

## Original Research Article

# A study to determine the knowledge of pharmacovigilance among pharmacy students from Mumbai university

Dnyanesh Limaye<sup>1\*</sup>, Purav Shah<sup>2</sup>, Akhil Shah<sup>2</sup>, Ragini Pillay<sup>2</sup>, Viraj Modak<sup>2</sup>,  
Ameya Chaudhari<sup>2</sup>, Arlan Sydymanov<sup>1</sup>, Vaidehi Limaye<sup>1</sup>, Ravi Shankar Pitani<sup>3</sup>,  
Sushama Sathe<sup>4</sup>, Gerhard Fortwengel<sup>1</sup>

<sup>1</sup>Department of Clinical Research, Hochschule Hannover, Hannover, Germany

<sup>2</sup>Department of Pharmacy, Institute of Chemical Technology, Mumbai, Maharashtra, India

<sup>3</sup>Department of Community Medicine, Sri Ramachandra University, Chennai, Tamil Nadu, India

<sup>4</sup>Department of Health Science, Research Institute of Health Sciences and Management, Chetan Dattaji Gaikwad Institute of Management Studies, Pune University, Maharashtra, India

**Received:** 03 May 2018

**Accepted:** 28 May 2018

### \*Correspondence:

Dr. Dnyanesh Limaye,

E-mail: [dnyanesh.limaye@hs-hannover.de](mailto:dnyanesh.limaye@hs-hannover.de)

**Copyright:** © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

## ABSTRACT

**Background:** Pharmacovigilance (PV); also known as drug safety surveillance, is the science of enhancing patient care and patient safety regarding the use of medicines by collecting, monitoring, assessing, and evaluating information from healthcare providers and patients. Pharmacists are pivotal players in adverse drug event (ADE) monitoring and reporting. However, most pharmacists are unaware or not knowledgeable about the guidelines used by their respective countries' drug regulatory bodies. It is the need of the hour to train pharmacy students on the concept of pharmacovigilance.

**Methods:** A cross-sectional study was carried out among pharmacy students from Mumbai University, India during May-June 2017. On the basis of the eligibility criterion 352 students were selected for the present study. Four hundred students were approached to participate in the study of which 201 agreed to participate (males: 179; females: 173). Pretested questionnaire was distributed and collected data was analyzed using IBM SPSS version 23.

**Results:** Overall pharmacovigilance knowledge (44%) and perception (58%) was low among the participants of the present study. Seventy four percent of the participants felt that adverse drug reaction (ADR) reporting should be made compulsory for healthcare professionals. And only 21% agreed that the topic of Pharmacovigilance is well covered in pharmacy curriculum.

**Conclusions:** Pharmacy council of India, pharmacy teacher's association and respective pharmacy college should take necessary steps to increase the knowledge and create awareness regarding pharmacovigilance and adverse drug reaction reporting among pharmacy students.

**Keywords:** Adverse drug event, Adverse drug reaction, India, Knowledge, Perception, Pharmacovigilance, Pharmacy

## INTRODUCTION

Pharmacovigilance (PV); also known as drug safety surveillance, is the science of enhancing patient care and patient safety regarding the use of medicines by collecting, monitoring, assessing, and evaluating

information from healthcare providers and patients.<sup>1</sup> Adverse drug reactions (ADR) are global problems and affects majority of children as well as adults causing both morbidity and mortality and also a major impact on public health.<sup>2-6</sup> A little is known about serious and rare adverse effects associated with a drug at the time of approval by the Food and Drug Administration.

Voluntary reporting of ADR is an important source of information to the health care professionals.<sup>7</sup> It helps to utilize the available drugs in a better way and reduce the drug related problems in patients. To detect and spontaneously report ADR and to ensure drug safety, National Pharmacovigilance Program was initiated in India in the year 2004.<sup>8</sup> It is now renamed as 'Pharmacovigilance Program of India' and is operational since July 2010 under the aegis of Central Drug Standard Control Organization.<sup>9</sup> The ADR reporting rate in India is below 1% compared to the worldwide rate of 5%.<sup>10</sup> One of the reasons for low reporting rate in India may be a lack of knowledge and sensitization towards pharmacovigilance and ADR among medical and allied health care professionals.

