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# KNOWLEDGE, ATTITUDE & PRACTICE ON ADVERSE EFFECT MONITORING AMONG HEALTHCARE PROFESSIONALS IN A SECONDARY CARE HOSPITAL: AN AWARENESS INITIATIVE THROUGH AN INFORMATIONAL LEAFLET

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**ABSTRACT**

Adverse drug reactions (ADRs) are a significant concern in healthcare and contribute to increased morbidity and healthcare burden. Effective pharmacovigilance depends largely on the active participation of healthcare professionals in ADR monitoring and reporting. This study aimed to assess the knowledge, attitude, and practice (KAP) of healthcare professionals towards adverse effect monitoring and reporting. A cross-sectional, questionnaire-based study was conducted over a period of six months among 120 healthcare professionals, including doctors, nurses, and pharmacists, working in both government sector. Data were collected using a validated semi-structured questionnaire covering demographic details and KAP domains. The results showed that the majority of participants had adequate knowledge and a positive attitude towards ADR monitoring. Doctors and pharmacists demonstrated comparatively better knowledge and attitude than nurses. However, the practice of ADR reporting was found to be suboptimal across all groups. Common barriers to reporting included lack of time, insufficient awareness of reporting procedures, and limited accessibility to reporting systems. In conclusion, although knowledge and attitude towards ADR monitoring are satisfactory, there is a need to improve reporting practices through continuous educational interventions and enhanced awareness programs to strengthen pharmacovigilance and ensure patient safety.

**KEYWORDS:** Adverse drug reactions, Pharmacovigilance, Knowledge, Attitude, Practice, Healthcare professionals.

## 1. INTRODUCTION

Adverse drug reactions (ADRs) represent a significant challenge to global healthcare systems due to their impact on patient safety, treatment outcomes, and healthcare costs. The World Health Organization (WHO) defines an ADR as a harmful and unintended response to a medicinal product occurring at normal therapeutic doses used for prevention, diagnosis, or treatment of diseases.[1] ADRs can affect individuals across all age groups and are recognized as one of the leading contributors to hospital admissions and mortality worldwide.[2]

Pharmacovigilance (PV) is an essential component of healthcare that focuses on the identification, evaluation, understanding, and prevention of adverse effects related to medications.[3] Among the various pharmacovigilance methods, spontaneous reporting systems play a central role in detecting unknown or rare adverse effects and in evaluating the safety profile of medicines in real-world settings.[4] Despite their importance, the effectiveness of these systems is often limited by underreporting, which remains a persistent issue, particularly in developing countries.

Healthcare professionals (HCPs), including physicians, pharmacists, and nurses, are directly involved in patient care and are therefore in a key position to detect and report ADRs. Their contribution is vital for the success of pharmacovigilance programs, as timely reporting can

help in early identification of drug-related risks and prevention of further harm.[5] However, several studies have highlighted that ADR reporting rates are low due to factors such as insufficient knowledge, lack of awareness about reporting procedures, time constraints, and uncertainty regarding the significance of reporting.[6]

Assessment of Knowledge, Attitude, and Practice (KAP) among healthcare professionals is an effective approach to understand their behavior toward ADR monitoring and reporting. KAP studies help in identifying gaps in awareness, misconceptions, and barriers that hinder effective pharmacovigilance activities.[7] Evidence from previous studies indicates that although healthcare professionals often demonstrate a positive attitude toward ADR reporting, their level of knowledge and actual reporting practices are frequently inadequate, contributing to underreporting.[8,9]

In India, pharmacovigilance programs have been implemented to improve drug safety monitoring; however, ADR reporting remains suboptimal. Identifying the underlying factors responsible for this gap is essential to enhance reporting systems and ensure patient safety.

Therefore, the present study aims to evaluate the knowledge, attitude, and practice of healthcare professionals regarding ADR monitoring and reporting. The findings of this study are expected to highlight existing gaps and provide insights for improving pharmacovigilance activities, ultimately promoting safer and more rational use of medicines.[10,11]

## 2. METHODOLOGY

**Study site**: Tirupattur Government hospital.
**Study design:** A Cross-sectional survey.
**Period of study:** 6 months.

