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A survey to assess knowledge, attitude and practices among doctors about pharmacovigilance

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ABSTRACT

The problem of ADRs is global. ADRs can lead to increased morbidity and mortality. Adverse drug reactions lead to unnecessary economic burdens. To decrease the incidence and consequences associated with ADRs is a major challenge. The ADR reporting rate in India is below 1% compared to the worldwide rate of 6-10 %. .This is basically due to the absence of an effective ADR monitoring system and also due to a lack of proper knowledge, attitude and practices about ADRs and pharmacovigilance. To assess knowledge, attitude and practices among doctors about pharmacovigilance in a tertiary care hospital of Lucknow, Uttar Pradesh. This was a cross sectional, questionnaire based survey conducted in a tertiary care hospital of Lucknow, Uttar Pradesh. Out of 250 questionnaires circulated, only 210 were duly filled and were considered for the analysis of result. Out of 210 respondents 53.8 % of the doctors knew about the definition of pharmacovigilance (Pv) and 49.1 % knew the correct purpose of Pv. only 38.6% had knowledge about the Regulatory body is responsible for monitoring of ADR's in India. 84.8 % agreed to the point that Pv should be taught in details. 86.2 % agreed to the importance of establishment of Pv center in each hospital. The results of the study suggest that there is underreporting of ADRs and doctors are lacking requisite knowledge of pharmacovigilance. Training programmes are urgently needed to improve the doctors knowledge and attitude towards ADR reporting.

Keywords: Pharmacovigilance, Adverse drug reaction, monitoring, reporting, knowledge

INTRODUCTION

According to World Health Organization (WHO) an Adverse drug reaction (ADR) is defined as a response to a drug which is noxious, unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function [1]. The problem of ADRs is global and has a major impact on public health [2]. ADRs can lead to increased morbidity and mortality, unnecessary hospital admissions and discontinuation of drugs [3]. To decrease the incidence and consequences associated with ADRs is a major challenge. Providing proper information on suspected ADRs is a duty of doctor as a part of patient care. Adverse drug reactions lead to unnecessary economic burdens knowing that most of these ADRs are preventable.

The ADR reporting rate in India is below 1% compared to the worldwide rate of 6-10 % [4,5]. The main reasons for low reporting rate in India maybe lack of adequate knowledge and proper sensitization towards pharmacovigilance and ADR among health care professional [6].

Pharmacovigilance as defined by the World Health Organization (WHO) is "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems" [7,8]. Nowadays Pharmacovigilance studies have become more important as new drugs are entering the market at a very high pace.

The important purposes of Pharmacovigilance are [9]:

1. To improve public health and safety in relation to the use of medicines.
2. To improve patient care and safety in relation to the use of medicines.
3. To contribute towards safer, rational and more cost-effective use of medicines
4. To promote education and training in pharmacovigilance and its effective communication to the public.

The Uppsala Monitoring Center (UMC, WHO), Sweden, maintains the international database of the adverse drug reaction reports. According to estimates only 6-10% of all the ADRs are reported. Although, India is participating in the program, its contribution to the UMC database is very little

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[10]. The ADR reporting rate in India is below 1%. This is basically due to the absence of an effective ADR monitoring system and also due to a lack of the reporting among doctors. The Pharmacovigilance program of India (PvPI) was launched in July 2010 with the main objective of patient safety by the Central Drug Standard Control organization, New Delhi under Ministry of health and Family welfare. National Coordinating Center (NCC) has been shifted from AIIMS, New Delhi to the Indian Pharmacopoeia Commission, Ghaziabad, (UP) in April, 2011 under Uppsala Monitoring Center World Health Organization (UMC-WHO). The main mechanism of reporting ADRs is by Spontaneous reporting system (SRS) and it is the basis of the WHO data [11, 12]. The main function of SRS is the early detection of any new, rare and serious ADRs. A spontaneous reporting system enables physicians, pharmacists and patients to report suspected ADRs to a pharmacovigilance center. But the SRS is affected by a number of factors, the most important of these being the under-reporting of ADRS from healthcare professionals especially doctors. Thus the aim of the present study is to assess the knowledge, attitude and perception and to explore the reasons behind under-reporting of ADRs among doctors in India.

MATERIAL AND METHODS

This was a cross sectional, questionnaire based survey conducted in a tertiary care hospital of Lucknow, Uttar Pradesh. The target sample included teaching faculty of doctors (professors, associate professors and assistant professors), postgraduate students. A pre designed questionnaire was used. It was structured to obtain information about the knowledge and attitude about the ADRs reporting, and the factors that in practice could affect the reporting among the doctors.

