Assessment of Knowledge and Attitude in Adverse Drug Reaction (ADR) Reporting of Final Year Undergraduate Pharmacy Students

Gopal Pokhrel, Gulshan Jahan Ansari, Rojina Napit, Santosh Kafle and Dipesh Kumar Yadav

Department of Pharmacy, Karnali College of Health Sciences, Kathmandu, Nepal

Abstract: Introduction: Adverse drug reaction (ADR) reporting is an important role of pharmacist apart from preparation and dispensing of prescribed drugs. A pharmacist can also educate the physicians and nurses, and can encourage participating in ADR reporting program. ADR is a major health problem that occurs worldwide and lack of ADR reporting makes it even more upsetting. **Objectives:** To assess the Knowledge and Attitude of final year undergraduate pharmacy students towards ADR reporting. **Methodology:** Descriptive, cross-sectional study was performed in 88 final year pharmacy students in selected colleges of Kathmandu valley that are affiliated to Purbanchal University. Printed Questionnaires were used to collect the data and collected data were reviewed, coded and analyzed by using SPSS version 16.Findings: Majority of the participants were female and were age group 20-25 with mean age 24.46 years. There is significant difference in knowledge of ADR reporting between male and female. **Conclusions:** Majority of the participants (i.e. 95.45%) have good knowledge on ADR reporting and final year pharmacy undergraduate students have good attitude towards ADR reporting. Therefore, to enhance ADR reporting pharmacist should be encouraged.

Key words: ADR reporting, Attitude, Knowledge.

1. Introduction

Adverse Drug Reaction (ADR) is defined by World Health Organization (WHO) as, "any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function" [1]. ADR is estimated to be the fourth leading cause of death in the United States and Canada and the sixth leading cause of death worldwide [2, 3]. The role of a pharmacist has been expanding from preparation and dispensing of prescribed drugs to patient care services including ADRs reporting, improving health of patients and improving economic outcomes [4]. A pharmacist can educate the physicians and nurses, and can encourage towards ADR reporting program [5].

National pharmacovigilance centre plays significant role in drug safety. Pharmacovigilance (PV) in Nepal is still in its infancy [6]. Nepal became a member of WHO Uppsala Monitoring Centre in 2007. The national pharmacovigilance centre coordinates with seven centres in Nepal of which five are situated in the Kathmandu valley. These centres collect ADR reports from health care professionals and forward them to the Department of Drug Administration (DDA) in Kathmandu from where the reports are sent to the Uppsala Monitoring Centre in Sweden which serves as a centre for international service and scientific research towards patient safety using an online program called Vigiflow [7]. Underreporting of ADR is widely prevalent in Nepal [8]. In Nepal, ADR reporting is not obligatory for pharmacist. This study was conducted to assess the Knowledge and Attitude of final year undergraduate pharmacy students towards ADR reporting.

Corresponding author: Gopal Pokhrel, Lecturer, research field: pharmacy. Email: gopalpokhrel70@gmail.com.

2. Methodology

The study was a descriptive, cross-sectional study conducted in final year pharmacy students from selected Bachelor of Pharmacy (B.Pharm) colleges of Kathmandu valley that are affiliated to Purbanchal University. Purposive sampling technique was used where 4 selected colleges in Kathmandu valley among 6 were selected using lottery method. 22 students were selected from each college using systematic sampling technique using attendance sheet.

2.1 Sample Size

Sample size was calculated using the Cochrane formula:

$$n = \frac{Z^2 \times p \times q \times deff}{d^2}$$

Where, n - the required sample size, Z - Score at confidence interval 95% = 1.96, P - Prevalence of ADR reporting as per previous study = 92% [9].

i.e. 0.92 (q = (1-P) = (1 - 0.92) = 0.08)

d is allowable error = 5%; i.e. 0.05

deff refers the design effect = 1.5

Now,

$$n_o = \frac{1.96^2 * 0.92 * 0.08 * 1.5}{0.05^2} = \frac{0.424}{0.0025} = 170$$

Again, for finite population

$$n = \frac{n}{1 + \frac{n_o - 1}{N}}$$

Where, n_o = required sample size; i.e. 170

N = Total number of final year students studying in the pharmacy colleges of Kathmandu valley that are affiliated to Purbanchal University

$$n = \frac{170}{1 + \frac{170-1}{180}} = 88$$

Thus, the desired sample size is 88.

