



## Public awareness and attitude regarding adverse drug reactions: a survey among general public in southern India

Kaushik Shetty<sup>1</sup>, Sneha Sara John<sup>1</sup>, Noah M Bose <sup>\*2</sup>

1 Pharm.D intern, Department of Pharmacy Practice, Karavali College of Pharmacy, Mangalore, Karnataka, India.

2 Assistant professor, Department of Pharmacy Practice, Karavali College of Pharmacy, Mangalore, Karnataka, India.

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### \*Corresponding author:

Phone : +91-8884857579

Email : nmb7bose@gmail.com

### ABSTRACT

**Objectives:** The study was undertaken to evaluate the perception and attitude of the general public towards adverse drug reactions. **Methods:** Study was carried out in the general public population using a questionnaire which included mostly open and few closed-ended questions regarding attitude and awareness toward ADRs. **Results:** A total of 206 individuals responded to the questionnaire of which 114 were male and 92 were female. Maximum respondents were aged between 19 & 29 years (35%). Most of the respondents resided in urban areas. Around 45% of the respondents reported that they experienced adverse drug reactions after taking medications. Poor awareness about adverse drug reactions and its reporting process was found in the study. There was a positive attitude towards reporting adverse drug reactions and more than 86% of the respondents thought it was necessary to report adverse drug reactions. Almost all respondents agreed that if any easy method to report adverse drug reactions are available, they themselves can report the adverse drug reactions. Most of the individuals suggested that online reporting is an appropriate tool for adverse drug reaction reporting. **Conclusion:** The study observed a positive attitude among people towards adverse drug reactions reporting if an easy option is provided, though adverse drug reaction awareness showed a low trend. Imparting the general public with knowledge and awareness of adverse drug reaction & its reporting will bring a reporting culture among patients and increased adverse drug reaction reporting rates and thus help enhance the safety and monitoring of marketed medications.

### INTRODUCTION

Adverse drug reactions are one of the key drug-related problems that have a major impact on morbidity and mortality and even on adverse health care outcomes. An adverse drug reaction (ADR) is defined by the World Health Organization (WHO) 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 functions". [1] In any health care setting, ADRs create a challenge to safety of the patient and public health, be it inpatient or outpatient. In addition to imposing major financial burdens, ADRs have a substantial effect on the quality of life of the patient.[2] For around 5 to 20 % of hospital admissions, ADRs are liable. Pharmacovigilance is an arm of patient care and surveillance and its studies are becoming more significant as new drugs are entering the market at a significantly rapid rate along

with the growing number of drugs getting withdrawn from the market due to various ADRs. [4] Pharmacovigilance is defined by the World Health Organization (WHO) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems.[5] Under the supervision of the Government of India, the Central Drug Quality Control Organization (CDSCO), New Delhi, India, initiated India's Pharmacovigilance (PvG) program in 2010 with the objective of safeguarding the public health.[6] Since 2014, the Indian Commission on Pharmacopoeia has been the national coordinating centre and nearly 173 ADR monitoring centres have been established. India contributes 3% to the WHO global individual case safety reports database. [7] Pharmacovigilance in India is still in its infancy and knowledge of this discipline is very limited. The Indian National Pharmacovigilance Program, however, lacks continuity due to the lack of knowledge and insufficient training among health care

professionals in India on drug safety monitoring. [8] Spontaneous reporting is one of the various ways of reporting ADRs that has contributed greatly to the development of pharmacovigilance systems across the world. Although spontaneous reporting can be undertaken by both health care professionals and patients alike, the latter group is often unaware of ADRs and its reporting and contributes scarcely to the same in most of the cases.[9] Enhanced cognizance of patients regarding ADRs and the importance of its reporting can drastically lead to higher outcomes in pharmacovigilance and post marketing surveillance programmes along with relieving significant economic and time burdens from the healthcare staffs. Spontaneous Reporting Systems (SRSs) being the most widely used method of Pharmacovigilance has predominantly been the sole responsibility of Health Care Professionals (HCPs). In addition to HCPs, consumers or the patients also play a cardinal role in Pharmacovigilance as they can expedite the process of ADR detection.[10] However, under reporting still remains a major obstacle in realizing the real potential of the surveillance programmes.[11] Studies have shown poor ADR reporting rates among the health care professionals, particularly in developing countries.[12]

