



Knowledge, Attitude and Perception of Undergraduate Health Sciences students on Pharmacovigilance: A Cross-Sectional Study in Nepal

Satish Kumar Deo¹, Biswash Sapkot², Aashma Dahal³

¹Department of Clinical Pharmacology, Institute of Medicine, Tribhuvan University, Kathmandu, Nepal

²Department of Pharmacy and Clinical Pharmacology, MadanBhandari Academy of Health Sciences, Hetauda, Nepal

³Department of Public Health and Community Medicine, MadanBhandari Academy of Health Sciences, Hetauda, Nepal

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Abstract: This study aims to assess and compare the levels of knowledge, attitudes, and perceptions regarding pharmacovigilance among students enrolled in various health sciences colleges across Nepal. A cross-sectional study employing a questionnaire-based approach was undertaken to gather data from currently enrolled health sciences students in Nepal. To facilitate data collection, an online survey utilizing Google Forms was deployed, with the survey link disseminated through email and social media, accompanied by a clear elucidation of the study's objectives. Ethical approval was granted by the Institutional Review Committee (IRC) of MadanBhandari Academy of Health Sciences, Hetauda, Nepal. A total of 231 healthcare students took part in the study, with 4 participants failing to complete the survey. Among the participants, approximately 61% (n = 141) were pursuing pharmacy degrees, 13.9% (n = 32) were in nursing programs, 13% (n = 30) were studying public health, and 3.5% (n = 8) were medical students. Notably, the majority of participants were female, accounting for 66.2% of the respondents. Upon evaluating the mean scores, it was observed that pharmacy students exhibited a good level of knowledge (mean score of 7.7) and public health students displayed a positive attitude (mean score of 6±3.52), when compared to their counterparts in different health sciences professions. The study findings indicate lower level of knowledge, attitude, and perception of pharmacovigilance among students. Consequently, the study underscores the importance of robust efforts to enhance awareness and augment student knowledge. This can be achieved through consistent sensitization programs, training initiatives, and prompt feedback. Implementing such strategies emerges as a critical approach to bolstering the spontaneous reporting of adverse drug reactions (ADRs) within healthcare facilities, directed towards the relevant authorities.

Keywords: Attitude, Knowledge, Perception, Pharmacovigilance, Undergraduate students

INTRODUCTION

Pharmacovigilance and medication safety stand as vital domains globally. The World Health Organization (WHO) defines pharmacovigilance (PV) as encompassing "the science and actions related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem" (1). A broad participation of around 137 countries is observed in the WHO PV program (2). To oversee drug safety, Nepal's government designated the Department of Drug Administration (DDA) in October 2004 as the National Pharmacovigilance Center. This center collaborates with the WHO Collaborating Center for International Drug Monitoring in Sweden, thus initiating the collection of adverse drug reaction (ADR) reports (3).

For healthcare professionals, understanding the safe and effective use of medications is paramount. Pre-marketing clinical trials provide inadequate pharmaceutical data (4). Consequently, post-marketing drug surveillance becomes indispensable to monitor safety and related concerns of currently utilized drugs. Substantial reduction in adverse drug reaction (ADR) impacts during prescription, dispensation, and drug use is attainable through appropriate precautionary measures (5). Research from developed nations demonstrates a strong connection between healthcare professionals' perspectives on ADRs and their reporting behavior (6). These findings underscore the necessity of enhancing healthcare professionals' viewpoints, a transformation that is most effectively instilled during

their student years. Numerous developed nations, including the United Kingdom and the United States, have seamlessly integrated pharmacovigilance into medical and healthcare curricula, effectively addressing this concern (7).

In Nepal, although pharmacovigilance concepts are integrated into university undergraduate curricula, inadequate information exists regarding ADR reporting (8). Undergraduate health sciences students, being future healthcare professionals, stand at the forefront of medication administration and patient care (9). Therefore, assessing their knowledge, attitudes, and perceptions towards pharmacovigilance becomes imperative to ascertain the potential success of this surveillance system in the country. Also, this study aims to fill the existing gap in information, shedding light on the state of pharmacovigilance education and ADR reporting among the country's aspiring healthcare professionals. As Nepal strives to strengthen its pharmacovigilance system, insights from this study could guide policy formulation and capacity-building efforts in this critical area of healthcare.

METHODS

Study design and sample:

This cross-sectional study was conducted using a questionnaire, with the participants being currently enrolled health sciences students (i.e. medicine, pharmacy, nursing, bsc.mlt and dentistry) in Nepal. The study protocol was approved by the Institutional Review Committee (IRC-

009-079) of MadanBhandari Academy of Health Sciences, Hetauda, Nepal.

