Artificial Intelligence for the Future of Pharmacovigilance in Pakistan: Barriers, Opportunities, and Comparison with Other Low and Middle-Income Countries

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ABSTRACT

Artificial intelligence (AI) is progressing day by day, and with it, the number of unreported adverse drug reactions (ADRs) linked to inadequate pharmacovigilance (PV) in Pakistan is increasing. PV is defined as the science of identifying, evaluating, and preventing side effects or other drug-related issues in order to make sure that the advantages of medications balance the risks over the course of their whole lifecycle. It has been estimated that more than 75% of healthcare professionals display poor practices when it comes to reporting ADRs. However, the majority of them, in principle, have a positive attitude towards reporting. In comparison, self-medication completely bypasses the formal system and is carried out by over 61.2% of the population in certain samples. Internationally, AI has been suggested as a means of overcoming this gap by enabling real-time detection of ADRs, using predictive analytics, and automatically extracting adverse events from unstructured clinical text. This narrative review brings together the available evidence on Pakistan's current PV system, compares its performance with that of other low- and middle-income countries (LMICs) using the World Health Organization (WHO) Indicator-based Pharmacovigilance Assessment Tool (IPAT), and sets out a route for the implementation of AI-assisted PV. We drew on evidence from AI-based pharmacovigilance studies in low-resource settings, research using electronic health records, and a controlled trial of a mobile ADR-reporting application in Uganda to identify strategies relevant to Pakistan. Based on this evidence, the immediate priority should be to build sound policies and a qualified workforce rather than focusing on advanced modelling. Once these foundations are in place, lightweight, text-based AI interventions can be introduced in settings where drug exposure already takes place. Hence, this review also proposes a three-tier implementation roadmap based on Pakistan's local context and evidence from other LMICs.

Keywords: Pharmacovigilance, Artificial intelligence, Adverse drug reactions, Pakistan, Low- and middle-income countries.

INTRODUCTION

Pharmacovigilance (PV) refers to the monitoring of medicines after they are used in patients to detect, assess, understand, and prevent adverse drug reactions [1]. PV is the methodical tracking and gathering of information on both avoidable and unavoidable adverse drug events. Through pharmacovigilance, the development of appropriate regulatory measures and communicating potential medicine-related risks to healthcare professionals, patients, regulators, and other relevant stakeholders can be achieved [1]. In Pakistan, the need for a reliable PV system became evident after one of its worst drug-safety failures. In 2012, a contaminated cardiac medicine entered the market and killed more than 300 patients in Lahore [2]. In response to this incident, the Drug Regulatory Authority of Pakistan (DRAP) established a national pharmacovigilance centre in 2015, and Pakistan became a full member of the World Health Organization (WHO) Programme for International Drug Monitoring in 2018 [3,4]. Despite that, more than a decade after the tragedy, according to independent assessments, it is described that Pakistan's PV system is structurally incomplete rather than simply immature. One of these gaps is the limited integration of AI into PV, despite its growing use internationally to support different PV activities. These include machine-learning-based safety-signal detection, natural language processing (NLP) for automated extraction and classification of adverse drug reactions (ADRs), automated Medical Dictionary for Regulatory Activities (MedDRA coding) [5], duplicate-report detection [6], causality assessment [7], and analysis of unstructured data such as electronic health records and clinical narratives.

A key consideration in the integration of AI into PV should be taken into account, and that is that technological performance alone does not guarantee successful implementation. Although it is observed that machine-learning and NLP models have shown potential for detecting and predicting ADRs, their effectiveness depends heavily on the quality, completeness, representativeness, and accessibility of the data used to develop and validate them [8,5,9,10]. Recent evidence suggests that most AI-based pharmacovigilance studies focus on model development, with few undergoing external validation [11,10]. This reduces the degree to which their results may be applied to various healthcare environments and demographics. The problem is especially significant to Pakistan, where AI systems that were mostly trained on data from wealthy nations would not be able to recognize regional prescription trends, illness profiles, healthcare-seeking behaviors, reporting customs or linguistic variety. AI implementation in Pakistan's pharmacovigilance system should therefore proceed in stages: strengthening data collection and reporting infrastructure, building locally relevant datasets, validating models within Pakistani healthcare settings, and keeping human oversight over AI-generated safety signals [10]. Under this approach, AI would support existing pharmacovigilance activities rather than substitute for regulatory and clinical expertise [11].

These methods have shown potential to improve the efficiency and scale of pharmacovigilance by identifying safety signals, reducing the burden of manual case processing, and helping detect adverse drug reactions that might otherwise go unreported [10]. Whether these benefits hold in Pakistan's specific context, however, remains unresolved.