**Sample to be recruited with justification**

The sample size calculated using open Epi (version 3.0) with 95% confidence internal 5% allowable error and on expected proportion(p) of 0.5 The final sample size was calculated as 108, to compensate for possible non-response or incomplete questionnaire, an additional 10% was added, and giving a final sample size of 120 participants.

$$n = \frac{z^2 X p X (1-p)}{d^2}$$

### 2.1 Participants selection criteria

**2.1a Inclusion criteria**

a. Healthcare professionals (Doctor, Nurses and pharmacists) working in the government and private sector.
b. Participants who have atleast 3 months of experience.
c. Participants who are available during the data collection period.

**2.1 b Exclusion criteria**

a. Interns, trainees or student who are not yet fully qualified healthcare professionals are excluded.
b. Participants who are not willing are excluded.

### 2.2 METHOD

The Cross-sectional, questionnaire-based study (KAP – Knowledge, Attitude, Practice) was carried out among healthcare professionals. A semi-structured questionnaire was developed from previously published research articles. The modified questionnaire was given to 3 subject experts in pharmacy practice to ensure content validity, relevance, and clarity.

### 2.3 Data collection

This study will be conducted in 110 participants as per the inclusion criteria after getting approval from the Hospital approval. A validated and published questionnaire will be used. Demographic details will be collected using data collection form and the questionnaire will be given to the study participants and the response obtained will be documented. Before the initiation of the study, the purpose of the study was explained to all participants and written informed consent was obtained from those willing to participate. After completion of the questionnaire, an informational leaflet on ADR monitoring was provided to participants to improve awareness regarding the importance of pharmacovigilance and ADR reporting.

### 2.4 Study tool used

This is a survey-based study which is carried out using a semi structured questionnaire which was developed taking the original questionnaire.

The modified questionnaire included multiple-choice and Yes/No type questions. It consists of four main domains, the first section includes Demographic information (Age, Gender, Experience, Qualification), the second section includes question regarding knowledge about ADR, the third section includes Attitude- related questions and the last section includes Practice-related questions.

### 2.5 Ethical Consideration

Permission to conduct the study was obtained from the hospital authority before initiating the study. Participants were informed about the purpose of the study, and confidentiality of their response was maintained throughout the study.

### 2.6 Statistical validation of the developed questionnaire

The modified KAP questionnaire was given to 3 pharmacy practice experts to validate item relevant. Responses were graded as highly relevant (3), relevant (2), and irrelevant (1). Inter-rater reliability was assessed using fleiss' kappa, yielding fair overall agreement (k=0.355; demographics k=0.324, attitude k=1.000, practice k= 0.286). Perfect agreement (k=1.00) was observed in the attitude section.

**Work Plan**

Literature review
⇩
Questionnaire preparation and validation
⇩
Hospital Approval
⇩
Data collection
⇩
Analysis of data & Outcome assessment
⇩
Report

The collected data were entered into Microsoft excel and analysed statistically. The result were expressed in frequency and percentage and p-value where applicable.

## 3. RESULTS

The collected data were analysed using Microsoft excel. Descriptive statistics such as frequency and percentage analysis were used to summarize the data. To determine the statistical significance among healthcare professionals (doctors, Pharmacist and nurse), two factor analysis of variance (ANOVA) was applied. A p-value < 0.05 was considered statistically significant.

### 3.7 Data analysis

**Table 1: Demographical Characteristics.**

| S.NO | CHARACTERISTIC | DOCTORS [N=34] | PHARMACIST [N=23] | NURSE [N=53] | p-VALUE |
|---|---|---|---|---|---|
| 1. | **Gender** | | | | |
| | Male | 17(50) | 14(60.8) | 11(20.7) | 0.622 |
| | Female | 17(50) | 9(39.1) | 42(79.2) | |
| 2. | **Professional status** | | | | |
| | Doctor | 34 | 0 | 0 | 0.727 |
| | Nurse | 0 | 0 | 53 | |
| | Pharmacist | 0 | 23 | 0 | |
| 3. | **Experience** | | | | |
| | <1 year | 0 | 0 | 0 | 0.28 |
| | 1-5 years | 3(8.8) | 9(39.1) | 11(20.7) | |
| | 6-10 years | 7(20.5) | 3(13) | 17(34) | |
| | >10 years | 24(70.5) | 11(47.8) | 25(47.1) | |
| 4. | **Qualification** | | | | |
| | Diploma | 0 | 4(17.3) | 32(60.3) | 0.79 |
| | UG | 0 | 16(69.5) | 18(33.9) | |
| | PG | 34 | 3(13) | 3(5.6) | |
| 5. | **Have you received formal training in ADR monitoring \ Pharmacovigilance** | | | | |
| | Yes | 28(82.3) | 8(34.7) | 17(32) | 0.84 |
| | No | 6(17.6) | 15(65.2) | 6(11.3) | |

