International Journal of Basic & Clinical Pharmacology
Manohar NS et al. Int J Basic Clin Pharmacol. 2022 Sep;11(5):378-383
http://www.ijbcp.com
pISSN 2319-2003 | eISSN 2279-0780

DOI: https://dx.doi.org/10.18203/2319-2003.ijbcp20221830

Original Research Article

A study on the knowledge, attitude and practice of junior doctors to adverse drug event reporting in a tertiary care hospital, Manipur

Neerajkumar Sharma Manohar[1], Ngamba Akham[2], Oinam Joychandra Singh[1]*, Hidam Surjikumari[3], Anisha Kh[4]

[1]Department of Pharmacology, [2]Department of Community Medicine, Shija Academy of Health Sciences, Langol, Manipur, India
[3]AGM and R-Quality, [4]DMO and Q, Shija Hospitals and Research Institute Pvt. Ltd., Langol, Manipur, India

Received: 30 June 2022
Revised: 12 July 2022
Accepted: 14 July 2022

***Correspondence:**
Dr. Oinam Joychandra Singh,
Email: joyoinam2007@rediffmail.com

ABSTRACT

Background: The aim of the present study is to find out the ways to improve the status of adverse drug effect (ADE) reporting to the pharmacovigilance centres.
Methods: The present study is a cross-sectional study with purposive sampling. Descriptive statistics is used for analysing the data from the questionnaire using frequencies and percentages.
Results: The response on the questionnaire was 77.7%. The 90 participants knew the definition of ADE. The 91 participants want to report the ADEs of newly marketed drugs. Only 70 participants know about the existence of PvPI. The 80 participants did not consider all OTC drugs to be safe. 95 participants opined that all Herbal and non-allopathic drugs are not safe. The 69 participants replied that no ADE monitoring centre was available in SHIJA hospitals and research institute Pvt. Ltd. Though 90 participants knew the definition of ADE, only 85.1% of them considered to report it as a professional obligation. Maximum ADEs are seen with skin, paediatric and elderly patients as opined by 57.4% of the participants. Varied opinions of occurrence of ADEs according to the participants with polypharmacy was 70.3% and with foods and drinks was 40.6%. Although 85.1% participants have the attitude of reporting ADE, only 63.4% participants have good clarity when reporting and filling the ADE forms with careful observation of the risks and behaviour of the patients.
Conclusions: To promote ADE reporting, a regular awareness cum sensitization programme coupled with CME program is necessary at various levels of health-care providers.

Keywords: ADE, PvPI, Polypharmacy, OTC, Herbal

INTRODUCTION

The adverse drug reaction (ADR) or adverse drug event (ADE) is a health problem which is not strictly noticed and detected by the health-care providers. That is why there is many casualties and hospital admissions. According to WHO, ADR is defined as a response to a drug which is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for the modifications of physiological function and pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.[1] There are many reasons for under-reporting of the ADR/ ADE by the health-care providers voluntarily or as an obligation.[2,3] The reporting of ADR is under the aegis of pharmacovigilance is made compulsory. Owing to the current trend of under-reporting, drug controller of India under the supervision of Indian pharmacopoeia commission, launched a national program on ADR/ADE

implementing the pharmacovigilance program/ pharmacovigilance program of India (PvPI) in 2014.[2-4]

PvPI provides a toll-free number 1800-1803-024 to make drug safety information available for the Indian population. Besides suspected ADR/ADE reporting form, PvPI has generated medicine side-effect reporting form for consumers and patients in their regional or local language. However, as India does not have a robust database on the ADRs/ ADEs, it has to depend on data from Western countries to make recommendations relating to banning and suspicion of any new or old drugs.[3]

Aims and objectives

The aims and objectives of the study were to study the knowledge, attitude and practice (KAP) of the junior doctors of Shija Hospitals and Research Institute Pvt. Ltd. (SHRI), Langol about the ADR reporting and also to point out various activities for better ADR/ADE reporting.

METHODS

Study design and setting

It is a cross-sectional, non-interventional, questionnaire-based study with purposive sampling at SHRI started on 22nd June 2022 till 25th June 2022.

Inclusion and exclusion criteria

Inclusion criteria

Junior doctors working in SHRI who give their consent will be included in the study. Accordingly, 130 junior doctors have given their consent for participation in the study.

Exclusion criteria

Health care professionals other than Junior doctors were excluded. Doctors who do not give their consent were excluded from the study.

Designing of questionnaire

The questionnaire is designed on the basis of primary objective of the study by referring questionnaires used by previous investigators.[5,6,11-13] It consists of three parts comprising-knowledge-10 questions, attitude-10 questions and practice-10 questions.

