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ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE OF PHARMACOVIGILANCE AMONG RESIDENT DOCTORS AND STAFF NURSES IN A TERTIARY CARE HOSPITAL, GUJARAT

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ABSTRACT

A cross-sectional questionnaire-based study was conducted on 75 resident doctors and 75 staff nurses of P.D.U govt. medical college, Rajkot, Gujarat for 6 months. The final KAP questionnaire Consisted of 19 questions out of which 1 to 11 were knowledge based, 12 to 16 were attitude based and 17 to 19 were practice based questions. Almost half of the resident doctors (56%) and one third of nurses (33.33%) knew the correct definition of the pharmacovigilance. Resident doctors had significantly ($p<0.001$) better knowledge (65.33%) of post marketing surveillance studies done by pharmaceutical companies. While nurses had better knowledge (29.33%) than resident doctors (22.66%) in within how many days SAE reported in India to regulatory body. Regarding regulatory body responsible for monitoring of ADR, resident doctors(69.33%) had significantly ($p<0.001$) better knowledge than nurse (17.33%). 78.66% of doctors and 57.33% of nurses believed that healthcare persons are responsible for ADR reporting in hospital. In attitude based questions lack of time for reporting was the major discouraging factor in resident doctors (52%) while difficult to decide whether ADR has occurred or not was the major discouraging factor in case of nurses (69.34%). Both resident doctors (96%) and nurses (84%) felt that reporting of

ADRs is necessary. Regarding practice based questions, In comparison to nurses (53.33%), far better number of resident doctors (89.33) [p<0.001] read article on prevention of adverse drug reactions. In practice there are more numbers of nurses (78.66%) who came with an ADRs than resident doctors (61.33%). Regarding training on how to report ADRs doctors (34.67%) had better training than nurses (9.33%). The results of the present study demonstrate that an educational interventions, CMEs and further such studies are needed to increase awareness of pharmacovigilance among the health care professionals.

KEYWORDS: Adverse drug reaction(ADR), Resident doctors, nurses, awareness.

INTRODUCTION

Pharmacovigilance(Pv) has constantly grown its importance in last 15 years, relating to the absolute amount of adverse drug reactions (ADRs) and to the fact of several hospital admissions are due to ADRs.[1-2].ADRs are responsible for about 5% to 20% of hospital admissions[3-4]. Adverse drug reactions (ADRs) are global problems of major concern. They affect both children and adults with varying magnitudes; causing morbidity and mortality.[5-6].The primary source of information for pharmacovigilance is from spontaneous reporting by health care professionals. Studies from different settings indicate that inadequate knowledge about pharmacovigilance among healthcare professionals as well as their attitude are associated with high degree of underreporting.[7-12] Pharmacovigilance is still in its growing phase 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.[13] .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 Knowledge, Attitude and Practice of pharmacovigilance among resident doctors and staff nurses in a tertiary care hospital, Gujarat.

MATERIAL AND METHODS

A cross-sectional questionnaire-based study was conducted on 75 resident doctors and 75 staff nurses of P.D.U govt. medical college, Rajkot, Gujarat. The study was held from March 2011 to September 2011. Prior approval was taken from the Institutional Ethics Committee to conduct the study.The final KAP questionnaire Consisted of 19 questions out of which 1 to 11 were knowledge based, 12 to 16 were attitude based and 17 to 19 were 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 KAP questionnaire is briefed to all participants about the purpose of the study and asked to submit the filled questionnaire. In case of unanswered questions, a participant was excluded from the study.Sufficient time provided to fill the KAP questionnaire to all participants.Comparison between KAP data obtained from resident doctors and nurses was performed using Chi-square test. $P<0.05$ was considered as significant.

RESULTS

All the resident doctors and nurses enrolled from different medical and surgical disciplines, viz medicine, surgery, obstetrics and gynecology, pediatrics, ophthalmology, oto-rhino laryngology, and dermatology completed the questionnaire.

