



## KNOWLEDGE, ATTITUDE, AND PRACTICES (KAP) REGARDING PHARMACOVIGILANCE AMONG POSTGRADUATE STUDENTS AND CLINICIANS AT A TERTIARY CARE CENTRE: A CROSS-SECTIONAL STUDY

Dr. Alivelu Anitha<sup>1</sup>, Dr. Anjaly Mary Varghese<sup>2</sup>, Dr. K. Nagavishnu<sup>3\*</sup>,  
Mr. Uchusagari Umar<sup>4</sup>

<sup>1</sup>Assistant professor Department of Pharmacology, GMC Kadapa,

<sup>2</sup>Assistant professor Department of Pharmacology Santhiram Medical College Nandyal,

<sup>3\*</sup>Assistant Professor Department of Pharmacology Santhiram Medical College Nandyal,

<sup>4</sup>3rd year MBBS student

Santhiram Medical College Nandyal, Andhra Pradesh, India.

**Corresponding Author:** Dr. K. Nagavishnu

Assistant Professor Department of Pharmacology, Santhiram Medical College Nandyal, Andhra Pradesh, India.

### ABSTRACT

**Background:** Pharmacovigilance plays main role in ensuring drug safety by detecting, assessing, and preventing adverse drug reactions (ADRs). Healthcare professionals, like postgraduate students and clinicians, are central to ADR reporting systems. Under-reporting is a major concern inspite of positive attitude toward pharmacovigilance. **Aim:** To assess the knowledge, attitude, and practices (KAP) regarding pharmacovigilance and ADR reporting among postgraduate students and clinicians at a tertiary care centre.

**Methods:** This hospital-based cross-sectional questionnaire study was done among 550 postgraduate students and clinicians at a tertiary care teaching hospital. Data were collected using a pre-validated structured questionnaire comprising sections on knowledge, attitude, and practices related to pharmacovigilance. Data were analyzed using SPSS version 17.0, and results were expressed as frequencies and percentages.

**Results:** Among the study subjects, 78% correctly defined pharmacovigilance, and 64% were aware of the national pharmacovigilance program. 48% knew the correct procedure for ADR reporting. A positive attitude was seen among 92% who considered ADR reporting a professional responsibility and 88% acknowledged its importance in improving patient safety. 58% had seen an ADR in clinical practice. 34% had reported an ADR.

**Conclusion:** Knowledge and attitude toward pharmacovigilance were satisfactory, but actual ADR reporting practices were suboptimal. Targeted educational interventions and regular training programs are needed to improve ADR reporting and strengthen pharmacovigilance systems.

**Keywords:** Pharmacovigilance, Adverse Drug Reactions, Knowledge, Attitude, Practice, ADR Reporting, Healthcare Professionals, Postgraduate Students, Clinicians, Tertiary Care Centre.

### INTRODUCTION

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse drug reactions (ADRs) and other drug-related problems.

ADRs contribute significantly to morbidity, mortality, and increased healthcare costs globally, and spontaneous reporting of ADRs is the cornerstone of pharmacovigilance systems worldwide.<sup>1</sup>

Healthcare professionals like postgraduate trainees and clinicians play main role in the success of pharmacovigilance programs as they are the 1st to encounter ADRs in clinical practice<sup>2</sup>. Some studies have shown positive attitudes towards ADR reporting, but actual reporting practices are suboptimal due to inadequate knowledge, lack of training, and limited engagement with pharmacovigilance activities.

Assessing the knowledge, attitude, and practices (KAP) of postgraduate students and clinicians



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regarding pharmacovigilance can show gaps in awareness and behavior that must be addressed to strengthen ADR reporting and patient safety initiatives. Previous KAP studies among medical trainees have showed that most participants recognize the importance of ADR reporting, but there is a substantial gap that exists between perceived importance and actual practice of reporting ADRs.<sup>3</sup>

Research also suggested that targeted educational interventions and sensitization programs are effective in improving both knowledge and reporting practices, informing the need for continuous professional development in pharmacovigilance.<sup>4</sup>

