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# EFFECT OF A SIMULATION-BASED PHARMACOVIGILANCE AND ADR REPORTING MODULE ON KNOWLEDGE AND SKILLS AMONG FINAL-YEAR MBBS STUDENTS: A QUASI-EXPERIMENTAL STUDY

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**Keywords:**

ADR Reporting, Pharmacovigilance, Knowledge and Skills, Final-Year MBBS Students

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**ABSTRACT: Background:** Pharmacovigilance training in undergraduate medical education remains largely theoretical, leading to inadequate real-world reporting competency. Simulation-based training may help bridge this gap. **Aim:** To evaluate the effectiveness of a structured simulation-based pharmacovigilance module in improving knowledge and ADR-reporting skills among final-year MBBS students. **Methods:** A quasi-experimental single-group pre-test/post-test study was conducted among 45 final-year MBBS students. The intervention comprised interactive lectures, case-based simulations, and ADR form-filling exercises over four days. Knowledge was assessed using a validated 15-item MCQ test; skills were assessed using an OSPE checklist based on CDSCO ADR reporting formats. Paired t-test was used for statistical comparison. **Results:** Mean MCQ scores improved significantly from 11.45 ± 3.90 to 13.18 ± 3.20 after the module ($p = 0.015$; Cohen's $d = 0.88$). The proportion of students achieving high scores (13–15) increased from 36% to 60%. OSPE scores improved from 5.2 to 8.1, demonstrating enhanced ability to identify ADRs and complete reporting forms accurately. **Conclusion:** The simulation-based pharmacovigilance module substantially improved theoretical knowledge and practical ADR-reporting skills among MBBS students. Such structured educational models may strengthen pharmacovigilance competency in undergraduate medical training.

**INTRODUCTION:** Adverse Drug Reactions (ADRs) is defined as 'A response to a drug that is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function" by World Health Organization (WHO) [1].

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Adverse drug reactions are usually a major public health concern and threat as they are responsible for significant morbidity and mortality of the general population. ADRs lead to increased costs of treatment, prolonged hospital stays, mortality risk, and several other medical and financial problems.

The Pharmacovigilance program was laid for the active involvement of the healthcare professionals such as doctors, pharmacists and nurses. WHO established an International Programme for Drug Monitoring in 1968, in coordination with Uppsala Monitoring Centre (UMC) in Sweden [2]. Pharmacovigilance is an essential component of safe clinical practice which monitors ADRs and

helps in reporting the ADRs to find the actual causal relationship of that particular reaction to the drug. Even though the undergraduate curriculum has Pharmacovigilance in the academics, medical students often lack confidence and practical skills in identifying and reporting the ADRs. Traditional lecture-based teaching focuses mainly on theoretical knowledge, with limited emphasis on real-world reporting processes and ADR documentation. Simulation-Based Training (SBT) significantly enhances the healthcare professional's knowledge, experience, clinical competency and has been a transformative approach in medical education [3]. A simulation-based classroom module using case vignettes and ADR form-filling can enhance both knowledge and practical skills without requiring patient contact [4]. As today's students are tomorrow's prescribers, strengthening the competencies early is a practical route to sustain the reporting culture. Sensitization of the medical undergraduate students during training in electives is therefore essential to instill early awareness, bridge knowledge gaps, and encourage proactive participation in ADR reporting [5].

This study evaluates the effectiveness of a structured, simulation-based pharmacovigilance module on knowledge, skills, and confidence among final-year MBBS students posted for Pharmacology electives.

## METHODS:

**Study Design and Setting:** This was a quasi-experimental, single-group pre-test/post-test educational intervention study conducted in the Department of Pharmacology at a tertiary medical teaching institution. The study was conducted between December 2025 and January 2026 during the final-year MBBS pharmacology elective posting and followed a structured 4-day simulation-based training module focused on pharmacovigilance and ADR reporting.

