Online Available at www.thepharmaresearch.info

THE PHARMA RESEARCH, A JOURNAL

The Pharma Research (T. Ph. Res.), (2010), 3; 1-9.
Published on- 15 June 2010

Case Study

ISSN 0975-8216

INVESTIGATION OF ATTITUDES AND PERCEPTION OF MEDICAL PRACTITIONERS ON ADVERSE DRUG REACTION REPORTING - A PILOT STUDY

Sourav Ghosh *, Shakir Ali, Lavi Chhabra, Chavi Prasad, Arvind Gupta

Affiliated to:
S.D. College of pharmacy &Vocational studies, Muzaffarnagar, U.P., India

ABSTRACT

The aim of our study was to assess the attitudes and perceptions of medical practitioners towards adverse drug reaction (ADR) reporting and factors that influence the reporting of ADR. A suitable self-administered survey questionnaire was designed and randomly circulated to 32 doctors in two different hospitals.

Of the 32 survey questionnaires circulated, 27 filled questionnaires were returned giving overall response rate of 84.37 %. Our survey results revealed that 88% of the responders were aware of existence of ADR reporting and monitoring system in India and 23% of them had repor ted suspected ADR to any of the pharmacovigilance centre located in India. If the ADR reporting and monitoring system is implemented, it has been found to be useful by 72% of responders, and 95% of the responders opined that the ADR reporting and monitoring system had been benefiting the patient. 92% responders told that pharmacist assistance in detection, reporting and management of ADR is usefull. Main factors that discouraged ADR reporting were Time consuming, tedious, mild reactions and absence of fees. Imparting knowledge and awareness of ADR reporting among medical practitioners would bring the reporting culture among medical practitioners and increase the reporting rates of ADR. Pharmacists have a greater role to play in the area of pharmacovigilance.

Keywords: Reporting of Adverse Drug Reaction, Questionnaire Survey, Medical Practitioners, Pharmacist

*Corresponding author:
Email: souravcology@gmail.com

1.0 INTRODUCTION

Adverse drug reactions (ADRs) are global problems of major concern. They affect both children and adults with varying magnitudes, causing both morbidity and mortality [1-4]. In addition to the human costs, ADRs have a major impact on public health by imposing a considerable economic burden on the society and the already- stretched health-care systems [5,6]. Post marketing surveillance of drugs is very important in analyzing and managing the risks associated with drugs once they are available for the use of the general population. Spontane- ous reporting has contributed significantly to successful pharmacovigilance. The contribution of health professionals, in this regard, to ADRs databases is enormously significant and has encouraged ongoing ascertainment of the benefit-risk ratio of some drugs [7,8] as well as contributed to signal detection of unsuspected and unusual ADRs previously undetected during the initial evaluation of a drug [9,10]. In spite of these benefits, under-reporting remains a major draw-back of spontaneous reporting [10, 11]. It is estimated that only 6–10% of all ADRs are reported [12, 13]. This high rate of under-reporting can delay signal detection and consequently impart negatively on the public health.

Many factors are associated with ADRs under-reporting among health professionals. These factors have been broadly classified as personal and professional characteristics of health careers, and their knowledge and attitudes to reporting [11]. Inman [14] has summarized these factors as the 'seven deadly sins'. His description of the 'sins' include: attitudes relating to professional activities (financial incentives: rewards for reporting; legal aspects: fear of litigation or enquiry into prescribing costs; and ambition to compile or publish a personal case series) and problems associated with ADR-related knowledge and attitudes (complacency: the belief that very serious ADRs are well documented by the time a drug is marketed; diffidence: the belief that reporting an ADR would only be done if there was certainty that it was related to the use of a particular drug; indifference: the belief that the single case an individual doctor might observe could not contribute to medical knowledge; and ignorance: the believe that it is only necessary to report serious or unexpected ADRs), and excuses made by professionals (lethargy: the procrastination and disinterestedness in reporting or lack of time to find a report card and other excuses). Lopez-Gonzalez et

al [11], in their review of determinants of ADRs under-reporting from the global perspective, have shown that three of the seven 'sins' proposed by Inman that are associated with professional activity (financial incentives, fear and ambition to publish) seem to contribute less significantly to under-reporting. Insecurity (the belief that it is nearly impossible to determine whether or not a medicine is responsible for a particular ADR) is another factor associated with under-reporting [11] but was not proposed by Inman. It therefore appears that factors that promote under-reporting may vary from one country to another.

