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INTERACTIVE EDUCATIONAL MODULE: AN INTERVENTION AMONG NURSES ON KNOWLEDGE, ATTITUDE AND PRACTICE TOWARDS PHARMACOVIGILANCE AND ADR REPORTING AT A TERTIARY CARE HOSPITAL

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ABSTRACT

Nurse's knowledge and expertise is important to the application of drug safety profile. Nurses are more likely to report & detect adverse drug reactions than other healthcare professionals as they are the first point of contact to patients and doctors. The main objective of the study is to find out the effect of educational intervention among the nurses towards the knowledge, attitude & participation in reporting adverse drug reactions at tertiary care hospital in New Delhi. This study was conducted using validated Knowledge Attitude Practice (KAP) questionnaire. A total of 230 nurses responded, from the hospital. In Pre-KAP survey it was observed that hospital nurses lacked awareness about pharmacovigilance and needs to update their knowledge and practice. After intervention, a significant improvement in the knowledge, attitude and practice towards pharmacovigilance was observed among hospital nurses.

Keywords: Pharmacovigilance, Adverse Drug Reaction, Educational intervention, Hospital Nurses, KAP.

INTRODUCTION

The awareness about the adverse drug reactions (ADRs) in emergence of the practice of pharmacovigilance can be defined as the science of detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems[1,2]. It is widely accepted that a drug has to go through phases of clinical trial to establish its safety and efficacy before it is marketed. However, clinical trial offers various limitations, as it excludes some population groups such as children, pregnant women, and old age population during the trials. Moreover some other factors causing adverse drug reactions such as genetic factors, environmental factors, and drug-drug interactions may not have been studied during the clinical trials[3].

Medicines have changed the life by controlling and managing the diseases. Besides their tremendous benefits, ample evidence continue to mount regarding adverse drug reaction such as they may cause illness, disability and even death, when taken for illness. ADRs rank top 10 leading causes of mortality[4,5]. Aside from the intrinsic dangers associated with the products themselves, individual patients may exhibit particular and unpredictable sensitivities to certain medicines. The selection and use of the best and safest medicines for a given individual out of many choices available, thus requires considerable skill on behalf of the prescribing practitioner[6].

World Health Organization (WHO) defines Pharmacovigilance "as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems"[7]. ADRs accounts for 0.2 to 24 % of hospital admissions, 3.7 % of patients have fatal ADRs[8]. ADR leads to number of medical and economic consequences like prolong hospital stay, increase the cost of treatment and risk of death. Hence, early detection and prevention of ADR is necessary. The global interest in the monitoring of drug safety showed a remarkable increase in the last four decades especially after the thalidomide disaster in pregnant women in the sixties[9]. In India, National Pharmacovigilance Program of India (PvPI) is responsible for conducting activities related to ADR monitoring. Spontaneous reporting of ADRs by health professionals is the corner stone of pharmacovigilance. The health professionals have major contribution in signal detection of unsuspected and unusual ADRs previously undetected during the initial evaluation of a drug[10]. The major limitation associated with spontaneous ADR reporting system is underreporting[11]. It is estimated that only 6–10% of all ADRs are reported[12]. India rates below 1% in terms of ADR reporting[13]. This clearly emphasizes that the current status of pharmacovigilance in India is far from satisfactory. Assessment of awareness of Pharmacovigilance among the healthcare professionals is very important due to under reporting of adverse drug reactions. Although previous studies indicated that Nurses are pivotal players in ADR monitoring and reporting, most nurses are unaware or not knowledgeable about the guidelines used by their respective countries, drug regulatory bodies responsible for assessing ADRs[14,15]. As drug experts, Nurses should be equipped with the skills to prevent, identify, and resolve drug related problems and counsel patients on drug therapy[16]. The involvement of Nurses in pharmacovigilance programs is considered to be vital. Modern nurses consider Pharmaceutical care as their prime focus and play an important role in patient care. Ensuring the safe use of drugs is a combined responsibility of the healthcare team that includes doctors, nurses, and other supporting staffs[17]. As future nursing staffs need to be well trained on how to recognize, prevent and report ADRs.

