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Pharmacovigilance: Ensuring Drug Safety and Patient Wellbeing, as an Elective in Competency-Based Medical Education Curriculum

Background: The shift to competency-based medical education (CBME) has led to the introduction of targeted electives, such as pharmacovigilance, to enhance practical skills among medical students. This elective is vital for educating students on drug safety, therapeutic efficacy, and adverse drug reactions (ADRs). This study aimed to evaluate knowledge, attitudes, practical skills, and their importance in promoting patient safety and rational drug use among phase III part 1 medical students as an elective. **Method:** A descriptive cross-sectional study was conducted in the Department of Pharmacology, Pramukhswami Medical College, Karamsad, Gujarat, India. A total of 22 students who have opted for pharmacovigilance as an elective were included in the study. Their knowledge (out of 10), attitude, completeness score (out of 10) of ADRs were reported and their feedback on course content, teachers' effectiveness and overall training were evaluated. **Results:** The average multiple-choice question score was 7.8 out of 10. While 21 (95.5%) students believed that reporting ADRs is necessary and 17 (77.3%) thought it was mandatory, a total of 36 ADRs were identified with an average completeness score of 8.81 ± 0.56 . Student feedback on the elective, assessed via a Likert scale, showed mean scores between 4.44 and 4.81, reflecting high satisfaction. **Conclusion:** The elective posting effectively improves students' knowledge, attitudes and practical skills regarding the quality of ADR reporting in terms of completeness. **Keywords:** Elective, Pharmacovigilance, Adverse Drug Reaction Reporting, Competency-Based Medical Education, Patient Safety

اليقظة الدوائية: ضمان سلامة الأدوية ورعاية المريض، كمادة اختيارية في مناهج التعليم الطبي القائمة على الكفاءة

الخلفية: أدى التحول إلى التعليم الطبي القائم على الكفاءة (CBME) إلى إدخال مقررات اختيارية مُستهدفة، مثل اليقظة الدوائية، لتعزيز المهارات العملية لدى طلاب الطب. يُعد هذا المقرر الاختياري حيويًا لتثقيف الطلاب حول سلامة الأدوية وفعاليتها العلاجية والآثار الجانبية للأدوية (ADRs). هدفت هذه الدراسة إلى تقييم المعرفة والمواقف والمهارات العملية وأهميتها في تعزيز سلامة المرضى والاستخدام الرشيد للأدوية لدى طلاب الطب في المرحلة الثالثة (الجزء الأول) كمادة اختيارية. **الطريقة:** أُجريت دراسة وصفية مقطعية في قسم علم الأدوية، بكلية براموكسوامي الطبية، كرامساد، غوجارات، الهند. شمل البحث ٢٢ طالبًا اختاروا اليقظة الدوائية كمادة اختيارية. تم الإبلاغ عن معارفهم (من ١٠) ومواقفهم، ودرجة اكتمالهم (من ١٠) للآثار الجانبية للأدوية، كما تم تقييم ملاحظاتهم على محتوى الدورة، وفعالية المعلمين، والتدريب الشامل. **النتائج:** بلغ متوسط درجة أسئلة الاختيار من متعدد ٧,٨ من ١٠. بينما رأى ٢١ طالبًا (٩٥,٥٪) أن الإبلاغ عن الآثار الضارة للأدوية ضروري، بينما رأى ١٧ طالبًا (٧٧,٣٪) أنه إلزامي، تم تحديد ٣٦ من الآثار الضارة للأدوية بمتوسط درجة اكتمال 8.81 ± 0.56 . أظهرت آراء الطلاب حول المقرر الاختياري، الذي تم تقييمه باستخدام مقياس ليكرت، متوسط درجات يتراوح بين ٤,٤٤ و ٤,٨١، مما يعكس رضاهم العالي. **الخلاصة:** يُحسن نشر المقرر الاختياري بشكل فعال معارف الطلاب ومواقفهم ومهاراتهم العملية المتعلقة بجودة الإبلاغ عن الآثار الضارة للأدوية من حيث اكتمالها. **الكلمات المفتاحية:** مقرر اختياري، اليقظة الدوائية، الإبلاغ عن الآثار الضارة للأدوية، التعليم الطبي القائم على الكفاءة، سلامة المرضى

