International Journal of Life Sciences, Biotechnology and Pharma Research Vol. 14, No. 3, March 2025 Online ISSN: 2250-3137
Print ISSN: 2977-0122

DOI: 10.69605/ijlbpr_14.3.2025.212

ORIGINAL RESEARCH

Knowledge, attitude and practice (KAP) of pharmacovigilance among undergraduate medical students and interns in a tertiary care teaching hospital

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Received: 10 February, 2025 Accepted: 25 February, 2025 Published: 19 March, 2025

ABSTRACT

Background: Pharmacovigilance plays a vital role in ensuring drug safety by detecting, assessing, and preventing adverse drug reactions (ADRs). But underreporting remains a major challenge. Medical students and interns, being future healthcare providers, are integral to ADR reporting, however, gaps in knowledge, attitude and practice hinder effective reporting. This study assesses knowledge, attitude, and practice (KAP) of pharmacovigilance among undergraduate medical students and interns in tertiary care teaching hospital. **Methods:** A cross-sectional, questionnaire-based study was conducted at Shri Guru Ram Rai Institute of Medical and Health Sciences from June to December 2023.Following approval from Institutional Ethics Committee and consent of participants, a pre-validated questionnaire assessing knowledge (7 items), attitude (3 items), and practice (5 items) was administered to MBBS students (2nd, 3rd, and 4th year) and interns via Google Forms. Responses were analysed using appropriate statistical tools. **Results:** Total 377 students participated, including 150, 2nd year, 168, 3rd year, 13, 4th year, and 46 interns. Knowledge assessment revealed 96.42% of 3rd year students were aware of ADR monitoring system in their institute. Attitude analysis showed 64.67% of 2nd year students and 55.95% of 3rd year students strongly agreed on necessity of ADR reporting. In practice, 94.64% of 3rd year students attended pharmacovigilance sessions, while 85.68% received ADR reporting training. **Conclusion:** While medical students and interns demonstrate positive attitude toward pharmacovigilance, their actual practice of ADR reporting remains inadequate. Strengthening pharmacovigilance education and integrating practical training at all levels of medical education can improve ADR reporting and enhance patient safety.

Key Words: Pharmacovigilance, PvPI (Pharmacovigilance Programme of India), ADRs (Adverse Drug Reactions)

INTRODUCTION

Pharmacovigilance is an essential component of healthcare, ensuring drug safety by detecting, assessing, understanding, and preventing adverse drug reactions (ADRs). The World Health Organization (WHO) defines pharmacovigilance as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem". [1] ADRs pose a significant global health burden, contributing to 2.4%–6.5% of hospital admissions, prolonged hospitalization, and increased healthcare costs. [2] Despite the importance of ADR reporting, underreporting remains a persistent challenge, particularly in developing countries like India, where the ADR reporting rate is much lower than the global average. [3]

DOI: 10.69605/ijlbpr_14.3.2025.212

Recognizing the need for a robust pharmacovigilance system, the Government of India launched the Pharmacovigilance Programme of India (PvPI) in 2010, with the Indian Pharmacopoeia Commission (IPC), Ghaziabad as the National Coordination Centre (NCC). The PvPI aims to strengthen ADR monitoring, promote spontaneous reporting, and enhance drug safety nationwide. [1] However, various studies have shown that healthcare professionals, including physicians, nurses, and pharmacists, often lack adequate knowledge and training in pharmacovigilance, leading to poor reporting practices. [2] Medical students and interns are at the forefront of patient care, making them crucial contributors to pharmacovigilance. [4] However, research from various tertiary care hospitals in India has demonstrated significant gaps in their knowledge, attitude, and practice (KAP) regarding ADR reporting. [5, 6] Although many medical students and interns exhibit a positive attitude towards pharmacovigilance, their actual reporting behaviour remains suboptimal due to a lack of awareness, inadequate training, and insufficient confidence. [7] To improve the awareness regarding the PvPI, the medical students in our institution are provided optimum exposure all through their training years, beginning from Second Phase. They are subjected to various exercises including real- time collection of ADRs during their clinical postings followed by their discussions.

