



Original article

Effectiveness of a self-instructional module on knowledge, attitude, and practice regarding pharmacovigilance among staff nurses

Sudeshna Banerjee^a, Sumity Arora^{a,*}, Gigi John^a, Siddhartha Dutta^b, Raminder Kalra^a, Rita Sapra^c^a Holy Family College of Nursing and Hospital, New Delhi, India^b Department of Pharmacology, All India Institute of Medical Sciences, Jodhpur, India^c Sir Ganga Ram School of Nursing, New Delhi, India

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ABSTRACT

Introduction: Drugs with beneficial effects do come with adverse effects called adverse drug reactions (ADRs) which may even lead to fatal reactions. Hence, awareness about ADRs among healthcare professionals is an essential component for a healthy healthcare system.

Objective: This study was carried out to assess the effectiveness of a self-instructional module on existing knowledge, attitude, and practice (KAP) regarding pharmacovigilance.

Materials and methods: A quasi-experimental approach with a repeated-measure design was used to compare the pretest and posttest assessment. Based on the reviews of previous research articles and literature on pharmacovigilance, the KAP questionnaire and self-instructional module were developed. A total of 60 nurses were included in the study. Assessment was conducted using a validated and modified structured KAP questionnaire which included 35 items, 20 items to test knowledge, eight to test attitude, and seven to test practice. Thirty minutes was allotted to fill up the questionnaire. Filled-up questionnaires were collected after the pretest assessment, and the self-instructional module was given to the participants after the test. The participants were instructed to study the module properly for the next seven days. After the completion of seven days, the KAP questionnaire was readministered to them for posttest assessment.

Results: Posttest performance significantly improved compared with the pretest performance, indicating the effectiveness of the educational self-instructional module on pharmacovigilance.

Conclusion: The self-instructional module on pharmacovigilance should be given priority and become a regular mandatory learning component of the nursing staffs.

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1. Introduction

The safe use of medicines is an important aspect because it is associated with the health of the society. Reducing the incidence associated with adverse drug reactions (ADRs) is a crucial challenge in drug therapy. Despite the importance of medicine in the prevention and curing of diseases, its usage is sometimes associated with unintended adverse reactions and can lead to even fatal reactions.

An ADR is defined as a response to a drug which is noxious and unintended and occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function.¹ An ADR typically presents as an unforeseen event, and in the present scenario, it stands as a serious health concern.

ADRs are a problem of drug therapy because they are a leading cause of morbidity and mortality in the healthcare process. It has been seen that an ADR accounts for almost 2.9–5.6% of total hospital admissions, and in the inpatients, nearly 35% of the patients during their hospitalization encounter ADRs.^{2,3} ADRs have led to a major impact on the public health system, and it imposes an unnecessary and unreasonable economic burden on the society, as

* Corresponding author.

E-mail address: sumityarora@gmail.com (S. Arora).

well as on the patient, because most of the ADRs are preventable. The monitoring and surveillance of ADRs are performed by an operation called pharmacovigilance (Pv).⁴ Pv is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem.^{1,5} To prevent or reduce harm to patients, thereby improving public health, the safety of medicines in clinical use must be monitored and evaluated through specialized systems. This requires a need to establish a well-organized Pv system which can monitor the safety of approved drugs and detect any change to their risk-benefit balance.^{1,6} Because of the variation in drug response among individuals, various prescribing habits, drug regulatory system, and availability of drugs, it has been suggested that every country should set up its own Pv programs.⁷ The ultimate aim of Pv is to ensure safe and rational use of medicines. The most important outcome of Pv is the prevention of negative consequences of pharmacotherapy.⁵

