

# Navigating the pharmacovigilance landscape: unveiling challenges and progress among healthcare professionals in Pakistan

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## ABSTRACT

**Background:** Every country is trying its best to establish a strong pharmacovigilance system and some developed countries got successful in this too but the developing countries like Pakistan still lack the basic infrastructure to establish it and Drug Regulatory Authority of Pakistan (DRAP) is the only regulatory authority to report adverse drug reactions here. Peshawar, Pakistan has many tertiary care centres but still it lacks proper system to report adverse drug reactions and many doctors and pharmacist till today are unaware of it. We tried to highlight problems and role of healthcare professionals in Adverse drug reactions (ADRs) reporting.

**Methodology:** A cross-sectional descriptive study was conducted in multiple public and private tertiary care hospitals from January to July 2023. The study included 190 healthcare professionals, and data were collected through a self-structured questionnaire. The analysis involved calculating means, standard deviations, frequencies, percentages, and one-sample t-tests.

**Results:** The majority of participants (82.6%) exhibited poor knowledge of pharmacovigilance. Knowledge gaps were identified in understanding pharmacovigilance activities, reporting processes, and the location of pharmacovigilance centres. Barriers to reporting included lack of awareness (15.3%) and resources (3.7%). Only 15% received guidance on reporting Adverse drug reactions (ADRs), and 20.5% knew where to report.

**Conclusion:** In Peshawar, Pakistan physicians are mostly unaware of Adverse drug reactions (ADRs) reporting and lack of knowledge, lack of training, work environment, and workload on physicians and pharmacist are the main reasons of under reporting of Adverse drug reactions (ADRs) as well as there should be other regulatory authorities like Drug Regulatory Authority of Pakistan (DRAP) in Pakistan.

**Keywords:** Pharmacovigilance, Adverse drug reactions (ADRs), Healthcare professionals, Medication safety, Drug safety.

## Introduction

A medication's therapeutic impact and side effects should always be balanced, but occasionally this balance is thrown off, resulting in adverse drug responses that send patients to the hospital or even cause death. An assessment system, known as pharmacovigilance, should be created to guarantee the monitoring and reporting of adverse drug responses in order to prevent such drug-related hospitalization and deaths.<sup>1</sup>

Pharmacovigilance is composed of two words *Pharmakon* (Greek) = medicinal substance, and *Vigilia* (Latin) = to keep watch.<sup>2</sup> The pharmacological science concerned with the gathering, identification, evaluation, monitoring, and prevention of negative effects with pharmaceutical goods is called pharmacovigilance, sometimes referred to as drug safety.<sup>3,4</sup> This information is then shared with the public and healthcare professionals to enhance patient safety and healthcare.<sup>5</sup> European Commission (EU) defined the Pharmacovigilance as the "Process and science of monitoring the safety of medicines and taking action to increase the benefits of medicines and reduce the risks".<sup>6</sup> International PV systems manage the medication's risk to benefit ratio while simultaneously enhancing patient safety and quality

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of life. Pharmacovigilance evaluation mechanisms include determining the underlying causes of issues with drug administration as well as identifying, documenting, tracking, and taking corrective action as necessary. The primary causes of Adverse drug reactions (ADRs) are polypharmacy, off-label drug use, patients with comorbidities, and individual genetic variations. Adverse drug reactions (ADRs) differ between nations due to factors like heredity, nutrition, medical procedures, and local customs. Clinical trials assess the safety of medications on a restricted group of subjects, and the post-marketing monitoring phase of the medication development process keeps an eye out for any negative drug reactions. Any unpleasant, unplanned, and undesirable pharmacological effect that occurs at regular therapeutic levels is considered an adverse drug reaction, according to the World Health Organization.<sup>3,7,8</sup> The WHO established the Program for International Drug Monitoring (PIDM) in the wake of the thalidomide disaster during World War II, primarily for the purpose of early identification of adverse drug reactions, as a result of the large number of babies born with missing or deformed limbs. "Science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems" is what pharmacovigilance is defined as.<sup>9</sup> The WHO established the Uppsala Monitoring Centre (UMC) in Sweden in 1978. 134 developed and developing nations are members of this centre, which reports medications that are more likely to cause Adverse drug reactions (ADRs). The UMC then conducts additional research and disseminates that information globally.<sup>10</sup> Only 27% of Low- and Middle-Income nations (LMICs) have created pharmacovigilance systems, owing to a lack of infrastructure and resources. In contrast, over 96% of wealthy nations have well-structured national pharmacovigilance systems in partnership with UMC.<sup>1</sup> The Uppsala Monitoring Centre in Sweden offers web-based lectures and seminars to healthcare professionals on signal recognition and causality evaluation. This allows them to become more knowledgeable about reporting Adverse drug reactions (ADRs) and to enhance the nation's pharmacovigilance system.<sup>11</sup> An adverse drug reaction (ADR) is an unwanted event which has an unknown aetiology and causes 5 - 20% of hospitalizations all around the world.<sup>12,13</sup> Physicians and pharmacists are regarded as the most skilled healthcare professionals in identifying and reporting Adverse drug reactions (ADRs); nonetheless, the

