

## A Questionnaire based comparative study to assess the knowledge, attitude, and practice of “adverse drug reaction reporting,” among 1<sup>st</sup>MBBS, 2<sup>nd</sup>MBBS and Post Graduate students in a medical college.

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### Abstract

**Background and objectives:** Spontaneous reporting of adverse drug reactions (ADR) is vital for pharmacovigilance. It is important to gain knowledge regarding adverse drug reaction in the undergraduate level. The present study was conducted to assess the knowledge, attitude, and practice (KAP) of ADR reporting among medical students both undergraduate and Post Graduates. **Materials & Methods:** This was a cross sectional questionnaire-based study conducted among medical students in a teaching hospital, of south India. There was a total of 24 questions of which 10, 8 and 6 were related to Knowledge, Attitude and Practice respectively. Data was analysed using SPSS (Statistical Package for Social Science) version 28 for descriptive and analytical statistics.

**Results:** The respective mean scores of 1<sup>st</sup>MBBS, 2<sup>nd</sup>MBBS and Post Graduate students are (3.04, 7.06, 6.59) for knowledge, (6.54, 7.18, 7.10) for attitude and (0.01, 2.96, 2.25) for practice. The KAP of 2<sup>nd</sup> MBBS students is more compared to other groups and this is statistically significant.

**Conclusion:** Most of the students have positive attitude towards ADR reporting but this was not reflected in their practice. Including ADR reporting as a part of pharmacology practical could be the reason for 2<sup>nd</sup>MBBS students having better KAP; compared to Post Graduates. Including pharmacovigilance as part of Post Graduate curriculum (irrespective of the specialty) could further improve spontaneous reporting.

**Key words:** Adverse Drug Reactions, Pharmacovigilance, Medical Students, Knowledge, Attitude, Practice

### Introduction

Adverse drug reaction (ADR) is defined as “a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function.” [1]

ADRs are an important cause of mortality and morbidity worldwide. They also cause a significant burden on health care resources. ADRs account for 4.2-30% of hospital admissions in the USA and Canada, 5.7-18.8% of admissions in Australia, and 2.5-10.6% of admissions in Europe. [2] It has been reported that between 2.5% and 21.4% patients across

the world were admitted due to adverse drug reactions. [3,4,5]. ADRs are the 4th to 6th leading cause of death in the United States.[6]

Pharmacovigilance (PV) is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.[7] Information collected during the pre-marketing phase of drug development is incomplete. So, post-marketing surveillance is important to detect less common, but sometimes very serious ADRs. Voluntary reporting helped in the improvement of information in labelling of many effective pharmaceutical products (new possible ADRs, contraindications, dosage modifications etc.). Some drugs are even withdrawn completely from the market. So, reporting of suspected adverse drug reactions can reduce the suffering and save thousands of patient lives.[8] Health care providers (HCPs) are in the best position to report on suspected ADRs.

Uppsala Monitoring Centre (UMC) is a World Health Organization (WHO) Collaborating Centre responsible for the operational and scientific support of the WHO Programme for International Drug Monitoring (WHO PIDM). The Ministry of Health and Family Welfare (MoHFW), Government of India launched the nationwide Pharmacovigilance Programme of India (PvPI) in the year 2010 with a broad objective to safeguard the health of people of India. Indian Pharmacopoeia Commission (IPC) under the MoHFW has been functioning as the National Coordination Centre (NCC) for PvPI since April 2011. PvPI- Indian Pharmacopoeia Commission (IPC), in Ghaziabad, India, became a WHO Collaborating Centre in 2017 [9]. According to annual performance report 2022, there are a total of 534 ADRs Monitoring Centres (AMCs) across the country.

These centres are covered in 6 zonal offices of Central Drugs Standard Control Organization (CDSCO) for administrative and logistic purpose. These AMCs report ADRs to NCC through VigiFlow, the software owned by WHO-UMC, (Sweden).[10]

India is the 9th largest reporter of ICSR to WHO-UMC. Contribution of India to the WHO global Individual Case Safety Reports (ICSRs) database is only 3% though we are one of the most populous countries in the world. [11] Health care professions play a significant role in successful implementation of Pharmacovigilance program of India. It is important to gain knowledge regarding adverse drug reaction in the undergraduate level.

