Original Article

Knowledge and Attitude Regarding Pharmacovigilance in General Population

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Abstract

Background: Pharmacovigilance is a cornerstone of the healthcare system. As patients are the end users, their contribution to such programs is inevitable. The National Pharmacovigilance Program of India emphasizes the same and this study has been conducted in the light of these findings. The study aims to ascertain public opinion, knowledge, and awareness regarding pharmacovigilance.

Methods: A cross-sectional study was conducted using a validated questionnaire in the form of an online and offline survey of the general population. A convenience sampling technique was used and data collection and analysis were done.

Results: Amongst the total 663 responses - 89% knew that drugs can have both beneficial and adverse effects, yet only 54% of them were aware of various drug adverse effects. A meagre 1% and 5% were aware of reporting them to the Adverse Event Monitoring Centre and banned drugs respectively. About 60% of participants believe that reporting adverse reactions is the responsibility of medical personnel only. Factors like lower education status, and rural setting were statistically significantly associated with study aspects like -lesser adverse drug reaction (ADR) reporting and poor knowledge of banned drugs.

Conclusion: The general population needs sensitization as regards ADR reporting and pharmacovigilance given patient safety and healthcare empowerment.

Keywords: knowledge, attitude, public perception, ADR reporting, pharmacovigilance

Introduction

Pharmacovigilance, as defined by the World Health Organization (WHO), encompasses the scientific endeavors and activities associated with detecting, assessing, understanding, and preventing adverse effects or any other drug-related issues [1]. Its significance lies in furnishing healthcare professionals and patients with adequate information to make informed decisions about drug selection for

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treatment [2]. All medications carry inherent risks, necessitating the monitoring of both intended and unintended effects to facilitate an evidence-based assessment of risk versus benefit, warranting the importance of a reliable pharmacovigilance system. The Pharmacovigilance Program of India (PvPI) was founded in 2010, with the ADR monitoring centers as its primary contact center for reporting. [3]. The primary objective of the PvPI is to detect, assess, and prevent adverse effects to ensure patient well-being and safety. When adverse effects and toxicity, particularly those previously unknown, manifest, they must be reported, analyzed, and effectively communicated to the audience to interpret the information [4].

Significant efforts to train healthcare professionals, including doctors, dentists, nurses, and pharmacists, on the importance of monitoring and reporting adverse drug reactions have been undertaken [5], but there is a notable lack of focus on training drug consumers or patients. This oversight can be attributed to the challenges associated with the widespread population, including confounding factors such as educational status, knowledge about medications and diseases, linguistic diversity, and variable socioeconomic status, which can influence public understanding and perception of drug safety practices [6]. Since the inception of global pharmacovigilance initiatives, the methods adopted by many countries have fallen short in promoting direct ADR reporting by patient drug consumers. In India, reactions occurring after drug intake are often underreported by patients and drug consumers, underscoring the PvPI system's efforts to reach the general population, despite mass educational strategies since 2010 [5].

The rational and safe use of drugs with early ADR detection remains fundamental to any pharmacovigilance program, emphasizing the active role of public reporting in providing valuable information based on their experiences, in contrast to reports from health professionals [7]. Consequently, this study aims to enhance our understanding of the knowledge and attitude of the general population while evaluating their perception of pharmacovigilance and ADRs.

Materials and Methods

Study design: This cross-sectional study was carried out using as elf-administered questionnaire circulated both offline and online in the general population of Maharashtra, India.

Study participants: The study population included members of the general population.

Inclusion and exclusion criteria: Patients visiting the OPD, relatives, patients from the inpatient department, and other members of the general population irrespective of age, gender, education, and experience, were included. Exclusion criteria included all healthcare professionals and those who did not provide voluntary consent to participate in the study.

Sampling: Convenience sampling technique was used to recruit the participants for the study.