فارماكوويزيلاانس: تضمين ايمني دارو ورفاه بیمار، به عنوان يك درس اختياري در برنامه درسی آموزش پزشکی مبتنی بر شایستگی

زمینه و هدف: تغییر شیوه آموزش به سمت آموزش پزشکی مبتنی بر شایستگی منجر به معرفی دروس اختیاری هدفمند مانند مراقبت دارویی، برای افزایش مهارت‌های عملی دانشجویان پزشکی شده است. این درس اختیاری برای آموزش دانشجویان در مورد ایمنی دارو اثربخشی درمانی و عوارض جانبی مضر دارو حیاتی است. این مطالعه با هدف ارزیابی دانش، نگرش و مهارت‌های عملی و اهمیت آنها در ارتقاء ایمنی بیمار و مصرف منطقی دارو بین دانشجویان پزشکی فاز سوم بخش یک به عنوان درسی اختیاری انجام شده است. **روش:** یک مطالعه توصیفی - مقطعی در بخش فارماکولوژی، کالج پزشکی پراموکسوامی، کرامساد، گجرات، هند انجام شد. در مجموع ۲۲ دانشجو که درس مراقبت دارویی را به عنوان یک درس اختیاری انتخاب کرده بودند در مطالعه گنجانده شدند. نمرات آنها در بخشهای دانش (از ۱۰) و نگرش (از ۱۰) در مورد عوارض جانبی مضر دارو گزارش شد و بازخورد آنها در مورد محتوای درس، اثربخشی اساتید و آموزش کلی ارزیابی شد. **یافته‌ها:** میانگین نمره سوالات چندگزینه‌ای، ۷/۸ از ۱۰ بود. در حالی که ۲۱ دانشجو (۹۵/۵٪) معتقد بودند که گزارش عوارض جانبی مضر داروها ضروری است و ۱۷ دانشجو (۷۷/۳٪) آن را اجباری می‌دانستند. در مجموع ۳۶ مورد عوارض جانبی مضر با میانگین نمره کامل 8.81 ± 0.56 شناسایی شد. بازخورد دانشجویان در مورد درس اختیاری، که از طریق مقیاس لیكرت ارزیابی شد، میانگین نمرات بین ۴/۴۴ و ۴/۸۱ را نشان داد که نشان‌دهنده رضایت بالا است. **نتیجه گیری:** ارائه دروس اختیاری به طور مؤثر دانش، نگرش و مهارت‌های عملی دانشجویان را در مورد کیفیت گزارش عوارض جانبی مضر داروها از نظر کمال بودن بهبود می‌بخشد. **واژه های کلیدی:** درس اختیاری، فارماکوويزيلاانس، گزارش عوارض جانبی داروها آموزش پزشکی مبتنی بر شایستگی، ایمنی بیمار

فارماکو ويجيلنس: قابليت پر مبني طبي تعليم كے نصاب ميں ايڪ اختياري كے طور پر منشيآت كى حفاظت اور مريض كى صحت كو يقيني بنانا

