to them and a high percentage (95.7%) believed the curriculum of nurses should include learning about ADRs. The current curriculum of nurses in Nepal does not emphasize ADRs and pharmacovigilance though they are trained in the clinical aspects of supportive care involved in managing life threatening ADRs, and method of sensitivity testing.

The feedback of the students was generally positive. They realized the growing need for pharmacovigilance in Nepal and of the understanding that the pharmacovigilance program in the country is not very successful and has a huge scope for improvements. A vast majority of students concurred with the idea of incorporating pharmacovigilance in the nursing curriculum. This shows the interest of the students in knowing more about the harmful effects of medicines. Even after training, a good percentage of the students felt that herbal drugs are safe, which needs further emphasis. Most of them stated that they would welcome similar sessions in the future. A recent review supported the idea that it is crucial to improve and innovate current pharmacovigilance education in undergraduate health profession students.^[23]

This study had few limitations. The study only focused on one nursing school and the sample size was small and hence the findings cannot be generalized to the entire nursing student population of the country. The training materials might have been also shared among the test and control group students and thus leading to contamination of the intervention.

The Cronbach alpha value of the KAP questionnaire was low and thus affecting the reliability of the tool.

5. CONCLUSIONS

Students had better attitude/practice scores, but a poor knowledge score at baseline. The feedback of the students showed a positive trend and students were willing for further sessions. The intervention improved the KAP scores. The responsibility lies in the hands of regional pharmacovigilance centers in teaching pharmacovigilance to the students.

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AUTHOR CONTRIBUTIONS

Subish Palaian was a PhD student at the Universiti Sains Malaysia, Penang, Malaysia. Mohamed Izham Mohamed Ibrahim and Pranaya Mishra were the research supervisor and co-supervisor respectively. All three were involved in conceptualization, design and conduct of the study and improving the manuscript contents and quality. P Ravi Shankar provided expert opinion in designing the educational module, conducting the study and helped in writing the manuscript and edited the initial version of the manuscript. Subish Palaian, Pranaya Mishra and P Ravi Shankar were staff members at the Regional Pharmacovigilance Center at the time when this research was conducted. All authors have read and approved the final submitted version of the manuscript.

CONFLICTS OF INTEREST DISCLOSURE

The authors do not have anything to declare.

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