primary reasons for the underreporting of Adverse drug reactions (ADRs) are the attitudes of physicians and their lack of education and awareness regarding Adverse drug reactions (ADRs) reporting.<sup>14</sup> Thus, the current study aims to identify the knowledge, attitudes, and barriers regarding the reporting of Adverse drug reactions (ADRs) among doctors and pharmacists in Peshawar, Pakistan.

## Methods

This study employed a cross-sectional descriptive design, conducted from January to July 2023 across multiple public and private tertiary care hospitals in Peshawar, Pakistan. The target population was 10,00,000 healthcare professionals, including house officers, medical officers, post-graduate trainees, clinicians, and pharmacists. Using OpenEpi's sample size calculator, aiming for a 50% prevalence, 80% confidence level, and 5% confidence limit, a sample size of 190 was determined. To ensure ethical conduct, the study design and variables were thoroughly evaluated by the Northwest School of Medicine institutional review board and ethics committee letter number IRB & EC /2022-SM/073 dated 15-Nov-2022. Additionally, each participant was clearly informed about the study's goals and purpose, and their verbal consent was obtained before their participation began. Data was collected via a self-structured questionnaire. Following a rigorous review of existing literature, the study questionnaire was meticulously constructed. This instrument, subsequently validated by field-specific experts, comprised two distinct sections. The first section gathered essential demographic data, while the second delved deeper with inquiries specifically tailored to the study's objectives. Data analysis in SPSS version 26 involved calculating means, standard deviations, frequencies, and percentages, with knowledge classified as either poor or good. One-sample t-tests were applied with a test value of 8 and a 95% confidence interval.

## Results

The demographic profile of the surveyed population, consisting of 190 participants, reveals an average age of 25.62 years with a standard deviation of 2.44, indicating a relatively consistent age distribution. Gender distribution shows a balanced representation, with 52.6% identifying as male and 47.4% as female. Professionally, the majority (43.7%) are House Officers, followed by Postgraduate Trainees (37.4%) and Pharmacists (16.3%). Medical Officers and

Clinicians constitute smaller percentages at 2.1% and 0.5%, respectively. This demographic composition presents a diverse sample of healthcare professionals, with a notable presence of House Officers and Postgraduate Trainees. (Table 1)

**Table-1: Demographics of the participants.**

AGE	Mean: 25.62yrs	Standard Deviation: ± 2.44yrs
<b>GENDER</b>	<b>Frequency</b>	<b>Percent</b>
Male	100	52.6
Female	90	47.4
Total	190	100.0
<b>PROFESSION</b>	<b>Frequency</b>	<b>Percent</b>
House Officer	83	43.7
Medical Officer	4	2.1
Postgraduate Trainee	71	37.4
Clinician	1	0.5
Pharmacist	31	16.3
Total	190	100.0

Approximately 45.8% indicated familiarity with pharmacovigilance, with primary information sources being college/hospital (39.08%), internet (32.18%), and colleagues (18.39%). However, 54.2% reported no knowledge of pharmacovigilance. Among those aware, 60.5% associated pharmacovigilance with activities related to adverse effect prevention and management. Authorities conducting pharmacovigilance were perceived as international institutions (10.5%), national institutions (7.9%), individual institutions (3.2%), or a combination (77.9%). Institutional involvement was limited, with 11.1% reporting the presence of a pharmacovigilance centre. Regarding awareness sessions, 10.0% attended, primarily at their college/hospital (52.63%). While 55.3% believed in the necessity of formal sessions, only 33.7% claimed to know the purpose of pharmacovigilance. Knowledge about where to report adverse drug reactions was limited (20.5%) and 79.5% had not been guided. The identification of rare adverse drug reactions was mostly associated with Phase IV studies (10.0%). Barriers included lack of awareness (15.3%) and lack of resources (3.7%). There was uncertainty about the location of pharmacovigilance centres in Pakistan (84.2%) and internationally (86.3%). Participants prioritized safety (78.4%) as the most important aspect of drug monitoring. Awareness of online adverse drug reactions reporting databases was limited (15.8%), but

