Review Article

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ROLE OF ARTIFICIAL INTELLIGENCE IN PHARMACO VIGILLANCE

Talluri Poojitha*, N.Ambika, K.Hemalatha, Chandu Babu Rao

Priyadarshini Institute of Pharmaceutical Education and Research, 5th Mile, Pulladigunta, Guntur-522017, Andhra Pradesh, India

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Abstract

Pharmacovigilance (PV) is a data-driven process to identify medicine safety issues at the earliest by processing suspected adverse event (AE) reports and extraction of health data. The PV case processing cycle starts with data collection, data entry, initial checking completeness and validity, coding, medical assessment for causality, expectedness, severity, and seriousness, subsequently submitting report, quality checking followed by data storage and maintenance. This requires a workforce and technical expertise and therefore, is expensive and time- consuming. There has been exponential growth in the number of suspected AE reports in the PV database due to smart collection and reporting of individual case safety reports, widening the base by increased awareness and participation by health-care professionals and patients. Theprimary goal of pharmacovigilance, the cornerstone of public health, is to track and evaluate adverse drug reactions in order to guarantee patient safety. Conventional approaches suffer from biases in human error, inefficiency, and scalability problems. A new era in pharmacovigilance is being ushered in by the introduction of artificial intelligence (AI), which holds the promise of vast data analysis, automated procedures, and enhanced safety signal detection

Keywords: Artificial intelligence, individual case safety reports processing, pharmacovigilance

***Corresponding Author**
Talluri Poojitha

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Introduction

Monitoring and evaluating the safety of pharmaceutical goods is the focus of pharmacovigilance, a crucial part of healthcare systems around the globe [1]. Underreporting in pharmacovigilance systems - the science revolving around the safety of drugs - significantly impacts patient safety by obscuring the true incidence and nature of adverse drug reactions (ADRs). The median underreporting rate is alarmingly high, around 94 %, which affects the ability to detect safety signals and make informed public health decisions [2]. These include the need to invest significantly in infrastructure, computational power, and regulatory compliance. Maintaining the correctness, dependability, and generalizability of AI-driven systems also requires ongoing algorithmic validation, monitoring, and improvement efforts [3]. This review article seeks to give a thorough picture of how artificial intelligence (AI) is changing public health protection and drug safety monitoring by examining the ethical and legal issues, as well as the trends and future implications of AI-driven pharmacovigilance [4].

Traditional Methods of Adverse Event Detection

Historically, adverse event detection heavily relied on spontaneous reporting systems where healthcare professionals and consumers voluntarily reported adverse reactions. While these systems have been instrumental in identifying known side effects, they suffer from underreporting, lack of standardized reporting criteria, and a delayed response to emerging safety concerns. Clinical trials, another cornerstone of traditional pharmacovigilance, provide valuable insights during the drug development phase but are limited in their ability to capture rare or long-term adverse events. Regulatory reporting, mandated by health authorities, adds an additional layer to the pharmacovigilance framework but is often reactive rather than proactive.

Traditional approaches to adverse event reporting and identification are essential for keeping an eye on patient safety and pharmaceutical safety in healthcare settings[5]. T he first approach, called voluntary reporting, is based on healthcare providers, patients, and caregivers informing regulatory bodies like the FDA or MHRA about suspected medication-related adverse events[6]. A methodical examination of patient records, including doctor notes and test findings, provides a

structured method for discovering adverse occurrences. This process is known as a medical record or chart review. Even though this approach makes it possible to gather comprehensive clinical data, it can be labour- and time-intensive and may miss adverse events that are not sufficiently recorded in the records. When providing clinical treatment, healthcare workers who engage in direct observation actively watch patients for indications of unfavourable events. With the help of this technique, bad events can be detected in real time, allowing for quick action to lessen patient harm. However, especially in busy hospital settings, it could require a lot of resources and miss unfavourable events that happen outside of the monitoring time [7].

