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ROLE OF ARTIFICIAL INTELLIGENCE IN PHARMACOVIGILANCE: A CONCISE REVIEW

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ABSTRACT
The rapid expansion of drug safety data from clinical trials, spontaneous reporting systems, electronic health records, literature, and social media has placed significant strain on traditional pharmacovigilance systems. The analyzed articles collectively highlight the transformative role of artificial intelligence (AI) in addressing these challenges and enhancing drug safety monitoring. AI techniques such as machine learning, deep learning, and natural language processing have demonstrated substantial improvements in adverse drug reaction (ADR) detection, signal identification, case processing, and literature screening. Compared with conventional methods, AI-driven systems enable earlier signal detection, reduced false positives, faster case triage, and improved data accuracy. Several studies report notable reductions in case processing time and increased sensitivity in detecting safety signals, supporting more proactive pharmacovigilance practices. Despite these advantages, the articles also identify key limitations, including data quality issues, lack of model transparency, regulatory uncertainty, ethical concerns, and the need for skilled human oversight. Integration challenges related to infrastructure, validation, and global regulatory harmonization remain critical barriers to widespread adoption. Overall, the findings suggest that AI, when implemented within robust regulatory and ethical frameworks, can significantly strengthen pharmacovigilance systems. The convergence of human expertise and AI technologies holds strong potential to improve patient safety, optimize regulatory decision-making, and advance the future of drug safety surveillance.

Keywords: Adverse drug reaction, machine learning, artificial intelligence, pharmacovigilance, regulatory integration, signal detection.

1. INTRODUCTION

After a case report by W. McBride was published in the Lancet in December 1961, pharmacovigilance (PV) was formally established. Australian doctor McBride was the first to suggest a link between thalidomide, a drug used as a sedative and antiemetic in pregnant women, and serious, deadly birth defects, particularly phocomelia. Pharmacovigilance (PV) is a datadriven procedure that analyzes reports of possible adverse events to determine the risks to the safety of medications. Validity checks, data entry, gathering, coding, medical evaluation, and report submission are all part of it. PV has raised the number of reports of possible adverse events and boosted patient and healthcare provider involvement, despite its high cost and timeconsuming nature.

Pharmacovigilance (PV) was officially created in December 1961 following the publication of a case report by W. McBride in the Lancet. Thalidomide, a medication used as a sedative and antiemetic in pregnant women, was originally linked by Australian physician McBride to severe, fatal birth abnormalities, especially phocomelia [1]. A data-driven process called pharmacovigilance (PV) examines reports of potential adverse events to assess the risks to medication safety. It includes validation checks, data entry, collection, coding, medical evaluation, and report submission. Despite being expensive and time-consuming, PV has increased the number of notifications of potential adverse events and increased patient and healthcare provider involvement.

2. HISTORICAL DEVELOPMENT OF PHARMACOVIGILANCE

A number of significant historical turning points can be used to track the development of pharmacovigilance:

- 1937: The Federal Food, Drug, and Cosmetic Act was created in response to the sulphadiazine tragedy in the United States.
- 1950s–1960s: Systematic drug monitoring systems were established as a result of the thalidomide catastrophe, which caused thousands of birth abnormalities worldwide.
- 1968 saw the creation of the WHO Programmed for International Drug Monitoring.
- The 1970s and 1980s saw the establishment of national pharmacovigilance centers and spontaneous reporting systems.
- 1990s: International Conference on Harmonization (ICH) guidelines and electronic reporting systems were introduced.
- The 2000s: Risk management strategies were put into action, and proactive pharmacovigilance was given more attention.
- 2010s: Several data sources and real-world evidence were integrated, laying the groundwork for AI applications.

This historical background illustrates how pharmacovigilance development is reactive, frequently progressing in response to public health emergencies. A paradigm shift in drug safety monitoring is currently occurring with the move toward proactive, technology-driven approaches.

3. NEED OF ARTIFICIAL INTELLIGENCE IN PHARMACOVIGILANCE

The number of suspected Adverse Event (AE) reports in the PV database has increased exponentially. It is difficult for important stakeholders, including pharmaceutical companies, regulatory bodies, medical and PV specialists, and managers of the National Pharmacovigilance Program, to process the vast amount and diversity of data sources, make sense of them, and separate "needles from hay stacks".

Due to a number of significant benefits, artificial intelligence (AI) has grown in importance in pharmacovigilance.

1. Massive Data Processing: Health care institutions and pharmaceutical corporations produce vast amounts of data about the safety of drugs. Millions of patient records, clinical trials, medical literature, and adverse event reports can be analyzed by AI significantly more quickly and precisely than by human reviewers.
2. Early Signal Detection: Compared to conventional manual monitoring techniques, machine learning algorithms are able to detect possible drug safety signals and bad reactions considerably earlier. These artificial intelligence (AI) tools are able to identify minute patterns and connections that human researchers might overlook.
3. Real-Time Monitoring: Medical records, social media, and international health databases can all be continuously monitored in real-time by AI-powered systems, giving prompt information on new drug safety issues.
4. Predictive Analytics: Complex medical data and past treatment results are analyzed by sophisticated AI models to forecast possible drug interactions, side effects, and patient dangers.
5. Diminishing Human Error: Artificial Intelligence (AI) reduces bias and human error in pharmacovigilance procedures by automating data processing and cross-referencing, guaranteeing more accurate and consistent safety evaluations.

