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RESEARCH ARTICLE

Impact of a continuing medical education programme on pharmacovigilance awareness among second-year medical students in an Indian medical college

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Abstract

Background: Pharmacovigilance is essential for ensuring drug safety by monitoring Adverse Drug Reactions (ADRs). However, awareness of ADR reporting among healthcare professionals, including medical students, is often inadequate. This study evaluates the impact of a Continuing Medical Education (CME) program on pharmacovigilance knowledge and ADR reporting awareness among second-year medical students at Mahatma Gandhi Memorial (M.G.M.) Medical College, Indore. **Methods:** A pre-post intervention study was conducted with 187 students. The CME programme covered ADR reporting under the Pharmacovigilance Programme of India (PvPI). Data were collected pre- and post-intervention using a structured questionnaire focusing on pharmacovigilance definitions, ADR reporting, signal detection, and ADR misconceptions. Descriptive statistics and paired t-tests were employed to evaluate significant differences in pre-test and post-test scores. **Results:** Significant improvements in knowledge were observed after attending the CME programme, particularly in ADR identification (30.43%), ADR reporting methods (29.17%), signal detection (76.56%), and roles of pharmacovigilance organisations (127.40%). Paired t-tests showed statistically significant differences between pre- and post-test scores ($p = 0.004$). **Conclusion:** The CME programme was effective in enhancing pharmacovigilance awareness among medical students, addressing knowledge gaps, and improving ADR reporting practices. Future studies should assess long-term knowledge retention.

Introduction

Pharmacovigilance refers to the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. It plays a pivotal role in ensuring medication safety and safeguarding public health (World Health Organization, 2024). Adverse Drug Reaction (ADR) reporting, designed to identify and mitigate risks associated with pharmaceutical products, is an integral component of pharmacovigilance. However, inadequate ADR reporting has substantial implications, including compromised patient safety, reduced drug efficacy, and potential public health crises, especially when adverse effects go unreported or undetected (Shukla *et al.,* 2024).

Research indicates that healthcare professionals, including medical students, often possess limited knowledge and insufficient practice regarding ADR reporting (Olsson, 2008). Despite the critical role of pharmacovigilance in ensuring medication safety, barriers, such as lack of awareness, inadequate training, time constraints, and apprehension about legal consequences, often hinder healthcare professionals, including medical students, from actively participating in ADR reporting. This gap underscores the importance of educational interventions, such as Continuing Medical Education (CME) programmes, which have been

identified as effective tools for enhancing healthcare professionals' skills and knowledge (Ganesan *et al.,* 2017). CME programmes specifically focused on pharmacovigilance are crucial to preparing future healthcare providers to accurately identify, assess, and report ADRs, thereby addressing knowledge gaps and improving overall healthcare quality (Ganesan *et al.,* 2017). VigiFlow, a case report management software developed by the Uppsala Monitoring Centre, serves as a tool for processing and analysing individual case safety reports, facilitating the global pharmacovigilance effort.

Educational interventions have been shown to significantly impact pharmacovigilance awareness. For instance, educational interventions improved the awareness of pharmacovigilance among medical undergraduates in a tertiary care teaching hospital (Kalikar *et al*., 2020). Additionally, pharmacovigilance-focused education significantly improved ADR reporting skills among healthcare professionals (Ganesan *et al.,* 2017). In India, ADR reporting remains alarmingly low, with only about 1% of ADRs reported, compared to the global average of around 5% (Shukla *et al.,* 2024). This disparity emphasises the urgent need for improvements in India's pharmacovigilance system.

This study aimed to evaluate the impact of a CME programme on pharmacovigilance awareness among second-year medical students at Mahatma Gandhi Memorial (M.G.M.) Medical College, Indore. The primary objectives are to assess baseline knowledge of pharmacovigilance and ADR reporting among the target group, evaluate knowledge improvement post-CME, and identify persisting knowledge gaps in specific areas. This study also sought to assess changes in students' attitudes towards ADR reporting following the CME programme and identify areas requiring further training and emphasis. By understanding the influence of educational strategies on pharmacovigilance knowledge and practice, this research would contribute to future policy and curriculum development in pharmacovigilance training, ultimately enhancing drug safety and improving patient care.

Methods

Design

The study was initiated following the ethics approval waiver from the Institutional Ethics Committee, ensuring compliance with ethical standards in research involving human subjects. This waiver allowed for the assessment of pharmacovigilance knowledge without the need for informed consent, as the study focused on anonymised data collection.

A pre-post intervention study design was employed to assess changes in knowledge and awareness of pharmacovigilance among medical students following a CME programme.