Challenges of adoption of artificial intelligence in pharmacovigilance

Pharmacovigilance is a critical and essential function in healthcare. However, the use of artificial intelligence (AI) in this field is still a relatively new and developing field. One of the main challenges in adopting to AI is availability of structured and curated data for training the software to identify potential drug safety issues. Additionally, there are privacy concerns with using AI for pharmacovigilance, as data could potentially be used for other purposes without consent from individuals involved [8].

1. Scientific challenges
2. Technological challenges

Scientific challenges

The AE case processing in PV is a complex task that involves multiple decision-making points and adjudication within a regulated and audited system. There has been a definite role of clinical evaluation and clinician's perspective for causality assessment and signal detection. The causality assessment of AE principally depends on expert judgment and global introspection [9]

The medical science and therapeutics are complex and ever-changing. The assessment of ICSRs is not a standardized or homogenous process that can be computerized. In fact, variations in the clinical presentation of the patients and adverse effects typically require human intervention and clinical evaluation for decision-making. The central question is whether the current AI tool is strong enough to determine temporality, causal association, predict potential drug–drug interaction and flag safety alerts in real-world data processing, and ensure generalizability and quality performance [10]. This leads to another question of accountability. If an AI tool makes a mistake in spite of being thoroughly validated, who will be held responsible: developer, technology firm, or regulator? Importantly, AI technology must be flexible and recognize the need for expert judgment for the assessment of complex difficult case scenarios. On the other hand, the researchers have warned for the naïve use of AI tool in science as this can lead to mistakes and false positives resulting in a waste of time and resources [11].

Technological challenges

The fundamental key to this impressive technology is training datasets used for the generation of AI algorithms. The dataset has to be vast and diverse, from different sources, covering all types of reports, representing the world's population to make the algorithm valid and robust in real-world settings [12]. This requires integration, linkage, annotation, labeling, and maintenance of datasets to teach and train the computers right from concept to implementation. Subsequently, the training model needs to be tested and validated before application on real-world data.

India has a well-established PV system and database. However, it does not represent the actual AEs happening in the real world due to underreporting and selective reporting. For a robust dataset, spontaneous AE reports need to be linked to electronic health records of public and private sector hospitals, outdoor patients, general practice records, disease registries, and published medical literature to provide high-quality evidence for causal association and signal detection. Unfortunately, the majority of the public and private hospitals across India use traditional systems for medical records, and their quality, completeness, and retrieval could be a challenge. Furthermore, the fragmented health-care system in India and different administrative arrangements will be another challenge to integrate and link the data from different sources [13].

Few superspecialty hospitals in India have initiated preparing disease- specific registries, albeit, require substantial efforts for quality, completeness, and linkage [14].

Need of Artificial Intelligence in Pharmacovigilance

There has been exponential growth in the number of suspected adverse event (AE) reports in the PV database . Processing of the enormous volume and variety of data sources, making its sensible use and separating "needles from haystack," is a challenge for key stakeholders such as pharmaceutical firms, regulatory authorities, medical and PV experts, and National Pharmacovigilance Program managers.

Program of India (PvPI) and the WHO Global database has increased dramatically in the past several years. Source: PvPI, IPC, MoHFW.

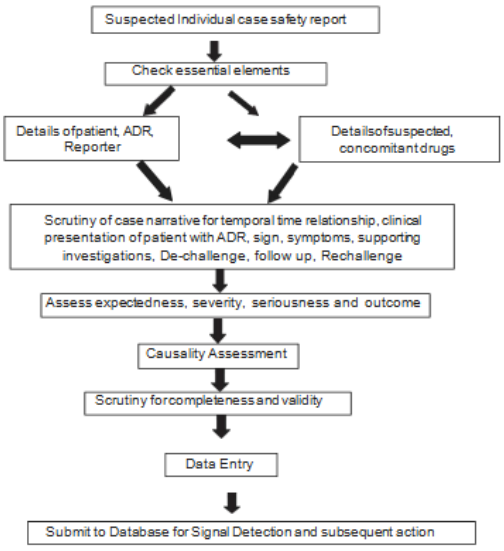
*Data as on October 10, 2023. PvPI = Pharmacovigilance Program of India, ICSR = Individual case safety report, IPC = Indian pharmacopoeia commission, MoHFW = Ministry of Health and Family Welfare case processing is evaluated for the expectedness of AE as per the prescribing information leaflet, the likelihood of causal relationship, determine severity and seriousness criteria, and finally

