KNOWLEDGE, ATTITUDE AND PRACTICE OF HEALTHCARE PROFESSIONALS TOWARDS PHARMACOVIGILANCE IN A PRIVATE SECTOR TERTIARY CARE HOSPITAL IN KARACHI

Dr Farah Amin (BDS, RDS,MHCM) ,Dr Zain Ahmed Farooqui (BDS, RDS, MHCM),Ihsan Ali, Dr KhushbakhtShoaib (BDS, RDS), Prof Farah Ahmed (director Healthcare Managemant)

ABSTRACT

BACKGROUND:

Pharmacovigilance plays an important role in detection of adverse drug reactions.

The objective of our study is to identify the knowledge, attitude and practice of healthcare professionals towards pharmacovigilance in a private sector tertiary care hospital in Karcahi, Pakistan.

MATERIALS & METHODS:

This is a cross sectional study conducted by using questionnaire from July to December 2018 in 3tertiary care hospitals. Convenience sampling technique was used & 400 questionnaires were distributed among healthcare workers including doctors, dentists, nurses & pharmacists. All healthcare workers who were qualified and practice medicine daily were included in the study. Trainees, house officers, students and managerial staff were excluded from the study. Data was then analyzed at SPSS version 20. Consent was taken from ethical board review committee.

RESULTS:

The results of our study showed that only n=154 (38.5%) knew about the pharmacovigillance and n=239 (59.8%) did not know about the existence of pharmacovigillance center in Pakistan. The healthcare professionals showed

positive attitude and n=285(71.3%) agreed that it is their professional duty to report adverse drug reaction (ADR). The major factor that discourages participants from reporting ADR was lack of time n=135 (33.75%). When inquired if they have experienced adverse drug reaction in their professional experience, n=188(47%) agreed that they did. Moreover, n=252(63%) have never reported ADR.

CONCLUSION:

Our study shows that healthcare workers do not have proper knowledge about pharmacovigilance and so they do not practice it. The attitude is positive and it should be a part of curriculum and taught properly to all the professionals who practice medicine.

KEY WORDS: Pharmacovigilance, adverse drug reaction (ADR)

> **INTRODUCTION:**

After the pharmaceutical launch of a licensed drug into the consumer market, its' foremost

to detect any ADR following that drug since the clinical trial phase may lack in complete evaluation which might result in mortalities and other problems.^[1] Not until sixties, but latter in 1968 when the sedative-hypnotic tragedy happened,the World Health Organization (WHO) developed a global drug programme^[2]in which drug reporting centers

were established in most countries.^[3]

Consequently, the reporting of adverse drug reactions (ADRs) is the basis of any pharmacovigilance system and the timely identification and reporting of ADRs to regional or national drug regulators is vital.PV or PHV aims to improve the safety of patients by assessing the drug's risk to benefit ratio. ^[4]

According to WHO Definition of ADR:

"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 modification of physiological function."^[1]

According to WHO Definition of pharmcovigilance:

"Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of ADR or any other medicine related problem to improve the safety of medicines.^[2] The cornerstone of safety observance of medicines in clinical practice is spontaneously reporting of ADRs (yellow card). The previously unrecognized adverse reactions can be detected and identification of risk factors that pre-dispose to drug toxicity. Not just distinguishing drug safety issues, it also helps to facilitate risk-benefit portfolio and comparisons inside therapeutic classes. This is the most widely used and value effective surveillance system. ^[5]

The desired aim of pharmacovigilance requires the immediate reporting of ADRs, reflecting the contribution of health care professionals towards this aspect. Unfortunately, the underdeveloped countries such as the African population have major reporting issues. ^[2]

While moreover, studies done in developing countries also demonstrates that ADRs are poorly reported by healthcare professionals collectively in hospitals and community settings causing higher rates of patient mortality and morbities; as per representation of ADR prevalence percentages in countries such as Sweden (12.0%), Norway (11.5%), New Zealand (12.9%), and Australia (16.6%). ^[3]

A look at of ADR reporting and pharmacovigilance in hospitals of Al-Madinah Al-Munawwarah, Saudi Arabia have discovered poor recognition of ADR reporting by healthcare specialists due to inadequate pharmacovigilance education.^[3] Some research completed in India has proven poor knowledge, mindset, and poor practices regarding ADR reporting among prescribers and healthcare experts, particularly physicians.^[5]

