WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 5.990
Volume 4, Issue 10, 2568-2575. Research Article ISSN 2277– 7105

AN EVALUATION OF IMPACT OF EDUCATIONAL INTERVENTION ON PHARMACOVIGILANCE AND ADR REPORTING AMONG NURSES IN TERTIARY CARE TEACHING HOSPITAL

Prem Kumar Goka*, Sowmya Nadendla, Sneha Gangisetty, Nallani Venkata RamaRao, Rama Rao Nadendla.

Dept Pharmacy Practice, Chalapathi Institute of Pharmaceutical Sciences, Lam Guntur-

Article Received on
12 Aug 2015,

Revised on 1 Sept 2015,
Accepted on 25 Sept 2015

***Correspondence for Author**
Prem Kumar Goka
Dept Pharmacy Practice, Chalapathi Institute of Pharmaceutical Sciences, Lam Guntur-

ABSTRACT

Objective: The purpose of the study was to assess the knowledge, Attitude, Practice of Pharmacovigilance (KAP) and ADR reporting among nurses and to evaluate the impact of an educational intervention. **Materials and Methods:** A suitable validated Knowledge, Attitude, Practice (KAP) questionnaire based survey was conducted among nurses & the impact of effectiveness of educational intervention was evaluated by using Chi square test & Fischer exact test in graph pad prism version (5.04). **Results:** A total 65 nurses were involved in Pre KAP and Post KAP survey questionnaire. The overall response rates between pre intervention and post intervention was statistically significant for nurses (P value <0.0001) shows the effectiveness of intervention for improving the awareness among the nurses. **Conclusion:** Imparting the knowledge and awareness of pharmacovigilance among healthcare professionals by means of continuous educational intervention would bring update knowledge of practice for drug safety.

KEYWORDS: Pharmacovigilance, educational intervention, KAP questionnaire, nurses.

INTRODUCTION

Adverse drug reaction(ADRs) continue to present as one of the greatest challenges towards the attainment of the gold standard of quality and safety in healthcare delivery world wide.[1] In the 1960's it was discovered that if thalidomide is ingested by mothers during pregnancy limb deformities in babies may occur. This incident became the modern starting point of a

science focusing on patient problems due to medicinal use. WHO defines ADR as "A response to a drug which is noxious & unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, cure or therapy of a disease, or for the modification of physiological function.[2,3] Adverse drug reactions account for 0.2%-24% of hospital admissions and 3.7% of the patients have fatal ADRs. Apart from accounting for significant health risk by increasing morbidity and mortality and prolonging hospital stay, it also leads to economic burden on the health care systems. Underreporting is another major problem and only 6-10% of all ADRs are reported.[4,5] Pharmacovigilance is an arm in the patient care and suvelliance. It aims at getting the best outcome from treatment with medicine. WHO defines Pharmacovigilance as "science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problem.[6,7] Physicians, pharmacist and nurses are in a position to play a major key role in pharmacovigilance program. Pharmacovigilance is still in its infancy in India and there exists very limited knowledge about this discipline. The central drug standard control organization **(CDSCO),** Directorate General of Health Services, Government of India in collaboration with Indian Pharmacopeia commission, Ghaziabad initiating a National wide Pharmacovigilance programme for protecting the health of patients by assuring drug safety.[8,9,10,11] Pharmacovigilance programme of india lacks continuity due to lack of awareness and inadequate training about drug safety monitoring among healthcare professionals in India.[12,13] Assessment of awareness of pharmacovigilance among the healthcare professionals is very important due to under reporting of adverse drug reactions. Therefore this study was conducted to assess awareness of pharmacovigilance among the healthcare professionals to evaluate the impact of an educational intervention on improving awareness of pharmacovigilance among nurses in an Indian tertiary care teaching hospital.[8,10,14]

METHODOLOGY

Study Design: An Observational Prospective Study

Study Period: Feb 2015 to July 2015 (6months)

Study Site: Government General Hospital (GGH), a 1300 beded tertiary care teaching hospital, Guntur.

Study Materials: KAP questionnaires for nurses.

Study Procedure: A KAP questionnaire based study was carried out which included a total of 65 nurses. A separate validated questionnaire comprising of 19 questions to nurses adapted

from previous studies were used in the study. Before the start of educational intervention all the participants included in the study were briefed about the purpose of the study. Later pre-KAP questionnaire was administered and asked to submit the same. An interactive educational intervention in the form of presentation consisting of definitions, regarding pharmacovigilance its objectives, ADR Reporting its classification, incidence, role of health care professional in reporting of ADR'S were discussed. Awareness was also improved by distributing a validated leaflet addressing ADR and its reporting. Later all participants of pre KAP were administered with post KAP questionnaire and it was analyzed question wise and their responses were documented.