scrutinize for completeness and validity for regulatory submission. Importantly, it encompasses manual tasks along with human cognition. Essentially, it needs a workforce and technical expertise and, therefore, is expensive and time consuming. To cope with this increased workload, there has been a lot of excitement and enthusiasm to adopt AI technology to automate PV.

Artificial Intelligence

AI is a branch of computer science. AI system contains a database of facts and uses an algorithm to make machines to imitate human behavior that requires understanding, creative composition, speech recognition, and decision-making [15].

The machine acquires human intelligence by learning and training using a huge volume of robust datasets, just like a child learns from teaching and training from the environment and becomes an intelligent human being. The new technology entails deep learning and natural language processing techniques having neural networks (like neurons in the human brain) to teach computers to process data like the human brain to solve a given problem that requires human understanding and reasoning. Interestingly, the computer creates an expert [16].



Need and key developments

The need for technological advancements in pharmacovigilance, specifically through AI and big data is being recognised. Several key developments have accompanied these needs. Firstly, the increasing volume and complexity of data from diverse sources such as electronic health records (EHRs), spontaneous reporting systems, and social media necessitate advanced tools for efficient data processing and analysis. AI and machine learning (ML) techniques, including natural language processing (NLP) and deep learning, can automate the extraction and analysis of ADRs [17].

On top of that, the efficiency of pharmacovigilance processes can be significantly improved through AI and intelligent automation. These technologies can automate routine tasks such as the initial quality check of individual case safety reports (ICSRs), verification of essential regu latory information, and duplicate searches. They can also assess case validity, and prioritize cases for further review, thereby increasing the speed of signal detection [18].

The Role of AI in Pharmacovigilance

Pharmacovigilance, the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems, plays a pivotal role in ensuring the safety of pharmaceutical products. As the pharmaceutical landscape evolves with the introduction of new therapies and an increased focus on personalized medicine, the traditional methods of pharmacovigilance are facing challenges in keeping pace with the growing complexity of healthcare data. In this context, Artificial Intelligence (AI) emerges as a transformative force, offering innovative solutions to enhance the efficiency and effectiveness of pharmacovigilance processes [19].

1. Automating Adverse Event Detection

One of the primary contributions of AI in pharmacovigilance is the automation of adverse event detection. Traditional pharmacovigilance relies heavily on manual reporting and analysis, which can be time consuming and may result in delays in identifying potential safety concerns. AI, particularly machine learning algorithms, excels in processing vast datasets at high speeds, enabling the real-time detection of adverse events.

2. Enhancing Signal Detection

Signal detection involves identifying patterns or signals that may indicate a potential association between a drug and an adverse event. AI augments traditional signal detection methods by offering advanced analytics and predictive modeling. Machine learning algorithms can analyze historical pharmacovigilance data to identify patterns and trends that might go unnoticed through conventional methods.

3. Real-time Monitoring and Surveillance

AI enables real-time monitoring and surveillance of healthcare data, contributing to the timely identification of adverse events. Continuous analysis of electronic health records, patient- reported outcomes, and other relevant data sources allows for a dynamic and ongoing assessment of drug safety [20].

4. Predictive Risk Assessment

AI facilitates predictive risk assessment by leveraging machine learning algorithms to assess the likelihood of adverse events associated with specific drugs. These algorithms can consider a multitude of variables, including patient demographics, medical history, and concomitant medications, to predict the potential risks for individual patients or specific populations [21].

