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**Original Research Article**

# Knowledge, attitude and practice of pharmacovigilance among medical students

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## ABSTRACT

**Background:** Spontaneous voluntary adverse drug reaction (ADR) reporting is the backbone for the successful functioning of the Pharmacovigilance Programme of India. The aim of pharmacovigilance is to ensure safe and rational use of medicines, once they are released for general use in the society. Targeting the younger doctor for sensitization toward pharmacovigilance is the key to ensure practice of adverse drug reactions (ADR) reporting in clinical practice. The objectives of this study are to evaluate the knowledge, attitude, and practice (KAP) of pharmacovigilance among medical students at LLRM Medical College, Meerut, a tertiary care teaching hospital.
**Methods:** A cross-sectional study was carried out using a pretested questionnaire. The questionnaire was designed to assess the KAP regarding pharmacovigilance. The medical students (2nd year, final year, and interns) were included in the study. Only the participants who gave their consent were included in the study. Results were calculated by proper statistical analysis.
**Results:** The current study was conducted in a LLRM Medical College, Meerut, which included a total of 250 medical students of which 40% 2nd year, 40% final year students, and 20% interns. Most of them (83%) accepted that reporting ADR is necessary, and pharmacovigilance should be taught in detail to health-care professionals.
**Conclusions:** This study demonstrated that knowledge of pharmacovigilance among medical students is improving gradually and pharmacovigilance and ADR reporting needs to be made compulsory, have better, interesting ways to learn and understand it, so that the students can practice it with confidence in their clinical practice.

**Keywords:** Pharmacovigilance, Adverse drug reactions, Knowledge, Attitude and practice

## INTRODUCTION

Adverse drug reactions (ADRs) are one of the leading causes of morbidity and represent a substantial economic burden on health-care resources. It has been reported that 2.4%−6.5% of the total admissions in the hospitals are due to adverse reactions, many of which are preventable. The incidence of serious ADRs is 6.7% in India.[1]

In India, all healthcare professionals including doctors, nurses, and pharmacists can report an ADR by filling an ADR form of the Central Drugs Standard Control Organization (CDSCO). The Uppsala Monitoring Centre (UMC, WHO), Sweden, maintains the international database of the ADR reports.

The World Health Organization (WHO) defines pharmacovigilance as "science and activities relating to detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems".[2] Many adverse effects of the drug, drug interactions, interactions with food, and other risk factors such as specific toxicities are known years after release of the medicine. Some rare adverse effects (1:100,000) manifest only after the exposure of drug to a large population.[3,4] Such rare adverse effects of the drug can only be known

through effective pharmacovigilance. Pharmacovigilance program (PP) has played a major role in the detection of ADRs and banning of several drugs from the market. However, under-reporting of ADRs is one of the major problems associated with PP.[5] Because of variation in drug response, individual prescribing habits, drug regulatory system, and availability of drugs, it has been recommended for every country to set up their own PP.[6] Various methods of detecting an adverse event (AE) include spontaneous reporting, prescription event monitoring, and others.[7] Reporting of AEs from doctors to ADRs database by use of these methods can significantly impact the signal detection of unexpected and rare ADRs. There is a lack of knowledge and practice of ADR reporting by the doctors.[8,9] Various reasons for under-reporting of AEs by doctors can be lack of time, feeling that a single case report may not be important, concern that reporting will generate extra work, and fear of legal implications.[7,10,11] The objectives of this study were to assess and evaluate knowledge, attitude, and practice (KAP) of pharmacovigilance among the medical students in a tertiary care hospital.

## METHODS

### *Study design*

The present study was conducted at LLRM Medical College, Meerut. It was questionnaire-based cross-sectional study aimed at assessing the knowledge, attitude and practice towards ADR reporting. The questionnaire was initially developed accordingly to meet the objectives of the study and after referring to various questionnaires used to assess the Knowledge, Attitude and Practice toward pharmacovigilance in other various studies performed within and outside India. The questionnaire was standardized and validated by the faculty members of the department of pharmacology.

### *Study population*

The target population of this study were the undergraduate students of 2nd year, final year, and interns, who were already exposed and familiar with ADR and pharmacovigilance. The duration of the study was 2 months, from September 2023 to October 2023. The standardized and validated questionnaire was distributed to all the students of second, pre-final, and interns. The students were explained about the questionnaire and the need for the study. The required instructions for answering the questionnaire was also explained. Willingness to answer the questionnaire was considered as informed consent, with the students signing on top of the questionnaire agreeing to consent to the study. 30 minutes was given for every participant to complete the questionnaire. Filled up forms were collected back from the students and were analyzed for the results. The statistics was done using Microsoft excel for obtaining the results. Final data was expressed as frequency and percentages.

