

# Patients Perception of Pharmacovigilance system: A Pre-Diagnostic and Post-Interventional Cross-Sectional Survey

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## Research Article

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# Abstract

## Background & Objective

The risk of adverse reactions necessitated the pharmacovigilance system for patient safety. Literature search documented better health literacy of patients through intervention. This investigation aims to assess the perception and the effect of an intervention on patients regarding adverse reactions caused by drugs.

## Methods

A pre-diagnostic and post-interventional cross-sectional investigation was designed in hospitals of Islamabad. The proportion of patients was selected based on a stratified probability technique. A prevalidated tool was used to collect the response twice through health promotion brochure with counseling was applied as an intervention.

## Results

The findings of the study disclosed that health intervention improved health literacy among patients. Knowledge of pharmacovigilance was known by 97.9% of the patients in the interventional survey compared to a diagnostic survey in which the majority of the sampled population was not aware. The outcome of intervention on paired variables of knowledge, communication, and practice showed significant differences at the 0.05 level by using t-test statistics.

## Conclusion

The finding of the investigation provided evidence that patient awareness significantly improved by the health promotion model. Patient participation in the reporting of adverse reactions of drugs will complement the hospital staff reporting. These reports will construct an authentic cross-checked database for rational drug safety practices in Pakistan.

## 1. Introduction

Adverse reactions by drugs are significant health care threats to public health worldwide (Karimian *et al.*, 2018). The adverse complications are escalating in patients due to disease co-morbidities that cause a forever-increasing demand of drugs (Chen *et al.*, 2019). Drug-related complications were due to genetic variation, substandard medicine, under or overconsumption of prescribed dosage, irrational medicine usage, environmental conditions, lack of patient counseling, and non-adherence by patients (Belayneh *et al.*, 2018). Adverse reaction by the same medication may differ between individuals and situations (Roden *et al.*, 2011). Risk of adverse reactions necessitated the pharmacovigilance system for patient safety. Adverse reaction by drugs was one of the major causes of deaths associated with new hospitalizations worldwide (Giardina *et al.*, 2018). Patient's health care costs may be increased due to hospitalization for anti-dote therapy. Adverse reactions by drugs are indeed a financial burden to the patients, hospital administration, and the government (Sultana *et al.*, 2018). The heavy cost of drug adverse responses may be envisaged that the patient's belief is lost in the health care delivery system (Inacio *et al.*, 2019).

World Health Organization has reported that adverse reactions are often a reaction by the drug that is noxious and undesirable usually develops at normal doses in disease diagnosis, prophylactic treatment, drug therapy or to modify physiological processes (Kalaiselvan *et al.*, 2019). Reporting of drug adverse reactions is also commonly called as Pharmacovigilance (Shamim *et al.*, 2016). Adverse reactions and adverse effects are used interchangeably but the effect is linked with the drug and reaction is associated with the patient (Arson JK., 2013). All the components of Pharmacovigilance are significant; however, most important is the patients' function under investigation as being the focal personnel in medication therapy model. The importance of adverse reactions by drugs is undoubtedly evident, but are generally not documented or considerably under-reported by health care stakeholders (Adisa *et al.*, 2019)

. The main limitations in reporting were insufficient awareness about Pharmacovigilance, non-availability of reporting documents in hospitals, and lack of knowledge about online reporting systems in patients. The patient accessible adverse drug reaction reporting online facility was offered by World Health Organization vigibase Sweden at Uppsala monitoring center, United States of America website of Food and drug administration, United Kingdom system of yellow card scheme labeled as Med watch and at the website of Pakistan drug regulatory authority (Weigmann, 2016, Hussain and Hassali, 2019). Lack of Pharmacovigilance awareness was observed in patients and educative intervention was proposed to enhance responsiveness in Nepal (Jha *et al.*, 2014).

