International Journal of PharmTech Research
CODEN (USA): IJPRIF ISSN : 0974-4304
Vol. 3, No.2, pp 678-692, April-June 2011

An Educational Intervention to assess Knowledge Attitude Practice of pharmacovigilance among Health care professionals in an Indian tertiary care teaching hospital

Radhakrishnan Rajesh*[1], Sudha Vidyasagar[2], Danturulu Muralidhar Varma[3]

*[1] Department of Pharmacy Practice,Manipal College of Pharmaceutical Sciences, Manipal University, Manipal – 576 104, Karnataka, India.

[2]Department of Medicine, Kasturba Medical College, Manipal University, Manipal – 576 104, Karnataka, India.

[3]Department of Medicine, Kasturba Medical College, Manipal University, Manipal – 576 104, Karnataka, India.

*Corres.Author: rrajesh3775@gmail.com, rrajesh3775@hotmail.com
Fax: +91-820-2571998, Telephone: +91-820-2922482, Mobile: +919448374166*

Abstract:
Objective: To assess awareness of pharmacovigilance among the healthcare professionals and to evaluate the impact of an educational intervention for improving awareness of pharmacovigilance among physician, pharmacist and nurses in an Indian tertiary care teaching hospital.
Material &Methods: A suitable self-administered Knowledge, attitude, practice (KAP) survey questionnaire was designed, validated using a method developed by Lynn M and survey was conducted among physician, nurses, pharmacist of kasturba hospital, where local hospital based ADR reporting system exist. An interactive educational intervention was designed for all participants of Pre-KAP questionnaire survey. The impact of effectiveness of educational intervention among health care professionals was evaluated by means of post-KAP questionnaire survey. The chi-square test and One- way Analysis of variance was used for statistical calculations.
Results: In our study a total of 255 health care professionals were responded and involved in the pre - KAP and post- KAP survey questionnaires. Health care professionals involved in the study were 85 Doctors, 85 Nurses and 85 pharmacists from each group. The overall response rates between pre intervention and post intervention was statistically significant between doctors, nurses and pharmacist *(P* value <0.001) shows that effectiveness of educational intervention for improving awareness of pharmacovigilance among physician, pharmacist and nurses.
Conclusion: Imparting the knowledge and awareness of pharmacovigilance among the health care professionals by means of continues educational intervention would bring update knowledge of practice for drug safety into their every day clinical practice and also brings the adverse drug reactions (ADRs) reporting culture among them.
Keywords: pharmacovigilance; physician; pharmacists; nurses; educational intervention; Knowledge attitude practice questionnaire, adverse drug reactions; India.

1. Introduction

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. [1-2] 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. ADRs are global problems of major concern. They affect both children and adults with varying magnitudes; causing both morbidity and mortality.[3-6] Physicians, pharmacist and nurses are in a position to play a major key role in pharmacovigilance programs,[7,8] but 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%,[9] and occurs frequently for serious and unlabeled reactions.[10,11] This can delay detection of important ADRs. Studies from different settings indicate inadequate knowledge about pharmacovigilance among healthcare professionals as well as attitudes that are associated with a high degree of underreporting.[12-17] pharmacovigilance is still in its infancy in India and there exists very limited knowledge about this discipline. However, The Indian national pharmacovigilance programme lacks continuity due to lack of awareness and inadequate training about drug safety monitoring among healthcare professionals in India.[18] 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 and to evaluate the impact of an educational intervention for improving awareness of pharmacovigilance among physician, pharmacist and nurses in an Indian tertiary care teaching hospital.

2. Material and Methods

The study was conducted in the Kasturba Hospital (KH), Manipal, which is a 2000-bedded tertiary care teaching hospital in South India were ADR reporting program exists in the hospital since July 2001 and the same is coordinated by the department of pharmacy practice of the Manipal College of pharmaceutical sciences, Manipal University Manipal. The ADR reporting unit of KH is one among the peripheral centers for the national pharmacovigilance program. This was a prospective Knowledge attitude practice (KAP) questionnaire study conducted among physician, nurses, pharmacist of kasturba hospital and graduated pharmacist from Manipal College of pharmaceutical sciences. This KAP questionnaire survey was conducted during October 2009 to June 2010 and approval from Institutional Ethical Committee of Kasturba Hospital, Manipal was obtained prior to administering the questionnaire survey. The survey questionnaire was administered to 85 doctors, 85 staff nurses, belonged to different specialties practicing across this major hospital and 85 pharmacists both from hospital (staff pharmacist) and also graduate pharmacist from Manipal College of pharmaceutical sciences with minimum qualification of bachelor in pharmacy degree. A suitable piloted self- administered KAP survey questionnaire was designed initially with 25 item interviewer administered questionnaire, using a combination of closed and open-ended questions. Prior to this study, KAP survey questionnaire was piloted and evaluated for its content validity using a method developed by Lynn M.[19] to test the content validity 10 content experts were selected. The panel of experts included was physician, staff nurses, and two senior clinical pharmacist of kasturba hospital, where the ADR reporting and monitoring system was implemented. These content experts were provided with a copy of the KAP survey questionnaire and the rationale and objective of the study were explained. Few changes in the order and phrasing of the questions were made after discussion with fellow clinical pharmacists and few physicians. The final KAP questionnaire (Appendix I) Consisted of 22 questions out of which question number 1 to 13 was knowledge based, question number 10 was match the following, question number 14 to 19 was attitude based and question number 20 to 22 was 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. Initially Pre-KAP questionnaire was briefed to all participants (physician, pharmacist and nurses about the purpose of the study and asked to submit the filled questionnaire to the identified nursing station of their respective departments in the hospital and senior clinical pharmacist was involved for collection and assessment of filled questionnaire. All participants were also provided with sufficient time of 15 days to fill the Pre-KAP questionnaire. Pre-KAP questionnaire was administered at the beginning of the study, in order to identify the Knowledge attitude practice of pharmacovigilance. The Pre-KAP survey questionnaire was analyzed, question wise and their percentage value was calculated. During Pre-KAP questionnaire administration the choices were not provided in order to assess the actual knowledge. In case of unanswered questions, a participant was excluded from the study. An interactive educational intervention was designed separately for all participants of Pre-KAP questionnaire survey (physician, pharmacist and

nurses) in order to facilitate the transfer of knowledge of pharmacovigilance program by getting approval from medical superintendent, head of the departments of medicine, chief nursing educator consultant, kasturba Hospital, manipal and chief pharmacist, KH, manipal. The educational intervention was divided into a theoretical and a practical 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). During this session physician, pharmacist and nurses were also encouraged to report all suspected ADRs, including those that were mild or anticipated. During this period physicians, pharmacist and nurses took part in a one-on-one ADR training session, which lasted approximately 1 hour. The sessions were held by trained senior grade lecturer in the field of pharmacovigilance research. The practical part of the intervention included practical examples of how to document serious ADRs using ADR notification and documentation forms. Two weeks after the educational intervention, all participants of Pre-KAP questionnaire (i.e. physician, pharmacist and nurses who participated in educational intervention program was administered. Post-KAP questionnaire was analyzed, question wise and their percentage value was calculated by trained senior grade lecturer in the field of pharmacovigilance research. Healthcare professionals were also asked if they had encountered any problems; if so, they were provided with support. 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 17.0. The level of statistical significance was set at $p < 0.05$.