Almost half of the resident doctors (56%) and one third of nurses (33.33%) were knew the correct definition of the pharmacovigilance. while 37.33% resident doctors and 22.66% nurses were knew the importance of Pv. Resident doctors had significantly ($p<0.001$) better knowledge (65.33%) of post marketing surveillance studies done by pharmaceutical companies. While nurses had better knowledge (29.33%) than resident doctors (22.66%) in within how many days SAE reported in India to regulatory body. Regarding regulatory body responsible for monitoring of ADR, resident doctors(69.33%) had significantly ($p<0.001$) better knowledge than nurse (17.33%).Regarding international center for ADR monitoring, 38.66% doctors while 20% of nurses have correct knowledge, while 66.66% doctors and 46.66% nurses knew the drug banned in India due to ADR, majority of respondents (84% doctors and 40% nurses) knew the major risk factor for the occurrence of maximum adverse drug reaction, question regarding scale most commonly used to establish the causality of an ADRs 26.6 % of doctors gave correct answer while only 17.33% of nurses have correct knowledge about that. about zonal/sub zonal Pv center both doctors and nurses(53.33% and 32% respectively) have good knowledge.78.66% of doctors and 57.33% of nurses believed that healthcare persons are responsible for ADR reporting in hospital.

In attitude based questions, lack of time for reporting was the major discouraging factor in resident doctors (52%) while difficult to decide whether ADR has occurred or not was the major discouraging factor in case of nurses (69.34%). 46.66% of resident doctors and 61.33% of nurses feel that ADR reporting is a professional obligation for them. More numbers of nurses (53.33%) believed that there should be ADR monitoring center in every hospital, while only 40% resident doctors believed so. Both resident doctors (96%) and nurses (84%)

felt that reporting of ADRs is necessary. Both categories respondents (resident doctors 97.33%, nurses 90.66%) felt that pharmacovigilance should be taught in detail to healthcare professionals.

Regarding practice based questions, In comparison to nurses (53.33%), far better number of resident doctors (89.33) [p<0.001] read article on prevention of adverse drug reactions. In practice there are more numbers of nurses (78.66%) who came with an ADRs than resident doctors (61.33%). Regarding training on how to report ADRs doctors (34.67%) had better training than nurses (9.33%).

Table. 1 Comparison of knowledge of resident doctors (n=75) and nurses(n=75) regarding pharmacovigilance and ADRs

Questions	Doctor		Nurses	
	Correct	Incorrect	Correct	Incorrect
Definition of pharmacovigilance	56	44	33.33	66.67
Imp. purpose of pharmacovigilance	37.33	62.67	22.66	77.34
Method use by pharmaceutical companies to monitor ADRs after drug launch	65.33	34.67	37.33	62.67
SAE reported in India within how many days	22.66	73.34	29.33	70.67
The international center for ADR monitoring is at	38.66	61.34	20	80
Drug banned due to ADR	66.66	33.34	46.66	53.34
Major risk factor for occurrence of max. ADRs	84	16	40	60
Regulatory body responsible for monitoring ADR	69.33	30.67	17.33	82.67
Scales most commonly used to establish causality of an ADR	26.6	73.4	17.33	82.67
City where zonal/subzonal center placed	53.33	46.67	32	68
Healthcare professional responsible for reporting ADR	78.66	21.34	57.33	42.67

Table 2. Comparison of attitude of resident doctors (n=75) and nurses(n=75) regarding pharmacovigilance and ADRs

Questions	Doctors(%)	Nurses(%)
Which factor discourage you from reporting ADRs?		
Non remuneration	40	13.33
Lack of time	52	17.33
Single case not affect ADR database	2.66	-
Difficulty in decision whether ADR has occurred or not	5.33	69.34
Do you think reporting is a professional obligation for you?		
a) Yes	46.66	61.34
b) No	40	8
c) Don't know	4	4
d)Perhaps	9.34	26.6
What is your opinion about establishing ADR monitoring center in every hospital?		
a) Should be in every hospital	40	53.33
b) Not necessary in every hospital	12	10.66
c) One in city is sufficient	30.6	33.33
d) Depends on number of bed size in the hospital	4	2.66
Do you think reporting of ADR is necessary?	96(Yes)	84(Yes)
Do you think Pv should be taught in detail to haelth care professionals?	97.33(Yes)	90.67(Yes)

