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Original Article

Assessing Knowledge, Attitude, and Practice of Adverse Drug Reaction Reporting Among Healthcare Professionals in a Tertiary Care Hospital in South Kerala: A Cross-Sectional Study

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ABSTRACT

Background: Adverse Drug Reactions (ADRs) contribute significantly to morbidity, mortality, and increased healthcare costs worldwide. Despite the establishment of pharmacovigilance systems, underreporting of ADRs remains a major challenge, particularly in developing countries like India.
Objectives: To assess the knowledge, attitude, practice, and barriers related to ADR reporting among healthcare professionals in a tertiary care centre in South Kerala.
Methods: A cross-sectional study was conducted among 254 healthcare professionals (127 doctors and 127 nurses) using a validated semi-structured questionnaire. The questionnaire assessed knowledge (14 items), attitude (11 items), practice (5 items), and barriers (10 items) related to ADR reporting. Data were analyzed using SPSS trial version 26. Descriptive statistics and chi-square tests were applied, with $p < 0.05$ considered statistically significant.
Results: The mean knowledge score was 7.25 ± 2.3, with good knowledge observed in 48% of doctors and 18.9% of nurses. A positive attitude towards ADR reporting was seen in 65.4% of doctors and 54.3% of nurses. Good practice was reported by 62.2% of doctors and 65.4% of nurses. Although more than 85% of participants had identified ADRs, actual reporting was lower (59.1% among doctors and 40.9% among nurses). Major barriers included uncertainty in identifying ADRs, lack of awareness regarding reporting methods, and perceived complexity of reporting procedures. Work experience was significantly associated with knowledge and practice among nurses.
Conclusion: Despite a generally positive attitude, ADR reporting practices remain suboptimal due to knowledge gaps and systemic barriers. Regular training programs and simplification of reporting procedures are essential to strengthen pharmacovigilance.

Keywords*: Adverse Drug Reaction, Pharmacovigilance, Knowledge, Attitude, Practice, Healthcare Professionals.*

INTRODUCTION

Adverse Drug Reactions (ADRs) are a major global public health concern and represent a significant cause of morbidity, mortality, and increased healthcare expenditure worldwide (1,2). ADRs not only prolong hospital stay but also contribute substantially to patient suffering and healthcare system burden (3). Studies have shown that approximately 5–10% of hospital admissions are due to ADRs, and a similar proportion of hospitalized patients experience ADRs during their hospital stay (4,5).

The World Health Organization (WHO) defines an ADR as "any noxious and unintended response to a drug occurring at doses normally used in humans for prophylaxis, diagnosis, or therapy" (6). Severe ADRs may lead to life-threatening conditions, prolonged hospitalization, disability, or even death, thereby emphasizing the importance of early detection and prevention (7).

Pharmacovigilance, defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems, plays a crucial role in ensuring drug safety (8). Effective pharmacovigilance systems help identify new risks, improve drug safety profiles, and contribute to rational drug use (9).

In India, the Pharmacovigilance Programme of India (PvPI), initiated under the Central Drugs Standard Control Organization (CDSCO), serves as the national system for monitoring drug safety (10). PvPI collaborates with the WHO Uppsala Monitoring Centre (UMC) in Sweden, which maintains the global ADR database (11). Despite these structured systems, ADR reporting rates in India remain significantly low, estimated to be less than 1% compared to the global average of 6–10% (12,13).

Healthcare professionals (HCPs), including doctors, nurses, and pharmacists, are the primary contributors to ADR reporting systems (14). Their active participation is essential for the success of pharmacovigilance programs (15). However, several studies have reported inadequate knowledge, underreporting practices, and various barriers among HCPs (16–18).

Knowledge regarding ADR reporting is a critical determinant of effective pharmacovigilance. Previous studies have shown varying levels of knowledge among healthcare professionals, with doctors generally demonstrating better awareness compared to nurses and pharmacists (19,20). However, gaps remain in areas such as reporting procedures, classification systems, and awareness of national pharmacovigilance programs (21).

Attitude towards ADR reporting is another important factor influencing reporting behavior. Most studies indicate that healthcare professionals have a positive attitude and recognize ADR reporting as a professional responsibility (22,23). However, this positive attitude does not always translate into actual reporting practices, highlighting a discrepancy between perception and action (24).

Practice of ADR reporting is often suboptimal despite adequate knowledge and attitude. Underreporting of ADRs is a well-documented issue worldwide (25). Factors contributing to underreporting include lack of time, uncertainty about causality, fear of legal consequences, lack of incentives, and complexity of reporting procedures (26–28).

Barriers to ADR reporting have been extensively studied. Commonly reported barriers include lack of awareness about reporting systems, insufficient training, unavailability of reporting forms, and lack of feedback from regulatory authorities (29). Additionally, misconceptions such as the belief that a single report does not contribute significantly also hinder reporting practices (30).

In the Indian context, several studies have highlighted the need for improved training and awareness programs to enhance pharmacovigilance activities (16,20). Addressing these gaps is crucial for strengthening ADR reporting systems and ensuring patient safety.

Given the importance of pharmacovigilance and the persistent issue of underreporting, it is essential to evaluate the knowledge, attitude, practice, and barriers related to ADR reporting among healthcare professionals. Such assessments help identify gaps and design targeted interventions to improve ADR reporting practices.

Therefore, the present study was undertaken to assess the knowledge, attitude, practice, and barriers in reporting adverse drug reactions among healthcare professionals in a tertiary care centre in South Kerala.

MATERIALS AND METHODS

Study Design and Setting

A hospital-based cross-sectional descriptive study was conducted among healthcare professionals at Dr. Somervell Memorial CSI Medical College, Karakonam, a tertiary care teaching institution in South Kerala, India. The study was carried out over a period of six months from April 2025 to September 2025.

Study Population

The study population comprised healthcare professionals (HCPs), including doctors and nurses working in various clinical departments of the institution.

Sample Size and Sampling Technique
The sample size was calculated using the standard formula:
$N=4pq/d^2$

Where:
- **p** = prevalence of good knowledge (28.57%) based on a previous study
- **q** = 100 – p = 71.43
- **d** = allowable error (20% of p)

The calculated sample size was **251**, which was rounded to **254** to improve study precision. The final sample included:
- **127 doctors**
- **127 nurses**

Participants were selected using a **convenience sampling technique**, based on their availability and willingness to participate during the study period.