Data collection:

The questionnaire was developed keeping in mind the aspects of knowledge and attitude assessment. Marathi translation of the questionnaire was also carried out owing to the regional language. It underwent validation by experts and representatives of the study population. This structured and validated questionnaire was then given to study participants either online (as a Google form) or offline. Consent was taken and participants willing to enroll were asked to complete the three-part questionnaire, including their demographic details, knowledge, and attitude-based questions (Table 1, 2, and 3). The questions were a mixture of multiple-choice questions and open-ended questions. Terms and concepts were clarified after form filling by providing handouts/pdf to create awareness.

Table 1: Questions to assess knowledge regarding pharmacovigilance

No.	Knowledge-based questions
1	Do you think drugs always have only therapeutic effects and do not have side effects?
2	Have you come across any side effects or drug reactions? If yes, what was it?
3	Do you know about any adverse reaction monitoring or reporting system available online or offline?
4	Are you aware of any drug that has been banned due to side effects? If yes, which?
5	Are you aware of the PV helpline to report any suspected ADRs after the use of medicine?
6	Who can report ADR?

Table 2: Questions (with Likert scale responses) to appraise attitude regarding pharmacovigilance

No.	Attitude-based questions (Likert scale)
1	Do you think side effects or adverse drug reactions should be reported to the concerned authority or doctor?
2	Do you think reporting of side effects should be done by doctors or medical personnel only?
3	Reporting should be done by patients and relatives to improve patient care in the long term.
4	Do you feel that reporting the side effects of drugs can affect your treatment or you may face any difficulty?

Table 3: Questions (Yes/No type) to appraise attitude regarding pharmacovigilance

No.	**Attitude based questions (Yes/No)**
1	Will you report about the side effects and adverse reactions in the future?
2	Would you like to know about pharmacovigilance?
3	Have you ever discussed with or asked your doctor about the side effects when you received a prescription?
4	Have you ever notified about any side effect or ADR that has occurred?

Statistical analysis:

The data was entered into a Microsoft Excel spreadsheet (Version 2312, Microsoft® Corp., Redmond, WA, USA).

Descriptive statistical analysis was done using online Sociostats software (https://www.socscistatistics.com). Data was expressed as percentages and chi-square test was used for subgroup analysis along with Fisher's exact test for data with low-frequency values.

Results and Discussion

Adverse drug reaction reporting by the drug consumers could be viewed as a fundamental step in pharmacovigilance. But, different factors such as education, awareness about medications and diseases, geographical distribution, and varying economic status can affect how the public understands and views drug safety practices [6]. Therefore, understanding the barriers to public participation in ADR reporting is important to achieve the goal of PvPI.

Table 4: Demographic details

Variable		**Frequency**	**%**	**p-value**
Age	16-35	398	60	< 0.00001*
	36-50	211	31.8	
	>51	54	8.1	
Gender	Male	341	51.4	0.460
	Female	322	48.6	
Education	Non graduates	141	21.3	< 0.00001*
	Graduates	522	78.7	
Area	Rural	184	27.8	< 0.00001*
	Urban	479	72.2	

*Chi-square test applied. p-value significant < 0.01

The demographic details of study participants are shown in Table 4. The ages of study participants ranged from 16-72 years, out of which the majority (60%) belonged to the 16-35 age group, followed by 36-50 (31.8%) and >51 (8.1%). It was observed that the majority of participants belonged to the younger age group (16-35), whereas in other such studies, maximum participation was seen by the age group ranging from 31-50 years. This could be attributed to the use of online method which is used more commonly by the younger population as compared to the offline surveys. Gender distribution was almost

equal accounting for 51.4% males and 48.6% females. A more uniform distribution was seen as regards gender distribution in our study and a study by Patel et al. [8], but a male preponderance was seen in a few studies [6, 9]. The disparity as regards educational status is consistent across other studies [8-11]. There was a significant difference in distribution according to education status and area of residence of the study participants (*p*-value is < .00001).