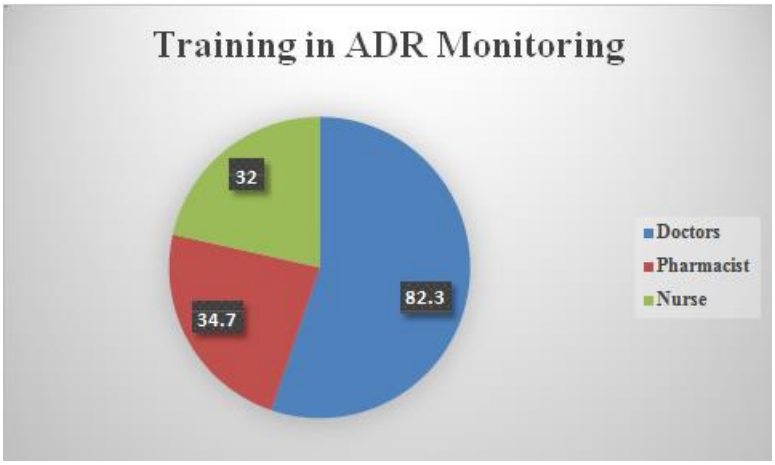


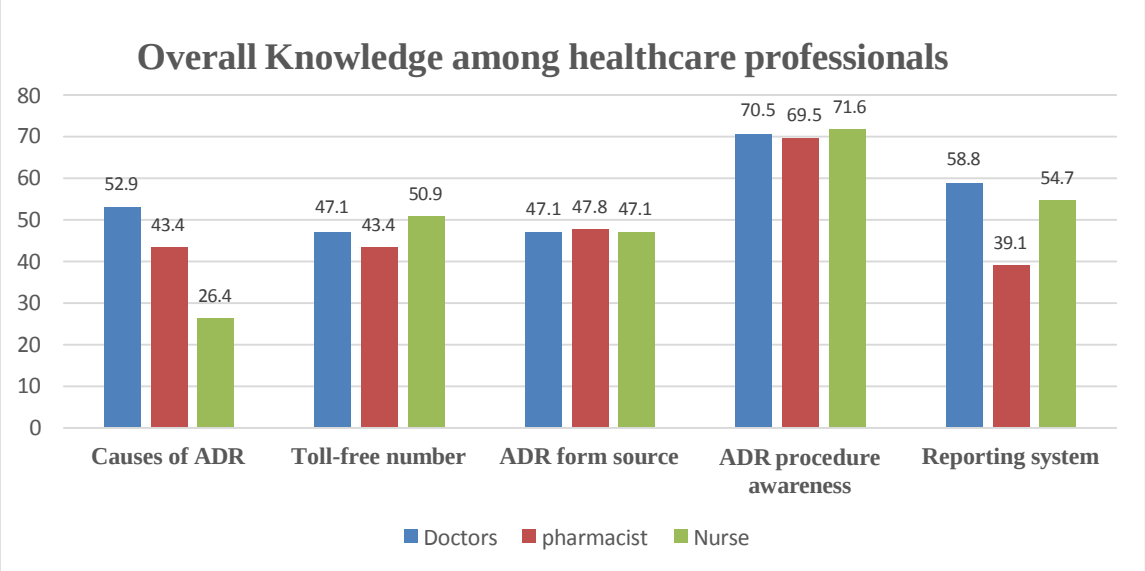

Table 1 represent the demographic characteristics of healthcare professionals including doctors (n=34), Pharmacist (n=23) and nurses (n=53). Among doctors, male and female participants were equal (50% each). Among pharmacists, males constituted 60.8% while females accounted for 39.1%. In contrast, the majority of nurses were female (79.2%). In terms of work experience, most doctors (70.5%), pharmacists (47.8%) and nurses (47.1%) had more than 10 years

of experience. The majority of doctors (82.3%) had received formal training in ADR monitoring compared to pharmacists (34.7%) and nurses (32%). However, the demographic variables were not statistically significant ($p > 0.05$).

