

DOI: <https://dx.doi.org/10.18203/2319-2003.ijbcp20251832>

Original Research Article

Knowledge, attitude and practice study on pharmacovigilance among nursing students and staff before and after a training session at a tertiary care hospital in India

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Received: 02 April 2025

Revised: 12 May 2025

Accepted: 14 May 2025

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ABSTRACT

Background: Adverse drug reactions (ADRs) contribute to significant morbidity, mortality and healthcare costs. Pharmacovigilance is essential for detecting and preventing ADRs in which nurses can play a key role. However, their involvement is very limited in this domain. The study aims to assess the knowledge, attitude and practices (KAP) among nursing students and staff regarding pharmacovigilance and the impact of a structured training session on them.

Methods: A quasi-experimental, cross-sectional study was conducted at a tertiary care hospital. Nursing students and staff completed a pre-validated questionnaire before and after a training session covering pharmacovigilance concepts and ADR reporting. Pre and post session responses were compared using basic statistics.

Results: Seventy participants (43 students, 27 staff) completed the study in which 54.3% reported no prior pharmacovigilance training. Post-training, the knowledge and awareness of ADR reporting procedures increased, with a positive attitude even before the session. The percentage recognizing ADR reporting as a nursing responsibility increased to 98.5%. While there were concerns of increased workload and legal consequences, 94.3% expressed interest in further training.

Conclusions: Training and awareness activity effectively increased KAP on pharmacovigilance among nurses. While knowledge and attitude improved, barriers exist for ADR reporting. Integrating pharmacovigilance into nursing education and addressing systemic challenges will positively impact drug safety awareness and monitoring. This study provides empirical evidence on the impact of focused training, supporting the development of strategies to improve pharmacovigilance awareness and reporting among nursing professionals.

Keywords: Adverse drug reaction, Attitude, Knowledge, Nursing, Practice, Pharmacovigilance

INTRODUCTION

Adverse drug reactions (ADRs) are a major public health concern as they are responsible for significant morbidity and mortality among the general population. ADRs lead to increased treatment costs and mortality risk, prolonged hospital stays and several other medical and financial repercussions. According to reports, adverse drug

reactions account for between 2.4% to 6.5% of all hospital admissions, many of which are preventable. The incidence of severe ADRs in India is 6.7%.¹ Additionally, in 3 out of every 1000 hospital admissions, the patient dies due to an ADR.² Hence, managing and preventing ADRs in the form of pharmacovigilance becomes essential for ensuring patient safety. The World Health Organization defines pharmacovigilance as the "science and activities related to

the detection, assessment, understanding and prevention of adverse effects or any other drug related issues".³ Pharmacovigilance programs are essential for detecting, assessing and preventing ADRs. The success of a pharmacovigilance program depends upon the active involvement of the healthcare professionals such as doctors, pharmacists and nurses.⁴ There are various national and international pharmacovigilance programs in place for this objective. WHO established an International Programme for Drug Monitoring in 1968, in coordination with the Uppsala Monitoring Centre (UMC) in Sweden. Started initially as a pilot program in 10 countries with established ADR reporting systems, the programme currently has participation from more than 180 countries and covers about 99% of the world's population.^{5,6} India became a member of the WHO programme in 1997 and in 2010, a robust system called the Pharmacovigilance Program of India (PvPI) was set up.⁷ As of 2021, PvPI has succeeded in establishing a nationwide network of 395 ADR Monitoring Centres (AMCs) across the country.⁸ Despite the existence of national pharmacovigilance programs, underreporting of ADRs still remains a concern. In India, the rate of ADR reporting is less than 1% compared to the global average of 5%.⁹ This suggests the need for more awareness on pharmacovigilance and ADR monitoring among healthcare providers such as doctors, nurses and pharmacists. The ADR reporting percentage of physicians is higher compared to other healthcare providers.

