

Assessment of knowledge and attitude on pharmacovigilance among the healthcare professional and pharmacy students at Dharan

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ABSTRACT

Introduction: Pharmacovigilance is the process of identifying, assigning, and reporting the adverse drug reaction (ADR) to prevent its possible effect of it. There are increasing cases of ADR in Nepal which is affecting the treatment protocol. This is due to the lack of knowledge and practice of pharmacovigilance-related activities.

Method: It is a cross-sectional questionnaire-based study conducted among 105 healthcare professionals and pharmacy students at Dharan. Total 17 open and closed ended structured questions were provided to the participant. Out of 17 questions, 11 were 'knowledge' related and 6 were 'attituded' related. All the doctors, nurses, and pharmacists working in hospital and pharmacy premises during the data collection period were included. The response of the participant is analyzed by plotting the data on an excel sheet and the result is interpreted.

Result: Almost 93.33% of participants gave a response and more than half of them (n=48; 54.54%) were female. Almost all the healthcare professionals 86.20% (n=50) were positive about establishing an ADR monitoring center in every hospital. Though the majority of respondent defined the term "pharmacovigilance", less than half were aware the activities of national pharmacovigilance center. This shows that there is a need to address on the important of pharmacovigilance course at college level. The knowledge and attitude of respondents have shown difference with education qualification, age category, and profession category. **Conclusion:** Respondents had moderate to good knowledge about pharmacovigilance and had a positive attitude towards it. Most of them believe that the establishment of a pharmacovigilance center in each hospital is necessary.

Keywords: Pharmacovigilance, ADR, knowledge, attitude

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INTRODUCTION

Pharmacovigilance (PV) is a broad subject in the field of clinical and therapeutic pharmacy for the monitoring of adverse drug reactions. It monitors the safe, cost-effective, rationale as well as the patient-oriented effective treatment therapy for a better outcome.¹ Thalidomide tragedy is one of the starting points of implementing strict safety regulations on the drug. That incident killed thousands of babies but gave birth to the organized body which regulates the safety of drugs throughout the world.² The World Health Organisation (WHO) defines pharmacovigilance as 'the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related

problems. Effective and educative drug regulation by using the information generated from the post-marketing surveillance of the new drug is the main concern of pharmacovigilance.³ The main aim of pharmacovigilance is to enhance the patient quality of life related to the healthcare system by reducing and assessing the risk-benefit profile of treatment therapy. The fundamental process of PV is ADR identification, and reporting the documented record of ADR to the regional, national, and international drug authorities.⁴

The WHO defines ADR as "a 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 modifications of physiological

function". ADR causes one of the most obvious reasons for morbidity and mortality all over the world, especially in under-developing countries like Nepal.⁵

In the context of the Nepal community and clinical pharmacists are considered one of the most accessible and relevant healthcare professionals for the ADR identification, monitoring, and reporting to the national drug authorities in collaboration with other healthcare professionals. In Nepal, the first-time pharmacovigilance concept at the hospital level was established in the year 2004 AD. But the PV activities

were conducted in full phase from the year 2007 onward. Nepal became a full member of the international pharmacovigilance program in the same year. There are two bodies for the ADR regulation the Department of Drug Administration (DDA) and, the national drug regulatory authority of Nepal.⁶

This study was aimed at investigating the knowledge and attitude of healthcare professionals and pharmacy students on PV at Dharan and comparing the knowledge between them.

The hospital Pharmacist, nurse, and doctor's team/ PV team report ADR.

