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Assessment of Health Care Professionals' Knowledge, Attitude and Practices of Pharmacovigilance in A Rural Tertiary Care Teaching Hospital of Uttar Pradesh, India

Pharmacology

KEYWORDS : Pharmacovigilance, KAP, Doctor, Pharmacists, Nurses, ADR.

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ABSTRACT

Objective: *To assess about knowledge, attitude and practice of pharmacovigilance (PV) among healthcare professionals working in a rural tertiary care teaching hospital of Uttar Pradesh, India.*

Material and Methods: *A questionnaire was prepared for assessing the Knowledge, Attitude and the Practice (KAP) and distributed among healthcare professionals including 20 pharmacist, 200 nurses and 50 resident doctors.*

Results: *The overall response of participants was encouraging. Most of the participants have mediocre knowledge about the PV program but they were in favour of regular teaching and sensitization program. 88.01% were in favour of honorarium for ADR reporting.*

Conclusion: *Regular training and the re-enforcement for the ADR reporting is recommended for all health care professionals. Imparting the knowledge and awareness of PV by means of continues educational intervention would bring update knowledge of practice for drug safety into their every day practice.*

INTRODUCTION

Adverse Drug Reactions (ADRs) are an important cause of morbidity and mortality worldwide[1]. ADRs are one of the major problems associated with prescribed drugs. In simple definition, an ADR is any undesirable/untoward effect of a drug beyond its anticipated therapeutics occurring during clinical use[2]. World Health Organization (WHO) defines the ADR as any noxious, unintended, and undesired effect of a medicine, which may occurs at the doses which are used in humans for purpose of prophylaxis, diagnosis, or therapy. ADRs are believed to be the one of the most common leading cause of death among hospitalized patients. ADRs have a major impact on public health by imposing a considerable economic burden on the society and health care systems[3].

Most common types of ADR are type A (augmented), which is dose related effects and type B (bizarre), elaborate effects related to abnormal interaction in between patient and drug[4]. PV is defined as "The science and the activities which relate to the detection, assessment, understanding and the prevention of adverse effects or any other drug-related problems"[5]. Monitoring and reporting of ADRs are very important aspects in identifying the adverse reaction trends and also to minimize or prevent harm to patients arising from drugs[6].

The international database of the adverse drug reaction reports are maintained by Uppsala Monitoring Centre (UMC, WHO), Sweden. It has been estimated that only 6-10% of all the ADRs are reported [7]. ADRs spontaneous reporting systems are the basic components for the comprehensive post-marketing surveillance of possible drug-induced risks[8]. Wherever drugs are being used, there should be a readiness to observe and report observed unwanted adverse events[9,10].

Although (PV) programs are successful in improving drug use patterns, but under reporting of ADRs is a serious major problem[11]. One of the reasons for under-reporting might be a poor knowledge of the healthcare professionals towards the existing PV program. In order to improve an existing PV program, there is a need to improve healthcare professionals' KAP.

Hence, the present study was carryout to analyze the knowledge, attitude and practice of healthcare professionals regarding ADRs.

MATERIALS AND METHOD

This was a cross sectional, questionnaire based assessment study which was conducted in a 750 bedded tertiary care teaching hospital located in a rural area of western Uttar Pradesh, India. The ADR monitoring centre was established in year 2011. The study was conducted on resident doctors (from the clinical, paraclinical and the preclinical departments), pharmacist and nurses working in the institute. The study instrument was a pre designed questionnaire in 3 sections (Knowledge, attitude and practice). The questionnaire consisted of a total of 25 questions in which 10 questions were related to the 'knowledge', 10 were related to 'attitude' and remaining 5 were related to the 'practice' aspects. A sensitization programme was also conducted before evaluation of questionnaire.

All the healthcare professionals (doctors, nurses and pharmacists) working in the hospital during the study period were included. The healthcare professionals who were not willing to participate in the study, who were discharging their routine duties and the ones who were on leave were excluded. The questionnaires are illustrated in table 1 to 3.

SAMPLING PROCEDURE

A total of 270 questionnaires were distributed to all the participants. Among them 242 filled questionnaire forms were returned. Thus the response rate was good.

RESULT

Out of 270 survey questionnaires circulated, 242 filled questionnaires were returned giving 89.62 % response rate. Our results revealed that 46.28%% were knowing the definition of PV. Although 73.55% were aware of meaning of IPC, but only 62.80 % knew the location of NCC. Knowledge of WHO PV centre and highest regulatory body of PV was known by only 50.41% and 59.09% of the candidates respectively. 77.27% were aware of existence of AMC in their institute. Only 44.62 % were thinking that all types of ADRs should be reported. 49.17% replied that ADRs should be reported by all health care professionals.54.95% respondents were not aware of post marketing surveillance.

