ejpmr, 2023, 10(12), 453-457

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

SJIF Impact Factor 6.222

Research Article

ISSN 2394-3211

EJPMR

A STUDY OF THE KNOWLEDGE, ATTITUDE AND PRACTICE OF ADVERSE DRUG REACTION REPORTING AMONGST UNDERGRADUATE STUDENTS IN A MEDICAL COLLEGE IN MANIPUR: A CROSS-SECTIONAL STUDY

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Article Received on 25/09/2023 **Article Revised on 15/10/2023** **Article Accepted on 05/11/2023**

ABSTRACT

Background*:** The objective of the current study is to detect new ways for improving the status and perception of Adverse drug reaction reporting (ADR) to the pharmacovigilance centres. ***Methods: It is a cross-sectional study with Universal sampling conducted on 2nd year MBBS students of Shija academy of health sciences, Langol. Descriptive statistics is used for analysing the data from the questionnaire using frequencies and percentages. ***Results:*** The response on the questionnaire was 83.3%. 98 participants knew the definition of ADR. 51 participants wanted to report the ADRs of over-the-counter (OTC) drugs. Only 59 participants knew about the existence of PvPI in SAHS. 83 participants did not consider all OTC drugs to be safe. 23 participants replied that no ADR monitoring centre was available in SAHS. Though 98 participants knew the definition of ADR, only 38.2% of them considered reporting it as a professional obligation. 45.1% participants stated maximum ADRs were seen with skin and elderly patients. 47.1% participants wanted to report ADRs from herbal products. Only 34.3% participants have the attitude of reporting ADR, and out of which only 25.5% participants have good clarity when reporting and filling the ADR forms with careful observation of the risks and behaviour of the patients. ***Conclusions:*** To promote ADR reporting, a regular awareness cum sensitization programme coupled with CME program is necessary at Undergraduate teaching including health-care providers.

KEYWORDS: ADR, PvPI, Polypharmacy, OTC, Herbal.

INTRODUCTION

Adverse drug reaction (ADR) is a health problem which largely goes unnoticed by the health-care providers. 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]

Reporting of ADR is under the aegis of pharmacovigilance in India. 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 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 reporting form, PvPI has generated medicine side-effect reporting form for consumers and patients in their regional or local language.[3]

However, India still depends on other resources to obtain data on both new and old drugs already available in the market.[4]

OBJECTIVES

The objectives of the current study are

1. To determine the knowledge, attitude and practice of Adverse drug reporting in undergraduate medical students.
2. To find the association with selected variables.

METHODOLOGY

Study design

It was a cross-sectional study.[5,6]

Study setting

It was conducted inside the lecture hall of SAHS.

Study duration
The study was completed within a period of 30 days.

Study population
Undergraduate medical students.

Inclusion criteria
All 2nd year undergraduate students who were present and consented to participate in the study.

Exclusion criteria
2nd year undergraduate students absent on the day of distributing the questionnaire.

Sampling method and sample size
Universal sampling was employed for this study. 145 undergraduate students were accounted for as the total sample size.

Data collection procedure
Pre-tested questionnaire was distributed to the 2nd year undergraduate medical students in the beginning of a lecture class on a stipulated date and time. The questionnaire was explained and verbal consent was obtained. Accordingly, those who consented were given the pre-tested questionnaire and a time of 10 minutes was given for responding to the questionnaire.

Data analysis
Chi-square test was utilised for the data analysis. For descriptive, frequency and percentages were used.

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.

Ethical considerations
The respondents remain anonymous and confidential. Ethical approval was obtained by the Institutional Ethics Committee, SHRI dated Ref: IEC/SHRI/APL/22 on 22/06/2022.

RESULTS
Out of 145 questionnaires distributed, 122 questionnaires were received back out of which 20 were rejected due to incomplete responses. Hence, the data was analysed on the basis of the responses obtained on the 102 questionnaires.

KNOWLEDGE: Details of analysis of the data on knowledge is given below in table-1

Table-1: Descriptive table for Knowledge responses and the bar graph.

