

## ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE REGARDING PHARMACOVIGILANCE AND ADVERSE DRUG REACTION REPORTING AMONG THE GENERAL PUBLIC: A CROSS – SECTIONAL STUDY

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### Abstract

Background: Pharmacovigilance is essential for monitoring drug safety and preventing adverse drug reactions (ADRs). However, ADR underreporting remains a major global concern. Objective: To assess knowledge, attitude, and practice (KAP) regarding pharmacovigilance among the general public. Methods: A cross-sectional study was conducted among 300 participants using a structured questionnaire. Data were analyzed using descriptive statistics. Results: Only 16.67% of participants were aware of pharmacovigilance. While 70% strongly agreed that ADR reporting is important, only 7.67% had reported ADRs. Major barriers included lack of awareness and lack of knowledge about reporting systems. Conclusion: Knowledge and practice are inadequate despite positive attitudes. Educational interventions are required to improve ADR reporting.

**Keywords:** Pharmacovigilance, ADR, KAP Study, Drug Safety.

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### INTRODUCTION

Pharmacovigilance is the scientific discipline that focuses on monitoring the safety of medicines and preventing adverse effects associated with drug therapy. The term pharmacovigilance is derived from two words: the Greek word “pharmakon”, meaning drug, and the Latin word “vigilare”, meaning to keep watch or stay alert. Thus, pharmacovigilance literally means “keeping watch over drugs [1]. The primary aim of pharmacovigilance is to identify and evaluate adverse drug reactions (ADRs) and ensure that medicines are used safely and effectively. Pharmacovigilance activities involve the collection, monitoring, analysis, and prevention of adverse effects or any other drug-related problems [2]. The importance of pharmacovigilance became widely recognized after several drug-related disasters in the past. One of the most notable events was the thalidomide tragedy in the late 1950s and early 1960s, where the drug thalidomide, prescribed to

pregnant women for nausea and insomnia, caused severe congenital abnormalities in thousands of newborns [3]. World Health Organization launched the WHO Programme for International Drug Monitoring, which aims to promote global collaboration in pharmacovigilance, program collects reports of adverse drug reactions from participating countries and stores them in a global database known as VigiBase, maintained by the Uppsala Monitoring Centre (UMC) in Sweden [4], Signal detection is a crucial process in pharmacovigilance. A signal refers to information that suggests a new potential causal relationship between a drug and an adverse event, Signal detection involves identifying patterns or trends in ADR reports that indicate a possible safety concern [4]. the Pharmacovigilance Programme of India (PvPI) was initiated by the Government of India to monitor the safety of medicines used in the country. The program aims to collect, analyse, and evaluate ADR reports to ensure safe use of medicines, the Indian Pharmacopoeia

Commission (IPC) functions as the National Coordination Centre (NCC) for PvPI [5]. Despite the importance of pharmacovigilance, ADR reporting rates remain low in many countries, Common barriers include: Lack of awareness about pharmacovigilance Lack of time among healthcare professionals Fear of legal, consequences Uncertainty about whether a reaction is drug-related addressing these barriers is essential to improve pharmacovigilance systems [6].

## MATERIALS AND METHODS

It is Cross-sectional questionnaire-based study carried out from December 2025 – March 2026 in and around Anantapur with a sample size of 300 and the questionnaire include Demographics of the sample, Knowledge, Attitude, Practice Regarding Pharmacovigilance and Barriers to Report Adverse Drug Reactions. All these questionnaires are self-Prepared and Evaluated before the study has started. Inclusion criteria were all the participants who are willing to participate in the study of both the genders and Exclusion criteria is those who are not willing to participate in the study.

