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ASSESSMENT OF KNOWLEDGE, ATTITUDE, AND PRACTICE OF ADVERSE DRUG REACTION REPORTING AMONG HEALTH CARE PROFESSIONALS IN TERTIARY CARE HOSPITAL: A CROSS SECTIONAL STUDY

Neelamma[1], Raghunandan[2], Mohd Fayazuddin[3], Mohammad Arshad[4*]

[1]Neelamma-Assistant Professor, Department Of Pharmacology, Karwar Institute Of Medical Sciences, Karwar, Karnataka, India
[2]Raghunandan-Associate Professor, Department Of Pharmacology, Raichur Institute Of Medical Sciences, Raichur, Karnataka, India
[3]Mohd Fayazuddin- Associate Professor, Department Of Pharmacology, Raichur Institute Of Medical Sciences, Raichur, Karnataka, India
[4*]Mohammad Arshad-Professor & HOD**,** Department of pharmacology, Raichur institute of medical sciences, Raichur, Karnataka, India

***Correspondence Author;** Dr Mohammad Arshad Professor and Head
*Department of Pharmacology, Raichur Institute of Medical Sciences, Raichur, karnataka-584101.
Email: arshadrims150@gmail.com Phone No: 9611189046

ABSTRACT

Objective: To assess the knowledge, attitude, and practices (KAPs) of ADRs reporting and Pharmacovigilance system in tertiary heath care center. **Methods:** A cross-sectional questionnaire-based observational study was carried out on health-care professionals (Doctors and Interns) after getting approval from the Institutional Ethics Committee. Total 20 KAP questionnaire toward Pharmacovigilance was adapted from the previous studies and consisted of 20 questions in total.
Results: A total 256 health-care professionals were participated and completed the questionnaire. The responses were analyzed using descriptive statistics. A total of 95.67% health-care professionals' good knowledge and agreed that reporting of ADR is necessary. Interns had better knowledge than postgraduates but most of them (75%) did not know where to report. **Conclusion:** Majority of the health-care professionals had a good knowledge and a positive attitude toward the need for ADR reporting. But, the reporting rate of ADRs by them is very low. Hence the various training programs, CMEs, and workshops on Pharmacovigilance for health-care professionals, so that the problem of under reporting could be minimized.

Keywords: Adverse Drug Reactions, Pharmacovigilance, Knowledge, Attitude, Practice.

INTRODUCTION

Drug therapy is an integral part of the medical management. It has many beneficial effects, but side effects and adverse drug reactions (ADRs) are some of its major disadvantages and leading causes of mortality and morbidity.[1]
ADR is defined by World Health Organization (WHO) as "a response to a drug that is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function". And Pharmacovigilance is defined by WHO

as "the science and activities relating to the detection, understanding, and prevention of adverse effects or any other drug-related problems".[2]

Pharmacovigilance Programme of India coordinated by Central Drug Standard Control Organization, New Delhi. They collect the data, analyze it and communicating the risk to healthcare professionals. The Uppsala Monitoring Centre, Sweden is, maintaining the international database of ADR reports.[3] Spontaneous reporting of adverse drug reaction (ADR) is the backbone of pharmacovigilance program Adverse Drug Reactions (ADRs) are scantly reported with poor contribution by health care professionals worldwide and Particular in developing countries. ADRs occur frequently and can adversely affect a patient's quality of life and length of stay can be prolonged and overall hospitalization costs may be increased.[4-6]

The need of this study was to assess the knowledge and awareness of adverse drug reactions (ADRs) reporting and pharmacovigilance system. So would help to create awareness and improve the practice of reporting ADRs and follow the rationality of prescription. With a proper knowledge and practice of ADR reporting will reducing incidence rate and health care cost and may help to banned harmful drugs.

OBJECTIVE

To assess the knowledge, attitude, and practices (KAP) of ADRs reporting and Pharmacovigilance system in interns, postgraduates and faculties of tertiary heath care center

MATERIALS AND METHODS:

Study Design: This study was a cross-sectional questionnaire-based observational study on pharmacovigilance was conducted in Raichur institutes of medical sciences, Raichur for a period of 3months from Sept 2023-nov 2023 after taking approval from the Institutional Ethics Committee RIMS Raichur. With Ref No: RIMS/IEC/2023-24/12

Source of data: Data like name of the department, affiliation i.e interns ,postgraduates, and faculty and knowledge attitude practice of participants was recorded from google form

Study period: Over a period of 06 months from August 2023 to January 2024 was recorded and analysed.

