

# Effect of educational intervention on awareness of pharmacovigilance among medical undergraduates in a tertiary care teaching hospital

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## Abstract

**Aim:** (1) To assess the knowledge and attitude of undergraduates about adverse drug reaction (ADR) reporting at a tertiary care teaching hospital. (2) To assess the effect of educational intervention among medical undergraduates on knowledge and attitude about pharmacovigilance (PV).

**Materials and Methods:** Cross-sectional, questionnaire-based survey conducted at a tertiary care teaching hospital. Respondents were 192 undergraduate students (2<sup>nd</sup> year). The study instrument was a self-developed, prevalidated semi-structured questionnaire. Participants were given 1 h to complete the questionnaire. After this, a 2 h lecture about PV was taken. Participants were asked to fill the same questionnaire after the educational intervention. Pre- and post-test questionnaire were compared.

**Results:** There was an overall improvement in all three aspects, i.e., awareness, knowledge, and attitude. Most of the students had knowledge of the meaning of PV and reporting of ADR by doctors. However, there was a significant improvement in the knowledge regarding reporting of ADR by dentist, nurses, and pharmacist. Similarly, students were aware of the fact that ADR with allopathic medicines should be reported, but postintervention, there was improvement in percentage regarding reporting of ADR in the case of herbal and traditional medicine, blood products, and biological and medical device. There was a significant improvement in percentage regarding awareness about process of reporting ADR after exposure to lecture.

**Conclusion:** There is a need of increasing awareness among the medical students to improve the reporting of ADRs. Adequate consideration needs to be given to the subject of ADRs in the clinical pharmacology and therapeutics curricula in undergraduate medical education.

**Keywords:** Adverse drug reaction, attitude, knowledge, practice

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## INTRODUCTION

Adverse drug reactions (ADRs) are associated with significant morbidity and mortality. Recent estimates suggest ADRs to be the fourth major cause of death in the United States of America.<sup>[1,2]</sup> In addition to the human costs, ADRs have a

major impact on public health by imposing a considerable economic burden on the society and the already-stretched health-care systems.<sup>[3]</sup> In a study from South India, it was observed that 3.7% of the total hospitalized patients were

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suffering from ADR, among which 1.3% were fatal. About 0.7% of hospital admissions were due to ADRs.<sup>[4]</sup> A study by Arulmani *et al.* revealed that among the collected ADR reports in the hospital, 3.4% were confirmed ADR-related cases which need to be hospitalized and 3.7% ADRs even developed in the patients during the time of hospital admission.<sup>[5]</sup> It is estimated that only 6%–10% of all ADRs are reported, and under-reporting of ADRs is a major problem.<sup>[6]</sup> Spontaneous reporting of ADRs is an important method for detecting new safety issues related to drugs. Pharmacovigilance (PV) is defined by the World Health Organization as “the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem.”<sup>[7]</sup>

PV not only helps early detection of ADRs but also facilitates identification of both, risk factors and the mechanism underlying the ADR. Although India is participating in the program, its contribution to the Uppsala monitoring database which is responsible for maintaining international database of ADRs is very little.<sup>[8]</sup> To improve the reporting rate, it is essential to improve the knowledge, attitude, and practices (KAPs) of health-care professionals regarding ADR reporting and PV. The right time to do it is probably during the undergraduate and postgraduate education of the doctors. Medical students could play a major role in successful implementation of PV program if adequate knowledge and skill are imparted to them during undergraduate training career, but at present, they do not have any significant role which is due to inadequate training to them regarding ADR reporting.<sup>[9,10]</sup> Education has an important role to play in increasing awareness about PV. PV has been included in the medical undergraduate and postgraduate curriculum in many medical colleges to instigate the PV program. Very few studies are there to assess the knowledge, attitude of PV among undergraduate medical students, and these studies indicate inadequate knowledge about PV among health-care professionals. In one study,<sup>[11]</sup> interactive educational intervention on PV among undergraduate medical students was found to be effective. However, the results of these studies cannot be applied to medical students in our institute as KAP among the students will differ from institute to institute. Hence, this study has been done to assess KAP of PV among the 2<sup>nd</sup> year medical students in a tertiary care teaching hospital which would help in planning interventions among this group depending on the results obtained.