The adverse drug reaction monitoring system is progressive in developed nations with the existence of a pharmacovigilance system at the hospital, regional, and national levels. The successful pharmacovigilance program of the Netherland noticed dissimilarity in several reports by health care staff and patients due to differences in opinions about the severity and outcome of adverse drug reaction (De *et al.*, 2008). Patient reporting may initially be voluntary in low-income countries but it must be mandatory after some time for a viable pharmacovigilance system. All of the stakeholder's involvement may identify risk factors in limited time to prevent or minimize adverse reactions (Pal *et al.*, 2013).

Pakistan is the 134<sup>th</sup> Uppsala monitoring center participant in Sweden to record the pharmacovigilance activities (Hussain and Hassali., 2019). Health policy based on the Pakistan constitution considered health as an essential right of all people. Pakistan's health care system is built on national health policy (Jooma and Sabatinelli ., 2013) Punjab cardiology institute, Lahore recorded casualties of more than a hundred cardiac patients in 2012 as a result of adverse drug reactions from contaminated Isotab. This incident endorsed the patient contribution in reporting of adverse drug reaction in its true perspective to ensure rational drug use in the country (Hussain and Hassali. 2019). The purpose of patient involvement is to increase patient safety as being the actual target of these reactions. The scarcity of research in Pakistan related to the patient's perception of the pharmacovigilance system provided evidence for an investigation. Therefore, a research survey was planned to determine the perception and the effect of the intervention on patients regarding adverse reactions caused by drugs in hospitals of Islamabad.

## **2. Methods**

### ***2.1 Survey design and population***

A pre-diagnostic and post-interventional cross-sectional investigation was designed. The current survey was carried out in all the public sector tertiary care hospitals of the capital city of Pakistan. The hospital administration and institutional research review boards of the Pakistan institute of medical sciences, sector G 8, Capital development authority hospital, Federal government chak shahzad hospital, Federal government polyclinic hospital, Sector G 6, and Social security hospital permitted the survey. The majority of the population of Islamabad was visiting outpatient departments of these hospitals for the treatment of diseases. All the tertiary care private health care facilities refused to allow the investigation in their premises. The survey populace involved both genders visiting the general medicine and general surgery outpatient department. All the patients who gave willingness according to the recruiting strategy were involved in the survey.

## ***2.2 Sampled population size and Technique for sampling***

The sampled population size was assumed on 50 % awareness prevalence with 5% allowable error and confidence interval limits of 95% due to the non-availability of any published investigation in the country. The addition of a 10% non-responsive population in Z formula resulted in 423 survey participants. The probability technique for sampling was considered as a quantitative procedure that was applied for collecting data. The number of contributors from each health care facility was selected based on average monthly outpatient department visits. The hospital wise patients were recruited by stratified random sampling. The software method was used for the random selection of respondents from the hospital outpatient department list. In total 423 patients were recruited for the research investigation from all the five hospitals in three months' duration. The number of patients calculated from each hospital was elaborated in Table 1.

**Table 1: Sample size calculation of Patients from each hospital**

Name of Hospital	Average Monthly patient visitors General Medicine	Sample	Average Monthly patient visitors General Surgery	Sample
Pakistan institute of medical sciences, sector G 8,	1908	104	1292	70
Federal government polyclinic hospital, sector G 6,	1802	98	1248	68
Capital development authority hospital	722	39	228	12
Federal government chak shahzad hospital	229	12	71	4
Social Security Hospital	188	10	112	6
Total population	4849	263	2951	160

## ***2.3 Instrument for collecting Data***

The survey was based on a well-developed pre-validated instrument used in Nepal (Jha et al., 2014). The tool was modified on recommendations of expert professionals according to the local pharmacovigilance needs inconsistency with the literature published. The pilot survey was conducted on ten participants from each hospital to test the easiness and average time interval calculation for each task. The reliability coefficient Cronbach's alpha value for the modified instrument was 0.90 in the statistical package for social sciences software.

## ***2.4 Health Promotion Model***

The educational intervention took an average of 30 minutes excluding filling the time of pre- and post-intervention questionnaires. The interventional activity was completed during the waiting time of the patients in the outpatient department of the hospitals. The educational brochure comprised of basic information regarding pharmacovigilance activities, awareness regarding side effects and adverse reaction to drugs, the procedure for suspected adverse reaction reporting, health care personnel's role in monitoring and treatment, self-reporting websites, and the importance of reporting drug adverse reactions. After ten minutes of the distribution of information brochures, counseling activity was conducted by trained pharmacists related to the information brochure.

