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TECHNOLOGY, ISLAMABAD



**Assessing the Barriers and
Facilitators Influencing
Pharmacovigilance Practices
among Healthcare Providers in
Pakistan**

by

Mariam Siddique

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degree of Master of Philosophy

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CERTIFICATE OF APPROVAL

Assessing the Barriers and Facilitators Influencing Pharmacovigilance Practices among Healthcare Providers in Pakistan

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(Mariam Siddique)

Abstract

Pharmacovigilance is essential for ensuring medication safety through the timely detection and reporting of adverse drug reactions (ADRs). Despite the establishment of a national pharmacovigilance framework in Pakistan, underreporting of ADRs remains a significant challenge. This study aimed to assess the barriers and facilitators influencing pharmacovigilance practices among healthcare providers in Pakistan. A cross-sectional study was conducted among HCPs working in hospital and community settings in Islamabad and Rawalpindi using a structured questionnaire. Data were analyzed using IBM SPSS version 27.0, employing descriptive statistics and non-parametric tests, including the chi-square test, Mann–Whitney U test, and Kruskal–Wallis test. HCPs demonstrated satisfactory knowledge of pharmacovigilance, with 76.7% correctly defining pharmacovigilance, 72.3% correctly defining ADRs and 70.5% identifying the correct ADR reporting method. However, only 21.0% of participants had received formal pharmacovigilance training. Participants demonstrated a positive attitude toward ADR reporting, with 83.7% considering it a professional responsibility and 86.5% agreeing that ADR reporting improves the quality of care and patient trust. ADR reporting practices were suboptimal, with only 29.0% of HCPs reporting suspected ADRs, despite 69.4% having identified ADRs during clinical practice. Heavy workload (53.4%) and insufficient pharmacovigilance training (46.6%) were the most commonly perceived barriers. Facilitators for ADR reporting in this study included clear reporting guidelines (87.3%), user-friendly electronic reporting systems (85.5%), and regular training (84.0%), which were identified and agreed upon by the majority of HCPs. Significant differences were observed in pharmacovigilance knowledge scores according to profession and work setting ($p < 0.001$), with pharmacists showing the highest knowledge level (mean rank = 242.72). Barrier scores significantly differed by profession ($p < 0.001$), work setting ($p < 0.001$), and years of professional experience ($p = 0.004$), with medical doctors and government-sector employees reporting higher perceived barriers to ADR reporting. Continuous pharmacovigilance education, strengthened institutional systems, and supportive reporting practices are essential to improve ADR reporting, enhance medication

safety, and strengthen the national pharmacovigilance system in Pakistan.

Keywords Pharmacovigilance, adverse drug reaction, healthcare providers, barriers, facilitators, ADR reporting, medication safety, Pakistan

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Abbreviations

ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
AE	Adverse Event
AEFI	Adverse Event Following Immunization
CUST	Capital University of Science and Technology
DRAP	Drug Regulatory Authority of Pakistan
EMA	European Medicines Agency
ERB	Ethical Review Board
ERRC	Ethical Research Review Committee
FDA	Food and Drug Administration
HCPs	Healthcare Providers
HIC	High-Income Countries
ICH	International Council for Harmonization
IQR	Interquartile Range
ISB	Islamabad
LMIC	Low- and Middle-Income Countries
M	Median
MoNHSRC	Ministry of National Health Services, Regulations and Coordination
NPC	National Pharmacovigilance Centre
NPP	National Pharmacovigilance Programme
OTC	Over-the-Counter
PASS	Post-Approval Safety Study
PIC	Punjab Institute of Cardiology

PIMS	Pakistan Institute of Medical Sciences
PMC	Pakistan Medical Commission
PPC	Provincial Pharmacovigilance Centre
PRAEC	Pharmacovigilance Risk Assessment Expert Committee
PV	Pharmacovigilance
QPPV	Qualified Person for Pharmacovigilance
RWP	Rawalpindi
SCOPE	Strengthening Collaboration for Operating Pharmacovigilance in Europe
SPSS	Statistical Package for the Social Sciences
UMC	Uppsala Monitoring Centre
WHO	World Health Organization

Chapter 1

Introduction

1.1 Pharmacovigilance

Pharmacovigilance is an important discipline worldwide to ensure patient safety and the appropriate use of medicines [1]. The World Health Organization (WHO) defines pharmacovigilance (PV) as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem" [2]. As medicines continue to play a vital role in disease prevention and treatment, monitoring their safety throughout their lifecycle has become increasingly important. A well-functioning pharmacovigilance system supports rational prescribing, enhances patient safety, minimizes preventable medicine related harm, and contributes to reducing healthcare costs associated with adverse drug related outcomes [3]. A key component of pharmacovigilance is the reporting of suspected adverse drug reactions (ADRs) by healthcare professionals (HCPs). Even when a causal relationship between a medicine and an adverse event is uncertain, reporting remains important because the accumulated information can help identify potential safety signals, assess risks, and support regulatory actions aimed at protecting public health [4].

1.2 Adverse Drug Reaction

An adverse drug reaction (ADR) is defined as a harmful and unintended response to a medicine that occurs at doses normally used for the prevention, diagnosis, or treatment of disease, or for restoring, correcting, or modifying physiological functions [5]. ADRs represent a significant public health concern and are among

TABLE 1.1: Type of ADRs

ADR Type	Classification	Description
Type A	Augmented (Intrinsic)	Predictable, dose dependent reactions resulting from the known pharmacological action of a medicine; usually reversible after dose adjustment or discontinuation.
Type B	Bizarre (Idiosyncratic)	Unpredictable, non-dose-dependent reactions that are uncommon and often associated with immunological or genetic factors.
Type C	Chronic (Continuing)	Reactions that develop following prolonged or repeated use of a medicine and are related to cumulative exposure.
Type D	Delayed	Adverse reactions that become evident after a period of time, sometimes even after treatment has ended.
Type E	End of use (Withdrawal)	Reactions that occur following dose reduction or abrupt discontinuation of a medicine, often presenting as withdrawal or rebound effects.
Type F	Failure of Therapy	Unexpected lack of the intended therapeutic effect despite appropriate use of the medicine, which may result from factors such as drug interactions, resistance, or inadequate dosing.

the leading causes of morbidity, mortality, and preventable hospital admissions worldwide [6].

Table 1.1 summarizes the classification of adverse drug reactions into six categories: Type A (Augmented), Type B (Bizarre), Type C (Chronic), Type D (Delayed), Type E (End of use), and Type F (Failure of Therapy). Each category is distinguished by its underlying mechanism, predictability, timing, and relationship to medicine use [7]. Despite advances in medicine safety monitoring, ADRs

continue to place a considerable burden on healthcare systems through increased hospitalizations, prolonged hospital stays, disability, and healthcare expenditure. Moreover, global evidence suggests that approximately 94% of ADRs remain unreported, limiting the ability of pharmacovigilance systems to detect emerging safety concerns and implement timely regulatory interventions [8].

1.3 Adverse Events

An adverse event (AE) is any unfavorable or unintended medical occurrence that develops in a patient or research participant following the use of a medicine or therapeutic product, regardless of whether a causal relationship with the treatment has been established [5]. Table 1.2 presents the major categories of adverse events encountered in pharmacovigilance, classified according to their severity, cause, and clinical context. This classification facilitates the systematic identification and reporting of medicine related safety issues, enabling timely risk assessment and appropriate regulatory action to enhance patient safety [9].

1.4 Incidence of ADRs Worldwide

ADRs remain a significant global patient safety concern and a major cause of medication related hospital admissions. A recent systematic review and meta-analysis estimated that 8.3% of hospital admissions are attributable to ADRs, of which 44.7% are preventable, highlighting substantial opportunities to reduce medicine related harm through effective pharmacovigilance. Additionally, ADEs account for 13.9% of hospital admissions, with 71.0% considered preventable [10]. A prospective cohort study from Uganda reported that 48.9% of hospitalized older adults experienced at least one adverse drug reaction during hospitalization, with an incidence of 78 ADRs per 1,000 person-days, highlighting the substantial burden of ADRs among high risk patients [11]. Older adults experience the highest burden, with ADR related hospitalization rates ranging from 3.3% to 23.1%, largely due to

TABLE 1.2: Type of AEs

Type of AEs	Description
Serious adverse event	An event that leads to death, is life threatening, requires hospitalization or prolongs hospital stay, results in significant disability or incapacity, causes a congenital anomaly or birth defect, or is considered medically significant.
Non Serious adverse event	An unwanted medical occurrence that does not meet the criteria of a serious adverse event.
AEFI	Any untoward medical occurrence after vaccination, whether or not it is caused by the vaccine.
AE with quality problem	An event linked with a suspected quality issue of a therapeutic good, such as substandard or falsified medicine.
AE due to medication error	Harm or potential harm caused by preventable errors in prescribing, dispensing, preparing, or administering medicine.
AE due to overdose	An event occurring after taking a dose higher than the recommended dose.
AE due to misuse	An event occurring when a therapeutic good is intentionally used inappropriately or not according to approved product information.
AE due to abuse	An event related to excessive intentional use of a therapeutic good, causing physical or psychological harm.
AE due to off label use	An event occurring when a medicine is used for an unapproved indication, age group, dose, route, or dosage form under healthcare supervision.
AE due to occupational exposure	An event caused by exposure to a therapeutic good at the workplace.
Lack of therapeutic efficacy	When a medicine does not produce the expected therapeutic effect, especially important for vaccines, contraceptives, antibiotics, and medicines used in life threatening conditions.

AEFI= Adverse event following immunization, AE=Adverse event

polypharmacy and multiple comorbidities [12]. However, reported ADR incidence varies considerably across countries because of differences in pharmacovigilance infrastructure and reporting practices rather than true differences in medicine safety [13]. So, strengthening of spontaneous reporting systems and healthcare professionals' participation is essential for accurately estimating the global burden of

ADRs and improving patient safety [14]. A nationwide pharmacovigilance study from Thailand reported that 25.13% of anti-infective related ADR reports were classified as serious, underscoring the need for targeted monitoring of high risk patients [5]. These findings suggest that while the burden of ADRs is well recognized globally, the reported incidence is strongly influenced by the maturity of national pharmacovigilance systems and the effectiveness of spontaneous reporting programmes.

1.5 Practices of Pharmacovigilance Worldwide

Pharmacovigilance globally rests on multitier regulatory frameworks and international cooperation. The new Global Smart Pharmacovigilance Strategy of WHO underscores that trust in medical products requires life cycle safety monitoring and strong regulatory systems. High-income regulators (e.g. FDA,EMA) and International Council for Harmonization (ICH) guidelines mandate exhaustive post marketing surveillance and leverage advanced databases (e.g. ICH E2B data standards feeding into VigiBase). By contrast, many low-and middle-Income countries historically had fragmented, underfunded PV: even before COVID-19 exposed vulnerabilities, WHO noted that PV systems in low resource settings are often disconnected from broader health infrastructure. So, the pharmacovigilance strategy calls for simple, risk based systems tailored to national needs, and emphasizes reliance/harmonization (e.g. through ICH and WHO collaboration) [15].

Reporting systems and technology vary widely. Many countries use centralized electronic databases linked to national regulatory authorities. For example, Uppsala Monitoring Centre's VigiBase aggregates all member countries' reports, and many regulators now mandate electronic submissions (e.g. E2B XML by industry) [5]. Emerging technology from mobile apps to AI driven signal detection is increasingly applied. Recent initiatives of WHO include VigiFlow/VigiMobile training for LMICs to improve capture of vaccine safety data [16]. Despite this, a global review found that reporting rates still correlate strongly with income: one

large analysis showed high-income countries (HICs) report dozens to hundreds of ADRs per million inhabitants per year, whereas low-and middle-Income countries (LMICs) often report only a few (often cited <20 per million) [17].

Workforce capacity and training are pivotal facilitators. WHO data indicate <30% of countries have reached the WHO maturity level 3 for regulatory systems. LMIC regulators face acute shortages of skilled staff and lack competency-based training pathways. WHO thus advocates systematic competency frameworks and continuous education for regulators and PV personnel [18].

TABLE 1.3: Comparison of Pharmacovigilance Practices

Domain	HICs	LMICs
Regulatory framework	Well established and mature	Often developing or recently established
Funding	Dedicated PV budgets	Limited or no dedicated funding
Human resources	Specialized PV workforce	Shortage of trained personnel
Reporting systems	Advanced electronic systems and databases	Often manual or basic electronic systems
Reporting culture	Higher reporting awareness and participation	Underreporting remains common
Active surveillance	Commonly implemented	Limited implementation
Patient reporting	Widely encouraged	Emerging and less developed
Signal detection capacity	Strong due to large reporting volumes	Limited due to low reporting rates

HICs = High-income countries, LMICs = Low-and middle-Income countries,
PV = Pharmacovigilance

Table 1.3 shows, pharmacovigilance systems in HICs are generally more advanced, with established regulations, dedicated funding, trained personnel, electronic reporting systems, and effective signal detection. In contrast, LMICs often face challenges such as limited resources, shortages of trained staff, underdeveloped reporting systems, and lower reporting rates, highlighting the need to strengthen pharmacovigilance infrastructure and reporting practices[19, 20]

1.6 Prevalence of ADRs in Pakistan

The prevalence of ADRs in Pakistan remains difficult to determine because of limited nationwide surveillance and persistent underreporting. A multicenter prospective study conducted in four tertiary care hospitals in Lahore reported 486 antibiotic associated adverse drug events among 1,249 hospitalized patients (38.9%), with 58.4% of these events considered preventable [21]. More recently, a retrospective audit at Hameed Latif Hospital identified an acute ADR prevalence of 1.9% among 11,510 hospital admissions, with 19% of affected patients requiring hospitalization and 3% requiring intensive care [22]. Despite these findings, accurate national estimates of ADR prevalence in Pakistan remain unavailable because the pharmacovigilance system is still evolving and substantial underreporting of ADRs persists [23, 24].

1.7 Need of Pharmacovigilance in Pakistan

Once a drug is marketed, little is known about its safety profile [25] because clinical trials are conducted in controlled settings and may not detect rare, delayed, or long term ADRs. Clinical trials typically involve relatively small and selected patient populations, limiting the ability to identify uncommon adverse events and safety concerns that may emerge in routine clinical practice [26]. Post marketing surveillance activities, such as post approval safety studies (PASSs), support

continuous risk management by monitoring the safety of medicines after their approval. These activities help identify previously unrecognized safety signals and potential risks that may not have emerged during pre-approval clinical trials [27]. Patients who experienced an ADR has increased risk of mortality as compared with those who did not [28].

Spontaneous ADR reporting is the pillar of pharmacovigilance [29] and is essential for ensuring medication safety after a drug is introduced into the market. Pharmacovigilance is therefore essential for the continuous detection, assessment, understanding, and prevention of adverse effects and other medicine related problems throughout a product's lifecycle. Effective pharmacovigilance systems facilitate the early identification of safety signals, support benefit–risk evaluations, and provide evidence for regulatory actions aimed at protecting public health [30]. Spontaneous adverse drug reaction reporting remains a cornerstone of pharmacovigilance and plays a critical role in identifying rare and serious ADRs that are unlikely to be detected during pre-marketing studies [31]. The growing burden of chronic diseases among older adults has led to an increase in polypharmacy, which significantly raises the risk of drug–drug interactions and ADRs. The high prevalence of multiple medication use among geriatric patients highlights the importance of robust pharmacovigilance systems for the early detection, monitoring, and prevention of medication related harms in routine clinical practice [32].

Improving reporting rates enables regulatory authorities to take timely actions such as label updates, safety alerts, or withdrawal of harmful medicines [33]. Even when a causal relationship between a medicine and an AE is uncertain, reporting remains important because further evaluation of accumulated reports may reveal clinically significant safety concerns. ADR reporting also contributes to safer clinical practice by increasing awareness of medicine related risks among healthcare professionals. Previous studies have shown that underreporting remains a major challenge, often due to lack of knowledge, uncertainty regarding causality, fear of professional consequences, or insufficient training in pharmacovigilance procedures. Strengthening education and continuous professional development programs can improve reporting behavior and enhance the effectiveness of national

pharmacovigilance systems [34, 35].

1.8 Practices of Pharmacovigilance in Pakistan

Pharmacovigilance has emerged as a national healthcare priority in Pakistan over the past decade. A major milestone was the establishment of the DRAP under the DRAP Act, 2012, which designated DRAP as the national authority responsible for regulating medicines and overseeing pharmacovigilance activities in the country. The need for a robust pharmacovigilance system became particularly evident following the drug related tragedy at the Punjab Institute of Cardiology (PIC) in 2012, which exposed significant deficiencies in medicine safety monitoring and regulatory oversight. This incident accelerated efforts to strengthen the national pharmacovigilance framework and improve ADRs surveillance [5] [36].

