

Assessment of Knowledge, Attitude and Practices of Pharmacovigilance and Adverse Drug Reactions Reporting Among Health Care Professionals in Tertiary Care Hospital of Western Nepal

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Abstract

Introduction: Ensuring patient safety and drug efficacy is a primary responsibility of healthcare professionals (HCPs). Pharmacovigilance (PV) plays a crucial role in identifying, assessing and preventing adverse drug reactions (ADRs) thereby promoting the safe and rational use of medicines in clinical practice. This study aimed to evaluate the knowledge, attitude, and practice (KAP) regarding pharmacovigilance and ADR reporting among healthcare professionals in a tertiary care hospital in Pokhara, Nepal.

Methods: A cross-sectional, prospective study was conducted among HCPs working in Pokhara Academy of Health Sciences (PoAHS). Data was collected by a structure and pretested questionnaire through convenience sampling method. Statistical package for social sciences (SPSS) version 23 was used for performing data analysis. Descriptive statistics were used to analyze the data

Results: A total of 102 healthcare professionals participated, with nurses forming the majority. While 55.88% of participants had encountered ADRs during their practice, only 10.78% had reported them to pharmacovigilance centers. Overall, 83.3% of respondents demonstrated good knowledge, and 93.13% expressed a positive attitude toward PV. However, only 8.8% exhibited good practices related to ADR reporting.

Conclusion: The findings of this study concluded that majority of healthcare professionals demonstrated positive knowledge and attitude but negative practice towards pharmacovigilance and adverse drug reaction reporting. Therefore the study highlights an urgent need for targeted educational programs, training sessions, workshops and establishment of PV unit in the healthcare setting to enhance awareness and improve ADR reporting behaviors among healthcare professionals.

Keywords: Adverse drug reaction, Attitude, Health care professionals, Knowledge, Practice, Pharmacovigilance

Introduction

For all medical personnel, ensuring the safety and well-being of patients taking medications is of utmost importance. An adverse drug reaction (ADR) is defined as an undesirable and harmful reaction to a medication that occurs at standard doses used for the prevention, diagnosis or treatment of disease or for altering physiological functions.¹ The World Health Organization defines pharmacovigilance (PV) as the science and activities related to the detection, assessment, understanding and prevention

of adverse effects or any other drug-related problems. Pharmacovigilance is essential for promoting the safe and rational use of medicines, thereby protecting patient health.²

A vital component of pharmacovigilance is post-marketing surveillance, which helps in the detection of rare and population-specific ADRs that may go unnoticed during clinical trials.³ ADRs are the fifth leading cause of mortality worldwide and account for approximately 3–4% of all hospital admissions. ADRs also present a significant clinical and economic burden in South Asian countries. A study conducted at Bhaktapur Cancer

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Hospital found a high occurrence of ADRs among cancer patients, with each enrolled patient experiencing one or more reactions and a mean of 8.44 ADRs per patient related to chemotherapy drugs.⁴ Similarly, a study conducted in South India reported that 26.88% of identified patients experienced ADRs, resulting in high management costs and prolonged hospital stays.⁵

The pharmacovigilance system in Nepal is still developing and currently covers only a limited number of institutions and geographical areas.⁶ The Department of Drug Administration serves as the national pharmacovigilance center and receives ADR reports from regional pharmacovigilance centers, which are then forwarded to the Uppsala Monitoring Centre.⁷ The Uppsala Monitoring Centre collects, assesses, and disseminates data from the national pharmacovigilance programs of member countries.⁸ Numerous studies have shown that improving healthcare professionals' knowledge, attitudes, and practices (KAP) regarding pharmacovigilance is crucial for developing effective strategies to strengthen the ADR reporting system and enhance patient safety.^{9,10}

Despite the importance of assessing healthcare professionals' KAP regarding pharmacovigilance and ADR reporting for ensuring patient safety, only a few studies have been conducted in Nepal. The findings of this study could help improve healthcare professionals' knowledge, attitudes, and practices regarding pharmacovigilance and ADR reporting, thereby enhancing patient safety. Therefore, the primary objective of this study was to assess the knowledge, attitudes, and practices regarding pharmacovigilance and ADR reporting among healthcare professionals working at Pokhara Academy of Health Sciences.