**Table 2: Knowledge of healthcare professionals regarding ADR monitoring.**

| S.NO | KNOWLEDGE RELATED QUESTIONS | DOCTORS [N=34] | PHARMACIST [N=23] | NURSE [N=53] | p-VALUE |
|---|---|---|---|---|---|
| 1. | **Which are the following leads to ADR** | | | | |
| | Drugs | 12(35.2) | 6(26.0) | 18(33.9) | 0.05* |
| | Vaccine | 4(11.7) | 3(13.0) | 16(30.1) | |
| | Traditional medicine | 0 | 4(17.39) | 5(9.4) | |
| | All the above | 18(52.9) | 10(43.4) | 14(26.4) | |
| 2. | **What is the toll free number to report ADR in PV?** | | | | |
| | 1800-180-3030 | 16(47.1) | 10(43.4) | 27(50.9) | 0.08 |
| | 1800-180-3024 | 14(41.1) | 11(47.8) | 20(37.7) | |
| | 1800-180-3034 | 4(11.7) | 2(8.69) | 6(11.3) | |
| 3. | **Do you know where to obtain an ADR reporting form?** | | | | |
| | AMCs | 11(32.3) | 9(39.1) | 20(37.7) | 0.01** |
| | CDSCO | 16(47.1) | 11(47.8) | 25(47.1) | |
| | IPC | 4(11.7) | 1(4.3) | 2(3.7) | |
| | All the above | 3(8.8) | 2(8.6) | 6(11.3) | |
| 4. | **Do you aware the procedure to report an ADR in your institutions?** | | | | |
| | Yes | 24(70.5) | 16(69.5) | 38(71.6) | 0.17 |
| | No | 10(29.4) | 7(30.4) | 15(28.3) | |
| 5. | **Does ADR reporting system is voluntary or mandatory** | | | | |
| | Yes | 20(58.8) | 9(39.1) | 29(54.7) | 0.13 |
| | No | 14(41.1) | 14(60.8) | 24(45.2) | |

*$p \leq 0.05$- Statistically significant
**$p \leq 0.01$-Highly statistically significant