This review addresses that gap through a pragmatic, infrastructure-first evaluation of AI for pharmacovigilance in Pakistan. Existing literature on

AI-based pharmacovigilance is concentrated in high-income settings and largely assumes the data quality and infrastructure needed for these tools already exist. We map Pakistan's specific systemic constraints like workforce shortages, reporting gaps, regulatory capacity, and linguistic diversity against AI interventions that are actually feasible given those constraints, distinguishing tools that could work now from those that depend on infrastructure Pakistan does not yet have. Pakistan's pharmacovigilance infrastructure continues to face limitations and gaps in reporting systems, hospital-level PV capacity, active surveillance, regulatory coordination, and availability of resources and expertise, which may restrict the immediate adoption and effectiveness of sophisticated AI-based systems [12].

In this literature review, we will examine Pakistan's PV system, identifying the specific workforce, reporting infrastructure, and regulatory gaps within each component. We will map these weaknesses to relevant AI-based interventions and evidence from other LMICs. Further, as we dive in, we will discuss the involvement of more than seventy languages, a large informal and self-medication sector, and limited surveillance of traditional and herbal medicines. By linking each technological intervention to an evidence-based root cause, this review aims to distinguish AI applications that are genuinely feasible and relevant to Pakistan from those that depend on infrastructure that the country does not yet possess. Our review aims to understand the purpose of AI, which relies on established findings and determines which AI and NLP approaches are realistically aligned with Pakistan's documented needs. This review presents an innovative and practical strategy for incorporating intelligent automated technologies into Pakistan's pharmacovigilance system. Instead of providing general advocacy, we concentrate solely on infrastructure readiness. The majority of current work focuses on sophisticated models created for high-income nations, but these studies frequently disregard the data quality and baseline infrastructure needed to run them.

This paper addresses this gap by examining Pakistan's specific challenges, including shortages in the pharmacovigilance workforce, underreporting, regulatory limitations, and the country's linguistic diversity. These factors are important when considering which approaches can realistically be implemented in Pakistan. We distinguish between tools that can be used with the existing system and those that would require infrastructure that is not yet available. Based on this assessment, we propose an evidence-based roadmap for the use of AI in pharmacovigilance in Pakistan, an area that has received limited attention in the existing literature.

METHODOLOGY

This literature review is a summary based on evidence derived from the current state of PV in Pakistan, with attention to system gaps, comparisons with other low- and middle-income countries, and the potential role of AI in pharmacovigilance.

The searches were conducted in a targeted manner to identify text from sources such as PubMed, Scopus, Google Scholar, and preprint servers (arXiv, medRxiv) for peer-reviewed research articles, cross-sectional and qualitative surveys published mainly between 2011 and 2026.

We combined the search terms pharmacovigilance, adverse drug reaction reporting, drug safety, Pakistan, low- and middle-income countries, artificial intelligence, machine learning, electronic health

records, and underreporting in various ways. Reference lists of key papers turned up a few more studies. Official reports and indicator-based assessments, including the WHO Indicator-based Pharmacovigilance Assessment Tool (IPAT), needed separate searches.

We sorted the findings into three themes: how the system functions and where the gaps are, how Pakistan compares with other countries, and what implementing AI would involve. As this was a narrative review rather than a systematic review, formal quality assessment tools and quantitative meta-analysis were not used.

1. The Present State of Pharmacovigilance in Pakistan

In its present state, Pakistan's PV framework operates through a mix of digital reporting and regulatory enforcement, yet it remains largely human-driven.[10] The National Pharmacovigilance Centre (NPC) currently facilitates adverse drug reaction (ADR) collection via the online Med Vigilance E-Reporting System and the VigiMobile E-Form. DRAP has also mandated the submission of Risk Management Plans (RMPs) and active surveillance data for all registration holders, specifically targeting high-risk biologicals, vaccines, and new chemical entities.[3] Despite the international discourse on AI-powered predictive monitoring, DRAP's current operational blueprint still centers on human-managed collaborative safety networks, standardized E2B XML electronic transmission, and strengthened institutional coordination, which raises a major question about the current PV system of Pakistan. Additionally, decisions have not been taken for an immediate shift toward automated AI signal engines. The most systematic evaluation of Pakistan's PV system to date was done using the WHO's Indicator-Based Pharmacovigilance Assessment Tool (IPAT). This standardized instrument scores national systems against structural, resourcing, and outcome indicators. The results revealed multiple structural gaps and concluded that the PV system is not adequately functional at all levels within the health system in Pakistan, as recommended by the guidelines [3]. Analyses of pharmaceutical drug packages and package inserts have also been examined for their contribution to the development of the pharmacovigilance system in Pakistan [56].