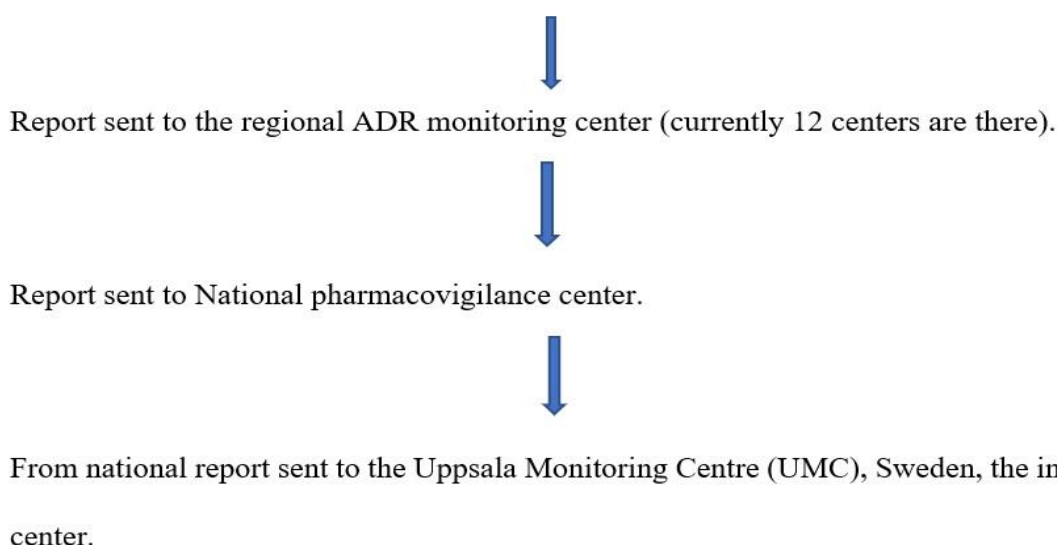


Diagram 1: Process of ADR monitoring and reporting in Nepal⁷

MATERIAL AND METHODOLOGY

Study design

A cross-sectional questionnaire-based study was conducted over a period of a month among community healthcare professionals in Dharan, Sunsari, Nepal. A similar study was conducted with the pharmacy student of Sunsari Technical College, Dharan.

Study site

The study was carried out at Bijayapur Hospital, Guardian Pharmacy, and another community pharmacy. For students' responses, we had taken Sunsari technical college, Dharan as a study site.⁸

Sample size

Simple random sampling method was used for sample collection. There was a total of 105 participants (22 pharmacists, 12 doctors, 35 nurses, and 36 pharmacy students). Sample size calculation was done by using calculator.net (<https://www.calculator.net/sample-size-calculator.html>)⁹, an online web server. We had taken following parameter for sample size calculation a). 95% Confidence level, b). 8% margin error, c). 50% population

proportion, and d). 340 population size. Population size was taken on the basis of information obtained from the department of drug administration (DDA) regarding the registered pharmacy at Dharan (203 retail pharmacy), administration of Sunsari Technical College, Dharan, and administration of Vijayapur hospital, Dharan.

Inclusion and exclusion criteria

All the doctors, nurses, and pharmacists working in Vijayapur hospital, Guardian community pharmacy, and some other pharmacies during the data collection period were included and the B. pharmacy final year students were also included. Participants' consent was taken.

Study tools

A questionnaire was developed by analyzing various research article^{10,11} and a total of 17 questions are included. Among these questions, 11 (Qs: 1- 11) were related to the 'knowledge', and 6 (Qs: 12-17) were related to 'attitude' aspects. We consider knowledge as the understanding of any given topic pharmacovigilance in this case and provided them four option to choose correct ans

er. Whereas, attitude refers to their feelings towards pharmacovigilance and we provide yes/no question. Questions are verified and rechecked by an expert before finalizing. The expert suggestion was taken to confirm the reliability of questionnaire. A pilot study was conducted on 12 pharmacy students to validate the questionnaire but those data were not included in the final analysis. The content validation method was used for validation of questionnaire. For pilot study the questionnaire was distributed to 12 pharmacy student and response was analysed. Thus, obtained result was reliable to our sample population. For final result scalar score method was choose to measure the various aspect of knowledge and attitude. To the correct response one point was recorded and zero for wrong response.

Modality of obtaining the knowledge and attitude responses:

Mostly, we collected the data through face-to-face interaction with the participant. The responses from the doctors, nurses, and pharmacists were mostly collected from the Vijayapur hospital and some from the Guardian community pharmacy, and some other community pharmacies. The response of students was collected from Sunsari Technical college. A questionnaire was printed clearly in bold letter to avoid misunderstanding and we make sure that respondents have no doubt. The ethical approval was taken from the Interna Research Committee (IRT), Sunsari technical College.