پس منظر: قابليت پر مبني ميڈيكل ايجوڪيشن (CBME) كى طرف تبديلى نے ميڈيكل طلباء ميں عملي مهارتوں كو بڑھانے كے ليے ٹارگٹڈ ليكتيوز، جيسے فارماكو ويجيلنس كو متعارف كرايا ہے۔ منشيآت كى حفاظت، علاج كى افاديت، اور منشيآت كے منفي رد عمل (ADRs) كے بارے ميں طلباء كو تعليم دينے كے ليے یہ انتخاب بہت ضروري ہے۔ اس مطالعہ كا مقصد علم، رويوں، عملي مهارتوں، اور فيز III حصہ ۱ كے ميڈيكل طلباء كے درميان بطور اختياري مريض كى حفاظت اور منشيآت كے عقلي استعمال كو فروغ دینے ميں ان كى اہميت كا جائزہ لینا تھا۔ **طريقہ:** فارماكولوجي ڈیپارٹمنٹ، پرمكسوامي ميڈيكل كالج، كرمساد، گجرات، انڈيا ميں ايڪ وضاحتی كراس سيكشنل مطالعہ كيا گیا۔ مجموعی طور پر ۲۲ طلباء جنہیں نے فارماكو ويجيلنس كو اختياري كے طور پر منتخب كيا ہے اس مطالعہ ميں شامل تھے۔ ان كے علم (۱۰ ميں سے)، رويہ، مڪمل اسكور (۱۰ ميں سے) ADRs كى اطلاع دي گئی اور كورس كے مواد، اساتذہ كى تاثير اور مجموعی تربيت پر ان كے تاثيرات كا جائزہ ليا گیا۔ **نتائج:** اوسط كثیر انتخابی سوال كا اسكور ۱۰ ميں سے ۷.۸ تھا۔ جيڪہ ۲۱ (۹۵.۵٪) طلباء كا خيال تھا كہ ADRs كى اطلاع دینا ضروري ہے اور ۱۷ (۷۷.۳٪) كا خيال تھا كہ یہ لازمی ہے، مجموعی طور پر ۳۶ ADRs كى نشاندہی كى گئی جن كا اوسط مڪمل اسكور 8.81 ± 0.56 رہا ہے۔ ليكتيوز پر طالب علم كے تاثيرات، جس كا جائزہ ليكرت اسڪيل كے ذريعے كيا گیا، نے ۴.۴۴ اور ۴.۸۱ كے درميان اوسط اسكور ظاہر كیے، جو كہ اعلى اطمینان كى عكاسی كرتا ہے۔ **نتیجہ:** انتخابی پوسٹنگ مڪمل طور پر ADR رپورٹنگ كے معيار كے حوالے سے طلباء كے علم، رويوں اور عملي مهارتوں كو مؤثر طريقے سے بہتر بناتی ہے۔ **كليیدی الفاظ:** انتخابی، فارماكو ويجيلنس، منشيآت كے منفي ردعمل كى رپورٹنگ، قابليت پر مبني طبي تعليم، مريض كى حفاظت

INTRODUCTION

The growing complexity of modern medicine, including polypharmacy and the increasing use of advanced drug therapies, underscores the importance of ensuring the safety of medications prescribed to patients. Adverse Drug Reactions (ADRs) are a significant concern in clinical practice and often lead to adverse health outcomes (1, 2). It is critical to integrate pharmacovigilance and ADR reporting into medical education to equip future healthcare professionals with the necessary knowledge and skills to manage these risks. In light of this, the shift towards Competency-Based Medical Education (CBME), which emphasizes mastery of practical competencies rather than merely completing time-based educational modules, presents an opportunity to enhance medical training, particularly in pharmacology (3, 4).

Pharmacovigilance, a vital component of clinical pharmacology, addresses drug safety, ADR monitoring, and optimization of therapeutic strategies (2). While medical students are expected to know pharmacovigilance, there is a gap in their practical understanding and attitudes toward ADR reporting, often due to insufficient exposure to real-world pharmacovigilance systems (2, 5). Therefore, there is a need for targeted educational interventions to bridge this gap and promote rational drug use.

The introduction of elective postings within the CBME framework, particularly in areas like Pharmacovigilance, offers a potential solution (6). An elective is a learning experience created in the curriculum to provide an opportunity for the learner to explore, discover and experience areas or streams of interest (3). By offering students hands-on experience in pharmacovigilance and ADR reporting, these elective postings could foster a deeper understanding of the practical applications of pharmacology. Furthermore, such postings could promote positive changes in students' attitudes, encouraging them to actively engage in patient safety practices and contribute to better healthcare outcomes (2, 4).

This study is designed to evaluate the impact of a pharmacovigilance elective posting on Phase III Part I MBBS students under the CBME curriculum. The primary focus of this study is to assess how such an intervention affects students' knowledge, attitudes, and practical skills in pharmacovigilance. This evaluation is essential for understanding the role of such electives in enhancing patient safety and fostering a culture of rational drug use among future medical practitioners.