Nursing staff and students play a vital role in patient care and spend more time with patients. However, in case of any adverse drug reactions (ADRs), they generally report them to the treating physician, who, if needed, forwards the information to the relevant higher authorities.¹⁰ A study assessing ADRs in hospitalized patients revealed that physicians often overlook a significant portion of these reactions. Up to 40% of these might be identified with the use of data collected by nursing staff.¹¹ As overlooking an ADR could result in inappropriate treatment, utmost care should be taken in identifying and diagnosing ADRs. This furthermore highlights the vital role of nursing staff in ADR monitoring. However, their involvement in pharmacovigilance is often limited due to inadequate knowledge and training.

This study aims to assess the Knowledge, Attitude and Practices (KAP) regarding pharmacovigilance among nursing students and staff in a tertiary care hospital in India and to evaluate the impact of a structured awareness and training session on these parameters.

METHODS

A quasi-experimental, cross-sectional observational study was conducted to assess the knowledge, attitude and practices related to pharmacovigilance before and after a training session on the topic. The study took place at the newly established Government Medical College (GMC), Mumbai and was carried out in the nursing colleges

affiliated with Gokuldas Tejpal Hospital and Cama and Albless Hospital, both constituent institutions of GMC located in South Mumbai. The study was conducted between February and March 2025 and included nursing students and staff from various departments who attended a pharmacovigilance training session organized by the Department of Pharmacology. Only those participants who successfully completed both the pre- and post-training KAP (Knowledge, Attitude and Practice) questionnaires were included in the analysis. Participants who failed to complete either the pre or post-session questionnaire were excluded from the study. The sample size was calculated based on previous KAP studies and a convenience sampling technique was employed. As the institution did not yet have an established Institutional Ethics Committee, ethical approval for the study was obtained from the head of the institution and the principals of the participating nursing colleges.

A structured awareness and training session covering pharmacovigilance concepts, various aspects of ADR reporting and the importance of active participation of nurses in pharmacovigilance programme, was conducted by subject experts from the department of pharmacology. A pre-validated self-administered questionnaire containing 24 questions was used to assess the knowledge, attitude and practice in pharmacovigilance was used before (pre-KAP) and after (post-KAP) the educational activity. It contained 8 questions each from the three domains knowledge, attitude and practices. The participants were asked to respond to the same KAP questionnaire before and after the session. The responses, along with participants' initials and basic demographic information such as designation (student or staff), year of study for students and years of professional experience for staff were compiled into a Microsoft Excel spreadsheet for analysis. KAP questionnaires were analyzed question wise and their percentage value was calculated using excel spreadsheet. Results of the study were represented in the form of simple percentages and the changes from before and after the session were compared question-wise. Pre and post-training knowledge scores were compared using paired t-tests. A p value less than 0.05 was considered statistically significant.

RESULTS

Nursing students and staff totalling 70 participated in the study, including 43 student nurses, 14 early-mid career nurses and 13 senior-veteran nurses (Table 1). The mean age was 28.81 with a standard deviation of 11.72. 26 participants were nursing staff (37.1%) and 3, 20 and 21 nursing students were from first, second and third year of nursing education respectively. A clear majority (80%) were female and the rest 20 % were male nurses. 54.3% of the participants revealed that they have not received formal training in pharmacovigilance. The proportion of students correctly defining pharmacovigilance as "Science of detecting, assessing, understanding and preventing adverse drug reactions (ADRs)" was found to be 58.6% before the

session. The most common incorrect definition was “study of drug interactions” by 34.3%. The proportion of correct responses rose to 80% in the assessment following the training session (Figure 1). Similarly, the percentage of students correctly identifying the primary purpose of pharmacovigilance as “Detecting and preventing adverse drug reactions” changed from 70% to 77.1% post-training. Prior to the session, 70% of the participants defined an ADR correctly as a harmful and unintended response to a drug at normal doses. In the evaluation conducted after the training session, the number increased to 84.3%.