Implementation of the national pharmacovigilance programme has continued to progress. DRAP has established the National Pharmacovigilance Centre (NPC) in Islamabad and supported the development of provincial pharmacovigilance centres (PPCs) to strengthen medicine safety monitoring across the country. In addition, DRAP has introduced national pharmacovigilance guidelines, published educational newsletters, organized awareness campaigns, and launched training programmes to enhance the knowledge and reporting practices of healthcare providers.

The introduction of digital reporting platforms, including the Urdu version of Vigi-Mobile, has further improved the accessibility of ADR reporting systems. These initiatives demonstrate Pakistan's commitment to aligning its pharmacovigilance practices with international standards [5, 15, 37].

Despite these regulatory advancements, several challenges continue to limit the effective implementation of pharmacovigilance in Pakistan. Studies among healthcare providers have consistently identified excessive workload, shortage of healthcare professionals, inadequate knowledge of pharmacovigilance, limited confidence in identifying and reporting ADRs, and insufficient access to user friendly reporting systems as major barriers to ADR reporting. Pakistan continues to have a

lower healthcare workforce density than the levels recommended by WHO, resulting in heavy clinical workloads that reduce opportunities for spontaneous ADR reporting. HCPs have also emphasized the need for continuing medical education, regular reminders, simplified electronic reporting systems, and institutional support to improve reporting practices [38][39][36][40].

Compared with established pharmacovigilance systems in many HICs, Pakistan's pharmacovigilance programme remains in the developmental stage. Patient reporting and active pharmacovigilance programmes are still limited, while awareness of national pharmacovigilance regulations among healthcare providers remains suboptimal. Furthermore, many healthcare institutions and pharmaceutical manufacturers have yet to establish dedicated pharmacovigilance units or appoint Qualified Persons for Pharmacovigilance (QPPVs).

Pharmacovigilance education is also inadequately integrated into undergraduate healthcare curricula, contributing to persistent knowledge gaps among newly qualified healthcare professionals. Continued investment in regulatory capacity, workforce training, institutional infrastructure, and public awareness will therefore be essential to strengthen pharmacovigilance practices and improve medicine safety in Pakistan [5, 36, 38, 40].

1.9 DRAP Pharmacovigilance Rules in Pakistan

DRAP Pharmacovigilance Rules, provide the legal framework for the implementation of pharmacovigilance activities in Pakistan. The primary objectives of these rules are to strengthen medicine safety surveillance, promote the timely detection and reporting of ADRs, establish a coordinated national pharmacovigilance system, and ensure compliance with international pharmacovigilance standards established by WHO [5, 41]. Under these rules, the NPC functions as the central coordinating authority for pharmacovigilance in Pakistan. Its responsibilities include collecting and evaluating ADR reports, detecting safety signals, maintaining

the national pharmacovigilance database, communicating medicine safety information, and coordinating with provincial PV centres, public health programmes, and international organizations such as the WHO and the Uppsala Monitoring Centre [5, 36]. The rules also PPCs to coordinate pharmacovigilance activities at the provincial level. These centres are responsible for receiving and evaluating ADR reports, supporting healthcare institutions, conducting training and awareness activities, and forwarding validated reports to the NPC for further assessment [5, 42].

Healthcare institutions are required to establish pharmacovigilance systems by appointing focal persons, forming pharmacovigilance committees, maintaining ADR reporting records, and submitting safety reports to the relevant provincial centres.

Healthcare professionals, including physicians, pharmacists, nurses, dentists, and other allied health professionals, are responsible for identifying, documenting, assessing, and reporting suspected ADRs, medication errors, therapeutic failures, overdose related events, and other medicine related safety concerns through the approved reporting channels [5, 34, 43].

To facilitate ADR reporting, DRAP has introduced multiple reporting mechanisms, including the Yellow Reporting Form, the Med Vigilance e-Reporting System, and the Med Safety Mobile Application (VigiMobile Pakistan).

These reporting tools enable healthcare professionals and patients to submit suspected ADR reports through paper based and electronic systems, thereby improving the accessibility and efficiency of pharmacovigilance reporting [5].

The Pharmacovigilance Rules also established the Pharmacovigilance Risk Assessment Expert Committee (PRAEC), which provides scientific advice on signal detection, causality assessment, benefit–risk evaluation, risk minimization measures, and regulatory recommendations.

The committee supports evidence based decision making to ensure the safe and effective use of medicines in Pakistan [44].

1.10 Current Situation of Pharmacovigilance in Pakistan

Despite the regulatory progress, actual ADR reporting in Pakistan remains very low [38]. Since the establishment of DRAP, a total of 6,587 ADR reports have been received by the National PV Centre, including 116 reports in 2018, 2,415 in 2019, and 4,056 in 2020. Of these, only 124 ADR reports were submitted by the PV Centre in Punjab. Although the number of reports has increased over time, ADR reporting remains below the WHO recommended target of at least 200 ADR reports per million population per year [36]. But DRAP reported “over 30,000 reports” since 2018 in a 2023 press release [45].

A study found that only 45.8% HCPs ever heard of pharmacovigilance. Knowledge regarding key pharmacovigilance practices was also limited, as only 20.5% knew where to report ADRs and 15.8% were aware of online ADR reporting databases. Overall, 82.6% of respondents were categorized as having poor knowledge of pharmacovigilance. In short, Pakistan’s spontaneous reporting rate is grossly suboptimal and underreporting remains a critical concern [46]. A study conducted in 2025 shows public knowledge is even lower: >75% of lay respondents in Karachi didn’t know an ADR form exists on DRAP’s site, and >50% said they would never report an ADR [37]. These awareness gaps mirror Pakistan’s human-resource constraints.

1.11 Role of Healthcare Professionals in Pharmacovigilance

HCPs are the cornerstone to the success of pharmacovigilance systems because they are often the first to recognize and manage suspected ADRs in clinical practice [41]. Their active participation in spontaneous reporting programmes contributes to the early detection of medicine related safety signals, enabling regulatory authorities to implement timely risk minimization measures and improve patient

safety [47]. This role is particularly important in low and middle income countries, where spontaneous reporting remains the primary method of post marketing drug safety surveillance [26]. Effective pharmacovigilance requires HCPs to have adequate knowledge of medication safety, ADR recognition, causality assessment, and reporting procedures. However, insufficient awareness, limited training, and heavy workloads continue to contribute to the underreporting of ADRs, with only 2–4% of all ADRs and approximately 10% of serious ADRs reported worldwide. Therefore, integrating ADR reporting into routine clinical practice and encouraging the reporting of all suspected reactions, especially those involving newly authorized medicines or serious events, are essential for strengthening pharmacovigilance systems and improving patient safety [44, 48].

The key responsibilities of healthcare professionals in pharmacovigilance include identifying, monitoring, and managing suspected adverse events associated with medicines and therapeutic products; documenting and reporting suspected ADRs, including those related to medication errors, overdose, misuse, abuse, occupational exposure, drug interactions, and lack of therapeutic efficacy; conducting an initial causality assessment; submitting reports through the appropriate pharmacovigilance reporting channel to avoid duplication; and educating patients to recognize adverse reactions and seek timely medical attention when necessary [5].

1.12 Research Gap

Despite growing research on pharmacovigilance in Pakistan, most studies have focused on healthcare providers knowledge, attitudes, and adverse drug reaction reporting practices. Evidence on the barriers and facilitators influencing participation in pharmacovigilance activities remains limited, particularly following the implementation of the DRAP Pharmacovigilance Rules. Furthermore, no recent study has comprehensively examined these factors among HCPs in Islamabad and Rawalpindi. This gap highlights the need for a focused evaluation of the factors affecting pharmacovigilance in the current regulatory environment.

1.13 Problem Statement

Despite the establishment of a national pharmacovigilance framework and regulatory initiatives by the DRAP, ADR reporting by healthcare providers remains inadequate, limiting the effectiveness of pharmacovigilance activities and the timely identification of medicine related safety concerns.

HCPs play a central role in pharmacovigilance, but the factors influencing their participation in ADR reporting are not fully understood, particularly within the current regulatory environment.

A comprehensive assessment of the barriers that hinder and the facilitators that promote pharmacovigilance practices is needed to generate evidence that can help in targeted interventions, strengthen ADR reporting, and enhance the effectiveness of the national pharmacovigilance system in Pakistan.

1.14 Rationale or Significance of Study

Understanding the factors that influence healthcare providers' engagement in pharmacovigilance is crucial for improving adverse drug reaction reporting.

This study seeks to generate evidence that supports policymakers, healthcare administrators, and the Drug Regulatory Authority of Pakistan in developing targeted interventions, effective training modules, and strategic policy reforms to enhance the culture of pharmacovigilance.

By analyzing both barriers and facilitators within local practice environments, the research seeks to promote a proactive safety reporting culture, strengthen the national pharmacovigilance framework, and ultimately improve patient safety and therapeutic outcomes in alignment with global standards.

1.15 Aim and Objectives

1.15.1 Aim

To evaluate the barriers and facilitators influencing pharmacovigilance practices among healthcare providers, with the goal of strengthening the national pharmacovigilance system.

1.15.2 Objectives

- i. To assess healthcare providers knowledge and attitude regarding the Pharmacovigilance reporting.
- ii. To identify key barriers that hinder healthcare providers participation in pharmacovigilance activities.
- iii. To explore facilitators that motivate and support healthcare providers in engaging with PV and ADR reporting.

Chapter 2

Literature Review

2.1 Knowledge, Attitude and Practices of PV and ADR Reporting

Healthcare providers play a central role in monitoring of ADRs and ensuring the effectiveness of pharmacovigilance systems [49]. Effective pharmacovigilance depends not only on HCPs awareness of ADRs but also on their knowledge of reporting procedures, positive attitudes toward reporting, and routine reporting practices. Research conducted in Pakistan and other countries consistently demonstrates that although HCPs generally acknowledge the importance of ADR reporting, deficiencies in practical knowledge and reporting behavior continue to contribute to substantial underreporting [39, 50, 51].

Studies conducted in Pakistan have consistently reported moderate knowledge of pharmacovigilance but limited awareness of national reporting systems and reporting procedures. Iffat et al. found that physicians were familiar with the concept of ADRs but lacked adequate knowledge regarding reporting mechanisms [37]. Similarly, Shamim et al. reported that pharmacists demonstrated better pharmacovigilance knowledge than physicians and nurses; however, many HCPs were unfamiliar with ADR reporting forms and pharmacovigilance centers [34]. Nisa et al. further observed that although HCPs recognized the importance of ADR

reporting, only a small proportion possessed sufficient knowledge of reporting procedures [52]. Ali et al. and Hussain et al. also reported that inadequate training, uncertainty regarding reportable reactions, and lack of institutional support significantly affected HCPs knowledge and confidence in ADR reporting [53, 54].

Despite these knowledge gaps, attitudes toward pharmacovigilance are generally positive. Pakistani studies consistently show that physicians, pharmacists, and nurses consider ADR reporting a professional responsibility and acknowledge its contribution to improving patient safety [34, 37, 54].

Nevertheless, positive attitudes have not translated into satisfactory reporting practices. Many HCPs reported encountering suspected ADRs during routine clinical practice but had never submitted an official ADR report because of uncertainty regarding reporting procedures, heavy workload, fear of legal consequences, lack of reporting forms, and absence of feedback from regulatory authorities [53, 55].

Similar findings have been reported internationally. In Saudi Arabia, Abdel-Latif et al. and Almandil found that HCPs appreciated the importance of pharmacovigilance but demonstrated limited knowledge of national ADR reporting systems [43, 56]. More recently, Abdulsalim et al. reported that community pharmacists in the Qassim region possessed satisfactory knowledge and positive attitudes toward pharmacovigilance; however, previous pharmacovigilance training was significantly associated with better reporting practices, emphasizing the importance of continuing professional education [57].

Likewise, Alshehri et al. found that although the Saudi general population demonstrated favourable attitudes toward medication safety, awareness of pharmacovigilance systems and ADR reporting remained limited, highlighting the continued need for educational initiatives to improve reporting culture [58].

Comparable evidence has also emerged from other countries. Hadi et al. reported that Malaysian hospital pharmacists recognized the value of ADR reporting but identified lack of time, uncertainty regarding causality assessment, and inadequate institutional support as major barriers to reporting [59]. In South

Africa, Haines et al. similarly observed that HCPs demonstrated positive perceptions of pharmacovigilance but low reporting rates due to insufficient knowledge of reporting procedures [47]. Recent evidence from the Philippines by Lirasan et al. further confirmed that underreporting remains a persistent challenge despite increasing awareness of pharmacovigilance. Their mixed methods study identified limited pharmacovigilance training, uncertainty regarding reportable ADRs, workload pressures, and lack of feedback from regulatory authorities as the primary reasons for underreporting, while participants emphasized that continuous education, simplified reporting systems, and institutional support would encourage greater participation in pharmacovigilance activities [60].

2.2 Limitations of Pre-Marketing Drug Evaluation and Historical Drug Safety Failures

Despite rigorous testing during pre-clinical and clinical phases, the safety profile of a medicinal product cannot be fully established before regulatory approval[61]. Clinical trials are generally conducted on a relatively small number of carefully selected participants and are limited in duration[62].

As a result, rare, delayed, or long term adverse drug reactions may remain undetected at the time a drug enters the market. Moreover, these trials often exclude patients with complex comorbidities, extremes of age, or those receiving multiple concurrent medications, which limits the generalizability of safety data.

Once a medicine is marketed and introduced into routine clinical practice, it is exposed to a much larger and more heterogeneous population. This includes individuals with varying genetic backgrounds, disease conditions, and treatment regimens.

Under these conditions, previously unrecognized or serious adverse effects may emerge, highlighting the importance of continuous safety monitoring after marketing approval [26].

2.2.1 Historical Lessons From Drug Safety Failures

One of the most significant events in pharmaceutical history is the thalidomide tragedy. Introduced in the late 1950s as a sedative and antiemetic for pregnant women, thalidomide was distributed across more than 40 countries.

The medicine was distributed across more than 40 countries, and thousands of infants were affected globally, with a large proportion not surviving beyond infancy. This public health catastrophe led to major reforms in drug regulation, including stricter requirements for safety evaluation and post approval monitoring systems [62].

The need to strengthen pharmacovigilance in Pakistan became starkly evident following the 2012 tragedy at PIC. In this incident, a contaminated batch of the locally produced cardiac medicine Isotab 20 mg (isosorbide mononitrate; batch J093) led to serious adverse drug reactions, causing more than 200 deaths and over 1,000 hospitalizations in Lahore.

A large number of additional patients were also exposed to the substandard drug, with clinical presentations including sudden bone marrow suppression and life threatening infections [40]. The incident exposed serious weaknesses in Pakistan's drug regulatory system after regulatory powers had been decentralized.

In response, the Supreme Court and provincial assemblies called for stronger oversight. As a result, the federal government established a national drug regulatory authority in February 2012 [63].

2.2.2 Importance of Post Marketing Surveillance

Modern drug safety systems are designed to address these limitations through continuous post-marketing surveillance. The World Health Organization emphasizes spontaneous reporting as the cornerstone of pharmacovigilance, relying on HCPs, patients, and manufacturers to report suspected adverse drug reactions [16].

Global evidence also highlights the scale of preventable harm in healthcare settings. WHO estimates that approximately one in ten patients experiences harm during medical care, and a substantial proportion of this harm is preventable. Medication errors and undetected adverse drug reactions represent a significant contributor to this burden.

Therefore, effective pharmacovigilance systems are essential not only for detecting rare and delayed reactions but also for reducing preventable patient harm and strengthening overall healthcare safety [64].

Overall, these historical and contemporary examples demonstrate that pre-marketing evaluation alone is insufficient to guarantee drug safety. Continuous monitoring aftermarket authorization remains essential for identifying new risks, guiding regulatory decisions, and ensuring patient protection.

2.3 Pharmacovigilance Benefits

Pharmacovigilance plays a vital role in ensuring the safe and effective use of medicines by generating evidence on their safety throughout the product lifecycle. Information obtained through pharmacovigilance supports regulatory decision making, guides clinical practice, and contributes to the continuous improvement of medicine safety [30, 65]. Consequently, pharmacovigilance provides important benefits to multiple stakeholders, including healthcare providers, patients, and regulatory authorities.

2.3.1 Benefits for HCPs

Pharmacovigilance plays an important role in strengthening the capacity of HCPs to ensure medication safety. Evidence suggests that HCPs with greater pharmacovigilance knowledge exhibited better ADR reporting practices and improved awareness regarding medication safety [54]. Pharmacovigilance training enhances HCPs competence in identifying and reporting ADRs, improves understanding of

reporting procedures, and supports patient safety by encouraging active participation in post marketing drug surveillance [36]. Shamim et al. also reported that pharmacovigilance education and increased awareness improve ADR reporting practices and strengthen medicine safety surveillance within healthcare settings. Similarly, Almandil found that better pharmacovigilance knowledge encourages ADR recognition and reporting, contributing to safer clinical practice [34, 43]. Collectively, pharmacovigilance education improves medication safety awareness, strengthens ADR detection and reporting skills, promotes evidence based practice, and enhances patient safety. These findings support incorporating pharmacovigilance training into routine professional development for HCPs.