87.19% were agreed that every hospital should have AMS, 77.68% were in favour of regular training program and 85.43% respondents needed detail teaching of PV and ADR reporting. Only 57.43% agreed that ADR reporting should be compulsory. 69% opined that mild ADRs are not needed

to report. 88.01% and 92.41% were opined that honorarium should be given for reporting and regular awareness programmes for training.

[Table-1]: Knowledge towards PV

S.No	Questions	Right answers	Wrong answers	Not Attempted
1	Meaning of IPC	(73.55%)178	(25.61%)62	02(.82%)
2	Location of National coordination centre	(62.80%)152	(34.71%) 84	06(2.47%)
3	In India highest regulatory body of PV is	(59.09%)143	(35.12%)85	14(5.78%)
4	WHO PV centre is situated in	(50.41%) 122	(45.04%)109	11(4.54%)
5	Are you aware of existence of ADRs reporting & monitoring centre in your hospital?	(77.27%) 187	(22.72%) 55	NIL
6	Definition of PV	(46.28%)112	(48.76%)118	12(4.95%)
7	A serious adverse event in India should be reported to regulatory body with in how many days	(32.64%) 79	(64.87%)157	06(2.47%)
8	All type of ADRs should be reported	(44.62%)108	(54.13%)131	3(1.23%)
9	Out of doctor, pharmacist & nurses, who is responsible for reporting of ADRs	(49.17%) 119	(50.82%)123	NIL
10	Are you aware of post marketing surveillance	(40.49%) 98	(54.95%)133	11(4.54%)

[Table-2]: Attitude towards PV

S.No	Questions	Yes	No	Not Attempted
1	Requirement of PV Centre in hospitals	(87.19%)211	(11.15%)27	4(1.65%)
2	Requirement of regular training for PV and ADRs reporting	(77.68%)188	(21.07%)51	3(1.23%)
3	Is it necessary for reporting of mild ADRs to PV centre	(30.16%)73	(69.00%)167	2(.82%)
4	Do you think ADRs reporting will increase patient safety	(82.23%)199	(17.76%)43	Nil
5	Does lack of honorarium discourage from reporting ADRs	(88.01%)213	(11.57%)28	1(.41%)
6	Does sensitization programmes should be conducted for awareness of ADRs reporting	(92.41%)223	(7.85%)19	Nil
7	Do you think that ADRs reporting should be compulsory	(57.43%)139	(41.73%)101	2(.82%)
8	Do you think PV should be taught in detail to healthcare professionals:	(85.43%)207	(14.04%)34	1(.41%)
9	ADR reporting should also be done by patients/ patients relatives	(49.48%)120	(50.41%)122	Nil
10	Will you trained or guided others for reporting of ADRs	(23.14%)56	(75.61%)183	3(1.23%)

[Table-3]: Practical factors in PV

S.NO	Questions	Yes	No	Not Attempted
1	Do lack of access to ADR reporting form discourage you for not reporting	(19.83%)48	(80.83%) 194	Nil
2	Do any possible legal issue discourage you for not reporting	(76.44%)185	(20.66%)50	7(2.89%)

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3	Have you ever attended any training voluntary for reporting of ADRs	(14.46%)35	(79.33%) 192	15(6.19%)
4	Have you reported any ADRs to AMC	(14.87%)36	(79.75%) 193	13(5.37%)
5	Have you Seen any patients experiencing an ADR	(83.88%)203	(14.46%)35	4(1.65%)

76.44% respondents revealed that possibility of legal issues discouraged them for reporting. Although about 83.88% were seen / experienced ADRs but only 14.87% had reported to AMC of the hospital. Only 14.46% were attended the training program voluntarily and remaining 79.3% had either not attended or if attended, due to orders of higher authorities. 22% were discouraged for reporting due to lack of access of ADR forms.

Responses regarding attitude of participants are as follows- 87.19 were in favour of PV centre in every hospital and 77.68% were favouring the regular training of reporting methods and ADR & PV. 30.16% respondents opined that mild ADRs should not be reported.82.23% knew that PV increases the patient's safety and 85.43% replied that it should be taught in detail. 88.01% required honorarium for reporting and 92.41% were favouring the regular awareness programmes for health care professionals.49.48% required reporting also by patients or by their relatives.

Our study revealed that lack of knowledge about ADR forms , time taken process of filling of forms , mild type of most of the reactions , and possibility of legal action against them after reporting discouraged them from reporting. Most of the respondents were agreed that this topic should be taught in detail and frequent training cum awareness programmes should be conducted for health care professionals.

Suggestions given by the participants that newsletters/news bulletin should be provided on regular basis and ADRs should be discussed in monthly meetings of healthcare professionals. Paramedical staff should also be trained for filling of ADR forms.

