



Original Article

Evaluation of Knowledge, Awareness and Attitude Practice among Health Care Professionals about Pharmacovigilance at Tertiary Care Hospital in Delhi

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ARTICLE INFO

A B S T R A C T

Received: 28 Aug 2017

Accepted: 12 Sep 2017

Objective: To study the knowledge of Health Care Professional's and their attitudes for reporting adverse drug reactions and also to find out their participation in reporting ADRs in Tertiary care hospital in Delhi.

Methods: This study was conducted by using validated KAP questionnaire. The reliability of validated KAP questionnaires was analyzed by conducting a 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 690 HCP's responded. The overall response rate was significantly in HCP's ($P < 0.001$). Health care professionals play a major responsible role in reporting ADRs. Knowledge, attitude and practice (KAP) survey was done among HCP's including physicians, pharmacists and nurses. Almost 1500 KAP questionnaire was distributed to assess their knowledge, attitude and practice towards Pharmacovigilance. Out of which 230 responded from each group of HCP's for the KAP questionnaire

Conclusion: Compared to nurses and pharmacists, physicians have a better understanding of Pharmacovigilance, but they lag in practice and attitude. The study demonstrated that there is a lack of awareness of Pharmacovigilance among the Health care professionals. There was a need for an educational intervention among the health care professionals to increase the knowledge, awareness and to change attitude towards Pharmacovigilance.

Keywords: Pharmacovigilance, Adverse Drug Reaction, Health Care Professionals, Tertiary care hospital, KAP.

1. INTRODUCTION

Adverse Drug Reactions (ADRs) are an important cause of morbidity and mortality worldwide^{1,2}. According to World Health Organization (WHO), "an Adverse Drug Reaction (ADR) is any noxious, unintended, and undesired effect of a drug, which occurs at the doses which are used in humans

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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 health care costs, which were caused by ADRs were 4 billion dollars. In a report published by the Food and Drug Administration (FDA) in 1989, 12000 cases of death were caused by ADRs. So, a proper monitoring for the prevention and the management of ADRs is the need of the hour. Pharmacovigilance is, "The science and the activities which relate to the detection, assessment, understanding and the prevention of adverse effects or any other drug-related problems"³.

ADRs are associated with significant morbidity and mortality^{4,5}. Recent findings show that one of the major causes of death in Unites States of America (USA) are the ADRs¹. 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 programs³.

Even though Pharmacovigilance programs successfully improves drug use patterns, but under-reporting of ADRs is a major problem⁶. To improve the reporting rate, the Knowledge, Attitude and Practices (KAP) of the Health Care Professionals (HCPs) regarding ADR reporting and Pharmacovigilance should be enhanced. Prior to carrying 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 a few studies that evaluate the KAP of the health care professionals^{7,8,9}.

2. MATERIALS AND METHODS

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

The reliability of validated KAP questionnaires was analyzed by conducting a pilot study on 50 pharmacist and calculating Cronbach Alfa value (0.823), in order to identify the Knowledge attitude practice of Pharmacists in Pharmacovigilance. The sample size (230) was calculated by using Statistical Package for Social Science (SPSS) version 21.0 with the significant level $P < 0.001$ [10, 11]. The standard deviation (SD) between pre- and post-KAP score is 24 and the mean percent difference is 4. 230 subjects were recruited 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 800 HCPs of different specialties practicing across the tertiary healthcare hospital in New Delhi. Among which 690 responded to the questionnaire. The final KAP questionnaire (Appendix I)

consisted of 22 questions 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 the 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.

Knowledge, Attitude and Practices of Pharmacovigilance Questionnaires.

Name: _____ :

Occupation: _____

Sex: M _____ F _____

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

Please mark ticks () 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 aadrug 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)
- | | |
|--|----------------|
| <input type="checkbox"/> 1) Yellow card | India |
| <input type="checkbox"/> 2) Green card | Scotland |
| <input type="checkbox"/> 3) ADR reporting Form | United Kingdom |
| <input type="checkbox"/> 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 committee
 - 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 the 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 centers in every hospital?
- Should be in every hospital
 - Not necessary in every hospital
 - One in a city is sufficient
 - Depends on the 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 health care 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

3. RESULTS AND DISCUSSION

The study was performed on the 690 HCPs from hospitals to evaluate the knowledge, attitude and practice of Pharmacovigilance of Delhi region, towards the reporting of ADRs and the awareness about Pharmacovigilance, was assessed by using a KAP questionnaire.

The overall response rate of HCPs was 53.07 %. It was observed that among the HCPs that participated, only half of them could give correct responses to the questions asked in the KAP questionnaire.

The present study was planned to know the thoughts, views and awareness of the Pharmacovigilance practice among HCPs. The survey showed that among HCPs, physicians were aware of Pharmacovigilance whereas in the case of nurses and pharmacist they were not even 50 % aware, few among them were aware of some aspects regarding Pharmacovigilance practices.