OBJECTIVE

The aim and objective of this study is to evaluate and compare the knowledge, attitude and practice about Pharmacovigilance and ADR reporting among nurses at various hospitals by an interactive educational module as an intervention.

MATERIALS AND METHODS

This study was conduct by using validated KAP questionnaire after getting approval from Institutional Ethics Committee of Apollo Hospitals, New Delhi, India. The survey was carried from 3rd April 2014 to 3rd June 2014 where we personally approached nurses of T-care hospitals in Delhi with the validated KAP questionnaire.

Based on our previous studies on the nurses towards the pharmacovigilance[18], briefly, the reliability of validated KAP questionnaires was analyzed by conducting pilot study on 50 Nurses and calculating Cronbach Alfa value (0.823), in order to identify the Knowledge attitude practice of Nurses in Pharmacovigilance. The sample size (230) was calculated using Statistical Package for Social Science (SPSS) version 21.0 with the significant level P <0.001. The standard deviation (SD) between pre and post KAP score is 24 and the mean per cent difference is 4. The survey questionnaire was administered to 230 staff nurses, and belonged to different specialties practicing across the tertiary healthcare hospital in New Delhi. The final KAP questionnaire (Appendix I) consisted of 22 questionnaire out of which question number 1 to 13 were knowledge based, question number 14 to 19 were attitude based and question number 20 to 22 were practice based questions, designed specifically to answer the awareness about Pharmacovigilance. In order to preclude any potential bias the disclosure of name of the responder was made optional. All participants were also provided with sufficient time to fill the KAP questionnaire. KAP questionnaire was administered at the beginning of the study, in order to identify the knowledge attitude practice of Pharmacovigilance. The KAP survey questionnaire was analyzed, question wise and their percentage value was calculated.

The nurses were taught with the importance of pharmacovigilance and reporting of ADRs. The nurses were also trained on ADR handling, types of report includes serious, non-serious and various regulations pertaining to ICH guidelines and Good vigilance practices. Overview of Uppsala monitoring centre was also given. After one month of educational intervention for same set of nurses who filled Pre-KAP Questionnaire[18], Post-KAP Questionnaire were given and the data was compared.

RESULT AND DISCUSSION

The overall response of the Nurses in filling the KAP was not good and most of them didn't have enough time to answer all the questions. Among the 500 Nurses selected for the study, only 230 responded and were involved in the KAP survey. While

comparing the pre-KAP[18] study with the post KAP response, the following observations were seen.

The study was performed on 230 nurses from tertiary care hospitals and Pre- and Post-KAP questionnaire were distributed after intervention in Delhi to evaluate the knowledge, attitude and practice of Pharmacovigilance and the results are tabulated in **table 1** and **2.**

Question 1 sought information about definition of Pharmacovigilance. A Pre-KAP response rate for Question 1 for nurses were 44.34 % whereas for Post-KAP found to be 71.30 %.

Question 2 dealt with the important purpose of Pharmacovigilance. A Pre-KAP response rate for was 40.86 % whereas for Post-KAP found to be 60.43 %.

Question 3 sought information about methods commonly employed by the pharmaceutical company for monitoring ADRs of new drugs once they are launched in the market. Pre-KAP response rates nurses were 41.73 % while it was 72.60 % response for Post-KAP.

Question 4 investigated health care professional's awareness of reporting serious adverse events with regulatory body in India. Approximately 23.91 % of nurses gave correct Pre-KAP response whereas it was 75.65 % for Post-KAP.

Question 5 sought information about international center for ADRs monitoring and the Pre-KAP response rate for nurses were 17.39 % and it was found to be 60.43 % for Post-KAP.

Question 6 sought information about agency in United States of America involved in drug safety issues. Pre-KAP response rate from hospital nurses found to be 40 % whereas for Post-KAP it was 80.43 %.

Question 7 sought information about major risk factors for the occurrence of maximum adverse drug reactions. Pre-KAP response rate was 43.47 % and it was found to be 56.08 % for Post-KAP.

Question 8 investigated about the regulatory body responsible for monitoring ADRs in India. Pre KAP response rate was found to be 28.26 % whereas for Post KAP it was 69.13 %.

Question 9 sought information about most commonly used causality assessment of ADRs. According to the Pre-KAP data, 18.69 % of nurses gave correct response. 57.39 % nurses after Post-KAP survey gave correct response.

