Section: Pharmacology

Original Research Article

A STUDY ON THE IMPACT OF PHARMACOVIGILANCE AWARENESS AMONG HEALTHCARE PROFESSIONALS IN REPORTING ADVERSE DRUG REACTIONS

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ABSTRACT

Background: Pharmacovigilance plays a vital role in ensuring patient safety through the detection, assessment, and prevention of adverse drug reactions (ADRs). Despite its importance, underreporting of ADRs remains a significant challenge, particularly in developing countries. This study aimed to evaluate the awareness, attitude, and practice of healthcare professionals regarding pharmacovigilance and ADR reporting. **Material and Methods:** A cross-sectional study was conducted among 100 healthcare professionals, including doctors, nurses, and pharmacists, using a pre-validated structured questionnaire. Data were collected on demographic characteristics, awareness of pharmacovigilance, attitudes towards ADR reporting, and actual reporting practices. The findings were analyzed and presented in descriptive statistics. **Result:** The majority of participants were doctors (40%), followed by nurses (35%) and pharmacists (25%). Awareness of pharmacovigilance was reported by 76% of respondents, while only 59% were aware of the National Pharmacovigilance Programme (PvPI) and 45% knew the process of ADR reporting. A positive attitude towards ADR reporting was observed, with 80% considering it a professional obligation and 88% acknowledging its role in enhancing patient safety. However, only 26% had ever reported an ADR, and 18% had used an ADR reporting form. Major barriers identified included lack of knowledge, time constraints, and fear of legal repercussions. **Conclusion:** Although healthcare professionals exhibited good awareness and a favorable attitude towards pharmacovigilance, actual ADR reporting practices were suboptimal. Regular training programs and sensitization campaigns are essential to bridge this gap and promote a robust culture of ADR reporting.

INTRODUCTION

Medications play a crucial role in the prevention, management, and cure of diseases; however, they are also associated with the risk of adverse drug reactions (ADRs), which can compromise patient safety and contribute to increased morbidity and healthcare costs. Pharmacovigilance, defined by the World Health Organization as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems, is vital for ensuring medication safety and protecting public health.

Despite the importance of pharmacovigilance, underreporting of ADRs is a persistent challenge across healthcare systems worldwide, particularly in low- and middle-income countries like India. Several studies have highlighted that although healthcare professionals are generally aware of the concept of pharmacovigilance, this awareness does not consistently translate into effective ADR reporting practices.[1,2] Lack of knowledge regarding the reporting process, fear of legal consequences, and time constraints are among the most frequently cited barriers.[1,3]

Recent research underscores the positive impact of educational interventions and sensitization initiatives in improving pharmacovigilance knowledge and reporting behavior among healthcare professionals.[3,4] Studies have demonstrated that

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targeted training programs significantly enhance not only the awareness but also the attitudes and confidence of healthcare workers in reporting ADRs.[5,6]

This study was undertaken to assess the awareness, attitude, and practice of pharmacovigilance among healthcare professionals in a tertiary care setting and to identify the key barriers hindering ADR reporting. The findings are expected to inform strategies aimed at improving pharmacovigilance activities and fostering a culture of patient safety.

MATERIALS AND METHODS

Study Design and Setting: A cross-sectional observational study was conducted at the Department of General Medicine, Sreenarayana Institute of Medical Sciences, Chalakka, Ernakulam, Kerala. The study was carried out over a period of six months, from March to September 2014.

Study Population: The study population consisted of healthcare professionals, including doctors, nurses, and pharmacists working in the hospital. Participants who were willing to provide informed consent and were directly or indirectly involved in patient care were included in the study. Healthcare workers not involved in prescribing, dispensing, or monitoring medication were excluded.

Sample Size: A total of 100 healthcare professionals were enrolled using a convenient sampling method.

Study Tool: Data were collected using a pre-validated, structured, self-administered questionnaire. The questionnaire was divided into four sections:

Demographic Information: Age, gender, profession, and years of experience.

Awareness: Knowledge of pharmacovigilance, adverse drug reactions (ADRs), and familiarity with the Pharmacovigilance Programme of India (PvPI).

Attitude: Perceptions and beliefs about the importance and necessity of ADR reporting.

Practice: Actual reporting behavior and barriers to ADR reporting.

