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ATTITUDE AND AWARENESS OF ADR REPORTING AMONG CLINICIANS IN A TERTIARY CARE HOSPITAL - A CROSS SECTIONAL STUDY

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ABSTRACT

BACKGROUND: ADR was one of the familiar causes of morbidity and mortality in both hospital and community settings and it is responsible for about 5% to 20% of hospital admissions. As many physicians are not aware of importance of monitoring and reporting of ADRs, they may be under reported. To this purpose we evaluated the attitude of ADR reporting and awareness about Pharmacovigilance among the medical doctors working in their clinical practice in a tertiary care teaching hospital. **METHODS:** This cross sectional study was conducted among medical doctors who actively participate in the treatment and care of patients such as Interns, clinical post graduate students; assistant, associate and professors participated in the study at Katuri Medical College & Hospital, Guntur during the period May 2007 to September 2007. **RESULTS:** A total of 150 doctors participated in the study. The age range of participants was 22-65 years. The experience of these doctors ranged from 0-25 years. The participants who answered the questions from 3 to 9 correctly were senior teaching faculty belongs General medicine and Dermatology. Overall, 70-95% of the participants were not aware of any of these questions. The percentage of correct answer for question 6 vs. 10 was 5-33 vs.89.33 respectively. **CONCLUSION:** Our study robustly recommended an immense need to create awareness among the clinicians to improve the reporting of ADRs. The ADR reporting should be made an integral part of the medical education and clinical activities in order to progress the patient care.

INTRODUCTION

Adverse Drug Reaction is defined as any noxious, unintended and undesired effect of the drug which occurs at doses used in humans for the prophylaxis, diagnosis or therapy of a disease or the modification of physiological state as per World Health Organization. ⁽¹⁾ ADR was one of the familiar causes of morbidity and mortality in both hospital and community settings and it is responsible for about 5% to 20% of hospital admissions. ⁽²⁻³⁾ It also an economic burden on our health care system as they prolong the hospital stays and increase the cost of the treatment ⁽⁴⁾ As many physicians are not aware of importance of monitoring and reporting of ADRs, they may be under reported ⁽⁵⁾ Pharmacovigilance is defined as science and activities related to detection, assessment, understanding and prevention of adverse drug reactions or any drug related problem. The success of Pharmacovigilance program is mainly concerned with the active involvement of health care professionals (physicians, nurses, pharmacist, and dentists). As a drug experts Pharmacists are more likely to detect ADRs than are other healthcare professionals, either in the hospital or community setting. ⁽⁶⁻⁷⁾ It is a well known fact that an inadequate awareness about the Pharmacovigilance system among the health care professionals is the leading cause of under reporting. The ultimate focus narrows to health care professionals spontaneous reporting of ADRs, for improving the reporting rates. ⁽⁸⁾ To this purpose we evaluated the attitude of ADR reporting and awareness about Pharmacovigilance among the medical doctors working in their clinical practice in a tertiary care teaching hospital.

METHODS

This cross sectional study was conducted among medical doctors who actively participate in the treatment and care of patients such as Interns, clinical post graduate students; assistant, associate and professors participated in the study at Katuri Medical College & Hospital, Guntur during the period May 2007 to September 2007. Health assistants, nurses and pharmacists were excluded from the study. Institutional Ethical committee has approved the study protocol. A Questionnaire containing 10 questions were designed and validated to know the attitude, knowledge and awareness about ADR reporting and Pharmacovigilance. The doctors were requested to complete the questionnaire and to return it same day.

1.	Difference between Adverse drug reaction and Adverse event	(R/W)
2.	What do mean by Serious Adverse Reaction (SAE)	(R/W)
3.	Whom to report ADR - Local/Regionally/National wide	(R/W)
4.	Definition of Pharmacovigilance	(R/W)
5.	Why new ADR has to informed to Pharmacovigilance Center	(R/W)
6.	Pharmacovigilance reporting is Compulsory	(Y/N)

7.	What do you mean by DCGI	(R/W)
8.	What do mean by CDSCO	(R/W)
9.	What do you mean by Post Marketing Surveillance	(R/W)
10.	ADR reporting is Compulsory	(Y/N)

RESULTS

A total of 150 doctors participated in the study. Age range of participants was 22-65 years. The experience of these doctors ranged from 0-25 years. The participants who answered the questions from 3 to 9 correctly were senior teaching faculty belongs General medicine and Dermatology. Overall, 70-95% of the participants were not aware of any of these questions. Percentage of correct answer for question 6vs.10 was 5-33vs.89.33 respectively. (Table-1)

Question	Right	%	Wrong	%
1.	46	30.67	104	69.33
2.	33	22.00	117	78.00
3.	15	10.00	135	90.00
4.	11	7.33	139	92.67
5.	8	5.33	142	94.67
6.	8	5.33	142	94.67
7.	16	10.67	134	89.33
8.	8	5.33	142	94.67
9.	8	5.33	142	94.67
10.	134	89.33	16	10.67

DISCUSSION

This study showed modest knowledge about the ADR reporting system among the medical doctors in a Hospital. 70-95% of clinicians did not know where and how the ADRs had to be reported and the regulatory agencies. So, it is essential to conduct awareness programs to improve the ADR reporting. In our study a majority of clinicians felt that the ADR reporting should be compulsory, which again corresponding with the results obtained by Qing et al and Bateman DN et al⁽⁹⁻¹⁰⁾ The percentage of correct answer for question 6 vs. 10 was 5-33 vs.89.33 respectively, suggests that the participants were new to the terminology Pharmacovigilance. Patil et al⁽¹¹⁾ also in their study found that the factors that discourage the doctors from a spontaneous reporting are a lack of knowledge about reporting procedure and other practical issues such as the patient management and the patient confidentiality issues.

CONCLUSION

Our study robustly recommended an immense need to create awareness among the clinicians to improve the reporting of ADRs. The training sessions must clarify the roles of the various healthcare professionals in Pharmacovigilance. There should be closer relationship between clinicians, Pharmacovigilance experts and centers. ADR reporting should be made an integral part of the medical education and clinical activities in order to progress the patient care.

CONFLICT OF INTEREST - None

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