Before the session, only 35.2% of the subjects identified the Central Drugs Standard Control Organization (CDSCO) as the organization responsible for ADR monitoring in India whereas 29.6%, 21.1% and 14.1% answered World Health Organization (WHO), Pharmacy Council of India (PCI) and Indian Medical Association (IMA) respectively (Figure 2). The correct response percentage rose to 64.3% post-session (Figure 2). 78.6% were aware that in India, ADRs should be reported to the Pharmacovigilance Programme of India (PvPI) before the session and the number improved to 94.3% afterward. Before the activity, only 47.1% of the nursing staff and students were aware that nurses and other healthcare professionals can report ADRs. Notably, 17.1% believed only doctors can report ADRs and 18.6% believed only pharmacists can do so. After the lesson, 85.7% were correctly made aware that ADRs can be reported by nurses and other healthcare professionals (Figure 3).

A paired t-test was conducted to evaluate the impact of the intervention on mean knowledge scores (maximum score=8). The mean knowledge score significantly increased from 5.00 ± 2.04 before the intervention to 6.27 ± 1.86 after the intervention ($t=4.65$, $df=69$, $p<0.0001$) (Table 3). The mean difference was -1.27 (95% CI: -1.82 to -0.73), indicating a statistically significant improvement following the intervention. Prior to the training session, 18.6% were of the opinion that only life-threatening reactions need to be reported, 14.3% believed only reactions caused by new drugs need to be reported and 64.3% were aware that all suspected adverse drug reactions need to be reported. Post the session, 85.7% correctly understood that all suspected adverse drug reactions need to be reported. The proportion of correct responses toward knowledge of pharmacovigilance and ADRs is summarised in Table 2. The difference in correct responses before and after the training session was found to be significant ($p<0.05$).

Regarding attitude towards pharmacovigilance among nursing students, the observations were as follows: 91.4% and 98.5% of the participants considered reporting ADRs as an important responsibility of nurses before and after the activity respectively. Prior to and following the session, 90% and 97.1% opined that pharmacovigilance should be an essential part of nursing education respectively. 78.6% participants felt confident in identifying and reporting ADRs prior to the activity whereas the number climbed to

91.4% following it. Before and after the session, 75.7% and 90% nurses agreed that underreporting of ADRs is a major concern in healthcare. 80% and 95.7% suggested ADR reporting to be made mandatory for all healthcare professionals before and after respectively. 85.8% before and 94.3% after the session held the opinion that nurses should receive more training on pharmacovigilance. Regarding reporting ADRs, 52.8% participants were convinced that it increases workload and takes up too much time. 60% revealed they were worried about the legal consequences when reporting an ADR, however, this proportion reduced to 45% after the session.

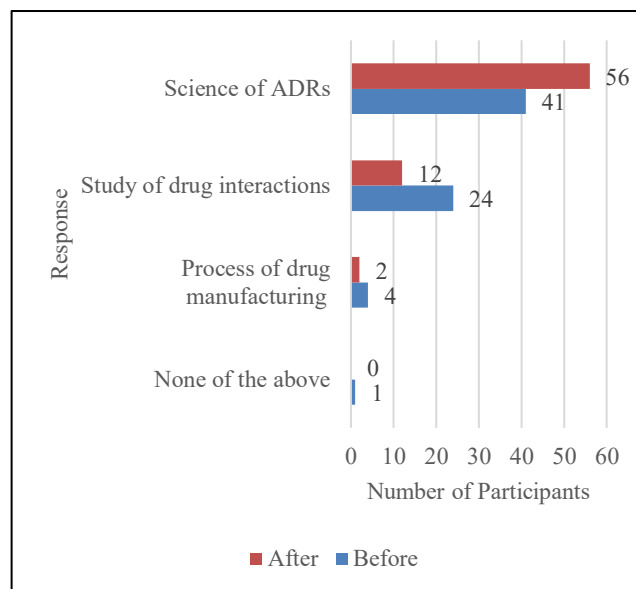


Figure 1: Response to the question ‘what is pharmacovigilance’ before and after the training session.

