

**ARTIFICIAL INTELLIGENCE IN PHARMACOVIGELLANCE: EMERGING DRUG
SAFETY MONITORING**

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ABSTRACT

Pharmacovigilance is an important aspect of healthcare that is dedicated to the identification, evaluation, interpretation, and prevention of adverse drug reactions (ADRs) to guarantee patient safety. Conventional pharmacovigilance systems use spontaneous reporting, clinical trials and manual signal-data analysis, but these approaches are susceptible to underreporting, slow signal recognition, and limited data analysis. Artificial Intelligence (AI) is one of the latest technologies that have changed the landscape of drug safety monitoring in the last few years by allowing quicker and more precise and data-driven decisions. This review discusses AI in pharmacovigilance focusing on the new drug safety monitoring systems. Machine learning, deep learning, and natural language processing (NLP) AI tools are getting more commonly used to process large and multifaceted healthcare data, such as electronic health records (EHRs), clinical databases, scientific literature, and social media platforms. These technologies enhance detection of adverse drug reactions, signal detection, and the risk assessment, and decrease the human error and workload. Pharmacovigilance systems, which are based on AI, also promote real-time monitoring and predictive analytics, which can identify possible safety risks before they become widespread. Moreover, AI can be incorporated with big data analytics and digital health platforms to increase the effectiveness and scale of international drug safety surveillance. Although these benefits exist, issues like data privacy, absence of standardized data, ethical concerns, and barriers to implementation need to be managed to achieve successful adoption. Altogether, AI can transform pharmacovigilance by transforming drug safety surveillance into a proactive and predictive method, which will ultimately enhance patient outcomes and enhance healthcare systems.

KEYWORDS: Artificial Intelligence, Pharmacovigilance, Adverse Drug Reactions, Machine Learning, Drug Safety Monitoring, Signal Detection.

1. INTRODUCTION

Pharmacovigilance is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. It plays a crucial role in ensuring patient safety by continuously monitoring the benefit–risk balance of

medicinal products after they are introduced into the market. Traditional pharmacovigilance systems mainly depend on spontaneous reporting systems, clinical trials, and manual evaluation of adverse drug reaction (ADR) reports. However, these conventional approaches are often associated with limitations such as underreporting,

delayed detection of safety signals, data fragmentation, and human interpretation errors.^[1] With the rapid expansion of healthcare data sources, including electronic health records (EHRs), clinical databases, social media platforms, and global pharmacovigilance databases, the volume and complexity of drug safety data have increased significantly. This has created a strong need for advanced computational techniques that can efficiently process large-scale heterogeneous data and identify potential drug safety issues in real time.^[2]

1.1 Background of Pharmacovigilance

The term pharmacovigilance refers to the scientific discipline concerned with monitoring the safety of medicines throughout their lifecycle. It involves collecting and analyzing data related to adverse drug reactions, identifying potential risks, and implementing regulatory actions when necessary. The primary goal is to reduce harm to patients and improve public health outcomes. Traditionally, pharmacovigilance relied heavily on Individual Case Safety Reports (ICSRs), manual data review, and expert clinical judgment. While effective to some extent, these methods are limited by slow processing speed and incomplete reporting. Furthermore, many adverse drug reactions remain unreported due to lack of awareness or reporting burden on healthcare professionals.^[3] Modern pharmacovigilance systems now deal with large-scale, unstructured, and diverse datasets, requiring more advanced analytical methods for efficient signal detection and risk assessment.^[4]

1.2 Need for Drug Safety Monitoring

Drug safety monitoring is essential because adverse drug reactions are a significant cause of morbidity and hospital admissions worldwide. Even after rigorous clinical trials, some rare or long-term side effects may only become apparent once the drug is widely used in real-world populations.

The need for effective pharmacovigilance arises due to several factors

1. Increasing number of newly approved drugs
2. Complex drug–drug interactions
3. Genetic variability among patients affecting drug response
4. Underreporting of adverse drug reactions
5. Delayed identification of safety signals in traditional systems

Studies indicate that adverse drug reactions contribute significantly to healthcare burden and can sometimes lead to severe or life-threatening conditions if not detected early.^[3] Therefore, continuous and efficient drug safety monitoring is essential throughout the lifecycle of a medicine.^[3]

1.3 Emergence of Artificial Intelligence in Healthcare
Artificial Intelligence (AI) refers to the simulation of human intelligence in machines that are programmed to

think, learn, and make decisions. AI technologies such as machine learning (ML), deep learning (DL), and natural language processing (NLP) are increasingly being applied in healthcare for diagnosis, treatment planning, drug discovery, and patient monitoring.

