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Knowledge, attitude, and practice of pharmacovigilance among prescribers in a tertiary care hospital: A cross-sectional study.

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Abstract

Background:

Pharmacovigilance plays a pivotal role in ensuring medication safety by detecting, assessing, and preventing adverse drug reactions (ADRs). Despite being a professional and ethical responsibility, ADR reporting remains suboptimal worldwide, particularly among undergraduate prescribers.

Objectives:

To assess the level of knowledge, attitude, and practice regarding pharmacovigilance among MBBS student prescribers in a tertiary care hospital and to identify key barriers contributing to under-reporting of ADRs.

Methods:

A descriptive, cross-sectional, questionnaire-based study was conducted among 150 MBBS students actively involved in prescription writing during clinical postings. Data were collected using a validated 20-item KAP questionnaire covering fundamental concepts of pharmacovigilance, attitudes toward ADR reporting, reporting practices, and perceived barriers. Data were analyzed using descriptive statistics and presented as frequencies and percentages.

Results:

Among the participants, 112 (74.7%) were aware of the term pharmacovigilance, and 98 (65.3%) correctly identified its primary objective as the detection and prevention of ADRs. A positive attitude was observed, with 124 students (82.7%) acknowledging ADR reporting as a professional obligation and a vital component of patient safety. However, practical engagement was limited, as only 18 students (12%) had ever reported an ADR. The major barriers identified were lack of knowledge regarding reporting procedures (44.6%), difficulty in diagnosing ADRs (32%), time constraints (14%), and non-availability of reporting forms (9.3%).

Conclusion:

Although MBBS prescribers demonstrated satisfactory knowledge and a favorable attitude toward pharmacovigilance, actual ADR reporting practice was notably poor. This highlights a significant knowledge–practice gap that requires targeted educational and system-level interventions.

Recommendations:

Incorporating structured pharmacovigilance training into the undergraduate curriculum, conducting regular hands-on workshops on ADR identification and reporting, integrating ADR reporting into routine clinical teaching, and implementing user-friendly digital reporting platforms are strongly recommended to improve reporting behavior and enhance patient safety.

Keywords: *Pharmacovigilance; Adverse Drug Reactions; Knowledge–Attitude–Practice; Bachelor of Medicine and Bachelor of Surgery students*
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Introduction

The global use of medications has expanded significantly in recent years, improving disease outcomes and enhancing life expectancy. However, this increased utilization is accompanied by a corresponding rise in adverse drug reactions (ADRs), which represent a major challenge to patient safety. ADRs are associated with increased rates of hospitalization, prolonged length of stay, additional treatment costs, and preventable morbidity and mortality [1,2]. Studies estimate that ADRs contribute substantially to patient harm and constitute a significant proportion of hospital admissions across healthcare systems worldwide [3-5].

To address these concerns, pharmacovigilance (PV) plays a central role in monitoring and evaluating drug safety following market approval. The World Health Organization defines pharmacovigilance as *"the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem"* [4]. Since preclinical research and controlled clinical trials often involve limited populations and shorter follow-up, many rare, delayed, or population-specific ADRs emerge only during real-world post-marketing use, highlighting the importance of spontaneous reporting systems [5].

Despite its importance, under-reporting remains the most critical limitation of spontaneous ADR reporting. Evidence suggests that only a small fraction of ADRs are documented and reported through national PV programmes [6]. Factors contributing to under-reporting include lack of awareness, uncertainty about causality, insufficient confidence in identifying ADRs, lack of time, unavailability of reporting forms, and fear of legal or professional consequences [7,8]. These barriers are widespread across different professional groups, irrespective of country or level of training.

In India, where pharmacotherapy constitutes a large proportion of clinical management and where the burden of polypharmacy is increasing, strong engagement of prescribers is fundamental for ensuring safe drug use [9]. Multiple studies evaluating PV among physicians, nurses, and pharmacists have revealed substantial knowledge deficits and poor reporting practices, even when general attitudes toward the value of ADR reporting are positive [10,11]. Research involving undergraduate MBBS students has similarly shown adequate theoretical awareness but low practical involvement in ADR reporting [12]. Since MBBS students participate in patient care and prescription under supervision during clinical postings, training them early in PV principles can promote a culture of safety and proactive ADR reporting during their later independent practice.