DATA ANALYSIS

The data obtained were entered in Advanced Microsoft excel spread sheet and evaluated. Descriptive analysis had been represented in percentage, mean with standard deviation. Chi square test & Fischer exact test were used to compare the difference in correctness for each question. Statistical calculations were executed using graph pad prism version (5.04) and the level of statistical significance was set at $p< 0.05$.

RESULTS

A total of 100 knowledge, attitude and practice (KAP) questionnaires were distributed among which 65 nurses responded to the study.

All the values and percentages of positive& negative responses for the KAP questionnaire (pre KAP & post KAP) comprising of 19 questions for nurses was evaluated and tabulated.

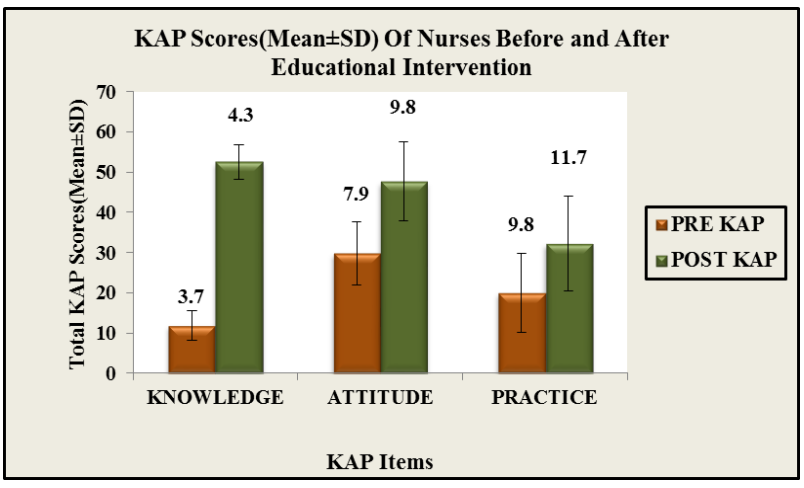
Knowledge, Attitude, Practice of Nurses towards Pharmacovigilance & ADR Reporting Questionnaire Before & After Educational Intervention.

S.no	KAP QUESTIONS	PRE-KAP(%) N=65	POST-KAP(%) N=65	p-value
	KNOWLEDGE			
1.	**What is an adverse drug reaction (ADR)?**			
	Harmful effects which occur when a drug is used in the usual dose.*	14(21.53)	59(90.76)	**<0.0001******
	Only allergic/hypersensitivity responses to drugs.	22(33.84)	2(3.07)	
	Effects occurring only when drugs are taken in excess dose.	26(40)	3(4.61)	
	None of the above	3(4.61)	1(1.53)	
2.	**Main purpose of ADR reporting system**			
	Identify safe drugs*	16(29.23)	51(70.76)	**<0.0001******
	Measure the incidence of ADRs	20(30.76)	12(18.46)	

	Identify predisposing factors to ADRs	24(36.92)	8(12.30)	
	Identify new ADRs	5(7.69)	4(6.15)	
3.	**One of the following is a major risk factor for the occurrence of maximum adverse drug Reactions**			
	Arthritis	20(30.76)	8(12.36)	
	Renal failure *	9(15.38)	43(73.84)	**<0.0001******
	Visual impairment	33(50.76)	8(12.30)	
	Vasculitis	3(4.61)	1(1.53)	
4.	**The important factors for deciding symptom to be ADR**			
	Seriousness of a reaction *	13(20)	52(80)	**<0.0001******
	Reaction to new product	26(40)	5(7.69)	
	Unusual reaction	11(16.92)	7(10.76)	
	Degree of confidence in diagnosing ADR	15(23.07)	1(1.53)	
5.	**ADRs should be reported only when they are**			
	Serious and life threatening	29(44.61)	6(9.23)	
	Severe and cause disability	27(41.53)	10(15.38)	
	Mild and cause less inconvenience	2(3.07)	0	
	All the above*	7(10.76)	49(75.38)	**<0.0001******
	ATTITUDE			
6.	**Have you ever experienced an adverse drug reaction (ADR) in patients during your practice?**			**0.0004*****
	Yes*	23(35.38)	44(67.69)	
	No	42(64.61)	21(32.30)	
7.	**Prefered ADR reporting system**			
	Need Based	15(23.07)	8(12.30)	
	Voluntary	4(6.15)	1(1.53)	
	Mandatory*	28(43.07)	52(78.64)	**0.0002*****
	Necessary	18(27.68)	4(6.90)	
8.	**Do you think reporting is a professional obligation for you?**			**0.0081****
	Yes *	22(35.48)	38(58.46)	
	No	43(66.15)	27(41.53)	
9.	**Do you feel confidentiality should be maintained while ADR reporting?**			**0.0087****
	Yes *	36(55.38)	51(78.46)	
	No	29(44.61)	14(21.53)	
10	**Do you feel that proper training should be provided to the nurses for ADR reporting?**			**<0.0001******
	Yes *	40(61.53)	63(96.92)	
	No	25(38.46)	2(3.07)	
	PRACTICE			
11	**Have you ever diagnosed an ADRs within the last 12 months?**			**0.0046****
	Yes*	13(20)	29(44.61)	
	No	52(80)	36(55.38)	
12	**H Have you ever sent a suspected ADR report**			**0.0987 N.S**

