



Changes in Pharmacovigilance Knowledge, Attitude and Adverse Drug Reaction Reporting Preparedness following an Educational Intervention among Diploma in Pharmacy Students: A Single-Group Pre–Post Study

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ABSTRACT

Adverse drug reactions (ADRs) contribute substantially to hospital admissions, morbidity and healthcare costs, yet under-reporting remains a persistent barrier to effective pharmacovigilance. Diploma in Pharmacy (D. Pharm) students form part of the future pharmacy workforce, and their preparedness to recognise and report ADRs is shaped early during training. This study examined whether a structured educational intervention was associated with changes in pharmacovigilance knowledge, attitude and self-reported ADR-reporting preparedness among D. Pharm students. A single-group pre–post design was used at one college of pharmacy in Bagalkote, Karnataka. Fifty-four D. Pharm students completed a validated, self-administered questionnaire assessing knowledge (10 items), attitude (5 items) and practice-related preparedness (5 items) before and one month after an interactive educational session on pharmacovigilance and ADR reporting. Domain scores were summarised as mean $\pm$ standard deviation and compared using the paired t-test, with $p < 0.05$ considered statistically significant. Mean knowledge scores rose from 3.76 ± 2.36 to 7.13 ± 1.76 , attitude scores from 16.35 ± 3.51 to 19.48 ± 2.98 , and practice-preparedness scores from 2.35 ± 1.24 to 3.81 ± 1.18 ; the mean total score improved from 21.85 to 28.54. All three domains showed statistically significant improvement ($p < 0.0001$). The proportion of participants classified as having good knowledge increased from 35.18% to 94.44%, positive attitude from 33.33% to 98.14%, and good practice preparedness from 40.74% to 88.88%. A short, structured educational intervention was associated with marked short-term gains across all three domains. The single-centre, single-arm design and reliance on self-reported measures limit causal inference and generalisability, and larger controlled studies with objective reporting outcomes and retention assessment are warranted.

Keywords: Adverse drug reaction; D. Pharm students; Educational intervention; Knowledge attitude practice; Pharmacovigilance; Reporting.

INTRODUCTION

Adverse drug reactions (ADRs) are among the most important avoidable causes of illness in modern healthcare. The World Health Organization defines an ADR as any noxious, unintended and undesired effect of a drug that occurs at doses used in humans for prophylaxis, diagnosis or therapy. As newer medicines continue to enter the market, the need to monitor drug safety after approval has grown, and pharmacovigilance has become an essential pillar of rational and safe drug use.¹

The burden of ADRs is well documented. Studies from India have reported that ADRs account for roughly 3.4% of hospital admissions, that about 3.7% of hospitalised patients experience an ADR during their stay, and that a proportion of these events prove fatal. The incidence of serious ADRs has been estimated at around 6.7%. Beyond the human cost, ADRs place a considerable economic strain on patients and health systems, which makes their early detection and prevention a public-health priority.^{1,2}

Spontaneous reporting is the cornerstone of post-marketing drug-safety surveillance. It is inexpensive, simple to operate and captures all drugs and patient groups, including special populations. Its central weakness, however, is chronic under-reporting, which limits the ability of surveillance systems to detect signals early. The Pharmacovigilance

Programme of India (PvPI), coordinated by the Indian Pharmacopoeia Commission as the National Coordination Centre since 2011, was established to strengthen this system, yet under-reporting persists across cadres of healthcare professionals.^{2,3}

A recurring explanation for under-reporting is inadequate knowledge, unfavourable attitudes and weak reporting practices among those expected to report. Continuing education, easier access to reporting tools and active training have all been proposed as remedies. Pharmacy students, including those pursuing the Diploma in Pharmacy (D. Pharm), represent an early and receptive group in whom sound reporting behaviour can be cultivated before it is displaced by workplace habits.^{3,4}

Although several studies have examined knowledge, attitude and practice (KAP) related to ADR reporting among physicians and practising pharmacists, comparatively few have focused on D. Pharm students or have tested whether a brief educational intervention can shift these measures. The present study was therefore undertaken to assess pharmacovigilance knowledge, attitude and self-reported ADR-reporting preparedness among D. Pharm students, and to examine the changes associated with a structured educational intervention using a single-group pre–post design.



