



AWARENESS OF PHARMACOVIGILANCE AND ADVERSE DRUG REACTION AMONG HEALTH CARE PROFESSIONALS OF TERTIARY CARE UNIVERSITY HOSPITAL OF CENTRAL INDIA. A- QUESTIONNAIRE BASED STUDY

Pharmacology

Chetna Ashok Shamkuwar*

Associate Professor, Department of Pharmacology, government Medical College, Chandrapur. *Corresponding Author

Manohar M. Bende Professor, Department of Pharmacology, government Medical College, Chandrapur.

Avisha A. Madavi Tutor, Department of Pharmacology, government Medical College, Chandrapur.

ABSTRACT

Objective: The objective of the study is to assess the knowledge, attitude and practice of pharmacovigilance among health care professionals (doctors, nurses, pharmacist, paramedical staff) of tertiary care teaching hospital of central India.

Material and Methods: This was a questionnaire based, cross sectional study, was carried out using prevalidated questionnaires. The questionnaire containing 20 questions was designed to assess the Knowledge, Attitude and Practice regarding pharmacovigilance of healthcare professionals (doctors, nurses, pharmacists, paramedical staff)

Results: Out of 150 health professionals studied, 79 were females and 71 were males with majority being more than 46 years old (18%) with a mean age of 35±21 years. Majority (30%) were nurses followed by resident doctors (19.3%), assistant professors (16.7%) while mere 5.3% were professors. Among the attitude based questions, 59.3% gave incorrect answer about factors discouraging them for reporting ADR. 65.3% gave correct opinion about establishment of ADR (Adverse drug reaction) monitoring center in every hospital. Majority i.e. 91.3% agreed that reporting of ADR is necessary and 92.7% wanted that pharmacovigilance should be taught in detail to them. Among the practice based questions, 66% told that they had come across an ADR and 79.3% had seen the ADR form. Also 68% told that they had been trained on how to report an ADR.

Conclusion: Majority of the healthcare professionals had good knowledge and attitude about pharmacovigilance and understand the need for reporting and agreed that pharmacovigilance should be taught in detail to healthcare professionals.

KEYWORDS

Pharmacovigilance awareness, adverse drug reaction, health care professionals

INTRODUCTION:

Throughout the world, adverse drug reaction is the most important health care problem and a significant cause for both morbidity and mortality.¹ Pharmacovigilance is a science and activities related to the detection, assessment, understanding and the prevention of adverse effects.² It is the study of drug-related adverse effects aimed at improving patient safety by means of issuing a warning to or recommending withdrawal of such products from the market.

The spontaneous adverse drug reaction (ADRs) reporting system is considered the back-bone for any pharmacovigilance system. Active involvement of healthcare professionals is very crucial to improve the rate and quality of ADRs reporting.³

Previous studies reveal that inadequate knowledge about pharmacovigilance among healthcare professionals is the reason for underreporting of ADR.⁴ Hence the present study was planned to assess the knowledge, attitude and practice of pharmacovigilance among health care professionals. (doctors, nurses, pharmacist)

METHODS:

This is a prospective, questionnaire based study conducted at Department of Pharmacology in a tertiary teaching hospital in Central India after approval of institutional ethics committee from January 2018-2019.

Approximately 150 health care professionals (doctors, nurses & pharmacist, Paramedical staff) were included in the study. They were explained about the study and an informed consent was obtained.

INCLUSION CRITERIA:

The health care professionals (doctors, nurses & pharmacist, paramedical staff) above 18 years of age and those willing to participate in the study were included.

Pre-validated structured questionnaire comprised of knowledge (12 questions), attitude (5 questions) and practice (3 questions), which evaluate the participant's knowledge of adverse drug reaction, attitude towards the reporting and practice.^{5,6}

STATISTICAL ANALYSIS:

The statistical analysis was done using SPSS 16 by percentage and mean value scored with their standard deviation.

OBSERVATION AND RESULTS:

Out of 150 health professionals studied, 79 were females and 71 were males with majority being more than 46 years old (18%) with a mean age of 35±21 years. Majority (30%) were nurses followed by resident doctors (19.3%), assistant professors (16.7%) while mere 5.3% were professors.

Table No.1 Demographic Details Of Health Care Professionals (n=150)

Demographic detail	Frequency (%)
Gender	
Female	79 (52.7%)
Male	71 (47.3%)
Mean age (in years)	35±21
Age distribution:	
19-25 years	24 (16%)
26-30 years	23 (15.3%)
31-35 years	33 (22%)
36-40 years	36 (24%)
41-45 years	07 (4.7%)
≥46 years	27 (18%)
Professional status	
Professor	8 (5.3%)
Associate professor	16 (10.7%)
Assistant professor	25 (16.7%)
Resident doctor	29 (19.3%)
Nurse	45 (30%)
Pharmacist	19 (12.7%)
Paramedical/social worker	8 (5.3%)

A majority of participants had knowledge about meanings of pharmacovigilance (62%) but only 38% could define ADR. 88.7% knew that ADR reporting is mandatory. 51.3% knew the importance of pharmacovigilance.

