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Assessment of Knowledge and Attitude of Pharmacovigilance Among Undergraduate Medical Students - A Questionnaire Based Study

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ABSTRACT

Pharmacovigilance plays a vital role in ensuring patient safety by detecting, assessing, understanding, and preventing adverse drug reactions (ADRs). Despite its importance, under-reporting of ADRs remains a significant issue, often due to inadequate knowledge and awareness among healthcare professionals, including medical students. To assess the knowledge of undergraduate medical students and interns regarding pharmacovigilance and evaluate their attitude towards pharmacovigilance and ADR reporting. A cross-sectional study was conducted among 164 medical students, comprising 23 from MBBS Phase II, 49 from MBBS Phase III Part I, 54 from MBBS Phase III Part II, and 38 interns. A structured questionnaire was used to evaluate their knowledge and attitude towards pharmacovigilance and ADR reporting. Overall, 59.26% of students demonstrated adequate knowledge of pharmacovigilance and ADR reporting, while 59.76% correctly defined ADRs. About 65.85% were able to correctly define pharmacovigilance, and nearly three-fourths were aware of the Pharmacovigilance Programme of India. However, less than half knew about the causality assessment scale. Knowledge levels were highest among MBBS Phase III Part II students. In terms of attitude, 68.29% supported the inclusion of pharmacovigilance in the undergraduate curriculum. More than half had never read any literature on ADRs. The study revealed that undergraduate medical students had a adequate level of knowledge and a positive attitude towards pharmacovigilance and ADR reporting. Incorporating pharmacovigilance into the medical curriculum is beneficial in enhancing awareness and fostering a culture of safe medication practices among future healthcare professionals.

Keywords: Pharmacovigilance, ADR reporting, Knowledge, Attitude, Medical undergraduates

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INTRODUCTION

Pharmacovigilance is defined as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems." [1] Over the years, there has been a significant increase in adverse drug reactions (ADRs) and hospital admissions resulting from them [1,2]. ADRs are recognized as a major cause of morbidity and mortality in both hospital and community settings [2].

To ensure patient safety and well-being, it is essential that healthcare professionals—including doctors, nurses, pharmacists, and support staff—as well as medical undergraduates, are adequately trained to recognize, prevent, and report ADRs [2].

In India, the Pharmacovigilance Programme of India (PvPI) was launched in July 2010 by the Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare. In April 2011, the Indian Pharmacopoeia Commission (IPC), Ghaziabad, was designated as the National Coordinating Centre. This centre functions under the Uppsala Monitoring Centre (UMC), Sweden, a WHO international collaborating centre. The primary aim of PvPI is to detect, assess, report, and monitor ADRs associated with prescribed medications [3].

Despite this initiative, India's contribution to the UMC's global drug safety database, VigiBase, was only 2% in 2013—mainly due to the under-reporting of ADRs [4]. Although healthcare professionals and medical students are vital for the success of pharmacovigilance programs, a lack of awareness, knowledge, and sensitization towards ADRs and pharmacovigilance are major contributing factors to this under-reporting [3,5].

Previous studies have shown that under-reporting of ADRs is closely linked to inadequate knowledge and poor attitudes among healthcare professionals [6,7]. This highlights the importance of introducing ADR reporting and pharmacovigilance concepts early in medical education i.e. during their under graduation itself [6].

Hence, the present survey was conducted to assess the knowledge and attitude of undergraduate medical students towards pharmacovigilance and ADR reporting.

OBJECTIVES:

1. To assess the knowledge of undergraduate medical students and interns regarding pharmacovigilance.
2. To evaluate their attitude towards pharmacovigilance and ADR reporting.

MATERIAL AND METHODS

After obtaining ethics committee approval [approval number – EC/18/XII/2K20(2/6)], a non-interventional, observational Knowledge and Attitude (KA) questionnaire-based study was conducted in our medical college over a period of one month.