In pharmacovigilance, AI has emerged as a transformative technology due to its ability to process large volumes of structured and unstructured data efficiently. Machine learning algorithms can identify patterns in adverse drug reaction data, while NLP techniques can extract relevant information from clinical notes, scientific literature, and social media posts.

AI-based systems significantly improve the speed and accuracy of signal detection, reduce manual workload, and enable real-time monitoring of drug safety data. However, despite its advantages, challenges such as data quality, model transparency, and regulatory acceptance still need to be addressed for full-scale implementation.^[5]

1.4 Scope of Artificial Intelligence in Pharmacovigilance
The application of AI in pharmacovigilance is rapidly expanding and has the potential to transform drug safety monitoring systems. AI enables the analysis of large-scale pharmacovigilance data from multiple sources, including electronic health records, spontaneous reporting systems, biomedical literature, and patient-generated data.

Applications include

1. Signal Detection

AI algorithms help identify early warning signals of adverse drug reactions from large datasets, improving the speed of detection compared to traditional methods.^[2]

2. Natural Language Processing (NLP)

NLP techniques extract meaningful information from unstructured text such as clinical reports, case narratives, and scientific publication.^[4]

3. Machine Learning Models

Machine learning models predict potential adverse drug reactions based on historical data and identify high-risk drug combinations.^[5]

4. Social Media and Real-World Data Analysis

AI tools analyze patient discussions on social media platforms to detect previously unreported side effects and real-world drug usage patterns.^[2]

5. Automated Pharmacovigilance Systems

AI supports automation in case processing, report generation, and regulatory compliance, thereby reducing manual workload and improving efficiency.^[1]

Overall, AI enhances the capability of pharmacovigilance systems by making them faster, more accurate, and more scalable. However, ethical concerns, data privacy issues,

and regulatory validation remain important challenges that need to be addressed.^[3]

Pharmacovigilance is a fundamental discipline in healthcare that ensures the safety of medicines after they are introduced into the market. It focuses on identifying, evaluating, and preventing adverse drug reactions (ADRs) and other drug-related problems to improve patient safety and treatment outcomes. With increasing drug usage and complex therapies, pharmacovigilance has become a critical component of modern healthcare systems.^[6]

2.1 Definition and Objectives

Pharmacovigilance is defined as the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. It plays a vital role in monitoring the safety of medicines throughout their lifecycle, especially after they are approved for public use.

Objectives of Pharmacovigilance

1. To detect adverse drug reactions (ADRs) at an early stage
2. To assess the risk–benefit profile of medicines
3. To prevent drug-related harm in patients
4. To improve rational and safe use of medicines
5. To support regulatory decision-making and policy development

The ultimate goal of pharmacovigilance is to ensure that medicines are used safely and effectively in real-world conditions.^[6]

2.2 Importance in Public Health

Pharmacovigilance is essential for protecting public health by ensuring that medicines available in the market are safe for human use. Even after clinical trials, some adverse effects may remain undetected due to limited sample size and controlled environments.^[7]

It is important because

1. Adverse drug reactions are a major cause of hospital admissions and morbidity
2. It helps in identifying rare and long-term side effects
3. It supports early warning systems for drug safety issues
4. It improves patient confidence in healthcare systems
5. It contributes to evidence-based medical practice

Effective pharmacovigilance systems help reduce healthcare burden and improve overall treatment outcomes.^[8]

2.3 Traditional Methods of Pharmacovigilance

Traditional pharmacovigilance methods mainly rely on manual and passive reporting systems.

These include:

1. Spontaneous Reporting System

2. Case Reports and Case Series
3. Clinical Trials
4. Literature Review
5. Regulatory Databases.^[9]

2.4 Limitations of Conventional Systems

Despite their importance, traditional pharmacovigilance systems have several limitations:

1. Underreporting of ADRs

A large number of adverse drug reactions are never reported due to lack of awareness or reporting burden on healthcare professionals.^[6]

2. Delayed Signal Detection

Manual processing of reports leads to slow identification of safety signals, delaying regulatory action.

3. Data Quality Issues

Reports may be incomplete, inconsistent, or inaccurate, affecting analysis reliability.

4. Limited Data Sources

Traditional systems rely mainly on clinical and hospital reports, ignoring real-world data sources such as social media and EHRs.

5. Human Error and Bias

Manual analysis is prone to interpretation errors and subjective bias.

