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## ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE OF PHARMACOVIGILANCE AMONG THE UNDERGRADUATE MEDICAL STUDENTS IN A NORTHERN INDIAN TERTIARY CARE TEACHING HOSPITAL – AN OBSERVATIONAL STUDY

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**ABSTRACT: Objective:** Underreporting of adverse drug reactions (ADRs) is the major drawback encountered in the pharmacovigilance programs. Inadequate knowledge and skill about pharmacovigilance among the health care professionals are the major reasons for underreporting of ADRs. This study was done to assess knowledge, attitude and practice (KAP) of undergraduate medical students about pharmacovigilance as they are the future health-care givers. **Materials and Methods:** This cross-sectional, questionnaire-based study was carried out to evaluate KAP of pharmacovigilance among undergraduate medical students in a Tertiary Care Teaching Hospital of North India. Data obtained from filled questionnaires was thereby analysed. **Results:** The mean score of 2<sup>nd</sup> year, prefinal and final year students for knowledge is (7.58, 6.92 and 6.73), for attitude (7.51, 6.91 and 7.23) and for practice is (1.53, 1.68 and 1.52) respectively. There is a significant difference in mean score between three groups for knowledge and attitude, but not for practice. **Conclusion:** Students have a good attitude but have an inadequate knowledge and poor practice towards pharmacovigilance. For this, pharmacovigilance related activities need to be incorporated in the undergraduate academic curriculum.

**INTRODUCTION:** Adverse Drug Reactions (ADRs) are representing a major concern of health-care systems in the modern era. Adverse drug reactions are among the significant cause of morbidity and mortality worldwide.<sup>1</sup> According to the World Health Organization (WHO), Adverse Drug Reaction (ADR) is defined as “any noxious, unintended and undesired effect of a drug which occurs at doses used in humans for prophylaxis, diagnosis or therapy of disease, or for the modification of physiologic function.”<sup>2</sup>

ADRs not only pose a risk to the patient’s safety, but also adversely affect their quality of life and increase the healthcare cost considerably.<sup>3, 4</sup> Studies suggest that ADR is responsible for 0.2-24% of hospital admission.<sup>5, 6</sup> Thus ADRs have a major impact on public health by imposing considerable economic burden on the society.<sup>7</sup>

The Uppsala Monitoring Centre (UMC) in Sweden maintains the international database of the ADR reports. India contributes to this database in the form of the Pharmacovigilance Programme of India (PvPI) which has been operational since July 2010 and is responsible for conducting activities related to ADR monitoring under the aegis of Central Drug Standard Control Organization (CDSCO).<sup>8</sup> Spontaneous reporting of ADRs by health care professionals is the cornerstone of pharmacovigilance.

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The major limitation associated with spontaneous ADR reporting system is underreporting.<sup>9</sup> It is estimated that only 6-10% of all ADRs are reported globally.<sup>10</sup> India rates below 1% in term of ADR reporting.<sup>11</sup> This clearly emphasises that the current status of pharmacovigilance in India is far from satisfactory.

Previous reported studies have found that underreporting of ADRs is related with shortcomings in the knowledge and attitude among healthcare professionals.<sup>12, 13</sup> Therefore, in order to improve the reporting rate and for the successful running of Pharmacovigilance program, it is important to improve the knowledge, attitude and practices (KAP) of the healthcare professionals regarding ADR reporting and pharmacovigilance. The best time to do it is probably during the undergraduate training career of the doctors. Medical students could play a major role and bring a paradigm shift in successful implementation of pharmacovigilance program if proper training regarding pharmacovigilance is imparted to them but at present they do not have any significant role which is due to inadequate training to them.<sup>14, 15</sup>

Therefore, the primary objective of this study was to evaluate the knowledge, attitude, and practices (KAP) towards pharmacovigilance among the undergraduate medical students and to compare the result among different groups according to year of study.

**MATERIALS AND METHODS:** The study was conducted at Acharaya Shri Chandra College of Medical Sciences and Hospital (ASCOMS&H), Jammu, J&K, India. It was a cross-sectional questionnaire-based observational study carried out on Two hundred and forty undergraduate MBBS students, 80 from each batch. The students who were willing to participate and gave written informed consent were included in the study. The study involved 2<sup>nd</sup> year, prefinal and final year undergraduate medical students. Prior approval was taken from the Institutional Ethics Committee to conduct the study. Structured pretested questionnaire contained 11 questions to check knowledge, 8 for attitude and 5 to study practices. These questions were designed based on earlier studies for assessing KAP of ADR reporting.

Before the commencement of the study, all the students were being explained about the purpose of the study and any doubts regarding questionnaire were clarified by the investigator. Students were given 30 minutes to fill the questionnaire. The data was analyzed with the help of computer software MS Excel and SPSS version 17.0 for Windows. Collected data was compiled and outcome was reported as mean  $\pm$  standard deviation with statistical significance assessed by ANOVA test; the level of statistical significance was set at  $p < 0.05$ .