Structured educational interventions and incorporation of PV into undergraduate curricula have been recommended as effective strategies for improving knowledge and behaviour related to ADR reporting [13,14]. Strengthening institutional support, simplifying reporting formats, and implementing electronic or mobile-based reporting systems are additional solutions proposed to enhance reporting compliance [15].

Considering the limited literature addressing MBBS prescribers specifically, particularly within Indian tertiary care settings, there is a need to evaluate the current level of knowledge, attitude, and practice (KAP) related to pharmacovigilance in this group. Identifying training gaps and barriers will help inform reforms in teaching, sensitization, and system support. Therefore, the present study was undertaken to assess the KAP of pharmacovigilance among MBBS student prescribers in a tertiary care hospital and to understand barriers that hinder ADR reporting.

Methodology

Study Design

This research employed a descriptive cross-sectional questionnaire-based study design to evaluate the KAP of pharmacovigilance among MBBS student prescribers. A cross-sectional framework was selected because it allows the capture of real-time perceptions and behaviours without altering routine academic or clinical activities. This design is widely accepted for KAP assessments where the objective is to understand existing levels of awareness and performance across a defined population at a specific point in time.

Study Setting

The study was conducted at Government Medical College and Hospital, Suryapet, Telangana, India. A tertiary care teaching hospital equipped with a broad range of clinical departments and active undergraduate training programs. The study was carried out from January 2025 to June 2025. The institution hosts a functional Pharmacovigilance Unit under the national pharmacovigilance programme, which provides a relevant environment for the study owing to regular exposure to patient care and drug therapy. The hospital caters to a large patient load, providing MBBS students with opportunities to participate in supervised prescription activities and observe real-time medication responses, making it an appropriate setting to explore pharmacovigilance awareness and reporting practices.

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Study Population

The study population consisted exclusively of MBBS students posted in clinical departments and permitted to participate in prescribing decisions under faculty supervision. These students routinely engage in patient evaluation, medication selection, and review of treatment outcomes, which makes them relevant stakeholders for pharmacovigilance education and ADR reporting. Students who were not involved in clinical postings at the time of data collection were excluded. Participation was voluntary, and no incentives were offered.

Sample Size and Sampling Technique

A total of 150 MBBS students were included in the study. The sample size was based on feasibility and supported by earlier studies reporting approximately similar numbers for single-institution KAP assessments. A convenient sampling technique was adopted, and participants were recruited from multiple clinical rotation groups to ensure a heterogeneous mix of levels of exposure and academic standing. This approach facilitated the collection of diverse viewpoints within the cohort.

Study Instrument and Data Collection

The study utilized a structured, pre-validated questionnaire comprising 20 items divided across three core domains—knowledge, attitude, and practice of pharmacovigilance. The knowledge component assessed familiarity with definitions, objectives of PV, functions of national monitoring centres, and reporting pathways for adverse drug reactions. The attitude section explored perceptions regarding the importance of ADR reporting, professional responsibility, and willingness to participate in pharmacovigilance activities. The practice segment focused on previous experience with ADR recognition and reporting, awareness of available reporting forms, and perceived barriers. The questionnaire incorporated multiple-choice and Likert-scale questions to allow detailed assessment. Before formal administration, a pilot test was conducted among a small subset of students to evaluate clarity, comprehension, and consistency. Adjustments were made where required to improve readability and avoid ambiguity.

Data Collection Procedure

After obtaining institutional permission, participants were approached during designated academic hours without interfering with regular clinical duties. The purpose and relevance of the study were explained in simple terms, and written informed consent was obtained. The questionnaires were distributed in hard-copy format and completed individually in a controlled environment without peer interaction to minimize response bias. Completed forms were collected immediately after completion to ensure response accuracy and avoid data contamination.

