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Development and Evaluation of a Pharmacovigilance Education Module for Medical Students in Nepal

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ABSTRACT

This study evaluated the impact of a pharmacovigilance educational module on the Knowledge, Attitude and Practice (KAP) of pharmacovigilance among students in a medical college in Nepal and obtained their feedback on the module. A pre-post study design was used. First to fourth semester (basic sciences) undergraduate medical students (n = 229) were included. Their baseline KAP towards adverse drug reactions (ADRs) and pharmacovigilance was evaluated using a pretested KAP questionnaire. The students were grouped into "control" (1st and 4th semester) and "test" (2nd and 3rd semester) groups. The test group received an educational intervention, which included the basic, technical and operational aspects of pharmacovigilance. The improvements in the KAP scores following the intervention was compared using Wilcoxon signed rank test; student feedback on the sessions was obtained using a feedback questionnaire' (maximum score = 100). Nearly, all students (n = 227; 99.1%) believed undergraduate medical students should be taught about ADRs and 224 (97.8%) felt ADRs reporting to be important. A statistically significant association was found between the baseline KAP scores and gender (p = 0.044), respondents' age (p = 0.017), method of financing of education (p < 0.001), nationality (p = 0.009) and the respondents' semester of study (p = 0.001). After the intervention, the median interquartile range (IQR) KAP scores improved from 32 (30–33) to 34 (32–36), (p < 0.001). Overall, the students' perception regarding the module was positive. This was reflected by a high median IQR feedback scores [83 (78.0–87.0)]. Post intervention, the knowledge scores improved significantly suggesting the effectiveness of the educational modules. Student feedbacks about the modules were positive. Findings also suggest the feasibility of conducting pharmacovigilance education modules for medical students in resource limited settings.

Keywords: *Adverse drug reactions, Education, Medical students, Nepal*

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INTRODUCTION

Healthcare professionals are required to be knowledgeable about safe and effective use of medicines. The information obtained about medicines during the premarketing clinical trials are incomplete (1). Hence post marketing surveillance of medicines is important to monitor the safety and related issues of medications currently in use. A good number of adverse drug reactions (ADRs) can be prevented if appropriate measures are taken while prescribing, dispensing and using medicines (2). Studies from developed countries acknowledge a strong association between attitudes towards and reporting of ADRs by healthcare professionals (3, 4, 5). These findings suggest the need for improving attitudes among healthcare professionals, which can be achieved by educating them while they are students, at which stage they may be more likely to accept changes. In order to tackle this problem, few developed countries such as the United Kingdom and the United States have incorporated pharmacovigilance into the curriculum of medical and other health care students (6, 7).

The "WHO-ISoP Core Elements of a Comprehensive Modular Curriculum" provides basic information on pharmacovigilance education modules (8). Medical doctors who prescribe medications should be knowledgeable about the safety profile of medicines they use. Errors in prescribing, if not corrected by the subsequent healthcare members involved in the medicine use process, can lead to ADRs. Training medical students, the future prescriber, is expected to improve their awareness and knowledge about pharmacovigilance and drug safety; and could help them perform a more active future role about pharmacovigilance. In a poorly resourced country like Nepal, pharmacovigilance is only covered superficially in the undergraduate medical curriculum (9, 10). This had led to a poor Knowledge, Attitude and Practice (KAP) on pharmacovigilance among medical doctors in the country (11). In the medical curricula, ADRs are only covered as a topic during the theory course and practical exposure to drug safety and available mechanisms of reporting ADRs is lacking. Many medical institutions in Nepal also lack the staffing, infrastructure, and facilities to teach pharmacovigilance.

However, Manipal College of Medical Sciences (MCOMS), Pokhara, has taken several initiatives to teach rational pharmacotherapy to the medical students. A Drug Information Center (DIC) and the Western Regional Pharmacovigilance Centre have been established in the college. Medical students during regular hospital visits are introduced to the daily operation of the centre. In the past, students from the institution were sensitised about pharmacovigilance (12). Considering the importance of incorporating pharmacovigilance education and the absence of a system of teaching pharmacovigilance to students in Nepal, the members of the regional pharmacovigilance centre initiated the educational programmes for the medical students.

This initiative can be adopted by other institutions and will help in incorporating pharmacovigilance education in the curriculum of medical students. This research aimed at evaluating the impact of an educational intervention on knowledge, attitude and practice of the medical students towards ADRs reporting and pharmacovigilance.

