Journal Of Harmonized Research (JOHR)

Journal Of Harmonized Research in Pharmacy
4(1), 2015, 76-86

ISSN 2321 – 0958

Original Research Article

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

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Abstract: Objective: To study knowledge of nurses and their attitudes for reporting Adverse Drug Reactions and also to find out the participation in reporting Adverse Drug Reactions in Tertiary care hospital in Delhi. **Methods:** This study was conducted by using validated KAP questionnaire. The reliability of validated KAP questionnaires was analysed by conducting pilot study on 50 Nurses 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 $P < 0.001$. **Result:** In this study total 230 Nurses responded. The overall response rate was significant in nurses ($P < 0.001$). **Conclusion:** The overall response of nurses showed that there is a lack of awareness of Pharmacovigilance among the nurses and they need to update knowledge of practice for drug safety and Pharmacovigilance practices. There is a need for an educational intervention to increase the knowledge and awareness; and to incorporate the gained knowledge into their everyday clinical practice.

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

Introduction: Adverse drug reaction (ADR) is defined as "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function" as per the World Health Organization (WHO)[1]. ADRs are the most important health care problem throughout the world affecting people with varying magnitudes and are the reason for both morbidity and mortality[2, 3].

Pharmacovigilance is defined as "the science and activity related to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems"[4]. Pharmacovigilance Programme of India (PvPI) initiated ADR monitoring centers (AMCs) to bring pharmacovigilance into practice and to enhance patient safety. AMCs

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Received on: February 2015
Accepted after revision: March 2015
Downloaded from: www.johronline.com

includes Medical Council of India (MCI) approved medical colleges & hospitals, private hospitals, public health programs and autonomous institute (ICMR etc.)[5].

Spontaneous reporting of ADRs plays a major role in the detection of unsuspected, serious, and unusual ADRs which were previously undetected during the clinical trial phases. Reporting of ADRs are the main cause of withdrawal of many drugs *viz.*, rofecoxib, cisapride, terfenadine, in the recent past[6]. Even though, health professionals contribute enormously, underreporting of the ADRs still remains a major hindrance in the complete success of pharmacovigilance program[7]. The most worrying part is that, only 6 – 10 % of all ADRs are reported[8,9]. This high rate of under-reporting is a matter of great concern which delays detection of serious ADRs and consequently has major negative impact on the public health.

Various factors based on knowledge and perception of health professionals, have been attributed for underreporting of ADRs. Inman[10] has described them as "seven deadly sins". These includes: *Financial incentives*: Rewards can be given for reporting ADRs; *Legal aspects*: Fear of lawsuit or inquiry into cost of prescribing and ambition to compile or publish a case; *Complacency*: Belief that very serious ADRs would have been well documented before the drug is marketed; *Diffidence*: Belief that ADR should be reported only if it was certain that the ADR was due to the use of a particular drug; *Indifference*: The single case observed by an individual doctor can't contribute to the medical knowledge; *Ignorance*: The belief that only serious or unexpected ADRs are necessary to report, and excuses given by the professionals; and *Lethargy*: The procrastination and disinterest to report ADR or no time to find report card, and other similar excuses[10].

The Uppsala Monitoring Centre: The principal function of the Uppsala Monitoring Centre is to manage the international database of ADR reports received from National Centers[11]. Hospitals and Academia: Many medical institutions have started adverse drug reaction and medication error close watch systems in their clinics, wards and emergency rooms. Case-control studies and other pharmacoepidemiological methods have been used to estimate the post-marketing toxicities of the medicines. Academic centers of pharmacology and pharmacy have played an important role through teaching, training, research, policy development, clinical research, ethics committees (institutional review boards) and the clinical services[11-13]. Health Professionals: Initially physicians were the only professionals invited to report ADRs and to judge whether a certain symptom is caused by a disease or medicine. Today, different categories of health professionals observe different kinds of drug related problems[14,15]. Patients: Only a patient can tell the real benefit and toxicity of a medicine taken. Direct participation of patients in the reporting of drug related problems is required to increase the competency of the pharmacovigilance system and compensate for the defect of system based on reports from health professionals.

Knowledge, awareness and attitude of the health care professionals (HCPs) play a major role in the reporting of adverse drug reactions[16]. Several studies have been conducted to study the importance and duties of doctors[17-20], nurses[21-22], pharmacists[23] and health care professionals[24-30] regarding their role in the reporting of adverse drug reactions and in pharmacovigilance.

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 3 April, 2014 to 3 Jun, 2014 where the Nurses were approached personally in the hospital with the questionnaire.

