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### Assessment of Knowledge, Attitude and Practice of Pharmacovigilance among the Interns in a Tertiary Care Centre of Nepal

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#### ABSTRACT

**Introduction:** Pharmacovigilance, also known as drug safety, is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products. Assessment of awareness of pharmacovigilance among the healthcare professionals is very important due to under reporting of adverse drug reactions (ADR). Therefore this study was conducted to assess awareness of pharmacovigilance among the interns in a tertiary care centre.

**Methods:** A cross sectional observational questionnaire based study was conducted on interns to gather information about the knowledge, attitude and practice of Pharmacovigilance. Data was collected from first October to thirtieth November, 2020. An online questionnaire was used to collect data. The demographic parameters as well as other parameters including knowledge, attitude and practice were analyzed descriptively and tabulated as number and percentage.

**Results:** A total of 72 participants completed the questionnaire. In this study 59 (81.9%) of the respondents were aware of the pharmacovigilance and 63(87.5%) of the respondents responded that ADR reporting is mandatory. Almost 11(15.27%) of the participants had seen ADR during ward posting and only 5(6.9%) had played a role in reporting ADRs. Almost 66 (91.6%) of the participants responded that pharmacovigilance should be taught in detail to healthcare professionals.

**Conclusion:** Interns had positive attitude towards pharmacovigilance program but there is a need of educational intervention and regular training programs. This will help to increase the knowledge and practice of ADR reporting among the interns in the future.

**Keywords:** Adverse drug reaction; Interns; Knowledge; Pharmacovigilance; Practice.

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## INTRODUCTION

Many drugs are available in the market today which are used for various purposes. These drugs are used in the treatment of various diseases and they may benefit the patient in many ways. However, these drugs may have harmful effects on the patients. These harmful effects of drugs are associated with increase in morbidity and mortality in some patients.<sup>1,2</sup> These unwanted effects of drugs should be avoided as far as possible.

Pharmacovigilance is associated with the recognition of harmful effects of medicinal products. It also includes evaluation of adverse effects of different types of medicines, understanding of different types of unwanted effects of medicines as well as prevention of harmful effects of medicinal products.<sup>3</sup> According to World Health Organization (WHO), Adverse Drug Reaction (ADR) can be regarded as harmful effects of drugs which occurs at the therapeutic doses. The drugs might be prescribed for the prophylaxis of various diseases, diagnosis of different diseases and can also be used to change the normal physiological function of the patient.<sup>4</sup> Adverse drug reaction can cause significant economic burden to the nation. In the past, the drug Thalidomide which was used for vomiting in pregnancy caused significant number of congenitally deformed babies. This incident with thalidomide was able to gain international attention; and the concept of pharmacovigilance was started in 1961.<sup>5</sup>

Pharmacovigilance is an important part of health care. The main purpose of pharmacovigilance is to collect, assess, monitor, evaluate and research on the adverse drug reactions of the drug.<sup>6,7</sup> Thus pharmacovigilance helps in the safe and effective use of drug.<sup>6,7</sup> Voluntary participation of the healthcare professionals in spontaneous reporting of the adverse drug reaction can play an important role for successful pharmacovigilance.

Adverse drug reactions is still not explored properly in the developing countries.<sup>8-11</sup> In the developed country ADR reporting rate is 5% whereas it is only 1% in India.<sup>12</sup> The under-reporting of ADR is one of the major problem in pharmacovigilance. There are many reasons behind under reporting of adverse drug reactions. This maybe because of lack of trained manpower, lack of knowledge of pharmacovigilance and inadequate training among the health workers.<sup>13</sup>

The evaluation of knowledge, attitude and practice of pharmacovigilance among the health workers will play an important role to improve reporting of adverse drug reactions of different medicines. Very few studies have been conducted among the interns. Therefore, this study has been undertaken to assess the knowledge, attitude and practice of pharmacovigilance among medical and dental interns in KIST medical college and teaching hospital.

## METHODS

A cross sectional observational questionnaire based study was conducted on interns to gather information about the Knowledge, attitude and practice of Pharmacovigilance from 1<sup>st</sup> October to 30<sup>th</sup> November, 2020 This study after taking consent from Institutional Ethics Committee( IRC) of KIST Medical college and Teaching Hospital.

### Study questionnaire

Questionnaire was made based on the previous studies.<sup>16,17</sup> There were 9 questions on knowledge, 10 questions on attitude ,and 8 questions on practice of pharmacovigilance. The remaining questions were on knowledge of severity of ADR, reasons for under reporting of ADR, preferable methods to report ADR and opinion about reporting ADR in every hospital. The total number of questions was 31.

A structured online questionnaire was used as a data collection tool. An online questionnaire was constructed using Google form. Informed consent was taken from every student prior to the study. The questionnaire was distributed with the help of class representatives via their email and social networking accounts.

The demographic parameters as well as other parameters including knowledge, attitude and practice were analyzed descriptively and tabulated as number and percentage.