METHODS

This descriptive cross-sectional study was

conducted in the Department of Pharmacology, Pramukhswami Medical College, Karamsad, a registered Adverse Drug Reaction (ADR) Monitoring Centre under the Pharmacovigilance Programme of India (PvPI), Indian Pharmacopoeia Commission (IPC), Ministry of Health and Family Welfare, Government of India. Ethical approval was obtained from the Institutional Ethics Committee-2, Bhaikaka University, Karamsad, Anand, Gujarat (IEC/BU/2025/Ex.12/32/2025; dated January 1, 2025).

Study Participants and Elective Posting

A total of 22 students from Phase III Part I MBBS (batches 2019 and 2020) voluntarily opted for a pharmacovigilance-focused elective posting. Ten students from the 2019 batch participated between January and February 2023, while twelve students from the 2020 batch participated between February and March 2024. The elective duration was 15 days. All students attended an interactive lecture series covering the principles of pharmacovigilance, including ADR identification, collection, reporting, and causality assessment. Following the training, students were posted in outpatient and inpatient departments of surgery and allied, and medicine and allied disciplines, where they actively identified and documented suspected ADRs on a daily basis. Under supervision of an internal faculty preceptor, students completed ADR reporting forms with accuracy.

Informed Consent

Informed consent was obtained electronically through a structured Google form prior to participation. The form explained study objectives, voluntary nature of participation, and ensured confidentiality and privacy of responses.

Study Tools and Assessment Parameters

1. Knowledge Assessment (MCQ Test): A structured test comprising 10 multiple-choice questions (MCQs) assessed students' knowledge of pharmacovigilance concepts. Each correct response was awarded 1 point, with a maximum score of 10. The test was validated by subject experts, and reliability was confirmed by question analysis.

2. Attitude Toward Pharmacovigilance and ADR Reporting: Attitudes were assessed using a pretested 5-question questionnaire, with each question requiring students to choose Agree or Disagree. Results were summarized as the number and percentage of students selecting each option. No numeric scoring system was applied. The questionnaire was validated (both external and internal validation) prior to commencing the study. The internal consistency of the scale was high, as indicated by a Cronbach's alpha value of 0.91 for all items.

3. Practical Skills in Pharmacovigilance: Skills were assessed by students' ability to identify suspected ADRs, complete ADR forms, and perform causality assessment. The quality of ADR

reports was evaluated using a completeness scoring system based on four mandatory domains: patient information, ADR details, suspected medication details, and reporter information.

Each domain was scored out of 10, giving a total possible score of 40. The final completeness score was expressed as an average score out of 10 (2, 7).
4. Feedback on Elective Posting: Student feedback was collected using a structured 15-item Likert scale questionnaire (Strongly Agree = 5 to Strongly Disagree = 1) covering course content, teaching quality, duration, and applicability. Scores were summarized as mean $\pm$ SD.

Data Analysis

Descriptive statistical analysis was performed using Microsoft 365 Excel. Knowledge scores were summarized as mean $\pm$ SD, attitude responses as number and percentage, practical skills using completeness scores (mean out of 10), and feedback as mean $\pm$ SD.

RESULTS

A total of 22 students entering Phase III Part I MBBS participated in the pharmacovigilance elective, including 12 males and 10 females. All students had completed their second year of MBBS. Data from all participants were included in the analysis, providing a comprehensive evaluation of knowledge, attitude, practical skills, and feedback related to the elective posting.

Evaluation of the knowledge by MCQ test after the end of elective posting and the result are shown in Figure 1. A total of 10 knowledge-based MCQs of pharmacovigilance and adverse drug reactions (ADRs) were administered. The assessment included 22 students, of whom 5 achieved a perfect score of 10. The range of scores attained by the students varied from 5 to 10. The average MCQ score was 7.8 out of 10, indicating a good understanding of pharmacovigilance concepts, with 17 out of 22 students scoring 7 or above.

