

Research Article**Evaluation of knowledge and awareness of adverse drug reaction reporting among patients visiting a tertiary care hospital in northern India****Anupriya Thadani¹, Afroz Abidi^{1*}, Fardan Qadeer¹, Deepak Bhagchandani², Roohana Hasan¹, Darakhshan Rizvi¹**¹Department of Pharmacology, Era's Lucknow Medical College, Lucknow, U.P. India²Department of Medicine, King George's Medical College, Lucknow, U.P. India

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Abstract

Objective: Spontaneous voluntary reporting of Adverse Drug Reactions (ADR) is of paramount importance to the Pharmacovigilance Programme of India, as well as for the benefit of mankind. There has however been minimal and sporadic voluntary reporting of ADRs by the patients at the various ADR Monitoring Centres (AMCs) across Northern India. Knowledge, perception, attitude, and awareness of patients are determinants of reporting practices. This questionnaire based study aims to evaluating these indicators in a tertiary care hospital and determines methods to improve existing reporting practices. **Materials and Methods:** This is a cross-sectional questionnaire-based observational study carried out in a tertiary care hospital over a period of 2 months. The questionnaires were filled by patients attending the OPD and returned to us. Data obtained from filled questionnaires were thereby analyzed. **Results:** While 74.4% respondents were aware that medicines can cause side effects, only 51.7% patients aptly feel the urgent need to report an ADR to a physician and receive prompt treatment. A majority of the respondents felt that it was the duty of the attending physician to warn the patients about the potential ADRs of medications while prescribing them, while newspaper reports and awareness campaigns could also be conducted to educate the community towards drug reactions and methods of reporting them to health care associates and receiving prompt treatment. **Conclusion:** The study indicates that although the respondents have an average knowledge and positive attitude towards ADR reporting and pharmacovigilance, there remains a lack of awareness and poor ADR reporting practices. Efforts are therefore required to enhance awareness and attitude towards pharmacovigilance and ADR reporting.

Keywords: Adverse drug reaction monitoring, knowledge, attitude, perception, pharmacovigilance

Introduction

The burden of Adverse Drug Reactions (ADR) in the global scenario is high and accounts for considerable morbidity, mortality and is of an unwanted economic burden to the patient. Therefore, proper monitoring of ADRs is a necessity, rather than a need of the hour. Although one of the essential objectives of the Pharmacovigilance Programme of India (PvPI) is to detect, assess, understand and prevent adverse effects to safeguard the general public, and there have been constant endeavours towards ADR monitoring, self-reporting among patients has

still remained an under-exploited aspect (Waller, 2010).

The Pharmacovigilance Programme of India has commended the inclusion of patient reporting, and it has been concluded that first hand reports from “medication consumers” have several distinguishing characteristics and benefits:

- They are uninfluenced/ unbiased by the drug prescriber's interpretation and provide essential information on causality.
- Such direct reports explicitly mention the effects of drug reactions on the quality of life- impairment of daily activities, and effects on family and career.
- They report different drugs and various types of reactions in contrast to the reports of professionals.
- They actively involve patients, thus enabling general

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awareness and improving health literacy.

Across the globe, many countries like the US, Australia, New Zealand have allowed patients to report ADRs directly since the conception of their pharmacovigilance schemes (Van Grootheste et al., 2003). However, there still remain several countries with deficient or non-existent methods for direct patient reporting (Hugman, 2006).

In India, the option of ADR reporting by patients to PvPI was started at NCC- PvPI on August 1, 2014 (Kalaiselvan et al., 2014) (Kalaivani et al., 2015). The patient or his/her representative is encouraged to report ADRs directly to the NCC- PvPI or to the nearest AMC under PvPI by submitting a "Medicine Side Effect Reporting form for Consumers" (which is available in ten vernacular languages to remove language barrier in ADR reporting) (Lihite et al., 2015). Moreover, the Indian Pharmacopoeia Commission in 2015 has launched a revolutionary mobile app "ADR PvPI", in order to ensure quick and hassle-free ADR reporting by the general population. ADRs can be also reported via PvPI helpline number (18001803024) on weekdays from 9:00 am to 5:30 pm. The obtained information is entered in the drug safety database, analysed and assessed by the experts to identify new signals.

Despite the continuous emphasis upon mass educational efforts and awareness, very few reports have come from the general population in the last decade. Therefore, the primary objective of this study was to evaluate the knowledge, attitude and practises (KAP) of the patients visiting a tertiary care centre in northern India about Adverse Drug Reactions and Pharmacovigilance.

In the past, most of the studies have explored and reported knowledge and perception towards ADR among health care professionals, pharmacists and medical students. However, studies on awareness among patients are limited. The secondary objective was to assess the causation of under-reporting of ADRs as perceived by the patients, and the changes that could be brought about in order to help the community recognise and report ADRs for the welfare of mankind.