## ***2.5 Statistical Analysis and Variables***

Entry and analysis of data were software-based. The statistical software for social sciences 21<sup>st</sup> version was used (Dembe et al., 2011). The descriptive statistical analysis involved the frequency and percentage calculation. The inferential investigation of data was computed on continuous variables by applying a paired t-test. The eight-item subscale was formulated for awareness and practice of adverse reactions by drugs, while a five-item subscale was formulated for communication in pharmacovigilance among patients for assessment of association level using the chi-square test.

## ***2.6 Ethics Approval***

The ethics review board of the Health services academy, Islamabad, Pakistan, and institutional review boards/Hospital administrators permitted the survey. The survey participants were informed about the project and consent was obtained in writing.

# **3. Results**

## ***3.1 Patient Demographics***

The patient education level was categorized into three subgroups of uneducated, up to 12 years of education, 14 years of education, and above. Age was also classified into three classes of uneducated, up to the intermediate level of education (12<sup>th</sup> Grade), graduate and above. Gender wise distribution disclosed 45.6% males and 54.4% of female's participants. The patient demographics were represented in table 2 containing information about the residential status and monthly income.

**Table 2: Patient demographics**

Patient Demographics	Frequency (Percentage)
<b>Educational level of respondents</b>	
Uneducated	161(38.1%)
Up to intermediate level of education	154(36.4%)
Graduate and above	108(25.5%)
<b>Age of respondents</b>	
18-40 years	162(38.3%)
41-60 years	145(34.3%)
61 years and above	116(27.4%)
<b>Gender of respondents</b>	
Male	193(45.6%)
Female	230(54.4%)
<b>Residence of respondents</b>	
Urban	301(71.2%)
Rural	122(28.8%)
<b>Monthly Income of respondents</b>	
Less than 50000	146(34.5%)
50000- 100000	160(37.8%)
More Than 100000	117(27.7%)

### ***3.2 Patient's knowledge of adverse reaction by drugs***

The 74.2% of patients immediately consult the doctor when suffering from the disease before the intervention, despite the fact, 16.1% replied that they will do self-medication when suffering from the disease in the future after counseling sessions and brochure intervention. The outcomes of the guidance provided by health care professionals for safe drug usage presented negligible improvement from 64.1% patients to 68.8%. Patient compliance to health care guide by the health care professional was fully followed by 51.8% initially, and 61.5% of the respondents in the final response. The 35.2% respondents knew that adverse reactions by the drug were the harmful response, while 75.2% participants identified correctly in the interventional survey. The data about the patient's knowledge of adverse reactions by drugs in the pre-post analysis is presented in table 3.

### ***3.3 Patient's communication in pharmacovigilance***

The 48.2% of the sampled population discuss the probability of adverse reactions by drugs before taking medication in pre-survey while the response was increased to 74.9% in the post-survey. As regards discussion about dose frequency and timing of medicine 59.6% participants before the intervention, while 95.3% aimed to

discuss it with the prescriber in future conversation. Precautions/instructions related to prescription were conversed with the physician by 63.1% of patients before counseling session and 84.9% of the patients intended to converse it with the prescriber in the forthcoming discussion. The data related to communication in pharmacovigilance among patients are presented in table 3