2. Key Structural and Systemic Barriers to Implementation of AI-based Pharmacovigilance in Pakistan

2.1 A Barrier of Healthcare Education and Awareness

According to studies, Pakistan's pharmacovigilance system faces significant gaps, including the underreporting of adverse drug reactions (ADRs) and limited knowledge of existing pharmacovigilance mechanisms among healthcare professionals, partly due to gaps in healthcare education and awareness.[10] This represents a significant concern while developing AI-based pharmacovigilance systems in Pakistan because the development and performance of these technologies depend on the availability of high-quality, complete, and consistent safety data in sufficient quantity to inform the various tasks for which AI has been developed in this context, such as signal detection, ADR classification, duplicate detection, and the extraction of safety information [10]. In Pakistan, healthcare professionals lack knowledge of ADR reporting procedures, and reporting rates remain significantly low; the limited volume and quality of routinely collected safety data would restrict AI models' ability to identify meaningful patterns and safety signals.[10]

Qualitative and survey-based studies consistently showed that healthcare professionals generally recognize the importance of ADR reporting but face practical barriers in doing so. A study has been reported across different healthcare professional groups in Pakistan. [1] Lack of training was cited as one of the biggest obstacles to ADR reporting in a multicenter study conducted in Khyber Pakhtunkhwa, where 79.5% of healthcare professionals demonstrated poor knowledge of pharmacovigilance and ADR reporting, while lack of training was reported as one of the most important barriers to ADR reporting [13]. It was further found that 84.3% of participants identified the provision of ADR-management guidelines and training as factors that could encourage reporting [13]. Awareness of pharmacovigilance and the adverse drug reporting system among pharmacy students and professionals in Pakistan has also been assessed [55].

2.2 A Self-Medicating Population outside the Formal System's View

In Pakistan, the pharmacovigilance (PV) system largely relies on healthcare services to identify and report adverse drug reactions (ADRs). However, a substantial proportion of medicine use occurs outside the direct supervision of healthcare professionals through self-medication and other informal routes. This limits the ability of the current PV system to capture ADRs from these settings, resulting in some ADRs remaining unreported or undetected [14]. This signifies that hospital-based reporting systems, regardless of how well they are designed, can only capture adverse events when patients come into contact with the formal healthcare system. This represents an important limitation in Pakistan, where medicine use frequently occurs without consultation with a physician. This means the maintenance of data required for AI systems in PV, such as electronic health records, patient reports, online health discussions, pharmacy records, and other digital sources, remains undetected.[15] The importance of reporting is due to its role in serving as the dataset for machine-learning models so they can assist in identifying patterns and associations between medicines and adverse events across large datasets, allowing potential safety signals to be detected more rapidly. In Pakistan, such approaches could be particularly valuable because they could complement hospital-based reporting with community-level and patient-generated data. Implementing solutions to address this issue is crucial because one of the main obstacles to creating and using safety data is the low number and poor quality of data on adverse medication occurrences [15]. The risks of such unsupervised use extend to common over-the-counter medicines; paracetamol, present in every home, has been described as a stealthy killer in this context [58].

2.3 The Absence of a Regulatory Pathway for AI-Based Tools

A well-developed regulatory pathway is required to oversee AI-based pharmacovigilance tools and ensure that their use does not compromise patient safety. Pakistan has a legal framework for collecting, monitoring, assessing, and acting on adverse-event data, and it established the National Pharmacovigilance Centre under DRAP [3]. These regulations were written mainly for conventional PV activities. They do not clearly specify how an AI-based system should be evaluated, validated, classified, approved, or monitored across its life cycle. This raises a question about AI adoption and how the current regulatory framework would implement it for PV across the country.

These considerations are particularly important when AI is applied to safety signal detection. The

performance and reliability of AI-based systems may be affected by several factors, including data quality, changes in reporting practices, model-related biases, and differences between the demographic characteristics of the population used for model development and those of the population in which the system is implemented [16]. The WHO has recognized AI and machine learning as having potential applications in pharmacovigilance, while also emphasizing the need for adequate regulatory capacity, high-quality data, appropriate performance evaluation, and ethical use of AI in safety monitoring [16].

In Pakistan, where the regulatory framework for AI-based pharmacovigilance is still developing, further strengthening of regulatory capacity will be necessary to support its safe and effective implementation. [3] The successful integration of AI into pharmacovigilance in Pakistan will require more than technical development. It will also depend on regulatory capacity to assess AI-based tools, institutional mechanisms for their ongoing monitoring and validation, and clear governance frameworks defining how AI-generated safety signals are reviewed and incorporated into regulatory decisions [3]. Existing studies suggest that organizational inefficiencies, inadequate infrastructure, and inconsistent regulatory enforcement may further limit the adoption and effective use of AI in pharmacovigilance.

2.4 Traditional and Herbal Medicine as an Almost Entirely Unaddressed Category

A huge majority of the population in Pakistan, especially those located in underdeveloped areas, use traditional & herbal medicines [17]. An approach is required to this situation so that measures can be taken for surveillance of the adverse reactions and monitoring of these medications. Artificial intelligence provides an opportunity to address both the information and surveillance dimensions of this problem.