Methods

A cross-sectional descriptive study was conducted among healthcare professionals at Pokhara Academy of Health Sciences, one of the major tertiary care hospitals in Gandaki Province. Data collection was carried out from December 1 to December 30, 2023. Healthcare professionals, including doctors, nurses, and pharmacists working at PoAHS during the study period, were included in the study, while other healthcare personnel such as Health Assistants (HAs) and Certified Medical Assistants (CMAs) were excluded.

Based on a review of previous surveys of a similar nature, a questionnaire was developed in English with necessary modifications.^{11,12,13} Once the initial version was prepared, it underwent a thorough review and validation process. Content validity was assessed through a pilot study conducted among 11 randomly selected healthcare professionals (HCPs) working in the same hospital setting. Cronbach's alpha was calculated and yielded a value of 0.7, indicating satisfactory reliability and internal consistency of the questionnaire items. The validated questionnaire consisted of two parts. The first part included demographic information of the participants, while the second part consisted of KAP-related questions, comprising a total of 27 items: 14 assessing knowledge, 7 evaluating attitude, and 6 examining practice.

A convenience sampling method was used for data collection. Respondents were requested to provide written informed consent, ensuring anonymity and voluntary participation in the study. The validated questionnaires were distributed to each respondent after obtaining written informed consent. Completed questionnaires were then collected and used for

data analysis. Statistical Package for the Social Sciences (SPSS) version 23 (SPSS Inc., Chicago, IL, USA) was used for data analysis. Descriptive statistics were applied to analyze the data. Continuous variables were presented as mean $\pm$ standard deviation (SD), whereas categorical variables were expressed as frequencies and percentages. Ethical approval was obtained from the Institutional Research Committee (IRC) of Pokhara Academy of Health Sciences (Ref no: 189/80) prior to the commencement of the study.

Results

Total 102 participants were included in the study

Table 1: Socio-demographic characteristics of participants (n=102)

Characteristics	Frequency	Percentage
Mean Age 28.58 ± 6.284		
Profession		
Doctor	24	23.5
Pharmacist	10	9.8
Nurses	68	66.7
Sex		
Male	44	43.1
Female	58	56.9
Experience		
< 1 year	6	5.9
1 – 5 years	51	50
5 – 10 years	30	29.4
> 10 years	15	14.7

Table 1 summarizes the socio-demographic characteristics of the participants. The mean age of the participants was 28.58 ± 6.28 years. Most participants were nurses (66.7%), followed by doctors (23.5%) and pharmacists (9.8%). In terms of sex, 56.9% were female and 43.1% were male. Regarding work experience, half of the participants had 1–5 years of experience, while 29.4% had 5–10 years, 14.7% had more than 10 years, and 5.9% had less than one year of experience.

Table 2: Knowledge of the respondents towards pharmacovigilance (n=102)