Questionnaire development:

After a thorough examination of the literature to discover existing tools, the questionnaire was created(10) . The questionnaire contain 1) Demographics, 2) Healthcare Students' knowledge of Pharmacovigilance and ADR reporting 3) Attitude towards Pharmacovigilance and ADRs reporting 4) Perception of Pharmacovigilance and ADRs reporting.

Validation of the questionnaire:

Questionnaire was evaluated for its relevancy, content, clarity, and how simple it was to understand the questions. The findings and suggestions of the researchers were considered. Every question on the survey was related to the goals of the study and covered every component of knowledge, attitude, and perception that was being measured. To make sure the questions were appropriate for the intended audience, the survey was pilot-tested among a small group of healthcare students from various healthcare colleges. The final analysis did not include the responses from these participants. The internal consistency "reliability" of the items was calculated using Cronbach's alpha. The survey items demonstrated high internal consistency (Cronbach's alpha for knowledge was 0.8, 0.7 for attitude and, 0.9 for perception).

Data collection:

The survey was distributed online via Google forms and the link was sent via email and social media explaining the purpose of the study. Each eligible participant was asked to complete an informed consent form that explained the purpose of the study and their right to withdraw from the study at any time before proceeding to complete online survey. The survey response rate was 98.3%. Non-responders include those who did not reply to the online survey, those who clicked on the link but did not respond and those who did not complete the survey.

Dependent variables:

The knowledge, attitude, reporting perspective, and actual practice of PV and ADRs in healthcare colleges were the study's dependent factors. We gauged student understanding of pharmacovigilance and ADR reporting by having them choose the right response to 12 questions. Each right answer received a score of 1, while an incorrect response received a score of 0. The least score was 0, and the highest was 12. Using a 5-point Likert scale, attitudes of students regarding pharmacovigilance and ADR reporting were evaluated (1 = strongly agree to 5 = strongly disagree). The minimum score required was 4, and the maximum score was 20. Lower scores suggest a favorable perspective on PV and ADR reporting. Students were asked to choose an answer to three questions in order to gauge their perceptions of pharmacovigilance activities and ADR reporting. The minimum score was 0, and the maximum was 3.

Independent variables:

Participants' age, gender, year of study (first, second, third, fourth, and intern), and type of college (private, governmental) were considered independent variables.

Statistical analysis:

The study findings were described using descriptive statistics. Dependent and independent variables were described using mean, standard deviation (SD), and frequency (%). Bivariate analyses on dependent and independent variables were performed using Chi-square tests. A statistically significant p-value of less than 0.05 was evaluated. SPSS software version 16.0 was used for all statistical analyses.

RESULTS

Demographic information:

Out of a total of 231 health science students who participated, 4 individuals did not complete the survey. The participants had an average age of 22.18±2.2 years. The majority of respondents were female, constituting 66.2% of the sample. Among the participants, approximately 61% (n = 141) were pursuing pharmacy studies, 13.9% (n = 32) were enrolled in nursing programs, 13% (n = 30) were studying Public Health, and 3.5% (n = 8) were medical students. In terms of academic year, 28.6% were in their 4th year, 29.4% were in the 3rd year, 35.1% were in the 1st year, and 5.2% were in the 2nd year. The majority of respondents were affiliated with private colleges, accounting for 56.38% of the sample. For a comprehensive overview of demographic information, the data is presented in Table 1.

Knowledge about Pharmacovigilance and ADRs reporting:

The study highlighted that the mean knowledge score of pharmacy students stood notably higher at 7.7, followed by public health students at 7.06. Elaborated details concerning knowledge among the respondent is presented on table 2.

A total of 184 participants (79.7%) had heard about pharmacovigilance (PV). The study revealed that 74.9% of healthcare students accurately defined PV, and an even higher proportion (92.2%) correctly identified adverse drug reactions (ADRs). Notably, a significantly greater percentage of pharmacy students accurately defined both pharmacovigilance and ADRs in comparison to other health science students (P-value < 0.0000). Additionally, a markedly higher proportion of pharmacy students correctly identified Nepal's governmental monitoring agency and the pharmacovigilance system, in contrast to other healthcare students (P-value < 0.0000).

Further insights regarding the comparison of PV knowledge among healthcare students are comprehensively presented in Table 3, encompassing questions related to pharmacovigilance knowledge and ADR reporting. There is no significant difference between mean knowledge score between private and Government College and the details is shown in table 4.