Population and sample size

The study initially targeted 250 second-year medical students from the M.G.M. Medical College to ensure a representative sample for evaluating the effectiveness of the CME programme. Ultimately, 187 students completed both pre-test and post-test evaluations, providing sufficient data for analysis. The decrease in sample size was primarily due to scheduling conflicts and personal commitments that hindered full participation.

Intervention

The 4-hour CME programme was centred on ADR reporting under the Pharmacovigilance Programme of India (PvPI). It consisted of comprehensive lectures and interactive sessions designed to cover critical topics in pharmacovigilance, including definitions, reporting procedures, signal detection, and the importance of ADR reporting.

Data collection

Data were collected through structured questionnaires administered before and after the CME programme. The pre-test assessed students' baseline knowledge of pharmacovigilance and ADR reporting. It aimed to identify their initial understanding and any existing knowledge gaps. A post-test was conducted immediately following the CME to evaluate the improvement in knowledge and awareness. The same set of questions was used to maintain consistency in measuring knowledge gain.

Questionnaire content and development

The questionnaire comprised ten statements divided into four sections. The first section, Basic Understanding of Pharmacovigilance and ADR Reporting, included three questions that assessed the participants' grasp of foundational concepts and definitions. The second section, Identification and Reporting of ADRs, contained three statements focused on the procedures and conditions for ADR reporting. The third section, Signal Detection and Safety Information comprised two statements that evaluated knowledge about the identification of safety signals. Finally, the fourth section, ADR Reporting Practices and Misconceptions, included two statements aimed at dispelling common myths related to ADR reporting practices. The questionnaire was developed through a

thorough process involving literature review and expert consultations to ensure its validity and relevance. Each question offered multiple-choice options to facilitate straightforward responses, enabling clear statistical analysis. Table I presents the detailed questionnaire.

Table I: Questionnaire content

Question	Options
1. Pharmacovigilance definition includes all except?	a)Detection b) Assessment ***c) Treatment*** d) Prevention
2. Regarding ADR, what is the most appropriate option?	a) All adverse events ***b) When an association between an adverse event and a drug is established*** c) All drug interactions d) All the above
3. What all comes under Serious Adverse Events [SAE]?	a) Fatal event b) Life-threatening event c) Permanent disability d) Hospitalization for the event ***e) All the above***
4. When healthcare professionals identify and report any suspected adverse drug reaction to the national pharmacovigilance center or to the manufacturer, it is called?	a) Mandatory reporting ***b) Spontaneous reporting*** c) Casual reporting d) Periodic Safety Update Reporting [PSUR]
5. What is signal detection?	a) It is new previously unknown safety information b) Reported information on a possible casual assessment between adverse events & a drug c) Relationship being unclear d) Incompletely documented previously ***e) All the above***
6. Which of the following is/are true?	***a) Uppsala Monitoring Center [UMC] is responsible for supervising the management of WHO Programmes*** b) WHO is responsible for supervising the management of UMC Programmes c) CDSCO manages both UMC & WHO d) WHO exchanges information between national centers by Vigimed
7. Vigiflow is?	a) Encyclopedia of ADR b) A software for information exchange ***c) A software for case report management designed to meet the needs of national centers*** d) None
8. ADR Timeline	a) For sponsor to licensing authority = 14 calendar days ***b) Investigator to sponsor within 24 days*** c) Sponsor to licensing authority = 7 days d) Investigator to sponsor = 24 days
9. National PV Programme of INDIA has its headquarters at:	a) Delhi ***b) Ghaziabad*** c) Chandigarh d) Lucknow
10. If a physician reports frequent ADR to the Regional PV centre:	a) He may be punished b) Be rewarded c) His ADR forms will not be accepted in the future ***d) All ADR reports are confidential***

Correct answers are in bold italics

Statistical analysis

The study employed both descriptive and inferential statistical methods to analyse the data. Descriptive statistics such as means, modes, and medians were calculated for pre-test and post-test scores to summarise the data. For inferential statistics, a paired *t*-test was used to compare pre-test and post-test scores. The paired *t*-test is appropriate for this analysis

as it compares two related samples (pre-test and post-test scores of the same group of students) to determine whether there is a statistically significant difference. Pre-test and post-test responses for each question were analysed to identify areas with significant improvements or persistent knowledge gaps. Changes in students' attitudes towards ADR reporting were assessed through responses to attitude-related questions. This methodology effectively demonstrates the impact of CME programmes on improving pharmacovigilance awareness among medical students.

Results

Table II provides a summary of the pre-test and post-test results across all questions.