The reporting of adverse drug reactions (ADRs) remains regularly disregarded through healthcare experts in Pakistan. Researchers have found that the excessive prevalence of substandard drug treatments, the irrational use of drugs, remedy mistakes, and drug-associated morbidity and mortality spotlight the want for pharmacovigilance centers in Pakistan. ^[6]

A research study at in Lahore, Pakistan to analyze the elements contributing to ADR below reporting amongst distinctive healthcare experts, ^[7] shows thatpharmacovigilance system in Pakistan is still in its early ranges of development, this is because of the lack of knowhow, lack of expertise or lack of training as only a few studies were carried out on ADR system within the beyond. ^[8]

Consequently, the rationale of this survey is to analyze the healthcare professionals' information, attitude and practice in the direction of unfavorable drug reactions and pharmacovigilance.

> <u>MATERIALS AND METHODS:</u>

✓ Study design and sampling strategy:

This cross-sectional investigation was conducted for the time of a half year from July to December 2018 in Karachi, Pakistan. The research is based on evaluating health care experts including approximately 400 doctors, nurses, dental practitioner and pharmacists from the three divisions of private segment tertiary care hospital. These numbers were chosen bynon-probability convenience sampling technique. The sample size was determined by utilizing the relative formula of Open-Epiby estimating the population size to be 100,000 and anticipated recurrence of 50 percent. Test measure turned out to be 384 at the certainty interval 95%. So as to maintain a strategic distance from whittling down in test estimate, 16 additional members has been included.

✓ Inclusion and exclusion criteria:

The majority of the medical service experts working at these hospitals who handles medicines regularly were viewed as qualified and capable to partake in the research study including doctors, nurses, dentists and drug specialists.

A year ago trainee pharmacists and MBBS residents, were barred from the examination. All of the representatives working in managerial positions were additionally excluded (for instance, enlistment registrars).

✓ Design of the questionnaire:

A self-administered questionnaire was utilized in this survey study, which was structured as per recently published global literature. ^[9] The poll was disseminated in English language in form of hard copies and online. The form encoded 4 segments. Initially was the socioeconomic segment, which included 5 questions. The other 3 segments contained 20 questions and intended to the accompanying themes: information and familiarity with pharmacovigilance and ADRs, disposition toward pharmacovigilance, and practices of ADR reporting.One researcher reviewed the questionnaire and checked the consistency, lucidity, and pertinence of the questions. Slight amendments were adjusted to improve the clarity of the inquiries without changing the significance.

✓ Statistical analysis:

Data from the arrived pretested survey was decoded and inputted into Statistical Package for Social Sciences (SPSS) adaptation 16 programming. Information analysis incorporated every statistics to portray the examination population in relation to the applicable factors.

► <u>RESULTS:</u>

Out of the total sample, n=169(42.25%) were males and remaining n=231(57.75%) were females. When discipline was enquired, majority n=132(33%) were dentist, n=121(30.25%) were doctors, n=87(21.75%) were pharmacist & remaining n=60(15%) were nurses. When inquired about postgraduate degree, n=246(61.5%) had postgraduate degree whereas n=154(38.5%) didnot have any postgraduate degree.

When enquired about pharmacovigillance the correct answer was given by n=154(38.5%) respondents. Majority of them were pharmacist (45.8%). The main purpose of pharmacovigilance is to identify the safety of drug and it was correctly answered by n=212(53.0%)

Majority of the respondents n=239(59.8%) didn't know regarding the existence of national pharmacovigilance program in Pakistan. When inquired about DRAP (drug regulatory authority Pakistan), regulatory body which is responsible for monitoring ADR n=223(55.8%) knew about it. Healthcare professionals who agreed that it is the responsibility of all of them (dentist, doctor, nurses, and pharmacist) for reporting ADR in hospital were n=219(54.8%). Regarding the international centre for adverse drug reaction in Sweden n=58(14.5%) knew about it. ADRs are identified during phase 4 clinical trial & n=74 (18.5%) healthcare professionals knew that. Meta analysis Spontaneous reporting system method is commonly employed by the healthcare professional to monitor adverse drug reactions of new drugs once they are launched in the market & it was correctly answered by n=108(27.0%). Healthcare professionals n=285(71.3%) agreed that ADR reporting is their professional obligation & n=274(68.5%) healthcare professionals agreed that reporting ADR is necessary. Healthcare professionals n=278(69.5%) agreed that pharmacovigilance should be taught in detail. ADR monitoring center should be establish in every hospital and it was the opinion of n=207 (51.8%). When enquired about training that how ADR should be reported n=260(65%) agreed that they were not given any training. Healthcare professionals n=145(36.3%) accepted that they had difficulty in deciding ADR has occurred whereas n=145(36.3%) didn't have difficulty in deciding. The factors discouraging participants from reporting ADRs were lack of time to report ADR n=135 (33.75%), difficulty to decide whether ADR has occurred or not n=107(26.75%) no remuneration n=88 (22%) & belief that a single unreported case may not affect ADR database n=70 (17.5%).