## RESULTS

Results are divided into Five categories and they are **1. Demographics** Which include (a) Age distribution, (b) Gender distribution, (c) Education status **2. Knowledge** which includes six questions those are: (a)Have you heard of the term Pharmacovigilance (b) Do you know that Medicines can cause side effects or Adverse Drug Reactions (c) Are you aware that ADRs can be reported to healthcare authorities (d) Do you know where to report an ADR in India (e) Can both prescription and over the counter medicines cause ADR (f) Do you think herbal/traditional medicines can also cause side effects **3. Attitude** which includes five questions those are: (a) Reporting side effects of medicines are important for patient safety (b) The general public should be encouraged to report ADRs (c) Reporting ADRs can help improve the safety of medicines. (d) Healthcare professionals should educate patients about ADR reporting (e) Do you believe ADR reporting is a shared responsibility of patients and healthcare providers **4. Practice** which includes four questions those are: (a) Have you ever experienced a side effect after taking a medicine (b) If yes, did you report it to a doctor or pharmacist (c) Have you ever stopped a medicine due to side effects without consulting a doctor (d) Have you ever reported an ADR using any reporting system **5. Barriers for Reporting ADR's** which include six options those are: Lack of awareness, do not know how to report, Side effect mild, Fear/hesitation, Time constraints, Others.

**1(a) Age distribution:** A total of 300 participants were included in the study. The majority of respondents belonged to the 18–30 years age group with 150 participants (50.0%), indicating that young

adults formed the largest proportion of the study population. The 31–45 years age group accounted for 70 participants (23.33%), followed by the 46– 60 years group with 50 participants (16.67%). Participants below 18 years represented 20 individuals (6.67%), while the age group above 60 years constituted the smallest proportion with only 10 participants (3.33%). This distribution suggests that the study population was predominantly composed of young adults.

Table 01: Distribution of Participants by Age

| Age Group | Count (n) | Percentage (%) |
|-----------|-----------|----------------|
| <18       | 20        | 6.67           |
| 18–30     | 150       | 50.0           |
| 31–45     | 70        | 23.33          |
| 46–60     | 50        | 16.67          |
| >60       | 10        | 3.33           |

**1.(b) Gender distribution:** females constituted the majority with 160 participants (53.33%), while males accounted for 140 participants (46.67%).

Table 02: Distribution of participants based on Gender

| Gender | Count (n) | Percentage (%) |
|--------|-----------|----------------|
| Male   | 140       | 46.67          |
| Female | 160       | 53.33          |

**1. (c) Education status:** The majority were graduates with 140 participants (46.67%). Postgraduates accounted for 70 participants (23.33%), while 50 participants (16.67%) had no formal education. Secondary education was reported by 30 participants (10%), and the least number belonged to the primary education group with 10 participants (3.33%). This indicates that a large proportion of respondents had higher educational qualifications.

Table 03: Distribution of participants based on Education

| Category            | Count (n) | Percentage (%) |
|---------------------|-----------|----------------|
| No formal education | 50        | 16.67          |
| Primary             | 10        | 3.33           |
| Secondary           | 30        | 10.0           |
| Graduate            | 140       | 46.67          |
| Postgraduate        | 70        | 23.33          |

**2(a)Have you heard of the term Pharmacovigilance;** Only a small proportion reported that they had heard about pharmacovigilance, while a larger proportion indicated that they had not heard about it or were unsure

Table 04: Distribution of participants based on Have you heard of the term Pharmacovigilance

| Response | Count (n)   |
|----------|-------------|
| Yes      | 50 (16.67%) |

|            |              |
|------------|--------------|
| No         | 130 (43.33%) |
| Don't know | 120 (40.0%)  |

## 2. (b) Do you know that Medicines can cause side effects or Adverse Drug Reactions:

Only a small proportion reported that they had heard about pharmacovigilance, while a larger proportion indicated that they had not heard about it or were unsure. This suggests limited awareness about pharmacovigilance among the study population.

Table 05: Distribution of participants based on "Do you know that Medicines can cause side effects or adverse drug reactions"

| Response   | Count (n)    |
|------------|--------------|
| Yes        | 50 (16.67%)  |
| No         | 130 (43.33%) |
| Don't know | 120 (40.0%)  |

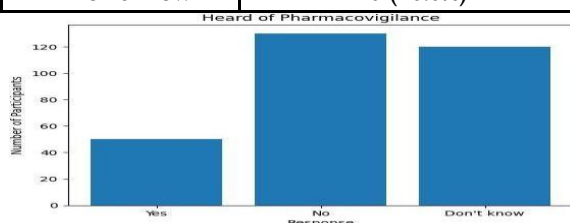


Figure 01: Distribution of Participants Based on Awareness of the Term Pharmacovigilance

**2.(c) Are you aware that ADRs can be reported to healthcare authorities:** The majority of respondents agreed that medicines can cause adverse drug reactions. However, some participants either disagreed or were not aware of this fact, indicating the need for improved public education regarding medicine safety.

