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ASSESSMENT ON ROLE OF CLINICAL PHARMACIST IN ADVERSE DRUG REACTION REPORTING: A QUESTIONNAIRE BASED STUDY

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ABSTRACT

Objectives

To create awareness about the existing ADR reporting system in the hospital, importance of ADR reporting and to identify the barriers of under reporting among the healthcare professionals.

Methods

It was a prospective, interventional study carried out in tertiary care hospital, Kanchipuram District for a period of six months from September 2011 to February 2012. A well designed closed ended questionnaire was used to assess the awareness of ADR reporting and the barriers of under reporting.

Results

A total of 154 questionnaires were circulated among the healthcare professionals, of whom only 125 questionnaires were filled by the healthcare professionals, the remaining 29 healthcare professionals were not willing to fill the questionnaire due to lack of time. Majority of the respondents were (59) 47% doctors, (20) 16% pharmacist and (46) 36.7% nurses and the barriers were mainly found to be lack of confidence, lack of time and fear of negative report.

Conclusion

The present study concluded that the educational intervention made by the clinical pharmacist regarding ADR reporting was very useful.

Keywords: ADR, Counselling, Clinical Pharmacist, Awareness.

INTRODUCTION

Adverse drug reaction 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 modifications of physiological function”¹. Adverse reactions are considered as hazard of drug therapy. Though some ADRs are minor, it can be fatal or can cause permanent morbidity. Most severe drug induced reactions cannot be identified

before licensing, so efficient post marketing surveillance is required. As more drugs are available in the market and patient taking multiple drugs, the occurrence of adverse drug reactions will probably continue to increase. Fortunately, several studies have shown that most ADRs are preventable, if the drugs are used rationally, monitoring the patient carefully, reporting the adverse drug reaction and circulating it properly^{1, 2& 4}. The retrospective study was conducted in UK

by the team of internal medicine specialists to establish the frequency of admissions due to adverse drug reactions and found that 0.5% of total admission is due to adverse drug reaction³. In a similar prospective observation, European studies performed in medical department admissions due to certain ADRs according to WHO (World Health Organization) criteria encounter 3.2% in France⁵. Of all the factors that are most associated with adverse drug reactions, polypharmacy is considered to be the most important although; the literature review has shown the lack of Indian studies to identify ADRs. Adverse drug reaction monitoring and reporting activity is in its infancy in India. The important reason is lack of awareness and lack of interest of healthcare professionals in ADR reporting and documentation⁶. Healthcare professionals are the primary reporter of the ADR either to pharmacovigilance center or to Pharma Company. There are various factors which encourage healthcare professionals to report ADRs. Reporting of each and every cases of ADR is important; however, reporting of previously unknown ADR, rare ADR and serious unlabeled ADR is more important to generate new signal^{7&8}. Healthcare professionals should have it in mind that while reporting ADRs, it does not mean that all the ADRs will have causal relationship between the drugs. However it is better to report ADRs than not reporting in doubtful case⁹. The present study was focused to create awareness among the healthcare professionals regarding the ADR monitoring and reporting.

MATERIALS AND METHODS

It was a prospective, interventional study carried out in tertiary care hospital, Kanchipuram District for a period of six months from September 2011 to February 2012. A well designed closed ended questionnaire, which consists of 15 questions with yes or no option, was used to assess the knowledge of healthcare professionals regarding ADR reporting. Questionnaire was circulated among the healthcare professionals and sufficient time was provided to fill the questionnaire, after the specified time the filled questionnaire was collected and it was scored, for each correct answer one mark was given and for the wrong answer no score was given. After the initial phase educational programme was conducted by the clinical

pharmacist and pamphlets was issued. Again the same questionnaire was circulated among healthcare professionals and was analyzed statistically by using student t test.

