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A Survey on Perception of ADR Reporting Among Healthcare Professionals



**Dr.Sreeja.P.A^{*1}, Dawn.V.J², Irene.V.R³,
Soumya.P.V⁴, Surabhi Mohan.K⁵**

1: Professor, Rungta Institute of Pharmaceutical Sciences, Bhilai, Chattisgarh 490023 India.

2: Associate Professor, Department of Pharmacy Practice, Sanjo College of Pharmaceutical Studies, Vellapara, Palakkad, Kerala-678702 India.

3. Assistant Professor, Department of Pharmacy Practice, Sanjo College of Pharmaceutical Studies, Vellapara, Palakkad, Kerala-678702 India.

4. Associate Professor, Department of Pharmacy Practice, Sanjo College of Pharmaceutical Studies, Vellapara, Palakkad, Kerala-678702 India.

5. Assistant Professor, Department of Pharmacy Practice, Sanjo College of Pharmaceutical Studies, Vellapara, Palakkad, Kerala-678702 India.

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ABSTRACT

Adverse drug reactions (ADRs) contribute serious health consequences and under reporting of ADRs by health care professionals (HCPs) is found to be a major problem due to the lack of awareness. The present study was carried out to evaluate the KAP about ADR reporting and pharmacovigilance among HCPs in a rural area in Palakkad District. A questionnaire-based observational survey was conducted among HCPs of a Community Health Centre and a private hospital in Palakkad District. The responses were analyzed and the results were entered in MS-Excel 2010, Statistical analysis was done using Graph pad Prism and chi-square test was done to find the level of significance. Out of 250 questionnaires circulated, 218 health care professionals positively completed and returned back of which 23 were from community health centre and 195 from a private hospital. Out of the total participants 104 (48%) were males and 114 (52%) were females. On analyzing the knowledge among health professionals, we found physicians and pharmacist have better knowledge than other HCPs and was found to have statistical relationship ($p < 0.05$). We found a positive response toward attitude and practice and the major problem of under reporting was lack of time and knowledge. Lack of knowledge is found to be a major issue of under reporting and must be rectified by proper awareness campaigns, continuing education programs etc.



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INTRODUCTION

All drugs available in the market are not completely safe and can cause mild to severe life-threatening ADRs.^[1] ADRs are serious health problems that increase morbidity and mortality. It is a common cause for the increase in both the length of hospital stays as well as the cost of treatment.^[2,3] Therefore, the necessity for pharmacovigilance emerges, which entails establishing specific procedures to manage such risks as well as assuring the early detection of new adverse reactions or patient subgroups of extraordinary sensitivity^[21].

The World Health Organization (WHO) defines pharmacovigilance (PV) as "the science and activities related to the detection, understanding, and prevention of side effects or other drug-related problems"(interactions, misuse, medication errors, abuse, overdose)^[4]. Adverse drug reaction (ADR) is defined by the WHO 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 the modification of physiological function"^{[5][24]}.

One of the main concerns facing health care delivery systems around the world is medication safety. Adverse drug reactions (ADRs) are a major problem that contribute significantly to morbidity, mortality, and additional expenses in both developed and developing countries. In many underdeveloped nations, such as India, pharmacovigilance (PV) and adverse drug reaction (ADR) monitoring are inadequate^[29]. All healthcare facilities must promote PV efforts as they are crucial to ensuring patient safety^[6,7]. The primary target group for the effective implementation of any healthcare initiative, including PV, is the HCPs because they make up the majority of a health care system's resources^[8]. Doctors, pharmacists, nurses, and other paramedics have a huge responsibility to report ADRs and improve the PV systems^[9]. Adverse drug reactions (ADRs) represent a significant issue related to pharmaceutical use. Any pharmacovigilance program's effectiveness and success are largely dependent on the involvement of medical experts. Pharmacovigilance is based on spontaneous reporting of adverse drug reactions. Pharmacists who voluntarily report adverse drug reactions (ADRs) help advance pharmaceutical safety. But because healthcare workers don't have a reporting culture, underreporting is a major issue. A variety of educational initiatives as well as many sociodemographic and professional characteristics have been linked to the reporting process' influence^[23]. A topic of rising importance for discussion in the hospital of Pharmacovigilance is the direct reporting of adverse drug reactions by patients. Medical drug safety surveillance relies heavily on voluntary adverse drug reaction

(ADR) reporting; yet, the primary shortcoming of the system is the significant underreporting that takes place^[27].