Appendix I

KAP Questionnaire

Instructions: You are requested to give information to the best of your knowledge. Please mark tick (√) for the correct response.

1) Define Pharmacovigilance? (Most appropriate any one only)
   a) □ The science of monitoring ADR's happening in a Hospital
   b) □ The process of improving the safety of Drugs
   c) □ The detection, assessment, understanding & prevention of adverse effects
   d) □ The science detecting the type & incidence of ADR after drug is marketed.
2) The important purpose of Pharmacovigilance is **(**Most appropriate one)
   a) □ To identify safety of drugs b) □ To calculate incidence of ADR's
   c) □ To identify predisposing factors to ADR's d) □ To identify unrecognized ADR's
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 b) □Post Marketing Surveillance (PMS) studies.
   c) □Population studies d) □Regression analysis
4) 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
5) The international center for adverse drug reaction monitoring is located in
   a) □Unites States of America b) □Australia c) □France d) □Sweden
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)
b) □United States food and drug administration (US FDA)
c) □American Medical Association (AMA)
d) □American Pharmaceutical Association (APA)

7) One of the following is a major risk factor for the occurrence of maximum adverse drug reactions
a) □Arthritis b) □Renal failure c) □Visual impairment d) □Vacuities

8) In India which Regulatory body is responsible for monitoring of ADR's?
a) □Central Drugs Standard Control Organization b) □Indian Institute of sciences
c)) □Pharmacy Council of India d) □Medical Council of India

9) Which of the following scales is most commonly used to establish the causality of an ADR?
a) □Hartwig scale b) □Naranjo algorithm c) □Schumock and Thornton scale d) □Karch & Lasagna scale

10) Match the ADR reporting systems to the respective countries. (Write the number in the appropriate boxes)

1) Yellow card	□ India
2) Green card	□ Australia
3) ADR reporting Form	□ United Kingdom
4) Blue card	□ Scotland

11) One among these is a Regional Pharmacovigilance centre?
a)□Kasturba Hospital, Manipal b)□JIPMER, Pondicherry c)□ JSS Medical College & Hospital, Mysore d) □CMC, Vellore

12) Which one of the following is the 'WHO online database' for reporting ADRs?
a) □ADR advisory committtee b) □ Medsafe c) □ Vigibase d) □Med watch

13) Rare ADRs can be identified in the following phase of a clinical trial
a) □During phase-1 clinical trials b) □During phase-2 clinical trials
c) □During phase-3 clinical trials d) □During phase-4 clinical trials

14) The healthcare professionals responsible for reporting ADR in a hospital is/are
a) □Doctor b) □Pharmacist c) □Nurses d) □All of the above

15) Which among the following factors discourage you from reporting Adverse Drug Reactions? (Any one only)
a) □Non-remuneration for reporting b) □Lack of time to report ADR
c) □A single unreported case may not affect ADR database
d) □ Difficult to decide whether ADR has occurred or not

16) Do you think reporting is a professional obligation for you?
a) □Yes b) □No c) □ Don't know d) □Perhaps

17) What is your opinion about establishing ADR monitoring centre in every hospital?
a) □Should be in every hospital b) □Not necessary in every hospital
c) □One in a city is sufficient d) □Depends on number of bed size in the hospitals.

18) Do you think reporting of adverse drug reaction is necessary?
a) □Yes b) □No

19) Do you think Pharmacovigilance should be taught in detail to healthcare professionals?
a) □Yes b) □ No

20) Have you anytime read any article on prevention of adverse drug reactions?
a) □Yes b) □ No

21) Have you ever come across with an ADR?
a) □Yes b) □ No

22) Have you ever been trained on how to report Adverse Drug Reaction (ADR)?
a) □Yes b) □ No

Table 1. Knowledge, attitude, practice of the Doctors towards Pharmacovigilance Questionnaires before and after educational intervention.

Q	KAP Items	Pre-KAP Responses (%) N = 85	Post- KAP Responses (%) N=85	p- Value
1.	Define Pharmacovigilance?			
	a) The science of monitoring ADR's happening in a Hospital	15 (17.7)	01(1.1)	
	b) The process of improving the safety of Drugs	15 (17.7)	00	
	c) The detection, assessment, understanding & prevention of adverse effects*	47(55.2)	84(98.9)	<0.001
	d) The science detecting the type & incidence of ADR after drug is marketed.	8(9.4)	00	
2.	The most important purpose of Pharmacovigilance is			
	a) To identify safety of drugs*	24 (28.3)	57(67)	0.796
	b) To calculate incidence of ADR's	17(20)	4(4.8)	
	c) To identify predisposing factors to ADR's	13(15.2)	14(16.4)	
	d) To identify previously unrecognized ADR's	31(36.5)	10(11.8)	
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	00	00	
	b) Post Marketing Surveillance (PMS) studies*	78(91.8)	85(100)	<0.001
	c) Population studies	7(8.2)	00	
	d) Regression analysis	00	00	
4.	A serious adverse Event in India should be reported to the Regulatory body within			
	a) One day	15(17.7)	4(4.7)	
	b) Seven calendar days	29(34.1)	11(13)	
	c) Fourteen calendar days*	33(38.9)	65(76.4)	0.002
	d) Fifteen calendar days	8(9.3)	5(5.9)	
5.	The international center for adverse drug reaction			
	monitoring is located in a) Unites States of America	37(43.5)	1(1.1)	
	b) Australia	16(19)	2(2.4)	
	c) France	17(20)	7(8.3)	
	d) Sweden*	15(17.5)	75(88.2)	<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)	10(11.8)	2(2.3)	
	b) United States food and drug administration* (US FDA)	70(82.4)	80(94.1)	<0.001
	c) American Medical Association (AMA)	2(2.3)	1(1.2)	
	d) American Pharmaceutical Association (APA)	3(3.5)	2(2.4)	
7.	One of the following is a major risk factor for the occurrence of maximum adverse drug reactions			
	a) Arthritis	35(41.1)	25(29.4)	
	b) Renal failure *	12(14.1)	30(35.2)	<0.001
	c) Visual impairment	25(29.4)	20(23.6)	
	d) Vacuities	13(15.4)	10(11.8)	

