

A Questionnaire Based Study to Assess Knowledge, Attitude and Practice of Pharmacovigilance Among Undergraduate Medical Students in a Tertiary Care Hospital

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Received: 03-08-2022 / Revised: 18-09-2022 / Accepted: 30-09-2022

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Conflict of interest: Nil

Abstract

Introduction: Drug therapy is an integral part of the medical management. It has many beneficial effects, but side effects and adverse drug reactions (ADR) are some of its major disadvantages. ADR is defined by World Health Organisation (WHO) as “a response to a drug that is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function”. Spontaneous reporting of these adverse drug reactions is the backbone of the Pharmacovigilance Programme. ADRs have been reported to be among leading causes of morbidity and mortality. Under-reporting is a major problem which still exists. ADR reporting does not currently appear to be considered part of routine professional practice by health care professionals. Medical students could play a major role and bring a paradigm shift in successful implementation of the Pharmacovigilance Programme.

Objectives: To assess the Knowledge, Attitude and Practice (KAP) of undergraduate medical students of Pharmacovigilance and ADR reporting.

Materials and Methods: It was a questionnaire based cross sectional study with validated 20 questions to evaluate the KAP of undergraduate medical students in a Tertiary Care Hospital.

Results: Data was compiled and entered in Microsoft (2010) excel sheet using SAS latest version and analysed by descriptive statistics, chi-square and ANOVA. In knowledge-based questions comparison of mean score was (70.8%,72.2%,79%) of final, prefinal and second year. In attitude-based questions the mean score was (85%,83.3%,85.6%) and in practice-based questions the mean score was (83.5%,80%,75%) of final, prefinal and second year students. p (<0.05)

Conclusion: In this study, even though the students had positive attitude towards the programme the skill or practice of reporting was lacking. This underreporting of ADRs which is the major problem of the programme can be overcome with various educational and practical integration in the curriculum of the students from second year onwards till final year including internship as the students are the backbone of future health care delivery systems.

Keywords: Adverse drug reaction, Pharmacovigilance Programme, Questionnaire, undergraduates

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Introduction

Pharmacovigilance is defined by WHO as “the science and activities relating to the detection, understanding, and prevention of adverse effects or any other drug-related problems”. To promote drug safety WHO started a Programme for International Drug Monitoring in 1961 and subsequent to that it promoted pharmacovigilance programme at country level in collaboration with Centre for International Drug Monitoring, Uppsala.

To detect and spontaneously report ADRs and to ensure drug safety, National Pharmacovigilance Programme was initiated in India in the year 2004. It is now renamed as Pharmacovigilance Programme of India (PvPI) and operational since July 2010 under the aegis of Central Drug Standard Control Organization (CDSCO). The Uppsala Monitoring Centre (UMC), Sweden maintains the international database of ADR reports received from different countries. Spontaneous reporting of ADR is considered as the foundation of post marketing surveillance of drug safety [10-12]. Study showed that only 6-10% of all ADR cases are reported. Health care professional has a major role in pharmacovigilance programme. ADR reporting does not currently appear to be considered part of routine professional practice by health care professionals. This is essentially due to the absence of vibrant and active ADR monitoring system and also lack of a reporting culture among health care professionals.

In the latest Competency Based Undergraduate Curriculum for the Indian Medical Graduate 2018, NMC (National Medical Council) has included Pharmacovigilance, ADR reporting system and management of ADRs in competency numbers PH1.6 and PH1.7 This is included in both the theory and practical

and a visit to an AMC centre made compulsory, and students in second year of MBBS are made to fill up ADR forms with various case scenario exercises and given a target to report at least one ADR during their clinical postings. This is a welcoming change by NMC in medical curriculum. This inclusion of Pharmacovigilance activities in the curriculum will improve the Knowledge, Attitude and Practice of the undergraduate students.

This year (2021) during the National Pharmacovigilance week from September 17-23 and with the Theme Pharmacovigilance: A Step towards Patient Safety was very active week for AMC, Andhra Medical College Visakhapatnam with awareness and sensitization programmes conducted in various colleges in Visakhapatnam with the help of faculties and technical associate. Undergraduate medical students and faculties were sensitized about Pharmacovigilance Programme, ADRs, Drug interactions, Medication Error, OTC (over the counter drugs) and self-medication.