**Table3: Patients knowledge of adverse reaction by drugs and Patients communication in pharmacovigilance**

Characteristics	Diagnostic Response	Interventional Response
	n (%)	n (%)
<b>Patients knowledge of adverse reaction by drugs</b>		
Patients immediate action after suffering from a disease		
a. Immediately consult the doctor for a prescription	314(74.2%)	355(83.9%)
b. Practice self-medication	109(25.8%)	68(16.1%)
Guidance provided by a health care professional for safe drug usage		
a. Yes	271(64.1%)	291(68.8%)
b. No	152(35.9%)	132(31.2%)
Patients Compliance to health care guidance		
a. Completely	215(50.8%)	260(61.5%)
b. Not entirely	107(25.3%)	89(21%)
c. Not followed	101(23.9%)	74(17.5%)
Patients understanding about the adverse reaction by drugs		
a. Harmful Response by a drug *	149(35.2%)	318(75.2%)
b. Routine side effect	67(15.8%)	57(13.5%)
c. Desired response	59(13.9%)	48(11.3%)
d. Do not know	148(35%)	0
Patients perception regarding the purpose of reporting adverse reactions by drugs		
a. Drug safety improve by reporting	80(18.9%)	270(63.8%)
b. Reoccurrence will be prevented	150(35.5%)	107(25.3%)
c. Prerequisite in the hospital setting	62(14.7%)	42(9.9%)
d. Enable physician for early diagnosis	131(31%)	4(0.9%)

Vulnerable population for developing adverse reactions by drugs		
a. Child populace	139(32.9%)	112(26.5%)
b. Adult Population	49(11.6%)	31(7.3%)
c. Old age people	82(19.4%)	53(12.5%)
d. All of the above	153(36.2%)	227(53.7%)
Appropriate Person in the health care team for reporting adverse reactions by drugs		
a. Physician	84(19.9%)	145(34.2%)
b. Pharmacist	42(9.9%)	58(13.7%)
c. Nurse	42(9.9%)	57(13.5%)
d. All of the above	107(25.3%)	163(38.6%)
e. Do not Know	148(35.0%)	0
Do you have the knowledge of Pharmacovigilance as the science of detecting adverse drug reaction		
a. Yes	121(28.6%)	414(97.9%)
b. No	302(71.4%)	9(2.1%)
Knowledge of online forms for reporting drug reactions		
a. Yes	242(57.2%)	420(99.3%)
b. No	181(42.8%)	3(0.7%)
<b>Patients communication in pharmacovigilance</b>		
Discussion with the physician about the probability of adverse drug reaction before taking medication		
a. Yes	204(48.2%)	317(74.9%)
b. No	219(51.8%)	106(25.1)
Discussion with the physician about dose frequency and timing of medicines		
a. Yes	252(59.6%)	403(95.3%)

b. No	171(40.4%)	20(4.7%)
Discussion with the physician about precautions and instructions related to prescription		
a. Yes	267(63.1%)	359(84.9%)
b. No	156(36.9%)	64(15.1%)
Show compliance to prescriber Instructions		
a. Yes	315(74.5%)	359(84.9%)
b. No	108(25.5%)	64(15.1%)
Did/Will you review the drug brochure about the adverse reaction of the drugs before taking the medication?		
a. Yes	219(51.8%)	370(87.5%)
b. No	204(48.2%)	53(12.5%)

\*Correct response

### ***3.4 Patient practice in the pharmacovigilance system***

The 45.9% of the participants experienced adverse reactions by drugs during their lifetime but the reporting rate was 30.2% only. The attitude towards reporting was modified by pharmacist counseling sessions and health brochure intervention and 99.3% of respondents showed the intention to report in the future. Media reports were recalled by 56.7% of the patients in the initial response and 60.8% in the final response. The prerequisite of pharmacovigilance center in the hospital was improved significantly from 56.7% to 97.9%. The data about pharmacovigilance practice among patients are described in table 4.

