

## Research Article

# An Educational Intervention to Assess Knowledge, Attitude and Practice of Pharmacovigilance among Nurses/Midwives at IIMSR Tertiary Care Teaching Hospital

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**Abstract: Introduction:** “Pharmacovigilance”: As per World Health Organization (WHO), “Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems”. An adverse drug reaction (ADR) has been defined as “any response to a drug that is noxious and unintended and that occurs at doses used in man for prophylaxis, diagnosis or therapy, excluding failure to accomplish the intended purpose”. **Materials and Methods:** This is cross-sectional, observational, questionnaire based study was carried out to evaluate the Knowledge, Attitude and Practice (KAP) among nurses/midwives working at Noor Hospital, Indian Institute of Medical Science and Research a tertiary care center towards ADRs and pharmacovigilance. **Results:** In our study, a total of 70 nurses/midwives were responded and involved in the pre - KAP and post- KAP survey questionnaires. The overall response rates between pre-intervention and post intervention was statistically significant nurses/midwives (P value <0.001) shows that effectiveness of educational intervention for improving awareness of pharmacovigilance among nurses/midwives. **Conclusion:** In conclusion of this study, the nurses/midwives had a relatively better attitude but lack of knowledge and least practices towards ADRs and Pharmacovigilance. The findings of the study suggest that there is need for continuous education and sensitization regarding Pharmacovigilance and ADR reporting system to nurses/midwives that improving the ongoing Pharmacovigilance activities in our hospital.

**Keywords:** Pharmacovigilance, adverse drug reaction, knowledge, attitude, practice.

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## INTRODUCTION

“Pharmacovigilance”: As per World Health Organization (WHO), “Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems [1]”. An adverse drug reaction (ADR) has been defined as “any response to a drug that is noxious and unintended and that occurs at doses used in man for prophylaxis, diagnosis or therapy, excluding failure to accomplish the intended purpose [2]”. An adverse drug event (ADE) is ‘any untoward medical occurrence that may present during treatment with a medicine, but which does not necessarily have a causal relationship with the treatment [3]’.

ADRs are negative consequences of drug therapy [4]. ADRs are common occurrences in a hospital setting, attributed to the severity and complexity of the disease process, the use of multiple drugs, drug interactions and possible negligence [5]. ADRs could be observed in 10-20% of hospitalized

patients and may be responsible for prolonged hospital stay [6]. Moreover, a plethora of new drugs are now available, for which reporting of unexpected and rare ADR rests mainly on the alertness of nurses/midwives [7]. ADRs reporting directly adds to increased vigilance and may even influence the recommendations of drug use through regulatory authorities or pharmaceuticals alike [8].

Many a times, nurses/midwives, being the first contact with patients throughout the day, also need to be sensitized regarding the reporting culture. Principles of safety of medicines are essential in nursery/midwifery practices which require the right medicine to be given to the right patient in the right way and dose, and at the right time. They observe the effects and adverse reactions of medicines after implementation and take interventions accordingly [9, 10]. Only a few studies evaluating the awareness of nurse/midwives regarding pharmacovigilance have been conducted [11, 12].

Apart from this, pharmacovigilance has been included in the medical undergraduate and postgraduate

pharmacology curriculum in many medical colleges in India. To inculcate, the culture of pharmacovigilance activities, the Medical Council of India (MCI) has made it mandatory to have functional pharmacovigilance unit in each medical college. In view of this, our institution has included pharmacovigilance in the medical teaching curriculum in pharmacology and is also one of the ADR monitoring centers (AMC) under the pharmacovigilance program of India. These efforts may develop knowledge and attitude among the future Health care professionals toward pharmacovigilance and ultimately may translate into increase in the ADR reporting.

Assessment of awareness of pharmacovigilance among the nurses/midwives is very important due to under reporting of adverse drug reactions. Therefore, this study will be conducted to assess awareness of pharmacovigilance among the healthcare professionals and will be evaluated the impact of an educational intervention for improving awareness of pharmacovigilance among nurses in an IMSR tertiary care teaching hospital.

## MATERIALS AND METHODS

**Study design:** Study design: A cross-sectional, observational, questionnaire based study was carried out to evaluate the Knowledge, Attitude and Practice (KAP) among nurses/midwives working at Noor Hospital, Indian Institute of Medical Science and Research a tertiary care center towards ADRs and pharmacovigilance.

