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Research Article

Assessment of Knowledge, Attitude and Awareness towards Adverse Drug Reaction Reporting System among Undergraduate Medical Students in Shyam Shah Medical College, Rewa

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ABSTRACT
Background: Adverse Drug Reactions (ADRs) are an important cause of morbidity and mortality worldwide. Although pharmacovigilance is included in the undergraduate medical curriculum, underreporting of ADRs remains a major limitation of spontaneous reporting systems. Raising awareness among healthcare professionals, especially medical students who are future prescribers, is essential to strengthen the pharmacovigilance system.
Aim and Objectives: To assess the knowledge, attitude, and awareness regarding the ADR reporting system among undergraduate medical students of Shyam Shah Medical College, Rewa.
Materials and Methods: An observational cross-sectional study was conducted in June 2024 using a pre-designed, structured questionnaire circulated through Google Forms. The questionnaire assessed knowledge, attitude, and awareness regarding ADRs and pharmacovigilance. A total of 277 undergraduate medical students from second year to final year MBBS participated in the study. Data were analyzed using descriptive statistics and expressed in percentages.
Results: Out of 277 students, 93 (33.6%) were from second year, 79 (28.5%) from third year, and 105 (37.9%) from final year. Overall, about 65% of students had adequate knowledge about ADRs and pharmacovigilance. A positive attitude towards ADR reporting was observed in nearly 92% of participants. Awareness was higher among final year students (approximately 69%), particularly regarding banned drugs, patient confidentiality, and legal responsibilities. However, nearly 30% of students still demonstrated insufficient awareness and practical understanding.
Conclusion: The study reveals satisfactory knowledge and attitude among undergraduate medical students; however, awareness and practical exposure to ADR reporting need further improvement. Regular training sessions, workshops, and integration of pharmacovigilance activities into clinical postings are recommended to strengthen ADR reporting culture among future healthcare professionals.

Keywords: Adverse Drug Reactions, Pharmacovigilance, Healthcare Professionals, Medical Students.

INTRODUCTION

Adverse Drug Reactions (ADRs) are defined by the World Health Organization (WHO) as *"a response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for prophylaxis, diagnosis or therapy of disease"* [1]. ADRs represent a major public health concern and are an important cause of morbidity and mortality worldwide. Several studies have shown that ADRs account for approximately 5–10% of hospital admissions and are responsible for a significant proportion of in-hospital adverse events [2, 3]. In addition to clinical consequences, ADRs contribute substantially to increased healthcare costs, prolonged hospital stays, and decreased patient quality of life [4].
Pharmacovigilance is defined by WHO as *"the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems"* [5]. The primary objective of

pharmacovigilance is to ensure patient safety by identifying previously unrecognized adverse effects and minimizing drug-related risks. A well-functioning pharmacovigilance system is essential for post-marketing surveillance, as many rare or serious ADRs may not be detected during pre-marketing clinical trials due to limited sample size and duration [6].

In India, the Pharmacovigilance Programme of India (PvPI) was launched in 2010 by the Ministry of Health and Family Welfare, with the Indian Pharmacopoeia Commission (IPC) functioning as the National Coordination Centre [7]. The programme aims to collect, analyze, and monitor ADR reports from healthcare professionals and consumers across the country. Despite the establishment of a national pharmacovigilance network with Adverse Drug Reaction Monitoring Centres (AMCs), the reporting rate in India remains significantly lower compared to developed countries [8].

Underreporting of ADRs is a global problem and is considered one of the major limitations of spontaneous reporting systems. It is estimated that only 6–10% of all ADRs are actually reported worldwide [9]. Factors responsible for underreporting include lack of awareness about reporting systems, fear of legal implications, uncertainty in identifying ADRs, lack of time, and absence of motivation among healthcare professionals [10,11]. In developing countries, additional challenges such as limited infrastructure and inadequate training further worsen the situation [12].

Medical students, being future prescribers and frontline healthcare professionals, play a crucial role in promoting patient safety and rational drug use. Early sensitization and training of medical students in pharmacovigilance have been shown to improve knowledge, attitude, and reporting behavior [13,14]. Studies conducted in different medical institutions in India have demonstrated variable levels of awareness among students, highlighting the need for structured educational interventions [15,16].

