# Revealing Insights: Investigating Pharmacovigilance Knowledge, Attitudes, and Practices at a Leading Tertiary Care Hospital in Faisalabad

SHAHEEN NAZAKAT<sup>1</sup>, MUHAMMAD SAJID<sup>1</sup>

<sup>1</sup>Lincoln University College, Malaysia

Corresponding author: Shaheen Nazakat, Email: Shaheennazakat1@gmail.com

## ABSTRACT

**Background:** The aim of present cross-sectional survey is to investigate healthcare workers' knowledge, attitude, and behaviour regarding pharmacovigilance at tertiary care hospital, Faisalabad.

**Methods:** The present cross-sectional survey was conducted in tertiary care hospital, Faisalabad. The study populations of Eighty (80) male and female health care workers were included in this study. Demographic data and information about workers' knowledge, attitude, and behaviour regarding pharmacovigilance was collected on an interview schedule administered through custom designed structured Performa. The data regarding healthcare workers' knowledge, attitude, and behavior concerning pharmacovigilance at a tertiary care hospital were analyzed using SPSS.

**Results:** The findings of study depicted a positive relationship between knowledge, attitudes, and practices among healthcare workers. Pharmacovigilance is a critical component of drug safety and plays a crucial role in identifying and managing adverse drug reactions and other drug-related problems.

**Conclusion:** Adequate knowledge, skills, and attitudes towards pharmacovigilance among healthcare workers are essential to ensure the safety of medications and promote better patient outcomes. Study can provide valuable insights into the current state of pharmacovigilance in the region and identify areas for improvement. The also enhancing education and training programs for healthcare workers in pharmacovigilance, fostering a reporting culture for adverse drug reactions and adverse events, and establishing robust pharmacovigilance systems and processes are crucial elements for safeguarding medication safety and efficacy, as well as enhancing patient care.

Keywords: Healthcare Workers, Pharmacovigilance, Knowledge, Attitude, Behavior, Cross-Sectional Survey, Tertiary Care Hospital, Faisalabad

## INTRODUCTION

Pharmacovigilance is the study and practice of identifying, evaluating, comprehending, and averting unintended medication reactions and other drug-related issues. It plays a crucial role in ensuring the safety and efficacy of medications, thereby protecting public health. Healthcare workers, including doctors, nurses, and pharmacists, are key players in the pharmacovigilance system, as they are responsible for prescribing, dispensing, and monitoring medications (1).

Understanding healthcare workers' knowledge, attitude, and behavior regarding pharmacovigilance is crucial to ensuring the safety and efficacy of medications. This information can be used to identify areas for improvement in pharmacovigilance training and to develop strategies to promote a culture of reporting adverse drug reactions. The knowledge, attitude, and behavior of healthcare workers regarding pharmacovigilance are critical to the success of the pharmacovigilance system. Adequate knowledge is required to recognize adverse drug reactions and report them to the appropriate authorities, while a positive attitude towards pharmacovigilance can help promote a culture of reporting adverse drug reactions. Proper behavior, such as reporting adverse drug reactions promptly, is essential to the success of the pharmacovigilance system (2).

Pharmacovigilance is a critical component of ensuring patient safety and improving the quality of healthcare. Adverse drug responses and other medication-related issues must be identified, evaluated, understood, and avoided if possible. Healthcare workers play a vital role in pharmacovigilance, as they are responsible for prescribing, dispensing, and monitoring medications. Therefore, it is essential to assess healthcare workers' knowledge, attitude, and behavior regarding pharmacovigilance to improve patient safety and the quality of healthcare delivery (3).

Healthcare workers need regular training and the implementation of rules to ensure the safe and accurate reporting of adverse events. Adverse drug reactions (ADRs) are a leading cause of illness and death across the globe. As a result, it's crucial to keep an eye on ADRs as they occur. Any medical staff member, from physicians to nurses to pharmacists, may submit an ADR report to the Central Drugs Standard Control Organization by filling out an ADR form. Previous research has linked gaps in knowledge

and attitude among healthcare personnel to underreporting of ADR. Healthcare providers should be aware of who to contact and where to report an ADR. Healthcare providers' involvement in the pharmacovigilance program has been shown to decrease the number of adverse events reported. Although the Pharmacovigilance Programme of Pakistan has been working hard to promote a culture of ADR monitoring, underreporting remains widespread (4).

