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Original Research Article

Comparison of Knowledge, Attitude, and Practice (KAP) of Pharmacovigilance among Medical and Paramedical Students of Parul University, Gujarat

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Abstract:

Introduction: Pharmacovigilance plays a crucial role in ensuring medication safety by monitoring and evaluating adverse drug reactions (ADRs). ADRs are significant contributors to morbidity and impose a considerable economic burden on healthcare systems. the importance of pharmacovigilance, under-reporting of ADRs remains a major challenge due to factors such as lack of knowledge, additional workload, and fear of legal consequences. Medical and paramedical students, as future healthcare providers, are pivotal in improving pharmacovigilance practices. Assessing their knowledge, attitude, and practice (KAP) towards pharmacovigilance is essential for enhancing their training and promoting proactive ADR reporting.

Material and Methods: This cross-sectional survey evaluated the KAP of pharmacovigilance among 239 students (137 medical, 50 nursing, and 52 pharmacy) at Parul University, Gujarat. Using a structured questionnaire, data were collected on students' understanding of pharmacovigilance concepts, their attitudes towards ADR reporting, and their practical experiences with ADR reporting forms. The questionnaire, validated and tailored to the university's context, included sections on knowledge, attitude, and practice. Descriptive statistics were used to analyze the data, and comparative analyses identified differences in KAP among the student groups. The study adhered to ethical guidelines, with informed consent obtained from participants.

Results: A total of 239 students, including 137 medical students, 50 nursing students, and 52 pharmacy students from Parul University, Gujarat, participated in the study to evaluate their knowledge, attitude, and practice (KAP) regarding pharmacovigilance. The knowledge section revealed that while 90% correctly defined pharmacovigilance, only 19% knew the regulatory body responsible for monitoring ADRs in India. Additionally, 93% were aware of the pharmacovigilance program in India, and 90% knew the location of the international center for pharmacovigilance. The attitude section showed that 75% of students recognized the necessity of ADR reporting, and 70% supported mandatory reporting, though 56% had concerns about legal liability. Moreover, 79% believed that an ADR collection box in clinical departments would improve reporting efficiency. In the practice section, 60% had seen an ADR reporting form by CDSCO, 56% had informed a ward physician about an ADR occurrence, and 79% expressed their intention to report ADRs in their future practice.

Conclusion: Our study revealed that while students at Parul University, Gujarat, demonstrated solid foundational knowledge of pharmacovigilance, significant gaps existed in areas like identifying the regulatory body for ADRs in India. Despite recognizing the importance of ADR reporting, concerns about legal liability and inadequate practical engagement were evident.

Key words: Pharmacovigilance, ADR Reporting, Medical Education, Regulatory Knowledge

Introduction

Pharmacovigilance is a critical component of the healthcare system, responsible for monitoring and evaluating adverse drug reactions (ADRs) to ensure the safety and efficacy of medications. [1] ADRs are one of the leading causes of morbidity and represent a substantial economic burden on healthcare resources. [2] Reports indicate that 2.4% to 6.5% of total hospital admissions are due to adverse reactions, many of which are preventable. [3] In India, the incidence of serious ADRs is approximately 6.7%. [4] These statistics underscore the importance of pharmacovigilance in detecting, assessing, understanding, and preventing ADRs, which the World Health Organization (WHO) defines as the science and activities relating to the detection, assessment, understanding, and

prevention of adverse effects or any other drug-related problems. [5]

Despite the critical role of pharmacovigilance programs in detecting ADRs and removing harmful drugs from the market, under-reporting remains a significant issue. [6] Various factors contribute to this problem, including a lack of knowledge and practice among healthcare professionals, concerns about the extra workload, and fear of legal implications. [6] Medical and paramedical students, as future healthcare providers, play a pivotal role in addressing this issue. Their knowledge, attitude, and practice (KAP) regarding pharmacovigilance can significantly influence the effectiveness of drug safety monitoring and reporting. Understanding their KAP is crucial for assessing their preparedness to manage and report ADRs effectively, guiding educators to enhance training programs, and promoting a proactive attitude towards pharmacovigilance practices.