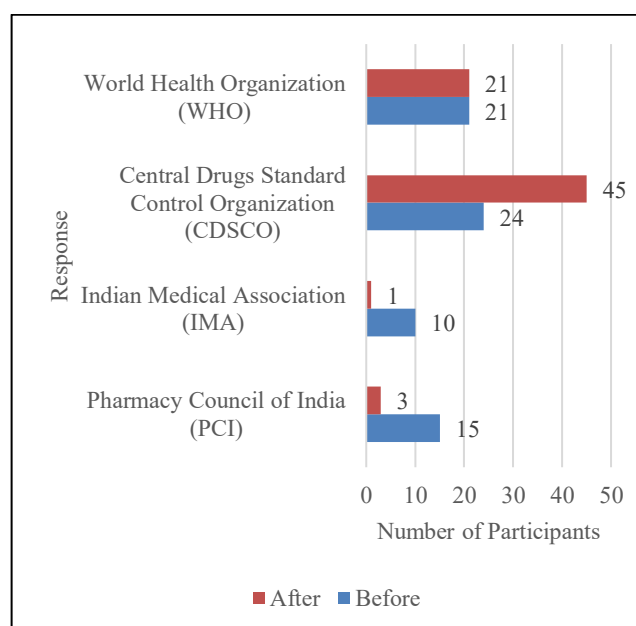


Figure 2: Responses to the question on organization responsible for ADR monitoring in India.

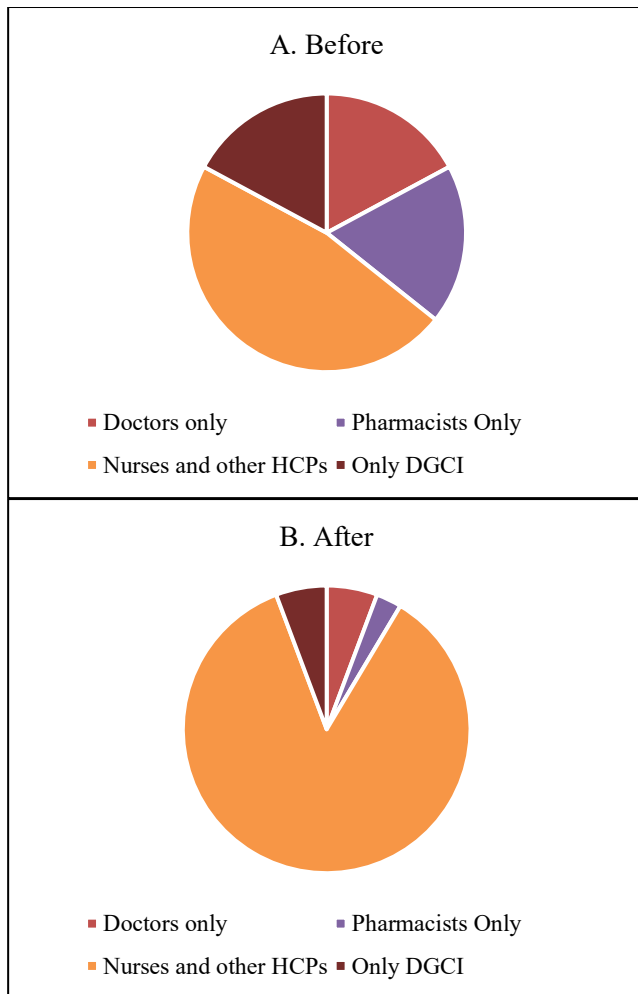


Figure 3 (A and B): Responses to the question 'which healthcare professionals can report ADRs.'

Coming to the practical aspect of pharmacovigilance, about half (51.4%) claimed that they have encountered an ADR during their clinical practice out of which 38.6% said they have reported an ADR. 54.3% of the participating nurses declared that they had been trained on how to report an ADR. Similarly, 54.3% stated that they always check for an adverse drug reaction while administering a medication while 11.4% declared they often do so and 17.1% revealed they sometimes do. 12.9% said they rarely check and 4.3% revealed they never do so.