8.	In India which Regulatory body is responsible for monitoring of ADR's?			
	a) Central Drugs Standard Control Organization*	37(43.6)	72(84.8)	<0.001
	b) Indian Institute of sciences	17(20)	9(10.6)	
	c) Pharmacy Council of India	19(22.3)	2(2.3)	
	d) Medical Council of India	12(14.1)	2(2.3)	
9.	Which of the following scales is most commonly used to establish the causality of an adverse drug reaction?			
	a) Hartwig scale	25(29.4)	12(14.1)	
	b) Naranjo algorithm*	12(14.0)	50(58.8)	0.076
	c) Schumock and Thornton scale	37(43.6)	16(18.8)	
	d) Karch & Lasagna scale	11(13)	7(8.3)	
10.	Match the ADR reporting systems to the respective countries.	Number of correct responses given from N = 85 for each answers.		
	1) Yellow card -United Kingdom*	40(47.0)	60(70.5)	<0.001
	2) Green card - Scotland*	30(35.2)	75(88.2)	
	3) ADR reporting Form - India*	70(82.4)	80(94.1)	
	4) Blue card - Australia*	55(64.7)	83(97.6)	
11.	One among these is a Regional Pharmacovigilance centre?			
	a) Kasturba Hospital, Manipal	5(5.9)	3(3.6)	
	b) JIPMER, Pondicherry*	40(47.0)	75(88.2)	<0.001
	c) JSS Medical College & Hospital, Mysore	10(11.8)	5(5.9)	
	d) CMC, Vellore	30(35.3)	2(2.3)	
12.	Which one of the following is the 'WHO online database' for reporting adverse drug reactions?			
	a) Adverse drug reaction advisory committtee	42(49.4)	13(15.2)	
	b) Medsafe	9(10.6)	4(4.8)	
	c) Vigibase*	22(25.9)	65(76.4)	<0.001
	d) Med watch	12(14.1)	3(3.6)	
13.	Rare ADRs can be identified in the following phase of a clinical trial			
	a) During phase-1 clinical trials	18(21.1)	23(27.0)	
	b) During phase-2 clinical trials	27(31.8)	12(14.1)	
	c) During phase-3 clinical trials	15(17.7)	13(15.2)	
	d) During phase-4 clinical trials*	25(29.4)	37(43.7)	0.288
14.	The healthcare professional/s responsible for reporting adverse drug reaction in a hospital is/are			
	a) Doctor	3(3.6)	00	
	b) Pharmacist	1(1.1)	00	
	c) Nurses	1(1.1)	00	
	d) All of the above*	80(94.2)	85(100)	<0.001
15.	Which among the following factor discourage you from reporting Adverse Drug Reaction? (Any one only)			
	a) Non-remuneration for reporting	2(2.4)	00	
	b) Lack of time to report ADR*	74(87)	83(97.6)	<0.001
	c) A single unreported case may not affect ADR database	3(3.6)	00	
	d) Difficult to decide whether ADR has occurred or not	6(7.0)	2(2.4)	
16.	Do you think adverse drug reaction reporting is a professional obligation for you?			
	a) Yes*	76(89.4)	85(100)	<0.001
	b) No	00	00	
	c) Don't know	00	00	

	d) Perhap	9(10.6)	00	
17.	What is your opinion about establishing ADR monitoring centre in every hospital?			
	a) Should be in every hospital*	60(70.6)	73(85.9)	0.355
	b) Not necessary in every hospital	7(8.2)	2(2.3)	
	c) One in a city is sufficient	9(10.6)	4(4.8)	
	d) Depends on number of bed size in the hospitals	9(10.6)	6(7.0)	
18.	Do you think reporting of adverse drug reaction is necessary?			
	a) Yes*	78(91.8)	82(96.5)	<0.001
	b) No	7(8.2)	3(3.5)	
19.	Do you think Pharmacovigilance should be taught in detail to healthcare professionals?			
	a) Yes*	80(94.1)	83(97.6)	<0.001
	b) No	5(5.9)	2(2.4)	
20.	Have you anytime read any article on prevention of adverse drug reactions?			
	a) Yes*	60(70.6)	85(100)	<0.001
	b) No	25(29.4)	00	
21.	Have you ever come across with an ADR?			
	a) Yes*	85(100)	85(100)	<0.001
	b) No	00	00	
22.	Have you ever been trained on how to report Adverse Drug Reaction (ADR)?			
	a) Yes*	43(50.5)	85(100)	<0.001
	b) No	42(49.5)	00	

Correct Response*

P < 0.001 (comparisons between the pre- KAP and Post- KAP responses).

Table 2. Knowledge, attitude, practice of the Nurses towards Pharmacovigilance Questionnaires before and after educational intervention.

Q	KAP Items	Pre-KAP Responses (%) N = 85	Post- KAP Responses (%) N=85	p- Value
1.	Define Pharmacovigilance?			
	a) The science of monitoring ADR's happening in a Hospital	25 (29.4)	2(2.3)	
	b) The process of improving the safety of Drugs	24(28.2)	12 (14.2)	
	c) The detection, assessment, understanding & prevention of adverse effects*	18(21.3)	65(76.5)	<0.001
	d) The science detecting the type & incidence of ADR after drug is marketed.	18(21.1)	6(7.0)	
2.	The most important purpose of Pharmacovigilance is			
	a) To identify safety of drugs*	18 (21.1)	45(53)	0.826
	b) To calculate incidence of ADR's	19(22.3)	12(14.1)	
	c) To identify predisposing factors to ADR's	19(22.3)	13(15.2)	
	d) To identify previously unrecognized ADR's	29(34.3)	15(17.7)	
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	20(23.6)	16(18.9)	
	b) Post Marketing Surveillance (PMS) studies*	30(35.2)	65(76.4)	<0.001
	c) Population studies	21(24.8)	4(4.7)	

