Original Research Article

Knowledge and attitude towards pharmacovigilance among healthcare students at a medical college in Nepal

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ABSTRACT

Background: Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse drug reactions (ADRs) and any other possible drug-related problems. Under reporting of adverse drugs reactions are the global health problem. The adequate knowledge and skills towards pharmacovigilance and adverse drugs reactions reporting are crucial for the health care students to ensure patients' medication safety. This study aims to assess the knowledge and attitude of the health care students towards pharmacovigilance and ADRs.
Methods: A closed ended, structured, self-administered questionnaire was administered to 204 undergraduate health care students to collect the data. Data were analyzed using SPSS version 21. Non-parametric tests (Mann Whitney *U test* and Kruskal Wallis test) were used for analysis.
Results: Among 204 respondents, the majority of them had a poor knowledge (91.18%) and positive attitude (87.25%) towards Pharmacovigilance. The inter quartile range (median) score of the respondents' knowledge was 5.0±2.211 and attitude was 27.0±2.88 towards Pharmacovigilance and ADRs reporting. The main reason for under reporting of ADRs was difficulty to decide whether ADR has occurred or not (32.4%) due to the lack of appropriate knowledge and training. There is a poor knowledge and positive attitude towards Pharmacovigilance.
Conclusions: Adequate coverage of Pharmacovigilance and ADRs reporting issues should be covered in the curriculum as well as hand on training and workshop should be conducted to increase the knowledge and confidence in detecting, monitoring and reporting ADR in their clinical posting.

Key words: Pharmacovigilance, Adverse drug reaction, Knowledge, Attitude, Healthcare students

INTRODUCTION

Drugs are the most common medical interventions used to relieve from suffering but their use often associate with the undesirable and unavoidable adverse drug reactions (ADRs).[1] So, patients' safety and wellbeing while taking medications are very important.[2-4] The World Health Organization (WHO) defines adverse drug reaction (ADR) as "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function".[3] ADRs may be classified in five groups. The two most common are dose dependent effects (type A: augmented) and effects related to immunological/abnormal reaction between patient and drug (type B: bizarre). ADR can also be classified based on an onset of an event as acute, sub-acute and latent; and based on the severity of reaction as mild, moderate and

severe.[5] Spontaneous ADR reporting schemes can improve the safety level of medicines and are the major source of detecting and monitoring of ADR.[6] Doctor, pharmacist and nurse are the key health care professionals responsible to report the suspected ADRs observed in their clinical practice.[7] The word "Pharmacovigilance " is made up of two words; Pharmakon (Greek word for "drug") and vigilare (Latin word for "to keep watch").[8] WHO has set up a pharmacovigilance (PV) center for detecting, reporting and monitoring ADRs at a global level and this is managed through the Uppsala Monitoring Center (UMC) based in Sweden. PV is defined as 'the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems'.[9] Nepal has joined the WHO PV program in July 2006 and the National Pharmacovigilance Center was established here at the Department of Drug Administration (DDA) to monitor PV activities.[10] There are 15 regional PV centers in Nepal which reports ADRs to the national center through Vigiflow online program.[4] ADRs are significant cause of morbidity and mortality in hospital and are responsible for increasing financial burden .[5]

ADRs are underreported due to lack of awareness about the existence of PV program, negative attitude towards ADR reporting and unavailability of ADR reporting forms.[10] For strengthening the PV program several strategies like awareness, trainings, inclusion of program in curriculum, expanding the program to community level can be lunched.[10-11] Government of Nepal have provided health insurance policy where a family of 5 members must pay 3500 NPR per year to cover all types of health service with maximum limit of 100,000 rupees and 700 NPR per person should be paid if there are more than five members in the family but there is no provision of support for the treatment of ADRs. That is why, spontaneous ADRs reporting is crucial to ensure patient safety and to achieve the treatment outcomes in cost-effective way.[12] Moreover, medical students are the future healthcare professionals and are also responsible for the detection, reporting and prevention of ADRs. So, there is a need to assess the knowledge and attitude (KA) of undergraduate medical students towards pharmacovigilance. Therefore; this study is conducted to assess the knowledge and attitude of medical students of Gandaki Medical College Teaching Hospital and Research Center (GMCTHRC) towards PV.