Global studies have shown vast under-reporting of ADRs among health care professionals with ADR reporting rates of only 6-10%.[13] A significant tool for minimizing under-reporting of ADRs is knowledge, attitude, practice (KAP) - based educational intervention. [14] In pharmacovigilance, the involvement of every contributor, including patients is of great importance. It is vital that patients have accurate knowledge and information about drug risks to make informed decisions about their medical treatment. Patients are becoming more aware of the possible side-effects of drug therapies. Moreover, patients often use various sources to obtain information about their medications and other health-related concerns. However, health professionals are responsible for ensuring that patients are well informed of the medications they are given.[2] It promotes better understanding of ADRs as the reports coming from patients are more direct, detailed and explicit than the reports from HCPs which are more prone to be brief and inaccurate as the information passes on from the patient to the different healthcare providers. For example, an untoward clinical effect explained by the patient to the nurse may be identified as an ADR by the doctor and the same may be reported them in treatment chart by another treating physician. The relay of information here may thus lead to inaccuracies and/or incompleteness in the finally reported ADR sent to the ADR reporting centre. This entire problem can be circumvented with the direct reporting of ADRs by the patient. It also has the potential to add value to Pharmacovigilance by reporting types of drug reactions which may otherwise be sometimes overlooked by the HCPs, generating new potential signals and describing suspected ADRs in sufficient detail to provide useful information on probable causality and impact on patients' lives.[15] Most of the previous studies have explored and reported knowledge and perception toward ADRs among health-care professionals, pharmacists, and medical students.[16,17] The studies on awareness among patients are limited.[18] This study was therefore aimed at finding out the knowledge and perception toward ADRs among patients visiting a tertiary-care teaching hospital. This study may thus help shed a light on the levels and lacunae regarding knowledge and perception of ADRs among the general public which can help identify focus areas to improve in order to enhance the pharmacovigilance outcomes. The objective of this study was to assess the awareness and attitude of the general population towards ADR and their reporting system.

## Experimental Methods

An online survey was conducted with the help of the author's developed questionnaire containing largely open and few close ended questions regarding attitude and awareness towards ADRs. The questionnaire was developed referring to related articles published in the scientific literature. Articles from the online sources such as PUBMED, WHO, FDA and GOOGLE SCHOLAR were collated and referred. Convenience sampling using online mediums such as social networking platforms and electronic mail were used to recruit participants for the study. The developed questionnaire was transmitted to maximum number of potential respondents via WhatsApp groups, electronic mail. Few of the responses, amounting to not more than 10 percent of the total sample was collated by the authors through direct interview and such respondents were nevertheless representative of the general public. There were 12 questions in all, and aspects that were investigated included the knowledge of the respondents regarding ADRs and their attitudes and awareness towards reporting of ADRs. The questionnaire was developed in Google Docs format for easy recovery and analysis of information for online respondents and for the offline respondents, the questionnaire was performed verbally. Detailed information on the questionnaire is further provided in the result section. A total of 206 individuals responded to this survey and the responses received were entered and analysed using Microsoft Excel 2010.

## RESULTS

### Respondent characteristics:

In this survey, 206 individuals participated and responded to the questionnaire.

Table 1 gives the demographic profile of the respondents. Of the 206 respondents, 55.34% (n=114) were male, 44.66% (n=92) were female. The age group ranged from 19 years and above, with the maximum number of respondents (35.92%) aged between 19 and 29 years. 53 (25.72%) respondents had an education of up to senior secondary level, 21(10.19%) up to high school, 97 (47.08%) were graduates and remaining 35 (16.99%) were post graduates. Most 68.93% (n=142) of the respondents resided in urban area while 31.07% (n=64) were from rural areas.