	d) Regression analysis	14(16.4)	00	
4.	A serious adverse Event in India should be reported to the Regulatory body within			
	a) One day	28(33)	00	
	b) Seven calendar days	12(14)	14(16.4)	
	c) Fourteen calendar days*	16(18.9)	71(83.6)	0.002
	d) Fifteen calendar days	29(34.1)	00	
5.	The international center for adverse drug reaction			
	monitoring is located in a) Unites States of America	23(27)	5(5.9)	
	b) Australia	12(14.2)	2(2.3)	
	c) France	6(7)	15(17.7)	
	d) Sweden*	44(51.8)	63(74.1)	<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)	23(27.2)	2(2.3)	
	b) United States food and drug administration* (US FDA)	48(56.4)	80(94.1)	<0.001
	c) American Medical Association (AMA)	6(7)	3(3.6)	
	d) American Pharmaceutical Association (APA)	8(9.4)	00	
7.	One of the following is a major risk factor for the occurrence of maximum adverse drug reactions			
	a) Arthritis	24(28.3)	15(17.7)	
	b) Renal failure *	40(47)	46(54.2)	<0.001
	c) Visual impairment	12(14.1)	18(21.1)	
	d) Vacuities	9(10.6)	6(7)	
8.	In India which Regulatory body is responsible for monitoring of ADR's?			
	a) Central Drugs Standard Control Organization*	17(20)	43(50.6)	<0.001
	b) Indian Institute of sciences	15(17.7)	26(30.6)	
	c) Pharmacy Council of India	1(1.1)	10(11.8)	
	d) Medical Council of India	52(61.2)	6(7.0)	
9.	Which of the following scales is most commonly used to establish the causality of an adverse drug reaction?			
	a) Hartwig scale	39(45.9)	17(20.2)	
	b) Naranjo algorithm*	30(35.2)	48(56.4)	0.076
	c) Schumock and Thornton scale	12(14.1)	7(8.2)	
	d) Karch & Lasagna scale	4(4.8)	13(15.2)	
10.	Match the ADR reporting systems to the respective countries.	Number of correct responses given from N = 85 for each answers.		
	1) Yellow card -United Kingdom*	40(47)	55(64.7)	<0.001
	2) Green card - Scotland*	48(56.4)	53(62.3)	
	3) ADR reporting Form - India*	35(41.1)	65(76.4)	
	4) Blue card - Australia*	63(74.1)	72(84.7)	
11.	One among these is a Regional Pharmacovigilance centre?			
	a) Kasturba Hospital, Manipal	32(37.7)	12(14.1)	
	b) JIPMER, Pondicherry*	26(30.5)	37(43.5)	<0.001
	c) JSS Medical College & Hospital, Mysore	21(24.8)	12(14.2)	
	d) CMC, Vellore	6(7.0)	24(28.2)	
12.	Which one of the following is the 'WHO online database' for reporting adverse drug reactions?			
	a) Adverse drug reaction advisory committtee	41(48.2)	10(11.8)	
	b) Medsafe	21(24.7)	10(11.8)	

	c) Vigibase*	20(23.5)	56(65.9)	<0.001
	d) Med watch	3(3.6)	9(10.5)	
13.	Rare ADRs can be identified in the following phase of a clinical trial			
	a) During phase-1 clinical trials	9(10.6)	2(2.3)	
	b) During phase-2 clinical trials	18(21.2)	2(2.3)	
	c) During phase-3 clinical trials	12(14.1)	19(12.4)	
	d) During phase-4 clinical trials*	46(54.1)	62(73)	0.273
14.	The healthcare professional/s responsible for reporting adverse drug reaction in a hospital is/are			
	a) Doctor	00	00	
	b) Pharmacist	00	00	
	c) Nurses	00	00	
	d) All of the above*	85(100)	85(100)	<0.001
15.	Which among the following factor discourage you from reporting Adverse Drug Reaction? (Any one only)			
	a) Non-remuneration for reporting	00	00	
	b) Lack of time to report ADR*	5(5.8)	1(1.1)	<0.001
	c) A single unreported case may not affect ADR database	00	12(14.1)	
	d) Difficult to decide whether ADR has occurred or not	80(94.2)	72(84.8)	
16.	Do you think adverse drug reaction reporting is a professional obligation for you?			
	a) Yes*	61(71.8)	79(92.9)	<0.001
	b) No	2(2.3)	00	
	c) Don't know	3(3.6)	00	
	d) Perhap	19(22.3)	6(7.1)	
17.	What is your opinion about establishing ADR monitoring centre in every hospital?			
	a) Should be in every hospital*	72(84.7)	84(98.8)	0.255
	b) Not necessary in every hospital	12(14.1)	1(1.2)	
	c) One in a city is sufficient	1(1.2)	00	
	d) Depends on number of bed size in the hospitals	00	00	
18.	Do you think reporting of adverse drug reaction is necessary?			
	a) Yes*	85(100)	85(100)	<0.001
	b) No	00	00	
19.	Do you think Pharmacovigilance should be taught in detail to healthcare professionals?			
	a) Yes*	72(84.7)	83(97.6)	<0.001
	b) No	13(15.3)	2(2.4)	
20.	Have you anytime read any article on prevention of adverse drug reactions?			
	a) Yes*	64(75.2)	64(75.2)	<0.001
	b) No	21(24.8)	21(24.8)	
21.	Have you ever come across with an ADR?			
	a) Yes*	85(100)	85(100)	<0.001
	b) No	00	00	
22.	Have you ever been trained on how to report Adverse Drug Reaction (ADR)?			
	a) Yes*	14(16.4)	81(95.2)	<0.001
	b) No	71(83.6)	4(4.8)	

Correct Response*

P< 0.001(comparisons between the pre- KAP and Post- KAP responses).