METHODS

An institution based cross-sectional study was conducted from 7 January2022 to 7 July 2022 among third, fourth and fifth years students of MBBS, BDS, Nursing and B.Pharm undergraduate program of GMCTHRC who had clinical posting in the hospital.

Study population

All the undergraduate healthcare students studying in the third, fourth and fifth year, a total of 420 were the study population, where MBBS students total 276 (87 third year; 98 fourth year; 91 fifth year); BDS students total 53 (25 third year; 17 fourth year first phase; 11 fourth year second phase); Nursing students total 80 (24 BNS third year; 30 B.Sc. Nursing third year; 26 B.Sc. Nursing fourth year) and B. Pharm total 11 (11 fourth year) were available.

Sample size calculation

For a finite population of size (N) 420 and based on the knowledge on Pharmacovigilance prevalence 68.5%, with 95% confidence interval and 5% permissible error, sample size estimation was calculated using standard formula (Cochran's Sample size formula).[7]

$$n = Z2pq/d2,$$

Where 10% non response rate was added, thus the total sample was 204.[7]

Sampling technique

A stratified random sampling technique was used to obtain the desired sample from different discipline.

Inclusion and exclusion criteria

The interested students to participate in the study (from third, fourth and fifth year) with aged >18 years were included and those who were not willing to participate in the study were excluded.

Study variables

The dependent variables of the study were the KA of the participants regarding PV whereas; the independent variables of the study were the socio-demographic characteristics of the participants such as age, gender, year and discipline.

Study tool

Self-administered structured questionnaire was prepared with slight modification by reviewing the validated questionnaire from previously published articles related to the PV.[10,11,13-15] The questionnaire was divided into 3 parts: part 1 of the questionnaire included demographic characteristics of the students: age, gender, year and department. Part 2 of the questionnaire assessed the participant's knowledge by using a set of 15 questions. A knowledge score was prepared as a guiding tool to assess knowledge, one point was given for correct answer and zero for the wrong answer. The sum of all items gives a maximum score of 15. Students were categorized based on their overall knowledge scores using the Bloom's cutoff points as "good knowledge" if a score ranges 80-100% (12-15 points), "moderate knowledge" if a score ranges 60-80% (9-12 point), and "poor knowledge" if a score ranges <60% (<9 points) of the maximum score. Part 3 of the questionnaire assessed the participant's attitude where

the participants were asked to indicate their level of agreement or disagreements on a five-point Likert scale containing "Strongly agree", "agree", "neutral", "disagree", and "Strongly disagree" on the scale, valued 5 to 1 respectively.

The sum of all items gives a maximum score of 30. The overall level of attitude was categorized using Bloom's cut-off point, as a "positive attitude" if the score was 80-100% (24- 30 points), "moderate attitude" if the score was 60-80% (18–24 points) and "negative attitude" if the score was less than 60% (<18 points). One question is design to explore the discouraging factor to report ADR.[16]

Reliability testing

The completeness of the filled questionnaire was checked. The questionnaire was pilot tested by administering it to 10% of the study population and this data was not included in the main study. Reliability of the tool was evaluated by calculating the Cronbach's alpha value and a value 0.756 was obtained. Participants were provided with a written summary of research and contact information of the principal investigator. The anonymity of subjects was maintained by asking them not to write their name and students were not forced to participate during the study period.

Data collection

The questionnaire was self-administered to the respondents, fifteen minute was provided to fill up the questionnaire and the filled questionnaires were collected after completion.

Data management and analysis tools

The completed questionnaires were coded, entered and analyzed using Statistical Package for Social Science (SPSS) version 21.0. All quantitative variables were presented using descriptive statistics with frequency and percentages. Descriptive statistics like mean ± standard deviation (SD) was calculated for normally distributed data and median±SD was calculated for non-normally distributed data variables. The normality distribution of the data was checked by using Kolmogorov-Smirnov test and a Skewness test. As the total score was not found to be normally distributed, a nonparametric test was applied. Comparisons of the total KA of the participants for each KA question were done based on their age, gender and discipline by using a Mann-Whitney U-test for groups with two categories and Kruskal-Wallis test for groups having more than two categories where a statistical significance was declared at a p value <0.05 and 95% confidence interval.

The study was approved by the Institutional Review Committee of Gandaki Medical College with the approval number 43/078/079 dated November 01, 2021.