### Objectives

1. To assess the knowledge and attitude of medical undergraduate students about ADR reporting at a tertiary care teaching hospital
2. To assess the effect of educational intervention among medical undergraduates on knowledge and attitude about PV.

### MATERIALS AND METHODS

This was cross-sectional, questionnaire-based survey conducted at a tertiary care teaching hospital after approval from the Institutional Ethics Committee. Respondents were 200 undergraduate students (2<sup>nd</sup> year), of which 192 consented. They were explained the nature and purpose of the study, and necessary consent was obtained. Students were explained about the voluntariness of participation in the study.

The study instrument was a self-developed, prevalidated semi-structured questionnaire consisting of both open- and close-ended items. The questionnaire was first pretested in five participants and suitable modifications done. The final version of the questionnaire was distributed to respondents. Appropriate instructions about filling the questionnaire were given. The following information was obtained: demographic characteristics, KAP of ADR reporting. The questionnaire consisted of 19 questions about PV, of which 8 questions were related to knowledge, 5 questions related to attitude, 4 questions related to awareness, and 2 questions related to practice. The binary scale was used. The correct responses were scored one point and wrong responses were given zero point for knowledge-, awareness-, and practice-related questions. Participants were given 1 h to complete the questionnaire. After this, a 2 h lecture about PV was taken. This educational intervention consisted of a theoretical PowerPoint presentation on what is PV, its main objectives, PV program in India, how to report and whom to report ADRs, who can report ADR, Vigiflow database, problems in reporting ADR, classification of ADRs, incidence of ADRs, various scales of causality assessment, role of health-care professionals in reporting of suspected ADR followed by what happens to reported ADR. Participants were asked to fill the same questionnaire after educational intervention in the form of lecture. Pre- and post-test questionnaire were compared.

### Statistical analysis

Data were expressed as counts and percentages. Statistical comparison of data between pre- and post-test was made using the Chi-square test using Graph Pad prism 5.0 and value of  $P < 0.05$  was considered statistically significant.

### RESULTS

A total of 192 medical students were involved in pre- and post-test questionnaire. Hundred and one of the respondents

were men and 91 women. Mean age of the respondents was  $20.32 \pm 1.06$  years. The correct response rates between pre- and post-intervention had improved in majority of the medical undergraduates which brings out the effectiveness of intervention for improving the reporting system. There was an overall improvement in all the three aspects, i.e., awareness, knowledge, and attitude. Results were significant with respect to knowledge of location of PV center (81.75% improvement). Most of the students had knowledge of meaning of PV and reporting of ADR by doctors. However, there was a significant improvement in the knowledge regarding reporting of ADR by dentist, nurses, and pharmacist ( $P < 0.0001$ ). Similarly, before educational intervention, most of the students were aware of the fact that ADR with allopathic medicines should be reported but were ignorant about reporting of ADR in case of herbal and traditional medicine, blood products, and biological and medical device. Postintervention, there was a significant improvement in percentage regarding awareness of reporting of ADR in the case of herbal and traditional medicine, blood products, and biological and medical device ( $P < 0.001$ ) [Table 1]. There was a significant improvement in percentage (82.3% improvement) regarding awareness about the process of reporting ADR after exposure to lecture ( $P < 0.001$ ) [Table 2]. After lecture, 70.31% felt that ADR reporting should be a professional obligation as compared to 55.2% before intervention [Table 3]. Most of the students (77%) responded that they have seen the Central drug standard control organization (CDSCO) ADR reporting form and have observed an ADR. After lecture, general attitude of the respondents about ADR reporting was as follows: ADR reporting should be voluntary (33.33%), remunerated (2%), identity of reporter should be concealed (40.5%), identity of prescriber should be concealed (19.7%), compulsory (67.18%) [Table 4].

## DISCUSSION

Reporting of ADRs is a vital component of PV and is fundamental to the safety surveillance of marketed medicinal products. Spontaneous ADR reporting plays a crucial role in the PV program. Many studies have evaluated the knowledge of health-care professionals about PV. However, reporting the same exclusively in undergraduates before and after an educational intervention was reported in very few studies.<sup>[12]</sup> This study was conducted on undergraduate students with aim to assess their KAP about PV. Medical students get exposed to the concept of PV in the 2<sup>nd</sup> year of their curriculum, but this is limited.