Outcome Measures

The principal outcome measures of this study included the overall level of knowledge regarding pharmacovigilance and ADR reporting, prevailing attitudes toward participation in pharmacovigilance activities, and actual practices related to reporting ADRs. Secondary outcomes included the identification of perceived obstacles that prevent reporting in clinical settings. These findings were intended to support recommendations for curriculum development, training reinforcement, and system improvements within the institution.

Statistical Analysis

The completed questionnaires were reviewed for completeness, and the data were entered into Microsoft Excel before statistical processing. Analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 26 or an equivalent software program. Descriptive statistics such as mean, standard deviation, frequency, and percentage were used to summarize the data across knowledge, attitude, and practice domains. Results were presented using tables, charts, and graphical illustrations where appropriate to enhance clarity and interpretability. Associations between variables, if applicable, were explored using appropriate statistical tests based on data distribution.

Ethical Considerations

Before commencement, ethical approval for the study was obtained from the Institutional Ethics Committee of Government Medical College and Hospital, Suryapet, Telangana, India. Participation was entirely voluntary, and respondents were informed that they could withdraw at any time without consequence. To maintain anonymity, no personal identifiers were collected. All responses were stored securely and used only for academic purposes.

Results

Demographic Characteristics

A total of 150 MBBS student prescribers participated in the study, yielding a 100% response rate. The mean age of participants was 21.6 ± 1.2 years, with 82 females (54.7%) and 68 males (45.3%). The majority of students were posted in General Medicine (32%), Surgery (24%), Pediatrics (18%), Obstetrics & Gynecology (15%), and other postings including Dermatology, ENT, and

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Psychiatry (11%). Among the participants, 82 students (54.7%) had clinical exposure for more than six months, whereas 68 students (45.3%) were in their first six months of clinical rotation.

Knowledge Domain

Out of 150 participants, 112 students (74.7%) reported they were familiar with the term *pharmacovigilance*, and 98 students (65.3%) correctly identified its primary purpose as detecting and preventing adverse drug reactions. Awareness regarding the National Pharmacovigilance Programme of India was present in 84 (56%) students. Only 62 participants (41.3%) were aware of the existence of an institutional pharmacovigilance committee, and merely 48 students (32%) knew where to obtain ADR reporting forms.

Mean knowledge score was **6.8 ± 2.4** out of a maximum score of 10. Students posted for more than 6 months demonstrated significantly higher mean knowledge scores than those with lesser exposure (**7.4 ± 2.1 vs. 5.9 ± 2.6; p = 0.004**, independent t-test). A significant association was also observed between academic year and knowledge level (χ^2 **= 10.32, p = 0.001**), indicating better understanding among students in later postings (Table 1).

Table 1: Association between Clinical Posting Duration and Knowledge Score

Posting Duration	Good Knowledge (n=112)	Poor Knowledge (n=38)	Total	χ^2	p-value
≤ 6 months (n=68)	45	23	68	**6.42**	**0.011**
> 6 months (n=82)	67	15	82		

Attitude Domain

The attitude of students towards pharmacovigilance was predominantly positive. A total of 124 students (82.7%) agreed that ADR reporting is a professional obligation, and 118 students (78.7%) strongly believed that reporting enhances patient safety. Furthermore, 129 respondents (86%) supported integrating structured pharmacovigilance training into the MBBS curriculum, and 107 students (71.3%) agreed that ADR reporting should be mandatory in hospitals.

The overall mean attitude score was **32.6 ± 4.8** out of 40, indicating a strong positive leaning. No significant difference in attitudes was detected between male and female respondents (χ^2 **= 1.84, p = 0.175**) (Table 2 & 3; Figure 1& 2).

Practice Domain

Despite positive attitudes, the actual practice of ADR reporting was markedly low. Only 18 students (12%) had ever reported or attempted to report an ADR during their clinical work, and 12 students (8%) had seen an ADR reporting form. Among those who had encountered ADRs, only 7 students (4.6%) followed a structured reporting pathway.

The mean practice score was **2.1 ± 1.4** out of 10, highlighting a significant gap between knowledge/attitude and practice. A strong association was found between knowledge level and ADR reporting practice (χ^2 **= 28.76, p < 0.001**), demonstrating that greater awareness significantly influences reporting behavior (Table 2 & 3; Figure 1& 2).

