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Original Article

The Impact of an Educational Module on Pharmacovigilance towards Improving Knowledge and Attitude of Nursing and Pharmacy Students

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ABSTRACT

Background: Pharmacovigilance is an integral part of patient safety and rational use of medicines. It is the professional responsibility of not just physicians but also of other health care professionals who use medicines such as nurses and pharmacists. Therefore it is essential to create awareness about pharmacovigilance through an educational module during their undergraduate course. **Objectives:** 1. To evaluate the knowledge and attitude of nursing and pharmacy students towards pharmacovigilance. 2. Based on the above, to design an educational module on pharmacovigilance. 3. To assess the impact of the educational module on knowledge and attitude towards pharmacovigilance. **Materials and Methods:** A cross-sectional study was conducted on nursing and pharmacy students pursuing pharmacology. A structured validated questionnaire consisting of 20 questions was used to assess the baseline knowledge and attitude. An educational module was designed and imparted to the participants. After a two week period the impact of the educational module was assessed. **Results:** The educational intervention significantly improved the knowledge of the nursing and pharmacy students about pharmacovigilance. The students had a positive baseline attitude towards pharmacovigilance which did not change much after the educational module. **Conclusion:** The knowledge of the nursing and pharmacy students improved significantly after the educational intervention. This highlights the need for such an educational module during their learning period so as to imbibe the safety culture and reporting practice early on in a healthcare professional's life. Periodical awareness activities for healthcare professionals to improve ADR reporting are however recommended for their sustained involvement in pharmacovigilance.

Keywords: Educational intervention, Learning, Pharmacovigilance, Nurses, Pharmacists.

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INTRODUCTION

Pharmacovigilance (PV) is defined by WHO as "the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problems."[1] It encompasses a range of activities such as the detection and reporting of adverse drug reactions (ADR), medication errors, counterfeit and substandard medicines, lack of efficacy of medicines, misuse and/or abuse of medicines, and drug–drug interactions.[2] An effective way to create a robust pharmacovigilance culture within the healthcare system is to involve all healthcare professionals, not just physicians but also nurses and pharmacists.[3-4] Nurses and pharmacists spend a great deal of time with medicines and patients in the inpatient and outpatient setting respectively. Nurses administer drugs and are in close contact with patients for a long duration and may often be in the best position to detect adverse effects and other problems with medicines.[5-6] A pharmacist's role is not limited to dispensing medicines alone, but includes medication counselling, improving compliance, monitoring safety and understanding of patients regarding the prescribed medicines.[7]

A majority of students in the healthcare profession (Medicine, Dentistry, Pharmacy and Nursing) start their clinical practice soon after graduation and are expected to prescribe, dispense, administer and monitor drug therapy routinely. In order to undertake these responsibilities efficiently and safely, these students should acquire basic knowledge about pharmacovigilance and issues in medication safety, have an attitude of 'do no harm' and acquire a reporting culture and essential skills in prescribing safely in their undergraduate curriculum.[8] The reality however is

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that in many healthcare curricula, pharmacovigilance is taught minimally or only about adverse effects.[9] This has often resulted in a low level of knowledge, inadequate skills and negative attitude related to pharmacovigilance not just in doctors but also in nurses and pharmacists.[10-12] These inadequacies accompanied by an ignorance towards the importance of pharmacovigilance and fear of legal liability are often responsible for the under-reporting of adverse drug reactions.[13-14] In order to improve the safety culture, it would be important to incorporate specific focussed learning modules in healthcare curricula for healthcare professionals. This should not just be for medical students, but other healthcare students also. To understand and improve the situation, a study was conducted with the following objectives:

1. To evaluate the knowledge and attitude of nursing and pharmacy students towards pharmacovigilance.
2. Based on the above, to design an educational intervention in the form of a learning module on pharmacovigilance
3. To assess the impact of the educational intervention on changing the knowledge and attitude towards pharmacovigilance.

MATERIALS AND METHODS

Setting: The study was conducted in Pushpagiri Group of Institutions, Tiruvalla, India. This group comprises colleges from various healthcare stream including medicine, dentistry, nursing and pharmacy. The study was conducted after obtaining approval from the Institutional Ethics Committee.

