

RESEARCH ARTICLE

A cross-sectional study on the knowledge, attitude, and practices of pharmacovigilance among health-care professionals at a tertiary care teaching hospital

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Received: June 23, 2020; Accepted: July 12, 2020

ABSTRACT

Background: Adverse drug reactions (ADRs) are significantly underreported and pose a major problem of concern globally. Pharmacovigilance programs are mandatory to detect and prevent ADR. It is important for every health-care professional to know the importance of ADR reporting. **Aim and Objective:** This study aims to assess the knowledge, attitude, and practices (KAPs) toward pharmacovigilance and ADRs reporting among health-care professionals at a tertiary level teaching hospital. **Materials and Methods:** A cross-sectional questionnaire-based observational study was carried out on health-care professionals after getting approval from the Institutional Ethics Committee. The KAP questionnaire toward pharmacovigilance was adapted from the previous studies and consisted of 21 questions in total. **Results:** A total number of 150 health-care professionals participated and completed the questionnaire. The responses were analyzed using descriptive statistics. A total of 92.67% health-care professionals agreed that reporting of ADR is necessary. About 96% had a difficulty in reporting ADR of which most of them (75%) did not know where to report. There was a huge gap between the ADR encountered (83.3%) and ADR reported (4.7%) by health-care professionals. **Conclusion:** Majority of the health-care professionals had an above average knowledge and a positive attitude toward the need for ADR reporting. In spite of that, the reporting rate of ADRs by them is very low. This emphasizes the need for a periodical, intense and continuous training programs, and workshops on pharmacovigilance for health-care professionals which will definitely play an important role in improving pharmacovigilance activities in our hospital.

KEY WORDS: Adverse Drug Reactions; Knowledge; Attitude; Practice; Pharmacovigilance

INTRODUCTION

Pharmacotherapy is an integral part of the management of various diseases. Although drug therapies have many beneficial effects, it also has its harmful effects like adverse drug reactions (ADRs). No drug is devoid of any adverse

reactions. The drug reactions can be either predictable or unpredictable.^[1] An ADR is defined by the WHO as “a response to a drug that is noxious and unintended and occurs at doses normally used in humans for the prophylaxis, diagnosis, and treatment of disease, or for modification of physiological function.”^[2]

ADRs are significantly underreported and pose a major problem of concern globally. ADRs claim to be the fourth leading cause of death higher than pulmonary diseases, AIDS, accidents, and automobile death.^[3] They are one of the leading causes of mortality and morbidity worldwide. The reason for most hospital admissions is due to ADRs related to

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Website: www.njppp.com	Quick Response code 
DOI: 10.5455/njppp.2020.10.07174202012072020	

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drug intake.^[4] ADRs impose a high economic burden for any country despite the rising financial burden for health-related issues. Adverse reactions when reported predict hazard from future administration and warrant prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product.^[5]”

Pharmacovigilance is defined as “The science and activities relating to detection, assessment, understanding, and prevention of adverse effects.^[2]” Pharmacovigilance programs are mandatory to detect and prevent ADR. It is important for every health-care professional to know the importance of ADR reporting as to how, where, and when to report an ADR.^[6]

All health-care professionals should actively participate in pharmacovigilance programs by reporting ADR.^[7] Hence, there is a need for constant training programs in ADR monitoring to improve the knowledge, attitude, and practices (KAPs) of these professionals toward ADR reporting and pharmacovigilance program activities.^[8]

Although many studies in India have been conducted on the KAP toward pharmacovigilance among the health-care professionals, it is obligatory to conduct similar studies in our hospital which is one among the new colleges and graduating its first batch in the year 2020. Hence, this study was conducted with the objective to evaluate the KAP toward pharmacovigilance and ADRs reporting among health-care professionals in our hospital, as these groups of professionals are the first to attend to a patient in emergency, who are most closely involved in the care of the patients admitted to the hospital and therefore most likely to encounter ADRs.