Out of 206 respondents, 59.71% (n=123) had experienced ADRs (side effects) after taking medicines, 24.27% (n=50) responded no to ever experiencing an ADR and 16.02% (n=33) were unsure about ever experiencing an ADR in the past.(Table.5)

### Public awareness on adverse drug reactions:

Responses to the awareness-based questions are depicted in the Table. 2. The awareness pattern, however showed low trend. On evaluation, majority of the respondents enrolled in the study believed that ADRs are harmful 68.44% (n=141) while 18.93% (n=39) of the respondents responded Don't know if adverse drug reactions are harmful or not. 60.68% (n=125) reported that all age groups are harmed from adverse drug reactions, while 20.87% (n=43) responded that only children are harmed from ADRs. Furthermore, the data also showed the poor awareness among respondents 93.69% (n=193) about the ADR reporting process in India. Though, 86.89% (n=179) people think it is important to report ADRs of medicinal products, when asked if medicines can cause ADRs, only half of the population responded Yes while others were unsure if medicines cause ADRs. Compared to individuals with lower education levels, postgraduates and undergraduates were more informed of ADR and respondents

**Table 1 :** Respondents demographic characteristics.

| Variable          |               | No of respondents | Frequency (%) |
|-------------------|---------------|-------------------|---------------|
| Age               | 19-29         | 74                | 35.92         |
|                   | 30-39         | 51                | 24.75         |
|                   | 40-49         | 42                | 20.38         |
|                   | 50-59         | 31                | 15.04         |
|                   | ≥60           | 08                | 3.88          |
| Gender            | Male          | 114               | 55.34         |
|                   | Female        | 92                | 44.66         |
| Education         | Post-graduate | 35                | 16.99         |
|                   | Graduate      | 97                | 47.08         |
|                   | 12th pass     | 53                | 25.72         |
|                   | High school   | 21                | 10.19         |
| Area of residence | Rural         | 64                | 31.07         |
|                   | Urban         | 142               | 68.93         |
| Occupation        | Not working   | 32                | 15.53         |
|                   | Student       | 87                | 42.23         |
|                   | Govt job      | 14                | 6.79          |
|                   | Private job   | 70                | 33.98         |
|                   | Retired       | 3                 | 1.45          |

**Table 2 :** Public awareness on ADRs.

| Questions   | No of respondents | Frequency (%) |
|---|-------------------|---------------|
| Do you think ADRs are serious/harmful?                    |                   |               |
| Yes   | 141               | 68.44         |
| No  | 2                 | 0.97          |
| May be  | 24                | 11.65         |
| Don't know  | 39                | 18.93         |
| Which age can be harmed from Adverse Drug Reaction?       |                   |               |
| All age   | 125               | 60.68         |
| Children  | 43                | 20.87         |
| Adults  | 08                | 3.88          |
| Elderly   | 12                | 5.83          |
| Don't know  | 18                | 8.74          |
| Are you familiar with the ADR reporting process in India? |                   |               |
| Yes   | 13                | 6.31          |
| No  | 193               | 93.69         |
| Do you think it is important to report ADRs of medicines? |                   |               |
| Yes   | 179               | 86.89         |
| No  | 27                | 13.11         |

**Table 3 :** Association between Respondents education level & awareness about seriousness of ADR.

| Qualification | Total no. of respondents | No. of respondents who are aware (n) | Awareness percentage |
|---------------|--------------------------|--------------------------------------|----------------------|
| PG            | 35                       | 31                                   | 88.5%                |
| Graduate      | 97                       | 79                                   | 81.44%               |
| 12th Pass     | 53                       | 23                                   | 43.39%               |
| High School   | 21                       | 8                                    | 38.09%               |

**Table 4 :** Public awareness about the ADR reporting

| Geographical location | Yes          | No         |
|-----------------------|--------------|------------|
| Urban                 | 132 (92.95%) | 10 (7.05%) |
| Rural                 | 47 (73.4%)   | 17 (26.6%) |

belonging to urban areas had greater knowledge of ADRs (Table.4).

#### Attitude and practice:

Table. 5 summarizes the consumer's attitude and practice responses on ADRs.

Close to 60% people had experienced one form of ADR or the other in their life out of which a majority were GIT disturbances & skin problems for which they consulted physician and received the treatment. The data also shows that more than three-fourth 79.13% (n=163) feel free to talk about ADRs. Regarding the right person to report ADRs, more than half of them opined doctor 54.85% (n=113) followed by more than one third 33.5% (n=69) reporting as pharmacists. Most of the respondents 96.12% (n=192) were of the opinion that consumers could be involved in reporting of ADRs of medicines. Almost all people responded that they will report ADR if any easy option is provided. Half of the population preferred online reporting (website) and 29.61% (n=61) responded drop box in in-patient and out-patient departments in a hospital is preferable for reporting ADRs.

