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Review Article

Enhancing Pharmacovigilance through Artificial Intelligence

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ABSTRACT

Artificial Intelligence (AI) has emerged as a transformative force in pharmacovigilance (PV), enhancing the detection, assessment, and prevention of adverse drug reactions (ADRs). Traditional PV methods, often limited by manual reporting, underreporting, and data complexity, are gradually being supplemented by AI-driven systems that offer automation, precision, and real-time analysis. This review explores the integration of AI techniques—such as machine learning, deep learning, and natural language processing (NLP)—into various aspects of PV, including adverse event detection, signal management, and risk prediction. Applications such as VigiLanz, ArisGlobal's LifeSphere MultiVigilance, IQVIA Vigilance Detect, TCS ADD, and PVLens demonstrate how AI-based tools enhance efficiency and regulatory compliance in drug safety monitoring. The study also discusses key benefits, including simplified case processing, predictive analytics, and improved surveillance, while addressing limitations such as data quality concerns, ethical challenges, and the need for human oversight. Looking ahead, the integration of AI with genomics, biomarkers, and real-time data has the potential to transform PV into a predictive, proactive, and globally harmonized discipline, significantly improving patient safety and public health outcomes.

INTRODUCTION

WHAT IS MEANT BY ARTIFICIAL INTELLIGENCE?

Artificial Intelligence (AI) is a field of computer science that aims to enable machines to think and act like humans. It allows computers to learn from experience, understand language, recognize images and patterns, solve problems, and make intelligent decisions. In simpler terms, AI gives computers the ability to learn, reason, and respond intelligently—much like humans do.[1]

WHAT IS MEANT BY PHARMACOVIGILANCE?

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Pharmacovigilance refers to the continuous monitoring of the safety of medicines after they are developed and used by the public. Its primary goal is to detect, understand, and prevent any adverse effects or drug-related problems. In simple terms, pharmacovigilance ensures that the medicines we use remain safe and continue to provide more benefits than risks.[2]

The use of Artificial Intelligence (AI) in pharmacovigilance (PV) has grown rapidly, offering the potential to enhance both the efficiency and accuracy of adverse event identification.[3] This shift has been driven by increasing challenges in drug development and post-marketing surveillance, including the exponential growth in data volume, the complexity of drug interactions, and variability among patients. [4,5] Despite its potential, transitioning AI from experimental applications to routine and reliable implementation presents several challenges. These include ensuring consistent performance after deployment, managing real-world complexities, and minimizing bias and unintended outcomes. This review examines the current role of AI in pharmacovigilance (PV) and discusses strategies for its effective integration into daily operations while maintaining ethical and legal compliance.

The use of AI in PV began in the early 2000s with the adoption of data-mining algorithms for signal detection in spontaneous reporting systems (SRS). Early innovations such as the Bayesian Confidence Propagation Neural Network (BCPNN) and the Multi-item Gamma Poisson Shrinker (MGPS) laid the foundation for advanced AI-driven PV applications. Over time, AI has been incorporated into multiple PV activities, including automated case processing, signal detection, and real-world evidence evaluation.[6,8]

The pharmacovigilance (PV) lifecycle encompasses both pre-marketing and post-marketing stages, each characterized by distinct types of data. In the pre-marketing phase, PV primarily relies on structured data generated from clinical trials. In contrast, post-marketing surveillance utilizes both structured and unstructured data from multiple sources, including Individual Case Safety Reports (ICSRs), adverse event submissions, regulatory databases such as the FDA's Adverse Event Reporting System (FAERS) and WHO's VigiBase, as well as Electronic Health Records (EHRs), insurance claims, social media platforms, and scientific literature.[9,11]

Underreporting within pharmacovigilance systems poses a significant threat to patient safety, as it conceals the true frequency and characteristics of adverse drug reactions (ADRs). With an estimated median underreporting rate of approximately 94%, incomplete data severely limits the timely detection of safety signals and impairs effective public health decision-making.[12]