6. Lack of Real-Time Monitoring

Conventional systems are not capable of continuous, real-time drug safety surveillance. These limitations highlight the need for advanced technologies such as Artificial Intelligence to enhance pharmacovigilance efficiency and accuracy.^[10]

3. Artificial Intelligence (AI) in Healthcare

Artificial Intelligence (AI) has emerged as one of the most transformative technologies in modern healthcare. It enables machines to simulate human intelligence, allowing them to learn from data, recognize patterns, and make decisions with minimal human intervention. In healthcare, AI is increasingly used to improve diagnosis, treatment planning, drug development, and patient safety monitoring.^[11]

The integration of AI in healthcare has significantly improved efficiency, reduced workload, and enhanced the accuracy of clinical decision-making systems. With the availability of large-scale medical data, AI plays a crucial role in analyzing complex datasets and generating meaningful insights for better healthcare outcomes.^[12]

3.1 Definition of Artificial Intelligence

Artificial Intelligence refers to the ability of computer systems or machines to perform tasks that normally require human intelligence, such as reasoning, learning, problem-solving, and decision-making. In healthcare, AI

is used to mimic cognitive functions of humans by processing medical data, identifying patterns in disease progression, and supporting clinical decisions. It allows systems to continuously improve performance through learning from new data.^[13]

3.2 Types of AI Techniques

AI in healthcare mainly involves three important techniques:

1. Machine Learning (ML)

Machine Learning is a subset of AI that enables systems to learn from data without being explicitly programmed. It uses algorithms to identify patterns and make predictions based on historical data.

Example in healthcare

Predicting disease risk

Identifying adverse drug reactions

Classifying medical images

ML is widely used in pharmacovigilance for detecting safety signals from large datasets.^[11]

2. Deep Learning (DL)

Deep Learning is an advanced form of machine learning that uses artificial neural networks inspired by the human brain. It is highly effective in processing large and complex datasets.

Example in healthcare

Cancer detection from medical images

ECG and brain signal analysis

Drug discovery modeling

Deep learning improves accuracy in pattern recognition and is especially useful in radiology and diagnostics.^[12]

3. Natural Language Processing (NLP)

NLP enables computers to understand and process human language. It is used to extract meaningful information from unstructured medical text such as clinical notes, research articles, and patient reports.

Example in healthcare

1. Extracting adverse drug reactions from reports
2. Analyzing electronic health records (EHRs)
3. Processing patient feedback and social media data

NLP plays a crucial role in pharmacovigilance by automating adverse event detection from textual data.^[14]

3.3 Applications of AI in Medicine and Pharmacy

AI has a wide range of applications in healthcare and pharmaceutical sciences:

In Medicine

1. Disease diagnosis and prediction
2. Medical image interpretation (X-rays, MRI, CT scans)
3. Personalized treatment planning
4. Virtual health assistants

In Pharmacy

1. Drug discovery and development
2. Adverse drug reaction detection
3. Clinical trial optimization
4. Medication adherence monitoring

AI helps reduce time and cost in drug development and improves the safety and effectiveness of medicines.^[15]

3.4 Role of AI in Data Analysis and Prediction

AI plays a crucial role in analyzing large and complex healthcare datasets. It can process structured and unstructured data from multiple sources such as electronic health records, clinical trials, and real-world evidence databases.

Roles

1. Identifying hidden patterns in medical data
2. Predicting disease outbreaks and patient risks
3. Detecting adverse drug reactions early
4. Supporting clinical decision-making
5. Improving accuracy of healthcare predictions

Machine learning models are particularly useful in predicting patient outcomes and drug safety risks with high accuracy. AI also enhances real-time data analysis, which is essential for modern pharmacovigilance systems and precision medicine approaches.^[11]

4. Integration of AI in Pharmacovigilance

AI-driven pharmacovigilance systems use machine learning, natural language processing (NLP), and deep learning models to improve the identification, evaluation, and prevention of drug-related risks. These technologies are increasingly being adopted by regulatory agencies, pharmaceutical industries, and healthcare institutions.^[3]

4.1 AI-Based Drug Safety Monitoring Systems

AI-based drug safety monitoring systems are designed to automatically collect, process, and analyze large volumes of pharmacovigilance data from multiple sources such as electronic health records (EHRs), clinical trials, scientific literature, and social media platforms.

These systems use machine learning algorithms to detect patterns associated with adverse drug reactions and assess potential safety risks in real time. Unlike traditional systems, AI-based platforms continuously learn from new data, improving their accuracy over time.