92.6% claimed knowledge about the safety of prescribed medications. Only 29.5% frequently checked adverse drug reactions updates, and 37.9% claimed that patients never presented with complaints of rare or serious adverse drug reactions. Views on reporting varied, with 43.2% favouring voluntary reporting and 52.6% supporting compulsory reporting. Major barriers identified included lack of awareness (15.3%) and lack of resources (3.7%). (Table 2)

**Table-2: Frequencies of various variables reported by the participants.**

Have you ever heard about Pharmacovigilance?		
Variable	Frequency	Percent
Yes	87	45.8
No	103	54.2
<b>Total</b>	<b>190</b>	<b>100.0</b>
If yes, you got the information regarding pharmacovigilance from?		
Variable	Frequency	Percent
Your College/ Hospital	34	39.08
Conference/ Seminar	9	10.34
Internet	28	32.18
Colleagues	16	18.39
<b>Total</b>	<b>87</b>	<b>100.00</b>
According to your understanding, pharmacovigilance is?		
Variable	Frequency	Percent
Activities relating to the detection, assessment and prevention of adverse effect	59	31.1
Activities relating to the prevention and management of adverse effect	115	60.5
Activities relating to the ethical protocol to be followed during clinical trials.	10	5.3
Activities relating to submission of a new drug application to FDA for clinical trials	3	1.6
Activities relating to the repurposing of the drugs to their off label uses	3	1.6
<b>Total</b>	<b>190</b>	<b>100.0</b>
Authorities that conduct the pharmacovigilance are?		
Variable	Frequency	Percent
International institutions	20	10.5
National institutions	15	7.9
Individual institutions	6	3.2
All of these	148	77.9
None of above	1	0.5
<b>Total</b>	<b>190</b>	<b>100.0</b>

Does your institute have a pharmacovigilance Centre?		
Variable	Frequency	Percent
Yes	21	11.1
No	169	88.9
<b>Total</b>	<b>190</b>	<b>100.0</b>
Have you ever attended an awareness session/workshop on pharmacovigilance?		
Variable	Frequency	Percent
Yes	19	10.0
No	171	90.0
<b>Total</b>	<b>190</b>	<b>100.0</b>
If yes, where?		
Variable	Frequency	Percent
Your College/ Hospital	10	52.63
Conference/ seminar	7	36.84
Online session	2	10.53
<b>Total</b>	<b>19</b>	<b>100.0</b>
Do you think formal sessions should be conducted to aware the health care professionals about pharmacovigilance?		
Variable	Frequency	Percent
Yes	105	55.3
No	85	44.7
<b>Total</b>	<b>190</b>	<b>100.0</b>
If yes, then at what level?		
Variable	Frequency	Percent
Students	14	13.33
Junior-Clinicians	8	7.62
Senior-Clinicians	7	6.67
All of them	76	72.38
<b>Total</b>	<b>105</b>	<b>100.00</b>
Do you know the purpose of pharmacovigilance?		
Variable	Frequency	Percent
Yes	64	33.7
No	126	66.3
<b>Total</b>	<b>190</b>	<b>100.0</b>
The information on pharmacovigilance is?		
Variable	Frequency	Percent
Department of institution	8	4.2
Available on request	29	15.3
Not available at all	18	9.5
Don't know	135	71.1
<b>Total</b>	<b>190</b>	<b>100.0</b>
Do you know where to report in case of identification of an adverse drug reaction?		
Variable	Frequency	Percent
Yes	39	20.5
No	151	79.5
<b>Total</b>	<b>190</b>	<b>100.0</b>
Have you ever been guided where to report in case of identification of an adverse drug reaction?		
Variable	Frequency	Percent
Yes	30	15.8
No	160	84.2
<b>Total</b>	<b>190</b>	<b>100.0</b>