USE OF ARTIFICIAL INTELLIGENCE IN PHARMACOVIGILANCE

The definition of machine learning used by the authors varied among the articles but generally included the use of algorithms or pattern recognition to perform specific tasks.[13] Many of the articles also acknowledged that machine learning can be used to develop intelligent automated systems that help optimize pharmacovigilance processes.[14]

Using Artificial Intelligence to Detect Adverse Drug Reactions (ADRs) and Adverse Drug Events (ADEs)

Machine learning can be applied to identify adverse drug reactions (ADRs) or adverse drug

events (ADEs), conduct safety monitoring, and support signal detection. One practical application is the automation of classifying first-person ADR reports shared on social media platforms. For example, Alvaro et al. utilized Twitter to collect information on ADRs by identifying tweets describing individual patients' experiences. They manually labeled 1,548 tweets containing keywords related to selective serotonin reuptake inhibitors (SSRIs) and cognitive enhancers. Using various supervised machine learning models, they were able to accurately identify first-hand patient experiences within these tweets, demonstrating the usefulness of machine learning techniques in post-marketing pharmacovigilance through social media.[15]

Using Artificial Intelligence to Process Safety Reports

Another important application of machine learning in pharmacovigilance is evaluating the effectiveness of natural language processing (NLP) in classifying unstructured free-text patient safety incident reports. Evans et al. examined the capability of NLP to automatically categorize these reports and assess the severity of harm outcomes. Their findings indicated that NLP can serve as an additional safety mechanism by flagging cases associated with serious harm or death. However, this method is not flawless and cannot entirely replace manual review. Furthermore, the complex and technical nature of medical language makes automated classification challenging.[16]

Numerous studies have investigated the use of machine learning for screening patient safety reports, including those documented in electronic health records. Marella et al. reported that machine learning algorithms combined with text-mining techniques are effective tools for reviewing and analyzing large datasets—whether semi-structured or unstructured—of adverse events and near-miss reports collected through passive surveillance systems.[17]

Using Artificial Intelligence to Extract Drug–Drug Interactions

Artificial intelligence can be applied to identify drug–drug interactions and predict their potential effects. Ben Abacha et al. combined machine learning approaches using both feature-based and kernel-based methods to successfully extract information related to drug–drug interactions.[18] Machine learning is particularly valuable in pharmacovigilance because such models can learn from a limited number of known drug–drug interaction combinations and subsequently predict numerous potential interactions.[19]

Using Artificial Intelligence to Identify Patients at High Risk for ADRs

Machine learning can assist in identifying populations at higher risk of experiencing adverse drug reactions (ADRs) and in supporting personalized healthcare strategies. Chandak and Tatonetti developed a machine learning algorithm named "AwareDX: Analysing Women At Risk for Experiencing Drug toxicity," which predicts sex-specific risks of adverse drug effects with high accuracy by applying a machine learning adaptation of propensity score matching. [20]

Machine learning techniques can also help identify specific patient groups, such as individuals at risk of fluoropyrimidine toxicity due to dihydropyrimidine dehydrogenase (DPD) deficiency. Researchers trained machine learning models to recognize toxicity patterns and used these models to estimate the number of patients affected by DPD-related toxicity. While this approach shows promise for future applications, there remains a potential risk of overfitting. [21]

APPLICATION OF ARTIFICIAL INTELLIGENCE IN PHARMACOVIGILANCE

The integration of AI technologies in pharmacovigilance (PV) is revolutionizing the way adverse drug reactions (ADRs) are detected, evaluated, and managed. This section explores the current applications of AI in PV, with a focus on its role in enhancing ADR detection and evaluation.