2.3.2 Benefits for Patients

Pharmacovigilance benefits patients by reducing preventable ADR related hospitalizations by identifying medication related risks early and supporting interventions before serious harm occurs; prospective studies have shown that a substantial proportion of ADR related hospital admissions are preventable through improved pharmacovigilance and monitoring [?]. In addition, patient reporting strengthens pharmacovigilance by providing detailed information on symptom severity, quality of life, and the impact of ADRs on daily activities, complementing healthcare professionals' reports and improving the detection of new safety signals [66].

2.3.3 Benefits for Regulatory Authorities

Pharmacovigilance strengthens regulatory authorities by enabling timely regulatory actions such as updates to prescribing information, strengthened safety warnings, and risk minimization measures that improve the safe use of medicines [67]. Collaborative initiatives such as the Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action have strengthened pharmacovigilance systems through capacity building and cooperation among regulatory authorities [42]. Advances in pharmacovigilance methodologies have also improved

regulatory decision making. Xiao et al. demonstrated that integrating multiple real world pharmacovigilance data sources improves drug safety signal detection and provides stronger evidence to support regulatory decision making and risk assessment [68]. Collectively, pharmacovigilance strengthens regulatory authorities by enhancing signal detection, risk communication, evidence based decision making, and the effectiveness of public health protection.

2.4 Pharmacovigilance Barriers

The literature consistently identifies multiple barriers that hinder the implementation of effective pharmacovigilance systems and ADR reporting. Frequently reported barriers include inadequate knowledge of pharmacovigilance, uncertainty regarding reporting procedures, lack of awareness of national reporting systems, excessive workload, time constraints, fear of legal liability, and absence of reporting forms, limited institutional support, and poor interprofessional communication. In Pakistan, Hussain et al. found that many physicians, pharmacists, and nurses lacked knowledge of ADR reporting procedures and were unaware of the national pharmacovigilance center [38]. Similar findings were reported by Ali et al., who observed poor knowledge of pharmacovigilance despite positive attitudes toward ADR reporting among HCPs [53]. Likewise, Zawiah et al. found that most pharmacists in Yemen were unaware of the national ADR reporting system, while insufficient clinical knowledge, lack of reporting forms, and inadequate training were major barriers to reporting [69]. At a broader policy level, Loomba identified weak legislation, inadequate infrastructure, limited pharmacovigilance capacity, and insufficient training as the key drivers that influence many other barriers and ultimately weaken national pharmacovigilance systems in emerging economies [70].

Beyond knowledge related barriers, evidence suggests that organizational and systemic factors significantly influence pharmacovigilance practices.

Hussain et al. reported that physicians were willing to participate in ADR reporting but were discouraged by inadequate training, time constraints, fear of legal

consequences, poor communication among HCPs, and the absence of an effective reporting system [39].

Supporting these findings, Alsaleh et al. highlighted that limited institutional support and lack of feedback from pharmacovigilance authorities reduced HCPs motivation to report ADRs [71].

Similarly, Varallo et al. demonstrated that weak reporting cultures and insufficient organizational commitment negatively affected pharmacovigilance activities [72], whereas Loomba (2022) emphasized that resource limitations, weak regulatory frameworks, and inadequate enforcement create interconnected barriers that undermine the overall effectiveness of pharmacovigilance systems in emerging economies [70].

Recent evidence also highlights the importance of patient engagement as a component of effective pharmacovigilance systems. Chinchilla et al. found that patient organizations faced both internal and external barriers, including limited awareness, insufficient education, poor communication with regulatory authorities, and lack of feedback, which restricted their participation in pharmacovigilance activities [73].

Similarly, Aslam et al. reported that patients ADR reporting remains limited due to inadequate awareness, complex reporting procedures, and insufficient support from HCPs, particularly in low-and middle-income countries [74].

These findings are consistent with Hussain et al., who reported that although hospital pharmacists understood medication safety, they lacked awareness of the national reporting system and faced barriers such as inadequate training, poor communication, and absence of formal reporting mechanisms [40].

Collectively, these studies suggest that strengthening pharmacovigilance requires not only improving HCPs knowledge and reporting practices but also increasing patient awareness, simplifying reporting mechanisms, and developing supportive institutional and regulatory environments.

2.5 Strategies to Overcome Pharmacovigilance Barriers

Educational interventions are consistently reported as an effective strategy to improve pharmacovigilance practices among HCPs. In Brazil, Varallo et al. demonstrated that a multifaceted intervention comprising lectures, practical sessions, and educational materials resulted in a 70 fold increase in adverse drug event reporting while significantly improving participants pharmacovigilance knowledge and reporting skills [75]. Similarly, Jha et al. observed significant improvements in pharmacists knowledge and attitudes following an educational programme in Nepal. Among medical students [76], Schutte et al. found that participation in a structured pharmacovigilance programme significantly enhanced knowledge, reporting confidence, and future intention to report ADRs [77]. These findings indicate that continuous education and curriculum integration are essential for strengthening pharmacovigilance systems.

Healthcare institutions can overcome reporting barriers by establishing supportive reporting environments and strengthening organizational commitment. In a multicentre study conducted in Türkiye, Khan et al. recommended periodic training, systematic follow up by health authorities, stronger interprofessional collaboration, and mandatory reporting policies to improve pharmacovigilance practices [8]. Likewise, Vural et al. reported that nurses' reporting behavior improved when hospitals provided clear reporting procedures and regular pharmacovigilance education [78].

The adoption of electronic reporting systems and continuous feedback mechanisms has also been identified as an important strategy for strengthening pharmacovigilance. El-Dahiyat et al. reported that educational sessions combined with practical guidance significantly improved HCPs pharmacovigilance knowledge in a tertiary hospital [79]. Similarly, Shanableh et al. found that pharmacists demonstrated better reporting practices when supported by accessible reporting systems and ongoing professional development [80]. In addition, Varallo et al. emphasized that

simplified reporting processes and regular feedback encouraged sustained participation in ADR reporting activities [75]. In an interventional study conducted in Saudi Arabia, Ali et al. demonstrated that introducing a recognition and incentive programme significantly increased the number of ADR reports submitted by HCPs [81]. Collectively, these findings suggest that educational, organizational, and technological interventions should be implemented simultaneously to improve ADR reporting and strengthen pharmacovigilance systems.

Chapter 3

Materials and Methods

3.1 Study Design

A cross-sectional study was conducted to assess the barriers and facilitators influencing healthcare providers' participation in pharmacovigilance activities.

Cross-sectional studies involve collecting data from a population at a single point in time, providing a snapshot of the characteristics or conditions being studied. These studies can be either descriptive or analytical in nature. Descriptive cross-sectional studies are primarily used to estimate the prevalence of diseases, health-related behaviors, attitudes, knowledge, or other population characteristics. In contrast, analytical cross-sectional studies go beyond describing a phenomenon by examining potential relationships or associations between different variables. Owing to their efficiency and practicality, cross-sectional studies are commonly employed in public health research to generate evidence and inform healthcare policies and interventions [19].

3.2 Study Setting

The study was conducted in the twin cities of Pakistan, Islamabad (the federal capital of Pakistan) and Rawalpindi (a district of Punjab Province). Data were collected from public and private healthcare settings, including government and private hospitals, community pharmacies, pharmacies providing physician consultation services, and physicians practicing in private clinics across Islamabad and Rawalpindi.

HCPs working at the Pakistan Institute of Medical Sciences (PIMS), Islamabad, were also recruited following institutional approval.

3.3 Study Population

The study population comprised registered HCPs, including physicians, pharmacists, dentists and paramedics, practicing in hospital and community healthcare settings.

3.4 Sample Size

The sample size was calculated using the Rao soft Sample Size Calculator based on a 95% confidence level, a 5% margin of error, and an assumed response distribution of 50% [82]. The minimum required sample size was estimated to be 380 participants.

To account for potential non-response and incomplete questionnaires, the target sample size was increased to 550 HCPs. Following data collection and eligibility screening, 386 completed questionnaires met the eligibility criteria and were included in the final analysis.

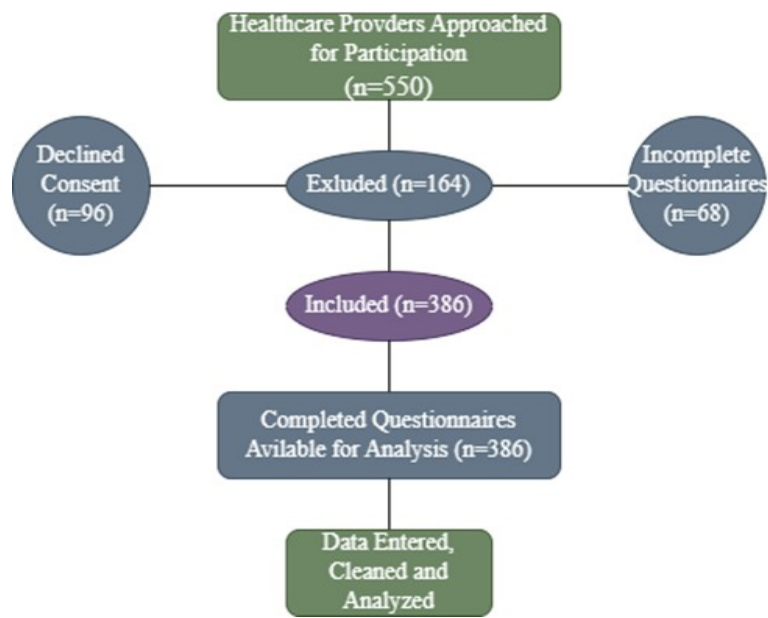


FIGURE 3.1: Flow Chart of Participant Selection

3.5 Sampling Technique

A convenience sampling approach, defined as a non-probability sampling technique that involves recruiting participants who are readily available and easy to access from the target population, was used to recruit participants from selected healthcare settings until the required sample size was achieved [83].

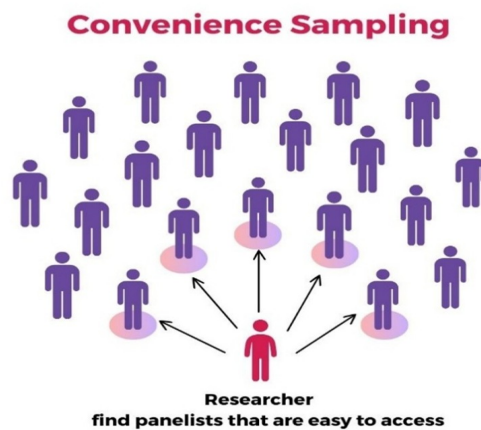


FIGURE 3.2: Convenience Sampling

3.6 Inclusion and Exclusion Criteria

3.6.1 Inclusion Criteria

HCPs were eligible for inclusion if they were registered or licensed practitioners aged between 25 and 65 years, had at least one year of continuous professional experience, and were currently practicing in community or hospital healthcare settings in Islamabad or Rawalpindi. Participants were also required to be willing to participate in the study, provide written informed consent, and be able to read, understand, and independently complete the structured questionnaire.

3.6.2 Exclusion Criteria

Unregistered HCPs and professionals with less than one year of professional experience were excluded from the study. HCPs aged below 25 years or above 65 years, those practicing outside Islamabad and Rawalpindi, individuals who declined or failed to provide written informed consent, and participants who had been involved in the pilot testing of the questionnaire were also excluded.

3.7 Data Collection Tool

Data collection tool was developed based on the DRAP Pharmacovigilance guidelines and previously published validated questionnaires available in the peer reviewed literature, particularly those assessing HCPs knowledge, attitudes, practices, barriers, and facilitators related to PV and ADR reporting [38, 84, 85]. Domain scores were categorized into low, moderate, and high levels using predefined score ranges established for this study based on the maximum attainable score for each domain. The final version of the questionnaire consisted of a total 55 items distributed across six sections.

The first section collected participants sociodemographic information and included nine questions on age, gender, educational qualification, healthcare profession, work setting, work area, work location, professional experience, and the average number of patients or prescriptions managed per day. The second section assessed participants knowledge of PV and ADR reporting and consisted of three parts. The first part comprised seven multiple choice questions that evaluated participants factual knowledge of PV and ADR reporting.

The second part included four Likert scale statements (1 = Strongly Disagree to 5 = Strongly Agree) assessing participants knowledge of PV and ADR concepts. The third part consisted of four awareness statements rated on a five point scale (1 = Not aware at all to 5 = Extremely aware) to assess participants' awareness of PV and ADR reporting procedures. The knowledge and awareness domains (Parts 2 and 3) were scored separately, with each domain having a total score ranging from 0 to 20. Scores of less than 12 were classified as low, scores of 12–16 as moderate, and scores of 17–20 as high. The third section consisted of ten Likert scale statements (1 = Strongly Disagree to 5 = Strongly Agree) assessing participants' attitudes toward PV and ADR reporting.

The total attitude score ranged from 10 to 50, with scores below 30 categorized as low, scores of 30–39 as moderate, and scores of 40–50 as high. The fourth section included six closed ended (Yes/No) questions assessing participants' practices related to ADR reporting and PV activities. The fifth section contained nine Likert scale statements (1 = Strongly Disagree to 5 = Strongly Agree) evaluating perceived barriers to ADR reporting, including lack of knowledge, limited access to reporting systems, insufficient training, workload, legal concerns, and motivational factors. The total barrier score ranged from 9 to 45.

Scores of less than 23 were categorized as low, scores of 23–35 as moderate, and scores of 36–45 as high. The sixth section comprised six Likert scale statements (1 = Strongly Disagree to 5 = Strongly Agree) assessing factors that may facilitate ADR reporting, including training opportunities, clear reporting guidelines, user friendly reporting systems, feedback mechanisms, and organizational support. The

total facilitator score ranged from 6 to 30, with scores of less than 15 classified as low, scores of 15–23 as moderate, and scores of 24–30 as high.

3.8 Face Validity

Prior to data collection, the questionnaire was pilot tested using a convenience sample of 20 HCPs to assess its clarity, comprehensibility, and suitability for achieving the study objectives.

3.9 Content Validity

The questionnaire was reviewed by experts in the field of pharmacovigilance and clinical pharmacy to evaluate its relevance, clarity, comprehensiveness, and suitability for achieving the study objectives. Based on their recommendations, minor modifications were made to improve the wording and organization of the questionnaire. The revised questionnaire was then used for data collection.

The following questions were added and minor revisions were made to the existing questions.

- i. I am aware of pharmacovigilance contact points in my hospital.
- ii. It's important to consult a physician before submitting an ADR report.
- iii. ADRs are properly documented and reported in my hospital/clinical setting.

3.10 Reliability Analysis

The internal consistency of the questionnaire was assessed using Cronbach's alpha coefficient [84]. The reliability analysis was conducted for all sections and sub-sections of the questionnaire. The knowledge section has cronbach's alpha of

0.534. The attitude section, consisting of 10 questions, demonstrated a Cronbach's alpha of 0.824, indicating good internal consistency. The practice section, consisting of 6 questions, demonstrated a Cronbach's alpha of 0.717, indicating acceptable internal consistency. The barriers section, consisting of 9 questions, demonstrated a Cronbach's alpha of 0.911, indicating excellent internal consistency. The facilitators section, consisting of 6 questions, demonstrated a Cronbach's alpha of 0.918, also indicating excellent internal consistency. The overall Cronbach's alpha value was 0.788, indicating acceptable reliability of the study instrument.

3.11 Data Collection Procedure

Data were collected using a paper based, self-administered structured questionnaire. HCPs working in the public and private healthcare settings in ISB and RWP were approached in person and informed about the purpose and objectives of the study. Participants who voluntarily agreed to participate provided written informed consent before completing the questionnaire. The questionnaire required approximately 3–5 minutes to complete, and all completed questionnaires were checked for completeness before being included in the final analysis. The study was conducted from March 2025 to May 2026.

3.12 Statistical Analysis

Data were entered and analyzed using the IBM SPSS Statistics version 27.0. Descriptive statistics were used to summarize the study findings. Categorical variables were presented as frequencies and percentages, whereas Likert scale responses were summarized using the median (M) and interquartile range (IQR). As the data were not normally distributed, non-parametric statistical tests were applied. The Chi-square test was used to examine associations between categorical variables. The Mann–Whitney U test was employed to compare differences between two independent groups, while the Kruskal–Wallis test was used to compare differences

among more than two independent groups. A p-value of less than 0.05 was considered statistically significant for all statistical analyses. Graphs were generated using Graphpad Prism (version 8.0) software.

