



ISSN : 2347-2251

**Indo-American Journal of
Pharma and Bio Sciences**



www.iajpb.com

iajpb.editor@gmail.com
editor@iajpb.com



An Evaluation of the ADR Monitoring Center's Impact on Pharmacovigilance: A Cross-Sectional Study of Outpatients at a Multi-Super Specialty Hospital in Nellore

B.Naveena, K.Arunchand Roby,
PRAPURNACHANDRA YADALA & S.Naga Bharathi

ABSTRACT

Objectives: The purpose of this study is to assess the level of staff and patient understanding of adverse drug reaction (ADR) and pharmacovigilance systems at a super specialty hospital. In addition, we want to raise patients' awareness of the ADR reporting system. **Research Tools and Procedures:** At a hospital with several different specialties, researchers performed a cross-sectional study. A random sample of outpatients seeking medical attention at KIMS multi-specialty hospital were surveyed, and their demographic information was recorded. **Created for the study:** a questionnaire to gauge level of understanding and sentiment about ADR. Both Telugu and English versions of the demographic data form and questionnaire are provided. The people who took part in the research were given patient information booklets. We educated patients on how to use the ADR PvPI app to report adverse drug reactions yourself. **Descriptive analysis** was used to examine the data. The results show that the patients who visited the tertiary care hospital had a better understanding of ADR than the individuals who did not. There were fifty patients included in the trial. There was a significant lack of knowledge of pharmacovigilance among the participants (56%). The internet and social media had a significant role in raising awareness about this topic. Fifteen people (or 30% of the total) have reported adverse drug reactions (ADRs) after taking medicine, although only ten of those people really told their doctors about it. To a large extent, they do not see ADR reporting as critical. Additional factors contributing to underreporting of adverse drug reactions were transportation challenges and hospital rush. The pharmacovigilance center was unknown to all of the participants. They would rather inform their doctor about adverse drug reactions (ADRs). It is estimated that almost all patients (96%) were unaware of the ADR PvPI app. **Results:** Everyone who took part in the study learned how to use the ADR PvPI app to record their own adverse drug reactions. All participants were given a patient education booklet that explained adverse drug reactions (ADRs), where they might find the institution's pharmacovigilance center, and what to do if an ADR occurs.

Keywords: Topics covered include pharmacovigilance, drug safety, adverse medication reactions, and PvPI.

INTRODUCTION

Any "noxious and unintended response to a drug that occurs at doses normally used in man for prophylaxis, diagnosis, therapy of disease, or for the modification of physiological function" is considered an adverse drug reaction (ADR) by the World Health Organization. Overdose, drug misuse, treatment failure, and medication administration errors are not included in the criteria.¹ Pharmacovigilance is the branch of pharmaceutical research that focuses on the study of side effects and how to identify, evaluate, monitor, and avoid them. In 1986, the

Indian government launched the Pharmacovigilance Programme, which included the proposal for a 12-center official ADR monitoring system. In a formal announcement made on July 14, 2010, the Indian government launched the PV Program for India (PvPI).³ To guarantee patient safety, the pharmacovigilance system relies on the spontaneous reporting of adverse drug reactions (ADRs), which are a leading cause of patient morbidity and death. Because many ADRs may go unrecognized when healthcare providers rely only on their own

Department of Pharmaceutics,
Ratnam Institute of Pharmacy, Pidathapalur (V), Muthukur (M), SPSR Nellore Dt.- 524346 A.P.,
India.



reports, patients' self-reports of ADRs have the potential to significantly advance medication safety. The majority of the existing research has focused on medical students' understanding of and reactions to adverse drug reactions. However, there is a lack of research on patients' levels of awareness. During the months of November 2021 and March 2022, researchers at Al-Shifa hospital Perinthalmanna conducted a cross-sectional study to assess patients' knowledge and perception of adverse drug reactions (ADRs). The goals of the study were to raise patients' awareness of ADRs, encourage better self-reporting, identify areas for potential improvement in our pharmacovigilance system, and uncover reasons for under-reporting.

MATERIALS AND METHODS

This study aimed to evaluate Knowledge and perception towards adverse drug reactions among patient visiting different departments of a multi super speciality hospital and to sensitize patients on ADR reporting system.