Most of the countries in the world have established formal procedures to encourage healthcare professionals (HCPs) to report suspected ADRs. Spontaneous ADR reporting has been a major contributor of information in Pv and is considered the mainstay of the Pharmacovigilance Program of India (PvPI).⁶ In India, spontaneous reporting of ADR is not a common practice, and it is due to multiple factors. HCPs are considered as the linchpin in the Pv programme because they are the ones who deal with medicines on a day-to-day basis. Earlier, physicians were the only HCPs who were allowed to report the ADR, but today, the scenario has changed and different categories of HCPs such as nurses, pharmacists, and even patients can report an ADR. This step was taken to maximize the self-reporting of ADRs.^{8,9}

For adequate and proper reporting of ADRs, it is essential to have good knowledge, attitude, awareness, and practice among HCPs.¹⁰ In the present scenario, underreporting of ADRs is very common and is a matter of concern. Previous studies had shown underreporting of ADRs due to various reasons such as lack of knowledge and awareness about PvPI, lethargy, attitude, fear, etc.¹¹ The current scenario of ADR reporting in India seems to be inadequate because the ADR-reporting rate is below 1% as compared with the worldwide rate of 5%.¹² The most common reason for lower reporting rate can be attributed to lack of knowledge, awareness, and sensitization toward Pv and ADRs among HCPs.¹³

In India, a spontaneous reporting system of ADRs generates signals about new possible ADRs, and currently, it solely relies on the HCPs. Nurses play an indispensable role in ADR reporting and constitute a potentially valuable workforce for spontaneous ADR reports in hospitals.¹⁴ Nurses form a pivotal point in this context because during their professional hospital practice, nurses have close contact with the patient. They are responsible for the administration of the drug in inpatients and even the monitoring of medications. In view of their role in patient care and their ability to identify and report ADRs, nurses have immense potential to play a vital role in enhancing and propagating the Pv system.¹⁵ Very few studies have been conducted to assess the knowledge, attitude, and practice (KAP) of Pv among nurses.^{5,10,16,17} However, none of them used a self-instructional module as an educational intervention. With this background, this study was planned to assess the effectiveness of an intervention of a self-instructional module on KAP pertaining to Pv in nurses.

2. Methodology

The present study was conducted in Holy Family Hospital, New Delhi, India. The study was approved by the institutional ethics committee. Pretest and posttest design was used to study the effect of intervention. A sample of 60 nurses were selected who

consented for the study from the various departments of the hospital after a convenient sampling approach.

2.1. Study tools

To study the effectiveness of the intervention, following tools were developed:

(i). **KAP Questionnaire:** Based on the earlier studies,^{10,16–19} a KAP questionnaire was designed and validated before the start of the study. Content validity of the structured KAP questionnaire and the self-instructional module was established by submitting them to various experts in the field of medicine and nursing. Items were judged on the basis of objectives, relevance, and adequacy of content, organization, clarity, and understanding. The tool was finalized after the suggestions and modifications were incorporated. The internal consistency (reliability) of the questionnaire was tested by Cronbach alpha coefficient and Kuder-Richardson-20 coefficient. A pilot study was conducted to ensure the clarity, feasibility, and practicability of items. Refer to [Appendix 1](#) for the validated KAP questionnaire.

(ii). **Interventional Module:** This module was developed on the basis of reviews of previous research studies and literature on Pv^{1–3,6,7} which could enhance the knowledge and improve the attitude and practice of the staff nurses. The module was made as simple as possible and easy to understand. Contents of the module were validated by 11 experts, and the final version of the module included concise topics on introduction, basics of pharmacology, adverse drug reactions, Pv, and reporting of ADRs.

The validated and modified structured KAP questionnaire contained 35 items – 20 to test knowledge, eight to test attitude, and seven to test practice. The purpose of the study was explained to the respondents, and their written consent was obtained before filling up the questionnaire. Thirty minutes was allotted to each respondent for filling up the questionnaire. The maximum possible score was 20, 40 and 4 for KAP, respectively. The knowledge questionnaire included items to assess the knowledge of staff nurses regarding Pv, its purpose, detection, assessment, and prevention of ADRs.

