Original Article

Questionnaire Based Survey to Assess Awareness on Drug Safety, ADR and ADR Reporting on Patients Attending OPD/IPD in a Tertiary Care Hospital, Kanpur During National Pharmacovigilance Week

Dr. Virendra Kushwaha*, Dr. Pooja Agrawal, Dr. Bk Shoraisham, Dr. Geeta Singh Rana Dr. Shivangi Raj Singh, Dr. Sarthak Goel, Dr. Mohd Aamir, Dr. Sonali Chandra

Department of Pharmacology, GSVM Medical College, Kanpur-208002, India.

***Corresponding author's E-mail:** vkushwaha1970@gmail.com

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ABSTRACT

Introduction: Pharmacovigilance is crucial for detecting and preventing adverse drug reactions (ADRs). This study examines patients' awareness and attitudes towards ADRs and reporting in a tertiary care hospital in Kanpur.

Material and Methods: A cross-sectional questionnaire-based study was conducted during National Pharmacovigilance Week. 1389 patients were surveyed, and data was collected from OPD and IPD attendees. Statistical analysis was performed using jamovi software.

Results: Male participation was higher (60%), with most participants married (72%). Majority visited for follow-up care (57%). 74% were aware of ADR. 55% had not experienced ADRs, while 32.5% had. 77.46% would contact their physician if they experienced any ADRs. However, 82.79% were unaware of self-reporting options. 54.35% did not report ADR due to non-severe nature of the ADR.

Discussion: The study highlights gender disparities in participation and the need for targeted education. While most patients recognized ADR risks, knowledge gaps exist in reporting mechanisms. Barriers to reporting included uncertainty and lack of awareness. Preferred information sources were healthcare providers and television ads.

Conclusion: Enhanced education and streamlined reporting mechanisms are imperative to bolster patient participation in pharmacovigilance. Addressing knowledge gaps and improving accessibility to reporting platforms can empower patients, ultimately enhancing drug safety and patient care.

Keywords: Pharmacovigilance, adverse drug reactions, patient awareness, ADR reporting.

INTRODUCTION

Pharmacovigilance is defined by WHO as "the science and activities relating to the detection, understanding, and prevention of adverse effects or any other drug-related problems".[1] To promote drug safety WHO started Program for International Drug Monitoring in 1961 and subsequent to that it promoted pharmacovigilance program at country level in collaboration with Centre for International Drug Monitoring, Uppsala.[2] As in other parts of the world, when many medical scientists started rational use of medicine and monitoring ADRs in the late 1960s, many eminent pharmacologists of India also started studying ADRs and trying to understand the concept of Pharmacovigilance.[3] A national seminar on pharmacovigilance was held in 1983 by the Indian Pharmacological Society (IPS) to raise awareness about adverse reactions to drugs at normal doses.[4] Following this, in 1989, the Indian Council of Medical Research (ICMR) sponsored a project on monitoring adverse drug reactions across multiple centres in India. In 1997, an agreement between the WHO and the Indian Drugs Controller General (DCGI) led to the establishment of working relationships with the WHO Collaborating Centre for International Drug Monitoring in Sweden and Pharmacovigilance Centres in India, primarily based in teaching hospitals.[5] In 2005, the Government of India, through the Central Drug Standard Control Organisation (CDSCO), launched the National Pharmacovigilance Program (NPVP), funded by the World Bank and WHO, based on WHO guidelines. To enhance its effectiveness, the NPVP was renamed the Pharmacovigilance Program of India (PPI) in 2009 after a workshop organized by AIIMS and CDSCO.[6]

Pharmacovigilance operates on three fundamental principles: the continual acquisition of new data from reliable sources such as pharmaceutical companies, healthcare providers, patients, and scientific literature; the systematic classification and analysis of this data; and the widespread dissemination of findings and any consequent actions across all sectors of healthcare.[7] The World Health Organization (WHO) defines adverse drug reactions (ADRs) as harmful and unrelated to the purpose of medication when normal doses of drugs are used to prevent, diagnose, treat diseases or regulate physiological functions.[8] Adverse drug reactions (ADRs) significantly impact patient health, contributing to increased global morbidity and mortality. Approximately 5% of hospitalized patients experience ADRs, with another 5% encountering them during hospitalization.[9] In the European Union, ADRs result in 197,000 deaths annually, while in the United States, the cost of hospitalization due to adverse drug events ranges from $13,994 to $19,685 per patient.[10] Consequently, monitoring ADRs is crucial for global healthcare. Most countries rely on spontaneous reporting systems for