Objective

The objective of the study was to assess the KAP toward pharmacovigilance and ADRs reporting among health-care professionals at a tertiary level teaching hospital.

MATERIALS AND METHODS

Study Design

This was a cross-sectional, questionnaire-based study.

Study Population

Doctors, nurses, and pharmacists in all the departments of Government Medical College and Hospitals, Omandurar Government Estate, Chennai-2.

Study Center

This study was conducted at Government Medical College and Hospitals, Omandurar Government Estate.

Sample Size

150.

Study Duration

The study duration was 2 months.

Study Period

The study period was from August 2019 to September 2019.

Inclusion and Exclusion Criteria

The doctors, nurses, and pharmacists working in the hospital in various departments during the study period were included in the study. Those who are not willing to participate in the study were excluded from the study.

Design of KAP Questionnaire

The KAP questionnaire toward pharmacovigilance and ADRs was generated from literature and adaptations from the previous studies.^[9-15] The questionnaire consisted of 21 questions which were divided as follows: Knowledge-based questions 1–10; attitude-based questions 11–15;^[16,17] and practice-based questions 16–21. One question was asked to determine the reasons for underreporting.^[18]

Study Procedure

After obtaining the Ethics Committee approval, the health-care professionals in various departments were briefed about the purpose of the study and those who were willing to participate were asked to fill the questionnaire. Any clarification needed in the understanding of questionnaire was provided.

Data Collection

One hundred and fifty questionnaires were distributed among the health-care professionals. A time of 1 day was given for collection of the filled up forms.

RESULTS

A total number of 150 health-care professionals participated in the study. All of them completed the questionnaire and all their completed forms were included for the study. The data were entered into Excel sheet and analyzed using descriptive statistics. Among the 150 participants, 84 (56%) were female and 66 (44%) were male. Based on the professional status, 88 (58.7%) were doctors, 54 (36%) were nurses, and only 8 (5.3%) participants were pharmacists [Figure 1]. Among the participants, 36–40 years (38.7%) constituted the most followed by >40 years (31.3%) [Table 1]. Other

findings of the present study are described in Tables 2-4 and Figures 2 and 3.

DISCUSSION

The need for reporting ADRs arises early from The Hippocratic Oath saying, First Do No Harm. Spontaneous ADR monitoring is the only effective and powerful tool to identify new ADRs. National spontaneous reporting schemes rely on health-care professional's reporting individual cases of suspected ADRs to a central or regional agency. A number of studies were conducted worldwide to survey their spontaneous ADR reporting by health-care professionals. Being a newly established college and hospitals, we need an effective ADR monitoring center and reporting of ADRs, completely lie on our health-care professionals. Hence, this study was conducted to assess the KAPs of the health-care professionals in our hospital to identify reasons for under-reporting and to determine what steps might be effective in increasing reporting rates.

Table 1: Age distribution

Age distribution in years	Number	Percentage
26–30 years	11	7.3
31–35 years	34	22.7
36–40 years	58	38.7
>40 years	47	31.3
Total	150	100

