



## ASSESSMENT OF KNOWLEDGE, ATTITUDE, AND PRACTICE OF PHARMACOVIGILANCE IN A MEDICAL COLLEGE OF NEPAL

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### ARTICLE INFO

### ABSTRACT

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**Introduction:** Pharmacovigilance is the science that relates to the collection, detection, assessment, monitoring and prevention of adverse drug reactions (ADR). The incidence of ADR is 2.4-6.5% in western countries, with only 6-10% reported worldwide. The under-reporting of ADR is due to inadequate knowledge, attitude, and practice among the prescribers about the system. Thus, medical students who are the future drug prescribers bear a crucial role in bridging this gap.

**Materials and Methods:** This cross-sectional questionnaire survey was carried out among 261 medical undergraduates including interns at Maharajgunj Medical Campus in Kathmandu. Self-administered questionnaire was used for data collection. The responses were analyzed and descriptive statistics are presented as frequencies and percentages.

**Results:** In this study, 94.3% of students responded that doctors, nurses, and pharmacists need to report ADR as they encounter them but only 13.8% responded to have reported ADR to the concerned authority. Also, 97.3% of respondents answered that ADR reporting should be taught in their medical college.

**Conclusion:** In conclusion, medical students are not adequately aware of ADR reporting system. A proper orientation to pharmacovigilance should be given to the medical students by incorporating it into the medical curriculum and providing training to future healthcare professionals.

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### 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.<sup>1</sup>

Spontaneous adverse drug reaction (ADR) reporting schemes have been a major source of information in pharmacovigilance. Providing information on suspected ADRs is as much a moral duty of healthcare professionals as other aspects of patient care.<sup>2</sup> The efficiency of the ADR reporting depends upon the knowledge, attitude, and practice of health care professionals.<sup>3</sup> The literature estimates the incidence of ADR to be 2.4-6.5% in western countries, with only 6-10% of ADRs reported worldwide.<sup>4</sup> Even the majority of health care professionals have inadequate knowledge and express poor practice towards ADR reporting.<sup>5</sup> Thus, medical students must be exposed to ADR reporting during their clinical teaching.<sup>6</sup> Hence, this survey was conducted to assess the knowledge, attitude, and practice of medical students, who are future drug prescribers, towards ADR.

#### **MATERIALS AND METHODS**

This cross-sectional descriptive study was conducted to study the knowledge, attitude, and practice of MBBS students at Maharajgunj Medical Campus (MMC) of the Institute of Medicine (IOM), Nepal from 2018 August to November. It involved the data collection using a self-administered questionnaire where the participants' socio-demographic profile, year of medical school and knowledge, attitude, and perceptions on reporting ADR was collected.

The structure and content of the questionnaire were based on those used in previous similar studies.<sup>2-6</sup> some modifications were done in the questionnaires to adapt in our research setting. Depending on the category, there were single or multiple answer responses, which was graded using a 5-point Likert scale or other scaling tools as applicable. No additional training was provided and no changes to the curriculum were made before or during the survey period. The semi-structured data sheet was pre-tested in the same study area and pretesting bias was

avoided. Necessary improvements were made to finalize the tools. Data collection was done after the proposal was approved by the Institutional Review Committee (IRC), IOM.

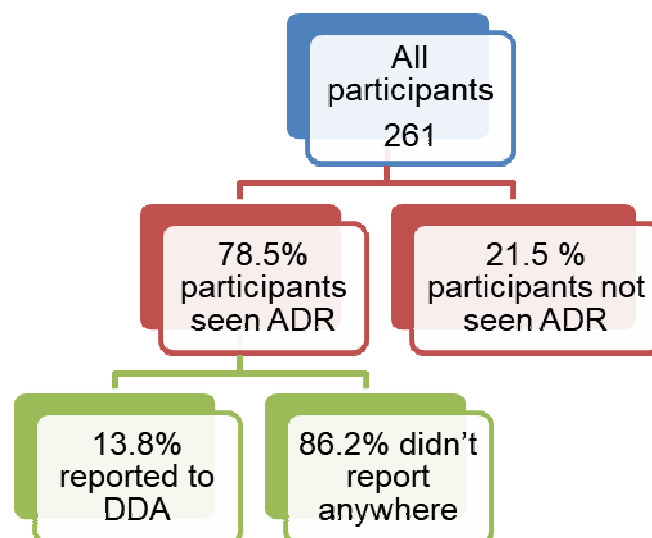
Data was collected by distributing the hard copy format of pre-designed self-administered questionnaires after the participants agreed to participate in the study by signing the informed consent form. A total of 261 medical students participated. The participants were selected using a non-probability census sampling method. No additional risk was posed to the participants.

The responses from the questionnaires were entered into the computer using EpiData. Each participant was provided a code number to maintain the confidentiality of the data. There was, however, a possibility of encountering the Hawthorne effect. Response for the different questions was coded to facilitate data entry and data analysis. The data were analyzed using the Statistical Package for the Social Sciences (SPSS) for Windows version 21.0. Armonk, NY: IBM Corp., SPSS Statistics. The descriptive statistics are presented as frequencies and percentages.