Data Collection Procedure: Participants were approached in person, and the purpose of the study was explained. Written informed consent was obtained. The questionnaire was distributed, and adequate time was given for completion.

Data Analysis: The collected data were compiled and analyzed using Microsoft Excel. Descriptive statistics such as frequencies and percentages were used to summarize the demographic details, awareness, attitudes, and practices related to pharmacovigilance.

RESULTS

The present study assessed the impact of pharmacovigilance awareness among 100 healthcare professionals, including doctors, nurses, and pharmacists, on their knowledge, attitude, and practice of adverse drug reaction (ADR) reporting.

As shown in Table 1, the study population comprised 40% doctors, 35% nurses, and 25% pharmacists. There was a slight female predominance (52%), with the majority of participants having 5–10 years of professional experience (42%).

Assessment of awareness regarding pharmacovigilance revealed that 76% of participants had heard about the concept of pharmacovigilance, while 59% were aware of the National Pharmacovigilance Programme of India (PvPI). However, only 45% knew how to report an ADR, and merely 34% had ever attended any training or workshop related to ADR reporting (Table 2).

The evaluation of participants' attitudes demonstrated that 80% agreed that ADR reporting is a professional obligation, and 88% believed that ADR reporting contributes to improved patient safety. Notably, 20% of participants expressed concern that ADR reporting could lead to legal problems, while 50% considered lack of time a significant barrier to reporting (Table 3).

In terms of actual practice, only 26% of healthcare professionals reported ever having submitted an ADR, and a mere 12% had done so within the last six months. The use of ADR reporting forms was low (18%), though 34% of participants reported encouraging their colleagues to report ADRs (Table 4).

Overall, the study identified a substantial gap between awareness, positive attitudes, and actual reporting practices among healthcare professionals, underscoring the need for targeted educational interventions to enhance pharmacovigilance activities.

Table 1: Demographic Profile of Participants (n = 100)

Characteristic	Frequency (n)	Percentage (%)
Profession		
Doctors	40	40%
Nurses	35	35%
Pharmacists	25	25%
Gender		
Male	48	48%
Female	52	52%
Years of Experience		
< 5 years	36	36%
5–10 years	42	42%
> 10 years	22	22%

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Table 2: Awareness About Pharmacovigilance and ADR Reporting

Awareness Parameter	Yes (n/%)	No (n/%)
Heard about Pharmacovigilance	76 (76%)	24 (24%)
Aware of National Pharmacovigilance Programme (PvPI)	59 (59%)	41 (41%)
Know how to report an ADR	45 (45%)	55 (55%)
Attended any training/workshop on ADR reporting	34 (34%)	66 (66%)

Table 3: Attitude Towards ADR Reporting

Statement	Agree (n/%)	Disagree (n/%)	Neutral (n/%)
ADR reporting is a professional obligation	80 (80%)	10 (10%)	10 (10%)
Reporting ADRs improves patient safety	88 (88%)	4 (4%)	8 (8%)
Reporting ADRs will create legal problems	20 (20%)	60 (60%)	20 (20%)
Lack of time is a barrier to ADR reporting	50 (50%)	30 (30%)	20 (20%)

Table 4: Practice of ADR Reporting

Practice Parameter	Frequency (n)	Percentage (%)
Ever reported an ADR	26	26%
Reported ADR in last 6 months	12	12%
Use of ADR reporting form	18	18%
Encouraged colleagues to report ADRs	34	34%

