Print ISSN: 2319-2003 | Online ISSN: 2279-0780

IJBCP International Journal of Basic & Clinical Pharmacology

DOI: http://dx.doi.org/10.18203/2319-2003.ijbcp20193177

Original Research Article

# Knowledge, attitude and practice among consumers about adverse drug reaction reporting

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**Received:** 03 May 2019
**Accepted:** 16 July 2019

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## ABSTRACT

**Background:** Background: Adverse Drug Reaction (ADR) reporting by consumers is quite low in India. Assessing knowledge and attitude of consumers regarding ADR reporting and observing practice of ADR reporting among them can help explore probable causes for underreporting of ADRs by consumers.
**Methods:** This was a cross-sectional study conducted in a tertiary care teaching hospital using investigator-administered questionnaire and interviewing indoor patients of Surgery, Medicine, Obstetrics & Gynaecology and Dermatology departments. The questionnaire was prepared to assess knowledge, attitude and practice of consumers about ADR reporting. Data was analysed using mean, standard deviation and percentages.
**Result:** A total of 820 consumers of medicines were included. It was found that 32.2% consumers were not aware that a drug can produce adverse effects. After being explained about adverse drug reactions, 94.6% consumers felt that adverse drug reactions should be reported. However, 98.8% consumers were not aware of Pharmacovigilance Programme of India. After consulting about consumer reporting programme, majority of respondents (96.1%) felt that the direct consumer reporting programme helps reporting of ADRs. Moreover, 93.7% of consumers were willing to use it to report ADRs in future. Consumers preferred the Telephonic method with a Toll free number for ADR reporting followed by informing a health care professional.
**Conclusion:** Poor knowledge and awareness about ADR reporting is the major factor for low to nearly absent ADR reporting by consumers in India.

**Keywords**: Adverse Drug Reaction, Adverse Drug Reaction Reporting, Consumers, Pharmacovigilance Programme of India

## INTRODUCTION

WHO defines Adverse Drug Reaction (ADR) as "a response to a drug which is noxious and 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] Adverse drug reactions (ADRs) are an important source of morbidity and mortality which account for approximately 5.3% of hospital admissions.[2,3] The incidence of fatal ADR range from 0.23%-0.41%.[4]

Pharmacovigilance (PV) is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems.[5] Many countries have recognized the importance of pharmacovigilance and have joined the WHO Programme for International Drug Monitoring.[6]

Traditionally only healthcare professionals (HCPs) report ADRs to national pharmacovigilance system but the consumers also have rights to report ADR of the drug consumed.[7] According to a review article[8], consumer reporting has some advantages like directness, ,proper estimation of the burden of ADRs for individuals, early detection of ADRs, ADRs reporting of over-the-counter medicines, and promotion of consumer rights. Knowing importance of consumer reporting, direct patient reporting systems exist in many countries from decades.[9]

None of the countries have reported poor quality of patient reports to be an issue with patient reporting systems.[10] A study investigated ADR reports by health care professionals and consumers in the United Kingdom concluded that although individually consumers' reports may be deficient or exaggerated, yet collectively they reflect good common sense.[9] In Sweden, consumers can report ADR directly to the non-profit organization KILEN since 1978, and serve as a good database for research .[10] Medicines and Health Related Products Regulatory Agency (MHRA) in the UK made substantial efforts in February 2008 to raise awareness so as to increase the number of reports from patients.[11]

Experience with consumer reporting (2004-2007) in the Netherlands was published showing differences in the categories of seriousness and outcome of the reported ADRs between patients and health-care professionals.[12]A study from Denmark analysing differences in ADR reporting patterns between consumers and health-care professionals (2004-2006) showed that consumers reported ADRs for the nervous systems medications and that patients report rather unspecific symptoms, as they use lay terms to describe reactions.[13]

The patients also reported several ADRs, which prescribers may not consider serious but may be troublesome to patients, and therefore, patients find worthy of reporting. Jarernsiripornkul et al, observed that patient perceptions of potential ADRs provides useful information but general practitioner do not report all the symptoms informed to them by patients, and thus, recommended that they should be an integral part of any pain management strategy.[14] Blenkinsopp et al observed that reports by patients had identified possible new ADRs that had previously not reported by health-care professionals.10 O'Brien et al observed the information on ADRs reported by consumers to be analytical.[15]

