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Original research article

ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICES REGARDING PHARMACOVIGILANCE AMONG MEDICAL STUDENTS OF A TERTIARY CARE TEACHING HOSPITAL IN CENTRAL INDIA

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Abstract

Background: Under Pharmacovigilance Programme of India (PvPI), huge efforts are being made to ensure Adverse Drug Reaction (ADR) reporting. Still, ADR under-reporting is quite prevalent. Active participation by all the various health-care professionals is required to increase ADR reporting and thereby improve public health and patient safety.

Aim and Objectives: This study attempted to assess the knowledge, attitude and practices (KAPs) regarding Pharmacovigilance (PV) among medical students of a tertiary care teaching hospital in central India.

Materials and Methods: In this cross-sectional survey, a pre-validated and pretested questionnaire containing 30 items was administered among medical students and the responses were analyzed.

Results: Out of 768, a total of 691 completely answered questionnaires were analyzed (response rate = 90%). Higher correct responses were seen among interns as compared to the second, pre-final and final MBBS students. Awareness regarding PvPI, online databases for ADR reporting, and various regulatory bodies for ADR reporting was less among the respondents. Majority of the students believed that ADR reporting is a professional obligation for all health-care practitioners and should be mandatory. However, majority of them never reported an ADR due to lack of information regarding how and whom to report and were not trained for the same.

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Conclusion: To increase ADR reporting rates in India, more awareness and training programs should be organized for all health-care practitioners. Moreover, early exposure to PvPI and ADR reporting should be included in MBBS curriculum.

Keywords: Pharmacovigilance programme of India, pharmacovigilance, knowledge, attitude, practice

Introduction

The pharmacological science dealing with the gathering of data, detection, assessment, monitoring and prevention of adverse effects or any other drug-related problems, mainly long term or short-term side effects of pharmaceutical products is known as Pharmacovigilance (PV). The WHO defines it as 'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem' [1, 2].

The Pharmacovigilance Programme of India (PvPI) was launched by the Government of India in July 2010 with the All India Institute of Medical Sciences (AIIMS), New Delhi as the National Coordination Centre (NCC) for monitoring Adverse Drug Reactions (ADRs) in the country for safe-guarding public health. Later on, the NCC was shifted from AIIMS, New Delhi to the Indian Pharmacopoeia Commission (IPC), Ghaziabad, (UP) for better implementation of the program. At present, there are 537 ADR monitoring centers (AMCs) under the PvPI [3].

ADR's contribute a substantial burden to India's economy and also to the loss of quality of life. Hence, prompt and efficient ADR reporting is an important moral responsibility of all health-care professionals in the country. As there is a great diversity in genetic make-up and cultural traditions across the country, this information can help formulating government policies to protect patient safety across the country [4].

The Uppsala Monitoring Centre (UMC), Sweden has international database of suspected ADR reports from all over the world [5]. Several studies conducted among hospitalized patient have revealed a high incidence of serious ADRs. These studies concluded that incidence of serious ADRs was around 6.7% of the total hospitalized patients with a fatality rate of 0.32% [6].

Currently, the main concern is underreporting of ADR's due to several factors [7]. The knowledge, attitude, and practices (KAP) is the best tool to assess ADR reporting among healthcare practitioners and to know their perspective towards Pharmacovigilance and patient's safety [8, 9, 10]. The future healthcare professionals should have basics knowledge of PV in order to rationally report ADRs [11]. Hence, this study was planned to assess the knowledge, attitude and practices (KAPs) about PV among medical students of a tertiary care teaching hospital in central India.

Materials and Methods

Study setting

This study was done at a tertiary care MBBS teaching hospital in central India. All the necessary approvals and clearances were obtained beforehand. The study was conducted during February to April, 2022.

Study design

It was a cross-sectional survey conducted on a total of 800 MBBS students [second

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year (n = 200), pre-final year (n = 200), final year (n = 200) and interns (n = 200)]. The study instrument was a pre-validated and pre-tested self-administered questionnaire which was designed based on recent previous studies [12, 13, 14]. There were 30 questions concerning KAPs (K = 12, A = 11, P = 7) about PV.