Table 06: Distribution of participants based on Do you know that Medicines can cause side effects or adverse drug reactions

| Response   | Count (n)    |
|------------|--------------|
| Yes        | 170 (56.67%) |
| No         | 50 (16.67%)  |
| Don't know | 80 (26.67%)  |

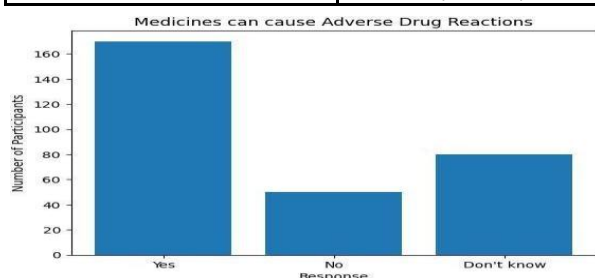


Figure 02: Distribution of Participants Based on Knowledge that Medicines Can Cause Side Effects or Adverse Drug Reactions (ADRs)

**2.(d) Do you know where to report an ADR in India:** Only a small proportion of participants were aware that adverse drug reactions can be reported. The majority reported that they were unaware of ADR reporting, highlighting the need for increased awareness programs.

Table 07: Distribution of participants based on Do you know where to report an ADR in India

| Response   | Count (n)   |
|------------|-------------|
| Yes        | 20 (6.67%)  |
| No         | 195 (65.0%) |
| Don't know | 85 (28.33%) |

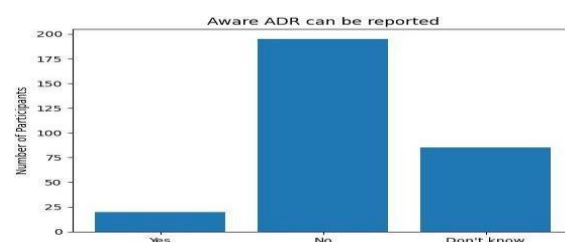


Figure 03: Distribution of Participants Based on Awareness of ADR Reporting Systems

**2. (e) Can both prescription and over the counter medicines cause ADR;** A considerable proportion of participants were unsure whether both over the counter and prescription medicines can cause adverse drug reactions. This suggests gaps in knowledge regarding medicine safety.

Table 08: Distribution of participants based on Can both prescription and over the counter medicines cause ADR

| Response   | Count (n)    |
|------------|--------------|
| Yes        | 36 (12.0%)   |
| No         | 85 (28.33%)  |
| Don't know | 179 (59.67%) |

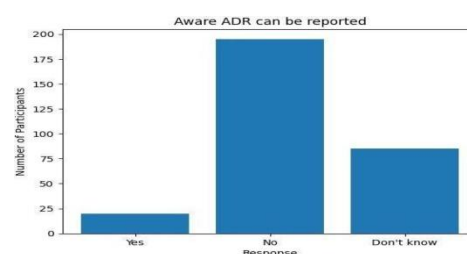


Figure 04: Distribution of Participants Based on Knowledge of Where to Report an ADR in India

**2. (f) Do you think herbal/traditional medicines can also cause side effects;** The findings indicate that many participants either believed that herbal medicines do not cause side effects or were unsure about it. This highlights a common misconception regarding the safety of herbal medicines.