National Coordination Centre (NCC)-PvPI (Pharmacovigilance Programme of India) has also launched "Medicines Side Effect Reporting form for Consumers" in 2014.[16] Patient or his/her representative (relative) are encouraged to report ADRs either directly to the NCC - PvPI through toll free helpline number or an email id or to their nearest AMC under PvPI by submitting the blue form .However, annual performance report of PvPI 2014-2015 suggests that consumer reporting is as low as 0. 08 % in India.[16]

Moreover, concerns about consumer ADR report lack in medical confirmation and report poor quality.8 Kalaiselvan V et al in 2014, found in their study that ADR reporting by non-Health Care Professionals was only 0.016%.[17] Annual performance report 2014-15 of PvPI showed that out of 34,988 ADR reports submitted to Vigi Base, only 27 reports were received from consumers or non-health care professionals.

This study is centred on the concern about the remarkably low level of consumer ADR reporting in India. The Regional Training Centre of PvPI at our institute promotes spontaneous reporting of ADRs by health care professionals. Consumer reporting of ADRs is yet to be initiated in this centre. We believe that knowledge and attitude about ADR reporting among consumers are one of the most important determinants of consumer ADR reporting. Moreover, observing ADR reporting practice of consumers can be useful in exploring the probable causes of under reporting as well as preferred method of ADR reporting among consumers. Hence, the present study was planned to evaluate knowledge, attitude and practice regarding ADR reporting among consumers.

## METHODS

This cross-sectional, investigator administered questionnaire-based study was carried out to assess knowledge, attitude and practice about ADR reporting among patients admitted to selected departments of a tertiary care hospital in India.

Indoor patients of 18-65 years, at Surgery, Medicine, Obstetrics & Gynaecology and Dermatology departments who gave written informed consent, were included for the study. Patients below age of 18 or above age of 65, patients visiting OPD and those not able to comprehend the questionnaire were excluded.

A representative sample of ten percent of patients admitted to Surgery, Medicine, Obstetrics & Gynaecology and Dermatology wards for two months were included for study. So, a total of 820 consumers of medicines (Patients) were included.

After receiving approval of Institutional Ethics Committee and the Head of the Department of Surgery, Medicine, Obstetrics & Gynaecology and Dermatology, data was collected by investigator administered method of survey. Study was conducted over a period of 4 months.

### *Study tools*

#### *Questionnaire*

The questionnaire was prepared to assess demographic details and knowledge, attitude and practice of consumers about ADR reporting. It had total 9 questions. Three questions were designed to evaluate consumer's knowledge about ADRs & reporting system in India, four

questions were designed to assess attitude of consumers about ADR reporting and one question was designed to observe the practice about ADR reporting. The preferred methods of ADR reporting by consumers was also evaluated. The questionnaire was prepared in local Gujarati and English languages and was prevalidated by five pharmacologists. The certified translated questionnaire was pretested on 10 randomly selected patients admitted to in-patient departments. Unclear questions were reframed to receive an accurate unambiguous response, following which the questionnaire was finalized.

***Data collection***

The patient was explained about the questionnaire in brief in the language that the patient understood. The investigator then recorded answer to each question of the questionnaire. At the end of the survey, the patients were explained about ADR and ADR reporting system.

***Data analysis***

Data was entered in Microsoft Excel to determine percentage of response. Demographic details were evaluated using descriptive statistics.

## RESULTS

**Table 1: Demographic details of consumers.**

| Age (years) | Number of consumers (n=820) |
|---|---|
| <20 | 7.8% (64) |
| 21-30 | 33.2% (272) |
| 31-40 | 19.2% (157) |
| 41-50 | 17.4% (143) |
| 51-60 | 11.6% (95) |
| >60 | 10.9% (89) |
| Gender | |
| Male | 51.8% (425) |
| Female | 48.2% (395) |
| Educational qualification | |
| None | 25.5% (209) |
| Elementary | 40.4% (331) |
| Secondary | 18.4% (151) |
| Higher secondary | 8.8% (76) |
| Graduate | 6.5% (53) |
| Postgraduate | 0 (0) |
| Work Status | |
| Working | 50.4% (413) |
| Not working or retired or studying | 49.6% (407) |

A total of 820 consumers were included, all patients completed the questionnaire (100% response). Most common age group of the consumer was 21-30 years with the mean age of 38.33±14.66 years. Male to female ratio was 1.07:1. Educational details and occupation of the consumers are mentioned in Table 1.