Machine-learning methods can assist in prioritizing large numbers of reports by identifying patterns that warrant further pharmacovigilance investigation. This is relevant because conventional pharmacovigilance depends heavily on structured information, whereas herbal products may be reported using local names, brand names, plant names, traditional terminology, or descriptions of preparations rather than standardized pharmaceutical names.[17] AI could therefore be trained to recognize synonyms and local terminology and link them to standardized botanical or medicinal-product identifiers. This would help in addressing the majority of the population and expanding the scope of Pharmacovigilance. The need for this is backed by the WHO (World Health Organization), which has recently highlighted AI as an emerging tool for traditional medicine, including applications related to data management, evidence generation, decision-making, and the digitization of traditional-medicine knowledge [18]. Therefore, an AI-assisted herbal pharmacovigilance approach could extend the reach of Pakistan's existing pharmacovigilance infrastructure associated with traditional and herbal medicines to be prioritized for assessment by pharmacovigilance professionals. [18]

2.5 Multilingualism as a Barrier to AI-Based Pharmacovigilance

Pakistan is a linguistically diverse country, with more than 70 languages spoken and major regional languages including Punjabi, Sindhi, Pashto, Balochi and Saraiki, Urdu [19]. This diversity creates a challenge for language barriers and data collection in healthcare settings [19]. For Pakistan, addressing this linguistic barrier could substantially expand the

population represented in pharmacovigilance data. A review of NLP-based adverse drug event detection found that multilingual and code-mixed content remain important challenges, while English dominates the available research datasets. Rather than restricting AI-based surveillance to English-language clinical records and formally documented ADR reports, a multilingual system could potentially incorporate patient reports expressed in Urdu and major regional languages, including Punjabi, Sindhi, Pashto and Balochi. [19]

A multilingual survey of pharmacovigilance terminology demonstrated substantial differences in the translation of safety-related terms across languages and highlighted the potential for linguistic differences to impair communication in pharmacovigilance [20]. The need for this approach in pharmacovigilance is due to the large number of reports that may be excluded because of language limitations, followed by potentially important safety information from large segments of the population that may remain absent from pharmacovigilance databases. [20] AI-assisted multilingual NLP could help overcome this limitation by translating, standardizing, and extracting information about medicines, symptoms, and suspected adverse reactions before the information is reviewed by pharmacovigilance professionals.

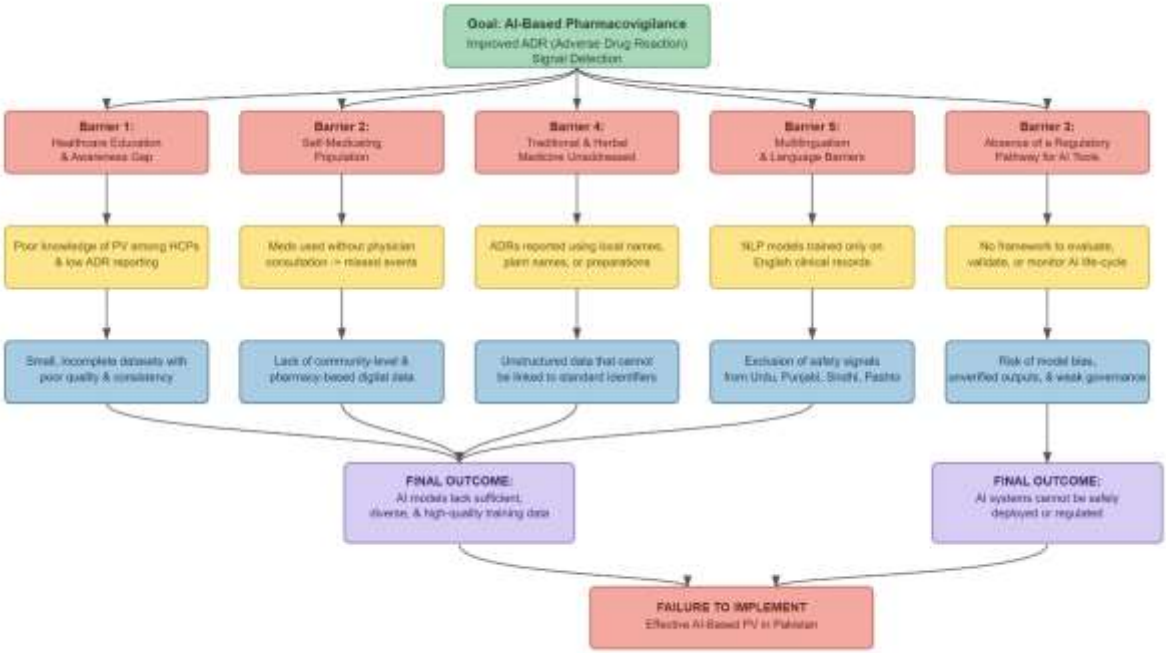


Figure 1: Flowchart overview representing the current barriers to implementation of AI-based pharmacovigilance in Pakistan

3. Pakistan in the Global Landscape of AI-Enabled Pharmacovigilance: Lessons from High-Income and LMIC Settings

High-income countries. High-income regulatory systems are increasingly incorporating artificial intelligence (AI) and machine learning into pharmacovigilance to manage the growing volume and complexity of medicine-safety data [21,22]. In the European Union (EU), the European Medicines Agency (EMA) is exploring AI applications across pharmacovigilance activities, including automated literature screening, adverse drug reaction (ADR) data extraction, case processing, case adjudication,

knowledge extraction and signal detection within EudraVigilance [21,22]. EMA, the US Food and Drug Administration (FDA), Health Canada and Japan's PMDA have also established an international AI-in-pharmacovigilance cluster to exchange experience and develop approaches for the responsible implementation of AI. These systems are being built as decision-support tools that assist pharmacovigilance professionals rather than replace them, and human oversight, validation, transparency, and data governance remain central to how they are used [23]. The WHO-Uppsala Monitoring Centre (WHO-UMC) VigiBase tools, the FDA Sentinel System, and the EMA's DARWIN EU show in practice how AI can help professionals handle large volumes of information and flag the cases that need closer assessment.

