IJCRR
Vol 06 issue 09
Section: Healthcare
Category: Research
Received on: 27/03/14
Revised on: 15/04/14
Accepted on: 30/04/14

CURRENT SCENARIO OF PHARMACOVIGILANCE AMONGST THE HEALTH CARE PROFESSIONALS WORKING IN A TEACHING HOSPITAL IN RAJASTHAN

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ABSTRACT

Aim: The concept of Pharmacovigilance has been given to keep a watch on ADRs. The science and the activities which relate to the detection, assessment, understanding and the prevention of adverse effects or any other drug-related problems is referred to as Pharmacovigilance.Adverse drug reactions (ADRs) have a major impact on public health as they are associated with significant morbidity and mortality .Healthcare professionals are one of the important pillars of an efficient Pharmacovigilance system because of their contribution in the form of spontaneous reporting.The objective of this study is to assess the awareness of Pharmacovigilance amongst the health care professionals working in NIMS medical college and hospital, Jaipur, India.

Methodology: An anonymous questionnaire based survey for health care professionals working in NIMS Hospital, Jaipur was conducted after getting approval from the Institutional Ethical Committee. A structured validated questionnaire consisting of thirteen questions was distributed amongst doctors and residents of all the departments during a single visit to the NIMS Hospital.

Results: 150 questionnaires were distributed amongst the doctors of NIMS Hospital after brief description about the study out of which 96 forms were included for evaluation .Hence response rate was 64% (96/150). In our study 66.66 % respondents were males and 33.34% were females. We found that 96% respondents were having knowledge that Pharmacovigilance deals with ADRs and 41.5% respondents had knowledge about the phases of clinical trial and knew that Pharmacovigilance is done in Phase IVof clinical trial. To our surprise only 21% doctors were of the view that all the physicians, dentists, nurses, physiotherapists and even pharmacists can report ADR. Interestingly only 36% doctors were aware of the fact that events related to allopathic drugs, herbal medicines, vaccines and blood products can be reported but maximum doctors thought that only allopathic drug ADRs should be reported. Interestingly 87.5% responders were aware of the National Pharmacovigilance Centre in India but only 16.7% actually reported suspected ADRs to any ADR Reporting centre.

Conclusion: To conclude poor knowledge of Pharmacovigilance and underreporting of ADRs in a developing country like India is a matter of great concern and needs prompt intervention.

Keywords: ADR, Pharmacovigilance, Reporting

INTRODUCTION

World Health Organization (WHO) has defined anAdverse drug reaction (ADR) as any noxious, unintended, and undesired effect of a drug, which occurs at the doses which are used in humans for prophylaxis, diagnosis, or therapy. [1] The concept

of Pharmacovigilance has been given to keep a watch on ADRs. The science and the activities which relate to the detection, assessment, understanding and the prevention of adverse effects or any other drug-related problems is referred to as Pharmacovigilance.[1][2] Adverse drug reactions (ADRs) have a major impact on public health as they are associated with significant morbidity and mortality.[3] Healthcare professionals are one of the important pillars of an efficient pharmacovigilance system because of their contribution in the form of spontaneous reporting. [4]Spontaneous reporting of ADRs is one method of Pharmacovigilance and which is undertaken through the Yellow Card Scheme (YCS) in UK.[5]

The Uppsala Monitoring Centre (UMC, WHO), Sweden is maintaining the international database of ADR reports.[6] In India it is maintained by Central Drugs Standard Control Organization (CDSCO) with the Drug Controller General(India) [DCG(I)] as its head.

Underreporting of ADRs is the major problem amongst doctors and needs serious rethinking. To improve this, the knowledge, attitude and practice of doctors towards Pharmacovigilance and the reporting system should be improved and awareness should be created.

The objective of this study is to assess the awareness of Pharmacovigilance amongst the health care professionals, working in NIMS medical college and hospital, Jaipur, India.

MATERIALS AND METHODS

This study was an anonymous questionnaire based survey for health care professionals working in NIMS Hospital, Jaipur. The study was conducted after getting approval from the Institutional Ethical Committee. A structured validated questionnaire consisting of thirteen questions was distributed amongst doctors and residents of all the departments during a single visit to the NIMS Hospital , to each of them and they were asked to tick the option/s which they felt was/ were the best. All the doctors and residents in all the OPDs and wards of all the departments were contacted during this single visit. Consenting participants anonymously completed the questionnaire and were collected on the same day. Doctors were allowed to give suggestions regarding improvement of ADR Reporting. Questionnaire was based on previous study done on pharmacovigilance.[1][6]

Survey was descriptive and after completion of data collection it was organized and compiled as percentages. The sum total of percentages was not always 100% because some questions contained multiple options to choose from.

STATISTICAL ANALYSIS: The data was subjected to descriptive analysis using microsoft excel. Different parameters were given as percentile.