Inclusion and Exclusion Criteria
Inclusion Criteria
- Doctors and nurses working in the hospital during the study period
- Those who provided **written informed consent**
- Participants available at the time of data collection

Exclusion Criteria
- Healthcare professionals not willing to participate
- Those unavailable even after two consecutive visits
- Incomplete or improperly filled questionnaires

Study Tool and Data Collection
Data were collected using a validated, semi-structured, self-administered questionnaire. The questionnaire was developed based on standard pharmacovigilance guidelines and previous literature and was validated by the Causality Assessment Committee (CAC) coordinator and deputy coordinator of the ADR Monitoring Centre of the institution.

The questionnaire consisted of five sections:
Section I: Socio-demographic Details
Included age, gender, professional status, department, qualification, years of experience, and area of residence.

Section II: Knowledge Assessment
Included **14 multiple-choice questions** assessing awareness regarding:
- Definition and classification of ADRs
- Serious adverse events
- Drugs causing ADRs
- Pharmacovigilance concepts
- Reporting systems and methods

Each correct response was awarded **1 mark**, and incorrect responses were given **0 marks**.

Knowledge scores were categorized as:
- **Good knowledge:** > 9
- **Moderate knowledge:** 6–9
- **Poor knowledge:** < 6

Section III: Attitude Assessment
Included **11 statements** assessed on a **binary scale (Agree/Disagree)** covering:
- Importance of ADR reporting
- Professional responsibility
- Perceived benefits and challenges

Attitude scores were categorized as:
- **Good attitude:** ≥ 8
- **Poor attitude:** < 8

Section IV: Practice Assessment
Included 5 questions assessing:

- Identification and reporting of ADRs
- Participation in training programs
- Preventive practices (drug allergy history, test dose, monitoring)
- Documentation of ADRs

Practice scores were categorized as:
- **Good practice:** ≥ 6
- **Poor practice:** < 6

Section V: Barriers to ADR Reporting
Included 10 items assessing potential barriers such as:
- Lack of knowledge
- Time constraints
- Complexity of reporting
- Fear of legal liability
- Lack of communication

Responses were recorded as **Yes / No / No opinion**.

Data Collection Procedure
Data collection was initiated after obtaining **Institutional Ethics Committee (IEC) approval (No: SMCSIMCH/EC(PHARM)03/10/22)**.
Participants were approached at their workplace after prior appointment. The purpose of the study was explained, and a **participant information sheet** was provided. Written informed consent was obtained before participation.
Participants were given **15–20 minutes** to complete the questionnaire. Confidentiality was maintained, and no personal identifiers were recorded.

Study Variables
Independent Variables
- Age
- Gender
- Professional status
- Department
- Qualification
- Years of experience
- Area of residence

Dependent Variables
- Knowledge regarding ADR reporting
- Attitude towards ADR reporting
- Practice of ADR reporting
- Barriers to ADR reporting

Data Entry and Statistical Analysis
Data were entered into **Microsoft Excel** and checked for completeness and accuracy. Statistical analysis was performed using **Statistical Package for Social Sciences (SPSS) trial version 26**.
- **Descriptive statistics** were used to summarize data:
  - Mean and standard deviation (SD) for continuous variables
  - Frequencies and percentages for categorical variables
- **Inferential statistics**:
  - Association between KAP variables and socio-demographic factors was analyzed using the **Chi-square test** or **Fisher's exact test** where applicable

A **p-value < 0.05** was considered statistically significant.

Ethical Considerations
The study was conducted following ethical principles for biomedical research. Approval was obtained from the **Institutional Ethics Committee** prior to commencement.
- Written informed consent was obtained from all participants
- Participation was voluntary

- Confidentiality and anonymity were maintained
- Data were stored securely in a password-protected system for a period of five years

Quality Control Measures

- Pre-validation of questionnaire by experts
- Standardized data collection procedure
- Data cleaning and verification prior to analysis

OBJECTIVES

Primary Objective

To assess the level of knowledge in reporting adverse drug reactions among health care professionals in a tertiary care centre in South Kerala

Secondary Objectives

To assess the attitude and practice in reporting adverse drug reactions among health care professionals in a tertiary care centre in South Kerala

To assess the barriers in reporting adverse drug reactions among health care professionals in a tertiary care centre in South Kerala

To determine the factors associated with knowledge, attitude and practice in reporting adverse drug reactions among health care professionals with selected demographic variables.

RESULTS

A total of 254 healthcare professionals participated in the study, comprising 127 doctors and 127 nurses. The mean age of the study population was 32.5 ± 7.02 years, with doctors having a mean age of 30.8 ± 6.5 years and nurses 34.3 ± 7.2 years. The age of participants ranged from 22 to 64 years. The majority of participants were females (76.4%), while males constituted 23.6%. Among males, most were doctors, whereas the majority of nurses were females. With regard to department-wise distribution, the highest proportion of participants belonged to General Medicine, followed by General Surgery and Paediatrics. In terms of work experience, a considerable proportion of doctors (22.8%) had 1–5 years of experience, while among nurses, 12.9% had 6–10 years of experience. Regarding residential status, 56.7% of doctors and 82% of nurses were from rural areas.

The assessment of knowledge regarding adverse drug reaction (ADR) reporting revealed a mean knowledge score of 7.25 ± 2.3, with scores ranging from 2 to 14. Based on scoring criteria, 48% of doctors demonstrated good knowledge compared to only 18.9% of nurses. Moderate knowledge was observed among 46.5% of doctors and 55.9% of nurses, while poor knowledge was more prevalent among nurses (25.2%) than doctors (5.5%). Most participants correctly identified the definition of ADR (96.9% doctors and 85.8% nurses) and recognized that any drug can cause ADRs (100% doctors and 89% nurses). However, knowledge gaps were evident in specific areas such as ADR classification (11% doctors and 4.7% nurses), ADR reporting software (19.7% doctors and 26.8% nurses), and awareness of the WHO Collaborating Centre (27.6% doctors and 15.7% nurses). Awareness regarding the Pharmacovigilance Programme of India was higher among doctors (74.8%) compared to nurses (41.7%).

The attitude towards ADR reporting among healthcare professionals was generally positive. The mean attitude score was 7.93 ± 1.3, with scores ranging from 5 to 11. A good attitude (score ≥8) was observed in 65.4% of doctors and 54.3% of nurses. Almost all participants agreed that ADRs should be reported promptly (100% doctors and 99.2% nurses), that reporting is a professional obligation (97.6% doctors and 98.4% nurses), and that ADR reporting enhances patient safety (100% doctors and 98.4% nurses). Additionally, nearly all participants supported making ADR reporting mandatory (98.4% in both groups). However, a considerable proportion perceived ADR reporting as time-consuming (37% doctors and 63% nurses) and the reporting forms as complex (26.8% doctors and 58.3% nurses). Willingness to report ADRs was high among both groups (>96%).

