

A STUDY TO ASSESS KNOWLEDGE ATTITUDE AND PRACTICES OF PHARMACOVIGILANCE AMONGST SECOND YEAR MEDICAL STUDENTS OF A TEACHING HOSPITAL IN NORTH MAHARASHTRA.

Dr. Smita Avhad¹, Major Dr. Jeetendra Singh², Miss Sakshi Mishra³

¹ JR-2 Department of Pharmacology and Therapeutics, Dr. Vasant Rao Pawar Medical College, Hospital & Research Centre, Vasantdada Nagar, Adgaon, NASHIK - 422003, Maharashtra, INDIA.

² Professor, Department of Pharmacology and Therapeutics Dr. Vasant Rao Pawar Medical College, Hospital & Research Centre, Vasantdada Nagar, Adgaon, NASHIK - 422003, Maharashtra, INDIA.

³ 3rd year MBBS student, Dr. Vasant Rao Pawar Medical College, Hospital & Research Centre, Vasantdada Nagar, Adgaon, NASHIK - 422003, Maharashtra, INDIA.

Article Info: Received 20 January 2020; Accepted 07 February 2020

DOI: <https://doi.org/10.32553/ijmbs.v4i2.940>

Corresponding author: Major Dr. Jeetendra Singh

Conflict of interest: No conflict of interest.

Abstract

Pharmacovigilance (PV) plays a vital role in the healthcare system through assessment, monitoring and discovery of interactions amongst drugs and their effects in human. Medicines do come with their respective adverse effects. Therefore it is imperative to do Adverse Drug Reaction (ADR) monitoring while they are being marketed. PV is a part of the second MBBS curriculum, but often given less importance by the students. If this Knowledge Attitude & Practice of PV can be made effective during the MBBS course itself, it may make the students better aware about ADR monitoring.

Aims & Objective: Our purpose was to find out the knowledge, attitude & practices amongst the second year medical students in a tertiary care hospital in North Maharashtra.

Methods: This was an observational based study which had predesigned questions. After seeking the approval from the Institutional Ethics Committee, questionnaire was given to second year students of a tertiary care hospital in north Maharashtra. MS Excel was used for data analysis.

Results: The overall response rate was 76%. 30% answered knowledge question correctly whereas 70% answered the attitude questions correctly. Only 4 % had reported an ADR and majority felt that busy duty hours and fear of legal action was the reason for underreporting.

Conclusion: Our study revealed that in spite of PV being part of 2nd year MBBS, it still needs more emphasis and attention. The student feedback regarding ADR after they visit wards may help in improving the general awareness.

Keywords: Pharmacovigilance, Knowledge, Attitude, ADR.

Introduction

Pharmacovigilance (PV) activities are essential to ensure patient safety and must be encouraged at all health-care institutes. However, lack of awareness, training, and underreporting of adverse drug reactions (ADRs) are the major hindrances in the successful implementation of PV programme [1]

Since the advent of drugs, the utilization of medicines has been connected with adverse events. There are only three activities of a medication: 'The one you want, the one you don't want and the one you don't know about'. Adverse drug reactions (ADRs) are described as 'a response to a medicament which is noxious and unforeseen and which happens at dosages ordinarily utilized for the diagnosis, prophylaxis or treatment of a disease or for the alteration of physiological function' [2]

Adverse Drug Reactions (ADRs) are associated with a significant morbidity and mortality. Recent estimates suggest ADRs to be the fourth major cause of death in the United States (US). In order to identify the offending drugs causing ADRs, several countries have initiated pharmacovigilance programs in the recent past. Because of the variation in drug response among individuals, prescribing habits, drug regulatory system, and availability of drugs, it has been recommended for every country to set up their own pharmacovigilance programs[3]

The World Health Organization (WHO) defines pharmacovigilance as the pharmacological science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. In latin Pharmakon = Drug and Vigilare = Vigilance, which means "To keep awake or alert, to keep watch [4,5]

Pharmacovigilance (PV or PhV), also known as drug safety, is the pharmacological science and activities relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products. [6]

The specific objectives of Pharmacovigilance:

- i. To improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions.
- ii. To improve public health and safety in relation to the use of medicines.
- iii. To contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more cost-effective use.
- iv. To promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public (Talbot and Nilsson, 1998).[7]

Currently 134 countries are participating. It is centrally coordinated by WHO & with collaboration centre **UPPSALA**, Sweden. Uppsala maintains database of > 4 million ADR, in software **VIGIBASE**. [6]

In India, a formal ADR monitoring system was started in 1986 with 12 regional centers. In 1997, India became the member of the WHO Programme for International Drug Monitoring managed by the Uppsala Monitoring Centre, Sweden. In July 2010, under Health Ministry, a nationwide revised ADR monitoring program was launched and named as Pharmacovigilance Programme of India.[8]

The expansion of scientific knowledge in drug safety is attributable to greater awareness and academic interest in this field. In many medical institutions, particularly in the developed countries, adverse drug reaction (ADR) monitoring is recognized as an essential quality assurance activity[9]

Adverse drug reactions (ADRs) are an important public health problem in terms of mortality, morbidity as well as costs.[10]

Underreporting of spontaneous adverse drug reaction (ADR) is a threat to pharmacovigilance. Various factors related with the knowledge and attitudes are responsible for underreporting of ADRs.[11]

ADRs are rather a complex issue which requires special attention; they involve patients, medical professionals, the pharmaceutical industries, drug regulatory agencies and academic scientist. ADR reporting does not currently appear to be considered a part of routine professional practice by health care professionals [12].

The effectiveness and success of the Pharmacovigilance system highly depends upon the participation of all health

care personnel's (HCP) right from the patient to the medical practitioner [13]

Studies have revealed major lack of awareness and perceptions about pharmacovigilance and consumer pharmacovigilance among HCPs. As HCPs play an important role in educating their patients and are respected people in local communities, it is important that they provide proper medical care to patients as their knowledge about pharmacovigilance can be transferred to patients, patients' families, and society.[14]

Medical students as the future healthcare authorities need to be professionally trained to be rational and holistic doctors. A medical doctor should also be capable of recognizing, managing and reporting the adverse drug reactions (ADRs) and drug interactions. ADRs are an important health care threat in both developed and developing countries and eventually increase more morbidity and mortality.[15]

Hence emphasizing PV in pharmacology curriculum more strongly and revising it again with interns will help in further awareness and more ADR reporting.

Method:

Study design

A cross sectional questionnaire based study was conducted amongst second year undergraduate medical students after due approval of Institutional Ethical Committee. Willingness to participate and completing the questionnaire will be taken as consent for the study.

120 questionnaires were distributed, out of which 92 were assessed.

Inclusion Criteria: 2nd yr medical students willing to participate

Exclusion criteria: Students not willing to participate

The questionnaire consisted of 19 questions. It was based on previous studies and was divided into three sections, i.e. knowledge, attitude, and practice regarding pharmacovigilance and ADR reporting

Data Analysis

The data were collected and analyzed using MS Excel and results were calculated in the form of percentage.

Results:

12 were Knowledge questions, 4 were Attitude questions, & 3 were Practice questions

92 students were assessed and were given 30 min to answer the questions.

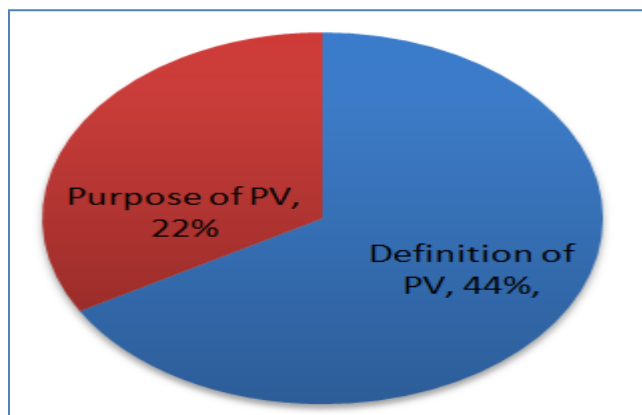
Response to Knowledge related questions:

Fig 1 shows 44% were aware of the definition of PV and 22% were aware of the purpose of PV, 15% knew the definition of ADR and 21% could identify the types of ADR. 40% knew who can report ADR and 31% knew the necessary steps to be taken.