Procedure

A briefing is done about the questionnaire and time factor of 10 minutes for answering the questionnaire. The response of those junior doctors who fail to comply fully are excluded from the study. Accordingly, 130 questionnaires are distributed.

Reliability of the study

This study can be reproduced easily in a different study population as assessment of knowledge, attitude and practice of health care professionals in other settings. However, the results are not expected to be consistent or similar.

Data analysis

Descriptive statistics is used for analysing the data using frequencies and percentages along with Chi-square test for testing association using IBM SPSS version 20.

Ethical considerations

The respondents remain anonymous and confidential. Ethical approval is obtained from the Institutional Ethics Committee, SHRI Ref: IEC/SHRI/APL/22 on 22nd June 2022.

RESULTS

Out of 130 questionnaires distributed, only 110 were questionnaires received back. Nine questionnaires were rejected due to incomplete responses. Therefore, the data was analysed on the basis of responses of 101 questionnaires.

Knowledge

Details of analysis of the data on knowledge is given below in Table 1.

Table 1: Responses for knowledge-based questions.

Questionnaires	Yes	No
Do you know the WHO definition of ADR?	90	11
Are all OTC drugs safe?	21	80
Should ADRs from OTC drugs be reported?	94	7
Are all Herbal and non-allopathic drugs safe?	6	95
Should all ADRs of newly marketed drugs be reported?	91	10
Is ADR and ADE the same?	8	93
Are all ADRs identified by the time it is approved for marketing?	15	86
Have you received training on how to report ADR?	9	92
Do you know the existence of pharmacovigilance program of India?	70	31
Is ADR monitoring centre available in your institute?	32	69

Attitude

Details of analysis of the data on attitude is given below in Table 2.

Practice

Details of the analysis of data on practice is given in Table 3.

On testing the association between the responses of knowing the definition of ADE and providing treatment to a case of ADE, they are found to be statistically not significant (p=0.05) (Table 4).

On testing association between the responses of all herbal and non-allopathic drugs being safe as well as any ADE happening with their prescription, they found not to be statistically significant (p>0.05) (Table 5).

On testing the association between the responses of having received training on ADE reporting and maximum ADE being due to polypharmacy, they are found to be statistically significant (p<0.05) (Table 6).

On testing association between the responses of existence of pharmacovigilance program of India and maximum ADE being due to polypharmacy, they found to be statistically significant (p<0.05) (Table 7).

Table 2: Responses for attitude-based questions.

Questionnaires	Strongly agree	Agree	Not agree	Can't say
ADR monitoring and reporting is a professional obligation	68	18	2	13
ADR form is too complex to fill	5	27	31	38
Prescribers desire to hide their identity	8	20	57	16
Reporting of only one ADR makes no significant contribution to the ADR database	4	19	62	16
There is lack of time in filling ADR form while at work	16	27	27	31
Reporting incident of ADR may be wrong as ADR is not seen consistently every time	9	41	35	16
Spontaneous ADR reporting by health care professional is recommended	41	53	2	5
Awareness program related to ADR will improve reporting	69	26	2	4
Pharmacovigilance related activities should be included in UGs and PG teaching	63	31	2	5
ADR reporting increases patient safety	78	16	2	5

Table 3: Responses on practice-based questions.

Questionnaires	Yes	No
ADR form seen and read	48	53
Adequate response taken when ADR was observed last time	66	35
Good clarity of ADR form when reporting and filling	64	37
Provided treatment of ADR for a patient	68	33
Ever referred ADR patient to others	29	72
Any ADR happened with your prescription	13	88
Maximum ADR cases observed in practice of skin, paediatric patients, elderly patients	58	43
Side effects like headache, fever and vomiting should not be reported	37	64
Maximum ADR is due to treatment involving polypharmacy	71	30
An ADR observed under treatment is due to drug interaction with food/ drinks	41	60

Table 4: Association between selected responses between knowledge and practice.

Variables		Responses to pprovided treatment of ADE for a patient		P value
		Yes	**No**	
Response to do you know the WHO definition of ADE?	Yes	61	29	0.78
	No	7	4	

Table 5: Association between selected responses between knowledge and practice.

Variables		Response to any ADE happened with your prescription		P value
		Yes	**No**	
Response to are all herbal and non-allopathic drugs safe?	Yes	0	6	0.33
	No	13	82	

Table 6: Association between selected responses between knowledge and practice.

Variables		Response to maximum ADR is due to treatment involving polypharmacy.		P value
		Yes	No	
Response to have you received training on how to report ADR?	Yes	9	0	0.04*
	No	62	30	

*P<0.05: statistically significant.

Table 7: Association between selected responses between knowledge and practice.

Variables		Response to maximum ADR is due to treatment involving polypharmacy.		P value
		Yes	No	
Response to do you know the existence of pharmacovigilance program of India?	Yes	56	14	0.001*
	No	15	16	

*P<0.05: statistically significant.

