

A Comprehensive Study of Knowledge and Attitudes Towards Pharmacovigilance Among Health Care Team

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ABSTRACT

Background: Pharmacovigilance is essential for ensuring the safety and efficacy of medications by monitoring and evaluating adverse drug reactions. A robust pharmacovigilance system supports early detection of drug-related risks and enables corrective actions, which is crucial for public health.

Aim: This study aims to assess healthcare professionals' awareness, understanding, and perspectives regarding the pharmacovigilance system.

Objectives: The objectives of this study were to (1) evaluate the current status of pharmacovigilance awareness within the healthcare system and (2) identify the factors necessary for effective functioning of the pharmacovigilance system.

Methodology: This descriptive cross-sectional study was conducted over one month across various healthcare sectors in Kozhikode district, India. A structured questionnaire was distributed via Google Forms to a sample of 384 healthcare professionals, including doctors, pharmacists, nurses, and paramedical staff, selected based on a calculated sample size for a finite population. Inclusion criteria focused on actively practicing professionals across government and private sectors, while students and non-practicing staff were excluded. Data on demographics, knowledge, and attitudes toward pharmacovigilance were collected and analyzed through descriptive statistics.

Results: The findings revealed that 63.53% of healthcare professionals were aware of the pharmacovigilance system, while 36.47% were unaware. This lack of awareness was identified as a potential barrier to the effective implementation of pharmacovigilance practices.

Discussion: Limited awareness among healthcare professionals could compromise drug safety and the quality of healthcare delivery. This gap highlights the need for strategies to foster a more informed healthcare workforce.

Conclusion: To strengthen pharmacovigilance, the study recommends increased training and education, simplified reporting mechanisms, expanded awareness campaigns, and a structured feedback system. These efforts could enhance medication safety and overall drug efficacy within healthcare systems.

Keywords: Pharmacovigilance; Adverse drug reactions; Healthcare professionals; Drug safety; Public health

INTRODUCTION

Pharmacovigilance (PV) is derived from the words *pharmacon* (greek), which means medicinal substance, and *vigilare* (latin), which means to keep watch over the safe use, effectiveness, and adverse reactions of medicinal products. The World Health Organization (WHO) defines^[1] pharmacovigilance as “the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems.” This system monitors and evaluates adverse drug reactions. In the healthcare system, pharmacovigilance plays an important role^[2] in ensuring the safety and efficacy of medications. Especially pharmacists, doctors, nurses, and patients can play an important role in the detection and reporting of suspected ADR. It is crucial to encourage pharmacists and other health care providers around the world to report ADR. Therefore, community pharmacists should understand the importance of safe use of medicines^[5], especially for outpatients, whereas nurses are more significant for inpatients.

In the 1960s, the WHO established the global^{1,2,3} ADR monitoring program, the WHO Collaborating Centre for International Drug Monitoring^[6]. This program aimed to collect and analyze ADR reports from around the world to identify potential safety concerns and improve the safety of drugs. The PvPI^[3,4] was started by the Government of India on 14th July 2010 with the AIIMS, New Delhi as the National Coordination Centre for monitoring ADRs in the country for safe-guarding Public Health. The Pharmacovigilance exertion in India is organized by The Indian Pharmacopoeia Commission and conducted by the CDSCO. The main responsibility of the IPC is to maintain and develop the pharmacovigilance database consisting of all suspected serious adverse reactions to medicines observed. IPC is functioning as NCC for PvPI. Aim of Pharmacovigilance. Improve patient care and safety for the use of medicines and para medical interventions. Research the efficacy of drug and by monitoring the adverse effects of drugs. Promote public health and safety in relation to the use of medicines. Contribute to the assessment of benefit, harm, effectiveness and risk of medicines. Encouraging drug safety, rational and more cost-effective use. Create awareness, and clinical training in pharmacovigilance and its effective communication to the public.

Need of Pharmacovigilance

- **Patient Safety:** It ensures the safety of patients by monitoring and reporting adverse reactions to medications, helps to prevent ADR.
- **Public Health Protection:** It helps to protect the public health by identifying potential risks related to drugs.
- **Regulatory Compliance:** Regulatory agencies require pharmacovigilance data to assess the safety of drugs and make informed decisions about their approval, labeling, and usage.
- **Quality Assurance:** It helps to maintain the quality and efficacy of medications by detecting and addressing issues related to their safety and effectiveness.
- **Risk Management:** Identifies and manages the risks associated with medications, allowing healthcare providers to make informed decisions about treatment options.

Absence of pharmacovigilance

1. **Underreporting of Adverse Events:** Without pharmacovigilance, adverse events related to medications may go unnoticed or unreported, leading to a lack of awareness about potential risks.

2. **Delayed Detection of Safety Issues:** Failure to monitor and analyze adverse events can result in delayed detection of safety issues, potentially causing ADR to patients.
3. **Increased Healthcare Costs:** ADR can lead to increased healthcare utilization, such as inpatients and additional medical treatments, resulting in higher healthcare costs.
4. **Loss of Public Trust:** Inadequate monitoring of medication safety can breakdown the public trust in healthcare systems, pharmaceutical companies, and regulatory agencies.
5. **Regulatory Consequences:** Regulatory agencies can sanction or remove medications if safety concerns aren't addressed, impacting revenue for pharmaceutical firms and patients' treatment options.

ADR reporting is organized in a pharmacovigilance system that is designed to protect human health and life through the detection, analysis, and prevention of ADRs and other drug-related problems. ADR causes significant morbidity and mortality across diverse populations worldwide and has an economic impact on the healthcare system. By empowering healthcare providers and patients to report adverse reactions, global pharmacovigilance programs help to address inconsistencies in drug safety monitoring and promote equitable access to safe and effective treatments. So, ADR reporting is crucial worldwide.

