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EFFECT OF EDUCATIONAL INTERVENTION ON KNOWLEDGE ATTITUDE AND PERCEPTIONS ABOUT PHARMACOVIGILANCE AND ADVERSE DRUG REACTIONS REPORTING AMONG NURSING STUDENTS IN A TERTIARY CARE HOSPITAL IN SOUTH INDIA

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ABSTRACT: Background: Medication safety among patients is one of the important issues in the modern world. Pharmacovigilance Programme of India was introduced with the aim of safeguarding the people's health in India. Major limitations are underreporting and poor quality of reports. To strengthen the healthcare system, a multidisciplinary team of health care professionals is essential. Nurses are the persons who take part in the direct care of the patients and they must be aware of common ADRs and about reporting of the same and pharmacovigilance. **Aim:** This study aims to assess the awareness of Pharmacovigilance and Adverse Drug Reaction (ADR) reporting among the nursing students. **Methods:** This study was a Prospective and KAP questionnaire based Interventional study. An interactive educational intervention was designed in the form of power point presentation was delivered to the participants. Pre and Post tests were conducted before and after the presentation. **Results:** Participants knowledge about the pharmacovigilance was improved immediately after the educational intervention and there was some difficulty to retain after a month ($p<0.05$). Attitude and perception was improved after a month when compared to immediately after the educational intervention. **Conclusions:** The present study showed that the educational intervention improves knowledge and attitude about pharmacovigilance and ADR reporting system among nursing students.

INTRODUCTION: Medication safety among patients is one of the important issues in the modern world. Entry of various medicinal products into the market is increasing day-by-day [4]. None of these products is free of adverse reactions. ADRs are the significant causes of morbidity and mortality in both hospital and community set up [1].

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According to the World Health Organization (WHO), ADR is defined as "A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the modification of physiological functions" [16, 17].

Hence, the detection, recording and reporting of ADRs have become essential for the safe use of medicines. For this purpose, the concept of Pharmacovigilance (PV) was introduced, which is an important tool to identify the safety issues associated with the medication use and to improve the patient safety and therapeutic outcomes [16].

India is one of the largest markets for pharmaceuticals in the world with too many new drugs introduced regularly [4, 6]. However, even with a huge population, large number of hospitals, healthcare professionals and wider usage of drugs, only less number of ADRs is reported. This increases the need to improve ADR monitoring system in India. Pharmacovigilance Programme of India (PvPI) was introduced in July 2010, with the aim to safeguard the people's health in India. Major limitations of this programme are underreporting, inability to calculate the incidence of ADRs and poor quality of reports [5].

Apart from doctors, lots of other health care professionals are also involved in patient care system. To strengthen the healthcare system and to improve the quality of patient care, an integrated approach through a multidisciplinary team of health care professionals and other Para-medical staff is essential [1-4]. Nurses are the persons who take part in the direct care of the patients and when an ADR occurs they are the first person to be informed by the patients [3]. They must be aware of common ADRs and about reporting of the same and Pharmacovigilance [3].

Nursing students are directly involved in patient care. Sensitization of these students about Pharmacovigilance and ADR reporting system will reduce the limitations such as under-reporting, inability to calculate the incidence of ADRs and poor quality of reports [3]. This study is to assess the knowledge, attitude and perception about Pharmacovigilance and ADR reporting system among nursing students during their training period at a tertiary care centre in south India by an interactive educational module as an intervention [1-5].

MATERIALS & METHODS: This study was conducted at Government College of Nursing, The Nilgiris, Tamil Nadu, India. The Research proposal was discussed with the principal of the Institute and permission was obtained. The ethical approval for conducting this study was obtained from the Institutional Human Ethics Committee, Government Medical College, The Nilgiris. The duration of this study was 3 months from April 2023 to June 2023. This study was a Prospective and Knowledge, Attitude; Perception (KAP) questionnaire based Interventional study. The study participants are the nursing students (first, second and third year) who were studying in this college during the study period.