This study aims to compare the KAP of pharmacovigilance among medical and paramedical students at Parul University, Gujarat, to identify gaps and suggest improvements in their education, ultimately enhancing pharmacovigilance practices and patient safety outcomes.

Material and Methods

This study was designed as a cross-sectional survey to evaluate the knowledge, attitude, and practice (KAP) of pharmacovigilance among medical, nursing, and pharmacy students at Parul University, Gujarat. The study aimed to compare the KAP across these different student groups to identify gaps and suggest improvements in their pharmacovigilance education and training.

The study population consisted of a total of 239 students, which included 137 medical students, 50 nursing students, and 52 pharmacy students. The participants were selected using a convenience sampling method from Parul University, ensuring a representative sample of the student population across these disciplines.

Data were collected using a structured questionnaire divided into three sections: knowledge, attitude, and practice. The questionnaire included both closed and open-ended questions to gather comprehensive data on students' understanding and behaviors related to pharmacovigilance. The knowledge section assessed students' awareness and understanding of pharmacovigilance concepts and regulatory bodies. The attitude section explored their perceptions and opinions on the importance and necessity of ADR reporting. The practice section examined their actual experiences and behaviors in reporting ADRs.

The questionnaire was developed based on previously validated tools and tailored to the context of Parul University. It underwent a pilot test with a small group of students to ensure clarity and relevance. The final version included the following:

- **Knowledge Section**: Questions on the definition, purpose, and regulatory aspects of pharmacovigilance, as well as the identification of ADRs.
- **Attitude Section**: Questions on the necessity of ADR reporting, mandatory reporting, legal liabilities, efficiency of reporting mechanisms, and the inclusion of pharmacovigilance in the curriculum.
- **Practice Section**: Questions on the actual reporting of ADRs, experience with ADR forms, and future intentions to report ADRs.

Data were analyzed using descriptive statistics to summarize the responses. Frequencies and percentages were calculated for each question to provide a clear understanding of the distribution of responses. Comparative analyses were conducted to identify significant differences in KAP among medical, nursing, and pharmacy students. The results were presented in tables and graphs to facilitate interpretation.

The study was conducted in accordance with ethical guidelines and received approval from the Institutional Review Board of Parul University. Informed consent was obtained from all participants prior to their involvement in the study. Participants were assured of the confidentiality and anonymity of their responses, and their participation was voluntary.

By systematically analyzing the KAP of pharmacovigilance among these student groups, this study aims to contribute to the optimization of pharmacovigilance education, ultimately leading to better patient safety outcomes.

Results

A total of 239 students participated in the study, comprising 137 medical students, 50 nursing students, and 52 pharmacy students from Parul University, Gujarat. The data collected provide a comprehensive overview of the knowledge, attitude, and practice (KAP) of pharmacovigilance among these student groups.

The knowledge section revealed varying levels of understanding among the students. A significant majority (90%) correctly defined pharmacovigilance, but only 19% knew which regulatory body in India is responsible for monitoring ADRs. Additionally, 93% of the students were aware of the existence of the Pharmacovigilance program in India, and 90% knew the location of the international center for pharmacovigilance.

Table 1: Knowledge Towards Pharmacovigilance Among Medical and Paramedical Students

Question	Correct (Frequency/%)	Incorrect (Frequency/%)
What is the definition of Pharmacovigilance?	179 (90%)	20 (10%)
What is the primary purpose of Pharmacovigilance?	84 (42%)	115 (58%)
Who are the healthcare professionals responsible for reporting ADRs in hospitals?	90 (45%)	110 (55%)
Are you aware of the existence of the Pharmacovigilance program in India?	186 (93%)	14 (7%)
Which regulatory body in India is responsible for monitoring ADRs?	38 (19%)	162 (81%)
Where is the international center for Pharmacovigilance located?	179 (90%)	20 (10%)
What is the term for a side effect occurring during pregnancy?	191 (95%)	10 (5%)
In which phase of Clinical Trials can rare ADRs be identified?	43 (21%)	158 (79%)
Where is the National Pharmacovigilance center located in India?	168 (84%)	32 (16%)
Is there a Pharmacovigilance Committee at your institute?	190 (95%)	10 (5%)

The attitude section showed that a majority of students recognized the importance of ADR reporting, with 75% affirming its necessity and 70% supporting mandatory reporting. However, 56% expressed concerns about legal liability following ADR reporting. Additionally, 79% believed that an ADR collection box in clinical departments would aid in efficient reporting.