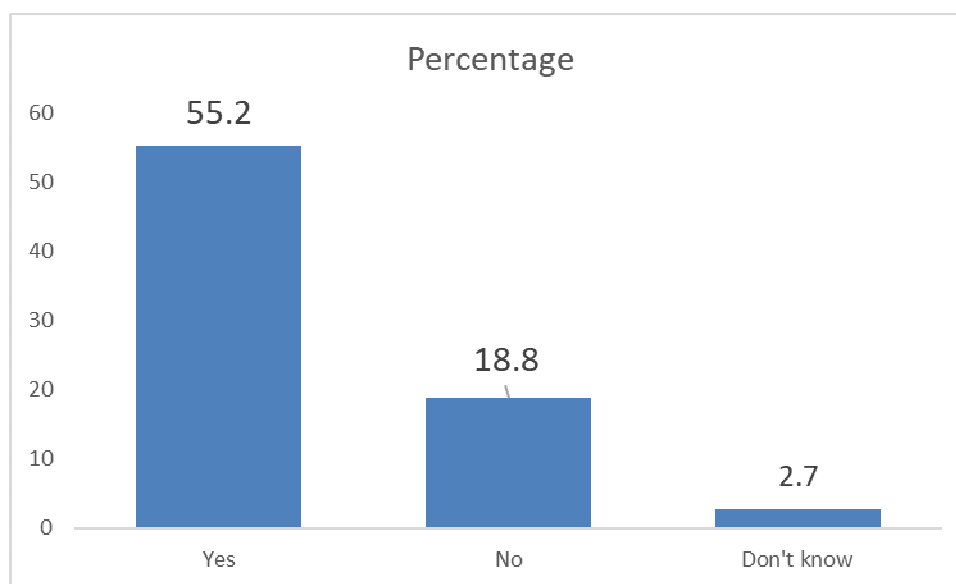
The different stages of the study were supervised and monitored by the principal investigator. The research team expected the information thus received to help in developing appropriate steps such as the introduction of the topic in the medical curriculum that might ultimately help the health system tackle the problem of ADRs and other unfavorable outcomes associated with it.

#### **RESULTS**

The mean age of the respondents was 21.14 years with the male population (63.2%) more than the females. Our study found that among the 78.5% of participants who had seen ADR, only 13.8% of them reported it to the Department of Drug Administration (DDA) Nepal (Figure 1). Figure 2 shows that 55.2% of participants knew the regional pharmacovigilance centers in Nepal.



**Figure 1:** Participants who had seen and reported ADR.



**Figure 2:** Knowledge of pharmacovigilance centers in Nepal.

There were 94.3% of participants, who felt that the reporting of ADR is important as a healthcare professional. Also, most of the participants (97.3%) felt the need for the

system of ADR reporting to be taught in medical school. Table 1 shows the percentage of answers to their corresponding questions.

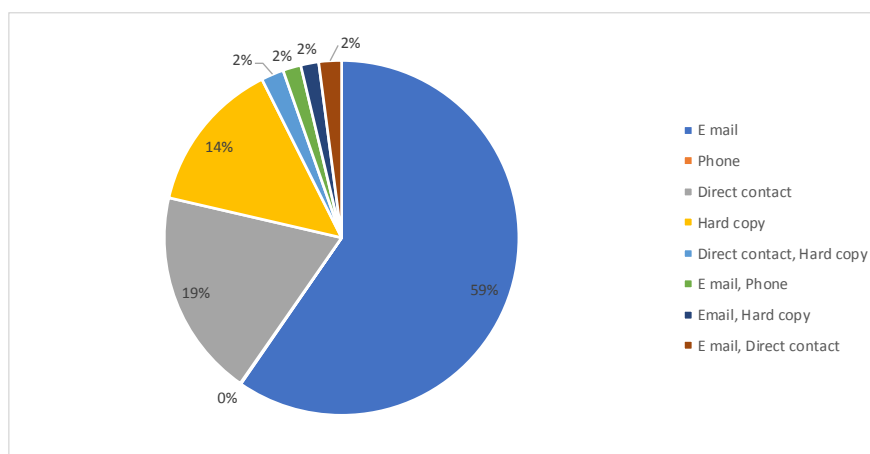
**Table 1:** Response of the participants to the questions.