#### Discussion:

ADRs and pharmacovigilance studies, considering patient treatment, have been impressive and one of the most vital topics. Consumers play a crucial role in the success of all health care related programs. Consumers reporting ADR in India is found to be very poor. Accordingly, the need for the moment is to increase number of patients reporting ADRs. In the past, many studies have examined and reported the knowledge and understanding of ADR among health-care practitioners as a research group, but there are minimal studies on public awareness.

Around 15% of individuals were not in a position to differentiate beneficial & harmful effects of a drug. Similar

findings were found in the study conducted by Ibrahim Sales et al in Saudi Arabia (2017). [20] Knowing the reasons for this is important and can be a subject for the future studies. The common reasons for not understanding the possible effects of a drug may be due to lack of knowledge. Proper counselling regarding the prescribed drug during prescribing and dispensing of medications will help consumers to better understand their medications.

A positive finding from the study was that around 60% of the respondents reported to Doctors/ Pharmacists after experiencing ADRs. Hardly none of the patients reported the ADRs directly using the consumer reporting forms, which provides an insight into both the current lacunae among the patient's knowledge regarding such reporting means and also the implied deficit of patient self-reported ADRs in the existing Pharmacovigilance system. Our study findings are in tune with the results of the study conducted by Anupriya Thadani et al (2019). [21] Certain studies Zaka Un et al (2018) [26] & A Raza et al (2015) [27] showed that the HCPs had poor knowledge regarding ADR reporting, meanwhile several other studies showed that the HCPs had sufficient knowledge regarding ADR reporting and this could be possibly due to the presence of proper functional ADR reporting system in the hospitals where such studies were conducted.

Present study revealed that 30% respondents in this study failed to acknowledge that ADRs are harmful and overwhelming majority of survey participants were not familiar with the ADR reporting process in India. A similar result was found in the studies conducted by Patel J J et al (2019). [22] One of the reasons behind this could be the deficit in the promotional campaign of ADR reporting education among public. The number of ADRs submission from consumers in India can be markedly improved by increasing awareness of ADR and ADR reporting. People's education will allow them to better understand and report ADR. Though most of our study participants didn't know about



**Table 5 :** Adverse drug reactions: Public attitude & practice

| Questions   | No of respondents | Frequency (%) |
|---|-------------------|---------------|
| Did you ever experience any side effects (ADR) on drug use?                     |                   |               |
| Yes   | 123               | 59.71         |
| No  | 50                | 24.27         |
| May be  | 33                | 16.02         |
| Common ADR (side effects) you experienced after taking medicine.                |                   |               |
| Skin rashes/ itching/ hypersensitivity  | 56                | 27.18         |
| GIT disturbances like nausea, vomiting, loose stools.                           | 61                | 29.62         |
| Weight gain/loss  | 08                | 3.88          |
| Other   | 81                | 39.32         |
| What did you do when you experienced ADRs (side effects)?                       |                   |               |
| Nothing, continue taking medicines  | 12                | 5.83          |
| Stop taking the medicines   | 13                | 6.31          |
| Reported to my doctor and received treatment.                                   | 83                | 40.29         |
| Reported to the pharmacist and took medication from him.                        | 46                | 22.33         |
| Other (included people who didn't experience ADR)                               | 52                | 25.24         |
| Do you always feel free to talk about ADRs (side effects)?                      |                   |               |
| Yes   | 163               | 79.13         |
| No  | 43                | 20.87         |
| Who is the right person to report ADRs (side effects)?                          |                   |               |
| Doctor  | 113               | 54.85         |
| Nurse   | 18                | 8.74          |
| Pharmacist  | 69                | 33.50         |
| Drug manufacturing company  | 06                | 2.91          |
| Consumer  | 00                | 0             |
| Do you feel that consumers could be involved in reporting of ADRs of medicines? |                   |               |
| Yes   | 198               | 96.12         |
| No  | 08                | 3.88          |
| If any easy option to report ADR is provided would you report it?               |                   |               |
| Yes   | 205               | 99.51         |
| No  | 01                | 0.49          |

ADR and its mode of reporting, more than 86% opined that it is important to report ADRs of medications. Comparable result was found in the study conducted by Ritu Pahuja et al (2014). [23] Also, majority of the respondents felt minimal hesitation towards freely talking about ADRs.