**RESULTS:** There were eleven knowledge-based questions. Among the respondents 97.5% of 2<sup>nd</sup> year, 81% of prefinal year and 90% of final year students responded correctly to the definition of ADR. 88.7% of 2<sup>nd</sup> year, 72.5% of prefinal and 82.5% of final year students knew who can report ADR. 68.7% of 2<sup>nd</sup> year, 72.5% of prefinal and 47.5% of final year students were aware about locality of National Pharmacovigilance Centre. 46.2% of 2<sup>nd</sup> year, 23.7% of pre-final and 37.5% of final year students were aware about the regulatory body responsible for monitoring ADRs in India. The details regarding the responses of medical students for knowledge based questions are listed in **Table 1**. Mean knowledge score of 2<sup>nd</sup> year students is more than pre-final and final year students. Difference in Knowledge score among three groups is statistically significant as shown in **Table 4** and **Fig. 1**.

There were eight questions to assess the attitude of students towards pharmacovigilance. 86.2% of 2<sup>nd</sup> year, 73.7% of pre-final and 87.5% of final year students felt that ADR reporting should be included under pharmacology practical. 92.5% of 2<sup>nd</sup> year, 90% of pre-final and 90% of final year students felt that medical students could play a role in ADR monitoring. The details regarding the responses of the medical students for attitude-based questions are listed in **Table 2**. Mean score of attitude between three groups respectively and difference in score among them is statistically significant as depicted in **Table 4** and **Fig. 2**.

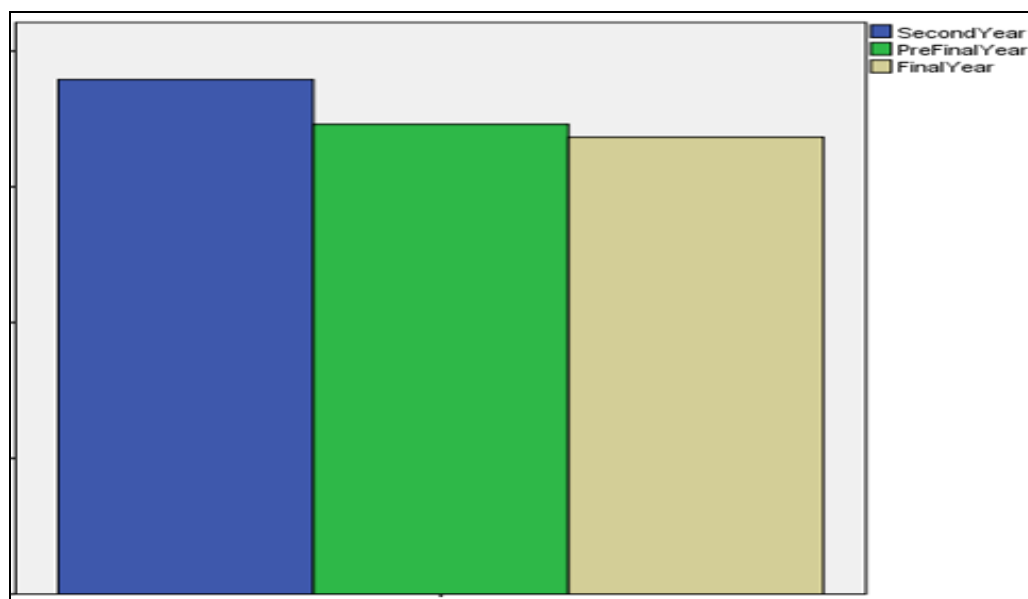
There were five practice-related questions. It was found that that 73.7% of 2<sup>nd</sup> year, 45% of pre-final and 27.5% of final year students had ever seen the adverse drug reaction form by CDSCO. 6.2% of 2<sup>nd</sup>

year, 8.7% of pre-final and 22.5% of final year students ever played any role in reporting ADR. The details regarding the responses of medical students regarding these questions are depicted in

**Table 3.** Difference in mean practice score among three groups is not statistically significant as shown in **Table 4** and **Fig. 3**.