2.2 Inclusion Criteria

- ➢ Willing to give consent
- ➢ Final year pharmacy students

2.3 Exclusion Criteria

1st, 2nd and 3rd year pharmacy students.

For the ethical consideration, approval letter was taken from college. Informed consent was taken from the selected college and the participants involved in the study.

2.4 Pretesting, Validity and Reliability of Tool

Pre-testing was done in 10% of calculated sample size in final year undergraduate pharmacy students in Karnali College of Health Sciences. Pre-tested data were excluded in the study. After pre-test, the questions were consulted with 3 clinical pharmacists and one statistician to maintain validity. Reliability was established by cross checking or rechecking the tools that are required for data collection. The internal consistency of the tool will be established through Cronbach alpha method.

2.5 Data Collection Tools and Techniques

The questionnaire included 3 domains: demographics, knowledge and attitude regarding ADR reporting. First domain included 4 questions about demographics details.

Domains of knowledge was consisted of 9 multiple choice questions about ADR reporting where a score of 1 set for the answer 'yes' and a score of 0 set for the answer 'no'. The total score were compared with the guideline scoring to interpret the level of knowledge.

The guideline for scoring was as follows:

Total score = Addition of the scores for all 9 items

Total score categories:

0-3 = no or little knowledge

4-9 = sufficient knowledge

Domain of attitude was comprised of 12 questions with 5 sub questions each, designed to five-point Likert scale (1 = strongly disagree and 5 = strongly agree).

2.6 Data Management and Analysis

Printed questionnaires were used for data collection.

All the collected data were reviewed, checked, coded, organized and entered in SPSS (Statistical Package for the Social Sciences). Data were analyzed using SPSS version 16 for statistical analysis. Descriptive statistics for all studied variables and chi-square test was used. A p-value < 0.05 was considered significant throughout the study.

3. Results

3.1 Demographic Characteristics of the Study

Population.

Table 1 showed that majority of the participants were female, 54 (61.4%) and 34 (38.6%) were male.

Table 1   Gender analysis.

Gender	Frequency	Percent (%)
Male	34	38.6
Female	54	61.4
Total	88	100.0

Fig. 1 showed that majority of the participants was age group 20-25 with mean age 24.46 years.
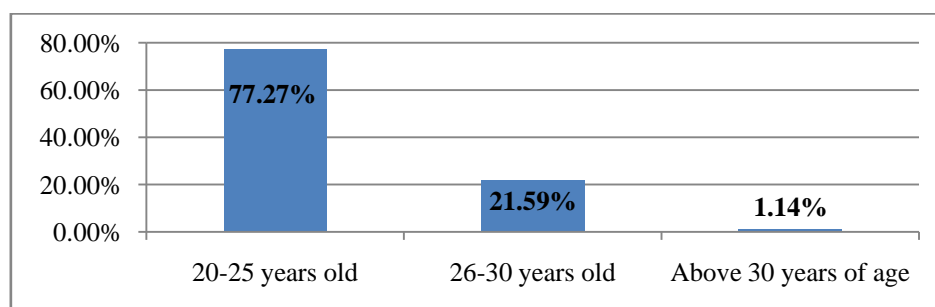

Fig. 1   Age group analysis (Mean age: 24.46).

Table 2 showed that 72.7% strongly agreed that ADR reporting is necessary whereas 27.3% agreed with ADR reporting. Similarly, 71.6% agreed that ADR reporting should be voluntary, 55.7% strongly agreed with ADR reporting should be compulsory, 55.7% strongly agreed that Pharmacovigilance should be taught to all health care students during their curriculum, 51.1% strongly agreed that information on reporting ADRs should be taught to all health care students in their curriculum. Likewise, 65.9% strongly agreed that pharmacist is one of the most important health care professional to report ADRs.

Table 2   Attitude of respondents towards ADR Reporting.