Study Populations

The Outpatient visiting various departments at multi super speciality hospital (KIMS Al shifa multi-specialty hospital Perinthalmanna) for medical care.

Study Site

A multi super speciality hospital established with an ADR monitoring and reporting centre under Indian pharmacopeial commission and ministry of health and family welfare Govt. of india.

Study Design

A cross-sectional survey among patients visiting tertiary care hospital (KIMS Al Shifa multi-specialty hospital Perinthalmanna) was conducted between November 2021 and March 2022 using the questionnaire developed. The questionnaire were both open ended and closed ended to assess knowledge about ADR and pharmacovigilance.

Inclusion Criteria

Out patients visiting different outpatient department of the hospital

Exclusion Criteria

- In patients and patients visiting emergency care of the department.
- Patients visiting gynecology department.
- Patients below 18 years of age.

Data analysis was done by descriptive analysis

RESULTS

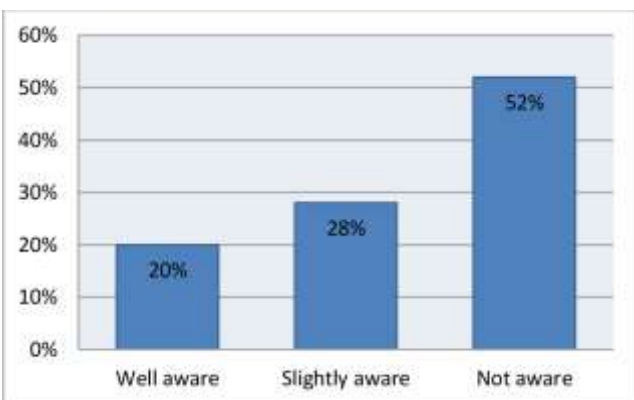
A total of 50 eligible patients were included in the study. In which 27 (54%) were men and 23 (46%) were women. Respondents were aged between 18 to 70 years. 15 respondents (30%) were having primary education. 21(42%) were educated up to high school and remaining 14 (28%) were graduates. Most of them have co morbid conditions like hypertension, diabetes, thyroid, Hyperlipidemia (80%). About 35(70%) respondents used to take medications without prescriptions which include antibiotics, medications for fever, cough, cold etc. About 20 (40%) participants are taking medicines other than allopathy. 15 patients (30%) are on ayurvedic treatment and 5 patients (10%) are receiving concurrent homeopathic treatment (Table 1). They are not aware about ADR caused by alternative medicines. About 52% of patients were not aware about their medications and its uses (Figure 1). More patients reported that they received counseling from pharmacists regarding elements of medication use (Figure 2). But 80% of the patients were not informed about the possible ADR of drugs by pharmacist (Figure 3).

Knowledge and awareness of Pharmacovigilance and ADR reporting system among patients

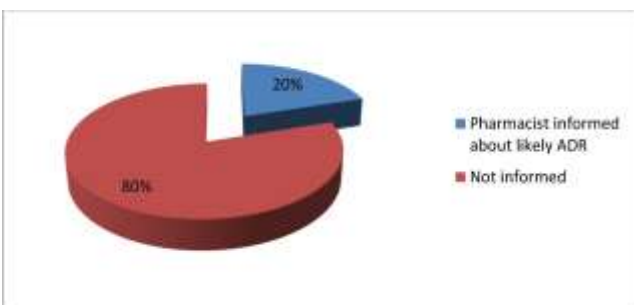
Most of the participants, about 56% (28 respondents) were not aware about Pharmacovigilance . Better

**Table 1: Patient details regarding co morbidities, usage of OTC and alternative system of medicine.**

Details of patients	No of patients (N)	Frequency (%)
Taking medication for more than one disease condition	40	80
Taking any OTC medications?	35	70
Taking other system of medicine	20	40%
Ayurveda	15	30
Homeopathy	5	10

**Table 3: sources of awareness on Pharmacovigilance.**

Source	no of participants	Frequency (%)
Social media	11	22
Internet	5	10
Newspaper	3	6
Television	2	4
Radio	1	2

Figure 1: Patients awareness about their medications.**Figure 2: Pharmacist informed patients about ADR of their medications.**

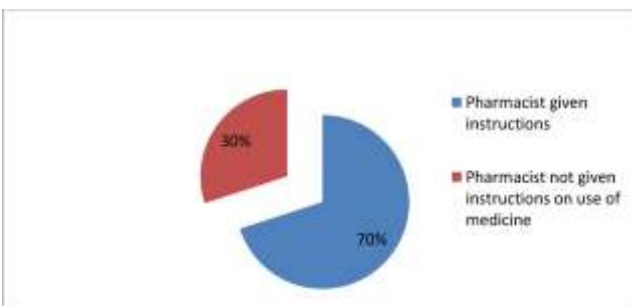


Figure 3: Pharmacist given instruction on their use of medicine.