Rare Adverse drug reactions are identified by which of the following?		
Variable	Frequency	Percent
Pre-Clinical trials	20	10.5
Phase I studies	9	4.7
Phase II studies	7	3.7
Phase III studies	6	3.2
Phase IV studies	19	10.0
Don't know	129	67.9
<b>Total</b>	<b>190</b>	<b>100.0</b>
Where is the Centre for Pharmacovigilance located in your country?		
Variable	Frequency	Percent
Islamabad	15	7.9
Lahore	1	0.5
Karachi	8	4.2
Peshawar	2	1.1
There is no Centre in Pakistan	4	2.1
I don't know	160	84.2
<b>Total</b>	<b>190</b>	<b>100.0</b>
Where is the Centre for Pharmacovigilance located internationally?		
Variable	Frequency	Percent
Washington	14	7.4
Sweden	4	2.1
London	2	1.1
China	6	3.2
I don't know	164	86.3
<b>Total</b>	<b>190</b>	<b>100.0</b>
Most important aspect of a drug monitoring, in your opinion is?		
Variable	Frequency	Percent
Efficacy	10	5.3
Cost effectiveness	6	3.2
Availability as generic drug	1	0.5
Safety	23	12.1
All of them	149	78.4
None of them	1	0.5
<b>Total</b>	<b>190</b>	<b>100.0</b>
Do you know about any Online Adverse drug reactions reporting database?		
Variable	Frequency	Percent
Yes	30	15.8
No	160	84.2
<b>Total</b>	<b>190</b>	<b>100.0</b>
Do you know the safety of medications, you prescribe?		
Variable	Frequency	Percent
Yes	176	92.6
No	14	7.4
<b>Total</b>	<b>190</b>	<b>100.0</b>

How frequently do patients come with a complaint of rare or serious Adverse drug reactions?		
Variable	Frequency	Percent
Not at all	72	37.9
25%	89	46.8
50%	15	7.9
75%	12	6.3
100%	2	1.1
<b>Total</b>	<b>190</b>	<b>100.0</b>

Do you frequently check the drug Adverse drug reactions updates?		
Variable	Frequency	Percent
Yes	56	29.5
No	134	70.5
<b>Total</b>	<b>190</b>	<b>100.0</b>

Do you think Adverse drug reactions should be reported?		
Variable	Frequency	Percent
Adverse drug reactions cannot be avoided	53	27.9
Reporting Adverse drug reactions is of no use	4	2.1
It is a time-consuming process	1	0.5
I don't know where to report	132	69.5
<b>Total</b>	<b>190</b>	<b>100.0</b>

Do you think pharmacovigilance reporting should be voluntary?		
Variable	Frequency	Percent
Yes	82	43.2
No	21	11.1
I don't know	87	45.8
<b>Total</b>	<b>190</b>	<b>100.0</b>

Do you think reporting should be compulsory?		
Variable	Frequency	Percent
Yes	100	52.6
No	9	4.7
I don't know	81	42.6
<b>Total</b>	<b>190</b>	<b>100.0</b>

What in your opinion is the major barrier in pharmacovigilance application in Pakistan?		
Lack of resources	7	3.7
Lack of sense of responsibility	8	4.2
It's not of much importance	1	0.5
All of the above	137	72.1
None of the above	8	4.2
<b>Total</b>	<b>190</b>	<b>100.0</b>

A significant majority of respondents (82.6%) reported poor knowledge, while a minority (17.4%) indicated good knowledge. This distribution underscores a prevailing lack of awareness or understanding among the studied population regarding the specific topic covered in the questionnaire. (Table 3)

**Table-3: Knowledge of the participants regarding pharmacovigilance.**

Knowledge	Frequency	Percent
Poor knowledge	157	82.6
Good knowledge	33	17.4
<b>Total</b>	<b>190</b>	<b>100.0</b>

The findings of a one-sample t-test covering a range of pharmacovigilance knowledge and perception variables, with a test value of 8 and a 95% confidence interval, are presented in Table 4. For every variable, the t-score, p-value, standard deviation, and mean are given. The p-values are 0.000 in every instance, which is exceptionally low and suggests that there is a significant difference between the test value and the sample mean. The sample means for these variables appear to be substantially lower than the test value of 8, according to the negative t-scores. This suggests that participants' average scores on all survey items pertaining to knowledge and perceptions of pharmacovigilance were significantly below the test value. The results point to a significant lack of knowledge or awareness of the subject matter among the respondents. (Table 4)

