



## REVIEW ARTICLE

### TO ASSESS THE KNOWLEDGE AND ATTITUDE REGARDING ADVERSE DRUG REACTION REPORTING IN PHARMACOVIGILANCE

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#### ARTICLE INFO

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#### ABSTRACT

**Aim:** To assess the knowledge and attitude regarding adverse drug reaction (ADR) reporting in pharmacovigilance (PV) and to determine the effectiveness of structured training program (STP) on the knowledge and attitude regarding ADR reporting in PV among Undergraduate nursing students in a selected nursing college in Mysuru. **Materials & Methods:** A quantitative experimental research approach was employed for this study. The sample consisted of 60 undergraduate (UG) nursing students, selected through simple random sampling. The study tools, including a Structured Knowledge Questionnaire and an Attitude Assessment Scale/Questionnaire, were self-developed and pre-validated. Reliability of these tools was ensured using split-half and test-retest methods. Participants underwent a pre-test using these questionnaires before receiving a 1-hour STP on the topic of PV. Following the STP, participants completed a post-test using the same questionnaires. Subsequently, results of pre- and post-test questionnaires were compared to assess the differences. **Results:** There was an overall notable improvement in both the post-test knowledge and attitude scores compared to their corresponding pre-test scores. The difference between the mean knowledge and attitude scores before and after the STP was found to be statistically significant. Furthermore, the pre-test knowledge and attitude scores exhibited a positive correlation. Upon further exploration of the association between pre-test knowledge and attitude scores and selected personal variables, it was observed that the knowledge and attitude remained independent of most personal variables. However, gender emerged as a personal variable associated with attitude. **Conclusion:** Overall, the study findings demonstrated a significant improvement in the knowledge and attitude of UG nurses regarding ADR reporting in PV following administration of STP. This study underscores the critical role of nursing education in advancing patient safety initiatives as part of pharmacovigilance education. Furthermore, the study provides a foundation for further research and the development of effective training methods aimed at enhancing ADR reporting practices among nurses and other healthcare professionals.

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## INTRODUCTION

Adverse drug reactions (ADRs) pose a significant challenge for public health management due to factors like multiple comorbidities, polypharmacy, and the introduction of new drugs. ADRs are a major cause of patient morbidity and mortality.<sup>1</sup>In today's world, particularly in India, healthcare professionals, including nurses and doctors, lack awareness about pharmacovigilance (PV) and ADR reporting. Many are unaware of the benefits and outcomes associated with reporting ADRs.<sup>2</sup> Modern medicine has significantly transformed disease prevention and treatment. However, alongside their benefits, medicinal products can also have undesirable and unexpected side effects. Before being authorized for use, all medications, including vaccines, undergo rigorous safety and efficacy testing through clinical trials.

These trials typically involve a relatively small group of selected individuals studied over a short period. It's important to note that certain side effects may only become apparent when these products are used outside clinical trials, by a diverse population, including individuals with other concurrent health conditions and those taking multiple medications over an extended period.<sup>3</sup> When a new drug enters the market after standard clinical trials, its safety profile remains partially understood. While some side effects (ADRs) are known by then, others emerge over time in real-world settings. This is where PV and ADR reporting play a crucial role, allowing healthcare professionals such as doctors, nurses, and pharmacists to contribute significantly to the safe and effective use of medications. Despite global recognition of the significance of PV, there remains insufficient emphasis on ADR reporting in clinical and educational contexts among healthcare professionals, including nurses.

This lack of attention is concerning, and concerted efforts should be made to enhance nurses' PV skills and knowledge. There is limited amount of research done so far, which has explored nurses' readiness for a role in pharmacovigilance, including assessing their awareness, skills, and knowledge. In the Indian context, there is a dearth of literature on this topic, highlighting the need for further investigation. This research aims to explore the knowledge and attitude related to ADR reporting in PV among undergraduate nurses at a Nursing college in Mysuru. Additionally, the study assesses the effectiveness of an educational intervention designed to enhance their understanding of PV and ADR reporting, which could contribute to safer drug use. Another aim of this study was to explore the association between knowledge and attitude concerning ADR reporting. The study further investigated how the level of knowledge and attitude regarding ADR reporting correlates with specific personal variables among these undergraduate nursing students. The researcher hopes that this study and the educational intervention will inspire nursing students to actively engage in ADR reporting and encourage their peers and colleagues to do the same once they enter professional practice.