Table II: Pre-test and post-test scores by question with improvement percentages

Question number	Pre-test score	Post-test score	Improvement (%)
1	185	187	1.08
2	92	120	30.43
3	186	187	0.54
4	120	155	29.17
5	64	113	76.56
6	73	166	127.40
7	172	180	4.65
8	83	119	43.37
9	159	185	16.35
10	168	183	8.93

Section 1: Basic understanding of pharmacovigilance and ADR reporting (Questions 1, 3, 7)

The comparison of pre-test and post-test scores demonstrated minimal improvement in Question 1 (Pharmacovigilance Definition) at 1.08%, indicating that participants had a good baseline knowledge of pharmacovigilance definitions. A minor improvement of 0.54% was noted for Question 3 (Serious Adverse Events), suggesting pre-existing awareness of this concept. Moderate improvement of 4.65% was recorded in Question 7 (Vigiflow), which reflects familiarity with pharmacovigilance organisations. Overall, the CME programme reinforced existing knowledge and clarified fundamental concepts of pharmacovigilance.

Section 2: Identification and reporting of ADRs (Questions 2, 4, 9)

Significant improvement was observed in Question 2 (Appropriate ADR Options) at 30.43%, highlighting enhanced understanding of ADR identification. Substantial improvement of 29.17% was noted for Question 4 (Reporting Methods), reflecting increased knowledge of ADR reporting procedures. Additionally, a noticeable improvement of 16.35% was achieved in Question 9 (National PV Programme Headquarters), indicating greater awareness of national reporting structures. The CME effectively enhanced students' ability to identify and report ADRs accurately.

Section 3: Signal detection and safety information (Questions 5, 6)

The analysis revealed a significant improvement of 76.56% for Question 5 (Signal Detection Definition), demonstrating increased understanding of signal detection. Question 6 (True Statements About Organizations) showed major improvement at 127.40%, indicating improved comprehension of pharmacovigilance roles. The CME successfully educated students on signal detection and the importance of accurate safety information.

Section 4: ADR reporting practices and misconceptions (Questions 8, 10)

Considerable improvement of 43.37% was observed in Question 8 (ADR Reporting Timeline), indicating success in clarifying reporting timelines. Moderate improvement of 8.93% was noted in Question 10 (Confidentiality and Reporting Consequences), reflecting a better understanding of confidentiality and associated consequences of ADR reporting. The CME helped dispel common misconceptions and improved knowledge regarding reporting practices and confidentiality. Table III and Figure 1 summarise these findings.

Table III: Brief summary of key findings from each section of questionnaire

Area assessed (Section)	Questions covered	Post-test improvement (%)	Average improvement per section (%)	Conclusion
Basic Understanding of Pharmacovigilance (Section 1)	1,3,7	1.08 (Q1), 0.54 (Q3), 4.65 (Q7)	2.09	Reinforced existing knowledge
Identification and Reporting of ADRs (Section 2)	2, 4, 9	30.43 (Q2), 29.17 (Q4), 16.35 (Q9)	25.98	Enhanced ability to identify and report ADRs
Signal Detection and Safety Information (Section 3)	5, 6	76.56 (Q5), 127.40 (Q6)	102.98	Improved understanding of signal detection
ADR Reporting Practices and Misconceptions (Section 4)	8, 10	43.37 (Q8), 8.93 (Q10)	26.15	Clarified misconceptions and improved reporting knowledge

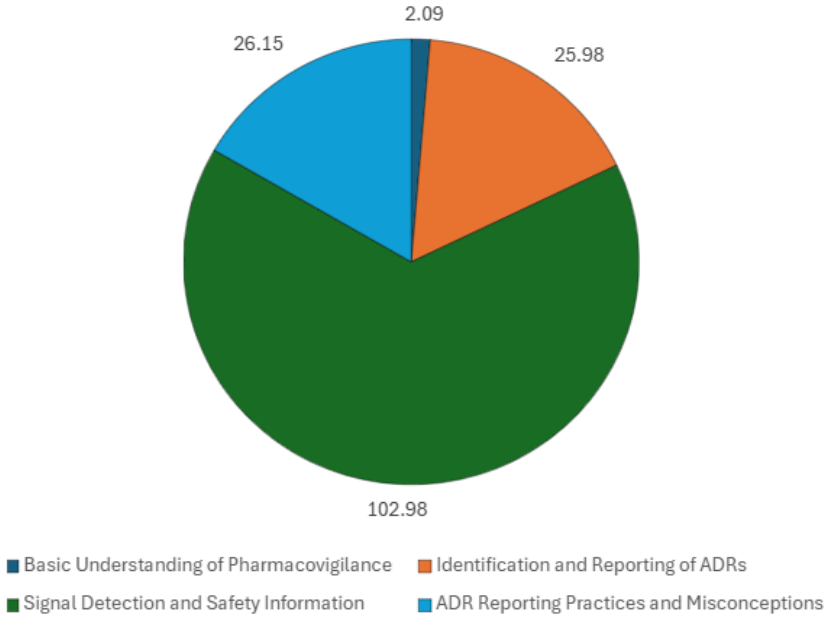

Figure 1: Section-wise improvement in knowledge areas

Descriptive statistics

Table IV provides a summary of measures for central tendency and dispersion regarding pre-test and post-test scores.