This study was aimed to ascertaining health professionals to understand and perspective regarding the pharmacovigilance system. The findings of the study are targeted towards interventions and educational initiatives for enhancing pharmacovigilance practice among healthcare professionals. This continuous learning will improve patient safety and optimize healthcare outcomes.

Many research papers have focused mainly on doctors or pharmacists^[14,15,16] Some studies are restricted to only certain categories. In order to avoid the adverse effects of drugs and improve the health care outcome, the pharmacovigilance system needs to be strengthened. The success of the implementation of this system needs the teamwork of health care professionals. Apart from the doctors and pharmacists, other patient- associated health care workers, such as nurses, physician assistants, medical assistants, medical social workers, counsellors, technicians also play a significant role in better implementation of pharmacovigilance system. There are no such studies reported. We designed the study to determine the presence and scenario of the pharmacovigilance system among healthcare professionals and identify the factors necessary to establish a better pharmacovigilance system in designated area. we hope that the study's findings may reflect the status of pharmacovigilance in other parts of the state and throughout the country, and that the established factors will improve the system after the research project.

METHODS

Study Design and Setting

This descriptive cross-sectional study was conducted to assess adverse events and quality of life in antiepileptic patients, focusing on healthcare professionals' roles in pharmacovigilance. The study was carried out over one month across multiple healthcare sectors in Kozhikode district, India, and included participants from both government and private institutions.

Study Population and Sample Size

Population: The study targeted healthcare professionals (HCPs) working across Kozhikode district, including doctors, pharmacists, nurses, and paramedical staff who interact with patients.

Sample Size Determination: Due to limited comparable studies, the sample size calculation was based on an infinite population formula, later adjusted for the district's finite healthcare workforce of approximately 20,000 professionals.

1. Infinite Population Sample Size: Using a 95% confidence interval and a 5% margin of error, the sample size was calculated with: $(S) = Z^2 P(1-P) / M^2$

where, (assuming 50% population proportion), and , resulting in a sample size of 384.

2. Finite Population Adjustment: Sample Size $(S.S) = S / 1 + (S - 1) / \text{Population}$

Based on a population of 20,000, the final required sample size remained approximately 384.

Inclusion and Exclusion Criteria

Inclusion Criteria: Practicing HCPs, including doctors, pharmacists, nurses, and paramedical staff. Individuals working in both urban and rural healthcare settings.

Exclusion Criteria: Medical, pharmacy, nursing, and paramedical students. Non-practicing professionals and paramedical staff without direct patient interaction.

Data Collection Procedure

Data were collected using a structured questionnaire distributed via Google Forms, ensuring accessibility across different sectors. The questionnaire, designed in English, included closed-ended questions targeting demographic information (e.g., age, profession, qualifications), as well as knowledge and attitudes toward pharmacovigilance. Specific questions assessed awareness of ADRs, pharmacovigilance center existence, reporting practices, and roles in promoting patient safety.

Statistical Analysis

The collected data were analysed to determine the frequency and proportion of healthcare professionals knowledgeable about ADRs and the pharmacovigilance system. Descriptive statistics and graphical representations were used to present the data. Statistical analysis covered key areas, including knowledge levels, attitudes toward ADR reporting, and perceived responsibilities in pharmacovigilance.

Data Presentation

Data were organized into tables, graphs, and bar charts to facilitate interpretation and highlight trends in pharmacovigilance awareness and reporting practices among healthcare professionals.

Reporting and Documentation

Following data analysis, findings were interpreted, documented, and summarized in a comprehensive report, aligning with the study's objectives to provide insights into pharmacovigilance practices and patient safety in antiepileptic therapy manage

RESULT

Knowledge about Pharmacovigilance

Table 1 and Figure 1 demonstrate the level of awareness about pharmacovigilance among healthcare professionals. A significant proportion of doctors (97.82%) and pharmacists (90.62%) had heard about pharmacovigilance, whereas only 50% of nurses and 15.68% of other paramedical staff reported familiarity.

Table 1: Knowledge about pharmacovigilance

HEALTH CARE PROFESSIONAL	PERCENTAGE YES	PERCENTAGE NO
DOCTOR	97.82 %	2.18%
PHARMACIST	90.62 %	9.38%
NURSE	50 %	50 %
OTHER PARAMEDICAL	15.68 %	84.32%

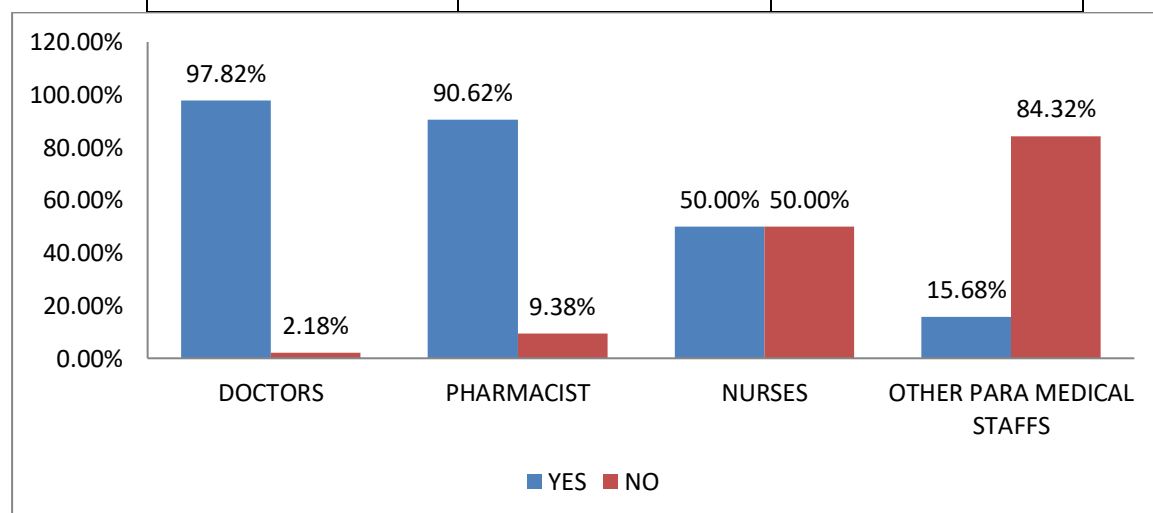


Figure 1 - Knowledge about pharmacovigilance system

Knowledge about Adverse Drug Reactions (ADRs)

As shown in Table 2 and Figure 2, 100% of doctors and pharmacists, and 85.71% of nurses, were aware of ADRs.