MATERIALS AND METHODS

Study Design

A prospective, interventional study was carried out among medical students and the KAP scores (pre- and post-intervention) were evaluated and compared. The study was conducted over a one-month period at Manipal Teaching Hospital, Pokhara, Nepal. The study was approved by the hospital ethics committee.

Study Population and Sampling Procedure

Medical students from the first four semesters (Semesters 1, 2, 3 and 4) were enrolled in the study. These are the semesters during which pharmacology is being taught. The second and third semester of medical students were taken as the test group while the first and fourth semester of medical students were taken as control group in order to have a uniform distribution of subjects following a convenience sampling method. All students who were willing to participate in the sessions were included in the study. 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.

Study Tools

KAP questionnaire: A KAP questionnaire was developed by pharmacists from the Western Regional Pharmacovigilance Centre of Nepal located in Pokhara city, in consultation with the research team and using information obtained from previously published researches (13, 14). This centre is one of the regional pharmacovigilance centres in Nepal reporting ADRs to the national pharmacovigilance centre. The questionnaire was in English, the language of instruction. The reliability analysis of the questionnaire indicated the Cronbach's alpha of 0.65. This questionnaire had 19 questions (10 questions on knowledge: 1, 2, 3, 6, 7, 12, 14, 15, 16, 19; and 9 questions on attitude/practice: 4, 5, 8, 9, 10, 11, 13, 17, 18). The questionnaire was pretested by administering to 24 medical students from all the four semesters and the data of these 24 students were excluded from the main study.

Feedback questionnaire: The feedbacks of the students about the sessions were evaluated using a questionnaire with 20 questions, developed by the researchers based on previously published articles (15, 16). The degree of agreement of the respondents with the questions was noted using a Likert scale.

The baseline KAP scores of the students were measured prior to the intervention in both the control and the test group. Only the students from the test group received the intervention and no intervention was provided to the control group.

Details of the intervention: An educational module was designed by the members of the regional pharmacovigilance centre based on their previous experiences on designing education modules on pharmacovigilance (15, 16, 17). The objective of the module was to improve the medical students' knowledge towards pharmacovigilance and ADRs reporting and focused mainly on introducing the existing national pharmacovigilance programme and carrying out causality and severity assessments of reported ADRs. The details of the programmes as follows:

Part I – Schematic presentation of the National Pharmacovigilance programme: Medical students drew the flow chart of the National Pharmacovigilance Programme of Nepal. Prior to the sessions they did not have any exposure to the national pharmacovigilance programme.

Part II – Designing of an ADR reporting form: Students were encouraged to design an ADR reporting form encompassing all necessary requirements for reporting. All necessary information needed to design an ADR reporting form was provided to the student participants.

Part III – Performing the causality assessment of ADRs: Students performed the causality assessment of four ADRs that were reported to the regional pharmacovigilance centre using Naranjo algorithm (18).

Part IV – Performing severity assessment of ADRs: Students then performed severity assessment of the same four ADRs used for causality assessment using Hartwig and Siegel scale (19).

Part V – Distribution of educational materials: The students were provided with copies of "Pharmacovigilance Nepal: a guide for healthcare professionals" (20), a booklet published by the regional pharmacovigilance center and other articles and materials related to medicine safety.

Each session lasts approximately 2–3 hours.

Adequate time was provided to complete the KAP questionnaires administered at baseline (day 0) and 30 days after the session. The duration was short for the medical students since the semester was short and the students were preparing for their exams. Feedback was obtained after completing the session from the test group students who received the training.

Scoring of the questionnaires: The completed KAP questionnaires and the feedback forms were analysed. Correct/positive responses in the KAP questionnaires were given a score of 2 and the wrong/negative responses were given a score of 1. The scores ranged from a minimum of 19 and maximum of 38. The attitude and practice domain were merged while calculating the scores. This was partly because the evaluation period was short and hence, the impact on practice could not have been significant within this time period.

The feedback questionnaires measuring students' agreement with a set of 20 statements regarding the pharmacovigilance module were scored using a 5-point Likert scale (1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree). The score ranged from a minimum of 20 to a maximum score of 100.