This study was aimed at evaluation of knowledge, attitude and practice of pharmacovigilance among undergraduate medical students and interns of a tertiary care teaching hospital situated in Dehradun, Uttarakhand. Identifying these gaps can help re-design targeted educational interventions and activities to improve pharmacovigilance awareness, augment ADR reporting, and ultimately enhance patient safety among the budding healthcare professionals.

MATERIAL AND METHODS

The present study was conducted at Shri Guru Ram Rai Institute of Medical and Health Sciences, a tertiary care teaching hospital in Dehradun, Uttarakhand. The study was conducted from June 2023 to December 2023 and included MBBS students of 2nd, 3rd and 4^{rth} year and interns. It was questionnaire-based, cross-sectional study which aimed at assessing the knowledge, attitude and practice towards pharmacovigilance amongst undergraduate medical students (2nd years onwards) and interns. A pre-validated questionnaire assessed and evaluated for its completeness and data by the department of pharmacology were used in the study. The questionnaire constituted of 7 questions of knowledge, 3 for assessing the attitude of participants and 5 pertaining to practice. The questionnaire was standardized and validated by faculty members of Pharmacology department prior to receiving approval from Institutional Ethics Committee.

The responses were collected from the students via Google forms. Students were briefly informed regarding the study before urging them to fill their responses. The results were analyzed using suitable statistical tools.

RESULTS

In the present study, a total of 377 responses were collected from medical undergraduate students and interns, of which 150 responses were received from MBBS 2nd year students, 168 from MBBS 3rd year students, 13 from MBBS 4rth year students and 46 responses were obtained from interns of the institute.

Knowledge based analysis: (Table 1)

It was observed that out of the total 377 participants, majority of students from group II 96.42% knew regarding the presence of ADR monitoring system in the institute. Majority, 79(20.90%) of the participants knew the correct responses to the knowledge based questions, majority 122 (72.61%) of participants of group II knew the location of national coordination centre [NCC] for PVPI, majority 135(80.35%) of Group II students were aware of the web based management system for pharmacovigilance is used in our institute, majority 155(92.26%)of Group II students were aware of the location of the Uppsala monitoring centre, students of group I performed best 114 (76%) in expanding the acronym CDSCO, most commonly used scale for causality assessment of ADR was correctly known to majority of group I students, 42(28%) and the next step after encountering a serious ADR in a patient was rightly answered by majority 11(84.61%) of group III students.

Attitude based analysis: (Table 2) (Figure 1)

On assessment regarding attitude of students towards Pharmacovigilance, it was observed that in each group (I, II, III, IV), 64.67%, 55.95%, 61.53% and 63.05% respectivelyof the participants exhibited positive attitude towards necessity of reporting ADRs.

Practice based analysis: (Figure 2, 3, 4, 5, 6)

70% of participants from Phase II, 94.64%from Phase III, 61.54% from Phase IV and 52.17% of interns reported to have attended a session on Pharmacovigilance. As per the assessment a total of 323 (85.68%) students mentioned that they have been trained on the process of reporting an ADR.

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Table 1: Knowledge based questions

S.No	Questions	GroupI (n=150) Correct Responses	Group II (n=169) Correct Response	Group III (n=13) Correct Response	Group IV (n=46) Correct Response	Total Correct Responses Received (n=378)
1.	**Are you aware about the existence of ADR reporting and monitoring system at your institute?**	139 (92.67%)	162 (96.42%)	11 (84.61%)	41 (89.13%)	353 (93.39%)
2.	**Where is the national coordination centre [NCC] for PVPI located?**	105 (70%)	122(72.61%)	08(61.53%)	31(67.39%)	266 (70.37%)
3.	**Which web based management system for pharmacovigilance is used in our institute?**	98 (65.33%)	135(80.35%)	04(30.76%)	35(76.08%)	272 (71.96%)
4.	**Where is the Uppsala monitoring centre located?**	137 (91.33%)	155 (92.26%)	09 (69.23%)	34 (73.91%)	335 (88.62%)
5.	**Expand the acronym CDSCO.**	114 (76%)	122(72.61%)	09(69.23%)	15(32.60%)	260 (68.78%)
6.	**Which is the most common scale used for causality assessment of ADR?**	42(28%)	32 (19.04%)	01 (7.69%)	04(8.69%)	79(20.90%)
7.	**Upon occurrence of serious ADR, what needs to be done with the suspected drug?**	107(71.33%)	120(71.42%)	11(84.61%)	31(67.39%)	269(71.16%)