The practice of ADR reporting showed moderate performance among healthcare professionals. The mean practice score was 5.6 ± 1.25, with scores ranging from 1 to 7. Good practice (score ≥6) was observed in 62.2% of doctors and 65.4% of nurses, while poor practice was noted in 37.8% of doctors and 34.6% of nurses. A large proportion of participants had identified ADRs in their clinical practice (85.8% doctors and 89% nurses). However, actual reporting rates were lower, with only 59.1% of doctors and 40.9% of nurses having reported or facilitated reporting of ADRs. Training exposure was limited, as only 36.2% of doctors and 55.1% of nurses had attended training programs related to ADR detection and reporting. Preventive practices such as taking drug allergy history, administering test doses, and monitoring patients after

drug administration were widely practiced by nearly all participants (>98%). ADR documentation was performed by 81.9% of doctors and 87.4% of nurses.

Barriers to ADR reporting were also assessed among participants. A major barrier identified was uncertainty in recognizing whether a reaction constituted an ADR, reported by 68.5% of doctors and 35.4% of nurses. Lack of awareness regarding reporting methods was another significant barrier, particularly among doctors (51.2%) compared to nurses (22.8%). Time constraints were reported by 35.4% of doctors but were less significant among nurses (0.8%). Complexity of reporting forms was perceived as a barrier by 30.7% of doctors and 4.7% of nurses, while lack of availability of reporting forms was reported by 31.5% of doctors and 6.3% of nurses. Fear-related barriers such as legal liability (21.3% doctors and 2.4% nurses) and confidentiality issues (22% doctors and 2.4% nurses) were less commonly reported. Lack of communication with patients was not considered a major barrier by the majority of participants.

Analysis of factors associated with knowledge, attitude, and practice revealed no statistically significant association between socio-demographic variables and knowledge or attitude among doctors ($p > 0.05$). However, among nurses, work experience was significantly associated with knowledge ($p = 0.03$), with higher experience correlating with better knowledge levels. Similarly, work experience was significantly associated with attitude among nurses ($p = 0.03$). In terms of practice, age ($p = 0.005$) and years of experience ($p = 0.02$) were significantly associated among doctors. Among nurses, age ($p = 0.002$), gender ($p = 0.001$), and years of experience ($p < 0.001$) showed statistically significant associations with practice of ADR reporting.

Overall, the study demonstrates that while healthcare professionals possess moderate knowledge and a positive attitude towards ADR reporting, actual reporting practices remain suboptimal, with several barriers influencing effective pharmacovigilance activities.

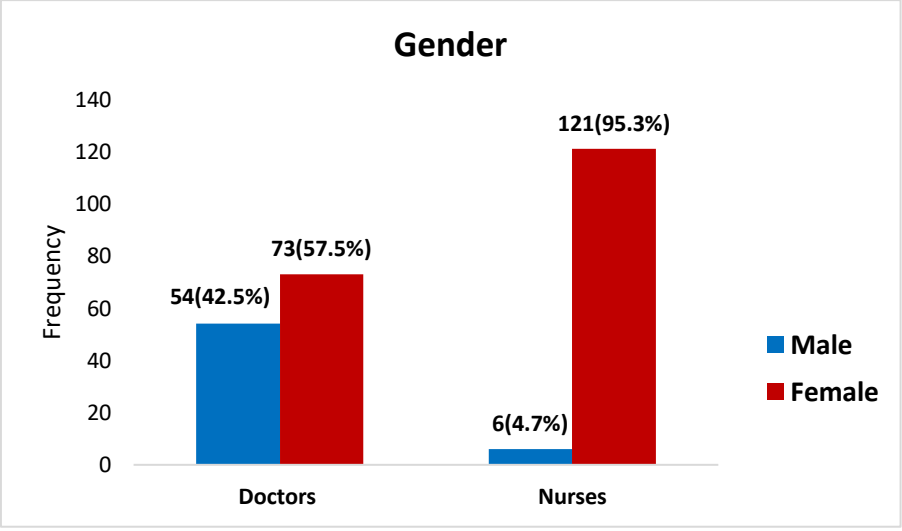
Data analysis was done using the software statistical package for social sciences (SPSS) trial version 26. The socio demographic details of the study participants were summarized using tables and appropriate graphs. The assessment of knowledge, attitude practice and barriers in reporting ADR were carried out using descriptive statistics with frequencies and percentages for qualitative data, mean and standard deviation for quantitative scores. Association between knowledge, attitude, practice and socio demographic variables were done using chi square test. p-value < 0.05 were considered as statistically significant.

Age distribution of study participants[n=254]

Age	Doctors [n=127]	Nurses [N=127]
Mean ± SD	30.8 ± 6.5	34.3 ± 7.2
Minimum	23	22
Maximum	64	52

The mean age (± SD) of the health professionals were 32.5 (± 7.02) with a minimum age of 22 and maximum age of 64. The mean age of nurses was higher than the total samples.

Gender distribution of study participants [n=254]



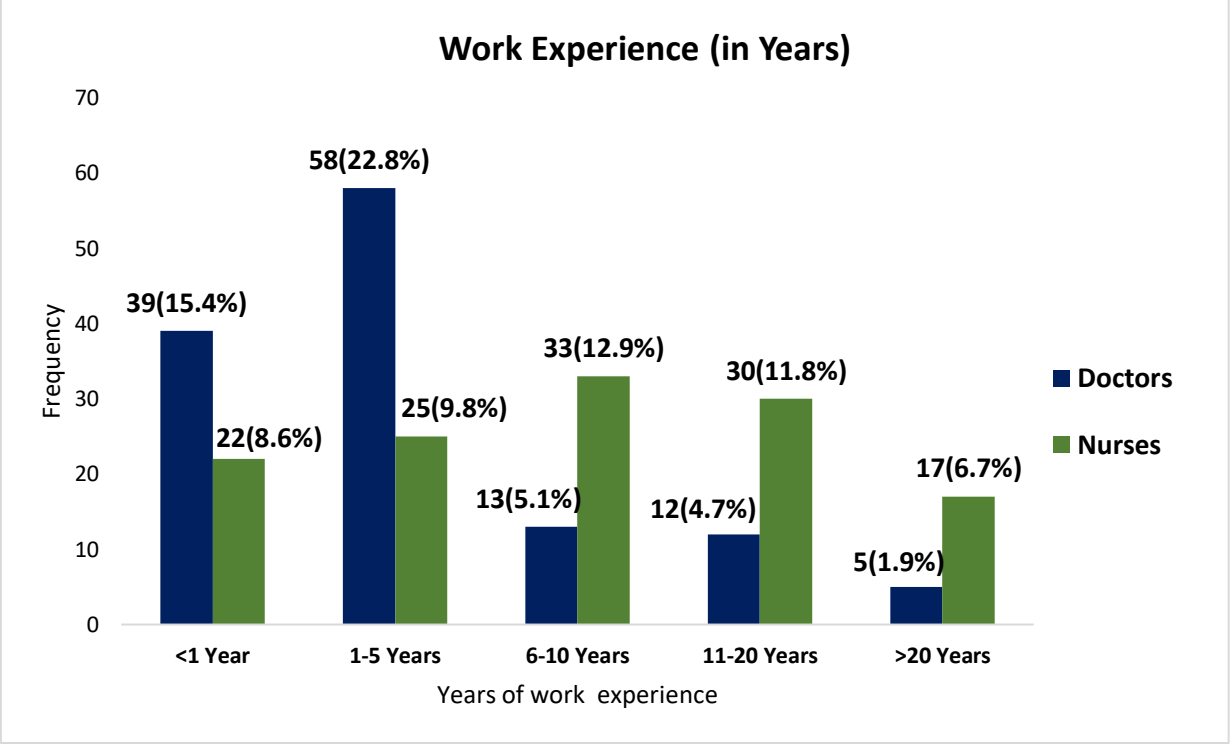
Among the 254 health care professionals, majority were females 194 (76.4%) and the males constituted 60 (23.6%). Of the male participants, most were doctors 54 and the remainder were nurses. Majority of the nurses were females.