Data analysis: The completed KAP questionnaires and the feedback forms were analysed as per the study objective. The Statistical Package for Social Sciences Version 16.0 was used for analysis. The normality test was carried out. The median (interquartile range) total score was compared among different subgroups of the respondents. Mann-Whitney U test and Kruskal-Wallis test were carried out to compare the scores between groups. Wilcoxon Signed Ranks test was used to compare the median KAP scores before and after intervention. A p value less than 0.05 was considered significant.

RESULTS

Demographic details of the medical students: A total of 229 students (127 in control group versus 102 in test group) participated in the study; majority were males (63.3%) and Nepalese (52.4%). Table 1 shows the demographic details of the medical students.

Table 1: Demographic details of the medical students (n = 229)

Demographic parameters		Frequency, n (%)
Gender	Female	84 (36.7)
	Male	145 (63.3)
Age (in years)	< 20	164 (71.6)
	21–25	56 (24.5)
	Not available	9 (3.9)
Method of financing	Self-financing	172 (75.1)
	Scholarship	44 (19.2)
	Not available	13 (5.7)
Nationality	Nepalese	120 (52.4)
	Indian	91 (39.7)
	Sri Lankan	13 (5.7)
	Others	2 (0.9)
	Not available	3 (1.3)
Native place	Urban	188 (82.1)
	Rural	23 (10.0)
	Not available	18 (7.9)
Semester of study	1st semester	69 (30.1)
	2nd semester*	44 (19.2)
	3rd semester*	58 (25.3)
	4th semester	58 (25.3)

Note: * = test group

Baseline knowledge, attitude and practice scores of the medical students: The median (interquartile range) overall baseline scores was 14.0 (13.0–16.0) for knowledge, 17.0 (16.0–18.0) for attitude/practice and 31.0 (29.0–33.0) for the total scores. The maximum possible total score was 38.

Response to the knowledge questions among medical students: One third (n = 67; 29.3%) of the students knew the organ system most commonly affected by ADRs. The details are enumerated in Table 2.

Response of the medical students to the attitude/practice questions: Almost all students (n = 227; 99.1%) believed undergraduate medical students should be taught about ADRs and 224 (97.8%) felt ADRs reporting was important. Table 3 shows the students' response to the attitude/practice questions.

Baseline knowledge, attitude and practice scores among different subgroups of medical students: The KAP scores were compared among different subgroups of respondents. Male students had a slightly higher score than females and the scores of the students increased with seniority (a higher semester having a higher score). A statistically significant association was found between all the demographic parameters and the baseline KAP scores. The details are listed in Table 4.

Effect of intervention on knowledge, attitude and practice among the medical students: The impact of the educational intervention was compared in terms of the KAP of the students. Following the intervention, the knowledge ($p < 0.001$), attitude/practice ($p = 0.013$) and the total scores ($p < 0.001$) improved significantly in the test group. However, an improvement was also noticed in the knowledge ($p < 0.001$) and the total ($p < 0.001$) scores among students in the control group. The details are listed in Table 5.

Table 2: Response to knowledge questions among medical students (n = 229)

Questions	Number of students answering correct response	Percentage
One of the following drugs is known to cause fatal anaphylaxis reactions	140	61.1
The commonly affected organ system due to adverse drug reactions is:	67	29.3
'Type I hypersensitivity' reactions can be prevented by one of the following methods	158	69.0
The regional pharmacovigilance center in western Nepal is located at:	134	58.5
Upon occurrence of an adverse drug reaction, what needs to be done with the suspected drug?	131	57.2
In Nepal, the pharmacovigilance activities started in the year:	47	20.5
The national pharmacovigilance center in Nepal is located at:	51	22.3
The international center for monitoring adverse drug reactions is located in:	25	10.9
The following is the agency in Unites States of America involved in drug safety issues:	102	44.5
Which one of the following is a predisposing factor for causing adverse drug reactions?	150	65.5

Note: These were multiple choice questions with 5-response options

Table 3: Response to attitude/practice questions among medical students (n = 229)

Questions	Number of students answering yes/positive response	Percentage
Do you think knowing more about adverse drug reactions is relevant to you?	224	97.8
The important factor necessary to report an adverse drug reaction is:	176	76.9
Do you think Nepal should be actively involved in Pharmacovigilance activities?	212	92.6
Are you interested in learning more about adverse drug reactions?	223	97.4
Do you think MBBS students should be taught about adverse drug reactions?	227	99.1
The healthcare professional responsible for reporting adverse drug reaction in a hospital is:	164	71.6
The responsibility of ensuring drug safety belongs to whom?*	144	62.9
Do you think reporting adverse drug reaction is important?	224	97.8
Do you think reporting adverse drug reaction should be made mandatory?	189	82.5