RESULTS

150 questionnaires were distributed amongst the doctors of NIMS Hospital after brief description about the study. The dully filled forms were collected on the same working day.Incompletely filled and forms which were not filled were excluded from the study. 96 forms were included for evaluation.

In our study 66.66 % respondents were males and 33.34% were females as shown in figure:1.

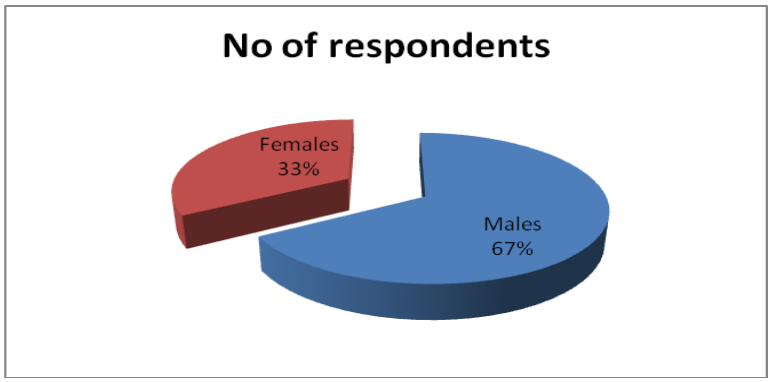

Figure-1: Sex differentiation amongst respondents

Response rate was 64% (96/150) as 96 dully filled forms were collected back. Out of 96 responders, 40 were senior doctors and 56 were residents.

We found that 96% respondents were having knowledge that Pharmacovigilance deals with ADRs. We found that 41.5% respondents had knowledge about the phases of clinical trial and knew that Pharmacovigilance is done in Phase IV of clinical trial. while 37.5% thought that pharmacovigilance is done in Phase I clinical trial. On the other hand 8.4% doctors were in favour of Phase II while 7.3% ticked on Phase III clinical trials.We found that knowledge of location of WHO Uppsala Monitoring centre(Sweden) was present amongst 68.8% doctors while rest were unaware of its location.

To our surprise only 21% doctors were of the view that all the physicians, dentists, nurses, physiotherapists and even pharmacists can report ADR. Still maximum number of doctors thought that only physicians can send the ADR report.

Interestingly only 36% doctors were aware of the fact that events related to allopathic drugs, herbal medicines, vaccines and blood products can be reported but maximum doctors thought that only allopathic drug ADRs should be reported.ADR reporting is generally done by most of the doctors only for allopathic drugs and vaccines. But it actually encompasses other products also like herbals, traditional medicines,and blood products, biological and medical devices .[6]Events which should be reported has been depicted in figure :2.

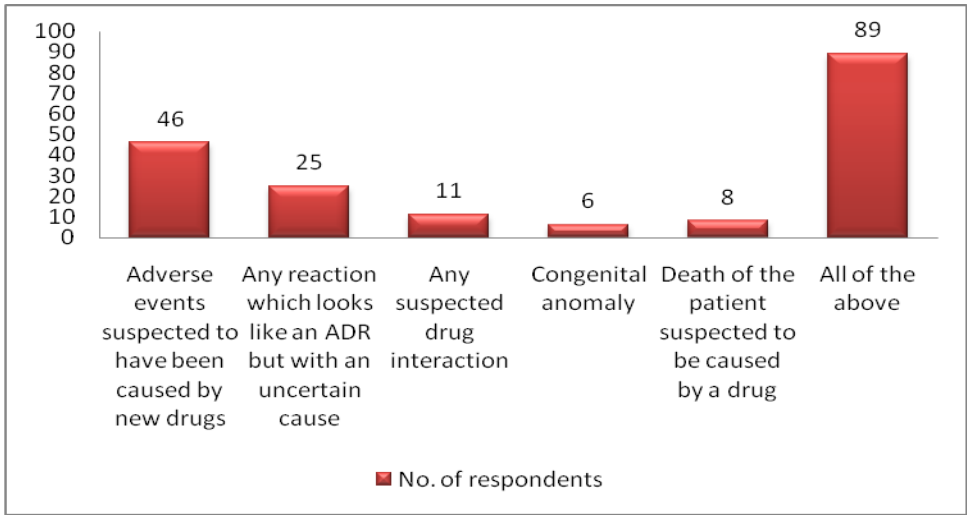

Figure-2: Elaborates events that can be reported to a Pharmacovigilancecentre

Interestingly 87.5% responders were aware of the National Pharmacovigilance Centre in India but only 16.7% actually reported suspected ADRs to any ADR Reporting centre.

In our study attitude regarding ADR Reporting amongst respondents has been shown in the following table:1.