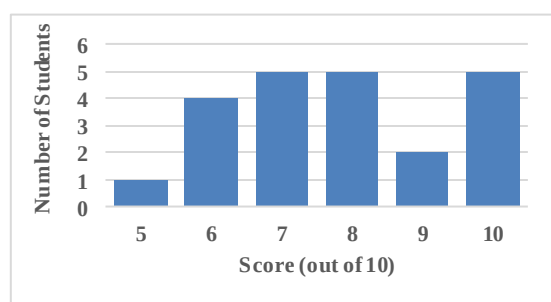


Figure 1. Knowledge of undergraduate students about pharmacovigilance and ADRs
ADRs, Adverse Drug Reactions.

The attitude of participants toward pharmacovigilance and ADR reporting assessed by questionnaire are given in Table 1. A total of 22 students participated in this study. Of them, 21

students agreed that reporting Adverse Drug Reactions (ADRs) is necessary, while 17 deemed it mandatory. Furthermore, 20 students recognized that ADR reporting can enhance patient safety. The study also identified challenges within the Pharmacovigilance Program of India (PvPI), with 14 students citing insufficient trained personnel and 20 pointing to a lack of a robust reporting culture. Table 2 shows the evaluation of the practical skill regarding pharmacovigilance assessed by identifying ADRs, filling them out, and reporting on them (A total 36 ADR forms were submitted during elective posting).

The analysis of the completeness scores for the suspected adverse drug reaction (ADR) forms indicated an average score of 8.81 ± 0.56 , with a range spanning from 7.5 to 10. The score associated with patient identifiers for the suspected ADR forms averaged 8.5 ± 1.28 , with a range of 6 to 10. The suspected ADR score for these forms yielded a mean of 7.83 ± 1.63 , with a range of 5 to 10. In contrast, the score for suspected medications within the ADR forms was notably high, averaging 8.91 ± 0.81 , with a range from 8 to 10. Finally, the score for reporter information on the ADR forms was a perfect 10, indicating complete adherence to reporting standards.

Table 3 presents student feedback on the teaching and supervision of the elective, evaluated using a Likert scale. Students found the course content highly relevant (4.75), instructors knowledgeable (4.81), and classroom interaction well encouraged (4.56). Training duration (4.50) and teaching methods, including clarity and use of examples (4.75), were positively rated. The course strengthened knowledge and skills in ADR reporting (4.63), improved confidence (4.58), and was considered important for future practice (4.46). Low variability in responses (SD: 0.40–0.73) indicates consistent satisfaction with both the course and instructors.

DISCUSSION

A total of 22 Phase III Part I MBBS students (12 males, 10 females) participated in the 15-day pharmacovigilance elective. Knowledge scores averaged 7.8 out of 10, and practical skills completeness scores were $8.81 \pm 0.56/10$. Attitude assessment showed 95.5% agreement on the importance of ADR reporting, while feedback indicated high satisfaction with mean scores of 4.43–4.81 (SD: 0.40–0.73), reflecting improved knowledge, skills, and confidence.

Pharmacovigilance plays a crucial role in ensuring drug safety by identifying and mitigating risks associated with Adverse Drug Reactions (ADRs). Integrating it as an elective within the Competency Based Medical Education (CBME) curriculum offers students valuable hands-on experience in this critical area (2, 4).

Table 1. Undergraduate student's attitude toward pharmacovigilance and ADRs* reporting (n=22)			
Sr. No.	Questions	Agree N (%)	Disagree N (%)
1	Is it important to report ADR cases?	21 (95.5)	1 (4.5)
2	Should there be a requirement to report ADRs?	17 (77.3)	5 (22.7)
3	Can reporting ADRs help improve patient safety?	20 (90.9)	2 (9.1)
4	What obstacles exist in implementing PvPI**?		
	A shortage of skilled professionals	14 (63.3)	8 (36.7)
	A weak culture of reporting	20 (90.9)	2 (9.1)
*ADRs: Adverse Drug Reactions			
**PvPI: Pharmacovigilance Program of India			

