

PHARMACOVIGILANCE AND PATIENT SAFETY IN PAKISTAN: EVALUATING AI-DRIVEN ADVERSE DRUG REACTION MONITORING IN HOSPITAL SETTINGS

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Abstract

The rising incidence of adverse drug reactions (ADRs) poses a significant challenge to patient safety in hospital settings, particularly in low- and middle-income countries such as Pakistan. This study evaluated the effectiveness of AI-driven pharmacovigilance systems in monitoring and managing ADRs across selected tertiary care hospitals. Using a mixed-methods approach, quantitative analysis measured ADR detection rates, response times, and severity reduction, while qualitative feedback assessed clinician perceptions and system usability. The findings showed a significant increase in ADR detection efficiency, a reduction in severe and moderate ADRs and positive clinician approval of AI integration. These results emphasize the possible of AI tools to enhance patient safety, rationalize pharmacovigilance work flows, and evidence-based clinical decision-making support. The study offers applied recommendations for, training, institutional adoption and policy development, underlining pathways for comprehensive application in healthcare systems.

Introduction

The science of Pharmacovigilance, and its activities related to the assessment, understanding, detection or any other drug related problems and prevention of adverse effects plays a critical role in ensuring patient safety, (WHO, 2022). In Pakistan, the healthcare structure faces substantial challenges in monitoring adverse drug reactions (ADRs), including lack of standardized protocols, under reporting and limited human resources dedicated to pharmacovigilance (Khan *et al.*, 2024; Rehman & Ali, 2023). These

challenges intensify the risk of drug related harm, making healthy monitoring mechanisms an urgent priority for hospitals and health facilities across the country.

In pharmacovigilance (AI) Artificial intelligence has arose as a transformative instrument , offering competences for real-time ADR detection, automated reporting and predictive analytics, (Sharma *et al.*, 2025). Pharmacovigilance systems (AI-driven) can analyze massive datasets from clinical notes, electronic health records (EHRs), and patient register office to identify

potential Adverse Drug Reactions more efficiently than traditional methods (Ahmed *et al.*, 2024). Worldwide, AI has demonstrated improved accuracy in reduced manual workload, signal detection to mitigate patient risk and facilitated proactive interventions (Li & Chen, 2024; Singh & Tiwari, 2025).

With reference to Pakistan, integrating AI into hospital-based pharmacovigilance presents both challenges and opportunities. On the other hand, AI can compensate for the existing gaps in enhance the timeliness of ADR detection, human resources, and support evidence-based clinical decisions, (Raza *et al.*, 2024). A part from its implementation is delayed by inconsistent data quality, infrastructure limitations and the need for staff facilitators training on AI tools (Hussain & Tariq, 2024). Considerate these suggestions is crucial for designing strategies that influence AI to improve patient safety without compromising regulatory standards and ethical.

This study aims to evaluate ADR monitoring systems by the effectiveness of AI- driven in hospital settings in Pakistan, focusing on their impact on patient safety outcomes and pharmacovigilance practices. By examining system performance, stakeholder perceptions and hospital readiness, this research contributes to adopting AI technologies in pharmacovigilance by evidence-based policies and enhancing overall healthcare excellence in Pakistan.

Problem Statement

Globally, patient safety is a serious concern in healthcare systems and effective pharmacovigilance is main to preventing medication related detriment. In Pakistan, pharmacovigilance frameworks in hospital settings remain weak, characterized by unreliable adverse drug reaction (ADR) reporting, limited utilization of digital tools and fragmented monitoring practices (Khan, Rehman, & Ali, 2024; Rehman & Ali, 2023). These systemic shortages hinder timely detection of ADRs, increasing the threat of preventable patient damage and paying to inefficiencies in clinical decision making.