S.N.	Question	Option	Number (n)	Percentage (%)
1.	Pharmacovigilance studies best defines as?	a. The science and activities of detecting, assessing, understanding & preventing adverse effects b. The process of improving the safety of drugs c. The science of detecting the type & incidence of ADRs after a drug is marketed d. The science of monitoring ADRs happening in a Hospital	92 7 2 1	90.16 6.86 1.96 0.98
2.	The purpose of pharmacovigilance	a. To enhance patients' safety in relation to use of drugs b. To calculate incidence of drug administration c. To report all the drugs used in hospital d. To promote proper recording and reporting of narcotics	96 1 1 4	94.11 0.98 0.98 3.92
3.	The health care professionals responsible for reporting ADRs in a hospital is/are	a. Doctor b. Pharmacist c. Nurses d. All of the above	10 7 3 82	9.80 6.86 2.94 80.39
4.	Are you aware of any drugs that has been banned due to ADRs?	a. Yes b. No	50 52	49.01 50.98
5.	Do you think that ADR reporting and monitoring system would benefit the patient?	a. Yes b. No	96 6	94.11 5.88
6.	Is there any nearby ADR reporting and monitoring center in your knowledge?	a. Yes b. No c. Don't know	18 37 47	17.64 36.27 46.07
7.	Which method is commonly employed by pharmaceutical companies for pharmacovigilance of new drugs once they are launched in the market?	a. Marketing b. Post marketing surveillance c. Feedback d. Adverse drug reaction reporting	9 49 12 32	8.82 48.03 11.76 31.37
8.	Which government body is responsible for ADRs monitoring in Nepal?	a. Nepal Pharmacy Council b. Nepal Nursing Council c. Department of drug administration d. Don't know	16 2 83 1	15.68 1.96 81.37 0.98
9.	The chain for reporting ADR in Nepal is	a. Hospital to regional Pharmacovigilance (PV) center department of drug administration (DDA) to Ministry of health and population (MoHP) b. Hospital to regional PV center to international drug monitoring center c. Hospital to pharmaceutical company to DDA to MOHP d. Hospital to pharmaceutical company to regional PV center to MoHP	83 1 12 6	81.37 0.98 11.76 5.88
10.	ADRs should be reported to whom?	a. Head of Department of your Institute b. Nearby regional pharmacovigilance center c. Government d. Drug Manufacturer e. All the above	6 42 1 10 43	5.88 41.17 0.98 9.80 42.15
11.	ADR in Nepal is reported through	a. By post b. Standard reporting form c. Telephone d. Email	0 87 7 8	0 85.29 6.86 7.84
12.	Role of a regional pharmacovigilance Centre is	a. To report ADRs to national pharmacovigilance center b. To coordinate with international federation of pharmacovigilance centers c. To report ADRs to the international pharmacovigilance center d. To report ADRs to council for international organizations of medical sciences	77 12 4 9	75.49 11.76 3.92 8.82
13.	Which of the following centers is a collaborating center for WHO programme for international drug monitoring?	a. International pharmaceutical federation, Netherland b. Food and drug administration, USA c. Uppsala monitoring center, Sweden d. Medicines and health care products, regulatory agency, UK	28 28 37 9	27.45 27.45 36.27 8.82
14.	Following types of ADR must be reported except	a. Bizzare ADR b. Life threatening ADR/ serious ADR c. Suspected ADR d. Causal ADR/ side effect	14 7 19 62	13.72 6.86 18.62 60.78

Table 2 reveals the knowledge of healthcare professionals (HCPs) regarding pharmacovigilance. A total of 90.19% of the participants correctly defined pharmacovigilance, and 94.11% were aware of its purpose. Regarding awareness of the national pharmacovigilance authority, 81.37% of healthcare professionals in our study identified the Department of Drug Administration (DDA) as the government body responsible for monitoring adverse drug reactions (ADRs) in Nepal. In terms of knowledge related to post-marketing surveillance, 48.04% of participants in our study were aware that it is a commonly employed method used by pharmaceutical companies for monitoring new drugs after market release. Awareness of the Uppsala Monitoring Centre (UMC) as the WHO Collaborating Centre for International Drug Monitoring was found among 36.27% of participants. Our findings also revealed that 49.01%

of healthcare professionals were aware of at least one drug banned due to ADRs. Lastly, 85.29% of participants in our study reported that a standard ADR reporting form is used in Nepal.

Table 3 depicts the attitude of participants towards pharmacovigilance. In the current study, 92.15% of healthcare professionals (HCPs) agreed that reporting adverse drug reactions (ADRs) is essential. Furthermore, 66.67% of participants believed that ADR reporting does not reflect professional mistakes nor does it harm the image of healthcare providers. Regarding professional responsibility, 80.39% of participants in our study viewed ADR reporting as a professional obligation. Additionally, 91.17% of participants believed that pharmacovigilance should be incorporated into the education and training of healthcare professionals, and 66.66% supported the establishment of ADR monitoring centers in every hospital.