Question 10 investigated the ADR reporting system of the respective countries by means of match the following. In case of Pre-KAP nurses response for yellow card – United Kingdom 48.69 %, green card – Scotland 36.52 %, ADR reporting form – India 67.82 %, blue card – Australia 43.04 %. For Post-KAP nurses response for yellow card – United Kingdom 64.78%, green card – Scotland 60.00 %, ADR reporting form – India 79.56 %, blue card – Australia 11.30 %.

Question 11 sought information about knowledge of National Pharmacovigilance centre in India. Nurses responded as 46.95 % in Pre-KAP. Whereas it was 64.34 % for Post-KAP.

Question 12 investigated about WHO online data base for reporting ADRs. The percentages of correct response in Pre-KAP was found to be 26.95 % and for Post-KAP it was 59.56 %.

Question 13 sought information about rare ADRs that can be identified during which phase of a clinical trial. The percentages of correct response in Pre-KAP nurses was 7.39 %. And it was 45.21 % for post-KAP response.

Question 14 sought information about professional responsibility for reporting ADRs. The percentages of correct Pre-KAP response was 52.60 % and Post-KAP response was 93.47 %.

Question 15 investigated about factors discouraging them for reporting ADRs. In Pre-KAP survey 38.26 % of nurses from hospital found lack of time to report ADRs where as in Post-KAP survey it was 22.17 %.

Question 16 dealt about attitude of reporting ADRs. The percentage of correct response of Pre-KAP hospital nurses was 52.60 % and 72.72 % for the Post-KAP.

Question 17 investigated opinion about establishing ADR monitoring centre in every hospital. The percentage of correct response in Pre-KAP and Post-KAP questionnaire were found to be 70.86 % and 83.91 % respectively.

Question 18 sought information about attitude of nurses towards pharmacovigilance by means of 'yes' or 'no' questionnaires. The percentage of correct response for Pre-KAP Questionnaire was 90 % whereas it was 100 % in Post-KAP.

Question 19 also sought information about attitude of nurses towards pharmacovigilance by means of 'yes' or 'no' questionnaires. The percentage of correct response for Pre-KAP Questionnaire was 87.82 % whereas it was 99.1 % in Post-KAP.

The aim of the Question 20 was to assess health care professionals' perception and practice of reading articles on prevention of adverse drug reaction. It was found in Pre-KAP survey that only 29.56 % of nurses were in habit of doing this whereas after intervention 66.95 % nurses attitude was changed.

Finally, Questions 21 and 22 sought information about practice of pharmacovigilance by means of 'yes' or 'no' questionnaires. In case of Question 21, in Pre-KAP 23.83 % nurses respond 'yes' and after intervention it was 33.33 %. In case of Question 22, 12.43 % nurses responded 'yes' and it was 45.45 % after intervention.

A significant improvement in the knowledge, practice and attitude of hospital nurses towards reporting of ADRs was observed after educational intervention. (**Figure 1 to 5**)

CONCLUSION

In conclusion, there was a need for an educational intervention to increase the knowledge, awareness and to change the attitude towards pharmacovigilance. The nurses were educated with the importance and procedures for ADRs reporting. After intervention, by using post KAP analysis it was noticed that there was significant increase in term of knowledge, attitude and practices towards pharmacovigilance among the nurses.

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Table 1. Pre and Post KAP analysis to evaluate the knowledge, attitude and practice towards Pharmacovigilance among nurses.