A score of 1 was given for each correct answer and 0 for the wrong answer. For assessment of the knowledge, the obtained scores were divided as follows: (a) score 15–20, good knowledge; (b) score 9–14, average knowledge; and (c) score <8, poor knowledge. The attitude scale was assessed by a 5-point Likert scale ranging from 'strongly agree' to 'strongly disagree.' It comprised 8 items: 6 positive and 2 negative items. The scoring system for positive statements was as follows: strongly agree, 5; agree, 4; uncertain, 3; disagree, 2; strongly disagree, 1. The scoring system for negative statements was as follows: strongly agree, 1; agree, 2; uncertain, 3; disagree, 4; strongly disagree, 5. The practice questionnaire comprised 7 questions, with two options of 'yes' or 'no' relating to reporting of ADRs. A score of '1' was given for each correct answer and '0' for the wrong answer.

Filled-up pretest questionnaires were collected, and the self-instructional module of Pv was handed over to the selected nurses. They were also explained about Pv, and their queries were properly addressed. Furthermore, they were asked to study the module thoroughly for the next seven days. The enrolled nurses were contacted after a follow-up period of seven days. On the seventh day of follow-up, the KAP questionnaire was readministered for posttest evaluation. The data of pretest and posttest evaluation were compiled, entered in Microsoft Excel, and analyzed using SPSS, version 20. Demographic data were expressed as frequencies and percentages. Data of pretest and posttest evaluation were expressed as means and standard

Table 1
Frequency and percentage distribution of demographic characteristics of staff nurses.

S.No.	Demographic characteristics	Frequency	Percentage (%)
1.	Age (in years)		
	20–25	48	80
	26–31	6	10
	32–37	5	8.33
	>37	1	1.67
2.	Marital status		
	Unmarried	52	86.60
	Married	8	13.40
3.	Previous information regarding pharmacovigilance		
	Yes	8	13.30
	No	52	83.30

deviations. The student 't'-test was used to test the statistical significance of the difference between means of pretest and posttest scores.

3. Results

Sixty nurses participated in this study and were followed up for a period of seven days. There was no loss to follow-up. A majority, that is, 48 (80%), of the staff nurses were in the age group of 20–25 years, 6 (10%) in the age group of 26–31 years, 5 (8.33%) in the age group of 32–37 years, and 1 (1.67%) in the age group of more than 37 years. A majority, that is, 52 (86.60%), of the staff nurses were unmarried and 8 (13.40%) were married. A majority, that is, 52 (83.30%), of the staff nurses did not have any previous information regarding Pv. The demographic data are summarized in Table 1.

The knowledge pretest score was analyzed, and the minimum score obtained was two and maximum 19. The minimum attitude score was 25 and maximum 40. The minimum practice score was 1 and maximum 6.

The knowledge posttest score was analyzed, and the minimum score obtained was 14 and the maximum 20. The minimum attitude score was 31 and maximum 40. The minimum practice score was 4 and maximum 7. These findings were analyzed and are summarized in Table 2.

The mean posttest knowledge score was higher than the pretest knowledge score, and the difference was found to be statistically significant. The standard deviation of posttest (1.32) was lesser than that of pretest (4.21). This signifies that there is an increased homogeneity of scores after the administration of the self-instructional module. The mean posttest attitude score was higher than the mean pretest score, and their difference was found to be statistically significant. The mean posttest practice score was higher than the mean pretest score, and their difference obtained was found to be statistically significant. The pretest and posttest results are summarized in Table 2.

The present study clearly indicated that there was significant improvement in KAP scores compared with the pretest evaluation

Table 2
Comparison of pretest and post scores of the self instructional module on knowledge, attitude and practices of staff nurses. (N = 60).

Variable	Pre test Score	Post test Score	p-value
Knowledge	10.6 ± 4.21 (2-19)	18.45 ± 1.32 (14-20)	<0.01
Attitude	32.33 ± 3.20 (25-40)	37.90 ± 1.98 (31-40)	<0.01
Practice	3.91 ± 1.36 (1-6)	6.38 ± 0.69 (4-7)	<0.01

SD, standard deviation. Data expressed as mean ± SD (range).

regarding Pv after administration of the self-instructional module (Fig. 1).