Therefore, assessing the current status of knowledge, attitude, and awareness regarding ADR reporting among undergraduate medical students is essential for identifying gaps and designing targeted educational strategies. This study was undertaken to evaluate these parameters among medical students of Shyam Shah Medical College, Rewa, with the aim of strengthening pharmacovigilance practices at the grassroots level.

MATERIALS AND METHODS

This observational, cross-sectional questionnaire-based study was conducted at Shyam Shah Medical College, Rewa, Madhya Pradesh in June 2024. The study population comprised undergraduate medical students from second year, third year, and final year MBBS. A total of 277 students participated in the study, including 93 students from second year, 79 from third year, and 105 from final year MBBS.

A pre-designed and structured questionnaire was used as the study tool, which consisted of three sections assessing knowledge, attitude, and awareness regarding adverse drug reactions and pharmacovigilance. The knowledge section included questions related to the definition of ADRs, purpose of pharmacovigilance, and reporting authorities. The attitude section assessed students' perceptions regarding the importance of ADR reporting, willingness to report, and professional responsibilities. The awareness section evaluated familiarity with ADR reporting forms, banned drugs, patient confidentiality, and legal aspects of pharmacovigilance.

Data were collected using Google Forms, and participation was entirely voluntary. Electronic informed consent was obtained from all participants prior to inclusion in the study. The collected data were analyzed using descriptive statistical methods and results were expressed in terms of frequencies and percentages.

RESULTS

Demographic Distribution of Study Participants- A total of 277 undergraduate medical students participated in the study. Among them, 93 (33.6%) were from second year MBBS, 79 (28.5%) from third year MBBS, and 105 (37.9%) from final year MBBS. (Table 1)

Knowledge Regarding ADRs and Pharmacovigilance- Overall, approximately 65% of students correctly identified the definition of ADRs. Awareness about the term pharmacovigilance was found in 68% of participants, while 60% knew about the existence of the Pharmacovigilance Programme of India (PvPI). Knowledge levels increased with the year of study, with final year students demonstrating higher awareness compared to second and third year students. (Table 2)

Attitude towards ADR Reporting- A highly positive attitude was observed among

participants. About 92% believed that ADR reporting is a professional responsibility, 88% expressed willingness to report ADRs in future clinical practice, and 85% felt that ADR reporting plays a vital role in improving patient safety. Final year students showed a more positive attitude compared to junior students. (Table 3)

Awareness Regarding Practical and Legal Aspects- Awareness regarding practical and legal aspects of pharmacovigilance was moderate. Only 55% of students were aware of the official ADR reporting form. Awareness about patient confidentiality and legal responsibilities was observed in 58% and 62% of students, respectively. Final year students demonstrated the highest awareness (~69%), reflecting the impact of increased clinical exposure. (Table 4)

Overall KAA (Knowledge–Attitude–Awareness) Comparison

When combined, knowledge and attitude levels were satisfactory, whereas awareness scores were comparatively lower, particularly among junior students.(Table 5)

The results demonstrate a progressive improvement in knowledge, attitude, and awareness with advancing academic year. Final year students consistently outperformed second and third year students across all domains. While attitude was uniformly positive, awareness of practical and legal aspects remained suboptimal, indicating a gap between theoretical knowledge and real-world pharmacovigilance practices.

Table 1. Distribution of Students According to Year of Study

Year of Study	Number of Students	Percentage
2nd Year	93	33.6%
3rd Year	79	28.5%
Final Year	105	37.9%
Total	277	100%

Table 2. Association between Year of Study and Knowledge Parameters

Knowledge Parameter	2nd Year (%)	3rd Year (%)	Final Year (%)	Overall (%)
Correct definition of ADR	58	64	72	65
Aware of term pharmacovigilance	62	67	74	68
Aware of PvPI	52	59	68	60

Table 3. Association between Year of Study and Attitude Parameters

Attitude Parameter	2nd Year (%)	3rd Year (%)	Final Year (%)	Overall (%)
ADR reporting is professional duty	89	91	95	92
Willing to report ADRs	84	87	92	88
ADR reporting improves patient safety	81	84	89	85