DISCUSSION:

The overall result was favourable for encouragement of PV program and it revealed that our healthcare professionals were not only knowing the about the program but they also knew the importance of reporting. Although in our study most of the participants did not know the definition of PV, NCC, the highest regulatory authority but they knew the existence of AMC at their institution and were aware of importance of ADR reporting for patient's safety because of the regular reporting by clinicians and running of PV OPD in the institute.

In our study about 83.88% came across ADRs but only 14.87% had reported. This could be due to mild type of nature of reactions that didn't affect the patient's daily activities, or they were not aware of reporting of all type of reactions.

There could be other factors also that discouraged them for reporting, and fear of legal issues could be one of them. Other reasons for not reporting an ADR could be non serious reaction or it could be one of the known reaction which can be easily managed with positive outcome, These reasons support that regular training and teaching programmes can increase the reporting rate by creating awareness and educating about the importance of reporting.

Majority of respondents had opined that every hospital should have ADR monitoring system and regular sensitization programmes should be conducted for reporting as this program concerned with safety of patients but honorarium should be given for reporting. This might be due to their thinking that they are doing extra work which is time consuming so they should be paid for that. Again that thinking can be changed by regular teaching cum awareness programmes.

Studies have shown that knowledge and training programmes can increase the numbers of reporting ([12-14]). It is evident from our study that health care professionals are in need of information regarding ADRs and their management. The overall attitude of the participants was positive. Majority have needed regular teaching cum training program, regular sensitization programmes and detail teaching of the topic to students and health care professionals

In the last of the study many have suggested for monthly discussion of ADR reports and newsletters for information. Participants felt that more information on reported ADRs may assist them in better understanding and management of patients.

The limiting factor in our study was limited number of participants as many were on essential duties and some of them were on leave. In addition our study paramedical staffs were more as compared to medical staff working in the institute so the study findings could not be applied to wider medical community and studies are required involving more number of participants so that strategies can be develops to improve ADR reporting system thereby making PV program successful.

References:

1. Lazarou J, Pomeranz BH, Corey PN. The incidence of adverse drug reactions in hospitalized patients-a meta- analysis of prospective stud ies. *JAMA.* 1998; 279: 1200-05. Doi:10.1001/jama.279.15.1200. Available from: http://jama.amaassn.org/cgi/content/full/279/15/1200.
2. Ramesh M, Pundit J, Parthasarathy G. Adverse drug reactions in a South Indian teaching hospital-their severity and cost involved. Pharmacoepidemiol Drug Saf. 2003; 12(8): 687-92.
3. John LJ, Arifulla M, Cheriathu J, Sreedharan J; Reporting of Adverse Drug Reactions: a study among Clinicians. Journal of Applied Pharmaceutical Science, 2012; 2(6): 135-139.
4. World Health Organization. International drug monitoring: The role of national centres. Report of a WHO meeting. World Health Organ Tech Rep Ser. 1972; 498: 1-25.
5. The World Health Organization. Safety of medicines: A guide to detecting and reporting adverse drug reactions. *Geneva.* 2002. WHO/ EDM/ QSM/2002.
6. Phatak A, Nagari BG. Safety of medicines. Pharma Times. 2003; 35(5): 19-21.
7. Feely J, Moriarty S, O'Connor P. Stimulating the reporting of an ad verse drug reaction by using a fee. *Br Med J* 1990, 300:22-23. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1661889/ pdf/bmj00160-0028.pdf.
8. Stricker, B.H., Psaty, B.M., 2004. Detection, verification, and quantification of adverse drug reactions. BMJ 329 (7456), 44–47. http:// dx.doi.org/10.1136/bmj.329.7456.44.
9. WHO (2002) The importance of pharmacovigilance: safety monitoring of medicinal products. Geneva, Switzerland http://appswhoint/ medicinedoc/en/d/Js4893e/.
10. WHO (2004). Pharmacovigilance: ensuring the safe use of medicines. WHO Policy Perspectives on Medicines, Geneva, Switzerland; 2004 http://whqlibdocwhoint/hq/2004/WHO_EDM_20048pdf.

11. Lee A, Thomas SHL. Adverse drug reactions In: Walker R and Edward C. Clinical pharmacy and Therapeutics. 3rd edition Churchill Livingstone, 2003, p.33-46.
12. Wallace SM, Suveges LG, Gesy KF, . Adverse drug reporting part 1: survey of pharmacist and physician in Saskatchewan,. Drug information journal 1995;29:581-589
13. Suveges LG, Gesy KF , Wallase SM, Blackburn JL, Appel WC. Adverse drug reaction reporting part II: Evaluation of the Sasketchewan pilot project for a regional reporting program in Canada. Drug information journal 1995; 29: 581-589
14. Scolt HD, Thacher- Renshaw A, Rosenbaun SE, Waters WJ, Green M , Andrews LG et al . Physician reporting of adverse drug reaction : results of the Rhode Island adverse drug reaction reporting project. JAMA 1990; 263: 1785-88