Original Article

Awareness on Adverse Drug Reaction Reporting System in India: A Consumer Survey

Ritu Pahuja*[1,2], Birendra Shrivastava[1], Pankaj Kumar Sharma[1], Kamal Kishore[2], Sandeep Mahajan[3] and Radhika Sood[4]

[1]School of Pharmaceutical Sciences, Jaipur National University, Jagatpura, Jaipur-302017, Rajasthan, India
[2]Department of Pharmacology, All India Institute of Medical Sciences, Ansari Nagar, New Delhi-110029, India
[3]Department of Nephrology, All India Institute of Medical Sciences, Ansari Nagar, New Delhi-110029, India
[4]Department of Foods and Nutrition, Lady Irwin College, University of Delhi, Sikandra Road, New Delhi-110001,India

Address for Correspondence

School of Pharmaceutical Sciences, Jaipur National University, Jagatpura, Jaipur-302017, Rajasthan, India.
E-mail: ritu.pahuja1987@gmail.com

ABSTRACT

Consumer adverse drug reaction reporting is a new concept in Pharmacovigilance which contribute to the enhancement of existing drug safety practices. At present, consumer adverse drug reactions reporting system exist in 44 countries which contributes 9% of the total adverse drug reaction reports. To begin with promoting culture of consumer adverse drug reaction reporting in our country, it is first imperative to check the awareness on adverse drug reaction reporting among consumers.

Objective: To determine level of consumer or patient awareness on adverse drug reaction reporting system in India.

Methods: The present study was a cross-sectional study which was conducted for a period of 4 months among patients hospitalised at All India Institute of Medical Sciences, New Delhi.

Main Outcome Measures: Knowledge on side effect or adverse effect of medicines, proportion of respondents experienced adverse drug reactions, whether participants reported adverse drug reactions, their perception towards reporting adverse drug reactions, awareness on existing system of Pharmacovigilance in India and their preferable mode of reporting adverse drug reactions in future.

Results: Of the 1000 questionnaires distributed, only 770 completed questionnaires were returned giving the overall response rate as 77%. A majority (74%) of respondents were aware of adverse drug reactions, of which only 29.4% had experienced adverse drug reaction. Only 8.9% of respondents thought of reporting adverse drug reactions while 40.6% considered it is important to report adverse

drug reaction. Doctors were considered to be the right person for reporting adverse drug reactions among 73.2% of respondents. A poor awareness was observed among consumers (4%) on the existence of National Pharmacovigilance Programme in India. Over 78.5% of respondents feel consumers should be involved in adverse drug reaction reporting and 86% were willing to report adverse drug reactions if they were provided with the convenient method of adverse drug reaction reporting. Majority (53.8%) of respondents found online reporting of adverse drug reactions as the most convenient method.

Conclusion: The survey of awareness among patients at All India Institute of Medical Sciences indicates low awareness and it could be improved by introducing educational interventional programs.

Keywords: Adverse drug reactions reporting, Awareness, Consumers, Pharmacovigilance, India.

INTRODUCTION

Medicines have, beyond any doubt, proved to be a boon for humanity and it fights against disease and suffering. However, like most other useful things, medicines come with inherent risks associated with their use, called Adverse Drug Reactions (ADRs). These reactions, though mild in most cases, have the potential to cause disability and even death. ADRs are often referred to as "any noxious and unintended effects of a drug that occurs at doses normally used in human beings for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function[1]. They account for approximately 4.2% to 6.0% of all hospital admissions and they occur in about 10%-20% of all hospitalized patients[2,3].

The process of identifying and preventing ADRs associated with post-marketed drugs i.e. Pharmacovigilance is becoming increasingly important due to the potential harmful effects of drugs on patient's health, economic burden associated with ADRs and circulation of large number of over-the-counter and counterfeit drugs in the market[4].

Spontaneous Reporting Systems (SRSs) being the most widely used method of Pharmacovigilance has traditionally been the sole responsibility of Health Care Professionals (HCPs). In addition to HCPs, consumers or patients also plays cardinal role in Pharmacovigilance as they can expedite the process of ADR detection[5]. It promotes better understanding of ADRs as the reports coming from patients are more direct, detailed and explicit than indirect reports from HCPs. It has the potential to add value to Pharmacovigilance by reporting types of drugs and reactions different from those reported by HCPs; generating new potential signals; and describing suspected ADRs in enough detail to provide useful information on likely causality and impact on patients' lives[6]. Furthermore, it provides the patients an opportunity to learn how to manage their medications and communicate better with HCPs.