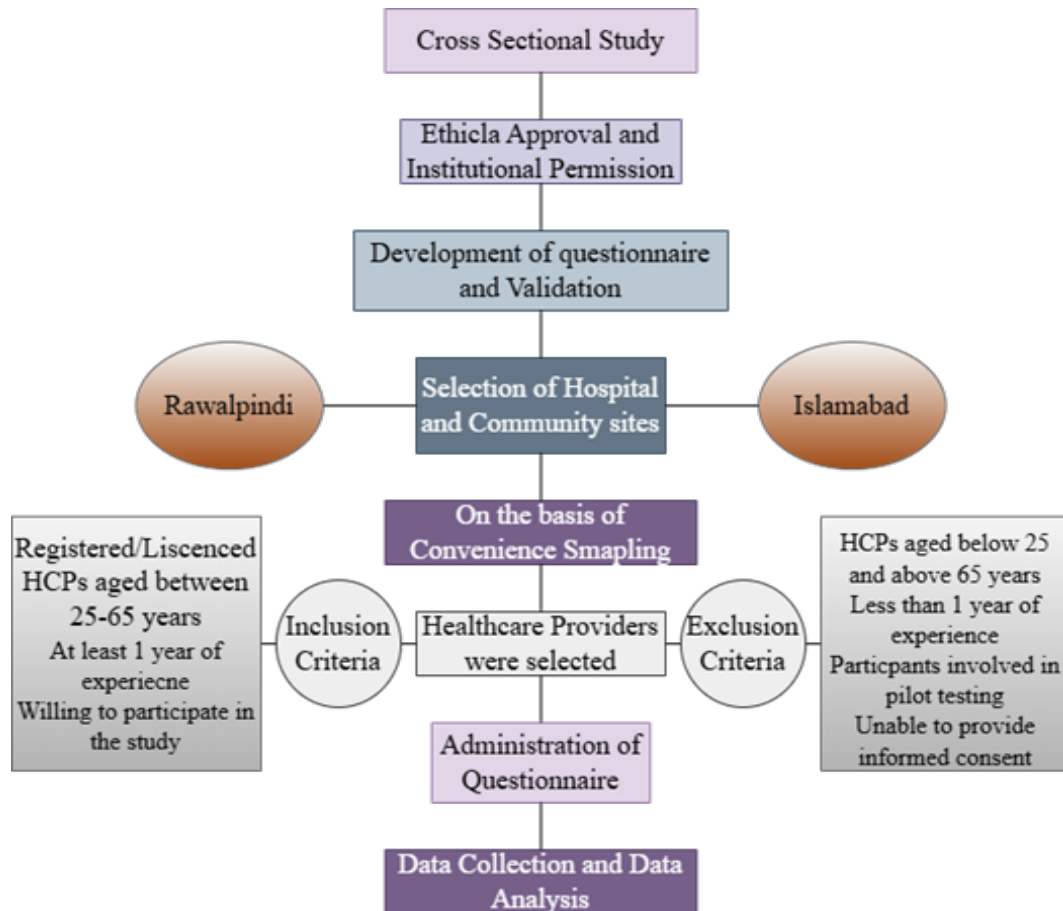


FIGURE 3.3: Methodology Flow Chart

3.13 Ethical Considerations

Ethical approval for this study was obtained from the Ethical Review Board (ERB) of the Capital University of Science and Technology (CUST), Islamabad (Reference No. CUST/DERC/PH/ERF/PG/2026/016), and ethical approval from Ethical Research Review Committee (ERRC) of PIMS (Reference No. F-5-2/2024(ERRC)/PIMS), Islamabad, prior to the commencement of data collection. Participants were provided with detailed information regarding the study

objectives and procedures before providing written informed consent. The confidentiality and anonymity of participants were strictly maintained by removing all personal identifiers from the dataset.

Chapter 4

Results

4.1 Sociodemographic Characteristics

The sociodemographic characteristics of the study participants are presented in Table 4.1. A total of 386 healthcare providers participated in this study. The majority of respondents were aged 25–35 years (82.6%), followed by those aged 35–45 years (12.7%) and above 46 years (4.7%). The gender distribution was nearly balanced, with males accounting for 51.6% of the respondents and females representing 48.4%. Regarding educational qualifications, most participants held a bachelor’s degree (74.1%), while 24.4% possessed a master’s degree and only 1.6% held a diploma qualification. In terms of professional background, medical doctors constituted the largest proportion of respondents (64.5%), followed by pharmacists (26.2%), paramedics (8.5%), and dentists (0.8%). With respect to employment sector, more than half of the respondents were employed in the government sector (58.5%), whereas 41.5% worked in the private sector. The majority of participants practiced in urban areas (78.0%), while 22.0% were based in rural settings. Most respondents were working in hospitals (81.1%), whereas 18.9% were employed in community based settings. Regarding professional experience, nearly three-quarters of the respondents (72.5%) had 1–5 years of experience, followed by 17.1% with 6–10 years of experience and 10.4% with more than 10 years of experience. The number of prescriptions handled per day varied among respondents. The

largest proportion reported managing 21–40 prescriptions daily (38.6%), followed by 41–60 prescriptions (22.5%), 10–20 prescriptions (20.7%), and more than 60 prescriptions per day (18.1%).

TABLE 4.1: Sociodemographic characteristics of HCPs (n=386)

Sociodemographic Characteristics	n (%)
Age	
25-35	319 (82.6)
35-45	49 (12.7)
>46	18 (4.7)
Gender	
Male	199 (51.6)
Female	187 (48.4)
Qualification	
Diploma	6 (1.6)
Bachelor's Degree	286 (74.1)
Master's Degree	94 (24.4)
Profession	
Medical Doctor	249 (64.5)
Pharmacist	101 (26.2)
Paramedic	33 (8.5)
Dentist	3 (0.8)
Work Setting	
Government Sector	226 (58.5)
Private Sector	160 (41.5)
Work Area	
Urban	301 (78)
Rural	85 (22)
Location	
Hospital	313 (81.1)
Community Setting	73 (18.9)

Table 4.1 continued from previous page

Sociodemographic Characteristics	n (%)
Experience	
1-5 years	280 (72.5)
6-10 years	66 (17.1)
More than 10 years	40 (10.4)
Prescriptions per day	
10-20	80 (20.7)
21-40	149 (38.6)
41-60	87 (22.5)
More than 60	70 (18.1)

4.2 Knowledge Levels about Pharmacovigilance Reporting

As presented in table 4.2, the respondents demonstrated a generally satisfactory level of knowledge regarding PV and ADR reporting. Most respondents (76.7%) correctly identified PV as the science concerned with the detection, assessment, understanding, and prevention of adverse effects of medicines. However, a small proportion of respondents incorrectly associated PV with monitoring drug prices (10.1%) or dispensing medications safely (4.9%), while 8.3% reported that they were not sure about its definition. Regarding ADR reporting procedures, most participants (70.5%) correctly stated that ADRs should be reported through an official ADR reporting form or online reporting system. Nevertheless, some respondents had misconceptions regarding the reporting process, with 13.5% believing that ADRs should be reported verbally to colleagues only, 6.5% indicating that formal reporting was not required, and 9.6% reporting that they were unsure of the correct reporting procedure.

When asked about responsibility for ADR reporting, more than half of the respondents (58.8%) correctly recognized that pharmacists, physicians, patients, and caregivers all have a role in reporting adverse drug reactions. In contrast, 21.5% believed that ADR reporting should be restricted to healthcare professionals only, while 16.6% and 3.1% considered pharmacists/physicians only and patients/caregivers only, respectively, to be responsible for reporting ADRs.

Participants were also assessed regarding their understanding of the scope of pharmacovigilance. Approximately half of the respondents (51.0%) correctly identified that PV covers drug related problems, herbal medicine related problems, and issues related to blood and blood products. However, 37.8% believed that PV is limited only to drug related problems. Awareness of PV systems at the workplace was relatively low. Only 30.1% of participants reported the presence of a pharmacovigilance programme or system in their workplace. More than one-third (36.0%) stated that no such programme existed, while 33.9% were unaware of whether a pharmacovigilance system was available in their institution. With regard to knowledge of the National Pharmacovigilance Programme in Pakistan, 63.7% of respondents correctly identified DRAP as the governing organization. Only 21.0% of respondents reported having received formal education or training related to pharmacovigilance or ADR reporting, whereas the majority (79.0%) had never received such training.

TABLE 4.2: Knowledge related questions and% of correct responses

Knowledge Part 1	Frequency (Percentage) n (%)
Pharmacovigilance	
Detection, assessment, understanding, and prevention of adverse effects of medicines	296 (76.7)
Monitoring drug prices	39 (10.1)
Dispensing medications safely	19 (4.9)
Not sure	32 (8.3)
How an ADR should be reported?	

Table 4.2 continued from previous page

Knowledge Part 1	Frequency (Percentage) n (%)
Through an official ADR reporting form/online system	272 (70.5)
Verbally to colleagues only	52 (13.5)
No formal reporting is required	25 (6.5)
Not sure	37 (9.6)
Who should report ADR?	
Pharmacist/Physicians only	64 (16.6)
Patient/Patient care giver only	12 (3.1)
Healthcare professionals only	83 (21.5)
All of the above	227 (58.8)
PV mainly deals with?	
Drug related problems only	146 (37.8)
Herbal medicine related problems only	29 (7.5)
Blood and blood product related problems only	14 (3.6)
All of the above	197 (51.0)
Is there any pharmacovigilance programme at your working premises?	
Yes	116 (30.1)
No	139 (36.0)
Do not know	131 (33.9)
Does Pakistan has NPP? If yes, which organization governs it?	
MoNHSRC	51 (13.2)
DRAP	246 (63.7)
PMC	34 (8.8)
WHO	55 (14.2)
Formal training or education related to PV or ADR reporting?	

Table 4.2 continued from previous page

Knowledge Part 1	Frequency (Percentage) n (%)
Yes	81 (21.0)
No	305 (79.0)

PV = Pharmacovigilance, ADR = Adverse drug reaction, NPP = National pharmacovigilance programme, MoNHSRC = Ministry of National Health Services, Regulations and Coordination, DRAP = Drug Regulatory Authority of Pakistan, PMC = Pakistan Medical Commission, WHO = World Health Organization

4.3 Knowledge Scores toward Pharmacovigilance Reporting

As presented in Table 4.3, most respondents demonstrated adequate knowledge of pharmacovigilance concepts.

More than two-thirds of participants agreed or strongly agreed that an ADR is any harmful or unintended response to a drug at normal doses (72.3%) and that ADRs are different from side effects (69.9%).

Likewise, 71.2% agreed or strongly agreed that the primary objectives of PV include monitoring drug safety, collecting and analyzing ADR reports, and preventing medicine related harm.

However, only 32.6% of respondents agreed or strongly agreed that they were aware of the guidelines, rules, and regulations of the Pharmacovigilance Centre in Pakistan, while 37.8% reported a neutral response.

The median scores for the first three knowledge statements were 4 (IQR = 2), whereas awareness of national pharmacovigilance guidelines had a median score of 3 (IQR = 2).

TABLE 4.3: Knowledge statements level of agreement

Statements	n (%)	Strongly Dis-	Disagree	Neutral	Agree	Strongly Agree	M (IQR)
An ADR is any harmful or unintended response to a drug at normal doses	31 (8.0)	27 (7.0)	49 (12.7)	131 (33)	148 (38.3)	4 (2)	
ADRs are different from side effects	17 (4.4)	38 (9.8)	61 (15.8)	126 (32.6)	144 (37.3)	4 (2)	
pharmacovigilance include monitoring drug safety, collecting and analyzing ADR reports,	18 (4.7)	14 (3.6)	79 (20.5)	132 (34.2)	143 (37.0)	4 (2)	
I am aware of the guidelines, rules and regulations of the PV Centre in Pakistan	65 (16.8)	49 (12.7)	146 (37.8)	71 (18.4)	55 (14.2)	3 (2)	

ADR = Adverse drug reaction, PV = Pharmacovigilance

4.4 Awareness Level towards Pharmacovigilance

As presented in Table 4.4, respondents demonstrated varying levels of awareness regarding PV and ADR reporting. Awareness of ADRs was relatively high, with 70.5% of respondents reporting that they were very or extremely aware of ADRs. In comparison, less than half of the respondents (47.4%) reported being very or extremely aware of the concept of PV, while 29.5% indicated a moderate level of awareness. The median scores for awareness of ADRs and PV were 4 (IQR = 2) and 3 (IQR = 1), respectively.

TABLE 4.4: Awareness levels towards pharmacovigilance

Level of awareness (%)	Not Aware at all	Slightly Aware	Mod Aware	Very Aware	Extremely Aware	M (IQR)
Aware of the concept of PV	18 (4.7)	71 (18.4)	114 (29.5)	98 (25.4)	85 (22.0)	3 (1)
Aware of ADRs	12 (3.1)	32 (8.3)	70 (18.1)	159 (41.2)	113 (29.3)	4 (2)
Aware of how to complete an ADR reporting form	64 (16.6)	73 (18.9)	129 (33.4)	55 (14.2)	65 (16.8)	3 (2)
Aware of the PV contact points in my hospital/-community setting	130 (33.7)	65 (16.8)	86 (22.3)	47 (12.2)	58 (15.0)	2 (3)

ADRs = Adverse drug reactions, PV = Pharmacovigilance, M = Median, IQR = Interquartile range

Awareness related to ADR reporting procedures and national pharmacovigilance regulations was comparatively lower. Only 31.0% of respondents reported being very or extremely aware of how to complete an ADR reporting form, whereas 35.5% reported being not aware at all or only slightly aware.

Similarly, only 27.2% of respondents reported being very or extremely aware of the guidelines, rules, and regulations of the Pharmacovigilance Centre in Pakistan, while 50.5% reported being not aware at all or only slightly aware of these regulations.

The median scores for awareness of ADR reporting forms and PV regulations were 3 (IQR = 2) and 2 (IQR = 3), respectively.

4.5 Attitude towards Pharmacovigilance Reporting

As presented in Table 4.5, most respondents generally demonstrated positive attitudes toward pharmacovigilance and ADR reporting. Approximately three-quarters of participants agreed or strongly agreed that PV is an important part of routine healthcare practice (80.3%) and that reporting ADRs is a professional responsibility of HCPs (83.7%).

Both statements had a median score of 4, with IQR of 1. Most respondents also agreed or strongly agreed that suspected ADRs related to over-the-counter (OTC) medicines should be reported (81.3%) and that reporting ADRs helps improve their understanding of medicine related safety issues in clinical practice (81.7%). Similarly, 86.5% of respondents agreed or strongly agreed that ADR reporting improves the quality of care and enhances patient trust. These statements had median scores of 4 (IQR = 1).

Regarding reporting behavior, 72.3% of respondents agreed or strongly agreed that they should report an ADR only when they were certain that it was caused by a medicine.

Furthermore, 67.4%, 70.5%, and 68.4% of respondents agreed or strongly agreed that they were more likely to report an ADR if it resulted in hospitalization, was life threatening, or caused long term disability or incapacity, respectively. The median score for each of these statements was 4 (IQR = 2), except for certainty of causality, which had a median score of 4 (IQR = 1.25). Additionally, 75.7% of respondents agreed or strongly agreed that it is important to consult a physician before submitting an ADR report. This statement had a median score of 4 (IQR = 1).

TABLE 4.5: Attitude towards pharmacovigilance reporting

Level of agreement n (%)	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	M(IQR)
Pharmacovigilance is an important part of routine healthcare practice	30 (7.8)	13 (3.4)	33 (8.5)	154 (39.9)	156 (40.4)	4 (1)
Reporting ADRs is a professional responsibility	12 (3.1)	6 (1.6)	45 (11.7)	149 (38.6)	174 (45.1)	4 (1)
I should only report an ADR when I am certain that it is caused by the medicine	18 (4.7)	20 (5.2)	69 (17.9)	183 (47.4)	96 (24.9)	4 (1.25)
Suspected ADRs related to OTC medicines should also be reported	9 (2.3)	9 (2.3)	54 (14.0)	171 (44.3)	143 (37.0)	4 (1)
Report an ADR if it results in hospitalization	26 (6.7)	44 (11.4)	56 (14.5)	157 (40.7)	103 (26.7)	4 (2)

Table 4.5 continued from previous page

Level of agreement n (%)	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	M(IQR)
Report an ADR if it is life threatening	32 (8.3)	24 (6.2)	58 (15.0)	133 (34.5)	139 (36.0)	4 (2)
Report an ADR if it causes long term disability	33 (8.5)	28 (7.3)	61 (15.8)	132 (34.2)	132 (34.2)	4 (2)
Reporting ADRs helps improve my understanding of medicine re- lated safety issues in practice	5 (1.3)	7 (1.8)	59 (15.3)	160 (41.5)	155 (40.2)	4 (1)
Reporting ADRs improves quality of care and patient trust	4 (1.0)	15 (3.9)	33 (8.5)	169 (43.8)	165 (42.7)	4 (1)
It is important to consult a physician before submitting an ADR report	6 (1.6)	23 (6.0)	65 (16.8)	169 (43.8)	123 (31.9)	4 (1)

ADR = Adverse drug reaction, OTC = Over-the-counter, M = Median, IQR = Interquartile range

4.6 Practice toward Pharmacovilance Reporting

4.6.1 Exposure to ADR Reporting Form

Figure 4.1 illustrates, the participants demonstrated limited exposure to the reporting form, with only 139 (36.0%) respondents reporting that they had seen an official ADR reporting form, whereas 247 (64.0%) had never seen one.