The most frequently identified barriers were lack of understanding of reporting procedures (44.6%), uncertainty regarding causality confirmation (32%), insufficient time during clinical postings (14%), and non-availability of reporting forms (9.3%).

Table 2: Comparative Assessment of Knowledge, Attitude, and Practice (n=150)

Domain	Mean Score ± SD	Score Range	% Above Midpoint
Knowledge (max 10)	**6.8 ± 2.4**	2 – 10	74.7%
Attitude (max 40)	**32.6 ± 4.8**	20 – 40	82.7%
Practice (max 10)	**2.1 ± 1.4**	0 – 7	12%

Table 3: Comparison Between Attitude and Reporting Practice

Variable	Positive Attitude (n=124)	Actual Reporting (n=18)	χ^2	p-value
Yes	124	18	**28.76**	**<0.001**
No	26	132		

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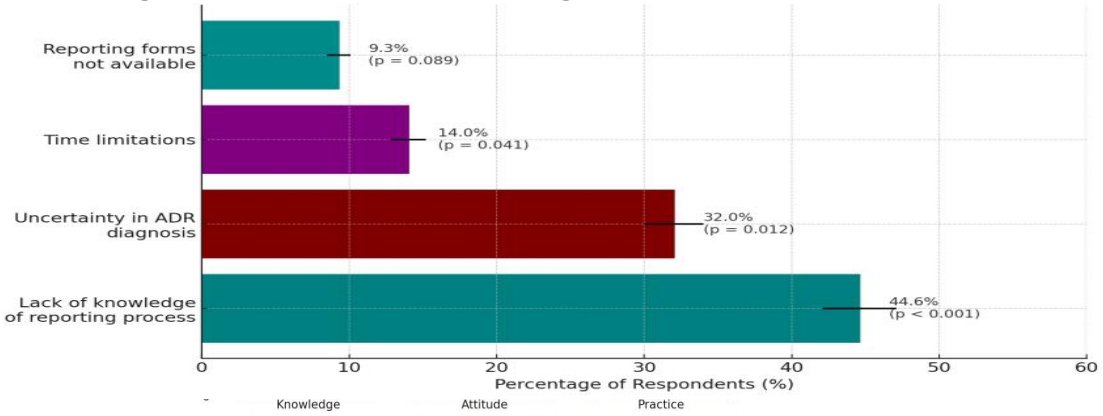
Figure 1: Distribution of Knowledge, Attitude, and Practice Scores



Discussion

The present study evaluated the knowledge, attitude, and practice of pharmacovigilance among Bachelor of Medicine and Bachelor of Surgery students and revealed a pronounced disparity between awareness and actual adverse drug reaction reporting behaviour. Although most participants demonstrated satisfactory theoretical knowledge and expressed positive attitudes toward pharmacovigilance, only a small proportion had ever reported an adverse drug reaction. This disconnect between knowledge and practice reflects a persistent global challenge in pharmacovigilance implementation [16].

Approximately three-quarters of the participants demonstrated adequate knowledge of pharmacovigilance concepts, which is comparable to findings reported among undergraduate medical students in similar institutional settings [17]. A significant association between duration of clinical exposure and knowledge scores suggests that experiential learning during clinical postings enhances understanding of adverse drug reactions and reporting systems [18]. These findings underscore the importance of early and continuous clinical exposure in reinforcing pharmacovigilance principles beyond didactic teaching.

Attitudes toward pharmacovigilance were overwhelmingly positive, with the majority of students recognizing adverse drug reaction reporting as a professional obligation and a critical component of patient safety. Support for incorporating structured pharmacovigilance training into the undergraduate curriculum was also high. Similar positive attitudinal trends have been documented among medical trainees across diverse healthcare systems, indicating that motivational barriers are relatively minimal in this population [19].