Table 2. Undergraduate student's practical skill regarding ADRs* reporting form filling						
Domain	Patient identifier	Suspected ADR	Suspected medication	Reporter information	Total score	Average score
Range	6-10	5-10	8-10	10	30-40	7.5-10
Mean (SD)	8.5 (1.28)	7.83 (1.63)	8.91 (0.81)	10	35.25 (2.23)	8.81 (0.56)
*ADRs: Adverse Drug Reactions						

Table 3. Feedback of undergraduate students in teaching and supervising the pharmacovigilance elective (n=22)	
Question	Mean (SD)
The content in the elective course was relevant and easy to understand.	4.75 (0.44)
Class participation and interaction were encouraged in the elective course.	4.56 (0.51)
The training time allotted was sufficient to cover the elective course.	4.50 (0.63)
The teachers had enough knowledge of the relevant subject.	4.81 (0.40)
The teachers were friendly and created a healthy training environment.	4.62 (0.50)
The teachers could satisfactorily answer the concerns/queries of the participants.	4.62 (0.50)
The elective course met my expectations.	4.43 (0.63)
The teachers spoke clearly with good command of language.	4.56 (0.63)
The teachers used teaching aids effectively for better understanding of the elective course.	4.56 (0.51)
The teachers used specific examples, images, diagrams, etc., to illustrate main ideas.	4.75 (0.45)
The teachers encouraged students to ask/answer questions.	4.50 (0.73)
The teachers summarize the most important points in the session.	4.62 (0.50)
The elective course has improved my knowledge and skills in ADR* reporting.	4.63 (0.51)
I feel confident in my ability to apply ADR reporting in clinical practice.	4.58 (0.49)
The elective course is important for my future professional practice.	4.46 (0.61)
*ADR: Adverse Drug Reaction	

of students (15 out of 22) scored between 7 and 10, indicating a strong understanding of pharmacovigilance. This contrasts with the findings of Rehan HS et al., which reported low knowledge regarding ADR monitoring, highlighting the need for more comprehensive and updated education in this field (8). A lack of time and insufficient knowledge about ADRs are often considered contributing factors to underreporting (9).

Our findings revealed that 95.5% of students agreed that ADR reporting is necessary, aligning with the study by Upadhyay et al. Furthermore, two-thirds of students viewed ADR reporting as mandatory for patient safety, with many emphasizing that creating a culture of reporting remains a significant challenge in India. These attitudes reflect a more favourable stance compared to Upadhyay et al.'s findings (9).

Regarding the completeness of ADR reporting forms, students scored an average of 8.81 ± 0.56 , with high marks in key sections such as patient information and suspected ADRs. This aligns with the results of Narwane et al.'s study (2). In our study, students demonstrated a high level of understanding and competence across all Knowledge, Attitudes, and Practices (KAP) domains. This contrasts with findings from Paneerselvam N et al., who observed good knowledge of pharmacovigilance practices but weaker attitudes and practices (10). Some studies, such as the one by Desai CK et al., have similarly shown high knowledge but poor ADR reporting practices among healthcare professionals (11). Student feedback indicated that the course content was relevant, instructors were knowledgeable, and classroom interaction was encouraged. The training duration and teaching methods were positively received. Students found the elective valuable for their future practice and felt prepared to identify and report adverse drug reactions. This confidence was attributed to the course's practical approach, which integrated theoretical instruction with real-world reporting experience, resulting in measurable outcomes that were consistent with Narwane et al.'s study (2). The findings of Schutte et al., indicate that this experiential learning approach substantially improved students' positive perceptions and their propensity to engage in ADR reporting (12).

This study has certain limitations. The small sample size (22 students) and single-center design may limit the generalizability of the findings to other medical colleges or larger MBBS cohorts. The elective posting was of short duration (15 days), which may have restricted long-term retention and application of pharmacovigilance skills.

CONCLUSION

The elective significantly improved students' knowledge, attitudes, and practical skills in complete ADR reporting, demonstrating the value of integrating pharmacovigilance into the CBME curriculum to strengthen patient safety and evidence-based practice.

Ethical Considerations:

Ethical issues including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc. have been completely observed by the authors.

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