Table 09: Distribution of participants based on Do you think herbal/traditional medicines can also cause side effects

| Response   | Count (n)    |
|------------|--------------|
| Yes        | 43 (14.33%)  |
| No         | 127 (42.33%) |
| Don't know | 130 (43.33%) |

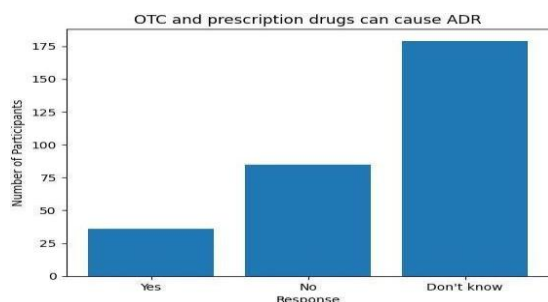


Figure 05: Distribution of Participants Based on Knowledge that Both Prescription and Over-the-Counter Medicines Can Cause ADRs

**3(a) Reporting side effects of medicines are important for patient safety:** The majority of participants strongly agreed that reporting side effects is important. This indicates a positive attitude toward pharmacovigilance and recognition of the importance of reporting adverse drug reactions.

Table 10: Distribution of participants based on awareness that reporting side effects of medicines is important for patient safety

| Response          | Count (n)   |
|-------------------|-------------|
| Strongly Agree    | 210 (70.0%) |
| Agree             | 71 (23.67%) |
| Neutral           | 19 (6.33%)  |
| Disagree          | 0 (0.0%)    |
| Strongly Disagree | 0 (0.0%)    |

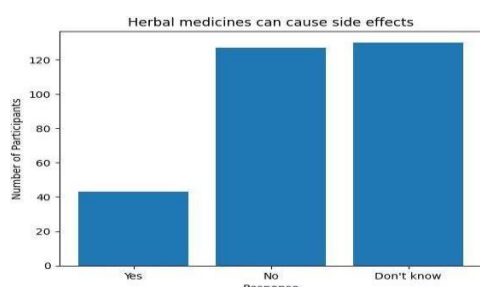


Figure 06: Distribution of Participants Based on Awareness that Herbal/Traditional Medicines Can Also Cause Side Effects

**3 (b) The general public should be encouraged to report ADRs;** Most participants strongly supported the idea that the public should be encouraged to report adverse drug reactions, this reflects a favourable attitude toward community participation in pharmacovigilance.

Table 11: Distribution of participants based on whether the general public should be encouraged to report ADRs

| Response          | Count (n)    |
|-------------------|--------------|
| Strongly Agree    | 229 (76.33%) |
| Agree             | 60 (20.0%)   |
| Neutral           | 11 (3.67%)   |
| Disagree          | 0 (0.0%)     |
| Strongly Disagree | 0 (0.0%)     |

Figure 07: Distribution of Participants Based on the Importance of Reporting Side Effects for Patient Safety  
**3.(c) Reporting ADRs can help improve the safety of medicines;** The majority of respondents agreed that reporting adverse drug reactions contributes to improving medicine safety. This demonstrates awareness of the role of pharmacovigilance in healthcare.

Table 12: Distribution of participants based on whether reporting ADRs can help improve the safety of medicines

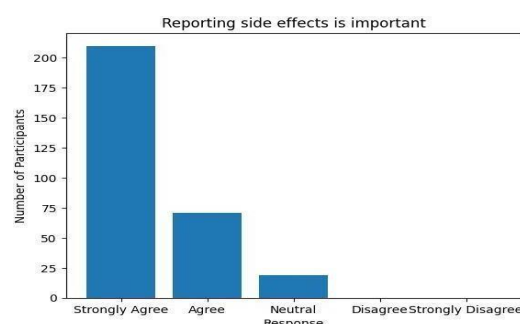


Table 12: Distribution of participants based on whether reporting ADRs can help improve the safety of medicines

| Response          | Count (n)   |
|-------------------|-------------|
| Strongly Agree    | 189 (63.0%) |
| Agree             | 94 (31.33%) |
| Neutral           | 17 (5.67%)  |
| Disagree          | 0 (0.0%)    |
| Strongly Disagree | 0 (0.0%)    |

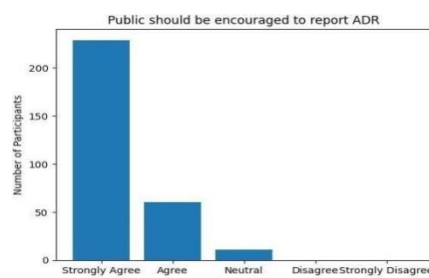


Figure 08: Distribution of Participants Based on the Opinion that the General Public Should Be Encouraged to Report ADRs

**3.(d) Healthcare professionals should educate patients about ADR reporting:** A large proportion of respondents agreed that healthcare professionals should educate patients regarding adverse drug reactions and their reporting. This indicates the perceived importance of professional guidance.