To assess the knowledge of the participants regarding pharmacovigilance, six questions were asked (Table 1) and the responses were in the form of yes or no for the first 5 questions (Figure 1). It was observed that even though about 89% of the participants were aware that drugs have both beneficial as well as side effects, only a meagre 1% were aware of the reporting system and pharmacovigilance programs. These findings were consistent with similar studies conducted by Munshi et.al and Pahuja et.al in Mumbai and Delhi respectively[6,10]. Similarly, only about 5% knew about drugs that have been banned like Nisetablets, Corex syrup, etc.

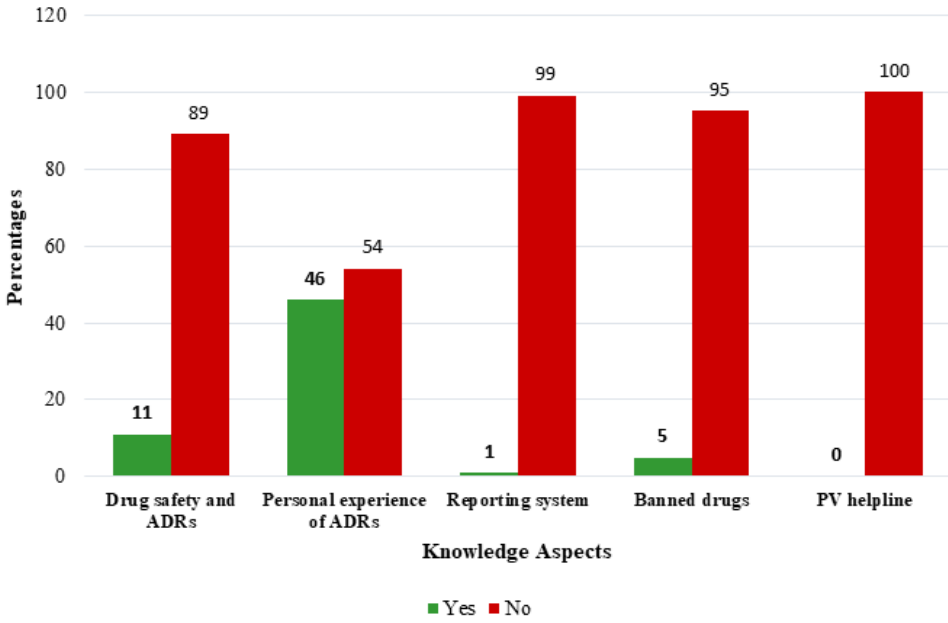

Figure 1: Knowledge regarding Pharmacovigilance

(y-axis represents the number of responses as percentages rounded off to whole numbers; x-axis represents the various knowledge aspects asked in the questionnaire.)

Level of education was positively associated with knowledge about banned drugs, significant at p <0.01 (Table 6). About 46% of participants had a personal experience of ADRs out of which most commonly experienced side effects were either rashes or nausea and vomiting. None of the participants were aware of the PV helpline to report suspected ADRs. The awareness amongst the participants about the reporting system was unsatisfactory, especially in the rural and less educated population (Table 5). This could be attributed to the lack of reach of the existing awareness programs to this set of populations. These findings were in line with findings from Kadhim et al in Iraq and Mohammad et al in Malaysia showing inadequate awareness and knowledge in those from rural areas and those less educated respectively[11,12].

Table 5: Association of correct responses with level of education and area of residence

Educational status and responses			
Education	**Correct**	**Incorrect**	**p-value**
Graduates	104	418	0.005904*
Non-Graduates	14	127	
Area of residence and responses			
Area	**Correct**	**Incorrect**	**p-value**
Rural	21	163	0.007723*
Urban	97	382	

*chi-square test applied. p <0.05 significant

Our study findings show that even though there is a lack of awareness regarding drug safety and reporting of adverse effects, there is still a positive attitude about knowing and reporting in the future. In a survey conducted in 11 countries on methods of patients reporting ADR by Van Hunsel et.al., it was evident that allowing the public to report will eventually give additional scientific value to the collected data[13].

