Journal Of Harmonized Research (JOHR)

Journal Of Harmonized Research in Pharmacy
4(2), 2015, 131-139

ISSN 2321 – 0958

Original Research Article

EVALUATION OF KNOWLEDGE, AWARENESS AND ATTITUDE PRACTICE AMONG PHARMACIST IN PHARMACOVIGILANCE AT TERTIARY CARE HOSPITAL IN DELHI

Sunita Kumari[1] and Palaniappan Senthilkumar[2*]

[1] Ph. D. Research Scholar, Sri Venkateshwara University, NH-24, Venkateshwara Nagar, Rajabpur, Gajraula, Amroha, (U.P.)
[2] KMCH College of Pharmacy, Kovai Estate, Kalapatti Road, Coimbatore – 641 048. India.

Abstract: Objective: To study the knowledge of pharmacist and their attitudes for reporting Adverse Drug Reactions and also to find out their participation in reporting Adverse Drug Reactions in Tertiary care hospital in Delhi. **Methods:** This study was conduct by using validated KAP questionnaire. The reliability of validated KAP questionnaires was analysed by conducting pilot study on 50 Pharmacist and calculating Cronbach Alfa value (0.823), in order to identify the Knowledge, attitude, practice of Pharmacovigilance. Based on the previous study conducted, the sample size (230) was calculated by using SPSS v21.0 with the significance level of $P < 0.001$.**Result:** In this study total 230 Pharmacists responded. The overall response rate was significant in pharmacists ($P < 0.001$).**Conclusion:** The overall response of pharmacist showed that pharmacist working in industrial as well in hospitals lack awareness about Pharmacovigilance and they need to update their knowledge and practice for drug safety and Pharmacovigilance. There is a regular basis need for an educational intervention to update the knowledge and awareness in their everyday clinical practice.

Keywords: Pharmacovigilance; Adverse Drug Reaction; Educational intervention; pharmacists; Tertiary care hospital; KAP.

Introduction: Adverse Drug Reactions (ADRs) are an important cause of morbidity and mortality worldwide[1,2]. According to World Health Organization (WHO), "an ADR is any noxious, unintended, and undesired effect of a drug, which occurs at the doses which are used in humans for prophylaxis, diagnosis, or therapy". ADRs are a threat to the patient's safety and the quality of life and they increase the health care cost considerably. In 1994, the healthcare costs which were caused by ADRs were 4 billion dollars. In a report published by the FDA in 1989, 12000 cases of death were caused by ADRs. So, a proper monitoring for the prevention and the management of ADRs is need of the hour.

Pharmacovigilance is, "The science and the activities which relate to the detection, assessment, understanding and the prevention of

For Correspondence:
drsenthilkumarp@gmail.com
Received on: May 2015
Accepted after revision: May 2015

adverse effects or any other drug-related problems"[3].

Adverse Drug Reactions (ADRs) are associated with significant morbidity and mortality[4,5]. Recent findings show that one of the major cause of death in Unites States of America (USA) are the ADRs[1]. In the recent past, several countries have started pharmacovigilance programs to identify the drugs causing ADRs. Due to the variation in drug response among individuals, prescription formats, drug regulatory systems, drug availability etc., it has been recommended for every country to set up their own pharmacovigilance programs[3].

Even though pharmacovigilance programs successfully improves drug use patterns, but under-reporting of ADRs is a major problem[6]. To improve the reporting rate, the Knowledge, Attitude and Practices (KAP) of the healthcare professionals regarding ADR reporting and Pharmacovigilance should be enhanced. Prior to carry out intervention among the pharmacists, it is necessary to evaluate the baseline KAP of the healthcare professionals regarding ADR monitoring and Pharmacovigilance. During our literature review, we could locate only few studies that evaluate the KAP of the healthcare professionals[7,8,9].

Materials and methods

This study was conducted using validated KAP questionnaire after getting approval from Institutional Ethics Committee of Apollo Hospitals. The survey was carried from 3rd April, 2014 to 3rd Jun, 2014, where the pharmacists were approached personally in the hospital with the questionnaire.