Table 13: Distribution of participants based on whether healthcare professionals should educate patients about ADR reporting

| Response          | Count (n)    |
|-------------------|--------------|
| Strongly Agree    | 120 (40.0%)  |
| Agree             | 170 (56.67%) |
| Neutral           | 10 (3.33%)   |
| Disagree          | 0 (0.0%)     |
| Strongly Disagree | 0 (0.0%)     |

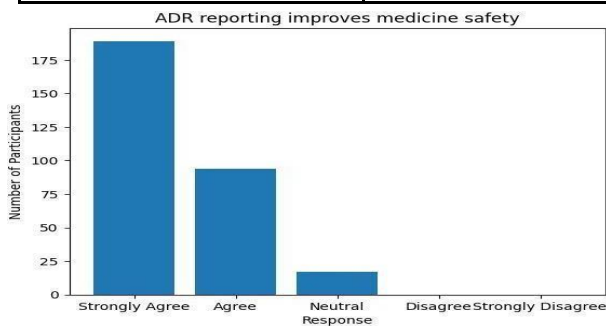


Figure 09: Distribution of Participants Based on the Belief that Reporting ADRs Can Improve Medicine Safety

**3.(e) Do you believe ADR reporting is a shared responsibility of patients and healthcare providers:** The findings show that most participants believe that ADR reporting is a shared responsibility among healthcare professionals and the public.

Table 14: Distribution of participants based on belief that ADR reporting is a shared responsibility of patients and healthcare providers

| Response          | Count (n)    |
|-------------------|--------------|
| Strongly Agree    | 77 (25.67%)  |
| Agree             | 184 (61.33%) |
| Neutral           | 39 (13.0%)   |
| Disagree          | 0 (0.0%)     |
| Strongly Disagree | 0 (0.0%)     |

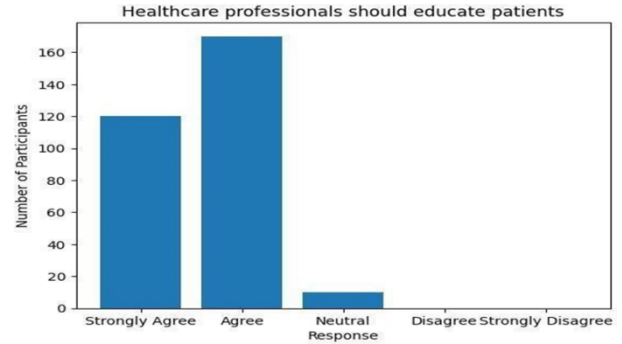


Figure 10: Distribution of Participants Based on the Opinion that Healthcare Professionals Should Educate Patients about ADR Reporting

**4.(a) Have you ever experienced a side effect after taking a medicine:** Only a small number of participants reported experiencing side effects after taking medicines, while the majority did not report such experiences.

Table 15: Distribution of participants based on whether they have ever experienced a side effect after taking a medicine

| Response | Count (n)    |
|----------|--------------|
| Yes      | 50 (16.67%)  |
| No       | 250 (83.33%) |

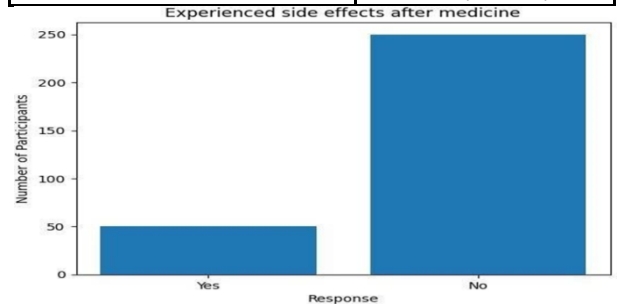


Figure 11: Distribution of Participants Based on the Belief that ADR Reporting Is a Shared Responsibility of Patients and Healthcare Providers

**4.(b) If yes, did you report it to a doctor or pharmacist:** Among those who experienced side effects, only a small proportion reported them to a healthcare professional, indicating limited reporting practices.