**Participants:** All participants were final-year MBBS students with no prior formal structured training in pharmacovigilance. None had significant prior experience in ADR reporting. All final-year MBBS students posted for Pharmacology electives during the study period were invited to participate. Inclusion criteria consisted of age, willingness to participate and completion of both pre-test and post-test assessments. Students absent on either day of evaluation were excluded. A total of 45 students completed all components of the study.

**Intervention:** The intervention consisted of a structured, simulation-based pharmacovigilance module delivered over 4 days. Day 1 included a pre-test MCQ assessment and OSPE task involving ADR identification and form completion. Day 2 comprised an interactive lecture on pharmacovigilance principles, ADR types, reporting pathways, and national PvPI mechanisms. Day 3 involved small-group simulation exercises using case vignettes to practice ADR identification and CDSCO reporting procedures. Day 4 included the post-test MCQ assessment and a second OSPE station using a different clinical vignette to assess skill acquisition. The module was standardized with predefined learning objectives and facilitator guidance. Each training day consisted of approximately 2–3 hours of structured sessions. Students were divided into small groups of 8–10 participants, with a faculty-to-student ratio of approximately 1:10 to ensure active participation and individualized feedback. The learning objectives for each session included identification of ADRs, classification of reaction types, understanding reporting pathways, and accurate completion of the CDSCO ADR reporting form.

**Outcome Measures:**

**Knowledge Assessment (MCQ):** The MCQ questionnaire was developed based on standard pharmacovigilance guidelines and core concepts of ADR reporting. Content validity was established through review by subject experts in pharmacology. The questionnaire was pilot tested among a small group of students to ensure clarity and relevance. Internal consistency of the tool was assessed using Cronbach's alpha. Internal consistency was assessed to ensure reliability of the tool. Knowledge gain was measured using a validated 15-item multiple-choice questionnaire addressing key pharmacovigilance concepts, ADR classification, reporting systems, and regulatory requirements. Each correct answer was scored as 1 point, yielding a maximum possible score of [15].

**OSPE Assessment (ADR Reporting Skills):** Practical competence was assessed through

Objective Structured Practical Examination (OSPE) stations based on standardized ADR case vignettes. A checklist aligned with CDSCO's Suspected ADR Reporting Form was used to evaluate ability to identify the suspected drug, describe the ADR, determine seriousness and type, assign an appropriate timeline, and complete the mandatory fields of the ADR reporting form. Each OSPE was scored out of 10. The OSPE checklist included key domains such as identification of the suspected drug, accurate description of the adverse drug reaction, classification of ADR type and seriousness, assessment of temporal relationship, and completeness of mandatory fields in the CDSCO ADR reporting form. Each domain was scored using a structured checklist-based rubric. Each OSPE station was scored out of a maximum of 10 marks, with predefined criteria for each component. Assessors were trained prior to the evaluation to ensure uniformity in scoring. The same evaluators conducted both pre-test and post-test assessments using standardized criteria.

**Statistical Analysis:** Data were analyzed using IBM SPSS Statistics version 30 (IBM Corp., Armonk, NY, USA). Normality of paired differences was assessed prior to applying the paired t-test. Pre- and post-test scores were compared using a paired t-test.

Effect size (Cohen's d) was calculated using pooled standard deviation to assess the magnitude of change. Additionally, 95% confidence intervals were calculated for the mean difference in scores. A two-tailed p-value of <0.05 was considered statistically significant. Continuous variables such as MCQ knowledge scores and OSPE performance scores were expressed as mean ± standard deviation, while categorical variables were reported as frequencies and percentages. The distribution of knowledge scores across performance categories (low, moderate, high) was also examined.