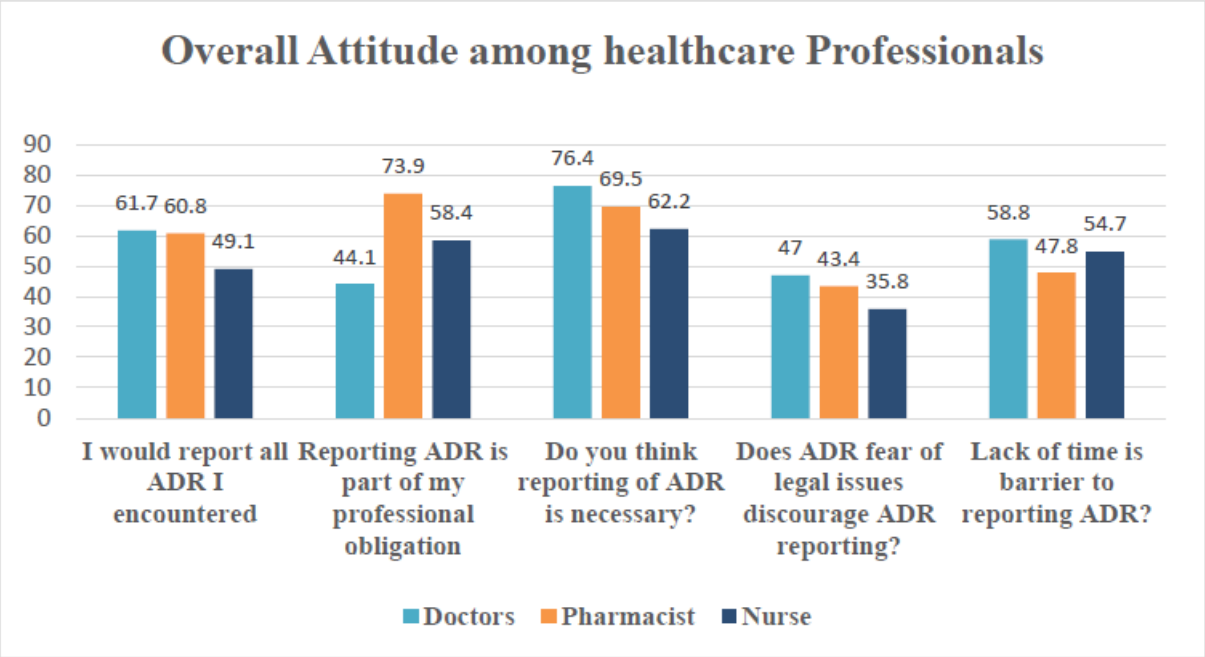

Knowledge among healthcare professionals regarding ADR monitoring are demonstrated in Table 2. Majority of the doctors (52.9%) and pharmacists (43.4%) correctly identified that all listed factors (drugs, vaccines, and traditional medicine) could lead to ADRs, whereas 33.9% of nurses identified drugs as the cause of ADRs. This association was statistically significant ($p = 0.05$)*. Nearly half of the participants identified CDSCO as the source for ADR reporting forms, and this variable showed statistical significance ($p = 0.01$)*.

Regarding the toll-free number for ADR reporting, about 47.1% of doctors, 43.4% of pharmacists and 50.9% of nurses selected the correct number.

**Table 3: Attitude of healthcare professionals towards ADR monitoring.**

| S.NO | ATTITUDE RELATED QUESTIONS | DOCTORS [N=34] | PHARMACIST [N=23] | NURSE [N=53] | p- VALUE |
|---|---|---|---|---|---|
| 1. | **I would report all ADR I encountered** | | | | |
| | Yes | 21(61.7) | 14(60.8) | 26(49.1) | 0.08 |
| | No | 13(38.2) | 9(39.1) | 27(50.9) | |
| 2. | **Reporting ADR is part of my professional obligation** | | | | |
| | Yes | 15(44.1) | 17(73.9) | 31(58.4) | 0.22 |
| | No | 19(55.8) | 6(26.1) | 22(41.5) | |
| 3. | **Do you think reporting of ADR is necessary?** | | | | |
| | Yes | 26(76.4) | 16(69.5) | 33(62.2) | 0.08 |
| | No | 8(23.5) | 7(30.4) | 20(37.7) | |
| 4. | **Does ADR fear of legal issues discourage ADR reporting?** | | | | |
| | Yes | 16(47) | 10(43.4) | 19(35.8) | 0.14 |
| | Maybe | 17(50) | 12(52.1) | 30(56.6) | |
| | No | 1(2.94) | 1(4.34) | 4(7.5) | |
| 5. | **Lack of time is barrier to reporting ADR?** | | | | |
| | Yes | 20(58.8) | 11(47.8) | 29(54.7) | 0.05* |
| | No | 14(41.1) | 12(52.1) | 24(45.2) | |

