

## A descriptive study of knowledge of Pharmacovigilance and adverse drug reactions among second professional undergraduate medical students in a teaching hospital

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### ABSTRACT

**Background:** Adverse drug reactions (ADRs) are adverse consequences of drug therapy being one of the leading causes of morbidity and represent a substantial burden of healthcare resources. Though Pharmacovigilance program was started in India in 1982, the awareness about it is much lower and underreporting of ADRs is a common problem with only 6-10% of all ADRs being reported. The objective of this study was to analyze the baseline knowledge of awareness regarding the ADRs and Pharmacovigilance activity in the undergraduate medical students who are future doctors of society so as to foster a culture of reporting ADRs, to fulfill various its lacunae and make adjustments of medical student's curriculum in order to improve practice of reporting.

**Methods:** A cross-sectional survey was conducted among second professional medical students in July 2015 to assess the knowledge of ADRs and Pharmacovigilance activities using a questionnaire to collect the information. Part "A" consisted of choosing the most appropriate answer and Part "B" included replying with "Yes" or "No." Data were expressed as percentage proportions.

**Results:** Out of the total of 150 enrolled students, 134 filled and returned the questionnaire with students having a mediocre knowledge about Pharmacovigilance and majority of them (94%) vouching that reporting of ADRs should be mandatory as it is going to benefit patients (99.2%).

**Conclusions:** Our study revealed that there are gaps between knowledge regarding ADRs and Pharmacovigilance that needs to be addressed on priority basis for the success of the Pharmacovigilance program and better clinical management of patients in general.

**Keywords:** Adverse drug reactions, Pharmacovigilance, Knowledge, Underreporting, Questionnaire

### INTRODUCTION

Pharmacovigilance is a systematic and structured process for the monitoring and detection of adverse drug reactions (ADRs) in a given context<sup>1</sup> and has been defined by WHO as a science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.<sup>2</sup> Though Pharmacovigilance Program was started in India in 1982, is still in its infancy in India and the Pharmacovigilance Programing (PvPI) of India like most others around the world suffers from underreporting of ADRs due to lack of awareness and inadequate training about drug safety monitoring among health care professionals in India<sup>3</sup> which delays the detection of ADRs, an important cause of mortality and morbidity worldwide.<sup>4</sup> According

to WHO definition, ADR is any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis or cure of a disease<sup>5</sup> which in addition to the human costs, have a major impact on public health by imposing a considerable economic burden on the society and the already stretched health care systems<sup>6,7</sup> and are responsible for about 5-20% of hospital admissions<sup>8,9</sup> with 3.7% of patients having fatal ADRs.<sup>10</sup> The ADR reporting rate in India is below 1% compared to the worldwide rate of 5%<sup>11</sup> with the average cost involved in treating these ADRs was INR 900 (USD 15\$) per patient.<sup>12</sup>

ADRs are rather a complex issue which requires special attention. Monitoring of ADRs is carried out by various methods of which voluntary or spontaneous reporting is

commonly practiced which offers many advantages such as being inexpensive and easy to operate. Because of variation in drug response, individual prescribing habits, drug regulatory systems, and availability of drugs, etc., it has been recommended for every country to set up their own Pharmacovigilance Program.<sup>5</sup> The Uppsala Monitoring Centre (UMC, WHO), Sweden is maintaining the international database of ADR reports from several national centers of different countries. Although, India is one of the participating in the program, its contribution to UMC database is very little. The program lacks continuity and suffers from underreporting of ADRs by the health care professionals, the reason for which may be meager funds, lack of trained staff and lack of awareness about detection, communication and spontaneous monitoring of ADRs.<sup>13</sup> To make Pharmacovigilance Program a success and improve reporting rate, it is important to improve the knowledge, attitude, and practice (KAP) of the healthcare professionals regarding ADR reporting and Pharmacovigilance and best time to do so is probably during undergraduate and postgraduate training of the doctors. Therefore, this study was planned to evaluate the baseline knowledge of the undergraduate medical students who are future health care professionals, so as to make reporting of ADRs more vibrant by inculcating culture of reporting and strengthen the Pharmacovigilance Program.

## METHODS

This cross-sectional questionnaire based survey was undertaken in the Department of Pharmacology of Government Medical College Srinagar, 800 bedded, tertiary care teaching hospital among 2nd year MBBS undergraduate students after approval of the Institutional Ethical Committee and taking informed consent from students. The students were explained the purpose of the study and giving any clarification needed in understanding the questionnaire. Data were collected through a structured, validated questionnaire which was developed by modifying the earlier ones. The questionnaire include 20 questions in all divided into two parts, the first part involving choosing of most appropriate option among four available options and second part included replying with “yes” or “no” followed by an open ended question about improving Pharmacovigilance practices in India. The results were analyzed by using simple descriptive statistics involving frequencies, percentages, and proportions.