### Study site

The study entitled “An Educational Intervention to assess Knowledge, Attitude and Practice of pharmacovigilance among nurses/midwives” was carried out in a 500-bedded tertiary care hospital located at Warudi, Tq. Badnapur, at Dist. Jalna.

### Study population and sampling

During the study period July 2019, there were a total of 70 nurses working in the hospital and they were approached to participate in the study. All of them were selected for study.

### Study tool

A questionnaire was developed comprising 25 questions, which included questions regarding demographic details, knowledge, and attitude regarding adverse reactions and pharmacovigilance. In addition, space was provided to give suggestions and furnish any additional information.

Initially Pre-Knowledge, Attitude and Practice (Pre-KAP) questionnaire was given to nurses about the purpose of the study and asked to submit the filled questionnaire answers. All nurses were provided with sufficient time of 20 minutes to fill the Pre-KAP questionnaire answers. An interactive educational

intervention was designed for nurses/midwives of Pre-KAP questionnaire survey in order to facilitate the transfer of knowledge of pharmacovigilance. The educational intervention was conducted into a theoretical part. The theoretical part consisted of a presentation on how to report a suspected adverse drug reaction followed by economic and epidemiological importance of reporting the ADRs and its effect on patient safety, as well as on the definition of pharmacovigilance, classification of ADRs (i.e. in terms of causality assessment, seriousness and severity, ADR reporting cards from various countries, ADR alert cards, WHO online database for reporting adverse drug reactions). The sessions were held by trained Assistant Professor and Professor in the field of pharmacovigilance research. Post-KAP questionnaire was given, after lecturer in the field of pharmacovigilance research.

## DATA COLLECTION

Prior approval was taken from medical superintendent and nursing superintendent to conduct the study. The nurses/midwives were informed about the aims of the study and their verbal consent was obtained before the study conduct.

### Data management and statistical analysis

To measure changes in the awareness of pharmacovigilance among the healthcare professionals between pre-intervention and post- intervention and to evaluate the impact of effectiveness of educational intervention among healthcare professionals, the chi-square test was used to compare the difference in correct responses for each question and a One-way Analysis of variance (ANOVA) was used for three or more group comparisons. All statistical calculations were performed using Statistical Package for Social Science (SPSS) Version 24<sup>th</sup>. The level of statistical significance was set at  $p < 0.05$ .

## RESULT

### Demographic characteristics

Demographic details of the participants involved in the study was categorized based on age distribution, gender distribution, educational qualification and work experience the results of which were thoroughly analyzed and reported in Table. 1. A total of 70 nurses/midwives was responded and involved in the Pre - KAP and post - KAP survey questionnaires in the study. The vast majority of respondents 58 (82.86%) were females, with males representing 12 (17.14%) of the total; this reflects the gender imbalance within health care services especially in the nursing field. It was found that average age of the nurse/midwives participating in the study was  $28.04 \pm 5.347$  years (range 20 to >35 years).

**Educational qualification of nurses/midwives**

Nearly one sixth of the respondents (n=8; 11.43%) had B.Sc. Nursing & PG, followed by ANM (n=20; 28.57%) & GNM (n=42; 60.00%).

**Duration of experience of nurses/midwives**

The duration of experience of nurses/midwives varied from less than one year to more than ten years months with a median (interquartile range) of 14.5 (6.0-36.0) months. Slightly more than one third (n=12; 17.14%) of respondents had a duration of work experience less than 1 year, and 1-5 years (n=37; 52.86%), 6-10 years (n=11; 15.71%), and more than 10 years (n=10; 14.29%).

**Table-1: Demographic characteristics of the participants**

Characteristics	Number	Percentage
<b>Age (28.04±5.347)</b>		
20-24	18	25.71
25-29	26	37.14
30-34	15	21.43
>35	11	15.71
<b>Gender</b>		
Male	12	17.14
Female	58	82.86
<b>Education</b>		
B.Sc. Nursing & PG	8	11.43
ANM	20	28.57
GNM	42	60.00
<b>Work Experience (In Yrs.)</b>		
<1	12	17.14
1-5	37	52.86
6-10	11	15.71
>10	10	14.29

**Table-2: Knowledge, attitude and practice of nurses/midwives towards Pharmacovigilance Questionnaires before and after educational intervention**