Table 1: Description of the sample study

	Total N (%)	Pharmacy N (%)	Nursing N (%)	Public Health N (%)	Medical Students N (%)	Dentistry N (%)	Laboratory Sciences N (%)	Others N (%)
Total	231 (100)	141 (61)	32 (13.9)	30 (13)	8 (3.5)	6 (2.6)	6 (2.6)	5 (2.2)
Gender								
Female	153(67.4)	85(36.79)	31(13.41)	25(10.82)	2(0.86)	6(2.59)	2(0.86)	2(0.86)
Male	74 (32.5)	56 (24.24)	1(0.43)	5(2.16)	6(2.59)	0	3(1.29)	3(1.29)
Year of Study								
1 st	81 (35.6)	64(28.19)	3(1.32)	9(33.33)	2(0.88)	0(0.00)	2(0.88)	1(0.44)
2 nd	12(5.28)	3(1.32)	4(1.76)	2(7.40)	1(0.44)	0(0.00)	0(0.00)	2(0.88)
3 rd	68 (29.95)	40(17.62)	11(4.84)	11(40.74)	4(1.76)	0(0.00)	1(0.44)	1(0.44)
4 th	66 (29.07)	34(14.97)	14(6.16)	8(29.62)	1(0.44)	6(2.64)	2(0.88)	1(0.44)
Types of colleges								
Private	128(56.38)	75(33.03)	22(9.69)	15(6.60)	6(2.64)	5(2.20)	2(0.88)	3(1.32)
Public	99(43.61)	66(29.07)	10(4.40)	15(6.60)	2(0.88)	1(0.44)	3(1.32)	2(0.88)

Questions on knowledge of PV and ADR reporting:

1. Have you heard the name of Pharmacovigilance?
2. Are ADR and Adverse drug event same?
3. Who can report ADR
4. Is reporting ADR mandatory?
5. Pharmacovigilance continue throughout:-
6. What is Pharmacovigilance?
7. What is an Adverse Drug Reaction
8. Website of WHO for Pharmacovigilance is.....
9. Type A pharmacological class of Adverse Drug Reaction stands for...
10. Do you know about yellow card scheme.....
11. Hypersensitivity reactions are.....to ADRs

12. The governmental monitoring agency for ADRs in Nepal is.....

Table 2 Mean score of Knowledge among different health care professional students

Education	Knowledge (12)
Pharmacy (n=141)	7.7
Nursing (n=32)	6.75
Public Health (n=30)	7.06
Medical students (n=8)	6.62
Dentistry (n=6)	6.66
Laboratory sciences (n=6)	5.83
Others (n=5)	6

Table 3 Healthcare Students' knowledge of Pharmacovigilance and ADR reporting

Q.N	Total N (%)	Pharmacy N (%)	Nursing N (%)	Public Health N (%)	Medical Students N (%)	Dentistry N (%)	Laboratory Sciences N (%)	Others N (%)	p-value
1	184 (79.7)	130(70.65)	19 (10.32)	22 (11.95)	5 (2.71)	2(1.08)	4 (2.17)	2(1.08)	0.000
2	137 (59)	94 (68.61)	14 (10.21)	17 (12.40)	5 (3.64)	2 (1.45)	2 (1.45)	3 (2.18)	0.000
3	154 (66.7)	89 (57.79)	25 (16.23)	22 (14.28)	6 (3.89)	6 (3.89)	2 (1.29)	4 (2.59)	0.000
4	168 (72.7)	110 (65.47)	21 (12.5)	22 (13.09)	3 (1.78)	6 (3.57)	4 (2.38)	2 (1.19)	0.000
5	145 (62.8)	81 (55.86)	25 (17.24)	24 (16.55)	6 (4.13)	3 (2.06)	4 (2.75)	2 (1.37)	0.000
6	173 (74.9)	120 (69.36)	24 (13.87)	19 (10.98)	3 (1.73)	2 (1.15)	3 (1.73)	2 (1.15)	0.000
7	213 (92.2)	135 (63.38)	30 (14.08)	26 (12.20)	7 (3.28)	6 (2.81)	5 (2.34)	4 (1.87)	0.000
8	115 (49.8)	75 (65.21)	16 (13.91)	15 (13.04)	4 (3.47)	2 (1.73)	2 (1.73)	1 (0.86)	0.000
9	145 (62.8)	101 (69.65)	17 (11.72)	9 (6.20)	5 (3.44)	6 (4.13)	4 (2.75)	3 (2.06)	0.000
10	49 (21.2)	31 (63.26)	3 (6.12)	6 (12.24)	3 (6.12)	3(6.12)	1(2.04)	2 (4.08)	0.000
11	21 (9.1)	16 (76.19)	1 (4.76)	2 (9.52)	0(0)	0 (0)	0 (0)	2(9.52)	0.000
12	179(77.5)	115 (64.24)	21 (11.73)	28 (15.64)	6 (3.35)	2 (1.11)	4 (2.23)	3 (1.67)	0.000