Statistical data analysis:

The filled questionnaires were collected and various demographical parameters as well as the statistical parameters for analysing 'knowledge' and 'attitude' were done using Microsoft Excel version 2016.¹²

RESULTS

Among the total 105 participants, 93.33% (n=98) provided their responses. Of these responses, 89.79% (n= 88) were analyzed and the rest 10.21% (n=10) were not included in the analysis because of incomplete information. More than half of them (n=48; 54.54%) were female and the rest were male (n=40; 45.46%) Detail demographic characteristics of the respondent are listed in table 1.

Table 1. Demographic distribution

Gender category	Frequency	Percentage
Male	40	45.45%
Female	48	54.54%

Age category(year)	Frequency	Percentage
20-25	51	57.95%
26-30	20	27.72%
31-35	12	13.63%
>35	5	5.68%
Profession category	Frequency	Percentage
Doctor	8	9.09%
Pharmacist	20	27.72%
Nurse	30	34.09%
Student	30	34.09%

Knowledge and attitude mean scores (Table 2)

We found that the overall mean score for knowledge and attitude of 4th-year pharmacy student had higher (23.2) as compared to the healthcare professional (14.71). The knowledge means a score of doctors had higher (18.5) than nurses (15.94) and pharmacists (15.4) (Table 2).

Comparing the response of the healthcare profession and students toward knowledge

70% of pharmacists and nurses gave the correct response towards Q1 while only 62.6% of doctors gave the same. 62.5% (n=5) doctor, 35% (n=7) pharmacist, 36.66% (n=11) and 86.66% (26) students were aware regarding the existence of a Pharmacovigilance Programme of Nepal. Nearly more than half of the doctors 50% (n=4), pharmacists 55% (n=11), and nurses 60% (18) were aware that the regulatory body responsible for monitoring ADRs in Nepal, is the Department of Drug Administration (DDA) (Table 3).

Comparison of the response of healthcare professionals and students towards attitude

A total of 87.5% of doctors, 95% of pharmacists, 93.33% of nurses, and 93.33% of students agreed that reporting ADR is necessary. Almost all doctors (87.5%), pharmacists (90%), nurses (93.33%), and students (96.66%) had a view that pharmacovigilance should be taught in detail to the healthcare profession (Table 4).

Respondent view on establishing an ADR monitoring center in every hospital:

Almost all the healthcare professionals 86.20% (n=50) were positive about establishing an ADR monitoring center in every hospital. Only very few (3.44%) said that one in a city is sufficient (Figure1). Similarly, 93.33% (n=28) of pharmacy students believed that the ADR monitoring center should be in every hospital, and the remaining 6.67% (n=2) voted for the option 'depends on the number of bed size of the hospital' (Figure 2).

Table 2. Mean score of knowledge and attitude among different healthcare profession and student group

Profession	Knowledge [max 22]	Attitude [max 10]	Total score [max 32]
Doctor(n=8)	11.75	6.75	18.5
Nurse(n=30)	10.6	5.34	15.94
Pharmacist(n=20)	9	6.4	15.4
Student(n=30)	15.5	7.8	23.3
Healthcare Profession and student mean score			
Healthcare profession(n=58)	8.82	5.89	14.71
student(n=30)	15.4	7.8	23.33

Table 3. Comparison of the response of participants toward the attitude-related question