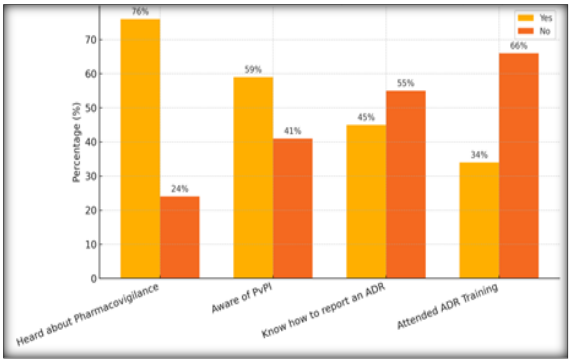

Figure 1: Awareness About Pharmacovigilance and ADR Reporting

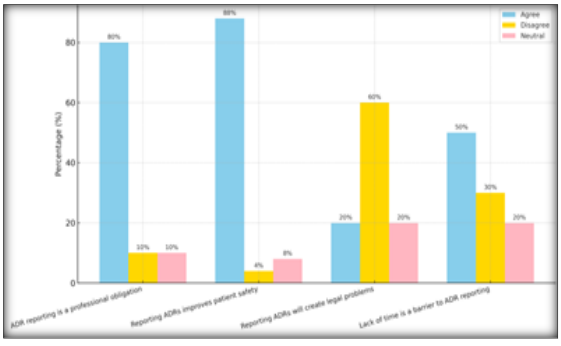

Figure 2: Attitude Towards ADR Reporting

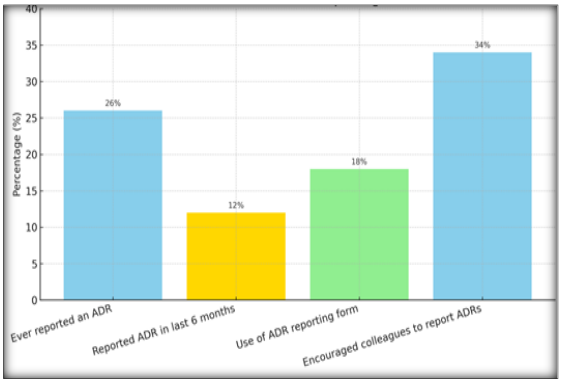

Figure 3: Practice of ADR Reporting

DISCUSSION

Pharmacovigilance plays a fundamental role in promoting patient safety by identifying, assessing, and preventing adverse drug reactions (ADRs). Despite this, underreporting of ADRs continues to be a significant global concern, particularly in developing and resource-limited settings. The present study revealed that although healthcare professionals exhibited a generally favorable attitude towards ADR reporting, their actual reporting practices remained limited—a finding consistent with previous studies conducted in various countries.[7,8]

Knowledge gaps, uncertainty about reporting procedures, and misconceptions about legal liability have been consistently identified as barriers to effective pharmacovigilance systems.[9] Our study also found that while a majority of participants acknowledged the importance of ADR reporting, less than one-third had ever reported an ADR, echoing observations from other international studies where similar discrepancies between awareness and practice were noted.[10,11]

Furthermore, research has shown that continuous education, hands-on training, and sensitization workshops can significantly improve healthcare professionals' pharmacovigilance knowledge and enhance ADR reporting behaviors.[7,12] However, without institutional support and simplified reporting mechanisms, even well-informed professionals may hesitate to report ADRs due to time constraints or fear of repercussions.[8,9]

The findings from this study emphasize the urgent need to implement structured educational programs on pharmacovigilance and to integrate ADR reporting into routine clinical practice. Additionally, fostering a non-punitive culture and raising awareness about the legal protections associated with ADR reporting can further encourage healthcare professionals to actively participate in pharmacovigilance efforts.

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CONCLUSION

The present study highlights that although healthcare professionals demonstrate good awareness and a positive attitude towards pharmacovigilance and adverse drug reaction (ADR) reporting, actual reporting practices remain significantly low. Key barriers identified include lack of knowledge on reporting procedures, time constraints, and concerns about legal consequences. These findings underscore the need for continuous education, training, and sensitization programs to bridge the gap between awareness and practice. Simplifying the ADR reporting process and integrating it into routine clinical practice can enhance reporting rates. Strengthening pharmacovigilance activities is essential to ensure patient safety, improve drug monitoring, and foster a proactive reporting culture among healthcare professionals.