Method of collection of data:

During study period following date were collected through online google format. A questionnaire was designed after a detailed review of relevant studies.[7-9] A questionnaire had containing 20 questions. Among that 12 were regarding knowledge, 5 and 3 were about Attitude and Practices respectively and sent to 256 health-care professional's interns (111) postgraduate (47) and faculties (98) through online as Google form along with inform consent. Explained the purpose of study and all doubts regarding questionnaire was clarified by investigator. A score of 1 for each correct answer or positive response and score 0 for wrong, unattempted answer, or negative response.

Inclusion Criteria:

Interns, Post graduates and doctors were included in the study

Exclusion criteria

Students and other health care professionals were excluded from study

Statistics and data analysis:

All data collected and analyzed by descriptive statistics such as percentages to represent. The data were entered in Microsoft Excel for Windows 10.

RESULT

In our study, out of the 256 participants, a total of 125 were filled Google form and were enrolled from all departments of intuition. And interns had better knowledge than postgraduates & Faculties (Graph 1).

Graph 1: Knowledge of faculties, Post graduates and Interns

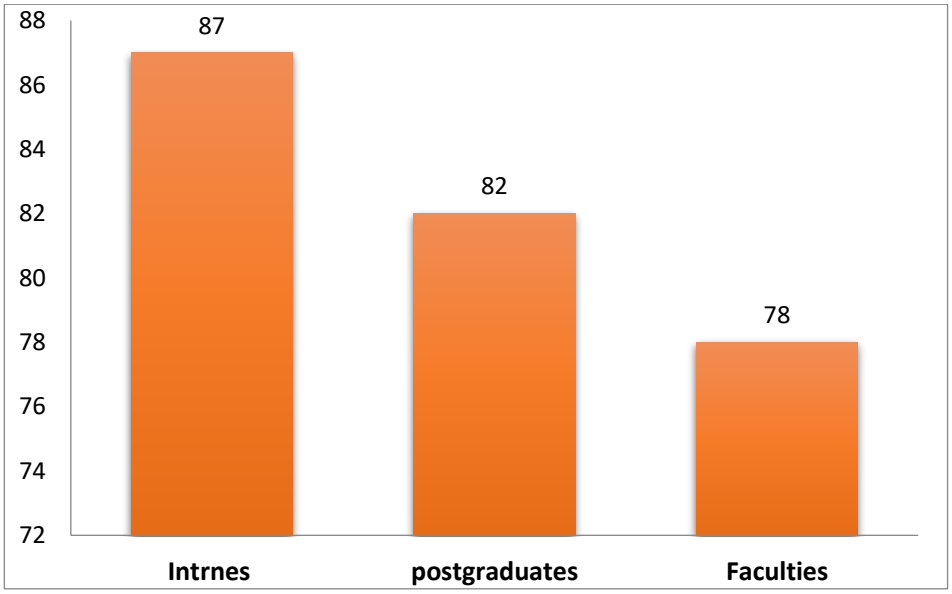

Table 1: Response of participants to knowledge-based question

SL. NO	Knowledge based questions	Number (%) of students responded correctly		
		Interns	Post graduates	Faculty
1.	Who can report ADR?	102(92)	46(99)	89(91)
2.	Whom to report ADR?	84(76)	26(57)	51(53)
3.	What type of ADR need to be reported?	76(69)	39(85)	59(61)
4.	Mandatory fields for suspected ADR Reporting Form	91(82)	37(79)	37(79)
5.	Is ADR reporting mandatory?	101(91)	39(85)	81(83)
6.	What happens to the submitted information?	79(72)	32(69)	59(67)
7.	What is Causality assessment in ADR Monitoring	91(82)	42(91)	71(73)

8.	What are the methods of causality assessment in Pharmacovigilance	91(82)	38(81)	69(71)
9.	What does PvPI stand for?	89(81)	38(82)	76(78)
10.	Where is national Pharmacovigilance center in India located?	86(78)	36(78)	76(78)
11.	Expand the acronym CDSCO	61(56)	33(71)	53(55)
12.	Where is UMC (Uppsala Monitoring Center) located	79(72)	32(69)	58(60)

An average 87.4%, 82%, 78% of interns postgraduates & Faculties respectively, have correct knowledge (Table 1). About 100%, 95.8%, 97.7% interns agreed that reporting ADR is necessary, benefit to patient and doctors and mandatory for MBBS curriculum (table 2).