3. Results

Of the 405 KAP questionnaires circulated, a total of 255 health care professionals (85 Doctors, 85 nurses and 85 pharmacists) was responded and involved in the Pre - KAP and post - KAP survey questionnaires. Question 1 sought information about definition of pharmacovigilance. Response rates for Question 1 from doctors, nurses, and pharmacist differ significantly between pre-KAP and post-KAP i.e. after educational interventions. (Table 1) doctors 55.2% to 98.9%, (Table 2) nurses 21.3% to 76.5% and pharmacist (Table 3) 77.7% to 93% respectively; *P* value <0.001 in all the three groups). Question 2 investigated important purpose of pharmacovigilance. According to the data for question 2, 28.3 % of doctors (Table 1) were given correct response in pre- KAP, 67 % of doctors were given correct response in post-KAP. In case of nurses (Table 2), 21.1% were given correct response in pre- KAP, 53% were given correct response in post- KAP. But response rates were statistically not significantly between doctors and nurses after educational interventions for question 2 (*P* value greater than 0.05). However, for question 2, response rates were statistically significant in case of pharmacist (Table 3) between pre- KAP and post-KAP questionnaires (71.7% to 93% respectively; *P* value <0.001). 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. Response rates for Question 3 from doctors, nurses, and pharmacist differ significantly between pre-KAP and post- KAP. i.e. after educational interventions (Table 1) Doctors 91.8% to 100%, (Table 2) Nurses 35.2% to 76.4% and pharmacist (Table 3) 97.6% to 100% respectively; *P* value <0.001 in all the three groups). Question 4 investigated health care professionals' awareness of reporting serious adverse events with regulatory body in India. In case of Question 4, 38.9 % of doctors (**Table 1**) were given correct response in pre- KAP, 76.4 % of doctors were given correct response in post-KAP. In case of nurses (**Table 2**), 18.9 % were given correct response in pre- KAP, 83.6% were given correct response in post- KAP. But response rates were statistically not significantly between doctors and nurses after educational interventions for question 4 (*P* value greater than 0.05). However, for question 4, response rates were statistically significantly in case of pharmacist (Table 3) between pre- KAP and post-KAP questionnaires (5.9% to 89.4% respectively; *P* value <0.001). Question 5 sought information about international center for adverse drug reactions monitoring. Response rates for Question 5 from doctors, nurses, and pharmacist, statistically significant between pre-KAP and post- KAP. Doctors 17.5% to 88.2% (Table 1), nurses 51.8% to 74.1% (Table 2) and pharmacist (Table 3) 95.3% to 100 % respectively; *P* value <0.001 in all the three groups). Question 6 sought information about agency in United States of America involved in drug safety issues. Response rates for Question 6 from doctors, nurses, and pharmacist, statistically significant between pre-KAP and post-KAP. Doctors 82.4% to 94.1% (Table 1), nurses 56.4% to 94.1% (Table 2) and pharmacist (Table 3) 80% to 100 % respectively; *P* value <0.001 in all the three groups). Question 7 sought information about major risk factors for the occurrence of maximum adverse drug reactions. Response rates for Question 7 from doctors, nurses, and pharmacist, statistically significant between pre-KAP and post- KAP. Doctors 14.1% to 35.2% (Table 1), nurses 47% to 54.2% (Table 2) and pharmacist (Table 3) 75.2% to 91.8 % respectively; *P* value <0.001 in all the three groups).Question 8 investigated which regulatory body is responsible for monitoring for ADRs in India. Response rates for Question 8 from doctors, nurses, and pharmacist, statistically significant between pre-KAP and post- KAP. Doctors 43.6% to 84.8% (Table 1), nurses 20% to 50.6% (Table 2) and pharmacist (Table 3) 97.6% to 100 % respectively; *P* value <0.001 in all the three groups).Question 9 sought information about most commonly used causality assessment of ADRs. According to the data for question 9, 14.0 % of doctors (Table 1) were given correct in response pre-KAP, 58.8% of doctors were given correct response in post-KAP. In case of nurses (Table 2), 35.2% were given correct response in pre- KAP, 56.4% were given correct response in post- KAP. But response rates were statistically not significantly between doctors and nurses after educational interventions for question 9 (*P* value greater than 0.05). However, for question 9, response rates were statistically significant in case of pharmacist (Table 3) between pre- KAP and post-KAP questionnaires (87% to 94.2% respectively; *P* value <0.001). Question 10 investigated the ADR reporting system to the respective countries by means of match the following. The overall results are statistically significant between pre-KAP and post- KAP in all the three groups *(P* value <0.001). In case of Doctor's(Table 1) response for pre-KAP and post-KAP results for yellow card- United Kingdom 47% to 70.5%, green card –Scotland 35.2% to 88.2%, ADR reporting form- India 82.4% to 94.1%, blue card-Australia 64.7% to 97.6%. In case of Nurse's(Table 2) responds for pre-KAP and post- KAP results for

yellow card- United Kingdom 47% to 64.7%, green card –Scotland 56.4% to 62.3%, ADR reporting form- India 41.1% to 76.4%, blue card- Australia 74.1% to 84.7%. In case of pharmacist's(Table 3) responds for pre-KAP and post- KAP results for yellow card- United Kingdom 94.1% to 96.4%, green card – Scotland 87% to 91.7%, ADR reporting form- India 97.1% to 100%, blue card- Australia 88.2% to 95.2%. Question 11 sought information about knowledge of regional pharmacovigilance centre in India. The overall results between pre-KAP and post- KAP in all the three groups are statistically significant *P* value <0.001; Doctor's (Table 1) responds for pre-KAP and post- KAP (47.0% and 88.2%), Nurse's (Table 2) response for pre-KAP and post- KAP (30.5% and 43.5%), pharmacist's (Table 3) response for pre-KAP and post- KAP (85.8% and 94.1%) respectively. Question 12 investigated about WHO online data base for reporting ADRs. The results are statistically significant between pre-KAP and post- KAP in all the three groups *P* value <0.001. The percentage of correct response with doctors (Table 1) for pre-KAP and post- KAP (25.9% and 76.4%), Nurse's (Table 2) response for pre-KAP and post- KAP (23.5% and 65.9%), pharmacist's (**Table 3**) response for pre-KAP and post- KAP (82.4% and 97.7%) respectively. Question 13 sought information about rare ADRs that can be identified during which phase of a clinical trial. The results are statistically not significant between pre-KAP and post- KAP in all the three groups (*P* value greater than 0.05). The percentage of correct response with doctors (Table 1) for pre-KAP and post- KAP (29.4% and 43.7%), Nurse's (Table 2) response for pre-KAP and post- KAP (54.1% and 73%), pharmacist's (Table 3) response for pre-KAP and post- KAP (73% and 90.6%) respectively. Question 14 sought information about professional responsibility for reporting ADRs. The percentage of correct response with doctors (Table 1) for pre-KAP and post- KAP (94.2% and 100%), Nurse's (Table 2), pharmacist's (Table 3) response for pre-KAP and post- KAP (100%). Question 15 investigated about factors discouraged them for reporting ADRs. The results are statistically significant between pre-KAP and post- KAP in all the three groups *P* value <0.001. The percentage of correct response with doctors (Table 1) for pre-KAP and post- KAP (87% and 97.6%), Nurse's (Table 2) response for pre-KAP and post- KAP (5.8% and 1.1%), pharmacist's (Table 3) response for pre-KAP and post- KAP (96.5% and 100%) respectively. Question 16 investigated about attitude of reporting ADRs. The results are statistically significant between pre-KAP and post- KAP in all the three groups *P* value <0.001. The percentage of correct response with doctors (Table 1) for pre-KAP and post- KAP (89.4% and 100%), Nurse's (Table 2) response for pre-KAP and post- KAP (71.8% ; 92.9%), pharmacist's (Table 3) response for pre-KAP and post- KAP (100%) respectively. Question 17 investigated about opinion about establishing ADR monitoring centre in every hospital. The results are not statistically significant between pre-KAP and post- KAP in all the three groups. The percentage of correct response with doctors (Table 1) for pre-KAP and post- KAP (70.6% and 85.9%), Nurse's (Table 2) response for pre-KAP and post- KAP (84.7% and 98.8%), pharmacist's (Table 3) response for pre-KAP and post- KAP (93% and 100%) respectively. Question 18 to 19 sought information about attitude of pharmacovigilance by means of 'yes' or 'no' questionnaires. In majority of all the three groups the percentage of correct response between pre- KAP and post- KAP was statistically significant *P* value <0.001. The aim of the question 20 was to assess health care professionals' perception and practice on prevention of adverse drug reaction. The percentage of correct response with doctors (Table 1) for pre-KAP and post- KAP (70.6% and 100%), Nurse's (Table 2) response for both pre-KAP and post- KAP (75.2%). pharmacist's (Table 3) response for pre-KAP and post- KAP (94.1% and 94%) respectively. Finally, questions 21 and 22 sought information about practice of pharmacovigilance by means of 'yes' or 'no' questionnaires.