**Table 4: Patient practice in the pharmacovigilance system**

Characteristics	Diagnostic Response	Interventional Response
	n (%)	n (%)
Experience of adverse drug reaction during the lifetime		
a. Yes	194(45.9%)	194(45.9%)
b. No	229(54.1%)	229(54.1%)
Did you report adverse drug reaction to anyone		
a. Yes	127(30.02%)	127(30.02%)
b. No	296(69.98%)	296(69.98%)
I will be reporting adverse drug reaction in future		
a. Yes	242(57.2%)	420(99.3%)
b. No	181(42.8%)	3(0.7%)
The prescribing and dispensing time should be improved to prevent adverse drug reaction		
a. Yes	252(59.5%)	332(78.5%)
b. No	171(40.5%)	91(21.5%)
Have you noticed/remembered any adverse drug reaction reported in media		
a. Yes	240(56.7%)	257(60.8%)
b. No	183(43.3%)	166(39.2%)
Is there need of pharmacovigilance center in hospitals		
a. Yes	240(56.7%)	414(97.9%)
b. No	183(43.3%)	9(2.1%)
Reporting of adverse reactions by drugs is beneficial for the populace as it reduces re-occurrence		
a. Yes*	260(61.5%)	374(88.4%)
b. No	163(38.5%)	49(11.6%)

Adverse drug reactions are a serious concern for health care stakeholders in Pakistan		
a. Yes*	226(53.4%)	418(98.8%)
b. No	197(46.6%)	5(1.2%)

\*Correct response

### 3.5 Paired-t-test

The patient's knowledge of adverse reactions by drugs, patient's communication in pharmacovigilance, and patient's practice in the pharmacovigilance system was correlated with the intervention response. The findings of the correlation showed that there is a strong correlation between patient's practice in the pharmacovigilance system, moderate correlation between patient's knowledge of adverse reactions by drugs, patient's communication in pharmacovigilance. The outcome of intervention on paired variables showed significant differences at the 0.05 level by using t-test statistics. The pre-diagnostic and post-interventional assessment using paired t-test are results are displayed in table 5.

**Table 5: Pre-diagnostic and Post-interventional assessment using paired t-test**

Variables	Response	Mean	SD	Mean difference	Correlation r-value	p-value	t-value df (422)	p-value
Patient's knowledge of adverse reactions by drugs	Diagnostic response	18.33	4.49	4.94	0.66	<0.01	30.03	<0.01
	Interventional response	13.39	2.71					
Patient's communication in pharmacovigilance	Diagnostic response	6.97	1.72	1.25	0.62	<0.01	18.90	<0.01
	Interventional response	5.72	0.89					
Patient's practice in the pharmacovigilance system	Diagnostic response	11.80	2.46	1.80	0.72	<0.01	20.89	<0.01
	Interventional response	10.00	1.27					

### 3.6 Chi-square test

The perception difference related to age, gender, and education of participants was computed by applying chi-square statistics. The findings of the research investigation revealed that all the variables except interventional response of communication in pharmacovigilance were significant for the age of the contributors. There were significant differences in gender among all variables. Communication in pharmacovigilance was only non-

significant for education. The chi-square statistics related to perception differences constructed on age, gender, and education are explained in table 6.

**Table 6: Perception difference based on age, gender and education**

Variable	Patient's knowledge of adverse reactions by drugs						
	Response	Diagnostic response	$\chi^2$	p-value	Interventional response	$\chi^2$	p-value
<b>Age</b>							
15-30 years	Don't Know	64.8%	63.61	<0.01	61.6%	11.09	<0.01
	Yes	35.2%			38.4%		
31-45 years	Do not Know	81.5%			43.2%		
	Yes	18.5%			56.8%		
46- and above years	Don't Know	33.9%			48.3%		
	Yes	66.1%			51.7%		
<b>Gender</b>							
Male	Don't Know	37.4%	95.28	<0.01	32.3%	55.01	<0.01
	Yes	62.6%			67.7%		
Female	Don't Know	83.6%			68.4%		
	Yes	16.4%			31.6%		
<b>Education in Years</b>							
Uneducated	Don't Know	58.3%	52.53	<0.01	56.4%	5.79	0.05
	Yes	41.7%			43.6%		
Matric and Intermediate	Don't Know	81.9%			43.9%		
	Yes	18.1%			56.1%		
Graduate and above	Don't Know	38.1%			55.2%		
	Yes	61.9%			44.8%		
Patient's communication in pharmacovigilance							
	Response	Diagnostic response	$\chi^2$	p-value	Interventional response	$\chi^2$	p-value
<b>Age</b>							
15-30 years	Don't Know	42.8%	7.47	0.02	51.6%	0.44	0.80
	Yes	57.2%			48.4%		