Strengthening pharmacovigilance at the institutional level requires the establishment of active ADR monitoring committees, regular feedback mechanisms, and simplified reporting pathways like online and mobile-based reporting systems. Providing periodic training workshops, incorporating pharmacovigilance modules into postgraduate curricula, and encouraging a non-punitive reporting culture can significantly enhance participation among healthcare professionals. Institutional support, combined with continuous medical education and real-time feedback on reported ADRs, not only improves reporting rates but also fosters a culture of patient safety and rational drug use.<sup>5-7</sup>

In India, the Pharmacovigilance Programme of India (PvPI) was established to strengthen the monitoring of adverse drug reactions and to ensure patient safety through a structured national reporting system. Under this programme, ADR Monitoring Centres (AMCs) function across tertiary care hospitals and medical institutions to facilitate spontaneous reporting by healthcare professionals. In spite of the the availability of standardized reporting forms and online submission platforms, under-reporting is a major challenge. So, evaluating the knowledge, attitude, and practices of postgraduate students and clinicians is essential to identify gaps and to enhance the effectiveness of pharmacovigilance activities at the institutional and national levels.

**Aim-** To assess the knowledge, attitude, and practices (KAP) regarding pharmacovigilance and adverse drug reaction (ADR) reporting among postgraduate students and clinicians at a tertiary care centre.

**Objectives**

1. To evaluate the knowledge and attitude of postgraduate students and clinicians regarding pharmacovigilance and ADR reporting.

2. To assess the current practices of ADR reporting and identify barriers to reporting among postgraduate students and clinicians.

**MATERIALS AND METHODS**

**Study Design-** This was a hospital-based, cross-sectional, questionnaire-based study.

**Study Setting-** The study was done at tertiary care teaching hospital- Santiram Medical College, Nandyal.

**Study Duration: 6 months:** July 2025 to December 2025.

**Study Population-** The study population included postgraduate students and clinicians working at the tertiary care centre during the study period.

**Sample Size-** 550 participants were included in the study.

**Inclusion Criteria**

- Postgraduate students of all clinical and preclinical departments.
- Clinicians working in the tertiary care centre.
- Participants who gave informed consent.

**Exclusion Criteria**

- Interns and undergraduate students.
- Healthcare professionals not willing to participate.
- Incomplete questionnaire responses.

**Data Collection Tool-** Data were collected using a pre-validated, self-structured questionnaire consisting of three sections:

1. Knowledge regarding pharmacovigilance and ADR reporting.
2. Attitude towards pharmacovigilance and ADR reporting.
3. Practices related to ADR detection and reporting.

The questionnaire was self-administered and distributed either in printed form or electronically

**Statistical Analysis-** Data were entered into Microsoft Excel and analyzed using SPSS version 17.0. Descriptive statistics such as frequency and percentage were used to summarize categorical variables.

**Ethical Considerations-** The study was done after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants.

**RESULTS**

**Knowledge regarding Pharmacovigilance-** 78% of the patients had correctly defined pharmacovigilance.

Table 1: Knowledge Regarding Pharmacovigilance

Parameter	Frequency	Percentage (%)
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Correctly defined pharmacovigilance	429	78%
Aware of national pharmacovigilance program	352	64%
Aware of ADR Monitoring Centre in institution	286	52%
Aware of availability of ADR reporting form	380	69%
Knew correct procedure for ADR reporting	264	48%
Total	550	100%

**Attitude towards Pharmacovigilance-** 92% of the patients informed that ADR reporting is a professional responsibility.