Table 3. Knowledge, attitude, practice of the Pharmacist towards Pharmacovigilance Questionnaires before and after educational intervention.

Q	KAP Items	Pre-KAP Responses (%) N = 85	Post- KAP Responses (%) N=85	
1.	Define Pharmacovigilance?			
	a) The science of monitoring ADR's happening in a Hospital	5 (5.9)	1(1.1)	
	b) The process of improving the safety of Drugs	9(10.5)	2 (2.3)	
	c) The detection, assessment, understanding & prevention of adverse effects*	66(77.7)	79(93)	<0.001
	d) The science detecting the type & incidence of ADR after drug is marketed.	5(5.9)	3(3.6)	
2.	The most important purpose of Pharmacovigilance is			
	a) To identify safety of drugs*	61 (71.7)	81(95.3)	<0.001
	b) To calculate incidence of ADR's	00	00	
	c) To identify predisposing factors to ADR's	00	00	
	d) To identify previously unrecognized ADR's	24(28.3)	4(4.7)	
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	2(2.4)	00	
	b) Post Marketing Surveillance (PMS) studies*	83(97.6)	85(100)	<0.001
	c) Population studies	00	00	
	d) Regression analysis	00	00	
4.	A serious adverse Event in India should be reported to the Regulatory body within			
	a) One day	6(7.0)	3(3.6)	
	b) Seven calendar days	73(85.9)	5(5.9)	
	c) Fourteen calendar days*	5(5.9)	76(89.4)	<0.001
	d) Fifteen calendar days	1(1.2)	1(1.1)	
5.	The international center for adverse drug reaction			
	monitoring is located in a) Unites States of America	1(1.2)	00	
	b) Australia	2(2.3)	00	
	c) France	1(1.2)	00	
	d) Sweden*	81(95.3)	85(100)	
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)	5(5.9)	00	
	b) United States food and drug administration* (US FDA)	80(94.1)	85(100)	<0.001
	c) American Medical Association (AMA)	00	00	
	d) American Pharmaceutical Association (APA)	00	00	
7.	One of the following is a major risk factor for the occurrence of maximum adverse drug reactions			
	a) Arthritis	8(9.4)	3(3.6)	
	b) Renal failure *	64(75.2)	78(91.8)	<0.001
	c) Visual impairment	9(10.6)	2(2.3)	

	d) Vacuities	4(4.8)	2(2.3)	
8.	In India which Regulatory body is responsible for monitoring of ADR's?			
	a) Central Drugs Standard Control Organization*	83(97.6)	85(100)	<0.001
	b) Indian Institute of sciences	00	00	
	c) Pharmacy Council of India	2(2.4)	00	
	d) Medical Council of India	00	00	
9.	Which of the following scales is most commonly used to establish the causality of an adverse drug reaction?			
	a) Hartwig scale	2(2.4)	00	
	b) Naranjo algorithm*	74(87)	80(94.2)	0.076
	c) Schumock and Thornton scale	3(3.6)	00	
	d) Karch & Lasagna scale	6(7.0)	5(5.8)	
10.	Match the ADR reporting systems to the respective countries.	Number of correct responses given from N = 85 for each answers.		
	1) Yellow card -United Kingdom*	80(94.1)	82(96.4)	<0.001
	2) Green card - Scotland*	74(87)	78(91.7)	
	3) ADR reporting Form - India*	83(97.1)	85(100)	
	4) Blue card - Australia*	75(88.2)	81(95.2)	
11.	One among these is a Regional Pharmacovigilance centre?			
	a) Kasturba Hospital, Manipal	4(4.8)	2(2.3)	
	b) JIPMER, Pondicherry*	73(85.8)	80(94.1)	<0.001
	c) JSS Medical College & Hospital, Mysore	5(5.8)	3(3.6)	
	d) CMC, Vellore	3(3.6)	00	
12.	Which one of the following is the 'WHO online database' for reporting adverse drug reactions?			
	a) Adverse drug reaction advisory committtee	5(5.8)	00	
	b) Medsafe	8(9.5)	2(2.3)	
	c) Vigibase*	70(82.4)	83(97.7)	<0.001
	d) Med watch	2(2.3)	00	
13.	Rare ADRs can be identified in the following phase of a clinical trial			
	a) During phase-1 clinical trials	9(10.5)	3(3.5)	
	b) During phase-2 clinical trials	6(7.0)	2(2.4)	
	c) During phase-3 clinical trials	8(9.5)	3(3.5)	
	d) During phase-4 clinical trials*	62(73)	77(90.6)	0.243
14.	The healthcare professional/s responsible for reporting adverse drug reaction in a hospital is/are			
	a) Doctor	00	00	
	b) Pharmacist	00	00	
	c) Nurses	00	00	
	d) All of the above*	85(100)	85(100)	<0.001
15.	Which among the following factor discourage you from reporting Adverse Drug Reaction? (Any one only)			
	a) Non-remuneration for reporting	00	00	
	b) Lack of time to report ADR*	82(96.5)	85(100)	<0.001
	c) A single unreported case may not affect ADR database	2(2.3)	00	
	d) Difficult to decide whether ADR has occurred or not	1(1.2)	00	
16.	Do you think adverse drug reaction reporting is a professional obligation for you?			
	a) Yes*	85(100)	85(100)	<0.001