2.0 METHODS

2.1 Study setting

This is a questionnaire based study and it was conducted at two different hospitals. The study centers included Muzaffarnagar medical Hospital and S.D.medical hospital located in North India. This questionnaire survey was conducted during March 2010.

2.2 Survey recipients

The survey questionnaire was administered to 32 doctors belonged to different specialties practicing across two major hospitals.

2.3 Survey questionnaire

A suitable piloted self- administered survey questionnaire was designed and randomly circulated to medical practitioners of all two hospitals. The study questionnaire was designed to assess the attitude and perception of medical practitioners towards adverse drug reaction reporting. Few changes in the order and phrasing of the questions were made after discussion with fellow clinical pharmacists and few physicians. The final questionnaire were designed for specifically to answer the awareness about ADR repor- ting and monitoring system, its operational procedure, its usefulness, their reporting culture and also to know whether the system needs any further modification and or improvement. In order to preclude any potential bias the disclosure of name of the responder was made optional. All participants were briefed about the purpose of the study and asked to submit the filled questionnaire to the identified nursing station of their respective hospital. All participants also were provided with sufficient time of 15 days to fill the pages of questionnaire.

2.4 Analysis

The survey questionnaire was analyzed question wise and their percentage value was calculated. In the analysis of all questions total number of responders to questionnaire survey was considered rather total number of responders to each question.

3.0 RESULT

Of the 32 survey questionnaires circulated, 27 filled questionnaires were returned giving overall response rate of 84.37 percent. The response rate from each study site was

80% and 91.6% for Muzaffarnagar medical and S.D. medical Hospital respectively.

Our survey results revealed that 88% of the responders were aware of existence of ADR reporting and monitoring system in India and 23% of them had reported suspected ADR to any of the pharmacovigilance centre located in India.

Table1: Attitude and perception of doctors towards the reporting.

QUESTIONS	PERCENTAGES	
	YES	NO
Are you aware existence of adverse drug reactions (ADRs) reporting and monitoring system (National pharmacovigilence centre) in India?	88	12
Have you reported any suspected adverse drug reaction to any of the reporting and monitoring centers?	23	77
Has this system created an awareness of ADR reporting in you?	31	69
If the ADR reporting and monitoring system in your hospital, it is useful for your practice?	72	28
Do you think that ADR reporting and monitoring system would benefit the patient?	95	05
Is pharmacist's assistance in detection, reporting and management of adverse drug reaction usefull?	92	08

ADR reporting and monitoring system had created awareness in 31% of the responders. If the ADR reporting and monitoring system is implemented, it has been found to be useful by 72% of responders, and 95% of the responders opined that the ADR reporting and monitoring system had been benefiting the patient. 92% responders told that pharmacist assistance in detection, reporting and management of ADR is usefull. The details of attitudes and perceptions of doctors towards ADR

reporting are summarized in Table-1.

Those factors that would discourage the respondents from reporting ADRs are listed in Table 2.

Table 2: Factors that discouraged doctors from reporting an ADR

FACTORS INFLUENCED	PERCENTAGE RESPONDERS (n=12)
1. Time consuming	32
2. Tedious process	18
3. Well known reactions	42
4. Mild adverse effect	08
5. The absence of fees of reporting	05
6. Concern that report will generate an extra work.	12
7. Fear of negative impact.	16