3 groups were involved in the study. 1<sup>st</sup> MBBS group represents students without prior knowledge on Pharmacovigilance, 2<sup>nd</sup> MBBS students represent students with basic knowledge on pharmacovigilance as part of their curriculum and Post Graduates represent the health care providers. Very few studies were done involving these 3 groups. So, the present study was done to assess the KAP of ADR reporting.

## Material and Methods

*Study design:* A cross-sectional questionnaire-based study

*Study place:* Bhaskar Medical College and General Hospital, Moinabad, Telangana.

*Study population:* A total of 328 subjects were involved in the study. 125 First MBBS, 112 Second MBBS and 91 Post Graduates.

*Study period:* The study was conducted for a period of 3 months from Feb 2022 to April 2022

*Inclusion criteria:*

- 1<sup>st</sup>MBBS, 2<sup>nd</sup>MBBS and Post Graduates of Bhaskar Medical College & General Hospital who are willing to participate in the study

*Exclusion criteria*

- Students who did not return the forms
- Incompletely filled or unanswered forms

*Ethical considerations:* Institutional ethics committee approval is taken.

Standard Structured Questionnaire was given to the students after explaining the purpose of the study. The questionnaire has three distinct domains, knowledge attitude and practice.

Aspects that are explored include

1. The knowledge of the respondents regarding ADR reporting
2. Their attitudes and opinion towards reporting, and
3. Actual ADR reporting practices being followed by the respondents.

Doubts regarding the questionnaire were clarified by the investigators. 30 minutes duration was given to the respondents to fill the forms. There was a total of 24 questions of which 10, 8 and 6 were related to Knowledge, Attitude and Practice respectively. For each correct or positive response, a score of “1” was given, and each incorrect or negative response was given “0”.

*Data analysis and statistics:* Collected data was entered into Microsoft Excel Sheet and analysed using SPSS (Statistical Package for Social Science) version 28. Descriptive statistics (Mean, frequency, percentage) were used to describe the data. Differences between the groups were assessed using Chi-square test and ANOVA. A p-value of < 0.05 was considered statistically significant.

The overall knowledge, attitude and practice were categorized into “Good knowledge” if the score ranges from 80-100%, Moderate 50-79% and poor <50%. Positive attitude 80–100%, moderate 50–79% and Negative <50%. Good Practice 80-100%. Moderate 50-79% and poor <50%.

## Results

The summary of the demographic distribution of students who participated in the study is presented in Table no 1.

**Table 1 Demographic details of Participants**

	1 <sup>st</sup> MBBS	2 <sup>nd</sup> MBBS	Post Graduates
Male	53(42.4%)	36(32.1%)	21(23.1%)
Female	72(57.6%)	76(67.9%)	70(76.9%)
Total	125(100%)	112(100%)	91(100%)
Mean Age (years)	18.9	21	27

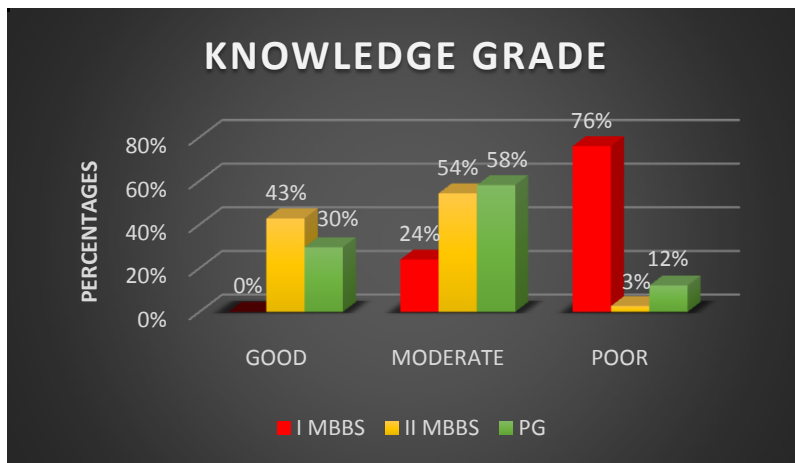
Among the 3 groups, mean knowledge score is highest in the 2<sup>nd</sup> MBBS students, followed by Post Graduates and 1<sup>st</sup> MBBS. This is statistically significant. Student's responses for knowledge-based questions are given in Table 2. The difference between the 3 groups is statistically significant for all the questions.