## RESULTS

Out of a total of 150 enrolled students, 134 participated and successfully completed the questionnaire within stipulated time frame of 15 mins with males and females comprising 70 and 64, respectively. The majority of them were from Kashmir (119), rest from Jammu and Ladakh province with most of them from rural areas. The response rate was 100% among students who participated in the study tabulated as

percentage frequency in tables with quite varied results as shown in Tables 1 and 2.

## DISCUSSION

Pharmacovigilance is an integral and essential part of patient care with reporting of ADRs an essential component of Pharmacovigilance Program and the most important outcome of the Pharmacovigilance is the prevention of patients being affected unnecessarily by negative consequences of pharmacotherapy.<sup>13</sup> The present study evaluated the baseline knowledge of second professional medical students regarding ADR reporting and Pharmacovigilance who are future doctors in our society and although a whopping 99.2% and 94% of students agreed that reporting ADR will benefit patients and reporting ADR should be mandatory which are in confirmation with study conducted by Desai et al.,<sup>14</sup> their basic knowledge about Pharmacovigilance and related aspects was quite mediocre as depicted in Tables 1 and 2 and needed further improvement as suggested by studies by Rehan et al.<sup>13</sup> which was conducted at the Lady Harding Medical College, New Delhi and showed that the KAP of both the undergraduates and the prescribers were comparable, but they needed further improvement. A good number of students, i.e. 85% had an idea that aim of Pharmacovigilance is to assess safety, 73.8% were aware of the fact that all the healthcare professionals, i.e. doctors, pharmacists and nurses are responsible for reporting ADR in a hospital, 86.5% were aware of that ADR reporting has a specific format while as the response in other questions was not that encouraging. A survey among medical residents in France<sup>15</sup> showed that the majority of them had a lower knowledge regarding Pharmacovigilance. A study from Italy<sup>16</sup> also reported that doctors had little information concerning ADRs and ADR reporting systems. A study from India<sup>17</sup> also identified that the awareness about Pharmacovigilance program and knowledge of ADR reporting were low among doctors. These findings suggest the need for interventions to improve the knowledge and attitude of the medical students so as to make program of Pharmacovigilance a success story.

An interesting finding was that 79.8% students opined that they have not been trained on how to report ADR and 54.4% cited that topic of Pharmacovigilance is not well covered in curriculum for which conducting continuing medical education (CME) on Pharmacovigilance and giving training to students and prescribers about Pharmacovigilance seems to be an immediate necessity. The training program should cover the location of Pharmacovigilance centres, reporting procedure and method of filling ADR reporting form.<sup>18-20</sup> A study by Li et al.<sup>21</sup> also showed that educational interventions improved awareness of KAP of healthcare professionals toward practice of Pharmacovigilance.

