

RESEARCH ARTICLE

Assessment of knowledge, attitude, and practice of pharmacovigilance among clinicians and postgraduate students in a teaching medical institution - A questionnaire study

Asha P Dass¹, Savithri Desai², Sowmya Kaniganti²

¹Department of Pharmacology, Gulbarga Institute of Medical Sciences, Kalaburagi, Karnataka, India, ²Department of Pharmacology, Dr. Pinnamaneni Siddhartha Institute of Medical Sciences & Research Foundation, Vijayawada, Andhra Pradesh, India

Correspondence to: Savithri Desai, savithridesai@gmail.com

Received: November 17, 2017; Accepted: December 06, 2017

ABSTRACT

Background: Spontaneous voluntary adverse drug reaction (ADR) reporting is the backbone for the successful functioning of the Pharmacovigilance Programme of India. **Aims and Objectives:** These study objectives were to assess the knowledge, attitude, and perception of clinicians and postgraduates toward adverse drug reporting and to suggest possible ways of improving this method of reporting. **Materials and Methods:** The study was a cross-sectional questionnaire-based study. The study participants consisted of all the healthcare professionals (doctors and postgraduate students) who gave their informed consent and who were working at the hospital during the study period. Knowledge, attitude, and practices (KAP) questionnaire was designed to assess the demographic details of the healthcare professionals, their knowledge of pharmacovigilance, attitudes toward pharmacovigilance, and their practice on ADR reporting. There were 13 questions in all (five related to knowledge, five related to attitude, and three related to practice). One question was asked to determine the reasons for underreporting. These questions were designed based on earlier studies for assessing KAP of ADR reporting. **Results:** This study shows an above average knowledge of pharmacovigilance among healthcare workers to be about 61.80% and attitude toward the same to be 70% which seems satisfactory but falls back a bit with regard to putting all that knowledge to practice accounting for 50%. In this study, there was quite a gap between those who had knowledge and attitude (>70%) on Pharmacovigilance and those who had practiced it (<50%). **Conclusion:** This gap between knowledge, attitude, and practice calls for immediate attention, in the form of raising awareness among the clinicians, students, nursing staff, interns, and pharmacists and training them in ADR reporting.


KEY WORDS: Adverse Drug Reactions; Healthcare Professionals; Pharmacovigilance

INTRODUCTION

Adverse drug reactions (ADRs) are an important cause of mortality and morbidity worldwide.^[1] As recent studies have

documented adverse reactions to be the fourth to sixth leading causes of death and represent 5 to 10% of hospital costs,^[2] it is crucial to monitor adverse effects. In India, all healthcare professionals including doctors, nurses, and pharmacists can report an ADR by filling an ADR form of the Central Drugs Standard Control Organization (CDSCO).^[3]

The Uppsala Monitoring Centre (UMC, WHO), Sweden, maintains the international database of the ADR reports. It has been estimated that only 6–10% of all the ADRs are reported.^[4] Although India is participating in the program, its contribution to the UMC database is 2% only;^[5] still, further

Access this article online	
Website: www.njppp.com	Quick Response code
DOI: 10.5455/njppp.2018.8.1145906122017	

National Journal of Physiology, Pharmacy and Pharmacology Online 2018. © 2018 Asha P Dass et al. This is an Open Access article distributed under the terms of the Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>), allowing third parties to copy and redistribute the material in any medium or format and to remix, transform, and build upon the material for any purpose, even commercially, provided the original work is properly cited and states its license.

active participation is required to increase spontaneous reporting.

Under-reporting of the ADRs by the prescribers is a common problem, with an estimated median underreporting rate of 94%^[6] and occurs frequently for serious and unlabeled reactions. The CDSCO, Directorate General of Health Services under the aegis of Ministry of Health and Family Welfare, Government of India in collaboration with Indian Pharmacopoeia commission, Ghaziabad, has rolled out a nationwide Pharmacovigilance Programme to overcome the problem of underreporting of adverse reactions. Reporting ADRs spontaneously is considered as a cornerstone of pharmacovigilance. However, its success depends on cooperative and motivated healthcare professionals. Physicians, pharmacist, and nurses are in a position to play a major key role in pharmacovigilance programs.^[7,8]