Table 16: Distribution of participants based on whether they reported a side effect to a doctor or pharmacist (if experienced)

| Response | Count (n)    |
|----------|--------------|
| Yes      | 50 (16.67%)  |
| No       | 250 (83.33%) |

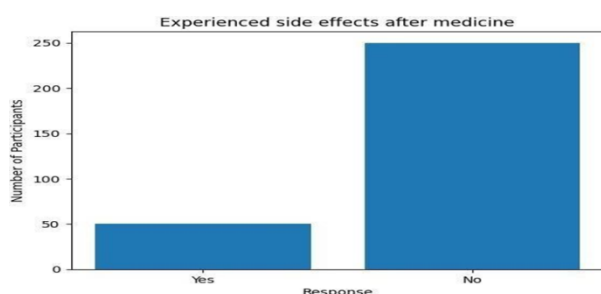


Figure 12: Distribution of Participants Based on Experience of Side Effects after Taking Medicines

**4.(c) Have you ever stopped a medicine due to side effects without consulting a doctor:** A small proportion of participants reported stopping medication without consulting a doctor, while the majority followed medical advice.

Table 17: Distribution of participants based on whether they have ever stopped a medicine due to side effects without consulting a doctor

| Response | Count (n)    |
|----------|--------------|
| Yes      | 37 (12.33%)  |
| No       | 263 (87.67%) |

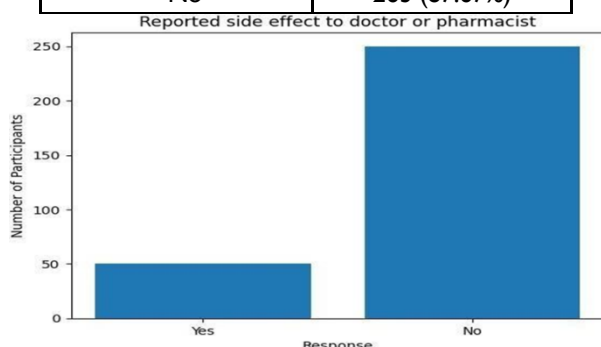


Figure 13: Distribution of Participants Based on Reporting Side Effects to a Doctor or Pharmacist

**4.(d) Have you ever reported an ADR using any reporting system:** Very few participants reported adverse drug reactions through the official reporting system, indicating low utilization of pharmacovigilance reporting mechanisms.

Table 18: Distribution of participants based on whether they have ever reported an ADR using any reporting system

| Response | Count (n)    |
|----------|--------------|
| Yes      | 23 (7.67%)   |
| No       | 277 (92.33%) |

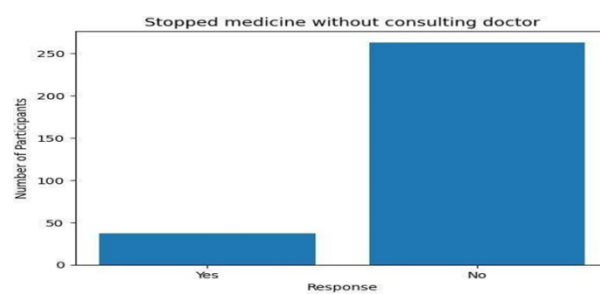


Figure 14: Distribution of Participants Based on Stopping Medicines Due to Side Effects without Consulting a Doctor

**5. Barriers for Reporting ADR's:** The major barriers to adverse drug reaction reporting among the participants were lack of awareness and lack of knowledge about how to report ADRs. Other barriers included perceiving the side effects as mild, time constraints, and hesitation.