Artificial intelligence has proven significant potential to enhance ADR detection

through electronic health records by automated monitoring, predictive modeling, and real-time analysis, (Sharma, Singh, & Gupta, 2025; Li & Chen, 2024). However, in the situation of Pakistani hospitals, there is limited practical evidence on the feasibility, effectiveness and impact of AI-driven pharmacovigilance systems. Challenges such as, ethical considerations around data privacy and digital literacy gaps among healthcare professionals further complicate AI adoption, (Hussain & Tariq, 2024; Raza, Shah, & Qureshi, 2024).

Mentioning these gaps is vital to strengthen hospital-based pharmacovigilance, support evidence based clinical decision making and enhance patient safety outcomes. This study pursues to assess the effectiveness of AI-driven ADR monitoring systems, ethical challenges, identify operational and provide actionable insights for integrating AI into pharmacovigilance performs in Pakistan.

Research Questions

1. How effective In Pakistan in hospital settings this AI-driven systems in detecting and monitoring adverse drug reactions?
2. What do AI-based pharmacovigilance tools have impact on patient clinical decision making and safety outcomes?
3. What types of infrastructural, operational and ethical challenges affect the implementation of pharmacovigilance AI driven in Pakistani hospitals?
4. How do healthcare professionals perceive the reliability, usability and potential benefits of AI assisted ADR monitoring systems?
5. What strategies can enhance the integration of AI tools in pharmacovigilance for improved patient safety in hospitals?

Research Objectives

General Objective:

To evaluate the impact of AI- driven adverse drug reaction, effectiveness and monitoring systems on pharmacovigilance and patient safety in Pakistan hospital settings.

Specific Objectives:

1. To evaluate the performance of AI-driven systems in identifying and reporting ADRs compared to conventional pharmacovigilance practices.

To examine the influence of AI-assisted monitoring on patient safety outcomes and clinical decision making processes.

2. To identify operational, infrastructural, and ethical barriers affecting the implementation of AI in hospital pharmacovigilance.

3. To explore healthcare professionals' perceptions regarding benefits of AI-based ADR monitoring systems its usability and reliability.

4. To propose practical strategies and recommendations for integrating AI into pharmacovigilance to enhance patient safety in hospitals.

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Literature Review

Pharmacovigilance and Patient Safety: Global and National Context

Pharmacovigilance is the assessment, systematic monitoring, detection and prevention of (ADRs) adverse drug reactions, it is essential for worldwide safeguarding patient safety and improving drug use practices. Old-style pharmacovigilance systems, dependent on spontaneous manual and reporting review, are often slow and unreliable, leading to delayed detection of safety signals and under reporting (WHO, 2022; Hussain & Tariq, 2024). (DRAP) The Drug Regulatory Authority of Pakistan has recognized a National Pharmacovigilance Centre to coordinate and collect ADR reports from institutions and healthcare professionals, signaling improvement in formalizing ADR monitoring. Though, the system remains weak and fragmented, with low reporting rates and limited hospital engagement by clinicians and pharmacists (DRAP, 2025; Nisa *et al.*, 2020). Studies specify that lack of inadequate training, awareness and weak integration of reporting tools contribute to tirelessly low ADR reporting practices in Pakistan (Nisa *et al.*, 2020).

Challenges in Traditional ADR Monitoring

In emerging healthcare systems, including Pakistan's, pharmacovigilance expressions

restrictions such as, limited digital infrastructure, as poor data quality and low participation by healthcare facilitators. Past case studies disclose that severe ADR events such as bulk drug reactions from locally manufactured products highlight the significances of weak pharmacovigilance frameworks and the critical requirement for systematic reporting mechanisms (Hussain & Hassali, 2019). These challenges are compounded by in the resourced nature of hospital settings, where clinicians are troubled with dense workloads that deprioritize ADR reporting. Therefore, ADRs remain under detected, discouragement patient safety efforts and restrictive regulatory responsiveness.

including spontaneous reports, EHRs, and social media sources. These systems combine deep learning,

Artificial Intelligence in Pharmacovigilance

As a transformative solution AI has emerged to the limitations inherent in outdated pharmacovigilance systems, offering automated and scalable approaches for signal generation and ADR detection. AI Systematic reviews applications in pharmacovigilance reveal that deep learning models and machine learning (ML) can improve ADR forecast accuracy, especially when unstructured clinical narratives and integrating structured patient data (Li *et al.*, 2024; Dsouza *et al.*, 2025). Research shows that advanced neural network techniques and NLP can extract applicable safety signals from mixed clinical datasets more efficiently than predictable disproportionality methods, improving sensitivity and decreasing the time to signal identification (Khemani *et al.*, 2025). Additionally, AI models have presented promise in identifying rare or multiline drug events and interpreting complex EHR systems, which are otherwise hard to detect through manual reporting systems.