**Table 1: Multiple Choice Questions.**

| Gender: M/F   |  |
|---|--|
| Resident: Jammu/Kashmir/Ladakh City/Village   |  |
| Choose the most appropriate one answer by using tick (✓)                            |  |
| 1. Pharmacovigilance is the study that relates to:                                  | (a). The science of monitoring ADRs happening in a hospital - 2.9%<br>(b). Safe, effective, appropriate and economic use of medicines - 8.9%<br>(c). The science detecting the type and incidence of ADR after drug is marketed - 17.1%<br>(d). The detection, assessment, understanding and prevention of adverse effects - 70.8% |
| 2. Aim of Pharmacovigilance is to assess:   | (a). Safety - 85%<br>(b). Efficacy - 14.9%<br>(c). Cost - 0<br>(d). None - 0   |
| 3. Pharmacovigilance includes:  | (a). Drug-related problems - 68.6%<br>(b). Blood-related products - 0%<br>(c). Medical devices and vaccines - 0%<br>(d). All of the above - 30.5%  |
| 4. National Pharmacovigilance Programme in India is governed by:                    | (a). CDSCO under the agenesis of Health and Family Welfare - 24.6%<br>(b). Medical Council of India - 14.9%<br>(c). ICMR - 34.3%<br>(d). Pharmacy Council of India - 22.3%   |
| 5. Hierarchy of Pharmacovigilance centres in India comprises of following:          | (a). Zonal, regional, peripheral - 15.6%<br>(b). Peripheral, regional, zonal - 30.5%<br>(c). Regional, zonal, peripheral - 18.6%<br>(d). Peripheral, zonal regional - 32.8%  |
| 6. Which one of the following is the “WHO online database” for reporting ADRs:      | (a). ADR advisory committee - 43.2%<br>(b). Medsafe - 23.1%<br>(c). Medwatch - 6.7%<br>(d). Vigibase - 16.4%   |
| 7. The international center for ADR monitoring is located in:                       | (a). U.S.A - 33.5%<br>(b). Australia - 2.2%<br>(c). France - 7.4%<br>(d). Sweden - 50.7%   |
| 8. The healthcare professionals responsible for reporting ADR in a hospital is/are: | (a). Doctor - 14.9%<br>(b). Pharmacist - 10.4%<br>(c). Nurses - 0.7%<br>(d). All of the above - 73.8%  |
| 9. The number of zonal, peripheral and regional centers in India are:               | (a). 2, 28, 5-16.4%<br>(b). 5, 28, 2-38.8%<br>(c). 28, 5, 2-23.8%<br>(d). 28, 2, 5-12.6%   |
| 10. Life-threatening ADR are those which result in:                                 | (a). Death - 22.3%<br>(b). Hospitalization - 4.4%<br>(c). Prolongation in hospitalization - 5.2%<br>(d). All of above - 67.1%  |

ADR: Adverse drug reactions

**Table 2: Reply with “Yes” or “No”.**

|   |
|---|
| 1. ADR and ADE are same<br>Yes - 20.1%<br>No - 73.1%  |
| 2. ADR reporting has a specific format<br>Yes - 86.5%<br>No - 11.1%   |
| 3. Do you think ADR monitoring and reporting will benefit patients?<br>Yes - 99.2%<br>No - 0.74%                                  |
| 4. Do you think reporting ADR should be mandatory?<br>Yes - 94.0%<br>No - 4.47%   |
| 5. Have you been trained on how to report ADR?<br>Yes - 16.4%<br>No - 79.8%   |
| 6. Have you ever come across with an ADR?<br>Yes - 32.0%<br>No - 66.4%  |
| 7. Commonly seen ADRs such as headache, fever, and vomiting should not be reported<br>Yes - 20.1%<br>No - 73.1%                   |
| 8. Reporting of ADRs is more for newer drugs<br>Yes - 64.1%<br>No - 35.8%   |
| 9. Are you aware of any drug/drugs that have been banned or withdrawn from market. Name few of them?<br>Yes - 83.5%<br>No - 10.4% |
| 10. Do you believe that topic of Pharmacovigilance is well covered in your curriculum?<br>Yes - 41.0%<br>No - 54.4%               |
| Any other comment or recommendation about improving Pharmacovigilance in India  |

ADR: Adverse drug reactions, ADE: Adverse drug event

Pharmacovigilance programs have played a major role in detection of ADRs and banning of several drugs from the market<sup>5</sup> about which majority of our students, i.e., 112 (83.5%) were aware of and 81 (60.4%) named drugs such as terfenadine, rofecoxib, pergolide, cisapride, and astemizole as the most common drugs that have been withdrawn but none had ever reported an ADR despite 32% responding in affirmative that they have come across an ADR. In an open ended question about improving Pharmacovigilance in India, few student had urged for spontaneous reporting of ADRs by patients themselves, creation of drop boxes for reporting of ADRs in hospitals, improving the manpower, conducting CMEs, inculcating habit of ADR reporting during undergraduation, improving quality of ADR monitoring units in every district hospital and creating round the clock communication system.

The main limitation of this study is that it is based on convenience sample which involves only one batch of 2nd year medical students from one single teaching hospital.

## CONCLUSION

The present study identified the knowledge of the undergraduate medical students regarding ADR monitoring and Pharmacovigilance and provides an insight into the possible interventions that could be planned to foster the culture of reporting by making urgent improvements like motivating and organizing training program regarding Pharmacovigilance in undergraduate medical curriculum under pharmacology department, conducting CMEs, reinforcement of guidelines for ADR reporting among health care personnel and patients themselves, setting up of a regional Pharmacovigilance centre, laying more emphasis on Pharmacovigilance topic in undergraduate curriculum and again adding training program during internship and residency. Furthermore, various incentives may be considered for reporting. Finally, mass media including the social media can be brought into use to spread awareness about ADRs. Our study also appreciates the need of 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 effectiveness of Pharmacovigilance activities.