The reliability of validated KAP questionnaires was analyzed by conducting pilot study on 50 Nurses and calculating Cronbach Alfa value (0.823), in order to identify the Knowledge attitude practice of Nurses in Pharmacovigilance. Based on the previous study conducted by Rajesh *et. al.*,[16] 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 [16] 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 Validated KAP questionnaire. The survey questionnaire was administered to 500 staff nurses 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 questionnaire 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. In order to preclude any potential bias the disclosure of name of the responder was made optional. All participants were also provided with sufficient time to fill the KAP questionnaire. KAP questionnaire was administered at the beginning of the study, in order to identify the Knowledge, attitude, and practice of Pharmacovigilance. The KAP survey questionnaires were analyzed question wise and their 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 — United Kingdom
   - ☐ 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
   - ☐ Nurses
   - ☐ 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 nurses in tertiary health care hospital in New Delhi responded and involved in the KAP survey questionnaires. The overall response of the nurses in filling the KAP was not good and most of them didn't have enough time to answer the questions. Among the 500 nurses selected for the srudy, only 230 responded and were involved in the KAP survey.

Question 1 sought information about definition of Pharmacovigilance. A response rate for Question 1 for nurses was 44.34 %.

Question 2 investigated important purpose of Pharmacovigilance. According to the data for question 2, 40.86 % of nurses 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 from nurses was 41.37 % respectively.

Question 4 investigated health care professional's awareness of reporting serious adverse events with regulatory body in India. In case of Question 4 approximately 23.91 % of nurses gave correct response.

Question 5 sought information about international center for adverse drug reactions monitoring and the response rate for nurses was 17.39 % respectively.

Question 6 sought information about agency in United States of America involved in drug safety issues. Response rate for Question 6 from nurses found to be 40.00 % respectively.

Question 7 sought information about major risk factors for the occurrence of maximum adverse drug reactions. Response rate for Question 7 from nurses was 43 %.

Question 8 investigated which regulatory body is responsible for monitoring ADRs in India. Response rate for Question 8 for nurses found to be 28.26 % respectively.

Question 9 sought information about most commonly used causality assessment of ADRs.

According to the data for question 9, 18.69 % of nurses gave correct response.

Question 10 investigated the ADR reporting system to the respective countries by means of match the following. In case of Nurse's response for yellow card – United Kingdom 43.04 %, green card – Scotland 36.52 %, ADR reporting form – India 67.82 %, blue card – Australia 43.04 %.

Question 11 sought information about knowledge of regional Pharmacovigilance centre in India. Nurses responded 46.95 % for KAP.

Question 12 investigated about WHO online data base for reporting ADRs. The percentage of correct response in Nurses was found to be 26.95 %.

Question 13 sought information about rare ADRs that can be identified during which phase of a clinical trial. The percentage of correct response in Nurse's was 7.39 %.

Question 14 sought information about professional responsibility for reporting ADRs. The percentages of correct response of nurses were 52.60 %.

Question 15 investigated about factors discouraged them for reporting ADRs. The percentage of correct response of nurses was 38.26 % respectively.

Question 16 investigated about attitude of reporting ADRs. The percentage of correct response of nurses was 52.60 % respectively.

Question 17 investigated about opinions to establish ADR monitoring centre in every hospital. The percentage of correct response of nurses was 70.86 %.

Question 18 sought information about attitude of Pharmacovigilance by means of 'yes' or 'no' questionnaires, the percentage of correct response was 90.00 % from nurses i.e. yes.

Question 19 sought information about attitude of Pharmacovigilance by means of 'yes' or 'no' questionnaires. The percentage of correct response among nurses was found to be 87.82 % *i.e.*, yes.

The aim of Question 20 was to assess health care professionals' perception and practice on prevention of adverse drug reaction. The percentage of correct response was 29.56 %.

Finally, Questions 21 and 22 sought information about practice of Pharmacovigilance by means of 'yes' or 'no' questionnaires. In case of Question 21, 27.39 % nurses respond 'yes'. In case of Question 22, 22.17 % nurses responded 'yes'.

The study was performed on 230 nurses 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 Nurses towards Pharmacovigilance questionnaires.