FIGURE 4.1: Healthcare providers exposure to official ADR reporting form

4.6.2 Familiarity with Methods of ADR Reporting

Figure 4.2 illustrates, the participants demonstrated limited familiarity with the methods used for submitting ADR reports, with only 146 (37.8%) respondents reporting that they were familiar, whereas 240 (62.2%) indicated that they were not familiar with the ADR reporting process.

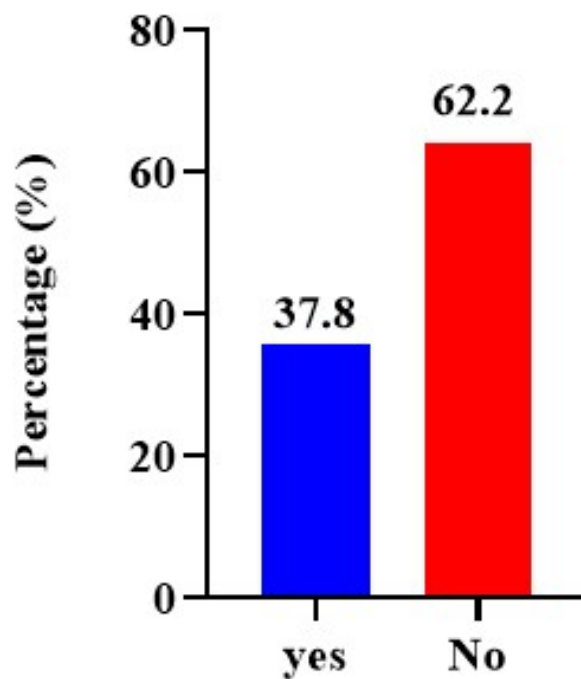


FIGURE 4.2: Healthcare providers familiarity with methods for ADR reporting

4.6.3 Reported ADR through Official Pharmacovigilance System

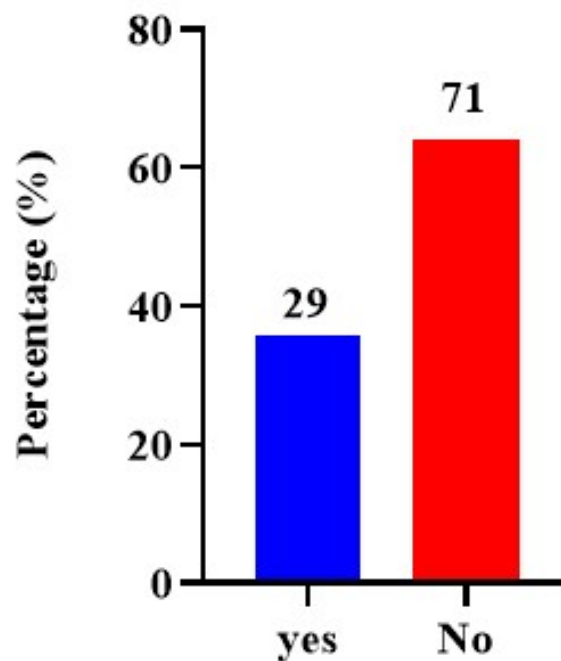


FIGURE 4.3: Reporting of ADRs through official pharmacovigilance system

Figure 4.3 illustrates, the participants demonstrated limited reporting experience, with only 112 (29.0%) respondents reporting that they had submitted a suspected ADR through an official pharmacovigilance system, whereas 274 (71.0%) had never submitted an ADR report.

4.6.4 Ever Reported Suspected ADRs during Practice

Figure 4.4 illustrates, the participants demonstrated a relatively high level of exposure to suspected ADRs, with 268 (69.4%) respondents reporting that they had identified a suspected ADR during their clinical practice, whereas 118 (30.6%) had not encountered a suspected ADR.

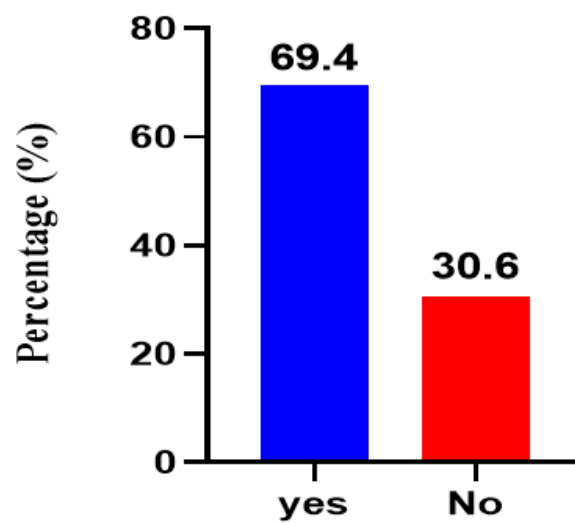


FIGURE 4.4: Identification of suspected ADRs during their clinical practice

4.6.5 Ever Read Educational Material Related to ADR Prevention

Ever read educational material related to ADR prevention Figure 4.5 illustrates, the participants demonstrated limited educational exposure, with only 142 (36.8%) respondents reporting that they had read articles or educational materials related to the prevention of ADRs, whereas 244 (63.2%) had not.

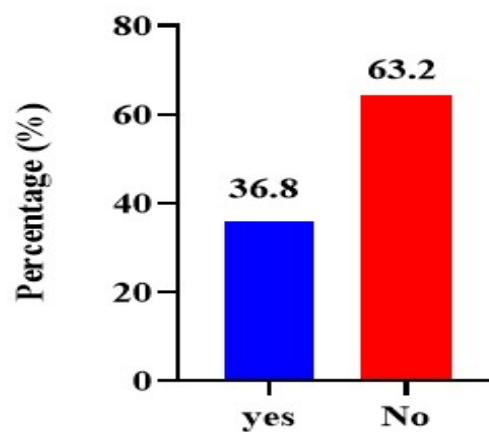


FIGURE 4.5: Healthcare providers engagement with educational materials on prevention of ADRs

4.6.6 ADRs Properly Documented at Workplace

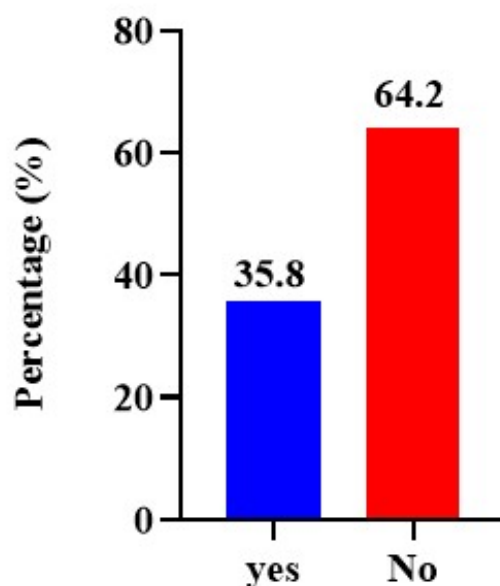


FIGURE 4.6: Practice regarding proper documentation of ADRs at their workplace

Figure 4.6 illustrates, the participants reported inadequate ADR documentation practices, with only 138 (35.8%) respondents indicating that ADRs were properly documented and recorded at their workplace, whereas 248 (64.2%) reported that such practices were not adequately implemented.

4.7 Barriers toward Pharmacovigilance Reporting

As presented in Table 4.6, several barriers to ADR reporting were identified among the respondents. More than half of the participants (53.4%) agreed or strongly agreed that heavy workload limited their ability to report ADRs. This item had the highest median score of 4 (IQR = 1).

Nearly half of the respondents (46.6%) agreed or strongly agreed that they had insufficient training to identify and report ADRs, while 44.6% agreed or strongly agreed that ADR reporting forms or systems were not readily available in their workplace.

TABLE 4.6: Barriers toward ADR Reporting

Level of agreement n (%)	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	M (IQR)
I do not know how to report ADRs	88 (22.8)	80 (20.7)	71 (18.4)	96 (24.9)	51 (13.2)	3 (2)
ADR reporting forms or systems are not easily available in my Workplace	48 (12.4)	55 (14.2)	111 (28.8)	103 (26.7)	69 (17.9)	3 (2)
The procedure for reporting ADRs is compli- cated.	37 (9.6)	73 (18.9)	150 (38.9)	85 (22.0)	41 (10.6)	3 (2)
Reporting ADRs takes too much time.	41 (10.6)	55 (14.2)	133 (34.5)	105 (27.2)	52 (13.5)	3 (1.25)
I have insufficient training to identify and report ADRs	50 (13.0)	54 (14.0)	102 (26.4)	117 (30.3)	63 (16.3)	3 (2)
Fear of legal consequences discourages me from reporting ADRs	64 (16.6)	69 (17.9)	111 (28.8)	92 (23.8)	50 (13.0)	3 (2)
Heavy workload limits my ability to report ADRs	38 (9.8)	48 (12.4)	94 (24.4)	125 (32.4)	81 (21.0)	4 (1)
Reporting ADRs may negatively affect my pro- fessional image.	60 (15.5)	102 (26.4)	83 (21.5)	89 (23.1)	52 (13.5)	3 (2)
Not motivated to report ADRs	60 (15.5)	96 (24.9)	89 (23.1)	79 (20.5)	62 (16.1)	3 (2)

ADRs = Adverse drug reactions, M = Median, IQR = Interquartile range

In addition, 38.1% of respondents agreed or strongly agreed that they did not know how to report an ADR. The median score for these statements was 3 (IQR = 2). Approximately 40.7% of respondents agreed or strongly agreed that ADR reporting takes too much time, whereas 32.6% perceived the reporting procedure as complicated. These statements had median scores of 3, with interquartile ranges of 1.25 and 2, respectively. Concerns regarding potential legal consequences and professional image were reported by 36.8% and 36.6% of respondents, respectively, who agreed or strongly agreed that these factors discouraged ADR reporting. Likewise, 36.6% of respondents agreed or strongly agreed that they were not motivated to report ADRs. The median score for each of these items was 3 (IQR = 2).

4.8 Facilitators towards Pharmacovigilance Reporting

As presented in Table 4.7, although P value is not significant but descriptively several facilitators of ADR reporting were identified among the respondents. The majority of participants agreed or strongly agreed that clear guidelines on how and where to report ADRs would improve reporting practices (87.3%), while 85.5% agreed or strongly agreed that the availability of a simple and user friendly digital ADR reporting system would increase ADR reporting. Both statements had a median score of 5 (IQR = 1).

Educational support was also perceived as an important facilitator, with 84.0% of respondents agreeing or strongly agreeing that regular training or workshops on pharmacovigilance are needed to enhance ADR reporting. This statement had a median score of 5 (IQR = 1).

Approximately 83.4% of respondents agreed or strongly agreed that receiving feedback and incentives from the pharmacovigilance center would motivate them to report ADRs.

Furthermore, 85.3% agreed or strongly agreed that including ADR reporting as part of professional duties would encourage reporting, while 88.3% agreed or strongly agreed that support from hospital administration and colleagues would facilitate ADR reporting. These statements had median scores of 4 (IQR = 1).

TABLE 4.7: Facilitators towards ADR reporting

Level of agree- ment n (%)	Strongly Dis- agree	Disagree	Neutral	Agree	Strongly Agree	M (IQR)
Regular training or workshops are needed for PV	13 (3.4)	5 (1.3)	44 (11.4)	125 (32.4)	199 (51.6)	5 (1)
Clear guidelines are needed on how and where to report ADRs, would improve reporting	5 (1.3)	5 (1.3)	39 (10.1)	134 (34.7)	203 (52.6)	5 (1)
User friendly digital ADR reporting system would increase reporting	5 (1.3)	10 (2.6)	41 (10.6)	129 (33.4)	201 (52.1)	5 (1)
Receiving feedback and incentives from the pharmacovigilance Center would motivate me to report ADRs.	4 (1.0)	12 (3.1)	48 (12.4)	143 (37.0)	179 (46.4)	4 (1)

Table 4.7 continued from previous page

Level of agree- ment n (%)		Strongly Dis- agree	Disagree	Neutral	Agree	Strongly Agree	M (IQR)
Including ADR reporting as part of profes- sional duties would encourage reporting		8 (2.1)	8 (2.1)	41 (10.6)	147 (38.1)	182 (47.2)	4 (1)
Support from hospital admin- istration and colleagues would encourage ADR reporting		5 (1.3)	5 (1.3)	35 (9.1)	151 (39.1)	190 (49.2)	4 (1)

ADR = Adverse drug reaction, PV = pharmacovigilance, M = Median, IQR = Interquartile range

4.9 Association between Sociodemographic Characteristics and Knowledge Score

As presented in Table 4.8, the Mann–Whitney U and Kruskal–Wallis tests were performed to examine differences in knowledge scores across respondents' demographic and professional characteristics. Statistically significant differences in knowledge scores were observed according to healthcare profession ($p < 0.001$) and work setting ($p < 0.001$). Among the professional groups, pharmacists had the highest mean rank (242.72), followed by paramedics (180.45), medical doctors (176.12), and dentists (122.33). Respondents working in the private sector demonstrated a higher mean rank (216.91) than those working in the government sector (176.92). No statistically significant differences in knowledge scores were found with respect to age ($p = 0.512$), gender ($p = 0.209$), highest qualification ($p = 0.963$), work area ($p = 0.810$), work location ($p = 0.193$),

years of professional experience ($p = 0.647$), or number of prescriptions handled per day ($p = 0.150$).

The highest mean rank for age was observed among respondents aged 25–35 years (195.67), while respondents aged 35–45 years had the lowest mean rank (178.61). Male respondents demonstrated a higher mean rank (199.48) than female respondents (187.13). With regard to educational qualification, diploma holders had the highest mean rank (202.25), followed by respondents holding a master’s degree (194.75) and a bachelor’s degree (192.91). Respondents working in community settings had a higher mean rank (206.72) than those working in hospitals (190.42). Participants with 6–10 years of experience demonstrated the highest mean rank (203.39), whereas those handling 21–40 prescriptions per day had the highest mean rank (203.01) among prescription categories.

TABLE 4.8: Association between sociodemographic characteristics and knowledge score

Variables	Mean Rank	P value
Age		0.512
25-35	195.67	
35-45	178.61	
>46	195.50	
Gender		0.209
Male	199.48	
Female	187.13	
Highest Qualification		0.963
Diploma	202.25	
Bachelor’s Degree	192.91	
Master’s Degree	194.75	
Healthcare Profession		0.000
Medical Doctor	176.12	
Pharmacist	242.72	
Paramedic	180.45	
Dentist	122.33	
Work Setting		0.000
Government Sector	176.92	
Private Sector	216.91	
Work Area		0.810
Urban	194.15	
Rural	191.21	

Table 4.8 continued from previous page

Variables	Mean Rank	P value
Work Location		0.193
Hospital	190.42	
Community Setting	206.72	
Experience		0.647
1-5 years	191.84	
6-10 years	203.39	
More than 10 years	188.81	
Prescriptions per day		0.150
10-20	181.38	
21-40	203.01	
41-60	201.49	
More than 60	177.16	

4.10 Association between Sociodemographic Characteristics and awareness Level Score

As presented in Table 4.9, the Mann–Whitney U and Kruskal–Wallis tests were performed to assess differences in awareness scores across respondents' demographic and professional characteristics. Statistically significant differences in awareness scores were observed according to healthcare profession ($p < 0.001$), work setting ($p < 0.001$), and work location ($p = 0.009$). Among the professional groups, pharmacists had the highest mean rank (255.78), followed by paramedics (205.79), medical doctors (167.38), and dentists (129.67). Respondents employed in the private sector demonstrated a higher mean rank (229.46) than those working in the government sector (168.04). Similarly, participants working in community settings had a higher mean rank (222.03) compared with those working in hospitals (186.85).

No statistically significant differences in awareness scores were found with respect to age ($p = 0.979$), gender ($p = 0.052$), highest qualification ($p = 0.569$), work area ($p = 0.981$), years of professional experience ($p = 0.394$), or number of prescriptions handled per day ($p = 0.218$).

The highest mean rank for age was observed among respondents aged above 46 years (197.58), followed by those aged 25–35 years (193.54) and 36–45 years (191.74). Male respondents demonstrated a higher mean rank (203.38) than female respondents (182.98). Regarding educational

qualifications, respondents holding a bachelor's degree had the highest mean rank (194.31), followed by those with a master's degree (193.88) and diploma holders (149.08). Participants with 1–5 years of professional experience demonstrated the highest mean rank (197.21), whereas respondents handling 41–60 prescriptions per day had the highest mean rank (210.07) among the prescription categories.

