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Effects of an Educational Intervention on the Pharmacovigilance knowledge, attitudes, and practices of nursing students at a Saudi Tertiary Care Teaching Hospital: A Cross-Sectional Study

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Abstract - The ability to report adverse drug reactions (ADRs) is a critical competency for healthcare providers. Healthcare providers must enhance their pharmacovigilance (PV) and adverse drug reaction (ADR) reporting knowledge, attitude, and practice (KAP) if reporting rates are to increase. It has been shown in earlier research that nursing students do not have enough understanding about pharmacovigilance (PV) and how to report adverse drug reactions (ADRs). For that reason, researchers at a Saudi tertiary care teaching hospital set out to determine how pharmacovigilance education affected the beliefs, practices, and abilities of nursing students. A total of ninety nursing students from a Saudi Arabian tertiary care teaching hospital participated in this interventional investigation. We gave each participant an explanation of the study's goals and had them fill out a questionnaire about their pharmacovigilance knowledge, attitude, and practice. At the conclusion of the intervention, participants were asked to fill out the post-KAP questionnaire again, and the results were analyzed using a Chi-square test. With a ratio of 1:2, the study included 90 nursing students, with an average age of 21.52 ± 1.11 years. Prism v10.1.0 from Graph Pad was used to conduct all statistical computations. After the educational session, participants' attitudes towards pharmacovigilance changed significantly, and there were notable variations in their grasp of the topic between before and after the intervention. The percentage of students who were informed about pharmacovigilance and adverse drug reaction forms was much higher.

Keywords: Pharmacovigilance, Healthcare, Nursing, AdverseDrugReactions, Tertiary Care Teaching.

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INTRODUCTION

The administration of medications in a manner that is both appropriate and effective is one of the most essential aspects of modern clinical practice. In spite of stringent regulatory oversight and substantial clinical research, adverse drug reactions (ADRs) continue to be a significant contributor to the occurrence of severe illnesses and fatalities on a worldwide scale. The discipline of pharmacovigilance, which seeks to monitor, detect, assess, and prevent drug-related difficulties or adverse effects, is an essential component in the process of lowering the risks that are associated with the use of pharmaceuticals. Nurses and other members of the medical staff are in a uniquely advantageous position to assist the pharmacovigilance system by seeing and reporting adverse drug reactions (ADRs). This is because they are the first line of healthcare providers. [1]

The delivery of medications and the monitoring of patient reactions take up a significant amount of time for nurses, who often serve as the first line of defence in the healthcare system. They are very important in the field of pharmacovigilance due to the fact that they are acquainted with the process of medication administration and are in close proximity to patients. Due to the fact that research has shown that both nursing students and practicing nurses lack knowledge and awareness about pharmacovigilance and adverse drug reaction reporting, targeted educational interventions are required. [2]

Nursing education has a significant impact on the manner in which future nurses are instructed, how they think about pharmacovigilance, and how they conduct in connection to it. Incorporating pharmacovigilance ideas into nursing curricula and providing students with hands-on training on adverse drug reaction reporting systems are two ways that nursing students may be assisted in understanding their role in ensuring the safety of patients and making logical decisions about the use of medications. [3]

Educational treatments like as workshops, seminars, and hands-on exercises are examples of educational interventions that have garnered significant recognition for their usefulness in enhancing the knowledge of pharmacovigilance among healthcare personnel. A culture of vigilance is something that should be encouraged among healthcare personnel and nursing students. The aims of these interventions are to clarify reporting procedures, enhance knowledge of the relevance of adverse drug reaction reporting, and clarify reporting protocols. [4]

METHDOLOGY

- **Aim**

In order to determine how a Saudi tertiary care teaching hospital's educational intervention affected the pharmacovigilance knowledge, attitude, and practice of nursing students

- **Study layout**

After receiving clearance from _____, cross-sectional interventional research using questionnaires was carried out in an Saudi tertiary care teaching hospital. In Saudi, at the _____ Department of Pharmacology.

- **Sample Size**

As a rough estimate, we used 90 nursing students as our sample size; all participants were required to provide written informed permission before being included in the study.