Table 3: Respondents attitude towards pharmacovigilance (n=102)

S.N.	Questions	Options	Number(N)	Percentage(%)
1.	Do you think reporting of adverse drug reaction is necessary?	a. Yes b. No c. Can't say d. May be	94 3 3 2	92.15 2.94 2.94 1.96
2	Do you think Pharmacovigilance should be taught in detail to healthcare professionals?	a. Yes b. No c. Can't say d. May be	93 5 1 3	91.17 4.90 0.98 2.94
3	Have you anytime read any article on prevention of adverse drug reactions?	a. Yes b. No c. Can't say d. May be	55 35 1 11	53.92 34.31 0.98 10.78
4	What is your opinion about establishing ADR monitoring centre in every hospital?	a. Should be in every hospital b. Not necessary in every hospital c. One in a city is sufficient d. Depends on number of bed size in the hospitals	68 9 15 10	66.66 8.82 14.70 9.80
5.	Reporting of ADR is the exploration of mistakes of health professionals?	a. Yes b. No c. Can't say d. May be	22 68 2 10	21.56 66.66 1.96 9.80
6	Reporting of ADR will increase patient safety?	a. Yes b. No c. Can't say d. May be	89 9 3 1	87.25 8.82 2.94 0.98
7	Is it our professional obligation to report ADR?	a. Yes b. No c. Can't say d. May be	82 8 2 10	80.39 7.84 1.96 9.80

Table 4: Practice of pharmacovigilance among respondents (n=102)

S.N	Questions	Options	Number(N)	Percentage (%)
1.	Have you ever observed an adverse drug reaction (ADR) in patients during your professional practice?	a.Yes b. No	57 45	55.88 44.11
2.	Have you ever reported any adverse drug reaction to pharmacovigilance center	a. Yes b. No	11 91	10.78 89.21
3.	Have you ever received any training on ADR reporting?	a. Yes b. No	11 91	10.78 89.21
4.	Do you feel that proper training should be provided to the health care personnels for ADR reporting?	a. Yes b. No c. Don't know	90 10 2	88.23 9.80 1.96
5	Have you ever seen the ADR reporting form	a. Yes b. No	20 82	19.60 80.39
6.	Is there any action in practice to minimize ADR in your institution?	a. Yes b. No c. Don't know	22 32 48	21.56 31.37 47.05

Table 4 summarizes the practice of pharmacovigilance among respondents. In this study, 55.88% of healthcare professionals (HCPs) reported having encountered adverse drug reactions (ADRs) during their clinical practice; however, only 10.78% of them had formally reported these incidents to pharmacovigilance (PV) centers. Furthermore, 89.21% of healthcare professionals (HCPs) had not received any formal training on ADR reporting. As a result, 88.23% of respondents expressed the need for proper training on ADR reporting for HCPs. In addition, only 21.56% of participants were aware of any institutional measures or practices aimed at minimizing ADRs in their institution.

Table 5: KAP score category of respondents (n=102)

Variables	KAP category	
	Good/positive (number/percentage)	Poor/negative (number/percentage)
Knowledge	85 (83.3)	17 (16.7)
Attitude	95 (93.13)	7 (6.9)
Practice	9(8.8)	93 (91.2)

Table 5 depicts the knowledge, attitude, and practice (KAP) categories among healthcare professionals, revealing varying levels of awareness and engagement with pharmacovigilance. Based on the scoring criteria, 83.3% of respondents demonstrated good knowledge, while 16.7% fell into the poor knowledge category. A vast majority (93.1%) of participants exhibited a positive attitude toward ADR reporting, whereas only 6.9% showed a negative attitude. However, the findings related to practice were less encouraging where only 8.8% of respondents reported good practice regarding ADR reporting, while a significant 91.2% demonstrated poor practice. These results suggest that although healthcare professionals at PoAHS possess adequate knowledge and maintain a positive attitude toward pharmacovigilance, there is a notable gap in translating this knowledge and attitude into actual reporting practices.