Medical students could play a major role and bring a paradigm shift in successful implementation of pharmacovigilance programme if adequate knowledge and skills are imparted to them during undergraduate training career. But very few studies are there to assess the knowledge, attitude, and practice (KAP) of pharmacovigilance among undergraduate medical students. So, it was decided to target the undergraduate MBBS students of our very own institution, to understand the reason for the gap in under reporting by assessing their knowledge, attitude and practice towards pharmacovigilance, adverse drug reactions reporting and to ensure efficient functioning of the AMC at

Andhra Medical College attached to a Tertiary Care Hospital Visakhapatnam

Aims & objectives

To assess the Knowledge, Attitude and Practice [KAP] of undergraduate medical students about ADR reporting and Pharmacovigilance Programme with a help of a validated questionnaire as a study tool on a total of 150 students belonging to Second year, Pre-final and Final year and to compare their score percentage.

Materials and Methods

Study centre: This study was carried out in Department of Pharmacology, Andhra Medical College, and King George Hospital Visakhapatnam.

Sample size and study population: Total 150 Undergraduate MBBS students, out of them 50 students each from second year, pre-final and final year who were attending clinical posting were included in the study

Study Design: Cross-sectional questionnaire based observational study

Study Duration: second week in the month of October 2021

The KAP questionnaire was designed by following preceding studies. Questionnaire was pretested/ pre validated in a small group of students by doing a cross sectional and observation-based study. The validated questionnaire contains 20 questions, out of them 10 is to test knowledge, 6 is to test the attitude, and 4 to test practice.

Study initiated after obtaining clearance from the Institutional Ethics Committee.

The questionnaire was handed over to the participants after explaining the purpose of the study. Any doubts regarding questionnaire were clarified by the investigator. 30 min was given for filling the questionnaire. A score of 1 was allocated for each correct answer or positive response and score 0 was allocated for wrong, unattempted answer, or negative response. Maximum possible

score was 10, 6 and 4 for KAP, respectively.

Data was compiled and entered in Microsoft excel /2010 sheet using SAS latest version & analysed by descriptive statistics, chi-square & ANOVA.

A test value of $p < 0.05$ is considered as statistically significant.

Observations and results

A total of 150 undergraduate medical students participated in the study. Out of them 65 were males and 85 were female students belonging to the age group of 20-25 years.

There were 10 knowledge-based questions. Among the respondents around 70% of final year, 76% of prefinal year and 80% of 2nd year student responded correctly to the definition of ADR. 60% of final year, 62% of prefinal year, and 72% of 2nd year students were aware about locality of National Pharmacovigilance Centre. 80%, 84% and 90% of final, prefinal and 2nd year students knew who can report ADR. 86% of final, 84% of prefinal and 82% of 2nd year student knew the definition of pharmacovigilance. Since the p value is more than 0.05 ($p > 0.05$) students belonging to all the three years were equally good in their knowledge about Pharmacovigilance. The response to knowledge-based questions given in Table 1 and fig 1.

Total number of questions to test the attitude was six. 84%, 82%, 84% respectively of final, prefinal, and 2nd year students felt ADR reporting benefits both Doctor and patients. Students thought it is relevant to have a discussion on pharmacovigilance in clinical posting. The details regarding the responses of the medical students for attitude-based questions are listed in Table 2 and Figure 2.

There were four practice related questions. It was seen that only 60% students of final, 50% of prefinal and 30% students of 2nd

year answered yes for the question of played any role in reporting ADR. p value of the response to this question is statistically significant. The response to practice-based questions is given in Table 3 and Figure 3. Andhra Medical college is an AMC (ADR Monitoring Centre), all the students had an opportunity to visit the centre. All the second-year students were made to fill up the ADR form as a part of competencies PH1.6 &1.7 of CBME

curriculum, therefore all the 50 students response was yes for the first question. Second year students got the least percentage for role in reporting ADR.

The mean score of knowledge and attitude among second year students is higher when compared to Final and Pre-final year, where-as Final year students practice percentage is higher since they had more opportunities being in clinical postings for 3 years.