Table 4: Mean Knowledge score of respondent based on college type

College Type/ Questions	1	2	3	4	5	6	7	8	9	10	11	12	Total
Private	.7813± 0.41	.5391±0. 500	.6953±0. 46	1.00±0.0 0	.2266±0. 42	.7656± 0.42	.9375± 0.24	.5156±0. 501	.6328±0. 483	.2578±0. 43	.0625± 0.24	.7578± 0.43	7.114 ±0.54 3
Governmental	.8485± 0.36	.6869±0. 486	.6566±0. 477	1.0000± 0.00	.2727±0. 477	.7576± 0.43	.9394± 0.23	.4949±0. 502	.6465±0. 480	.1616±0. 369	.1313± 0.33	.8283± 0.379	7.36± 0.565

Attitude towards Pharmacovigilance and ADRs reporting:

The study included a set of four questions aimed at assessing the attitudes of healthcare students. The findings indicate that public health students exhibited favorable attitudes toward pharmacovigilance and ADR reporting, with a mean attitude score of 6±3.52, closely followed by

pharmacy students, who achieved a score of 6.13±3.655. Further insights into attitude scores are presented in Table 5. Moreover, the data reveals that governmental college students displayed more positive attitudes when compared to their counterparts in private colleges. Specific details regarding these attitude scores are outlined in Table 6.

Table 5: Mean Attitude of respondent based on different program

Programs	Reporting ADR make a significant contribution to reporting system	Reporting ADR make a significant contribution to patient safety	Reporting ADR is a responsibility of me	Reporting ADR should be made compulsory for all healthcare professionals	Total
Medicine	2.25±1.389	1.75±1.165	1.25±.463	1.50±0.756	6.75±3.77
Pharmacy	1.65±0.971	1.33±0.772	1.63±0.989	1.52±0.923	6.13±3.655
Dentistry	1.83±0.983	1.83±1.329	1.50±0.548	1.67±1.633	6.83±4.49
Nursing	1.63±0.871	1.69±0.998	1.59±0.911	1.63±0.833	6.54±3.61
Public Health	1.43±0.679	1.37±1.066	1.73±1.172	1.47±0.937	6±3.52
Others	1.60±1.34	1.80±1.30	2.20±1.30	1.60±1.34	7.2±5.28

Table 6: Mean Attitude of respondent based on college type

Collegetype	Reporting ADR make a significant contribution to reporting system	Reporting ADR make a significant contribution to patient safety	Reporting ADR is a responsibility of me	Reporting ADR should be made compulsory for all healthcare professionals	Total mean
Private	1.61±0.941	1.50±1.019	1.72±1.094	1.56±1.002	6.39±4.05
Governmental	1.70±0.952	1.33±0.7	1.59±0.845	1.51±0.825	6.13±3.32

Perception of Pharmacovigilance and ADRs reporting:

There were 4 perception related questions. The study found that around 35.6% of healthcare students perceive that they are adequately prepared to report ADRs. Around 65.1 % of students believed that PV and ADR reporting system

education is needed in their schools, and 55.06 % showed a willingness to participate in such education. Table 6 shows that a significantly higher percentage of pharmacy students have better perceptions regarding the need for PV education and willingness to participate in PV education.

Table 6 Perception of Pharmacovigilance and ADRs reporting

Q.N	Total N (%)	Pharmacy N (%)	Nursing N (%)	Public Health N (%)	Medical Students N (%)	Dentistry N (%)	Laboratory Sciences N (%)	Others N (%)	p-value
Do you feel you are adequately prepared to report ADR in your future practice?	81 (35.6%)	56 (69.1)	10 (12.34)	8 (9.87)	1 (1.23)	2 (2.46)	1 (1.23)	3 (3.70)	0.038
Do you believe that all medical students' need education about PV and ADR reporting system?	148 (65.1%)	100 (67.56)	18 (12.16)	21 (14.18)	4 (2.70)	1(0.67)	1 (0.67)	3 (2.02)	0.000
If you offered an opportunity to undertake education in PV and ADR reporting system, would you be willing to participate?	125(55.06%)	82 (65.6)	13 (10.4)	22 (17.6)	2 (1.6)	1 (0.8)	2 (1.6)	3 (2.4)	0.000

DISCUSSION

Presently, Nepal boasts a network of 15 regional pharmacovigilance centers, with a notable concentration within the nation's capital, Kathmandu. Interestingly, 13 out of these 15 centers are affiliated with academic hospitals, underscoring their significance in the healthcare landscape(11). The prevailing circumstances in the country could potentially be linked to a deficiency in students' comprehension of pharmacovigilance and the reporting of adverse drug reactions (ADRs). The educational curriculum and training programs in Nepal may not be adequately equipped to address these complexities, leading to students grappling with the intricacies of pharmacovigilance and ADR reporting(12).