Materials and Methods

The study was conducted at the Medicine OPD of a tertiary care hospital in Lucknow, Uttar Pradesh.

Study design and study participants

This was a cross-sectional, observational, prospective, questionnaire based study at a tertiary care hospital, conducted over a period of 2 months (October to December, 2017). Informed consent from the participants was obtained verbally, and confidentiality was assured.

Study questionnaire

A pre-validated questionnaire containing open and few close-

ended questions regarding knowledge, attitude and perception towards ADR was developed after referring to previous studies. The questionnaire has a format that provides information regarding three distinct domains—knowledge, attitude, and practice (KAP). The questionnaire comprises 19 questions, and aspects that are explored include the knowledge of the respondents regarding ADR's, their attitudes and awareness to reporting, factors that may influence reporting, their training, and actual ADR reporting practices being followed by the respondents. The questionnaire was modified according to regional need and translated into vernacular (Hindi) language.

Data Collection

202 patients attending a tertiary care hospital were selected randomly on daily basis for one hour. Inpatients, as well as paediatric patients were excluded. The study, its purpose and research hypothesis were well explained to the patients. Basic personal information such as age, gender, educational qualifications was noted.

Data analysis

The data collected from the questionnaire was entered into Graph Pad Prism version 3.0. Chi-Square test was used to evaluate the association between variables. A p-value of less than 0.05 indicated statistical significance.

Results

Respondent characteristics

In this study, 172 patients out of the 202 patients that were

Table 1. Socio-Demographic Characteristics

Groups		Number of respondents	Frequency (%)
Age (years)	19 -29	57	33.1
	30-39	34	19.8
	40- 49	39	22.7
	50-59	26	15.1
	>60	16	9.3
Gender	Male	63	36.7
	Female	109	63.3
Education	12 th Pass	51	29.6
	Graduate	89	51.7
	Post graduate	32	18.7
Occupation	Not working	40	23.2
	Student	29	16.9
	Government Job	34	19.8
	Private Job	52	30.2
	Retired	17	9.9

selected, agreed to participate by giving verbal informed consent and 30 patients declined. Table 1 gives the demographic profile of the respondents.

Of the 172 respondents, 63 were male, 109 were female. The age group ranged from 19 years and beyond, with a maximum of 57 (33.1%) respondents aged between 25 and 32 years. 51 (29.6%) respondents were educated upto 12th standard, 89 (51.7%) were graduates and remaining 32 (18.7%) were post graduates.

Knowledge

Table 2 gives details of the responses to the knowledge-based questions. Regarding knowledge about ADRs 128 (74.4%) respondents were aware that medicines can cause side effects. Most participants 72 (41.9%) selected the definition “any effect from a medication”. Almost equal proportion of responders 34 (19.8%) selected “Expected reaction after taking the normal dose” and the correct definition 38 (22.1%).

Table 2. Knowledge and questions detail

Questions	Number of respondents	Frequency (%)
Do you know whether medicines can cause ADR?	Yes 128	74.4
	No 44	25.6
What does Adverse Drug Reaction- mean?		
Any effect from the medication	72	41.9
Unexpected reaction after taking the normal dose	38	22.1
Expected reaction after taking the normal dose	34	19.8
Don't know	28	16.2
Which age can be harmed from Adverse Drug Reaction?		
Children	51	29.7
Adult	8	4.6
Elderly	11	6.4
All age	98	57.0
Don't Know	4	2.3
Do you think ADR is harmful?		
Very harmful	52	26.7
Somewhat serious	92	53.5
Not harmful	19	11.0
Don't know	9	5.2
Who should be notified about any serious ADR?		
Physician	89	51.7
Pharmacist	61	35.5
Nurses	17	9.8
Pharmacovigilance centre	5	3.0

While a majority of patients enrolled in the study believed that all ages could be harmed from ADRs 98 (57.0%), 92 (53.5%) think that ADRs are “somewhat serious”. About 89 (51.7%) patients aptly feel the urgent need to report an ADR to a physician and receive prompt treatment.

The post graduates had the maximum correct response rate (15.69%) while those who were 12th pass had the least response rate (0.59%). However, the overall correct response rate was only 19.19 %. Pearson's Chi-square test was applied using Graph Pad Prism Version 6.01 to find out any association between qualification and knowledge. A significant association was found ($\chi^2 = 107.3$; $P < 0.0001$) (Figure 1).