Explainable AI and Real Time for Drug Safety Monitoring

Current scholarship highlights the push toward explainable pharmacovigilance systems and real time that can handle worldwide drug safety data streams,

and signal detection algorithms, explainable AI techniques to improve clearness and clinician trust (Ali *et al.*, 2026). In spite of these improvements, challenges remain, including, validation, bias mitigation, ensuring algorithmic transparency and regulatory compliance for AI systems, mainly when applied in real world clinical settings.

AI Pharmacovigilance in Healthcare Delivery

In pharmacovigilance the integration of AI lengthens beyond model performance to include practical implementation concerns such as, data governance, interoperability with hospital information systems, and end-user training. Signal from international studies shows that many AI models best in controlled research settings but shortage external validation and real world willingness, raising concerns about adoption and generalizability in hospital workflows (Dsouza *et al.*, 2025). This gap highlights the necessity

for contextualized research that assesses AI performance in definite national settings, including Pakistan, where healthcare digitization differs considerably between facilities.

Relevance to Pakistan's Healthcare Landscape

Pharmacovigilance systems in Pakistan are still progressing and ADR reporting remains largely unpaid with significant under reporting by pharmacists and clinicians (Nisa *et al.*, 2020). So in this context integrating AI to presents unique challenges and opportunities. While AI could address resource limitations and hospital infrastructure, enhance signal detection, clinician readiness and digital maturity differ widely across regions, affecting implementation possibility. Furthermore, ethical considerations relating to patient algorithmic transparency, data privacy and clinician trust commitment be addressed for responsible AI deployment.

Hypotheses

H1: AI-driven Implementation of adverse drug reaction (ADR) observing in hospital settings significantly increases the detection rate of ADRs compared to old pharmacovigilance methods.

H2: AI-driven monitoring systems of ADR positively affect patient safety consequences by reducing the severity and incidence of adverse drug events in hospital settings.

H3: Acceptance and clinician awareness and of pharmacovigilance tools AI- driven mediate the effectiveness of AI systems in successful ADR reporting rates.

H4: Integration ADR of AI-driven monitoring with hospital (EHRs) electronic health records enhances the accuracy and timeliness of ADR signal detection.

H5: Hospital specific aspects, such as staff training and digital infrastructure readiness moderate the relationship between pharmacovigilance effectiveness and AI implementation.

Methodology

Research Design

A quantitative and cross sectional research scheme was adopted to assess the effectiveness of AI-driven adverse drug reaction (ADR) monitoring and its impact on patient safety in hospital settings This design enabled systematic analysis and data collection, allowing for the assessment of relationships between patient safety outcomes and AI implementation, ADR detection,.

Study Setting and Population

The study was led in five tertiary care hospitals in Pakistan, selected based on the presence of implementation of AI-driven pharmacovigilance tools and electronic health record (EHR) systems. The target population included hospital physicians, pharmacists and nurses who were directly involved in patient care and ADR monitoring.

Sampling Technique

A purposive sampling technique was working to select members with direct experience in and interaction with AI-driven pharmacovigilance systems and ADR reporting. A total of 250 healthcare specialists participated in the study, certifying adequate representation from all related clinical departments.

Data Collection Instruments

Data were collected using hospital records and a structured questionnaire. The questionnaire measured three main constructs:

1. **ADR Detection Efficiency:** Timeliness of ADR identification and frequency before and after AI implementation.
2. **Patient Safety Outcomes:** Severity of ADR related adverse events and incidence.
3. **Clinician Perception and Acceptance:** Ease of use, perceived effectiveness and attitudes toward AI tools.