MATERIALS AND METHODS

Study design

This was a single-group, pre–post educational interventional study conducted among D. Pharm students at Hanagal Shri Kumareshwar College of Pharmacy, Bagalkote, Karnataka. Each participant served as their own control, with assessments performed immediately before and one month after the educational session.

Study setting and duration

The study was carried out in the Department of Pharmacy Practice over a period of four months among D. Pharm students of the college.

Sample size

The sample size was estimated to use OpenEpi software with an absolute precision of 10%, yielding a minimum requirement of 54 participants. Fifty-four eligible D. Pharm students were subsequently enrolled.

Eligibility criteria

D. Pharm students of any age and either sex who provided consent to participate were included. Students from other courses and those unwilling to participate were excluded.

Study instrument

A structured, self-administered questionnaire was developed after review of comparable published studies and refined by the investigators for comprehension and clarity. It comprised 20 items across three domains: 10 knowledge items, 5 attitude items and 5 practice-preparedness items. Knowledge items were scored one point for each correct response (maximum 10); a score greater than 5 was classified as good knowledge and a score of 5 or below as poor knowledge. Attitude items were rated on a five-point Likert scale (strongly agree = 5 to strongly disagree = 1; maximum 25); a score of 15 or above was classified as a positive attitude and below 15 as a negative attitude. Practice-preparedness items were scored one point each (maximum 5); a score above 3 was classified as good practice preparedness and 3 or below as poor. The full questionnaire is provided in the Annexure.

Intervention and procedure

After the baseline (pre-intervention) assessment, participants took part in an interactive educational session on pharmacovigilance and ADR reporting, covering the recognition, documentation and reporting of ADRs, the role of the PvPI, and the practical use of reporting forms. One month after the session, the same questionnaire was re-administered to assess post-intervention scores. Participants were encouraged to identify and report ADRs using the reporting forms made available in the department.

Ethical approval

The study protocol was approved by the Institutional Ethics Committee of Hanagal Shri Kumareshwar College of

Pharmacy, Bagalkote (Ref. No. HSKCOP/IEC/24/1, dated 15 July 2024). Written informed consent was obtained from all participants, and a copy of the consent document was provided to each participant.

Statistical analysis

Data was compiled in Microsoft Excel. Categorical responses were summarised as frequencies and percentages, and domain scores as mean $\pm$ standard deviation. Pre- and post-intervention scores were compared using the paired t-test, and a p-value of less than 0.05 was considered statistically significant. Results were presented as tables and summary figures.

RESULTS

A total of 54 D. Pharm students completed both the pre- and post-intervention assessments. Of these, 33 (61.11%) were male and 21 (38.89%) were female. The majority were 19 years of age (26; 48.14%), followed by 20 years (18; 33.33%) and 21 years and above (6; 11.12%), with the fewest aged 18 years (4; 5.55%) (Table 1).

Table 1: Age- and gender-wise distribution of participants (N = 54)

Variable	Frequency (n)	Percentage (%)
Age – 18 years	4	5.55
Age – 19 years	26	48.14
Age – 20 years	18	33.33
Age – 21 years and above	6	11.12
Gender – Male	33	61.11
Gender – Female	21	38.89

Knowledge

At baseline, 19 participants (35.18%) demonstrated good knowledge and 35 (64.81%) poor knowledge. Following the intervention, good knowledge rose to 51 participants (94.44%) and poor knowledge fell to 3 (5.55%). Item-level responses (Table 2) showed gains across every knowledge item. For example, familiarity with the term pharmacovigilance increased from 42.59% to 94.40%, awareness of the importance of ADR reporting from 68.51% to 94.40%, awareness of the PvPI mobile application and toll-free number from 16.66% to 79.62%, and awareness of the regulatory body responsible for ADR monitoring from 51.85% to 74.07%.