Google forms with participant information sheet, informed consent, and a structured, pre-validated, questionnaire was used to record the responses of the participants. The questionnaire consisted of 32 questions and was divided into two sections. The first section included 21 multiple choice questions which assessed the Knowledge about pharmacovigilance and the second section had 11 questions which evaluated the attitude of the participants towards pharmacovigilance. The responses for attitude related questions were recorded based upon the participant's degree of agreement using responses as agree, disagree, strongly agree, strongly disagree.

Inclusion criteria:

All the students who voluntarily gave informed consent for participation in the study.

Exclusion criteria:

Students who were not willing to participate in the study.

Statistical analysis:

The data was entered into excel spread sheet using Microsoft excel version 2019. Statistical analysis was done by applying descriptive statistics to generate percentages.

RESULTS

After obtaining informed consent, a total of 164 participants responded to the questionnaire through the Google forms. All participants had responded to all the questions included in the questionnaire.

Among 164 participants, it was noted that majority of the participants i.e., 32.93% were MBBS Phase III Part 2. The other details regarding the number of participants were depicted in the table no. 1.

In the knowledge-based questions, the number of participants who gave correct responses was: 98 (59.76 %) for question no.1, 104 (63.41%) for question no.2, 85 (51.83%) for question no.3, 131 (79.88 %) for question no.4, 43 (26.22%) for question no.5, 101 (61.59%) for question no.6, 108 (65.85%) for question no.7, 92 (56.1%) for question no. 8, 118 (71.95%) for question no. 9, 107 (65.24%) for question no.10, 87 (53.05 %) for question no.11, 69 (42.07%) for question no.12, 85 (51.83%) for question no.13, 88 (53.66%) for question no.14, 97 (59.15%) for question no.15, 130 (79.27%) for question no.16, 112 (69.29%) for question no.17, 120 (73.17%) for question no.18, 126 (76.83%) for question no. 19, 67 (40.85%) for question no.20 and 73 (44.51%) for question no.21. The data regarding the knowledge-based questions are depicted in table no.2.

The results for the attitude-based questions responses were: 119 participants (72.56%) strongly agreed that reporting of adverse drug reactions is necessary, 112 (68.29%) strongly agreed that there is a need to include Pharmacovigilance in undergraduate curriculum to create awareness among the budding doctors. It was observed that 88 (53.66%) strongly agreed that they had read articles on prevention of adverse drug reactions, 95(57.93%) strongly agreed that establishing adverse drug reaction monitoring centre in every hospital is necessary. It is also observed that 102(62.2%) strongly agreed that ADR reporting system will benefit patient and doctors, 78(47.56%) agreed that ADRs can be suspected when drug is administered in normal dose. About 98(59.76%) strongly agreed that reporting all ADRs for a new drug is essential, 85(51.83%) strongly agreed that ADR reporting should be included under pharmacology practical. It was observed that 76(46.34%) strongly agreed that medical students can play a role in ADR monitoring, 91(55.49%) strongly agreed that discussion on ADR during clinical posting will have its relevance. About

100(60.97%) strongly agreed that there is a need of information on drugs causing ADRs and their management strategies. The data regarding the attitude-based questions are depicted in table 3

Table No. 1: Number of participants according to MBBS phases

MBBS phases	Number of students (n)	Percentage (%)
MBBS Phase II	23	14.02
MBBS Phase III Part 1	49	29.88
MBBS Phase III Part 2	54	32.93
Interns	38	23.17
TOTAL	**164**	**100**

