



Research Article

Knowledge, Attitude and Practices on Spontaneous Reporting of Adverse Drug Reactions at Fortis Escorts Hospital, Jaipur

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ABSTRACT

Background: Caregivers and bedside Doctors have an outstanding position in monitoring subjects under drug therapy and they are the 1st to observe adverse drug reactions (ADRs). Pharmacovigilance studies and knowledge of ADRs by Doctors widely assist in maximizing the quality of hospitals pharmacotherapy and effectively minimize the occurrence of ADRs.

Aims and Objective: This study was conducted to evaluate the knowledge, attitude, and practices (KAP) regarding the report of ADR among prescribers at the Fortis Escorts Hospital, Jaipur, also to have a better understanding why there is under reporting of these ADRS.

Methods: Questionnaire based data collection method was carried out at Fortis Escorts hospital, Jaipur. This pretested KAP questionnaire comprising of 15 questions (knowledge 6, attitude 5, and practice 4) was administered to 436 prescribers. The questionnaires were evaluated to determine their completeness (maximum score 20) and the pattern of ADR reporting responses. The filled KAP questionnaires were statistically analyzed in question-wise and their percentage value was calculated using Microsoft excel spread sheet and online statistical software.

Results: A total of 260 (61%) prescribers completed the questionnaire (mean score of completion 18.04). The response rate of resident doctors (70.7%) was better than consultants (34.5%) ($P < 0.001$). ADR reporting was considered important by 97.3% of the respondents found ADR reporting important; primarily for improving patient safety (28.8%) and identifying new ADRs (24.6%). Most the respondents (56%) reported that they'll always want to report serious ADRs. However, only 15% of the prescribers had reported ADRs previously. The reasons cited for this were lack of information on where (70%) and how (68%) to report and the lack of access to reporting forms (49.2%). The two most preferred methods for reporting were e-mail and personal communication (56% and 42%).

Conclusion: The level of knowledge of these Doctors were moderate and practice was very poor, although Doctors had a high level of attitude. Pharmacovigilance programs in India requires necessary measures to be undertaken. Doctors should be trained spontaneously on how to report ADRs.

INTRODUCTION:

The drug and manufacturing body of India; Central Drugs Standard Control Organization (CDSCO), located at New Delhi, under the aegis of Ministry of Health and Family Welfare, Government of India, has introduced a nationwide pharmacovigilance program in July 2010 for monitoring ADRs in the country to protect the nation's public health.[5] Pharmacovigilance is the study and overall activities concerning the detection, assessment, understanding, and prevention of adverse effects or any other possible problems related to drugs. Spontaneous and voluntary reporting is the most commonly used ADR reporting system worldwide. Meanwhile, significant less reporting of ADRs by healthcare professionals has been identified as a serious setback of the voluntary reporting system and is prevalent in different countries. [4] Previously, many studies have underlined the importance of ADR reporting. The motivation behind the establishment of the ADR reporting system is the fact that ADRs are common, yet preventable causes of illness and disability. ADRs are ranked as the top 10 causes of mortality in the United States of America (USA), United Kingdom (UK) and Europe. For instance, 6.5% of all hospital admissions in the UK were caused by ADRs. In terms of the economic burden, this is equivalent to £466 million annually. [5] Hence, establishing a well-organized and efficient pharmacovigilance system to evaluate and monitor the safety of medicines in clinical use is crucial. The current system of reporting depends on spontaneous reports submitted by doctors and pharmacists. Involvement of consumers in ADR reporting can reinforce their rights and ensure the safer use of medicines in future. Consumers' experiences and views can provide additional information about ADRs. ADR reporting by consumers has been possible for almost 15 years in developed countries. However, only a few countries currently accept patient reports. Countries like Sweden started consumer reporting for ADRs in 1978 and the USA followed in 1993. Denmark started consumer reporting in 2003, Canada and Australia started in 2003 the Netherlands in 2004, and the UK in 2005. [1] In Europe and the United States there is now over two decades of experience regarding consumer ADR reporting. A study done to investigate the relative contribution of patient reporting to signal detection in the UK showed that patient reporting may provide

a positive complementary contribution to the reports received from health care practitioners (HCPs). [5] Similarly, another study indicated that free text comments often contained in case reports directly submitted by subjects can be of value in pharmacovigilance and provide important information on how a drug may affect the person using it and the influence it may have on his or her personal life.