A self-designed, pre-validated pre-test questionnaire was used for data collection as a research tool in this study. KAP questionnaire consisted of two parts; First part included participant details and the later part included three sub divisions for knowledge, attitude and perception related questions and options. A total of 22 multiple choice and close-end type questions related to the Knowledge (9 questions), Attitude (8 questions), and Perception (5 questions) of ADR reporting and Pharmacovigilance were included.

Before the start of educational intervention, the students were given an introduction about the purpose of the study and consent was obtained; later pre-KAP questionnaire was administered and the students were requested to fill the questionnaire.

An interactive educational intervention was designed in the form of power point presentation by trained faculty and was delivered to the participants in order to facilitate the transfer of knowledge of Pharmacovigilance and ADR reporting. The educational intervention consisted of a theoretical presentation on what is Pharmacovigilance, its main objectives, adverse drug reactions reporting, Vigiflow database, incidence of ADRs, role of health care professionals, reporting of suspected adverse drug reaction followed by economic and epidemiological importance of reporting the ADRs and its effect on patient safety and causality assessment of ADRs. After the interactive educational intervention program on Pharmacovigilance, all participants of Pre-KAP questionnaire in the study was administered with Post-KAP questionnaire which was done at 0 and 30 days and it was analyzed, question wise and their responses were documented. The filled KAP questionnaires were evaluated as per the study objectives, the KAP scores were analyzed. The data obtained were entered in Microsoft excel spread sheet and evaluated. The impact of educational intervention on the awareness of Pharmacovigilance and ADR's reporting among the nursing students is evaluated.

All results obtained were entered in Microsoft excel and the statistical calculations were executed in SPSS. The p value ($p<0.05$) was considered to be statistically significant.

RESULTS: In total, 114 nursing students participated and all are females.

TABLE 1: NO. OF PARTICIPANTS INVOLVED AND AS PERCENTAGE

Year	N	%
First Year	44	38.6
Second Year	38	33.3
Third Year	32	28.1
Total	114	100.0

TABLE 2: KNOWLEDGE BASED QUESTIONS

Question	Pre-test n (%)	Post test 1 n (%)	Post test 2 n (%)	P value
1. Pharmacovigilance is (a) The science detecting the type and incidence of ADR after drug is marketed (b) The science of monitoring ADR's occurring in a Hospital (c) The process of improving the safety of the drug (d) The detection, assessment, understanding and prevention of adverse effects	47 (41.2)	96 (84.2)	95 (83.3)	Pre-test vs Post test 1 <0.001 Pre-test vs Post test 2 <0.001 Post test 1 vs Post test 2=1.000
2. The most important purpose of Pharmacovigilance is (a) To identify safety of the drug (b) To calculate incidence of ADRs (c) To identify predisposing factors to ADR's (d) To identify previously unrecognized ADR's	75 (65.8)	61 (53.5)	80 (70.2)	Pre-test vs Post test 1 =0.070 Pre-test vs Post test 2 =0.542 Post test 1 vs Post test 2=0.016
3. Which regulatory body in India is responsible for monitoring ADRs? (a) Central Drugs Standard Control Organization (CDSCO) (b) Indian Council of Medical Research (ICMR) (c) Indian Clinical Research Institute (ICRI) Medical Council of India (MCI)	37 (32.5)	98 (86.0)	89 (78.1)	Pre-test vs Post test 1 <0.001 Pre-test vs Post test 2 <0.001 Post test 1 vs Post test 2=0.175
4. Healthcare professionals responsible for reporting ADRs in a hospital is/are (a) Doctor (b) Nurses (c) Pharmacist (d) All of the above	87 (76.3)	96 (84.2)	108 (94.7)	Pre-test vs Post test 1 =0.163 Pre-test vs Post test 2 <0.001 Post test 1 vs Post test 2=0.012
5. A serious adverse event in India should be reported to the regulatory body within (a) One day (b) Seven calendar days (c) Fourteen calendar days (d) Fifteen calendar days	8 (7.0)	21 (18.4)	34 (29.8)	Pre-test vs Post test 1 =0.019 Pre-test vs Post test 2 <0.001 Post test 1 vs Post test 2=0.041
6. Which of the following scales is commonly used to assess the causality of an ADR's? (a) Hartwig scale (b) Naranjo algorithm (c) Schumock & Thornton scale (d) Karch & Lasagna scale	32 (28.1)	91 (79.8)	89 (78.1)	Pre-test vs Post test 1 <0.001 Pre-test vs Post test 2 <0.001 Post test 1 vs Post test 2=0.871
7. Which of the following is the 'WHO online database' for reporting ADRs? (a) ADR's advisory committee	17 (14.9)	99 (86.8)	88 (77.2)	Pre-test vs Post test 1 <0.001 Pre-test vs Post test 2