Table No.2: Knowledge based questions and responses

Question numbers	Correct response	MBBS Phase II (n=23)	MBBS Phase III – Part 1 (n=49)	MBBS Phase III – Part 2 (n=54)	Interns (n=38)	Total (n = 164)	Percentage (%)
Q.No 1	Noxious, undesired or unintended of a drug, which may occur at doses normally used in man for various purposes or for the modification of a physiological state	15	27	29	27	98	59.76
Q.No 2	No	15	30	31	28	104	63.41
Q.No 3	Doctor, Pharmacist, Nurses and Lay person	12	22	29	22	85	51.83
Q.No 4	Yes	19	38	41	33	131	79.88
Q.No 5	Phase-4 clinical trials	6	8	18	11	43	26.22
Q.No 6	Type A is predictable, dose related and Type B is unpredictable, non-dose related	14	25	36	26	101	61.59
Q.No 7	The detection, assessment, understanding and prevention of adverse effects	15	33	37	23	108	65.85
Q.No 8	To identify safety of drugs	12	23	34	23	92	56.1
Q.No 9	Pharmacovigilance programme of India	17	35	36	30	118	71.95
Q.No 10	Ghaziabad, UP	16	30	37	24	107	65.24
Q.No 11	Sweden	14	22	29	22	87	53.05
Q.No 12	Naranjo algorithm	11	16	27	15	69	42.07
Q.No 13	Vigibase	11	20	30	24	85	51.83
Q.No 14	Cleft lip- Phenytoin	15	16	29	28	88	53.66
Q.No 15	Neural tube defects- Valproic acid	12	25	29	31	97	59.15
Q.No 16	Yes	20	39	42	29	130	79.27
Q.No 17	Thalidomide	15	35	32	30	112	68.29
Q.No 18	Post Marketing Surveillance (PMS) studies	19	36	38	27	120	73.17
Q.No 19	Central Drugs Standard Control Organization	19	36	40	31	126	76.83
Q.No 20	All of the above	11	20	19	17	67	40.85
Q.No 21	Yes	13	24	23	13	73	44.51

Table No. 3: Attitude based questions and responses

Question numbers	Level of agreement	MBBS Phase II (n=23)	MBBS Phase III – Part 1 (n=49)	MBBS Phase III – Part 2 (n=54)	Interns (n=38)	Total (n = 164)	(%)
Q.No 1	agree	3	13	13	8	37	22.56
	strongly agree	18	35	38	28	119	72.56
	disagree	1	0	2	2	5	3.05
	strongly disagree	1	1	1	0	3	1.83
Q.No 2	agree	4	13	16	9	42	25.61
	strongly agree	18	30	37	27	112	68.29
	disagree	0	4	1	2	7	4.27
	strongly disagree	1	2	0	0	3	1.83
Q.No 3	agree	8	17	21	16	62	37.8
	strongly agree	12	27	29	20	88	53.66
	disagree	2	4	3	2	11	6.71
	strongly disagree	1	1	1	0	3	1.83
Q.No 4	agree	8	14	25	10	57	34.75
	strongly agree	13	29	28	25	95	57.93
	disagree	1	4	1	3	9	5.49
	strongly disagree	1	2	0	0	3	1.83
Q.No 5	agree	7	12	18	9	46	28.05
	strongly agree	15	29	32	26	102	62.2
	disagree	0	4	3	3	10	6.09
	strongly disagree	1	4	1	0	6	3.66
Q.No 6	agree	10	22	29	17	78	47.56
	strongly agree	6	14	14	15	49	29.88
	disagree	6	10	10	6	32	19.51
	strongly disagree	1	3	1	0	5	3.05
Q.No 7	agree	8	18	22	9	57	34.75
	strongly agree	14	27	30	27	98	59.76
	disagree	1	2	2	2	7	4.27
	strongly disagree	0	2	0	0	2	1.22
Q.No 8	agree	9	20	28	12	69	42.07
	strongly agree	11	27	23	24	85	51.83
	disagree	2	1	2	2	7	4.27
	strongly disagree	1	1	1	0	3	1.83
Q.No 9	agree	8	22	22	15	67	40.85
	strongly agree	12	21	25	18	76	46.34
	disagree	2	2	6	5	15	9.15
	strongly disagree	1	4	1	0	6	3.66
Q.No 10	agree	4	19	24	12	59	35.97
	strongly agree	17	24	27	23	91	55.49
	disagree	1	5	0	3	9	5.49
	strongly disagree	1	1	3	0	5	3.05
Q.No 11	agree	8	17	18	10	53	32.32
	strongly agree	13	28	33	26	100	60.97
	disagree	1	3	0	2	6	3.66
	strongly disagree	1	1	3	0	5	3.05