* Group I- 2nd year MBBS students, Group II- 3rd year MBBS students, Group III- 4rth year MBBS students and Group IV- Interns

Table 2: Attitude related questions

S. No.	Question	Response	Group I (n=150)	Group II (n=168)	Group III (n=13)	Group IV (n=46)
1.	Is the reporting of ADR necessary?	Strongly Disagree	0	5 (2.97%)	0	0
		Disagree	4 (2.67%)	2 (1.19%)	0	0
		Neither agree nor disagree	1 (0.67%)	3 (1.78%)	0	2 (4.35%)
		Agree	48 (38%)	64 (38.09%)	5 (38.46%)	15 (32.60%)
		Strongly Agree	97 (64.67%)	94 (55.95%)	8 (61.53%)	29 (63.05%)
2.	Should only healthcare professionals be allowed to report an ADR?	Strongly Disagree	34 (22.67%)	25 (14.88%)	3 (23.07%)	8 (17.39%)
		Disagree	51 (34%)	59 (35.11%)	4 (30.76%)	13 (28.26%)
		Neither agree nor disagree	13 (8.67%)	16 (9.52%)	1 (7.69%)	3 (6.52%)
		Agree	35 (23.33%)	50 (29.79%)	3 (23.07%)	16 (34.78%)
		Strongly Agree	17 (11.33%)	18 (10.71%)	2 (15.35%)	6 (13.05%)
3.	Should an ADR monitoring centre be	Strongly Disagree	3 (2%)	5 (2.97%)	0	4 (8.69%)

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	established in every hospital?					
		Disagree	1 (0.67%)	3 (1.78%)	0	1 (2.17%)
		Neither agree nor disagree	8 (5.33%)	5 (2.97%)	0	1 (2.17%)
		Agree	54 (36%)	69 (41.07%)	3 (23.07%)	18 (39.14%)
		Strongly Agree	84 (56%)	86 (51.19%)	10 (76.93%)	22 (47.83%)

* Group I- 2nd year MBBS students, Group II- 3rd year MBBS students, Group III- 4rth year MBBS students and Group IV- Interns