*p ≤ 0.05- Statistically significant



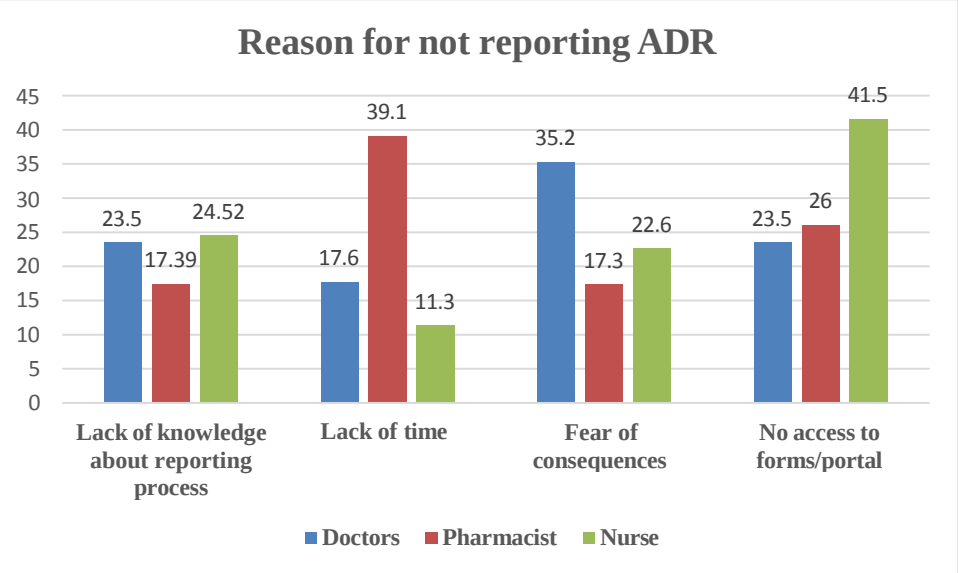

Attitude of healthcare professionals toward ADR monitoring reported in table 3. Most doctors (61.7%) and pharmacist (60.8%) reported that they would report all ADRs encountered. The majority of healthcare professionals believed that ADR reporting is necessary. Lack of time as a barrier to ADR reporting was reported by 58.8% of doctors, 47.8% of pharmacists and 54.7% of nurses, and this variable showed statistical significance (p = 0.05)*.

**Table 4: ADR reporting practices among healthcare professionals.**

| S.NO | VARIABLES | DOCTORS [N=34] | PHARMACIST [N=23] | NURSE [N=53] | p- VALUE |
|---|---|---|---|---|---|
| 1. | **How often do you give advice to your patient on possible ADR you prescribed, dispensed or administered** | | | | |
| | Usually | 16(47) | 5(21.7) | 17(32) | 0.21 |
| | Never | 8(23.5) | 8(34.7) | 20(37.7) | |
| | Sometimes | 7(20.5) | 4(17.3) | 7(13.2) | |
| | Always | 3(8.8) | 6(26) | 9(16.9) | |
| 2. | **If you encountered ADR have you ever reported it, while monitoring the patients?** | | | | |

| | | | | | |
|---|---|---|---|---|---|
| | Yes | 23(67.6) | 14(60.8) | 33(62.2) | 0.07 |
| | No | 11(32.3) | 9(39.1) | 20(37.7) | |
| 3. | **Have you ever encountered patients with ADR in your clinical practice in the last 12 months, if yes how many patients with ADR have you encountered during the last 12 months?** | | | | |
| | None | 12(35.2) | 7(30.4) | 18(33.9) | 0.02* |
| | 1 | 12(35.2) | 5(21.7) | 15(28.3) | |
| | 2 | 2(5.8) | 2(8.6) | 4(7.5) | |
| | 3 | 1(2.9) | 2(8.6) | 2(3.7) | |
| | More than 3 | 7(20.5) | 7(30.4) | 14(26.4) | |
| 4. | **Have you always counselled patients about the side effects and possible ADRs of drugs?** | | | | |
| | Yes | 18(52.9) | 15(65.2) | 29(54.7) | 0.02* |
| | No | 16(47) | 8(34.7) | 24(45.2) | |
| 5. | **How do you usually report the ADRs?** | | | | |
| | Paper form | 12(35.2) | 6(26) | 26(49) | 0.16 |
| | Online reporting | 17(50) | 11(47.8) | 19(35.8) | |
| | Phone/email | 3(8.8) | 2(8.6) | 5(9.4) | |
| | Never reported | 2(5.8) | 4(17.3) | 3(5.6) | |
| 6. | **If you have not reported ADRs, what is the main reason?** | | | | |
| | Lack of knowledge about reporting process | 8(23.5) | 4(17.39) | 13(24.52) | 0.14 |
| | Lack of time | 6(17.6) | 9(39.1) | 6(11.3) | |
| | Fear of consequences | 12(35.2) | 4(17.3) | 12(22.6) | |
| | No access to forms/portal | 8(23.5) | 6(26.0) | 22(41.5) | |

*p ≤ 0.05- Statistically significant




ADR reporting practices among healthcare professionals reported in table 4. A majority of healthcare professionals had reported ADRs when encountered, including 67.6% of doctors, 60.8% of pharmacists and 62.2% of nurses. The number of ADR cases encountered in the last 12 months, a considerable proportion of respondents reported none or only one case. This variable showed statistical significance (p = 0.02)*. More than half of the doctors (52.9%), pharmacists (65.2%) and nurses (54.7%) reported that they always counselled patients regarding side effects and ADRs, which was also statistically significant (p = 0.02)*.