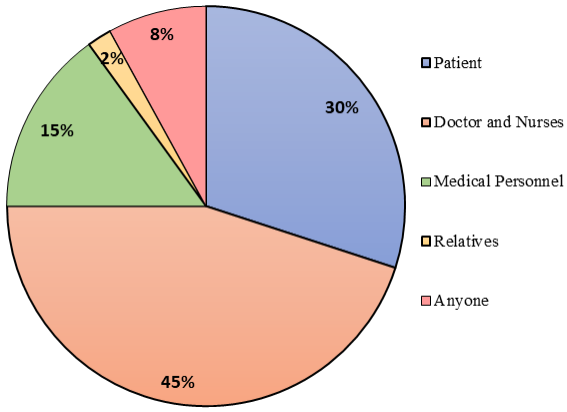

Figure 2: Who can report Adverse Drug Reactions?

The last question asked was in the form of an MCQ (Figure 2) and it shows that the majority (45%) of the participants believed that reporting was the responsibility of Doctors and Nurses alone, and only 8% believed that anyone could report (patients, relatives, doctors, medical personnel, etc.).

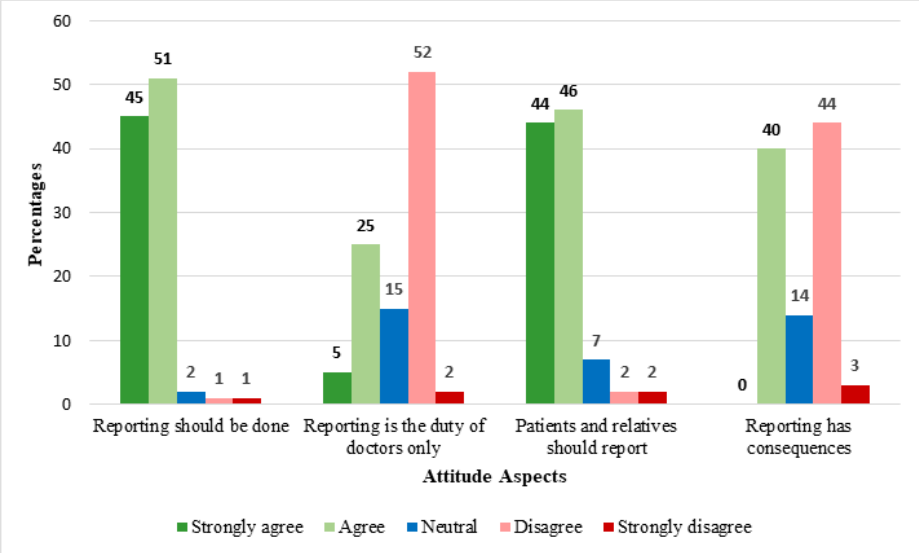

Figure 3: Attitude regarding Pharmacovigilance (Likert scale based responses)

(y-axis represents the number of responses as percentages rounded off to whole numbers; x-axis represents the various attitude aspects asked in the questionnaire.)

In the next section of the questionnaire, to assess the attitude of study participants and identify any barriers in reporting, questions were asked in two formats- Likert scale type (Table 2) and binary yes/no response type (Table 3).Figure 3 shows that a maximum number of participants believe that reporting is important and the responsibility of doctors, patients, and relatives. It was noted that when asked if they thought reporting might have some consequences, about 40% felt that they might face certain issues like treatment getting affected or any change in the

attitude of the treating doctor, etc. This belief that reporting has negative consequences was more amongst the participants who were non-graduates and hailing from rural areas showing a statistically significant association (Table 6 & 7).