## RESULTS

In this study, a total of 250 students were assessed regarding their knowledge about pharmacovigilance, of which 100 were 2nd year students, 100 were pre-final year students, and 50 were interns. The distribution of student involvement is depicted in Figure 1.

### *Analysis of knowledge*

The results of the knowledge-based questions are shown in Table 1. Of the 250 who were included in the study, only 62.52% (52 [52%], 74 [74%], and 28 [56%]) of the responders knew what is pharmacovigilance. The final year students seemed to know the actual definition of an adverse drug reaction than the other two groups. Out of 250 students, 80% 2nd year students, 77% pre-final year students, and 54% interns were aware of who can report ADRs. Among all the participants 60% of the responders (46% second year students, 52%final year students and 56% interns) knew about the existence of pharmacovigilance programme of India. About the knowledge of location of WHO-UMC 57% responders (58% second year students, 52% final year students and 66% interns) knew about the location of WHO-UMC.

### *Analysis of attitude*

Table 2 shows the overall attitude of the undergraduate students toward pharmacovigilance and ADR reporting. 83% of the participants totally agreed that ADR reporting is necessary. However, 83% 2nd year students, 77% final year students, and 85% of the participants supported that reporting of ADRs to be a professional obligation. 67% 2nd year students, 10% final year students, and 47% interns feel that filling of ADR form is complex, and majority 91% students thought that pharmacovigilance should be taught to all health-care professionals.

### *Analysis of practice*

Table 3 shows the practice of 2nd year, final year students, and interns toward ADR reporting. About one-third of the total responders said that they had witnessed an ADR in their clinical postings but only 162 out of 250 had seen an ADR form, and 96% final year students had filled ADR form, whereas only 10% 2nd year students and 33% interns had filled an ADR form. 80% 2nd year students, 98% final year students, and 80% interns accepted that they have been trained for how to report ADR.

**Table 1: Correct response toward knowledge of pharmacovigilance and ADRS reporting of pharmacovigilance.**

| Question | Second year n (%) | Final year n (%) | Intern n (%) |
|---|---|---|---|
| **What is pharmacovigilance** | 52 (52) | 74 (74) | 28 (56) |

Continued.

| Question | Second year n (%) | Final year n (%) | Intern n (%) |
|---|---|---|---|
| **The most important purpose of pharmacovigilance is** | 66 (66) | 72 (72) | 30 (60) |
| **What is an adverse event** | 69 (69) | 75 (75) | 34 (68) |
| **Who can report ADRs** | 80 (80) | 77 (77) | 27 (54) |
| **Do you think ADR reporting is professional responsibility** | 80 (80) | 76 (76) | 39 (78) |
| **Are you aware of pharmacovigilance programme of India** | 46 (46) | 81 (81) | 28 (56) |
| **Which regulatory body is responsible for monitoring of ADR** | 61 (61) | 58 (58) | 26 (56) |
| **International units for ADR monitoring is lated in** | 58 (58) | 52 (52) | 33 (66) |
| **What type of ADR should be reported** | 83 (83) | 68 (68) | 24 (48) |
| **What is a serious adverse effect** | 63 (63) | 84 (84) | 34 (68) |

**Table 2: Attitude toward pharmacovigilance and ADR reporting.**

| Question and response | Second year n (%) | Final year n (%) | Intern n (%) |
|---|---|---|---|
| **ADR reporting is necessary** | | | |
| Yes | 86 (86) | 82 (82) | 45 (90) |
| No | 14 (14) | 18 (18) | 5 (10) |
| **Is ADR reporting a professional obligation** | | | |
| Yes | 83 (83) | 77 (77) | 42 (84) |
| No | 17 (17) | 23 (23) | 8 (16) |
| **ADR form is complex to fill** | | | |
| Yes | 67 (67) | 10 (10) | 24 (48) |
| No | 33 (33) | 90 (90) | 26 (52) |
| **Do you think pharmacovigilance should be taught in details to healthcare professional** | | | |
| Yes | 92 (92) | 90 (90) | 47 (94) |
| No | 8 (8) | 10 (10) | 3 (6) |
| **ADR reporting will ensure patient safety** | | | |
| Yes | 94 (94) | 88 (88) | 48 (96) |
| No | 6 (6) | 12 (12) | 2 (4) |