## 4. DISCUSSION

Adverse drug reaction (ADRs) is a major concern in clinical practice because they can lead to increased morbidity, prolonged hospitalization, and additional healthcare costs. Effective pharmacovigilance systems rely heavily on the active participation of healthcare professionals in identifying and reporting ADRs. The present study assessed the knowledge, attitude, and practice (KAP) of healthcare professionals regarding ADR monitoring and reporting. The findings of the present study indicate that healthcare professionals generally possess basic knowledge about adverse drug reactions and the importance of pharmacovigilance. However, the practical implementation of ADR reporting remains limited. Similar observations have been reported in several studies conducted in different countries where

healthcare professionals were aware of ADR monitoring but showed inadequate reporting practices.

A recently published study conducted in Timor-Leste reported that many HCPs possess basic knowledge about ADRs and pharmacovigilance, but they understanding of the official reporting procedure and system remains limited. The finding indicates that although HCPs generally recognize the importance of PV, the actual reporting rate of ADR remain low. The study finds the reporting barriers include lack of training on PV, absence of clear reporting guidelines.[12]

Another study in Nigeria state that the HCPs where largely aware of pharmacovigilance but so low level of adverse drug reaction and pharmacovigilance. Overall, (72.5%) healthy worker had learned of pharmacovigilance, but only (5.2%) correctly understood the pharmacovigilance concept (50.0%) showed adequate knowledge of adverse drug reaction while (46.2%) demonstrated positive attitude toward adverse drug reaction reporting. This perhaps underscores need for regular mandatory education and training adverse drug reaction\ pharmacovigilance concept among the primary health care unite health workers.[13,14] Adverse drug reaction monitoring pharmacovigilance study conducted in south India among health care professional that the study demonstrated that knowledge and attitude towards pharmacovigilance is gradually improving HCPs but unfortunately the actual practices of adverse drug reaction reporting is still deficient among them.[5,6,8]

The result of this study highlights the need for strengthening pharmacovigilance awareness and simplifying the adverse drug reaction reporting process within healthcare institutions. Establishing adverse drug reaction monitoring centers, providing easy access to reporting forms and integrating pharmacovigilance training into professional education may help bridge the gap between knowledge and practice.

Continuous education and training programs are essential to improve awareness about ADR reporting among healthcare professionals. Regular workshops, seminars, and awareness programs can significantly enhance participation in pharmacovigilance activities and encourage healthcare professionals to actively report ADRs.

In India, ADR monitoring is carried out under the Pharmacovigilance Programme of India, which is coordinated by the Indian Pharmacopoeia Commission. This national program encourages healthcare professionals to report suspected ADRs through ADR monitoring centres to improve drug safety surveillance.

## 5. CONCLUSION

This study assessed the knowledge, attitude, and practice of healthcare professionals (Doctor, pharmacist, nurse) regarding adverse effect monitoring and reporting. The finding show that majority of health professionals had adequate knowledge and positive attitude towards ADR reporting; However, the actual reporting practice was not satisfactory.

Pharmacist and doctors showed comparatively better knowledge and positive attitude about ADR reporting procedure. Nurses also had a positive attitude, but their knowledge and practice slightly lower compare to the other groups. The term of practice, although all three groups had encountered ADR in their clinical work, consistent reporting was not observed across all professionals. Barriers such as lack of time, limited awareness about reporting procedures and accessibility issues may influence ADR reporting practice.

## POST-SURVEY EDUCATIONAL INITIATIVE

After completion of the data collection, an ADR awareness leaflet was distributed to all participating healthcare professionals. The leaflet included basic information about ADR monitoring, reporting procedure and role of healthcare professionals in pharmacovigilance. The purpose of this initative was to improve awareness and encourage better ADR reporting practice in future.

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