Attitude

At baseline, 18 participants (33.33%) held a positive attitude and 36 (66.67%) a negative attitude towards ADR reporting. After the intervention, positive attitude increased to 53 participants (98.14%) and negative attitude fell to 1 (1.85%). Agreement that ADR reporting is necessary, that it increases patient safety, that consulting the physician is important before reporting, and that pharmacovigilance should be taught in detail all increased, while the belief that reporting is time-consuming and without benefit declined markedly (Table 3).



Table 2: Participant responses to selected knowledge items before and after the intervention (N = 54)

Knowledge item (respondents answering correctly / “Yes”)	Pre n (%)	Post n (%)
Familiar with the term pharmacovigilance	23 (42.59)	51 (94.40)
ADR reporting is important	37 (68.51)	51 (94.40)
Aware of PvPI mobile app and toll-free number	9 (16.66)	43 (79.62)
Aware of formal reporting systems in other countries	15 (27.77)	34 (62.96)
Aware of a drug banned worldwide due to ADR	29 (53.70)	43 (79.62)
Ever shared ADR information with anyone	19 (35.18)	41 (75.92)
Correctly identified the types of ADRs	17 (31.48)	35 (64.81)
Aware of the WHO online database for ADR reporting	10 (18.51)	34 (62.96)
Correctly identified what to report	15 (27.79)	32 (59.25)
Aware of the regulatory body monitoring ADRs in India	28 (51.85)	40 (74.07)

Table 3: Participant responses to attitude items before and after the intervention (positive responses, N = 54)

Attitude statement (positive/agreement response)	Pre n (%)	Post n (%)
ADR reporting is necessary	51 (94.44)	53 (98.14)
ADR reporting is time-consuming with no outcome	13 (24.07)	28 (51.85)
Reporting ADRs will increase patient safety	45 (83.33)	53 (98.14)
Consulting the physician is important before reporting	43 (79.62)	51 (94.44)
Pharmacovigilance should be taught in detail to HCPs	38 (70.36)	53 (98.14)

Table 3 presents item-level agreement, whereas the positive/negative attitude classification above is based on the total attitude score (≥ 15 = positive); the two therefore describe different measures and are not directly comparable.

Table 4: Participant responses to practice-preparedness items before and after the intervention (“Yes” responses, N = 54)

Practice-preparedness item (“Yes” response)	Pre n (%)	Post n (%)
Have seen an ADR reporting form	12 (22.22)	46 (85.18)
ADR monitoring can promote rational use of medicines	14 (25.92)	40 (74.07)
Have read an article on prevention of ADRs	10 (18.51)	39 (72.22)
Have come across an ADR	15 (27.77)	38 (70.37)
Training on completing ADR reporting forms is necessary	18 (33.33)	45 (83.33)

Practice preparedness

At baseline, 22 participants (40.74%) showed good practice preparedness and 32 (59.25%) poor preparedness. After the intervention, good preparedness rose to 48 participants (88.88%) and poor preparedness fell to 6 (11.11%). Improvements were seen across all five practice items, including having seen an ADR reporting form, recognising that ADR monitoring supports rational drug use, and agreeing that training on completing ADR forms is necessary (Table 4).

Comparison of pre- and post-intervention scores

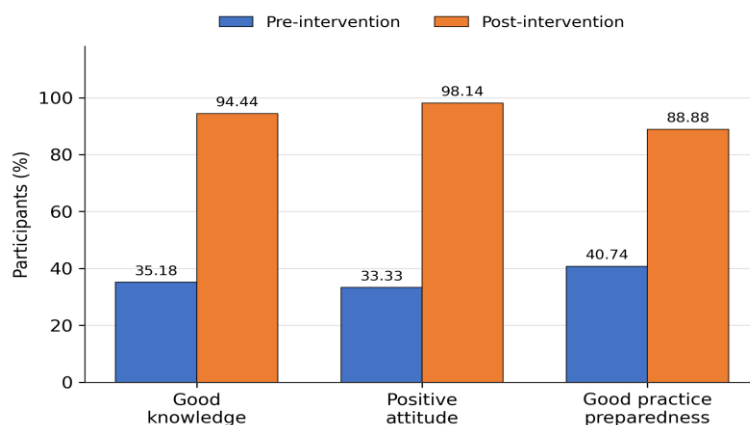
Mean domain scores improved across all three domains and for the total score. The paired t-test showed a statistically significant improvement in knowledge, attitude and practice preparedness ($p < 0.0001$ for each) (Table 5). The classification-level shifts across the three domains are summarised in Figure 1, and the mean total-score change is shown in Figure 2.