S. No.	Question	Pre – KAP		Post – KAP	
		Nurses Response N=230	Percentage response	Nurses Response N=230	Percentage response
1.	**Define Pharmacovigilance**				
	The science of monitoring ADR's happening in a Hospital	48	20.86%	18	7.82%
	The process of improving the safety of Drugs	66	28.69%	39	16.95%
	The detection, assessment, understanding & prevention of adverse effects*	102	44.34%	164	71.30%
	The science detecting the type & incidence of ADR after drug is marketed.	14	6.08%	9	3.91%
2.	**The important purpose of Pharmacovigilance is**				
	To identify safety of drugs*	94	40.86%	139	60.43%
	To calculate incidence of ADR's	51	22.17%	34	14.78%
	To identify predisposing factors to ADR's	61	26.52%	42	18.26%
	To identify unrecognized ADR's	24	10.43%	15	6.52%
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**				
	Meta analysis	81	35.21%	29	12.60%
	Post Marketing Surveillance (PMS) studies*	96	41.73%	167	72.60%
	Population studies	38	16.52%	24	10.43%
	Regression analysis	15	6.52%	10	4.34%
4.	**A serious adverse Event in India should be reported to the Regulatory body within**				
	One day*	55	23.91%	174	75.65%
	Seven calendar days	87	37.82%	22	9.56%
	Fourteen calendar days	50	21.73%	16	6.95%
	Fifteen Calendar days	38	16.52%	18	7.82%
5.	**The international centre for adverse drug reaction monitoring is located in**				
	Unites States of America	128	55.65%	56	24.34%
	Australia	28	12.17%	15	6.52%
	France	34	14.78%	20	8.69%
	Sweden*	40	17.39%	139	60.43%
6.	**One of the following is the agency in Unites States of America involved in drug safety issues.**				
	American Society of Health System Nurses (ASHP)	25	10.86%	11	4.78%
	United States food and drug administration (US FDA)*	92	40%	185	80.43%
	American Medical Association (AMA)	59	25.65%	14	6.08%
	American Pharmaceutical Association (APA)	54	23.47%	20	8.69%
7.	**One of the following is a major risk factor for the occurrence of maximum adverse drug reactions**				
	Arthritis	56	24.34%	46	20.00%
	Renal failure*	100	43.47%	129	56.08%

	Visual impairment	53	23.04%	35	15.21%
	Vasculitis	21	9.13%	20	8.69%
8.	**In India which Regulatory body is responsible for monitoring of ADR's**				
	Central Drugs Standard Control Organization*	65	28.26%	159	69.13%
	Indian Institute of sciences	42	18.26%	21	9.13%
	Pharmacy Council of India	108	46.95%	41	17.82%
	Medical Council of India	15	6.52%	9	3.91%
9.	**Which of the following scales is most commonly used to establish the causality of an ADR**				
	Hartwig scale	78	33.91%	40	17.39%
	Naranjo algorithm *	43	18.69%	132	57.39%
	Schumock and Thornton scale	85	36.95%	46	20.00%
	Karch & Lasagna scale	24	10.43%	12	5.21%
10.	**Match the ADR reporting systems to the respective countries.**				
	1) Yellow card - United Kingdom	112	48.69%	149	64.78%
	2) Green card – Scotland	84	36.52%	138	60.00%
	3) ADR reporting Form - India	156	67.82%	183	79.56%
	4) Blue card – Australia	99	43.04%	141	61.30%
11.	**One among these is a national Pharmacovigilance centre**				
	Kasturba Hospital, Manipal	46	20%	26	11.30%
	AIIMS Delhi*	108	46.95%	148	64.34%
	JSS Medical College & Hospital, Mysore	51	22.17%	35	15.21%
	CMC, Vellore	25	10.86%	21	9.13%
12.	**Which one of the following is the 'WHO online database' for reporting ADRs**				
	ADR advisory committee	111	48.26%	58	25.21%
	Medsafe	39	16.95%	25	10.86%
	Vigibase*	62	26.95%	137	59.56%
	Med watch	18	7.82%	10	4.34%
13.	**Rare ADRs can be identified in the following phase of a clinical trial**				
	During phase-1 clinical trials	77	33.47%	28	12.17%
	During phase-2 clinical trials	76	33.04%	55	23.91%
	During phase-3 clinical trials	60	26.08%	43	18.69%
	During phase-4 clinical trials*	17	7.39%	104	45.21%
14.	**The healthcare professionals responsible for reporting ADR in a hospital is/are**				
	Doctor	8	3.47%	15	6.52%
	Pharmacist	54	23.47%	00	00%
	Nurses	47	20.43%	00	00%
	All of the above*	121	52.60%	215	93.47%
15.	**Which among the following factors discourage you from reporting Adverse Drug Reactions**				
	Non-remuneration for reporting	54	23.47%	14	6.08%
	Lack of time to report ADR*	88	38.26%	51	22.17%
	A single unreported case may not affect ADR database	19	8.26%	53	23.04%
	Difficult to decide whether ADR has occurred or not	69	30%	112	48.68%
16.	**Do you think reporting is a professional obligation for you**				
	Yes*	121	52.60%	221	96.08%
	No	59	25.65%	00	00%
	Don't know	24	10.43%	00	00%
	Perhaps	26	11.30%	9	3.91%
17.	**What is your opinion about establishing ADR monitoring centre in every hospital**				
	Should be in every hospital*	163	70.86%	193	83.91%
	Not necessary in every hospital	12	5.21%	12	5.21%
	One in a city is sufficient	29	12.60%	19	8.26%
	Depends on number of bed size in the hospitals.	26	11.30%	6	2.60%
18.	**Do you think reporting of adverse drug reaction is necessary**				