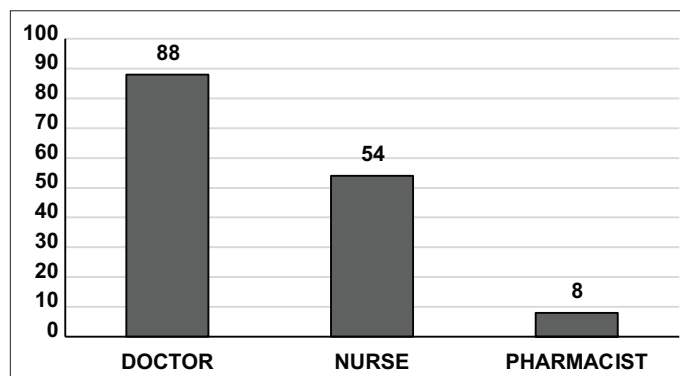


Figure 1: Professional status of the participants

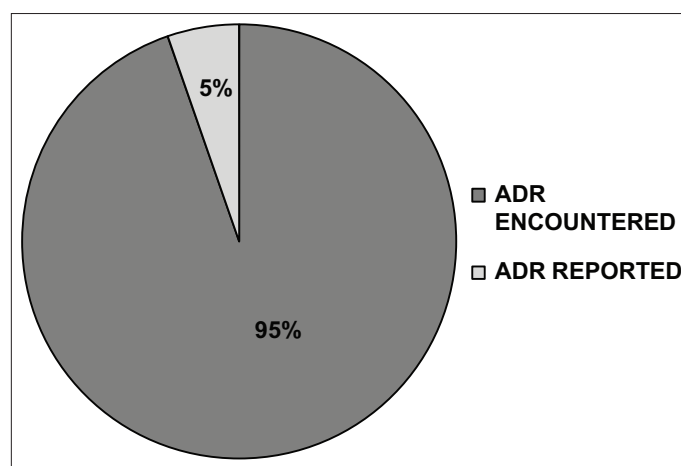


Figure 2: Percentage of participants encountered adverse drug reaction (ADR) and reported ADR

Table 2: Assessment of knowledge-based questions

Knowledge-based questions	Correct answer	Doctors n=88 (%)	Nurses n=54 (%)	Pharmacist n=8 (%)	Total n=150 (%)
Pharmacovigilance is defined as	The detection, assessment, understanding, and prevention of ADRs	24 (27.3)	22 (40.7)	2 (25)	48 (32)
What is the main purpose of pharmacovigilance	To identify the safety of drugs	22 (25)	19 (35.1)	3 (37.5)	44 (29.3)
Location of international ADR monitoring center	Sweden	17 (19.3)	6 (11.1)	1 (12.5)	24 (16)
Pharmacovigilance includes	ADR due to drugs, blood products, vaccines, and medical devices All of the above	27 (30.7)	18 (33.3)	2 (25)	47 (31.3)
The National Pharmacovigilance Programme of India is governed by	CDSCO	12 (13.6)	9 (16.6)	5 (62.5)	26 (16)
Who can report ADR	Health-care professionals, patients, lay person All of the above	34 (38.6)	22 (40.7)	3 (37.5)	59 (39.3)
A serious adverse reactions should be reported the regulatory body within	15 calendar days	9 (10.2)	7 (12.9)	2 (25)	18 (12)
An ADR is defined as	Noxious and unintended response to drug	29 (32.9)	14 (25.9)	6 (75)	49 (32.7)
Which of the following is the WHO online database for reporting ADR	VigiBase	7 (7.9)	3 (5.5)	0 (0)	10 (6.7)
Is there a pharmacovigilance ADR monitoring center (AMC) in your college hospital	No	19 (21.5)	12 (22.2)	6 (75)	37 (24.7)

ADR: Adverse drug reaction, CDSCO: Central Drug Standard Control Organization

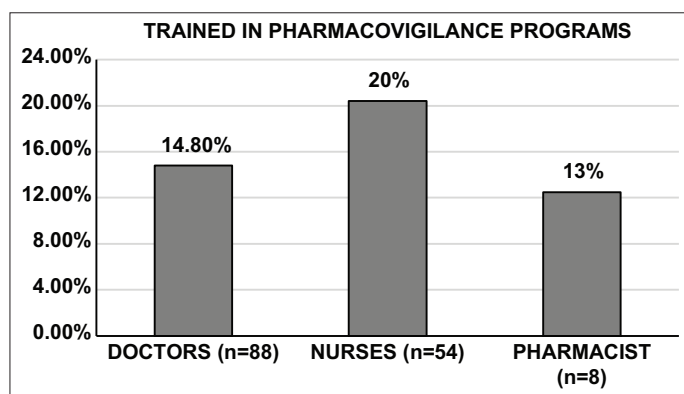


Figure 3: Percentage of health-care professionals trained in reporting adverse drug reaction