Questions	Likert scale					Missing
	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	
Do you think adverse drug reaction reporting is necessary?				27.3%	72.7%	
Do you think reporting adverse drug reaction is a professional obligation?	1.1%	8.0%	21.6%	40.9%	22.7%	5.7%
Do you think ADR reporting should be voluntary?		3.4%	10.2%	71.6%	12.5%	2.3
Do you think ADR reporting should be compulsory?		2.3%	1.1%	40.9%	55.7%	
Do you think that it is necessary to report only serious and unexpected reactions?	5.7%	40.9%	14.8%	21.6%	15.9%	1.1
Pharmacovigilance should be taught to all health care students during their curriculum?		2.3%	2.3%	38.6%	55.7%	1.1
The topic on pharmacovigilance is well covered in my curriculum.	2.3%	12.5%	21.6%	35.2%	25.0%	3.4
I do not have any idea on how to report ADRs to the relevant authorities in Nepal.	5.7%	30.7%	26.1%	30.7%	5.7%	1.1
Information on reporting ADRs should be taught to all health care students in their curriculum.		1.1%	5.7%	42.0%	51.1%	
Information on reporting ADRs shall be better learnt during the internship/training/clinical Posting		4.5%	10.2%	47.7%	36.4%	1.1

Table 2 continued.

A pharmacist is one of the most important health care professional to report ADRs.		1.1%	3.4%	28.4%	65.9%	1.1
With my present knowledge, I am very well prepared to report any ADRs notice in my future practice.	1.1%	10.2%	19.3%	52.3%	15.9%	1.1

Table 3 showed that there is association between male and female in knowledge of ADR reporting because p-value of Pearson's chi-square test is 0.035* (p < 0.05). The result indicates that there is significant difference in knowledge of ADR reporting between male and female.

Table 3   Association between knowledge on ADR reporting and gender.

Chi-Square Value	p-value
8.578[a]	0.035 *

Fig. 2 showed that majority of the participants (i.e. 95.45%) has good knowledge on ADR reporting whereas 4.55% participants do not have sufficient knowledge on ADR reporting.
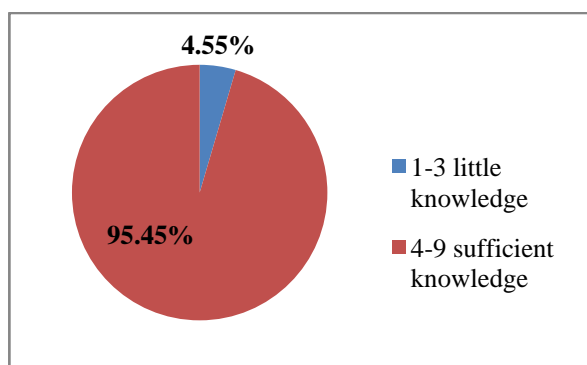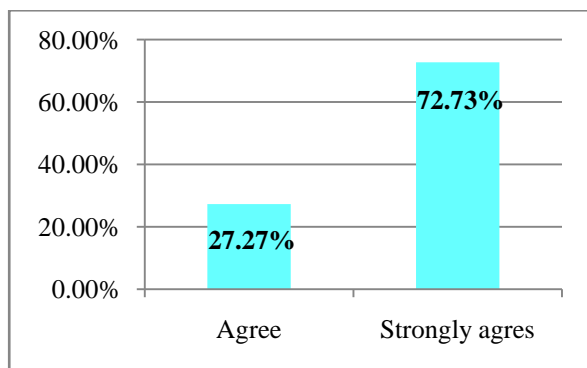

Fig. 2   Level of knowledge of ADR reporting.

Fig. 3 showed that 72.73% respondents strongly agreed and 27.27% agreed that ADR reporting is necessary.

Fig. 3   Attitude towards ADR reporting.

4. Discussion

Our study showed that among 88 respondents, 61.4% were female and 38.6% were male. Similarly as per Reddy et al [10], female were 50.7% and male were 49.3%, which showed that majority of, respondents were female. According to Nair et al [5], the gender distribution was found to be 34.4% male and 65.6% of female and study conducted in 244 community pharmacists; the mean age of participants was found to be 27.08 years. Whereas in our study the mean age group was found to be 24.46 years since our study was carried out on the undergraduate final year pharmacy students rather than community pharmacists. However, according to study by Rajiah et al [11], the mean age was found to be 22.9 years.