MATERIAL AND METHOD

This was a cross-sectional, observational, questionnaire-based study conducted at tertiary-care teaching hospital during February to March 2017. A prevalidated 15-item questionnaire (knowledge 6, attitude 5, and practice 4) containing open and close-ended questions regarding knowledge and perception toward ADRs was developed after referring previous studies conducted about pharmacovigilance and consumer pharmacovigilance.

Those who were not willing to participate or did not return the questionnaire within the stipulated time were excluded. Four questions were open ended, while the others were close ended. The questionnaire was designed in such a way that the answers were not mutually exclusive. More than one answer was allowed in some questions. It was consensually validated by faculty members and then pretested on 10 Doctors. The study was approved by institutional human research ethics committee and waiver of written informed consent was obtained as the questionnaire was made anonymous. The data collected from the questionnaire was entered into SPSS software. w2 -Test was used to see the association between variables. A p-value of less than 0.05 indicated statistical significance.

Before study, The KAP questionnaires towards Pharmacovigilance and ADRs were developed and peer viewed of all questions by expert faculties from pharmacology and different clinical department of the institute. All Doctors of different clinical department were consented and briefed about purpose of the study. All study participants were contacted directly in their respective department and distributed the questionnaires, given 30 minutes to fill them. Any clarification needed in understanding the questionnaires and additional time to filled form was provided. The KAP survey questionnaire was analyzed, question wise and their percentage value

was calculated with the help of Microsoft excel spread sheet.

The questionnaires were evaluated for their completeness, and completeness scores were assigned as pre-decided (maximum score: 20). One point was given to each answered question (15 points) and the remaining five points were allotted for the demographic information (3 points), suggestions given (1 point), and one point was allotted for completing the concluding information. The knowledge of the respondents was also scored (out of 17) as per their responses to questions 2, 3, 9, 10, 13, and 15. The information was recorded and analyzed using the Microsoft Excel worksheet (Microsoft Office 2016) and the Chi-Square test. P value less than 0.05 was statistically significant.

RESULTS

The questionnaire was administered to 426 prescribers, of whom 139 were faculty consultants and 287 were postgraduate students (resident doctors). A total of 260 questionnaires were returned, giving a response rate of 61%. The average time taken to complete the questionnaire was 11 minutes and the mean score of completeness of the questionnaire was 18.04 out of 20. Of the total respondents (260), 18.5% were faculty members, while the rest were postgraduate students. The response rate of postgraduate students (70.7%) was significantly higher than that of faculty members (34.5%) ($P < 0.001$). Even as the attitude and practice of the respondents was not quantified, an attempt was made to quantify the knowledge of the

respondents. It was calculated by assessing the responses to certain questions. A maximum score of 3 was assigned to question 2, while a maximum score of 2 was assigned to questions 3, 9, and 10. Questions 13 and 15 were assigned a maximum score of 1 and 7, respectively. One point was given for each correct option. Using this scoring system, it was observed that the overall mean score of the knowledge of the respondents was 6.46 (38.2%), and faculty and postgraduate students scored 7.27 (42.7%) and 6.28 (36.9%), respectively.

A total of 221 respondents out of 260 (85%) stated that they encountered up to five ADRs / week. One hundred and sixteen respondents (44.6%) mentioned that up to 10% of the ADRs they encountered were serious. The common drug groups observed to cause ADRs were antimicrobials (41.6%) and analgesics (15.9%). The common ADRs observed were cutaneous (35.7%) (which included rashes, urticaria, anaphylaxis, and SJ syndrome) followed by gastrointestinal adverse effects (27.7%) (which included nausea, vomiting, gastritis, and diarrhea). Adverse drug reaction reporting was important by 97.3% of the respondents. The need to improve patient safety (28.8%) and the detection of new ADRs (24.6%) were the common reasons cited for reporting ADRs [Table 1]. Thirty-nine (15%) respondents said that they had reported an ADR previously. The ADRs were usually reported to an ADR reporting center (41%), pharmaceutical companies (33.3%), presented at conferences, or published in journals (15.4%).

Reasons	Frequency (%)
To Identify relatively safe drugs	43 (13.7)
To identify and detect new ADRs	77 (24.6)
To improve patient safety	90 (28.8)
To share information regarding ADRs with colleagues	53 (16.9)
To measure the incidence of ADRs	50 (16)

The reasons cited by prescribers for not reporting ADRs are listed in Table 2. Lack of knowledge on how (68%) and where (70%) to report the ADRs and lack of easy access to ADR reporting forms (49.2%) were the major factors that discouraged reporting.