The questionnaire was validated by a panel of five AI experts and pharmacovigilance and pilot tested on Twenty (20) healthcare professionals to confirm clarity and reliability. Hospital records were reviewed to patient safety data and corroborate ADR reporting rates.

Data Collection Procedure

After obtaining ethical approval informed consent from hospital review boards, data were collected over a three month period. Anonymized hospital records were extracted for analysis and Questionnaires were administered in person.

Data Analysis Technique

Using SPSS (Version 28), quantitative data were analyzed. Descriptive statistics summarized participant ADR detection rates, demographics, and patient safety outcomes. Inferential statistics, including regression analyses and paired t-tests were conducted to examine.

- Variances in ADR detection rates before and after AI application.
 - Relationships between clinician perception patient safety outcomes and AI system use.
 - Moderating properties of hospital particular features on AI effectiveness.
 - The significance level was set at $p < 0.05$.
- All data were handled with confidential strictly and hospital identifiers were anonymized to certify ethical compliance.

Data Analysis

Descriptive Statistics

The study included 250 healthcare professionals, comprising 90 nurses (36%), 50 pharmacists (20%) and 110 physicians (44%). The majority of participants were aged 25 to 40 years (62%), with an average of 8.5 years of clinical experience.

Table 1. Participant Demographics

Demographic Variable	Frequency (n)	Percentage (%)
Profession		
Physician	110	44
Nurse	90	36
Pharmacist	50	20
Age (years)		
25–40	155	62
41–55	80	32
56+	15	6
Clinical Experience		
0–5 years	60	24
6–10 years	110	44
11+ years	80	32

The sample mirrored varied clinical roles and experience ranks, ensuring demonstration from

the major investors involved in ADR monitoring. The majority of participants were

mid career professionals, suggesting familiarity with both AI-assisted pharmacovigilance systems and traditional .

ADR Detection Efficiency

ADR detection rates were compared before and after AI system.

Table 2. ADR Detection Rates Before and After AI Implementation

Variable	Mean (SD) Before AI	Mean (SD) After AI	t-value	p-value
ADRs detected per 100 patients	5.2 (1.3)	8.7 (1.7)	18.45	<0.001
Time to ADR detection (hours)	24.3 (6.2)	12.1 (3.8)	21.32	<0.001

ADR detection rates significantly increased by AI-driven pharmacovigilance and reduced the time required to identify adverse events ($p < 0.001$). This shows improved monitoring efficiency, allowing improved patient safety outcomes and earlier intervention.

Patient Safety Outcomes

The impact of AI on patient safety was assessed by comparing ADR-related adverse events before and after AI implementation.

Table 3. ADR-Related Adverse Events

Severity of ADRs	Frequency Before AI	Frequency After AI	χ^2 -value	p-value
Mild	85	90	0.56	0.45
Moderate	60	35	12.34	<0.001
Severe	25	10	9.87	0.002

The number of severe and moderate ADRs significantly decreased following AI implementation, while minor ADRs remained stable. This reveals that AI not only improves detection but also donates to reducing clinically significant adverse events.

Clinician Perception and AI Acceptance

Clinician perceptions of AI were evaluated by means of a 5-point Likert scale (1 = strongly disagree, 5 = strongly agree).

Table 4. Clinician Perception of AI Systems

Perception Statement	Mean (SD)
AI improves ADR detection efficiency	4.35 (0.62)
AI is easy to use and integrate into workflow	4.12 (0.75)
AI enhances overall patient safety	4.28 (0.68)
Willingness to rely on AI for ADR monitoring	4.05 (0.80)

Strong acceptance and recognition of AI’s role in improving ADR monitoring and patient safety is indicating by Clinicians which reported positive perceptions of AI systems.

Regression Analysis

Multiple regression analysis examined the relationship between clinician perception, AI usage and patient safety outcomes.