TABLE 4.9: Association between sociodemographic characteristics and awareness level

Variables	Mean Rank	P value
Age		0.979
25-35	193.54	
35-45	191.74	
>46	197.58	
Gender		0.052
Male	203.38	
Female	182.98	
Highest Qualification		0.569
Diploma	149.08	
Bachelor's Degree	194.31	
Master's Degree	193.88	
Healthcare Profession		0.000
Medical Doctor	167.38	
Pharmacist	255.78	
Paramedic	205.79	
Dentist	129.67	
Work Setting		0.000
Government Sector	168.04	
Private Sector	229.46	
Work Area		0.981
Urban	193.44	
Rural	193.73	
Work Location		0.009
Hospital	186.85	
Community Setting	222.03	
Experience		0.394
1-5 years	197.21	
6-10 years	177.93	
More than 10 years	193.23	
Prescriptions per day		0.218
10-20	181.99	
21-40	196.12	

Table 4.9 continued from previous page

Variables	Mean Rank	P value
41-60	210.07	
More than 60	180.49	

4.11 Association between Sociodemographic Characteristics and Attitude Score

As presented in Table 4.10, the Mann–Whitney U and Kruskal–Wallis tests were performed to examine differences in attitude scores across respondents' demographic and professional characteristics. A statistically significant difference in attitude scores was observed according to the number of prescriptions handled per day ($p = 0.028$). Respondents handling 41–60 prescriptions per day demonstrated the highest mean rank (217.90), followed by those handling 21–40 prescriptions (193.97), more than 60 prescriptions (180.95), and 10–20 prescriptions per day (177.08).

No statistically significant differences in attitude scores were found with respect to age ($p = 0.349$), gender ($p = 0.647$), highest qualification ($p = 0.282$), healthcare profession ($p = 0.210$), work setting ($p = 0.721$), work area ($p = 0.102$), work location ($p = 0.499$), or years of professional experience ($p = 0.889$).

The highest mean rank for age was observed among respondents aged above 46 years (198.25), followed by those aged 25–35 years (196.10) and 36–45 years (174.85). Male respondents demonstrated a slightly higher mean rank (195.68) than female respondents (191.18). Regarding educational qualifications, respondents holding a master's degree had the highest mean rank (204.20), followed by those with a bachelor's degree (190.88) and diploma holders (150.67).

Among healthcare professions, pharmacists demonstrated the highest mean rank (208.12), followed by medical doctors (190.74), paramedics (173.48), and dentists (150.67). Respondents employed in the private sector had a slightly higher mean rank (195.59) than those working in the government sector (192.02).

Participants working in community settings demonstrated a higher mean rank (200.38) compared with those working in hospitals (191.89). With respect to professional experience, respondents with 1–5 years of experience had the highest mean rank (194.63), followed by those with 6–10 years (192.79) and more than 10 years of experience (186.80).

TABLE 4.10: Association between sociodemographic characteristics and attitude score

Variables	Mean Rank	P value
Age		0.349
25-35	196.10	
35-45	174.85	
>46	198.25	
Gender		0.647
Male	195.68	
Female	191.18	
Highest Qualification		0.282
Diploma	150.67	
Bachelor's Degree	190.88	
Master's Degree	204.20	
Healthcare Profession		0.210
Medical Doctor	190.74	
Pharmacist	208.12	
Paramedic	173.48	
Dentist	150.67	
Work Setting		0.721
Government Sector	192.02	
Private Sector	195.59	
Work Area		0.102
Urban	197.77	
Rural	178.38	
Work Location		0.499
Hospital	191.89	
Community Setting	200.38	
Experience		0.889
1-5 years	194.63	
6-10 years	192.79	
More than 10 years	186.80	
prescriptions per day		0.028

Table 4.10 continued from previous page

Variables	Mean Rank	P value
10-20	177.08	
21-40	193.97	
41-60	217.90	
More than 60	180.95	

4.12 Association between Demographic Characteristics and Barriers Score

As presented in Table 4.11, the Mann–Whitney U and Kruskal–Wallis tests were performed to examine differences in barrier scores across respondents' demographic and professional characteristics. Statistically significant differences in barrier scores were observed according to healthcare profession ($p < 0.001$), work setting ($p < 0.001$), and years of professional experience ($p = 0.004$). Among the professional groups, medical doctors demonstrated the highest mean rank (217.45), followed by dentists (204.00), paramedics (183.67), and pharmacists (137.37).

Respondents employed in the government sector had a higher mean rank (219.63) than those working in the private sector (156.60).

With respect to professional experience, respondents with 6–10 years of experience demonstrated the highest mean rank (229.48), followed by those with more than 10 years of experience (201.64) and those with 1–5 years of experience (183.86).

No statistically significant differences in barrier scores were found according to age ($p = 0.203$), gender ($p = 0.276$), highest qualification ($p = 0.621$), work area ($p = 0.497$), work location ($p = 0.141$), or number of prescriptions handled per day ($p = 0.917$).

The highest mean rank for age was observed among respondents aged above 46 years (225.83), followed by those aged 35–45 years (207.20) and 25–35 years (189.57).

Female respondents demonstrated a higher mean rank (199.32) than male respondents (188.04). Regarding educational qualifications, respondents holding a bachelor's degree had the highest mean rank (196.45), followed by diploma holders (178.67) and respondents with a master's degree (185.48). Respondents working in hospital settings demonstrated a higher mean rank (197.18) than those working in community settings (177.72).

TABLE 4.11: Association between demographic characteristics and barriers score

Variables	Mean Rank	P value
Age		0.203
25-35	189.57	
35-45	207.20	
>46	225.83	
Gender		0.276
Male	188.04	
Female	199.32	
Highest Qualification		0.621
Diploma	178.67	
Bachelor's Degree	196.45	
Master's Degree	185.48	
Healthcare Profession		0.000
Medical Doctor	217.45	
Pharmacist	137.37	
Paramedic	183.67	
Dentist	204.00	
Work Setting		0.000
Government Sector	219.63	
Private Sector	156.60	
Work Area		0.497
Urban	191.63	
Rural	200.11	
Work Location		0.141
Hospital	197.18	
Community Setting	177.72	
Experience		0.004
1-5 years	183.86	
6-10 years	229.48	
More than 10 years	201.64	
Prescriptions per day		0.917

Table 4.11 continued from previous page

Variables	Mean Rank	P value
10-20	189.52	
21-40	195.48	
41-60	189.48	
More than 60	198.83	

4.13 Association between Demographic Characteristics and Facilitators Score

As presented in Table 4.12, the Mann–Whitney U and Kruskal–Wallis tests were performed to examine differences in facilitator scores across respondents' demographic and professional characteristics. A statistically significant difference in facilitator scores was observed according to the number of prescriptions handled per day ($p = 0.036$). Respondents handling 41–60 prescriptions per day demonstrated the highest mean rank (206.72), followed by those handling 21–40 prescriptions (197.95), more than 60 prescriptions (191.05), and 10–20 prescriptions per day (172.98). No statistically significant differences in facilitator scores were found with respect to age ($p = 0.213$), gender ($p = 0.847$), highest qualification ($p = 0.179$), healthcare profession ($p = 0.577$), work setting ($p = 0.538$), work area ($p = 0.107$), work location ($p = 0.269$), or years of professional experience ($p = 0.098$).

The highest mean rank for age was observed among respondents aged 35–45 years (204.98), followed by those aged 25–35 years (193.21) and above 46 years (167.31). Female respondents demonstrated a slightly higher mean rank (194.29) than male respondents (192.76). Regarding educational qualifications, respondents holding a master's degree had the highest mean rank (206.23), followed by diploma holders (201.25) and bachelor's degree holders (189.15).

Among healthcare professions, medical doctors demonstrated the highest mean rank (197.33), followed by paramedics (191.39), pharmacists (185.46), and dentists (169.50). Respondents employed in the government sector had a slightly higher mean rank (195.56) than those working in the private sector (190.59).

Participants working in hospital settings demonstrated a higher mean rank (195.62) compared with those working in community settings (184.40). Respondents with 6–10 years of professional experience demonstrated the highest mean rank (212.20), followed by those with more than 10 years (192.93) and 1–5 years of experience (189.18).

TABLE 4.12: Association between demographic characteristics and facilitators score

Variables	Mean Rank	P value
Age		0.213
25-35	193.21	
35-45	204.98	
>46	167.31	
Gender		0.847
Male	192.76	
Female	194.29	
Highest Qualification		0.179
Diploma	201.25	
Bachelor's Degree	189.15	
Master's Degree	206.23	
Healthcare Profession		0.577
Medical Doctor	197.33	
Pharmacist	185.46	
Paramedic	191.39	
Dentist	169.50	
Work Setting		0.538
Government Sector	195.56	
Private Sector	190.59	
Work Area		0.107
Urban	196.90	
Rural	181.45	
Work Location		0.269
Hospital	195.62	
Community Setting	184.40	
Experience		0.098
1-5 years	189.18	
6-10 years	212.20	

Table 4.12 continued from previous page

Variables	Mean Rank	P value
More than 10 years	192.93	
Prescriptions per day		0.036
10-20	172.98	
21-40	197.95	
41-60	206.72	
More than 60	191.05	

4.14 Association between Sociodemographic Characteristics with Participants Knowledge of Pharmacovigilance

Table 4.13 presents the association between participants sociodemographic characteristics and their responses to the question regarding the definition of pharmacovigilance. The chi-square test and Fisher's exact test were applied. Significant associations were observed for age ($p = 0.049$), profession ($p = 0.017$), and work setting ($p = 0.024$).

Among respondents who correctly identified pharmacovigilance as the detection, assessment, understanding, and prevention of adverse effects of medicines, the majority were aged 25–35 years (79.4%), followed by those aged 36–45 years (15.2%) and above 46 years (5.4%).

Significant differences in responses were observed across age groups. Profession was also significantly associated with participants' responses. Among those providing the correct definition, doctors constituted the largest proportion (61.8%), followed by pharmacists (30.4%), paramedics (6.8%), and dentists (1.0%).

Variations in responses among professional groups were statistically significant. A significant association was additionally found between work setting and knowledge of pharmacovigilance.

More than half of respondents who correctly identified the definition were employed in the government sector (54.7%), while 45.3% were employed in the private sector.

No statistically significant associations were observed between knowledge of pharmacovigilance and gender ($p = 0.156$), qualification ($p = 0.065$), or years of professional experience ($p = 0.112$).

TABLE 4.13: Association between sociodemographic characteristics and participants knowledge of pharmacovigilance

What is Pharmacovigilance?					
Variable	Correct Definition n (%)	Monitoring drug prices n (%)	Dispensing medica- tions safely n (%)	Not sure (%)	P value
	n (%)	n (%)	n (%)	n (%)	
Age (Years)					0.049
25-35	235 (79.4)	38 (97.4)	19 (100.0)	27 (84.4)	
36-45	45 (15.2)	1 (2.6)	0 (0.0)	3 (9.4)	
>46	16 (5.4)	0 (0.0)	0 (0.0)	2 (6.3)	
Gender					0.156
Male	161(54.4)	18(46.2)	6(31.6)	14(43.8)	
Female	135(45.6)	21(53.8)	13(68.4)	18(56.3)	
Qualification					0.065
Diploma	4(1.4)	0(0.0)	0(0.0)	2(6.3)	
Bachelor's Degree	212(71.6)	34(87.2)	17(89.5)	23(71.9)	
Master's De- gree	80(27.0)	5(12.8)	2(10.5)	7(21.9)	
Profession					0.017
Doctor	183(61.8)	29(74.4)	16(84.2)	21(65.6)	
Pharmacist	90(30.4)	6(15.4)	1(5.3)	4(12.5)	
Paramedic	20(6.8)	4(10.3)	2(10.5)	7(21.9)	
Dentist	3(1.0)	0(0.0)	0(0.0)	0(0.0)	
Work Set- ting					0.024
Government Sector	162(54.7)	27(69.2)	16(84.2)	21(65.6)	

Table 4.13 continued from previous page

Variable	Correct Definition n (%)	Monitoring drug prices n (%)	Dispensing medica- tions safely n (%)	Not sure n (%)	P value
Private Sec- tor	134(45.3)	12(30.8)	3(15.8)	11(34.4)	
Experience					0.112
1-5 years	204(68.9)	33(84.6)	16(84.2)	27(84.4)	
6-10 years	55(18.6)	5(12.8)	3(15.8)	3(9.4)	
More than 10 years	37(12.5)	1(2.6)	0(0.0)	2(6.3)	

4.15 Association between Sociodemographic Characteristics and Participants Knowledge of ADR Reporting

Table 4.14 presents the association between sociodemographic characteristics and participants' knowledge regarding appropriate methods of adverse drug reaction (ADR) reporting. The chi-square test and Fisher's exact test were applied. Significant associations were observed for age ($p = 0.005$), profession ($p = 0.001$), and work setting ($p = 0.001$), while gender ($p = 0.287$) and qualification ($p = 0.223$) were not statistically significant.

Regarding age, the majority of respondents who correctly identified that ADRs should be reported through an official ADR reporting form or online system were aged 25–35 years (84.6%), followed by those aged 36–45 years (12.1%) and above 46 years (3.3%). Significant differences in responses were observed across age groups. Profession was strongly associated with knowledge of ADR reporting methods. Among respondents selecting the correct reporting method, doctors constituted the largest proportion (61.4%), followed by pharmacists (31.6%), paramedics (6.3%), and dentists (0.7%). In contrast, higher proportions of doctors were observed among those who reported ADRs verbally to colleagues only (84.6%).

Work setting also showed a statistically significant association with responses. Among participants selecting the correct reporting method, 52.6% were from the government sector and 47.4%

from the private sector. In contrast, a higher proportion of government sector participants was observed among those reporting ADRs verbally only (80.8%). Experience was significantly associated with ADR reporting knowledge ($p < 0.001$). The majority of correct responses were reported by participants with 1–5 years of experience (73.5%), followed by those with 6–10 years (18.4%) and more than 10 years (8.1%).

TABLE 4.14: Association between sociodemographic characteristics and participants knowledge of ADR reporting

How should an ADR be reported?					
Variable	Through an official ADR reporting system n (%)	Verbally to colleagues only n (%)	No formal reporting is required n (%)	Not sure	P value
Age (Years)					0.005
25-35	230(84.6)	35(67.3)	22(88.0)	32(86.5)	
36-45	33(12.1)	9(17.3)	2(8.0)	5(13.5)	
>46	9(3.3)	8(15.4)	1(4.0)	0(0.0)	
Gender					0.287
Male	135(49.6)	31(59.6)	16(64.0)	17(45.9)	
Female	137(50.4)	21(40.4)	9(36.0)	20(54.1)	
Qualification					0.223
Diploma	3(1.1)	0(0.0)	1(4.0)	2(5.4)	
Bachelor's Degree	200(73.5)	37(71.2)	20(80.0)	29(78.4)	
Master's Degree	69(25.4)	15(28.8)	4(16.0)	6(16.2)	
Profession					0.001
Doctor	167(61.4)	44(84.6)	14(56.0)	24(64.9)	
Pharmacist	86(31.6)	3(5.8)	5(20.0)	7(18.9)	
Paramedic	17(6.3)	5(9.6)	5(20.0)	6(16.2)	
Dentist	2(0.7)	0(0.0)	1(4.0)	0(0.0)	

Table 4.14 continued from previous page

Variable	Through an official ADR reporting system n (%)	Verbally to colleagues only n (%)	No formal reporting is required n (%)	Not sure	P value
Work Setting					0.001
Government Sector	143(52.6)	42(80.8)	15(60.0)	26(70.3)	
Private Sector	129(47.4)	10(19.2)	10(40.0)	11(29.7)	
Experience					0.000
1-5 years	200 (73.5)	33 (63.5)	19 (76.0)	28 (75.7)	
6-10 years	50 (18.4)	4 (7.7)	5 (20.0)	7 (18.9)	
More than 10 years	22 (8.1)	15 (28.8)	1 (4.0)	2 (5.4)	

4.16 Association between Sociodemographic Characteristics and Participants Knowledge of who Should Report ADR

Significant associations were identified in table 4.15 for qualification ($p = 0.002$), profession ($p = 0.002$), and work setting ($p < 0.001$). No statistically significant associations were observed for age ($p = 0.925$), gender ($p = 0.397$), or years of professional experience ($p = 0.286$). The chi-square test and Fisher's exact test were applied. The majority of participants who correctly identified that ADRs can be reported by all relevant stakeholders, including healthcare professionals, patients, and caregivers, belonged to the 25–35 years age group (84.6%), while 11.5% were aged 36–45 years and 4.0% were above 46 years. Similar response patterns were observed across age categories. Among participants who selected the correct response, males and females were almost equally represented, accounting for 50.7% and 49.3% of respondents, respectively.

TABLE 4.15: Association between sociodemographic characteristics and participants knowledge of who should report ADR
Who should report ADR?