Table 4. Association between Year of Study and Awareness Parameters

Awareness Parameter	2nd Year (%)	3rd Year (%)	Final Year (%)	Overall (%)
Aware of ADR reporting form	46	53	64	55
Aware of patient confidentiality	51	56	66	58
Aware of legal/ethical responsibility	55	60	70	62
Overall awareness score	51	56	69	59

Table 5. Overall KAA Comparison across Academic Years

Parameter	2nd Year (%)	3rd Year (%)	Final Year (%)
Knowledge	57	63	71
Attitude	85	88	92
Awareness	51	56	69

Discussion

The present study assessed the knowledge, attitude, and awareness regarding adverse drug reaction (ADR) reporting among undergraduate medical students at Shyam Shah Medical College, Rewa. The findings reveal that while students demonstrated satisfactory knowledge and a highly positive attitude towards pharmacovigilance, awareness regarding practical and legal aspects of ADR reporting remained suboptimal.

In the current study, approximately 65% of students correctly identified the definition of ADR and 68% were aware of the term pharmacovigilance. These findings are comparable to studies conducted by Gupta et al. and Khan et al., who reported knowledge levels ranging between 60% and 70% among medical students and healthcare professionals [4,5]. Similar results were also observed by Ganesan et al., where 66% of undergraduate students possessed adequate theoretical knowledge about pharmacovigilance [16]. This indicates that pharmacology teaching in the undergraduate curriculum is effective in imparting core conceptual knowledge.

A highly positive attitude towards ADR reporting was observed, with 92% of students considering it a professional responsibility and 88% expressing willingness to report ADRs in future practice. These findings are consistent with earlier studies by Rehan et al. and Gupta et al., who reported positive attitudes in more than 85% of participants [13,14]. A favorable attitude is a crucial determinant for successful pharmacovigilance, as willingness to report is directly linked to actual reporting behavior in clinical practice.

However, despite satisfactory knowledge and attitude, awareness regarding the practical implementation of ADR reporting was relatively lower. Only 55% of students were aware of the official ADR reporting form, and 58% were aware of patient confidentiality and legal aspects. Similar gaps have been reported by Lopez-Gonzalez et al. and Oshikoya et al., who identified lack of procedural knowledge and legal uncertainty as major barriers to ADR reporting [10,12]. This reflects a disconnect between theoretical learning and practical application.

The present study also demonstrated a progressive improvement in knowledge, attitude, and awareness with increasing academic year. Final year students consistently outperformed second and third year students across all domains, particularly in awareness (~69%). This trend has also been observed in studies by Khan et al. and Ganesan et al., where senior students showed significantly better awareness due to increased clinical exposure [5,16]. This highlights the importance of early and continuous clinical integration in pharmacovigilance education.

Despite adequate theoretical knowledge, a significant proportion of students lacked confidence in actual ADR reporting. This observation aligns with findings by Hazell and Shakir, who reported that uncertainty in diagnosis and fear of incorrect reporting are major contributors to underreporting [9]. Edwards and Aronson also emphasized that lack of experiential learning limits effective pharmacovigilance practice [6].

Overall, the findings suggest that while the current undergraduate curriculum successfully builds foundational knowledge and positive attitude, it fails to adequately address the operational aspects of pharmacovigilance. Therefore, incorporating hands-on training, case-based learning, and mandatory ADR reporting exercises during clinical postings may significantly improve practical awareness and reporting behavior.

CONCLUSION

The present study concludes that undergraduate medical students at Shyam Shah Medical College possess satisfactory knowledge and a highly positive attitude towards adverse drug reaction reporting. However, a considerable proportion of students, particularly in the junior years, still demonstrate inadequate awareness and limited practical preparedness regarding the operational and legal aspects of pharmacovigilance. This gap between theoretical knowledge and practical application highlights the need for strengthening pharmacovigilance training within the undergraduate curriculum. Regular workshops, case-based learning, hands-on training with ADR reporting forms, and mandatory reporting exercises during clinical postings are strongly recommended to enhance awareness, improve reporting skills, and promote a sustained culture of patient safety among future healthcare professionals.

Recommendations

1. Regular pharmacovigilance workshops for students.
2. Inclusion of ADR reporting exercises in clinical postings.
3. Hands-on training with ADR reporting forms.

4. Integration of pharmacovigilance in assessment methods.

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