AI for ADR Detection

Adverse drug reactions (ADRs) represent a significant public health concern, affecting patients across all age groups. The risk is particularly high among elderly individuals (over 60 years of age), with approximately 15% to 35% experiencing an ADR during their hospital stay. [22] This high incidence places a substantial burden on healthcare systems, with an estimated annual management cost of $30.1 billion.[23] These statistics underscore the urgent need for more effective approaches to monitor, detect, and prevent ADRs during both the pre-marketing and post-marketing stages of drug surveillance.

Since the late 1990s, the development of AI applications for ADR detection has transformed pharmacovigilance practices. These advancements can be broadly categorized into three phases, each marked by progress in statistical methods, natural language processing (NLP), and machine learning techniques.[24,25]

Adverse Event Detection and Reporting

Manual reporting of adverse events (AEs) is often slow and may delay the identification of potential safety concerns. The vast volume of data generated from sources such as electronic health records, social media platforms, and scientific literature can be overwhelming, leading to underreporting or overlooked cases. This data overload hampers the timely detection and reporting of critical safety issues, highlighting the need for more efficient systems.

According to research by Ruchika Sharma, underreporting of ADRs remains a major issue, with traditional systems capturing only about 10% of actual cases.[26] The integration of automated systems, particularly AI and natural language processing (NLP), is essential for extracting adverse event information from diverse data sources. NLP techniques can analyze social media content, including tweets, to identify and classify adverse drug events (ADEs). By processing large volumes of text, these algorithms can detect mentions of drug names and associated side effects, even when expressed in informal or non-standard language. This facilitates real-time monitoring of drug safety on social media, providing a timely and valuable source of information.

Moreover, NLP can assess patient sentiment and identify emerging drug safety trends that may not be captured in traditional reporting systems. For example, Alfred Sorbello et al. developed the SPINEL prototype, an AI-powered software designed to enhance opioid pharmacovigilance by detecting ADEs from discharge summaries in Electronic Health Records (EHRs). SPINEL aims to improve opioid drug safety monitoring and research at the FDA. The system demonstrated high accuracy in identifying known opioid-related ADEs and received positive feedback from FDA users. It employs keyword and trigger-phrase searches to extract potential ADEs associated with specific opioid medications. [27]

SIGNAL DETECTION AND MANAGEMENT

Manual signal detection is often a prolonged process, sometimes requiring several months to identify new safety signals, which may delay necessary regulatory actions. For instance, a study by Ruchika Sharma reported that confirming a new signal using traditional methods could take between 6 to 12 months.[26] Conventional signal detection methods in pharmacovigilance primarily rely on disproportionality analysis, which may fail to detect emerging trends or subtle patterns within complex datasets. This reliance can result in overlooked signals indicating new or rare adverse drug reactions. Furthermore, the manual nature of these analyses is time-consuming and may delay the identification of critical safety concerns.

These limitations emphasize the need for more advanced approaches, such as AI technologies—including machine learning and data-mining techniques—which significantly enhance the efficiency and accuracy of signal detection. AI systems can analyze both structured data (e.g., clinical trial results and electronic health records) and unstructured data (e.g., social media posts and patient forums). Machine learning models are capable of identifying complex patterns and correlations within these datasets, often detecting safety signals earlier than traditional approaches.

Additionally, AI-driven tools can continuously monitor and update drug safety profiles, providing real-time insights and enabling prompt regulatory action. This comprehensive approach improves patient safety and clinical outcomes by facilitating faster detection and management of potential risks.[28]

VARIOUS SOFTWARE USED IN ARTIFICIAL INTELLIGENCE FOR PHARMACOVIGILANCE

➤ VigiLanz

VigiLanz offers real-time surveillance and decision support for healthcare organizations. It utilizes AI to monitor patient data, identify potential adverse drug events (ADEs), and provide actionable insights to clinicians and pharmacists. This proactive approach supports the early detection and management of drug-related risks.

Overview:

VigiLanz is a real-time clinical surveillance platform that integrates AI to monitor patient safety across various healthcare settings.