According to the World Health Organization (WHO), pharmacovigilance is a scientific discipline encompassing a range of activities dedicated to the identification, evaluation, comprehension, and prevention of adverse effects and other potential drug-related issues. Its primary objective is to systematically detect and assess any untoward effects or problems associated with the use of medications. This definition emphasizes the scientific nature of pharmacovigilance and underscores its role safeguarding public health by ensuring the safety and in effectiveness of drugs. This definition includes numerous aspects tied to medication safety. It covers the issue of substandard and counterfeit drugs, errors in medication administration, instances of drug abuse and misuse, and drug exposure during pregnancy and lactation. It also takes into account overdosing, cases of therapeutic inefficacy, occupational drug exposure, and off-label drug use. Environmental contamination (ecopharmacovigilance), the use of medical devices and diagnostics, and potential transmission of infectious diseases through medicines are also part of this broad definition (5).

Despite the establishment of pharmacovigilance systems in Pakistan, there is limited research on healthcare workers' knowledge, attitude, and behavior regarding pharmacovigilance. This lack of understanding may impede the success of pharmacovigilance systems, which can compromise patient safety and the quality of healthcare delivery. Therefore, this study aimed to investigate healthcare workers' knowledge, attitude, and behavior regarding pharmacovigilance at a tertiary care hospital in Faisalabad. The specific problem addressed in this study is the need to assess healthcare workers' knowledge of pharmacovigilance, including their ability to recognize adverse drug reactions, their knowledge of reporting mechanisms, and their understanding of the importance of pharmacovigilance. Thereby

improving patient safety and the quality of healthcare delivery at the tertiary care hospital in Faisalabad, Pakistan (6).

The present study was planned to assess healthcare workers' knowledge of pharmacovigilance, including their ability recognize adverse drug reaction, to identify gaps in pharmacovigilance training for healthcare workers at the tertiary care hospital in Faisalabad and to evaluate the effectiveness of the pharmacovigilance system in place at the tertiary care hospital in Faisalabad.

This study contributes to the body of knowledge on pharmacovigilance practices in Pakistan, which can use for policy decisions and enhance patient safety and the quality of healthcare delivery. The study's findings can help identify gaps in pharmacovigilance training for healthcare workers at the tertiary care hospital in Faisalabad. By understanding the level of knowledge and attitudes towards pharmacovigilance, the study can help develop strategies to improve pharmacovigilance practices, which can enhance the quality of healthcare delivery and patient safety. the study evaluates the effectiveness of the pharmacovigilance system in place at the tertiary care hospital in Faisalabad. By identifying the types of adverse drug reactions that healthcare workers commonly encounter and report, the study can help improve the pharmacovigilance system's efficiency and effectiveness.

Despite recent attempts to standardize pharmacovigilance norms and regulations in numerous regional economic communities, there is still only minimal integration and dependability of pharmacovigilance systems across LMIC (10). The very low percentage of spontaneous reporting, along with the poor quality of the reports, makes it difficult to conduct meaningful signal detection analysis (7). The integration of pharmacovigilance systems into public healthcare systems continues to be a difficulty in many countries, despite the fact that these systems improve access to safe drugs and treatment (8).

#### **RESEARCH METHODOLOGY**

**Study Design:** This cross-sectional survey-based study was conducted in tertiary care hospital, Faisalabad, to investigate healthcare workers' knowledge, attitude, and behaviour regarding pharmacovigilance. Tertiary care hospital was selected to collect data which majorly included student's female. Healthcare workers at tertiary care hospital were randomly select to interview.

**Study Duration:** This study was conducted from October 2022 to March 2023.

Targeted Population and Sample size: The population of the present study was eighty healthcare workers. The study sample was selected at the tertiary care hospital from those who met the specific selection criteria.

#### Sample Size:

80

 $n = Z^2 1 - \alpha/2 p (1-p)/d^2$ 

Z =1st Standard normal variate error at 95% = 1.96

P= Expected proportion in population in Previous Study (50%)

d= Absolute error or Precision = 0.05

Sampling Technique: Convenient sampling technique.

Table 1: Inclusion and Exclusion Criteria

Inclusion criteria	Exclusion criteria	
1. The healthcare	1. Healthcare workers on medication	
workers at tertiary care	<ol><li>Healthcare workers having health</li></ol>	
hospital Faisalabad.	problems and chronic illness.	

**Data Collection:** The current study, a group of 80 healthcare professionals, both men and women, from a tertiary care hospital in Faisalabad, were selected as participants. The researchers sought official authorization from the institution's authorities to gather the required data. The participants were briefed about the study's topic and objectives, and their informed consent was duly obtained. They were reassured that their information would be used solely for the study's purpose and would remain confidential.