- **Data gathering instrument**

After sending it out to a group of ten pharmacovigilance (PV) specialists, we were able to confirm its validity and implement their suggestions for improvement. Questions on pharmacovigilance knowledge, attitude, and practice were adopted from a self-developed and validated semi-structured questionnaire.

- **Procedure for Studying**

There was a total of 18 questions in the survey, 12 of which dealt with participants' knowledge, 3 with their attitude towards pharmacovigilance, and 3 with their actual reporting of adverse drug reactions (ADRs) encountered in the course of their work. The purpose of the survey was to gather demographic information. We made sure that everyone understood the study's goals and the questionnaire's contents before we started the intervention. The participants were given the guarantee that their personal information would remain private and that the data obtained would be used only for research. Twenty minutes were allotted to each participant to complete the questionnaire while the researcher watched. Question by question, the percentage value of the pre-KAP survey questionnaire was computed. These findings highlighted the critical need of raising awareness among those involved in this pharmacovigilance system. So, all participants were scheduled to attend a Continuing Medical Education (CME) presentation given by a panel of specialists with backgrounds in pharmacovigilance. It was strongly suggested that everyone involved make it to the talk. The investigator made an effort to invite all participants by stressing how important it was that they attend the presentation. It was requested that department heads urge their staff physicians to attend the meeting.

- **Intervention in education**

The three-hour class covered the following topics: what is pharmacovigilance, how adverse drug reactions (ADRs) are classified (based on factors like type, severity, causality assessment, and more), pharmacovigilance itself, a brief overview of the Pharmacovigilance Programme (PvP), and an opportunity to practice using ADR reporting forms. The ADR reporting form only takes five minutes to fill out, as stressed throughout the presentation. After the intervention was over, individuals were asked to fill out the post-KAP questionnaire again, and the results were studied.

- **Analytical Statistics**

Numbers and percentages (%) were used to convey the data wherever relevant. A chi-square test was used to examine the data collected before and after the intervention. Graph Pad Prism v10 was used for all statistical computations. Statistical significance was defined as a P value less than 0.05 (1.0).

RESULTS

Ninety nursing students filled out the pre- and post-intervention surveys. There were 30 men and 60 women that took part. The participants in this research had an average age of 21.52 ± 1.11 years and a standard deviation of 1.11.

Table 1: Details about the participants' demographics (n=90)

MeanAge	21.52 ±1.11
Females	66.66%

Males	33.33%

The educational intervention raised the level of knowledge about pharmacovigilance among nursing students to about 76%. Nevertheless, only 52% of nursing students had a working knowledge of what pharmacovigilance was prior to the instructional intervention. The educational intervention caused this to rise to 95%.

Only approximately a third of students were aware that Saudi had a mechanism in place to track adverse medication reactions before the educational intervention. Following the educational intervention, there was a statistically significant rise to 89% (P<0.0001).

Approximately eighty-five percent of nursing students had the belief that allopathic medications should include adverse drug reaction reports prior to the lesson. But few knew that traditional and herbal medicine adverse medication responses also needed to be recorded. Nursing students' knowledge of which medications need reporting of adverse drug reactions increased significantly after the educational intervention.

Table 2: What the Participants Knew About Pharmacovigilance (n=90)