Despite favourable attitudes, actual reporting practices remained poor, with only 12% of participants having reported an adverse drug reaction. This observation is consistent with previous evidence demonstrating that under-reporting persists even among healthcare professionals who acknowledge the importance of pharmacovigilance [20,21]. The statistically significant association between knowledge level and reporting practice in the present study suggests that insufficient procedural understanding plays a major role in limiting reporting behaviour.

The principal barriers identified, lack of familiarity with reporting procedures, uncertainty in diagnosing adverse drug reactions, time constraints, and non-availability of reporting forms, closely mirror those reported in earlier studies [22,23]. Diagnostic uncertainty, in particular, has been recognized as a major deterrent, especially among trainees who may fear submitting inaccurate or incomplete reports. Globally, it is estimated that fewer than 10% of adverse drug reactions are reported, significantly limiting effective signal detection and regulatory action [23].

Targeted educational interventions, including hands-on workshops, case-based discussions, and simulation exercises, have been shown to significantly improve reporting confidence and compliance [24]. Additionally, the introduction of electronic and mobile-based reporting systems has been associated with improved accessibility and reduced reporting burden [25]. Given the strong positive attitudes observed in this study, addressing procedural and system-level barriers may yield substantial improvements in reporting behaviour.

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Generalizability

The findings of this study are generalizable to MBBS students and undergraduate prescribers in similar tertiary-care teaching hospitals, particularly within resource-limited healthcare settings. Given the comparable medical curricula, clinical exposure patterns, and pharmacovigilance frameworks across many institutions, the observed knowledge–practice gap and reporting barriers are likely to reflect broader trends among medical trainees.

Conclusion

The findings of this study highlight an important imbalance between awareness and implementation of pharmacovigilance among MBBS student prescribers. Although most participants demonstrated satisfactory knowledge and a strongly positive attitude towards the importance of adverse drug reaction reporting, actual reporting practices were found to be considerably inadequate. The substantial difference between intention and action underscores the need for institutional initiatives that simplify reporting procedures, improve accessibility of reporting tools, and provide structured hands-on training. Strengthening undergraduate education on pharmacovigilance, incorporating practical learning experiences, and integrating digital reporting mechanisms could play a key role in supporting early engagement and fostering a culture in which ADR reporting becomes a routine professional responsibility. Addressing the identified barriers may significantly enhance medication safety and improve the quality of patient care within clinical settings.

Limitations

This study was conducted at a single tertiary-care institution, which limits external applicability. Data were self-reported, introducing the possibility of recall and social desirability bias. The cross-sectional design restricted causal inference between knowledge, attitude, and practice. In addition, long-term changes in reporting behavior following training interventions were not assessed.

Recommendations

Structured pharmacovigilance training should be formally integrated into the undergraduate MBBS curriculum with emphasis on practical ADR identification and reporting. Regular workshops, case-based discussions, and simulation exercises can improve diagnostic confidence and reporting skills. Introducing simplified digital or mobile-based ADR reporting platforms within teaching hospitals may reduce procedural barriers. Active involvement of pharmacovigilance units during clinical postings, along with feedback and acknowledgement for submitted reports, can reinforce positive behavior. Continuous mentorship and periodic assessment of reporting practices are essential to sustain long-term improvement.

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Abbreviations

ADR – Adverse Drug Reaction
KAP – Knowledge, Attitude, and Practice
MBBS – Bachelor of Medicine and Bachelor of Surgery
PvPI – Pharmacovigilance Programme of India
WHO – World Health Organization

Source of funding

The study had no funding.

Conflict of interest:

The authors declare no conflict of interest.

Author contributions

CM-Concept and design of the study, results interpretation, review of literature, and preparation of the first draft of the manuscript. Statistical analysis and interpretation, revision of manuscript. **PM-**Results interpretation, review of literature, and revision of manuscript. **TRCK**- Review of literature and preparing the first draft of the manuscript. Statistical analysis and interpretation, revision of manuscript. **ARR**-Concept and design of the study, results interpretation, review of literature, and preparing the first draft of the manuscript. Statistical analysis and interpretation, revision of manuscript.**TC-**preparing first draft of manuscript. Statistical analysis and interpretation, revision of the manuscript

Data availability

Data available on request

Author Biographies

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