Table 2: Attitude towards ADR reporting

Questions on attitude	**Percentage of positive response / Agree**		
	Interns	**Postgraduates**	**Faculties**
What do you think about ADR reporting? Is it necessary	**100**	**99.2**	**99.8**
Do you think ADR reporting benefits both patients and doctors	**95.8**	**84.6**	**95**
Should ADR reporting be included under MBBS curriculum?	**97.7**	**98.6**	**66.4**
Do you think ADR reporting is a part of professional obligation of all related to health care?	**89**	**87**	**78.9**
Do you think discussion on ADR during clinical posting has any relevance?	**93.8**	**98.5**	**100**

Table 3: Practice of ADR reporting

Question on reporting of ADR	**Percentage of positive response / Agree**		
	Interns	**Postgraduates**	**Faculties**
Have you seen an adverse drug reporting form by CDSCO?	92.8	89.5	91
Have you ever report a case of ADR during your ward posting/ duty	24.3	35.7	38.3
Are you aware of installation of ADR reporting box in RIMS and opec hospital?	72.6	49	58.6

A total of 95.67% doctors have good knowledge and agreed that reporting of ADR is necessary. 75% did not know where to report. There was a huge gap between the Attitude (95.43%) and ADR report (table 3).

DISCUSSION

The pharmacovigilance system is improving the safe use of medicines. Uppsala Monitoring Centre (World Health Organization Collaborating Centre) for International Drug Monitoring. The UMC works by collecting, assessing and communicating information from member countries' national programs in regard to the benefits, harm, effectiveness and risks of drugs[10]. In our study around 82.9% of interns were aware of the term pharmacovigilance, which is satisfactory. 78% of doctors showed adequate knowledge of ADRs. These results were comparable with other studies conducted by Thakuria et al and Korde et al.[11-12]

A positive attitude was obtained from the participants, 78.9% prescribers consider ADR reporting as a professional obligation. Similar observations were reported in other study.[13] In our study 38 % faculties 35.7% postgraduates and only 24% of interns have sent and reported ADR. 63 % ADR was reported in study conducted by Desai CK et al.[14]

Above average healthcare professionals were not aware of installation of ADR reporting box in our hospital. So necessity of awarenes program on PvPI is felt very much. Meher, et al. concluded that Students lack adequate knowledge and skill of reporting ADR, but they have a positive attitude toward pharmacovigilance program. The integration of pharmacovigilance with undergraduate curriculum may help in improving ADR monitoring and reporting.[15] Nguyen-Thi et al was taken a study on Adverse drug reaction monitoring, About 61.7% reported once in their career, 49.7% had training. Major reason for not reporting was lack of information and instruction.[16]

CONCLUSION

The doctors, Interns have a great responsibility in reporting ADRs and strengthening the pharmacovigilance system. can be used in the future evaluation or re-enforcement plans and educational initiatives for improving the pharmacovigilance practices and ADRs reporting in hospitals

Majority of the health-care professionals had less interest, a good knowledge and a positive attitude toward ADR reporting. ADR reporting and Pharmacovigilance practical Class was included under MBBS curriculum is good part to improve the knowledge But, the reporting rate of ADRs by them is very low. Hence the various training programs, CMEs, and workshops on Pharmacovigilance for health care professionals, so that the problem of under reporting could be minimized.

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AUTHORS' CONTRIBUTIONS- All authors have contributed equally in developing the concept of the study, collection of data, analysis, and drafting the manuscript.

CONFLICT OF INTEREST: The present study was performed in the absence of any conflicts of interest.

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