Study design and process: A cross-sectional questionnaire-based study was conducted on nursing and pharmacy students pursuing pharmacology during a period of 6 months. All the nursing and pharmacy students who gave their consent were included in the study. The process included the following steps:

Step 1: A structured validated questionnaire was administered to students to collect demographic details and assess baseline knowledge and attitude of these students towards pharmacovigilance. There were 20 questions in the questionnaire; out of which, 10 questions assessed knowledge and the remaining 10 assessed the attitude. The questionnaire also included space to give suggestions, views and other additional information. Once completed, the questionnaires were collected, analyzed and the results tabulated and interpreted.

Step 2: Based on the outcomes from the questionnaire, an educational intervention in the form of a module on pharmacovigilance was developed to impart further knowledge and improve the attitude of participants. The module was taught to the participants as a lecture using powerpoint presentation. The module focused on the definition, importance, scope of pharmacovigilance, the Pharmacovigilance programme of India, the stakeholders and details of the ADR reporting form.

Step 3: After a period of 2 weeks, a post-test with same questionnaire was administered. The data from post-test was tabulated and interpreted. The impact of the educational intervention was assessed by comparing the results of the pre-test and post-test for any change in knowledge and attitude of the participants.

Participants: There were 157 participants in the pre-test. Seven participants were not available on the day of post-test. Hence, there were 150 participants in the post-test. Participants were recruited after an informed consent process.

Statistical analysis: The data from the pre-test and post-test questionnaires was analysed using SPSS version 20. Paired t tests were used to compare knowledge of participants before and after the module. P value < 0.05 was considered significant.

RESULTS

Demographic Details

The demographic details of the participants are presented in Table 1.

Impact of the educational module on knowledge of the participants regarding pharmacovigilance

Pre-test: Baseline overall knowledge of the nursing students was 36.66% and of pharmacy students was 42.81%.

Post-test: After imparting the education module, the overall knowledge of the nursing students was 52.55% and of pharmacy students was 55.56%.

The overall impact of the educational intervention on knowledge of the participants regarding pharmacovigilance significantly improved for both nursing and pharmacy students *($p < 0.05$).*

After the educational intervention, the nursing students showed significant knowledge improvement in specific themes: the primary purpose of pharmacovigilance, individuals who can report ADRs and who benefit from ADR reporting, the start of The Pharmacovigilance Programme of India and the International body to which India sends its ADR reports *($p < 0.05$)* (Table 2).

After the educational intervention, the pharmacy students showed significant knowledge improvement in specific themes: individuals who can report ADRs and who benefit from it, the

Table 1: Demographic details of the participants.

	Pre-test (n = 157)	Post-test (n = 150)
Gender		
Male	13 (8.28%)	9 (6%)
Female	144 (91.71%)	141 (94%)
Mean age (years)	20.22	20.31
Professional status		
Nursing students	48 (30.57%)	44 (29.33%)
Pharmacy students	109 (69.43%)	106 (70.67%)

Table 2: Impact of the educational module on knowledge about pharmacovigilance.

	Nursing students		Pharmacy students	
Knowledge related questions	**Pre-test (correct response %)**	**Post-test (correct response %)**	**Pre-test (correct response %)**	**Post-test (correct response %)**
1. Pharmacovigilance definition.	35 (72.9)	37 (84.1)	78 (71.56)	77 (72.64)
2. Primary purpose of pharmacovigilance.	23 (47.9)	32 (72.7)*	85 (77.98)	80 (75.47)
3. Who can report adverse drug reactions?	19.75 (41.1)	25.75 (58.5)*	45 (41.28)	72 (67.92)*
4. ADR reporting should be done for?	15.5 (32.3)	13.25 (30.1)	33.5 (30.73)	40.25 (37.97)*
5. Who benefits from ADR reporting?	15.7 (32.7)	20.2 (45.9)*	36.6 (33.58)	51.35 (48.44)*
6. Components of ADR reporting form.	26 (54.2)	29 (65.9)	58.5 (53.67)	75.5 (71.23)*
7. Serious adverse event reporting timeline.	2 (4.2)	7 (15.9)	4 (3.67)	11 (10.38)*
8. In which year was The Pharmacovigilance Programme of India started.	15 (31.2)	26 (59.1)*	53 (48.62)	83 (78.3)*
9. In India, which regulatory body is responsible for monitoring ADRs.	22 (45.8)	17 (38.6)	66 (60.55)	71 (66.98)
10. To which international body, does India send its ADR reports.	(4.2)	24 (54.5)*	7 (6.42)	28 (26.42)*

*Indicates $p < 0.05$.

areas for which ADR reporting should be done, components of ADR reporting form, serious adverse event reporting timeline, the start of The Pharmacovigilance Programme of India and the International body to which India sends its ADR reports *($p < 0.05$)* (Table 2).