The analysis of the questionnaire showed that 32.2% consumers were not aware that a drug can produce adverse effects. About 56.1% consumers thought that adverse drug reactions can be serious. 43 % of consumers did not know the cause of ADRs. Consumers' opinion regarding the most common cause of ADR was improper choice of drug (22.6%) followed by improper dose (21%), drug "doesn't suit the body" (7.9%), drugs taken after expiry date (7.2%). Table 2 summarizes respondents' views about the cause of adverse effects due to medicines.

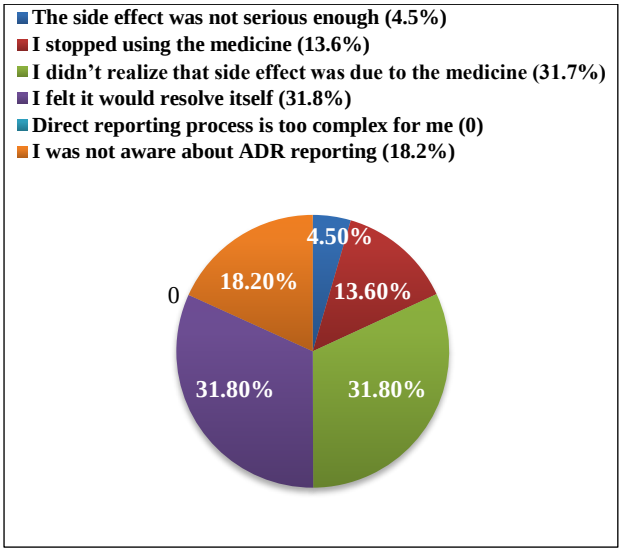
**Table 2: Consumers' opinions about the cause of adverse drug reactions due to medicines.**

| Response* | Respondents (%)** |
|---|---|
| Improper drug | 185(22.6%) |
| Improper dose | 172(21.0%) |
| Dependent upon disease | 31(3.8%) |
| Expired drug causes ADR | 59 (7.2%) |
| Drug does not suit body | 65 (7.9%) |
| Interaction of more than one drug in body | 6(0.7%) |
| Interaction of drug with certain food, e.g., sour food | 6(0.7%) |
| Drug taken without prescription | 1(0.1%) |
| Error in prescribing by doctor due to wrong diagnosis | 12(1.5%) |
| Own carelessness in taking medicine, e.g. irregular intake | 23(2.8%) |
| Occurs in alcoholic or with other addiction | 4(0.5%) |
| Duplicate drug | 4(0.5%) |
| Error in dispensing medicine by pharmacist | 4(0.5%) |
| Don't know | 353(43%) |

*Multiple opinions allowed, **Total number of respondents is 820.

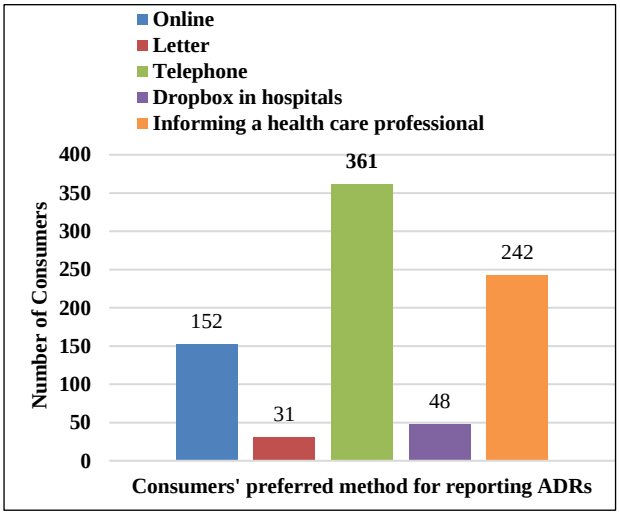
After explaining what adverse drug reaction is, majority of consumers (94.6%) felt that adverse reactions of medicines should be reported. However, 98.8% of respondents were not aware of Pharmacovigilance Programme of India. Eleven percent consumers had experienced adverse effects from medicines, of which 76% reported it to a health care professional. Among the respondents who had experienced adverse effects, majority of respondents (73%) purchased medicine from pharmacy with prescription, 19% got without prescription, and 6.6% received medicine from friend or quack while one consumer didn't remember. The common reasons for not reporting ADRs given by consumers, who experienced ADR but didn't report it, are shown in Figure 1. The common reasons mentioned by consumers were unawareness that side effect was due to medicine, it would resolve itself and also unawareness about ADR reporting.