In India, people have easy access to drugs. They approach local community pharmacists for medicines without consulting a physician for many illnesses as it is convenient, less time-consuming and economical for them. Prevalence of self-medication in India varies widely from 27.6% to 81.5%.<sup>11</sup> Pharmacists can play a pivotal role in both ADE reporting and PV activities.<sup>12</sup> Pharmacists are more likely to detect adverse drug events (ADEs) than are other healthcare professionals, either in the hospital or community setting.<sup>12</sup>

In the hospital setting, pharmacists can play an important role in ADE reporting because they have access to the information necessary to report ADEs.<sup>13,14</sup> Because they may be the first to be contacted by patients for information about ADEs, community pharmacists are an important source of ADE reports. Although previous studies indicated that pharmacists are pivotal players in ADE monitoring and reporting, most pharmacists are unaware or not knowledgeable about the guidelines used by their respective countries' drug regulatory bodies responsible for assessing ADEs.<sup>15-17</sup> It is the need of the hour to train pharmacy students on the concept of pharmacovigilance, how to recognize, prevent, and report ADE as they may turn into pharmacy practitioners, or work in pharmaceutical industry in the future. The objective of this study was therefore to determine the knowledge of pharmacovigilance among pharmacy students from Mumbai University, so as to know the kind of education and awareness strategies applicable to them.

## METHODS

**Study design and respondents:** This descriptive study was performed in May-June 2016, among students from Mumbai University, India. Pharmacy students were contacted by study team member in their classrooms and were given a brief introduction about the research project. Four hundred students, who desired to participate were explained the purpose and objectives of the study. On the basis of the eligibility criterion (have heard about ADR, ready to give a written informed consent and are registered pharmacy students of Mumbai university) 352 students were selected for the present study.

**Study instrument:** The survey questionnaire was prepared in English after reviewing the literature for similar studies. The questionnaire was framed to gather information on demographics and knowledge, behavior and attitude towards pharmacovigilance.

A pilot study was done with a sample of 30 students, to know the average time required for face to face interview for completing the questionnaire and to ensure that it is appropriate and understandable to students. Pilot population was not part of the final study.

## Collection of data

Students were interviewed face to face in the student office with prior appointment by a study team member. The purpose of the research was explained to the respondents, anonymity and confidentiality were guaranteed and maintained. The researchers complied with the international ethical guidelines for research. The data was recorded into the predesigned data record form (DRF) by interviewers.

## Data entry and analysis

Collected data from individual DRF was entered into Microsoft excel and was verified by the authors other than interviewers. Data were analyzed by using descriptive statistical methods and a bivariate analysis was conducted with all relevant independent variables. P-value  $\leq 0.05$  was considered as significant. IBM SPSS version 23 was used for statistical analysis.

## RESULTS

Out of total 400 pharmacy students contacted, 352 were selected based on the eligibility criterion (have heard about ADR, ready to give a written informed consent and are registered pharmacy students of Mumbai university) for the present study.

Table 1 represents the participant details regarding gender, education, knowledge about PV. It also shows the bivariate analysis to determine if any, the association between knowledge about PV and the gender of the respondents. There were total 352 respondents comprising of 179 (47%) males and 173 (53%) females. The first column of the table shows the input variables to measure the knowledge about PV. Second column gives all the expected answers, and next columns represent the gender wise responses to the questions. Rest of the columns show bivariate analysis i.e. chi square and p-value. Maximum (76%; 266/352) study participants belonged to bachelor of pharmacy category. Out of a total 12 questions about knowledge, for 9 questions more than 50 percent of the participants answered incorrectly. In the knowledge section of this study, sixty-six percent participants did not have the knowledge about reporting of ADRs. Fifty nine percent of the participants did not know that they can report ADRs during their studies.