**Table 2 Response of students to knowledge based questions**

S.No	Questions	Number (%) of students responded correctly			P Value
		1 <sup>st</sup> MBBS	2 <sup>nd</sup> MBBS	Post Graduate	
1	Pharmacovigilance means:	41(32.8)	104(92.9)	85(93.4)	<0.05
2	CDSCO stands for	31(24.8)	53(47.3)	52(57.1)	<0.05
3	Uppsala Monitoring Centre is located at?	46(36.8)	84(75.0)	65(71.4)	<0.05
4	Are Adverse Drug Event and ADR the Same? (Yes/ No)	52(41.6)	81(72.3)	71(78.0)	<0.05
5	Is ADR reporting Mandatory (Yes / No)	52(41.6)	71(63.4)	42(46.2)	<0.05
6	Name of the WHO online database for reporting ADR	44(35.2)	72(64.3)	72(79.1)	<0.05
7	Minimum criteria required for ADR reporting	26(20.8)	48(42.9)	27(29.7)	<0.05
8	Seriousness criteria	22(17.6)	104(92.9)	68(74.7)	<0.05
9	The causality assessment is carried out at AMCs by using the scale	31(24.8)	90(80.4)	47(51.6)	<0.05
10	Channels of ADR reporting?	35(28.0)	84(75.0)	71(78.0)	<0.05

Most of the 1<sup>st</sup> MBBS students had poor knowledge (74%) regarding ADR reporting. Whereas majority of 2<sup>nd</sup> MBBS (54%) and Post Graduates (58%) have moderate knowledge as depicted in Figure1.

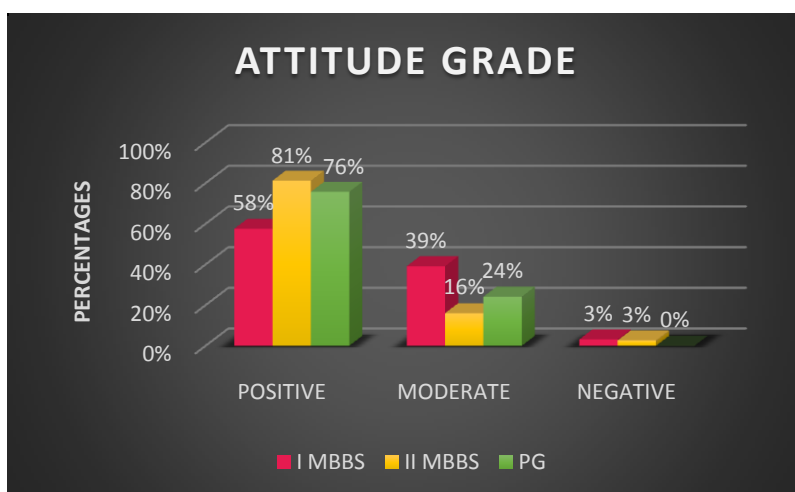
**Figure 1 Knowledge score**



Most of the 2<sup>nd</sup> MBBS and Post Graduate students knew the definition of pharmacovigilance. 35% of 1<sup>st</sup> MBBS, 64% of 2<sup>nd</sup> MBBS and 79% of Post Graduates identified the correct WHO online database for reporting ADR. 25% of 1<sup>st</sup> MBBS, 80% of 2<sup>nd</sup> MBBS and 52% of Post Graduates identified the correct causality assessment scale.

Most of the students (58%, 81%, 76% of 1<sup>st</sup> MBBS 2<sup>nd</sup> MBBS and Post Graduates respectively) have positive attitude towards ADR reporting Figure 2.

**Figure 2 Attitude Score**



Almost all the 2<sup>nd</sup> MBBS (99%) and Post Graduates (99%); majority of 1<sup>st</sup> MBBS (81%), felt that ADR reporting is necessary. 99% of Post Graduates, 95% 2<sup>nd</sup> MBBS and 90% of 1<sup>st</sup> MBBS students felt that the process of reporting should be simple, convenient, and less time-consuming. The response of students to all the attitude-based questions is given in the Table 3.