Q. No.	Questions	Pre-KAP Responses (%) N = 70	Post- KAP Responses (%) N=70	p-Value
1.	Define Pharmacovigilance?			
	a) The science of monitoring ADR's happening in a Hospital	8 (11.4)	1 (1.4)	
	b) The process of improving the safety of Drugs	9 (12.8)	2 (2.8)	
	c) The detection, assessment, understanding & prevention of adverse effects*	49 (70)	67 (95.7)	<0.001
	d) The science detecting the type & incidence of ADR after drug is marketed.	4 (5.7)	1 (1.4)	
2.	The most important purpose of Pharmacovigilance is			
	a) To identify safety of drugs*	31 (44.2)	52 (74.2)	0.06
	b) To calculate incidence of ADR's	12 (17.1)	4 (5.7)	
	c) To identify predisposing factors to ADR's	9 (12.8)	2 (2.8)	
	d) To identify previously unrecognized ADR's	18 (25.7)	6 (8.5)	
3.	Which of the following methods is commonly employed by the pharmaceutical companies to monitor adverse drug reactions of new drugs once they are launched in the market?			
	a) Meta-analysis	15 (21.4)	4 (5.7)	
	b) Post Marketing Surveillance (PMS) studies*	23 (32.8)	58 (82.8)	<0.001
	c) Population studies	21 (30)	5 (7.1)	
	d) Regression analysis	11 (15.7)	3 (4.2)	
4.	A serious adverse Event in India should be reported to the Regulatory body within			
	a) One day	21 (30)	2 (2.8)	
	b) Seven calendar days	11 (15.7)	1 (1.4)	
	c) Fourteen calendars days*	29 (41.4)	58 (82.8)	<0.001
	d) Fifteen calendar days	9 (12.8)	3 (4.2)	
5.	The international centre for adverse drug reaction monitoring is located in			
	a) Unites States of America	19 (27.1)	2 (2.8)	
	b) Australia	12 (17.1)	1 (1.4)	
	c) France	13 (18.5)	1 (1.4)	
	d) Sweden*	26 (37.1)	66 (94.2)	<0.001

6.	One of the following is the agency in Unites States of America involved in drug safety issues			
	a) American Society of Health System Pharmacists (ASHP)	17 (24.2)	4 (5.7)	
	b) United States food and drug administration* (US FDA)	23 (32.8)	62 (88.5)	<0.001
	c) American Medical Association (AMA)	19 (27.1)	3 (4.2)	
	d) American Pharmaceutical Association (APA)	11 (15.7)	1 (1.4)	
7.	One of the following is a major risk factor for the occurrence of maximum adverse drug reactions			
	a) Arthritis	21 (30)	3 (4.2)	
	b) Renal failure *	29 (41.4)	56 (80)	<0.05
	c) Visual impairment	7 (10)	7 (10)	
	d) Vacuities	13 (18.5)	3 (4.2)	
8.	In India which Regulatory body is responsible for monitoring of ADR's?			
	a) Central Drugs Standard Control Organization*	19 (27.1)	49 (70)	<0.05
	b) Indian Institute of sciences	16 (22.8)	8 (11.4)	
	c) Pharmacy Council of India	18 (25.7)	7 (10)	
	d) Medical Council of India	17 (24.2)	6 (8.5)	
9.	Which of the following scales is most commonly used to establish the causality of an adverse drug reaction?			
	a) Hartwig scale	23 (32.8)	2 (2.8)	
	b) Naranjo algorithm*	27 (38.5)	51 (72.8)	<0.05
	c) Schumock and Thornton scale	16 (22.8)	9 (12.8)	
	d) Karch & Lasagna scale	4 (5.7)	8 (11.4)	
10.	Which one of the following is the 'WHO online database' for reporting adverse drug reactions?			
	a) Adverse drug reaction advisory committee	16 (22.8)	3 (4.2)	
	b) Medsafe	19 (27.1)	5 (7.1)	
	c) Vigibase*	22 (31.4)	54 (77.1)	<0.001
	d) Med watch	13 (18.5)	8 (11.4)	
11.	Rare ADRs can be identified in the following phase of a clinical trial			
	a) During phase-1 clinical trials	11 (15.7)	11 (15.7)	
	b) During phase-2 clinical trials	13 (18.5)	12 (17.1)	
	c) During phase-3 clinical trials	25 (35.7)	8 (11.4)	
	d) During phase-4 clinical trials*	21 (30)	39 (55.7)	0.06
12.	The healthcare professional/s responsible for reporting adverse drug reaction in a hospital is/are			
	a) Doctor	16 (22.8)	3 (4.2)	
	b) Pharmacist	13 (18.5)	7 (10)	
	c) Nurses	19 (27.1)	6 (8.5)	
	d) All of the above*	22 (31.4)	54 (77.1)	<0.05
13.	Which among the following factor discourage you from reporting Adverse Drug Reaction? (Any one only)			
	a) Non-remuneration for reporting	11 (15.7)	2 (2.8)	
	b) Lack of time to report ADR*	23 (32.8)	61 (87.1)	<0.001
	c) A single unreported case may not affect ADR database	15 (21.4)	3 (4.2)	
	d) Difficult to decide whether ADR has occurred or not	21 (30)	4 (5.7)	
14.	Do you think adverse drug reaction reporting is a professional obligation for you?			
	a) Yes*	22 (31.4)	62 (88.5)	<0.001
	b) No	16 (22.8)	3 (4.2)	
	c) Don't know	18 (25.7)	1 (1.4)	
	d) Perhap	14 (20)	4 (5.7)	
15.	What is your opinion about establishing ADR monitoring centre in every hospital?			
	a) Should be in every hospital*	27 (38.5)	66 (94.2)	<0.001