There is lot of debate whether consumer reporting will be of any advantage? Yes, it cannot replace the existing Pharmacovigilance program, but it can complement and strengthen it.

Consumer reporting as a new concept, will enhance the impact of the reporting system and can improve the knowledge about the ADRs of over-the-counter medicines, the off-label use of medications, traditional medicines and alternative medicines about whose risks doctors may be not familiar enough[7]. At present, consumer ADR reporting systems exist in 44 countries which contributes 9% of the total ADR reports, the remaining coming from HCPs[8]. The program was first commenced in the United States where the consumers received the opportunity to report directly to the Food and Drug Administration (FDA) in 1960[9]. Similarly, in 2003 consumers in the Netherlands started reporting ADRs to Lareb, a foundation established separate to the country's national drug regulatory authority[10]. Denmark joined the league soon after the Netherlands in 2003, followed by Italy in 2004. A consumer organization, Test-Achats/Test-Aankoop (TA), was established in Belgium in 2006 to accept reports from patients and transfer them to Federal Agency of Medicines and Health Products (FAMHP) [9]. The Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK made substantial efforts to promote consumer ADR reporting. The website of Swedish Medical Products Agency (MPA) added an interactive section to enable patients and consumers to report ADRs in June 2008. Norwegian Medicines Agency started accepting electronic reports directly from patients since March 2010[9].

Another question on the consumer reporting of ADRs is regarding is the quality of reports coming from them. Literature on consumer reporting shows that none of the countries with consumer reporting systems had reported poor quality of patient reports to be an issue[5].

The major problem with the SRSs is the under-reporting of ADRs. Hazel and Shakir published a review article analyzing the data from 12 countries and reported median under-reporting rate as 94%[11]. Direct reporting by patients have been identified as an important strategy to address under-reporting of ADRs[12]. Reporting rate of ADRs in India is less than 1%, which is below the world wide reporting rate of 5%[13]. Given lower rate in India, it is important to increase awareness on ADR monitoring among HCPs and consumers. To begin with promoting the culture of consumer ADR reporting in our country, it is first important to check consumer awareness on ADR reporting. Thus, the present study was designed to assess the consumer's awareness on ADR reporting system in India and to determine their views on preferred methods of ADR reporting.

MATERIALS AND METHODS

Study centre

The study was conducted at All India Institute of Medical Sciences (AIIMS), New Delhi which is a premier tertiary care centre with comprehensive facilities for education, research and patient care. The institute provides full time postgraduate and doctoral courses in 42 disciplines and has a nursing college to train nurses in various disciplines. AIIMS with a bed strength of 2048 beds has also been nominated as ADR monitoring centre and the same is coordinated by the Department of Pharmacology.

Study design

A cross-sectional survey was carried out to determine patient awareness on ADR reporting systems in India.

Study duration

This study was conducted for a period of 4months (August 2012 – November 2012) after obtaining approval from Institutional Ethics Committee of AIIMS, New Delhi.

Study population

The survey questionnaire was administered to 1000 patients visiting main hospital at AIIMS.

Inclusion criteria

- All the patients admitted to the in-patient departments.
- Patients agreed to participate in the survey and willing to co-operate during the study.

Exclusion criteria

- Patients visiting out-patient departments were excluded.

Study tools

A questionnaire was developed after extensive review of literature, discussion with experts in the field of Pharmacovigilance, mentors and colleagues.

The final questionnaire consisted of 11 questions and was also translated into regional Hindi language in order to increase acceptability among consumers who do not understand English language.

Question 1 and 2 were designed to evaluate demographic profile of consumers.

Questions 3 to 10 were designed to assess consumers knowledge on the ADR reporting system and,

Question 11 was designed to check preferable methods for reporting ADRs among consumers.

The content validity and reliability of the questionnaire were measured prior to using the questionnaire.

The questionnaire was validated through a pilot study. The questionnaire was distributed among a group of randomly selected 50 patients visiting at AIIMS. The survey questionnaire was analyzed and percentage of response was calculated. As a result of validation, some of the questions were altered and reframed to elicit a better response. The data collected from the pilot study was not included in the results of the study.