In this study, almost all of the students had knowledge about the meaning of ADR before intervention. However,

**Table 1: Respondents knowledge about adverse drug reaction reporting (n=192)**

	Pretest score, n (%)	Posttest score, n (%)	P
Who can report an ADR?			
Medical doctors	183 (95.31)	192 (100)	0.035
Dentist	101 (52.60)	192 (100)	<0.0001***
Nurses	31 (16.14)	187 (97.39)	<0.0001***
Pharmacist	97 (50.52)	186 (96.87)	<0.0001***
Physiotherapist	87 (45.23)	180 (93.67)	<0.0001***
All of the above	7 (3.64)	157 (81.77)	<0.0001***
ADR with which of the following should be reported?			
Allopathic medicines	180 (93.75)	187 (97.39)	0.1345
Herbal/traditional medicine	48 (25.00)	156 (81.25)	<0.0001***
Blood products	63 (32.81)	152 (79.16)	<0.0001***
Biological and medical devices	108 (56.25)	169 (88.02)	<0.0001***
All of the above	20 (10.41)	128 (66.66)	<0.0001***

\*\*\* $P < 0.0001$  by using Chi-square test. ADR=Adverse drug reaction

**Table 2: Awareness about adverse drug reaction reporting practices (n=192)**

Questions	Pretest score, n (%)	Posttest score, n (%)	P
Aware of PV?	188 (97.91)	192 (100)	0.123
Aware of location of PV?	36 (18.75)	192 (100)	<0.0001***
Aware of ADR monitoring and reporting centre in India?	80 (41.46)	187 (97.39)	<0.0001***
Aware about the process of ADR reporting?	34 (17.70)	191 (99.47)	<0.0001***
ADRs should be reported for newly marketed agents?	181 (94.27)	189 (98.47)	0.0529
Observed any ADR in a patient?	33 (17)	147 (76.56)	<0.0001***
Seen an ADR form from CDSCO?	7 (3.64)	149 (77.60)	<0.0001***

\*\*\* $P < 0.0001$  by using Chi-square test. ADRs=Adverse drug reactions, PV=Pharmacovigilance, CDSCO=Central drug standard control organization

they were not aware of location of PV center in India. In a study by Meher *et al.*,<sup>[13]</sup> similar finding was reported regarding the 2<sup>nd</sup>-year students knowledge about location of PV center in India. Although the fact that medical professionals like doctors and dentists can report an ADR is well known, the awareness that even nurses (16.14%), pharmacists (50.52.%) can do so was very less in this study before educational intervention. However after the lecture, there was a significant improvement in percentage regarding knowledge about who can report ADR ( $P < 0.0001$ ). Awareness regarding who can report an ADR is important as involvement of paramedical staff in spontaneous reporting of ADRs is essential and will help in improving the reporting rates, since they are in close contact with the patients for longer duration, than the doctors. Similar findings were reported in some studies.<sup>[8,14]</sup> In one study by Harish G. Bagewadi, there was a significant improvement regarding awareness about healthcare professionals reporting ADR after educational intervention.<sup>[11]</sup> Preintervention, majority of

**Table 3: Respondents' attitude regarding adverse drug reaction reporting (n=192)**

Factors encouraging reporting of ADR	Number of respondents (pretest, n=192)	Number of respondents (posttest, n=192)
Training/projects/CME/newspaper/social media	16.14	50.23
Increase awareness among people and patients	15.02	30.33
Co-operation amongst various stake holders	1.2	10.05
Incentives	20	28
Easy process of reporting and easy availability of forms	30	32
Reporting ADR is a professional obligation	55.23	70.31
Medical students play a role in ADR reporting	92.7	95.31
ADR reporting benefit both doctor and patient	98	100

ADR=Adverse drug reaction, CME=Continuing medical education

**Table 4: Respondents' awareness about what should be applicable to adverse drug reaction reporting (n=192)**

What should be applicable to ADR reporting	Pretest score (%)	Posttest score (%)	P
Voluntary	44 (22.92)	64 (33.33)	0.0308
Remunerated	3 (1.56)	4 (2)	>0.9999
Conceal identity of the prescriber	39 (20.31)	38 (19.72)	>0.9999
Conceal identity of the reporter	49 (25.52)	77 (40.05)	0.0033
Compulsory	16 (8.33)	129 (67.18)	<0.0001***