Table 2: Educational qualification and awareness on Pharmacovigilance

Educational qualification	no of participants (n= 50)	No of respondents aware about Pharmacovigilance
Primary education	15	3
High school	21	7
Graduates	14	12

Pharmacovigilance awareness (24%) was observed with secondary or tertiary educational status compared to those with lower educational qualification (Table 2). 11 (22%) patients had heard of the term “Pharmacovigilance” through the social media platform (Table 3).

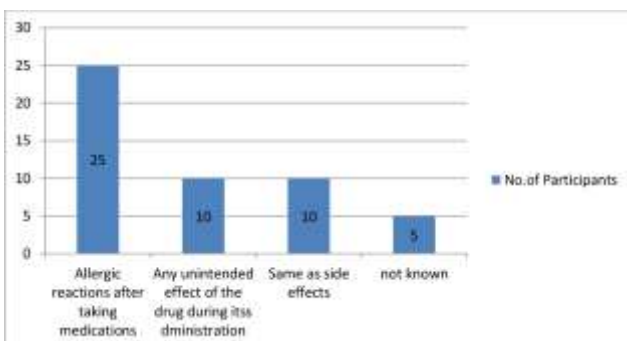


Figure 4: Patients understanding on ADR.

Table 4: Adverse drug reaction practice among patients.

Adverse drug reaction reporting practice among patients	No of patients (N)	Frequency (%)
Patients Experienced any unexpected/expected reaction after taking medications	15	30
Informed about the ADR to physician?	10	20

Sources of awareness on Pharmacovigilance



Ten (20%) had knowledge about short message service (SMS) alert short code for reporting experienced ADRs, through advertisement and online source. 2 (4%) respondents have heard of ADR PvPI app through internet. But they were not aware about the ADR Reporting center in the hospital. 96% were not heard about ADR PvPI App for reporting ADR (Figure 4). 4% were heard about the ADR PvPI app for self reporting ADR and their source of knowledge were social media.

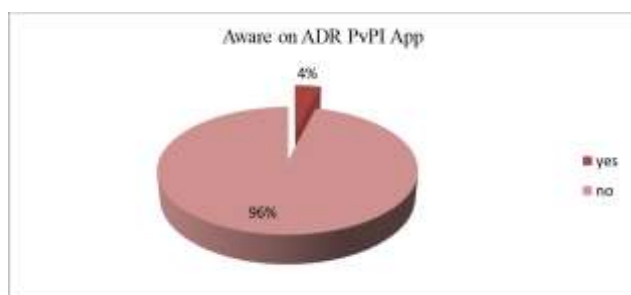


Figure 5: out patients awareness about ADR PvPI App.

Table 5: Reasons for under reporting ADR by the patients.

Reasons why patients do not report experienced ADR	No of patients	Frequency %
Difficulty in travelling	1	20
Rush in the hospital	1	20
Not consider ADR reporting important	3	60
Others	0	0



Figure 6: Patient information leaflet.

DISCUSSION

We wanted to see how well our patients understood ADR, so we ran this cross-sectional survey to find out. Fifty individuals met the inclusion criteria for this investigation. various demographic characteristics are associated with various levels of knowledge and attitudes among

Adverse Drug Reaction Reporting Practice among Patients

All the participants (100%) were not aware about the Pharmacovigilance centre of the hospital and no one yet reported ADR to Pharmacovigilance centre. No out patients were not ever been trained on ADR reporting. 30% of patients experienced any unexpected reactions after taking medications. Among the 15 patients experienced ADR only 10 patients were reported it to their physician (Table 4).

respondents. There was parity in the sex distribution among the volunteers' ages, which ranged from 18 to 70. There were 15 people (30%) with just a basic school education, 21 (42%) with a high school diploma or equivalent, and 14 (28%) with a bachelor's degree or above.