Questions	Health professionals' correct response			Students correct response
	Doctor	Pharmacist	Nurse	
Q1	n=5 (62.5%)	n=14 (70%)	n=21(70%)	n=26 (86.66%)
Q2	n=5 (62.5%)	n=15 (75%)	n=25 (83.33%)	n=25 (83.33%)
Q3	n=6 (75%)	n=17 (85%)	n=24(80%)	n=25 (83.33%)
Q4	n=4 (50%)	n=4 (20%)	n=5(16.66%)	n=15(50%)
Q5	n=5 (62.5%)	n=11(55%)	n=23(76.66%)	n=25(83.33%)
Q6	n=5 (62.5%)	n=7(35%)	n=11(36.66%)	n=26(86.66%)
Q7	n=4 (50%)	n=11 (55%)	n=18 (60%)	n=25 (83.33%)
Q8	n=5 (62.5%)	n=3 (15%)	n=17 (56.66%)	n=20 (66.66%)
Q9	n=3 (37.5%)	n=3 (15%)	n=3 (10%)	n=16 (53.33%)
Q10	n=2 (25%)	n=2 (10%)	n=2 (6.66%)	n=15 (50%)
Q11	n=3 (37.5%)	n=3 (15%)	n=10 (33.33%)	n=13 (43.33%)

Questions

Q1= Define Pharmacovigilance., Q2= the most important purpose of PV., Q3= PV includes, Q4= when PV activities started in Nepal, Q5= Health care professionals responsible for reporting ADRs in hospital is/are, Q6= Existence of a national PV program in Nepal, Q7= Central regulatory body for ADR monitoring in Nepal, Q8=. International center for ADR monitoring location, Q9= Causality scale for ADR, Q10= Severity scale for ADR, Q11= Method to monitor the ADR of a new drug, after they launched, by a health professional.

Table 4. Comparison of the response of participants toward the attitude-related question

Questions	Healthcare profession's correct response			Students correct response
	Doctor	Pharmacist	Nurse	
Q1	n=7(87.5%)	n=19(95%)	n=28(93.33%)	n=28(93.33%)
Q2	n=7(87.5%)	n=18(90%)	n=28(93.33%)	n=29(96.66%)
Q3	n=4(50%)	n=12(60%)	n=15(50%)	n=26(86.66%)
Q4	n=5(62.5%)	n=5(25%)	n=5(16.66%)	n=16(53.33%)
Q5	n=4(50%)	n=10(50%)	n=4(13.33%)	n=18(60%)