To encourage healthcare professionals and patients for the safe use of medicine, the Ministry of Health and Welfare, Government of India launched the nationwide Pharmacovigilance Programme of India (PvPI) in the year 2010^[10]. Our study aimed to assess the knowledge attitude and practice of ADR reporting and PV among HCPs as we found most of the studies were done among physicians, postgraduate students etc but assessing the knowledge among other health care professionals like laboratory technicians, dieticians, social workers etc were also important as they all are an integral part of health care system.

In India, more clinical preliminary exams and clinical assessments are required for the accurate practice of PV. A fully functional photovoltaic system is required for the responsible and safe consumption of medication. Pharmaceutical companies, medical professionals, government regulators, and Indian consumers who want to screen medications will all find PV to be quite helpful^[26]. Pharmacovigilance first appeared in India in 1986, at which point the country's official ADR monitoring system was divided into 12 regional centers, each with a population of 50 million. The operational overview of pharmacovigilance starts with a range of safety sources, including clinical trial data, safety call center, automatic reports, and material discovery, all of which anyone can design their own hair. As more security information is gathered, frequent security update reports (PSURs) are sent to the regulatory body. The entire data regarding security issues is examined, and the risks against profit are evaluated. It has existed throughout the product's life^[25]. The Indian Pharmacopoeia Commission in Ghaziabad is in charge of coordinating the National Pharmacovigilance Programme. At this point, the Pharmacovigilance Programme of India (PvPI) is operating nonstop. Approximately ninety adverse drug reaction monitoring centers, or AMCs, are dispersed throughout the nation. The initiative offers the AMCs technical, logistical, and financial help. The ADR could initially only be reported by medical experts. PvPI now allows anyone who takes medication, not just medical experts, to report adverse drug reactions^[28].

Standardizing the process of risk management and signal identification in the context of clinical trials and post-marketing pharmacovigilance is a difficult task. Nonetheless, there is a pressing need to comprehend and apply pharmacovigilance given the increased number of clinical trials and clinical research activities being carried out in India, as well as the phase

of clinical trials and pharmaco epidemiology studies^[22]. India's Pharmacovigilance Program seeks to build an ADR reporting system and an indigenous ADR database for the nation. One significant obstacle that PVPI must overcome in order to overcome the under-reporting of ADRs is the use of technological improvements. Because of their extensive drug expertise and position in the many levels of the health care system, pharmacists are an essential component of PVPI. Hospital pharmacists are important because hospitals are the sites of most serious adverse drug reactions. PVPI is expanding in India as a result of the remarkable rise of the clinical research and pharmaceutical industries^[30].

MATERIALS AND METHODS

A cross sectional questionnaire-based study design was adapted for a cross sectional survey by convenience sampling method. The participant's convenient accessibility and proximity was considered for convenient sampling method^[11,12]. The survey was conducted for a period of 3 months from September to November 2022. A pre-designed validated self-structured questionnaire was used to collect the details about the knowledge, attitude and practice on ADR reporting and Pharmacovigilance among health care professionals at a Community Health Centre and a Private hospital in Palakkad district.

The purpose of the study was explained to the participants and those willing to participate and returned the fully completed questionnaire were included in the study. The questionnaire was circulated among the health care professionals and the responses were collected.

Validation of Questionnaire:

The questionnaire was designed after reviewing previous research and review articles. Some questions were added on observing the importance of those questions in our study. The prepared questionnaire was circulated among randomly selected professional in the institution and a medical officer. The responses obtained were analyzed and finalized.