S. No.	Questions	Nurses Response N=230	Percentage Response
1.	**Define Pharmacovigilance.**		
	The science of monitoring ADR's happening in a Hospital	48	20.86
	The process of improving the safety of Drugs	66	28.69
	The detection, assessment, understanding & prevention of adverse effects*	102	44.34
	The science of detecting the type & incidence of ADR after drug is marketed.	14	6.08
2.	**The important purpose of Pharmacovigilance is**		
	To identify safety of drugs*	94	40.86
	To calculate incidence of ADR's	51	22.17
	To identify predisposing factors to ADR's	61	26.52
	To identify unrecognized ADR's	24	10.43
3.	**Which of the following methods is commonly employed by the pharmaceutical companies**		

	to monitor adverse drug reactions of new drugs once they are launched in the market ?		
	Meta analysis	81	35.21
	Post Marketing Surveillance (PMS) studies*	96	41.73
	Population studies	38	16.52
	Regression analysis	15	6.52
4.	**A serious adverse Event in India should be reported to the Regulatory body within**		
	One day*	55	23.91
	Seven calendar days	87	37.82
	Fourteen calendar days	50	21.73
	Fifteen Calendar days	38	16.52
5.	**The international centre for adverse drug reaction monitoring is located in**		
	Unites States of America	128	55.65
	Australia	28	12.17
	France	34	14.78
	Sweden*	40	17.39
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)	25	10.86
	United States food and drug administration (US FDA)*	92	40.00
	American Medical Association (AMA)	59	25.65
	American Pharmaceutical Association (APA)	54	23.47
7.	**One of the following is a major risk factor for the occurrence of maximum adverse drug reactions.**		
	Arthritis	56	24.34
	Renal failure*	100	43.47
	Visual impairment	53	23.04
	Vasculitis	21	9.13
8.	**In India which Regulatory body is responsible for monitoring of ADR's ?**		
	Central Drugs Standard Control Organization*	65	28.26
	Indian Institute of sciences	42	18.26
	Pharmacy Council of India	108	46.95
	Medical Council of India	15	6.52
9.	**Which of the following scales is most commonly used to establish the causality of an ADR ?**		
	Hartwig scale	78	33.91
	Naranjo algorithm *	43	18.69
	Schumock and Thornton scale	85	36.95
	Karch & Lasagna scale	24	10.43
10.	**Match the ADR reporting systems to the respective countries.**		
	1) Yellow card - United Kingdom	112	48.69
	2) Green card - Scotland	84	36.52
	3) ADR reporting Form - India	156	67.82
	4) Blue card - Australia	99	43.04
11.	**One among these is a national Pharmacovigilance centre.**		
	Kasturba Hospital, Manipal	46	20.00
	AIIMS Delhi*	108	46.95
	JSS Medical College & Hospital, Mysore	51	22.17
	CMC, Vellore	25	10.86

12.	**Which one of the following is the 'WHO online database' for reporting ADRs ?**		
	ADR advisory committee	111	48.26
	Medsafe	39	16.95
	Vigibase*	62	26.95
	Med watch	18	7.82
13.	**Rare ADRs can be identified in the following phase of a clinical trial.**		
	During phase-1 clinical trials	77	33.47
	During phase-2 clinical trials	76	33.04
	During phase-3 clinical trials	60	26.08
	During phase-4 clinical trials*	17	7.39
14.	**The healthcare professionals responsible for reporting ADR in a hospital is/are**		
	Doctor	8	3.47
	Pharmacist	54	23.47
	Nurses	47	20.43
	All of the above*	121	52.60
15.	**Which among the following factors discourage you from reporting Adverse Drug Reactions ?**		
	Non-remuneration for reporting	54	23.47
	Lack of time to report ADR*	88	38.26
	A single unreported case may not affect ADR database	19	8.26
	Difficult to decide whether ADR has occurred or not	69	30.00
16.	**Do you think reporting is a professional obligation for you ?**		
	Yes*	121	52.60
	No	59	25.65
	Don't know	24	10.43
	Perhaps	26	11.30
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	12	5.21
	One in a city is sufficient	29	12.60
	Depends on number of bed size in the hospitals.	26	11.30
18.	**Do you think reporting of adverse drug reaction is necessary ?**		
	a) Yes*	207	90.00
	b) No	23	10.00
19.	**Do you think Pharmacovigilance should be taught in detail to healthcare professionals ?**		
	a) Yes*	202	87.82
	b) No	28	12.17
20.	**Have you anytime read any article on prevention of adverse drug reactions ?**		
	a) Yes*	167	72.60
	b) No	63	27.39
21.	**Have you ever come across with an ADR ?**		
	a) Yes*	125	54.34
	b) No	105	45.65
22.	**Have you ever been trained on how to report Adverse Drug Reaction (ADR) ?**		
	a) Yes*	161	70.00
	b) No	69	30.00

The overall knowledge among nurses was 31.66 %. 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 nurses was 49.02 %. Overall attitude based on ADR reporting, responsibility, professional obligation, importance of ADR and teachings, towards nurses were 47.17 %. 87.82 % 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 case if unreported, 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 nurses. 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, 26.37 % of nurses 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 nurses as they spent maximum time with patient and they are the first point of contact for the patient and hence 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.

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