Table 1: Response of students to knowledge-based questions

Knowledge	Number (%) of students responded correctly			p value
	Final year	Prefinal year	Second year	
1. Define ADR	35(70)	38(76)	40(80)	>0.05
2. Are Adverse Drug event and ADR are same	38(76)	40(80)	44(88)	>0.05
3. Who can report ADR?	40(80)	42(84)	45(90)	>0.05
4. Is ADR reporting Mandatory	45(90)	43(86)	42(84)	>0.05
5. PvPI stands for	46(92)	47(94)	48(96)	>0.05
6. What is Pharmacovigilance	43(86)	42(84)	41(82)	>0.05
7. Which causality assessment method is used?	28(56)	25(50)	31(62)	>0.05
8. Where is national PvPI centre located?	30(60)	31(62)	36(72)	>0.05
9. Expand CDSCO	21(42)	22(44)	32(64)	>0.05
10. Where is UMC located?	28(56)	31(62)	36(72)	>0.05

ADR – Adverse Drug Reaction; PvPI- Pharmacovigilance programme of India; CDSCO- Central Drug Standard Control Organization; UMC – Uppsala Monitoring Centre

Table 2: Response of students to attitude based questions yes=1 mark, No=0 mark

Attitude	Number (%) of students responded correctly			P value
	Final year	Prefinal year	Second year	
1. Do you think ADR reporting benefits both Doctor and Patients	42(84)	41(82)	42(84)	>0.05
2. Should ADR reporting be included under Pharmacology practical?	45(90)	45(90)	46(92)	>0.05
3. Do you think, medical students could play a role in ADR reporting	45(90)	45(90)	46(92)	>0.05
4. Do you think ADR reporting is a part of professional obligation of all related to health care?	35(70)	33(66)	34(68)	>0.05
5. Do you think discussion on ADR during clinical posting has any relevance	42(84)	41(82)	43(86)	>0.05
6. Do you think collecting box at all clinical department is helpful for proper reporting	46(92)	45(90)	46(92)	>0.05

Table 3: Response of students to practice based questions yes=1 mark, No =0 mark

Practice	Number (%) Of Students Responded Correctly			P Value
	Final Year	Prefinal Year	Second Year	
1. Have you seen an adverse drug reporting form by CDCSCO?	45(90)	45(90)	50(100)	>0.05
2. Have you ever seen a case of ADR during your ward posting?	42(84)	40(80)	35(70)	>0.05
3. Have you ever played any role in reporting ADR from your institution?	30(60)	25(50)	15(30)	<0.05
4. Have you ever visited any ADR monitoring centre?	50(100)	50(100)	50(100)	>0.05

Table 4: Comparison of Mean Score

	Final Year %	Prefinal Year %	Second Year %
Knowledge	70.8	72.2	79
Attitude	85	83.3	85.6
Practice	83.5	80	75