The researcher personally approached these individuals for data collection. All participants, male and female, self-rated their responses. They were also given clear instructions on how to respond to the questionnaire. Demographic data and information about regarding pharmacovigilance was collected on an interviewer administered, custom designed structured Performa. Questionnaire was used to diagnose to investigate healthcare workers' knowledge, attitude, and behaviour regarding pharmacovigilance at tertiary care hospital, Faisalabad.

Statistical analysis: The study employed descriptive statistics to analyze the demographic information of the participants, including gender distribution, age categories, healthcare professional types, qualifications, and years of experience. These demographic variables were presented as percentages and frequency distributions. To investigate the relationship between healthcare workers' knowledge, attitudes, and behavior regarding pharmacovigilance, a statistical analysis was conducted. However, the specific statistical tests and measures used for this analysis are not provided in the information provided by using SPSS software version 27.

#### **RESULTS AND DISCUSSION**

This chapter is predicated on the comprehensive analysis of data acquired from healthcare workers, specifically focusing on their knowledge, attitude, and behavior towards pharmacovigilance. The initial section of the chapter encompasses the demographic information of the participants, providing a contextual background to the study population. The subsequent section delves into the participants' viewpoints and perspectives concerning various variables of interest. The ensuing tables presented in this chapter serve as a product of meticulous observation and rigorous analysis of the data collected from the participating healthcare workers. These tables play a crucial role in providing a visual representation of the key findings, facilitating a comprehensive discussion and interpretation of the observed trends and patterns. Thus, the inclusion of these tables serves as a justifiable means to enhance the clarity and coherence of the research findings, enabling a more rigorous examination of the participants' knowledge, attitude, and behavior towards pharmacovigilanc

Demographic Information: The gender distribution of the participants is as follows: 8.8 percent are male, while the majority, accounting for 91.3 percent, are females. In terms of age, the participants are categorized as follows: 23.8 percent fall within the 25-30 years range, 45.0 percent are aged 31-35 years, 16.3 percent are between 36-40 years, and 15.0 percent fall within the 41-45 years range. When considering the healthcare professional types among the participants, 75.0 percent are nurses, while the remaining 25.0 percent are categorized as "other workers." Regarding gualifications, 16.3 percent of the participants have completed an intermediate level of education, 72.5 percent hold a Bachelor's degree, and 16.3 percent have achieved a Master's degree. In terms of experience, the participants' distribution is as follows: 41.3 percent have five years or less of experience, 52.5 percent have 6-10 years of experience, and 6.3 percent have 11-15 years of experience.

**Hypothesis Testing: Correlation Analysis:** Pearson Correlations between healthcare workers' knowledge, attitude, and behaviour regarding pharmacovigilance.

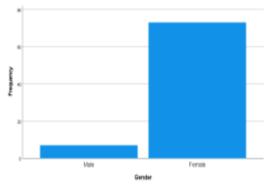
Table 2: The Relationship between healthcare workers' knowledge, attitude, and behaviour regarding pharmacovigilance (n = 80).

Variables	Knowledge	Attitudes	Practices
Knowledge	0.87		
Attitudes		0.63	
Practices			0.81

Correlation is insignificant at the .219 level (2-tailed)

The Table shows that there is positive relationship between knowledge, attitudes, and practices among healthcare workers. So

 $H_1$  is accepted that there would be positive relationship between knowledge, attitudes, and practices among healthcare workers.





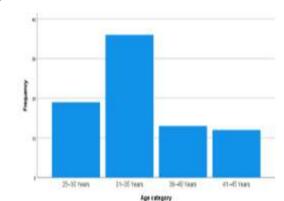


Figure 2:

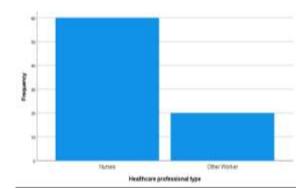
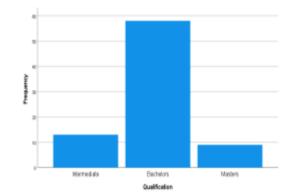
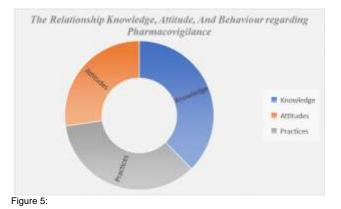


Figure 3:







**Descriptive Information:** "The participants' responses regarding their understanding of the primary objective of pharmacovigilance, which is to ensure drug safety, revealed that 78.8% responded affirmatively, while 21.3% responded negatively. The mean score for this question was 1.2125 with a standard deviation of 0.41166. In Table, pertaining to awareness of the "Vigibase" online database for reporting adverse drug reactions by the World Health Organization, 65.0% of participants indicated awareness, while 35.0% reported being unaware. The mean score for this item was 1.3500 with a standard deviation of 0.47998.