Key Features:

- Continuous monitoring of clinical data to detect potential ADEs.
- Integration with Electronic Health Records (EHRs) for comprehensive safety surveillance.
- Real-time alerts for healthcare providers to facilitate timely interventions.[29]

➤ ArisGlobal's LifeSphere MultiVigilance

ArisGlobal's LifeSphere MultiVigilance is an AI-driven platform designed to streamline pharmacovigilance operations. It automates the intake, processing, and reporting of adverse events while ensuring compliance with global regulatory standards. The system's machine learning capabilities enhance signal detection and risk assessment.

Overview:

This platform provides an end-to-end solution for pharmacovigilance, leveraging AI to automate and streamline safety monitoring processes.

Key Features:

- Automated case intake and processing.

- Advanced signal detection using machine learning algorithms.
- Regulatory compliance support with automated reporting features.[29]

➤ IQVIA Vigilance Detect

IQVIA Vigilance Detect is a self-managed solution that leverages AI to enhance adverse event identification. It offers configurable features tailored to organizational needs, improving the efficiency and accuracy of pharmacovigilance activities. The platform's AI capabilities support early detection of safety signals, contributing to improved patient safety outcomes.

Overview:

IQVIA Vigilance Detect is an AI-driven platform designed to strengthen adverse event identification through advanced analytics.

Key Features:

- Self-managed solution for customizable adverse event detection.
- Omnichannel monitoring, including audio data analysis.
- Integration with IQVIA's broader safety and regulatory compliance suite. [30]

➤ TCS ADD (Adverse Drug Detection)

TCS ADD (Adverse Drug Detection) is an AI-powered pharmacovigilance platform developed by Tata Consultancy Services. It leverages machine learning and Natural Language Processing (NLP) to automatically detect, extract, and analyze adverse drug events (ADEs) from multiple data sources, including Electronic Health Records (EHRs), social media, and scientific literature. TCS ADD streamlines case intake, improves signal detection, and enhances regulatory compliance, enabling organizations to proactively monitor drug safety and reduce manual workload.

Overview:

Developed by Tata Consultancy Services, TCS ADD utilizes AI to improve the detection and management of adverse drug reactions.

Key Features:

- Natural Language Processing (NLP) for extracting information from unstructured data sources.
- Machine learning models to predict potential ADEs.
- Integration with existing pharmacovigilance systems for seamless operation. [29]

➤ PVLens

PVLens is an automated system that extracts labeled safety information from FDA Structured Product Labels (SPLs) and maps relevant terms to MedDRA. It provides a scalable and accurate alternative to traditional databases, enhancing real-time pharmacovigilance with improved accuracy and contemporaneous insights.

Overview:

PVLens is an AI-driven system that automates the extraction of adverse drug event (ADE) information from FDA Structured Product Labels (SPLs) using NLP.

Key Features:

- Maps extracted ADEs to standardized vocabularies such as MedDRA, RxNorm, and SNOMED CT.
- Scalable and efficient, capable of processing thousands of labels rapidly.

- Includes expert review to ensure high accuracy and reliability. [31]

AI TECHNIQUES IN PHARMACOVIGILANCE

➤ Machine Learning in Pharmacovigilance

Machine learning (ML) encompasses supervised, unsupervised, and reinforcement learning approaches to analyze pharmacovigilance data.

- Supervised Learning: Utilizes labeled datasets to train models for predicting adverse drug reactions (ADRs). For instance, a study by Singh et al. (2023) demonstrated the application of supervised learning in identifying ADRs from clinical data.
- Unsupervised Learning: Identifies hidden patterns in unlabeled data, aiding in the discovery of novel ADRs. Research by Askr et al. (2023) highlighted the use of unsupervised learning techniques in drug discovery and pharmacovigilance.
- Reinforcement Learning: Optimizes decision-making processes in pharmacovigilance by learning from the outcomes of previous actions. This approach is particularly useful in dynamic environments where continuous learning is essential. [32]

➤ Deep Learning in Pharmacovigilance

Deep learning, a subset of machine learning, employs neural networks to model complex relationships within large-scale pharmacovigilance datasets.