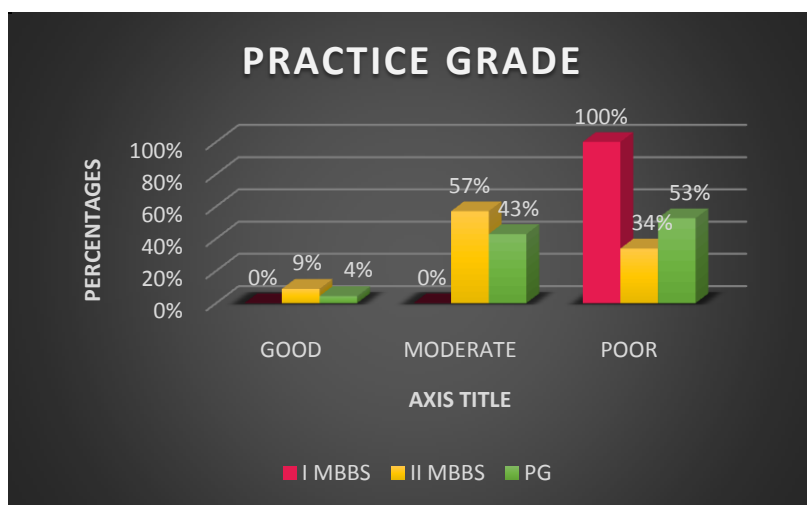
**Table 3 Response of students to attitude based questions**

S.No	Questions	Number (%) of students had positive attitude			P Value
		1 <sup>st</sup> MBBS	2 <sup>nd</sup> MBBS	Post graduate	
1	Is it necessary to report ADR's	101(80.8)	111(99.1)	90(98.9)	<0.05

2	Should reporting ADRs be a professional obligation?	75(60.0)	96(85.7)	75(82.4)	<0.05
3	Do you think reporting ADRs will increase patient safety	96(76.8)	100(89.3)	75(82.4)	<0.05
4	Do you think NMC including ADR reporting as part of 2 <sup>nd</sup> MBBS pharmacology practical is helpful	92(73.6)	85(75.9)	66(72.5)	>0.05
5	Advertisements and awareness campaigns regarding ADR reporting should be undertaken to reach the common man	117(93.6)	99(88.4)	77(84.6)	>0.05
6	CME's, workshops should be conducted at all health care centers.	116(92.8)	101(90.2)	88(96.7)	>0.05
7	The process of reporting should be simple, convenient, and less time- consuming.	112(89.6)	106(94.6)	90(98.9)	<0.05
8	Regulatory authorities should instruct all HCPs to print Toll free numbers for ADR'S reporting on all prescription's scripts	108(86.4)	106(94.6)	85(93.4)	>0.05

All the 1<sup>st</sup> MBBS students had poor practice towards ADR reporting. Only one student saw the ADR reporting form and all the students gave a negative response for the remaining questions. Among the 2<sup>nd</sup> MBBS and Post Graduate students 57%, 43% students had moderate practice whereas 34% and 53% had poor practice respectively as shown in Figure 3.

**Figure 3 Practice Score**



All the 2<sup>nd</sup> MBBS students (100%) and about half of the Post Graduates (48%) had seen ADR reporting form. 106(94.6%) 2<sup>nd</sup> MBBS students and 16(17.6%) Post Graduates were trained in ADR reporting. Only 18(19.8%) Post Graduates documented and sent filled ADR'S forms to AMC. The details regarding the response of the students to practice based questions is given in the Table 4.