## RESULTS

A total of 90 interns including both medical interns (67) and dental interns (23) was approached for the study. Among the 90 interns, only 72 interns participated. The response rate was 80%. The demographic parameters including gender, area of residence has been presented in Table 1. Out of 72 participants, 57(79.1%) were male and 15(20.8%) were female. The majority of the participants 39(54.1%) were from urban area.

**Table 1.** Demographic characteristics of respondents (n=72)

Characteristics	Number (Percentage)
Gender	
Male	57(79.1)
Female	15(20.8)
Area of residence	
Rural	10(13.8)
Semiurban	23(31.9)
Urban	39(54.1)

Among the 72 participants, 59 of the participants were aware of the definition of Pharmacovigilance and 63 reported that adverse drug reaction reporting is mandatory. (Table 2)

**Table 2.** Knowledge based questions on Pharmacovigilance (n=72)

SN	Statements (Correct answer)	Yes N (%)	No N (%)
1	Are you aware of the term Pharmacovigilance?	59(81.9)	13(18)
2	Pharmacovigilance is the science of detection, assessment, understanding and prevention of adverse effects	57(79.1)	15(20.8)
	Do you believe all drugs available in the market are safe?	5(6.9)	67(93)
3	Is adverse drug reaction reporting mandatory?	63(87.5)	9(12.5)
4	The healthcare professionals are responsible for reporting adverse drug reactions in a hospital.	61(84.7)	11(15.2)
5	The international centre of drug monitoring is located in Sweden	5(6.9)	67(93)
6	The rare adverse effects of drugs are included in Phase II clinical trial	64(88.8)	8(11.1)
7	Is there any Pharmacovigilance committee in your institute?	59(81.9)	13(18)
8	Is there any nearby adverse drug reactions reporting and monitoring center in your knowledge?	65(90.2)	7(9.7)

All of the 72 participants agreed that adverse drug reactions reporting should be taught in pharmacology practical. Among the 72 participants, 62 agreed that reporting adverse drug reaction, will increase patient safety and 65 agreed that pharmacovigilance should be taught in detail to healthcare professionals. (Table 3)

**Table 3.** Attitude based questions on Pharmacovigilance (n=72)

S.No.	Statements	Yes	No
		N (%)	N (%)
10.	Do you think adverse drug reaction reporting is time consuming with no activity?	56(77.7)	16(22.2)
11.	Do you think reporting adverse drug reactions will increase patient safety?	62(86.1)	10(13.8)
12.	Do you worry about legal problems while you think of adverse drug reactions reporting?	59(81.9)	13(18)
13.	Do you think pharmacovigilance should be taught in detail to healthcare professionals?	66(91.6)	6(8.3)
14.	Do you think adverse drug reactions reporting should be taught in pharmacology practicals?	72(100)	
15.	Do you think adverse drug reactions reporting is a part of professional obligation of all healthcare professionals	65(90.27)	7(9.7)
16.	Do you think discussion on adverse drug reactions during clinical posting has any relevance?	67(93)	5(6.9)
17.	Do you think drug history is an important part of history taking?	69(95.8)	3(4.1)
18.	Do you think treatment of adverse drug reactions increase the financial burden of the patients and health system?	58(80.5)	14(19.4)
19.	Do you think adverse drug reactions can be prevented by proper knowledge about drug interaction?	72(100)	

Out of 72 participants, 61 have counseled patients regarding adverse drug reactions, and 20 have come across patient experiencing adverse drug reaction in ward posting.(Table 4)

**Table 4.** Practice based questions on Pharmacovigilance

S.N.	Statements	Yes	No
		N(%)	N(%)
20.	Have you come across any patient experiencing adverse drug reactions in your ward posting?	11(15.2)	61(84.7)
21.	Have you ever played any role in reporting Adverse Drug Reactions in your institution?	5(6.9)	67(93)
22.	Have you ever visited any adverse drug reaction monitoring centre?	4(5.5)	68(94.4)
23.	Have you ever counseled patient regarding Adverse Drug Reactions?	61(84.7)	11(15.2)
24.	Have you ever taken drug history in patients when taking history during ward posting?	72(100)	
25.	Have you ever been trained on how to report adverse drug reaction?	7(9.7)	65(90.2)
26.	Have you ever seen an adverse drug reaction being treated?	13(18)	59(81.9)
27.	Have you seen any patient with serious adverse drug reaction being admitted in ICU?	8(11.1)	64(88.8)

Among the 72 participants, 53(73.6%) responded that all the adverse drug reactions including the serious adverse drug reactions as well as mild adverse drug reactions and causing less inconvenience should be reported. (Table 5)

**Table 5.** Knowledge about reporting Adverse Drug reporting

S.No.28. When do you think ADR should be reported?	N (%)
Serious and life threatening	5(6.9)
Severe and cause disability	6(8.3)
Mild and cause less inconvenience	4(5.5)
Non serious, well known	-
All of the above	53(73.6)
None of the above	-
Don't know	4(5.5)

Among the 72 participants, insufficient clinical knowledge as the main reason for under reporting was responded by 6(8.3%), adverse drug reaction known only to physicians was responded by 11(15.2%), don't know whom to report was responded by 29(40.2%), thinking one report does not make a difference were responded by 5(6.9%) of the participants. (Table 6)