Variable	Pharmacist or Physicians only n (%)	Patient or Patient care giver only n (%)	Healthcare profession- als only n(%)	All of the above n(%)	P value
Age (Years)					0.925
25-35	52 (81.3)	9 (75.0)	66 (79.5)	192 (84.6)	
36-45	9 (14.1)	2 (16.7)	12 (14.5)	26 (11.5)	
>46	3 (4.7)	1 (8.3)	5 (6.0)	9 (4.0)	
Gender					0.397
Male	30 (46.9)	5 (41.7)	49 (59.0)	115 (50.7)	
Female	34 (53.1)	7 (58.3)	34 (41.0)	112 (49.3)	
Qualification					0.002
Diploma	0 (0.0)	2 (16.7)	0 (0.0)	4 (1.8)	
Bachelor's Degree	48 (75.0)	6 (50.0)	63 (75.9)	169 (74.4)	
Master's Degree	16 (25.0)	4 (33.3)	20 (24.1)	54 (23.8)	
Profession					0.002
Doctor	47 (73.4)	5 (41.7)	65 (78.3)	132 (58.1)	
Pharmacist	13 (20.3)	4 (33.3)	11 (13.3)	73 (32.2)	
Paramedic	4 (6.3)	2 (16.7)	7 (8.4)	20 (8.8)	
Dentist	0 (0.0)	1 (8.3)	0 (0.0)	2 90.9)	
Work Set- ting					0.000
Government Sector	41 (64.1)	4 (33.3)	66 (79.5)	115 (50.7)	
Private Sector	23 (35.9)	8 (66.7)	17 (20.5)	112 (49.3)	
Experience					0.286

Table 4.15 continued from previous page

Variable	Pharmacist or Physi- cians only n (%)	Patient or Patient care giver only n (%)	Healthcare profession- als only n(%)	All of the above n(%)	P value
1-5 years	43 (67.2)	10 (83.3)	55 (66.3)	172 (75.8)	
6-10 years	15 (23.4)	0 (0.0)	17 (20.5)	34 (15.0)	
More than 10 years	6 (9.4)	2 (16.7)	11 (13.3)	21 (9.3)	

The distribution of responses did not differ significantly according to gender. A significant association was observed between qualification and knowledge regarding ADR reporters. Of those who selected the correct response, 74.4% held a bachelor's degree, 23.8% possessed a master's degree, and 1.8% had a diploma qualification. Professional category was also significantly associated with participant's responses. Doctors represented the largest proportion of respondents who correctly identified that ADRs can be reported by all stakeholders (58.1%), followed by pharmacists (32.2%), paramedics (8.8%), and dentists (0.9%). Work setting demonstrated a significant relationship with knowledge regarding ADR reporting responsibility. Among respondents selecting the correct option, 50.7% were employed in the government sector and 49.3% in the private sector. However, among those indicating that ADRs should be reported only by healthcare professionals, the majority were from the government sector (79.5%). No significant association was found between years of professional experience and knowledge regarding who should report ADRs. Among respondents providing the correct response, 75.8% had 1–5 years of experience, 15.0% had 6–10 years of experience, and 9.3% had more than 10 years of experience.

4.17 Association between Sociodemographic Characteristics and Knowledge Regarding the Availability of a Pharmacovigilance Programme at the Workplace

Table 4.16 summarizes the association between sociodemographic characteristics and participants' awareness of the availability of a pharmacovigilance programme at their workplace. The

chi-square test and Fisher's exact test were applied. Significant associations were observed for age ($p = 0.014$), qualification ($p < 0.001$), work setting ($p = 0.001$), and years of experience ($p = 0.001$), whereas gender ($p = 0.833$) and profession ($p = 0.123$) were not significantly associated with participants responses. Among respondents who reported the presence of a pharmacovigilance programme, 74.1% were aged 25–35 years, 16.4% were aged 36–45 years, and 9.5% were older than 46 years. Qualification was significantly associated with awareness, with bachelor's degree holders accounting for 60.3% of positive responses, followed by participants with master's degrees (38.8%).

Work setting also showed a significant association. Respondents from the private and government sectors contributed similar proportions among those reporting the presence of a programme (50.9% and 49.1%, respectively). However, government-sector employees represented a larger proportion of participants who reported the absence of a programme (54.7%) or were unaware of its availability (71.0%).

A significant relationship was observed between years of experience and awareness of pharmacovigilance programmes. Among participants reporting the presence of a programme, 65.5% had 1–5 years of experience, 15.5% had 6–10 years of experience, and 19.0% had more than 10 years of experience. No significant differences were observed across gender or professional groups.

TABLE 4.16: Association between sociodemographic characteristics and participants knowledge regarding the availability of PV programme at their workplace
Is there any pharmacovigilance programme at your working premises?

Variable	Yes n(%)	No n(%)	Do not know n(%)	P value
Age (Years)				0.014
25-35	86 (74.1)	123 (88.5)	110 (84.0)	
36-45	19 (16.4)	13 (9.4)	17 (13.0)	
>46	11 (9.5)	3 (2.2)	4 (3.1)	
Gender				0.833
Male	62 (53.4)	72 (51.8)	65 (49.6)	
Female	54 (46.6)	67 (48.2)	66 (50.4)	
Qualification				0.000
Diploma	1 (0.9)	4 (2.9)	1 (0.8)	
Bachelor's Degree	70 (60.3)	109 (78.4)	107 (81.7)	

Table 4.16 continued from previous page

Variable	Yes n(%)	No n(%)	Do not know n(%)	P value
Master's Degree	45 (38.8)	26 (18.7)	23 (17.6)	0.123
Profession				
Doctor	72 (62.1)	83 (59.7)	94 (71.8)	
Pharmacist	35 (30.2)	39 (28.1)	27 (20.6)	
Paramedic	9 (7.8)	14 (10.1)	10 (7.6)	0.001
Dentist	0 (0.0)	3 (2.2)	0 (0.0)	
Work Setting				
Government Sector	57 (49.1)	76 (54.7)	93 (71.0)	
Private Sector	59 (50.9)	63 (45.3)	38 (29.0)	0.001
Experience				
1-5 years	76 (65.5)	112 (80.6)	92 (70.2)	
6-10 years	18 (15.5)	18 (12.9)	30 (22.9)	
More than 10 years	22 (19.0)	9 (6.5)	9 (6.9)	

Chapter 5

Discussion of Studies

5.1 Discussion

The present study was conducted among HCPs (Doctors, Pharmacist, Paramedics, and Dentists), who were working in hospital or community settings, to evaluate their knowledge, attitudes, practices, barriers and facilitators about pharmacovigilance. So that we can identify areas requiring targeted interventions, which can lead to optimum functioning of the pharmacovigilance programme [86].

5.1.1 Sociodemographic Characteristics

The sociodemographic profile of the participants was predominantly composed of young healthcare professionals. Most participants (82.6%) were aged 25–35 years, which is consistent with the findings of Alqahtani et al. [87] and Raza et al. [88], where early career healthcare professionals constituted the majority of respondents. The near absence of senior clinicians aged above 46 years (4.7%) represents a limitation that has been noted in a survey by Hussain et al. that only 1.2% of participants were above 45 years [38]. Gender distribution showed slight male predominance, with 51.6% male and 48.4% female participants, similar to the gender distribution reported by Alqahtani et al. [87] and Hadi et al. [59],

although several previous pharmacovigilance studies have reported predominantly female participants [36, 89, 90]. It indicates that gender distribution varies across healthcare settings and study populations. Medical doctors represented the largest professional group, followed by pharmacists, a distribution comparable to that reported by Güner et al. [91], but higher than reported by Hussain et al. [38] and Khan Z et al. [8]. Most participants held a bachelor's degree (74.1%), consistent with previous study conducted in comparable healthcare settings [92].

Government sector healthcare professionals and respondents from urban healthcare facilities constituted the majority of the sample, similar to the findings of Hayek et al. [50] and Elsharif et al. [93]. The majority of our participants (89.6%) had less than 10 years of professional experience, reflecting the predominance of early career healthcare professionals, a trend also reported by Shanableh et al., Alsammari et al., and Alsaleh et al. [71, 80, 94]. This demographic composition of the study population is comparable to that reported in previous pharmacovigilance studies and provides a representative basis for interpreting the knowledge, attitudes, practices, barriers, and facilitators related to ADR reporting among healthcare professionals in Pakistan.

5.1.2 Knowledge and Awareness of Pharmacovigilance Reporting

The knowledge of HCPs regarding PV and ADR reporting were generally satisfactory at the conceptual level, consistent with the findings of Alsaleh et al. [71]. However, awareness of the practical aspects of pharmacovigilance remained sub-optimal. Our findings contrast with those reported in studies conducted in Egypt, Türkiye, and Jordan, which reported poor PV knowledge among HCPs and emphasized the need for targeted educational interventions to improve ADR reporting practices [56, 86, 91]. These differences are likely attributable to variations in pharmacovigilance infrastructure, formal training opportunities, and institutional implementation of ADR reporting systems across countries. In the present study, pharmacists achieved significantly higher knowledge scores (mean rank = 242.72,

$p < 0.001$) and awareness scores (mean rank = 255.78, $p < 0.001$) than medical doctors, paramedics, and dentists, similar to the results observed in the study conducted by Abdel-Latif et al. [56]. Apart from profession and work setting (for knowledge) and profession, work setting, and work location (for awareness), respondents sociodemographic characteristics were not significantly associated with pharmacovigilance knowledge or awareness. This finding suggests that institutional and professional factors may exert a greater influence on pharmacovigilance competency than individual demographic characteristics. These findings are consistent with findings reported by Shanker et al. [95].

A more detailed assessment of individual knowledge components revealed both strengths and important deficiencies. The proportion of respondents who correctly distinguished ADRs from side effects (69.9%) was slightly lower than that reported by Ahmed et al. (77.1%) [96]. Similarly, 70.5% of healthcare professionals correctly identified the appropriate method for ADR reporting, which was comparable to the findings of Hayek et al. (71.1%) [50].

Knowledge of the national pharmacovigilance system was comparatively encouraging, with 63.7% of respondents correctly identifying DRAP as the national authority responsible for pharmacovigilance, this proportion was higher than that reported by Hayek et al. (34.4%) [50], Hussain et al. (43.7%) [54] and Bajaj et al. (59%) [97], suggesting relatively better awareness of the national regulatory framework among the present study population.

Despite these encouraging findings, respondents demonstrated limited awareness of institutional pharmacovigilance activities. Only 30.1% of respondents reported the presence of a pharmacovigilance programme at their workplace, although this proportion exceeded the 11.1% reported by Jahan et al. [46]. Furthermore, awareness of practical ADR reporting procedures remained inadequate, with only 31.0% of respondents indicating that they knew how to complete an ADR reporting form. This finding is substantially lower than the 62.9% reported by Güner et al. [91], highlighting persistent deficiencies in the practical implementation of pharmacovigilance despite satisfactory conceptual knowledge.

A particularly concerning finding was that only 21.0% of respondents had received formal training on pharmacovigilance or ADR reporting. This proportion was comparable to that reported by Datta and Sengupta (16%) and lower than those reported by Hayek et al. (43.4%) and Güner et al. (28.3%) [50, 91, 98].

Similarly, Gordhan et al. reported that 85% of community pharmacists in South Africa had not received formal or informal training on ADR reporting during the preceding two years, indicating that only 15% had received any training [99].

This finding is consistent with evidence indicating that inadequate pharmacovigilance training is a major factor contributing to poor ADR reporting practices among healthcare professionals and underscores the importance of regular educational programmes to strengthen pharmacovigilance systems [100].

5.1.3 Attitude towards Pharmacovigilance Reporting

The present study demonstrated a highly positive attitude toward pharmacovigilance and ADR reporting, consistent with findings reported among HCPs in several previous studies worldwide [8, 54, 71, 95]. Attitude scores were generally consistent across respondents' sociodemographic and professional characteristics, with the exception of the number of prescriptions handled per day.

Healthcare professionals managing 41–60 prescriptions daily demonstrated significantly more positive attitudes than other groups ($p = 0.028$), while no significant associations were observed for the remaining variables. This finding may reflect greater clinical engagement among respondents managing a moderate to high patient workload, providing more opportunities to recognize suspected ADRs and appreciate the value of pharmacovigilance in improving medication safety.

Overall, 83.7% of respondents recognized ADR reporting as a professional responsibility, a proportion comparable to that reported by Bajaj et al. (80.2%), higher than the 64.8% reported by Hussain et al., and lower than reported by Hayek et al. (91%) [50, 54, 97].

Most respondents acknowledged that ADR reporting improves medicine safety, quality of care, and patient trust (81.7% and 86.5%, respectively). Similarly, Bajaj et al. reported a positive attitude toward PV, with approximately 92.6% of HCPs believing that ADR reporting is necessary for improving drug safety [97]. Despite these encouraging attitudes, important misconceptions remain. Nearly three-quarters of respondents (72.3%) believed that an ADR should only be reported when they were certain that it was caused by the suspected medicine.

According to WHO pharmacovigilance recommendations, suspected ADRs should be reported even when a definite causal relationship has not been established, as signal detection depends on the accumulation of suspected reports [101].

Approximately two-thirds of participants indicated that they were more likely to report ADRs only when they resulted in hospitalization (67.4%), were life threatening (70.5%), or caused permanent disability (68.4%), suggesting that respondents prioritized reporting serious ADRs over mild or unexpected reactions. Comparable reporting preferences have been observed in study by Gordhan et al. (95.3%, 97.2%, and 94.4%, respectively) [99]. Furthermore, 75.7% of respondents agreed that consultation with a physician was necessary before submitting an ADR report.

This is consistent with the finding of Hussain et al., who reported that 70.6% of respondents held the same belief [54]. This perception may reflect hierarchical clinical practices and uncertainty regarding the independent reporting responsibilities of other healthcare professionals. However, international pharmacovigilance guidelines emphasize that all healthcare professionals are encouraged to report suspected ADRs directly without requiring prior physician authorization, as timely reporting is essential for effective signal detection and patient safety [65, 102, 103]. Overall, these findings indicate that although healthcare professionals exhibited a highly positive attitude toward pharmacovigilance, targeted educational interventions are still required to correct misconceptions regarding causality assessment and reinforce the importance of reporting all suspected ADRs, regardless of their severity or certainty.

5.1.4 Practices toward Pharmacovigilance Reporting

The present study revealed suboptimal pharmacovigilance practice despite generally satisfactory knowledge and positive attitudes toward ADR reporting. Similar findings have been reported in several other studies [54, 104]. Only 36.0% of HCPs had ever seen an official ADR reporting form, which is considerably lower than the 81.0% reported by Gordhan et al. [99].

Furthermore, only 37.8% were familiar with ADR reporting procedures, and 29.0% had ever reported an ADR through an official pharmacovigilance system. These findings are consistent with those reported by Thilini Madhushika et al. in Sri Lanka, where 35.3% of HCPs had seen an ADR reporting form, 38.7% were aware of the formal ADR reporting process, and only 18.2% had ever submitted an ADR report [105].

A persistently low rate of ADR reporting among healthcare professionals has been reported across multiple countries [13, 17, 47]. Together, these findings suggest that limited familiarity with ADR reporting systems and procedures may contribute to the persistently low reporting rates observed across different healthcare settings.

Despite the low reporting rate, 69.4% of respondents in the present study identified suspected ADRs during routine clinical practice. A similar discrepancy was observed by Alsaleh et al. among hospital pharmacists in Kuwait, where 68.4% of respondents had identified an ADR during clinical practice, yet only 26.8% had ever submitted an ADR report [71].

Likewise, Shanableh et al. reported that 71.1% of hospital pharmacists in the United Arab Emirates had encountered ADRs during the previous year, but only 53.2% reported them to the relevant authorities. Although the reporting rate observed by Shanableh et al. was substantially higher than the 29.0% reported in the present study [80]. Several other studies have reported comparable findings, showing that most healthcare professionals do not report ADRs even when they encounter them in routine clinical practice [99, 106, 107].

5.1.5 Barriers toward Pharmacovigilance Reporting

The present study identified heavy workload as the most commonly perceived barrier to ADR reporting, with 53.4% of healthcare professionals agreeing that workload limited their ability to report ADRs. This finding is comparable to the 51.0% reported by Alshehri et al. but lower than the 60.1% reported by Hussain et al. Insufficient training to identify and report ADRs was reported by 46.6% of respondents, which is substantially lower than the 74.0% reported by Hussain et al. and 81.8% reported by Sharif et al. [38, 58, 108]. The high prevalence of workload related barriers may reflect the broader shortage of HCPs in Pakistan.

A Dawn editorial published on June 28, 2024, highlighted that Pakistan's doctor-to-patient ratio is approximately 1:1,300, compared with the WHO recommended ratio of 1:1,000 for developing countries. The editorial emphasized that this shortage places considerable strain on the healthcare system and may negatively impact the quality and accessibility of patient care [109].