The foundation of international pharmacovigilance is its robust regulatory structure, which emphasizes that AI systems should be properly evaluated, their limitations should be recognized, and human specialists should continue to be involved in decisions when a mistake could have serious repercussions [23]. Working Group XIV of the Council for International Organizations of Medical Sciences (CIOMS) released its final report on "Artificial Intelligence in Pharmacovigilance" in December 2025 [23]. A risk-based strategy, human oversight, validity and robustness, transparency, data privacy, fairness, and governance are the seven fundamental concepts identified in the research [23]. These principles are relevant to Pakistan because the successful use of AI will require pharmacovigilance professionals who understand not only medicine safety but also the strengths and limitations of AI systems. In March 2026, EMA and FDA jointly published ten guiding principles for good AI practice across the medicine lifecycle [24]. The HMA-EMA updated work plan for 2026–2028 also places greater emphasis on data standards, AI development, and the use of real-world evidence through DARWIN EU. Rather than developing an entirely new governance structure, Pakistan could adapt these existing principles to its own regulatory and healthcare environment.

Low- and middle-income countries. LMICs generally face greater constraints in pharmacovigilance, including underreporting, limited numbers of trained personnel, fragmented information systems, inadequate resources and poor access to reliable medicine-utilization data [25,26]. Nevertheless, several LMICs are increasingly adopting digital technologies as a practical first step toward strengthening these systems. India, for example, has developed a nationwide Pharmacovigilance Programme with hundreds of adverse drug reaction monitoring centres and has identified AI applications such as natural language processing, optical character recognition, text mining, automated case processing and machine-learning-based signal detection as important tools for improving pharmacovigilance efficiency [27]. These approaches are particularly relevant to LMIC settings because they can automate repetitive tasks and extract useful information from large amounts of structured and unstructured data without requiring a complete transformation of the existing health system.

In LMICs, AI-enabled pharmacovigilance is developing at different rates, with most countries currently concentrating on strengthening the digital infrastructure required before more sophisticated AI applications can be introduced [26]. **India** has progressed relatively far in this area through its Pharmacovigilance Programme of India (PvPI), which has identified artificial intelligence, machine

learning, natural language processing, optical character recognition and text mining as potential tools for automating safety-data extraction and improving signal detection [27]. Uganda has focused more strongly on digital data collection and reporting, with its National Drug Authority using VigiFlow and VigiMobile to improve the electronic reporting and transmission of adverse drug events [28]. WHO also supported Uganda in expanding these tools in 2025 to improve the speed, accuracy and accessibility of safety reporting. Botswana has similarly adopted VigiFlow and connected digital reporting applications to facilitate adverse-event reporting and reduce underreporting [29]. Ghana, Rwanda, Sierra Leone and Zimbabwe have also been strengthening regulatory pharmacovigilance capacity through WHO-supported risk-management and safety-monitoring programmes [30, 29], demonstrating that many African LMICs are currently prioritizing standardized reporting, electronic systems and regulatory capacity as foundations for more advanced pharmacovigilance technologies. Pakistan's own pharmacovigilance literature includes, for example, a pharmacovigilance study of bleeding patterns among women using hormonal contraceptives [57].

Pakistan's current state concludes that rather than immediately attempting to replicate the highly advanced AI-enabled systems emerging in high-income countries, Pakistan could follow the more incremental pathway observed in resource-limited settings. This includes first strengthening electronic ADR reporting, data quality, standardization and interoperability between hospitals, provinces and the national system [3]. Research on AI-enabled pharmacovigilance in limited-resource settings emphasizes that reliable databases, trained personnel, appropriate technology and government support are prerequisites for successful AI implementation [31]. Pakistan's pharmacovigilance system lags behind those of many high-income countries and still has notable gaps even when compared with other LMICs. In the IPAT assessment by Khan et al., the country scored 80.76% on core indicators, yet the authors judged the system not fully functional, largely because provincial and hospital-level structures remained weak [3]. Limited active surveillance, poor coordination, budgetary constraints, and the lack of a comprehensive mandatory ADR-reporting framework were also noted. Evidence from other LMICs suggests an order of priorities: reliable reporting channels, structured databases, trained personnel, and firmer institutional support should come first, with advanced technologies added afterwards [32]. Once that base exists, Pakistan could move gradually toward the AI-enabled approaches now being developed by regulators in high-income settings [23, 24]. A staged approach looks like the most realistic path. Automated data extraction and case triage could come first, followed by duplicate detection and signal prioritization, and eventually predictive safety surveillance, with local datasets, AI governance standards, and specialist workforce capacity built up alongside. Such a sequence would give the country a workable route from its current, partially functional system to the data-driven, AI-assisted models seen in wealthier countries.