	b) No	00	00	
	c) Don't know	00	00	
	d) Perhap	00	00	
17.	What is your opinion about establishing ADR monitoring centre in every hospital?			
	a) Should be in every hospital*	79(93)	80(94.1)	0.285
	b) Not necessary in every hospital	1(1.1)	00	
	c) One in a city is sufficient	3(3.6)	3(3.6)	
	d) Depends on number of bed size in the hospitals	2(2.3)	2(2.3)	
18.	Do you think reporting of adverse drug reaction is necessary?			
	a) Yes*	85(100)	85(100)	<0.001
	b) No	00	00	
19.	Do you think Pharmacovigilance should be taught in detail to healthcare professionals?			
	a) Yes*	79(93)	84(98.8)	<0.001
	b) No	6(7)	1(1.2)	
20.	Have you anytime read any article on prevention of adverse drug reactions?			
	a) Yes*	80(94.1)	80(94.1)	<0.001
	b) No	5(5.9)	5(5.9)	
21.	Have you ever come across with an ADR?			
	a) Yes*	85(100)	85(100)	<0.001
	b) No	00	00	
22.	Have you ever been trained on how to report Adverse Drug Reaction (ADR)?			
	a) Yes*	76(89.4)	85(100)	<0.001
	b) No	9(10.6)	00	

Correct Response*

P < 0.001 (comparisons between the pre- KAP and Post- KAP responses).

Table 4. Comparison of effectiveness of educational intervention for awareness of pharmacovigilance among physician, pharmacist and nurses.

Group	Group compared	N = 85	Mean	Standard deviation	*P* value
Doctors	Nurses	85	4.14	1.336	0.011
	Pharmacist	85	5.08	1.328	<0.001
Nurses	Doctors	85	4.14	1.336	0.011
	Pharmacist	85	9.22	1.328	<0.001
Pharmacist	Doctors	85	5.08	1.328	<0.001
	Nurses	85	9.22	1.328	0.001

4. 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 physician, pharmacist and nurses to enhance the relationship between them for reporting adverse drug reactions. The overall results of the post-KAP questionnaire in our study was encouraging among physician, pharmacist and nurses and revealed that physicians, nurses and pharmacists enhanced awareness of reporting ADRs was reflected by an

increased in the number of ADR reports submitted to department of pharmacy practice, after they had received educational training program on pharmacovigilance. Studies[20-22] has also shown that enhancing knowledge, attitude, and practice of improving awareness can increase the number of ADR reports. This finding indicate in our study that educational intervention increased among physician, pharmacist and nurses' awareness of pharmacovigilance and able to transfer their gained knowledge into their everyday clinical practice. Although there are 22 post-KAP questionnaires that either encouraged or discouraged physician, pharmacist and nurses to know more about pharmacovigilance in our study (98.9%) of doctors, (76.5%) of nurses, (93%) of pharmacist have responded correctly to the definition of pharmacovigilance. This data suggests that continuing educational intervention is an important tool for increasing physician, pharmacist and nurse's awareness to pharmacovigilance. Based on our study results and the finding of Cosentino et al [23] and Figueras et al[24] recommend including "pharmacovigilance" as a topic in continuing education programmes and would also recommend a yearly repetition of such educational interventional program. It was also evident from our study that after educational intervention physician, pharmacist and nurse's 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 physician, pharmacist and nurse's awareness 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 8 from 43% before to 84.8% after the intervention from physician, from 20% before to 50.6% after the intervention from nurse's, from 97.6% before to 100% after the intervention from pharmacist. Question 9 from (table 1) physician shows that 14% before to 58.8% after the intervention from 35.2% before to 56.4% after the intervention from nurse's, from 87% before to 94.2% after the intervention from pharmacist. 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 94.2% before pre - KAP to 84.8% 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 E. Salehifa et al[25] in which there is lack of satisfactory knowledge of pharmacovigilance among nurses and pharmacists should educate nursing staff in reporting and managing ADRs. It was also evident from our study that pharmacist 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. We observed that in our study, doctors had a low awareness of various adverse drug reactions reporting system and adverse drug reporting cards that exist for reporting ADRs across various countries. This was supported by a study conducted by Madhan Ramesh et al.[26] which stated that doctors were less aware of the national and international pharmacovigilance programs. In the literature, a lack of time and knowledge about ADRs is often considered to be a cause of underreporting [27 - 29]. The results of the present study show that the factor discourage doctors from reporting ADRs was lack of time and types of reaction to be preferentially reported. This was supported by the study conducted by Chatterjee et.al[30] 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. 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 Li Q, Zhang et al[31] showed that educational intervention improved awareness of knowledge, attitudes, practice of healthcare professionals towards practice of pharmacovigilance. This study has two important limitations. Firstly, the study period was too short. Secondly, the study findings could not be applied to the wider community pharmacist as well as to medical community as the study was restricted to nurses, pharmacist and to physicians practicing at kasturba hospital, manipal. Therefore we recommend that several such studies of similar kind should be conducted among community pharmacist as well as to all types of medical practionnaires so as to develop strategies to improve the knowledge, attitudes, practice of pharmacovigilance in India.

5. Conclusion

In conclusion, the results of the present study demonstrate that an educational intervention can increase awareness of pharmacovigilance among the health care professionals and incorporate this gained knowledge of pharmacovigilance into their every day clinical practice. Further studies needed to strengthen effectiveness of pharmacovigilance activities are necessary.

Acknowledgements

We wish to thank all the health care professionals of Kasturba Medical College and hospital, manipal who participated in the survey. Special thanks to medical superintendent, head of the departments of medicine, chief nursing educator consultant, kasturba Hospital, manipal and chief pharmacist, KH, manipal. Also we extend our thanks to graduate pharmacist of Manipal College of pharmaceutical sciences principal, Manipal College of pharmaceutical sciences, manipal for their constant support and encouragement.

