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ASSESSMENT OF KNOWLEDGE ATTITUDE PRACTICE ON PHARMACOVIGILANCE AND ADR REPORTING AMONG MEDICAL INTERNS IN TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Background and Objective: The field of Patients" drug safety has been receiving a great deal of attention, since adverse drug reactions are recognized as hazards of drug therapy. The purpose of the study was to assess the knowledge, Attitude, Practice of Pharmacovigilance (KAP) & ADR reporting among medical interns 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 medical interns & 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 110 medical interns were involved in Pre KAP and Post KAP survey questionnaire. The overall response rates between pre intervention and post intervention was statistically significant for medical interns (P value < 0.0001) shows the effectiveness of intervention for improving the awareness among the medical interns. **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, KAP questionnaire, educational intervention, medical interns.

INTRODUCTION

WHO defines Pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem." [1,2,3]. Pharmacovigilance has constantly grown in importance in last 15 years, relating to absolute amount of adverse drug reactions (ADRs) and to the fact that several hospital admissions are due to ADRs.[4,5] Pharmacovigilance plays a key role in ensuring that patients receive safe drugs. It is the process of being alert to the possible harmful effects of therapeutic medications so that they could be detected early and remedial measures instituted.[6,7]Good pharmacovigilance programs will identify the risks and the risk factors in the shortest possible time so that harm can be avoided or minimized. When communicated effectively, this information allows for the intelligent, evidence-based use of medicines and has the potential for preventing many adverse reactions. Physicians, pharmacist and nurses are in a position to play a major key role in pharmacovigilance programs.[8,9,10]ADR's are the global problems of major concern. ADR's are responsible for 5%-20% of hospital admissions. Much of these ADRs (50%) were preventable.[11] ADRs leads to number of medical and economic consequences like prolong hospital stay, increase the cost of treatment and risk of death also increases. Hence, early detection and prevention of ADR is necessary.[12,13,14] The World Health Organization defines adverse drug reactions (ADRs) as 'a reaction which is noxious and unintended and which occurs at doses normally used in humans for prevention, diagnosis or therapy of disease, or for the modification of physiological functions'.[15] ADR monitoring programmes are not new to India. In 1982, five centres were established by Drug Controller General of India for nationwide monitoring of Adverse drug Reaction (ADR).[16] To improve the pharmacovigilance activities in India, the Ministry of Health and Family Welfare had initiated the National Pharmacovigilance Programe (NPP) on 1 January 2005 which was further reviewed in July 2010. This program is overseen by Central Drugs Control Organization (CDSCO), New Delhi. ADR reports will be collected at the Monitoring centers which will then be dispatched to the coordinating center as per the standard operating procedures. The coordinating center will conduct causality assessment and upload the reports into the pharmacovigilance software. Lastly, the integrated ADR data will be transmitted through vigiflow software interface into the Uppsala Monitoring Center's ADR database where

signal processing can be carried out.[17] Adverse drug reaction (ADR) monitoring and reporting activity is in its infancy in India. 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.[18,19] Underreporting is very common, with an estimated median underreporting rate (defined as percentage of ADRs detected from intensive data collection that were not reported to relevant spontaneous reporting systems) of 94% and occurs frequently for serious and unlabeled reactions. The aim and objective of the study was to evaluate knowledge, attitude and perception of pharmacovigilance and ADR reporting among medical interns by an interactive educational intervention.[20]

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 medical interns.

STUDY PROCEDURE: A KAP questionnaire based study was carried out which included a total of 110 medical interns. A separate validated questionnaire comprising of 20 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 200 knowledge, attitude and practice (KAP) questionnaires were distributed among which 110 medical interns responded to the study.All the values and percentages of positive& negative responses for the KAP questionnaire (pre KAP & post KAP) comprising of 20 questions for medical interns was evaluated and tabulated.

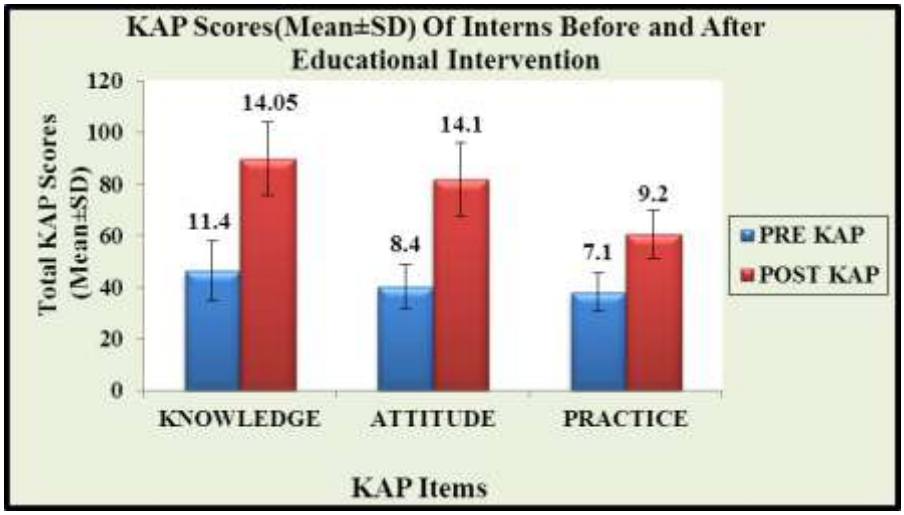
Knowledge, Attitude, Practice of Interns towards Pharmacovigilance and ADR Reporting Questionnaire Before and After Educational Intervention.