Table 5. Regression Analysis: Predicting Patient Safety Outcomes

Predictor Variable	β (Standardized)	t-value	p-value
AI system usage	0.42	6.15	<0.001
Clinician perception	0.36	5.02	<0.001
Hospital size	0.12	1.87	0.06

Positive clinician perception and AI system usage ($p < 0.001$) significantly predicted improved patient safety outcomes. Hospital size did not have a significant statistically effect. This highlights the importance of both clinician engagement and technology in maximizing the impact of AI on patient safety.

The data analysis demonstrates ADR detection efficiency significantly enhances by AI-driven pharmacovigilance in hospital settings, improves overall patient safety and reduces moderate-to-severe ADRs. High clinician acceptance additional strengthens the potential for sustainable integration of AI tools in routine pharmacovigilance workflows.

Discussion

The results of this study specify that AI-driven pharmacovigilance systems considerably enhance the management and monitoring of adverse drug reactions (ADRs) in hospital settings in Pakistan. The findings demonstrate a significant increase in ADR detection rates and a considerable reduction in the time required for identification after the implementation of AI-based monitoring. This make parallel with previous research signifying that AI tools improve the accuracy and efficiency of pharmacovigilance processes by rapidly analyzing large volumes of clinical data and identifying patterns that may be missed by conventional methods (Hussain *et al.*, 2024; Khan & Ahmed, 2025).

Additionally, the study revealed a significant decrease in severe and moderate ADRs, emphasizing the direct involvement of AI systems to patient safety. This development is likely a result of timely interventions and early detection, which are eased by real-time alerts and predictive algorithms. These findings support the idea that AI not only serves as a preventive mechanism

but also acts as a monitoring tool, reducing the potential clinical consequences of ADRs and severity (Fatima *et al.*, 2024).

Clinician insights of AI were commonly positive, reflecting high levels of trust in AI-driven pharmacovigilance and acceptance. Participants reported that AI improved patient outcomes and workflow efficiency, while being quite easy to integrate into daily hospital routines. This proposes that the successful adoption of AI in pharmacovigilance is dependent not only on technological performance but also on institutional support and user engagement, training, (Rehman & Iqbal, 2025).

Conclusion

This research work concludes that AI-driven pharmacovigilance significantly enhances ADR detection and contributes to improved patient safety in hospital settings in Pakistan. Both qualitative and quantitative evidence from this study indicates that AI systems reduce the frequency of moderate and severe ADRs while being well established by healthcare professionals. These outcomes underscore the transformative potential of AI in modern pharmacovigilance, supporting evidence-based clinical decision- making and bridging gaps in traditional monitoring systems.

Implications

The integration of AI in pharmacovigilance has numerous practical consequences. Firstly, healthcare institutions by adopting AI-driven monitoring tools can enhance patient safety outcomes, leading to improved clinical care and fewer adverse events and Secondly, policymakers can develop guidelines to facilitate AI implementation in hospital pharmacovigilance programs and regulatory frameworks and Finally, the study highlights the

significance of clinician engagement, suggesting that capacity-building initiatives and training programs are critical for successful AI adoption (Ali *et al.*, 2025).

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Future Directions

Future research should explore the long-term impact of AI-driven pharmacovigilance on patient mortality and morbidity, intensifying the scope beyond ADR detection efficiency. Relative studies across various hospital types, including private and public institutions, could identify contextual features that effect AI adoption and effectiveness. Furthermore, integrating AI systems with national pharmacovigilance databases and electronic health records (EHRs) could further improve facilitate nationwide patient safety initiatives and cross-institutional monitoring (Hossain *et al.*, 2025).

Recommendations

Based on the study findings, the following recommendations are proposed:

1. **Institutional Integration:** To enhance early detection and management ADRs. Hospitals should implement AI-driven pharmacovigilance systems as part of routine clinical workflows.
2. **Training and Capacity Building:** Continuous training programs for pharmacists, nurses and physicians are essential to maximize the effective use of AI tools.
3. **Policy Development:** National health organization should establish guidelines for AI integration in pharmacovigilance, ensuring data privacy, ethical use and standardization of reporting.
4. **Continuous Monitoring and Evaluation:** Hospitals should update algorithms and regularly evaluate AI system performance, to adapt to evolving emerging drug safety concerns and clinical data.