Future Perspectives of AI in Pharmacovigilance

The use of AI in pharmacovigilance presents exciting opportunities for the future that will transform the man agement and monitoring of drug safety[22]. Furthermore, regulatory agencies and medical experts may take prompt and decisive action in response to growing safety issues by using AI-driven predictive analytics. AI integration also has the potential to enhance pharmacovigilance reporting requirements and expedite regulatory compliance procedures[23]. All things considered, the use of AI in pharmacovigilance presents a revolutionary way to improve drug safety monitoring and protect public health. The following suggestions for further study and advancement have been made in order to effectively use AI in pharmacovigilance.

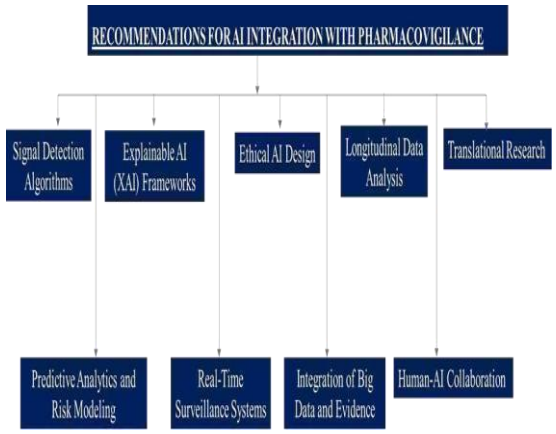


Fig: 1 RecommendationsFor Future Research and Developments In AI Integration with Pharmacovigilance

Application of AI

AI helps to reduce mortality chances by detection of diseases at an early stage from patients electronic footprints. Cyber-attack may cause serious health issues of an individual like heart hacking stimulators, death of a person may occur. Hence, implementation of regulation framing produces safe and effective use of AI in healthcare[24]

1. AI Applications in Robotics

The field of robotics involves the designing and creation of automated machines or robots in such a way that they possess the ability to perform tasks on their own. Nowadays, robots are becoming more and more advanced and efficient in accomplishing tasks without human intervention. This is because AI tools and techniques are specially designed for the field of robotics. Advanced robots consist of sensors, high-definition cameras, voice recognition devices, etc.These robots can learn from their past mistakes and experiences and adjust the algorithms according to the environment. AI is a handy tool for robotic applications. When combined with advanced devices, it can help optimize. It helps enhance the complex manufacturing process in industries such as aerospace. The packaging process in industries also uses AI to enhance productivity and lower the overall cost.

2. AI Applications in Defense

Defense is one of the most crucial sectors for AI's contributions. Defense security systems can be vulnerable to attacks from hackers to steal confidential government or defense data. This can prove to be detrimental to any country. The manual identification and processing of unusual activities may not detect potential threats and can be time-consuming; this is where the involvement of AI proves to be of great use.

3. AI Applications in Transport

AI has completely transformed the transport industry. As the competition in the transport industry is high, there is a need to analyze all the factors that influence the various facets of the business. These may be price, seasons, festivals, number of passengers, etc.

4. AI Applications in Healthcare

These days, most healthcare organizations are relying on AI-based software for their day-to-day tasks. These tasks vary from patient diagnosis to hospital data management. The amount of data generated by the healthcare industry is 44 trillion gigabytes per day; so, there is a need for AI-based advanced processors that can extract, manipulate, analyze, and draw meaningful insights from this data. AI and ML technologies are doing a fabulous job in the healthcare industry. The AI-based algorithms that are fed into the systems are capable enough to spot patterns much more efficiently than humans. These algorithms also help in the analysis of patient data, thus helping with the diagnosis [25].

5. AI Applications in Marketing

One of the key factors in running a successful business is marketing. Proper marketing strategies lead to generating high profits. According to Forbes, the revenue generated by the marketing industry in 2019 was more than US$300 million [26].