Nearly 20% new about the international ADR centre 12% new about the regulatory body for PV in India.

46% were aware about PV centre in VPMC, 5% were aware about National PVPI programme.

An average of 30% students answered Knowledge related questions about PV correctly [Table 1]

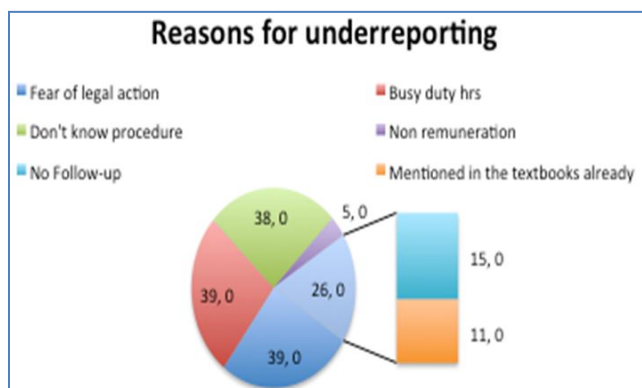
**Graph 1:****Response to Attitude related questions:**

Attitude section had four questions and was better answered than the other two sections. On an average the percentage of students who answered the attitude related questions correctly were 70%.

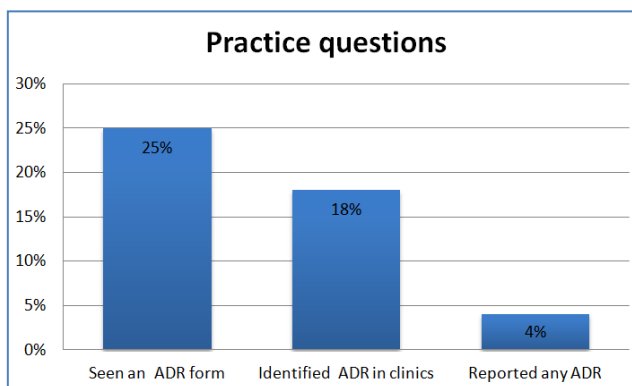
69% agreed that it was necessary to report ADR.

82% felt that PV and ADR reporting should be taught in the undergraduate classes. 46% had also read articles related to PV. [Table 2]

Following were the students' views regarding underreporting of ADR:

**Graph 2:****Response to Practice related questions:**

Three practice questions were answered in this study. 25% had seen an ADR form, 18% have identified an ADR in clinics but only 4% had reported ADR to their respective seniors. [Table 3]

**TABLE 1: Response to Knowledge questions of Pharmacovigilance**

Q No	Questions	Correct Response n (%)
1	What is the definition of pharmacovigilance?	41 (44%)
2	What is the purpose of pharmacovigilance?	21 (22%)
3	What is the definition of ADR?	19 (15.8%)
4	What are the types of ADR?	20 (21%)
5	Which is the most common ADR?	58 (48%)
6	Which ADRs should be reported?	65 (70%)
7	Where is international ADR center located?	25 (20.8%)
8	What is the regulatory body for monitoring ADRs in India?	15 (12.5%)
9	Is there pharmacovigilance center in VPMC?	56 (46%)
10	Knowledge about national PV program	6 (5%)
11	Who can report ADRs?	49 (40%)
12	What steps to be taken once an ADR is detected?	38 (31%)

TABLE 2: Response to Attitude questions of Pharmacovigilance

Q No	Questions	Correct Response n (%)
1	Is it necessary to report ADR?	64 (69%)
2	Should pharmacovigilance and ADR monitoring be taught in detail in MBBS curriculum?	76 (82%)
3	Have you read any article related to PV or ADR monitoring?	43 (46%)
4	What are the reasons for underreporting?	
a	Busy duty hours	36 (39%)
b	Do not know how the reporting procedure works	35 (38%)
c	No time to follow-up patients	14 (15%)
d	Textbooks and other literature already have ADRs mentioned	11 (11%)
e	Fear of legal consequences	36 (39%)
f	Non-remuneration	5 (5%)