RESULTS

Socio-demographic characteristics of the participants

Out of 204 students 134 MBBS, 26 dental, 39 nursing and 5 pharmacy students had participated in the study. The mean (±SD) age of the respondents was 23.122 (±1.33) years, ranging from 20 to 27 years. The majority (61.3%) of the participants were females (Table 1).

Table 1: Comparison of the overall KA of MBBS, BDS, nursing and pharmacy students based on their age, gender and discipline towards PV (n=204).

Variables	Category	N (%)	Knowledge Mean rank Score	P value	Attitude Mean rank Score	P value
Age (years)[a]	≤23	140(68.63)	98.64	0.163	93.67	<0.001*
	>23	64 (31.37)	110.94		121.82	
Gender[a]	Male	79 (38.72)	108.19	0.269	105.04	0.62
	Female	125(61.27)	98.90		100.89	
Discipline[b]	MBBS 3rd yr	42 (20.59)	100.40		91.39	
	MBBS 4th yr	47 (23.04)	97.29		82.55	
	MBBS 5th yr	45 (22.06)	109.33		139.87	
	BDS 3rd yr	12 (5.88)	121.08		101.46	
	BDS 4th yr first phase	8 (3.92)	81.31	<0.001*	81.56	<0.001*
	BDS 4th yr second phase	6 (2.94)	118.92		35.17	
	BNS 3rd yr	11(5.39)	170.23		138.00	
	B.Sc. Nursing 3rd yr	15 (7.35)	49.10		102.30	
	B.Sc. Nursing 4th yr	13 (6.37)	59.46		90.12	
	B. Pharm 4th yr	5 (2.45)	200.30		118.50	

*p value <0.05; [a]Mann-Whitney U-test; N- number; [b]Kruskal- Walli'stest, PV-pharmacovigilance, KA- knowledge, attitude, yr-year; MBBS- bachelor of medicine, bachelor of surgery; BDS-bachelor of dental surgery; BNS- bachelor of nursing science; B.Sc. nursing-bachelor of nursing; B. Pharm-bachelor of pharmacy.

Table 2: Knowledge of the participants towards PV (n=204).

Characteristics (correct response)	Medical, Frequency (%) (N=134)	Dental, Frequency (%)(N=26)	Nursing, Frequency (%)(N=39)	Pharmacy, Frequency (%)(N=5)	Total, Frequency (%)
Nepal joined the WHO PV program in 2006 AD.	43 (32.09)	15 (57.69)	20 (51.30)	4 (80.00)	82 (40.20)
Definition of PV.	114 (85.07)	18 (69.23)	19 (48.72)	4 (80.00)	155 (75.98)
The appropriate purpose of PV is to identify safety of the drug.	74 (55.22)	8 (30.77)	10 (25.64)	1 (20.00)	93 (45.59)
DDA is responsible for monitoring of ADR in Nepal.	34 (25.37)	2 (7.69)	11 (28.21)	5 (100.00)	52 (25.49)
Vigiflow is the online database for reporting ADR.	51 (38.06)	11 (42.31)	15 (38.46)	5 (100.00)	82 (40.20)
The WHO approved international PV center is in Uppsala.	16 (11.94)	9 (34.62)	18 (46.15)	5 (100.00)	48 (23.53)
Awareness about the regional PV center inGandaki Province.	9 (6.72)	11 (42.31)	10 (25.64)	5 (100.00)	35 (17.16)
Regional PV center is located in Manipal Teaching Hospital.	12 (8.96)	2 (7.69)	0 (0)	5 (100.00)	19 (9.31)
Purpose of post marketing surveillance	43 (32.09)	3 (11.54)	9 (23.08)	5 (100.00)	60 (29.41)
Naranjo Probability scale is used to major causality of an ADR.	40 (29.85)	11 (42.31)	15 (38.46)	4 (80.00)	70 (34.31)
Hartwig scale is used to major severity of an ADR.	45 (33.58)	8 (30.77)	7 (17.95)	3 (60.00)	63 (30.88)
Dr., nurses and Phr., can report an ADR in Nepal.	72 (53.73)	14 (53.85)	30 (76.92)	4 (80.00)	120 (58.82)
Reporting of ADR in Nepal is voluntary.	53 (39.55)	5 (19.23)	11 (28.21)	3 (60.00)	72 (35.29)
Form used to report ADR in Nepal is ADR reporting form.	14 (10.45)	9 (34.62)	1 (2.56)	2 (40.00)	26 (12.75)
Anaphylaxis is belonging to allergic reaction type I.	105 (78.36)	25 (96.15)	16 (41.03)	4 (80.00)	150 (73.53)