Table 19: Distribution of participants based on barriers to reporting adverse drug reactions (ADRs)

| Response                  | Count (n)    |
|---------------------------|--------------|
| Lack of awareness         | 250 (83.33%) |
| Do not know how to report | 240 (80.0%)  |
| Side effect mild          | 230 (76.66%) |
| Fear/hesitation           | 170 (56.66%) |
| Time constraints          | 200 (66.66%) |

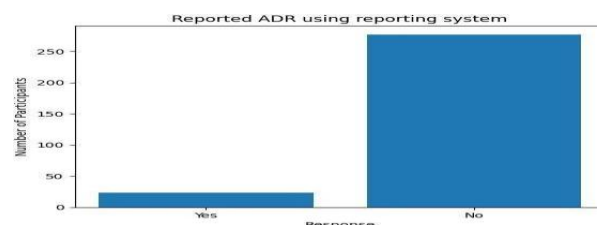


Figure 15: Distribution of Participants Based on Previous ADR Reporting Experience

Reasons for Underreporting (Pie Chart)

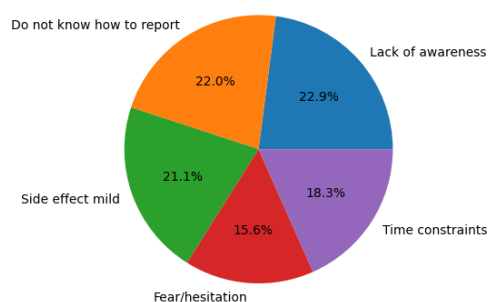


Figure 16: Distribution of Participants Based on Barriers to ADR Reporting

## DISCUSSION

The majority of participants belonged to the 18–30 years age group (50%), followed by 31– 45 years (23.33%) and 46–60 years (16.67%), Female participants (53.33%) slightly outnumbered male participants

(46.67%), Most participants were graduates (46.67%), followed by postgraduates (23.33%), Employed individuals constituted the largest occupational group (33.33%), followed by students (23.33%), Only 16.67% of participants had heard about pharmacovigilance, while 43.33% had not heard about it and 40% were unsure. 56.67% of participants knew that medicines can cause adverse drug reactions. Only 6.67% knew that ADRs can be reported to healthcare authorities. 73.33% of participants did not know where ADRs can be reported in India. 70% strongly agreed that reporting side effects is important for patient safety, 76.33% strongly agreed that the public should be encouraged to report ADRs, 63% strongly agreed and 31.33% agreed that ADR reporting improves medicine safety. Only 16.67% of participants reported experiencing side effects after taking medicines. Very few participants reported ADRs to doctors or pharmacists, 12.33% reported stopping medicines due to side effects without consulting a doctor, Only 7.67% reported ADRs using official reporting systems. Major barriers included lack of awareness and lack of knowledge about ADR reporting procedures, other barriers included mild perception of side effects, time constraints, and hesitation to report, these findings highlight the need to improve awareness and education regarding pharmacovigilance.

## CONCLUSION

The present study assessed the knowledge, attitude, and practice regarding pharmacovigilance among the general public. The findings revealed that knowledge regarding pharmacovigilance among participants was limited. Many individuals were unaware of the concept of pharmacovigilance, ADR reporting systems, and the potential risks associated with different types of medicines. Despite this limited knowledge, the attitude toward pharmacovigilance was positive. Most respondents agreed that ADR reporting is important for improving patient safety and believed that patients and healthcare professionals should both participate in reporting adverse drug reactions. However, the practice of ADR reporting was low. Even though some participants experienced side effects from medicines, only a small number reported these reactions through formal reporting systems. Therefore, increasing public awareness about pharmacovigilance is essential. Educational programs, patient counselling, community awareness campaigns, and simplified digital reporting systems can help improve ADR reporting. Strengthening public participation will support national initiatives such as the Pharmacovigilance Program of India and contribute to global drug safety monitoring efforts. Overall, improving awareness, encouraging ADR reporting, and strengthening pharmacovigilance systems will help ensure safer and more effective use of medicines.

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Not Declared

## FUNDING STATEMENT

No

## CONFLICT OF INTEREST

No

## INFORM CONSENT AND ETHICAL STATEMENT

Taken from the study participants.

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