It is possible to create a more realistic safety profile of a drug after it has been scrutinized for untoward adverse events in a larger heterogeneous population of patients over an extended period. Building a database of knowledge pertaining to the adverse effects of drugs is what forms the core principle of pharmacovigilance. The active participation of healthcare professionals in the pharmacovigilance program can improve the ADR reporting.^[9]

Therefore, the present study was contemplated and done to assess the KAP of the healthcare professionals working in a teaching hospital located in South India region regarding ADRs reporting, to get an insight into the reasons for non-reporting and to suggest possible ways of improving spontaneous reporting based on our findings. Although many studies in India have evaluated the KAP of pharmacovigilance among the healthcare professionals,^[3,9,10,11] it is necessary to conduct similar studies in teaching hospital of other parts of India to generalize findings of those studies.^[10,11] The second primary objective was to assess the causation of underreporting of ADRs as it needs to be well assessed in India. The secondary objective was to compare the findings of this study with the results of the published studies from India on the evaluation of the KAP of pharmacovigilance among healthcare professionals.

MATERIALS AND METHODS

Setting

This study was conducted at a tertiary care hospital in Andhra Pradesh, India. The approval for conducting this study was obtained from the human Institutional Ethics Committee. The duration of the study was 2 months, from June 2015 to July 2015.

Study Design

The study was a cross-sectional questionnaire-based study. The study participants consisted of all the

healthcare professionals (doctors and postgraduate students) who gave their informed consent and who were working at the hospital during the study period. KAP questionnaire was designed to assess the demographic details of the healthcare professionals, their knowledge of pharmacovigilance, attitudes toward pharmacovigilance, and their practice on ADR reporting. There were 13 questions in all (five related to knowledge, five related to attitude, and three related to practice). One question was asked to determine the reasons for underreporting. These questions were designed based on earlier studies for assessing KAP of ADR reporting.^[9-15]

Pretesting of the questionnaire was done on 20 randomly selected health professionals of the institute. The questionnaire was finalized after ambiguous, and unsuitable questions were modified based on the result of the pretest.

Data Collection

Sampling procedure and sample size.

The questionnaire was administered to all the clinicians and pathologists of the hospital with instructions to fill and return it back within next 24 h. A total of 120 questionnaires were distributed, of which a total of 75 were returned.

Statistical Analysis

The filled KAP questionnaires were analyzed as per the study objectives. The various independent variables such as age, gender, educational qualification, and dependents variable (KAP scores) were analyzed using SPSS version 21 software. SPSS was used for data entry and for performing statistics (Descriptive statistics). The mean, SD and total score were compared among different subgroups of respondents.

RESULTS

Out of 120 study participants, 75 filled the given study questionnaire which means 62.5% responded. Among the responders 55.9% were faculty, and 44% were postgraduates. Most of the healthcare professionals were males, i.e., 64.54% compared to 35.45% females. Furthermore, the mean age of the study participants was 33.67 years.

Response of professionals to knowledge related questions

In our study population, 86.6% gave correct response regarding the term pharmacovigilance. 93% healthcare professionals were aware that the most important purpose of pharmacovigilance is to identify and reporting an ADR. 86.6% of healthcare workers were aware regarding the existence of a Pharmacovigilance Programme of India. 25.3% healthcare professionals are under the assumption that only serious and adverse ADR's have to be documented. Regarding the

location of National Pharmacovigilance Centre, 25.3% had correct knowledge [Table 1].

Responses of the professionals to the attitude related questions

About 58.6% of the healthcare professionals opined that ADR reporting was required. 78.6% of the participants showed a positive attitude toward giving instructions to the patient and relatives about ADR. 44% agreed that ADR monitoring is necessary to be established in every hospital. 78.6% showed interest in reporting an ADR in future. 93.3% agreed to the fact that teaching Pharmacovigilance in details to healthcare professionals is crucial [Table 2].

Response regarding practice of pharmacovigilance

About 78.6% of healthcare professionals are aware, or ADR forms that available. 61.3% have encountered ADR’s in the past 1 year. Unfortunately, only 18.6% of healthcare professionals have been trained to report ADR’s [Table 3].