Limitations

Though this study provides valuable understandings, certain limitations should be observed. Firstly, the study was performed in a few number of hospital settings, which may affect the generalizability of the outcomes across

on self-reported clinician observations may introduce bias, even though exertions to ensure secrecy and honest responses. Thirdly, the study primarily focused on patient safety outcomes and short-term ADR detection; long-term effects on clinical consequences and hospital budgets were not assessed. Finally, differences in AI system configurations and integration across hospitals may have influenced the results, emphasizing the need for consistent AI deployment protocols.

Hussain, T., & Tariq, N. (2024). Challenges and opportunities in AI adoption for healthcare in Pakistan. *Pakistan Journal of Health Technology*, 8(2), 67–82.

REFERENCES

- Ahmed, R., Malik, S., & Khan, F. (2024). Artificial intelligence in pharmacovigilance: Enhancing drug safety monitoring in hospital settings. *Journal of Clinical Pharmacy*, 12(3), 145–160.
- Ahmed, S., Khan, F., & Ali, R. (2024). Artificial intelligence in pharmacovigilance: Enhancing adverse drug reaction monitoring in hospital settings. *Journal of Patient Safety and Risk Management*, 29(3), 142–155.
- Bashir, M., Qureshi, T., & Farooq, U. (2023). Implementation of AI-based clinical decision support systems in Pakistani hospitals: Challenges and opportunities. *Health Informatics Journal*, 29(2), 101–115.
- Bhatti, A., & Hussain, S. (2025). Adverse drug reactions in tertiary hospitals: Current trends and reporting practices in Pakistan. *Journal of Pharmaceutical Policy and Practice*, 18(1), 55.
- Choudhury, P., & Singh, R. (2024). Machine learning approaches in pharmacovigilance: A systematic review. *Computers in Biology and Medicine*, 159, 106902.
- Hussain, M., Iqbal, A., & Rehman, S. (2024). Enhancing patient safety through AI-enabled ADR detection: Evidence from South Asian hospitals. *International Journal of Medical Informatics*, 171, 104974.

- Khan, A., & Mahmood, F. (2023). Pharmacovigilance systems in Pakistan: Status, challenges, and opportunities for digital transformation. *Pakistan Journal of Pharmaceutical Sciences*, 36(6), 2117–2129.
- Khan, M., Rehman, A., & Ali, S. (2024). Adverse drug reaction reporting practices in Pakistani hospitals: Gaps and recommendations. *Journal of Patient Safety and Risk Management*, 29(1), 23–36.
- Li, X., & Chen, Y. (2024). AI-assisted adverse drug reaction detection: Global trends and future prospects. *International Journal of Medical Informatics*, 174, 105025.
- Malik, N., & Saeed, H. (2024). Role of electronic health records and AI in reporting adverse drug reactions in hospitals. *Journal of Clinical Pharmacy and Therapeutics*, 49(5), 625–638.
- Parveen, S., & Ahmed, Z. (2023). Integrating AI-based tools in pharmacovigilance workflows: Clinician perspectives and usability assessment. *BMC Medical Informatics and Decision Making*, 23(1), 198.
- Qureshi, M., Tariq, F., & Shah, A. (2024). Adverse drug reaction monitoring in Pakistan: Trends, gaps, and the potential of artificial intelligence. *Frontiers in Pharmacology*, 15, 124567.
- Raza, H., & Khan, S. (2025). Predictive analytics in pharmacovigilance: Improving patient safety in low-resource hospital settings. *Computers in Biology and Medicine*, 171, 105012.
- World Health Organization. (2022). *The importance of pharmacovigilance: Safety monitoring of medicinal products*. WHO Press.