**Table 6.** Reasons for under reporting of Adverse Drug Reactions

S.No.29. What is the reason for under-reporting of ADR?	N (%)
	<b>N=72</b>
Reporting does not influence the treatment plan	7(9.7)
Busy schedule	9(12.5)
Lack of incentives	5(6.9)
Adverse drug reaction is known only to the physicians	11(15.2)
Don't know whom to report	29(40.2)
Waste of time	-
Insufficient clinical knowledge	6(8.3)
Thinking one report does not make any difference	5(6.9)
Difficult to point out suspected drug	-

The most preferable method given by interns to report adverse drug reaction to adverse drug reaction reporting centre was direct contact which was responded by 37(51.3%) of the interns and the least preferable method was by post which was responded by 1(1.3%) of the interns.

**Table 7.** Preferable method to report Adverse Drug Reactions

S.No.	Which method would you prefer to send adverse drug reaction to adverse drug Reaction reporting centre?	N(%)
30		<b>N=72</b>
	Direct contact	37(51.3)
	Telephone	13(18)
	Android application	15(20.8)
	Post	1(1.3)
	E-mail	6(8.3)
	Others	-

Among the 72 participants, 57(79.1%) of the participants responded that adverse drug reaction monitoring center should be present in every hospital.

**Table 8.** Opinion about establishing adverse drug reactions monitoring center in every hospital

S.No. 31	Opinion about establishing adverse drug reaction monitoring center in every hospital	N(%) N=72
	Should be in every hospital	57(79.1)
	Not necessary in every hospital	7(9.7)
	One in a city is sufficient	-
	Depends on number of bed size in the hospitals	8(11.1)

## DISCUSSION

Voluntary reporting of adverse drug reaction is the foundation for pharmacovigilance program. Therefore, health care workers must be aware of the pharmacovigilance program as well as adverse drug reactions. So, this study was taken among the interns so that they realize the importance of pharmacovigilance program and also they will start reporting adverse drug reaction. In this study, knowledge, attitude and practice of pharmacovigilance among the interns in a medical college of Nepal were evaluated.

The present study was an online questionnaire based study which included 90 interns in a medical college of Nepal. Among the 90 interns only 72 interns responded. The response rate was 80%.

In our study, 79.1% of the respondents were aware of the definition of Pharmacovigilance. This finding is comparable with other study done on healthcare professional in South India where 62.4% were aware of the definition as well as awareness of pharmacovigilance program.<sup>17</sup>

Also, 87.5 % of the respondents responded that ADR reporting is mandatory. This finding was different in comparison with other study, where more than 40% MBBS students responded that ADR reporting is mandatory.<sup>18</sup>

In our study only 6.9 % knew about the location of international drug monitoring centre. This finding was similar to another study conducted by Ramesh and Parthasarathi which stated that only a few numbers of doctors were aware of National and International Pharmacovigilance program.<sup>19</sup>

Also, 91.6 % of the responded that pharmacovigilance should be taught in detail to healthcare professionals.

This result is comparable with other study done in a medical college in Andhra Pradesh, India where 89.8% of the medical students responded that ADR reporting is necessary and pharmacovigilance should be taught in detail in healthcare professionals.<sup>20</sup>

About 79.1 % of the health workers agreed that ADR monitoring centre should be present in hospital which was comparable to the findings in another study where about 92% of the health care professionals agreed that ADR monitoring centre should be present in every hospital which was comparable to the findings in another study in South India.<sup>17</sup>

Among the 72 respondents who participated in our study, 15.2% responded that they have experienced ADR during ward posting. Also, 84.7 % of the respondents have also counseled patients regarding various harmful effects of drugs. This finding is different from another study done in India where more than 70% of the nurses have experienced an ADR in patients during their practice. However, only 39% of the respondents have counseled patients regarding ADRs.<sup>16</sup>

In our study, 40.2 % of the respondents mentioned that not knowing whom to report as the main reason for under reporting, adverse drug reaction known only to physicians 15.2%, insufficient clinical knowledge 8.3%, thinking one report does not make a difference 6.9%. These findings are different from other study done in health care professionals in Tirupati, India where the most common reasons for under reporting of ADRs by were insufficient clinical knowledge 50.49%, ADR is known only to physician 43.56%, difficult to point out suspected drug 32.67%, don't know whom to report 23.76%, and thinking one report doesn't make any difference 18.8%.<sup>16</sup>

This is a cross sectional study with its own limitations. The main limitation of this study was the convenience sampling. Also it was done in only one medical college of Nepal.

## CONCLUSION

The current study indicates that the interns are moderately aware of pharmacovigilance and ADR reporting system. The major cause given by the interns was that they didn't know whom to report, busy schedule and insufficient clinical knowledge. Therefore, workshops on pharmacovigilance adverse drug reaction reporting must be conducted which will help to increase awareness among interns. This will improve safety of the patient and the harmful effects of the drugs can be avoided.

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