When inquired about reading article on prevention of adverse drug reaction, n=229(57.3%) agreed that they have never read any article regarding ADR. It was agreed by n=188(47%) that they have experienced adverse drug reaction in their professional experience whereas n=169 (42.3%) said that they haven't. When healthcare professionals were questioned about reporting of ADR to

pharmacovigilance centre, n=252(63%) agreed that they have never reported it. Reporting form was never seen by n=243(60.8%). When enquired about pharmacovigillance committee in institute n=167(41.8%) healthcare professionals agreed that there's no committee in their institute.

KNOWLEGE	DOCTO	DR	NURSE		DENT	IST	PHARI	MACIST	P VALUE	
	n	%	n	%	n	%	n	%		
Define pharmacovigillance	44	29.1%	14.3	9.3%	47	31.1%	38	25.2%	0.199	
Purpose of pharmacovigillance	66	31.1%	24	11.3%	66	31.1%	45	21.2	.132	
Existence of a National Pharmacovigilance Programme in Pakistan	22	27.5%	6	7.%	27	33.8%	19	23.%	.146	
Healthcare professionals responsible for reporting ADRs	69	31.5%	22	10%	70	32%	46	21%	.000	
Regulatory body responsible for monitoring ADRs in Pakistan	67	30%	22	9.9%	72	32.3%	51	22.9%	.274	
International center for adverse drug reaction	14	24.1%	4	6.9%	22	37.9%	12	20.7%	.086	
phase of a clinical trial in which ADRs are identified method commonly employed by the healthcare professional to monitor adverse drug reactions of new drugs	20	27%	12	16.2%	24	32.4%	16	21.6%	.095	
Method employed by healthcare professional to monitor ADR of new drugs	43	30.5%	17	12.1%	43	30.5%	33	23.4%	.644	

ATTITUDE		Doctor		Nurse		Dentist		Pharmacist		P value
		n	%	n	%	n	%	n	%	
ADR reporting is professional obligation	Yes	84	29.5%	46	16.1%	85	29.8%	60	21.1%	.828
ADR reporting is necessary	Yes	82	29.9%	44	16.1%	80	29.2%	59	21.5%	.161
Pharmacovigilance should be taught	Yes	72	27.7%	41	14.7%	90	32.4%	59	21.2%	.201
Establishing ADR monitoring center should be in every hospital		52	25.1%	31	15%	70	33.8%	46	22.2%	.006
Training on reporting ADR	Yes	23	31.1%	11	14.9%	20	27	16	21.6%	.487
Taking decision if ADR has occurred or not	yes	36	24.8%	30	20.7%	47	32.4%	27	18.6%	.152

Practice		Doc	Doctor Nurse		e	Dentist			macist	P value
		n	%	n	%	N	%	n	%	
Read article on prevention of ADRs	Yes	32	27.1%	10	8.5%	39	33.1%	32	27.1%	
	No	73	31.9%	41	17.9%	62	27.1%	42	18.3%	.176
	Cant say	2	11.8%	2	11.8%	10	58.8%	2	11.8%	
	Maybe	9	33.3%	3	11.1%	8	29.6%	6	22.2%	
Experienced ADRs in patient during practice	Yes	58	30.9%	21	11.2%	58	30.9%	43	22.9%	
	No	50	29.6%	28	16.6%	50	29.6%	34	20.1%	.432
	Cant say	2	11.8%	4	23.5%	6	35.3%	3	17.6%	
	maybe	6	40%	3	20%	3	20%	2	13.3%	