Department wise distribution of study participants [n=254]

Department	Doctors [n=127]		Nurses [N=127]	
	Frequency	Percentage	Frequency	Percentage
General Medicine	6	4.7	41	32.3
Cardiology	1	0.8	2	1.6
Nephrology	2	1.6	2	1.6
General Surgery	12	9.4	34	26.8
Neurosurgery	4	3.1	1	0.8
Emergency Medicine	4	3.1	17	13.4
Dermatology	11	8.7	-	-
ENT	10	7.9	4	3.1
Anaesthesiology	7	5.5	-	-
Respiratory medicine	3	2.4	-	-
Community medicine	5	3.9	-	-
Gynaecology	10	7.9	3	2.4
Paediatrics	13	10.2	9	7.1
Orthopaedics	11	8.7	6	4.7
Radiology	4	3.1	-	-
Psychiatry	5	3.9	4	3.1
Urology	1	0.8	-	-
Dental	3	2.4	-	-
Ophthalmology	12	9.4	4	3.1
Neuro medicine	3	2.4	-	-

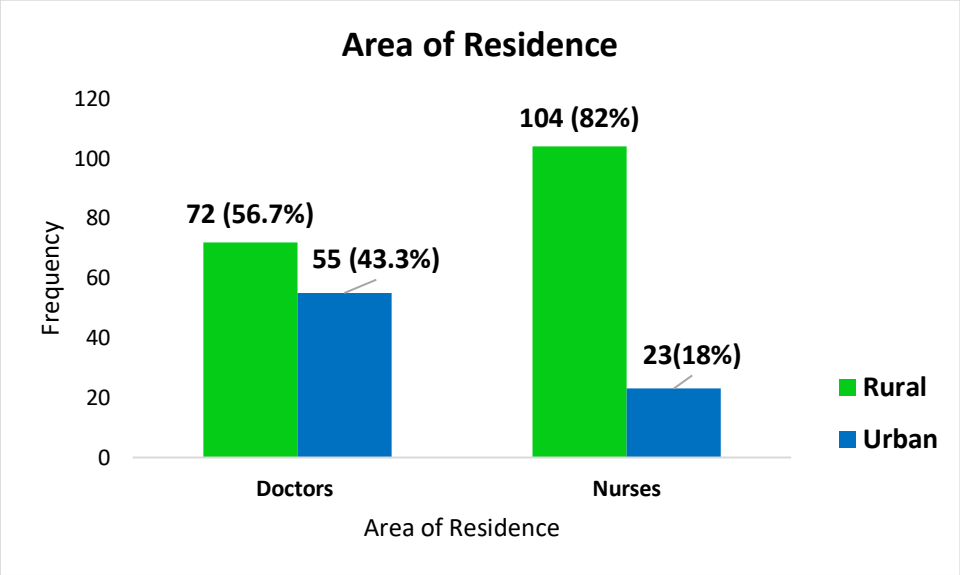
Among the study participants, the highest proportion was from Department of General Medicine 37%, followed closely by the Department of General Surgery 36.2%, and the Department of Paediatrics 17.3%

Distribution of study participants based on their years of work experience[n=254]



Among the study Participants, 22.8% of the doctors had a work experience of 1-5 years, whereas 12.9% of the nurses had a work experience of 6-10 years

Distribution of study participants based on their area of residence[n=254]



Among the study Participants, 56.7% of the doctors and 82% of the nurses were residing in rural area

Knowledge in ADR reporting among health care professionals [n=254]

A total of 14 questions were asked to the health professionals regarding knowledge on ADR reporting. The descriptive statistics of the knowledge scores are given below.

Knowledge score	Mean ± SD	Q_1	Q_2	Q_3	minimum	maximum
	7.25 ± 2.3	6	7	9	2	14

Based on the quartiles obtained from knowledge scores, knowledge was categorized as good knowledge (> 9), moderate knowledge (6 – 9) and poor knowledge (< 6).

Knowledge	Doctors (%) n=127	Nurses (%) n=127
Good (> 9)	61 (48%)	24 (18.9%)
Moderate (6 – 9)	59 (46.5%)	71 (55.9%)
Poor (< 6)	7 (5.5%)	32 (25.2%)

Doctors (48%) had good knowledge on adverse drug reaction reporting compared to nurses (19%).

Attitude in ADR reporting among health care professionals [n=254]

A total of 11 questions were asked to the health professionals to assess their attitude on ADR reporting. The descriptive statistics of the attitude scores are given below.

Attitude score	Mean ± SD	Q_1	Q_2	Q_3	minimum	maximum
	7.93 ± 1.3	7	8	9	5	11

Based on the median scores obtained, Attitude scores was categorized as good attitude (≥ 8) and poor attitude (< 8).

Attitude	Doctors (%) n=127	Nurses (%) n=127
Good (≥ 8)	83 (65.4%)	69 (54.3%)
Poor (< 8)	44 (34.6%)	58 (45.7%)

Considering the overall attitude of health care professionals towards ADR reporting, majority of the doctors and nurses (65.4%) and (54.3%) had a positive attitude.

Practice in ADR reporting among health care professionals [n=254]

A total of 5 questions were asked to the health care professionals to assess their practice towards ADR reporting. The descriptive statistics of the practice scores obtained are given below.