In terms of their employment, 24% are in the private sector, 20% are in the public sector, 46% are jobless, and 10% are involved in some other kind of labor. Conditions such as hypertension, diabetes, thyroid, and hyperlipidemia are present in the majority of these individuals. The risk of adverse medication reactions was three times higher in patients with comorbidity compared to those without, as shown in the research by Bassi et al.⁶ Table 1 shows that 35 respondents (or 70% of the total) used to self-medicate using antibiotics, fever reducers, cough syrups, and the like. While OTC medications are generally safe, they do have the potential to induce adverse drug reactions. Bukic J et al.'s research

corroborated this.⁷ In this case, patients were given antibiotics without a valid prescription, which does not fall under over-the-counter drugs. Forty percent of the people included are using non-allopathic medications, such as those from ayurveda, siddha, unani, and homeopathy (Table 1). Drug interactions and side effects are possible outcomes of integrative medicine. Eight of the patients had no idea about it. Figure 1 shows that over half of the patients did not know the proper way to take their medicine. Figure 3 shows that a higher percentage of patients had received medication use advice from pharmacists. Unbeknownst to 80% of patients, however,

Table 6: Preferred method of ADR reporting by the patients.

Preferred methods of ADR reporting	No of patients	Frequency %
Phone call	8	16
Directly reporting to physician	40	80
Filling medicine side effect report reporting form	2	4

Reason for under reporting ADR by the Patients

Suggested reasons for non-report of experienced ADRs included ignorance of the importance of ADR reporting, as well as unserious nature of the ADRs. Rush in the hospital is another reason for not reporting ADR Table 5.

Preferred methods of ADR reporting by the patients

Table 6 shows that most consumers prefer that their pharmacists notify their doctors directly when they have any adverse drug reactions to their medications (Figure 2). Ensuring the safety of outpatients is a crucial responsibility of pharmacists. Outpatients who received patient counseling had a reduced risk of avoidable adverse effects, according to research by Schnipper JL et al.⁹

The ADR Reporting program has a serious issue with underreporting. The field of public health is negatively affected by it.⁵ The participants were all unaware that the hospital had set up an ADR reporting center. So far, no adverse drug reactions have been documented since they are unaware of the risks. They are all in the dark about the ADR PvPI Application. They may also report ADR by calling the toll-free number 1800-180-3024.

Figure 4 shows that 50% of participants thought that adverse drug responses (ADRs) are "allergic reactions after taking medications," 20% thought that ADRs are "Any unintended effect of the drug during its administration," 20% thought that ADRs are "the same as side effect," and



10% were unaware that ADRs existed. This goes against what most patients in the Joshi et al.¹⁰ research believed, which is that ADRs are the same as side effects.

Concerning pharmacovigilance education Pharmacovigilance was unfamiliar to the majority of the participants (about 56 percent). Whereas, compared to individuals with less education, those with a secondary or tertiary degree had a higher rate of pharmacovigilance awareness (24%). Adisa et al. found comparable results.¹¹ A quarter of their information came from social media, 10% from the internet, 6% from newspapers, 4% from television, and 2% from radio. Section 3. People are starting to pay more attention to the role that social media plays in pharmacovigilance. This includes platforms like Facebook and Twitter. The impact of social media on pharmacovigilance is explained in a review paper that was published in the British Journal of Clinical Pharmacology.¹² One potential future use of social media in pharmacovigilance systems is the reporting and discussion of adverse drug reactions; however, this area must be carefully monitored from a regulatory and ethical perspective.