Table 1. A comparative observation for AI in pharmacovigilance between LMIC, high-income countries and Pakistan.

Feature	High-income countries	LMICs	Pakistan
Electronic PV infrastructure	Advanced	Developing	Developing
AI/NLP use	Increasing	Limited/emerging	Very limited

ADR reporting	Established	Underreported	Underreported
EHR integration	Relatively strong	Variable	Fragmented
Multilingual NLP	More developed	Major challenge	Major challenge
AI-specific regulation	More established	Limited	Emerging
Human/technical capacity	High	Limited	Limited
Potential AI strategy	Advanced AI	Incremental adoption	Phased implementation

4. Future Directions for AI-Based Pharmacovigilance in Pakistan

The above comparison suggests that the adoption of AI in pharmacovigilance in high-income countries depends on better infrastructure rather than just better technology [23, 24]. But, it is more of a step-by-step process carried under human supervision with standardized data transmission, validated regulatory channels, and continuous review of algorithmic output [23]. In Pakistan, the challenge is to address the gaps identified in this review and not to replicate these systems as quickly as possible.

4.1. Addressing Foundational Gaps before AI Deployment

Through analysis, three interconnected systemic vulnerabilities are highlighted that Pakistan must resolve before successfully integrating artificial intelligence into its pharmacovigilance framework. [13] These difficulties include the lack of a national governance model for AI, the ongoing lack of professional knowledge and training, and the absence of uniform policy and regulatory frameworks. Each of these crucial areas will be rigorously assessed in the conversation that follows.

4.1.1 Closing the Healthcare Professional Awareness Gap:

The significant role of education and awareness of health professionals needs to be strengthened due to the existing gap. This need arises from these professionals being the primary reporters and first users of any AI pharmacovigilance system. To close the gap, attention to two coordinated actions is required.[13] First, pharmacovigilance, including its emerging applications with artificial intelligence support, should be formally integrated into the curricula of pharmacy, medicine and nursing schools, to ensure that knowledge of reporting obligations and digital reporting tools is in place before practitioners enter the clinical field. Second, the Drug Regulatory Authority of Pakistan (DRAP) could launch structured continuing education and refresher training programmes for practitioners of medical sciences, which respondents in Khyber Pakhtunkhwa identified as the most likely to increase reporting [13]. The AI literacy programme that the European Medicines Agency has put in place for its own regulatory staff, which is discussed in more detail in section 4.3, provides a model for how DRAP-led training for frontline journalists could be adapted in the same way once the AI tools are introduced [23]. Preliminary insights from future pharmacy practitioners in Karachi on the integration of artificial intelligence into healthcare education are relevant to such curricular reform [59].

4.1.2 Policy and Regulatory Reform

Parallel policy and regulatory progress is also essential. Policies promoting the integration and improvement of electronic health records would help Pakistan to store and manage clinical data more effectively [33]. The Pakistan Drug Regulatory Authority already issues safety alerts, runs training programmes for health care professionals and operates an online spontaneous reporting system like MedVigilance, where patients, health care

professionals, and pharmaceutical companies can report side effects [34]. However, there is still considerable scope for further regulatory progress on the increasing number of cases of ADR in the country [34].

The lack of a formal legal need for reporting adverse drug reactions should be addressed by legislation [3]. According to Holdbrook et al. (2026), a structural deficit that is prevalent in the majority of low- and middle-income nations would be similarly addressed by a small digital-health or Software as a Medical Device assessment unit within the regulator [35].

4.1.3 Adapting International AI Governance Frameworks

International organizations have started creating standards for the appropriate use of AI as it becomes increasingly prevalent in pharmaceutical regulation. These frameworks are especially relevant to Pakistan because they offer direction on how AI might be implemented without letting technology advance at the expense of accountability and safety.

In January 2025, the proposed guidelines titled Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products was published by the FDA [36]. The guidelines included a risk-based approach, which meant that when an AI system has the potential to do more harm through poor judgment then more proof and analysis should be needed [36].

In December 2025, the final report on artificial intelligence in pharmacovigilance was released by CIOMS Working Group XIV [23]. In that report seven core principles are outlined including a risk-based approach, human oversight, validity and robustness, transparency, data privacy, fairness, and governance [23]. A lifecycle governance model is also proposed that defines roles and responsibilities, which include version control and auditability [23]. As compared to developing a new framework from ground up, adopting these principles would be a more practical approach. This would also ensure that proper oversight and validation standards used for future AI applications in Pakistan follow similar to those used in well-established regulatory systems.