Distribution and collection of data

The questionnaire was distributed individually to patients. Before filling up the questionnaire, the objectives of the study and the contents of the questionnaire were personally briefed to each participant. The respondents were asked to answer and return the questionnaire.

Data analysis

The data collected was consolidated in Microsoft Excel spread sheet (2007). The consolidated data was rechecked for completeness and accuracy. The question-naire was analysed and percentage of response was determined. The demographic data was evaluated by using mean, standard deviation and percentage as appropriate.

All statistical calculations were performed using Statistical Package for Social Science (SPSS) Version 20.0.

RESULTS

A total of 1000 questionnaires were distributed, of which 770 completed questionnaires were returned. The overall response rate was found to be 77%. The analysis in the study is based on the 770 respondents who participated in the study. Demographic details of the respondents are shown in Table 1.

The age group ranged from 25-50 with a mean age of 42.6 (SD =12.42) years, 57.8% of respondents were found to me female and 42.2% were males.

Most of the respondents (31.2%) were matriculate, 26% were graduates, 20% completed post-graduation, 12.9% completed high school, 8.5% were below matriculates while 1.4% respondents did not provide information on the highest educational level attained.

A majority of the respondents were found to be working full-time, 22.1% were retired population, 7.0% were working part-time, 6.8% were not working whereas 0.6% did not mention their profession.

Table 2 summarizes the responses provided by consumers regarding awareness on ADR reporting in India. Upon evaluation, it was observed that 74% of respondents were aware of ADRs, of which only 29.4% have experienced ADR. Only 8.9% of respondents thought of reporting ADRs while 40.6% considered it is important to report ADR. A majority of respondents (73.2%) considered doctors to be the right person to report ADRs. A poor awareness was observed among consumers (4%) on the existence of National Pharmacovigilance Programme in India. Over 78.5% of respondents feel consumers should be involved in ADR reporting and 86% were willing to report ADRs if they were provided with the convenient method of ADR reporting.

Figure 1 illustrates the respondent's views on preferable method of ADR reporting. It reflects that the majority (53.8%) of respondents found online reporting of ADRs as the most convenient method followed by one-third of respondents (37%) who preferred drop-box in the hospital in both in-patient and out-patient departments as the preferable method for ADR reporting. However, a relatively lower response was observed for the remaining 3 methods of ADR reporting.

DISCUSSION

In this study, the sample of over 1000 subjects was representative of general population (patients) vishing AIIMS hospital, New Delhi. The overall response rate in our study was found to be 77% which was comparable to the response rate i.e. 74% reported from a study conducted in Nepal to assess the Pharmacovigilance knowledge among patients at a teaching hospital[14].

The findings from our study indicates that many consumers (29.4%) experience ADRs however, only few 8.9% thought of reporting it. This indicates possibly lack of awareness of the reporting mechanisms as a major limiting factor. The study results were found to be lesser than with a similar UK study in which reporting rate of ADRs among consumers was found to be 23.5%[15].

Although 74% of the respondents were aware what an ADR is, 73.3% considered only doctors are to be the right person among other HCPs to report ADRs, 40.6% considered it is important to report ADRs while very few 4% were aware on the existence of National Pharmacovigilance Programme in India. The findings could be attributed to the lack of knowledge among consumers on what ADRs to report, were to report and how to report.

Maximum number of respondents 662 (86%) had positive attitude towards ADR reporting if they are provided with the convenient method to report ADRs. This indicates their willingness to participate provided that proper knowledge is imparted to them. Thus, their participation will contribute to generate more ADR reports particularly the drug induced ADRs which are not reported by HCPs and identification of potential medication risk. A UK study has found that, compared with reports made by HCPs, patient ADR reports tend to be longer, contain more suspected ADRs, and refer to more than one suspected drug[16].

The study results on preferable method of reporting ADRs by consumers in future were found to be interesting. With the increasing trend of internet usage, it is not surprising that majority (53.8%) of the respondents preferred online reporting of ADRs as the most convenient method. Following which 37% considered putting

the ADR forms in the drop box in hospitals whereas only 4% considered the telephonic method of reporting ADRs to Pharmacovigilance cell. In contract to this a questionnaire based study reported that people will prefer to report ADRs by post (59.8%), 32.8% preferred online reporting and only 6.3% by telephone[3]. Therefore, it is recommended to conduct few pilot studies using internet, postal and telephonic methods of ADR reporting and determine the effectiveness, strengths and weakness of each ADR reporting methods among consumers. LAREB in Netherlands piloted it for one year between April 2003 and March 2004 before it decided to continue the reporting station for patients[17].