Table 3. Comparison of practice of resident doctors (n=75) and nurses(n=75) regarding pharmacovigilance and ADRs

Questions	Doctors (%)	Nurses (%)
Have you any time read an article on prevention of adverse drug reaction?		
a)Yes	53.33	10.67
b)No	46.67	89.33
Have you ever come across with an ADR?		
a)Yes	61.33	78.67
b)No	38.67	21.33
Have you ever been trained on how to report ADR?		
a)Yes	34.67	9.33
b)No	65.33	90.67

DISCUSSION

This is the first study in our set up assessing the Knowledge, attitude, practice of pharmacovigilance among the resident doctors and nurses. A number of studies suggest that healthcare professionals' attitude toward ADR reporting is a significant determinant of the reporting rate.[1,2] In India, Pharmacovigilance is rapidly growing with the shift of pharmaceutical activities (i.e., new drug development and clinical trials) from west to east.

Hence, it is imperative to develop task force to handle trials and patient care as per ICH-GCP[3] guidelines to ensure patient safety. Results pertaining to knowledge of the resident doctors and nurses in this study were encouraging.

In this study there are 19 KAP questionnaires that either encourage or discourage doctors and nurses to know more about pharmacovigilance. In our study 56% of doctors and (33.33%) of nurses have responded correctly to the definition of pharmacovigilance. Nurses knowledge about "when to report" ADRs was better than resident doctors. Difference in reporting behavior of the doctors and nurses has been observed, which may be due to the lack of tradition or habit.[1,6] In countries where nurses are participating in the ADR reporting scheme, studies have shown that they indeed contribute positively toward promoting ADR reporting.[7] We observed that in our study, doctors had a low awareness of scales used most commonly to establish the causality for ADR and regulatory body responsibility of ADRs. This was supported by a study conducted by Madhan Ramesh et al.26.

we observed that in our study lack of time and non remuneration (52% and 40%) are major discouraging factors for underreporting among doctors while in nurses(69.33%) their low level of clinical knowledge makes them difficult to decide whether ADR has occurred or not. This results in underreporting of ADRs among nurses. In the literature, a lack of time and knowledge about ADRs is often considered to be a cause of underreporting.[10-12] Another study conducted by chatterjee et.al[13] support this results, 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 this study, resident doctors and nurses opined that ADR reporting is necessary and majority of resident doctors and nurses feel that there should be ADR monitoring centre in every hospital. We observed that in this study majority of doctors (97.33%) and nurses (90.66%) believed that pharmacovigilance should be taught in detail to healthcare professions. Regarding training on how to report ADRs doctors (34.67%) had better training than nurses (9.33%). This results shows us that healthcare professionals are in need of more and more educational training and awareness programs about pharmacovigilance which is supported by study done by Li Q, Zhang et al[1] showed that educational intervention improved awareness of knowledge, attitudes, practice of healthcare professionals towards practice of pharmacovigilance.

In our study one of the focus was to increase resident doctors and nurses' awareness to pharmacovigilance, regulatory bodies responsible for monitoring of ADRs and to explain on the causality assessment of ADRs. Continuing such studies and other educational programs are an important tool for increasing healthcare professionals awareness to pharmacovigilance. Based on our study results and the finding of Cosentino et al[4] and Figueras et al[5] recommend that such studies and programs should be held repeatedly at regular intervals to increase awareness about pharmacovigilance.

This study has limitations. One of them is the study findings could not be applied to the wider medical community as the study was restricted to nurses and doctors practicing at P.D.U. govt. medical college, Rajkot. Therefore we recommend that several such studies of similar kind should be conducted among healthcare professionals so as to develop strategies to improve the knowledge, attitudes, practice of pharmacovigilance in India.

CONCLUSION

In this study, Both resident doctors and nurses had knowledge about pharmacovigilance and it is significantly higher in resident doctors than nurses. Resident doctors and nurses had low awareness of ADR reporting and their practices and attitude regarding reporting ADRs needs to be improved. The results of the present study demonstrate that an educational interventions, CMEs and further such studies are needed to increase awareness of pharmacovigilance among the health care professionals.

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