4.2 A Pakistan-Focused Pathway for Early AI Adoption

After the foundations described in Section 2.1 are in place, Pakistan can move on to the step of introducing AI in a targeted and low-risk manner. This phased-approach would differ from trying to match the scale of high-income systems at an unprepared stage. The evidence shows caution on AI performance through causality assessments. This includes general-purpose large language models that have shown limited agreement with the WHO causality algorithm. This has also shown weaknesses in assessing temporal and biological plausibility by these models [37]. In comparison, on the same task there has been higher agreement with human experts observed in the biomedical large language models using prompting [38]. For Pakistan this evidence suggests that the initial use of AI for extraction, triage, and notification should be done. These are areas where AI can provide useful support. The role of AI should not replace human judgement in complex causality assessments. The three pilot interventions are proposed based on these considerations. Each intervention is discussed to address a specific barrier which has been identified earlier in this review.

Reducing underreporting through offline-capable mobile reporting. The development of an offline-capable mobile application used for adverse drug reaction reporting can help reduce under

reporting. This application can be based on the features in Uppsala Monitoring Centre's VigiMobile and integrated with DRAP's existing VigiFlow infrastructure. This would impact the decreased reporting observed by frontline health workers in areas with limited internet access [28, 39]. Due to the presence of VigiMobile which is already a part of the VigiFlow system used by Pakistan's Med Vigilance system, this adoption would build on existing infrastructure instead of requiring a separate system. The application could be further simplified by including multi lingual-language support and simpler drop-down menus making it more accessible. This approach has already been used in Oman and Mauritius, where more than 100 health professionals were trained on VigiMobile before its national launch [29]. This provides a useful training model that Pakistan could adapt.

Recovering unreported events already in clinical records. A simple natural language processing tool could be added to existing hospital dispensing software to help identify adverse events that are already mentioned in clinical notes but are not formally reported. This approach is supported by a study which found that only 28.6% of statin-related adverse reactions were recorded in a structured format in one hospital information system [28]. The rest were found in unstructured clinical notes [28]. At this stage, the pilot would focus on identifying and notifying possible adverse events rather than using advanced signal detection. This would allow AI to make better use of information that is already available without replacing human judgement in causality assessment.

Extending coverage to herbal and traditional medicine. A separate reporting channel can be used for herbal and traditional medicines and could help extend pharmacovigilance to people who are often not covered by conventional reporting systems [17]. This approach could be based on the module already used in India's Pharmacovigilance Programme [40].

4.3 Multi-Stakeholder Governance

The effective deployment of AI in pharmacovigilance at the national level would require the participation of several stakeholders [41, 42]. Government organizations, pharmaceutical corporations, technology companies, hospitals, and patient advocacy groups can all help to create and execute the system. In Pakistan, the significance of collaboration among many stakeholders in enhancing pharmaceutical safety has previously been recognized [41, 42]. Long-term improvement will also require government-led initiatives to set clear policies and raise knowledge about pharmacovigilance. These initiatives can also be added to the curriculum and training measures outlined in Section 2.1.1.

The CIOMS WG XIV framework can help DRAP establish this governance structure [23]. Its seven fundamental concepts, lifecycle governance architecture, and emphasis on interdisciplinary pharmacovigilance teams may be tailored to the Pakistani context [23]. The framework also emphasizes the necessity for pharmacovigilance experts to learn new skills in order to work with and manage AI-based systems [23]. Pakistan may benefit in AI literacy training for regulatory workers from the European Medicines Agency's implementation [22]. This training would cover the fundamental AI ideas, the EU AI Act and data protection [22].

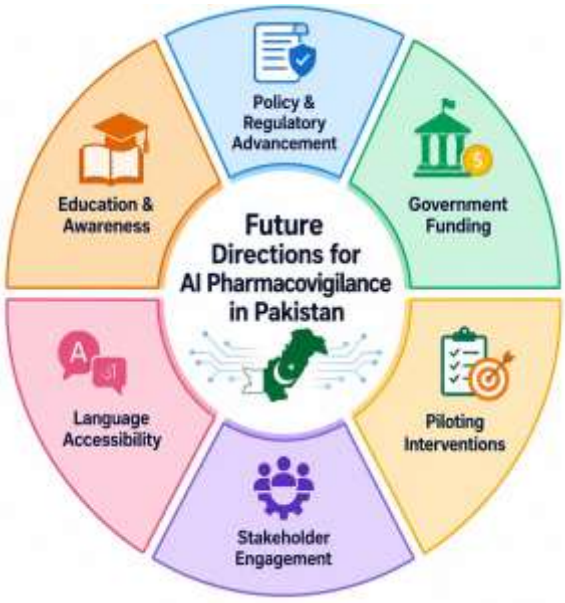


Figure 2: An overview of future directions for AI pharmacovigilance in Pakistan

4.4 A Three-Tiered Approach to AI Implementation in Pakistan

Considering these interventions together, they can be divided based on the conditions needed into three tiers Table 2. The first tier focuses on the basic gaps as discussed in Section 2.1. These include investments in Urdu-language clinical text resources, a legal obligation for reporting adverse drug reactions, a small digital health or software unit inside DRAP as a medical device evaluation unit, and organized awareness and training programs for healthcare personnel. Pakistan has not yet reached the necessary level of development in these sectors.