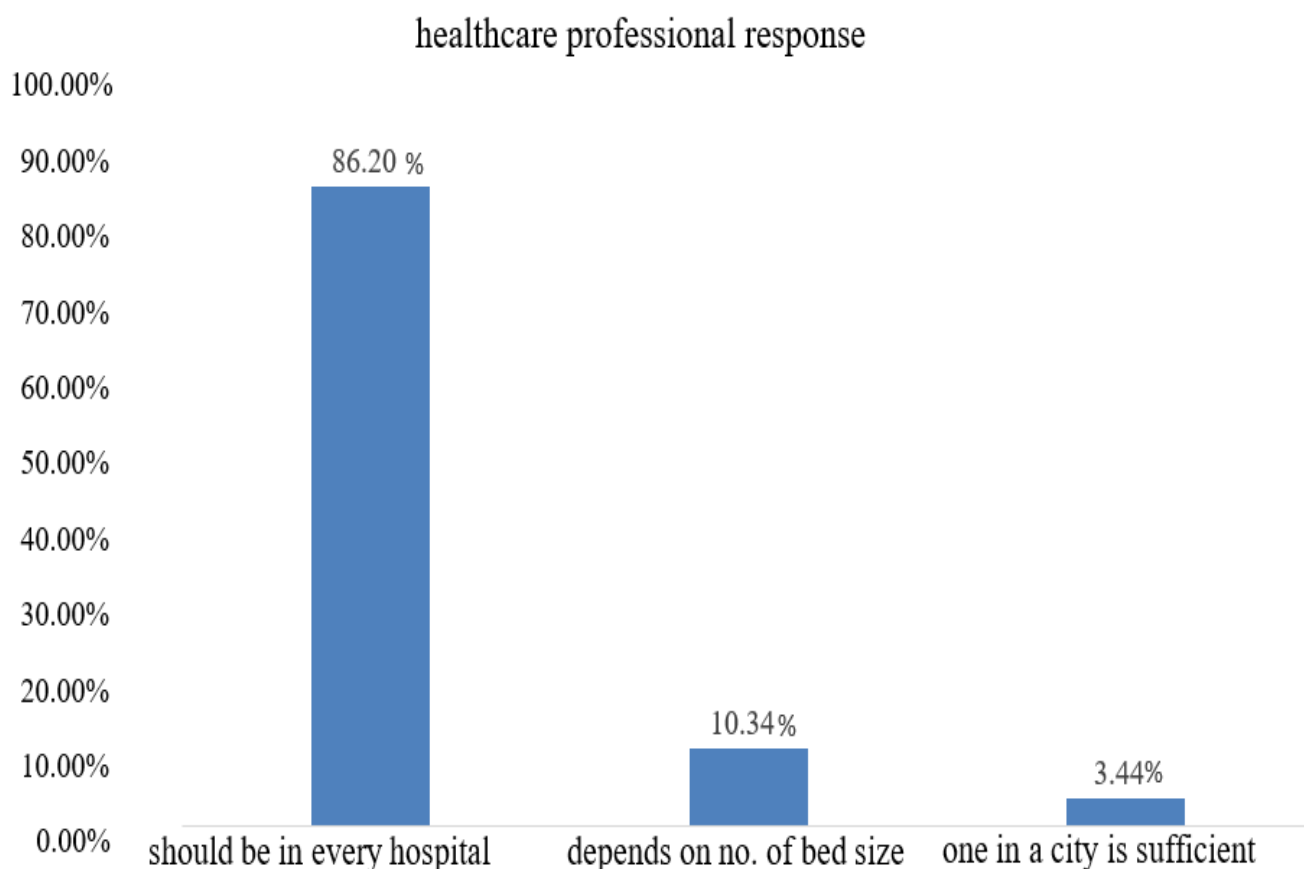


Figure 1. Response of healthcare professionals to the question is necessary that PV in every hospital

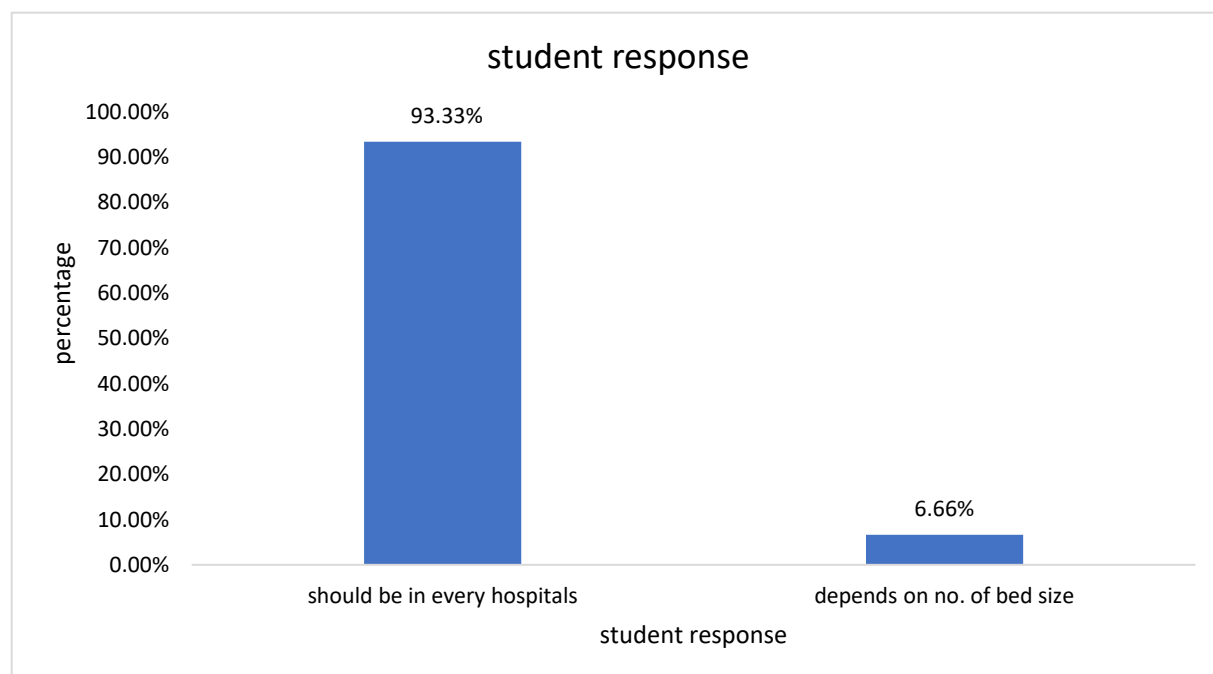


Figure 2. Response of pharmacy students to the question is necessary that PV in every hospital