	(b) Med safe				<0.001
	(c) Vigibase				Post test 1 vs Post test 2=0.080
	(d) Med watch				
8.	**What is/are the mandatory information required to fill an ADR reporting form?**	65 (57.0)	83 (72.8)	80 (70.2)	Pre-test vs Post test 1 =0.003
	(a) Suspected drug				Pre-test vs Post test 2 =0.040
	(b) Suspected reaction				
	(c) Both a & b				Post test 1 vs Post test 2=0.766
	(d) None of the above				
9.	**A 50 years old female patient had a permanent disability due to drug X, which is a known ADR of drug X. She filed a case against the doctor who prescribed the drug X. How the ADR reporting system helps to that doctor in this case?**	33 (28.9)	21 (18.4)	15 (13.2)	Pre-test vs Post test 1 =0.073
	(a) Valid support				Pre-test vs Post test 2 =0.004
	(b) It is not useful in this case				
	(c) May used as supportive role only				Post test 1 vs Post test 2=0.362
	(d) No Idea				

Knowledge part contains nine multiple choice questions. These includes definition, purpose and functions of Pharmacovigilance, methods of causality assessment, ADR reporting and form filling.

Initially participants didn't know much about the Pharmacovigilance. But their knowledge improved immediately after the educational intervention which was shown in **Table 2.** Their knowledge about Pharmacovigilance was retained significantly which was evident by the post-test and after a month, there was some difficulty in retaining the already known facts and that was shown in **Table 2.**

TABLE 3: ATTITUDE BASED QUESTIONS

	Question	Pre-test N (%)	Post test 1 N (%)	Post test 2 N (%)
1.	**Do you think reporting of ADR is necessary?**			
	(a) Yes	83 (73)	95 (83)	105 (92)
	(b) No	11 (10)	6 (5)	3 (3)
	(c) May be	19 (17)	12 (11)	5 (4)
	(d) Don't know	10 (9)	1 (1)	0
2.	**Do you think the close monitoring of the drug is necessary?**			
	(a) Yes	63 (55)	86 (75)	92 (81)
	(b) No	19 (17)	15 (13)	13 (11)
	(c) May be	25 (22)	12 (11)	9 (8)
	(d) Don't know	4 (4)	0	0
3.	**What are your suggestions to improve the reporting of ADR in our country? *(Multiple answers)***			
	(a) Regular updates	52 (46)	69 (61)	63 (55)
	(b) Increase in number of AMC	11 (10)	20 (18)	20 (18)
	(c) Periodical review of reported ADRs	32 (28)	27 (24)	31 (27)
	(d) No idea	9 (8)	1 (1)	0
4.	**Do you agree that ADR's reporting system would benefit patient care?**			
	(a) Yes	14 (12)	21 (18)	36 (32)
	(b) No	41 (36)	55 (48)	46 (40)
	(c) Maybe	21 (18)	8 (7)	8 (7)
	(d) Don't know	31 (27)	28 (25)	19 (17)
5.	**Which of the following factor discourage you from reporting ADRs?**			
	(a) No remuneration	88 (77)	106 (93)	106 (93)
	(b) Lack of time to report ADR	5 (4)	3 (3)	0