pharmacovigilance, where healthcare professionals, pharmaceutical companies, or individuals report suspected ADRs to a national coordinating center.[11] While spontaneous reports offer advantages in identifying potential safety concerns, they suffer from significant drawbacks, including underreporting, poor report quality, difficulty in quantifying risk, and uncertainty regarding the total exposed population.[12]

This study aims to assess awareness levels regarding drug safety, adverse drug reactions (ADR), and ADR reporting among patients attending outpatient and inpatient departments (OPD/IPD) at a tertiary care hospital in Kanpur. This research during National Pharmacovigilance Week can contribute vital insights to improve pharmacovigilance practices, ultimately ensuring better drug administration, reduced adverse events, and more effective ADR reporting systems for enhanced patient care.

MATERIALS AND METHODS

It was a cross-sectional questionnaire-based study carried out in a Tertiary Care Teaching Hospital in Kanpur during the national pharmacovigilance week from 17 November 2023 to 23rd November 2023. A well-structured questionnaire containing 23 questions including demographic details of the patients was developed and used for the study. Data collection was done in OPD and IPD by interviewing those patients and their attendants who visited in OPD or admitted in ward for getting treatment. However, we used the data collected only from patients for analysis. A total of 1389 patients were interviewed and the responses obtained were recorded in hard copy. Collected data was entered properly in excel sheet and jamovi software was used for statistical analysis.

RESULTS

Out of 1389 participants, 834 were males (60%) and 555 (40%) were females (table 1). This showed that men participated more actively when compared to women**.** Out of 1389 participants, 997 (72%) were married and 392 (28%) were unmarried (table 1). 788 (57%) of the participants came to OPD/ IPD for follow up visit and the remaining 601 participants (43%) were of first visit (table 1).

Table 1: Demographic details of the participants

	Male (%)	**Female (%)**
Gender	834 (60%)	555(40%)
	Unmarried	**Married**
Marital status	392 (28%)	997 (72%)
	First visit	**Follow up visit**
Type of visit	788 (57%)	601 (43%)

30% of the participants were of graduate standard followed by 12th standard (26%), 10th standard (18%), 8th standard (13%), postgraduate (2%) and remaining 11% were illiterate (figure 1).

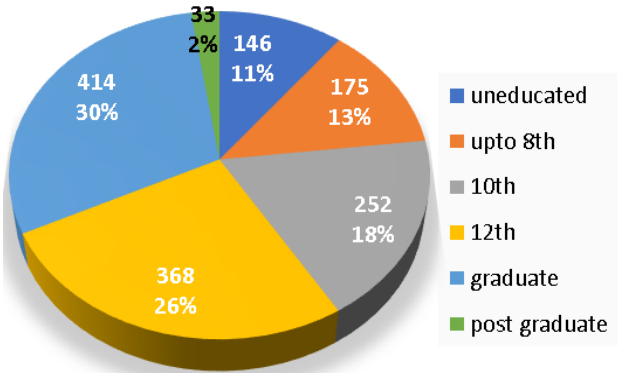

Figure 1: Educational levels of the participants

Majority of the participants (74%) were aware of the fact that drugs are not fully safe and cause ADR, whereas 14. 47% did not know that drugs can cause ADR and remaining 11.53% were not sure that drugs can cause ADR (table 2). Out of 1389 patients, 763 (55%) had not experienced any unpleasant effects from medicines whereas 452 (32.5%) of the patients had experienced some forms of unpleasant effect from medicines and remaining 12.5% could not remember whether they had experienced any unpleasant effect or not (table 2). In case of experiencing any ADR, majority of the patients (77.46%) responded that they would contact their treating physician, 63 (4.53%) patients said that they would contact a nurse whereas the remaining 3.2% of the patients stated that they would contact a pharmacist, 1.22% said they will report by themselves directly by going to website. 2.59 % of the patients said they will not inform anyone and 150 patients (10.79%) had no idea about whom to contact in case of experiencing any ADR (fig 2).