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Yes	13	24.5%	6	11.3%	17	32.1%	13	24.5%	
No	83	32.9%	35	13.9%	79	31.3%	48	19%	
D	42	22.20(20.4%		25.00/		25.00/	241
Don't know	12	22.2%	11	20.4%	14	25.9%	14	25.9%	.241
where to submit									
reporting form									
Don't know how	8	25.8%	4	12.9%	8	25.8%	7	22.6%	
to fill ADR form									
Yes	23	25.6%	16	17.8%	22	24.4%	25	27.8%	
•	0.0	22 70/	24	42.00/	74	20.20/	40	40.00/	
NO	82	33.7%	31	12.8%	/1	29.2%	48	19.8%	
Cant say	Δ	21.1%	2	15.8%	q	17.4%	2	10.5%	.261
cant say	-	21.170		15.070	5	47.470	2	10.570	
maybe	7	20.6%	6	17.6%	14	41.2%	5	14.7%	
		2010/0		27.070				, .	
Yes	23	31.1%	8	10.8%	23	31.1%	15	20.3%	
No	51	30.5%	24	14.4%	52	31.1%	36	21.6%	
Not yet formed	14	35.9%	7	17.9%	13	33.3%	4	10.3%	.582
Don't know	20	25 20/	17	1 5 20/	21	27.00/	27	24 20/	
	Yes No Don't know where to submit reporting form Don't know how to fill ADR form Yes No Cant say maybe Yes No No Yes	Yes13No83Don't know where to submit reporting form12Don't know how to fill ADR form8Yes23No82Cant say4maybe7Yes23No51Not yet formed14	Yes1324.5%No8332.9%Don't know where to submit reporting form1222.2%Don't know how to fill ADR form825.8%Yes2325.6%No8233.7%Cant say421.1%maybe720.6%Yes2331.1%No51130.5%Not yet formed1435.9%	Yes1324.5%6No8332.9%35Don't know where to submit reporting form1222.2%11Don't know to fill ADR form825.8%4Yes2325.6%16No8233.7%31Cant say421.1%3maybe720.6%6Yes2331.1%8No5130.5%24Not yet formed1435.9%7	Yes 13 24.5% 6 11.3% No 83 32.9% 35 13.9% Don't know 12 22.2% 11 20.4% where to submit reporting form 12 22.2% 11 20.4% Don't know how to fill ADR form 8 25.8% 4 12.9% Yes 23 25.6% 16 17.8% No 82 33.7% 31 12.8% maybe 7 20.6% 6 17.6% Yes 23 31.1% 8 10.8% No 51 30.5% 24 14.4% Not yet formed 14 35.9% 7 17.9%	Yes1324.5%611.3%17No8332.9%3513.9%79Don't know where to submit reporting form1222.2%1120.4%14Don't know how to fill ADR form825.8%412.9%8Yes2325.6%1617.8%22No8233.7%3112.8%71Cant say421.1%315.8%9maybe720.6%617.6%14Yes2331.1%810.8%23No5130.5%2414.4%52Not yet formed1435.9%717.9%13	Yes1324.5%611.3%1732.1%No8332.9%3513.9%7931.3%Don't know where to submit reporting form1222.2%1120.4%1425.9%Don't know where to submit reporting form1222.2%1120.4%1425.9%Don't know how to fill ADR form825.8%412.9%825.8%Yes2325.6%1617.8%2224.4%No8233.7%3112.8%7129.2%Cant say421.1%315.8%947.4%Yes2331.1%810.8%2331.1%No5130.5%2414.4%5231.1%Not yet formed1435.9%717.9%1333.3%	Yes1324.5%611.3%1732.1%13No8332.9%3513.9%7931.3%48Don't know where to submit reporting form1222.2%1120.4%1425.9%14Don't know how to fill ADR form825.8%412.9%825.8%7Yes2325.6%1617.8%2224.4%25No8233.7%3112.8%7129.2%48Cant say421.1%315.8%947.4%2maybe720.6%617.6%1441.2%5No5130.5%2414.4%5231.1%36Not yet formed1435.9%717.9%1333.3%4	Yes1324.5%611.3%1732.1%1324.5%No8332.9%3513.9%7931.3%4819%Don't know where to submit reporting form1222.2%1120.4%1425.9%1425.9%Don't know how to fill ADR form825.8%412.9%825.8%722.6%Yes2325.6%1617.8%2224.4%2527.8%No8233.7%3112.8%7129.2%4819.8%Cant say421.1%315.8%947.4%210.5%Yes2331.1%810.8%2331.1%1520.3%No5130.5%2414.4%5231.1%3621.6%Not yet formed1435.9%717.9%1333.3%410.3%