**Table 4 Response of students to Practice based questions**

S.No	Questions	Number (%) of students responded correctly	P Value
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		<b>1<sup>st</sup> MBBS</b>	<b>2<sup>nd</sup> MBBS</b>	<b>Post graduate</b>	
1	HaveyoueverseenanADRreportingform?	1(0.8)	112(100)	44(48.4)	<0.05
2	Attendedworkshops/trainingonADRreporting	0(0)	106(94.6)	16(17.6)	<0.05
3	IdentifiedanADRbyyourself	0(0)	58(51.8)	55(60.4)	<0.05
4	HaveyoudonecausalityassessmentofADRs?	0(0)	25(22.3)	31(34.1)	<0.05
5	Documentedandsent filled ADR'SformstoAMC	0(0)	0(0)	18(19.8)	<0.05
6	Haveyouseenanypatientwith seriousADR	0(0)	15(13.4)	41(45.1)	<0.05

Difference in means score for KAP is statistically significant and is given in Table 5

**Table 5 Comparison of means score**

	<b>1<sup>st</sup> MBBS</b>	<b>2<sup>nd</sup> MBBS</b>	<b>Post graduate</b>	<b>P value</b>
<b>Knowledge (maximum=10)</b>	3.04±1.85	7.06±1.47	6.59±1.520	<0.05
<b>Attitude (maximum=11)</b>	6.54±1.35	7.18±1.25	7.10±1.15	<0.05
<b>Practice (maximum=6)</b>	0.01± 0.09	2.96±0.93	2.25±1.54	<0.05

## Discussion

Pharmacovigilance plays an important role in ensuring that the patient's receives safe drugs. ADR reporting plays a key role in monitoring drug safety. Health care professionals play a significant role in successful implementation of Pharmacovigilance program of India. It is important to gain knowledge regarding adverse drug reaction in the undergraduate level.

In the present study, all the 1<sup>st</sup>MBBS students had poor knowledge whereas 2<sup>nd</sup>MBBS and Post Graduates have moderate knowledge regarding pharmacovigilance. Interestingly, knowledge of the 2<sup>nd</sup>MBBS students is more than Post Graduates. This contrasts with the study done by Meher et al. who found that pre final MBBS students scored better than the 2nd MBBS students.[12] In the new curriculum by National Medical Council (NMC),

“Recognizing and reporting ADR reactions” is part of 2<sup>nd</sup>MBBS pharmacology practicals, where all students are trained in ADR reporting.[13]

This could be the reason for them to fare better than the Post Graduates. Training and awareness programs regarding ADR reporting should be conducted to students of old curriculum to improve their knowledge regarding pharmacovigilance. Awareness programmes targeting the general population should be conducted as patients also play a role in ADR reporting.

Most of the students showed positive attitude towards ADR reporting. This is in line with the study conducted by Alwhaibi, M et al who showed similar results [14]. Despite having poor knowledge, majority of the 1<sup>st</sup>MBBS students had positive attitude.

All 1<sup>st</sup>MBBS students showed poor practice. Among 2<sup>nd</sup>MBBS students, majority (57%) had moderate practice, whereas majority (53%) of post graduates showed poor practice. 2<sup>nd</sup>MBBS students being trained in ADR reporting could again be the reason for better practice in this group. This further emphasizes the importance of adequate training to improve ADR reporting. Raquel Herrera Comoglio in the article titled “Undergraduate and Post Graduates pharmacovigilance education: A proposal for appropriate curriculum content ” stressed the need to train both undergraduates and Post Graduates towards pharmacovigilance.[15] Though most of the 2<sup>nd</sup>MBBS and Post Graduates have good to moderate knowledge, their practice is relatively less (moderate to poor). Studies by Chatterjee et al, Gupta et al and Gosh et al, also showed that doctors exhibited high knowledge but poor practice for ADR reporting.[16,17,18]

In the present study most of the student’s had positive attitude towards ADR reporting. However, this was not reflected in practice. Studies by Upadhyaya et al, Desai et al also showed positive attitude but poor practice.[19,20] This highlights the need for more CME’s and workshops, focusing on the importance of ADR reporting; for both undergraduates and Post Graduates. This study offers huge hope for improving KAP related to ADR reporting among medical students.

## **Conclusion**

1<sup>st</sup>MBBS students who represent the general population had poor knowledge. So, more awareness programmes targeting towards the general population should be conducted. Including ADR reporting as a part of pharmacology practical could be the reason for 2<sup>nd</sup>MBBS students having better knowledge attitude and practice compared to Post Graduates. Including pharmacovigilance as part of Post Graduates curriculum (irrespective of the



specialty) could further improve spontaneous reporting. Also, the process of ADR reporting should be made easy and convenient.

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