**Table 1: Knowledge and perception of PV.**

Variable	Expected answer	Male n (%)	Female n (%)	Total n (%)	$\chi^2$ value	P-value
<b>Demographic data</b>						
<b>Gender</b>		179 (47)	173 (53)	352 (100)		
<b>Education</b>						
BS Pharmacy		142(79)	123(71)	266(76)	2.9	0.23
MS Pharmacy		29(16)	38(22)	67(19)		
PhD Pharmacy		8(5)	11(64)	19(5)		
<b>Knowledge of PV</b>						
I have knowledge of how to report ADR to the relevant authorities in India.	Yes	53(29)	68(39)	121(34)	3.6	0.05
Students can perform adverse drug reactions reporting during their studies.	Yes	70(39)	74(43)	144 (41)	0.49	0.48
I know the different classifications of ADR.	Yes	53(30)	63(36)	116(33)	1.8	0.17
Hypersensitivity reactions are related to ADR.	Yes	86(30)	86(50)	172(49)	0.09	0.75
There is a difference between ADR and the adverse event.	Yes	50(28)	57(33)	107(30)	1.04	0.3
I know the different types of hypersensitivity reactions.	Yes	60(34)	67(39)	127(36)	1.03	0.31
I know what Post-Marketing Surveillance is.	Yes	68(38)	76(44)	144(41)	1.3	0.25
I know how causality assessment of ADR is done.	Yes	44(25)	36(21)	80(23)	0.71	0.39
Serious and unexpected reactions that are not fatal or life threatening during clinical trials must not be reported.	No. They should be reported	142(79)	129(75)	271(77)	1.1	0.29
The purpose of ADR spontaneous reporting system is to measure the incidence of ADR.	Yes	66(37)	71(41)	137(39)	0.64	0.43
Any ADR (serious or non-serious) should be reported spontaneously.	Yes	122(68)	119(69)	241(68)	0.02	0.89
Reason for not reporting a suspected ADR is due to the uncertainty of its association with drugs.	No	119(66)	95(55)	214(61)	4.9	0.02
<b>Perception about PV</b>						
Reporting of known ADRs makes a significant contribution to the reporting system.	Yes	101(56)	112(65)	213(61)	2.5	0.11
The topic of Pharmacovigilance is well covered in my curriculum.	Yes	32(18)	42(24)	74(21)	2.2	0.14
ADR reporting should be made compulsory for healthcare professionals.	Yes	132(74)	128(74)	260(74)	0.002	0.95
Information on how to report ADRs should be taught to students.	Yes	117(65)	121(70)	238(68)	0.84	0.35
With my present knowledge, I am very well prepared to report any ADRs noticeable in my future practice	Yes	37(21)	49(28)	86(24)	2.8	0.09
Healthcare is one of the most important professions to report adverse drug reactions.	Yes	127(71)	124(72)	251(71)	0.02	0.88
Patients should be counselled about ADR every time their medications are dispensed.	Yes	121(68)	141(82)	262(74)	8.9	0.002
Female patients should be asked if she is pregnant when dispensing medications to them.	Yes	130(73)	139(80)	269(76)	1.1	0.3

Only 33% participants knew the different classification of ADR. Fifty-one percent participants were not aware that hypersensitivity reactions are related to ADR. Seventy

percent participants were not aware that there is a difference between ADR and the adverse event. Sixty four percent students did not know the different types of hypersensitivity reactions. Only 41% of the students

knew about post marketing surveillance. Seventy seven percent of the participants did not know how the causality assessment of ADR is done. Seventy seven percent of the participants rightly responded that serious and unexpected reactions that are not fatal or life threatening during clinical trials should be reported. Sixty one percent of the participants did not know that the purpose of ADR spontaneous reporting system is to measure the incidence of ADR. Similarly, only 68% of the participants knew that any ADR (serious or non-serious) should be reported spontaneously. Thirty nine percent of the participants thought that the reason for not reporting a suspected ADR is due to the uncertainty of its association with drugs.