Data collection

Out of 800 respondents, 768 gave a valid informed consent for participation in the study. The participants were distributed the questionnaires and were given one day to complete and submit the questionnaires.

Statistical analysis

All the collected data were entered into and analyzed by SPSS (Statistical Package for Social Sciences) version 22 software.

Results

Out of 768 participants who gave a valid consent to participate, 691 [second year (n = 193), pre-final year (n = 181), final year (n = 172) and interns (n = 145)] students completed the questionnaire satisfactorily. Higher response rates were observed in second MBBS students, whereas interns showed the least response. The total response rate was 89.97% (Table 1)

Table 1: Response rates among medical students

	Second MBBS (n=200)	**Pre-final MBBS (n=200)**	**Final MBBS (n=200)**	**Interns (n=200)**	**Total (n= 800)**
Gave a valid consent to participate, n (%)	196 (98)	197 (98.5)	190 (95)	185 (92.5)	768 (96)
Completed the questionnaire, n (%)	193 (98.47)	181 (91.88)	172 (90.53)	145 (78.38)	691 (89.97)

Higher correct response rates were observed for definition, purpose, and scope of PV, ADR reporting and Health-care professional/s responsible for ADR reporting in a hospital. However, awareness regarding PvPI, online databases for ADR reporting and various regulatory bodies for ADR reporting was poor among the respondents. Majority of the students were aware of any drug/s banned due to ADR (Table 2).

Table 2: Knowledge about PV among medical students

Construct	**Correct Response [N (%)]**			
	Second MBBS (n=193)	**Pre-final MBBS (n=181)**	**Final MBBS (n=172)**	**Interns (n=145)**
Definition of Pharmacovigilance	139	81 (45)	93 (54)	62 (90)

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	(72)			
Main purpose of Pharmacovigilance	133 (69)	74 (41)	91 (53)	87 (60)
Scope of Pharmacovigilance	116 (60)	71 (39)	88 (51)	84 (58)
Post Marketing Surveillance (PMS) Studies	104 (54)	63 (35)	57 (33)	87 (60)
Definition of ADR	97 (50)	80 (44)	79 (46)	80 (55)
ADR Reporting	120 (62)	87 (48)	89 (52)	94 (65)
Health-care professional/s responsible for ADR reporting in a hospital	93 (48)	72 (40)	62 (36)	80 (55)
Pharmacovigilance Programme of India (PvPI)	77 (40)	58 (32)	48 (28)	65 (45)
WHO online databases for ADR reporting	19 (10)	22 (12)	19 (11)	41 (28)
Indian body for ADR monitoring	17 (9)	18 (10)	19 (11)	32 (22)
International body for ADR monitoring	14 (7)	9 (5)	10 (6)	15 (10)
Awareness of any drug/s banned due to ADR	135 (70)	118 (65)	117 (68)	109 (75)

Majority of the students believed that ADR reporting is a professional obligation for all health-care practitioners and it should be mandatory, and ADR monitoring center should be there in all hospitals. Majority of the respondents were of the opinion that PV should be taught in detail to health-care professionals and early exposure on ADR form filling should be introduced in the MBBS curriculum (Table 3).

Table 3: Attitude regarding PV among medical students

Construct	**Positive Response [n (%)]**			
	Second MBBS (n=193)	**Pre-final MBBS (n=181)**	**Final MBBS (n=172)**	**Interns (n=145)**
ADR reporting is a professional obligation for all health-care professionals	174 (90)	152 (84)	150 (87)	138 (95)
ADR reporting is beneficial for both doctors and patients	170 (88)	157 (87)	155 (90)	133 (92)
ADR reporting should bemade mandatory for all health-care professionals	145 (75)	123 (68)	112 (65)	102 (70)
There is a need of information on ADRs and their management	141 (73)	127 (70)	103 (60)	96 (66)
Establishing ADR monitoring center in every hospital is useful	120 (62)	116 (64)	100 (58)	102 (70)
ADR monitoring center should be there in all hospitals	125 (65)	110 (61)	103 (60)	96 (66)
Practical on ADR reporting in second year MBBS is	135	132	120	113