Ten patients (20%) were aware of the short messaging service (SMS) alert short code for reporting adverse drug reactions (ADRs), either from internet sources or advertisements. Figure 5 shows that almost all respondents (96%), when asked about the ADR PvPI app for reporting ADR, had never heard of it. Of those respondents, 4% learned about it via social media. Some individuals are still confused by the ADR PvPI app, even after the Indian government released it in 2017. Health care providers and customers alike may now report adverse drug reactions (ADRs) with the tap of a button.¹³ One hundred percent of participants had no idea that the hospital had a pharmacovigilance center, and none had reported an adverse drug reaction (ADR) to them as of yet. There were no adverse drug reactions (ADRs) recorded by anybody other than healthcare providers in the preceding year, according to data from the institution's pharmacovigilance center. Located in Chennai, it serves as the only regional pharmacovigilance

center. Patients are a window into the community. This means that public education and training are much needed. None of our patients received any kind of training on adverse event reporting. Medication-related side effects were reported by 30% of patients. Table 4 shows that out of the fifteen patients that encountered ADR, only ten informed their doctor about it. See Table 5 for a breakdown of the reasons patients did not report adverse drug reactions: 60% were unaware of the need of reporting them, 20% were in a rush while in the hospital, and 20% had trouble getting there. Direct communication with the doctor is preferred by the majority of patients (Table 6). Understanding the accessible ADR reporting method is crucial for patients in order to enhance the pharmacovigilance system. Participants were instructed on how to use the ADR PvPI smartphone app for self-reporting ADRs, and they were also informed about the ADR reporting system via patient information booklets (Figure 6). Without exception, every single responder has agreed to notify their doctor or local ADR hotline if any adverse drug reactions occur in the future. When it comes to protecting individuals, they both think it's a good idea.

CONCLUSION

Patients using the outpatient services of a multi-superspecialty hospital were asked to fill out a survey measuring their familiarity with adverse drug reactions (ADRs) and the pharmacovigilance system. In terms of awareness of adverse drug reactions and the pharmacovigilance concept, outpatients scored poorly. Also, only few patients really reported adverse drug reactions (ADRs). It shows that outpatients need training and instruction on the pharmacovigilance concept. Healthcare providers are on hand to identify and document adverse drug reactions (ADRs) in inpatients as soon as they occur after medication delivery. However, it is important for our patients, particularly those with chronic conditions or who are undergoing alternative therapies at the same time as their medicine, to have a basic understanding of the most common adverse drug reactions. The majority of patients are either unaware that the government of India has released

an app called ADR PvPI for the purpose of ADR reporting or are unsure on how to utilize it. Our patients may be made more knowledgeable if we gave them informational brochures and showed them how to utilize the ADR PvPI app. Although the hospital has an adverse drug reaction reporting center, none of the people who took part in the trial knew about it. This finding suggests that the general public and outpatients are still in the dark about pharmacovigilance. Increasing ADR reporting rates and bolstering pharmacovigilance efforts may be achieved via the implementation of educational programs and the creation of a supportive atmosphere for ADR reporting.

Strengths of the Study

Patient reporting make an important contribution to drug safety. Most of the studies covered knowledge and perception toward ADRs among various health care Professionals. But studies on awareness among out patients are limited. Patients safety should begin from them. In case of inpatients health care professionals are always available to identify and report the ADR once it occur after administration. But it is a different situation in terms of outpatients. Patient informational leaflets were distributed to all the participants. Investigators trained Patients on use of ADR PvPI app for self reporting ADR.

Limitations of the Study

Patients were from single center so results may be difficult to generalize to other populations of the country. There may be difference in the knowledge and perspective of people in a developing country like India and people in other developed countries. The study participants were from Andrapradesh and the result may not be generalizable to patients from other states. Involving more patients from other states would have given a better understanding about the knowledge and perception of ADR among patients across the country and community. We were unable to interview and educate more people as the study period were in the time of COVID outbreak. So sample size obtained was small.

ACKNOWLEDGEMENT

Thank management of KIMS hospital for providing an opportunity, Pharmacovigilance associate for helping in the preparation of Patient information leaflet, Dr. Kumar, Dept. of Pharmacy Practice for the support and encouragement.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

ADR: Adverse drug reactions; **PvPI:** Pharmacovigilance Programme of India.

SUMMARY

Knowledge and perception towards ADR reporting was evaluated by using questionnaire prepared. The study reveals 100% unawareness among outpatients representing public health about the regional pharmacovigilance centre at the institution they visited frequently. Patients were educated about ADR reporting with the help of a patient information leaflet prepared (Figure 6). They were trained on use of ADR PvPI app for self reporting ADR.