## MATERIALS AND METHODS

This research was carried out at a nursing college in Mysuru, following approval from the Institutional Ethics Committee. The study employed an experimental research approach, specifically utilizing the pre-experimental one-group pretest-post-test design. As part of the study design, a STP about ADR reporting was administered after the pretest. The study included a sample of 60 participants – 30 from final-year basic BSc and another 30 from final-year post-basic BSc, who were students at this nursing college. Simple random sampling was employed to choose these 60 participants, who were selected based on predefined inclusion and exclusion criteria. The participants were informed about the study's nature and purpose, and their consent was obtained. They were made aware of the voluntary nature of their participation. The study utilized self-developed, pre-validated, structured questionnaires that contained close-ended questions only.

A pilot study was conducted with 6 participants to assess the feasibility of the study tools and design and was found to be feasible. The final version of the questionnaires was distributed to study participants. Instructions on how to complete the questionnaires were provided. The knowledge questionnaire comprised 30 questions related to PV and ADR reporting. Correct responses were scored one point, while incorrect responses received zero points. The attitude questionnaire consisted of 15 questions. This was scored based on the Likert scale, with options that included 'strongly disagree', 'disagree', 'neutral', 'agree', and 'strongly agree.' Participants were given 1 hour to complete the questionnaires. Following this, a STP was conducted on PV and specific aspects of ADR reporting. Participants were asked to fill out the same questionnaires after the educational intervention. Pre- and post-test knowledge and attitude scores were compared to evaluate the impact of the training program.

## RESULTS

Of the 60 participants, majority were within the age group of 20-24 years and were female [Table 1].

**Table 1. Frequency and percentage distribution of participants according to their selected personal variables**

(n=60)		
Personal Variables	Frequency (f)	Percentage (%)
<b>Age (in years)</b>		
1.1. 20-24	57	95.00
1.2. ≥25	3	5.00
<b>Gender</b>		
2.1. Male	13	21.66
2.2. Female	47	78.34
<b>Course of Study</b>		
3.1. PBBSc	30	50.00
3.2. BSc	30	50.00
<b>Awareness about Pharmacovigilance</b>		
4.1. Yes	17	28.33
4.2. No	43	71.67
<b>Ever attended education program regarding ADR reporting in PV?</b>		
5.1. Yes	0	0
5.2. No	60	100.00
<b>Ever reported an ADR?</b>		
6.1. Yes	0	0
6.2. No	60	100.00

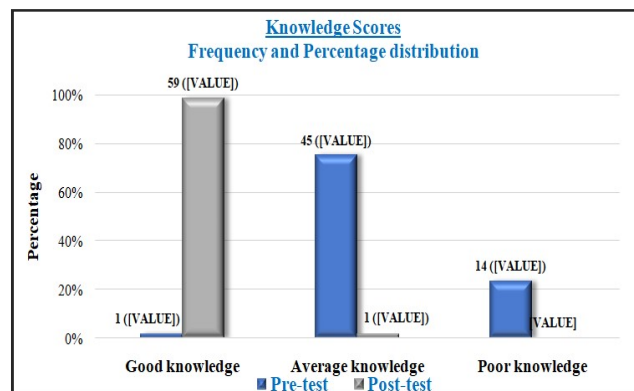
The study results indicated that after the STP intervention, the mean post-test knowledge scores improved significantly compared to their mean pre-test knowledge scores [Table 2].

**Table 2. Mean, Mean difference, Standard deviation difference, Standard error and paired 't' value of pre-test and post-test knowledge scores**

(n=60)					
Knowledge scores	Mean	Mean difference	S.D difference	Standard error	Paired 't' test value
Pre-test	13.07				
		14.06	±1.93	0.18	29.67*
Post-test	27.13				

$t_{(59)}=2.000$ ;  $p<0.05$  \*significant

Additionally, the post-test frequency and percentage distribution of knowledge scores among participants improved significantly across each of the knowledge categories (*good, average, poor*) compared to their pre-test knowledge levels [Figure 1].



**Figure 1. Frequency and Percentage distribution according to their level of Knowledge**

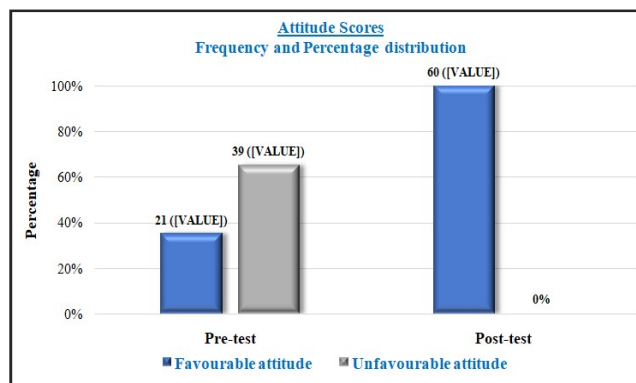
Similarly, the post-test attitude scores exhibited significant improvement when compared to their pre-test scores (Table 3). This positive trend was concurrent with the post-test frequency and percentage distribution of attitude scores, which also demonstrated significant enhancement across each of the attitude categories (*favourable & unfavourable*) (Figure 2). It is worth mentioning that the pre-test attitude scores of most participants were under the 'unfavourable attitude' category, which showed a major change following the STP.