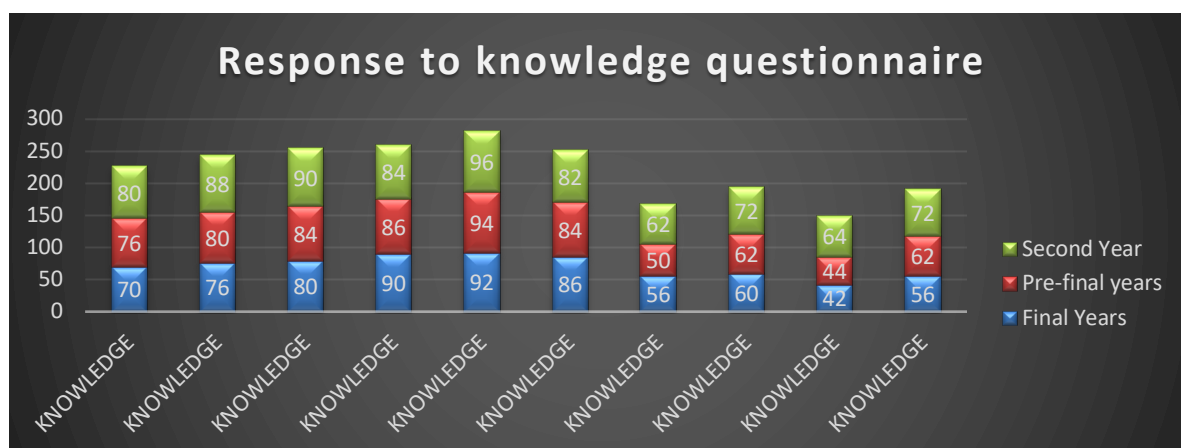


Figure 1: Response to knowledge questionnaire in percentage

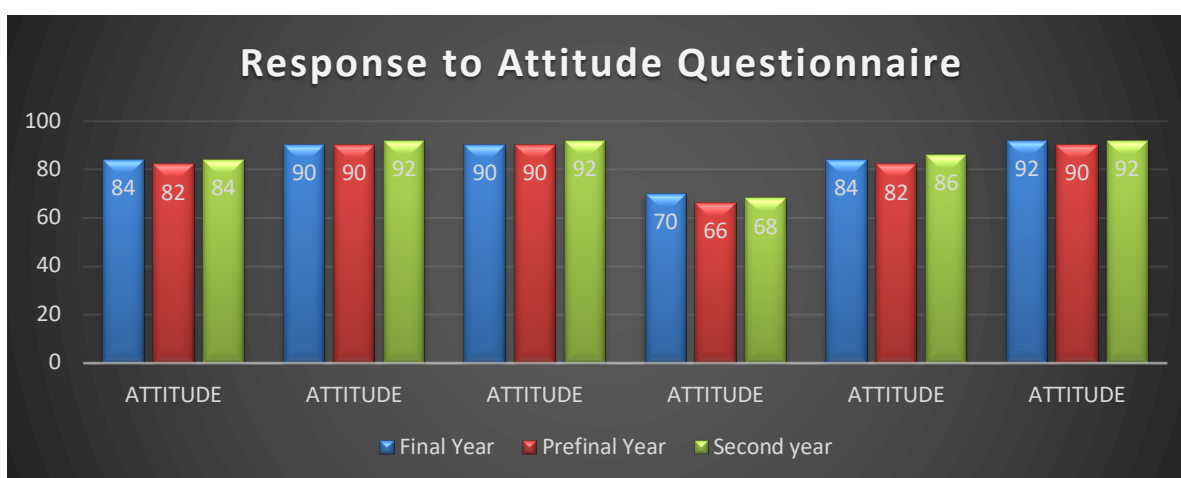


Figure 2: Response to Attitude Questionnaire in percentage

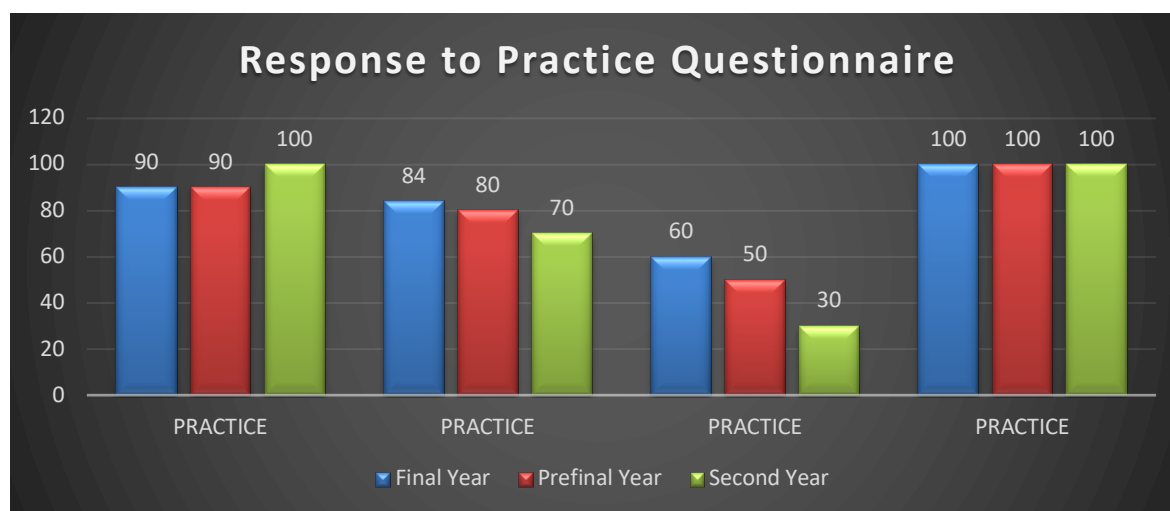


Figure 3: Response to Practice Questionnaire in percentage

Discussion

Pharmacovigilance is an integral part of holistic health care. It helps in detection and prevention of ADR of medicinal products. Spontaneous reporting of ADR is vital for the success of pharmacovigilance programme. There are innumerable studies to evaluate the KAP of health care providers toward pharmacovigilance programme, but a very few studies have been done among the budding doctors to capture their knowledge about the same. [13-15]. This study is one of the few studies done among undergraduate medical students regarding KAP of pharmacovigilance.