The questionnaire consists of total 20 questions, of which 8 knowledge, 8 attitudes and 4 practice based questions were asked. Out of the 8 questions, 7 responses are 'yes' or 'no' and 1 was multiple choice. The second part consists of 7 Attitude based questions whose responses were given as 'positive' and 'negative' and a multiple-choice question for analyzing barriers for reporting of ADRs.

The third part comprise of 4 Practice based questions and the responses were given as 'yes', 'no' and 'don't know'. The various types of ADR reported by HCPs were also studied.

The data obtained were analyzed and entered in MS Excel 2010. Descriptive statistics like frequency and percentage were used to explain the result. The appropriate statistical analysis was done by Graph Pad Prism software and the level of significance among the participants were calculated by using chi-square test where the p value <0.05 was considered to be significant.

RESULT

Out of 250 questionnaires circulated, 218 health care professionals positively completed and returned back of which 23 were from community health centre and 195 from a private hospital. Out of the total participants 104 (48%) were males and 114 (52%) were females. Among them most of the participants were of age between 26 to 45 years with a mean age \pm SD, 35 ± 8.37 . Of the total HCPs, 24(11%) doctors, 7(3.21%) house surgeons, 134 (61.46%) nurses, 17 (7.79%) pharmacists, 14 (6.42%) Lab technicians, 9 (4.12%) radiology staffs, 10 (4.58%) social workers and 3(1.37%) dieticians (**Table 1**).

a. Knowledge on ADR Reporting and Pharmacovigilance among Each Professional:

Our study compared the KAP among each professional. Out of the 8 knowledge-based questions, regarding the knowledge on ADR reporting. The result showed that doctors and HS (93.5%) followed by Pharmacists (76.5%) had answered for the question related to safety of medicines available in market as not safe while half of the enrolled nurses (58.2%) and other HCPs (52.8%) found them safe. For the question 2 about safety of medicines other than allopathy, doctors and HS (83.9%) and pharmacist (64.7%) answered not safe but nurses (79.1%) and other HCPs (80.6%) answered that they are safe. 93.5% of Doctors and HS, 82.4% pharmacists, 50.7% nurses and 47.2% of other HCPs respectively have heard about ADRs. On analysis of whether all drugs can cause ADRs and prevention of ADRs, doctors and HS and pharmacist have profound knowledge while nurses and other HCPs have limited. Doctors and HS (80.6% and 74.2%), pharmacist (74.2 and 70.6%) have heard about ADR reporting and pharmacovigilance respectively. Our study found to have statistical significance (p -value ≤ 0.05) between each group (**Table 2**).

On analyzing the knowledge on organization responsible for monitoring and reporting

ADRs, both Doctors and pharmacist had equal response of answering CDSCO correctly with 29%. Most of the other participants had opted IMA which shows that they were not aware about CDSCO (**Figure 1**).

b. Attitude on ADR Reporting and Pharmacovigilance among Each Professional:

Out of the 7 attitude-based questions, most of the health care professionals think that pharmacist can only report ADR and ADR reporting should be compulsory and voluntary. They also believe that institutions should encourage reporting ADRs and have found a statistically significant relation between each group (p -value ≤ 0.05) (**Table 3**).

Our study participants were interested in learning as well as participating in ADR reporting system. All the participants showed a positive attitude towards institutional documentation system of ADRs. However, on statistical evaluation we couldn't find any significant relation among the groups.

Lack of time and knowledge was found to be the main factor of under reporting ADRs. Doctors and HS [n=17(55%)] found lack of time as most remarkable factor followed by negligence [n=6(19%)] in not reporting ADRs. Nurses found lack of knowledge/training [n=104% (78%)] as the prime factor followed by lack of time [n=99 (74%)] for not reporting ADRs. Pharmacist found lack of time [n=8(47%)] and lack of knowledge/training [n=4 (24%)] as the prominent factor for not reporting ADRs respectively. The other HCPs mostly admits lack of knowledge/training [n=26 (72%)] as the barrier for underreporting of ADRs (**Figure 2**).

c. Practice on ADR Reporting and Pharmacovigilance among Each Professionals:

During the daily practice doctors and HS (90.3%), dispensing pharmacist (70.6%) and nurses (70.9%), other HCPS like radiology staff and laboratory technicians (38.9%) have encountered ADRs in their practice. Among the study subjects, Doctors and HS (64.5%), nurses (54.5%) pharmacist (29.4%) and other HCPs (8.3%) have filled the ADR reporting form and reported to the institution. Some doctors reported ADRs directly to zonal ADR monitoring centres. Most of the Doctors, Pharmacists and Nurses admit that the institution submits the ADR reporting form to zonal ADR monitoring centres (**Table 4**).

The various types of ADRs reported by HCPs were Serious & life threatening, Severe &

cause disability, Moderate & cause difficulty, Mild. The reported ADRs by Doctors and HS were mainly Serious & life threatening [n=20 (65%)] and severe & that caused disability [n=19 (61%)]. Nurses and pharmacist reported mainly those ADRs with moderate and cause difficulty [n=68 (51%)] and [n=4 (24%)] respectively followed by mild [n=73 (54%)] and [n=5 (29%)] respectively (**Figure 3**).

Table-1: Basic characteristics of the study population (n=218)

Characteristics	No of participants (n=218)	Percentage (%)
Gender Male		
	104	47.7
Female	114	52.3
Age group in years		
≤ 25	16	7.3
26-35	108	49.5
36-45	60	27.5
46-55	29	13.3
>55	5	2.3
Mean age ± SD	35 ± 8.37	
Study participants		
Doctors	24	11
House surgeons	7	3.2
Nurses	134	61.5
Pharmacist	17	7.8
Lab technicians Radiology staffs	14	6.4
Social workers	9	4.1
Dietician	10	4.6
	3	1.4

Table-2: assessment of knowledge about ADR, ADR reporting and pharmacovigilance (n= 218)

Sl No.	Questions	Category	Yes n (%)	No n(%)	p value
1	Do you think that all medicines available in market are safe.	Doctors+HS	2(6.5)	29(93.5)	<0.001
		Nurses	78(58.2)	56(41.8)	
		Pharmacist	4(23.5)	13(76.5)	
		Other HCP	19(52.8)	17(47.2)	
2	Do you think that drugs belonging to other system of medicine (except allopathy) are safe.	Doctors+HS	5(16.1)	26(83.9)	<0.001
		Nurses	106(79.1)	28(20.9)	
		Pharmacist	6(35.3)	11(64.7)	
		Other HCPs	29(80.6)	7(19.4)	
3	Have you heard about ADR.	Doctors+HS	29(93.5)	2(6.5)	<0.001
		Nurses	68(50.7)	66(49.3)	
		Pharmacist	14(82.4)	3(17.6)	
		Other HCPs	17(47.2)	19(52.8)	
4	Do you think all drugs can cause ADR.	Doctors+HS	27(87.1)	4(12.9)	<0.001
		Nurses	57(42.5)	77(57.5)	
		Pharmacist	12(70.6)	5(29.4)	
		Other HCPs	14(38.9)	22(61.1)	
5	Do you think that ADR can be prevented.	Doctors+HS	29(93.5)	2(6.5)	<0.001
		Nurses	62(46.3)	72(53.7)	
		Pharmacist	12(70.6)	5(29.4)	
		Other HCPs	15(41.7)	21(58.3)	
6	Have you ever heard of ADR reporting.	Doctors+HS	25(80.6)	6(19.4)	0.002
		Nurses	64(47.8)	70(52.2)	
		Pharmacist	12(70.6)	5(29.4)	
		Other HCPs	16(44.4)	20(55.6)	
7	Have you ever heard about Pharmacovigilance.	Doctors+HS	23(74.2)	8(25.8)	0.002
		Nurses	58(43.3)	76(56.7)	
		Pharmacist	12(70.6)	5(29.4)	
		Other HCPs	14(38.9)	22(61.1)	