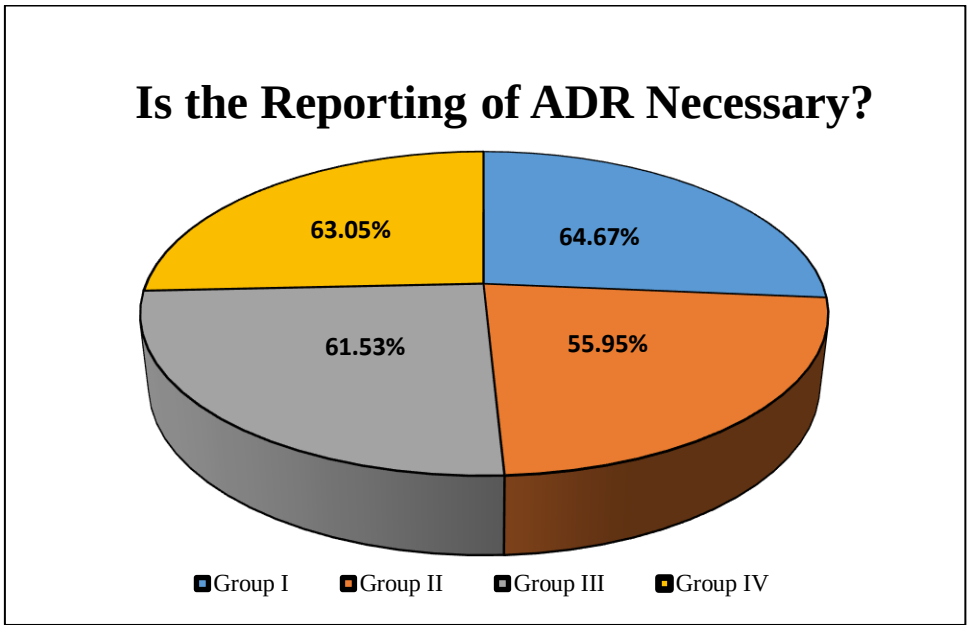

Figure 1: Attitude based question

* Group I- 2nd year MBBS students, Group II- 3rd year MBBS students, Group III- 4rth year MBBS students and Group IV- Interns

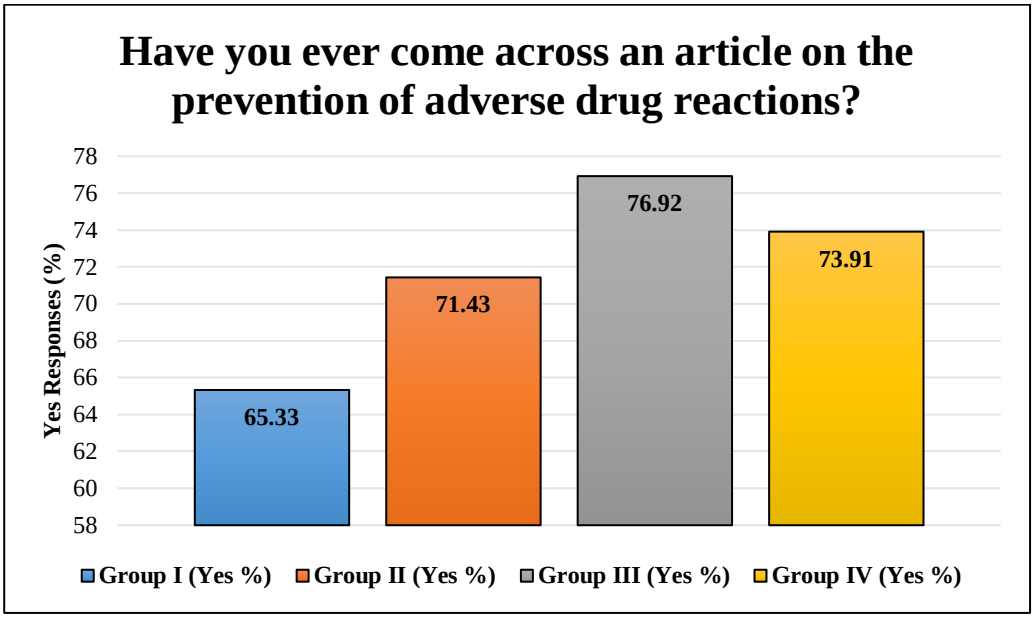

Figure 2: Practice related questions- I

* Group I- 2nd year MBBS students, Group II- 3rd year MBBS students, Group III- 4rth year MBBS students and Group IV- Interns