> <u>DISCUSSION:</u>

Studies have demonstrated that pharmacist have an important role in reporting ADRs ⁽¹⁰⁾. It is significant for doctors as well as drug specialists, dentists and nurses to have incredible learning of ADR and methodology of reporting ADR⁽⁸⁾. Our results showed that only 38.5% professional knew the correct definition of pharmacovigillance. It is in correspondence with the study which was conducted in Saudia Arabia where 62.5% didn't know about the pharmacovigillance⁽³⁾. Where as a study was conducted in South India in Dhanalakshmi Srinivasan Medical College and Hospital (DSMCH), Perambalur (Tamil Nadu), a tertiary care teaching hospital in which 62.4% gave correct answer about the definition of pharmacovigillance⁽⁹⁾. Our study showed that 55.8% of healthcare professionals knew about drug regulatory authority Pakistan (DRAP). A similar study conducted in Lahore, Pakistan which aimed to evaluate knowledge attitude and practice of pharmacovigillancecentre of Pakistan ⁽¹¹⁾. Similarly another study was carried out in Pakistan, Islamabad and it also

revealed that only 19.2% knew where to report ADR in Pakistan ⁽⁸⁾. Therefore it's very essential to educate healthcare professionals about ADRs and how to report them. The results of our study revealed that only 14.5% of participants had knowledge about the international center for adverse drug reaction which is in Sweden, Uppsala. The results are in correspondence with another study carried out in Abbotobad, Pakistan in which only 12% respondents were aware of the location of international monitoring center of drug ⁽¹²⁾. Another study carried out in Pakistan Islamabad also revealed the similar result in which 23.7% respondents answered it correctly ⁽⁸⁾. The results are different from the study carried out in South India where 41.6% were aware about the location of International Center for ADR monitoring⁽⁹⁾.

The attitude of healthcare professionals about reporting ADR was very much encouraging. The results of our study revealed that 71.3% of healthcare professional considers reporting ADR is their professional obligation. Similar results were found in another study in Pakistan in which 84% medical& pharmacy students agreed that reporting ADR is their professional responsibility^{(12).} similar results were seen in a study done at Amhara region Ethopia in which 95.4% healthcare professional considered reporting ADR as their professional duty⁽²⁾. Similarly, a study was carried out in Saudia Arabia in which 98.3% professionals considered reporting of ADR to be integrated to their professional duties⁽¹³⁾. In order to avoid ADR, it is necessary to report them and it was revealed in our study. The result of our study shows that 68.5% healthcare professionals agreed reporting of ADR is necessary. Another study carried out in tertiary hospital of Islamabad Pakistan also had the same result in which 70.6% respondents strongly agreed that ADR reporting is necessary⁽⁸⁾. In another study carried out in Pakistan among pharmacy and medical students, 79.1% pharmacy students and 43.5% medical students agreed that ADR reporting is as important as managing patients⁽⁶⁾. Similarly a study carried out among healthcare professionals in teaching hospital in South India also had the similar result in which 97% respondents agreed that ADR reporting is necessary^{(9).} A study took place at King Fahd Hospital of the University (KFHU), Khobar, Kingdom of Saudi Arabia in which 87.1 % agreed with the necessity of reporting ADR^{(3).} The findings are also consistent with Nigeria and Netherlands where majority of respondents agreed about the necessity of reporting ADR ^(14, 15). It is important to teachpharmacovigillance to all the healthcare professionals in detail so that there are fewer cases of ADRs. Our study shows that 69.5% of healthcare professionals agreed with it i.e.pharmacovigillance should be taught in detail. A study, assessment of knowledge, attitudes and practice among the medical and pharmacy students towards pharmacovigilance and adverse drug reactions in Abbottabad, Pakistan showed that 83.5% agreed that pharmacovigillance should be a part of curriculum ⁽¹²⁾. The results are in correspondence with a study carried out in Majmaah, Saudia Arabia in which 77.7% agreed the same ⁽¹⁶⁾. In another study carried out in Yemen, 73.3% physician & 84.7% nurses scored highly for the importance of pharmacovigilance and that it should be