RESULTS

Out of 250 questionnaires circulated, only 210 were duly filled. Among 210, faculty members were 130 and post-graduate students were 80.

Table: Knowledge, attitude, practice of the Doctors towards Pharmacovigilance

QUESTIONS	CORRECT ANSWER	NO. OF CORRECT RESPONCES (%)	NO. OF WRONG RESPONCES (%)
Definition of Pharmacovigilance	The detection, assessment, understanding & prevention of adverse effects	113 (53.8)	97 (46.2)
The most important purpose of Pharmacovigilance is	To identify safety of drugs	103 (49.1)	107 (50.9)
methods is commonly employed by the pharmaceutical companies to monitor adverse drug reactions of new drugs once they are launched in the market	Post Marketing Surveillance	138 (65.7)	72 (34.3)
A serious adverse Event in India should be reported to the Regulatory body within	Fourteen calendar days	70 (33.3)	140 (66.7)
The international center for adverse drug reaction monitoring is located in	Sweden	108 (51.4)	102 (48.6)
Rare ADRs can be identified in the following phase of a clinical trial	During phase-4 clinical trials	144 (68.6)	66 (31.4)
One of the following is the agency in Unites States of America involved in drug safety issues	United States food and drug administration***** (US FDA)	143 (68.1)	67 (31.9)
In India which Regulatory body is responsible for monitoring of ADR's?	Central Drugs Standard Control Organization	81 (38.6)	129 (61.4)
Which of the following scales is most commonly used to establish the causality of an adverse drug reaction	Naranjo algorithm	57 (27.1)	153 (72.9)
ADR reporting systems in India	By ADR reporting Form	119 (56.7)	91 (43.3)
Do you think adverse drug reaction reporting is a professional obligation for you	Yes	102 (48.6)	108 (51.4)
Do you think reporting of adverse drug reaction is necessary	Yes	169 (80.5)	41 (19.5)
Do you think Pharmacovigilance should be taught in detail to healthcare professionals	Yes	178 (84.8)	32 (15.2)
Have you ever been trained on how to report Adverse Drug Reaction (ADR)	Yes	45 (21.4)	165 (78.8)
Your opinion about establishing ADR monitoring center in every hospital	Should be in every hospital	181 (86.2)	29 (13.8)
Have you ever come across with an ADR	Yes	194 (92.4)	16 (7.6)
Have you ever reported any ADRs	Yes	67 (31.9)	143 (68.1)

DISCUSSION

Out of 210 respondents 53.8 % of the doctors knew about the definition of pharmacovigilance (Pv) and 49.1 % knew the correct purpose of Pv. Only 33.3 % had the knowledge about the time to report serious adverse event to the regulatory bodies. 51.4 % knew about the international center for ADR monitoring. To our great surprise only 38.6% had knowledge about the Regulatory body is responsible for monitoring of ADR's in India. Out of all 56.7 % said that method of reporting ADRs in India is by filling ADR forms.

Only 48.6 % considered reporting ADRs as an obligation while 80.5 % said that reporting of ADRs is necessary. 84.8 % agreed to the point that Pv should be taught in details. 86.2 % agreed to the importance to establishment of Pv center in each hospital. Among all 92.6 % said that they have encountered ADRs but only 31.9 % have reported any ADR to authorities. On asking whether they have received any training on how to report ARDs only 21.4 % said yes. The participants of our study suggested that reporting of ADRs can be improved by increasing the awareness by educational programmes.

CONCLUSION

The results of the study suggest that there is underreporting of ADRs and is mainly due to the gaps in the knowledge and attitudes. KAPs of doctors were not up to the mark. Knowledge about reporting center is also found to be lacking and large number of doctors were ignorant of the PV center. It is very much essential for doctors to have an in-depth knowledge on ADRs and ADR reporting procedure. The fact that also came into the light is that ADR reporting was not given much importance during training of the doctors. Most of them felt the need of training on ADR reporting.

Majority of the doctors were ignorant about what type of ADR should be reported. The factors leading to the under-reporting includes lack of knowledge of reporting procedure, lack of time, uncertainty about the ADR, availability of the reporting form etc. our study concludes that the awareness programmes are urgently needed to improve the doctors' attitude towards ADR reporting. It is very urgent for all stake holders to come together to ensure proper implementation of PV program and establishing more ADRs monitoring centers.

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