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## REFERENCES

1. WHO. Policy perspectives on medicines. Pharmacovigilance: ensuring the Safe Use of Medicines. Geneva: World Health Organization; 2004. Available at <http://www.who.int/medicines>. Accessed 03 July 2015.
2. WHO. The Importance of Pharmacovigilance. Geneva: WHO; 2002.
3. Rajesh R, Vidyasagar S, Nandakumar K. Highly active antiretroviral therapy induced adverse drug reactions in Indian human immunodeficiency virus positive patients. J Adv Pharm Technol Res. 2011;9:48-55.
4. Lazarou J, Pomeranz BH, Corey PN. Incidence of ADR in hospitalized patients: a meta-analysis of prospective studies. JAMA. 1998;279:1000-5.
5. World Health Organization. Safety of Medicines: a Guide to Detecting and Reporting Adverse Drug Reactions. WHO/EDM/QSM/2002. Geneva: WHO; 2002.
6. Ayani I, Aguirre C, Gutiérrez G, Madariaga A, Rodríguez-

- Sasiain JM, Martínez-Bengoechea MJ. A cost-analysis of suspected adverse drug reactions in a hospital emergency ward. *Pharmacoepidemiol Drug Saf*. 1999;8(7):529-34.
7. Wu WK, Pantaleo N. Evaluation of outpatient adverse drug reactions leading to hospitalization. *Am J Health Syst Pharm*. 2003;60(3):253-9.
  8. Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. *BMJ*. 2004;329(7463):15-9.
  9. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *JAMA*. 1998;279(15):1200-5.
  10. Kulkarni MD, Baig MS, Chandaliya KC, Doifode SM, Razvi SU, Sidhu NS. Knowledge, attitude and practice of pharmacovigilance among prescribers of Government Medical College and Hospital, Aurangabad (Maharashtra). *Int J Pharm Ther*. 2013;3(3):10-8.
  11. Amrita P, Kharbanda B. Knowledge, attitude and skills of nurses of Delhi towards adverse drug reaction reporting. *Indian J Pharm Pract*. 2012;5:45-51.
  12. Ramesh M, Pandit J, Parthasarathi G. Adverse drug reactions in a south Indian hospital--their severity and cost involved. *Pharmacoepidemiol Drug Saf*. 2003;12(8):687-92.
  13. Rehan HS, Vasudev K, Tripathi CD. Adverse drug reaction monitoring: knowledge, attitude and practices of medical students and prescribers. *Natl Med J India*. 2002;15(1):24-6.
  14. Desai CK, Iyer G, Panchal J, Shah S, Dikshit RK. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. *Perspect Clin Res*. 2011;2(4):129-36.
  15. Graille V, Lapeyre-Mestre M, Montastruc JL. Drug vigilance: opinion survey among residents of a university hospital. *Therapie*. 1994;49(5):451-4.
  16. Cosentino M, Leoni O, Banfi F, Lecchini S, Frigo G. Attitudes to adverse drug reaction reporting by medical practitioners in a Northern Italian district. *Pharmacol Res*. 1997;35(2):85-8.
  17. Bharathan B, Raju NA. Survey about the knowledge, attitude and practice of adverse drug reaction reporting among doctors in Bangalore City. Sixth Annual Conference of the Society of Pharmacovigilance (India); November 11-12, 2006; Kurupanidhi College of Pharmacy, Bangalore, India.
  18. Palaian S, Ibrahim MI, Mishra P. Health professionals' knowledge, attitude and practices towards pharmacovigilance in Nepal. *Pharm Pract (Granada)*. 2011;9(4):228-35.
  19. Fadare JO, Enwere OO, Afolabi AO, Chedi BA, Musa A. Knowledge, attitude and practice of adverse drug reaction reporting among healthcare workers in a tertiary centre in Northern Nigeria. *Trop J Pharm Res*. 2011;10(3):235-42.
  20. Vora MK, Paliwal NP, Doshi VG, Barvaliya MJ, Tripathi CB. Knowledge of adverse drug reactions and pharmacovigilance activity among the undergraduate students of Gujarat. *Int J Pharm Sci Res*. 2012;3(5):1511-5.
  21. Li Q, Zhang SM, Chen HT, Fang SP, Yu X, Liu D, et al. Awareness and attitudes of healthcare professionals in Wuhan, China to the reporting of adverse drug reactions. *Chin Med J (Engl)*. 2004;117(6):856-61.

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