Practice score	Mean ± SD	Q_1	Q_2	Q_3	minimum	maximum
	5.6 ± 1.25	5	6	7	1	7

Practice	Doctors (%) n=127	Nurses (%) n=127
Good (≥ 6)	79 (62.2%)	83 (65.4%)
Poor (< 6)	48 (37.8%)	44 (34.6%)

A minimal difference was observed in the practice of ADR reporting between doctors (62.2%) and nurses (65.4%).

Knowledge regarding ADR reporting among health care professionals [n=254]

Questions regarding knowledge		Doctors (%) [n=127]	Nurses (%) [n=127]
1. Which of the following accurately defines an Adverse Drug Reaction	Correct Response	123 (96.9%)	109 (85.8%)
	Incorrect Response	4 (3.1%)	18 (14.2%)
2. Which of the following is a Serious Adverse Event (SAE)	Correct Response	83 (65.4%)	30 (23.6%)
	Incorrect Response	44 (34.6%)	97 (76.4%)
3. Which of the following can cause an Adverse Drug Reaction	Correct Response	127 (100%)	113 (89%)
	Incorrect Response	0	14 (11%)
4. Which of the following is the extended Rawlins and Thompson Classification of ADRs	Correct Response	14 (11%)	6 (4.7%)
	Incorrect Response	113 (89%)	121 (95.3%)
5. Which of the following drug has been banned in India due to its ADRs	Correct Response	91 (71.7%)	106 (83.5%)
	Incorrect Response	36 (28.3%)	21 (16.5%)
6. What are the complications of an Adverse Drug Reaction	Correct Response	89 (70.1%)	45 (35.4%)
	Incorrect Response	38 (29.9%)	82 (64.6%)
7. What types of ADRs should be reported	Correct Response	122 (96.1%)	118 (92.9%)
	Incorrect Response	5 (3.9%)	9 (7.1%)
8. Who all can report an Adverse Drug Reaction	Correct Response	111 (87.4%)	117 (92.1%)
	Incorrect Response	16 (12.6%)	10 (7.9%)
9. Which is the government programme for ADR reporting	Correct Response	95 (74.8%)	53 (41.7%)
	Incorrect Response	32 (25.2%)	74 (58.3%)
10. Which of the following correctly defines Pharmacovigilance	Correct Response	88 (69.3%)	46 (36.2%)
	Incorrect Response	39 (30.7%)	81 (63.8%)
11. What are the various methodsof reporting Adverse Drug Reactions	Correct Response	47 (37%)	46 (36.2%)
	Incorrect Response	80 (63%)	81 (63.8%)
12. Which one is the latest version of ADR reporting form available in India	Correct Response	7 (5.5%)	27 (21.3%)
	Incorrect Response	120 (94.5%)	100 (78.7%)
13. Which of the following is the software for reporting ADRs	Correct Response	25 (19.7%)	34 (26.8%)
	Incorrect Response	102 (80.3%)	93 (73.2%)
14. Where is the "WHO Collaborating Centre for International Drug Monitoring" located	Correct Response	35 (27.6%)	20 (15.7%)
	Incorrect Response	92 (72.5%)	107 (84.3%)

Attitude regarding ADR reporting among health care professionals [n=254]

Questions regarding attitude		Doctors (%)	Nurses (%)
1. ADRs should promptly be reported	Agree	127 (100%)	126 (99.2%)
	Disagree	0	1 (0.8%)
2. ADR reporting is our professional obligation	Agree	124 (97.6%)	125 (98.4%)
	Disagree	3 (2.4%)	2 (1.6%)

3. ADR reporting increases patient safety	Agree	127 (100%)	125 (98.4%)
	Disagree	0	2 (1.6%)
4. ADR reporting is time consuming	Agree	47 (37%)	80 (63%)
	Disagree	80 (63%)	47 (37%)
5. ADR reporting form is too complex to fill	Agree	34 (26.8%)	74 (58.3%)
	Disagree	93 (73.2%)	53 (41.7%)
6. Are you willing to report ADRs	Agree	125 (98.4%)	123 (96.9%)
	Disagree	2 (1.6%)	4 (3.1%)
7. Reporting of only one case makes no significant contribution to the ADR reporting scheme	Agree	25 (19.7%)	24 (18.9%)
	Disagree	102 (80.3%)	103 (81.1%)
8. Identity of healthcare worker reporting the ADR must be kept confidential	Agree	90 (70.9%)	59 (46.5%)
	Disagree	37 (29.1%)	68 (53.5%)
9. Awareness, information and knowledge regarding pharmacovigilance should be provided to healthcare professionals	Agree	127 (100%)	108 (85%)
	Disagree	0	19 (15%)
10. ADR reporting should be made mandatory	Agree	125 (98.4%)	125 (98.4%)
	Disagree	2 (1.6%)	2 (1.6%)
11. Reporting an ADR may assess my clinical skill	Agree	76 (59.8%)	22 (17.3%)
	Disagree	51 (40.2%)	105 (82.7%)

Practice regarding ADR reporting among health care professionals [n=254]

Questions regarding practice		Doctors (%) [n=127]	Nurses (%) [n=127]
1. Have you ever identified an ADR in any patient	Yes	109 (85.8%)	113 (89%)
	No	18 (14.2%)	14 (11%)
2. Have you ever reported/ facilitated in reporting an ADR	Yes	75 (59.1%)	52 (40.9%)
	No	52 (40.9%)	75 (59.1%)
3. Have you ever attended any trainingprogrammes to detect, report and prevent ADR	Yes	46 (36.2%)	70 (55.1%)
	No	81 (63.8%)	57 (44.9%)
4. Have you ever done any of the following approaches in preventing ADRs during practice/prevented ADRs during practice			
i) Taking history on drug allergy	Yes	126 (99.2%)	126 (99.2%)
	No	1 (0.8%)	1 (0.8%)
ii) Administering test dose	Yes	126 (99.2%)	127 (100%)
	No	1 (0.8%)	0
iii) Monitoring the patient after drug administration	Yes	125 (98.4%)	127 (100%)
	No	2 (1.6%)	0
5. Have you ever done ADR documentation	Yes	104 (81.9%)	111 (87.4%)
	No	23 (18.1%)	16 (12.6%)

Barriers in ADR reporting among health care professionals [n=254]

Questions regarding barriers		Doctors (%) [n=127]	Nurses (%) [n=127]
1. Not sure whether it is an ADR	Yes	87 (68.5%)	45 (35.4%)
	No	40 (31.5%)	82 (64.6%)
2. Not aware of the methods of ADR reporting	Yes	65 (51.2%)	29 (22.8%)
	No	62 (48.8%)	98 (77.2%)
3. Lack of interest	Yes	22 (17.3%)	4 (3.1%)
	No	80 (63%)	120 (94.5%)
	No opinion	25 (19.7%)	3 (2.4%)
4. Lack of time	Yes	45 (35.4%)	1 (0.8%)
	No	68 (53.5%)	122 (96.1%)
	No opinion	14 (11%)	4 (3.1%)
5. Lack of communication with patient	Yes	28 (22%)	1 (0.8%)