Question	Yes	No
K1=Do you know the definition of ADR?	98	4
K2=Do you know the abbreviation of OTC drugs?	61	41
K3=Are all OTC drugs safe?	19	83
K4=Do you know where to report ADR?	87	15
K5=Should you report ADR for OTC drugs?	51	51
K6=Is ADR and ADE the same?	20	82
K7=Do you know how to report ADR?	82	20
K8=Should you report ADRs from Herbal products?	48	54
K9=Is PvPI existent in your institute?	59	43
K10= Is there ADR monitoring centre in your institute?	79	23

ATTITUDE: Details of analysis of the data on attitude is given below in table-2.

Table 2: Descriptive table for Attitude Responses and the bar graph.

Question	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
A1= Do you think ADR reporting is a professional obligation?	20	19	24	29	10
A2=Do you think ADR form is difficult to fill up?	2	33	41	25	1
A3=Do you think ADR reporting will be beneficial to both patients and doctor?	18	0	3	28	53
A4=Do you think the prescribers desire to hide their identity on reporting ADR?	21	15	55	35	3
A5=Do you think reporting of one ADR will be helpful to the community?	27	14	20	20	21
A6=Do you believe that there is lack of time in filling ADR at work?	15	14	57	23	3

A7=Do you think that a case of ADR reporting will be wrong as it is not seen every time?	16	15	41	25	5
A8=Do you think that ADR reporting by the health care professional should be spontaneous?	19	16	20	39	8
A9=Do you believe that ADR reporting will decrease treatment costs during therapy?	12	14	46	29	7
A10=Do you think that pharmacovigilance related activities should be included in UG curriculum for patient safety?	25	0	14	26	37

PRACTICE: Details of analysis of the data on practice is given below in table-3

Table 3: Descriptive table for Practice Responses and the bar graph.

Question	Yes	No
P1=Have you received training on ADR reporting?	81	21
P2=Have you observed cases of ADR in your hospital?	30	72
P3=Was adequate response taken after observing ADR?	29	73
P4=Have you observed physicians referring a case of ADR patient?	2	100
P5=Has any ADR happened with the prescription in hospital wards?	5	97
P6=Have you ever asserted the causality of ADR?	9	93
P7= Do you report side-effects like headache, fever, vomiting to the ADR centre?	23	79
P8=Do you maintain logbook of ADR?	17	85
P9=Do you find maximum ADRs with elderly, dermatology patients, etc?	46	56
P10=Have you attended any pharmacovigilance awareness program?	20	82

On testing the association between the response of knowing the existence of Pharmacovigilance program of India in the institute and attending pharmacovigilance awareness program, it was found to be statistically significant (p=0.005) as shown in table-4.

Table 4: Test of Association between P10 and K9.

		P10		χ^2	p-value
		No	Yes		
K9	No	29	14	7.9	0.005*
	Yes	53	6		
Total		82	20		

*** = p < 0.05; statistically significant**

Then, on analysing the association between the response of knowing the ADR reporting centre in the institute and attending pharmacovigilance awareness program, it resulted in no statistical significance (p=0.13) as shown in table-5.

Table 5: Test of Association between P10 and K10.

		P10		χ^2	p-value
		No	Yes		
K10	No	21	2	2.24	0.13
	Yes	61	18		
Total		82	20		

Again, on analysing the association between responses in attitude regarding single ADR reporting being helpful to the community and maximum ADRs occurring with elderly, dermatology patients, etc it was not statistically significant (p=0.21) as shown in table-6.

Table 6: Cross tabulation between P9 and A5.

		P9		χ^2	p-value
		No	Yes		
A5	Strongly Disagree	11	8	5.85	0.21
	Disagree	11	5		
	Neutral	12	8		
	Agree	16	23		
	Strongly Agree	6	2		
Total		56	46		

On further assessment, the association between the responses of attitude regarding spontaneous ADR reporting by the health care professional and attending Pharmacovigilance awareness program, it was also not found to be statistically significant (p=0.07)as shown in table-7.

Table 7: Cross tabulation between P10 and A8.