In the second tier, the pilot interventions are described in Section 2.2. These can be introduced once the basic foundations are in place. The third tier focuses on expanding the system to a level closer to that seen in more developed systems. This would include full integration with VigiFlow and VigiBase, a nationally available multilingual natural language processing system, and stable funding through the public health budget.

Table 2. A three-tiered approach for AI-assisted pharmacovigilance implementation in Pakistan.

Tier	Intervention	Rationale
Tier 1: Foundation	A legal requirement for adverse drug reaction reporting A small digital health or Software as a Medical Device evaluation unit within DRAP A funded effort to develop Urdu-language clinical text resources Structured awareness and training programmes for healthcare professionals	Khan et al. (2022a) identify the lack of a legal requirement for adverse drug reaction reporting as a basic need rather than a technical issue [3]. Holdbrook et al. (2026) report a similar lack of regulatory systems in most low- and middle-income countries [35]. Faisal and Yousaf (2024) found that there is currently no Urdu clinical natural language processing resource available for this purpose [43]. Sharif et al. (2022) also found that most healthcare professionals in Pakistan lack basic pharmacovigilance training. They suggested that this gap can be

		addressed through proper guidance and training [13].
Tier 2: Pilot	An offline mobile application for adverse drug reaction reporting based on VigiMobile, a simple natural language processing tool added to existing hospital dispensing software, and a separate reporting system for herbal and traditional medicines.	VigiMobile has already been used successfully in Mauritius and Oman [29]. Skentzos et al. (2011) support the use of text mining rather than developing a completely new system [28]. Kalaiselvan et al. (2015) also show that a separate reporting system for herbal medicines can be successfully used.
Tier 3: Scale	This involves full integration with VigiFlow and VigiBase, the development of a multilingual natural language processing system that is available across the country, and stable funding through the public health budget.	Ampadu et al. (2016) and Sabblah et al. (2022) show the challenges caused by limited integration with VigiBase [45,46]. Menang et al. (2025) also found that unstable funding is a major reason why pharmacovigilance systems in low- and middle-income countries often fail to continue after an initial pilot [32].

The order of these tiers is intentional. As discussed in this review, the main value of AI in Pakistan in the near term is to identify adverse events that are already occurring but are not being reported. It can also help address the lack of awareness that prevents these events from being reported. Due to the limitation of available data, the main goal at this stage should not be to develop a completely new signal detection system. Automating a system that isn't yet functioning properly could result in moving to the second or third tier before the first tier is set. The comparative evidence, which indicates that integrating AI into an unstable pharmacovigilance system may exacerbate rather than improve current weak processes, further supports this worry [32]. After strengthening these foundations, Pakistan could gradually introduce AI for natural language processing, automated adverse drug reaction extraction and signal prioritization. The use of these applications have already been explored in pharmacovigilance research in other settings [5,6]. The development of local datasets including Urdu and other relevant clinical language data is going to be important for this progress [43,44]. Additionally, AI validation with proper governance and workforce training will be needed [23]. In combination, these steps could help Pakistan transition from a strengthened digital pharmacovigilance system towards more advanced AI-supported systems which are currently being explored in high-income regulatory systems.

5. Limitations

The limitations of this review stem from its narrative rather than its systematic design. The search was mostly restricted to English-language sources, which may have left out Urdu-language regulatory or gray literature. Also, no systematic search protocol was used, and no independent dual-rater screening of included research was done. The statistics and contribution percentages should be understood as accurate as of each source's publication date rather than as a static image because the evidence base is always evolving. Every claim made about Pakistan's system is supported by evaluations that have already been published, some of which were completed years prior to the writing of this research. For this review, no primary data collection, survey work, or stakeholder interviews were conducted. Furthermore, before any particular recommendation could be responsibly implemented, piloting, costing, and direct stakeholder consultation would be necessary. The gap-to-intervention mapping and phases are conceptual contributions meant to organize current evidence and direct future work, not validated implementation plans.

6. CONCLUSION

In Pakistan pharmacovigilance remains largely undeveloped, questioning the possibility of AI adoption and implementation in this system. Despite the existence of a formal regulatory system through the Drug Regulatory Authority of Pakistan, which is currently working on advancing the PV system, there are still barriers that set the country behind in terms of AI adoption. These barriers include underreporting, the training of healthcare professionals, underdeveloped infrastructure, and language diversity. The IPAT-based comparison in this review also places Pakistan alongside other low- and middle-income countries that share the same challenges, suggesting that these are structural issues common to countries at comparable levels of development and not specifically relevant to Pakistan. Artificial Intelligence, particularly NLP-based extraction of adverse events from unstructured clinical records and multilingual text, may represent a step forward in this system. However, the success of AI deployment depends on solving the problems through a phased approach. Some ways include the implementation of parallel investments in healthcare professional education, electronic health record infrastructure, and functioning stakeholder coordination. Phased pilot programs, using internationally proven platforms and supported by clear regulatory and financial arrangements, represent the most practical approach to developing a functioning AI-supported pharmacovigilance system in Pakistan in the short to medium term.

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