	No	92 (72.4%)	125 (98.4%)
	No opinion	7 (5.5%)	1 (0.8%)
6. Not considered the reaction serious enough to report	Yes	40 (31.5%)	3 (2.4%)
	No	78 (61.4%)	123 (96.9%)
	No opinion	9 (7.1%)	1 (0.8%)
7. Reporting forms are too complicated	Yes	39 (30.7%)	6 (4.7%)
	No	71 (55.9%)	118 (92.9%)
	No opinion	17 (13.4%)	3 (2.4%)
8. Reporting forms are not available	Yes	40 (31.5%)	8 (6.3%)
	No	71 (55.9%)	117 (92.1%)
	No opinion	16 (12.6%)	2 (1.6%)
9. Fear of legal liability	Yes	27 (21.3%)	3 (2.4%)
	No	85 (66.9%)	122 (96.1%)
	No opinion	15 (11.8%)	2 (1.6%)
10. Fear of confidentiality issues	Yes	28 (22%)	3 (2.4%)
	No	89 (70.1%)	123 (96.9%)
	No opinion	10 (7.9%)	1 (0.8%)

Lack of communication with the patient was not perceived as a barrier to ADR Reporting by 72.4% of the doctors and 98.4% of the nurses.

There is an uncertainty regarding whether a reaction constitutes an ADR was identified as a barrier by 68.5% of the doctors and 35.4 % of the nurses

Factors associated with level of knowledge among doctors

Socio demographic factors		Level of knowledge			Chi - Square	p-value
		Good [n=61]	Moderate [n=59]	Poor [n=7]		
Age	22 – 32 Years	46 (47.4%)	46 (47.4%)	5 (5.2%)	3.83*	0.84
	33 – 43 Years	10 (47.6%)	9 (42.9%)	2 (9.5%)		
	44 – 54 Years	5 (62.5%)	3 (37.5%)	0		
	55 - 65 Years	0	1 (100%)	0		
Gender	Male	29 (53.7%)	23 (42.6%)	2 (3.7%)	1.43*	0.48
	Female	32 (43.8%)	36 (49.3%)	5 (6.8%)		
Department	Medical	30 (46.9%)	30 (46.9%)	4 (6.3%)	0.23*	1.00
	Surgical	31 (49.2%)	29 (46%)	3 (4.8%)		
Work Experience	<1 Year	19 (48.7%)	15 (38.5%)	5 (12.8%)	7.06*	0.47
	1-5 Years	28 (48.3%)	29 (50%)	1 (1.7%)		
	6-10 Years	5 (38.5%)	7 (53.8%)	1 (7.7%)		
	11-20 Years	7 (58.3%)	5 (41.7%)	0		
	>20 Years	2 (40%)	3 (60%)	0		
Residence	Rural	34 (47.2%)	36 (50%)	2 (2.8%)	2.63*	0.30
	Urban	27 (49.1%)	23 (41.8%)	5 (9.1%)		

* Fisher's Exact value

No socio demographic factors were significantly associated with level of knowledge among doctors with a non - significant p-value >0.05.

Factors associated with level of knowledge among Nurses

Socio demographic factors		Level of knowledge			Chi - Square	p-value
		Good [n=24]	Moderate [n=71]	Poor [n=32]		
Age	22 – 32 Years	11 (19.3%)	27 (47.4%)	19 (33.3%)	8.25*	0.07
	33 – 43 Years	9 (15.3%)	40 (67.8%)	10 (16.9%)		
	44 – 54 Years	4 (36.4%)	4 (36.4%)	3 (27.3%)		
Gender	Male	1 (16.7%)	4 (66.7%)	1 (16.7%)	0.34*	1.00
	Female	23 (19%)	67 (55.4%)	31 (25.6%)		
Department	Medical	16 (21.3%)	41 (54.7%)	18 (24%)	0.73	0.71
	Surgical	8 (15.4%)	30 (57.7%)	14 (26.9%)		

Education	GNM	17 (20%)	48 (56.5%)	20 (23.5%)	1.53*	0.93
	BSc	4 (22.2%)	11 (61.1%)	3 (16.7%)		
	ANM	0	1 (100%)	0		
Work Experience	<1 Year	2 (9.1%)	13 (59.1%)	7 (31.8%)	8.52*	**0.03**
	1-5 Years	4 (16%)	12 (48%)	9 (36%)		
	6-10 Years	6 (18.2%)	18 (54.5%)	9 (27.3%)		
	11-20 Years	7 (23.3%)	20 (66.7%)	3 (10%)		
	>20 Years	5 (29.4%)	8 (47.1%)	4 (23.5%)		
Residence	Rural	18 (17.3%)	58 (55.8%)	28 (26.9%)	1.47*	0.49
	Urban	6 (26.1%)	13 (56.5%)	4 (17.4%)		

* Fisher's Exact value

Experience regarding ADR reporting among nurses were statistically associated with level of knowledge with a p -value 0.03.

When the association between selected sociodemographic factors and the level of knowledge among nurses were assessed, 29.4 % of those with good knowledge had more than 20 years of work experience compared to those with moderate and poor knowledge, and this association was found to be statistically significant

Factors associated with level of attitude among doctors

Socio demographic factors		Attitude		Chi - Square	p-value
		Good [n=83]	Poor [n=44]		
Age	22 – 32 Years	63 (64.9%)	34 (35.1%)	1.75*	0.71
	33 – 43 Years	15 (71.4%)	6 (28.6%)		
	44 – 54 Years	4 (50%)	4 (50%)		
	55 - 65 Years	1 (100%)	0		
Gender	Male	40 (74.1%)	14 (25.9%)	3.16	0.09
	Female	43 (58.9%)	30 (41.1%)		
Department	Medical	42 (65.6%)	22 (34.4%)	0.004	1.00
	Surgical	41 (65.1%)	22 (34.9%)		
Experience	<1 Year	29 (74.4%)	10 (25.6%)	4.38*	0.36
	1-5 Years	36 (62.1%)	22 (37.9%)		
	6-10 Years	7 (53.8%)	6 (46.2%)		
	11-20 Years	9 (75%)	3 (25%)		
	>20 Years	2 (40%)	3 (60%)		
Residence	Rural	51 (70.8%)	21 (29.2%)	2.20	0.19
	Urban	32 (58.2%)	23 (41.8%)		

* Fisher's Exact value

No socio demographic factors were significantly associated with attitude among doctors with a non - significant p-value > 0.05.