**Table-4: One-Sample t-test table of various variables with a test value of 8, and confidence interval of 95%.**

Variable	Mean	St. Deviation	t-score	P value
Have you ever heard about Pharmacovigilance?	0.47	0.531	-195.231	0.000
According to your understanding, pharmacovigilance is?	0.31	0.464	-228.465	0.000
Authorities that conduct the pharmacovigilance are?	0.78	0.416	-239.238	0.000
Do you know the purpose of pharmacovigilance?	0.34	0.474	-222.904	0.000
The information on pharmacovigilance is?	0.15	0.361	-299.983	0.000
Do you know where to report in case of identification of an adverse drug reaction?	0.21	0.405	-265.317	0.000
Have you ever been guided where to report in case of identification of an adverse drug reaction?	0.16	0.366	-295.663	0.000
Rare Adverse drug reactions are identified by which of the following?	0.10	0.301	-362.023	0.000
Where is the Centre for Pharmacovigilance located in your country?	0.08	0.270	-403.834	0.000
Where is the Centre for Pharmacovigilance located internationally?	0.02	0.144	-764.088	0.000
Most important aspect of a drug monitoring, in your opinion is?	0.12	0.327	-332.071	0.000
Do you know about any Online Adverse drug reactions reporting database?	0.16	0.366	-295.663	0.000
Do you know the safety of medications, you prescribe?	0.92	0.270	-360.901	0.000
Do you frequently check the drug Adverse drug reactions updates?	0.29	0.457	-232.341	0.000
Do u think reporting should be compulsory?	0.53	0.501	-205.778	0.000

## Discussion

As a result of the efforts of the Drug Regulation Authority of Pakistan (DRAP), Pakistan became a full member of UMC in 2018. In order to provide a framework for post-marketing medication surveillance, DRAP partnered with the United States Pharmacopoeia and Promoting Quality Medicines (USP-PQM). In 2017, the National Pharmacovigilance Centre was formed, and more regional pharmacovigilance centres followed in 2018.<sup>1</sup> The Drug Regulatory Authority of Pakistan (DRAP) was established in 2012 in response to the deaths of over 200 patients in Lahore from a locally produced drug called ISOTAB 20 mg (Isosorbide mononitrate, batch number J093). The Supreme Court of Pakistan ordered the government to establish an independent drug regulatory authority, and Drug Regulatory Authority of Pakistan (DRAP) is the first of the six ministerial divisions of the National Health Services Regulation and Coordination (NHSRC) to regulate the safety, quality, and availability of medical devices and medicines in the nation (WHO, 2018).<sup>15</sup> In addition to developing guidelines for pharmacovigilance activities, DRAP is also involved in educating and training healthcare professionals about pharmacovigilance, organizing special training for its officers and focal persons from tertiary care hospitals

under the banner of "Training of Trainers, Pharmacovigilance Development of Pakistan," and publishing drug safety alerts on a regular basis based on post-marketing surveillance. In order to help patients, pharmaceutical companies, and other healthcare professionals report Adverse drug reactions (ADRs), Drug Regulatory Authority of Pakistan (DRAP) has also introduced an online reporting form called "Med Vigilance" on its official website (DRAP, 2018).<sup>1</sup> Due to a lack of communication between the administrative bodies of the centres and the hospital staff, our study reveals that the majority of the participating physicians were unaware of the country's local pharmacovigilance centres as well as the activities carried out by these centres. Pharmacovigilance might be included as a crucial component of healthcare workers' education, particularly for physicians, to address this issue. National pharmacovigilance centres should also inform doctors about what they are up to. Our study revealed that doctors typically record adverse drug reactions on patient information sheets, talk about them with pharmaceutical companies, or give the information to the hospital's administration or the department in charge of procuring medications, but they don't always fill up the forms. Rather than talking to pharmacists or the pharmacy department, doctors