S.No	KAP QUESTIONS	PRE-KAP(%) N=110	POST-KAP(%) N=110	*p*-value
I	**KNOWLEDGE**			
1.	**What is an adverse drug reaction (ADR)?**			**<0.0001******
	Harmful effects which occur when a drug is used in the usual dose.*	51(78.46)	103(93.63)	
	Only allergic/hypersensitivity responses to drugs.	26(23.63)	2(1.81)	
	Effects occurring only when drugs are taken in excess dose.	30(27.27)	3(2.72)	
	None of the above	2(1.8)	0	
2.	**Are you aware of suspected adverse reaction reporting system in India?**			**<0.0001******
	Yes*	48(43.63)	102(92.72)	
	No	62(56.36)	8(7.27)	
3.	**Are you familiar with the term Pharmacovigilance?**			**<0.0001******
	Yes *	42(38.18)	101(91.81)	
	No	74(67.27)	9(8.18)	
4.	**If yes, please define the term Pharmacovigilance?**			**<0.0001******
	Safe, effective, appropriate and economic use of medicines	9(8.18)	1(0.90)	
	Therapeutic drug monitoring	12(10.90)	3(2.72)	
	Detection, assessment, understanding & prevention of adverse effects.*	36(32.72)	101(91.81)	
	All.	57(51.81)	5(4.54)	
5.	**Are you aware of regional center of ADR reporting?**			**<0.0001******
	Yes*	33(30)	84(76.36)	

	No	77(70)	26(23.63)	
6.	**Following are commonly associated with ADRS**			
	a. Old age			**<0.0001******
	Yes*	50(45.45)	97(88.18)	
	No	60(54.54)	13(11.81)	
	b. Multiple co-morbidities			**<0.0001******
	Yes*	52(47.27)	96(87.27)	
	No	58(52.72)	14(12.72)	
	c. Poly-pharmacy			**<0.0001******
	Yes*	54(49.09)	98(89)	
	No	56(50.90)	12(10.90)	
	d. Patients in ICU			**0.0018****
	Yes*	46(41.81)	70(63.63)	
	No	64(88.18)	40(36.36)	
	e. Children aged 1-4yrs			**<0.0001******
	Yes*	41(37.27)	96(87.27)	
	No	69(62.72)	14(12.72)	
7.	**Following are essential information while reporting an ADR**			
	a. Patients initials			**<0.0001******
	Yes*	38(34.54)	90(81.81)	
	No	72(65.45)	20(18.18)	
	b. Date of start of reaction			**<0.0001******
	Yes*	42(38.18)	102(92.72)	
	No	68(61.81)	8(7.27)	
	c. Suspected medication			**<0.0001******
	Yes*	39(35.45)	105(95.45)	
	No	71(64.54)	5(4.54)	
	d. Outcome of the event			**<0.0001******
	Yes*	26(23.63)	72(65.45)	
	No	84(76.36)	38(34.54)	
	e. Name of reporter			**0.6851 N.S**
	Yes*	57(51.81)	61(55.45)	
	No	53(48.18)	49(44.54)	
8.	**Are you aware of any drug withdrawn from market due to safety reason?**			**0.0012****
	Yes*	58(52.72)	82(74.54)	
	No	52(47.27)	28(25.45)	
9.	**ADR reporting is required in following circumstances**			
	a. When it is caused by herbal medicine			**0.0002*****
	Yes*	61(55.45)	88(80)	
	No	49(44.54)	22(20)	
	b. When it is not certain that drug has caused the reaction			**<0.0001******
	Yes*	40(36.36)	83(75.45)	
	No	70(63.63)	27(24.54)	
	c. When it is caused by OTC drugs			**<0.0001******
	Yes*	76(69.09)	104(94.54)	
	No	34(30.90)	6(5.45)	
	d. When it is caused by topical agents			**0.0004*****
	Yes*	36(32.72)	63(57.27)	
	No	74(67.27)	47(42.72)	
II	**ATTITUDE**			
10.	**Do you agree that ADR reporting system would benefit patient care?**			**<0.0001******
	Strongly agree*	42(38.18)	83(75.45)	
	Agree	62(56.36)	23(20.90)	
	Neutral	6(5.45)	4(3.63)	
	Disagree	-	-	