The reliability of validated KAP questionnaires was analyzed by conducting pilot study on 50 pharmacist and calculating Cronbach Alfa value (0.823), in order to identify the Knowledge attitude practice of Pharmacists in Pharmacovigilance. Based on the previous study conducted by Rajesh *et. al.*,[10] the sample size (230) was calculated by 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. We recruited 230 subjects at 80 % power and 5 % level of significance. The study was conducted in the tertiary healthcare hospital in New Delhi, by using the validated KAP questionnaire. The survey questionnaire was administered to 500 staff pharmacists belonging to different specialties practicing across the tertiary healthcare hospital in New Delhi. Among which 230 responded to the questionnaire. The final KAP questionnaire (Appendix I) consisted of 22 question out of which question number 1 to 13 is knowledge based, question number 14 to 19 is attitude based and question number 20 to 22 is practice based questions, designed specifically to answer the awareness about Pharmacovigilance. The disclosure of name of the responder was made optional to preclude any potential bias. 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, and practice of Pharmacovigilance. The KAP survey questionnaires were analyzed question-wise and the percentage value was calculated.

Appendix I

Knowledge, Attitude and Practices of Pharmacovigilance Questionnaires.

Name: Age:

Occupation: Sex: M F

Instructions: You are requested to give information to the best of your knowledge.

Please mark tick (√) for the correct response.

(Knowledge based questions 1-13; Attitude based questions 14-19; Practice based questions 20-22)

1) Define Pharmacovigilance? (Most appropriate any one only)
   - ☐ The science of monitoring ADR's happening in a Hospital
   - ☐ The process of improving the safety of Drugs
   - ☐ The detection, assessment, understanding & prevention of adverse effects

- ☐ The science detecting the type & incidence of ADR after drug is marketed.

2) The important purpose of Pharmacovigilance is (Most appropriate one)
   - ☐ To identify safety of drugs
   - ☐ To calculate incidence of ADR's
   - ☐ To identify predisposing factors to ADR's
   - ☐ 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?
   - ☐ Meta analysis
   - ☐ Post Marketing Surveillance (PMS) studies.
   - ☐ Population studies
   - ☐ Regression analysis
4) A serious adverse Event in India should be reported to the Regulatory body within
   - ☐ One day
   - ☐ Seven calendar days
   - ☐ Fourteen calendar days
   - ☐ Fifteen Calendar days
5) The international centre for adverse drug reaction monitoring is located in
   - ☐ Unites States of America
   - ☐ Australia
   - ☐ France
   - ☐ Sweden
6) One of the following is the agency in Unites States of America involved in drug safety issues.
   - ☐ American Society of Health System Pharmacists (ASHP)
   - ☐ United States food and drug administration (US FDA)
   - ☐ American Medical Association (AMA)
   - ☐ American Pharmaceutical Association (APA)
7) One of the following is a major risk factor for the occurrence of maximum adverse drug reactions
   - ☐ Arthritis
   - ☐ Renal failure
   - ☐ Visual impairment
   - ☐ Vasculitis
8) In India which Regulatory body is responsible for monitoring of ADR's?
   - ☐ Central Drugs Standard Control Organization
   - ☐ Indian Institute of sciences
   - ☐ Pharmacy Council of India
   - ☐ Medical Council of India
9) Which of the following scales is most commonly used to establish the causality of an ADR?
   - ☐ Hartwig scale
   - ☐ Naranjo algorithm
   - ☐ Schumock and Thornton scale
   - ☐ 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	Scotland
☐ 3) ADR reporting Form	U.K.
☐ 4) Blue card	Australia

11) One among these is a national Pharmacovigilance centre?
   - ☐ Kasturba Hospital, Manipal
   - ☐ AIIMS Delhi
   - ☐ JSS Medical College & Hospital, Mysore
   - ☐ CMC, Vellore
12) Which one of the following is the 'WHO online database' for reporting ADRs?
   - ☐ ADR advisory committtee
   - ☐ Medsafe
   - ☐ Vigibase
   - ☐ Med watch
13) Rare ADRs can be identified in the following phase of a clinical trial
   - ☐ During phase-1 clinical trials
   - ☐ During phase-2 clinical trials
   - ☐ During phase-3 clinical trials
   - ☐ During phase-4 clinical trials
14) The healthcare professionals responsible for reporting ADR in a hospital is/are

- ☐ Doctor
- ☐ Pharmacist
- ☐ Pharmacists
- ☐ All of the above

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

16) Do you think reporting is a professional obligation for you?
- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Perhaps

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

18) Do you think reporting of adverse drug reaction is necessary?
- ☐ Yes
- ☐ No

19) Do you think Pharmacovigilance should be taught in detail to healthcare professionals?
- ☐ Yes
- ☐ No

20) Have you anytime read any article on prevention of adverse drug reactions?
- ☐ Yes
- ☐ No

21) Have you ever come across with an ADR?
- ☐ Yes
- ☐ No

22) Have you ever been trained on how to report Adverse Drug Reaction (ADR)?
- ☐ Yes
- ☐ No

Results & Discussion

Out of 500 KAP questionnaires circulated, all pharmacists in tertiary health care hospital in New Delhi were involved in the KAP survey questionnaires. The overall response of the pharmacists in filling the KAP was not good and most of them didn't have enough time to answer the questions. Among the 500 pharmacists selected for the study, only 230 responded and were involved in the KAP survey.