REFERENCES

1. Putri RA, Ikawati Z, Rahmawati F, Yasin NM. An Awareness of Pharmacovigilance Among Healthcare Professionals Due to an Underreporting of Adverse Drug Reactions Issue: A Systematic Review of the Current State, Obstacles, and Strategy. Curr Drug Saf. 2024;19(3):317-331. doi: 10.2174/0115748863276456231016062628. PMID: 38989832; PMCID: PMC11327747.
2. Almandil NB. Healthcare professionals' awareness and knowledge of adverse drug reactions and pharmacovigilance. Saudi Med J. 2016 Dec;37(12):1359-1364. doi: 10.15537/smj.2016.12.17059. PMID: 27874152; PMCID: PMC5303775.
3. Shenoy AK, Kamath A, Chowta MN, Boloor A, Aravind A, Thakur PB, Kumar S. Knowledge of pharmacovigilance among healthcare professionals and the impact of an educational intervention. Med Pharm Rep. 2023 Oct;96(4):406-412. doi: 10.15386/mpr-2076. Epub 2023 Oct 26. PMID: 37970197; PMCID: PMC10642735.
4. Alqahtani SS, Ahmad S, Alam N, Kashan Syed N, Syed MH, Khardali A, Yasmeen A, Alshahrani AM, I Alzarea A, Alanazi AS, Hassan Elnaem M. Healthcare professionals' awareness, attitudes and practices towards pharmacovigilance and spontaneous adverse drug reaction reporting in Jazan Province, Saudi Arabia: A survey study. Saudi Pharm J. 2023 Jun;31(6):979-988. doi: 10.1016/j.jsps.2023.04.021. Epub 2023 Apr 25. PMID: 37234340; PMCID: PMC10205759.
5. Raikar SR, Sneha S, G S, R J. Awareness and Knowledge of Adverse Drug Reactions and Pharmacovigilance Among Medical and Nursing Students and Staff in a Tertiary Care Hospital. Cureus. 2024 Sep 23;16(9):e69981. doi: 10.7759/cureus.69981. PMID: 39445248; PMCID: PMC11498074.
6. Kumari A, Prajapati H. Transformative education: Enhancing pharmacovigilance awareness among healthcare professionals through sensitization initiatives. J Family Med Prim Care. 2025 May;14(5):2026-2030. doi: 10.4103/jfmpc.jfmpc_1869_24. Epub 2025 May 31. PMID: 40547774; PMCID: PMC12178524.
7. Hayek A, Sridhar SB, Rabbani SA, Shareef J, Wadhwa T. Exploring pharmacovigilance practices and knowledge among healthcare professionals: A cross-sectional multicenter study. SAGE Open Med. 2024 May 8; 12:20503121241249908. doi: 10.1177/20503121241249908. PMID: 38725923; PMCID: PMC11080773.
8. Aziz AA, Rogers S, Hassanien O, Shalaby L, Nagy M. Knowledge, attitudes and practice regarding pharmacovigilance and adverse drug reaction reporting among physicians and pharmacists in Egypt: a step toward personalized medicine implementation. Per Med. 2022 Nov;19(6):495-507. doi: 10.2217/pme-2022-0030. Epub 2022 Oct 14. PMID: 36239598.
9. Curtolo E, Micallef B, Szijj JV, Serracino-Inglott A, Borg JJ. An exploratory study of knowledge, attitudes, practice and barriers towards adverse drug reaction reporting among healthcare professionals in Malta. Int J Risk Saf Med. 2024;35(3):271-286. doi: 10.3233/JRS-230055. PMID: 38820023.
10. Bepari A, Assiri RA, AlYahya MA, AlGhamdi SJ, AlGhamdi AM, AlOnazi AA. The comparative assessment of awareness, perspective, and basic practice skills about the Saudi pharmacovigilance system among students of different health-care professionals of a Saudi Female University. Saudi Pharm J. 2020 Jul;28(7):828-836. doi: 10.1016/j.jsps.2020.06.002. Epub 2020 Jun 12. PMID: 32647484; PMCID: PMC7335728.
11. Abdel-Latif MM, Abdel-Wahab BA. Knowledge and awareness of adverse drug reactions and pharmacovigilance practices among healthcare professionals in Al-Madinah Al-Munawwarah, Kingdom of Saudi Arabia. Saudi Pharm J. 2015 Apr;23(2):154-61. doi: 10.1016/j.jsps.2014.07.005. Epub 2014 Jul 9. PMID: 25972735; PMCID: PMC4420988.
12. Khan Z, Karatas Y, Martins MAP, Jamshed S, Rahman H. Knowledge, attitude, practice and barriers towards pharmacovigilance and adverse drug reactions reporting among healthcare professionals in Turkey: a systematic review. Curr Med Res Opin. 2022 Jan;38(1):145-154. doi: 10.1080/03007995.2021.1997287. Epub 2021 Nov 3. PMID: 34694167.

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