	a) Yes*	207	90%	230	100%
	b) No	23	10%	00	00%
19.	**Do you think Pharmacovigilance should be taught in detail to healthcare professionals**				
	a) Yes*	202	87.82%	228	99.13%
	b) No	28	12.17%	2	0.86%
20.	**Have you anytime read any article on prevention of adverse drug reactions**				
	a) Yes*	68	29.56%	154	66.95%
	b) No	162	70.43%	76	34.08%
21.	**Have you ever come across with an ADR**				
	a) Yes*	63	27.39%	150	65.21%
	b) No	167	72.60%	80	34.78%
22.	**Have you ever been trained on how to report Adverse Drug Reaction (ADR)**				
	a) Yes*	51	22.17%	201	87.93%
	b) No	179	77.82%	29	12.60%

Table 2. Knowledge Response towards the KAP Questionnaire-Pre and Post KAP Survey

Knowledge	Pre – KAP	Post – KAP
PV Definition	44.34 %	71.30 %
Purpose PV	40.86 %	60.43 %
PMS	41.73 %	72.60 %
Time lines for reporting	23.91 %	75.65 %
International center for ADR monitoring	17.39 %	60.43 %
Regulatory agencies	40.00 %	80.43 %
ADR	43.00 %	56.08 %
Regulatory body India	28.26 %	69.13 %
Scale CA	18.69 %	57.39 %
PVPI	46.95 %	64.34 %
WHO online data base	26.95 %	59.56 %
Rare ADRS	7.39 %	45.21 %

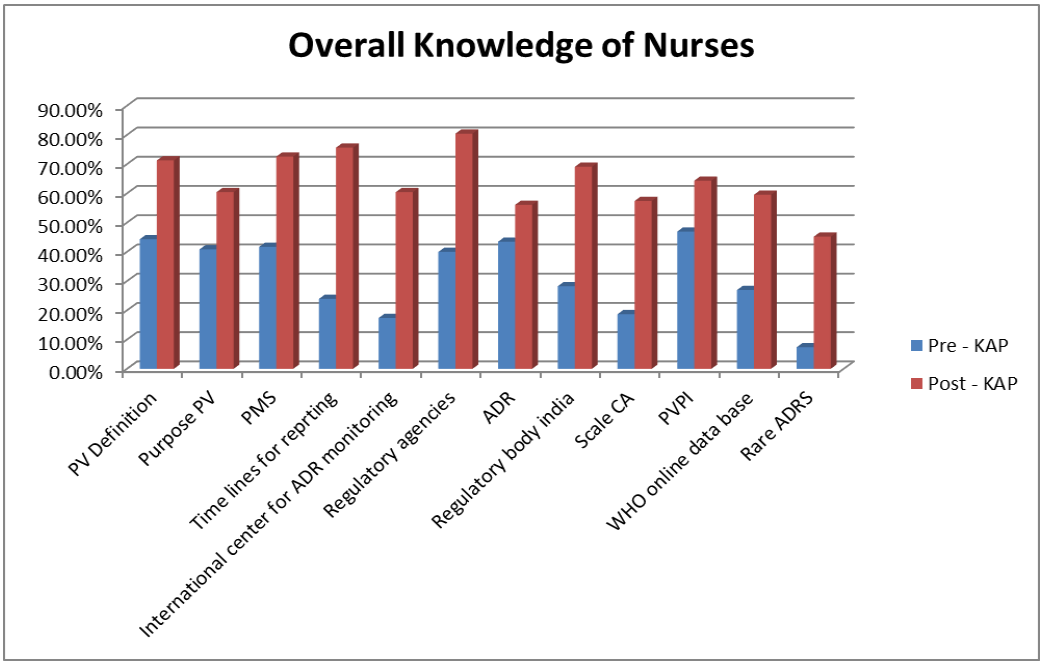

Figure 1. Graphical representation of overall knowledge of nurses before (Pre-KAP) and after (Post-KAP) intervention