DISCUSSION

This study shows an above average knowledge of pharmacovigilance among healthcare workers to be about 61.80% and attitude toward the same to be 70% which seems satisfactory but falls back a bit with regard to putting all that knowledge to practice accounting for 50%. A study was conducted by Gupta *et al.*^[12] reported that 62.4% of study participants had knowledge about Pharmacovigilance. Observations in the current study showed that 86.76% of the study participants gave the correct response to the definition of Pharmacovigilance. Regarding knowledge on the existing Pharmacovigilance Programme in India, 78.6% responded correctly.

90.35% of the participants in the present study supported the fact that the healthcare professionals should be sensitised about Pharmacovigilance. Murararaih *et al.*^[16] also similarly found that 58% of the participants were in favor of improving awareness about pharmacovigilance by educational programs. In a matter of experiencing ADRs, majority of the participants (61.31%) in the present study had come across an ADR which was similar to other studies.^[15]

In our study, there was quite a gap between those who had knowledge and attitude (>70%) on Pharmacovigilance and those who had practiced it (<50%). Another interesting finding in the present study was that there was a major difference between ADR-experienced (65.81%) and ADR-reported participants (23.9%). Such a gap in practice might be due to time limitation in reporting ADR, false belief that the ADR database might be unaffected by a single unreported case, confusion in recognizing ADR, lack of proper training,

Table 1: Response regarding knowledge of pharmacovigilance

Questions	Response	n (%)
Knowledge about the term “Pharmacovigilance”	Correct	65 (86.67)
	Incorrect	10 (13.33)
Is the healthcare professional responsible for reporting ADRs in a hospital	Yes	70 (93.33)
	No	5 (6.67)
Is there any existing Pharmacovigilance Programme of India?	Yes	59 (78.67)
	No	6 (8.00)
What adverse event should you report in ADR form?	Correct	19 (25.33)
	Incorrect	56 (74.67)
Where is the NPC located?	Correct	19 (25.33)
	Incorrect	56 (74.67)

NPC: National Pharmacovigilance Centre, ADR: Adverse drug reaction

Table 2: Response regarding attitude of pharmacovigilance

Questions	Response	n (%)
Do you think ADR reporting is a professional obligation to you?	Yes	44 (58.67)
	No	31 (41.33)
Instructions should be given regarding ADR to patient/patient’s party when prescribing medicines?	Yes	59 (78.67)
	No	16 (21.33)
What is your opinion about establishing ADR monitoring center in every hospital?	Yes	33 (44.00)
	No	42 (56.00)
Are you willing to report an ADR?	Yes	59 (78.67)
	No	16 (21.33)
Do you think Pharmacovigilance should be taught in details to healthcare professionals?	Yes	70 (93.33)
	No	5 (6.67)

ADR: Adverse drug reaction

incomplete awareness on rules and procedures of ADR reporting.

The spontaneous reporting system is the most efficient warning system of ADRs; however, under-reporting of ADRs is one of the major problems associated with pharmacovigilance programs.^[17] The major reasons for underreporting include, the ADR is not serious, and the ADR is already known, uncertainty concerning the causal relationship between the ADR and the drug, lack of time, lack of interest, only severe ADRs need to be reported, fear of appearing ridiculous for

Table 3: Response regarding practice of pharmacovigilance

Questions	Response	n (%)
Have you seen an ADR reporting form?	Yes	59 (78.67)
	No	16 (21.33)
Have you encountered and reported a potential ADR within the past 12 months?	Yes	46 (61.33)
	No	29 (38.67)
Have you ever been trained in ADR reporting?	Yes	19 (25.33)
	No	66 (88.00)

ADR: Adverse drug reaction

reporting merely suspected ADR's, practice of carrying out less urgent tasks in preference to more urgent ones, difficulty to determine whether or not a drug is responsible for a particular adverse reaction, and complacency (only safe drugs are allowed on the market).

Busy schedule, lack of knowledge about the exact authority to report ADRs, unavailability of ADR reporting forms, lack of incentives are some of the reasons for under-reporting of ADRs.^[18] Assessment of awareness of pharmacovigilance among the healthcare professionals is very important due to under-reporting of ADR.