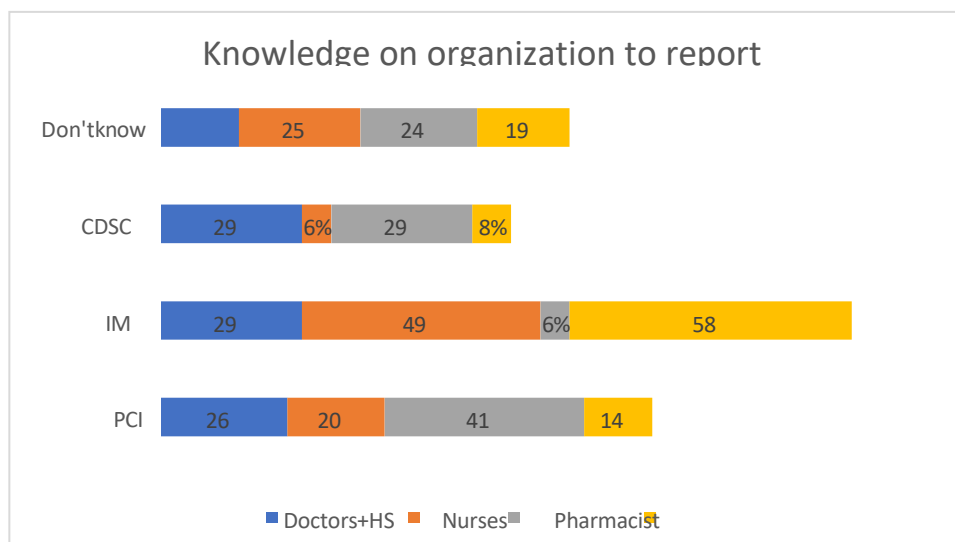


Figure 1-knowledge on organization to report ADRs

Table 3-Attitude towards reporting ADRs among study participants (n=218)

Sl. No	Attitude Questions	Category	Positive n (%)	Negative n (%)	p-value
1	Do you think that only pharmacist can report ADR.	Doctors+HS	24(77.4)	7(22.6)	<0.001
		Nurses	88(65.7)	46(34.3)	
		Pharmacist	15(88.2)	2(11.8)	
		Other HCPs	11(30.6)	25(69.4)	
2	Do you think ADR reporting should be compulsory	Doctors+HS	26(83.9)	5(16.1)	<0.001
		Nurses	61(45.5)	73(54.5)	
		Pharmacist	12(70.6)	5(29.4)	
		Other HCPs	15(41.7)	21(58.3)	
3	Whether ADR reporting should be voluntary.	Doctors+HS	26(83.9)	5(16.1)	<0.001
		Nurses	46(34.3)	88(65.7)	
		Pharmacist	10(58.8)	7(41.2)	
		Other HCPs	15(41.7)	21(58.3)	
4	Do you believe that workplace environment should encourage reporting an ADR.	Doctors+HS	27(87.1)	4(12.9)	0.004
		Nurses	113(84.3)	21(15.7)	
		Pharmacist	13(76.5)	4(23.5)	
		Other HCPs	21(58.3)	15(41.7)	
5	Are you interested in participating ADR reporting system.	Doctors+HS	24(77.4)	7(22.6)	0.52
		Nurses	111(82.8)	23(17.2)	
		Pharmacist	16(94.1)	1(5.9)	
		Other HCPs	29(80.6)	7(19.4)	
6	Are you interested in learning/get training about PV.	Doctors+HS	23(74.1)	8(25.8)	0.61
		Nurses	113(84.3)	21(15.7)	
		Pharmacist	14(82.4)	3(17.6)	
		Other HCPs	30(83.3)	6(16.7)	
7	Do you think that every institution should monitor and document ADR	Doctors+HS	29(93.5)	2(6.5)	0.87
		Nurses	123(91.8)	11(8.2)	
		Pharmacist	15(88.2)	2(11.8)	
		Other HCPs	32(88.9)	4(11.1)	