4. Discussion

For a smooth and effective run of a Pv programme in any system, spontaneous ADR reporting seems to play a very critical role. Lack of knowledge among HCPs has been the biggest hurdle in the smooth running of the Pv programme. Because nurses being the HCPs who spend their maximum time with the patients, this study was conducted to assess the change in KAP on Pv after an intervention in the form of a self-instructional educational module. In the present study, most nurses were from the age group of 20–25 years which was similar to the study conducted by Palaian et al.¹⁵ and Chenchu and Rathinavelu.²⁰ It was evident from the present study that 83.3% of the nurses had no previous information regarding Pv. A low level of knowledge and awareness about Pv has also been observed by a number of research studies.^{5,14,15,19,20,22–25} As compared with other previous studies, the present study demonstrated comparatively higher ignorance of Pv among nurses. This could be due to a lack of awareness and teaching of Pv in the nurses' curriculum. The lack of a Pv cell or ADR-monitoring center in the hospital setup can be a reason for low level of awareness among them.

There was an increase in knowledge of staff nurses regarding Pv after administration of the self-instructional module ($p < 0.01$). The increase in the knowledge score in the KAP questionnaire suggested the module was effective in enhancing the knowledge of staff nurses regarding Pv. There was a significant change in the scores of attitude and practice of staff nurses regarding Pv after administration of the self-instructional module ($p < 0.01$). Thus, the study showed that the self-instructional module was an effective tool in creating awareness regarding Pv among the staff nurses. There were few studies whose results were in favor of our study results. A study conducted by Chandrakapure et al.²⁵ showed the effectiveness of an educational intervention continuing medical education (CME) on the KAP of staff nurses regarding Pv. A similar study conducted by Sarayani et al.²⁶ showed that educational interventions in the form of lectures can improve short-term learning, whereas retention of knowledge can be enhanced by simple interactive techniques. Studies^{17,27} showed that nurses and interns lack the knowledge regarding Pv and ADR-reporting system which was linked to their limited exposure to the pharmacology and related activities. The study by Hanafi et al.²² showed significant improvement of knowledge in nurses' after intervention of an educational programme. Fadare et al.²⁸ conducted a study which showed that only 42.7% of the respondents had ever reported an ADR and that the reports were verbally communicated by the HCPs in more than 75% of cases. The study conducted by Nadendla et al.²⁹ showed a significant rise of pretest and posttest KAP score from 78.5% to 93.3%, respectively, when intervened by an educational presentation. Rajesh et al.³⁰ conducted a study which documented that interactive educational interventions such as theoretical and practical intervention can improve the KAP of HCPs regarding Pv. A study conducted by Jha et al.³¹ demonstrated that an educational intervention such as power point presentation teaching can increase knowledge and change the attitude of the community pharmacists. Studies by Valente et al.³² and Conforti et al.³³ also stressed the importance of an educational interventional programme with increase in ADR reporting.

Underreporting of ADRs by nurses is predominantly due to the lack of knowledge regarding Pv among them and also the improper management of healthcare settings which should provide the appropriate environment to support them in performing this activity. The subject of Pv should be introduced in their teaching



Fig. 1. Figure showing the mean pretest and posttest score of knowledge, attitude, and practice of staff nurses before administration of the self-instructional module.

curriculum. Regular dedicated educational sessions and sensitization programmes may further help in upgrading their knowledge and ultimately help them in avoiding unseen eventualities for better health management.

5. Conclusion

The present study strongly emphasizes the need of Pv in view of its low level of awareness among the nursing professionals. The gravity of the situation demands its sensitization through teaching programmes, holding seminars, workshops, etc. So as to enable the nursing professionals to do their jobs with higher responsiveness in coping with the risk of ADRs.

Conflict of Interest

None.

Funding sources

None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.cmp.2019.05.001>.

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