Impact of the educational module on attitude of the participants towards pharmacovigilance

Out of 10 questions used to assess the attitude of the participants, 3 were in the form of multiple- choice questions (Q1 to Q3) and remaining 7 questions (Q4 – Q10) had a 5-point Likert scale. The participants had a positive baseline attitude towards pharmacovigilance which did not change significantly after the educational module. However, there was a significant change in the question related to the pharmaceutical products which should be monitored for ADRs (Table 3).

DISCUSSION

Pharmacovigilance helps to improve patient safety and rational drug use. Anticipating, identifying, treating and reporting adverse drug reactions (ADRs) are an integral part of rational and safe prescribing, and are incorporated into the WHO-six-step Guide to Good Prescribing.[15] It is a professional obligation for all healthcare professionals. Although the Pharmacovigilance Programme of India (PvPI) was started in 2010, India's contribution in 2016 to the WHO global Individual Case Safety Reports (ICSRs) database was 3%.[16] This highlights the need for enhancing pharmacovigilance activities. Even though all healthcare professionals can report ADRs to National Co-ordinating centre (NCC-PvPI), physicians (56%) remained the major source of reported ADRs, followed by other healthcare professionals (19%), pharmacists (13%) and consumers (12%).[17] This signifies the need to involve healthcare professionals other than physicians in ADR reporting, and especially so considering the proximity of nurses and pharmacists to patients and medicines. This involvement should start in the early stage of one's career. Hence incorporating the need and purpose within a learning curriculum for students in these healthcare professions is important. This study was therefore conducted to understand the baseline awareness, knowledge and attitude of nursing and pharmacy students towards various aspects of pharmacovigilance and evaluate the impact of an educational module on their knowledge and attitude. Such an assessment would help to understand whether such a module would be useful within the learning curriculum of the student's degree programmes.

Before the educational intervention, the baseline overall knowledge of the nursing students and pharmacy students was low. This is similar to the findings of studies by Alwhaibi *et al.* and Bepari A *et al.*[18-19] After the educational intervention, there was a statistically significant improvement in their knowledge ($p < 0.05$). After any educational intervention, such a positive improvement is to be expected, but the overall improvement did not show a uniform improvement in various specific themes within pharmacovigilance. After the pre-test, gaps in the knowledge of the participants such as the primary purpose of pharmacovigilance, individuals who can report ADRs, the areas for which ADR reporting should be done, and serious adverse event reporting timeline were improved through the educational intervention. The relatively poor baseline knowledge highlighted the need to create awareness that all healthcare professionals have a role to play in pharmacovigilance. An overall module may need to be broken into multiple specific theme areas with practical examples so as to have a better improvement in knowledge and also for that knowledge improvement to be sustainable.

The attitude of the participants towards pharmacovigilance was mostly positive. A majority of them agreed that ADRs should be reported. Most of the participants felt that an ADR monitoring

Table 3: Impact of the educational module on attitude of the participants towards pharmacovigilance.

	Nursing students		Pharmacy students	
Attitude related questions	**Pre-test (correct response %)**	**Post-test (correct response %)**	**Pre-test (correct response %)**	**Post-test (correct response %)**
1. What type of ADR reporting system do you think is essential?	18 (37.5)	16 (36.4)	44 (40.37)	39 (36.79)
2. Which of the following pharmaceutical products do you think should be monitored for ADRs?	15.75 (32.8)	16.75 (38.1)	44.25 (40.59)	55.25 (52.12)*
3. How can one benefit from ADR reporting?	32 (66.7)	29 (65.9)	86 (78.89)	87 (82.08)
	(No. of participants who agreed %)	**(No. of participants who agreed %)**	**(No. of participants who agreed %)**	**(No. of participants who agreed %)**
4. Do you think reporting of ADR is needed?	47 (97.92)	43 (97.73)	105 (96.33)	102 (96.23)
5. Do you think ADR reporting is an obligation for healthcare professionals?	27 (56.25)	17 (38.64)	41 (37.61)	28 (26.41)
6. Do you think ADR reporting damages professional image?	34 (70.83)	36 (81.82)	75 (68.81)	88 (83.02)
7. Should an ADR monitoring centre be established in every hospital?	45 (93.75)	38 (86.36)	81 (74.31)	100 (94.34)
8. Is there a need for availability of information on ADRs and their management strategies within a hospital?	41 (85.42)	39 (88.64)	103 (94.49)	100 (94.34)
9. Do you think Pharmacovigilance should be taught to healthcare professionals?	37 (77.08)	36 (81.82)	96 (88.07)	95 (89.62)
10. Do you think conducting workshops/modules on Pharmacovigilance would improve ADR reporting?	40 (83.33)	37 (84.09)	101 (92.66)	99 (93.4)