Table 5: Comparison of pre- and post-intervention domain scores (paired t-test, N = 54)

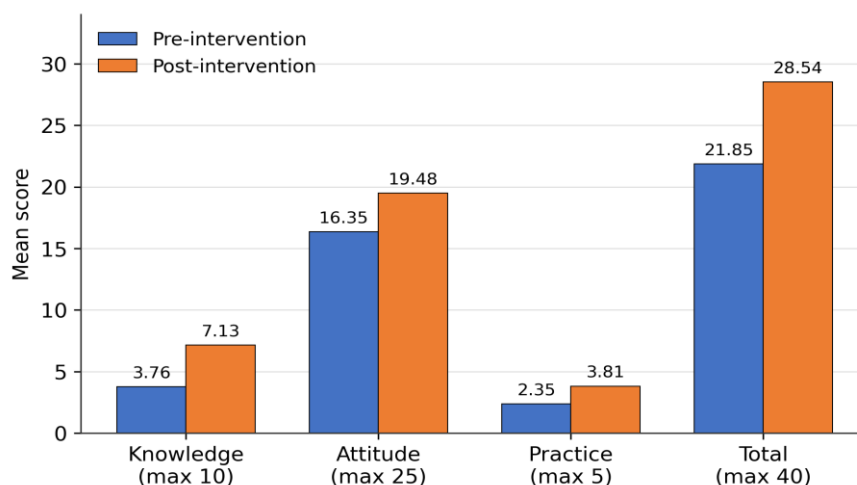
Domain (max score)	PreMean $\pm$ SD	PostMean $\pm$ SD	Mean change	p-value
Knowledge (10)	3.76 $\pm$ 2.36	7.13 $\pm$ 1.76	+3.37	< 0.0001
Attitude (25)	16.35 $\pm$ 3.51	19.48 $\pm$ 2.98	+3.13	< 0.0001
Practice (5)	2.35 $\pm$ 1.24	3.81 $\pm$ 1.18	+1.46	< 0.0001
Total (40)	21.85 $\pm$ 6.38	28.54 $\pm$ 4.81	+6.68	—

SD, standard deviation. Standard deviations were derived from the standard error of the mean ($n = 54$). The paired t-test was applied to the total scores of each domain; the total-row p-value is not reported separately as it aggregates the three domains.



Figure 1: Proportion of participants classified as good knowledge, positive attitude and good practice preparedness before and after the intervention

Good knowledge rose from 35.18% to 94.44%, positive attitude from 33.33% to 98.14%, and good practice preparedness from 40.74% to 88.88%.

Figure 2: Mean domain and total scores before and after the intervention

Mean total score increased from 21.85 to 28.54, with consistent gains across all three domains.

DISCUSSION

This study examined pharmacovigilance knowledge, attitude and self-reported ADR-reporting preparedness among D. Pharm students, and the changes associated with a short structured educational intervention. Across all three domains, post-intervention scores were significantly higher than baseline, and the proportion of students in the favourable category rose substantially for knowledge, attitude and practice preparedness.