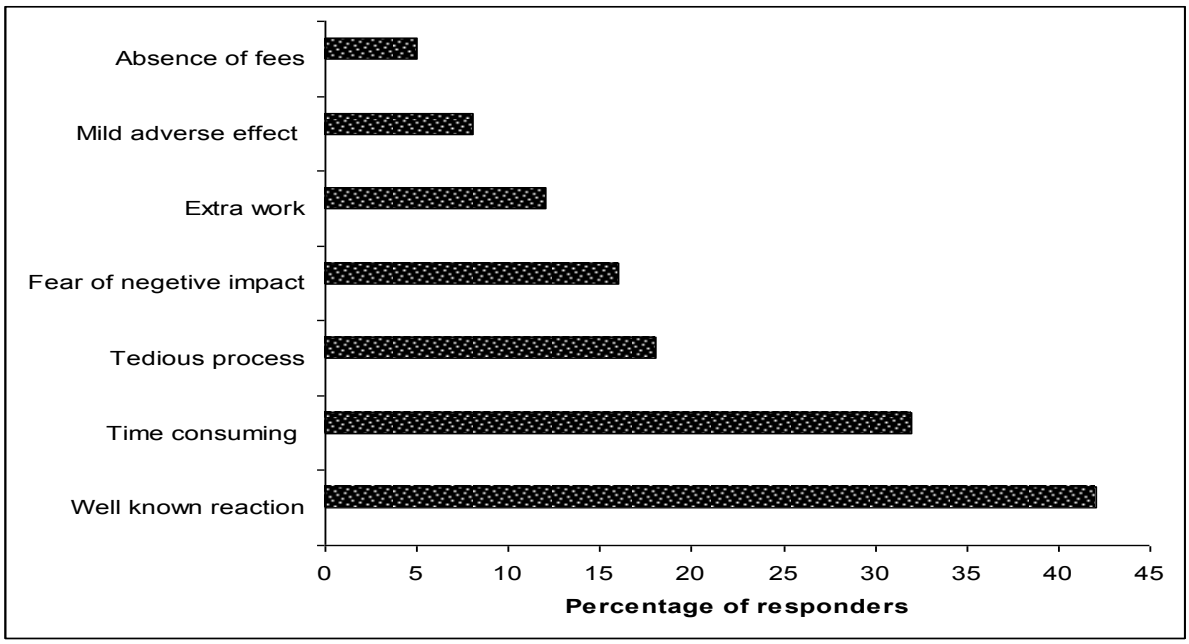

Fig1: Factors that discouraged doctors from reporting an ADR

Some of the suggestions provided by the survey participants are presented in Table-3.

Table3: Common suggestions provided by the responders.

IMPORTANT SUGGESIONS	PERCENTAGE RESPONDERS (n=23)
1. Continue the same system	21
2. Need more feedback on reported reactions	56
3. Educate the nursing stuff.	24
4. Discuss the rare ADRs in monthly meeting.	38
5. Provide information of ADRs to newer drugs	62
6. Bring out monthly and quarterly bulletin on ADRs	16

4.0 DISCUSSION

This study has shown inadequate knowledge of doctors about reporting and monitoring the ADRs. Perhaps, the undergraduate training in pharmacovigilance and medicine risk perceptions may be either insufficient or improperly delivered to prepare the doctors for the task of ADR monitoring and reporting in their future career.

Spontaneous ADR reporting by other health professionals and individuals is practiced in many countries [15-17] and it is recommended by the NPC [18] but not recognized by the respondents. This is reflected in their low percentages that considered individuals and physiotherapists qualified to report ADRs. A significant number of the respondents were not aware of the existence of a national pharmacovigilance centre in India. Lack of knowledge of where ADRs should be reported would automatically affect reporting, therefore, awareness programmes; through publicity, would appear necessary to improve ADR reporting in North India.

When we compared the factors that may influence reporting by the respondents with those reported by Lopez- Gonzalez et al [11], the results were similar. Our study has shown that, like most countries around the world, ignorance (not feeling the need to report well recognized reaction), diffidence (concern that the ADR report may be wrong) and indifference (lack of time to fill in a report

and a single unreported case may not affect ADR database) (Table 2) would significantly influence ADR-reporting among the doctors working in a hospital of North India. However, complacency, fear, financial incentives and bureaucracy involved in filling in the ADR reporting form would have a little influence on the respondents to report ADRs. Therefore ADR under-reporting in North India appears to be associated more with knowledge gaps and attitudes of the doctors rather than with personal and professional characteristics reported in other studies.

It was also evident from our study that medical practitioners are in need of information in managing ADRs especially information on ADRs to newer drugs. We observed that medical practitioners of our study sites were enthusiastic and encouraging as considerable number of responders of questionnaire survey expressed that they were in need of more feedback either in terms of discussing on ADRs during monthly academic meeting and publishing bulletin on ADRs. Few of the responders suggested that pharmacists should educate nursing staff in reporting and managing ADRs. Doctors opined that adopting the ADR reporting system which is simple to operate, monitoring the newer drugs, creating wider publicity among medical staff and pharmacists involvement would enhance ADR reporting rates. Several studies have shown that not only improving knowledge and awareness of ADR reporting can increase the reporting rates but also the convenient ADR reporting system. In addition, doctors felt that providing more information to them on reported ADRs may assist them in better management of patient. Providing assistance therefore may likely to encourage doctors to report more often than ever.

In our survey, majority (95%) of responders not only reported that ADR reporting and monitoring system is benefiting the patients but also opined (92%) that pharmacist's involvement in the detection, reporting, monitoring and management of adverse drug reactions is very useful. This suggests that trained and skilled pharmacists could be of value to medical practitioners in detecting, reporting and managing ADRs.