Table-1: Attitude regarding ADR Reporting amongst respondents

Question asked	Options	Responders	Percentage
1. ADR Reporting is necessary	a. Yes	84	87.5%
	b. No	12	12.5%
2. ADR Reporting is a professional obligation	a. Yes	88	91.2%
	b. No	8	8.3%
3. Pharmacovigilance reporting should be:			
a. Compulsory	a. Yes	75	78.2%
	b. No	21	21.87%
b. Voluntary	a. Yes	16	16.7%
	b. No	80	83.33%
c. Remunerated	a. Yes	5	5.2%
	b. No	91	94.79%
4. Discouraging factors in ADR Reporting:			
a. Lack of time to look for ADR	a. Yes	24	25%
	b. No	72	75%
b. Treating patient is important than ADR reporting	a. Yes	64	66.7%
	b. No	32	33.33%
c. Lack of knowledge	a. Yes	7	7.29%
	b. No	89	92.70%
d. Not interested in ADR reporting	a. Yes	1	1.04%
	b. No	95	98.95%

Majority of doctors were of the view that the doctors should be trained in ADR reporting (37.5%) and ADR reports should be kept confidential. 18.6% opined thatmore CMEs should be arranged on Pharmacovigilance while 8.4% felt need about tollfree number for ADR reporting. There should be an emphasis oninculcation of knowledge about Pharmacovigilance right from the second year when a medical student steps into the world of pharmacology.

DISCUSSION

Male preponderance was seen in our study which corresponds with the study done by Pankaj G *et al* 2011[6] . In contradiction to our study female preponderance was seen in study performed by Subish P et al 2011 in Nepal.[8]

We got a response rate of 64% in our study. Our findings coincide with the findings of Khan S A *et al* 2013 (response rate was 62.9%). [7] while it was 67.9% in a study done in Nepal.[8] In contradiction to this very high response rate of 93.3% was present in a study done by Pimpalkhute SAetal 2012[3] Similarly in a Nigerian study response rate of 82.5% was observed.[9]

We found that 96% respondents were having knowledge that Pharmacovigilance deals with ADRs. But in another Indian study 77% of the subjects knew the term 'Pharmacovigilance.[1] In an Indian study by Chopra D *et al* nearly two third

(66%) of the doctors knew the definition of ADR. [11]

We found that 41.5% respondents had knowledge about the phases of clinical trial and knew that Pharmacovigilance is done in Phase IV of clinical trial. In a study done by Hardeep et al 2013 68.9% knew about Periodic Safety Update Report.[1]

In our study, only 21% doctors were of the view that all the physicians, dentists, nurses, physiotherapists and even pharmacists can report ADR. Similarly in Nigeria 89.9% considered doctors, as the most qualified health professionals to report ADRs.[9]

Interestingly in a study by Khan SA et al 2013 , major proportion (85.3%) of the doctors were aware that all ADRs should be reported.[7] Surprisingly in a study done by Chopra D et al 2011, only one tenth of the doctors (10%) knew ,what should be reported ? [11] In a study performed in China , 61.7% of the doctors, 62.7% of the nurses and 61.1% of the administrators had ever encountered an ADR during their practices, but did not report to the national monitoring center or other centers.[16]

Interestingly 87.5% responders in our study were aware of the National Pharmacovigilance Centre in India but only 16.7% actually reported suspected ADRs to any ADR Reporting centre. But, only 59% subjects were aware of the existence of a National Pharmacovigilance Centre in India in a previous Indian study.[1] 73% respondents were aware of the existing programme in India in another study.[11] Santosh KCet al2013 concluded that there were 74.8% of healthcare professionals who had seen patient experiencing an ADR; however, only 20.1% had reported.[13] Similarly in a study performed in Tamil Nadu , 47.5% respondents had observed ADRs in their practice, and 37% had reported it to the national pharmacovigilance center.[14] In an Iranian study done amongst pharmacists, more than half of those responding felt that ADR reporting should be voluntary, while 26% felt it was a professional obligation. [15]

CONCLUSION

This study has given us an overall pattern of awareness of pharmacovigilance amongst doctors working in NIMS Hospital. Our study will help in promoting knowledge about Pharmacovigilanceamong clinicians. To conclude despite of shortcomings our study can offer a wealth of data on implementation of Pharmacovigilance.Poor knowledge of Pharmacovigilance and underreporting of ADRs in a developing country like India is a matter of great concern and needs prompt intervention.

CONFLICTS OF INTEREST

The authors declare that they have no competing interests.

FUNDING: Not applicable.

ACKNOWLEDGEMENT

I would like to thank Dr. Manjula Bhargavaand all the doctors of NIMS Hospital who participated in this study. Authors acknowledge the immense help received from the scholars whose articles are cited and included in references of this manuscript. The authors are also grateful to authors / editors / publishers of all those articles, journals and books from where the literature for this article has been reviewed and discussed.

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