REFERENCES

1. p. 82 of Tripathi KD's Essentials of Medical Pharmacology, 7th ed. New Delhi: Jaypee Brothers, 2013.
2. Pedrolle RB and Weerasuriya K. How can consumer reporting of adverse medication reactions complement procedures now in place for health professionals? Pay attention to the poor countries. *Safe Drug Practices*. 2003;26(4):219-25. Google Scholar, PMID, and doi: 10.2165/00002018-200326040-00002.
3. 4. Getova VI, Stoimenova AH, Georgiev SR, Petkova-Georgieva ES. A retrospective database assessment of the Bulgarian experience with adverse medication reaction reports from consumers and patients. The article is published in *Folia Med (Plovdiv)* in 2018 and has the DOI: 60(3): 447–853. Bibcode: 2018Folmed.0016, PubMed ID: 30355838.
4. Researchers Hedna K., S. Hägg, K. Andersson Sundell, et al. conducted a population-based investigation on refill adherence, self-reported adverse medication responses, and sub treatment outcomes. *Google Scholar, PMID, and Pharmacoepidemiol Drug Safety* (2013), 22(12):1317–25, doi: 10.1002/pds.3528.
5. The authors of this work are Pirmohamed, Atuah, Doodoo, and Winstanley. Clinical drug monitoring in low-income nations. A free article from the British



- Medical Journal published in 2007 with the DOI: 10.1136/bmj.39323. 586123.BE. Web of Science, PubMed, and Google Scholar.
6. Assi PU, Osakwe AI, Ogar CK, Elagbaje C, Nwankwo BB, Balogun ST, and others. Cohort of Nigerian patients treated with artemisinin combination therapy for simple malaria: effect of co-morbidities on adverse medication reaction profile. *Research in Pharmaceuticals*, 2017;5(2):e00302. DOI: 10.1002/prp2.302; PMCID: PMC5368966; PMID: 28357128.
 7. The authors were Bukic, Rusic, Mas, Karabatic, Bozic, Seselja Perisin, and others. Study of OTC medications used for pain relief purposes that did not have analgesic properties and the number of reported suspected adverse drug events from 2008 to 2017. Bose SP, Singh DP, and Nivsarkar M. authored the following article in 2019 (*BMC Pharmacol Toxicol*, 20(1):60; doi: 10.1186/s40360-019-0338-2, PMID 31627740, PMCID PMC6798506). Recognizing the need of research on herb-drug interactions, with an emphasis on interactions, is a necessary condition for integrative medicine. The citation is from the following sources: *Porto Biomed J*. 2019;4(2):e15, PMID 31595257, PMCID PMC6726296. The online version of the article can be found at doi: 10.1016/j.pbj.0000000000000015.
 8. 9. The authors of the study include Schnipper, Kirwin, Cotugno, Wahlstrom, Brown, and Tarvin among others. How hospital pharmacists may help reduce the risk of medication side effects upon discharge. This article was published in 2006 by *Arch Intern Med* and has the DOI: 10.1001/archinte.166.5.565. The patient's medical history was cited as 16534045.
 9. 10. The authors are Joshi, Shah, Mistry, and Gor. Assessment of patients' understanding and perceptions of adverse medication responses in a tertiary-care teaching hospital. *National Journal of Physiology, Pharmacy, and Therapeutics*. 2015;5(4):280-4. doi: 10.5455/njppp.2015.5.2502201543.
 10. 11. Adisa R, Omitogun TI. Adverse drug reaction reporting: a survey of healthcare providers and patients in Ibadan, southwest Nigeria, on their understanding, attitudes, and behaviors in this area. *Public Health Res* (2019) 19(1): 926, PMID 31796034, doi: 10.1186/s12913-019-4775-9.
 11. The potential and difficulties of social media in pharmacovigilance are reviewed by Sloane, Osanlou, Lewis, Bollegala, Maskell, and Pirmohamed (2012). This is the citation for the article: *Br J Clin Pharmacol*. 2015;80(4):910-20. Posted on the internet. The entry with the DOI number 26147850 is 10.1111/bcp.12717.
 12. The authors of the article are Prakash, Joshi, Malik, Mishra, Sachan, And Kumar. Download the "ADR PvPI" app for Android to report adverse drug reactions whenever and wherever they occur in India. The citation for this article is "*Indian Journal of Pharmacology*" (2019, 51(4):230-242). 31571709 (DOI: 10.4103/ijp.IJP_595_18).