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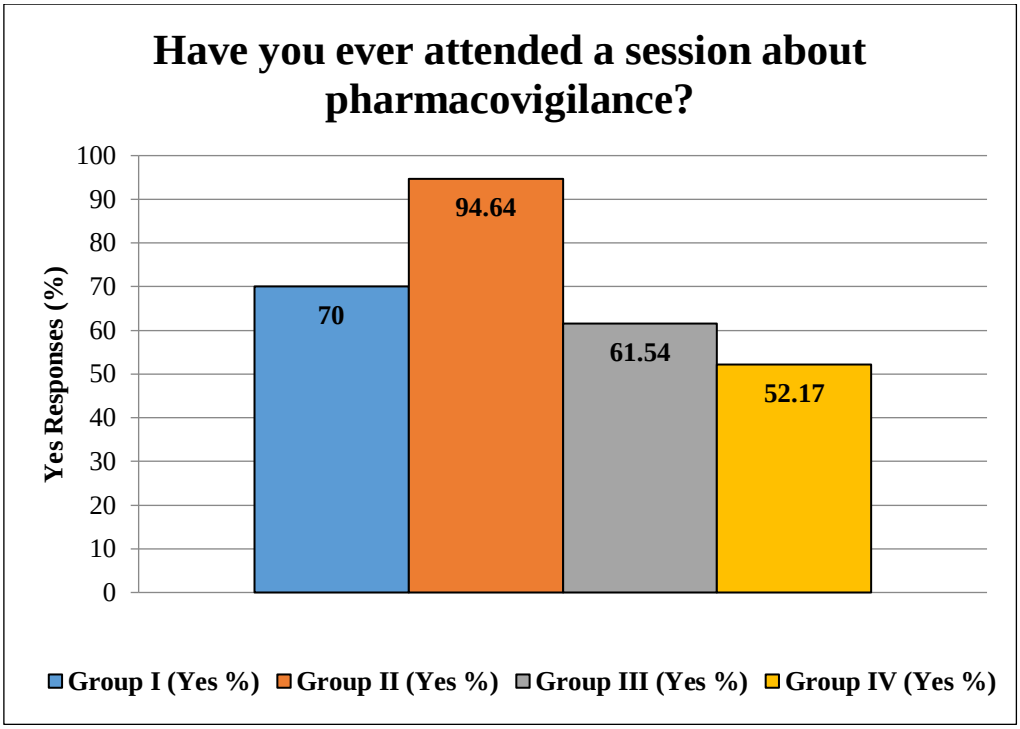

Figure 3: Practice related questions- II

* Group I- 2nd year MBBS students, Group II- 3rd year MBBS students, Group III- 4rth year MBBS students and Group IV- Interns

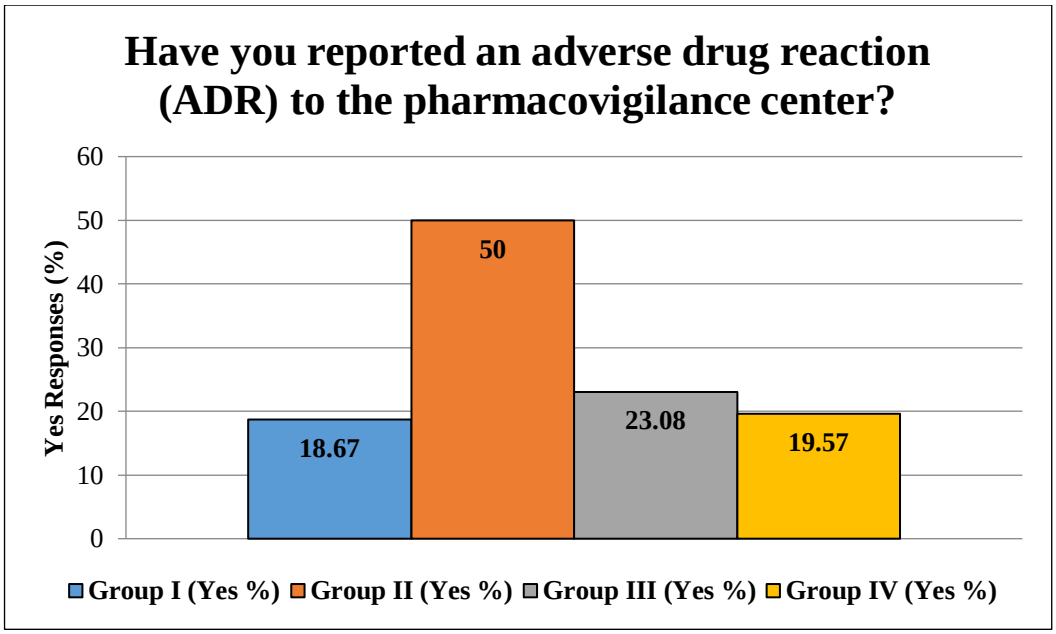

Figure 4: Practice related questions- III

* Group I- 2nd year MBBS students, Group II- 3rd year MBBS students, Group III- 4rth year MBBS students and Group IV- Interns