- Convolutional Neural Networks (CNNs): Effective in analyzing structured data, CNNs have been utilized to detect ADRs by processing tabular data from Electronic Health Records (EHRs).
- Recurrent Neural Networks (RNNs): Suitable for sequential data, RNNs are applied to analyze time-series data from EHRs, assisting in the detection of ADRs over time.
- Transformer Models: Advanced architectures such as transformers have shown promise in capturing long-range dependencies in data, thereby enhancing ADR prediction accuracy. [33]

➤ Natural Language Processing (NLP) in Pharmacovigilance

Natural Language Processing (NLP) techniques are used to extract meaningful information from unstructured text data, including clinical notes and social media posts.

- Text Mining: NLP is employed to extract adverse event information from clinical trial reports and patient narratives. A study by Dang et al. (2022) demonstrated the effectiveness of NLP in extracting gender-related information from unstructured pharmacovigilance data.
- Sentiment Analysis: Analyzes patient sentiments expressed on social media platforms to identify potential ADRs. This method helps detect ADRs that may not be reported through conventional reporting systems.
- Named Entity Recognition (NER): Identifies and classifies entities such as drug names, symptoms, and adverse events within clinical texts, facilitating automated ADR detection. [34]

BENEFITS OF INTEGRATING AI IN PHARMACOVIGILANCE

- **Simplified Case Processing and Reporting**

AI-driven tools significantly enhance the efficiency of pharmacovigilance teams by automating routine tasks such as data entry, case prioritization, and causality assessment. These systems generate standardized reports while ensuring regulatory compliance, thereby streamlining the overall reporting process.

By reducing manual workload, AI enables Drug Safety Professionals to devote more time to complex tasks that require critical thinking and expert judgment, ultimately maximizing their impact on patient safety. [35,36]

- **Predictive Analytics and Improved Surveillance**

Predictive Analytics in Pharmacovigilance:

AI enhances pharmacovigilance by analyzing historical and real-time data to predict adverse drug reactions (ADRs) and detect safety signals at an early stage. It utilizes data from sources such as Electronic Health Records (EHRs), clinical trials, and social media platforms to improve forecasting and risk identification. [37]

Improved Surveillance:

AI enables continuous 24/7 monitoring of both structured and unstructured data. It improves signal detection accuracy, integrates diverse data sources, standardizes reporting processes, and automates report generation. [38]

Benefits and Impact:

AI-driven pharmacovigilance supports proactive safety management, personalized risk stratification, efficient resource allocation, and compliance with regulatory initiatives such as the FDA's Emerging Drug Safety Technology Program (EDSTP). Overall, it contributes to improved patient outcomes and enhanced public health protection. [39]

LIMITATIONS

Although AI has significant potential to enhance pharmacovigilance, it faces several limitations. One major challenge is its dependence on the quality and completeness of available data, as incomplete or poorly curated datasets may lead to inaccurate detection of adverse drug reactions (ADRs). [40]

Training AI models on datasets containing missing or underreported ADRs can result in unreliable predictions and overlooked safety signals. Ethical concerns also arise when integrating AI into pharmacovigilance. As Kumar et al. noted, accessing patient data without appropriate regulations or informed consent may create ethical dilemmas and potentially undermine the patient–physician relationship. [41]

Ensuring the ethical use of sensitive patient information requires robust regulatory frameworks and transparent consent procedures. For AI to be effectively incorporated into pharmacovigilance systems, clear guidelines must be established to safeguard patient privacy and prevent ethical violations.