The major limitation of our study is that the study was conducted in a one hospital setting and region in India so it is difficult to extrapolate findings to a wider medical community. Additionally, only one method for collecting survey data was applied, however, the use of other methods like online survey and telephonic survey would have helped to collect more data in short span of time.

CONCLUSION

This study provides a baseline idea about the knowledge and perception of consumers towards ADR reporting. The results of our study concludes, consumer awareness towards ADR reporting was found to be low and could be improved. Introduction of educational interventional programs in hospitals, clinics and social media will create awareness and encourage consumers to report ADRs.

ACKNOWLEDGEMENTS

The authors acknowledge all the respondents for their time and active participation.

REFERENCES

1. WHO. International drug monitoring: the role of national centres. Tech Rep Ser WHO 1972, p 498.
2. Muehlberger N, Schneeweiss S, Hasford J. Adverse drug reaction monitoring-cost and benefit considerations. Part I: frequency of adverse drug reactions causing hospital admissions. *Pharmacoepidemiology & drug safety* 1997; 6 (S3): 71-77.
3. Classen DC, Pestotnik SL, Evans RS, Lloyd JF, Burke JP. Adverse drug events in hospitalized patients-excess length of stay, extra costs and attributable mortality. *Journal of the American Medical Association* 1997; 277: 301-6.
4. Moore TJ, Psaty BM, Furberg CD. Time to act on drug safety. *Journal of the American Medical Association*, 1998; 279:1571-1573.
5. Blenkinsopp A, Wilkie P, Wang M, Routledge P.A. Patient reporting of suspected adverse drug reactions: a review of published literature and international experience. *British Journal of Clinical Pharmacology*. Feb 2007; 63 (2): 148-156.
6. Avery AJ, Anderson C, Bond CM, Fortnum H, Gifford A, Hannaford PC et al. Evaluation of patient reporting of adverse drug reactions to the UK 'Yellow Card Scheme': literature review, descriptive and qualitative analyses, and questionnaire surveys. *Health Technology Assess* 2011 May; 15(20):1-234.
7. Ahmed AM, Izham IM, Subish P. The Importance of the Consumer Pharmacovigilance System in Developing Countries: A Case of Malaysia. *Journal of Clinical and Diagnostic Research* 2010 Aug; 4:2929-2935.
8. Margraff F, Bertram D. Adverse drug reaction reporting by patients: an overview of fifty countries. *Drug Safety* 2014. Jun; 37 (6): 409-19.
9. Herxheimer A, Crombag MR, Alves C TL. Direct patient reporting of adverse drug reactions. A twelve-country survey and literature review. Briefing Paper Health Action International. January 2010.
10. Langen J, van Hunsel, Passier, van den Berg L, van Grootheest K. Adverse Drug Reactions

Reporting by Patients in the Netherlands. *Drug Safety* 2008; 31:515-24.
11. Hazell L, Shakir SA. Under-reporting of adverse drug reactions: a systemic review. *Drug Safety*, 2006; 29:385-396.
12. National Statistics Opinions (Omnibus) Survey. User guide. URL: www.statistics.gov.uk/about/services/omnibus/downloads/User_Guide.pdf (accessed 8 October 2014).
13. Amrita P, Kharbanda B. Knowledge, attitude and skills of nurses of Delhi towards adverse drug reaction reporting. *Indian J Pharm Pract* 2012; 5: 45-51.
14. Jha N, Rathore DS, Shankar PR, Gyawali S. Pharmacovigilance Knowledge among Patients at a Teaching Hospital in Lalitpur District, Nepal. *Journal of Clinical Diagnostic Research*. 2014 March: 8(3): 32-4.
15. Fortnum H, Lee AJ, Rupnik B, Avery A; Yellow Card Study Collaboration. Survey to assess public awareness of patient reporting of adverse drug reactions in Great Britain. *J Clin Pharm Ther* 2012; 37: 161-165.
16. Avery AJ, Anderson C, Bond C et al. Evaluation of patient reporting to the yellow card scheme. *Health Technology Assessment* 2011 May; 15(20):1-234.
17. Van Grootheest AC, Passier JL, van Puijenbroek EP. Direct reporting of side effects by the patient: favourable experience in the first year. *Ned Tijdschr Geneeskd* 2005; 149:529-33.