Comparison of results of knowledge-related questions with another research

Table 5. Comparison of knowledge with published studies

Question	Our result	MTH Result(6)	South India result(15)
Definition/Activities of PV	68.96%	NA	65%
In Nepal, the pharmacovigilance activities started in the year	22.41%	21.3	NA
The National Pharmacovigilance Centre in Nepal/India is located at	56.89%	46.1%	51%
The international center for adverse drug reaction monitoring is located in	43.10%	25.8%	50%
One of the following scales is used to establish the causality of an adverse drug reaction	15.51%	30.3%	NA
One of the following scales is used to establish the severity of an adverse drug reaction	10.34%	28.1%	NA

Table 6. comparison of attitude scores with published studies

Question	Our result	MTH result(6)	South India result(15)
Do you think reporting ADR is necessary?	93.10%	93.4%	88%
Do you think PV should be taught in detail in the healthcare profession?	91.37%	NA	80%
Do you read an article on the prevention of ADR?	53.44%	65.2%	6%

*MTH = Manimal Teaching Hospital

Some of the limitations of this study should be considered. The sample size was small so the result may not be generalized. The study was only focused on a particular place (Dharan). Sample heterogeneity and open and closed-end question patterns may develop biased results.

DISCUSSION

One of the integral parts of the modern health care system is pharmacovigilance. This helps in minimizing the incidence of ADR by the spontaneous detection method. Spontaneous reporting of ADR is essential for the success of the pharmacovigilance program. This study is one of the few studies done among health professionals and pharmacy students regarding KA of pharmacovigilance.

The same study was conducted by Subish and colleagues among the community pharmacist. A total of 116 participants respond to the questionnaire and the mean KAP score was 31.25 out of the maximum possible score of 40 which is better than our study. The reason behind it could be the time of questioner administration and busy schedule in pharmacy. The same study concluded that there was a lack of knowledge among healthcare professionals compared to pharmacy students regarding ADR monitoring which is similar to our finding.¹² Lack of awareness programs and lack of effective strategies by the government body on PV is the main factor that hinders the quality of the healthcare system regarding ADR monitoring. It was interesting to know that 39.55% of the healthcare professionals are aware of the location of the national pharmacovigilance center. This finding was somehow similar to the observations made from the South Asian country (Malaysia). A study done by Aziz Z. et al in Malaysia reported that around 40% of the

respondents had no clue about the existence of a national ADR reporting system.¹³ Surprisingly, 93.10% of the healthcare professional and 93.33% of pharmacy students in our study felt that ADR reporting is important. Kenneth K.C. Lee *et al* found that only 14.7% reported an ADR in the past year of their profession but interestingly 93 percent of the pharmacists agreed that ADR reporting is necessary to optimize the therapeutic outcome.¹⁴

A huge portion (89.66%) of the healthcare professionals are not sure about severity assessment scales while only half of the pharmacy students are aware. Shakya Gurung R et al also reported only 26.3% of healthcare professionals related the causality assessment scale in a tertiary hospital in Kathmandu.¹⁵ The health professional was not aware of PV because there may be no pharmacovigilance center in their hospital for practice.

CONCLUSION

The pharmacy students displayed relatively good knowledge and an excellent attitude toward other healthcare professionals. We concluded that the establishment of a PV center in each hospital is very important to enhance the quality of the healthcare system. It indicates that a requirement of continuous learning strategy for the healthcare profession is necessary. A positive attitude towards PV will increase patient safety. So, we conclude that

all the healthcare professionals and pharmacy students have moderate knowledge of PV but they all have a very excellent attitude.

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