TABLE 3: Response to Practice questions of Pharmacovigilance

Q No	Questions	Correct Response n (%)
1	Have you ever come across an ADR form?	23 (25%)
2	Have you ever identified an ADR in a patient during the clinics?	17 (18%)
3	Have you ever reported ADR?	4 (4%)

Discussion

- Our study was planned to assess the knowledge, attitude and practice of second year medical students towards ADRs and PV. This was done at a tertiary care hospital in Maharashtra.
- Since PV is taught to the second year students, they have role to play in implementing the same. They can also be of help in gathering and reporting the ADRs.
- In our study 76% of students answered the questionnaire. It was 73% in a study conducted in Goa on final year students by **Gaude et al.**[8]
- We found that the term PV was known to 44% of the students. 46% knew there was a centre in VPMC. 69% felt it was imp to report ADR as compared to 74% seen **Vakade et al** [16]
- As per the guidelines only health care professionals and patients can report ADR, 53% answered this question correctly. The knowledge about PV was very inadequate among the students and was similar to study by **Vora et al** [17]
- The aim of pharmacovigilance is to ensure patient safety and rational use of medicines. Though it has played a role in detecting ADRs , but under reporting still remains as major drawback towards achieving the goals of PV. In our study students felt that lack of knowledge on how to report an ADR was the main reason for underreporting. It corroborates with the finding of studies done previously by **Radhakrishnan et al.** [18]
- This was indicating that continuous sensitization is required regarding ADR reporting and pharmacovigilance. It can be done by educational interventions like incorporation of pharmacovigilance related activities in the undergraduate practical, continuous medical education (CME), and workshop on pharmacovigilance
- Our study showed better attitude towards PV amongst students but poor knowledge and practice. This shows that there is immense scope for introspection with regards to teaching PV at undergraduate level.
- In our study factors that the students felt with regards to under-reporting were mainly due to busy duty hours.
- An observational study conducted in teaching hospital in India has also concluded that underreporting of ADRs is a major threat to the success of pharmacovigilance program. Various factors have been found to be responsible for underreporting of ADRs by doctors. These factors are mainly related with the knowledge and attitudes. The results reflect upon the lack of awareness of participants about the existence of ADR reporting system, which would ultimately affect the reporting. [19]
- A study in Gujarat mentioned that one of the ways of reducing the under reporting is to emphasize on the Knowledge of the medical professional regarding ADR monitoring and Pharmacovigilance programs. [17]

- **M. Aylin et al** in their study concluded that the undergraduate medical students are prospective prescribers of society. Therefore, increasing awareness about PV program through training starting in medical school appears to be necessary to enhance reporting. [20]
- Participants of the study conducted by **Kulkarni et. al** though had good knowledge about pharmacovigilance but lacked in attitude and practice towards reporting ADR. Greater awareness of pharmacovigilance and incorporation of it in medical curriculum will further strengthen pharmacovigilance activity was also explained .[21]

Conclusion

This study showed that students had better attitude, but limited knowledge and poor practice toward pharmacovigilance and ADR reporting. Although pharmacovigilance is being taught to some extent in theory, the knowledge on the practical aspect is lacking.

Mohit Kulmi et al study concluded that respondents of study were only moderately aware of Pharmacovigilance and ADR reporting. There is a demanding need to create awareness and to educate residents as well as students about pharmacovigilance as they are the future health professionals. This can be achieved by imparting knowledge and awareness of pharmacovigilance and through implementing regular sensitization programs for the healthcare professionals. [13]

Revision of present academic curriculum is necessary to include the application of pharmacovigilance in medical practice. The result of this study is just the tip of an iceberg. Awareness about pharmacovigilance and ADRs should be a priority.

This is going to reflect on the future practice and decreased irrational use of drugs.