\*\*\*  $P < 0.0001$  by using Chi-square test. ADR=Adverse drug reaction

the respondents were of the opinion that ADR reporting has to be done only for allopathic medicines which is similar to the findings reported by Gupta and Udupa.<sup>[8]</sup> This concept of the respondents changed after the educational intervention. It is necessary to create awareness among health-care professionals that ADR with drugs from any systems of healthcare should be reported because many patients are in the habit of taking medicines from different systems of healthcare such as Ayurvedic, Homeopathy, and Unani, and none of the medicines is free from ADRs. Majority of respondents were of the opinion that ADRs should be reported for new drugs. This widely prevalent misconception needs to be addressed and measures taken to rectify the same. PV is particularly concerned with ADRs, which are drug responses that are noxious and unintended, and which occur at doses normally used for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.<sup>[15]</sup> Hence, ADR is to be reported for all drugs. Another study in resident doctors' has reported that 93% of the doctors' were more inclined to report an ADR if it is with a new drug.<sup>[8]</sup>

There was a significant improvement in percentage ( $P < 0.0001$ ) of respondents regarding awareness about process of ADR reporting and monitoring center in India after intervention. Majority of respondents opined that increasing awareness about ADR reporting through various educational programs such as seminars and conferences is the only way to improve ADR reporting. Percentage of awareness regarding this increased after the lecture (16.14% pretest response vs. 50.23% posttest). Less number of respondents cited other reasons such as making ADR

reporting compulsory, providing incentives for reporting, simplifying the process of reporting, increasing awareness of patients etc., After the lecture, 70.31% of the respondents in this study felt that ADR reporting is a professional commitment. A small number of respondents (10.05%) mentioned that improved co-operation among various stakeholders is one of the measures to overcome this problem. This appears to be a very good suggestion as ADR reporting is teamwork which is not possible without proper cooperation between different disciplines involved in this. Postintervention, 67.1% of respondents suggested that ADR reporting should be made compulsory. This can certainly help in improving the reporting rates. It is also encouraging that majority of the students are aware of the fact that medical students play an important role in ADR reporting and ADR reporting is beneficial for both doctors and patients. On assessing the practice, it was found that none of the participants had ever reported an ADR. During lecture, the students were shown ADR reporting form by CDSCO. The above observations point out to the lack of knowledge about reporting system as one of the causes of under-reporting; similar observations were also reported in other studies.<sup>[16,17]</sup> When asked about what should be applicable to ADR reporting, to improve ADR reporting rate most of the students were of the opinion that it should be made compulsory. There was a significant improvement in percentage postintervention regarding this ( $P < 0.0001$ ). Less number of respondents cited other reasons such as making, providing incentives for reporting, concealing identity of the reporter and prescriber as to what should be applicable to ADR reporting so as to improve ADR reporting rate. Another published study has also suggested the use of financial incentives as a tool to enhance reporting of ADRs.<sup>[18]</sup> This does not appear to be an appropriate solution to address this problem as doing so increases the possibility of over-reporting to obtain financial rewards.<sup>[19]</sup> The response of students in our study group regarding ADR monitoring showed that educational intervention has improved their knowledge toward practice of reporting of ADR. This study has an important limitation that the number of students participated in this study was relatively small as only 2<sup>nd</sup>-year students were enrolled in

this study. Therefore, these results may not necessarily be extrapolated to all medical students at this institute as well as other institutes and health-care professionals. We recommend that several such studies of similar kind should be conducted among other institutions to develop strategies to improve the KAP of PV in India.

## CONCLUSION

The study strongly suggests that there is a need of increasing awareness among the medical students to improve the reporting of ADRs. Adequate consideration needs to be given to the subject of ADRs in the clinical pharmacology and therapeutics curricula in undergraduate medical education which can be considered the first step in sensitizing the medical students about this important issue. Finally, to conclude, undertaking educational programs like continued medical education and seminars aimed at increasing awareness about PV will be helpful in improving the status of ADR reporting.

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## Conflicts of interest

There are no conflicts of interest.

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