Table IV: Summary of central tendency and dispersion measures for pre-and post-test scores

Statistic	Pre-test value	Post-test value
Mean	130.2	159.5
Median	139.5	173
Mode	N/A	187

Inferential statistics

The *p*-value obtained from the paired *t*-test was 0.004, indicating a statistically significant difference between pre-test and post-test scores. This result implies that the CME programme significantly improved pharmacovigilance knowledge and awareness among second-year medical students. The paired *t*-test analysis revealed that the CME Programme had a significant positive impact on students' understanding of pharmacovigilance, as evidenced by the statistically significant improvement in post-test scores, highlighting the effectiveness of educational interventions in enhancing medical students' knowledge and preparedness for ADR reporting and pharmacovigilance practices.

Discussion

This study aimed to evaluate the impact of a CME programme on pharmacovigilance awareness among

second-year medical students at Mahatma Gandhi Memorial Medical College, Indore. A unique subgroup analysis of specific questions provided a detailed understanding of the areas where students benefitted the most. Significant improvements were noted in ADR identification, signal detection, and reporting practices, highlighting the effectiveness of the CME programme in addressing both foundational and advanced concepts of pharmacovigilance.

These findings align with those of a study demonstrating that a knowledge, attitudes, and practices (KAP)-based educational intervention in a South Indian tertiary care hospital significantly improved healthcare professionals' knowledge and attitudes towards ADR reporting. Additionally, the intervention led to a doubling in ADR reporting rates post-intervention, underscoring the need for continued educational initiatives to establish a sustained ADR reporting culture among healthcare professionals (Ganesan *et al.,* 2017). Similarly, a structured educational workshop significantly enhanced healthcare providers' knowledge and perceptions of pharmacovigilance in a Jordanian teaching hospital, emphasising the importance of combining knowledge-based interventions with practical solutions for real-world challenges in ADR reporting (El-Dahiyat *et al.,* 2023).

Furthermore, an educational intervention in a Nepalese oncology-based hospital demonstrated a notable increase in healthcare providers' knowledge and attitude scores post-intervention (Shrestha *et al.,* 2020). This improvement underscores the effectiveness of pharmacovigilance education in diverse clinical settings and suggests that similar interventions could be beneficial across different levels of healthcare, including medical students. Similar to the present study, early integration of pharmacovigilance training within healthcare education was emphasised as essential for fostering positive attitudes and ensuring consistent reporting practices (Shrestha *et al.,* 2020).

A systematic review and meta-analysis identified educational interventions—particularly workshops—as the most effective method for enhancing pharmacovigilance knowledge and increasing ADR reporting rates (Cervantes-Arellano *et al.,* 2024). These findings support the CME programme's focus on interactive learning sessions, suggesting that these methods might be optimal for achieving long-term improvements in pharmacovigilance awareness and reporting behaviours. Similarly, a study among medical students reported a significant improvement in pharmacovigilance knowledge and attitude following an educational intervention (Kalikar *et al.,* 2020). It also suggested the need to integrate pharmacovigilance education into undergraduate curricula to address gaps in ADR reporting knowledge early in medical training (Kalikar *et al.,* 2020).

The subgroup analysis in this study provided detailed insights into specific areas of pharmacovigilance knowledge. While students demonstrated adequate baseline understanding of basic pharmacovigilance concepts, there was considerable room for improvement in more complex areas such as signal detection and reporting practices. This detailed approach allows for more effective tailoring of educational content and enables a more accurate measurement of its impact.

Limitations

The study was conducted at a single institution with a specific cohort of students, which may limit the generalisability of the findings. Additionally, the study did not assess long-term knowledge retention, which is crucial for understanding the lasting impact of the CME programme.

Future research

Future studies should include multiple institutions and diverse student populations to validate these findings. Long-term follow-up assessments are also recommended to evaluate the retention of pharmacovigilance knowledge and its impact on actual ADR reporting practices. Further research could also explore the practical barriers to ADR reporting and develop strategies to address these issues.

Conclusion

The CME programme effectively strengthened students' knowledge across various areas of pharmacovigilance, particularly in identifying and reporting ADRs and understanding signal detection. It highlighted the need for continuous education and training to address specific gaps and reinforce fundamental concepts in pharmacovigilance. The improved post-test scores demonstrate the value of educational interventions in preparing future healthcare professionals for their roles in ensuring drug safety.

Conflict of interest

The authors declare no conflict of interest.

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