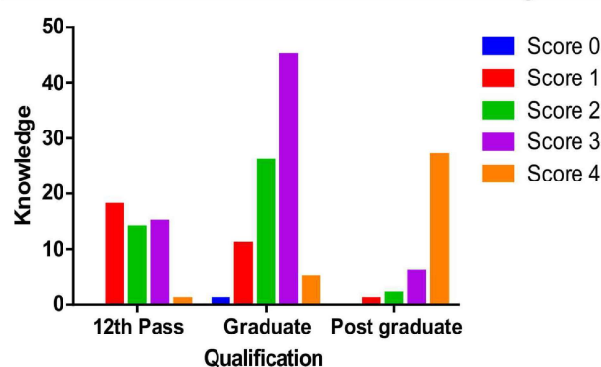


Figure 1. Association between Qualification of the patients and their knowledge about adverse drug reaction

Attitude and Practise

The response to the attitude and practice-based questions is depicted in table 3. On evaluation of attitude and the practise of patients towards ADR reporting, 92 (53.5%) feel that it is essential to gather information from the physician who has prescribed the medication. Only 2 (1.2%) patients have ever referred to the leaflet with the medication to gather information about ADRs associated with that particular drug. Only one of the patients was aware that alternative medicines, particularly herbal medicines could also cause ADR. On enquiring about medication consumption, 80 (46.5%) patients revealed that they approached a doctor for treatment, whereas 66 (38.4%) patients accepted the fact that sometime or the other, they have resorted to self-medication.

Nearly, all the respondents claimed to have taken an over-the-counter (OTC) medication sometime in their life. Only 8 (4.7%) respondents said that they had never taken an OTC drug in his life without consulting a doctor.

Out of the total 172 respondents, 103 (60%) felt the need and inquisitiveness to enquire about the ADRs arising from the medicines before consuming. 52 (30.2%) patients stated

Table 3. Attitude & Practise

Questions	Number of respondents	Frequency (%)
Which resources do you use to gather information about an ADR?		
Asking your physician who prescribed the medication	92	53.5
Asking your pharmacist who dispensed the medication	46	26.7
From Books or magazine	12	6.9
From Internet	20	11.7
From the leaflet that comes with the medication	2	1.2
Do you know about herbal medicines causing ADR?		
Yes	1	0.6
No	171	99.4
Where do you usually take your medicines from?		
Self-medication	66	38.4
From a pharmacist	26	15.1
From a Doctor	80	46.5
How frequently do you take medicine an Over-the-counter from the pharmacist without consulting a doctor?		
Always	62	36.0
Sometimes	102	59.3
Never	8	4.7
Do you ask about your medication's ADRs?		
Yes	103	60.0
No	69	40.0
Have you ever experienced any side effect after taking a medicine?		
Yes	77	45.0
No	95	55.0
Have you ever experienced an ADR due to any herbal medication?		
Yes	52	30.2
No	120	69.8
If yes, then what type of ADR have you experienced?		
Skin problem-itching, hypersensitivity, rashes etc.	32	61.5
Gastrointestinal problem-nausea, vomiting, loose stools etc	14	26.9
Others	6	11.6
Have you ever seen any side effect after taking medicine in other person?		
Yes	103	60.0
No	69	40.0
What did you do when you or any person you know experienced an ADR?		
Reported to a doctor and received treatment	80	77.8
Reported to the pharmacist and took medication from him	17	16.7
Did not do anything	6	5.5
Have you ever reported an ADR to a health care professional that you or your family have suffered?		
Yes	116	67.5
No	56	32.5
Why do patients not report ADRs according to you?		
Does not know if it is from the medication or not	93	54.2
The ADR is not serious	49	28.3
Common ADR	30	17.5
How can we educate the community about the importance of ADR reporting?		
Doctor should explain the patient while prescribing medicines	102	59.2
Publish reports in newspaper	20	11.7
Awareness campaign	50	29.1
What advantages the community can get from ADR reporting system?		
Increase medication safety	95	55.0
Increase awareness among community	40	23.3
Increase quality of life	20	11.7
Strengthen human rights	17	10.0

that they have experienced an ADR sometimes during their life, or seen an ADR in another individual 103 (60%) out of which a majority were non-specific skin problems including itching, hypersensitivity, rashes etc for which they reported to a physician and received prompt treatment.

In order to understand the psychology of the general population behind the lack of spontaneous ADR reporting, 93 (54.2) patients stated that they were not sure whether the ADR was from a medication or not. A majority of the population felt that it was the duty of the attending physician to warn the patients about the potential ADRs of medications while prescribing them, while newspaper reports and awareness campaigns could also be conducted to educate the community towards drug reactions and methods of reporting them to health care associates and receiving prompt treatment. This would lead to an increase in safe and effective use of medicines, thereby lowering the economic burden and hence, improving the overall quality of life.