Questions	Pre-Intervention (Yes/Correct)(%)	Post-Intervention (Yes/Correct)(%)	PValue
Can you tell me what pharmacovigilance is?	69 (76.67%)	90 (100%)	<0.0001
What does "pharmacovigilance" refer to?	47 (52.22%)	85 (94.44%)	<0.0001
Are you familiar with the term "adverse drug reaction"?	61 (67.78%)	85 (94.44%)	<0.0001
Are negative drug responses and negative drug events synonymous?	22 (24.44%)	75 (83.33%)	<0.0001
Is there a mechanism in place to track and report adverse drug reactions in Saudi?	30 (33.33%)	80 (88.89%)	<0.0001
Can you tell me where Saudi's Pharmacovigilance Centre is?	33 (36.67%)	88 (97.78%)	<0.0001
Is GMCH Nagpur an accredited pharmacovigilance reporting facility?	70 (77.78%)	88 (97.78%)	<0.0001
Have you ever needed to report an adverse drug reaction?	29 (32.22%)	86 (95.56%)	<0.0001
Which of the following adverse drug reactions (ADRs) need reporting?			
Traditional medical treatment	77 (85.56%)	81 (90%)	0.37*
Alternative and complementary medicine	47 (52.22%)	69 (76.67%)	0.0001
Blood-related goods	63 (70%)	74 (82.22%)	0.08
Medical and biological gadgets	44 (48.89%)	65 (72.22%)	0.0003
When it comes to reporting medication side effects, which of these medical professionals is most suited?			
Medical professionals	82 (91.11%)	88 (97.78%)	0.09
Dental professionals	51 (56.67%)	80 (88.89%)	<0.0001
Registered nurses	74 (82.22%)	88 (97.78%)	0.0004
Drugstore workers	66 (73.33%)	83 (92.22%)	0.0008
Physical therapists	26 (28.89%)	45 (50%)	0.0043
medical trainees	56 (62.22%)	61 (67.78%)	0.53*
Do I just need to report major or unexpected adverse drug reactions?	59 (65.56%)	62 (68.89%)	0.639*
Which Saudian regulatory agency keeps tabs on ADRs?	57 (63.33%)	77 (85.56%)	0.0006

Regarding knowledge of the procedure of reporting adverse drug reactions (ADRs), there was a notable increase from 32% before the intervention to 95% after the lecture (P < 0.001).

About eighty-five percent of participants held the belief that only allopathic medicine-related adverse drug reactions (ADRs) should be reported before the educational intervention began, whereas only a small percentage were aware that traditional and herbal medicine, blood products, biological and medical device ADRs should also be reported. On the other hand, everything looked much better after the intervention.

While the difference between the two groups was not statistically significant, 52% of participants after the lecture believed that reporting adverse drug reactions should be a professional requirement, compared to 28% before the intervention.

Table 3: Perspectives on Pharmacovigilance among the Subjects (n=90)

No.	Questions	Pre-Intervention (Yes/Correct)	Post-Intervention (Yes/Correct)	P Value
1	Is it your professional duty to report an ADR?	26 (28.89%)	47 (52.22%)	0.1141*
2	When reporting ADRs, which of the following should be in effect?			
	Mandatory	61 (67.78%)	32 (35.56%)	<0.0001
	Willing	18 (20%)	50 (55.56%)	<0.0001
	compensated	0	0	>0.99*
	Keep the prescriber's identity secret	8 (8.89%)	5 (5.56%)	0.56*
	Keep reporter's identity secret	4 (4.44%)	2 (2.22%)	0.68*
3	What role do you see for medical students in reporting adverse drug reactions?	81 (90%)	88 (97.78%)	0.0296

In general, after hearing the lecture, the participants felt as follows about adverse event reporting: that it should be mandatory (35%), voluntary (55%), paid 0%, that the name of prescribers should be hidden (5%), and so should the identity of reporters (2%).

42% of those who took the survey before the intervention reported seeing an ADR. Only 6% of patients had filled out CDSCO ADR reporting forms; this number rose to 51% and 66% after the intervention.

Table 4: Participants were given pharmacovigilance practice questions. (n=90)

No.	Questions	Pre-Intervention (Yes/Correct)	Post-Intervention (Yes/Correct)	P Value
1	Have you ever seen adverse drug reactions in a patient?	38 (42.22%)	46 (51.11%)	0.186*
2	Is CDSCO's ADR reporting form anything you've ever filled out?	6 (6.67%)	60 (66.67%)	<0.0001
3	Out of the following, which one makes you less likely to report adverse drug reactions?			
	Receiving no compensation for reporting	21 (23.33%)	20 (22.22%)	>0.999*
	Missing deadline for ADR reporting	34 (37.78%)	50 (55.56%)	0.018
	The ADR database could be unaffected by a single reported instance.	24 (26.67%)	27 (30%)	0.74*
	Challenging to determine whether ADR has taken place.	48 (53.33%)	62 (68.89%)	0.05

Participants were less likely to report adverse drug reactions (ADRs) when these criteria were included. The percentage of respondents who reported a lack of compensation as a discouraging factor dropped from 23.3% before the intervention to 22.2% after it. With a marked rise from 37.7% before the intervention to 55.5% after, the lack of time to report ADRs became a major problem. Furthermore, 26.6% of participants before the intervention and slightly more than 30% after it considered the possibility that a single reported instance could not substantially affect the ADR database. These results demonstrate that interventions have the ability to favorably affect healthcare personnel' attitudes about reporting adverse drug reactions.