31-45 years	Don't Know	57.5%			49.3%		
	Yes	42.5%			50.7%		
46- and above years	Don't Know	44.9%			53.4%		
	Yes	55.1%			46.6%		
<b>Gender</b>							
Male	Don't Know	13.6%	180	<0.01	30.8%	62.56	<0.01
	Yes	86.4%			69.2%		
Female	Don't Know	79.1%			69.3%		
	Yes	20.9%			30.7%		
<b>Education in Years</b>							
Uneducated	Don't Know	41.7%	5.17	0.07	49.1%	4.28	0.11
	Yes	58.3%			50.9%		
Matric and Intermediate	Don't Know	54.2%			47.7%		
	Yes	45.8%			52.3%		
Graduate and above	Don't Know	50.5%			60%		
	Yes	49.5%			49%		
<b>Patient's practice in the pharmacovigilance system</b>							
	Response	Diagnostic response	$\chi^2$	p-value	Interventional response	$\chi^2$	p-value
<b>Age</b>							
15-30 years	Don't Know	54.7%	77.79	<0.01	80.05%	37.40	<0.01
	Yes	45.3%			19.5%		
31-45 years	Don't Know	8.2%			47.3%		
	Yes	91.8%			52.7%		
46- and above years	Don't Know	45.8%			58.5%		
	Yes						

	Yes	54.2%			41.5%		
<b>Gender</b>							
Male	Don't Know	23.7%	24.92	<0.01	58.6%	2.94	0.05
	Yes	76.3%			41.4%		
Female	Don't Know	47.1%			66.7%		
	Yes	52.9%			33.3%		
<b>Education in Years</b>							
Uneducated	Don't Know	49.7%	78.89	<0.01	71.2%	26.25	<0.01
	Yes	50.3%			28.8%		
Matric and Intermediate	Don't Know	9.0%			47.1%		
	Yes	91.0%			52.9%		
Graduate and above	Don't Know	55.2%			73.3%		
	yes	44.8%			26.7%		

Note: \* specifies the level of significance at 0.05.

## 4. Discussion

Patients' perception of the disease and drugs plays a vital role in the successful therapy model in health management. Patient education involves counseling that is important for disease understanding, awareness of pharmacological and non-pharmacological approaches in the treatment. Compliance with therapy may be improved by effective active and passive counseling of the patients. Active counseling involves face to face conversation while passive counseling involves the use of written information (Saood *et al.*, 2020). The current investigation involved a mixed method of face to face counseling sessions with health brochure intervention. The 423 patients from the targeted outpatient departments were evaluated for the survey. The majority of the sampled population were women because of the high incidence of disease also testified by Gove (Gove *et al.*, 1984). Self-ingestion of medicines without physician consultation was reported as one of the significant etiological cause of adverse drug reaction (Mahmood *et al.*, 2011). The present research investigation reported a decrease in patient's intention toward self-medication when they suffered from disease after the intervention.

World Health Organization documented that majority of the patients globally fail to take medicines correctly (Ofario *et al.*, 2016). The poor drug adherence contributing factors are related to patients and physicians. The barrier in communiqué with the physician and lack of communication in pharmacovigilance were the most important physician contributing factors (Brown *et al.*, 2011). Similar results were reported by the majority of the