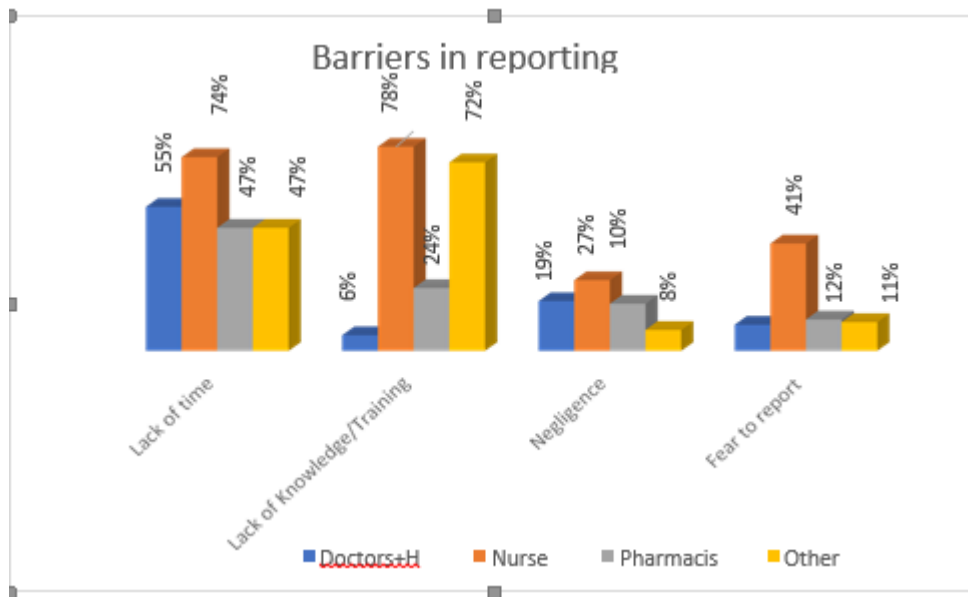


Figure 2 - Barriers for not reporting ADRs

Table 4- Practice based questions.

S. No.	Practice Questions	Category	Yes n (%)	No n (%)	Don't know n (%)	p-Value
1.	Do you come across any ADR in practice.	Doctors+Hs	28(90.3)	2(6.5)	1(3.2)	0.001
		Nurses	95(70.9)	28(20.9)	11(8.2)	
		Pharmacist	12(70.6)	3(17.4)	2(11.8)	
		Other HCPs	14(38.9)	15(41.7)	7(19.4)	
2.	Have you ever filled any ADR reporting forms.	Doctors+Hs	20(64.5)	9(29.0)	2(6.5)	<0.001
		Nurses	73(54.5)	35(26.1)	26(19.4)	
		Pharmacist	5(29.4)	8(47.1)	4(23.5)	
		Other HCPs	3(8.3)	17(47.2)	16(44.4)	
3.	Whether your institution is practicing ADR reporting to higher centres	Doctors+Hs	16(51.6)	7(22.6)	8(25.8)	<0.001
		Nurses	64(47.8)	47(35.1)	23(17.2)	
		Pharmacist	4(23.5)	6(35.2)	7(41.2)	
		OtherHCPs	3(8.3)	14(38.9)	19(52.7)	
4.	Does your institution provide information or training on ADR monitoring and reporting?	Doctors+Hs	8(25.8)	15(48.3)	8(25.8)	0.626
		Nurses	47(35.1)	56(41.8)	31(23.1)	
		Pharmacist	6(35.3)	5(29.4)	6(35.3)	
		OtherHCPs	13(36.1)	11(30.6)	12(33.3)	