Note: These were multiple choice questions with 5-response options
*The response "All of the above" was considered as a correct response

Student feedback about the educational module: The median (interquartile range) scores was 83.0 (78.0–87.0). Overall, the students had a positive perception regarding the sessions. However, for a question on the success of the pharmacovigilance programme in Nepal, the scores were poor with the median (interquartile range) scores being 3 (2–3). The median (interquartile range) of the individual statements are shown in Table 6.

DISCUSSION

This is the first study in Nepal that designed and evaluated a pharmacovigilance education module for medical students. A locally developed curriculum is expected to be more practice friendly and feasible. However, a session on pharmacovigilance was conducted for the first-year medical students at another medical college in Nepal in which the medical students were provided with a brief overview of the programme and informed about the workings of the pharmacovigilance centre (21). Thus, the present study is significant in terms of its depth and uniqueness in researching an important and unique topic. This research identified the knowledge and awareness of the medical students in western Nepal towards ADRs and pharmacovigilance and showed that a locally developed education module can be significant in improving these parameters. The education provided to the students by the regional pharmacovigilance centre has been well received by the students as shown by the high feedback scores. The education programmes improved their KAP scores regarding ADRs and pharmacovigilance. It is well understood that medical doctors play an important role in pharmacovigilance and hence should be taught the same (22). Data from both developing and developed countries suggested a poor knowledge among healthcare professionals regarding ADRs and existing pharmacovigilance programmes (23, 24, 25). A poor knowledge

Table 4: Baseline KAP scores among different subgroups of medical students (n = 229)

Demography	Parameters	Median (interquartile range)	*P* value
Gender	Female (n = 84)	31.0 (29.0–33.0)	**0.044****
	Male (n = 145)	32.0 (29.2–33.0)	
Age (in years)	15–20 (n = 164)	31.0 (29.0–33.0)	**0.017****
	21–25 (n = 56)	32.0 (30.0–34.0)	
Method of financing	Self-financing (n = 172)	31.0 (29.0–33.0)	**<0.001****
	Scholarship (n = 44)	33.0 (31.0–35.0)	
Native place	Urban (n = 188)	31.0 (29.0–33.0)	0.910**
	Rural (n = 23)	32.0 (29.0–33.0)	
Nationality	Nepalese (n = 120)	32.0 (30.0–33.0)	**0.009*****
	Indian (n = 91)	30.0 (29.0–32.2)	
	Sri Lankan (n = 13)	32.0 (29.0–33.5)	
	Others (n = 2)	29.0 (29.0–29.0)	
Semester of study	1st semester (n = 69)	29.0 (28.0–31.0)	**<0.001*****
	2nd semester (n = 44)*	32.0 (31.0–35.0)	
	3rd semester (n = 58)*	32.0 (29.7– 33.0)	
	4th semester (n = 58)	33.0 (31.0–34.0)	

Note: The total frequency may not total up to 229 in some parameters as some of the respondents did not fill all the demographic parameters; The bold items reflect the *p* value that are statistically significant.
*= test group
**Mann-Whitney U test at α = 0.05
***Kruskal Wallis test at α = 0.05

Table 5: KAP scores among medical students before and after the intervention

Groups	Variables	Scores [Median (interquartile range)]		*P* value*
		Baseline	Post intervention	
Control (n = 127) 1st and 4th semester	Knowledge	14 (12–16)	15 (13–16)	**0.000**
	Attitude/practice	17 (16–18)	17 (16–18)	0.678
	Total score	31 (29–33)	32 (30–33)	**0.000**
Test (n=102) 2nd and 3rd semester	Knowledge	15 (14–16)	16 (15–18)	**0.000**
	Attitude/practice	17 (16–18)	18 (17–18)	**0.013**
	Total score	32 (30–33)	34 (32–36)	**0.000**

Note: *Wilxocon signed ranks test at α = 0.05; The bold items reflect the *p* values that are statistically significant.

can eventually be linked to a poor practice of ADRs reporting, a common problem noted in any developing country. Another study found lack of awareness and knowledge of pharmacovigilance and ADRs reporting among healthcare practitioners (23). A survey among healthcare professionals in Ireland also emphasised on improving awareness about pharmacovigilance of medicines (24). It is important to initiate appropriate measures to enhance medical practitioners' knowledge towards drug safety.