This study revealed the awareness of professional MBBS students towards ADR reporting and Pharmacovigilance in our institution and also clearly showed the importance of early sensitization through educational interventions, which improved the KAP in pharmacovigilance in them. Educating medical students will improve the challenge of underreporting of ADRs and will increase the numbers of ADRs reported in our country [14].

Out of the 10 knowledge-based questions. Among the respondents 70% of final year, 76% of pre-final year and 80% of 2nd year student responded correctly to the definition of ADR. 60% of final year, 62% of pre-final year, and 72% of 2nd year

students were aware about locality of National Pharmacovigilance Centre. 80%, 84% and 90% of final, pre-final and 2nd year students knew who can report ADR. 86% of final, 84% of pre-final and 82% of 2nd year student know the definition of pharmacovigilance. Since the p value is more than 0.05 ($p > 0.05$) students belonging to all the three years were equally good in their knowledge about Pharmacovigilance. From this study it is clear that students have adequate knowledge and good attitude towards Pharmacovigilance Programme and it corroborates with the findings done previously by Dr. T. Meenakshi *et al* [16].

It was seen that only 60% students of final, 50% of prefinal and 30% students of 2nd year answered yes for the question of if they have played any role in reporting ADR. p value of the response to this question is statistically significant. The study conducted by K. Vishnu *et al* suggests that even though majority of postgraduates have better knowledge and attitude towards pharmacovigilance and ADR, the practice of reporting ADRs is inadequate and this is at par with our study K. Vishnu *et al*. [17]. In the present study the practice of reporting ADRs was assessed, which revealed that, though many came across ADRs, very few

reported the same as majority did not know how to report ADRs like the study of Nikhil E *et al.* [18]. In this study, the results shown that knowledge and attitude level was good among the undergraduate students of all the three years and comparable except for practice of reporting significantly lower in the second-year students compared to other prefinal and final year students.

This shows that the second-year students did not get much opportunity in clinical posting as compared to final year students since they have already spent 3 years in clinical postings. One unique feature in our study is in practice-based question the percentage of the response was 100% among all the three years because they all had an opportunity to visit our AMC centre during their study period in Pharmacology. Under reporting (UR) of adverse drug reactions (ADRs) is widespread and a daunting challenge in pharmacovigilance (PV) [15,19,20]. This is because primarily most countries, including India follow the spontaneous or voluntary system of ADR reporting. There are patient-related reasons for UR like failure to recognize ADR or inability to link the ADR with a drug. The commonest doctor related reasons are the feeling of guilt, fear of litigation, ignorance, lethargy, inadequate risk perception about newly marketed drugs, diffidence, insufficient training to identify ADRs, and lack of awareness about PV program [21].

Conclusion

The present study identified the awareness of KAP undergraduate MBBS students towards ADR reporting and pharmacovigilance. An increase has been observed in the current reporting culture of ADRs under PvPI after conducting regular training and awareness programme and circulating PvPI Drug Safety Newsletter. The National Pharmacovigilance Week which is conducted every year in the month of September will improve their knowledge, attitude and practice in future

with respect to ADR reporting and make them aware about their role in supporting PvPI and to ensure the safety of medications in patients. We recommend all the senior health care professionals to implement educational interventions like CMEs and workshops regularly and sensitise medical students on the programme which will improve the skill of budding doctors.

Finally, mass media including the social media can be brought into use to spread awareness about ADRs. Even the patients are now encouraged to report ADRs which is a welcoming decision to improve under reporting. Our study also appreciates the need for conducting further such multi-centric studies involving wider sections of medical professionals to estimate the magnitude of the problem so as to fill the existing gaps and strengthen the effectiveness of Pharmacovigilance activities.

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