	to CENTER or manufacturer?			
	Yes*	11(16.92)	20(30.76)	
	No No	54(83.07)	45(69.23)	
13	**Have you ever reported any ADRs related to OTC or herbal products in the last 12 months?**			**0.2100N.S**
	Yes*	22(33.84)	30(46.15)	
	No	43(66.15)	35(53.84)	
14	**Have you ever reported a new ADR (not mentioned in drug leaflet) for any drug?**			**0.8268 N.S**
	Yes*	12(18.46)	14(21.53)	
	No	53(81.53)	51(78.46)	
15	**Have you ever prevent any serious ADRs?**			**0.0155***
	Yes*	15(23.07)	29(44.61)	
	No	50(76.92)	36(55.38)	
16	**Have you read an article related to ADRs in the last 12 months?**			**0.0002*****
	Yes*	21(32.30)	43(66.15)	
	No	44(67.69)	22(33.84)	
17	**Have you ever counselled patient regarding ADRs in the last 12 months?**			**0.0451***
	Yes*	18(27.69)	30(46.15)	
	No	47(72.30)	35(53.84)	
18	**Have you ever counselled patient regarding food /drug interaction in the last 12 months?**			**0.3350 N.S**
	Yes*	43(66.15)	49(75.38)	
	No	22(33.84)	16(24.61)	
19	**Have you ever been trained on how to report (ADR)?**			**0.0004*****
	Yes*	25(38.46)	46(70.76)	
	No	40(61.53)	19(29.23)	

NOT SIGNIFICANT –P>0.05, *-P≤ 0.05, **-P≤ 0.01, *-P≤ 0.001, ****- P≤0.0001**



From the above graph the total Pre-KAP scores on knowledge (11.8±3.70), attitude (29.8±7.94), practice (20±9.88) when compared to total post-KAP scores on knowledge (52.5±4.32), attitude (47.6±9.81), practice (32.2±11.72) respectively, the overall increase in correct response rate with statistical significance for most of the questions was observed after educational intervention.

DISCUSSION

The study showed the response of a total 19 KAP Questionnaire obtained from 65 Nursing staff. Question (Q)-1 sought information about the basic knowledge of the term adverse drug reaction (ADR). Pre KAP to Post KAP results shows a very significant raise from 21.5% to 90.7%. Q2 deals with purpose of ADR reporting shows result from 29.2% to 70.7% after intervention. Q3 deals with term pharmacovigilance shows raise from 13.8% to 73.8% after intervention.[8,9] Q5 was framed to obtain knowledge on ADR reporting among Nurses shows 10.7% Pre KAP to 75.3% Post KAP. This strongly indicates that the ADR reporting among Nurses was poor in Pre KAP and improved much more after educational intervention so one of the better means of overcoming the problem of underreporting of ADR's is to continue Pharmacovigilance training programmes in addition to it strengthening of monitoring centers, increasing the economic incentives of healthcare professionals, patient self reporting may decrease the burden among healthcare professionals to some extent is necessary.[15] Observations regarding the attitude of nurses towards training programmes for ADR reporting shows a result of 40% Pre KAP to 63% Post KAP which were quite encouraging, Although practice among nurses for the ADR diagnosing, counseling, reporting to PV centre did not show any improvement. Q9 framed to obtain information on training on how to report this gives a response rate 38.4% to70.7% after intervention.Our study also recommends a yearly repetition of such educational interventional programme as mentioned in the previous study.[8] for practical improvement**.** However this study demonstrates the overall improved awareness of Knowledge, attitude, practice of healthcare professionals nurses after educational intervention. Main limitation of the study was observed finding could not be applied to wider population & study period was too short. Therefore we recommend several such KAP studies of similar kind to be carried out so as to develop strategies to improve Knowledge attitude practice of Pharmacovigilance in India.