68% knew who is the regulatory body for monitoring of ADR in India while 52.7% knew the correct location of international center for ADR monitoring.

A majority 58.7% did not know what is the time limit for reporting a serious adverse event in India and also 52% did not know in which phase of clinical trial rare ADR can be identified. 72.7% knew who are the health care professionals responsible for reporting of ADR.

Table No. 2 Response Of Health Care Professionals To Knowledge Based Questions.

Sr. No.	Knowledge questionnaire	Correct Response (%)	Incorrect Response (%)	Other (Not answered)
1.	Define Pharmacovigilance	93 (62%)	54 (36%)	3
2	Define ADR	57 (38%)	89 (59.3%)	4
3	Is ADR reporting mandatory	133 (88.7%)	17 (11.3%)	
4	Where is national pharmacovigilance centre located in India	64 (42.7%)	81 (54%)	5
5	The important purpose of pharmacovigilance is	77 (51.3%)	68 (45.3%)	5
6	Regulatory body is responsible for monitoring of ADR's in India	102 (68%)	43 (28.7%)	5
7	The international center for adverse drug reaction monitoring is located in	79 (52.7%)	65 (43.3%)	6
8	A serious adverse event in India should be reported to the regulatory body within	59 (39.3%)	88 (58.7%)	3
9	Which of the following method is commonly employed by the pharmaceutical companies to monitor adverse drug reactions of new drugs once they are launched in the market	95 (63.3%)	48 (10.7%)	7
10	Which one among these is a national pharmacovigilance centre in India	107 (71.3%)	42 (28%)	1
11	Rare ADRs can be identified in the following phase of clinical trial	63 (42%)	78 (52%)	9
12	The health care professionals responsible for reporting ADR in a hospital is/are	109 (72.7%)	40 (26.7%)	1

ADR=adverse drug reaction

Among the attitude based questions, 59.3% gave incorrect answer about factors discouraging them for reporting ADR. 65.3% gave correct opinion about establishment of ADR monitoring center in every hospital. Majority i.e. 91.3% agreed that reporting of ADR is necessary and 92.7% wanted that pharmacovigilance should be taught in detail to them. 92% thought that ADR reporting benefits both patients and doctors.

Among the practice based questions, 66% told that they had come across an ADR and 79.3% had seen the ADR form. Also 68% told that they had been trained on how to report an ADR.

Table No. 3 Attitude And Practice Based Questions

Sr no	Attitude questionnaire (1-5) and then practice questionnaire (6-8)	Correct response	Incorrect response	Yes/NO (%)
1	Which among the following factors discourage you from reporting Adverse Drug Reactions	52 (34.7%)	89 (59.3%)	No ans=9
2	What is your opinion about establishing ADR monitoring centre in every hospital	98 (65.3%)	52 (34.7%)	
3	Do you think reporting of adverse drug reaction is necessary	137 (91.3%)	13 (8.7%)	
4	Do you think pharmacovigilance should be taught in detail to health care professionals	139 (92.7%)	11 (7.3%)	
5	Do you think ADR reporting benefits both patient and doctors	138 (92%)	12 (8%)	
6	Have you ever come across with an ADR	99 (66%)	48 (32%)	No ans-1 Can't say-2
7	Have you ever seen the ADR reporting form	119 (79.3%)	30 (20%)	MAY BE -1
8	Have you ever been trained on how to report Adverse Drug Reaction [ADR]	102 (68%)	47 (31.3)	MAY BE -1

ADR=adverse drug reaction

Table 4. Comparison with results of some other published studies from India

	Our result (%)	Pimpalkhute et al ⁸ (%)	Rajesh R et al ⁹ (%)	Hardeep et al ¹⁰ (%)	Khan et al ¹¹ (%)	Ramesh A et al ¹² (%)	Desai et al ⁵ (%)
KNOWLEDGE:							
1. Definition of PV/ awareness regarding PV.	62	64.28	55.2	77	NA	NA	NA
2. ADR reporting is mandatory.	88.7	35.72	69.4	NA	66.2	80	NA
3. Existence of PV programme in india	68	52.38	NA	59	69.1	67.2	NA
ATTITUDE:							
1. Reporting of ADR is necessary.	91.3	NA	91.8	NA	95.6	89	97.3
2. PV should be taught to HCP.	92.7	NA	94.1	NA	NA	76	NA
3. ADR monitoring center should be established in every hospital	65.3	NA	70.6	90.2	NA	NA	NA
PRACTICE:							
1. Ever experienced an ADR.	66	67.55	NA	NA	NA	82	85
2. Ever seen form for reporting ADR	79.3	55	NA	23	19.1	17.2	15
3. Trained on how to report ADR	68	NA	50.5	NA	28	21.8	NA

PV=Pharmacovigilance, HCP=health care providers

DISCUSSION:

Spontaneous adverse drug reaction reporting is the cornerstone of pharmacovigilance. Majority of ADRs are preventable through improve prescribing and monitoring. The present study was conducted in upcoming tertiary care teaching hospital of Central India. There is a high prevalence of illness viz. chronic obstructive pulmonary disorder, anemia, tuberculosis and skin disorders. As all the categories of drugs are used therefore drug utilization patterns is very important in this region. ADR reporting is infrequent in majority of the medical professionals. This makes the Pharmacovigilance programme unsuccessful.⁷

In our study, 52.7% were females and the mean age was 35±21 years with majority of the participants i.e. 22% between 31-35 years age followed by 18% above 46 years of age. 8 professors, 16 associate professors, 25 assistant professors and about 20% i.e. 29 resident doctors took part in the study along with 30% nurses, 12.7% pharmacists and 5.3% paramedical and social workers.

The healthcare professionals should spontaneously report ADR as it is recommended by national PvPI (Pharmacovigilance programme of India). Our results show that the awareness toward pharmacovigilance is 62% although the awareness towards national reporting centers only

42.7% comparing with the study of Madhan Ramesh and Gurumurthy Parthasarathi in the year 2009 which is 89% & 41% respectively.⁽⁶⁾ On studying the attitude of health care professional towards pharmacovigilance, it was found that the health care professionals give importance to pharmacovigilance – 91.3% are in favor of its necessity, 92.7% are in favor that it should be taught in detail in MBBS curriculum and 65.3% are in favour of establishing ADR monitoring centre in every hospital. This depicts that doctors, staff nurses & pharmacist should be made aware about the knowledge of ADR and its reporting. Our study shows that although the professionals have the knowledge of identifying the ADR but they are not keen to report it or they don't want to spend time on filling the form & to clarify/decide that there is occurrence of ADR although it is not very difficult to fill the form. But this has not become into the habit to fill the form. Although, 92% health professionals are in favor of the system and they assume that the patient and society will be benefitted by it.

There are many factors which become hindrances in the reporting of ADR. 66% subjects had come across an ADR, 79.3% subjects had seen the ADR reporting form and 68% told that they were trained in reporting it.

The comparison with the results of the published studies from India [Table 4] demonstrated that knowledge and attitude towards pharmacovigilance is gradually improving among healthcare professionals, but unfortunately the actual practice of ADR reporting is still deficient among them. The adverse event knowledge and attitude from our study is similar to previously reported different Indian studies by Pimpalkhute et al⁸, Rajesh et al⁹, Hardeep et al¹⁰, Khan et al¹¹, Ramesh A et al¹², Desai et al.⁵ Most importantly, the huge gap between the ADR experienced and ADR reporting form seen by healthcare professional was also evident in previously reported studies conducted in Ramesh A et al¹² Pimpalkhute et al⁸, Desai et al.⁵ In our study, less percentage of participants had ever been trained on reporting ADRs which is similar to the low percentage of training imparted to healthcare professionals in previously reported studies by Khan et al¹¹ and Ramesh A et al.¹²

CONCLUSION:

In conclusion, this study showed that majority of the healthcare professionals had good knowledge and attitude about pharmacovigilance and understand the need for reporting. The fact that majority of respondents agreed that reporting of ADR is necessary and awareness that pharmacovigilance should be taught in detail to healthcare professionals emphasize that they have started to understand the importance of pharmacovigilance.

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REFERENCES:

1. Pir mohammad M, James S, Meakin S, Green C, Scon AK, Walley TJ. Adverse drug reactions as cause of admission to hospital: Prospective analysis of 18820 patients. *Br Med J.*, 2004;329, 15-9
2. World Health Organization. Safety of Medicines: A guide to detecting and reporting adverse drug reactions. Geneva, Switzerland; 2002
3. Lopez-Gonzalez E, Herdeiro MT, Figueiras A. Determinants of under-reporting of adverse drug reactions: a systematic review. *Drug Saf.* 2009;32:19-31.
4. Figueiras A, Tato F, Fontaines J, Gestal-Oterro JJ. Influence of physicians' attitudes on reporting adverse drug events: A case control study. *Medical Care* 1999;37(8):809-14
5. Desai CK, Iyer G, Panchal J, Shah S, Dixit RK. An evaluation of knowledge, attitude and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. *Perspect Clin Res* 2011;2:129-136
6. Ramesh M, Parthasarathi G. Adverse drug reaction reporting: the attitudes and the perceptions of the medical practitioners. *Asian Journal of Pharmaceutical and Clinical Research.* April-June 2009;2(2):10-14.
7. Kharkar M, Bowalekar S. Knowledge, attitude and perception/practices (KAP) of medical practitioners in India towards adverse drug reaction (ADR) reporting. *Perspect Clin Res.* 2012 Jul-Sep;3(3): 90–94.
8. 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.
9. 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.
10. 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.
11. 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.
12. Ramesh A. Identifying the reasons for under reporting of ADR: A cross sectional survey. *Res J Pharm Biol Chem Sci.* 2012;3:1379–86.