DISCUSSION

The present study is a part of mass awareness program of ADR reporting and existence of AMC under PvPI at the department of pharmacology, JNIMS and RIMS in Manipur. The response obtained on the pre-tested questionnaire as a whole with 77.7% was encouraging.[14-17] 79.2% doctors know that all OTC drugs are not safe and 94.1% know all herbal and ono-allopathic drugs are not either.[15,17] With the current trends of globalisation and blooming business in the consumer sector, Indian market is flooded with new drugs comprising allopathic, non-allopathic and herbal drugs many of which are OTC drugs. As such, even a single ADE reporting is very much essential and therefore recommended. The 90.1% doctors express their desire to report ADE of newly marketed drugs and 93.1% doctors want to report ADE of OTC drugs. These findings are very much encouraging and appreciated as all ADE associated with new drugs are not observed entirely at the time of approval for clinical use.[15-17] 31.7% doctors find ADE form to be complex while 42.6% doctors cite lack of time in filling the ADE form. 22.8% doctors view reporting of a single ADE to be insignificant with 27.7% doctors wanting to hide their identity. 85.1% doctors have a positive approach to report ADE.[9,10,17] The 77.2% doctors opine that a single ADE is significant on the database and as such, majority of them view ADE reporting as a professional obligation.[16-19] The attitude of 14.9% doctors who do not have a positive response to ADE reporting needs to be changed. Also, 9.9% doctors feel that ADE from OTC, herbal/ non-allopathic drugs need not be reported. These group of doctors need to be sensitised with the fact that all drugs are not 100% safe.[9,10,17]

The 22.8% doctors not able to fill ADE citing other reasons out of which 42.6% doctors held their view due to lack of time and 27.7% doctors due to want of hiding identity. The 70.3% doctors observe ADE with polypharmacy, 57.4% doctors with skin, paediatric and elderly patients and 40.6% doctors with food and drinks.[16-19]

The 8.9% doctors received adequate training on ADE reporting prior to this study. In spite of this, 69.3% doctors know the implementation of PvPI in Manipur, 68.3% doctors know that there is no AMC in SHRI. However, 92.1% doctors know that ADR and ADE are not same with 63.4% doctors stating to have a good clarity in reporting ADE. Further, 94.1% doctors opine to have a greater awareness program on ADR/ADE and PvPI so as to have greater reporting on a large scale. The 93.1% doctors want inclusion of PvPI in PG and UG teaching.[10,13,17-,23]

On testing the association between the responses of doctors having received training on ADE reporting and their response on the maximum ADE being due to polypharmacy, they are found to be statistically significant. ($p<0.05$). Also, on testing the association between the responses of doctors about the existence of Pharmacovigilance program of India and their responses that maximum ADE are due to polypharmacy, they are found to be statistically significant ($p<0.05$).

Limitations

The study was conducted at one institution. The data obtained and conclusions drawn were specific to this environment. Also, this did not include other health care practitioners other than junior doctors. However, similar studies could be done in other hospitals in order to get a more complete picture of pharmacovigilance in the Manipur.

CONCLUSION

There is a significant gap on the levels of knowledge, attitude and practice relating to ADE reporting and Pharmacovigilance activities of the Junior doctors. Inadequate knowledge, improper training of health care professionals, their attitude and invalid perceptions and various other hurdles are the main obstacles to a strong reporting database and monitoring system.

This artificial drawback can be improved with proper and extensive training of health care professionals about the various activities of pharmacovigilance activities at tertiary care hospitals. The investigators suggest a large mass scale awareness program with regards to pharmacovigilance and understanding the basics of ADR/ADE and its reporting. Special emphasis about the inclusion of pharmacovigilance scopes and prospects in both UG and PG teaching need to implemented along with a mandatory rotatory internship in the department of pharmacology at the colleges of India. The process of reporting the ADE both by the general public and health care professionals should be made plain and simple without any hassle.