Table 2: Attitude Towards Pharmacovigilance Among Medical and Paramedical Students

Question	Yes (Frequency/%)	No (Frequency/%)
Is it necessary to report ADRs?	179 (75%)	60 (25%)
Should ADR reporting be mandatory?	167 (70%)	72 (30%)
Is there fear of legal liability following ADR reporting?	105 (44%)	134 (56%)
Should already known ADRs be reported?	155 (65%)	84 (35%)
Can reporting by doctors/paramedical staff be more efficient than by consumers/patients?	170 (71%)	69 (29%)
Will putting up an ADR collection box in all clinical departments help in efficient reporting of ADRs?	190 (79%)	49 (21%)
Should ADR reporting be included in the curriculum?	200 (84%)	39 (16%)
Should regular sensitization programs on pharmacovigilance be carried out for proper reporting of ADRs?	195 (82%)	44 (18%)
Will you report the event of chloroquine-induced nausea and vomiting?	160 (67%)	79 (33%)
Is there any benefit to both doctor and patient because of ADR reporting?	180 (75%)	59 (25%)
Should there be a simpler way of reporting ADRs?	205 (86%)	34 (14%)
Do you believe ADR reporting should be a part of clinical trials only?	95 (40%)	144 (60%)
Is it necessary to confirm that the ADR has occurred because of the prescribed drug?	179 (75%)	60 (25%)

In the practice section, 60% of the students had seen an ADR reporting form by CDSCO, and 56% had informed a ward physician about an ADR occurrence. Additionally, 79% of the students expressed their intention to report ADRs in their future practice.

Table 3: Practice Towards Pharmacovigilance Among Medical and Paramedical Students

Question	Yes (Frequency/%)	No (Frequency/%)
Have you ever seen an ADR reporting form by CDSCO?	143 (60%)	96 (40%)
Have you ever informed about the occurrence of any ADR to a ward physician?	134 (56%)	105 (44%)
Have you ever experienced any ADR?	155 (65%)	84 (35%)
With the knowledge that you have, will you report ADR in future practice?	190 (79%)	49 (21%)

Discussion

The knowledge of pharmacovigilance among medical and paramedical students at Parul University showed promising results, with 90% correctly defining pharmacovigilance and 93% aware of the Pharmacovigilance program in India. However, only 19% knew which regulatory body in India is responsible for monitoring ADRs, indicating a gap in specific regulatory knowledge. These findings align with a study conducted from Madhya Pradesh, by Marko [7], where a significant proportion of students were aware of pharmacovigilance, but detailed knowledge about specific regulatory aspects was lacking.

In comparison, a study from Gujarat, by Acharya et al. [8], found that 89.25% of second-year students and 89.19% of pre-final year students knew the definition of ADRs, but only 21-32% were aware of the national pharmacovigilance center's location. This underscores a common trend observed in various studies where students generally possess a good understanding of basic pharmacovigilance concepts but struggle with more detailed regulatory knowledge.

However, consistent with findings by Vohra et al. [9], only 19% of our respondents knew the regulatory body responsible for monitoring ADRs in India, highlighting a critical gap in specific knowledge areas. The positive attitudes towards pharmacovigilance in our study, with 95% acknowledging the presence of a pharmacovigilance committee at their institute, align with the attitudes observed in studies by Vohra et al. [9] and Marko. [7] However, our study, like those of Kulmi et al. [10] and Manandhar et al. [11], underscores a significant discrepancy between knowledge and practice. For instance, only 21% of our participants knew the phase of clinical trials where rare ADRs can be identified, reflecting a need for more practical, hands-on training. Kulmi et al. [10] also noted that while participants were aware of the importance of ADR reporting, this knowledge did not translate into practice, with only 15% having reported an ADR.