It is found from the study that respondents from urban areas were more aware about ADRs than those from rural areas. Most of the respondents in the study felt comfortable to talk about ADRs. Though majority preferred HCPs to report adverse drug reactions but when asked whether they would report an ADR if an option was provided, most of them ended up saying Yes (99.51%). A study conducted by Anuradha Joshi et al (2015)[24] had similar findings as well where patients although preferred the doctors to report the ADRs, nevertheless they were disposed towards self-reporting if they were made aware of simple tools for the same.

Study participants had a positive view with regard to the ADR reporting process. They think consumers can be involved in reporting process and responded that they will report ADRs if an easy option to report is provided. A favourable public perception regarding consumer participation in the reporting of ADRs was reported by Anuradha Joshi et al (2015).[24] Most participants, irrespective of whether they were well informed about the value of ADR reporting or not, had a positive attitude towards ADR reporting if they were educated about ADR reporting. In addition, consumer reports are far more likely to contain information regarding the impact of ADRs on the everyday activities as well as the economic, emotional and social impacts of the ADRs which may be otherwise missed out when reporting is done by an HCP. Patients reporting may also include ADRs that occur due to self-medication. Respondents with a higher education level were more likely to be confident to report ADRs compared to those with primary or no formal education. These results were consistent with the results of the study conducted by Kadhim (2015).[25]

Online reporting (website) was preferred by half of the study participants while 29.61% (n=61) opted for a drop box in the hospital as the preferable method for reporting ADRs. A contrasting result was obtained by Patel JJ et al (2019)[22] where it was reported that 45.87% of the study participants chose telephonic method of reporting ADR followed by 30.7% who preferred direct reporting to HCPs and only 19.3% preferring online reports. This disparity in the results could be attributed to the lower level of education among the study participants in that study which can have a potential hindering effect towards online reporting which inherently requires basic knowledge of technology which may be lacking among people with a poor education background. Nevertheless, a study conducted in AIIMS New Delhi supported our study in which half of the populations preferred online reporting.[23]

Some suggestions that may be inferred from our study are the following;

- a. Patients should be educated regarding possible ADRs and its reporting in the hospital (for inpatients) or in the pharmacy (for outpatients) whenever they receive a prescription for a new medication.
- b. Reporting process should be made smooth, trouble free, simple and least time consuming as possible.
- c. In order to make the general public and the health care professionals aware of the scope and role of PvPI, advertisements in print and visual medias including social media platforms can be utilized.
- d. Workshops, campaign programs and training sessions should be undertaken in local/ regional settings by the government as well as other concerned authorities towards enhancing the PvPI outcomes.
- e. Educational intervention programs should be conducted regularly at ADR Monitoring Centres in order to strengthen the awareness and ensuring due diligence from the side of the HCPs towards patient education regarding the reporting of ADRs.
- f. Patients should be informed about the possible adverse reactions of the prescribed drug during prescribing by the doctor or while dispensing by the pharmacist. Proper counselling regarding the importance of ADR reporting must be provided to each patient. Information regarding the process of ADR reporting including a brief step by step guide for reporting can be printed on the hind side of each prescription in order to ensure that it is not missed.

Studies on public awareness and attitude toward ADR and its reporting is minimal in the published literature and the present study shines a light on the awareness and attitude amongst the general public towards ADR and its reporting. The study participants were restricted to a small geographical region in India. It may therefore be difficult to generalise the findings to other populations in the country. Further studies can be done in the future to fill this lacuna by including a larger sample from a wider geographical area.

## CONCLUSION

The study findings show a low level of knowledge and awareness among consumers regarding the various aspects of Pharmacovigilance, which could be a major contributing factor towards the low consumer reporting of ADRs in the country. Nevertheless, the majority of respondents showed a positive attitude towards ADR reporting when enquired. This perhaps serves to highlight the need for regular and repeated awareness & educational programs particularly regarding identification and the process of reporting of ADRs. Patients are likely to identify and report more ADRs than health care professionals if made adequately aware regarding the same. Patients should be encouraged to fill ADR reporting forms - the Medicines Side Effect Reporting Form (blue form). They must also be informed on how to send the ADR report by either directly mailing the scanned copy of the duly filled form to [pvpi@ipcindia.net](mailto:pvpi@ipcindia.net) or [pvpi.ipcindia@gmail.com](mailto:pvpi.ipcindia@gmail.com) or calling the helpline number 1800-180-3024.

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## CONFLICT OF INTEREST

Nil

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