In the perception section of this study, only 61% of the participants believed that reporting of known ADRs makes a significant contribution to the reporting system. Seventy nine percent of the participants opined that the topic of PV is not well covered in their curriculum. Seventy four percent of the participants thought that ADR reporting should be made compulsory for healthcare professionals. Sixty eight percent of the participants thought that information on how to report ADRs should be taught to students. Only 24 percent of the participants mentioned that with their present knowledge, they are very well prepared to report any ADR noticeable in their future practice. Seventy one percent of the participants believed that healthcare is one of the most important professions to report adverse drug reactions. Seventy four percent of the participants agreed that patients should be counselled about ADR every time their medications are dispensed. Seventy six percent participants agreed that female patient should be asked if she is pregnant when dispensing medications to them.

Except for one question each from knowledge and perception sections of this study, there were no significant gender differences in the responses. For the question in the knowledge section-“Whether the reason for not reporting a suspected ADR is due to the uncertainty of its association with drugs?” significantly higher number of male (119/179; 66%) than female (95/173; 55%) respondents answered “no” as the correct response. For the question in the perception section-“Whether the patients should be counselled about ADR every time their medications are dispensed?” significantly higher number of female (141/173; 82%) than male (121/179; 68%) respondents answered “no” as the correct response. Average scores were calculated by average of the total percentage of correct responses. Based on this, the average knowledge score was 44%, whereas average perception score was 58%.

## DISCUSSION

Pharmacovigilance is an integral part of health care. It helps in detection and prevention of ADR of medicinal products. Spontaneous reporting of ADR is vital for the success of pharmacovigilance program. Present study

showed that overall pharmacovigilance knowledge of pharmacy students from Mumbai University was 44%. Our results are in line with the studies from India which showed the knowledge was 44-45% among pharmacy students.<sup>18,19</sup> These results are surprising as drug safety pharmacovigilance is an integral part of the pharmacy studies in India. In our study overall perception of PV was 58%. Participants were asked if they were prepared to report any ADRs with present knowledge, only 24% gave a positive answer. A study by Kothari et al reported lower percentage (13%) than the present study.<sup>18</sup> While study done by Elkalmi et al in Malaysia, 87% said they are prepared to report ADRs.<sup>20</sup>

Present study revealed that only 21% participants said that the topic of Pharmacovigilance is well covered in their curriculum, which is lower (55%) than the study done by Rajiah et al, among pharmacy students in Kuala Lumpur.<sup>21</sup> In the present study, only 39% respondents agreed that the purpose of ADR spontaneous reporting system is to measure the incidence of ADR which is lower (92.5%) than the study done by Zawahir et al, among pharmacy students from Malaysia.<sup>22</sup> These findings from the present study show that the students of Mumbai University do not have good knowledge about Pharmacovigilance even though it is part of their syllabus.

## CONCLUSION

Present study indicates that there might be gaps in the teaching methodology of pharmacovigilance at the undergraduate program of 'Bachelor of Pharmacy. It might be appropriate to invite the industry personnel well acquainted with PV process and formalities to teach pharmacy students rather than regular regular teachers. As this will enable students not only to understand and memorize theory but also to get the hands on practical knowledge. We feel that pharmacy council of India, pharmacy teachers association should take necessary steps to increase the knowledge and create awareness regarding pharmacovigilance and adverse drug reaction reporting among pharmacy students.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the VV Research Independent Ethics Committee, Mumbai, India*