According to the World Bank, the availability of nurses and midwives remains low at 0.5 per 1,000 population, compared with the recommended 3 per 1,000 population [110]. Likewise, pharmacist availability is 0.9 per 100,000 population, substantially below the WHO recommended ratio of 1 pharmacist per 2,000 population. An inadequate healthcare workforce can lead to excessive clinical workload, making it difficult for healthcare professionals to allocate sufficient time for ADR reporting. [38].

Similarly, 44.6% of respondents reported that ADR reporting forms or systems were not readily available in their workplace, which is lower than the 92.5% reported by Sharif et al. Furthermore, 38.1% of respondents acknowledged that they did not know how to report an ADR, which was considerably lower than the 55.5% reported by Hussain et al., 70.6% by Sharif et al., and nearly 90% by Alshehri et al., suggesting relatively better awareness of reporting procedures in the present study despite remaining knowledge gaps [38, 58, 108]. The limited availability of reporting tools and incomplete understanding of reporting procedures among

a substantial proportion of respondents indicate that deficiencies in institutional support and continuous pharmacovigilance training remain important barriers to effective ADR reporting.

Perceived complexity and time required for ADR reporting were moderate in the present study, with 32.6% considering the reporting procedure complicated and 40.7% reporting that ADR reporting was time consuming. These proportions were lower than those reported by Amrain and Bečić, where 51.2% considered ADR reporting complicated and 59.7% perceived it as time consuming.

Likewise, fear of legal consequences discouraged 36.8% of respondents in the present study, which was comparable to the 37.9% reported by Hussain et al. But higher than reported by Sharif et al. (25.1%) and Amrain and Bečić (25.5%). Finally, lack of motivation to report ADRs was reported by 36.6% of respondents, which was lower than the 51.4% observed by Sharif et al. but higher than the 27.6% reported by Amrain and Bečić [38, 108, 111].

However, the persistence of these barriers indicates that the reporting process is still perceived as burdensome by a considerable proportion of healthcare professionals, potentially limiting spontaneous ADR reporting, a finding that is consistent with previous studies identifying reporting complexity and time constraints as important contributors to ADR underreporting [80, 100].

Statistically significant differences in barrier scores were observed according to healthcare profession ($p \leq 0.001$), work setting ($p \leq 0.001$), and experience ($p = 0.004$). Medical doctors and respondents working in the government sector demonstrated the highest mean barrier scores. No significant differences were found across other sociodemographic characteristic. These findings are consistent with previous studies demonstrating that professional role, workplace setting, and experience influence barriers to ADR reporting. Higher barrier scores among medical doctors and government sector healthcare professionals may be attributed to heavier clinical workloads and resource limitations [38, 80], while the lack of significant associations with demographic characteristics suggests that organizational factors

play a more important role in influencing ADR reporting practices than individual characteristics.

5.1.6 Facilitators toward Pharmacovigilance Reporting

The present study demonstrated strong support for several interventions that could enhance ADR reporting among healthcare professionals. Regular pharmacovigilance training was strongly supported by respondents (84.0%), which is comparable to the 85.9% reported by Hussain et al. [38] but higher than the 69.9% reported by Hadi et al., where approximately two-thirds of hospital pharmacists recommended education and training to improve ADR reporting [59]. Similarly, Carandang et al. reported that all pharmacists emphasized continuous education and training as essential for accurately identifying and reporting ADRs and further recommended integrating pharmacovigilance into undergraduate pharmacy curricula [112].

The availability of a simple and user friendly digital ADR reporting system was endorsed by 85.5% of respondents, which is slightly higher than the 80.2% reported by Hussain et al. [38], highlighting the increasing recognition of digital platforms as a means of facilitating spontaneous ADR reporting. Although the DRAP has introduced digital ADR reporting tools, their utilization remains limited, likely due to inadequate awareness and insufficient training among healthcare professionals. Increasing awareness and promoting the use of these digital reporting platforms may therefore enhance ADR reporting practices [5]. Likewise, 87.3% of respondents agreed that clear guidelines on how and where to report ADRs would improve reporting, exceeding the 60% reported by Hughes and Weiss, where pharmacists identified clearer reporting guidance as an important facilitator [113].

Organizational support was another major facilitator identified in the present study. Nearly nine out of ten respondents (88.3%) agreed that support from hospital administration and colleagues would encourage ADR reporting. Similarly, Hadi et al. recommended better collaboration with clinicians (55.8%) and the establishment of dedicated ADR reporting teams within hospitals (52.1%) to

strengthen pharmacovigilance activities [59], while Carandang et al. emphasized the importance of interprofessional collaboration, clearly defined professional responsibilities, and structured reporting processes for improving pharmacovigilance practice [112].

Receiving feedback and incentives from the pharmacovigilance center was considered an important facilitator by 83.4% of respondents, which is substantially higher than the 51.0% reported by Hussain et al. [38], the 27% reported by Hughes and Weiss [113], and the mixed opinions described by Carandang et al., where some pharmacists supported incentives whereas others considered ADR reporting to be primarily a professional responsibility [112]. Collectively, these findings suggest that healthcare professionals perceive pharmacovigilance to be strengthened through a combination of continuous education, clear reporting guidance, accessible digital reporting systems, supportive institutional environments, and regular feedback mechanisms.

5.2 Strengths and Limitations

This study is among the few in Pakistan to comprehensively assess pharmacovigilance knowledge, awareness, attitudes, practices, barriers, and facilitators among multiple healthcare professional groups working across public and private healthcare settings. The use of a validated and pilot-tested questionnaire enhances the reliability and policy relevance of the findings. However, the study also has several limitations. The cross-sectional design does not permit causal inferences, while convenience sampling and data collection limited to Islamabad and Rawalpindi may restrict the generalizability of the findings to other regions of Pakistan, but the information is still useful for both HCPs and policymakers. Furthermore, the questionnaire relied on self-assessment by HCPs, including doctors, pharmacists, dentists, and paramedics, participants may have felt pressured to complete the survey or may have been reluctant to disclose shortcomings in their knowledge, attitudes, practices, barriers and facilitators.

Chapter 6

Conclusion and Future Recommendations

6.1 Conclusion

This study demonstrates that although healthcare providers generally possess satisfactory knowledge and positive attitudes towards pharmacovigilance reporting, significant gaps remained in formal training, and actual reporting practices. While most healthcare providers recognized ADR reporting as a professional responsibility and acknowledged its importance in improving medication safety, only a small proportion had received formal pharmacovigilance training or had previously submitted ADR reports through the official reporting system, indicating that positive attitudes alone are insufficient to promote active participation in pharmacovigilance. The study further identified heavy workload, inadequate pharmacovigilance training, limited knowledge of reporting procedures, insufficient availability of reporting systems, and lack of motivation as the major barriers to ADR reporting. Although P-value is not significant but descriptively, regular training programs, clear reporting guidelines, user friendly electronic reporting systems, constructive feedback from pharmacovigilance authorities, and strong organizational support were recognized as key facilitators for improving reporting practices. The

results emphasize the need for continuous education and competency based training programs for healthcare professionals, alongside greater awareness of national pharmacovigilance policies and reporting mechanisms. Integrating pharmacovigilance into undergraduate and continuing professional education, strengthening institutional pharmacovigilance systems, and promoting a supportive reporting culture may substantially improve ADR reporting practices. Implementing these measures will contribute to strengthening the national pharmacovigilance system, enhancing medication safety, and supporting evidence based regulatory decision making, ultimately leading to improved patient care and public health outcomes in Pakistan.

6.2 Future Recommendations

The findings of this study support the need for coordinated educational, institutional, and regulatory strategies to strengthen pharmacovigilance practices in Pakistan. Pharmacovigilance and ADR reporting should be integrated into undergraduate curricula and continuing professional development programmes for all healthcare professionals. Healthcare institutions should establish clear reporting pathways, promote awareness regarding electronic reporting systems, and provide regular feedback to encourage reporting. Greater awareness of the DRAP pharmacovigilance programme should also be promoted through national initiatives. Future research should include multicenter studies across different regions of Pakistan using probability sampling and longitudinal or interventional designs to evaluate the effectiveness of educational and policy interventions and to assessing the impact of the implementation of the DRAP Pharmacovigilance Rules on ADR reporting rates, pharmacovigilance practices, and patient safety outcomes would provide valuable evidence to guide future policy development and strengthen the national pharmacovigilance system.

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Appendix A

Appendix A: Ethical Letter



**ISLAMABAD HOSPITAL
PAKISTAN INSTITUTE OF MEDICAL SCIENCES
G-8/3, ISLAMABAD**

Your Ref. No. _____

Our Ref. No. — F-5-2/2024(ERRC)/PIMS

Date: 6/3/26

Subject: - APPROVAL LETTER ETHICAL RESEARCH REVIEW COMMITTEE

1. DR. MARIAM SIDDIQUE
2. DR. FARMAN ULLAH KHAN
3. DR. RABIA ZAHID

Reference your application submitted for study titled. "ASSESSING THE BARRIERS AND FACILITATORS INFLUENCING PHARMACOVIGILANCE PRACTICES AMONG HEALTHCARE PROVIDERS IN TWIN CITY OF PAKISTAN." After close review of the proposal, the study is approved on behalf of ethical and research review board. In case of any change in topic, authors or research methodology new ERRC certificate will be required.

The Board Reserves Right to stop the research project if report is received regarding any violation of ethics/ deviation from the proposed study plan.


PROF. MUMTAZ AHMAD KHAN NIAZI
Chairman
Ethics Research Review Committee (ERRC)
Professor of General Surgery



DR. MARIAM SIDDIQUE
M.Phil. SCOLAR PHARMACY,
CAPITAL UNIVERSITY OF SCIENCES
& TECHNOLOGY (CUST),
ISLAMABAD
03209074087

Copy to:-
> PS to Dean, PIMS, Islamabad
> Relevant file.

Appendix B

Appendix B: Questionnaire

Instructions to Respondents

This questionnaire aims to assess your knowledge, attitude, practice, perceived barriers, and facilitating factors related to pharmacovigilance and adverse drug reaction (ADR) reporting.

We request few minutes of your time to complete this questionnaire. Your participation in this study is entirely voluntary. Your responses will be kept confidential and used for research purposes only.

Informed Consent

By signing below, you confirm that you have read and understood the information above and agree to participate in this study voluntarily.

Signature: _____

Contact Information (Email/Phone): _____

Section A: Demographics

Please tick (✓) appropriate box. Your responses will remain confidential and will be used solely for research purposes.

1. **Age (in years):** _____
2. **Gender:**
 - ☐ Male
 - ☐ Female
3. **Highest Educational Qualification:**
 - ☐ Diploma
 - ☐ Bachelor's degree
 - ☐ Master's degree
4. **Healthcare Profession:**
 - ☐ Medical Doctor
 - ☐ Pharmacist
 - ☐ Paramedic
 - ☐ Dentist
5. **Work Setting:**
 - ☐ Government Sector
 - ☐ Private Sector
6. **Work Area:**
 - ☐ Urban
 - ☐ Rural
7. **Primary Work Location:**
 - ☐ Hospital
 - ☐ Community Setting
8. **Professional Experience:**
 - ☐ 1–5 years
 - ☐ 6–10 years
 - ☐ More than 10 years
9. **Average number of patients/prescriptions seen per day:**
 - ☐ 10–20

- ☐ 21–40
- ☐ 41–60
- ☐ More than 60

Section B: Knowledge about Pharmacovigilance

Part 1: Multiple Choice Questions (MCQs)

Please tick (✓) one most appropriate answer.

1. What is pharmacovigilance?
 - ☐ a) Detection, assessment, understanding, and prevention of adverse effects of medicines
 - ☐ b) Monitoring drug prices
 - ☐ c) Dispensing medications safely
 - ☐ d) Not sure
2. How should an adverse drug reaction (ADR) be reported?
 - ☐ a) Through an official ADR reporting form/online system
 - ☐ b) Verbally to colleagues only
 - ☐ c) No formal reporting is required
 - ☐ d) Not sure
3. Who should report ADR?
 - ☐ a) Pharmacist/Physicians only
 - ☐ b) Patient/Patient care giver only
 - ☐ c) healthcare professionals only
 - ☐ d) All of the above
4. Pharmacovigilance mainly deals with which of the following?
 - ☐ a) Drug-related problems only
 - ☐ b) Herbal medicine-related problems only
 - ☐ c) Blood and blood product-related problems only

- ☐ d) All of the above
5. Is there any pharmacovigilance programme or system present at your working premises?
- ☐ a) Yes
- ☐ b) No
- ☐ c) Do not know
6. Does Pakistan have a National Pharmacovigilance Programme? If yes, which organization governs it?
- ☐ a) Ministry of National Health Services, Regulations and Coordination (MoNHSRC)
- ☐ b) Drug Regulatory Authority of Pakistan (DRAP)
- ☐ c) Pakistan Medical Commission (PMC)
- ☐ d) World Health Organization (WHO)
7. Have you received formal training or education related to Pharmacovigilance or ADR reporting?
- ☐ Yes
- ☐ No

Part 2: Knowledge Statements

Please indicate your level of agreement with each statement.

Scale: 1 = Strongly Disagree — 2 = Disagree — 3 = Neutral — 4 = Agree — 5 = Strongly Agree

No.	Statement	1	2	3	4	5
1	An ADR is any harmful or unintended response to a drug at normal doses					
2	ADRs are different from side effects					

3	The main objectives of pharmacovigilance include monitoring drug safety, collecting and analyzing ADR reports, and preventing medicine-related harm					
4	I am aware of the guidelines, rules and regulations of the Pharmacovigilance Centre in Pakistan					

Part 3: Awareness Level

Please indicate your level of awareness by ticking (✓) one option for each statement.

Scale: 1 = Not aware at all — 2 = Slightly aware — 3 = Moderately aware — 4 = Very aware — 5 = Extremely aware

No.	Statement	1	2	3	4	5
1	I am aware of the concept of pharmacovigilance					
2	I am aware of ADRs					
3	I am aware of how to complete an ADR reporting form					
4	I am aware of pharmacovigilance (PV) contact points in my hospital or community setting					

Section C: Attitude towards Adverse Drug Reaction (ADR) Reporting

Please indicate your level of agreement with each statement by ticking (✓) one option.

Scale: 1 = Strongly Disagree — 2 = Disagree — 3 = Neutral — 4 = Agree — 5 = Strongly Agree

No.	Statement	1	2	3	4	5
1	Pharmacovigilance is an important part of routine healthcare practice					
2	Reporting ADRs is a professional responsibility of healthcare providers					
3	I should only report an ADR when I am certain that it is caused by the medicine					
4	Suspected ADRs related to over-the-counter (OTC) medicines should also be reported					
5a	I am more likely to report an ADR if it results in hospitalization					
5b	I am more likely to report an ADR if it is life-threatening					
5c	I am more likely to report an ADR if it causes long-term disability or incapacity					
6	Reporting ADRs helps improve my understanding of medicine-related safety issues in practice					
7	Reporting ADRs improves quality of care and patient trust					
8	It is important to consult a physician before submitting an ADR report					

Section D: Practice towards ADR Reporting

Please select the most appropriate response for each statement.

No.	Statement	Yes	No
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1	I have seen an official ADR reporting form (paper or electronic)	☐	☐
2	I am familiar with the methods used for submitting ADR reports	☐	☐
3	I have identified suspected adverse drug reactions during my clinical practice	☐	☐
4	I have reported suspected ADRs through an official pharmacovigilance system	☐	☐
5	I have read articles or educational material related to the prevention of adverse drug reactions	☐	☐
6	ADRs are properly documented and recorded in my hospital/clinical setting	☐	☐

Section E: Barriers to Adverse Drug Reaction (ADR) Reporting

Please indicate your level of agreement with each statement.

Scale: 1 = Strongly Disagree — 2 = Disagree — 3 = Neutral — 4 = Agree — 5 = Strongly Agree

No.	Statement	1	2	3	4	5
1	I do not know how to report an ADR.					
2	ADR reporting forms or systems are not easily available in my workplace.					
3	The procedure for reporting ADRs is complicated.					
4	Reporting ADRs takes too much time.					
5	I have insufficient training to identify and report ADRs.					

6	Fear of legal consequences discourages me from reporting ADRs.					
7	Heavy workload limits my ability to report ADRs.					
8	Reporting ADRs may negatively affect my professional image.					
9	I am not motivated to report ADRs.					

Section F: Facilitators / Factors Encouraging ADR Reporting

Please indicate your level of agreement with each statement.

Scale: 1 = Strongly Disagree — 2 = Disagree — 3 = Neutral — 4 = Agree — 5 = Strongly Agree

No.	Statement	1	2	3	4	5
1	Regular training or workshops are needed for Pharmacovigilance.					
2	Clear guidelines are needed on how and where to report ADRs would improve reporting.					
3	Simple and user-friendly digital ADR reporting system would increase reporting.					
4	Receiving feedback and incentives from the pharmacovigilance center would motivate me to report ADRs.					
5	Including ADR reporting as part of professional duties would encourage reporting.					
6	Support from hospital administration and colleagues would encourage ADR reporting.					