Examples include

1. Automated pharmacovigilance databases
2. AI-driven signal detection platforms
3. Intelligent clinical decision support systems

Such systems enhance efficiency, reduce human workload, and improve early detection of drug safety issues.^[4]

4.2 Automated Adverse Drug Reaction (ADR) Detection

Automated ADR detection uses AI techniques such as NLP and machine learning to identify adverse drug reactions from unstructured data sources. These include clinical notes, discharge summaries, case reports, and patient feedback. systems have shown higher sensitivity compared to traditional manual methods.^[1]

4.3 Signal Detection and Risk Assessment

Signal detection is a critical component of pharmacovigilance that involves identifying new or previously unrecognized safety risks associated with drugs. AI significantly enhances this process by analyzing large datasets and detecting subtle patterns that may indicate potential safety signals. Machine learning algorithms can process millions of reports simultaneously and identify correlations between drugs and adverse events. These models also help in risk assessment by predicting the severity and likelihood of adverse outcomes.

AI improves the speed, accuracy, and reliability of signal detection compared to traditional statistical methods.^[16]

4.4 Real-Time Data Monitoring

Real-time data monitoring is one of the most advanced applications of AI in pharmacovigilance. It enables continuous surveillance of drug safety data as it is generated from various sources such as hospitals, wearable devices, electronic health records, and online platforms. AI systems process incoming data streams instantly and detect potential safety issues without delay. This allows healthcare professionals and regulatory authorities to take timely action.

Real-time AI monitoring systems significantly improve pharmacovigilance responsiveness and help prevent widespread drug-related harm.^[17]

5. Emerging Technologies in Drug Safety Monitoring

The field of pharmacovigilance is rapidly evolving due to the integration of advanced digital technologies. Emerging technologies such as Natural Language Processing (NLP), Machine Learning (ML), Big Data Analytics, and Social Media Mining are transforming traditional drug safety monitoring systems into more intelligent, predictive, and real-time platforms. These technologies enhance the detection of adverse drug reactions (ADRs), improve signal accuracy, and support faster regulatory decision-making.^[18]

5.1 Natural Language Processing in ADR Reporting

Natural Language Processing (NLP) is a branch of Artificial Intelligence that enables computers to understand and interpret human language. In pharmacovigilance, NLP is widely used to extract relevant information about adverse drug reactions from unstructured text sources such as clinical notes, discharge

summaries, electronic health records (EHRs), and biomedical literature.

NLP techniques help in

1. Identifying drug-event relationships
 2. Extracting ADR mentions from text
 3. Automating case report processing
 4. Improving pharmacovigilance database accuracy
- By converting unstructured data into structured information, NLP significantly reduces manual workload and improves the speed of ADR reporting.^[19]

5.2 Machine Learning Models for Prediction of Drug Reactions

Machine Learning (ML) models play a crucial role in predicting potential adverse drug reactions by analyzing historical pharmacovigilance data. These models learn patterns from large datasets and identify relationships between drugs and side effects.

Common ML approaches include:

1. Supervised learning (classification of ADRs)
2. Unsupervised learning (pattern detection)
3. Deep learning models for complex prediction tasks

ML algorithms are used to

1. Predict high-risk drug combinations
 2. Identify patient-specific drug risks
 3. Support early warning systems
- These predictive models improve the accuracy and efficiency of drug safety monitoring systems compared to traditional statistical methods.^[20]

5.3 Big Data Analytics in Pharmacovigilance

Big Data Analytics refers to the processing and analysis of extremely large and complex datasets generated from multiple healthcare sources such as hospitals, clinical trials, insurance records, and wearable devices.

In pharmacovigilance, big data enables:

1. Integration of multiple data sources
2. Identification of rare adverse drug reactions
3. Long-term safety monitoring
4. Improved regulatory decision-making

Advanced analytics tools process structured and unstructured data to identify hidden safety signals that may not be detected through conventional methods. The use of big data improves transparency, speed, and accuracy in drug safety evaluation.^[21]

5.4 Social Media and Digital Health Data Mining

Social media platforms and digital health forums have become valuable sources of real-world drug safety information. Patients often share their experiences, side effects, and treatment outcomes on platforms such as Twitter, Facebook, and online health communities.

Although social media data is unstructured and noisy, AI-based filtering techniques help improve the reliability of

extracted information. This approach provides a more patient-centric view of drug safety.^[22]

6. Benefits of AI in Pharmacovigilance

The integration of Artificial Intelligence (AI) into pharmacovigilance has significantly improved the efficiency and effectiveness of drug safety monitoring systems. AI technologies such as machine learning, natural language processing, and predictive analytics enhance the ability to detect, analyze, and prevent adverse drug reactions (ADRs) more efficiently than traditional manual methods. Overall, AI contributes to safer medication use and improved public health outcomes.^[1]

6.1 Improved Accuracy and Speed

6.2 Early Detection of Adverse Drug Reactions.

6.3 Reduced Human Error

6.4 Cost-Effective Monitoring Systems.^[23]

7.1 Data Privacy and Security Issues

One of the major challenges in AI-driven pharmacovigilance is ensuring the privacy and security of sensitive patient health data. AI systems often rely on large datasets obtained from electronic health records (EHRs), clinical trials, and real-world sources.