## REFERENCES

1. Suke SG, Kosta P, Negi H. Role of pharmacovigilance in India: An overview. Online J public health informatics. 2015;7(2).
2. Lazarou J, Pomeranz B, Corey P. Incidence of adverse drug reactions in hospitalized patients: A meta-analysis of prospective studies. JAMA. 1998;279:1200-5.
3. 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(7456):15-9.
4. Oshikoya K. Adverse drug reaction in children: Types, incidence and risk factors. *Niger J Paediatr.* 2006;33:29-35.
  5. Martínez-Mir I, García-López M, Palop V, Ferrer JM, Rubio E, Morales-Olivas FJ. A prospective study of adverse drug reactions in hospitalized children. *Brit J Clin Pharmacol.* 1999 Jun 1;47(6):681-8.
  6. Oshikoya K, Awobusuyi J. Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos, Nigeria. *BMC Clin Pharmacol.* 2009;11(9):14.
  7. Gavaza P, Brown CM, Lawson KA, Rascati KL, Steinhardt M, Wilson JP. Pharmacist reporting of serious adverse drug events to the Food and Drug Administration. *Journal of the American Pharmacists Association.* 2012 Sep 1;52(5):e109-12.
  8. Adithan C. National pharmacovigilance programme. *Indian J Pharmacol.* 2005;37:34.
  9. CDSCO. Pharmacovigilance programme of India 2010. Ministry of Health and Family Welfare, Government of India; 2010. Available from: <http://www.cdsc.nic.in/pharmacovigilance> (Last accessed on May 2018).
  10. 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.
  11. Limaye D, Limaye V, Krause G, Fortwengel G. A systematic review of the literature on survey questionnaires to assess self-medication practices. *Inter J Comm Med Pub Heal.* 2017 Jul 22;4(8):2620-31.
  12. van Grootheest AC, de Jong-van den Berg LT. The role of hospital and community pharmacists in pharmacovigilance. *Res Social Adm Pharm* 2005;1:126-33.
  13. Thompson A, Osgood T, Ragucci K. Patient care interventions by pharmacy students in the intensive care unit. *Am J Health Syst Pharm* 2007;64:1788-9.
  14. Kaboli PJ, Hoth AB, McClimon BJ, Schnipper JL. Clinical pharmacists and inpatient medical care: a systematic review. *Archives of internal medicine.* 2006 May 8;166(9):955-64.
  15. Su C, Ji H, Su Y. Hospital pharmacists' knowledge and opinions regarding adverse drug reaction reporting in Northern China. *Pharmacoepidemiol Drug Saf.* 2010;19:217-22.
  16. Vallano A, Cereza G, Pedròs C, Agustí A, Danés I, Aguilera C, Arnau JM. Obstacles and solutions for spontaneous reporting of adverse drug reactions in the hospital. *Brit J Clin Pharmacol.* 2005 Dec 1;60(6):653-8.
  17. Bäckström M, Mjörndal T, Dahlqvist R. Underreporting of serious adverse drug reactions in Sweden. *Pharmacoepidemiol drug Saf.* 2004;13:483-487.
  18. Kothari N. An evaluation of knowledge and perception of pharmacy students toward pharmacovigilance and adverse drug event reporting. *Asian J Pharmaceutics (AJP): Free full text articles from Asian J Pharm.* 2015 Nov 24;9(4):262-5.
  19. Sharma S, Sharma J, Aggarwal T. A survey on knowledge and perception of pharmacy students towards adverse drug reaction (ADR) reporting. *Asian J Pharm Clin Res.* 2012;5(3):129-31.
  20. Elkalmi RM, Hassali MA, Ibrahim MI, Widodo RT, Efan QM, Hadi MA. Pharmacy students' knowledge and perceptions about pharmacovigilance in Malaysian public universities. *Am J pharmaceutical education.* 2011 Jun;75(5):96.
  21. Rajiah K, Maharajan M, Nair S. Pharmacy students' knowledge and perceptions about adverse drug reactions reporting and Pharmacovigilance. *Saudi Pharmaceutical J.* 2016;24:600-4.
  22. Zawahir S, Sultan RA, Asmani MF, Bushell MJ. Pharmacy students' knowledge and perceptions of adverse drug reactions and reporting. *Pharmaceutical J Sri Lanka.* 2015;5:25-33.

**Cite this article as:** Limaye D, Shah P, Shah A, Pillay R, Modak V, Chaudhari A, et al. A study to determine the knowledge of pharmacovigilance among pharmacy students from Mumbai university. *Int J Res Med Sci* 2018;6:2621-5.