	(c) (1)Fear / hesitation	12 (11)	4 (4)	6 (5)
	(d) Difficult to decide whether ADR has occurred or not	7 (6)	1 (1)	1 (1)
6.	**Herbal drugs have no ADRs. your view:**			
	(a) Yes	44 (39)	16 (15)	9 (8)
	(b) No	33 (29)	56 (49)	75 (66)
	(c) Maybe	25 (22)	13 (11)	25 (22)
	(d) Don't know	10 (9)	6 (5)	4 (4)
7.	**Can you consider vaccination induced reactions as ADR?**			
	(a) Yes	37 (32)	90 (79)	91 (80)
	(b) Not necessary	35 (31)	12 (11)	7 (6)
	(c) Maybe	21 (18)	8 (7)	13 (11)
	(d) Don't know	9 (8)	4 (4)	2 (2)
8.	**Are you interested in learning more about adverse drug Reactions?**			
	(a) Yes	104 (91)	107 (94)	114 (100)
	(b) No	7 (6)	5 (4)	0

Attitude part consists of eight questions. It includes what is their attitude about Pharmacovigilance and ADR reporting system. The result shows the participants know more about the importance of Pharmacovigilance and ADR reporting system after the educational intervention. Most of the participants suggested regular updates and periodical review of reports will improve the ADR reporting system [1-5].

Participants accepted the fact that ADR reporting will benefit the health care system by our educational intervention. Lack of remuneration is one of the important discouraging factors in ADR reporting system. Next to this factor, fear or hesitation plays the major role. Participants know that herbal drugs also cause ADR and vaccine induced reactions are also to be considered as ADRs through educational intervention [17]. Finally all the participants showed interest in learning more about Pharmacovigilance and ADR reporting system.

The importance of close monitoring of drugs and ADR monitoring in the patient care were improved in post test 2 when compared to post test 1. This shows that the participants might implement the points insisted by the educational intervention to their routine duties. Otherwise no significant changes were shown in between post 1&2 tests.

TABLE 4: PERCEPTION BASED QUESTIONS

Question	Pre-test N (%)	Post test 1 N (%)	Post test 2 N (%)
1. Have you identified/experienced any ADR?			
(a) Yes	45 (39)	66 (58)	90 (79)
(b) No	27 (24)	23 (20)	19 (17)
(c) Have not seen any ADR	32 (28)	24 (21)	4 (4)
(d) Don't know	4 (4)	1 (1)	0
2. How did you report an ADR?			
(a) To the ward doctor	48 (42)	10 (9)	22 (19)
(b) To the head of the AMC	17 (15)	9 (8)	4 (4)
(c) Online app through mobile	8 (7)	25 (22)	30 (26)
(d) Any of the above	40 (35)	70 (61)	58 (51)
3. Have you ever counseled a patient about ADR?			
(a) Yes, very frequently	51 (45)	66 (58)	22 (19)
(b) Yes, very rarely	39 (34)	28 (25)	4 (4)
(c) No	17 (15)	15 (16)	30 (26)
(d) Can't reveal	6 (5)	5 (4)	58 (51)
4. Are you able to report the ADR by yourself?			
(a) Yes	42 (37)	70 (61)	81 (71)
(b) No	16 (14)	5 (4)	10 (9)
(c) Needs support	56 (49)	39 (34)	22 (19)

5. A 45 year old male patient is admitted for acute exacerbation of asthma. He had experienced tremors of both hands following third day of admission. Following adequate supportive treatment he recovered on next day. The suspected drug was T. Salbutamol and the suspected reaction was tremors. What is the causality assessment in this case?			
(a) Certain	29 (25)	46 (40)	49 (43)
(b) Probable	22 (19)	24 (21)	15 (13)
(c) Possible	51 (45)	35 (31)	43 (38)
(d) Unlikely	8 (7)	9 (8)	7 (6)

Perception part has 5 questions. Only 39% of participants were able to identify or have experienced ADR before the intervention. This was increased to 58% immediately after the educational intervention. 4 weeks after the intervention, this was increased to 79%. 28% of the participants have not seen any ADR in pre test and this was reduced to 4% once the intervention was given. It shows that nursing students were able to identify the ADRs in their practice. They were willing to report through the ward doctors in pre test and after the intervention their thought was changed and most of the participants were willing to report through online application method.