The baseline picture echoed a recurring finding in the literature: knowledge and reporting practices were weak even where attitudes were relatively favourable. Fewer than half of the students were initially familiar with the term pharmacovigilance, and awareness of practical reporting tools such as the PvPI application and the WHO database was particularly low. Comparable gaps have been described among pharmacy and medical undergraduates elsewhere, where poor knowledge coexisted with a broadly positive disposition towards reporting.^{8,12}

The improvement observed after the session is consistent with previous interventional studies. Educational interventions among undergraduate medical and pharmacy students have repeatedly produced statistically significant gains in KAP scores, supporting the view that structured teaching can raise short-term awareness of pharmacovigilance and ADR reporting.^{8,9,10}

When set against comparable regional work, the direction of change was similar even where absolute baseline values differed. A multi-faceted educational intervention among pharmacy undergraduates in Ballari, Karnataka, likewise reported significant post-intervention improvement in knowledge scores, and studies from other centres have documented favourable attitudes towards the necessity of reporting and its role in patient safety.^{15,16} Differences in baseline scores across studies are plausibly explained by variation in setting, curriculum stage, sample size and instrument.

The practical implication is that pharmacovigilance and ADR reporting merit explicit, hands-on coverage within the D.

Pharm curriculum rather than incidental mention. Short interactive sessions, familiarisation with reporting forms and repeated exposure may help convert a positive attitude into sustained reporting behaviour, which is where under-reporting ultimately originates.

Limitations

Several limitations temper these findings. The single-group, single-centre design without a control arm means that improvement cannot be attributed to the intervention alone, as maturation, repeated testing and other influences cannot be excluded. The sample was small and drawn from one institution, which limits generalisability. Outcomes relied on self-reported knowledge and preparedness rather than objective, verified ADR-reporting behaviour, and the post-intervention assessment measured only short-term retention one month later. Larger, controlled studies incorporating objective reporting outcomes and longer follow-up are needed to confirm and extend these results.

CONCLUSION

A short, structured educational intervention was associated with significant short-term improvement in pharmacovigilance knowledge, attitude and self-reported ADR-reporting preparedness among D. Pharm students. Given the persistent problem of ADR under-reporting,

integrating focused pharmacovigilance teaching and practical reporting exercises into the D. Pharm curriculum may help build sound reporting habits early. The single-arm design and self-reported outcomes call for cautious interpretation, and larger controlled studies with objective reporting measures and longer follow-up are recommended to establish durable effects.

DECLARATIONS

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ANNEXURE: STUDY QUESTIONNAIRE

Annexure I – Knowledge questions

1. Are you familiar with the term pharmacovigilance? (Yes/No)
2. Do you think ADR reporting is important? (Yes/No)
3. Are you aware of the PvPI mobile application and toll-free number? (Yes/No)
4. Are you aware of any formal reporting system available in another country? (Yes/No)
5. Are you aware of any drug that has been banned worldwide due to an ADR? (Yes/No)
6. Have you ever shared information about ADRs with anyone? (Yes/No)
7. Identify the types of ADRs. (a) Type A–G (b) Type 1–7 (c) Known/unknown, common/uncommon (d) Reversible/irreversible (e) Do not know
8. Which of the following is the WHO online database for reporting ADRs? (a) ADR advisory committee (b) MedSafe (c) VigiBase (d) MedWatch (e) Do not know
9. What to report? (a) Serious adverse event (b) Adverse event (c) Adverse drug reaction (d) Side effect (e) All (f) Do not know
10. In India, which regulatory body is responsible for monitoring ADRs? (a) CDSCO (b) Indian Institute of Sciences (c) Pharmacy Council of India (d) Medical Council of India

Annexure II – Attitude questions

Rated on a five-point Likert scale (Strongly agree / Agree / Neutral / Disagree / Strongly disagree).

1. Is ADR reporting necessary?
2. Do you feel ADR reporting is time-consuming with no outcome?
3. Do you think reporting ADRs will increase patient safety?
4. Do you feel consulting the physician is important before reporting an ADR?
5. Do you agree pharmacovigilance should be taught in detail to healthcare professionals?

Annexure III – Practice questions

1. Have you ever seen an ADR reporting form? (Yes/No)
2. Can ADR monitoring help to promote rational use of medicines? (Yes/No)
3. Have you anytime read any article on prevention of ADRs? (Yes/No)
4. Have you ever come across an ADR? (Yes/No)
5. Is training on completing the ADR reporting form necessary? (Yes/No)



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