Table 2: Knowledge about ADR

HEALTH CARE PROFESSIONAL	PERCENTAGE YES	PERCENTAGE NO
DOCTOR	100 %	NIL
PHARMACIST	100%	NIL
NURSE	85.71%	14.29 %
OTHER PARAMEDICAL	39.21%	60.79%

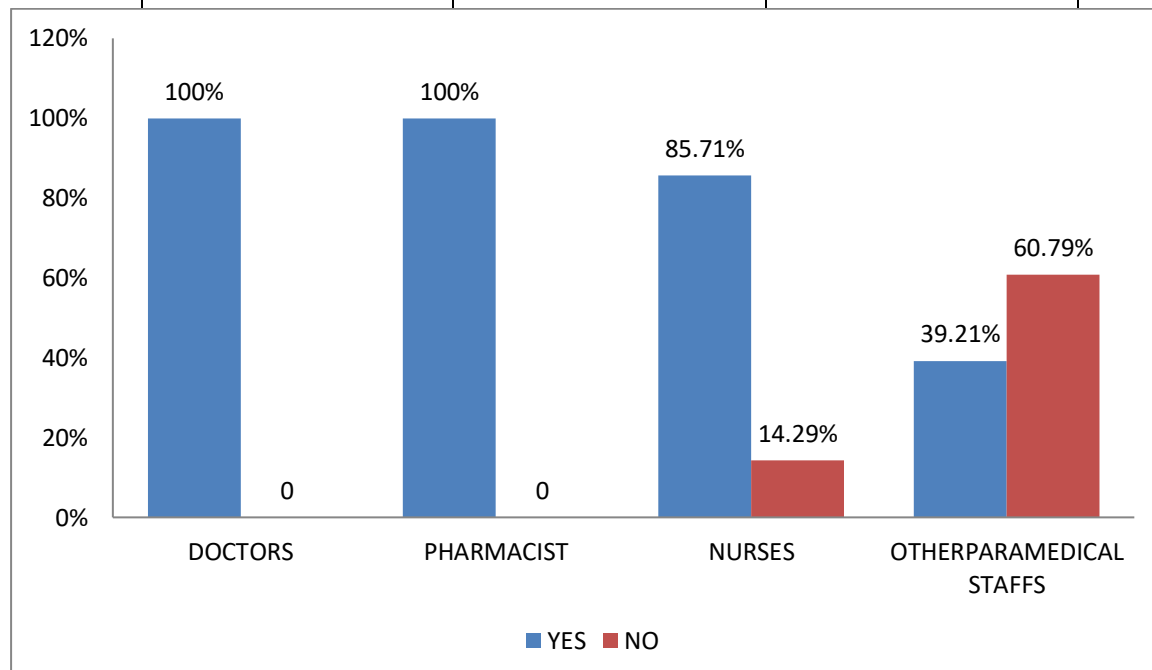


Figure 2 - Knowledge about ADR

Awareness of Nearby Pharmacovigilance Center

Table 3 and Figure 3 indicate that 41% of doctors, 48.97% of pharmacists, and 17.8% of nurses knew about a nearby pharmacovigilance center.