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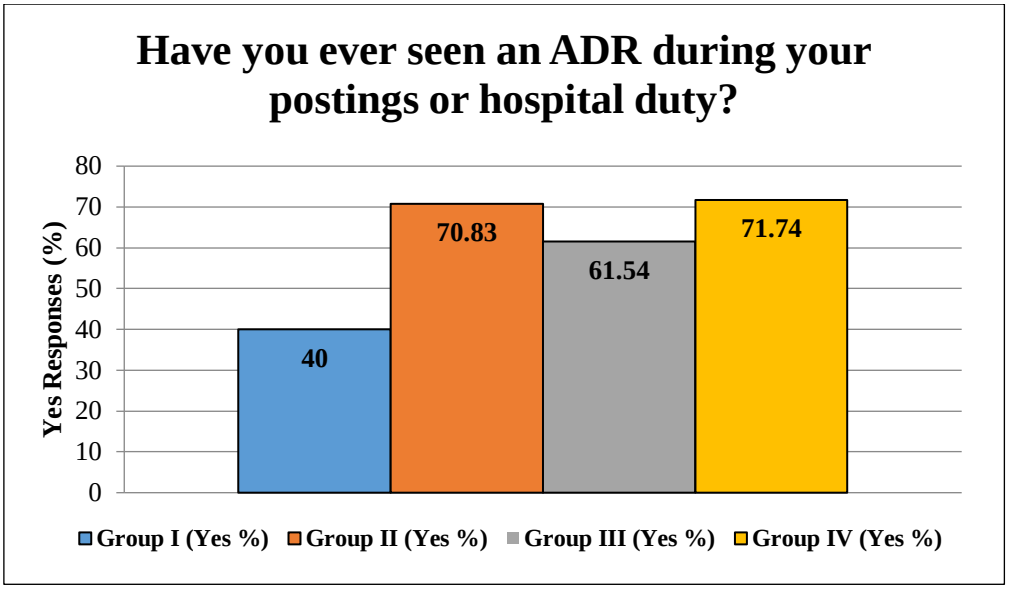

Figure 5: Practice related questions- IV

* Group I- 2nd year MBBS students, Group II- 3rd year MBBS students, Group III- 4rth year MBBS students and Group IV- Interns