		P10		$\chi 2$	p-value
		No	Yes		
A8	Strongly Disagree	25	2	8.65	0.07
	Disagree	11	3		
	Neutral	15	5		
	Agree	16	4		
	Strongly Agree	12	9		
Total		79	23		

DISCUSSION

The present study is a part of mass awareness program of ADR reporting and existence of AMC under PvPI in the Department of Pharmacology, Shija Academy of Health Sciences, Langol in Manipur. The response obtained on the pre-tested questionnaire as a whole with 83.3%% was encouraging.[1,7,8] 81.4% doctors know that all OTC drugs are not safe.[1] 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 ADR reporting is very much essential and therefore recommended. 50% doctors express their desire to report ADR of OTC drugs. These findings are very much encouraging and appreciated as all ADR associated with new drugs are not observed entirely at the time of approval for clinical use.[9,10] 34.3% doctors find ADR form to be complex while 28.4% doctors cite lack of time in filling the ADR form. 22.8% doctors view reporting of a single ADR to be insignificant with 35.2% doctors wanting to hide their identity. 34.3% doctors have a positive approach to report ADR. 38.2% doctors view ADR reporting as a professional obligation.[11] The attitude of 65.7% doctors who do not have a positive response to ADR reporting needs to be changed. Also, 52.9% doctors feel that ADR from herbal drugs need not be reported. These group of doctors need to be sensitised with the fact that all drugs are not 100% safe.[1,10,12]

34.3% doctors were not able to fill ADR citing other reasons out of which 42.6% doctors held their view due to lack of time and 35.3% doctors due to their want of hiding their identity. 45.1% doctors observe ADR with dermatology patients, elderly patients, etc.[13,14]

79.4% doctors received adequate training on ADR reporting prior to this study. However, only 57.8% knew the implementation of PvPI in Shija Academy of Health Sciences, Langol. 77.4% doctors know that there is AMC in SHRI. However, 80.4% doctors know that ADR and ADE are not same. A poor 16.7% students observed maintenance of ADR log book. Further, only 24.5% doctors want inclusion of PvPI in UG teaching for patient safety.[11,15]

On testing the association between the response of knowing the existence of Pharmacovigilance program of India in the institute and attending pharmacovigilance awareness program, it was found to be statistically significant (p=0.005).

Then, on analysing the association between the response of knowing the ADR reporting centre in the institute and attending pharmacovigilance awareness program, it resulted in no statistical significance (p=0.13)

Again, the association between responses in attitude regarding single ADR reporting being helpful to the community and maximum ADRs occurring with elderly, dermatology patients, etc it was not statistically significant (p=0.21).

On further assessment, the association between the responses of attitude regarding spontaneous ADR reporting by the health care professional and attending Pharmacovigilance awareness program, it was also not found to be statistically significant (p=0.07).

LIMITATIONS

The present study was conducted on one institution and thus, the data obtained was specific to this environment. Also, this study did not take into account Junior doctors, nurses and paramedics who were the first contacts for the patients. Similar studies could be done in other institutes to obtain a more significant picture of Pharmacovigilance reporting in Manipur.

CONCLUSION

A significant gap on the levels of knowledge, attitude and practice relating to ADR reporting and Pharmacovigilance activities among the 2nd year undergraduate MBBS students was observed. Inadequate knowledge, lack of positive attitude along with improper training and awareness are the main obstacles to a stronger ADR reporting database and monitoring system for the benefit of the patient and society as a whole.

This artificial drawback can be improved with proper and extensive training of 2ndyear MBBS students including health care professionals about various activities of pharmacovigilance activities at both the lecture halls and tertiary care hospitals. The investigators suggest a large mass scale awareness program with regards to pharmacovigilance and understanding the basics of ADR and its reporting. Special emphasis about

the inclusion of pharmacovigilance scopes and prospects in UG teaching need to be implemented along with a mandatory rotatory internship in the department of Pharmacology at the colleges of India. The process of reporting the ADR both by the general public and health care professionals should be made plain and simple without any hassle.

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