None of the respondent mentioned that ADR reporting process is complex and hence difficult to practice. After consulting respondents about consumer reporting programme, majority of consumers (96.0%) felt that such direct consumer reporting programme is helpful. Moreover, 93.7% of consumers were willing to use consumer reporting programme of PvPI to report side effects of medicines in future. None of the consumers had used consumer reporting programme of PvPI. The respondents' preferred method for ADR reporting in future was Telephonic method on toll free number (44%) followed by informing a health care professional (29.5%) and online reporting (18.5%). Other consumers preferred writing letter to PvPI and drop-box. (Figure 2).




*n=number of consumers who experienced ADRs but didn't report it.

**Figure 1: Reasons given by consumers for not reporting of ADRs (n=22).***




*Multiple answers allowed, **n is equal to number of consumers who felt that direct consumer reporting programme should be run and selected a preferred method for reporting ADR.

**Figure 2: Preferred method for reporting ADRs* by consumers (n= 787).**

When the educational level of the consumers was compared with the preferred method of reporting ADR, it was observed that consumers with no education preferred telephonic method (12.9%) while respondents with elementary education preferred telephonic method (17.8%) as well as informing a health care professional (12%). Consumers with secondary education preferred telephonic method (7.9%). Consumers with higher secondary education preferred online as well as telephonic and informing a health care professional. Graduate consumers preferred both telephonic and online method for reporting ADRs

## DISCUSSION

The Pharmacovigilance Programme of India (PvPI) was initiated by the Government of India for monitoring ADRs in the country for safe-guarding Public Health. Consumers are the end users of pharmaceutical products, to ensure the safe use of them is the ultimate goal of pharmacovigilance activities. ADR reporting by consumers is found to be quite low in India. Therefore, improving consumer reporting of ADRs is the need of hour. A total of 820 in-door patients from Medicine, Surgery, Obstetrics & Gynaecology and Dermatology were enrolled in this study.

Data regarding knowledge, attitude and practice about ADR reporting among consumers was collected and administered in investigator administered questionnaire. Knowledge about ADRs and its reporting among consumers is the most important determinant of consumer reporting. According to our study, 32.2% consumers didn't know about ADR and 98.8% consumers were not aware about consumer ADR reporting programme run by PvPI.

P Hanumanthain et al, assessed awareness and perspective about National Pharmacovigilance Programme among consumers in three states of India and concluded a favourable picture on the involvement of consumers in reporting ADRs.[18]

The study was conducted in Andhra Pradesh, Maharashtra and Uttar Pradesh and found that less than 2% of respondents were aware about consumer ADR reporting programme. Comparing to a study done in AIIMS hospital, New Delhi in which 26% of respondents didn't know about ADRs and 96% of respondents were not aware about consumer ADR reporting Poorer knowledge about ADR among consumers in this study as compared to other study can be justified by overall lower education level of the respondents in this study.[19] Education of people may help them for better understanding and also reporting of ADRs.

Moreover, 22 consumers who had experienced ADR didn't report by any method. The common reasons for not reporting ADR were lack of knowledge that the side effect was due to medicine and belief that side effect would resolve itself. Therefore, counselling consumers about common ADRs of drugs will be helpful to make them understand and report ADRs. Among 69 consumers who

had reported ADR in past, 68 reported ADR to a doctor either in private or government hospital and, one consumer reported it to a pharmacist. None of the consumers used consumer reporting programme which can be correlated with deficient awareness about the programme in public. Though PvPI has launched consumer ADR reporting programme in 2014, knowledge regarding ADR reporting has remained very low among consumers in different regions of India. Deficit in promotion of ADR reporting education among consumers can be one of the reasons behind it. Increasing the awareness about ADR and ADR reporting can significantly increase the number of ADRs reported by consumers in India.

Attitude towards ADR reporting among consumers is bridge between their knowledge and practice about it. Though one third of the consumers in our study didn't know about ADRs, 94.6% felt that side effects of medicines should be reported. This is positive sign and spreading awareness about PvPI programme for consumer reporting can facilitate ADR reporting, signal detection and safety of drugs.

Though only 1.2% consumers were aware of PvPI, 96.0% consumers felt that such direct consumer reporting programme should be run. Our method of study included briefing consumers about every question and consulting them after every question, can explain these contrasts. It can be said, from the above-mentioned contrasts in responses of consumers, that majority of the consumers, either knowing the importance of ADR reporting or not, had a positive attitude regarding ADR reporting if they are informed properly about ADR reporting. Having positive attitude towards ADR reporting, 93.7% consumers were willing to report an ADR using PvPI.