There was no statistically significant association between any of the selected sociodemographic factors and the level of attitude among doctors

Factors associated with level of attitude among nurses

Socio demographic factors		Attitude		Chi - Square	p-value
		Good [n=69]	Poor [n=58]		
Age	22 – 32 Years	34 (59.6%)	23 (40.4%)	3.89	0.14
	33 – 43 Years	32 (54.2%)	27 (45.8%)		
	44 – 54 Years	3 (27.3%)	8 (72.7%)		
Gender	Male	5 (83.3%)	1 (16.7%)	2.14	0.22
	Female	64 (52.9%)	57 (47.1%)		
Department	Medical	40 (53.3%)	35 (46.7%)	0.07	0.86
	Surgical	29 (55.8%)	23 (44.2%)		
Education	GNM	44 (51.8%)	41 (48.2%)	1.13	0.70
	BSc	10 (55.6%)	8 (44.4%)		
	ANM	0	1 (100%)		

Work Experience	<1 Year	13 (59.1%)	9 (40.9%)	10.38	**0.03**
	1-5 Years	16 (64%)	9 (36%)		
	6-10 Years	22 (66.7%)	11 (33.3%)		
	11-20 Years	14 (46.7%)	16 (53.3%)		
	>20 Years	4 (23.5%)	13 (76.5%)		
Residence	Rural	54 (51.9%)	50 (48.1%)	1.34	0.26
	Urban	15 (65.2%)	8 (34.8%)		

Experience regarding ADR reporting among nurses were statistically associated with attitude with a p -value of 0.03.

Factors associated with practice regarding ADR reporting among doctors

Socio demographic factors		Practice		Chi - Square	p-value
		Good [n=79]	Poor [n=48]		
Age	22 – 32 Years	53 (54.6%)	44 (45.4%)	11.15*	**0.005**
	33 – 43 Years	17 (81%)	4 (19%)		
	44 – 54 Years	8 (100%)	0		
	55 - 65 Years	1 (100%)	0		
Gender	Male	36 (66.7%)	18 (33.3%)	0.79	0.46
	Female	43 (58.9%)	30 (41.1%)		
Department	Medical	37 (57.8%)	27 (42.2%)	1.06	0.36
	Surgical	42 (66.7%)	21 (33.3%)		
Experience	<1 Year	21 (53.8%)	18 (46.2%)	10.8	**0.02**
	1-5 Years	32 (55.2%)	26 (44.8%)		
	6-10 Years	10 (76.9%)	3 (23.1%)		
	11-20 Years	11 (91.7%)	1 (8.3%)		
	>20 Years	5 (100%)	0		
Residence	Rural	43 (59.7%)	29 (40.3%)	0.44	0.58
	Urban	36 (65.5%)	19 (34.5%)		

* Fisher's Exact value

Age (p =0.005) and years of experience (p = 0.02) were statistically associated with practice regarding ADR reporting among doctors.

Factors associated with practice regarding ADR reporting among nurses

Socio demographic factors		Practice		Chi - Square	p-value
		Good [n=83]	Poor [n=44]		
Age	22 – 32 Years	28 (49.1%)	29 (50.9%)	11.74*	**0.002**
	33 – 43 Years	46 (78%)	13 (22%)		
	44 – 54 Years	9 (81.8%)	2 (18.2%)		
Gender	Male	0	6 (100%)	11.88*	**0.001**
	Female	83 (68.6%)	38 (31.4%)		
Department	Medical	46 (61.3%)	29 (38.7%)	1.31	0.26
	Surgical	37 (71.2%)	15 (28.8%)		
Education	GNM	62 (72.9%)	23 (48.2%)	4.00*	0.11
	BSc	9 (50%)	9 (50%)		
	ANM	1 (100%)	0		
Experience	<1 Year	4 (18.2%)	18 (81.8%)	34.75	**< 0.001**
	1-5 Years	13 (52%)	12 (48%)		
	6-10 Years	29 (87.9%)	4 (12.1%)		
	11-20 Years	24 (80%)	6 (20%)		
	>20 Years	13 (76.5%)	4 (23.5%)		
Residence	Rural	69 (66.3%)	35 (33.7%)	0.25	0.63
	Urban	14 (60.9%)	9 (39.1%)		

* Fisher's Exact value

Age (p =0.002), gender (p=0.001) and years of experience (p < 0.001) were statistically associated with practice regarding ADR reporting among nurses.

DISCUSSION

The present study evaluated the knowledge, attitude, practice, and barriers (KAP) related to adverse drug reaction (ADR) reporting among healthcare professionals in a tertiary care centre in South Kerala. The findings reveal important insights into the current status of pharmacovigilance awareness and practices among doctors and nurses, highlighting both strengths and critical gaps that need to be addressed.

Socio-demographic Characteristics

The mean age of the study participants was 32.5 ± 7.02 years, with the mean age of nurses being slightly higher than the mean age of the doctors. This reflects the workforce distribution commonly observed in tertiary care settings, where nursing staff tend to have longer service duration. A predominance of female participants (76.4%) was noted, particularly among nurses, which is consistent with similar studies conducted in India and globally (3,13). The higher rural representation among nurses (82%) compared to doctors (56.7%) suggests a potential disparity in exposure to training and resources, which may influence ADR reporting practices.

Knowledge Regarding ADR Reporting

In the present study, doctors demonstrated better knowledge compared to nurses, with 48% of doctors having good knowledge compared to only 18.9% of nurses. This finding is consistent with studies by Gupta et al. and Prakash et al., where physicians showed significantly higher knowledge levels than nurses and other healthcare professionals (3,19).

The overall mean knowledge score (7.25 ± 2.3) indicates moderate awareness among healthcare professionals. While most participants correctly identified the definition of ADR and understood that any drug can cause ADRs, significant knowledge gaps were identified in technical aspects such as ADR classification, reporting software (VigiFlow), and awareness of global pharmacovigilance systems. Similar deficiencies have been reported by Bepari et al. and Abidi et al., who observed that healthcare professionals often lack in-depth knowledge of pharmacovigilance tools and processes (16,17).

Awareness regarding the Pharmacovigilance Programme of India (PvPI) was also suboptimal, especially among nurses. This is in agreement with previous studies where limited awareness of national pharmacovigilance programs was identified as a major contributor to underreporting (10,12). The low level of knowledge regarding ADR reporting forms and software further highlights the need for structured educational interventions.

Attitude Towards ADR Reporting

The study demonstrated a predominantly positive attitude towards ADR reporting among both doctors and nurses, with 65.4% and 54.3% respectively showing good attitude scores. Nearly all participants agreed that ADR reporting is essential, improves patient safety, and should be mandatory.