**Table 3. Mean, Mean difference, Standard deviation difference, Standard error and paired ‘t’ value of Pre-test and post-test attitude scores**

Attitude scores	Mean	Mean difference	S.D difference	Standard error	Paired ‘t’ test value
Pre-test	43.67				
		20.33	±0.67	0.09	19.01*
Post-test	64.00				

(n=60)

t<sub>(59)</sub>=2.000; p<0.05 \*significant



**Figure 2. Frequency and Percentage distribution according to their level of attitude**

**Table 4. Correlation coefficient between pre-test knowledge and attitude scores (n=60)**

Variable	Correlation coefficient
Pre-test Knowledge and Attitude	0.59*

r<sub>(58)</sub>=0.2500; p<0.05 \*significant

**Table 5. Chi-square of the Knowledge level of participants regarding ADR reporting in PV with their selected personal variables (n=60)**

Variables	Average/Good Knowledge	Frequency	Percentage	Poor Knowledge	Frequency	Percentage	Chi-square value
<b>AGE</b>							
a)20-24 years	43	71.66%		14	23.33%		NA
b) ≥25 years	0	0.00%		0	0%		
<b>GENDER</b>							
a)Male	10	16.66%		03	05.00%		0.09 <sup>#</sup>
b)Female	36	60.00%		11	18.33%		
<b>COURSE OF STUDY</b>							
a) PBBSc	25	41.66%		05	08.33%		1.49
b) BSc	21	35.00%		09	15.00%		
<b>AWARENESS OF PHARMACOVIGILANCE</b>							
a) Yes	15	25.00%		02	03.33%		2.33 <sup>#</sup>
b) No	31	51.66%		12	20.00%		
<b>ATTENDANCE in any educational programme regarding ADR reporting in PV</b>							
a) Yes	0	0%		0	0%		NA
b) No	46	76.66%		14	23.33%		
<b>EVER REPORTED AN ADVERSE DRUG REACTION?</b>							
c) Yes	0	0%		0	0%		NA
d) No	46	76.66%		14	23.33%		

χ<sup>2</sup><sub>(1)</sub> = 3.841; p<0.05; <sup>#</sup> = Yates correction done; NA – not applicable.

The correlation coefficient, calculated using Karl Pearson’s coefficient of correlation, revealed a statistically significant association between the pre-test knowledge and attitude scores regarding ADR reporting in PV [Table 4] among the participants. Further examination of the data revealed no statistically significant association between the pre-test knowledge scores of participants concerning ADR reporting and their selected personal variables, including gender, course of study, and awareness of pharmacovigilance [Table 5]. The feedback from students in our study group on ADR reporting indicates that educational interventions have enhanced their knowledge and attitude towards ADR reporting practices. However, a significant limitation of this study is the relatively small sample size and the fact that only nursing students, not practicing nurses, were included. Consequently, these findings may not be generalizable to all nurses.

We recommend conducting similar studies across various institutions and hospitals to develop strategies for improving the knowledge, attitude, and practice of pharmacovigilance (PV) in India.

## CONCLUSION

The analysis of the findings of this study clearly indicated that the Structured Training Programme was effective in increasing the knowledge and attitude of UG nursing students regarding ADR reporting in PV. The study also revealed a statistically significant association between the pre-test knowledge and attitude scores concerning ADR reporting, implying that a higher knowledge regarding ADR reporting in PV was associated with positive attitude towards ADR reporting in PV.

It is also worth mentioning that there was no clear statistical association between the pre-test knowledge scores of participants about ADR reporting and their selected personal variables among these undergraduate nursing students. This study strongly suggests that there is a need of increasing awareness among the nurses to improve the reporting of ADRs. Adequate consideration needs to be given towards organising regular educational programmes and workshops regarding ADR reporting, which could improve the awareness of nurses regarding PV. Other strategies must also be developed for facilitating the ADR reporting culture in our country.

Finally, to conclude, undertaking educational programs aimed at increasing awareness about PV will be helpful in improving the status of ADR reporting, as evidenced by the results of this study.

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