were mostly speaking with pharmaceutical corporations about Adverse drug reactions (ADRS). Reducing the engagement of pharmaceutical firms with doctors and implementing a pharmacist role in the ward are two ways to address this issue. Effective use of a pharmacist's function can improve the results of pharmacotherapy since pharmacists are crucial in ensuring the safe use of drugs.<sup>16</sup> In the current study, 54.2% of the study participants had never even heard of the term pharmacovigilance and the most common sources of information regarding pharmacovigilance were the educational institutes and hospitals in 39% followed by the internet in 32% of the participants. Only 31% of the participants could, however, correctly define pharmacovigilance. Comparatively, in questionnaire research on the participant's knowledge, attitudes, and pharmacovigilance practices, when asked to define pharmacovigilance, 62.4% of medical staff members in a South Indian teaching hospital provided the right answer.<sup>17</sup> A total of 77.9% of the participants were aware that the authorities carrying out pharmacovigilance are located at local, national as well and international levels, however only 7.9% knew where the national pharmacovigilance centre was. Meanwhile, a study done in Nepal showed that 60.7% of their respondents knew the location of their national pharmacovigilance centre.<sup>18</sup> In another study about 40% of respondents in Malaysia did not know that the national reporting system existed.<sup>19</sup> Only 15% of the participants have received guidance about reporting adverse drug reactions and 20% were aware of the process of reporting. Contrary to this pattern, 71% of medical personnel in China were ignorant of the reporting process.<sup>17</sup> These results point to the necessity of an Adverse drug reactions (ADRS) reporting awareness campaign for healthcare providers. The pharmacovigilance centre's address, the reporting process, and how to complete the Adverse drug reactions (ADRS) reporting form should all be included in the training course. In our study, 69.5% of participants did not know the significance of reporting the Adverse drug reactions (ADRS) and 20% had previously observed the Adverse drug reactions (ADRS) of the drugs that they had prescribed. Just one-third (33.7%) of the respondents in a study reported having at least one Adverse drug reactions (ADRS), even though 96.6% of them believed that reporting Adverse drug reactions (ADRS) is necessary.<sup>18</sup> Only 32% of the doctors in a Nigerian study<sup>20</sup> had ever reported an adverse drug reaction. Total of 22.8% of nurses and 28.5% of doctors in China filed a report of the Adverse drug reactions (ADRS).<sup>17</sup>

While 93 percent of pharmacists in Hong Kong believed that it is important to report Adverse drug reactions (ADRS), only 14.7% of them had done so in the preceding year.<sup>21</sup> There is a great deal of room for improvement in the Adverse drug reactions (ADRS) reporting rate in this environment through intervention programs, as nearly all healthcare professionals in our study agreed on the importance of Adverse drug reactions (ADRS) monitoring. Pakistan must to develop a pharmacovigilance system to prevent Adverse drug reactions (ADRS), as well as to understand their cause and severity. However, this system's establishment would not be easy due to logistical, budgetary, and legal obstacles. No Adverse drug reactions (ADRS) statistics data from Pakistan has been provided to UMC as of yet. To enhance communication between healthcare providers and Pakistan Pharmacovigilance Centre, a variety of tactics are required, including letters to doctors, medication alerts, newsletters, media announcements, patient awareness pamphlets, and direct input to the Adverse drug reactions (ADRS) reporter.<sup>16</sup> Healthcare personnel need to receive training on reporting Adverse drug reactions (ADRS), including the proper format, timing, location, and information to include. As new medications enter the market every day, stakeholders in public health initiatives and drug regulation should pay close attention to pharmacovigilance in order to improve the delivery of healthcare.<sup>15</sup> Increasing physician numbers nationwide, particularly in tertiary care hospitals, could potentially address the several obstacles that the doctors identified to Adverse drug reactions (ADRS) reporting, including their own increasing workload. The ignorance of the significance of pharmacovigilance is another obstacle. This is due to two factors: inadequate or incorrect medication risk perceptions; and inadequate training to equip physicians for Adverse drug reactions (ADRS) monitoring and reporting in the future. Another factor given for not reporting was found to be ineffective communication between medical professionals and administrative healthcare authorities. By providing doctors with adequate training on Adverse drug reactions (ADRS) reporting, these issues can be resolved. Inadequate or non-existent online and offline reporting systems, including training programs, seminars, and ongoing education,<sup>4, 16, 17, 18, 19</sup> hinder government efforts to ensure the safe and efficient utilization of medications.<sup>22</sup> Reports indicate that obstacles to pharmacovigilance include organizational

culture and occasional pressure from senior physicians on junior physicians.<sup>23,24</sup>

## Conclusion

The study's findings demonstrated that tertiary care facilities in Peshawar, Pakistan lack an appropriate method for reporting adverse drug reactions. Lack of awareness about Adverse drug reactions (ADRs) reporting, inadequate training, the workplace culture, and the workload of doctors and pharmacists are the main obstacles to Adverse drug reactions (ADRs) reporting. The results of our study indicated that more drug regulatory authorities are needed to support improved pharmacovigilance systems in Pakistan's cities, provinces, and healthcare facilities. Currently, there is only one drug regulatory authority in Pakistan, known as "Drug Regulatory Authority of Pakistan (DRAP)".