Pre-test and post-test MCQ scores were compared using a paired t-test to evaluate the statistical significance of knowledge improvement following the training intervention. Effect size (Cohen's d) was computed to assess the magnitude of change, with thresholds interpreted according to established educational research standards. OSPE scores were analyzed descriptively to determine improvement in ADR reporting skills, with mean differences used to quantify performance gains. A two-tailed p-value of <0.05 was considered statistically significant. To minimize assessment bias, standardized scoring rubrics were used across both pre- and post-intervention assessments. Different but comparable clinical vignettes were utilized for pre- and post-test OSPE stations. Equivalence in difficulty level was ensured through expert review prior to implementation.

## RESULTS:

**Knowledge Assessment (MCQ Performance):** All 45 students completed both pre-test and post-test MCQ assessments. A clear improvement in knowledge was observed following the pharmacovigilance teaching module. The mean MCQ score increased from 11.45 ± 3.90 to 13.18 ± 3.20, reflecting a 15.1% improvement in overall knowledge levels **Table 1**.

Performance shifted notably toward the higher score range after the intervention, with the proportion of students scoring in the high category (13–15) rising from 36% to 60% **Table 2.**

A paired t-test demonstrated that the improvement in MCQ scores was statistically significant ($t = -2.93$, $p = 0.015$), with a large effect size (Cohen's $d = 0.88$), indicating substantial educational impact.

**TABLE 1: MEAN KNOWLEDGE SCORES BEFORE AND AFTER THE EDUCATIONAL INTERVENTION**

| Assessment | Mean ± SD |
|---|---|
| Pre-test MCQ | 11.45 ± 3.90 |
| Post-test MCQ | 13.18 ± 3.20 |
| Mean Difference | +1.73 |

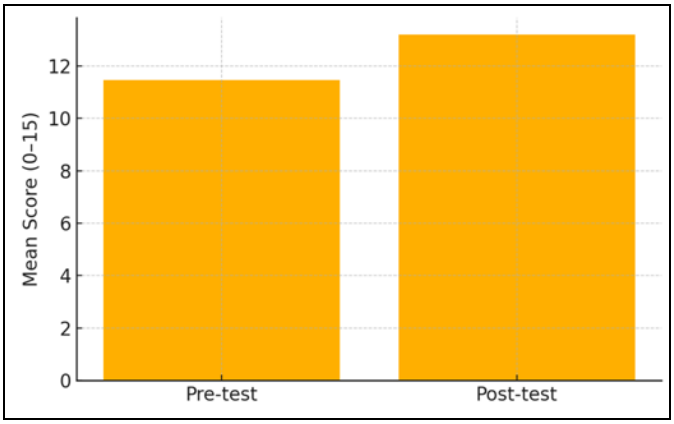


**FIG. 1: COMPARISON OF MEAN MCQ KNOWLEDGE SCORES BEFORE AND AFTER THE INTERVENTION**

**TABLE 2: DISTRIBUTION OF STUDENTS ACROSS KNOWLEDGE SCORE CATEGORIES**

| Category | Pre-test n (%) | Post-test n (%) |
|---|---|---|
| Low (0–7) | 9 (20%) | 4 (9%) |
| Moderate (8–12) | 20 (44%) | 14 (31%) |
| High (13–15) | 16 (36%) | 27 (60%) |