| S. No. | Question  | Correct/positive Response (%) | Incorrect response (%) | Don't know (%) |
|--------|---|-------------------------------|------------------------|----------------|
| 1      | Pharmacovigilance is related to which concept of pharmacology?            | 68.6                          | 30.6                   | 0.8            |
| 2      | Which of the following is the national pharmacovigilance center of Nepal? | 67.4                          | 31.8                   | 0.8            |
| 3      | What is ADR?  | 77.8                          | 22.2                   | Nil            |

|    |   |      |      |     |
|----|---|------|------|-----|
| 4  | Is the topic of pharmacovigilance well covered in your curriculum?  | 6.5  | 93.5 | 0.4 |
| 5  | Have you heard about the term Naranjo Probability Scale, the generally accepted and most widely used methods for casualty assessment in ADRs?   | 16.5 | 83.1 | 0.4 |
| 6  | Where is the World Health Organization Collaborating Centre for International Drug Monitoring, the Uppsala Monitoring Centre (WHO-UMC) located? | 34.9 | 59.4 | 5.7 |
| 7  | Do you know about any drug withdrawal from the Nepalese market because of potent drug toxicity?   | 52.9 | 47.1 | Nil |
| 8  | Are the terms ADR and side-effects similar?   | 28   | 72   | Nil |
| 9  | Are you willing to report ADR in case you encounter it?   | 88.9 | 11.1 | Nil |
| 10 | Have you experienced any ADR to date?   | 52.1 | 47.9 | Nil |
| 11 | Have you ever read an article regarding adverse drug reactions?   | 57.1 | 42.9 | Nil |
| 12 | Have you seen an ADR reporting form?  | 15.3 | 84.7 | Nil |

Most of the participants responded to Email as a better source for reporting ADR (Figure 3). Also, the respondents felt a practical approach

(47.9%) followed by classroom teaching (22.6%) as the better way of teaching the pertinent topics.



**Figure 3:** Best source/medium to report ADR.

## DISCUSSION

The current study measures the knowledge, attitude, and practice of pharmacovigilance among students in a medical college in Nepal. A spontaneous reporting system of ADRs is fundamental to

drug safety surveillance but under-reporting is a well-recognized issue. Numerous studies have been done to assess the knowledge, attitude, and practice of health care professionals towards pharmacovigilance, but very few studies have been done among the

undergraduate or postgraduate doctors to evaluate their knowledge.<sup>2,7,8</sup>

This study was done among 261 undergraduate medical students for measuring their knowledge, attitude, and practice level of pharmacovigilance. In this study, 78.5% of the participants had heard about pharmacovigilance and 68.5% knew that it is related to ADR. A similar study done among the undergraduate medical students by Kulkarni *et al.* showed that 87% of them heard the term and 65% knew about its use.<sup>3</sup> In a study by Parthiban *et al.*, it was concluded that 81% knew about “pharmacovigilance”, but among them, only 53% knew its relation to ADR reporting.<sup>9</sup> The results of the current study are in agreement with similar research done by Upadhyaya *et al.*<sup>10</sup>

In this study, 67.4% of the participants correctly answered DDA as the national pharmacovigilance center of Nepal. Only 34.9% correctly answered that the International Drug Monitoring Centre was in Sweden, showing their lack of knowledge. A study by Parthiban *et al.* also reported a lack of awareness about the International ADR reporting system (23%) while only 17.4% of the students had the awareness regarding the National Pharmacovigilance Program.<sup>9</sup> In the current study, 94.3% of students responded that doctors, nurses, and pharmacists need to report ADR as they encounter them but only 13.8% had reported them to the concerned authority. The responses showing good knowledge but poor practice about ADR reporting centers were also seen among the undergraduate students and interns in various other studies.<sup>9,11</sup>

A majority of students felt that ADR reporting and monitoring were allocated very little time because of a lack of awareness and knowledge of pharmacovigilance and ADR.<sup>10</sup> Sound knowledge on ADR reporting is crucial in removing the misconceptions and barriers to create a wave of ADR reporting culture in our context. We can see that practices for reporting are lacking which is also observed in various other studies.<sup>3,12,13</sup>

A striking 97.3% of the respondents answered that ADR reporting should be taught to them in their colleges which is similar to a study by Nayak *et al.* showing 92.1 % believing this topic to be taught in their curriculum.<sup>14</sup> The causes of underreporting include indifference to reporting, lack of interest in registration, and lack of time for too many activities in the clinical routine.<sup>15</sup> This gap can be overcome by easing access to registration forms, simplifying documents, toll-free number assistance, financial incentives, creating more ADR centers, facilitating communication between registrars and pharmacovigilance centers that can help improve the notification rates of problems related to the medication.<sup>16-18</sup>

Therefore, it is time to develop proper strategies to increase ADR reporting by healthcare professionals. A proper training facility, educational and awareness campaigns about increasing the reporting of ADR, prioritizing topics like Pharmacovigilance in the curriculum of undergraduate and postgraduate students are crucial to address the problem of underreporting.

## CONCLUSION

There is an absence of a proper ADR monitoring system including a very limited awareness about pharmacovigilance and ADR reporting among the undergraduate medical students. This can be solved by including awareness and training sessions for healthcare students and professionals. This study concludes that medical students who are the future healthcare professionals are not adequately aware of the system of ADR reporting including a very low practice of reporting culture seen among the interns. Therefore, proper orientation about pharmacovigilance should be given to the medical students which can be achieved by incorporating it into the medical curriculum itself and by providing awareness and training to the healthcare professionals.

**Conflict of Interest:** None.

## ACKNOWLEDGMENTS:

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