DISCUSSION

The findings of this study demonstrate the significance of educational intervention in terms of enhancing pharmacovigilance knowledge, attitude, and practice. In addition, it highlights the need of teaching healthcare professionals and nursing students about the necessity of pharmacovigilance and adverse drug reactions in order to increase the number of instances in which these occurrences are seen and reported.

For the purpose of this study, the objective was to assess the impact that an educational intervention had on the pharmacovigilance and adverse drug reaction (ADR) monitoring knowledge, attitude, and practice of nursing students. Following the implementation of the intervention, there was a discernible and significant rise in the level of awareness about pharmacovigilance. This outcome is in agreement with the results of the research, which indicated that training interventions significantly improved chemists' comprehension of adverse drug reaction (ADR) reporting [5]. In a similar vein, educational interventions significantly improved the level of comprehension that medical students had about pharmacovigilance [6].

An improvement in understanding of the phrase "Pharmacovigilance" was seen following the intervention in the present experiment, and this improvement was statistically significant. According to the findings of the research, educational interventions significantly improved the level of understanding that resident doctors had about pharmacovigilance [19]. These results are consistent with those findings. "Similarly, research in underdeveloped nations found that pharmacovigilance knowledge improved following educational interventions" [7]

In addition, after the session, 88 (94.62%) of the participants were able to describe the importance of adverse pharmaceutical reactions, which is an increase from the previous percentage of 63 (67.74%). This provides further evidence that the findings of the study, which demonstrated that the pharmacovigilance knowledge of medical professionals greatly increased after the training intervention [8], are accurate.

As a result of the training, individuals' comprehension of the difference between adverse drug reactions and adverse drug occurrences significantly enhanced. There was a significant amount of ignorance among the participants, as shown by the fact that 84% of them were not aware that adverse pharmaceutical reactions and adverse events are not the same thing [9]. Prior to the implementation of educational interventions, the participants in this study had a much lower likelihood of being aware of the fact that adverse drug reactions (ADRs) may be reported by all members of the medical community, not only dentists and doctors. On the contrary, consequent to the lecture, there was a noteworthy rise in the percentage of participants who were aware of individuals who were capable of reporting adverse drug reactions ($P < 0.0001$). Graduate students believe that medical experts, nurses, and chemists are the right individuals to report bad drug reactions to. This conclusion is in line with the results of the survey, which demonstrate that graduate students have this perception. It is the number 10. It is very necessary for the paramedical personnel to actively participate in the reporting of adverse drug reactions (ADRs) in order to achieve the high reporting rates that are desired. Due to the fact that they spend more time with patients than doctors do, paramedical professionals are required to have a thorough understanding of who may report adverse drug reactions for treatment.

An examination of the professional obligation to report an adverse drug response (ADR) was carried out in this research; nevertheless, statistical significance was not attained. Prior to the intervention, 55.2% of participants held the belief that the reporting of adverse drug reactions (ADRs) ought to be a professional necessity. However, following the intervention, 70.31 percent of individuals had the same sentiment. It is [10]. The findings are in agreement with the pre-intervention opinion held by the respondents, which was that adverse drug reaction reporting is obligatory for only allopathic medications. Following the instructional session, the participants showed a shift in their opinions of themselves. It is essential to make nursing students aware that they are required to report any adverse reaction (ADR) that is associated with the use of medication. This is because a significant proportion of patients use medications that are derived from non-Western medical traditions, such as homoeopathy, unani, and ayurveda, and none of these treatments are fully free of adverse drug responses. This is the reason why this is the case.