*Indicates $p < 0.05$.

centre should be established in every hospital and information on ADRs and their management should be available. This reflected their willingness to contribute to pharmacovigilance. Comparable findings were described by other studies which reported the positive attitude of nursing and pharmacy students towards pharmacovigilance.[20-21] However, there was no significant overall change in the attitude of the participants after the educational intervention. Attitudinal change is often based on an emotional connect and when individuals experience it, they buy into a theme. This can be achieved through case studies within the educational module or by real bedside assignments.

A majority of the participants wanted pharmacovigilance to be taught during their undergraduate education so that they are able to recognise and report an ADR after graduation. This signifies the need for an educational module which can fulfil this learning need, and also help the student to form a safety and reporting culture for medicine use. Most also highlighted the need for regular workshops on pharmacovigilance to improve ADR reporting. This has been supported by a number of studies which showed that educational interventions have beneficial impact on ADR reporting.[22-23] However, several studies have highlighted that the improvement in knowledge and attitude of healthcare professionals was temporary and the practice of reporting ADRs improved only initially after such initiatives.[24-25] Therefore, it should be emphasized that constant efforts are essential for improving the pharmacovigilance practices of healthcare professionals by conducting regular workshops and training. These educational interventions are needed not just during degree programmes, but also as continuing education throughout a healthcare professional's career. Other strategies to sustain awareness and to facilitate ADR reporting include sending periodic emails and SMS alerts to healthcare professionals.

Promoting the culture of ADR reporting among healthcare professionals is a tedious process. It should be emphasized that awareness about pharmacovigilance should start early in undergraduate teaching and should be sustained during internship training. Along with academic knowledge, practical skills such as recognising and reporting ADRs, filling up an ADR reporting form, assessment of causality and severity of ADRs, and data entry in vigiflow should be included. It would also be important to showcase the role of all healthcare professionals in pharmacovigilance by highlighting important case studies in which their role has proved to have spotlighted important safety events. This would help to reinforce the need and build a platform for involvement among all healthcare professionals.

Strengths and Limitations of the Study

Our study is one among the few studies done to assess the impact of an educational intervention on the knowledge and attitude of nursing and pharmacy students towards pharmacovigilance. Since pharmacovigilance requires a team effort involving nursing and pharmacy staff, it is important to train the nursing and pharmacy students in pharmacovigilance so that they will contribute actively to ADR monitoring and reporting.

The major limitation of this study is that since the participants are students and not actively involved in pharmacovigilance, we

could not assess the practice-based aspects of pharmacovigilance. Another limitation was recall bias. This can be overcome by providing a longer interval between educational intervention and post-test.

CONCLUSION

The educational intervention through a learning module on pharmacovigilance had a significant impact on the overall knowledge of nursing and pharmacy students about medicine safety. The participants had a positive baseline attitude towards pharmacovigilance which did not change much following the educational intervention. This study shows the need to improve awareness among other healthcare professionals, especially pharmacy and nursing professions which have a close relationship with both patients and students. The need to inculcate this awareness as early as possible and within their student period is important due to the need to imbibe a safety culture and practice before dispensing or administering medicines at the start of a career. For this, an educational module with practical examples would be ideal within the curriculum. For sustained improvement in knowledge and attitude however, having such modules on a regular basis throughout one's career is our recommendation.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

ADR: Adverse drug reactions; ICSR: Individual Case Safety Reports; NCC: National Co-ordinating centre; PV: Pharmacovigilance; PvPI: Pharmacovigilance Programme of India; SPSS: Statistical Package for Social Sciences; WHO: World Health Organization.

Ethical approval

The Institutional Ethics committee has approved this study.

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