

RESEARCH ARTICLE

Assessment of knowledge, attitude, and practice of pharmacovigilance among undergraduate medical students in a tertiary care teaching hospital of Eastern India: A questionnaire-based study

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ABSTRACT


Background: Despite the untiring efforts of pharmacovigilance (PV) program in safeguarding public health by ensuring patient safety nationwide, underreporting is still much prevalent. Active participation of all health-care professionals in the PV program can improve the adverse drug reaction (ADR) reporting. **Aim and Objective:** The present study tried to assess the knowledge, attitude, and practices (KAPs) of medical students about PV in a tertiary care teaching hospital in Eastern India. **Materials and Methods:** A cross-sectional questionnaire-based observational study was carried out on undergraduate medical students in a tertiary care teaching hospital in Eastern India. A structured, pretested questionnaire assessing KAPs of the respondents, adapted from extensive literature review was administered to each student who was given 30 min to fill the questionnaire. Responses were analyzed. **Results:** A total of 247 questionnaires were assessed. Improved responses were observed in final year students as compared to the second and prefinal years. However, awareness pertaining to ADR reporting system in India and scales involved in causality was less among students. Awareness regarding necessity of ADR reporting was lacking in 50% of respondents. The practice of PV and reporting ADRs was assessed, which revealed though many came across ADRs, very few reported the same as majority did not know how to report ADRs to the national program. **Conclusion:** The various domain components of the study necessitate the need of infusing the reporting culture by introducing the concept of medication safety in early curriculum of therapeutics in medical undergraduates. The barriers to reporting the ADRs may be lack of training and awareness of this issue such as where to report and whom to report and who to report.

KEY WORDS: Knowledge; Attitude; Practice; Pharmacovigilance; Pharmacovigilance Programme of India

INTRODUCTION

Adverse drug reactions (ADRs) remain one of the most prime reasons of morbidity and mortality worldwide.^[1] However,

despite the ever-increasing statistics of ADR prevalence, underreporting of ADRs is the prime problem of drug reporting system. Uppsala Monitoring Centre (UMC), located in Uppsala, Sweden functions as the World Health Organization (WHO) Collaborating Centre for International Drug Monitoring, which works by collecting, assessing, and communicating information from its member country's national pharmacovigilance (PV) centers in regard to the benefits, harm, effectiveness, and risks of drugs.^[2] The PV Programme of India (PvPI) was launched with a mission to safeguard the health of the Indian population by ensuring the safety of the marketed drugs.^[3] Data regarding drug safety

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are primarily pooled from the individual case safety reports reported by health-care providers or consumers from the member countries of the WHO Programme. This vast data pool is maintained by UMC in a global database platform called VigiBase. Spontaneous reporting system of ADRs is one of the principle methods used globally to monitor the benefit and hazard of drugs. This voluntary reporting system has the potential to identify rare, unexpected ADRs more quickly than any other study designs. The rate at which ADRs are reported depends on many factors such as time since the launch of PV programs, regulations, and attitude of health-care professionals.^[4]

In India, all health-care professionals including doctors, dentists, nurses, and pharmacists and even consumers can voluntarily report an ADR by filling an ADR reporting form as devised by Central Drugs Standard Control Organization. Notwithstanding the constant endeavor by the PvPI toward inculcating a healthy reporting culture, underreporting is still much prevalent and a barrier to smooth PV system. Constant training and enactment of regulations for ADR reporting among health-care professionals are thus required. Inculcating the ADR reporting culture during early days of medical training can help with this situation. Not many studies have focused on the need of inclusion of PV in early medical training. Undergraduate medical students need to be apprised regarding importance of adverse event reporting, laying the inception of pharmacovigilance health-care professionals.^[5] The present study tried to assess the knowledge, attitude, and practices (KAPs) of medical students about PV among undergraduate medical students in a tertiary care teaching hospital in Eastern India.

MATERIALS AND METHODS

A cross-sectional questionnaire-based observational study was carried out on undergraduate medical students (2nd professional students, 3rd professional students, and final year) in a tertiary care teaching hospital in Eastern India. Consenting students

only after providing written informed consent were included in the study. The study commenced only after obtainment of permission of conduct from the Institutional Ethics Committee. A structured, pretested questionnaire adapted from extensive literature review was administered to each student who was given 30 min to fill the questionnaire. The first part (question no. 1–10) contained the set of questions seeking the knowledge in depth of medical students about PV. Part two (question no. 11–15) contained questions to know their attitude toward PV. The third part (question no. 16–19) contained set of questions to assess their practical aspects of PV. The responses were analyzed, tabulated, and statistically presented in terms of frequency, mean, or percentages as applicable.

RESULTS

In this cross-sectional study, among the 270 participants, 247 questionnaires were returned with the response rate of 91.48%. Knowledge about the PV among the participants was assessed by Part-I (question no. 1–10) of the questionnaire [Table 1]. Knowledge regarding PV was assessed in terms of concept and role of PV, system of ADR monitoring in India. Improved responses were observed in final year students as compared to the second and prefinal years. However, awareness pertaining to ADR reporting system in India and scales involved in causality was less among students. Attitude in PV reporting was adjudged. Awareness regarding necessity of ADR reporting was lacking in 50% of respondents [Table 2]. The practice of PV and reporting ADRs was assessed, which revealed though many came across ADRs, very few reported the same as majority did not know how to report ADRs to the national program [Table 3].