These findings are consistent with studies by Miyatra et al. and Khan et al., where more than 70% of healthcare professionals expressed a positive attitude towards pharmacovigilance (13,20). Similarly, Rajesh et al. reported that healthcare professionals recognize ADR reporting as a professional obligation and an important component of patient safety (22).

However, despite this positive attitude, certain concerns were noted. A significant proportion of participants perceived ADR reporting as time-consuming and the reporting forms as complex, particularly among nurses. These findings align with studies by Lopez-Gonzalez et al. and Backstrom et al., which identified workload and procedural complexity as major deterrents to ADR reporting (15,27).

The discrepancy between positive attitude and actual reporting behavior observed in this study reflects a well-documented phenomenon in pharmacovigilance research, where favorable perceptions do not necessarily translate into effective practice (24).

Practice of ADR Reporting

The practice component revealed that although a high proportion of participants had encountered ADRs in their clinical practice (85–89%), the actual reporting rates were significantly lower (59.1% among doctors and 40.9% among nurses). This indicates a substantial gap between identification and reporting of ADRs.

This finding is consistent with global and Indian studies reporting widespread underreporting of ADRs (24,25). Hazell and Shakir estimated that only 6–10% of all ADRs are reported globally, while in India, the reporting rate is less than 1% (12,24). Similarly, Som et al. reported that only 20% of healthcare professionals had ever reported an ADR, highlighting the persistent issue of underreporting (14).

Training exposure was limited, particularly among doctors, with only 36.2% having attended pharmacovigilance training programs. Lack of training has been consistently identified as a key factor contributing to poor reporting practices (26,28). In contrast, preventive practices such as taking drug allergy history, administering test doses, and monitoring patients were widely followed, indicating that healthcare professionals are clinically vigilant but lack engagement in formal reporting systems.

ADR documentation rates were relatively high (>80%), suggesting that while clinicians recognize ADRs, they may not be translating this into formal reporting to pharmacovigilance systems. This gap emphasizes the need for integration of ADR reporting into routine clinical workflows.

Barriers to ADR Reporting

The study identified several important barriers to ADR reporting. The most prominent barrier was uncertainty in identifying whether a reaction qualifies as an ADR, especially among doctors (68.5%). This finding is consistent with studies by Figueiras et al. and Oshikoya et al., where uncertainty about causality was a major deterrent to reporting (26,28).

Lack of awareness regarding reporting methods was another significant barrier, particularly among doctors. This highlights a paradox where doctors have better theoretical knowledge but limited awareness of practical reporting mechanisms. Similar observations have been reported in previous Indian studies (16,17).

Time constraints were reported as a barrier by a considerable proportion of doctors, which aligns with findings from Lopez-Gonzalez et al., where workload was identified as a major limiting factor (15). However, this barrier was less prominent among nurses in the present study.

Other barriers included complexity of reporting forms, lack of availability of forms, and fear of legal liability and confidentiality issues. Although fear-related barriers were less commonly reported in this study, they have been highlighted in other studies as significant contributors to underreporting (29,30).

Interestingly, lack of communication with patients was not perceived as a major barrier, suggesting that interpersonal factors may play a lesser role compared to systemic and knowledge-related issues.

Association Between KAP and Socio-demographic Variables

The study found no significant association between socio-demographic variables and knowledge or attitude among doctors. However, among nurses, work experience was significantly associated with knowledge and attitude, indicating that experience plays a crucial role in improving pharmacovigilance awareness.

Similarly, practice was significantly associated with age and experience among doctors, and with age, gender, and experience among nurses. These findings suggest that senior healthcare professionals are more likely to engage in ADR reporting, possibly due to increased clinical exposure and confidence.

These results are consistent with previous studies, which have shown that experience and professional maturity are important determinants of ADR reporting behavior (20,23).

Implications for Practice

The findings of this study have important implications for strengthening pharmacovigilance systems. While healthcare professionals demonstrate good clinical awareness and positive attitudes, gaps in knowledge and practice highlight the need for targeted interventions.

Regular training programs, workshops, and continuing medical education (CME) sessions should be conducted to improve awareness regarding ADR identification and reporting procedures. Simplification of reporting systems, availability of reporting forms, and integration of digital reporting tools such as VigiFlow can enhance reporting efficiency.

Furthermore, creating a supportive environment with feedback mechanisms and incentives may encourage healthcare professionals to actively participate in ADR reporting.

Overall Interpretation

Overall, the study demonstrates that although healthcare professionals possess moderate knowledge and a positive attitude towards ADR reporting, actual reporting practices remain suboptimal. The gap between knowledge and practice is primarily influenced by barriers such as uncertainty, lack of awareness, and procedural challenges.

Addressing these issues through structured educational and system-level interventions is essential to improve ADR reporting rates and strengthen pharmacovigilance activities, ultimately enhancing patient safety and quality of healthcare delivery.

CONCLUSION

The present study concludes that healthcare professionals in a tertiary care setting possess moderate knowledge and a generally positive attitude towards adverse drug reaction (ADR) reporting. Doctors demonstrated comparatively better knowledge than nurses, while both groups showed a favorable perception of the importance of pharmacovigilance in improving patient safety.

Despite this positive attitude, actual ADR reporting practices remain suboptimal, with a clear gap between identification and reporting of ADRs. Although a majority of healthcare professionals had encountered ADRs in clinical practice, a significantly lower proportion had reported them through formal pharmacovigilance systems.

The study identified several key barriers contributing to underreporting, including uncertainty in recognizing ADRs, lack of awareness regarding reporting procedures, time constraints, and perceived complexity of reporting systems. Additionally, work experience was found to play a significant role in influencing knowledge and practice, particularly among nurses.

These findings highlight the urgent need for regular training programs, awareness campaigns, and simplification of ADR reporting processes. Strengthening institutional support and integrating pharmacovigilance into routine clinical practice can significantly enhance ADR reporting rates and ultimately improve patient safety and quality of healthcare.

LIMITATIONS

- The study was conducted in a **single tertiary care centre**, which may limit the generalizability of the findings to other healthcare settings.
- The use of a **convenience sampling technique** may introduce selection bias, as participants were included based on availability and willingness.
- The study relied on a **self-administered questionnaire**, which may be subject to reporting bias, recall bias, and socially desirable responses.
- The **cross-sectional design** limits the ability to establish causal relationships between knowledge, attitude, practice, and associated factors.
- The study included only **doctors and nurses**, excluding other healthcare professionals such as pharmacists, which may have provided a more comprehensive assessment of pharmacovigilance practices.

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