In case of a suspected ADR, prior to the training session, 70% stated that they would report it to a senior nurse or doctor and 18.6% said they would report it to the pharmacovigilance center at the hospital. After the session, these numbers evolved to 48.6% and 44.3% respectively.

Before the activity, the most commonly cited challenge to ADR reporting was a lack of knowledge about pharmacovigilance (72.9%) followed by fear of legal consequences (18.6%). These changed post-training with 58.6% citing lack of knowledge and 31.4% stating lack of time and high workload as the common challenges while fear of legal challenges was reduced to a minor fraction.

Finally, an overwhelming 94.3% expressed interest in attending further pharmacovigilance workshops. Feedback from the participants indicated that the training session was well-received, with many expressing strong interest in additional lectures, workshops and refresher courses. Many suggested incorporating pharmacovigilance into the nursing curriculum and advocated for further practical and hands-on sessions to enhance their knowledge and skill in the pharmacovigilance domain.

Table 1: Age distribution and category of participants.

Age group (in years)	Category	Number of people
18-24	Students	43
25-34	Early career nurses	4
35-44	Mid-career nurses	10
45-54	Senior nurses	12
55+	Veteran nurse	1

Table 2: Correct response toward knowledge of pharmacovigilance and ADRs.

Question	Before session N (%)	After session N (%)
What is Pharmacovigilance?	41 (58.6)	56 (80)
Which of the following is the primary purpose of pharmacovigilance?	49 (70)	54 (77.1)
What does an Adverse Drug Reaction (ADR) mean?	49 (70)	59 (84.3)
Which organization is responsible for monitoring ADRs in India?	24 (34.3)	45 (64.2)
Where should ADRs be reported in India?	55 (78.6)	66 (94.3)
Which healthcare professionals can report ADRs?	33 (47.1)	60 (85.7)
What is the official reporting tool for ADRs in India?	54 (77.1)	44 (62.9)
What type of ADRs should be reported?	45 (64.2)	60 (85.7)

Table 3: Comparison of mean knowledge scores before and after intervention (n=70).

Group	Before session	After session
Sample size (N)	70	70
Mean	5.00	6.27
Standard Deviation (SD)	2.04	1.86
Standard Error of Mean (SEM)	0.24	0.22

DISCUSSION

The present study assesses the knowledge, attitude and practice (KAP) of nursing students and staff regarding pharmacovigilance before and after a structured training session on the same. Findings indicated a significant improvement in participant's understanding and awareness of adverse drug reactions and pharmacovigilance, which highlighted the effectiveness of such academic activities. Prior to the training, a major part of the participants has not received formal training in pharmacovigilance. Only 58.6% correctly understood the concept of pharmacovigilance and 70% correctly defined an ADR.

This was higher than that reported by Upadhyaya et al (34.83%) and Nisa et al, (26.4%, 34.6%), was comparable to Bhatt and Kumar (62.52%), but lower than findings of Reddy et al, (92%, 90%).^{4,12-14} The findings, consistent with previous studies highlights the gaps in pharmacovigilance knowledge among healthcare professionals who play a critical role in ADR reporting and patient safety.^{4,12,13} However post training session, a marked improvement was observed, with 80% and 84.3% correctly defining pharmacovigilance and ADR respectively. This underscores the importance of including formal pharmacovigilance training in the nursing curriculum in order to enhance the knowledge and subsequently patient safety.

A crucial observation from the study was an increase in the number of participants correctly identifying the central drug standard control organization (CDSCO) as the organization responsible for monitoring ADRs in India, from 35.2% to 64.3% following the awareness session. This was comparable to the finding of Goel et al, in which the correct response to the same question rose from 29.59% to 88%.¹⁵