Question 1 sought information about definition of Pharmacovigilance. The response rate was 30.00 %.

Question 2 investigated important purpose of Pharmacovigilance. Only 22.17 % of pharmacists gave correct response.

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 rate for Question 3 was 35.21 %.

Question 4 investigated health care professional's awareness of reporting serious adverse events with regulatory body in India. In case of Question 4 approximately 22.17 % of pharmacists gave correct response.

Question 5 sought information about international center for adverse drug reactions monitoring and the response rate was 21.73 %.

Question 6 sought information about agency in United States of America involved in drug safety issues. Response rate for Question 6 from pharmacists was found to be 35.65 %.

Question 7 sought information about major risk factors for the occurrence of maximum adverse drug reactions. Response rate for Question 7 was 35.21 %.

Question 8 investigated which regulatory body is responsible for monitoring ADRs in India. Response rate for Question 8 from pharmacists was found to be 37.39 %.

Question 9 sought information about most commonly used causality assessment of ADRs. According to the data for question 9, 26.08 % of pharmacists gave correct response.

Question 10 investigated the ADR reporting system to the respective countries by means of match the following. In case of Pharmacist's response for yellow card – United Kingdom 46.95 %, green card – Scotland 37.82 %, ADR reporting form – India 54.78 %, blue card – Australia 39.56 %.

Question 11 sought information about knowledge of regional Pharmacovigilance centre in India. Pharmacists responded 39.56 % for KAP.

Question 12 investigated about WHO online data base for reporting ADRs. The percentages of correct response were found to be 25.21 %.

Question 13 sought information about rare ADRs that can be identified during each phase of a clinical trial. The percentage of correct response was 25.21 %.

Question 14 sought information about professional responsibility for reporting ADRs. The percentage of correct response from pharmacists was 50.86 %.

Question 15 investigated about factors discouraged them for reporting ADRs. The percentage of correct response from pharmacists was 51.73 %.

Question 16 investigated about attitude of reporting ADRs. The percentage of correct response was 57.39 %.

Question 17 investigated about opinion about establishing ADR monitoring centre in every hospital. 70.86 % of pharmacist gave correct response.

Question 18 sought information about attitude of Pharmacovigilance by means of 'yes' or 'no' questionnaires, the percentage of correct response was 82.17 % from pharmacists *i.e.*, yes.

Question 19 sought information about attitude of Pharmacovigilance by means of 'yes' or 'no' questionnaires. The percentage of correct response among pharmacists was found to be 86.52 % *i.e.*, yes.

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 that 70 % pharmacists were in habit of doing this and most of them were from industry. Finally, Questions 21 and 22 sought information about practice of Pharmacovigilance by means of 'yes' or 'no' questionnaires. In case of Question 21, 24.78 % pharmacists responded 'yes'. In case of Question 22, 15.65 % pharmacists responded 'yes'.

The study was performed on 230 pharmacists from tertiary care hospitals in Delhi to evaluate the knowledge, attitude and practice of Pharmacovigilance and the results are tabulated in **table 1.**

Table 1. Responses for knowledge, attitude and practice of Pharmacists towards Pharmacovigilance questionnaires.

S. No.	Question	Pharmacists Response N=230	Percentage Response
1.	**Define Pharmacovigilance**		
	The science of monitoring ADR's happening in a Hospital	71	30.86
	The process of improving the safety of Drugs	81	35.21
	The detection, assessment, understanding & prevention of adverse effects*	69	30.00
	The science detecting the type & incidence of ADR after drug is marketed.	9	3.91
2.	**The important purpose of Pharmacovigilance is**		
	To identify safety of drugs*	51	22.17