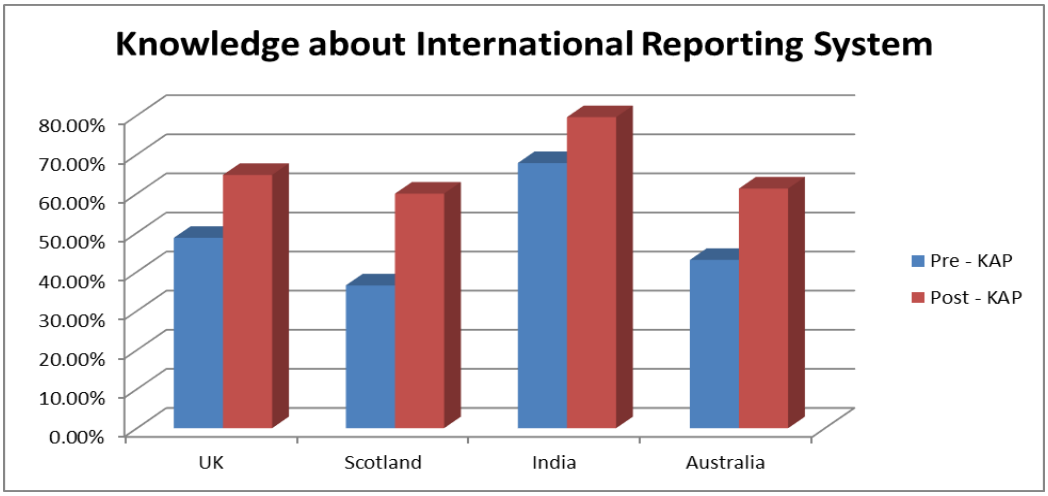

Figure 2. Knowledge of nurses towards International organization for ADR reporting system (Pre- and Post-KAP)

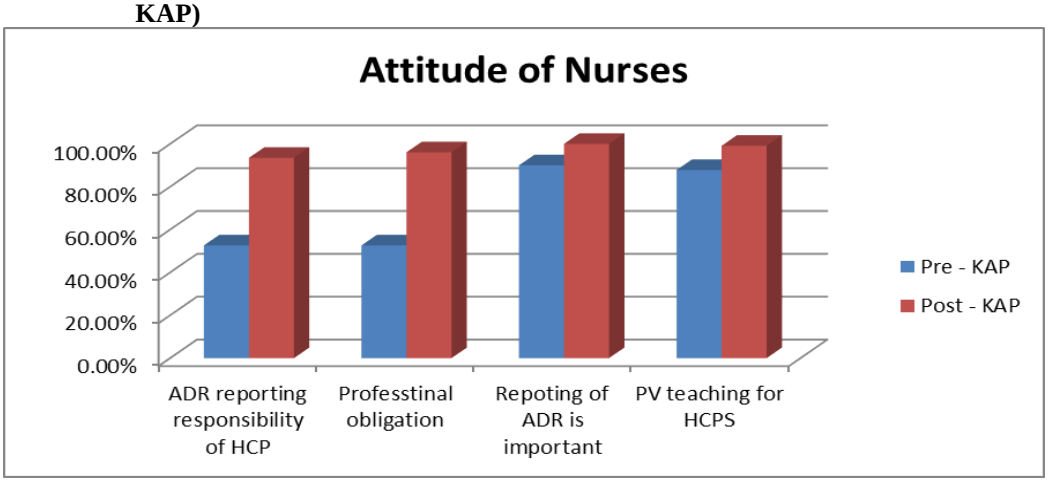

Figure 3. Change in attitude of nurses towards Pharmacovigilance after educational intervention