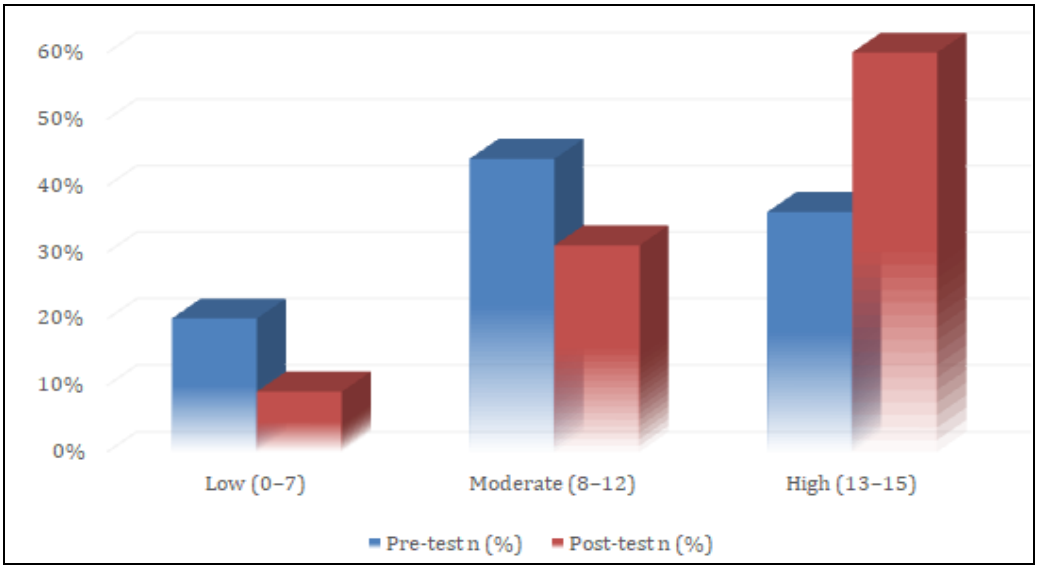


**FIG. 2: DISTRIBUTION OF MCQ SCORES BEFORE AND AFTER THE INTERVENTION (IN %)**

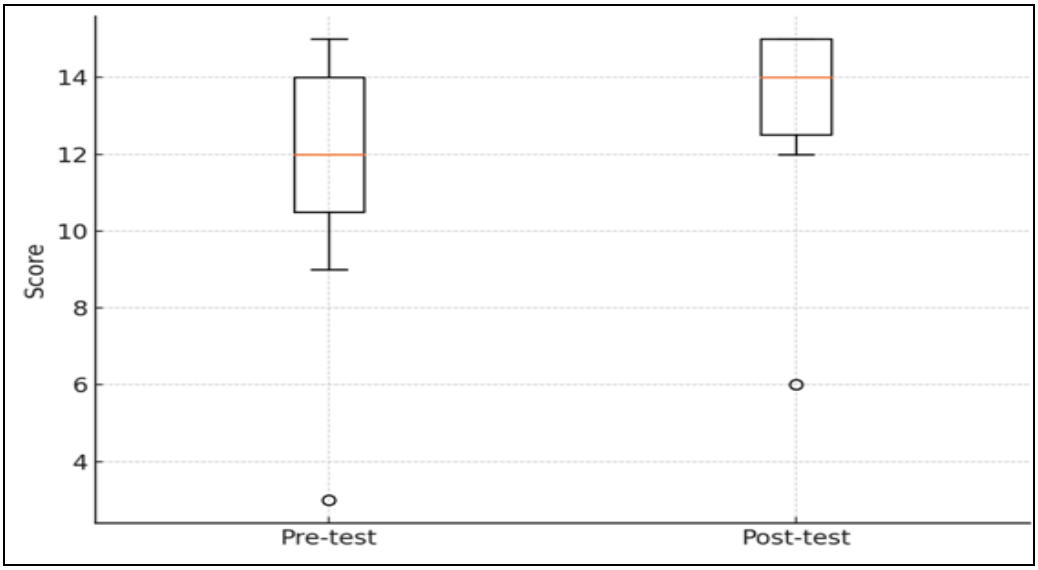


**FIG. 3: DISTRIBUTION OF MCQ SCORES BEFORE AND AFTER THE INTERVENTION (BARPLOT)**

**OSPE (ADR Reporting Skills):** Students underwent OSPE assessment using structured ADR reporting case vignettes before and after the simulation-based module.

The mean OSPE score improved from 5.2 ± 1.4 to 8.1 ± 1.2 (out of 10), indicating a substantial improvement in practical ADR reporting skills. Students demonstrated better performance in identifying the suspected drug, accurately describing the adverse drug reaction, classifying ADR type and seriousness, and completing mandatory fields in the CDSCO ADR reporting form. This represents an absolute improvement of 2.9 points in OSPE performance.