Although both groups of respondents cited similar reasons for not reporting ADRs, a greater percentage of residents responded that they did not report ADRs because they did not know how to do it ($P = 0.02$) [table:2]

Factors	Frequency(%)
Don't know how to report	177 (68) *
Legal liability issues	45 (17.3)

It is not important	34 (13)
Subject confidentiality issues	32 (12.3)
Don't know where to report	182 (70)
Lack of access to ADR reporting forms	128 (49.2)
Instead of ADRs report subject management is important	75 (28.8)
Concerns about professional liability	37 (14.2)
Others (non-serious ADRs, manpower shortage	4 (1%)

*P<0.05 (Chi Square test) (PG Residents Vs. Faculty members)

However, both groups had similar views on which ADRs should be reported, with a preference for serious ADRs. Fifty-one percent of the respondents stated that they would like to report all ADRs, while 56% said that they would like to report only serious

ADRs. As against this, 34.2% said they would report ADRs caused by new drugs. Most respondents, however, did not emphasize on reporting ADRs to herbal and non-allopathic medicines [Table 3].

ADRs to be reported	Frequency (%)
ADRS related to herbal and non-allopathic drugs	19 (7.3)
All ADRs	133 (51)
Unknown ADRs to old drugs	57 (22)
ADRs to vaccines	53 (20.3)
All serious ADRs	146 (56)
None	1 (0.3)
others	1 (0.3)
ADRs to new drugs	89 (34.2)

The respondents were tested for their awareness about the ADR reporting center. Twenty-five of them were aware that ADRs could be reported to hospital pharmacology department. Seven respondents were aware of other ADR reporting systems worldwide.

A total of 101 (38.8%) respondents said that they shared information about ADRs observed by them, mostly with their colleagues and teachers. Textbooks (80.4%) and scientific journals (54.2%) were the preferred sources from which the

respondents updated their knowledge regarding ADRs of new drugs, followed by the Internet (50%), seminars (46.5%), and drug advertisements (33.8%). A greater number of faculty referred to scientific journals as a source of information about ADRs of new drugs, as compared to the residents (P = 0.002). It was however evident that most respondents relied on multiple sources of information for their knowledge about ADRs [Table 4].

Sources	Frequency (%)
Internet	130 (50)
Seminars	121 (46.5)
Direct mail brochures	12 (4.6)
Drug advertisement	88 (33.8)
Text books	209 (80.4)
Journals	141 (54.2) *
Medical Representatives	50 (19.2)

*P<0.05 (Chi Square test) (PG Residents Vs. Faculty members)

Most of the respondents felt that they, as medical practitioners (92.3%) were qualified to report ADRs. Dentists (41.2%), Doctors (34.2%), and pharmacists (34.2%) were also considered qualified for reporting ADRs. Interestingly about 26.2% of the respondents opined that subjects should also be allowed to report ADRs. Opinion was sought from the respondents about their preferred mode of reporting. Electronic media like e-mails or websites (56%) and reporting by a personal communication to the reporting center (42%) were the methods preferred by most respondents.

Several measures were suggested for improving ADR reporting. These included creating awareness about ADR monitoring among the healthcare personnel and consumers, through appropriate educational interventions, making ADR reporting forms easily accessible, and simplifying the process of reporting. Feedback provided to the reporters about the causality of ADRs reported by them would also encourage them to continue reporting. It was also suggested that pharmacologist(s) from the institute should be posted in clinical wards to promote and assist in the reporting and management of ADRs.

DISCUSSION:

The factors, which have resulted in under-reporting of ADR according to our study, include lack of knowledge about ADR forms for reporting ADR, ignorance about pharmacovigilance system, and not being sure of the type of reactions to be reported. According to a study conducted by Vallano et al., four types of obstacles to spontaneous reporting were considered particularly important: Problems with the ADRs diagnosis; problems with the usual workload and lack of time; problems related to the organization and activities of the pharmacovigilance system; problems related to potential conflicts. Most of the studies in the past had explored and reported knowledge and perception toward ADR among health-care professionals, pharmacists, and medical students as study population; but studies on awareness among subjects are limited.[12–14] This study was conducted to find out awareness of ADR among the subjects who actually experienced the same. Majority of respondents belonged to rural areas. This study showed that majority study subjects understood ADRs as side effects that can occur after taking any medicine. Study conducted by Jha et al.[14] had also showed similar results. This study found that respondents from urban areas were more aware about ADR than those from rural areas.