Discussion

World Health Organization defines an ADR as “a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function” (WHO, 1972). According to a report “Importance of ADR reporting in India”, the incidence of serious ADR's is reported to be 6.7% in the Indian subpopulation. A study by Ramesh et al. in 2003 showed that about 0.7% of hospital admissions were due to ADR's, and a total of 3.7% of the hospitalized patients experienced an ADR, out of which 1.3% were fatal.

Spontaneous reporting of drug reactions is essential for the success of any pharmacovigilance program. A report on the recent trends and future developments in Pharmacovigilance by Kalaiselvan et al. (2016) stated that the progress of the Pharmacovigilance Programme of India (PvPI) has, to a large extent, been impeded by the lack of coordinated spontaneous reporting which is a matter of concern, not only in India, but also around the world. Investigators across India have attempted to investigate into the reasons behind this under-reporting, the possible drawbacks specific to our system and take proper and adequate corrective measures. A study by Hardeep et al. (2013) on the KAP practices among the health care professionals also suggests that the attitude of health professionals towards ADR monitoring is a critical determinant of reporting rate.

The responses to the questions in this study indicate an average degree of knowledge in the general population regarding diverse aspects of pharmacovigilance. Bringing to limelight was the most alarming response towards reporting of ADRs caused is herbal medications. 99.4 % respondents were completely unaware that even herbal medicines could lead to ADRs. The reasonable lacunae of knowledge of the respondents observed in

this study could be attributed to decreased awareness created by the medical fraternity into the subject.

Moreover, the use of Over-The-Counter (OTC) drugs was reported by 59.3% patients at some time or other. This brought forward various aspects such as poor community literacy and inadequate pharmaceutical regulatory guidelines towards safe and effective use of drugs. This was found to be in concordance with a study by Goyal et al., 2018 in which a majority of the participants had taken OTC medication, and chiefly due to its low cost.

Similar to a study conducted by Pahuja et al. (2014), a vast majority of the respondents in our study shared the view that the reporting of ADR's was necessary, but very few considered it to be an obligation. This indicates that there exists a positive attitude toward the need to report ADRs, but a relative lack of commitment to do so. Moreover, there exists incomplete information about how to report, and whom to report this information. Therefore, educational interventions are a must to update knowledge and consequently bring a greater degree of awareness towards pharmacovigilance in the general population. Concerted efforts aiming at an active and progressive enhancement of knowledge, through educational workshops, utilization of the print and social media and awareness campaigns could possibly translate into better awareness and ADR reporting practices. This is an avenue where there is an ample scope of improvement, and needs to be certainly addressed.

Findings from published research, such as one by Alomar in 2014, suggest that if made adequately aware, patients are likely to identify and report more ADRs than health professionals. A study by Weigmann (2016) states that patients are often able to attribute quickly and correctly possible newly recognized ADRs. The experience of drug reactions is received without filtering or 'interpretation' by a health professional. This may add to a better understanding and evaluation into the subject.

The reporting by general population is also associated with as many shortcomings as there are benefits. Their reports, the quality of which is 'lower' than that of healthcare associates, may often contain incorrect clinical attributions of symptoms to specific medicines. There also exists a possible duplication of reports and potential for multiple reporting of the same ADR. This could create additional 'noise' that could distract from signal detection, and result in system overload. However, currently the magnitude of distraction from signals is not much, as patient reporting comprises only 10% of the total reports received (Blenkinsopp et al., 2007). Some suggestions are offered on the basis of findings of this study.

- (a). Publicity of the PvPI in the visual and print media should be made, in order to make health professionals, as well as the general population at large, aware of its presence and scope.
- (b). Regional awareness campaigns, workshops and training should be carried out, with assistance of funding agencies if necessary.
- (c). Follow-up educational sensitization programs should be conducted yearly at all the AMCs in order to reinforce and emphasize the importance of physicians making their patients aware of drug reactions and their reporting.
- (d). Paramedical staff like nurses and pharmacists should also educate patients to be involved in the reporting process.
- (e). The process of reporting should be made as seamless, hassle free, convenient, and less time-consuming as possible
- (f). Coordination between the National Coordinating Centre, regional and peripheral AMC and the hospitals where the actual adverse drug event is encountered is required.

Conclusion

The aim of the study was to judge the attitude and perception of the respondents towards pharmacovigilance. There is however an alarming deficiency of awareness regarding the process of ADR reporting for drugs as well as herbal medicines, and the presence and activities of the PvPI. The lack of reporting practices in the northern population can thus be attributed to these very reasons. It would therefore be of utmost importance to create awareness among the general population in order to fill the void between those who actually experience the adverse drug reaction, and the reporting authorities.

Conflicts of interest: None

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