Table 2: Attitude towards Pharmacovigilance

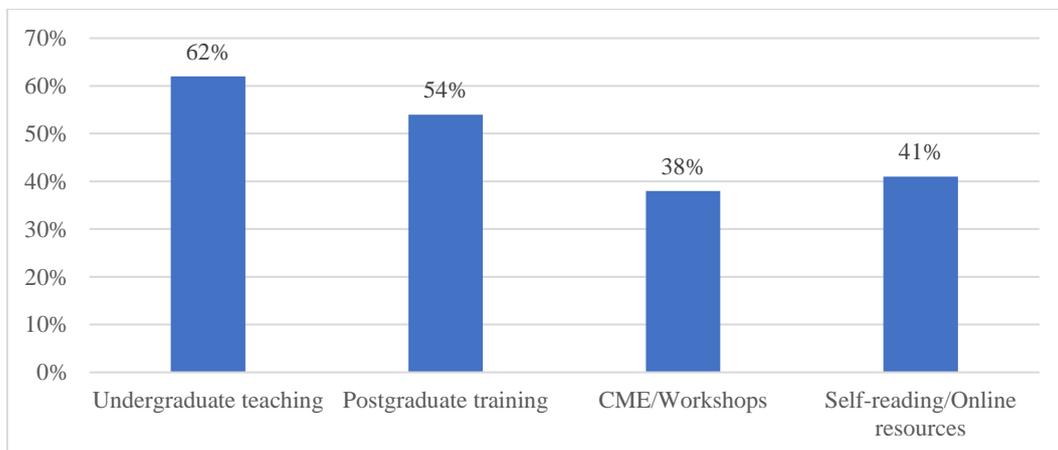
Parameter	Frequency	Percentage (%)
ADR reporting is a professional responsibility	506	92%
Pharmacovigilance improves patient safety	484	88%
Need for regular training programs	468	85%
Total	550	100%

**Practices and Barriers in ADR Reporting-** 58% of the patients had encountered ADR in practice.

Table 3: Practices and Barriers in ADR Reporting

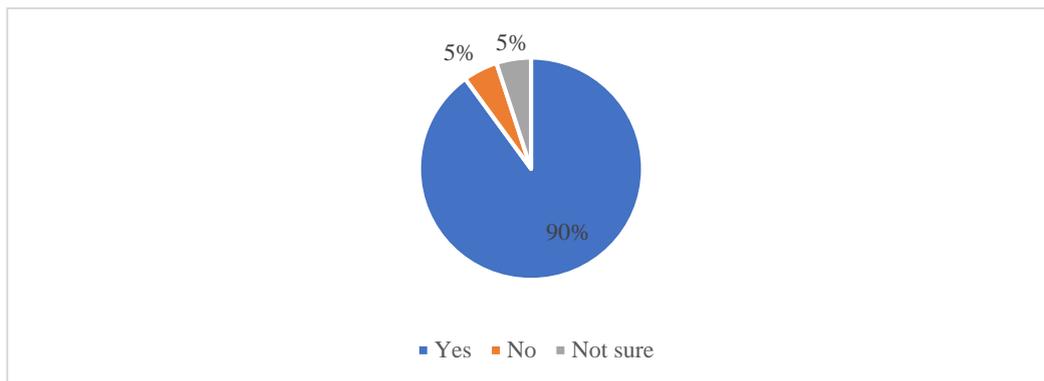
Parameter	Frequency	Percentage (%)
Encountered ADR in practice	319	58%
Ever reported an ADR	187	34%
Lack of knowledge on how to report	253	46%
Uncertainty about drug-reaction relationship	226	41%
Lack of time	209	38%
Fear of legal consequences	66	12%
Total	550	100%

**Source of Knowledge about Pharmacovigilance-** 62% of the patients were undergraduate teaching.



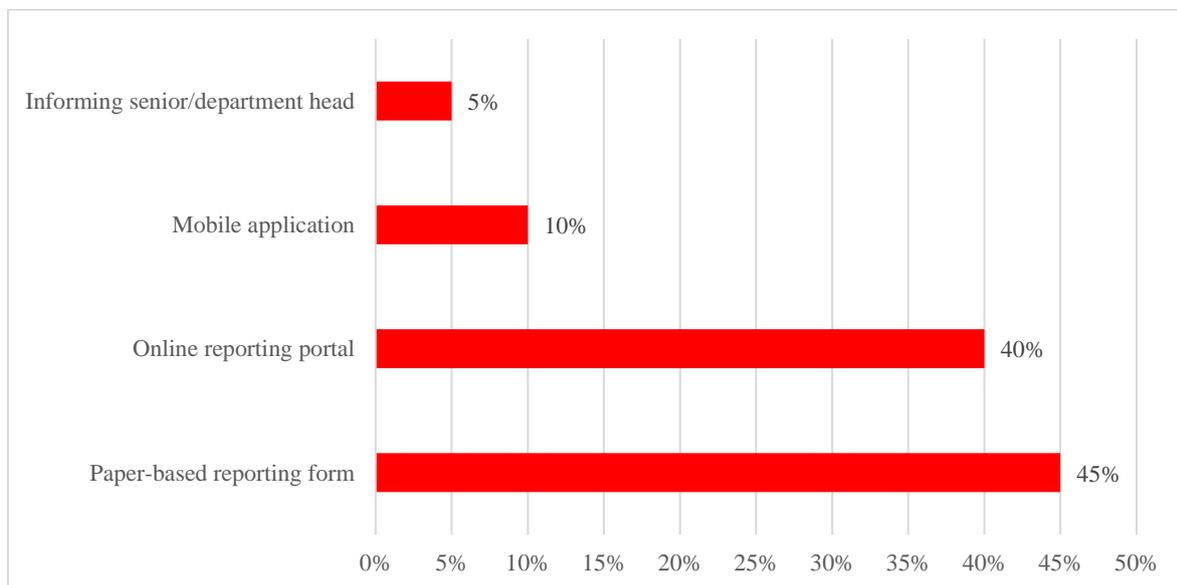
Graph 1: Source of Knowledge about Pharmacovigilance