**Table 3: Practice towards ADR reporting.**

| Question and response | Second year n (%) | Final year n (%) | Intern n (%) |
|---|---|---|---|
| **Do you experience ADR** | | | |
| Yes | 24 (24) | 27 (27) | 10 (20) |
| No | 76 (76) | 73 (73) | 40 (80) |
| **Have you seen an ADR reporting form** | | | |
| Yes | 55 (55) | 95 (95) | 32 (64) |
| No | 45 (45) | 5 (5) | 18 (36) |
| **Have you reported ADR or have you filled ADR reporting form** | | | |
| Yes | 10 (10) | 96 (96) | 17 (34) |
| No | 90 (90) | 4 (4) | 33 (66) |
| **Have you ever been trained on how to report ADR** | | | |
| Yes | 80 (80) | 98 (98) | 40 (80) |
| No | 20 (20) | 2 (2) | 10 (20) |

## DISCUSSION

The current study was conducted in a medical college which included a total of 250 medical students in which 100 2nd year, 100 final year students, and 50 interns. In the present study, more than 60% and 73% responder have knowledge about pharmacovigilance and ADR reporting, respectively. Moreover, 60% of responders were aware about pharmacovigilance program (PP) of India. Regarding attitude more than 80% have positive attitude toward ADR reporting and more than 90% students thought that pharmacovigilance should be taught to all health-care professional. In study done by Gupta and Udupa, only 43% are aware of ADR reporting, whereas in this study, more than 60% of students know regarding

pharmacovigilance and ADR reporting.[10] Despite having good knowledge and attitude towards pharmacovigilance, the practice of ADR reporting is high only in final year students more than 90% whereas very less in second year students and interns 10% and 33% respectively. This was because more emphasis was laid by the department of pharmacology in making them understand the importance of pharmacovigilance by having extra practical demonstrations, case studies, and group tasks related to adverse drug reactions, which has not yet been implemented for the 2nd year students. The importance of pharmacovigilance leads to the development of international and nationwide PP but only 57% knew about the existing WHO monitoring center. Few of them 60% knew about nationwide program. In contrast to this, Gupta and Udupa identified 43% of the participants being were aware of National pharmacovigilance centers in India. In another survey, Oshikoya and Awobusuyi from Nigeria reported that 51.5% of the doctors were aware of the existing national pharmacovigilance center.[8] In a study done by Kutmi et al, more than 40% MBBS students think that ADR reporting is compulsory, whereas in this study, more than 80% students think that ADR reporting is necessary which is similar to the study done by Gupta and Udupa who identified 89.5% participants, suggesting necessity of ADR reporting.[10,12] According to another study done by Ponmary et al, 2nd year MBBS students have adequate knowledge and attitude regarding pharmacovigilance compared to residents, and even though nurses have good knowledge about pharmacovigilance, they do not have adequate knowledge about reporting ADR.[5] Finding from all the studies including our study implies that there is a significant dearth of ADR reporting practice in spite of a fair attitude toward ADR reporting. Since the doctors are the first tier to come across the patient, they should be motivated to report ADRs.[13] Busy schedule, lack of knowledge about the exact authority to report ADRs, unavailability of ADR reporting forms, lack of incentives are some of the reasons for under-reporting of ADRs.[14] Assessment of awareness of pharmacovigilance among the healthcare professionals is very important due to under-reporting of ADR.

### *Limitations*

Use of qualitative research methodology involving face-to-face and in-depth interviews would have been more appropriate. Inclusion of other health-care professional in such studies can give us a better insight into the current state of affairs and suggest appropriate measures.

## CONCLUSION

In this study, it was showed that majority of the students had knowledge about pharmacovigilance and understand the need for reporting. In spite of that the reporting rate of ADRs by them is very low. Hence, there was huge gap between the ADR experienced and ADR reported by health-care professional. Here, majority of respondents agreed that reporting of ADR is necessary and it should be made an integral part of the clinical activities to improve the patient care. So finally, from the study, we can conclude that the overall knowledge and attitude are definitely better among the undergraduate students. The practice of pharmacovigilance and ADR reporting has to improve, and it can be done so by including pharmacovigilance throughout the entire course of medical curriculum and incorporating better, efficient and interesting methods to teach, sensitize, and practice pharmacovigilance. The findings of the study suggest a huge scope for improving the awareness and knowledge about pharmacovigilance among the healthcare professionals who are the backbone of safe and better healthcare delivery. For this, there is a need for continuous educational initiatives like CME, and hands-on training for ADR reporting, it should also be included in their curriculum as part of their study.

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