KA knowledge, attitude; ADR-adverse drug reactions; Dr-doctor, Phr- Pharmacist, DDA-department of drug administration

Comparison of the overall KA of the participants towards PV

A statistically significant difference was seen in the mean rank knowledge and attitude score of participants based on discipline (p<0.001). Respondents' age >23 years old had slightly higher knowledge scores but significantly difference in an attitude (p<0.001) (Kruskal Walli's test) as compared to students with age ≤23 years old. Similarly, a slightly higher knowledge, and attitude score was seen on male students than female students. Among the group of participants, pharmacy students had the highest mean rank knowledge score and on attitude the MBBS fifth year students had average highest score (Table 1).

Knowledge of the participants towards PV

The majority (91.18%) of the participants had a poor knowledge (Table 5). More than 75% of the respondents correctly define the term PV. More than half of the respondents knew that doctors, pharmacists and nurses could report ADR in Nepal. Similarly, 73.53% respondents had correct knowledge of anaphylaxis.

Moreover, quarter of the respondents (25.49%) knew that DDA is the national PV center in Nepal but majority of them (87.25%) were not familiar with the ADR reporting form of DDA and less than 50% respondents knew the appropriate purpose of PV (Table 2). The median score of the respondents' knowledge towards PV was 5.00±2.211.

Table 3: Median KA score of the participants towards PV.

Median (IQR) KA score of participants		
Variables	Median (IQR)	Maximum
Knowledge	5.00±2.211	13
Attitude	27.00±2.88	30

Attitude of the participants towards PV

Majority of them (87.25%) had positive attitude (Table 5). Around three fourth of the students agreed that ADR

reporting is necessary in the hospital. Therefore, training on ADR reporting is needed because it is beneficial to patients and health care professionals. Similarly, more than half of the students agreed that ADR should be discussed in their clinical posting (Table 4).

Table 4: Attitude of the participants towards PV.

| Characteristics	Strongly agree N (%)	Agree N (%)	Neutral N (%)	Disagree N (%)	Strongly Disagree N (%)
ADR reporting is necessary in hospital.	150 (73.53)	46 (22.55)	7 (3.43)	0 (0)	1 (0.49)
Discussion in ADR is needed during clinical posting.	130(63.73)	57 (27.94)	14 (6.86)	2 (0.98)	0 (0)
Training on detection and reporting of ADR is needed.	113 (55.39)	80 (39.22)	11(5.39)	0 (0%)	0(0)
ADR reporting should be included in pharmacology practical.	83 (40.69)	101(49.51)	19 (9.31)	1 (0.49)	0 (0)
Medical students could play a role in ADR reporting.	74 (36.27)	89 (43.63)	32 (15.69)	9 (4.41)	0 (0)
ADR reporting benefits both to patients and health care professionals.	123 (60.30)	67 (32.84)	11(5.39)	3 (1.47)	0 (0)

The median attitude score of the respondents was 27.00±2.88 (Table 3).

Table 5: KA of the participants towards PV.

Variable	Category	N	%
Knowledge	Good	3	1.47
	Moderate	15	7.35
	Poor	186	91.18
Attitude	Positive	178	87.25
	Moderate	26	12.75

Reasons of the participants for not reporting ADRs

In this study, majority of participants (32.4%) reported that the reason for not reporting ADR was difficulty to decide whether ADR has occurred or not followed by no remuneration for reporting (Figure 1).
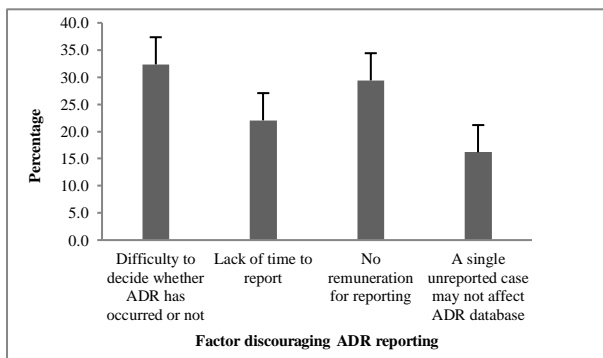
Figure 1: Reasons discouraging ADR reporting by the participants.