	b) Not necessary in every hospital	13 (18.5)	2 (2.8)	
	c) One in a city is sufficient	16 (22.8)	1 (1.4)	
	d) Depends on number of bed size in the hospitals	14 (20)	1 (1.4)	
16.	Do you think reporting of adverse drug reaction is necessary?			
	a) Yes*	59 (84.2)	66 (94.2)	<0.05
	b) No	11 (15.7)	4 (5.7)	
17.	Do you think Pharmacovigilance should be taught in detail to healthcare professionals?			
	a) Yes*	54 (77.1)	67 (95.7)	<0.05
	b) No	16 (22.8)	3 (4.2)	
18.	Have you anytime read any article on prevention of adverse drug reactions?			
	a) Yes*	49 (70)	62 (88.5)	<0.05
	b) No	21 (30)	8 (11.4)	
19.	Have you ever come across with an ADR?			
	a) Yes*	67 (95.7)	67 (95.7)	-
	b) No	3 (4.2)	3 (4.2)	
20.	Have you ever been trained on how to report Adverse Drug Reaction (ADR)?			
	a) Yes*	39 (55.7)	70 (100)	<0.001
	b) No	31 (44.2)	0 (0)	

Correct Response\*

**Table-3: Responses of the nurses/midwives to the attitude towards Pharmacovigilance Questionnaires before and after educational intervention**

Question No.	Questions	Pre-KAP Responses (%) N = 70	Post- KAP Responses (%) N=70	p- Value
21.	Do you think reporting adverse drug reaction will increase patient safety?			
	a) Yes	54 (77.1)	67 (95.7)	<0.05
	b) No	16 (22.8)	3 (4.2)	
22.	Do you think it is necessary to confirm that an ADR is related to a particular drug before reporting it?			
	a) Yes	59 (84.2)	62 (88.5)	0.65
	b) No	11 (15.7)	8 (11.4)	
23.	Isn't lack of facilities to report ADRs in our hospital			
	a) Yes	49 (70)	68 (88.5)	<0.05
	b) No	21 (30)	2 (2.8)	
24.	Isn't lack of knowledge about report of ADRs in our hospital			
	a) Yes	57 (81.4)	66 (94.2)	0.15
	b) No	13 (18.5)	4 (5.7)	
25.	Isn't lack of time to report ADRs to pharmacovigilance center in our hospital			
	a) Yes	56 (80)	62 (88.5)	0.23
	b) No	14 (20)	8 (11.4)	

Correct Response\*

## DISCUSSION

This is the first study assessing the Knowledge, attitude, practice of pharmacovigilance among the healthcare professionals who attended educational training program on pharmacovigilance at the hospital where hospital based ADR reporting and monitoring system exist. The present study shows that

healthcare professional who attended theoretical and also practical part of educational intervention on pharmacovigilance are much satisfied with them and consider them very useful. This educational intervention program on pharmacovigilance encouraged nurses/midwives to enhance the relationship between them for reporting adverse drug reactions. The overall

results of the postKAP questionnaire in our study was encouraging among nurses/midwives and revealed that nurses/midwives enhanced awareness of reporting ADRs was reflected by an increased in the number of ADR reports submitted to Department of Pharmacology practice, after they had received educational training program on pharmacovigilance.