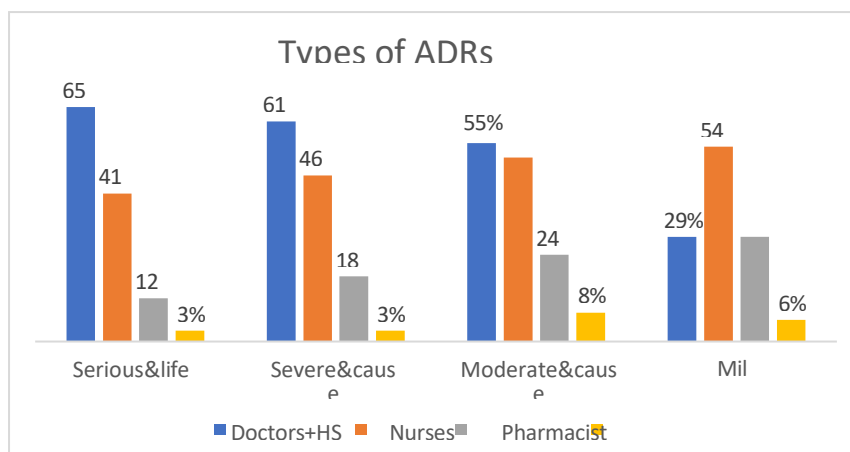


Figure 3-Represents the types of ADRs reported by HCPs.

DISCUSSION

The present observational study aimed on the assessment of knowledge, attitude and practice on ADR, ADR reporting and pharmacovigilance. Our study participants include doctors and HS, nurses, pharmacists, radiology staffs, laboratory technicians, social workers and dieticians. 87.2% responses were obtained from the total distributed questionnaires which was nearly similar to previous studies conducted by Hussain *etsal*^[11]; Alsaleh *etal*^[13]. Most of our participants were females and the mean age \pm SD was 35 ± 8.37 . Most participants were nurses followed by doctors, pharmacist, laboratory technicians, social workers, radiology staff, HS and dieticians.

On analyzing the knowledge about general safety of medicines, ADR reporting and pharmacovigilance, we found that there is lack of knowledge among HCPs other than Doctors and pharmacist which was similar to a study conducted by Jagjit Singh in which they mentioned that physicians had good knowledge when compared to nurses ^[14]Even though many of the health care professionals have heard about ADR, most of them doesn't know about the importance of reporting it. A study conducted by Rasaan Adisa have also mentioned the same in their study^[15]. Various studies were conducted for the assessment of knowledge about ADR reporting and pharmacovigilance in and around world stating the importance of monitoring and assessing the same. A study conducted by Ganesans *etal.*, also mentioned about the in adequate knowledge of health care professionals about pharmacovigilance ^[16,17,18].

On assessing the attitude and practice of the health care professionals, majority had a

positive response towards participating in ADR reporting system and recommended to have proper training on how to report an encountered ADR. Conducting more training programs in hospitals can improve knowledge about the ADR reporting centres and availability of reporting forms. Major problem found in our study for under reporting an ADR was lack of knowledge/training and lack of time, which was also found to be common in many of the similar studies. A study conducted by Chetna K. Desai reported that lack of knowledge and availability of ADR reporting forms were the major concern of under reporting ADRs.^[19] The practice of documenting the reported ADRs by the institution should also be encouraged which in our study, the participants responded positively. Reporting all types of encountered ADRs by the health care professionals must be practiced and in our study majority of doctors reported serious life threatening cases more while nurses and pharmacists had a practice of reporting all types of ADRs especially mild to moderate. ^[20]

LIMITATIONS:

We have assessed the KAP of health care professionals other than physicians, nurses and pharmacist which were rarely done in previous studies. We felt it important to assess the knowledge of other health care professionals like laboratory technicians, radiology staffs, dieticians and others as they also come across several ADRs of various severity types in their daily practice. Limitation of our study is the smaller number of study participants which can be biased. The value of the study may be added up with a greater number of participants. Although we asked the involvement of more health care professionals, they were not willing to participate due to their busy schedule.

CONCLUSION

Our study concluded, that other than doctors, healthcare professionals have limited knowledge of ADR reporting and Pharmacovigilance. The results proved the need for more frequent awareness campaigns emphasizing the value of timely reporting of experienced ADRs to healthcare professionals by conducting continuous medical education programs or public education. We recommend the posting of a clinical pharmacist with adequate knowledge for the timely monitoring and reporting of ADRs.

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CONFLICT OF INTEREST

NIL

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NIL

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