Table 3: Awareness of nearby pharmacovigilance center

HEALTHCARE PROFESSIONALS	PERCENTAGE YES	PERCENTAGE NO
DOCTOR	41%	59%

PHARMACIST	48.97%	51.03%
NURSE	17.8%	82.2%
OTHER PARAMEDICALS STAFFS	9.8 %	90.2 %

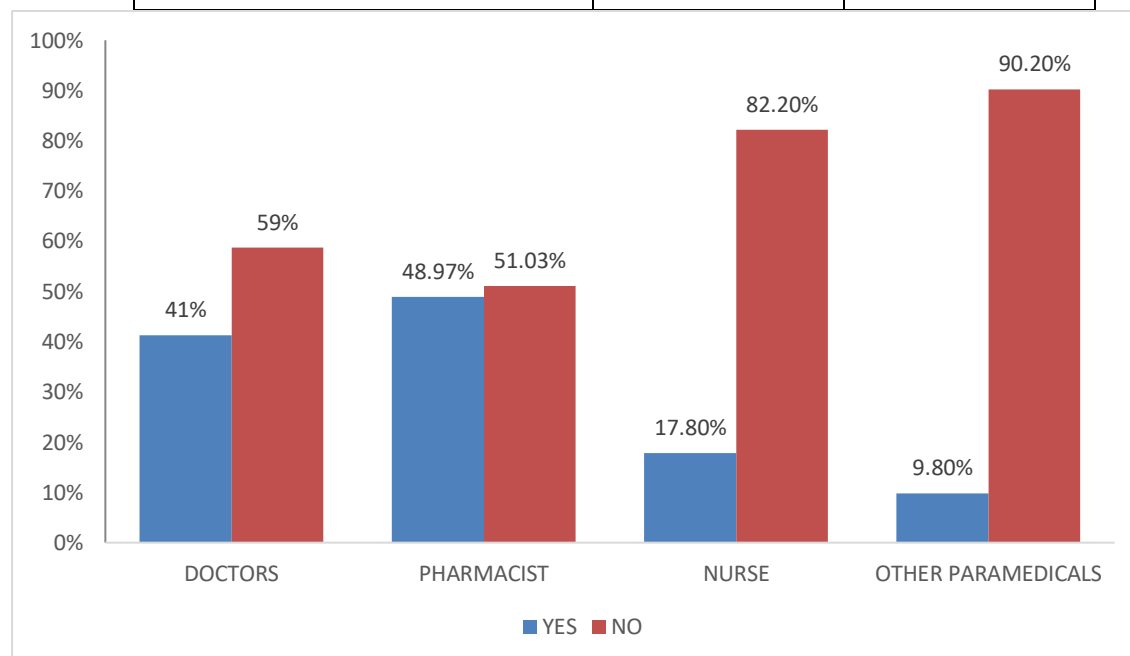


Figure 3: Awareness of nearby pharmacovigilance center

Reporting Knowledge and Practices

Tables 4-6 and Figures 4-6 demonstrate varying levels of knowledge and reporting practices among healthcare professionals.

HEALTHCARE PROFESSIONALS	PERCENTAGE YES	PERCENTAGE NO
DOCTORS	50%	50 %
PHARMACIST	60.41%	39.59%
NURSES	37.5%	62.5%
OTHER PARAMEDICAL STAFFS	5.88%	94.12%

Table4:Reporting knowledge

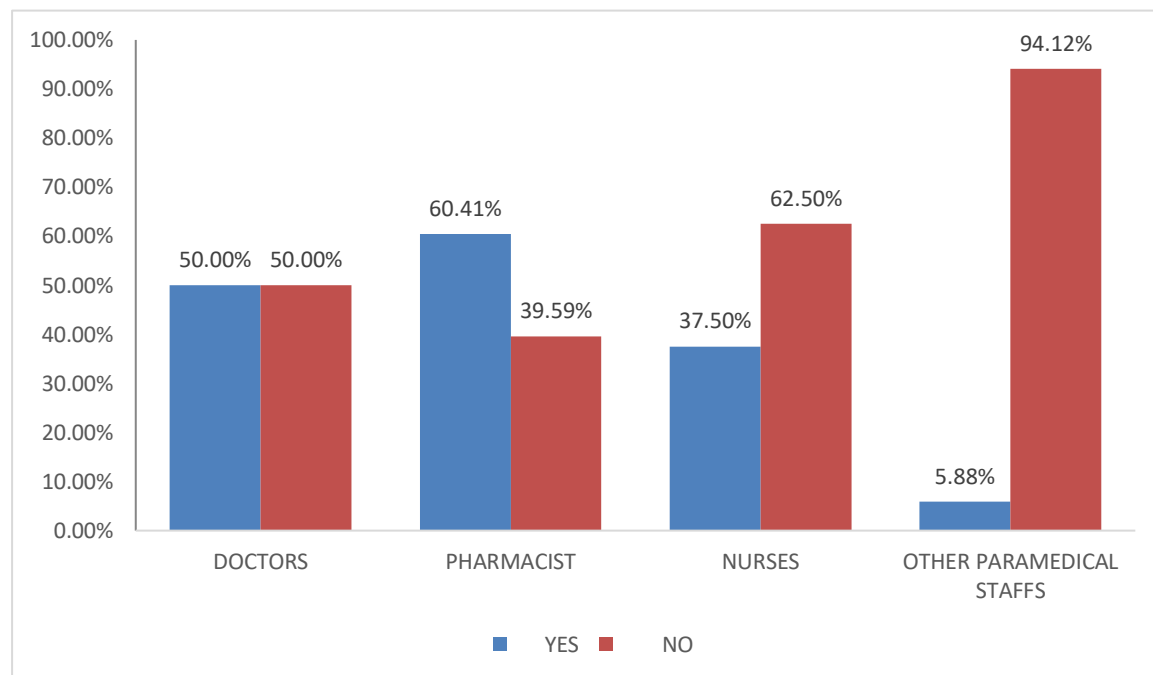


Figure 4 – ADR reporting knowledge
Consequences of Not Reporting ADRs

Table 10 and Figure 10 show that 50% of doctors, 81.63% of pharmacists, and 60% of nurses recognized the consequences of not reporting ADRs.

*	HEALTHCARE PROFESSIONALS	PERCENTAGE YES	PERCENTAGE NO
	DOCTORS	50%	50%
	PHARMACIST	81.63%	18.37%
	NURSES	60%	40%
	OTHER PARAMEDICAL STAFFS	9.8%	90.2%