Concerns include

1. Risk of unauthorized access to patient data
2. Potential data breaches in healthcare systems
3. Difficulty in anonymizing unstructured datasets
4. Compliance with data protection regulations

Maintaining confidentiality while enabling data sharing for analysis remains a significant challenge in healthcare AI applications.^[24]

7.2 Lack of Standardized Data

Pharmacovigilance data is often collected from multiple sources such as hospitals, regulatory databases, social media, and literature reports. However, these datasets are not standardized, which creates difficulties in integration and analysis.

Problems include

1. Different reporting formats across systems
2. Inconsistent terminology for adverse drug reactions
3. Missing or incomplete data entries
4. Variability in data quality across regions

This lack of standardization reduces the accuracy of AI models and limits their ability to generate reliable predictions.^[25]

7.3 Ethical Concerns

The use of AI in pharmacovigilance raises several ethical issues that must be carefully considered. Since AI systems make predictions based on algorithms, there is a risk of bias and lack of transparency.

Ethical challenges include

1. Algorithmic bias affecting certain populations

2. Lack of explainability in AI decision-making (“black box” problem)

3. Accountability for incorrect predictions

4. Informed consent for data usage

Ensuring fairness, transparency, and accountability in AI systems is essential for ethical implementation in healthcare.^[23]

7.4 Technical and Implementation Barriers

Despite technological advancements, several technical and practical barriers hinder the widespread adoption of AI in pharmacovigilance.

These include

1. High computational requirements for processing large datasets
2. Need for advanced infrastructure and skilled professionals
3. Integration difficulties with existing healthcare systems
4. Limited validation and regulatory approval of AI models

Additionally, AI models require continuous updates and training with high-quality data to maintain accuracy and relevance.^[24]

8. Future Perspectives of AI in Pharmacovigilance

The future of pharmacovigilance is strongly influenced by rapid advancements in Artificial Intelligence (AI), data science, and digital health technologies. AI is expected to transform traditional drug safety monitoring into a more proactive, predictive, and patient-centered system. With increasing availability of real-world data and computational power, AI will play a central role in shaping next-generation pharmacovigilance systems.^[26]

8.1 AI-Driven Personalized Drug Safety Systems

Future pharmacovigilance systems will move toward personalized drug safety monitoring, where AI tailors drug risk assessment based on individual patient characteristics.

These systems will consider

1. Genetic profile of patients
2. Age, gender, and medical history
3. Lifestyle and environmental factors
4. Drug–drug interactions specific to individuals

Machine learning models will predict how a particular patient may respond to a drug, enabling personalized risk assessment and safer treatment decisions. This shift will support precision medicine and reduce adverse drug reactions significantly.^[27]

8.2 Integration with Electronic Health Records (EHRs)

The integration of AI with Electronic Health Records (EHRs) is expected to be a major advancement in pharmacovigilance. EHRs contain vast amounts of structured and unstructured clinical data that can be analyzed in real time.

AI-powered EHR integration will enable

1. Continuous monitoring of patient drug responses
2. Automatic detection of adverse drug reactions
3. Real-time safety alerts for clinicians
4. Improved data sharing across healthcare systems

This integration will significantly enhance the speed and accuracy of drug safety surveillance and support clinical decision-making.^[26]

8.3 Development of Advanced Predictive Models

Future pharmacovigilance will rely heavily on advanced predictive models powered by deep learning and artificial neural networks. These models will go beyond detection and focus on predicting adverse drug reactions before they occur.

Developments include

1. Predictive modeling of rare and complex ADRs
 2. Risk stratification of patients based on drug exposure
 3. Simulation of drug–drug interaction outcomes
 4. Continuous learning systems that improve over time
- Such models will enable proactive pharmacovigilance, shifting the focus from reaction-based systems to prevention-based systems.^[28]

8.4 Role in Global Pharmacovigilance Systems

AI is expected to play a crucial role in developing global pharmacovigilance networks by integrating data from different countries, healthcare systems, and regulatory agencies.

Future global applications include

1. Standardized international drug safety databases
 2. Cross-border sharing of ADR information
 3. Real-time global safety signal detection
 4. Harmonization of regulatory decision-making
- This global integration will improve transparency, strengthen drug safety regulations, and ensure faster response to emerging safety threats worldwide.^[29]

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