Knowledge

About 32% of health care workers gave correct response regarding the definition of pharmacovigilance. About 29.3% health-care professional were aware that the main purpose of pharmacovigilance is to identify the safety of drugs. About 16% health-care professional were aware that in Sweden, the international center for ADR monitoring is located. About 16% were aware that the National Pharmacovigilance Programme of India (PVPI) is governed by Drug Controller General of India. About 39.3% were aware of who can report ADR. About 12% health-care professionals were aware that a serious adverse reaction should be reported to the regulatory body within 15 calendar days. About 32.7% were aware of

Table 3: Assessment of attitude-based questions

Attitude-based questions	Answer	Doctors n=88 (%)	Nurses n=54 (%)	Pharmacists n=8 (%)	Total n=150 (%)
Do you think reporting of an ADR is necessary	Yes	82 (93.18)	49 (90.74)	8 (100)	139 (92.67)
	No	6 (6.82)	5 (9.26)	0 (0)	11 (7.33)
Do you think reporting ADR will increase patient safety	Yes	79 (89.77)	47 (87.03)	8 (100)	134 (89.33)
	No	9 (10.23)	7 (12.97)	0 (0)	16 (10.67)
Should there be an ADR monitoring center in every hospital	Yes	84 (95.45)	48 (23.79)	8 (100)	140 (93.33)
	No	4 (4.55)	6 (11.11)	0 (0)	10 (6.67)
Do you think pharmacovigilance should be taught in detail to all health-care professionals	Yes	88 (100)	53 (98.15)	8 (100)	149 (99.33)
	No	0 (0)	1 (1.85)	0 (0)	1 (0.67)
Do you think reporting of an ADR is time consuming and cumbersome activity	Yes	13 (14.77)	21 (38.89)	4 (50)	38 (25.33)
	No	75 (85.23)	33 (61.11)	4 (50)	112 (74.67)

ADR: Adverse drug reaction

Table 4: Assessment of practice-based questions

Practice-based questions	Answer	Doctor n=88 (%)	Nurses n=54 (%)	Pharmacists n=8 (%)	Total n=150 (%)
Have you ever experienced or encountered an ADR before	Yes	75 (85.23)	43 (79.63)	7 (87.5)	125 (83.3)
	No	13 (14.77)	11 (20.37)	1 (12.5)	25 (16.7)
Have you ever reported an adverse drug reaction to the pharmacovigilance center	Yes	7 (7.95)	0 (0)	0 (0)	7 (4.7)
	No	81 (92.05)	54 (100)	8 (100)	143 (95.3)
Have you ever seen an ADR reporting form	Yes	16 (18.18)	12 (22.22)	3 (37.5)	31 (20.7)
	No	72 (81.82)	42 (77.78)	5 (62.5)	119 (79.3)
Have you ever been trained as how to report ADR	Yes	13 (14.77)	11 (20.37)	1 (12.5)	25 (16.7)
	No	75 (85.23)	43 (79.63)	7 (87.5)	125 (83.3)
Have you maintained any records of ADR in your hospital	Yes	5 (5.68)	0 (0)	0 (0)	5 (3.3)
	No	83 (94.32)	54 (100)	8 (100)	145 (96.7)
Do you find any difficulties in reporting ADR?	Yes	82 (93.18)	54 (100)	8 (100)	144 (96)
	No	6 (6.82)	0 (0)	0 (0)	6 (4)
Factors causing difficulties in reporting ADR	Answered yes for Q.No.21	(n=82)	(n=54)	(n=8)	(n=144)
	Did not know how to report	32 (39.02)	54 (100)	8 (100)	94 (65.3)
	Not knowing where to report	46 (56.09)	54 (100)	8 (100)	108 (75)
	Managing the patient is more important than reporting ADR	52 (63.41)	28 (51.85)	4 (50)	84 (58.3)
	Lack of time	0 (0)	18 (33.3)	0 (0)	18 (33.3)
	Difficult to decide whether ADR occurred or not	0 (0)	9 (16.6)	0 (0)	9 (16.6)

ADR: Adverse drug reaction

the definition of ADRs. About 6.7% were aware of the WHO online database for reporting ADR is VigiBase. About 24.7% were known about the absence of pharmacovigilance AMC – ADR monitoring center in our college and hospitals. The above average knowledge of ADR reporting and PVPI among health-care professionals emphasized the need for continuous and regular conduct of training programs, workshops, and hands on training for a complete and spontaneous reporting in our hospital.