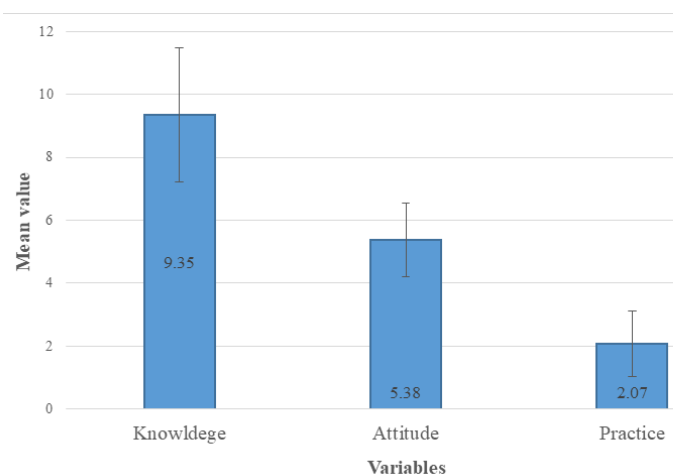
**Figure 1:** KAP score (Mean ± SD) (n=102)

Figure 1 shows the knowledge, attitude, and practice (KAP) scores among healthcare professionals. The mean knowledge and attitude scores were high, whereas the mean practice score was low. The mean knowledge score was 9.35 ± 2.119 whereas attitude scores were also favorable, with a mean score of 5.38 ± 1.16 . However, the findings related to practice were less encouraging. The mean practice score was only 2.07 ± 1.06 .

Discussion

In the present study, 55.88% of healthcare professionals (HCPs) reported having encountered adverse drug reactions (ADRs) during their clinical practice; however, only 10.78% had formally reported these incidents to pharmacovigilance (PV) centers. Comparatively higher reporting rates were observed in a study where 68.7% of HCPs identified ADRs, and 26.8% reported them to a PV center.¹⁴ In contrast, another study reported that 38.9% of respondents had observed ADRs, yet only 6.3% submitted reports to the appropriate authority.¹⁵

The reasons for under-reporting included heavy workload, lack of knowledge regarding reporting procedures, insufficient training, time constraints for patient follow-up, and lack of remuneration.^{16,17,18} In the present study, only 19.60% of participants had seen an ADR reporting form, which may have

contributed to the low reporting rate. A similar finding was reported in another study, where only 15.3% of participants had seen the reporting form.¹⁹

In the present study, 83.3% of respondents demonstrated a good level of knowledge regarding pharmacovigilance (9.35 ± 2.11 out of 14), which is notably higher than findings from other studies, where only 8.82% and 19.90% of participants demonstrated good knowledge in this area.^{20,21} However, some studies have reported higher levels of knowledge among participants.^{22,23} These variations may be attributed to differences in study population, study setting, questionnaire design, variation in educational background between students and practitioners, and sample size.

Furthermore, a majority of participants (93.13%) exhibited a positive attitude toward PV; however, only 8.8% demonstrated good practice in ADR reporting. Similar findings of positive attitudes but poor practice have been reported in other studies as well.^{21,24,25} This gap between attitude and practice may be due to time constraints in ADR reporting, the misconception that a single unreported case does not significantly impact the pharmacovigilance database, difficulty in recognizing ADRs, inadequate training, and limited awareness of reporting procedures and guidelines.²⁵

Conclusion

The findings of this study indicate that the majority of healthcare professionals demonstrated good knowledge and a positive attitude toward pharmacovigilance and adverse drug reaction (ADR) reporting; however, their practice was poor. More than half of the respondents had encountered ADRs during their clinical practice, but only a small proportion had reported them to nearby pharmacovigilance centers. These findings highlight the urgent need for targeted educational programs, training sessions, and workshops, as well as the establishment of pharmacovigilance units in healthcare settings, to enhance awareness and improve pharmacovigilance practices among healthcare professionals.

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