Alhough only 6.3% consumers were either unsure or not willing to report ADRs, it is crucial to know the reasons behind it to further aid in strengthening of consumer reporting programme and it can be an objective for the future studies. Consumers can report novel adverse reactions to prescription and complementary medicines which may not be reported by health professionals. Moreover, consumer reports are more likely to include events that affected everyday activities, referred to symptoms and high- light the emotional and social impact on their lives.

Underreporting is a matter of concern for PvPI.[20] Kalaiselvan V et al, found that ADR reporting by non-health care professionals was only 0.016%. Annual performance report 2014-2015 of PvPI showed that out of 34,988 ADR reports submitted to VigiBase, only 27 reports were received from consumers or non-health care professionals.[17]

Various reasons for underreporting of ADRs observed by investigator in our study were – lack of education, not able to decide if it is side effect of the medicine, an attitude that it is doctor's duty to report ADRs etc. Before providing consumers with a system of ADR reporting, it is important to observe current practice of ADR reporting among consumers. Among the consumers with past history of ADR, majority had consumed prescribed medicine. Considerable number of consumers had either self-medicated or consumed medicine that was suggested by other than doctor. It shows that consumers reporting can also cover ADRs occurring due to self-medication.

Discussing about various methods of ADR reporting and allowing the consumers to choose more than one preferred method, majority chose telephonic method. 30.7% consumers preferred rather reporting directly to a health care professional who is expert in this field. Thus, physicians, pharmacists, nurses and other health professionals, by improving their roles as "information intermediaries" with patients and the public, can contribute significantly as also revealed by Mukherjee and colleagues.[8]

Other consumer preferred methods of ADR reporting were online reporting (19.3%) followed by drop-box in hospital (6.1%) and postal method (3.9%) respectively. In contrast to this, study conducted in AIIMS New Delhi18, reported that among respondents, 53.8% preferred online reporting, 37% preferred drop-box in hospitals and very few percentage of respondents preferred toll free number of vigilance cell (4%), toll free number on medicine (3%) and consumer medicine cell in country (2.3%).

When the preferred method of reporting was correlated with education, it was found that telephonic method was more preferred amongst respondents with lower educational qualification, while both telephonic and online methods were preferred by consumers with higher educational qualification.

Popularity of other methods were variable in different educational groups. Thus, according to the level of education in certain region, providing convenient methods can have a profound influence on level of consumer reporting. Therefore, conducting studies to find out effectiveness of different methods of ADR reporting among consumers with different education level will be useful.

The current study is confined to only one tertiary care hospital in a specific region of India and only one method of survey is used due to lack of resources. More data can be obtained by expanding the study area and also including other study methods such as online and telephonic surveys in short span of time. Other limitations of investigator-administered questionnaire such as interviewer's bias could also have affected the results of this study. Very few studies have assessed the KAP of consumers about ADR reporting in India.

Our study used a face to face interview based on prevalidated questionnaire which was piloted on consumers before administration in the studypopulation.

The method allowed in-depth data collection probing for explanations of responses from the consumers. The results shows an evidence of low knowledge and awareness about ADR reporting among the consumers, which could be the major contributory factor in under reporting of ADRs by consumers in India. However, after being informed about ADRs and reporting systems, majority of respondents showed a positive attitude towards ADR reporting, if they were provided with their preferred methods like telephonic method and informing a health care professional about ADRs. The PVPI creates awareness through advertisement in different media to educate the consumers about ADR reporting. Also, ADR forms should be made available in local language to facilitate consumer reporting of ADRs.

## CONCLUSION

The present study suggests favourable outcome by involving consumers in ADR reporting Increasing awareness about ADRs and its reporting by various educational interventions can significantly improve ADRs reported by consumers in India. Thus, promotion of PvPI Toll free number and involving health care professionals to encourage consumers to report ADRs will be particularly useful in improving ADR reporting.

## ACKNOWLEDGEMENTS

Authors would like to thank Indian Council of Medical Research (ICMR) for approving and providing funding for this project.

*Funding: Funding sources from ICMR student projects*
*Conflict of interest: None declared*
*Ethical approval: The study was approved by the Institutional Ethics Committee*

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**Cite this article as:** Patel JJ, Shah MK, Patel PP, Gandhi AM, Desai MK. Knowledge, attitude and practice among consumers about adverse drug reaction reporting. Int J Basic Clin Pharmacol 2019;8:1776-82.