Participants' awareness of the existence of a pharmacovigilance program in Pakistan was examined, with 71.3% acknowledging its presence and 28.7% expressing unawareness. The mean score for this variable was 1.2875 with a standard deviation of 0.45545. Regarding the responsibility for monitoring adverse drug reactions (ADRs) by the Drug Regulatory Authority of Pakistan, 55.0% confirmed this responsibility, while 45.0% disagreed. The mean score for this aspect was 1.4500 with a standard deviation of 0.50063.

Additionally, the participants' awareness of reporting ADRs to the "Vigibase" online database by the World Health Organization was assessed, resulting in 96.3% affirming awareness and 3.8% indicating lack of awareness. The mean score for this measure was 1.0375 with a standard deviation of 0.19118.

Participants' beliefs regarding the importance of ADR reporting as a means to enhance medication safety were also evaluated. The majority (75.0%) agreed that ADR reporting is crucial, while 25.0% disagreed. The mean score for this item was 1.2500 with a standard deviation of 0.43574.

The participants' opinions on the effectiveness of various educational backgrounds in providing sufficient information about ADR reporting were assessed. Among the respondents, 60.0% believed that their educational background had provided enough information, while 40.0% expressed the opposite viewpoint. The mean score for this variable was 1.4000 with a standard deviation of 0.49299.

Furthermore, participants were asked about their perception of being the most important healthcare professional to report ADRs, with 92.5% agreeing and 7.5% disagreeing. The mean score for this aspect was 1.0750 with a standard deviation of 0.26505. Regarding the professional obligation to report ADRs, 77.5% agreed it was a responsibility, while 22.5% disagreed. The mean score for this item was 1.2250 with a standard deviation of 0.42022.

Participants' opinions about whether the workplace environment should encourage ADR reporting. The majority (78.8%) believed it should, while 21.3% disagreed. The mean score for this measure was 1.2125 with a standard deviation of 0.41166.

Inquiring about prior ADR reporting experiences, 92.5% of participants had reported an ADR before, while 7.5% had not. The mean score for this variable was 1.0750 with a standard deviation of 0.26505. Additionally, participants were asked if they had

reported an ADR in the last 12 months, with 91.3% responding affirmatively and 8.8% reporting no recent ADR reporting. The mean score for this item was 1.0875 with a standard deviation of 0.28435.

The participants' practice of keeping records of ADRs was assessed, with 55.0% indicating they did keep records, while 45.0% did not. The mean score for this measure was 1.4500 with a standard deviation of 0.50063.

Moreover, participants were asked whether they had sent a suspected ADR report to the Drug Regulatory Authority of Pakistan (DRAP) or the manufacturer. In response, 66.3% confirmed having sent such reports, while 33.8% had not. The mean score for this variable was 1.3375 with a standard deviation of 0.47584.

Participants' utilization of different reporting methods for ADRs was examined. For the option of verbal information, 65.0% confirmed using this method, while 35.0% did not. The mean score for this option was 1.3500 with a standard deviation of 0.47998. Regarding the utilization of ADR forms, 57.5% indicated using them, while 42.5% did not. The mean score for this aspect was 1.4250 with a standard deviation of 0.49746. Similarly, for direct reporting to hospital management, 60.0% reported utilizing this method, while 40.0% did not. The mean score for this item was 1.4000 with a standard deviation of 0.49299. Additionally, 68.8% of participants indicated informing the manufacturer of ADRs, while 31.3% did not. The mean score for this measure was 1.3125 with a standard deviation of 0.46644.

These findings contribute to the understanding of healthcare workers' knowledge, attitudes, and practices regarding pharmacovigilance, providing valuable insights into the current state of ADR reporting practices and identifying areas for improvement in medication safety systems.

### DISCUSSION

The role of healthcare workers in pharmacovigilance is crucial, and it is imperative that they possess adequate knowledge, skills, and attitudes towards this field (12). Investigating the knowledge, attitude, and behavior of healthcare workers regarding pharmacovigilance can offer valuable insights into the current state of pharmacovigilance and identify areas that require improvement. The research findings were in line with (5) who also analyze the knowledge, skill and attitude level of farmers was corelated with pharmacovigilance awareness. Furthermore, considering the data from developing and developed countries as examined by (Isha, 2012) identified training needs among health care worksers and they identified practices of pharmacovigilance and hygienic condition was low as compared to developed counties. The findings of (13) also supportive and in line with the data as they find a inverse relationship in death rates with increase with decrease in pharmacovigilance awareness and adoption practices in hospitals.