Contrary to the poor knowledge scores, medical students had high attitude/practice scores. Nearly, all students felt that knowing more about ADRs is relevant

Table 6: Student's feedback about the pharmacovigilance module

Statements	Median (IQ range) scores (n = 99)
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 (4–5)
3. Adverse drug reactions are one of the major causes for death in the world	4 (3–4)
4. Herbal drugs also carry equal risk of causing ADRs as that of modern medicines	3 (3–4)
5. Pharmacovigilance programme in Nepal is successful	3 (2–3)
6. The ADRs reporting form should be in a single page	4 (3–4)
7. Pharmacovigilance should be made mandatory in Nepal	4 (4–5)
8. Pharmacovigilance should be incorporated in the curriculum of doctors, pharmacists and nurses	5 (4–5)
9. The pharmaceutical industry should report adverse drug reactions	5 (4–5)
10. This session may be useful for me in my job	4 (4–5)
11. Hospital drug and therapeutics committee should be a part of the pharmacovigilance programme	4 (4–5)
12. Causality assessment is an important step in pharmacovigilance	4 (4–5)
13. Severity assessment is not an important step in pharmacovigilance*	4 (4–5)
14. A good number of adverse drug reactions can be prevented if appropriate measures are taken	4 (4–5)
15. Patients should not be allowed to report adverse drug reactions*	5 (4–5)
16. Dosage adjustment is an important strategy to prevent the occurrence of ADRs	4 (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	4.5 (4–5)
20. I would welcome similar sessions in the future	5 (4–5)

Note: The score ranges from a minimum of 1 and a maximum of 5
*Questions 13 and 15 were reversed (negative questions) and hence were scored reversely while calculating the scores

to them. Similarly, almost all students believed medical students should be taught about ADRs and nearly all mentioned that they are interested in learning more about ADRs. In a study from India, author's found medical students possessed inadequate skill on reporting ADRs, but a positive attitude suggesting the need for education programmes (26). In a Nigerian study, author's evaluated the fourth- and fifth-year medical students' KAP on ADRs reporting and pharmacovigilance. Findings showed that 80% knew the definition of ADRs, 63% knew the functions of pharmacovigilance programmes and 82% of them "strongly agreed" that ADRs reporting is a responsibility of healthcare workers. Authors noted a good knowledge and attitude among the medical students with respect to ADRs and pharmacovigilance, but poor scores in relation to their practices and recommended for curriculum changes (27).

Since, the students had poor knowledge and high attitude/practice scores; it suggests the importance of training the students to improve their knowledge. The knowledge improvement was attained after the training sessions and the analysis of the feedback questionnaires showed a positive tendency among students. The students agreed that the sessions made them aware about pharmacovigilance and felt pharmacovigilance will be useful in countries like Nepal. They also realised that the pharmacovigilance programme in Nepal is not very successful. This finding clearly agrees with other research conducted elsewhere wherein underreporting is a common problem (28, 29, 30, 31). Thus, it is a mandatory to improve the ADRs reporting system in the country for which educating future prescribers is of paramount importance.

A high percentage of the students felt pharmacovigilance needs to be incorporated in the curriculum of health care students. 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. In developing countries like Nepal, with multiple drug use problems, incorporating pharmacovigilance learning among medical and other health care students is useful. The regional pharmacovigilance centres can take the responsibility in teaching pharmacovigilance to the students and preparing them as future healthcare practitioners who are concerned about patient safety.

This study had a few disadvantages. It was conducted only in one institution and may be difficult to generalise to other locations. Moreover, researchers were able to carry out only one intervention for the students since they were appearing for an examination and their semester was about to end. In addition, the attitude and practice components of the results were merged together and hence, it may be difficult to interpret the attitude and practice outcomes of the study interventions separately.

CONCLUSION

The educational intervention provided to the students was useful in improving the KAP. After the sessions, significant improvement was seen in the KAP scores of the students who attended the sessions. The module and the educational materials developed could be used by researchers in different parts of Nepal and other countries with similar healthcare challenges, either directly or with modifications.

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