DISCUSSION

Underreporting of ADRs is a prime challenge in PV. The PvPI follows spontaneous or voluntary ADR reporting system to

Table 1: Knowledge domain

Variables	Correct response (n[%])		
	Second year (n=85)	Prefinal (n=82)	Final (n=80)
What is PV?	41 (48.23)	45 (54.87)	54 (67.5)
What is the main function of PV?	40 (47.05)	43 (52.43)	52 (65)
Who regulates the national PV program in India?	34 (40)	43 (52.43)	47 (58.75)
Define ADR	45 (52.94)	49 (59.75)	57 (71.25)
Where International Center of ADR monitoring is located?	14 (16.47)	15 (18.29)	17 (21.25)
What is the ADR reporting system in India?	9 (10.58)	12 (14.63)	15 (18.75)
Which one of the following is most commonly used scale to establish causality of an ADR?	8 (9.41)	12 (14.63)	14 (17.5)
The health-care professional responsible for ADR reporting in a hospital is/are?	31 (36.47)	40 (48.78)	48 (60)
Which kind of ADRs should be reported?	41 (48.23)	50 (60.97)	55 (68.75)
Which one of the following is the “WHO online databases” for reporting ADRs?	11 (12.94)	14 (17.07)	16 (20)

ADRs: Adverse drug reactions, WHO: World Health Organization

Table 2: Attitude domain

Variables	Positive responses [n (%)]		
	Second year (n=85)	Prefinal (n=82)	Final (n=80)
Do you think ADR reporting is necessary	40 (47.05)	49 (59.75)	54 (67.5)
Do you think ADR reporting is a professional obligation and should be mandated?	29 (34.11)	32 (39.02)	42 (52.5)
Do you think ADR monitoring center should be there in all hospitals?	34 (40)	40 (48.78)	50 (62.5)
Do you think PV should be taught in detail to health-care providers?	48 (56.47)	50 (60.97)	52 (65)
Do you think early exposure on ADR form filling should be introduced in the MBBS curriculum?	56 (65.88)	53 (64.63)	57 (71.25)

ADRs: Adverse drug reactions, PV: Pharmacovigilance

Table 3: Practice domain

Variables	Positive responses (n [%])		
	Second year (n=85)	Prefinal (n=82)	Final (n=80)
Have you ever come across with an ADR?	29 (34.11)	40 (48.78)	50 (62.5)
If yes, have you reported any ADR?	9 (10.58)	12 (14.63)	14 (17.5)
If no, why you did not report it			
Do not know how to report	48 (56.47)	43 (52.43)	34 (46.25)
Do not know where to report	17 (20)	15 (18.29)	12 (15)
Did not feel the need to report	9 (10.58)	12 (14.63)	14 (17.5)
Other reasons	2 (2.35)	4 (48.78)	5 (62.5)
Have you ever been trained on how to report ADR?	11 (12.94)	15 (18.29)	18 (22.5)

ADRs: Adverse drug reactions

gather information on drug safety. The various stakeholders for the program include health-care professionals (physicians, dentists, pharmacists, and nurses), drug manufacturers, regulatory authorities, and last but not the least patients or patients' caregivers. Being the prime prescriber, physicians are regarded to take the center stage in PV. However, the program has faced the challenge of underreporting since its inception. Over the years, the major factors driving underreporting in case of physicians has been found to be fear of litigation, ignorance, lethargy, diffidence, insufficient training to identify ADRs, and lack of awareness about ongoing program. Physicians including residents and house staffs along with nurses and pharmacists need to be more actively involved in reporting ADRs, to widen the reporter base. The present study was conducted with an aim to investigate the KAP of PV among the undergraduate medical students. The various domain components of the study necessitate the need of infusing the reporting culture by introducing the concept of medication safety in early curriculum of therapeutics in medical undergraduates. The barriers to reporting the ADRs may be lack of training and awareness of this issue such as where to report and whom to report and who to report. Approaches such as in-built ADR reporting network within the hospital, undertaking periodic sensitization workshops or awareness seminars on drug safety alerts, and periodic E-mail/SMS alerts may help to foster an improved reporting culture.

Our study witnessed around 68% of final year respondents being aware of PV, while the figure was 48% in case of the

2nd year students. Around 52% of final year respondents regard ADR reporting as a professional obligation in contrast to other studies which reported the same from around 85% of final year respondents.^[6] Our study revealed that though around 50% of respondents encountered ADR, but only around 20% reported. This underreporting has also been detailed in other studies.^[6,7]

Our study is strengthened by close evaluation of PV awareness among undergraduate students year wise. The authors strongly believe that introduction of early PV exposure in young brains of Indian medical graduate can further strengthen the ADR reporting and better patient safety. Moreover, our studies exactly try to put this into perspective. Limitation of the study exists in not being able to evaluate the same study respondents post awareness as an intervention. Appropriate interventions to include ADR reporting and PV as a mandate in medical and paramedical undergraduate coaching in an appropriate format should be mandated in the curriculum by the Medical Council of India and respective stakeholders in nursing and pharmacy education also.

CONCLUSION

Underreporting of ADRs is one of the prime hurdles in the pathway of national PV program. Concept of medication safety and PV should be well introduced in the early curricula of medical training to ensure safer patient outcomes and to foster a better reporting culture nationwide.

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