## Study Strengths & Limitations

The study conducted in Peshawar, Pakistan, exhibits notable strengths in shedding light on critical deficiencies within the pharmacovigilance system. The research effectively identifies and quantifies the lack of awareness among healthcare professionals regarding adverse drug reactions (ADRs) reporting, showcasing a clear need for educational interventions. The study's strengths lie in its comprehensive assessment of barriers, including inadequate training and resource constraints. By highlighting specific percentages and statistics, the research provides a quantitative understanding of the current state of pharmacovigilance in tertiary care facilities. The emphasis on improving communication channels and proposing regulatory enhancements adds depth to the study, offering actionable insights for strengthening the pharmacovigilance infrastructure in Pakistan. The study has several limitations that affect the generalizability and robustness of its findings. Firstly, the focus on a specific geographical area, Peshawar, Pakistan, raises concerns about the applicability of the results to other regions or countries with distinct healthcare systems and cultural contexts. The small sample size of 190 participants may compromise the study's ability to draw comprehensive conclusions, highlighting the need for a larger and more diverse sample for greater representativeness. Additionally, the cross-sectional design provides only a snapshot of participants' perspectives at a specific moment, and a longitudinal approach would be more informative for understanding changes over time. Finally, the

recruitment of participants from specific tertiary care hospitals may lead to selection bias, limiting the insights into the perspectives of healthcare professionals in smaller or non-tertiary care settings.

## Recommendations

Recommendations for enhancing pharmacovigilance includes; developing targeted training programs for healthcare professionals, conducting awareness campaigns about pharmacovigilance centres, and integrating pharmacovigilance education into medical and pharmacy school curricula. Improving communication channels between professionals and pharmacovigilance centres, fostering collaboration with pharmaceutical companies for streamlined reporting, and establishing a national pharmacovigilance network with regional centres are crucial steps. Implementing a continuous monitoring and evaluation system will gauge the impact of interventions, and advocating for increased government support will fortify pharmacovigilance activities.

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## References

1. Hussain R, Hassali MA. Current status and future prospects of pharmacovigilance in Pakistan. *Journal of pharmaceutical policy and practice*. 2019 Dec; 12(1):1-3.
2. Fornasier G, Francescon S, Leone R, Baldo P. An historical overview over Pharmacovigilance. *International journal of clinical pharmacy*. 2018 Aug; 40:744-7.
3. Hussain S, Afzal H, Saeed R, Iltaf N, Umair MY. Pharmacovigilance with transformers: A framework to detect adverse drug reactions using BERT fine-tuned with FARM. *Computational and Mathematical Methods in Medicine*. 2021 Aug 13; 2021.
4. Hussain R, Hassali MA, ur Rehman A, Muneshwarao J, Hashmi F. Physicians' understanding and practices of Pharmacovigilance: qualitative experience from A lower middle-income country. *International journal of environmental research and public health*. 2020 Apr; 17(7):2209.
5. Rodríguez S, Muñoz A, Bustos RH, Jaimes D. Pharmacovigilance of biopharmaceuticals in rheumatic diseases, adverse events, evolution, and perspective: An overview. *Biomedicine*. 2020 Aug 23; 8(9):303.
6. Van Hunsel F, Gardarsdottir H, de Boer A, Kant A. Measuring the impact of pharmacovigilance activities, challenging but important. *British Journal of Clinical Pharmacology*. 2019 Oct; 85(10):2235-7
7. Khan Z, Karataş Y, Rahman H. Adverse drug reactions reporting in Turkey and barriers: an urgent need for