Table10Consequences of not reporting ADR

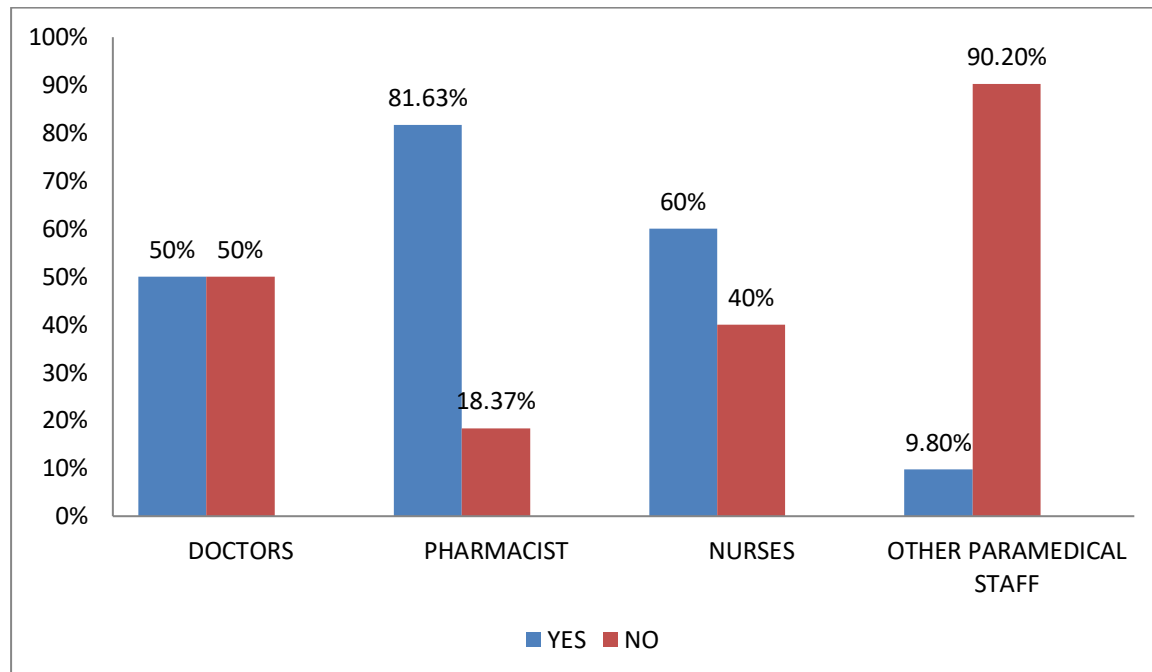


Figure 10- consequence regarding not reporting ADR

Necessity and Professional Obligation

Tables 11-12 and Figures 11-12 indicate that most healthcare professionals considered ADR reporting necessary and a professional obligation.

HEALTHCARE PROFESSIONALS	PERCENTAGE
DOCTORS	95.65%
PHARMACIST	95.91%
NURSES	82%
OTHER PARAMEDICAL STAFFS	41.17%

Table 11- Necessity of ADR reporting

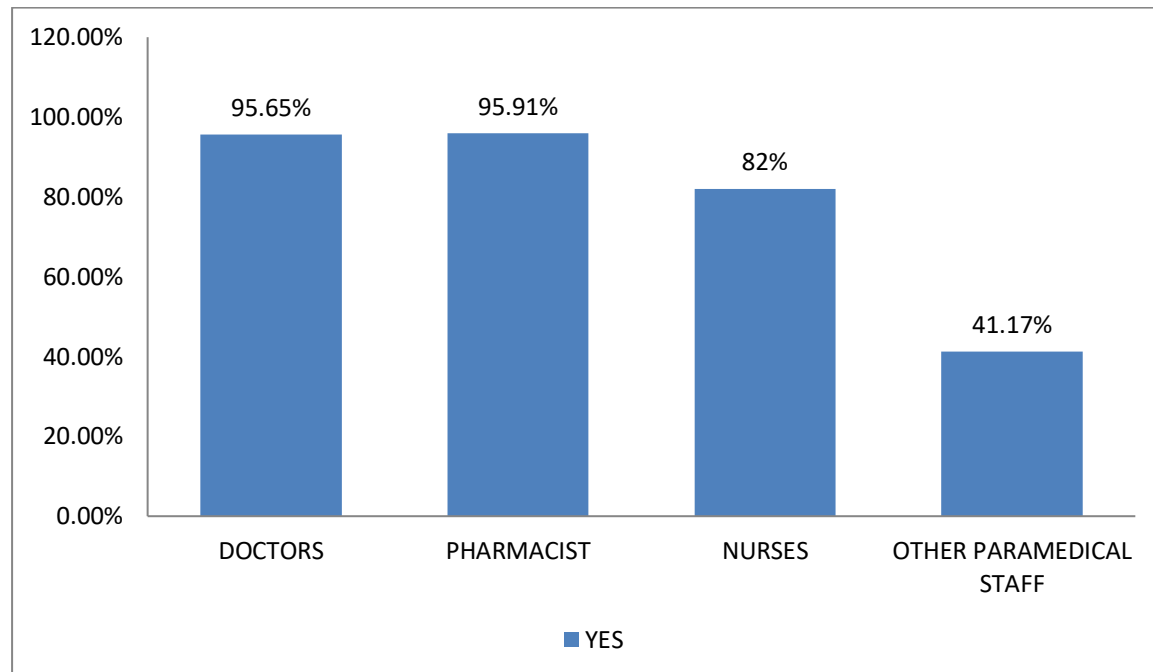


Figure 11 - Necessity of ADR reporting

HEALTHCARE PROFESSIONAL	PERCENTAGE YES	PERCENTAGE NO
DOCTORS	91.03%	8.7%
PHARMCIST	71.92%	28.58%
NURSES	58.18%	41.82%
OTHER PARAMEDICAL STAFFS	17.64%	82.36%