Studies have also shown that enhancing knowledge, attitude, and practice of improving awareness can increase the number of ADR reports [13]. This finding indicates in our study that educational intervention increased among nurses/midwives awareness of pharmacovigilance and able to transfer their gained knowledge into their everyday clinical practice. Although there are 25 post-KAP questionnaires that either encouraged or discouraged nurses/midwives to know more about pharmacovigilance in our study nurses/midwives (97.5%) have responded correctly to the definition of pharmacovigilance. This data suggests that continuing educational intervention is an important tool for increasing nurses/midwives awareness to pharmacovigilance. Based on our study results and the finding of Khalili H *et al.* and John LJ *et al.* recommend including “pharmacovigilance” as a topic in continuing education programmes and would also recommend a yearly repetition of such educational interventional program [14, 15]. It was also evident from our study that after educational intervention nurses/midwives are aware of not only importance of the national pharmacovigilance centers but also the international pharmacovigilance center for reporting ADRs.

In our study one focus of the educational intervention was to increase nurses/midwives to pharmacovigilance topics, regulatory bodies responsible for monitoring of ADRs and to explain on the causality assessment of ADRs. This was demonstrated by an increase in the correct responses in pre-and post KAP question from 20% before to 50.6% after the intervention from nurses/midwives. Question 9 from (table 1) nurses/midwives shows that 38.5% before to 72.5%. Our study strongly suggests that nurses are in need of information regarding the adverse effects of drugs especially information on occurrence of common and rare adverse drug reactions. We observed that nurses of our study have reported that their low level of clinical knowledge makes them difficult to decide whether ADR has occurred or not. This results in under reporting of ADRs among nurses.

Question 15 from (table 2) nurses shows that 32.8% before pre - KAP to 87.1% post- KAP, strongly suggests that there is great need to create awareness and to promote the reporting of ADRs among nurses. This was supported by a study conducted by Hanafi S *et al.* in which there is lack of satisfactory knowledge of pharmacovigilance among nurses and pharmacists should educate nursing staff in reporting and managing

ADRs [16]. It was also evident from our study that few nurses/midwives were found to be more aware regarding practice of pharmacovigilance this is because they were taught about detection, assessment, understanding and prevention of adverse drug reaction to a certain extent in their syllabus during graduation. This was supported by a study conducted by Upadhyaya P *et al.* which stated that doctors were less aware of the national and international pharmacovigilance programs [17].

In the literature, a lack of time and knowledge about ADRs is often considered to be a cause of underreporting [18, 19]. The results of the present study show that the factor discourage nurses/midwives from reporting ADRs was lack of time and types of reaction to be preferentially reported. This was supported by the study conducted by Desai CK *et al.* which stated that a 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 [20]. In India to date, ADRs have been reported primarily by pharmacists and physicians, but nurses can also play an important role. However, in a similar educational interventional program in pharmacovigilance study of Olsson S *et al.* showed that educational intervention improved awareness of knowledge, attitudes, practice of healthcare professionals towards practice of pharmacovigilance [21].

This study has two important limitations. Firstly, the study period was too short. Secondly, the study findings could not be applied to the wider medical community as the study was restricted to nurses/midwives practicing at hospital. Therefore, we recommend that several such studies of similar kind should be conducted among medical community, so as to develop strategies to improve the knowledge, attitudes, practice of pharmacovigilance in India.

## CONCLUSION

In conclusion of this study, the nurses/midwives had a relatively better attitude but lack of knowledge and least practices towards ADRs and Pharmacovigilance. The majority of the healthcare professionals felt ADR reporting and monitoring to be important, but only a few had ever reported an ADR. The major difficulties are don't have time and patient co-operation and discourages factors like managing patient more important than reporting ADR and legal issues from reporting by nurses/midwives. The findings of the study suggest that there is need for continuous education and sensitization regarding Pharmacovigilance and ADR reporting system to nurses/midwives that improving the ongoing Pharmacovigilance activities in our hospital.

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