a part of educational curricula⁽¹⁷⁾. The results of our study shows that 65% respondents were not given any training that how ADR should be reported. Another study carried out in Pakistan revealed that 86.9% healthcare professional had not receive any training on ADR ⁽⁸⁾. Similarly another study carried out in India. An evaluation of knowledge, attitude and practice of Indian pharmacists towards adverse drug reaction reporting: A pilot study in which only 30% participants reported that they were trained for ADR reporting ⁽⁵⁾. Another study carried out in south India reported that 53.5% healthcare workers have received adequate training on reporting adverse drug reaction(9)⁽⁹⁾. The results are not in correspondence with a study carried out in Ethopia in which only 16.9% were adequately trained for reporting ADR ⁽¹⁸⁾. Another study carried among the pharmacists of royal pharmaceutical society of Great Britain, Training had been received by 109 (37.9%) pharmacists⁽¹⁵⁾. Our study has also focused on the factors which discouraged participants from reporting ADR. The results of our study show that 33.75% didn't report because of lack of time. Other factors that discouraged from reporting were 26.75% had difficulty to decide whether ADR has occurred or not, 22% didn't because of no remuneration and 17.5 % didn't report because they belief that a single unreported case doesn't affect the ADR database. In a study carried out in capital city of Pakistan, identified the factors that discourage respondents to report ADR include not knowing where and how to report ADR 20.2% and 10.4% respectively. Others reported that ADR is not important 12.3%, lack of access to ADR reporting form 6.3% & managing patient is more important 12.8%⁽⁸⁾. A study carried out in Abbotobad, Pakistan found that the important factors that may discourage a Health care Professional (HCP) from reporting ADR were, no reward or compensation for reporting 16.5%: lack of time required for reporting 29.5%: single unreported case may not affect ADR database 9.5%; non availability of reporting center 19.5%. ⁽¹²⁾. Studies carried out in Ethopia and Nigeria revealed that lack of knowledge is the main reason for not reporting ADR^(14, 19). A study carried out in India revealed that lack of time is the main reason for not reporting ADR⁽²⁰⁾. In another study carried out in khobar, kingdom of Saudia Arabia, found the factors that may discourage healthcare workers from reporting ADRs were 43.8% did not know how to report an ADR, 17.5% did not believe that it was significant, 8.6% considered that patient management was more necessary, 9.9% didn't considered it the not part of their job, and 10.3% had patient confidentiality issues⁽³⁾.

The results of our study show that 42.3% of healthcare professionals have never experienced adverse drug reaction in their professional experience. In a study conducted in Amhara region of Ethopia, 61.9% never experienced of noting ADR ⁽²⁾. In a study conducted in South India, the results revealed that 64.4% have experienced ADR in their professional experience ⁽⁹⁾. One of the finding of our study was that 63% of healthcare professional never reported ADR anywhere. The results are in line with another study carried out in capital city of Pakistan in which 88.3% never reported ADR⁽⁸⁾. Moreover in another study

carried out in Saudia Arabia, 88.8% had never reported, submitted or identified ADR⁽³⁾.The results are totally different from a study conducted in Sweden where 60% reported ADR to a proper authority ⁽²⁾.

The major strength of this study is that it has focused on the assessment of knowledge, attitude and practice of healthcare workers which included doctors, pharmacist, nurses & dentist. We took healthcare workers from different strata& department. Data was collected by primary investigator. Sample size was adequate. To the best of our knowledge, this is the first study that has assessed knowledge, attitude & practice of healthcare workers in private tertiary care hospital in Karachi.

The main weakness of our study was that the target population was from private tertiary care hospital. For future study, we recommend that data should be collected from government hospital as well as other private hospitals. Other than that we recommend the hospital policies and pharmaceutical companies should be aligned to record ADRs. Proper data should be recorded whenever the ADR is reported.

> <u>CONCLUSION:</u>

The results of our study have revealed that all healthcare professional have limited knowledge about pharmacovigilance but the attitude is positive. There's no proper practice of reporting ADR. This is because pharmacovigillance is not taught properly in our institute. Pharmacovigillance policy should be developed in each hospital. Incentives or any reward should be given to anyone who reports adverse drug reaction.

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