**TABLE 1: RESPONSE OF STUDENTS TO KNOWLEDGE-BASED QUESTIONS**

S.no.	Questions	Number (%) of Students Responded Correctly		
		Second year (n=80)	Pre-final year (n=80)	Final year (n=80)
<b>Knowledge-based questions</b>				
1	Define ADR	78 (97.50)	65 (81.25)	72 (90.00)
2	Who can report ADR	71 (88.75)	58 (72.50)	66 (82.50)
3	Does ADR reporting has any specific format	70 (87.50)	68 (85.00)	67 (83.75)
4	What is pharmacovigilance	70 (87.50)	57 (71.25)	64 (80.00)
5	Do you know regarding the existence of PvPI	62 (77.50)	50 (62.50)	48 (60.00)
6	Where is national pharmacovigilance centre in India located	55 (68.75)	58 (72.50)	38 (47.50)
7	Which regulatory body in India is responsible for monitoring ADRs	37 (46.25)	19 (23.75)	30 (37.50)
8	Which scale is most commonly used to establish ADR causality	16 (20.00)	28 (35.00)	18 (22.50)
9	In which phase of the clinical trial rare ADRs can be identified	35 (43.75)	52 (65.00)	44 (55.00)
10	Where is international centre for adverse drug reaction monitoring is located	59 (73.75)	31 (38.75)	21 (26.25)
11	Are you aware of any drug banned due to ADR	54 (67.50)	68 (85.00)	71 (88.75)



**FIG. 1: MEAN KNOWLEDGE SCORE**

**TABLE 2: RESPONSE OF STUDENTS TO ATTITUDE-BASED QUESTIONS**

S.no.	Questions	Number (%) of Students Responded Correctly		
		Second year (n=80)	Pre-final year (n=80)	Final year (n=80)
<b>Attitude-based questions</b>				
12	Do you think reporting of adverse drug reaction is necessary	79 (98.75)	74 (92.50)	78 (97.50)
13	Do you think ADR reporting benefits both patients and doctors	76 (95.00)	72 (90.00)	79 (98.75)
14	Do you think ADR reporting should be included under pharmacology practical	69 (86.25)	59 (73.75)	70 (87.50)
15	Do you think that ADR reporting is a part of professional obligation of all related to health care	76 (95.00)	62 (77.50)	72 (90.00)
16	Do you think that medical students could play a role in ADR monitoring	74 (92.50)	72 (90.00)	72 (90.00)
17	Do you think that discussion on ADR during clinical posting has	78 (97.50)	68 (85.00)	70 (87.50)

18	any relevance Do you think that there is a need of information on drugs causing ADRs and their management strategies	77 (96.25)	76 (95.00)	72 (90.00)
19	What is your opinion about establishing ADR monitoring centre in every hospital	72 (90.00)	70 (87.50)	66 (82.50)

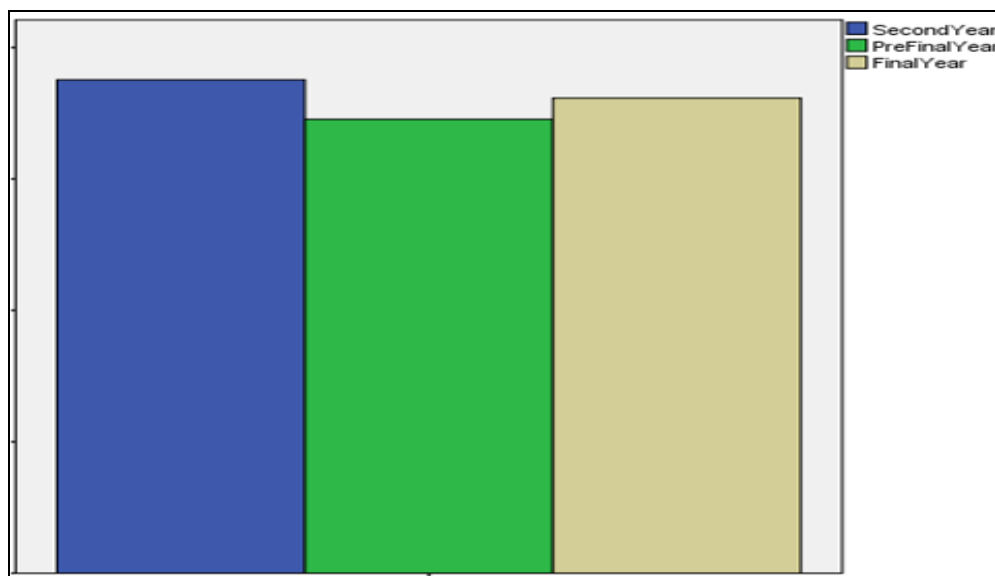


FIG. 2: MEAN ATTITUDE SCORE

TABLE 3: RESPONSE OF STUDENTS TO PRACTICE-BASED QUESTIONS

Questions	Number (%) of Students Responded Correctly			
	Second year (n=80)	Pre-final year (n=80)	Final year (n=80)	
<b>Practice-based questions</b>				
20	Have you seen an adverse drug reporting form by CDSCO	59 (73.75)	36 (45.00)	22 (27.50)
21	Is there any routine discussion on ADRs during your ward posting	24 (30.00)	46 (57.50)	32 (40.00)
22	Have you ever played any role in reporting ADR from your institution	5 (6.25)	7 (8.75)	18 (22.50)
23	Have you anytime read any article on prevention of ADRs	29 (36.25)	40 (50.00)	46 (57.50)
24	Have you ever visited any ADR monitoring centre	5 (6.25)	6 (7.50)	4 (5.00)