Table 12 - ADR reporting: professional obligation

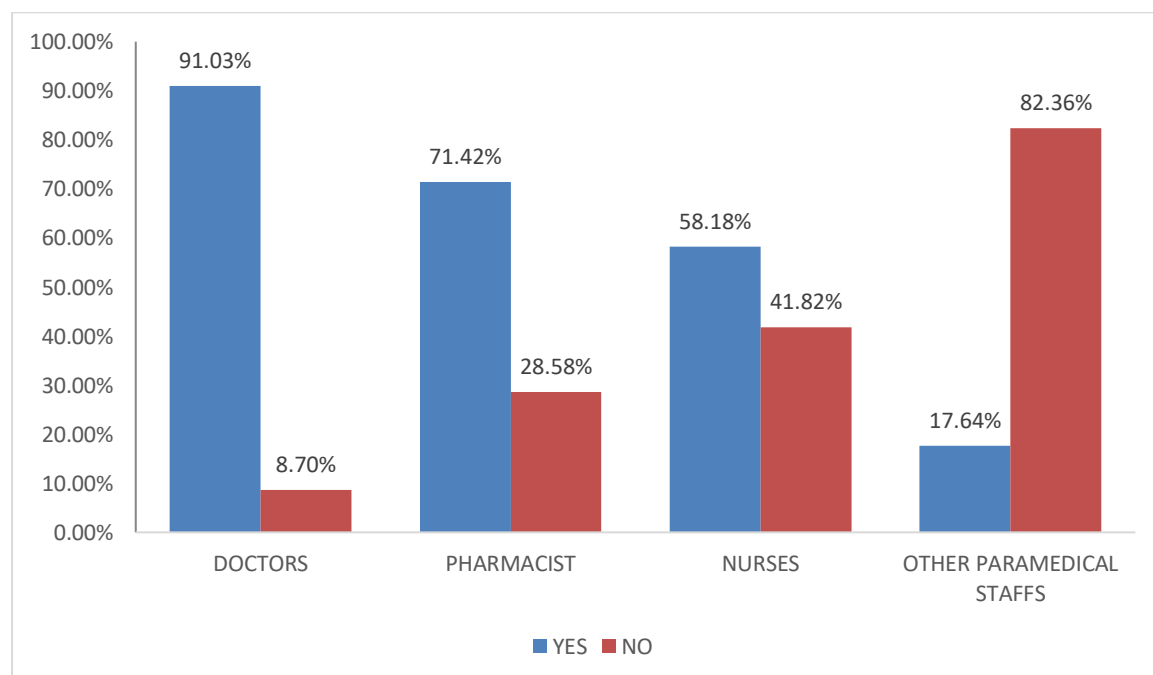


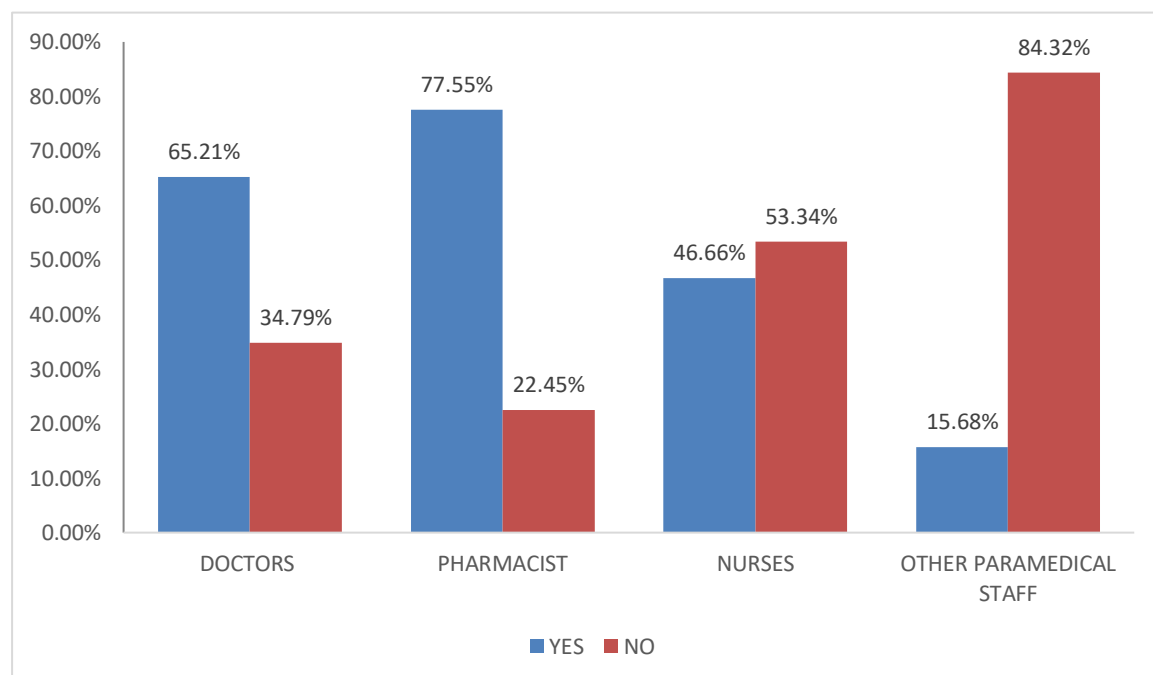
Figure 12 - ADR reporting: Professional obligation

Benefits of ADR Reporting

Table 13 and Figure 13 show that 65.21% of doctors, 77.55% of pharmacists, and 46.66% of nurses recognized the benefits of ADR reporting.

HEALTHCARE PROFESSIONAL	PERCENTAGE YES	PERCENTAGE NO
DOCTORS	65.21%	34.79%
PHARMCIST	77.55%	22.45%
NURSES	46.66%	53.34%
OTHER PARAMEDICAL STAFFS	15.68%	84.32%

Table 13 – benefit of ADR reporting



benefit of ADR reporting

❖ **Graphical representation of knowledge and awareness of pharmacovigilance among healthcare professionals in rural and urban areas.**