Our findings are consistent with Manandhar et al.'s [11] study among medical and dental students, which reported good attitudes towards pharmacovigilance but inadequate knowledge and practice. Similarly, Adithan et al. [12] found that while students had positive attitudes, their practical engagement with pharmacovigilance activities was lacking. Educational interventions are necessary to bridge the knowledge gaps identified in this study and others. Integrating detailed pharmacovigilance training into the medical and paramedical curriculum can enhance students' understanding of regulatory bodies and reporting processes.

The attitude section showed that a majority of students recognized the importance of ADR reporting, with 75% affirming its necessity and 70% supporting mandatory reporting. However, 56% expressed concerns about legal liability following ADR reporting. Additionally, 79% believed that an ADR collection box in clinical departments would aid in efficient reporting. These findings are consistent with the results of similar studies. For instance, Meher et al. [13] found that students had a positive attitude towards pharmacovigilance, with 95% of final-year students and 88% of pre-final-year students affirming the necessity of ADR reporting. This mirrors our finding of 75% of students recognizing the importance of reporting ADRs. Similarly, the study by Ganesan et al. [12] (2016) showed that more than 89% of doctors and 94% of nurses felt that reporting ADRs was necessary, supporting the positive attitude towards ADR reporting found in our study.

However, the concern about legal liability expressed by 56% of our respondents reflects a significant barrier to ADR reporting. This concern was also noted by Ganesan et al. [12], where underreporting was attributed to fears of legal consequences among healthcare professionals. The study by Kulmi et al. [10] further supports this, indicating that legal concerns and lack of awareness are major hurdles in effective ADR reporting. Moreover, the belief that an ADR collection box in clinical departments would improve reporting efficiency, supported by 79% of our respondents, aligns with the suggestions by Vohra et al. [9] for practical measures to enhance ADR reporting. This approach was also endorsed by Tejendra et al. [11], who highlighted the need for accessible and user-friendly reporting systems to facilitate better pharmacovigilance practices.

Our study, which surveyed 239 medical, nursing, and pharmacy students from Parul University,

Gujarat, reveals significant insights into the practice of pharmacovigilance. In the practice section, 60% of the students had seen an ADR reporting form by CDSCO, and 56% had informed a ward physician about an ADR occurrence. Additionally, 79% of the students expressed their intention to report ADRs in their future practice. These findings align with those of Meher et al. [13], who observed that while students had a positive attitude towards pharmacovigilance, their practical engagement was limited, with only 61.67% having seen an ADR reporting form. Similarly, Ganesan et al. [11] reported that although a majority of doctors and nurses had seen patients experiencing ADRs, a much smaller percentage actually reported them, highlighting a common challenge in translating awareness into practice.

Consistent with our findings, Kulmi et al.[10] and Tejendra et al. [11] also noted significant gaps between positive attitudes and practical implementation of ADR reporting among medical students. Kulmi et al. [10] pointed out that many students lacked confidence in reporting ADRs due to insufficient training, while Tejendra et al. [11] emphasized the need for better integration of pharmacovigilance training into medical curricula. Our study's finding that 79% of students intend to report ADRs in the future is promising and suggests that with proper training and support, the practical application of pharmacovigilance can be significantly improved. These studies collectively underscore the necessity for comprehensive training programs, practical workshops, and ensuring easy access to ADR reporting forms and systems to enhance pharmacovigilance practices among future healthcare professionals, ultimately improving patient safety and healthcare outcomes.

Conclusion

Our study revealed that while students at Parul University, Gujarat, demonstrated a solid foundational knowledge of pharmacovigilance, there were significant gaps in specific areas such as identifying the regulatory body responsible for monitoring ADRs in India. Despite a strong recognition of the importance of ADR reporting and a proactive attitude towards integrating pharmacovigilance practices, concerns about legal liability and inadequate practical engagement were evident. Most students expressed a willingness to report ADRs in their future practice, indicating that with enhanced training and support, the practical application of pharmacovigilance could be significantly improved.

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