Table 6: Association of Education with ADR knowledge and reporting

Q. Do you know about any banned drug?			
Education	**Agree**	**Disagree**	**p-value**
Non-Graduates	2	139	0.043*
Graduates	30	492	
Q. Does ADR reporting have negative consequences?			
Education	**Yes**	**No**	**p-value**
Non-Graduates	104	418	<0.00001#
Graduates	113	28	

*Fisher exact test applied. p <0.05 significant

chi-square test applied. p <0.05 significant

Table 7: Association of the area of residence with ADR reporting

Q. Does ADR reporting have negative consequences?			
Area	**Agree**	**Disagree**	**p-value**
Rural	96	88	0.00014*
Urban	162	317	
Q. Have you reported ADR?			
Area	**Yes**	**No**	**p-value**
Rural	46	138	0.0012*
Urban	69	410	

*chi-square test applied. p <0.05 significant

Table 3 depicts the attitude-based questions which were answered in the form of yes or no, responses for which are demonstrated in Figure 4.It was found that only about 32% of the participants had asked their doctors about the side effects of the drugs they were prescribed in the past and as low as 17% had reported the adverse effects they experienced, of which those from rural areas were less in number (Table 7). Kitabayashi et al from Japan mentioned that the traditional physician-patient relationship may be one of the important causative factors attributed to poor awareness and utilization of the reporting system which needs to be improved[14]. This is also true for our study where a considerable number of people have never discussed ADRs with their doctor, and some also believe that reporting might affect their treatment negatively.

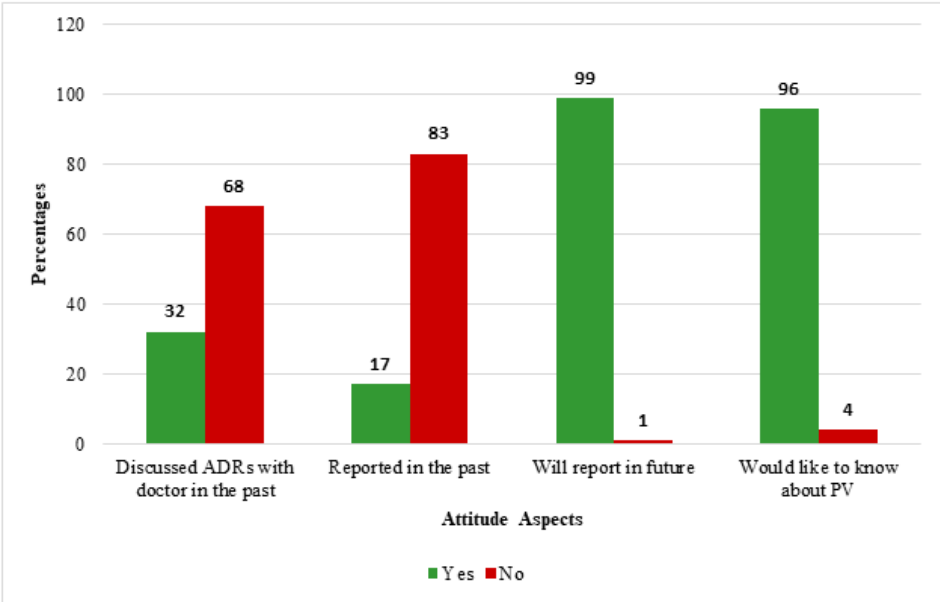

Figure 4: Attitude regarding Pharmacovigilance (Yes/No type responses)

(y-axis represents the number of responses as percentages rounded off to whole numbers; x-axis represents the various attitude aspects asked in the questionnaire.)

A positive attitude was seen as 99% were willing to report in the future and 96% were interested in learning more about pharmacovigilance. Hence, a majority of participants agreed that reporting ADRs can improve treatment safety and limit the future recurrence of ADRs, and most of them had a favorable attitude toward this practice.

The limitation of our study constituted the inhomogeneity of the study population as regards to geographical distribution, age, and education. A more targeted approach including a wider audience is necessary to generalize the study findings.

Conclusion

The overall study findings unravel the positive attitude, but the lack of awareness about the reporting system presents as one of the hindrances in the pharmacovigilance program. Subgroup analysis further reveals the association of urban status and level of education with better awareness and knowledge about PvPI. This suggests the need for percolation of the PvPI program to rural population and/or less educated classes through simple and effective awareness campaigns.

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