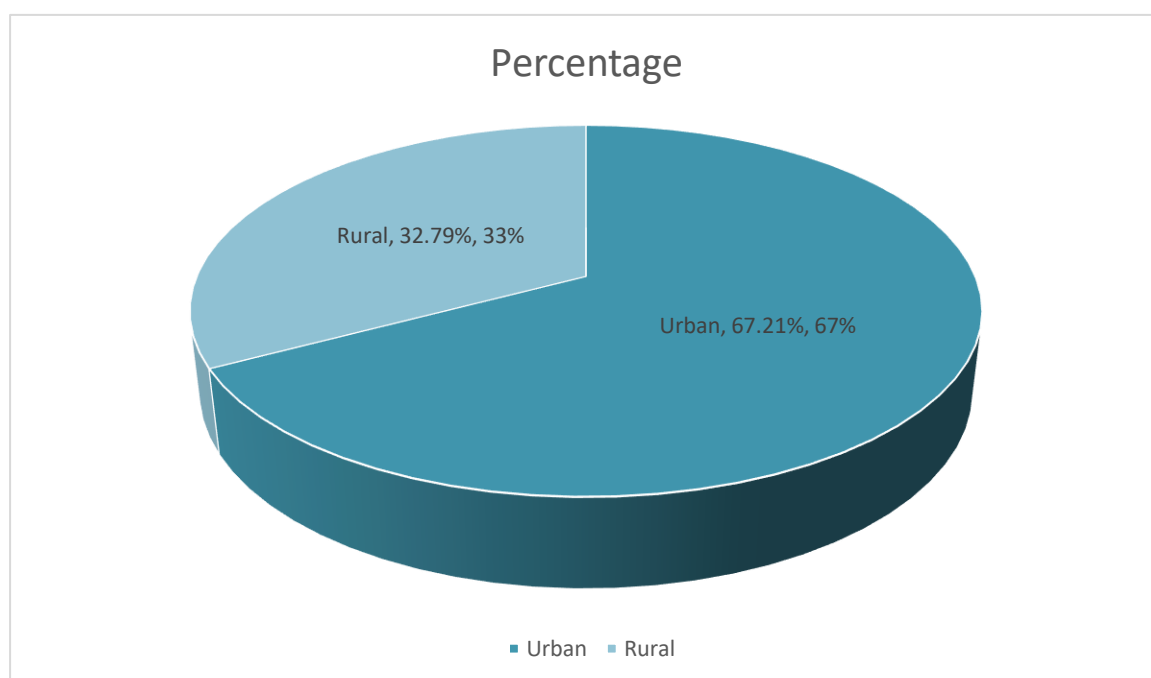
DISCUSSION

We are conducted a cross-sectional study about understanding and perspective regarding the pharmacovigilance system among healthcare professionals in different hospitals in Kozhikode district. The study report shows the knowledge and attitude of professional to pharmacovigilance. Hence through the study we can understand the seriousness taken by health care professionals about pharmacovigilance system.

The awareness of the pharmacovigilance system is highest among doctors (97.82%) and pharmacists (90.62%), while it is lower among nurses (50%) and other paramedical staff (15.68%). The awareness of the pharmacovigilance system is highest among doctors and pharmacists, with almost all doctors and high percentage of pharmacists knowing about it. However, nurses and other paramedical staff shows significantly lower awareness level, highlighting a need for targeted education and training in these groups. That indicates the pharmacovigilance system is notable to reach all healthcare professionals successfully. This is mainly due to work load and time constraints; professionals are often busy with patient care and may prioritise immediate clinical needs over reporting over ADRs.

Knowledge about adverse drug reactions (ADR) is universal among doctors and pharmacists (100%), while it is 85.71% among nurses and 39.21 % among other paramedical staff. All doctors and pharmacists are knowledgeable about ADRs. Nurses have a high level of awareness but not as complete as doctors and pharmacists' knowledge is considerably lower among other paramedical staffs, indicating a gap that needs to be addressed through educational programs.

Awareness of nearby pharmacovigilance centers is relatively low among health care professionals, with only 41.3% of doctors, 48.97 % of pharmacists, 17.8% nurses, and 9.8% of other paramedical staff being aware, highlighting need for improved communication and resources. Awareness of nearby pharmacovigilance centers is relatively low across all groups, with even doctors and pharmacists showing less than 50 % awareness. This



indicates a need for improve communication and resources to inform health care professional about available pharmacovigilance centers.

“Health care professionals ‘knowledge of reporting adverse drug reactions (ADRs)varies, with 50 % of doctors 60.41% pharmacists, 37.5% of nurses, and only 5.88% of other paramedical staff knowing how to report ADRs, highlighting a significant knowledge gap. A significant proportion of healthcare professional do not know how to report ADRs, particularly nurses and other paramedical staff. Training and resources should be provided to ensure all health care professionals can effectively report ADRs.

Awareness of the ADR reporting form varies among healthcare professionals, with 63.04% of doctors, 68.75 % pharamcists, 57.1% of nurses and only 9.8% of other paramedical staff having heard of the adverse drug reaction form, indicating a need for wider dissemination of information. While the majority of doctors and pharmacists are aware of ADR reporting forms, a significant portion of nurses and vast majority of others paramedical staff are not. This point to a need for greater dissemination of information regarding these forms.

Actual reporting of adverse drug reactions (ADRs) is low among health care professionals, with only 45.65 % of doctors17.64% pharmacists , 30.35 % of nurses, 4.16 % of other paramedical staff having reported and ADR, highlighting a significant underreporting issue .Actual reporting of ADRs is low across all groups especially among pharmacists , nurses and other paramedical staff .This could be due to lack of knowledge or confidence in the reporting process, suggesting the need for more practical training and encouragement to report ADRs.

Regarding the importance of ADR reporting 93.47% of doctors, 85.72 % pharmacists, 78.5 % of nurses, and 32.69 % of other paramedical staff believe it is mandatory, while the remaining percentage do not. Most health care professionals, especially doctors and pharmacists recognize the importance of ADR reporting. However, a considerable number of nurses and the majority of other paramedical staff do not, indicating a need for better education on the importance of ADR reporting.

A significant proportion of health care professionals have personally experienced adverse drug reactions (ADRs) in their patients, with 78.26 % of doctors 29.41 % of pharmacists, 49.09 of nurses and 14 % of other paramedical staff having witnessed ADRs, highlighting the importance of ADR reporting and monitoring. Most doctors have encountered ADRs, which is lower among pharmacist and nurses, and significantly lower among other paramedical staff. This could reflect a varied nature of their interaction with patients conditions they treat

A significant percentage of health care Provisionals have not reported adverse drug reactions (ADRs), 26.08 % of doctors, 10.41 % pharmacists, 14.5 % nurses and 13. 72 % of other paramedical staff admitting to not reporting ADRs, indicating a need for improved reporting practices and awareness. A notable proportion of health care professionals have encountered ADRs but did not report them, with doctors showing the highest percentage. This suggests barriers to reporting, such as lack of time, awareness, or perceived importance.