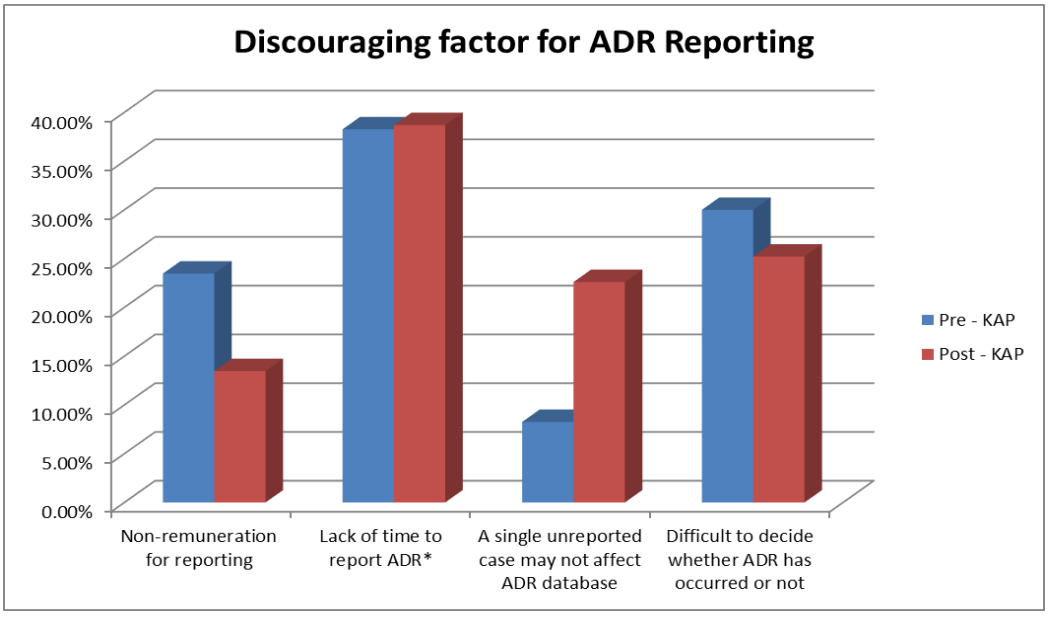

Figure 4. Knowledge of various discouraging factors for ADR reporting (Pre- and Post- KAP Analyses)

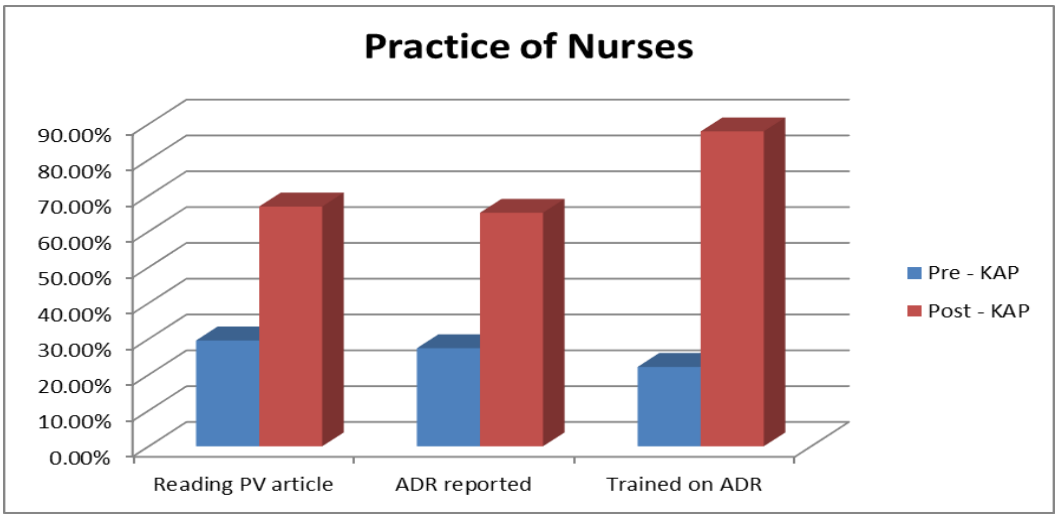

Figure 5. Pre- and Post- KAP analysis after educational intervention towards practice among the nurses.

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