References

1. Singh J, Singh H, Rohilla R, Kumar R, Gautam CS. Lack of awareness of pharmacovigilance among young health-care professionals in India: An issue requiring urgent intervention. *International Journal of Applied and Basic Medical Research*. 2018 Jul;8(3):158.
2. Goel D, Farooq M. Impact of educational intervention on knowledge, attitude and practice of pharmacovigilance among interns. *Advances in Human Biology*. 2017 May 1;7(2):75.
3. Palaian S, Ibrahim MI, Mishra P. Health professionals' knowledge, attitude and practices towards pharmacovigilance in Nepal. *Pharmacy practice*. 2011 Oct;9(4):228.
4. World Health Organization. The importance of pharmacovigilance – safety monitoring of medicinal products [Internet]. Geneva: World Health

- Organization; 2002 [cited 2016 Sep 21]. Available from: <http://apps.who.int/medicinedocs/pdf/s4893e/s4893e.pdf>.
5. Pharmacovigilance World Health Organization. [cited 2016 Sep 21]. Available from: http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/.
 6. Amale PN, Deshpande SA, Nakhate YD, Arsod NA (2018) Pharmacovigilance
 7. Process in India: An overview. *J Pharmacovigil* 6: 259. doi:10.4172/2329-6887.1000259
 8. bubakar AR, Simbak NB, Haque M. A systematic review of knowledge, attitude and practice on adverse drug reactions and pharmacovigilance among doctors. *Journal of applied pharmaceutical science*. 2014 Oct 30;4(10):117-27.
 9. Gaude OS, De Sa S. Assessment of knowledge, attitude, and practices of pharmacovigilance and adverse drug reaction reporting among final year medical students - A questionnaire-based study in a tertiary care hospital in Goa. *Natl J Physiol Pharm Pharmacol* 2018;8(12):1657-1661.
 10. Moore N. The role of the clinical pharmacologist in the management of ADRs. *Drug Safety*. 2001;24(1):1-7.
 11. Leena A, Jose M. Knowledge, practice, and attitude toward adverse drug reaction reporting among interns at a tertiary health care centre. *National Journal of Physiology, Pharmacy and Pharmacology*. 2018;8(4):465-9
 12. Vallano A, Cereza G, Pedros C, Agusti A, Danes I, Aguilera C, et al. Obstacles and solutions for spontaneous reporting of adverse drug reactions in the hospital. *Br J Clin Pharmacol*. 2005;60(6):653-8
 13. Bremanan T, Leape L, Lared N. Incidence of adverse events and negligence in hospitalized patients- Result of Harvard Medical Practice Study-I. *New Eng J Med* 1991; 324:370-6
 14. Kulmi M, Reddy P, Dhakre S, Shinde M, Goyal C. Knowledge, attitude and practices of pharmacovigilance among the postgraduate and undergraduate medical students in a tertiary care hospital in Central India. *Int J Basic Clin Pharmacol* 2017;6:1127-32.
 15. Jha N, Rathore DS, Shankar PR, Gyawali S, Alshakka M, Bhandary S. An educational intervention's effect on healthcare professionals' attitudes towards pharmacovigilance. *The Australasian medical journal*. 2014;7(12):478.
 16. Rabiou A, Haque M. Pharmacovigilance practice: the current challenges and the gaps in the medical students' curriculum. *Journal of Applied Pharmaceutical Science*. 2016 May;6(05):210-5.
 17. Vakade K, Sangiseti V, Binayke M, Abhavathi V, Nayak B. An evaluation of knowledge, attitude and practice of pharmacovigilance among interns in a tertiary care teaching hospital of North Maharashtra. 2018;5:2321-5
 18. Vora MB, 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;3:1511-5.
 19. Radhakrishnan R, Vidyasagar S, Varma DM. An educational intervention to assess knowledge attitude practice of pharmacovigilance among health care professionals in an Indian Tertiary Care Teaching Hospital. *Int J PharmTech Res*. 2011;3:678-92
 20. Khan SA, Goyal C, Chandel N, Rafi M. Knowledge, attitudes, and practice of doctors to adverse drug reaction reporting in a teaching hospital in India: An observational study. *Journal of natural science, biology, and medicine*. 2013 Jan;4(1):191.
 21. Arici MA, Gelal A, Demiral Y, Tuncok Y. Short and long-term impact of pharmacovigilance training on the pharmacovigilance knowledge of medical students. *Indian J Pharmacol*. 2015;47(4):436-439. doi:10.4103/0253-7613.161272
 22. Dhananjay K, Himasri E. IJBCP International Journal of Basic & Clinical Pharmacology. *International Journal of Basic & Clinical Pharmacology*. 2017 Jan;6(1):43.