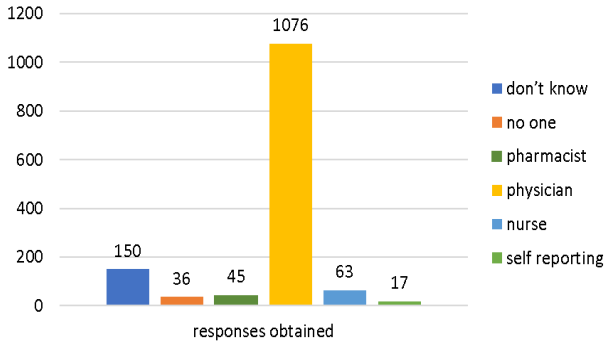

Figure 2: Responses to the statement "DO YOU KNOW WHOM TO CONTACT IN CASE OF EXPERIENCING ANY ADR"

Majority of the patients (82.79%) had no idea that they can also self-report ADR directly via toll free reporting to NCC-PVPI by visiting a website. 151 (10.87%) patients had the idea of self-reporting through website whereas the remaining 4 patients were not sure whether they can self-report directly or not (table 2). Majority of the patients (79.76%) believed that reporting ADR is important. 241 (17.35%) patients were not sure whether reporting ADR is important or not whereas the remaining 40 (2.87%) patients did not believe that reporting ADR is important (table 2). Regarding reporting of ADR, 764 (55%) patients stated that only serious or life-threatening ADR must be

reported. 44. 56% of the patients responded that all ADR, including serious and non-serious must be reported whereas the remaining 4 patients were not sure whether only serious ADR must be reported or not (table 2). 38.15% of the patients were confident about self-reporting of ADR but 29.44% of the patients were confident that they can report to their treating physician or nurse or pharmacist but were not confident about self-reporting directly to authority. 26.70% and 5.39% of the patients respectively were not confident and not sure about self-reporting of ADR to the authority (fig 3). If any awareness programme is launched related to ADR reporting, majority of the patients (50%) were willing to participate and 23.54% of the patients were not willing to participate whereas the remaining 26.85% of the patients were not sure whether they will participate in such programme or not (table 2).

About reporting of ADR again, majority of the patients (62%) had not reported any ADR before but, interestingly 30% of the patients' reported ADR before participating in our study, whereas 8.49% of the patients could not remember exactly whether they had reported any ADR in the past or not (table 2). Out of 410 patients who had reported ADR, 391 of them reported it to their physician and the remaining reported it to pharmacist and nurses.

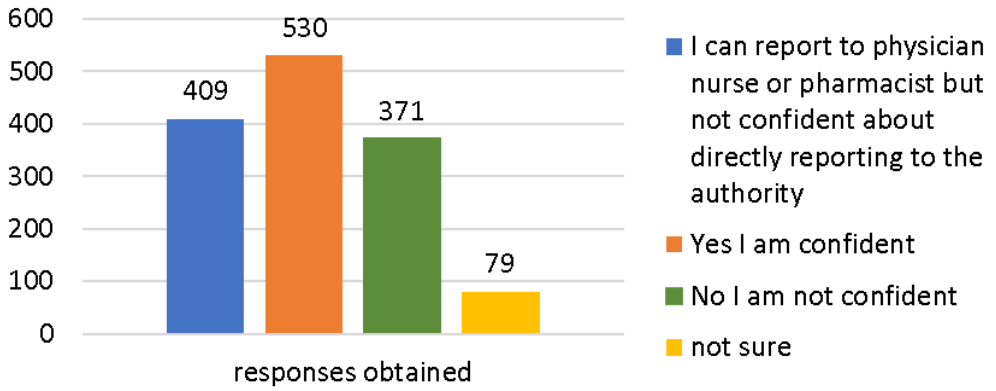

Figure 3: Responses to the statement "ARE YOU CONFIDENT THAT YOU CAN SELF REPORT ADR"