RESULTS

Distribution of healthcare professionals by years of experience was shown in table 1. In the present study was intended to carry out with good experienced healthcare professionals like doctors, pharmacist and nurses. Among the healthcare professionals the highest numbers of doctors were participated. Knowledge based questionnaires which consist of 15 questions were shown in the table 2. A total of 154 questionnaires were circulated among the healthcare professionals, of whom only 125 questionnaires were filled by the healthcare professionals, the remaining 29 healthcare professionals were not willing to fill the questionnaire due to their busy schedule. The overall response rate was found to be good 81.2%, among the respondents (59) 47% were doctors, (20) 16% were pharmacist and (46) 36.7% were nurses. The results showed that 100 (80%) respondents knew the exact definition of ADR among them 50 (85%) doctors, 16 (80%) were pharmacist and 34 (74%) were nurses. 96 (76.8%) respondents were aware of the existing ADR reporting system in hospital. 95 (76%) respondents have identified ADR in their practice but only 52 (41.6%) were reported. 93 (74.4%) respondents accepted it's their responsibilities to identify and report the ADR. 110 (88%) of the respondents agreed that clinical pharmacist assistance in monitoring and reporting ADR was very useful. The statistical analysis was performed for all the questionnaires and revealed that there was a significant improvement ($p < 0.0001$) after counselling on healthcare professionals. A barrier for under reporting was shown in figure 1. The reason for under reporting could be lack of confidence (51%), lack of time (54%) and fear of negative report (60%).

DISCUSSION

Pharmacists in organized health care systems should develop various educational programs for monitoring and reporting adverse drug reactions (ADRs) which encourage ADR surveillance, facilitate documentation of ADR, increases the

percentage of ADR reporting, thereby ensure the safety of drug use in high-risk patient populations, and create awareness among healthcare professionals regarding potential ADRs⁶. The results revealed that awareness regarding ADR reporting among the healthcare professionals was found to be low at the initial stage and this was improved by the clinical pharmacist by issuing the pamphlets and explaining verbally about the importance of ADR by in - person. Among the healthcare professional nurses found to have poor knowledge of ADR reporting. Awareness of ADR based on experience was assessed and found that

the healthcare professionals who are more experienced were more aware compared to those with less experience. Though most of them are aware of existing adverse drug reaction reporting system in hospital the reporting of ADR was found to be 52 (41.6%). The reporting rates was increased after the educational intervention by the clinical pharmacist.

Previous results suggested that the causes for under reporting may be lack of time, lack of confidence and fear of negative reports. The present study data was clearly shown the above parameters hindered ADR reporting.

Table: 1 Distribution of healthcare professionals by years of experience

Healthcare professionals N = 125	Years of experience		
	<5 yrs	5 – 10 yrs	>10 yrs
DOCTORS N = 59	14 (23.7%)	26 (44.07%)	19 (32.20%)
PHARMACIST N= 20	13 (65%)	4 (20%)	3 (15%)
NURSES N = 46	32 (69.6%)	9 (19.6%)	5 (10.9%)

Table 2: Knowledge based questionnaire

SL. NO	KNOWLEDGE REGARDING ADR	Doctors N = 59		Pharmacist N = 20		Nurses N = 46		P Valve
		Pre test	Post test	Pre Test	Post test	Pre test	Post test	
1.	Do you know what ADR is?	50 (85%)	59 (100%)	16 (80%)	20 (100%)	34 (73.9%)	45 (98%)	< 0.0001
2.	Have you identified any ADR in your practice?	52 (88%)	57(96.6%)	11 (55%)	18 (90%)	32 (70%)	41 (89%)	
3.	Do you know how to report an ADR?	45 (76%)	58 (98%)	09 (45%)	19 (95%)	16 (34.8%)	43 (93.5%)	
4.	Do you know what to report?	43(73%)	57(97%)	07 (35%)	18 (90%)	13 (28%)	42 (91%)	
5.	Do you know where to report?	45 (76%)	59 (100%)	11 (55%)	20 (100%)	15 (33%)	45 (98%)	
6.	Are you aware of adverse drug reactions (ADRs) monitoring and reporting system in your hospital	48 (81%)	59 (100%)	15 (75%)	20 (100%)	33 (72%)	46 (100%)	