ACKNOWLEDGEMENT

We are thankful to All Nursing staff of Government General Hospital (GGH) Guntur for their participation in the survey & We wish to express heartful thanks to Miss K. Surekha professor in Statistics, Govt College of engineering,Amalapuram & Mrs B.Vasundhara professor in statistics, Chalapathi institute of pharmaceutical sciences, Guntur for helping and guiding us regarding the statistical tools.

CONCLUSION

The results of our study indicated that there a need to sensitize & orient the nurses towards ADR reporting to Pharmacovigilance centers (PVPI) by means of the Continuous Medical Educational programmes along with the incorporation of Pharmacovigilance in syllabus of courses of nursing would update the knowledge of practice for drug safety into their everyday clinical practice.We recommend further KAP studies of similar kind for longer study periods to be conducted in order to strengthen the effectiveness of Pharmacovigilance activities in Ind

REFERENCES

1. Raymond C O, Sunday O, Grace N E, Matthew J O. Awareness, Attitude, and Practice of Pharmacovigilance among Health Care Professionals in Nigeria. Int J of Hosp Research, 2013; 2(3): 99-108.
2. Essentials of Medical Pharmacology, K.D. Tripathi, 6th Edition.
3. WHO, The Importance of pharmacovigilance. safety Monitoring of medicinal products, WHO 2002.
4. Information about national pharmacovigilance program [Internet] [cited 17th may 2015].
5. Afroz A, Ahmad A, S.K Gupta. Evaluation of knowledge, attitude, perception of Pharmacovigilance and ADR reporting among prescribers and nurses in a tertiary care teaching hospital of Northern india.World J of Pharmaceu Research, 2014; 3(6): 771-786.
6. Pirmohamed M, Dodoo A, Winstanley P. Pharmacovigilance in developing countries. BMJ, 2007; 335: 462.
7. V.Lokesh Reddy. Assessment of Knowledge, Attitude, Perception of Pharmacovigilance and Adverse Drug Reaction (ADR) Reporting among the Pharmacy Students in South India IOSR J of Pharmacy and Biological Sciences, 2014; 9(2): 34-43.
8. Kavitha R, Nivedha. V, Rajesh. M, Evaluation of Knowledge, Attitude and Practices of Healthcare Professionals on Pharmacovigilance in a Tertiary Care Teaching Hospital, Int J of Uni Pharma and Bio Sci, 2014.Jun; 3(3): 732-756.

9. Radhakrishnan R, Sudha V, D M Varma. Educational Intervention to Assess Knowledge Attitude Practice of Pharmacovigilance among Health Care Professionals in an Indian Tertiary Care Teaching Hospital.Int.J. PharmTech Res, 2011; 3(2): 678-692
10. Bagewadi HG, Venkatadri. T.V. Impact of educational intervention on knowledge, attitude, perception of Pharmacovigilance and adverse drug reactions in fifth term medical students and their feedback. Int.J of Res in Pharmacol & Pharmacotherapeutics 2015.Jun; 4(2): 164-174.
11. Palain S, Ibrahim MI, Mishra P. Healthcare professionals knowledge attitude practices towards pharmacovigilance in Nepal. Pharmacy practice, 2011.Oct-Dec; 9(4): 228-235.
12. Dr.Mukeshkumar B Vora. Knowledge Attitude, Practice of Pharmacovigilance among Health Care Professionals and ADRs in healthcare professionals of Tertiary care hospital, Bhavnagar.Inter J of Pharma Sciences and Research, 2014.Nov; 5(11): 820-826.
13. Kumari S, Anurag S, Senthikumar P. Evaluation of Knowledge, Attitude and Practice among nurses in Pharmacovigilance in a Tertiary Care Teaching Hospital in Delhi. Jour of Harmo Res Pharma, 2015; 4(1): 76-86.
14. Tanya M T, Padmaja U, Scandashree K. Knowledge, Attitude and Practice of Adverse drug reaction reporting among doctors in a Tertiary Health Care Centre in South India. Int J of Pharmacol and Clin Sci, 2013.Sep; 2(3): 82-88.
15. Prajapathi R, Dumatar C, Dikshit R.K. Knowledge, Attitude and Practice regarding Adverse Drug Reaction Monitoring & Reporting amongst physicians in a tertiary care teaching hospital. Ind J of Applied Research.2014.Sep; 4(9): 455-458.