References

1. Von Laue NC, Schwappach DL, Koeck CM. The epidemiology of preventable adverse drug events: a review of literature. Wien Klin Wochenschr 2003 July 15; 115(12):407-15.
2. Wu WK, Pantaleo N. Evaluation of outpatient adverse drug reactions leading to hospitalization. Am J Health Syst Pharm 2003 February 1; 60(3):253-9.
3. Lazarou J, Pomeranz BH, Corey PN: Incidence of adverse reactions in hospitalized patients. A meta-analysis of prospective studies. JAMA 1998, 279:1200-1205.
4. Pirmohamed M, James S, Meakin S, Green C, Scott AK, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. Br Med J 2004, 329:15-19.
5. Oshikoya KA: Adverse drug reaction in children: types, incidence and risk factors. Nig J Paediatr 2006, 33:29-35.
6. Martinez-Mir I, Garcia-Lopez M, Palop V, Ferrer JM, Rubio E, Morales- Olivas FJ: A prospective study of adverse drug reactions in hospitalized children. Br J Clin Pharmacol 1999, 47:681-688.
7. Ahmad SR. Adverse drug event monitoring at the Food and Drug Administration. J Gen Intern Med.2003; 18:57-60.
8. Wysowski DK, Swartz L. Adverse drug event surveillance and drug withdrawals in the United States, 1969-2002: the importance of reporting suspected reactions. Arch Intern Med. 2005;165:1363-1369.
9. Hazell L, Shakir SA. Under-reporting of adverse drug reactions: a systematic review. Drug Saf. 2006; 29:385-396.
10. Moride Y, Haramburu F, Requejo AA, Begaud B. Under-reporting of adverse drug reactions in general practice. Br J Clin Pharmacol. 1997; 43:177-181.
11. Heeley E, Riley J, Layton D, Wilton LV, Shakir SAW. Prescription-event monitoring and reporting of adverse drug reactions. Lancet. 2001; 358:1872-1873.
12. Figueiras A, Tato F, Fontainas J, Gestal-Otero JJ.Influence of physicians' attitudes on reporting adverse drug events: a case-control study. Med Care.1999; 37:809-814.
13. Williams D, Feely J. Underreporting of adverse drug reactions: attitudes of Irish doctors. Ir J Med Sci. 1999; 168:257-261.
14. Perlik F, Slanar O, Smid M, Petracek J. Attitude of Czech physicians to adverse drug reaction reporting. Eur J Clin Pharmacol. 2002; 58:367-369.
15. Belton KJ, Lewis SC, Payne S, Rawlins MD. Attitudinal survey of adverse drug reaction reporting by medical practitioners in the United Kingdom. Br J Clin Pharmacol. 1995; 39:223-226.
16. Hasford J, Goettler M, Munter KH, Muller-Oerlinghausen B. Physicians' knowledge and attitudes regarding the spontaneous reporting system for adverse drug reactions. J Clin Epidemiol. 2002; 55:945-950.
17. Herdeiro MT, Figueiras A, Polo´ nia J, Gestal-Otero JJ. Physicians' attitudes and adverse drug reaction reporting: a case-control study in Portugal. Drug Saf. 2005; 28:825-833.
18. Rajesh R, Vidyasagar S, Nandakumar K. Highly active antiretroviral therapy induced adverse drug reactions in Indian human immunodeficiency virus positive patients. Pharmacy Practice 2011 Jan-Mar; 9(1):48-55.
19. Lynn M: Determination and quantification of content validity. Nursing Research.1986; 35:382-85.
20. Wallace SM, Suveges LG, Gesy KF. Adverse drug reaction reporting part I: a survey of pharmacists

and physicians in Saskatchewan. Drug Information Journal 1995; 29: 571-79.
21. Suveges LG, Gesy KF, Wallace SM, Blackburn JL, Appel WC. Adverse drug reaction reporting part II: evaluation of the Saskatchewan pilot project for a regional reporting program in Canada. Drug Information Journal 1995; 29: 581-589.
22. Scolt HD, Thacher – Renshaw A, Rosenbaum SE, Waters WJ, Green M, Andrews LG et al. Physician reporting of adverse drug reactions: results of the Rhode Island adverse drug reaction reporting project. JAMA 1990; 263: 1785-1788.
23. Cosentino M, Leoni O, Banfi F, Lecchini S, Frigo G: Attitudes to adverse drug reaction reporting by medical practitioners in a Northern Italian district. Pharmacol Res 1997, 35:85-88.
24. Figueiras A, Herdeiro MT, Polonia J, Gestal-Otero JJ: An educational intervention to improve physician reporting of adverse drug reactions: a cluster-randomized controlled trial. JAMA 2006, 296:1086-1093.
25. E. Salehifar, Kh. Gholam. Knowledge, attitude and performance of pharmacists and nurses in Mazandaran province, Iran regarding adverse drug reaction and its reporting. Journal of Mazandaran University of Medical Sciences 2007; 16: 115-125.
26. Ramesh M, Parthasarathi G. Adverse Drug Reactions Reporting: Attitudes and Perceptions of Medical Practitioners. Asian J of Pharmaceutical and Clinical Research 2009; 2:10-14.
27. Lopez-Gonzalez E, Herdeiro MT, Figueiras A: Determinants of under-reporting of adverse drug reactions: a systematic review. Drug Saf 2009, 32:19-31.
28. Eland IA, Belton KJ, van Grootheest AC, Meiners AP, Rawlins MD, Stricker BH: Attitudinal survey of voluntary reporting of adverse drug reactions. Br J Clin Pharmacol 1999, 48:623-627.
29. Hasford J, Goettler M, Munter KH, Muller-Oerlinghausen B: Physicians' knowledge and attitudes regarding the spontaneous reporting system for adverse drug reactions. J Clin Epidemiol 2002, 55:945-950.
30. Chatterjee S, Lyle N, Ghosh S: A survey of the knowledge, attitude and practice of adverse drug reaction reporting by clinicians in eastern India. Drug Saf 2006, 29:641-642.
31. Li Q, Zhang SM, Chen HT, Fang SP, Yu X, Liu D, Shi LY, Zeng FD: Awareness and attitudes of healthcare professionals in Wuhan, China to the reporting of adverse drug reactions. Chin Med J 2004, 117:856-861.

*****