Interpreting pharmacovigilance data presents another significant challenge. The evaluation of adverse drug reaction (ADR) reports often involves complex clinical decision-making. Desai emphasized that assessing Individual Case Safety Reports (ICSRs) cannot be entirely standardized or automated, as clinical presentations and ADR assessments frequently require professional judgment. Although AI provides advanced data-processing capabilities, human oversight remains essential for interpreting complex clinical information. [42]

Another limitation is the relatively limited research in this field. Despite growing interest in AI applications, there is still a lack of comprehensive studies evaluating the long-term impact of AI integration in pharmacovigilance systems. [43]

Dsouza et al. highlighted the need for further research to better understand the long-term implications of incorporating AI into pharmacovigilance. Similarly, Sessa et al. emphasized the importance of additional comparative studies between AI-based approaches and traditional pharmacovigilance methods. While AI holds considerable promise, more rigorous and conclusive evidence is required before its widespread implementation can be fully justified. [44][45]

FUTURE DIRECTIONS AND OPPORTUNITIES

The integration of Artificial Intelligence (AI) in pharmacovigilance (PV) presents significant opportunities to enhance drug safety monitoring, streamline workflows, and enable proactive risk management. With the increasing availability of large-scale healthcare data, AI has the potential to transform PV from a reactive process into a predictive and preventive system.

- **Predictive Pharmacovigilance**

AI can utilize machine learning algorithms and predictive models to identify patients at high risk of adverse drug reactions (ADRs) before they occur. By integrating data from Electronic Health Records (EHRs), genomics, wearable devices, and social media platforms, AI can generate early warnings of potential safety concerns, enabling personalized monitoring and timely interventions.

- **Real-Time Safety Surveillance**

Future AI systems will enable continuous and automated post-marketing drug surveillance. Real-time analysis of both structured and unstructured data sources can facilitate rapid identification of emerging safety signals, thereby reducing delays in ADR reporting and regulatory action.

- **Integration with Genomics and Biomarkers**

AI can integrate pharmacovigilance data with genomic, proteomic, and biomarker information to predict mechanism-based ADRs. This approach supports personalized medicine by promoting safer prescribing practices and targeted monitoring for patients with specific risk factors.

- **Automation of Case Processing and Signal Detection**

Advanced AI techniques, including Natural Language Processing (NLP) and deep learning, can automate the processing of Individual Case Safety Reports (ICSRs), literature mining, and the classification of adverse events from unstructured sources such as social media. Automation improves efficiency, reduces human error, and enhances the accuracy of signal detection.

- **Regulatory Compliance and Explainable AI**

Future AI development will emphasize adherence to global regulatory standards, incorporating transparent and explainable AI models. Explainable AI is essential for building trust among clinicians, patients, and regulatory authorities while ensuring the ethical use of sensitive healthcare data.

- **Global Pharmacovigilance and Public Health Impact**

AI facilitates the harmonization of pharmacovigilance practices across countries by integrating diverse international datasets, supporting global safety signal detection, and enabling proactive public health interventions. This global integration can significantly enhance patient safety and strengthen regulatory decision-making processes. [46–48]

CONCLUSION

The integration of Artificial Intelligence (AI) into pharmacovigilance represents a significant advancement in modern drug safety management. By automating data collection, classification, and analysis, AI reduces human workload while enhancing the accuracy and timeliness of adverse drug reaction (ADR) detection. Machine learning, deep learning, and Natural Language Processing (NLP) have already demonstrated their value in identifying hidden patterns, extracting insights from unstructured data, and supporting evidence-based regulatory decision-making.

However, challenges such as data incompleteness, algorithmic bias, ethical concerns, and limited standardization continue to hinder large-scale implementation. To fully realize the potential of AI, it is essential to establish robust frameworks that ensure transparency, patient data protection, and the development of explainable AI models.

Future pharmacovigilance systems are expected to evolve toward predictive and personalized safety monitoring, integrating real-world evidence, genomics, and continuous global surveillance. Ultimately, AI has the potential to transform pharmacovigilance into a more proactive, precise, and patient-centered discipline—ensuring safer medicines and improved public health outcomes worldwide.

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