These findings confirm that the simulation exercise effectively strengthened real-world pharmacovigilance skills.

**TABLE 3: OSPE SCORE IMPROVEMENT**

| Assessment | Mean Score (0–10) |
|---|---|
| Pre-test OSPE | 5.2 |
| Post-test OSPE | 8.1 |
| Improvement | +2.9 |

**Overall Impact of the Educational Module:** The pharmacovigilance training module produced clear improvement in both theoretical knowledge and practical ADR reporting abilities. Knowledge improvement was statistically significant ($p = 0.015$), with a large effect size indicating strong educational benefit. Practical OSPE scores showed substantial gains, reflecting enhanced competency in completing ADR reporting forms and identifying key elements of ADRs. Together, these results indicate that simulation-based teaching is an effective strategy for strengthening both conceptual understanding and hands-on pharmacovigilance skills among MBBS students.

**DISCUSSION:** The present study demonstrated that a structured simulation-based pharmacovigilance module significantly improved both knowledge and ADR-reporting skills among final-year MBBS students. The statistically significant increase in MCQ scores, along with the large effect size, indicates that simulation-based learning offers substantial advantages over traditional lecture-based approaches. Similar educational interventions have shown that active, case-based methods enhance conceptual retention and promote application of pharmacovigilance principles in clinical contexts [6, 7].

Improvement in OSPE performance further highlights the value of experiential learning in ADR reporting. Students demonstrated better accuracy in completing CDSCO ADR forms, identifying suspected drugs, and describing reaction characteristics after the intervention. Reports from other institutions also support the idea that practical hands-on training improves ADR reporting competence and reduces underreporting a persistent challenge in India's pharmacovigilance programme [8].

The transition of students from lower and moderate scoring categories into high-performance groups suggests that simulation-based modules can address existing knowledge gaps effectively. This aligns with global recommendations that undergraduate curricula incorporate applied pharmacovigilance activities rather than rely solely on didactic teaching [9]. By providing structured exposure to simulated ADR scenarios, the intervention equips students with skills they are likely to use during internship and early clinical practice, where ADR recognition and reporting are essential for patient safety.

Finally, the positive trends observed in this study reinforce the emerging consensus that strengthening pharmacovigilance education at the undergraduate level is critical for improving national ADR reporting rates. Integrating such simulation-based modules into routine training could create a more confident and competent future workforce in line with WHO pharmacovigilance objectives [10].

**Limitations:** This study has certain limitations. The single-group pre–post study design is subject to testing effects and lacks a control group for comparison. The assessment was conducted immediately after the intervention, limiting evaluation of long-term knowledge retention. Additionally, real-world ADR reporting behavior was not assessed. Future studies with larger sample sizes, control groups, and long-term follow-up are recommended to validate and extend these findings.

**CONCLUSION:** A structured simulation-based pharmacovigilance module significantly improved both theoretical knowledge and practical ADR reporting skills among final-year MBBS students. Integrating such modules within the undergraduate curriculum may enhance national ADR reporting systems by preparing future clinicians with stronger pharmacovigilance competencies.

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**Ethical Approval:** This study involved a minimal-risk educational intervention conducted as part of routine academic training. As no patient data were involved and all assessments were anonymised, formal ethical clearance was not sought. Participation was voluntary, and informed consent was obtained from all students. The study was conducted as part of a routine academic educational activity involving minimal risk to participants. As per institutional norms for educational interventions without patient involvement, formal ethical clearance was not mandated.

All participants provided informed consent, and data were anonymised prior to analysis.

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**Methodology & Data Collection:** Dr. Manju Priya

**Analysis & Interpretation:** Dr. Navneeth Selvan

**Final Approval:** All authors

**CONFLICT OF INTEREST:** The authors declare that there are no conflicts of interest related to this study.

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