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useful	(70)	(73)	(70)	(78)
Discussion on PV during clinical posting is useful	131 (68)	136 (75)	122 (71)	107 (74)
Medical students can play a role in PV	125 (65)	138 (76)	120 (70)	113 (78)
PV should be taught in detail to health-care professionals	127 (66)	129 (71)	124 (72)	102 (70)
Early exposure on ADR form filling should be introduced in the MBBS curriculum	135 (70)	118 (65)	124 (72)	133 (92)

Regarding the practice domain, majority of the students never reported an ADR due to lack of information regarding how and whom to report and were not trained for the same (Table 4).

Table 4: Practice regarding PV among medical students

Construct	**Positive Response [n (%)]**			
	Second MBBS (n=193)	**Pre-final MBBS (n=181)**	**Final MBBS (n=172)**	**Interns (n=145)**
Have you ever come across an ADR?	44 (23)	62 (34)	83 (48)	94 (65)
Have you ever reported an ADR?	19 (10)	25 (14)	34 (20)	44 (30)
If you came across an ADR and did not report it, why so?				
Did not know how to report	139 (72)	119 (66)	112 (65)	65 (45)
Did not know whom to report	135 (70)	118 (65)	114 (66)	70 (48)
Did not feel the need to report	19 (10)	27 (15)	21 (12)	44 (30)
Other reason/s	10 (5)	18 (10)	14 (8)	17 (12)
Have you attended any training program on PV and ADR reporting?	29 (15)	36 (20)	40 (23)	51 (35)

Discussion

Since its inception, underreporting of ADRs has been a major concern in PvPI. Because a knowledge, attitude, and practices (KAP) study is the best tool to assess the perspective and practices towards Pharmacovigilance in healthcare professionals, this study was planned with the aim to assess the KAPs about PV among medical students of a tertiary care MBBS teaching hospital in central India. The total response rate among the respondents was close to 90% in our study.

It was observed that majority of the students were aware of the concept of PV. However, awareness regarding PMS studies, PvPI, WHO online databases for ADR reporting and regulatory bodies for ADR reporting was less among the students (Table 2). This could be an important reason for under-reporting of ADRs. These results regarding awareness about PV are slightly higher when compared to previous similar studies [2, 10, 15]. These differences could be due to various factors like timing and place of study, sample size and increased use of internet services after COVID-19 pandemic.

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We found positive attitude among students about PV and ADR reporting (Table 3) as majority of the students believed that ADR reporting is a professional obligation for all health-care practitioners and it should be made mandatory. The positive response rates were higher in our study as compared to similar studies conducted in the past [16, 17]. This could be due to higher sample size of our study, regional differences, and increased awareness about PV with time.

Despite increased awareness and positive attitude regarding ADR reporting, majority of the respondents did not report an ADR due to lack of information regarding how and whom to report and were not trained for the same (Table 4). Similar results on underreporting are observed in previous studies [12, 13, 16, 17]. This aspect should be adequately addressed in PvPI by conducting more training programs on ADR reporting systems, providing remuneration for correct ADR reporting, and making the ADR reporting systems user friendly and less time consuming. Such dedicated efforts are likely to increase ADR reporting rates in the country thereby improving patient safety and public health.

Limitations

Since we used convenience sample of MBBS students from a tertiary care teaching hospital in central India, it may not be representative of all the health care professionals. Similar studies can be conducted for all the stake holders of PvPI. Also, some other factors associated with self-administered questionnaire-based surveys like, recall bias, attitudinal bias and practical bias could have an impact on our results.

Conclusion

To increase ADR reporting rates in India, more awareness and training programs should be organized for all health-care practitioners. Moreover, early exposure to PvPI and ADR reporting should be included in MBBS curriculum.

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Conflict of interest: There are no reported conflicts of interest.

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