**Willingness to Report ADRs in Future-** 90% of the patients showed willingness to reported ADR s in future.



Graph 2: Source of Knowledge about Pharmacovigilance

**Preferred Method of ADR Reporting-** 45% of the patients preferred paper-based reporting form.



Graph 3: Preferred Method of ADR Reporting

## DISCUSSION

The present study assessed the knowledge, attitude, and practices (KAP) regarding pharmacovigilance among postgraduate students and clinicians at a tertiary care centre. Pharmacovigilance plays main role in ensuring drug safety, as adverse drug reactions (ADRs) significantly contribute to patient morbidity, mortality, and increased healthcare burden. The World Health Organization (WHO) defined pharmacovigilance as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.<sup>8</sup>

In the present study, though the majority of participants demonstrated satisfactory knowledge regarding the definition and importance of pharmacovigilance, awareness about procedural aspects such as ADR reporting forms and reporting pathways was comparatively lower. Similar findings were reported by Gupta et al.,<sup>5</sup> who found adequate theoretical knowledge but poor practical awareness

among healthcare professionals.<sup>9, 10</sup> Upadhyaya et al.<sup>1</sup> found that postgraduate students were familiar with the concept of pharmacovigilance, detailed knowledge regarding reporting procedures was limited.

A positive attitude towards ADR reporting was seen among most participants in the present study, with a majority considering ADR reporting as a professional responsibility and essential for patient safety. These findings are consistent with those of Desai et al.,<sup>7</sup> who reported that healthcare professionals generally possess a favorable attitude toward pharmacovigilance but fail to translate it into practice.<sup>11</sup>

In spite of seeing ADRs in clinical practice, only a smaller proportion of participants had actually reported an ADR. Under-reporting of ADRs is a recognized global problem. Hazell and Shakir, in their systematic review, reported that the median under-reporting rate across studies was 94%, showing the magnitude of the issue. Lopez-

Gonzalez et al<sup>10</sup> informed that under-reporting is one of the major limitations of spontaneous reporting systems worldwide.<sup>12-14</sup>

One study done on nursing students reported idea on nearest available pharmacovigilance center.<sup>15</sup> This was not reported in the current study, which is a limitation.

Common barriers found in the present study—lack of knowledge about reporting procedures, uncertainty regarding causality, and lack of time—are comparable with previously published literature. Educational interventions, structured training programs, and sensitization workshops have been shown to significantly improve ADR reporting rates and awareness among healthcare professionals.<sup>16, 17</sup>

Overall, the findings of this study inform the need for continuous medical education, structured pharmacovigilance training during postgraduate education, and simplification of reporting systems to strengthen ADR monitoring at tertiary care centres.

## CONCLUSION

Though postgraduate students and clinicians showed satisfactory knowledge and a generally positive attitude toward pharmacovigilance and adverse drug reaction (ADR) reporting, actual reporting practices us suboptimal. A clear gap exists between awareness of the importance of pharmacovigilance and its practical implementation in routine clinical work.

Strengthening institutional support systems, simplifying reporting mechanisms, and fostering a proactive, non-punitive reporting culture are essential to improve ADR reporting rates. Enhancing knowledge and translating positive attitudes into consistent practice will ultimately strengthen pharmacovigilance systems and contribute to improved patient safety at tertiary care centres.

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