Awareness of the consequence of not reporting adverse drug reaction (ADRs) varies among health care professionals, with 50 % of doctors 81.63 % of pharmacist 60% of nurses, and only 9.8 % of other paramedical staff being aware of the potential consequences, highlighting a need for education and training to improve adverse drug reaction reporting. While pharmacists are highly aware of the consequence of reporting ADRs, awareness is lower among doctors, nurses, and particularly other paramedical staff. Education on the importance and impact of ADR reporting could help improve this.

The majority of health care professionals recognize the necessity of adverse drug reaction (ADR) reporting, with 95.65 % of doctors 95.91% pharmacists, 82% of nurses and 41.17 % of other paramedical staff believing it is necessary, highlighting a consensus on the importance of ADR reporting for patient safety. Most health care professionals especially doctors and pharmacists, recognize the necessity of ADR reporting. However, there is significant proportion of nurses and other paramedical staff who do not indicating a need for targeted awareness campaign.

Health care professional have varying views on ADR reporting as professional obligation, with 91.03% of doctors, 71.92 % of pharmacist 58.18 % of nurses and 17.64 % other paramedial staff considering it an obligation, highlighting a need for clearer g guidelines and emphasis on responsible reporting practices. Most doctors consider ADR reporting a provisional obligation, but this belief is less common among pharmacists, nurses, and particularly other paramedical staff. This underscores the need for reinforcing the provisional responsibility of all healthcare workers in pharmacovigilance awareness of the benefits adverse drug reaction (ADR) reporting varies among health care Provisionals, with 65.21 % doctors, 77.55 % of pharmacists, 46.66 % of nurses, and only 15.68% of other paramedical staff being aware of the benefits, highlighting a need for education and training to improve understanding of ADR reporting's importance. While pharmacists show high awareness of the benefits of ADR reporting, a significant proportion of doctors, nurses and especially other paramedical staff are not aware. Increasing awareness of the benefits could motivate more consistent reporting.

Health care Provisionals have varying levels of awareness about their role in pharmacovigilance, with 82.6 % of doctors, 87.75 % of pharmacists, 43.33 % nurses and only 12.5 % of other paramedical staff being aware of their responsibilities in monitoring and reporting adverse drug reactions, highlighting a need for education and training to improve pharmacovigilance practices. Awareness of their role in pharmacovigilance is high among doctors and pharmacists but significantly lower among nurses and other paramedical staff. Enhanced role - specific training and education can help address this gap .The provided figures illustrate the data for each question, highlighting the disparities in knowledge and awareness among different groups of health care professionals. The visual representation underscores the need for targeted intervention to improve pharmacovigilance practices across all health care.

Key Findings and Implications

1. **Limited awareness of pharmacovigilance:** Despite its importance, only 63.53% of healthcare professionals had heard about pharmacovigilance. This lack of awareness may hinder effective reporting of adverse drug reactions (ADRs).
2. **Gaps in knowledge of ADRs:** While doctors and pharmacists demonstrated good knowledge of ADRs, significant gaps were observed among nurses and paramedical staff. This underscores the need for targeted education and training.
3. **Underreporting of ADRs:** Only 24.45% of healthcare professionals reported ADRs, citing lack of awareness, complex reporting processes, and time constraints. Simplifying reporting processes and providing feedback mechanisms may improve reporting rates.

4. Variability in perceived importance of ADR reporting: While 72.57% agreed that ADR reporting is mandatory, 27.43% did not recognize its importance. This highlights the need for education on the benefits of ADR reporting.

Comparison with Existing Literature

Our findings are consistent with previous studies highlighting gaps in pharmacovigilance knowledge and practices among healthcare professionals.^[1,2] However, our study provides insights into the specific challenges faced by healthcare professionals in Kozhikode district.

Strengths and Limitations

Strengths: - Large sample size, - Representation from various healthcare professionals

Limitations: Cross-sectional design limits causal inference, - Self-reported data may be subject to bias

CONCLUSION AND RECOMMENDATIONS

This study highlights the need for enhanced training, education, and awareness campaigns to improve pharmacovigilance practices among healthcare professionals. Simplifying reporting processes, establishing feedback mechanisms, and ensuring robust policy support are crucial for promoting a culture of pharmacovigilance.

Recommendations for Future Research

1. Investigate barriers to ADR reporting,
2. Develop and evaluate targeted education programs
3. Explore the impact of pharmacovigilance training on reporting practices

RECOMMENDATION

- 1) Enhanced training and educations – Incorporate comprehensive pharmacovigilance training in medical and nursing curriculum. Provide regular workshop and seminar to update all healthcare professional on the importance and process of ADR reporting.
- 2) Streamlined reporting process – Simplify ADR reporting procedure to make them more accessible and less time consuming for busy healthcare providers.
- 3) Awareness campaigns – Implement targeted awareness campaign to reach under informed groups particularly nurse, other paramedical staff to bridge the knowledge gap.
- 4) Feedback mechanism – Establish a feedback system for healthcare professional who report ADR to reinforce the value of contribution and encourage continued participation.
- 5) Policy system support – Ensure the institution policy support and mandate the ADR reporting and that adequate resource are allocated to maintain efficient pharmacovigilance system by addressing this gap, the healthcare system can improve the safety and efficacy of medication use, ultimately enhancing patient care public health.

By addressing theses gaps, the healthcare system can improve patient safety and drug efficacy, ultimately enhancing patient care and public health.

CONCLUSION

The study highlights, the significant gaps in the awareness, knowledge and practices regarding pharmacovigilance between healthcare professionals in society. To address this gap, it is recommended to enhance training, education, simplifying report process, increasing awareness and campaigns, establish feedback mechanism and ensure robust policy support for pharmacovigilance. By doing so the healthcare system can improve patient safety and drug efficacy better which enhances pharmacovigilance practices.

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Conflict of interest: None

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