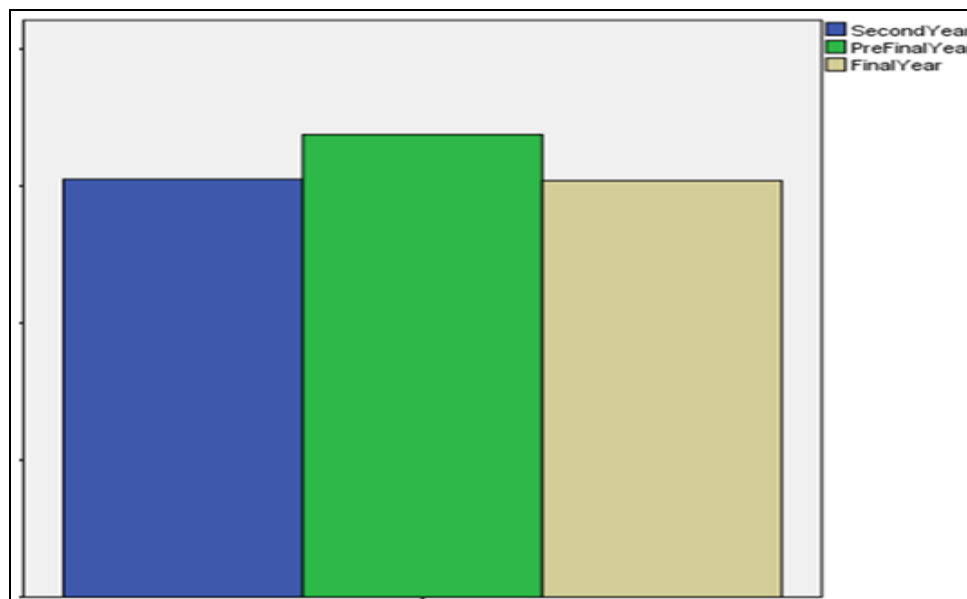


FIG. 3: MEAN PRACTICE SCORE

**TABLE 4: COMPARISON OF MEAN SCORE**

Variables	Second year (n=80)	Prefinal year (n=80)	Final year (n=80)	Statistical inference
Knowledge (maximum=11)	7.58 ± 1.34*	6.92 ± 1.46*	6.73 ± 1.41*	p=0.001 F=8.075
Attitude (maximum=8)	7.51 ± 0.08*	6.91 ± 0.95*	7.23 ± 0.823*	p=0.0001 F=21.169
Practice (maximum=5)	1.525 ± 0.87	1.6875 ± 0.95	1.52 ± 0.96	p=0.45 F=0.793

\*p<0.05 and difference in mean score of different groups are significant

**DISCUSSION:** Reporting of ADRs is essential for the success of any pharmacovigilance program but the main drawback encountered with the pharmacovigilance program is the lack of coordinated spontaneous reporting which is a matter of concern not only in India, but also around the world. There are enormous studies to assess the KAP of healthcare professionals towards pharmacovigilance but there are very few studies among the undergraduate medical students to assess their knowledge about the same.<sup>16, 17</sup> This study is one of the few studies done among the undergraduate medical students regarding KAP of pharmacovigilance.

In this study students showed better attitude but poor practice and limited knowledge towards pharmacovigilance which is consistent with the findings of other studies.<sup>15</sup> In the present study, the average knowledge score of second year students is relatively better than prefinal and final year students.

The main focus of the pharmacovigilance is to promote the safe and the rational use of medicines. It has played a major role in detection of ADRs but previous studies suggest that under-reporting of ADRs is one of the major problems associated with pharmacovigilance program.<sup>18</sup> Major reason for under reporting is lack of knowledge and skill about pharmacovigilance program, which was reflected in our study, and is consistent with the findings of other studies.<sup>19, 20</sup> This was indicating that continuing sensitization is required regarding ADR reporting and pharmacovigilance. It can be done by educational interventions like incorporation of pharmacovigilance related activities in the undergraduate practical, continuous medical education (CME), and workshop on pharmacovigilance.<sup>21</sup>

**CONCLUSION:** In conclusion, this study showed that the undergraduate medical students had a relatively better attitude but limited knowledge and poor practice towards pharmacovigilance. The findings of the study suggest that there is need for continuous education regarding pharmacovigilance and ADR reporting system among the students who will be the future health-care givers. For this, pharmacovigilance related activities should be included in the medical teaching curriculum in pharmacology as a part of their study. Thus these efforts may develop increase in awareness towards pharmacovigilance among students and ultimately may translate into increase in the adverse drug reaction (ADR) reporting in future.

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