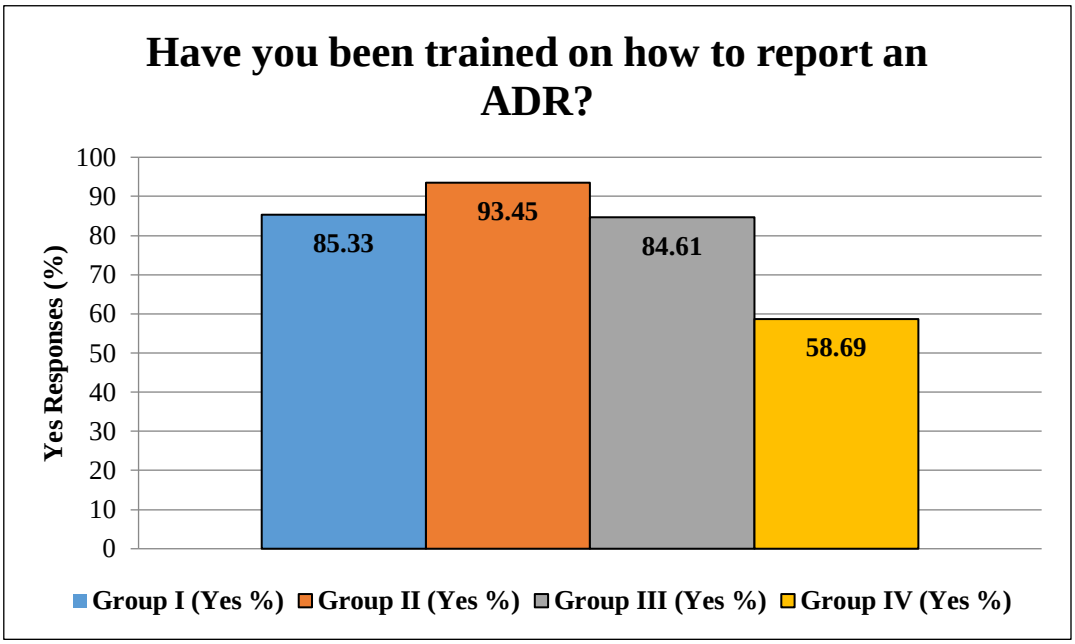

Figure 6: Practice related questions- V

* Group I- 2nd year MBBS students, Group II- 3rd year MBBS students, Group III- 4rth year MBBS students and Group IV- Interns

DISCUSSION

The current study was conducted at Shri Guru Ram Rai Institute of Medical and Health Sciences, Dehradun, which is a tertiary care teaching institute. On analysis it was seen that majority of the participants of Phase II and III performed well in knowledge based questions, this could be credited to the academic curriculum of Phase II which involves active participation of Phase II students in ADR collection, assessment and discussion as a routinely evaluated exercise under the aegis of department of Pharmacology, in our institution.

A total of 378 participants participated of which 150 (39.68%) were students of Phase II, 169 (44.71%) were studying in Phase III and 13 (3.44%) and 46 (12.17%) respectively were Phase IV students and interns.

In study conducted by Oshikoya KA and Awobusuyi JO, 40.4% respondents were aware of the existence of National Pharmacovigilance Centre (NPC), which was contrasting to the current study 266 (70.37%) , this significant difference could be credited to active incorporation of regular Pharmacovigilance related activities being conducted in the institution. [8] We also observed that only 04(30.76%) participants, from

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4rth year MBBS students were aware of the web based management system used in our institute for pharmacovigilance which is very low as compared to the participants from MBBS 2nd and 3rd year and interns, this highlights the importance of requirement of continued training for pharmacovigilance and related aspects to be incorporated at all levels of medical education and clinical departments also.In our study, 92.67% and 96.42% students of 2nd and 3rd yearMBBS were aware of the existence of Pharmacovigilance centre in their institute, which was significantly more than the observations received from study conducted by Kulmi et al 42.2% of MBBS 2nd year students and 50.6% of MBBS 3rd year students. It was also observed that majority of the participants, irrespective of the group they belong to, lacked information regarding the most commonly used scale for causality assessment of ADR. [9]

In the current study 64.67% students of 2nd year MBBS and 55.95% of MBBS 3rd year MBBS students strongly agreed that it is necessary to report ADRs which is similar to the results obtained in study conducted by Kulmi et al. [9] A positive attitude towards reporting of ADRs was witnessed on analysis, which could be due to the early exposure of future medical graduates to the pros and cons of ADR reporting and its complications if remain unreported.

In our study 18.67% and 50 % students of MBBS 2nd and 3rd year have reported ADRs during their medical training whereas in study conducted by Kulmi et al only 7.2% and 5.1% students of Phase II and II have ever reported an ADR. [9] These results bring in light the attitude and practice of budding healthcare professionals towards ADR reporting which was found to be inadequate in studies conducted by Praveen et al, Vora et al and Savanandy et al also.[10-13] Lack of enthusiasm of practicing ADR reporting could be due to lack of regular support and motivation amongst the senior healthcare practitioners who are role-models to the upcoming army of healthcare professionals.

In spite of PVPI, being more than two decades old and rigorous initiatives at governmental, institutional and academic levels and conducive attitude of medical students towards ADR reporting there has been no striking increase in the practice of ADR reporting in our country. There may be requirement of a paradigm shift towards promoting practice of ADR reporting more than the emphasis being laid on the attitude towards it.

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