ACKNOWLEDGEMENTS

The authors would like to thanks to the medical superintendent of SHRI, the staffs of the administrative section of SHRI and all the participants involved in the study for their co-operation and time in participating in the survey.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Brunton L, Knollman B, Hilal-Dandan R. Goodman and Gilman's, The pharmacological basis of therapeutics. 13th edn. McGraw-Hill Education/ Medical. 2018.
2. World Health Organization. Glossary of terms related to patient and medication safety: World Health Organization. 2005. Committee of Experts on Management Safety and Quality in Health Care (SP-SQS) Expert Group on Safe Medication Practices. 2005;13. Available at: http://www.bvs.org.ar/pdf/seguridadpaciente.pdf. Accessed on 2 May 2022.
3. Lihite RJ, Lakhar M. An update on the pharmacovigilance programme of India. Front Pharmacol. 2015;6:194.
4. Kumar DA, Reddenna L, Basha SA. Pharmacovigilance program of India. Innovations in Pharmacy. 2015;6(1):189.
5. Kesharwani R, Singh D, Jacob V. Pharmacovigilance: present status and future prospects in India. Pharmatutor Pharmacy Infopedia. 2018.
6. Nimesh S, Chaudhary A, Sharma A. Pharmacovigilance program of India: a review. Acta Scientific Pharmaceutical Sci. 2019;3(9):12-7.
7. Desai CK, Iyer G, Panchal J. An evaluation of knowledge, attitude and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. Perspectives Clin Res. 2011;2(4):129-36.
8. Dutta S, Sengupta S. An evaluation of knowledge, attitude and practice of adverse drug reaction reporting in a tertiary care teaching hospital of Sikkim. Perspect Clin Res. 2015;6(4):200-6.
9. Tandon VR, Mahajan V, Khajuria V. Under-reporting of adverse drug reactions: a challenge for pharmacovigilance in India. Indian J Pharmacol. 2015;47(1):65-71.
10. Mulchandani R, Kakkar AK. Reporting of adverse drug reactions in India: a review of the current scenario, obstacles and possible solutions. Int J Risk Safety Med. 2019;30(1):33-44.
11. Amale PN, Deshpande SA, Nakhate YD. Pharmacovigilance Process in India: an overview. J Pharmacovigilance. 2018;6(2):259.
12. Dhananjay K, Himasri E. A study of assessing knowledge, attitude and practice of pharmacovigilance among medical students of a south Indian teaching Hosptial. Int J Basic Clin Pharmacol. 2017;6(1):43-7.
13. Kalyani SSA, Shristha P. An epidemiological study on adverse drug reactions in Indian population: metaanalysis. Indian J Pharmaceutical Clin Res. 2017;9(10):654-9.
14. Khan SA, Goyal C, Chandel N. Knowledge, attitudes and practice of doctors to adverse drug reaction reporting in a teaching hospital in India: an observational study. J Natural Sci Biol Med. 2013;4(1):191-6.
15. Singh OJ, Valte V, Oinam J. To study the knowledge, attitude and practice of the pharmacovigilance among the second professional MBBS students of The JN Institute of Medical Sciences, Imphal. J Evolution of Med and Dental Sci. 2015;4(61):10619-23.
16. Biswas M, Singh KNM, Shetty YC. Prescription pattern and adverse drug reactions of prokinetics. Indian J Med Res. 2019;149(6):748-54.
17. Manohar NS, Valte V, Singh OJ. An observational study of the knowledge, attitude and practice of ADR reporting among the junior doctors of jawaharlal nehru institute of medical sciences (JNIMS), Imphal. J Evolution Med Dent Sci. 2020;9(24):1800-3.
18. Modi A, Desai M, Shah S. Analysis of cutaneous adverse drug reactions reported at the regional ADR monitoring centre. Indian J Dermatol. 2019;64(3):250.
19. Tekel MT, Bekalu AF, Sema FD. Knowledge, Attitude, and Practice of Medical, Pharmacy, and Nursing Students Towards Pharmacovigilance and Adverse Drug Reaction Reporting at University of Gondar College of Medicine and Health Sciences, Northwest Ethiopia: A Cross-Sectional Study. Adv Med Educ Pract. 2021;12:1129-39.
20. Kumari A, Haque I, Bhyan SJ, Sreelakshmi M, Goel N, Jain A et al. Knowledge, Attitude and Practice of Adverse Drug Reaction Monitoring and Pharmacovigilance among Various Healthcare Professionals in India. Preprints. 2020;2020080067.
21. Haines HM, Meyer JC, Summers RS. Knowledge, attitudes and practices of health care professionals towards adverse drug reaction reporting in public

sector primary health care facilities in a South African district. Eur J Clin Pharmacol. 2020;76:991-1001.
22. Acharya R, Naik R, Rang S, Jani CA, Galib R. Knowledge, attitude and practice towards pharmacovigilance among Ayurveda physicians and teachers of Gujarat State: A cross sectional study. J Family Med Prim Care. 2022;11:623-32.
23. Gordhon Y, Padayachee N. Evaluating the knowledge, attitudes and practices of healthcare workers towards adverse drug reaction reporting at a public tertiary hospital in Johannesburg. Int J Africa Nursing Sci. 2020;12:100191.

Cite this article as: Manohar NS, Akham N, Singh OJ, Surjikumari H, K Anisha. A study on the knowledge, attitude and practice of junior doctors to adverse drug event reporting in a tertiary care hospital, Manipur. Int J Basic Clin Pharmacol 2022;11:378-83.