DISCUSSION: The study showed that nursing students who participated in this study on Pharmacovigilance and ADR's reporting were satisfied with the intervention [13]. In our study, educational intervention was designed to increase the nursing students' awareness on Pharmacovigilance, regulatory bodies responsible for adverse drug reactions monitoring and the functions of ADR reporting system. This was demonstrated by an increase in the correct responses in pre and post-KAP questions (1 to 9) about Pharmacovigilance and ADR's reporting with statistical significance ($p<0.05$), after the educational intervention highlighting the impact on its effectiveness.

Q4 to Q8 in table 1, framed to obtain the knowledge of their roles and responsibilities in Pharmacovigilance and ADR reporting. The response rate is significantly($p<0.05$) increased in post test 1 & 2 when compared with pre test and some improvement in post test 2 and some decline in post test 2 because of the inability to retain the information. This result suggests that periodical sensitization programs about Pharmacovigilance and ADR reporting among nursing students will help to improve their knowledge and attitudes about Pharmacovigilance and ADRs. Total Pre-test scores on knowledge, attitude and perception when compared to total post-test 1 & 2 scores, there was a maximum increase in correct response rate and statistical significance ($p<0.05$) was observed after educational intervention.

Q1 & 2 of table 2, framed to know the attitude of the participants about the necessity of ADRs. After the educational intervention, most of the participants accepted that the ADR monitoring is necessary for patient care. Q5 showed the discouraging factors for monitoring and reporting of ADRs. An earlier study was conducted by Chaterjee *et al.* which stated that the main reason for under reporting of ADRs was the clinical negligibility of the adverse reaction due to lack of time and little knowledge about the types of reactions to be preferentially reported.

This study differ from our study by obtaining results as Lack of remuneration plays a major role and fear or hesitation plays the next one. After the intervention, the fear or hesitation reduced and it was shown in the results. The response rate of post test 1(5%) & post 2(2%) was reduced when compared to pre test (11%).

Q3 carries the suggestion to improve the ADR monitoring and the participants suggested regular updates and periodical reviews will improve the ADR reporting. Earlier studies by Suveges LG *et al*, Scolt HD *et al* and Zhang *et al* has also shown that educational intervention improved the awareness of Pharmacovigilance, ADR reporting on knowledge, attitude and practice of all healthcare professionals.

Q1 to Q4 of table 4 focuses the perception of nursing students about ADR monitoring and reporting. The response rate of Q1-4 was drastically improved in post test 2 when compared

with post test 1 and pre test. This shows that the participants who attended the study have applied the knowledge to their clinical practice.

The response rate of Q2 and Q4, improved in post test 2 when compared with post test 1 and pre test. This shows that the participants were able to identify the ADRs. They are also confident enough to report through any of the approved methods by themselves.

During educational intervention, methods of causality assessment were discussed with the participants. Q5 of table 4 carries a case scenario regarding causality assessment and the response rate was increased in post tests when compared with pre test.

Therefore we recommend that several such studies of similar kind should be conducted among all types of health care professionals so as to develop various strategies to improve the knowledge, attitudes, perception of Pharmacovigilance and ADR reporting.

CONCLUSION: In conclusion, results of the present study demonstrate that an educational intervention has the ability to increase the awareness of Pharmacovigilance and ADR reporting among the nursing students and to incorporate the same in their future clinical practice. The nursing students should be aware of the safety of marketed medicines.

Periodical updates, training programs and CME on Pharmacovigilance can be conducted among the various strata of health care workers in order to strengthen the ADR reporting system [1, 2]. Proper recognition and appreciation of the health care workers who report ADRs can also be done to encourage them.

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