The overall knowledge among doctors was found to be 60.75 %, whereas nurses and pharmacists have overall 31.66 % and 29.63 % knowledge respectively. The basic factors considered to determine the knowledge of Pharmacovigilance were Definition of Pharmacovigilance, Purpose of Pharmacovigilance, PMS, Time lines for

Reporting, Drug International Centre for monitoring, Regulatory agencies, ADR, Regulatory Body of India, Scale CA, PVPI, WHO online data base and rare ADRs. The data is given in Table 1 and Figure 1.

The awareness about the International ADR reporting system among HCPs showed that 49.13 % were aware of the reporting system, 49.02 % nurses were aware of the reporting system and 48.26 % nurses were aware of the reporting system. The results are give in Table 2 and Figure 2.

Overall attitude based on ADR reporting responsibility, Professional obligation, importance of ADR and Teachings to HCPs among doctors towards Pharmacovigilance was found to be 59.96 %. Nurses and pharmacists have 47.17 % and 46.13 % of attitude respectively. Among these, 86.52 % of doctors, 87.82 % of nurses and 86.52 % of pharmacists believe that HCPs should be given the teachings on Pharmacovigilance. This clearly shows that they have a very positive attitude towards Pharmacovigilance but they lack knowledge in the field. Therefore, knowledge about the importance of PV should be regularly given to the HCPs (Table 3 and Figure 3).

The most discouraging factor due to which tertiary health care hospital lacks in ADR reporting was that 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 the reporting of ADRs are not necessary, reporting a single ADR will not affect any data (Table 4 and Figure 4).

The attitude towards the establishment of an ADR monitoring center in hospitals was 83.04 % among doctors, 70.86 % among nurses and 70.86 % among the pharmacists as illustrated in Table 5 and Figure 5. While the rest percentage believes that it is not necessary in every hospital, one is sufficient in the city or depends on the number of bed size in hospitals.

Among 230, 47.82 % of doctors, 26.37 % of nurses and 23.48 % of pharmacists are practicing Pharmacovigilance like Reading Pharmacovigilance articles, come across with ADRs and are trained on ADRs, which is extremely low. Pharmacovigilance practice should be increased by training the HCPs about its importance. The results are tabulated in Table 6 and Figure 6.

Table 1: Comparison between HCPs on the basis of Knowledge

Topics	Physicians	Nurses	Pharmacists
PV Definition	56.08 %	44.34 %	30.00 %
Purpose PV	66.95 %	40.86 %	22.17 %
PMS	83.91 %	41.73 %	35.21 %
Time lines for reporting	40.86 %	23.91 %	22.17 %
International center for ADR monitoring	48.62 %	17.39 %	21.73 %
Regulatory agencies	88.69 %	40.00 %	35.65 %
ADR	80.00 %	43.00 %	35.21 %
Regulatory body India	46.95 %	28.26 %	37.39 %

Scale CA	31.30 %	18.69 %	26.08 %
PVPI	78.26 %	46.95 %	39.56 %
WHO online database	37.82 %	26.95 %	25.21 %
Rare ADRS	69.56 %	7.39 %	25.21 %

Table 2: Knowledge about International Reporting System among the HCPs

S. No	Topics	Doctors	Nurses	Pharmacists
1	UK	43.91 %	48.69 %	53.47 %
2	Scotland	36.52 %	36.52 %	37.82 %
3	India	74.34 %	67.82 %	62.17 %
4	Australia	41.73 %	43.04 %	39.56 %

Table 3: Comparison of the HCPs on the basis of Attitude of HCPs

S. No	Topics	Doctors	Nurses	Pharmacists
1	ADR reporting responsibility of HCP	83.04 %	52.60 %	50.68 %
2	Professional obligation	73.91 %	52.60 %	57.39 %
3	Reporting of ADR is important	98.26 %	90.00 %	82.17 %
4	PV teaching for HCPS	86.52 %	87.82 %	86.52 %

Table 4: Discouraging factors for ADR Reporting

S. No	Topics	Physicians	Nurses	Pharmacists
1	Non – remuneration for reporting	16.95 %	23.47 %	22.17 %
2	Lack of time to report ADR*	36.95 %	38.26 %	35.21 %
3	A single unreported case may not affect the ADR database	9.56 %	8.26 %	18.26 %
4	Difficult to decide whether ADR has occurred or not	36.52 %	30.00 %	24.34 %

Table 5: Comparison among HCPs on the basis of establishment of ADR monitoring center in Hospital

S. No	Topics	Physicians	Nurses	Pharmacists
1	Should be in every hospital	83.04 %	70.86 %	70.86 %
2	Not necessary in every hospital	5.21 %	5.21 %	9.13 %
3	One in a city is sufficient	2.60 %	12.60 %	8.26 %
4	Depends on the number of bed size in the hospitals.	9.13 %	11.30 %	11.73 %