Increasing trend in awareness as per education level was observed. Approximately one-third of respondents had experienced side effects after taking a medicine in the past.

A study conducted by Elkalmi et al.[15] in Malaysia showed same results. In this study, irrespective of their educational background, participants did not report any experience of side effects due to their medications. Underreporting is a major threat to success of pharmacovigilance program and is a matter of great concern. None of the respondents were aware of the fact that there was an ADR reporting center at this institute and they did not report any ADR till now. Lack of awareness among them is also one of the reasons responsible for underreporting of ADR. This also highlights that subjects might not have proper knowledge about the adverse effects of their prescribed medications. A study conducted in the United Kingdom reported poor knowledge of the potential side effects of their medications.[16] Spontaneous reporting of ADR can be significantly increased if the subjects are aware of ADR and its reporting system. It is, therefore, important to give adequate and sufficient information about their medications and to inform the patient about the reporting of any unexpected symptoms to their doctors or pharmacists. It is necessary to promote safe use of medicines. Majority of the respondents had perception that ADR reporting can improve patient safety and prevent recurrence of ADR.

Maximum number of respondents had positive attitude toward ADR reporting agreed to report ADRs at this institute in future when they come across the ADR. The common view shared by most of (96%) respondents that reporting of ADR is beneficial for people whereas a study conducted in Nepal also showed similar results regarding this.[14] The subjects believed that knowledge about adverse reactions would protect them from negative effects of the drugs. In this study, according to most of the subjects, information regarding ADR and its reporting can be given by awareness campaign and prescribing doctors. While similar study showed that majority of participants opined that consultation with pharmacist is the best way to educate subjects.[14] Sources of information such as campaigns, the Internet, newspapers, and television seem to play a key role in increasing awareness of the pharmacovigilance program and existence of adverse drug reaction monitoring centers. ADR reporting form for consumers is available in India

since August 2014, but educating consumers about the significance and importance of ADR reporting is required.[19] They should be encouraged to fill consumer ADR form and those reports should be addressed appropriately. This view is being supported by a review of published literature and international experience.[20]

A study from France in 2002 reported that consumers were asked to make telephone calls for registering the side effects to pharmaceutical companies and the companies entered these reports to drug safety database.[21] Greater awareness among consumers will reduce the harmful effects and suffering caused by medicines.[22] Consumer reporting can promote consumer rights and equity.[23] The Yellow Card Scheme is the UK system for collecting information on suspected ADRs to medicines. The scheme allows the safety of the medicines and vaccines that are on the market to be monitored.[24] Basically two main domains should be covered in the process of educating subjects: 1. Subjects should be aware of ADR so that they can recognize any unusual effect of medicine and contact doctor to report the same. 2. Subjects should know the existence and importance of ADR reporting system. Strengths of the Study Studies to explore and report the knowledge and perception toward ADR among subjects are limited and this study is a pioneer in India. An understanding about the current scenario of perception and awareness of pharmacovigilance among consumers in India was obtained. Limitations of the Study Subjects were from single center so results may be difficult to generalize to other populations of the country.

CONCLUSION:

This study provides a baseline idea about the knowledge and perception toward ADRs among subjects visiting an outpatient department at tertiary-care teaching hospital in India. Respondents were unaware about the process of reporting ADRs, reporting by the consumers, and the possible benefits to them by doing so. There is a strong need to do the work to make consumers aware about the same. Educational interventions are needed to improve awareness among subjects regarding importance of ADR reporting. Having a proper and effective ADR reporting system is crucial for every country as it could reduce potential health hazards such as morbidity and mortality. The economic burden associated with these hazards can also be alleviated. Even though spontaneous and voluntary ADR reporting system has been the mainstay since its inception, the status quo is now changing due to increased awareness of all stakeholders on the need to incorporate consumers into the existing reporting

system. This may partly alleviate the problem of underreporting which has plagued the system. Based on the facts presented above, it is clear that consumer reporting is the way forward to attain a proper and effective pharmacovigilance program that can address the very fundamental task of alleviating morbidity and mortality rates, as well as reducing the economic burden. Knowledge of health professionals towards ADR reporting appear to be strongly related with reporting in this study. Awareness raising program on the ADR reporting system need to be designed to health professionals by relevant bodies and ADR reporting system need to be introduced and given an emphasis at higher institution training. On top of this, establishing strong feedback and increasing options of reporting would improve the reporting system.

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