	To calculate incidence of ADR's	34	14.78
	To identify predisposing factors to ADR's	74	32.17
	To identify unrecognized ADR's	71	30.86
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	10	4.34
	Post Marketing Surveillance (PMS) studies*	81	35.21
	Population studies	25	10.86
	Regression analysis	144	62.60
4.	**A serious adverse Event in India should be reported to the Regulatory body within**		
	One day*	51	22.17%
	Seven calendar days	81	35.21%
	Fourteen calendar days	41	17.82%
	Fifteen Calendar days	57	24.78%
5.	**The international centre for adverse drug reaction monitoring is located in**		
	Unites States of America	153	66.52
	Australia	1	0.43
	France	26	11.30
	Sweden*	50	21.73
6.	**One of the following is the agency in Unites States of America involving in drug safety issues.**		
	American Society of Health System Pharmacists (ASHP)	12	5.21
	United States food and drug administration (US FDA)*	82	35.65
	American Medical Association (AMA)	135	58.69
	American Pharmaceutical Association (APA)	1	0.43
7.	**One of the following is a major risk factor for the occurrence of maximum ADRs**		
	Arthritis	00	00.00
	Renal failure*	81	35.21
	Visual impairment	75	32.60
	Vasculitis	74	32.17
8.	**In India which Regulatory body is responsible for monitoring of ADR's**		
	Central Drugs Standard Control Organization*	86	37.39
	Indian Institute of sciences	00	00.00
	Pharmacy Council of India	11	4.78
	Medical Council of India	133	57.82
9.	**Which of the following scales is most commonly used to establish the causality of ADR**		
	Hartwig scale	76	33.04
	Naranjo algorithm *	60	26.08
	Schumock and Thornton scale	79	34.34
	Karch & Lasagna scale	15	6.52
10.	**Match the ADR reporting systems to the respective countries.**		
	1) Yellow card - United Kingdom	108	46.95
	2) Green card - Scotland	87	37.82
	3) ADR reporting Form - India	126	54.78

	4) Blue card - Australia	91	39.56
11.	**One among these is a national Pharmacovigilance centre**		
	Kasturba Hospital, Manipal	69	30.00
	AIIMS Delhi*	91	39.56
	JSS Medical College & Hospital, Mysore	68	29.56
	CMC, Vellore	2	0.86
12.	**Which one of the following is the 'WHO online database' for reporting ADRs**		
	ADR advisory committee	99	43.04
	Medsafe	3	1.30
	Vigibase*	58	25.21
	Med watch	70	30.43
13.	**Rare ADRs can be identified in the following phase of a clinical trial**		
	During phase-1 clinical trials	141	61.30
	During phase-2 clinical trials	7	3.04
	During phase-3 clinical trials	24	10.43
	During phase-4 clinical trials*	58	25.21
14.	**The healthcare professionals responsible for reporting ADR in a hospital is/are**		
	Doctor	39	16.95
	Pharmacist	42	18.26
	Nurses	32	13.91
	All of the above*	117	50.86
15.	**Which among the following factors discourage you from reporting ADRs**		
	Non-remuneration for reporting	38	16.25
	Lack of time to report ADR*	119	51.73
	A single unreported case may not affect ADR database	27	11.73
	Difficult to decide whether ADR has occurred or not	46	20.00
16.	**Do you think reporting is a professional obligation for you**		
	Yes*	132	57.39
	No	55	23.91
	Don't know	23	10.00
	Perhaps	20	8.69
17.	**What is your opinion about establishing ADR monitoring centre in every hospital**		
	Should be in every hospital*	163	70.86
	Not necessary in every hospital	21	9.13
	One in a city is sufficient	19	8.26
	Depends on number of bed size in the hospitals.	27	11.73
18.	**Do you think reporting of adverse drug reaction is necessary**		
	a) Yes*	189	82.17
	b) No	41	17.82
19.	**Do you think Pharmacovigilance should be taught in detail to healthcare professionals**		
	a) Yes*	199	86.52
	b) No	31	13.47
20.	**Have you anytime read any article on prevention of adverse drug reactions**		
	a) Yes*	69	30.00
	b) No	161	70.00

21.	**Have you ever come across with an ADR**		
	a) Yes*	57	24.78
	b) No	173	75.21
22.	**Have you ever been trained on how to report Adverse Drug Reaction (ADR)**		
	a) Yes*	36	15.65
	b) No	194	84.34

The overall knowledge among pharmacist was 29.63 %. The basic factors considered to determine the knowledge of Pharmacovigilance is Definition of pharmacovigilance, Purpose of pharmacovigilance, PMS, Time lines for Reporting, Drug International centre for monitoring, Regulatory agencies, ADR, Regulatory Body of India, Scale Causality Assessment, PvPI, WHO online data base and rare ADRs.