patients in this survey. The suboptimal level of health literacy in patients evoked poor compliance (Millar *et al.*, 2016). The instructions of the prescriber were fully followed by less than 62% of the patients after intervention. Low health literacy of the patients may be linked with uneducated and less educated participants in the survey. The majority of the respondents were not able to recognize the concept of adverse reactions by drugs in the diagnostic survey. Perception regarding adverse drug reactions was also low in some areas of Nepal and Nigeria (Jha *et al.*, 2014, Adisa *et al.*, 2019). The understanding of adverse drug reaction was improved in two-thirds of the participants after health communication. Almost, half of the counseled respondents correctly identified vulnerable populations to develop adverse drug reactions. The literature search also nullified the concept that the children were most susceptible to adverse reactions by drugs. Everyone may be endangered to adverse reactions by drugs irrespective of age group, sex, race, and other factors (Inacio *et al.*, 2017, Mahmood *et al.*, 2011). The familiarity of the pharmacovigilance concept was less in 1/3<sup>rd</sup> of the sampled population in the diagnostic survey also reported in fifty nation's metanalysis reports on adverse drug reaction (Margraff *et al.*, 2014). The intervention created awareness in more than 95% of the participants. The knowledge of patient regarding an appropriate person in the health care team is a prerequisite for reporting. Health care team members of all specialties were involved in signal detection in pharmacovigilance system globally. The majority of the patients did not appropriately recognize the responsible person for reporting adverse drug reactions in the diagnostic survey but after the intervention, they were able to identify the health personnel's involvement in adverse drug reactions. Patient reporting had generated positive outcomes in previous literature and is prerequisite of the day for patient's safety (Mahmood *et al.*, 2011).

Eric's report declared that drug safety data need to be transmitted effectively for educating health care stakeholders so that the risk-benefit of medicines may be interpreted timely and the exchange of such data at the international and national levels should be recommended (Hugman, 2006). The health conversation of patients with prescribers related to the effect of adverse drug reaction was less than 50% in the current response and aimed to be less than 75% in the future response. The patient-physician communication of dose and timing is important because type A reactions are dose-dependent (Coleman and Pontefract. 2016) The initial response of 62% of dose and timing of medication conversation with the physician was improved significantly to 95.3% in the final response. The lack of patient compliance to therapy resulted in resistance to treatment, therapy failure, deaths, prolong hospital duration, and increased expenditure on health care. Chronic medication adherence was 50% detected in patients ( DiMatteo *et al.*, 2002). The patient compliance to prescriber instructions was 74.5% in the initial response and 84.9% in the final response. The drug leaflet guide is a source of providing relevant information to consumers (Adepu and Swammy.,2012). The current investigation reported that 51.8% reviewed the drug literature brochure before taking the medication, while 87.5% of the patients stated that they will practice in the future.

A substantial number of participants (45.9%) declared that they experience adverse reactions by drugs and only 30.2% documented that to health personnel. Medical professionals' illiteracy in signal detection and rare practice of reporting are major constraints in a viable pharmacovigilance system in the countries. (AlShammari and Almoslem. 2018, Fernandopulle and Weerasuriya. 2003) The majority of patients intended in both surveys for future reporting of adverse reactions by drugs. Medical professionals underreporting in developing nations will be supplemented by an autonomous patient pharmacovigilance reporting practice. The consumer reporting of adverse reactions may be a beneficial project for safety assurance. The majority of the patients were able to recall media reports, therefore the potential of media should be utilized in Pakistan for

the dissemination of pharmacovigilance reports (Van Hunsel *et al.*, 2009) Patients believed that physician prescribing time and pharmacist dispensing time should be improved for better understanding about drugs. Mostly patients proposed a hospital-based pharmacovigilance system in the country for effective health communication among stakeholders for patient safety (. Saqib *et al.*, 2019) The personalized drug model proposed by Wertheimer may guide for efficient, suitable, economical, and safe drug usage globally(Wertheimer,2017).

## 5. Conclusion

The results of the pioneer survey concluded that health literacy improved significantly in the interventional survey but the baseline results indicated a low awareness level of pharmacovigilance among patients in the federal capital of Pakistan. Patient participation in the reporting of adverse reactions of drugs will complement the hospital staff reporting. These reports will construct an authentic cross-checked database for rational drug safety practices in Pakistan. There is a need for further research to investigate the predictors, promoters, and barriers in adverse reaction reporting among patients in Pakistan.

## Declarations

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### Conflict of Interest

The authors have no conflicts of interest to declare for this study

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### Author Contributions

Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Project administration, Writing original draft: Atta ur Rehman

Supervision, Review & Editing: Samina Naeem Khalid

Project administration, Review & editing: Ume Hani

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