Similarly, knowledge of the Pharmacovigilance Programme of India (PvPI) as the ADR reporting system also grew from 78.6% to 94.3%. This was similar to the trend observed by Hingorani et al, who observed an improvement of this knowledge from 71% to 94%.¹⁶ Similar trends were observed in the awareness of the ADR reporting form as the official ADR reporting tool, the types of ADRs to be reported and the categories of healthcare workers who can report them. These observations highlighted the lack of knowledge about the official ADR reporting mechanism and its functioning, which was effectively addressed through the training programme. It

further reinforces the need for such educational activities in order to strengthen pharmacovigilance awareness among the nurses. The attitude of the nursing students and staff towards pharmacovigilance was also assessed by the study, which revealed a positive perception even before the training session. The percentage of respondents who believed ADR reporting to be an important responsibility of nurses improved from 91.4 to 98.5% with support for making pharmacovigilance a fundamental part of nursing education increasing from 90% to 97.1%. This is consistent with similar study findings by Meher et al and Marko et al, which demonstrated favourable attitude of healthcare practitioners towards pharmacovigilance.^{17,18}

These findings along with a rise in confidence in identifying and reporting ADRs from 78.6% to 91.4%, show a strong inclination among the nursing students and staff towards adopting pharmacovigilance practices. Following the session, an increased number of participants believed that ADR underreporting is a major healthcare concern with more people advocating for ADR reporting to be made mandatory for all healthcare professionals and encouraging nurses to receive more training in pharmacovigilance. These trends indicate a strong positive change in the attitude towards pharmacovigilance and ADR reporting following an interactive training session which improves the knowledge in this domain.

Despite these advancements, there are still barriers to effectively reporting ADRs. Initially, 60% participants expressed concern regarding legal consequences and 52.8% believed reporting ADRs would lead to increased workload. This is in line with findings of Hingorani et al, who reported that 68% of participating nursing staff cited lack of time as barrier to ADR reporting.¹⁶

In terms of practice, 51.4% of participants had encountered an ADR in clinical settings, out of which 38.6% claimed to have reported the ADR. This is higher than the figures reported by Goel et al, who mentioned that 35.7% participants had come across an ADR, of which 54.3% participants had ever reported an ADR.¹⁵ 54.3% reported having prior training on ADR reporting, which is significantly higher than 4.1% as reported by Goel et al.¹⁵ The training session led to an increased understanding of reporting pathways, with more participants recognizing that ADRs should be reported to hospital pharmacovigilance centers rather than only to senior nurses or doctors. Encouragingly, an overwhelming 94.3% of participants expressed interest in attending further

workshops on pharmacovigilance, reflecting a strong demand for continuous learning in this domain. Overall, the study underscores the critical role of structured training sessions in enhancing the KAP of nursing students and staff regarding pharmacovigilance. While knowledge and attitudes improved significantly, practical barriers to ADR reporting remain a challenge. Future efforts should focus on integrating pharmacovigilance education into nursing curricula, addressing systemic challenges such as workload concerns and implementing user-friendly ADR reporting mechanisms to encourage active participation in drug safety monitoring.

The single-center design of this study limits the generalizability of the findings as the results may be different from that of other institutions or healthcare settings with different demographics, resources or training environments. In addition, the lack of follow-up in this study restricts the ability to evaluate long term impact of the training session on pharmacovigilance awareness and ADR reporting practices over time. Future studies aiming to evaluate the long-term effectiveness of such educational interventions should constitute multi-center designs, include larger and more diverse participant groups and adopt longer follow-up periods to enhance the generalizability of the findings.

CONCLUSION

Training interventions have been shown to significantly enhance the knowledge, attitudes and practices related to pharmacovigilance among nursing staff and students. The integration of structured pharmacovigilance modules into nursing curricula along with continued training programs, is vital for building a strong culture of ADR reporting among the nursing personnel. By offering concrete data on the immediate effects of focused training activities, this study contributes to the knowledge in the field and aids in the creation of effective strategies to improve pharmacovigilance awareness and reporting practices among nursing professionals.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Gafoor A, Mutha AS, Sahai J, Sankpal JT. Knowledge, attitude and practice study on pharmacovigilance among nursing students and staff before and after a training session at a tertiary care hospital in India. *Int J Basic Clin Pharmacol* 2025;14:492-8.