Table 2: Statements asked and number of responses obtained

Statements and no. of responses	Yes	No	Not sure
do you know drugs are not fully safe and can cause ADR	1027	201	140
	Yes	**No**	**Don't remember**
have you experienced any unpleasant effects from medicines	452	763	172
	Yes	**No**	**Not sure**
do you know you can also self report your ADR directly via toll-free reporting to NCC-PVPI by visiting a website	151	1150	4
do you think ADR reporting is important	1108	40	241
if any awareness programme is launched related to ADR reporting, are you willing to participate	688	327	373
	Yes	**No, all must be reported**	**Not sure**
do you think only serious/ life threatening ADR must be reported	764	619	4
	Yes	**No**	**Don't remember**
have you ever reported any ADR	410	861	118

One of the commonest reasons for not reporting ADR was found to be not having any serious ADR among patients followed by not knowing whom to inform the ADR. Other reasons for not reporting ADR were patients having only mild ADR and nobody asking them to report ADR (fig 4).

Majority of the patients (41%) said that the best way to get knowledge about ADR reporting is informed by doctors, 33.47% of the patient said the best way is through advertisement on television, 15.4% of the patients said the best way is through poster and charts, 5.97% of the patients said through leaflets and remaining 1.65% said the best way to get knowledge is through messages on mobile phones (fig 5).

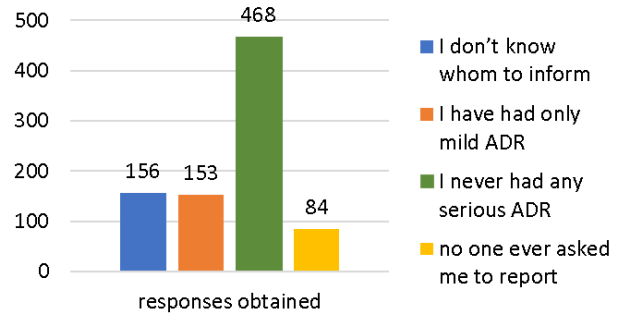

Figure 4: Reasons for not reporting ADR

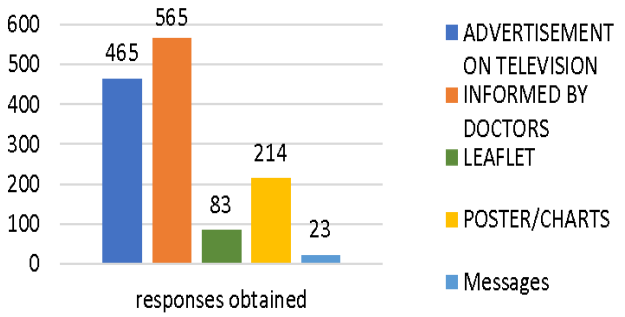

Figure 5: Responses to the statement "BEST WAY TO GET KNOWLEDGE ABOUT ADR" "REPORTING"

DISCUSSION

The findings from our study shed light on several key aspects of participation, awareness, and attitudes towards adverse drug reactions (ADRs)and ADR reporting among patients. The demographic analysis revealed that there was a higher participation rate among males compared to females, with 60% of the participants being male and 40% female. This is in contrast to studies conducted by Valinciute A et al.[13] and Varshini A et al.[14] which showed higher proportion of females compared to males. Additionally, a significant proportion of the participants were married (72%) compared to unmarried individuals (28%) which is similar to the finding in the study conducted by Varshini A et al. Furthermore, a majority of the participants (57%) visited the outpatient department (OPD) or inpatient department (IPD) for follow-up visits rather than first-time visits (43%).

In terms of educational background, the study found that the majority of participants had attained education up to graduate standard (30%), followed by 12th standard (26%), 10th standard (18%), 8th standard (13%), and postgraduate (2%). A notable percentage (11%) of participants were illiterate.

Regarding awareness of ADRs, a substantial portion of participants (74%) were aware that drugs are not entirely safe and can cause ADRs. However, 14.47% were unaware of this fact, and 11.53% were uncertain about it. Interestingly, 55% of the patients had not experienced any unpleasant effects from medicines, while 32.5% had experienced some form of unpleasant effect, and the remaining 12.5% were unsure. This finding is consistent when compared to the study conducted by Valinciute et al. which showed 66.7% of the patients not experiencing any ADR before and 28.3% of the patients experiencing some form of ADR.