Attitude

A total of 92.67% health-care professionals agreed that reporting of ADR is necessary. About 89.33% agreed that reporting ADR will increase patient safety. About 93.33% of health-care professionals agreed that ADR monitoring center should be there in every hospital. About 99.3% agreed that pharmacovigilance should be taught in detail to health-care professional. About 74.67% disagreed that reporting ADR is time consuming and cumbersome activity.

Practice

In this study, there was huge gap between the ADR experienced (83.3%) and ADR reported (4.7%) by health-care professionals. Only 20.7% have seen the ADR reporting form. Only 3.3% health-care professional maintained records of ADR in hospital. About 96% reported a difficulty in reporting ADRs. About 75% did not know where to report. About 58.3% believed that managing the patient is more important than reporting ADR. Some participants had difficulty to decide whether ADR has occurred or not (16.6%). About 33.3% health-care professionals did not report ADR due to lack of time.

Comparison of Results

In our study, 39.3% were aware of who can report ADR compared to 36.47% in the 2nd year students in the study done by Era *et al.*^[9] The doctors participated had only an average knowledge in reporting ADR similar to the study done by Hardeep *et al.*^[10] A total of 92.67% health-care professionals agreed that reporting of ADR is necessary similar to the study done by Desai *et al.*^[11] where 97.3% agreed the same. The fact that majority of respondents agreed that reporting of ADR is necessary and awareness that pharmacovigilance should be taught in detail to health-care professionals emphasize that they have started to understand the importance of pharmacovigilance which was agreed by Khan *et al.*^[12] in their study.

In this study, there was huge gap between the ADR experienced (83.3%) and ADR reported (4.7%) by health-care professional similar to the study done by Gupta *et al.*^[13] where only 22.8% reported ADR, despite 64.4% experienced ADR. Among the participants, despite 16.7% being trained,

only a very few and that too doctors (4.7%) have ever reported an ADR to the pharmacovigilance center similar to the study done by Muraraiah *et al.*^[14] Only 20.7% have seen the ADR reporting form. Nurses and pharmacists have not reported any ADR so far in our hospital indicating the high time to train them. No nurse has reported an ADR, the results of which are similar to the study done by Rehan *et al.*^[15] The factors discouraging participants from reporting ADRs were lack of information on how to report (65.3%) similar to the study done by Gupta *et al.*^[13]

CONCLUSION

The effectiveness of pharmacovigilance activity is directly dependent on the active participation of the health-care professionals. In our study, the participants responded very well to the questionnaire indicating their keen in ADR reporting and also their understanding of the importance of ADR reporting. In conclusion, this study showed that majority of the health-care professionals had above average knowledge about pharmacovigilance and a positive attitude toward the need for ADR reporting. In spite of that the reporting rate of ADRs by them is very low. There was a huge gap between the ADR experienced or encountered and the ADR reported. This emphasizes the need for a periodical, intense, and continuous teaching cum training programs and workshops on pharmacovigilance for health-care professionals. These techniques definitely will play an important role in improving pharmacovigilance activities in our hospital.

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- How to cite this article:** Anuradha CR, Komathi J, Subashree A. A cross-sectional study on the knowledge, attitude, and practices of pharmacovigilance among health-care professionals at a tertiary care teaching hospital. *Natl J Physiol Pharm Pharmacol* 2020;10(08):682-687.

Source of Support: Nil, **Conflicts of Interest:** None declared.