7. Are you aware of National Pharmacovigilance Centre in India?	50 (85%)	59 (100%)	13 (65%)	20 (100%)	29 (63%)	46 (100%)
8. Are you aware of the Uppsala Monitoring Centre	51 (86%)	59 (100%)	13 (65%)	20 (100%)	28 (61%)	46 (100%)
9. Have you reported any suspected adverse drug reactions to ADR monitoring and reporting system at your hospital	30 (51%)	55 (93%)	9 (45%)	18 (90%)	13 (28%)	43(94%)
10. Should all ADRs be reported for newly marketed agents?	50 (85%)	59 (100%)	17 (85%)	20 (100%)	33 (72%)	46 (100%)
11. Should serious reactions be reported for established products?	49 (83.1%)	59 (100%)	16 (80%)	20 (100%)	33 (72%)	46 (100%)
12. Are you aware of the database (Vigibase, Vigiflow etc.) for ADR reporting?	29 (49%)	59 (100%)	08 (40%)	20 (100%)	15 (33%)	46 (100%)
13. Do you think it's your responsibility to monitor and to report an ADR?	50 (85%)	58 (98%)	14 (70%)	19 (95%)	29 (63%)	44 (96%)
14. Do you think the ADR reporting and monitoring system would benefit the patient or improve the patient care?	53 (90%)	58 (98%)	17 (85%)	20 (100%)	41 (89%)	46 (100%)
15. Will role of clinical pharmacist in detection, management and reporting of adverse drug reaction are useful?	55 (93%)	59 (100%)	16 (80%)	20 (100%)	39 (85%)	46 (100%)

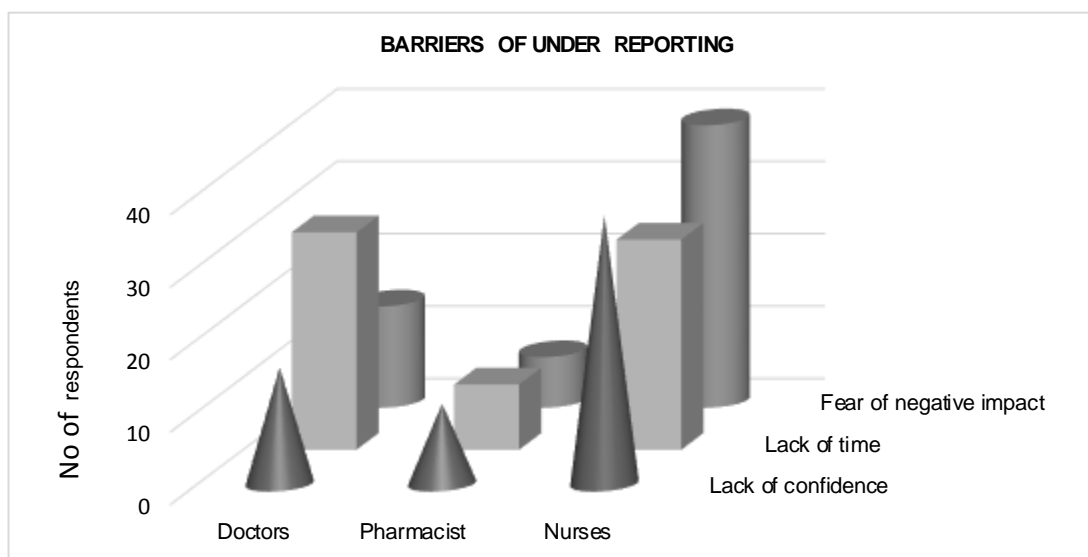


Figure 1: Barriers of ADR under reporting

CONCLUSION

The results concluded that the educational intervention made by the clinical pharmacist increases the awareness of ADR reporting system

in the hospital. The limitations of this study was it includes only the healthcare professionals, in future its recommended to conduct the study in various hospitals including the patients.

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