In terms of response to experiencing ADRs, the majority of patients (77.46%) stated that they would contact their treating physician, while smaller percentages would contact a nurse (4.53%), pharmacist (3.2%), or self-report directly through a website (1.22%). Notably, a significant proportion (10.79%) had no idea whom to contact in case of experiencing any ADR.

Concerning self-reporting of ADRs, the study found that the majority of patients (82.79%) were unaware that they could self-report ADRs directly via a toll-free reporting system on a website, which is similar to the finding in the study conducted by Valinciute et al. showing 73.3% of the participants having no idea about direct reporting of ADR. Furthermore, only a small percentage (10.87%) of patients were aware of this option.

The study also assessed the perceived importance of reporting ADRs, with the majority of patients (79.76%) considering it important which in accordance to the finding in the study by Valinciute et al. in which 96.7% of the patients saying ADR reporting is necessary. However, a notable portion (17.35%) were unsure, and a minority (2.87%) did not consider it important.

Regarding the types of ADRs that should be reported, opinions varied, with 55% of patients stating that only serious or life-threatening ADRs should be reported, while 44.56% believed that all ADRs, including non-serious ones, should be reported. This is slightly different from the finding in the study by Varshini A et al. which had 73.8% of the patients showing interest to report all types of ADR.

Confidence in self-reporting of ADRs was mixed, with 38.15% of patients expressing confidence in self-reporting, while 29.44% were confident in reporting to their treating physician, nurse, or pharmacist but not directly to the authority.

When asked about their willingness to participate in awareness programs related to ADR reporting, half of the patients expressed willingness, while a significant portion (23.54%) were not willing, and the remainder (26.85%) were unsure.

Finally, the study explored past experiences with reporting ADRs, revealing that a majority of patients (62%) had never reported any ADRs before. However, 30% had reported ADRs prior to participating in the study, and 8.49% were unsure if they had reported any ADRs in the past.

Common reasons for not reporting ADRs included not experiencing any serious ADRs, uncertainty about whom to inform, having only mild ADRs, and not being prompted to report by healthcare providers. This is similar to the finding in the study conducted by Valinciute et al. which showed 40.48 % of the patients not reporting ADR due to non - severe type of ADR and 26.19 % not realizing it was an ADR. In the study conducted by Varshini et al. 57.5% of the

patients did not report ADR due to lack of knowledge and 20% of the patients did not report any ADR because the assumption that only safe drugs are in the market.

In terms of preferred sources of information about ADR reporting, most patients indicated that information from doctors (41%) and television advertisements (33.47%) were the most effective methods, followed by posters and charts (15.4%), leaflets (5.97%), and mobile phone messages (1.65%).

Overall, these findings underscore the need for targeted educational interventions to enhance awareness and understanding of ADRs among patients, as well as to improve reporting practices. A study conducted by Kushwaha et al. concluded that Adverse drug reactions (ADRs) have significant impact on patient well-being and can strain the healthcare system. Implementing an ADR collection program in hospitals aids in evaluating the safety of drug therapies.[15] Tracking ADRs over time educates healthcare professionals about drug effects, enhancing their awareness and understanding of ADRs. Additionally, efforts should be made to streamline reporting mechanisms and increase accessibility to reporting platforms to empower patients in actively contributing to pharmacovigilance efforts.

CONCLUSION

In conclusion, this study provides crucial insights into patient participation, awareness, and attitudes regarding adverse drug reactions (ADRs) and ADR reporting. Key findings include a higher participation rate among males, with the majority visiting outpatient departments for follow-up visits. While a significant proportion of participants were aware of the potential risks associated with drugs, many lacked awareness of ADR reporting mechanisms, indicating a need for targeted educational interventions. Confidence in self-reporting ADRs was varied, with a notable portion unsure of whom to contact in case of experiencing an ADR. Common barriers to reporting included uncertainty about the severity of ADRs and lack of knowledge about reporting procedures. Preferred sources of information about ADR reporting included healthcare providers and television advertisements. These findings underscore the necessity for improved patient education and streamlined reporting mechanisms to facilitate active participation in pharmacovigilance efforts, ultimately enhancing drug safety and patient care.

CONFLICT OF INTEREST: There are no conflicts of interest to disclose regarding the publication of this research. We have no financial or personal relationships with any individuals or organizations that could potentially bias our work or influence the interpretation of our finding.

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