Table 1. Socio-demographic characteristics of respondents

Characteristic	Respondents
Age group (Years)	
18-25	14.2% (109)
25-50	62.8% (484)
>50	23.0% (177)
Gender	
Male	42.2% (325)
Female	57.8% (445)
Highest level education	
Below matriculation	8.5% (66)
Matriculation	31.2% (240)
12^{th}	12.9% (99)
Graduation	26% (200)
Post-graduation or above	20% (154)
None of the above	1.4% (11)
Working status	
Full time	63.5% (489)
Part time	7.0% (54)
Not working	6.8% (52)
Retired	22.1% (170)
None of the above	0.6% (5)

Table 2. Reported answers to questions pertaining awareness on ADR reporting in India

Questions	% (n)
Do you know what an adverse drug reaction (side effect) is or unwanted, noxious effect of a medicinal product?	
Yes	74 (570)
No	26 (200)
Have you ever experienced an adverse drug reaction (side effect) or unwanted, noxious effect of a medicinal product in your life?	
Yes	29.4 (226)
No	70.6 (544)
Have you ever thought of reporting adverse drug reaction (side effect) or unwanted, noxious effect of a medicinal product?	
Yes	8.9 (69)
No	91.1 (701)
Do you think it is important to report the adverse drug reaction (side effect) or unwanted, noxious effect of the medicinal products?	
Yes	40.6 (313)
No	59.4 (457)
According to you, who is the right person to report an adverse drug reaction (side effect)?	
Doctor	73.2 (564)
Nurse	16.8 (129)
Pharmacist/chemist	3 (23)
Drug company	7 (54)
Do you know that in India there is a National Pharmacovigilance Program for reporting of adverse drug reactions with main goal of patient safety?	
Yes	4 (31)
No	96 (739)
Do you think that consumers should be involved in reporting of adverse drug reaction (side effect) of the medicinal products?	
Yes	78.5 (604)
No	21.5 (166)
If you are provided with an easy option to report any adverse drug reaction due to medicinal product, would you report it?	
Yes	86 (662)
No	14(108)

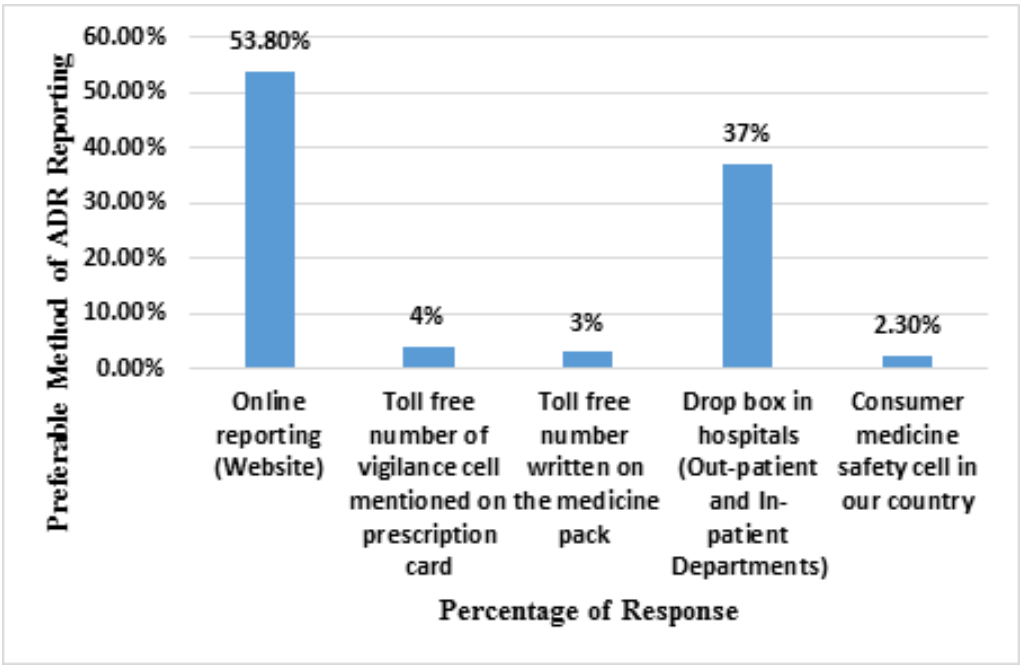

Figure 1. Consumer's preferable method for reporting ADRs