	Strongly disagree	-	-	
11.	**Would you suspect ADRs when drug is administered in normal dose?**			**<0.0001******
	Strongly agree*	38(34.54)	79(71.81)	
	Agree	36(32.72)	16(14.54)	
	Neutral	30(27.27)	13(11.81)	
	Disagree	4(3.63)	2(1.81)	
	Strongly disagree	2(1.81)	-	
12.	**Do you think reporting of seemingly insignificant ADRs is required?**			**<0.0001******
	Strongly agree*	35(31.81)	86(78.18)	
	Agree	42(38.18)	13(11.81)	
	Neutral	23(20.90)	7(6.36)	
	Disagree	10(9.09)	4(3.63)	
	Strongly disagree			
13.	**Reporting of all ADRs for a new drug is essential?**			**<0.0001******
	Strongly agree*	28(25.45)	56(50.90)	
	Agree	76(69.09)	44(40)	
	Neutral	19(17.27)	10(9.09)	
	Disagree			
	Strongly disagree			
14.	**Reporting of ADR is duty of health care professional?**			**<0.0001******
	Strongly agree*	46(41.81)	92(83.63)	
	Agree	48(43.63)	18(16.36)	
	Neutral	16(14.54)	-	
	Disagree	-	-	
	Strongly disagree	-	-	
15.	**Do you agree that reporting of ADRs be made compulsory?**			**<0.0001******
	Strongly agree*	52(47.27)	96(87.27)	
	Agree	32(29.09)	14(12.72)	
	Neutral	26(23.63)		
	Disagree			
	Strongly disagree			
III.	**PRACTICE**			
16.	**Have you reported any suspected adverse drug reaction?**			**0.0011****
	Yes*	46(41.81%)	71(64.54%)	
	No	64(58.18%)	39(35.45%)	
17.	**Have you attended any CME on ADR reporting?**			**0.0039****
	Yes*	34(30.90%)	56(50.90%)	
	No	76(69.09%)	54(49.09%)	
18.	**Have you read any article on prevention of ADRs**			**0.0018****
	Yes*	41(37.27%)	65(59.09%)	
	No	69(62.72%)	45(40.90%)	
19.	**Have you ever been trained on how to report ADRs**			**0.0102***
	Yes*	38(34.54%)	47(42.72%)	
	No	72(65.45%)	63(57.27%)	
20.	**Can Non medical person report ADR to a nearby Healthcare professional**			**0.0045****
	Yes*	52(47.27%)	62(56.36%)	
	No	58(52.72%)	48(43.63%)	

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 (46.3±11.48), attitude (40.16±8.44), practice (38.2±7.1) when compared to total post-KAP scores on knowledge (89.9±14.05), attitude (82±14.12), practice (60.6±9.28) respectively, the overall increase in correct response rate with statistical significance for most of the questions was observed after educational intervention.

DISCUSSION

Out of 20 KAP Questionnaire obtained from 110 medical interns, Question (Q)-1 sought information about the term adverse drug reaction (ADR). Pre KAP to Post KAP result shows a significant raise from 78.5 % to 93.3%. Q2 was framed about awareness of reporting system in India this shows 43.6% Pre KAP to 92.7% Post KAP. Q3,4 deals with being aware of term pharmacovigilance & defining it. Response rate for Pre KAP to Post KAP was 38.8% to 91.8% and 32.7% to 91.8%.This data suggests that continuing educational intervention is an important tool for improving awareness among healthcare professionals as mentioned in the similar study**.** [4] Q5 was designed in such a way to obtain knowledge about ADR reporting centre, shows response rate 30% Pre KAP to 76.3% Post KAP highlighting impact of educational intervention. Knowledge building can also be improved by adding pharmacovigilance topic in undergraduate curriculum. Q7,9 were framed to obtain knowledge on required essential information & reporting of ADR. It was demonstrated by showing a raise from 40% Pre KAP to 86% Post KAP& 53% Pre KAP to 84.5% Post KAP respectively. This reveals the positive impact of our educational intervention However 50% respondents after Post KAP Still feel that there is no need of disclosing the name of reported while ADR reporting which is similar to the previous study.[18] Observation regarding the attitude aspect of ADR reporting among medical interns reveal that results to be statistically significant ($P<0.05$) showing a good impact of Educational intervention. With regards to practice of Pharmacovigilance among medical interns suggests conducting Continuous Medical Training (CME) programme and Training programme should cover location of pharmacovigilance centre, reporting procedures & method of filling ADR reporting forms. Main limitation of the study was observed finding could not be applied to wider population & study period was too short. Therefore we recommend several studies of similar kind to be carried out so as to develop strategies to improve Knowledge attitude practice of Pharmacovigilance in India**.** [19]

CONCLUSION

Post Knowledge attitude practice (KAP) of our educational intervention programme indicated that there a need to sensitize the medical interns towards ADR reporting to Pharmacovigilance centers (PVPI) by means of the Continuous Medical Educational (CME) programmes along with the incorporation of Pharmacovigilance in syllabus of UG & PG courses of medicine. Other measures to improve ADR reporting can be Incorporation of ADR drop boxes at Strategic locations in hospitals, Facilitating ADR reporting by SMS, Email, Fax & Phone, Conduction of Pharmacovigilance Workshops, Accessibility of ADR Reporting Forms & ADR Alert Cards to physicians, Having an ADR Specialist, Providing Incentives for ADR Reporting, supplying ADR information leaflets and also there a need for the strict government rules and regulations to be made compulsory for ADR reporting.

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