DISCUSSION

The present study was conducted among undergraduate healthcare students of third, fourth and fifth year to assess the knowledge and attitude towards PV in GMCTHRC. To the best of our knowledge, this is the first study that assessed KA of medical, dental, nursing and pharmacy students of GMCTHRC in Gandaki Province, Nepal. In the present study, male students were found to have slightly higher knowledge and positive attitude towards PV and ADR reporting than female students. Similarly, students with the age group >23 years had better knowledge and positive attitude compared to the age group ≤23 years (p<0.001). This finding is in agreement with the previous study.[16] Furthermore, mostly MBBS fifth year and BNS third year students were in age group of (24 to 27) years and they had more clinical exposure as compared to other respondents therefore, they might had more positive attitude towards PV and ADR reporting. The study revealed that the majority (91.18%) of the participants had a poor level of knowledge towards PV. However, pharmacy students had highest mean rank knowledge score as compare to medical, dental and nursing students, a noteworthy finding of this study. This result is consistent with the previously conducted studies globally.[17-21]This finding is somehow expected because pharmacy students had more exposure to the topic of PV and ADR reporting in their academic curriculum as compared to other healthcare students. PV program ensure safe and rational use of medicines and is one of the important post-marketing tools to evaluate the safety of pharmaceuticals.[22,23]That is why, the undergraduate healthcare students (medical, dental, nursing and pharmacy) should have sound knowledge and positive attitude towards the PV. The most efficient way of reporting ADR is the spontaneous reporting system however; under-reporting of ADRs is one of the major problems associated with PV programs. The common reasons for under- reporting of ADRs are like; difficulty to decide whether ADR has occurred or not (32.4%), lack of time to report (22.1%), no remuneration for reporting (29.4%) and belief of a single unreported case may not affect ADR database (16.3%). Similar reason was reported

for under reporting of ADRs from the study conducted in post graduate residents in Gandhi Medical College, Bhopal India.[24] Only one quarter students were aware about the national PV center in Nepal and few of them (12.75%) knew about ADR reporting form and reporting process. This lack of undergraduate education and training in PV and ADR reporting is consistent with the low level of knowledge, skills, and actions seen on medical, dental, nursing and even pharmacy students. Our findings complies with the findings of Rermerman et al.[25]

In contrast to these finding, Tiwari et al from central India reported that the three fourth of the medical students were aware about the PV and ADR reporting because their institute has functioning adverse drug reaction monitoring center where adverse events from all the clinical disciplines were being reported regularly as well as PV and ADR reporting were in the curriculum of the medical students so they were sensitized about the importance of the ADR reporting and patient medication safety.[26] However, in developing countries like Nepal the PV program is still in the initial stage and this could lead to poor knowledge score. Majority of the students are unaware of ADR reporting system in Nepal and the significance of PV. Therefore, to facilitate the ADR reporting, it is essential to include the PV activities and ADR reporting system in the early undergraduate curriculum and educational interventions (workshop and training) should be provided to the students for spontaneous reporting of ADR. By providing the knowledge regarding the significant of PV program, ADR reporting culture can be promoted among them leading to reduction on drug related problems, under reporting of ADR cases and medication error.[20,27] In agreement to this, more than half of the participants (55.39%) agreed training on ADR detection and reporting was needed and should be discussed in their clinical posting. This finding complied with the previously published studies.[5,28] Despite the lower knowledge majority of the students (87.25%) had positive attitude regarding PV. A better attitude score among the students in this study indicates their willingness to contribute to the PV program. Around three fourth (73.53%) students were found to strongly agree that ADR reporting is necessary in hospital. This finding was consistent with many studies.[6,15,29,30]

CONCLUSION

Majority of the students had poor knowledge regarding PV and ADR reporting. The lack of knowledge regarding PV and ADR reporting may lead to under-reporting of ADR. Fortunately, in the present study, majority of the students had positive attitude towards PV. Therefore, an educational intervention on PV and ADR reporting should be provided in order to increase the knowledge sore which would thereby help them in reporting ADR in their clinical practice. Moreover, the curriculum of medical, dental, nursing and pharmacy should adequately cover the issues of PV and ADR reporting.

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