### CONCLUSION

Based on the objective of the study and the principal findings, it can be concluded that there is a positive relationship between healthcare workers' knowledge, attitudes, and practices regarding pharmacovigilance at the tertiary care hospital in Faisalabad. The study revealed that healthcare professionals who possess better knowledge of pharmacovigilance principles are more likely to exhibit positive attitudes and engage in recommended practices related to pharmacovigilance. This highlights the importance of continuous training and educational programs to enhance healthcare professionals' expertise in pharmacovigilance and ensure patient safety. Further research and interventions should be focused on addressing the identified gaps in training and improving the effectiveness of the pharmacovigilance system in place at the hospital. By strengthening healthcare professionals' knowledge, attitudes, and practices, the detection and reporting of adverse drug reactions can be enhanced, ultimately leading to improved patient outcomes and medication safety.

#### REFERENCES

- 1 ELkhwsky FS, El Sayed I, Yassine OGM, Abdelmonem S, Salama MM. Healthcare professionals' knowledge and practice of and attitudes towards pharmacovigilance in Alexandria, Egypt: a crosssectional survey. Drugs & Therapy Perspectives. 2021;37:124-36.
- 2 Chen Y, Wang Y, Wang N, Xiang Y, Zhang R, Xiao J, et al. Knowledge, attitude, and practice regarding pharmacovigilance among the general public in Western China: a cross-sectional study. Current Medical Research and Opinion. 2021;37(1):101-8.
- 3 Hussain R, Hassali MA, Hashmi F, Akram T. Exploring healthcare professionals' knowledge, attitude, and practices towards pharmacovigilance: a cross-sectional survey. Journal of pharmaceutical policy and practice. 2021;14(1):1-13.
- 4 Hussain, R., & Hassali, M. A. (2019). Current status and future prospects of pharmacovigilance in Pakistan. Journal of pharmaceutical policy and practice, 12(1), 1-3.
- 5 Pavithra M, Vijendra R, Xaviar S. A Questionnaire based Crosssectional Study to assess Knowledge, Attitude and Practice of Pharmacovigilance and Adverse Drug Reaction Reporting among Postgraduate Medical students in a Tertiary Care Teaching Hospital of South India. Research Journal of Pharmacy and Technology. 2022;15(6):2391-4.
- 6 Alwhaibi M, Alhindi G, Alshamrani M, Essa MB, A. Al Aloola N, Alhawassi TM. Pharmacovigilance in healthcare education: students' knowledge, attitude and perception: a cross-sectional study in Saudi Arabia. BMC Medical Education. 2020;20:1-7.
- 7 Shoukat M, Hussain M, Perveen K, Afzal M, Saghir M. Assessment of Knowledge, Attitude, and Practices of Nurses towards Pharmacovigilance and Adverse Drugs Reactions Monitoring and Reporting: Cross-Sectional Study in Lahore, Pakistan. International Journal of Health, Medicine and Nursing Practice. 2021;3(1):24-43.
- 8 Kiguba R, Olsson S, Waitt C. Pharmacovigilance in low-and middleincome countries: A review with particular focus on Africa. British journal of clinical pharmacology. 2023;89(2):491-509.
- 9 Adenuga BA, Kibuule D, Bamitale KDS, Rennie TW. Effective integration of pharmacovigilance systems at public health facilities in resource-limited settings: A qualitative study. Research in Social and Administrative Pharmacy. 2020;16(8):1111-6.
- 10 Aswath N, VT H. Pharmacovigilance, Adverse Drug Reactions and Future Aspects of Pharmacovigilance in India: A Review Article. Indian Journal of Public Health Research & Development. 2019;10(12).
- 11 Abdulrasool Z. The development of a pharmacovigilance system in Bahrain. Saudi Pharmaceutical Journal. 2022;30(6):825-41.
- 12 Mustafa ZU, Salman M, Asif N, Rao AZ, Khan QU, Nawaz AS, et al. Knowledge, Attitude, Practices, and Barriers of Pharmacovigilance among Healthcare Workers: A Cross-sectional Survey from Lahore, Pakistan. Bulletin of Faculty of Pharmacy Cairo University. 2021;59(1):33-43.
- 13 Hotel FG, editor Conference venue. 2 nd International Conference on Tomography of Materials and Structures; 2019.
- 14 Aydin OC, Aydin S, Guney HZ. Pharmacovigilance and radiologists: How well do they get along? The British Journal of Radiology. 2020;93(1115):20200596.