Moreover, the awareness about the International ADR reporting system among pharmacist was 48.26 %. Overall attitude based on ADR reporting, responsibility, professional obligation, importance of ADR and teachings, towards nurses were 46.13 %. 86.52 % believed that HCPs should be given teachings on Pharmacovigilance. This clearly shows that they have very positive attitude towards Pharmacovigilance but they lack the knowledge in the field of Pharmacovigilance. Therefore updating knowledge and importance of pharmacovigilance should be regularly given to the HCPs.

The most discouraging factor due to which tertiary health care hospital lacks in ADR reporting was found that the HCPs do not have sufficient time for it. The second factor was found that HCPs fail to decide whether the ADR has occurred or not. While some HCPs believe that a single unreported case may not affect the ADR database, as well as Non-Remuneration for reporting. Most of the HCPs think that reporting of ADR are not necessary, reporting a single ADR will not affect any data.

The attitude towards the establishment of ADR monitoring centre in hospitals was 70.86 % among pharmacist. While the rest percentage believes that it is not necessary in every hospital, one is sufficient in city or depends on the number of bed size in hospitals.

Among 230, 23.48 % of pharmacist are practicing Pharmacovigilance like Reading PV articles, came across with ADRs and are trained on ADRs, which is extremely low. Pharmacovigilance practice should be increased by training the HCPs about its importance.

With new drugs coming to the market as well as the older widely used drugs being banned for one or other serious side effects, it is of utmost importance that there should be awareness among the HCPs so that they can guide the patients on safe usage of drugs.

With a strong knowledge of pharmacovigilance and using that knowledge in daily practice it will be easy to monitor the adverse effects of a drug and it would ensure the safety of patients. To increase the awareness of reporting of ADRs, workshops and seminars should be arranged from time to time.

Summary & Conclusions

In conclusion, the study demonstrated that there is a lack of awareness of Pharmacovigilance among the pharmacists as they spent maximum time with patient, nurses and paramedical staff and hence play a are very important role in practicing pharmacovigilance. There is a need for an educational intervention to increase the knowledge and awareness and to incorporate the gained knowledge into their every day clinical practice.

This can be achieved by incorporating pharmacovigilance as subject in academics of HCPs and by arranging seminars and workshops on Pharmacovigilance on regular basis so that they are aware about all the recent changes so that the common people are kept aware and safe.

References

1. Lazarou J, Pomeranz BH, Corey PN. The incidence of adverse drug reactions in hospitalized patients: A meta-analysis of prospective studies. *JAMA*, 1998, 279, 1200–5.
2. Classen DC, Pestotnik SL, Evans RS. The adverse drug events in hospitalized patients. *JAMA*, 1997, 277, 4, 301–6.
3. The World Health Organization. Safety of medicines: A guide to detecting and reporting adverse drug reactions. Geneva, 2002, WHO/EDM/QSM/2002 2.
4. Beard K. Adverse reactions as a cause of hospital admission in the aged. *Drugs and Aging*, 1992, 2, 356-67.
5. Murphy BM, Frigo LC. Development implementation and results of a successful multidisciplinary adverse drug reaction reporting program in a university teaching hospital. *Hosp Pharm.*, 1993, 28, 1199-204.
6. Lee A, Thomas SHL. Adverse drug reactions In: Walker R and Edward C. Clinical pharmacy and Therapeutics. 3rd edition Churchill Livingstone. 2003, 33-46.
7. Rehan HS, Vasudev K, Tripathi CD. Adverse drug reaction monitoring: knowledge, attitude and practices of medical students and prescribers. *Natl Med J India*, 2002, 15, 24-6.
8. Graille V, Lapeyre-Mestre M, Montastruc JL. Drug vigilance: opinion survey among residents of a university hospital. *Therapie.*, 1994, 49, 451-4.
9. Cosentino M, Leoni O, Banfi F, Leechini S, Frigo G. Attitudes to adverse drug reaction reporting by medical practitioners in a Northern Italian district. *Pharmacol Res.*, 1997, 35, 85.
10. Rajesh R, Vidyasagar S, Varma DM. An educational intervention to assess knowledge attitude practice of pharmacovigilance among Health care professionals in an Indian tertiary Care teaching hospital. *International journal of pharmtech research.*, 2011, 3(2), 678-92.