In the PV program, where spontaneous reporting of ADR is crucial, under-reporting is a key concern. Therefore, it is essential to evaluate health care students' PV knowledge, attitude, and perceptions, especially at a Regional PV Center, as doing so ensures the level of correct information, attitude, and reporting an ADR practice(13). All healthcare students should be alert for any unexpected or suspected drug reactions in patients, assessing, managing, and reporting any adverse events that happen as part of the pharmaceutical care process because ADRs are a significant cause of morbidity and mortality as well as increased healthcare costs(14).

The current study revealed that students had little awareness of many facets of PV. The findings from the current study and those from investigations conducted in China, Yemen, Pakistan, India, Iran, Nigeria, and Malaysia were quite comparable(15). This may be due to the fact that the PV programs in many nations, including Nepal, are still in the early stages of development. Although student understanding in South East European nations was adequate, underreporting of ADR remained a problem in these nations as well(16)(17). Thapa et al. did comparable study with healthcare professionals and pharmacy students in Dharan, where the maximum knowledge score was 22 and pharmacy students received 15.5 points which is very similar to our study(18).

The study's findings, which indicate that only 49.8% of respondents answered questions about the WHO website for pharmacovigilance correctly, while even fewer were knowledgeable about the Yellow Card Scheme (21.2%) and hypersensitivity reactions (9.1%) which is not comparable to the study carried out in Saudi Arabia by Alwhaibi et al. the notable disparity in pharmacovigilance knowledge levels between respondents in Nepal and those in Saudi Arabia, as highlighted in the study, underscores the need for curriculum improvements in healthcare education in Nepal. Addressing these deficiencies can enhance patient safety, align healthcare practices with global standards, and contribute to more effective pharmacovigilance efforts in the country(19).

It is encouraging to observe that both public health and pharmacy students exhibited positive attitudes towards pharmacovigilance and ADR reporting. This indicates that these cohorts of healthcare students recognize the importance of monitoring and reporting ADRs as a crucial aspect of patient safety and public health. The mean attitude scores of 6 ± 3.52 for public health students and 6.13 ± 3.655 for pharmacy students suggest a strong inclination towards responsible pharmacovigilance practices. This finding is similar to the finding of Palaian et al in which most of the health professionals shows the positive attitude towards reporting of ADR(20). The distinction in attitudes between students from governmental and private colleges is an intriguing finding. Governmental college students demonstrated more favourable attitudes, suggesting that institutional factors or curriculum differences may influence students' perceptions. Further research is warranted to explore the specific reasons behind this variation, as it could inform educational strategies and policies.

Moreover, more than half of the students, specifically 55.06%, demonstrated a willingness to actively participate PV education programs. This willingness highlights their commitment to enhancing their knowledge and skills in the field of PV and ADR reporting, which is essential for ensuring patient safety and the effectiveness of healthcare systems. Interestingly, when comparing healthcare students across different disciplines, it became evident that pharmacy students, in particular, exhibited significantly more positive perceptions regarding the necessity of PV education and

their eagerness to engage in such educational initiatives. This distinction may be attributed to the specialized nature of their field and the emphasis on drug-related matters within their curriculum.

The adverse drug events is the condition in which person is harmed by medicine(21) while adverse drug reaction is an appreciably harmful or unpleasant reaction resulting from an intervention related to the use of a medicinal product but only 59% of the students were able to distinguish adverse drug reaction and adverse drug events which is not the significant number. The healthcare students should clearly distinguish the ADR and ADE(22).

CONCLUSION

The current study found that health sciences students' understanding of the WHO pharmacovigilance reporting website, the yellow card program, and hypersensitivity reactions was lacking. Students' views about pharmacovigilance and ADR reporting are not significant. In a similar study, it is discovered that the majority of students are not sufficiently trained to report ADR in future practice. Comparing to other healthcare professionals, pharmacy students had significant attitudes, knowledge, and perception. Thus, the current study strongly emphasizes that raising awareness and enhancing student knowledge through regular sensitization programs, trainings, and timely feedback is a very crucial strategy to increase spontaneous ADRs reporting in health facilities to the concerned body, which ultimately impacts student learning.

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Conflict of Interest

None

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