Benefits of AI

- For spontaneous reporting signal detection GPS (Gamma Poison Shrinkage) is used.
- Information component can also be used for signal detection.
- Sources of data obtained to cognitive services are changes from healthcare professionals, dentists, physicians, patients, literature reviews, and social media.
- In 1961, the thalidomide disaster needs earlier detection of AE hence that it takes nearly two years for Australian obstetricians and germen pediatricians to identify phocomelia side effects. For that reason, the WHO sets regulations to prevent such tragedies.
- For rapid electronic identification of data points the spontaneous reporting system (SRS) is used because they are difficult to detect via manual research.
- **Machine learning (ML):** supervised learning used in PV for ICSR processing can teach ML algorithm where ground truth i.e., Human annotated answer

file while unsupervised learning has no ground truth and is used for signal management.

- **Semanticsearching:** enhance the accuracy of searchers understanding.
- **Optical character recognition (OCR):** identify text in scanned documents, also for verification of handwriting text.
- **Chabot's:** use NLP for conducting conservation of human via audio or text method.
- **Text mining:** examine collected data of resources into evidence form by transforming unstructured text to structure data.

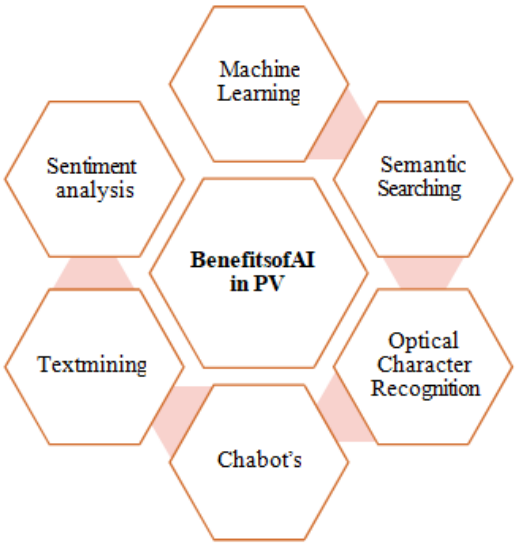


Fig: 02 Benefits of applying Artificial Intelligence Techniques in Pharmacovigilence

Conclusion

The future perspectives of AI in pharmacovigilance are marked by advancements in technology, a shift toward real-time monitoring, and a commitment to patient centric approaches. The integration of emerging technologies, coupled with a focus on explainability and ethical considerations, will shape the next phase of AI-driven drug safety monitoring. As these innovations unfold, AI is poised to become an indispensable ally in ensuring the safety and well-being of patients worldwide, revolutionizing the landscape of pharmacovigilance for years to come.

With a focus on current trends and future perspectives, this review paper on Advanced Applications of Artificial Intelligence in Pharmacovigilance: Current Trends and Future Perspectives provides a thorough overview of how AI is transforming drug safety monitoring and public health protection. Proactive risk assessment through predictive analytics, timely safety indicator identification through real time monitoring, and the creation of improved signal detection algorithms to identify adverse drug reactions from various data sources are the future directions of AI driven pharmacovigilance.AI- enabled cooperative decision making also creates networks for knowledge exchange among interested parties, which enhances pharmaceutical safety monitoring and surveillance. Integrating AI and big data into pharmacovigilance holds trans formative potential, addressing many challenges posed by increasing data complexity and the need for real-time drug safety monitoring. However, ongoing efforts are required to fully leverage these technol ogies to improve data quality, enhance model transparency, and ensure regulatory frameworks are in place. With continuous advancements in AI and machine learning, the future of pharmacovigilance can be more efficient, accurate, and comprehensive, ultimately improving rational drug use across healthcare system. Artificial intelligence allows for the processing and analysis of large amounts of data and can be applied to various disease states. The automation and machine learning models can optimize pharmacovigilance processes and provide a more efficient way to analyze information relevant to safety, although more research is needed to identify if this optimization has an impact on the quality of safety analyses. It is expected that its use will increase in the near future, particularly with its role in the prediction of side effects and ADRs.

Author Contributions

All authors are contributed equally

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Declaration of Competing Interest

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