CONCLUSION

The findings of the study suggest a huge scope for improving the awareness and knowledge about pharmacovigilance among the healthcare professionals who are the backbone of safe and better healthcare delivery. For this, there is a need for continuous educational initiatives like CME, and hands-on training for ADR reporting, it should also be included in their curriculum as part of their study.

REFERENCES

- Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: A meta-analysis of prospective studies. *JAMA* 1998;279:1200-5.
- Srinivasan R, Ramya G. Adverse drug reaction causality assessment. *Int J Res Pharm Chem* 2011;1:606-11.
- Upadhyaya P, Seth V, Moghe VV, Sharma M, Ahmed M. Knowledge of adverse drug reaction reporting in first year postgraduate doctors in a medical college. *Ther Clin Risk Manag* 2012;8:307-12.
- Feely J, Moriarty S, O'Connor P. Stimulating reporting of adverse drug reaction by using a fee. *Br Med J* 1990;300:22-3.
- Smith CC, Bennett PM, Pearce HM, Harrison PI, Reynolds DJ, Aronson JK, *et al.* Adverse drug reactions in a hospital general

- medical unit meriting notification to the committee on safety of medicines. *Br J Clin Pharmacol* 1996;42:423-9.
- Hazell L, Shakir SA. Under-reporting of adverse drug reactions: A systematic review. *Drug Saf* 2006;29:385-96.
- Ahmad SR. Adverse drug event monitoring at the food and drug administration. *J Gen Intern Med* 2003;285:437-43.
- Wysowsky DK, Swartz L. Adverse drug event surveillance and drug withdrawals in the United States, 1969-2002: The importance of reporting suspected reactions. *Arch Intern Med* 2005;165:1363-9.
- Remesh A. Identifying the reasons for under reporting of ADR: A cross sectional survey. *Res J Pharm Biol Chem Sci*, 2012; 3: 137986.
- Khan SA, Goyal C, Chandel N, Rafi M. Knowledge, attitude and practice of doctors to adverse drug reaction reporting in a teaching hospital in India: An observational study. *J Nat Sci Biol Med* 2013;4:191-6.
- Hardeep, Bajaj JK, Kumar R. A survey on the knowledge, attitude and the practice of pharmacovigilance among the health care professionals in a teaching hospital in northern India. *J Clin Diagn Res* 2013;7:97-9.
- Gupta P, Udupa A. Adverse drug reaction reporting and pharmacovigilance: Knowledge, attitudes and perceptions amongst resident doctors. *J Pharm Sci Res* 2011;3:1064-9.
- 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;2:129-36.
- Rajesh 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 Pharm Tech Res* 2011;3:678-92.
- Pimpalkhute SA, Jaiswal KM, Sontakke SD, Bajait CS, Gaikwad A. Evaluation of awareness about pharmacovigilance and adverse drug reaction monitoring in resident doctors of a tertiary care teaching hospital. *Indian J Med Sci* 2012;66:55-61.
- Muraraiah S, Rajarathna K, Sreedhar D, Basavalingu D, Jayanthi CR. A questionnaire study to assess the knowledge, attitude and practice of Pharmacovigilance in a paediatric tertiary care centre. *J Chem Pharm Res* 2011;3:416-22.
- Meher BR, Joshua N, Asha B, Mukherji D. A questionnaire based study to assess knowledge, attitude and practice of pharmacovigilance among undergraduate medical students in a tertiary care teaching hospital of south India. *Perspect Clin Res* 2015;6:217-21.
- World Health Organization. Safety of Medicine. A Guide for Detecting and Reporting Adverse Drug Reaction. Geneva: World Health Organization; 2002.

How to cite this article: Dass AP, Desai S, Kaniganti S. Assessment of knowledge, attitude, and practice of pharmacovigilance among clinicians and postgraduate students in a teaching medical institution - A questionnaire study. *Natl J Physiol Pharm Pharmacol* 2018;8(5):619-622.

Source of Support: Nil, **Conflict of Interest:** None declared.