The majority of respondents to the study are of the opinion that adverse drug reactions (ADRs) for newly developed medications need to be made public. In order to clear up this widespread misconception, there has to be an effort made. Adverse drug responses (ADRs) are of special interest to PV because to the fact that they may occur at levels that are employed for the prevention, diagnosis, or

treatment of illness, as well as for the change of physiological functioning. Therefore, adverse drug reactions (ADRs) that are caused by any medication must to be tracked out and recorded. According to the findings of the researchers, residents were more likely to report an adverse drug reaction (ADR) when they took a new prescription, which was 94% of the time [11]. The fact that the majority of participants were aware of the significance of medical students reporting adverse medication responses was another comforting aspect of the process.

It is important to note that, in a manner that is comparable to a study finding [12], there was an acknowledgment of the notion that adverse drug reaction reporting may be beneficial to both patients and doctors.

When students were asked about ideas to improve the number of adverse event reports, the majority of them supported making it necessary to report an adverse event. The vast majority of participants believed that it ought to be voluntary, and the percentage decreased after the intervention has been implemented. The findings of this investigation contrasted a study in which the subjects demonstrated a considerable improvement [13]. Fewer individuals participated in the poll.

Explored a number of strategies for increasing the number of adverse drug reactions (ADRs) that are reported, including as providing incentives for reporting and concealing the identity of prescribers and reports. Nearly half of those who participated in the survey said that they had never seen alternative dispute resolution (ADR) in operation. Despite the fact that six people, or six percent, had filled out an adverse drug reaction (ADR) reporting form by CDSCO before to the intervention, this percentage was much lower after the intervention. Following the implementation of the intervention, the number of participants had a substantial rise, reaching sixty (66.6%). This indicates that there was a noteworthy enhancement in the participants' active engagement in reporting adverse drug reactions to the CDSCO (P Value < 0.0001). following the intervention, there was a discernible increase in the number of times people filled out the CDSCO form. This was due to the fact that participants were given instructions to fill out the ADR reporting form during the lecture, and they were then reminded to do so following the intervention.[14] This is consistent with the findings of prior studies that shown that undergraduate medical students made considerable improvements in their ADR reporting behaviors. It has also been reported that there has been an increase in the number of adverse medication responses that have been reported by resident doctors.

Additionally, there were changes in the participants' views after the intervention, as shown by the examination of the factors that inhibit the reporting of adverse drug reactions for the participants. The number of individuals who were dissuaded from reporting adverse drug reactions (ADRs) caused by a lack of time dramatically increased, as did the difficulty in determining whether or not an ADR had occurred. On the other hand, concerns about the lack of compensation and the impact of a single reported occurrence on the adversarial dispute resolution database revealed only small changes. The participants' perspectives and issues about the characteristics that impede the reporting of adverse drug reactions (ADRs) altered both before and after the intervention, which is consistent. Both of these studies, which outlined the challenges and roadblocks that healthcare professionals encounter when attempting to report adverse medication reactions, highlighted the need of implementing targeted training interventions in order to address these issues. Additionally, workshops and telephone interviews were successful educational interventions that increased the amount and quality of adverse drug reactions (ADRs) that were spontaneously reported by chemists in industrialized countries such as Northern Portugal [15]. According to the shifts in participants' views that occurred after the intervention, there is an ongoing need for comprehensive educational interventions that are aimed at addressing the many factors that inhibit adverse drug reaction reporting.

CONCLUSION

Ultimately, this research shows that educational interventions are crucial for enhancing nursing students' understanding of pharmacovigilance and adverse drug reaction monitoring. As a result, healthcare providers should be required to complete pharmacovigilance training in order to enhance patient safety and lessen the impact of negative medication responses. To improve the status of ADR reporting, it is beneficial to increase knowledge about pharmacovigilance. The observations represent the influence of the intervention on participants' preferences and perceptions. They reveal how participants' views and thoughts about the essential aspects of ADR reporting changed over time.

Educational intervention was shown to be effective in this research in improving Pharmacovigilance's KAP. The incorporation of PV into medical practice needs to be a mandatory component of the existing academic curricula. Additionally, it might be helpful to display posters and make ADR reporting rules accessible in booklet form. Pharmacovigilance (PV) and ADRs (Adverse Drug Reactions) education should take precedence. By consistently delivering educational interventions to nursing students and other health personnel, the tertiary care center can enhance the frequency of adverse event reports. In order to make PV efforts in Saudi more effective, further research is required.

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