In our study, 72.7% were found to strongly agree that ADR reporting is necessary. A study by Sivadasan [12] showed that 69.0% strongly agreed that an ADR report was necessary. The findings of Palaian [6] show that 96.6% strongly agree that ADR reporting is necessary. Our research found that 55.7% of respondents strongly agreed that pharmacovigilance should be taught to all healthcare students during the course. According to the findings of Farcas [9], 75.4% strongly agreed that pharmacovigilance should be taught to all healthcare students during the course. Similarly, the study by Tekel et al. [13] showed that 49.0% strongly agreed that pharmacovigilance should be taught in the curriculum of all healthcare students. A study by Sivadasan [12] showed that 35.7% strongly agreed that pharmacists were among the most important healthcare professionals reporting ADRs.

5. Conclusions

This study showed thatmajority of the participants (i.e. 95.45%) have good knowledge on ADR reporting and final year pharmacy undergraduate students have good attitude towards ADR reporting. Therefore, to enhance ADR reporting pharmacist should be encouraged.

Funding Statement

Declaration of Conflicting Interests

The Authors declare that there is no conflict of interest.

References

[1] World Health Organization. Technical Report No 498: international drug monitoring, the role of national centres. Geneva: The Institute. 1972.

[2] Kongkaew, C., Noyce, P. R., and Ashcroft, D. M. 2008. "Hospital Admissions Associated with Adverse Drug Reactions: A Systematic Review of Prospective Observational Studies." *Ann Pharmacother* 42 (7-8): 1017-25.

[3] Lazarou, J., Pomeranz, B. H., and Corey, P. N. 1998. "Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-analysis of Prospective Studies." *JAMA* 279 (15): 1200-5.

[4] Othman, G. Q., Ibrahim, M. I. M., Alshakka, M., et al. 2017. "Knowledge and Perception about Pharmacovigilance among Pharmacy Students of Universities in Sana'a Yemen." *J Clin Diagn Res* 11 (6): FC09-FC13. doi: 10.7860/JCDR/2017/24228.10028.

[5] Alwhaibi, M., and Al Aloola, N. A. 2020. "Healthcare Students' Knowledge, Attitude and Perception of Pharmacovigilance: A Systematic Review." *PLoS One* 15 (5): e0233393. doi: 10.1371/journal.pone.0233393.

[6] Palaian, S., Ibrahim, M. I., and Mishra, P. 2011. "Health Professionals' Knowledge, Attitude and Practices towards Pharmacovigilance in Nepal." *Pharm Pract (Granada)* 9 (4): 228-235.

[7] Jha, N., Rathore, D. S., Shankar, P. R., et al. 2015. "Strengthening Adverse Drug Reaction Reporting in Nepal." *Asian Journal of Medical Sciences* 6 (4): 9-13.

[8] Danekhu, K., Shrestha, S., Aryal, S., and Shankar, P. R. 2021. "Health-care Professionals' Knowledge and Perception of Adverse Drug Reaction Reporting and Pharmacovigilance in a Tertiary Care Teaching Hospital of Nepal." *Hosp Pharm* 56 (3): 178-86.

[9] Farcaş, A., Bucşa, C., Crişan, A., et al. 2021. "Knowledge, Opinion and Attitudes towards Adverse Drug Reactions Reporting among Pharmacy Students in Romania." *Farmacia* 69 (3): 602-8.

[10] Reddy, V. L., Pasha, S. J., Rathinavelu, M., and Reddy, Y. P. 2014. "Assessment of Knowledge, Attitude and Perception of Pharmacovigilance and Adverse Drug Reaction (ADR) Reporting among the Pharmacy Students in South India." *IOSR-JPBS* 9 (2): 34-43.

[11] Rajiah, K., Maharajan, M. K., and Nair, S. 2016. "Pharmacy Students' Knowledge and Perceptions about Adverse Drug Reactions Reporting and Pharmacovigilance." *Saudi Pharm J* 24 (5): 600-4.

[12] Sivadasan, S., Yuong, N. Y., Chyi, N. W., et al. 2014. "Knowledge and Perception towards Pharmacovigilance and Adverse Drug Reaction Reporting among Medicine and Pharmacy Students." *World Journal of Pharmacy and Pharmaceutical Sciences* 3 (3): 1652-76.

[13] Tekel, M. T., Bekalu, A. F., and Sema, F. D. 2021. "Knowledge, Attitude, and Practice of Medical, Pharmacy, and Nursing Students Towards Pharmacovigilance and Adverse Drug Reaction Reporting at University of Gondar College of Medicine and Health Sciences, Northwest Ethiopia: A Cross-Sectional Study." *Advances in Medical Education and Practice* 12: 1129-1139.