Table 6: Comparison among HCPs on the basis of practice of HCPs

S. No	Topics	Physicians	Nurses	Pharmacists
1	Reading PV article	56.52 %	29.56 %	30.00 %
2	ADR reported	63.47 %	27.39 %	24.78 %
3	Trained in ADR	23.47 %	22.17 %	15.65 %

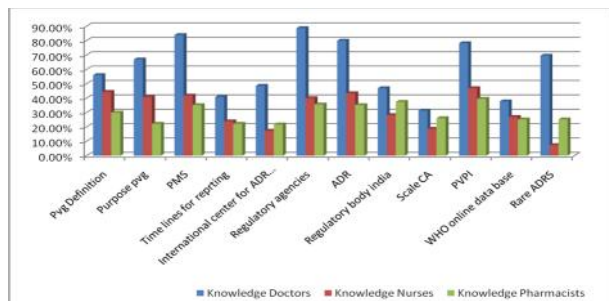


Fig 1: Bar diagram comparing the knowledge of physicians, nurses and pharmacists

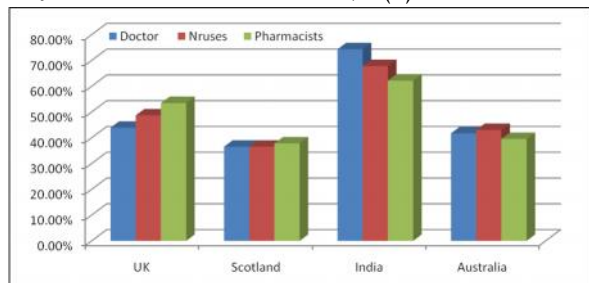


Fig 2: Bar diagram comparing the knowledge of physicians, nurses and pharmacists about International Reporting System

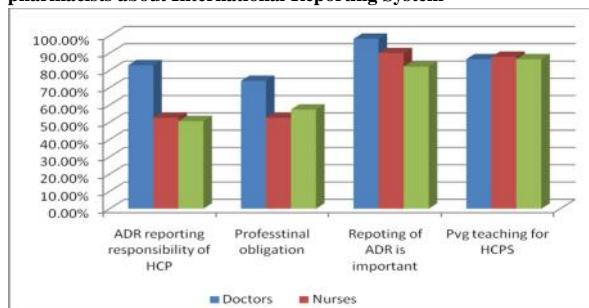


Fig 3: Bar diagram comparing the attitude of physicians, nurses and pharmacists.

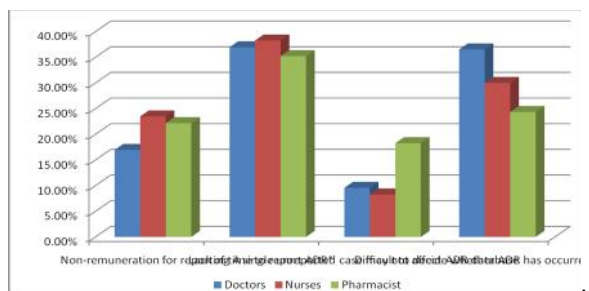


Fig 4: Different discouraging factors for ADR reporting

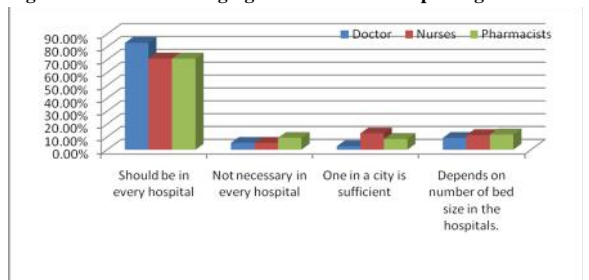


Fig 5: Responses of HCPs for establishment of ADR monitoring center in Hospital

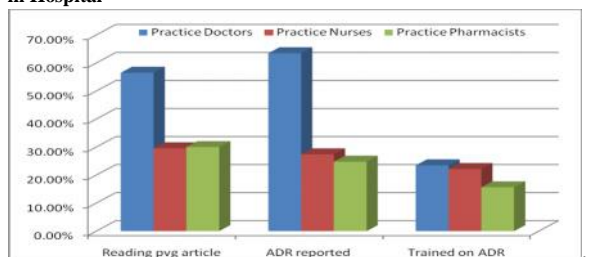


Fig 6: Comparison of HCPs on the basis of practice of HCPs

4. SUMMARY AND CONCLUSIONS

KAP survey was done among HCP's including physicians, pharmacists and nurses. Almost 800 KAP questionnaire was

distributed to assess their knowledge, attitude and practice towards Pharmacovigilance. A sample size of 230 from each group of HCP's responded for the KAP questionnaire.

Compared to Nurses and Pharmacists, Physicians have a better understanding, but they were lagging in practice and attitude towards Pharmacovigilance as they are busy with the medical practice and reporting an ADR seems to be a waste of time for them. And compared to Nurses and Pharmacists, physicians attend more seminars, conferences and read various research letters. 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 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 everyday 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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Conflict of Interest: None

Source of Funding: Nil