The major limitation of our study is that the study findings could not be applied to the wider medical community as the study was restricted to physicians practicing in hospital setup Therefore we recommend that several studies of similar kind especially in community setup scattered throughout the nation need to be conducted to know the attitudes of community doctors and other healthcare professionals towards ADR reporting so as to develop strategies to improve the ADR reporting system in India.

Our study strongly suggests that there is greater need to create awareness and to promote the

reporting of ADR among healthcare professionals of the country. Only such approach can greatly influence in bringing reporting culture among healthcare professionals and may improve the reporting rates of ADR in our country. Pharmacists, as doctors opined that their involvement may increase the reporting rate, have a greater role to play in the area of pharmacovigilance.

5.0 CONCLUSION

There are gaps between knowledge and ADRs reporting among doctors working in a hospital in North India. These gaps need to be filled by improved training in pharmacovigilance and risk perceptions of drugs. It may take the doctors some time to fully accept ADR reporting as a role if continuous medical education, reminders and awareness on the ADR reporting scheme are not instituted in the hospital. Attitudinal and cultural changes, whereby ADR reporting is seen as an integral part of the clinical activities of the doctors, are very necessary for a long term improvement of ADR reporting.

REFERENCES

1. Lazarou J, Pomeranz BH, Corey PN: reactions studies. JAMA 1998, 279:1200-1205.
2. Pirmohamed M, James S, Meakin S, Green C, Scott AK, et al.: Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. Br Med J 2004, 329:15-19.
3. Oshikoya KA: Adverse drug reaction in children: types, incidence and risk factors. Nig J Paediatr 2006, 33:29-35.
4. Martinez-Mir I, Garcia-Lopez M, Palop V, Ferrer JM, Rubio E, Morales-Olivas FJ: A prospective study of adverse drug reactions in hospitalized children. Br J Clin Pharmacol 1999, 47:681-688.
5. Ayani I, Aguirre C, Gutierrez G, Madariaga A, Rodríguez-Sasiaín JM,Martínez-Bengoechea MJ: A cost analysis of suspected adverse drug reactions in a hospital emergency ward. Pharmacoepidemiol Drug Saf 1999, 8:529-534.
6. WK, Pantaleo N: Evaluation of outpatient adverse drug reactions leading to hospitalization. Am J Health Syst Pharm 2003, 60:253-259.
7. Edwards I, Olsson S: WHO: global monitoring. In Pharmacovigilance Edited by: Mann RD, Andrew E. Chichester: John Wiley & Sons; 2002:169-182.
8. Ahmad SR: Adverse drug event monitoring at the Food and Drug Administration. J Gen Intern Med 2003, 285:437-443.

9. Wysowsky DK, Swartz L: Adverse drug event surveillance and drug withdrawals in the United States, 1969–2002: the importance of reporting suspected reactions. Arch Intern Med 2005, 165:1363-1369.
10. Lexchin J: Is there a role for spontaneous reporting of adverse drug reactions? CMAJ 2006, 174:191-192.
11. Lopez-Gonzalez E, Herdeiro MT, Figueiras A: Determinants of under-reporting of adverse drug reactions: a systematic review. Drug Saf 2009, 32:19-31.
12. Son JK, Grahame-Smith DG: Adverse drug reaction in a hospital general medical unit meriting notification to the Committee on Safety of Medicines. Br J Clin Pharmacol 1996, 42:423-429.
13. Feely J, Moriarty S, and O'Connor P: Stimulating reporting of adverse drug reaction by using a fee. Br Med J 1990, 300:22-23.
14. Inman WH: Attitudes to adverse drug-reaction reporting. Br JClin Pharmacol 1996, 41:433-435.
15. Van Grootheest AC, Van Puijenbroek EP, de Jong-van den Berg LT: Contribution of pharmacists to the reporting of adverse drug reactions. Pharmacoepidemiol Drug Saf 2002, 11:205-210.
16. Morrison-Griffiths S, Walley TJ, Park BK, and Breckenridge AM, Pirmo- hamed M: Reporting of adverse drug reactions by nurses. Lancet 2003, 361:1347-1348.
17. Blenkinsopp A, Wilkie P, Wang M: Patient reporting of suspected adverse drug reactions: a review of published literature and international experience. Br J Clin Pharmacol 2006, 63:148-56.
18. National Pharmacovigilance Centre (NPC), NAFDAC, Nigeria. Safety of medicines in Nigeria: a guide for detecting and reporting adverse drug reactions. NAFDAC-NPC-NIG-2004-1.Lagos: National Agency for Food and Drug Administration and Control; 2004.