- pharmacovigilance education. *Therapeutic Advances in Drug Safety*. 2020 May; 11:2042098620922483.
8. Bawani S, Munawar R, Ali I, Masood S, Naseem R, Shahnaz S, et al. Exploration of perception, need and barriers against pharmacovigilance and adverse drug reactions reporting: healthcare professionals' insight. *Journal of Pharmaceutical Research International*. 2021 Mar 5; 33(7):78-86.
  9. Syed A, Azhar S, Raza MM, Saeed H, Jamshed SQ. Assessment of knowledge, attitude and barriers towards pharmacovigilance among physicians and pharmacists of Abbottabad, Pakistan. *Pharmacy*. 2018 Mar 31; 6(2):29.
  10. Ozcan G, Aykac E, Kasap Y, Nemutlu NT, Sen E, Aydinkarahaliloglu ND. Adverse drug reaction reporting pattern in Turkey: analysis of the national database in the context of the first pharmacovigilance legislation. *Drugs-real world outcomes*. 2016 Mar; 3:33-43.
  11. Badejoko OO. Patient safety in maternity: The Nigerian context. *Tropical Journal of Obstetrics and Gynaecology*. 2019 Sep 1; 36(3):348.
  12. Wu WK, Pantaleo N. Evaluation of outpatient adverse drug reactions leading to hospitalization. *American journal of health-system pharmacy*. 2003 Feb 1; 60(3):253-9.
  13. Kongkaew C, Noyce PR, Ashcroft DM. Hospital admissions associated with adverse drug reactions: a systematic review of prospective observational studies. *Annals of Pharmacotherapy*. 2008 Jul; 42(7-8):1017-25.
  14. Al-Arifi MN, Mayet AY, Wajid S, Al-Saadi M, Babelghaith AI, Al Ayoubi FZ. Knowledge, attitude and perception of physicians towards adverse drug reaction reporting at King Khalid University Hospital, Riyadh, Saudi Arabia. *Tropical Journal of Pharmaceutical Research*. 2015 Oct 2; 14(5):907-11.
  15. Hussain R, Hassali MA, Hashmi F, Farooqui M. A qualitative exploration of knowledge, attitudes and practices of hospital pharmacists towards adverse drug reaction reporting system in Lahore, Pakistan. *Journal of pharmaceutical policy and practice*. 2018 Dec; 11:1-0.
  16. Almandil NB. Healthcare professionals' awareness and knowledge of adverse drug reactions and pharmacovigilance. *Saudi medical journal*. 2016 Dec; 37(12):1359-64.
  17. Gupta SK, Nayak RP, Shivaranjani R, Vidyarthi SK. A questionnaire study on the knowledge, attitude, and the practice of pharmacovigilance among the healthcare professionals in a teaching hospital in South India. *Perspectives in clinical research*. 2015 Jan; 6(1):45-52.
  18. Bello SO. Knowledge and attitudes of physicians relating to reporting of adverse drug reactions in Sokoto, northwestern Nigeria. *Annals of African medicine*. 2011; 10(1):13-8.
  19. Ahmad A, Patel I, Balkrishnan R, Mohanta GP, Manna PK. An evaluation of knowledge, attitude and practice of Indian pharmacists towards adverse drug reaction reporting: A pilot study. *Perspectives in clinical research*. 2013 Oct; 4(4):204-10.
  20. Palaian S, Ibrahim MI, Mishra P. Health professionals' knowledge, attitude and practices towards pharmacovigilance in Nepal. *Pharmacy practice*. 2011 Oct; 9(4):228.
  21. Aziz Z, Siang TC, Badarudin NS. Reporting of adverse drug reactions: predictors of under-reporting in Malaysia. *Pharmaco epidemiology and drug safety*. 2007 Feb; 16(2):223-8.
  22. Babar ZU, Ibrahim MI, Hassali MA. Pharmaceutical industry, innovation and challenges for public health: case studies from Malaysia and Pakistan. *Journal of Pharmaceutical Health Services Research*. 2011 Dec; 2(4):193-204.
  23. Mikkola L, Suutala E, Parviainen H. Social support in the workplace for physicians in specialization training. *Medical Education Online*. 2018 Jan 1; 23(1):1435114.
  24. Aljadhey H, Mahmoud MA, Alshammari TM, Al-Dhaeefi M, Le Louet H, Perez-Gutthann S, et al. A qualitative exploration of the major challenges facing pharmacovigilance in Saudi Arabia. *Saudi Medical Journal*. 2015 Sep; 36(9):1097.

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