DISCUSSSION

Pharmacovigilance aims to ensure patient safety and the rational use of medicines once a drug is approved for general use in the population. It plays a crucial role in the detection of adverse drug reactions (ADRs) and has led to the withdrawal of several harmful drugs from the market. Recognizing its importance, pharmacovigilance has been integrated into the Competency-Based Medical Education (CBME) curriculum for undergraduate medical students. However, under-reporting of ADRs remains one of the major challenges in pharmacovigilance programs.

In this study, a total of 164 medical students participated: 23 were from MBBS Phase II, 49 from MBBS Phase III Part 1, 54 from MBBS Phase III Part 2, and 38 were interns.

Approximately 59.26% of the participants demonstrated overall knowledge of pharmacovigilance and ADR reporting, which aligns with findings from a study conducted by Shaily Bhatt et al. [8]. Furthermore, 59.76% were able to correctly define ADRs—slightly lower than results reported by Meher et al.[3]and Shaily Bhatt et al. [8]. Analysis showed that 65.85% of students correctly defined pharmacovigilance, which was again lower than in the study by Shaily Bhatt et al. [8].

Nearly three-fourths of the respondents were aware of the Pharmacovigilance Programme of India (PvPI), a result consistent with the findings of Umashankar N et al. [9]. However, less than half of the participants were familiar with the scale used for causality assessment significantly lower compared to Umashankar N et al. [9].

Notably, MBBS Phase III Part 2 students demonstrated better overall knowledge of pharmacovigilance and ADR reporting than students from other phases.

Regarding attitude-based responses, 68.29% of participants expressed a positive attitude toward the inclusion of pharmacovigilance in the undergraduate curriculum to raise awareness among future doctors. This figure was lower than that reported in the study by Shaily Bhatt et al. [8]. Additionally, more than half of the students indicated that they had never read any literature related to ADRs, a finding similar to the study by Umashankar N et al. [9].

This study found that participants had adequate knowledge and a positive attitude towards pharmacovigilance and ADR reporting, although certain areas particularly awareness of causality assessment tools require further emphasis.

CONCLUSION

The participants demonstrated adequate knowledge related to ADR reporting, along with a positive attitude towards pharmacovigilance. Integrating pharmacovigilance and ADR reporting into the undergraduate medical curriculum appears to be effective in enhancing both knowledge and attitude towards pharmacovigilance and ADR reporting.

Limitations:

As this study was conducted at a single medical institution, the findings may not be generalizable to medical students in other regions or institutions. The relatively small sample size may also limit the representativeness of the results. Moreover, the study did not assess students' practical skills or real-world behaviour in ADR reporting, which are crucial for effective pharmacovigilance practice.

Conflicts of Interest: None declared

Author's Contribution:

Dr D. SHAILENDRA: was involved in the conception and design of the study, definition of intellectual content, literature search, manuscript preparation, manuscript editing, manuscript review, and also served as the guarantor of the study. Dr MD AMIRUNNISA BEGUM and Dr M. SNEHA MANJU contributed in defining the intellectual content, conducting the literature search, data analysis, statistical analysis, manuscript preparation, manuscript editing, and manuscript review. Dr PANDILLAPALLI SAI KETAN, Dr NAKSHATRAM SRI KRISHNA and Dr BHUMIREDDYPEDDIREDDY PREMCHAND contributed in data acquisition, data analysis, manuscript editing, and manuscript review.

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Informed consent: Informed written consent was obtained from all participants through Google forms.

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