4. IMPLEMENTATION OF ARTIFICIAL INTELLIGENCE TOOLS IN PHARMACOVIGILANCE

It has been suggested that the AI tool will help with repetitive and routine manual tasks like data entry, drug-drug interactions, AE identification, subtle data patterns, and single case reviews.AI is also capable of transforming handwritten documents and unstructured, free text drug safety data into machine-readable formats. In addition, the application can automatically code Medical Dictionary for Regulatory Activities, detect serious reports, filter out nonserious reports, verify duplicate reports, and classify reports into consumer or physician reports [2]. Intriguingly, the AI platform can also analyze unstructured data, extract text, and find pertinent information to create clinically sound auto narratives. It can also find patterns in both structured and unstructured narratives, eliminating the need for manual signal identification and validation as well as routine case reviews. Furthermore, it has the ability to extract ICSR information from a wide range of public documents, including discharge summaries, case reports, medical literature, social media medicine reviews, and free text clinical notes in electronic health records [3]. According to a recent poll, scientists save time and money by using AI technologies to digest data quickly and expedite computations that were previously impractical. Adoption of AI techniques will lower the effort, time, and cost of case processing, increase data quality, and potentially revolutionize PV activities due to the vast amount of drug safety data that is maintained electronically.

6. ROLE OF AUTOMATION IN VARIOUS PHARMA COVIGILANCE PROCESSES

Too few adverse events are reported, which is a major problem for pharmacovigilance. The inability of experts to handle a large number of cases is caused by a number of factors, such as a lack of infrastructure, time, and expertise, as well as an increase in workload. The fear of legal action or the failure to recognize a potential link between a medication and a negative event can also lead to under-reporting. The 1961 Thalidomide tragedy brought to light the necessity of disclosing adverse medication effects. However, it took a German pediatrician and an Australian obstetrician almost two years to determine the causal link between the medicine and the phocomelia-causing adverse effects. AI and automation have the potential to greatly increase efficiency in Post-Marketing Surveillance (PMS), which is the process of monitoring medication safety after a product has been put on the market. This is primarily because of the large number of real-world datasets that can be integrated at this point, such as case reports, academic literature, and active monitoring.

6. APPLICATIONS AND ROLE OF AI IN PHARMACOVIGILANCE

AI technology integration in PV is transforming the detection, assessment, and management of ADRs. The present uses of AI in PV are examined in this part, with an emphasis on how it might improve ADR evaluation and detection.

6.1 AI for ADR detection

ADRs have a substantial influence on patient populations across all demographic groups, making them a serious public health concern. With 15% to 35% of hospitalized patients (over 60) reporting an adverse drug reaction (ADR), the risk is particularly high in this demographic [4]. This demonstrates the urgent need for more effective techniques to track, identify, and stop adverse drug reactions (ADRs) during the pre-marketing and post-marketing stages of medication surveillance.

PV procedures have changed as a result of the development of AI tools for ADR detection since the late 1990s. It may be roughly divided into three stages, each of which is distinguished by unique developments in machine learning, natural language processing (NLP), and statistical methodologies.

Improving signal detection in spontaneous reporting systems was the main goal of early AI applications in PV. Both Bate et al.'s BCPNN approach and DuMouchel's MGPS, represented notable advancements above conventional statistical techniques. NLP approaches were essential when PV data sources grew beyond organized spontaneous reports to incorporate unstructured data from social media and EHRs. With F-measures of 0.82 and 0.72 for ADR detection from networks like Daily Strength and Twitter, Nonfarm et al. showed the potential of NLP in extracting ADR data from social media [6].

These graphs have the ability to combine several data sources and depict intricate connections between medications, side effects, and other elements. More advanced AI models have been applied in PV in recent years. Yang et al. showed how well machine learning methods work to identify drugs and adverse drug reactions (ADRs) in electronic health records.

6.2 AI for signal detection and active surveillance

An essential part of PV is signal detection, which entails locating possible connections between medications and side effects. Traditional approaches based on disproportionality analysis of SRS have proven useful, but they frequently have drawbacks such underreporting, biases in reporting, and difficulties identifying intricate drug-event relationships. AI is being used in specific regulatory intelligence platforms to expedite safety monitoring and reporting procedures, in addition to general data source analysis. PV teams' ability to access, analyze, and operationalize vast amounts of safety and regulatory data is being greatly enhanced by recent developments in AI-enabled regulatory intelligence tools, which are typically AI-enabled chatbots programmed to search or web scrape public domain regulatory documents.

A Gradient Boosting Machine model was created by Bae et al. to identify safety signals for the medications docetaxel and nivolumab. According to recent research, advanced ML/AI implementations might be superior to conventional disproportionality metrics in some circumstances, however it is important to carefully evaluate these results. Third, methodological comparisons seldom take into account the temporal dimension of signal detection, or the speed at which a safety concern is detected. By integrating conventional techniques with machine learning techniques, Jeong et al. increased the precision and effectiveness of ADR detection. They combined three existing algorithms-CERT (Comparison of Extreme Laboratory Test findings), CLEAR, and others-using 21 years of inpatient EHR data.

(Comparison of Extreme Abnormality Ratio) and PACE (Percentile of Adverse event risk in Comparison to Entire population)-as inputs for machine learning models, such as neural networks, random forests, L1 regularized logistic regression, and support vector machines. [28] Deep learning techniques have demonstrated encouraging outcomes in biological named entity recognition (NER) and normalization (NEN), especially those that integrate bidirectional long short-term memory (Bi-LSTM) networks with convolutional neural networks (CNN) and conditional random fields (CRF). On benchmark datasets such as BC5CDR and NCBI Disease, these techniques obtained high F1-scores of 0.87

and 0.89 for NER and NEN, respectively [7]. The application of AI for signal detection in practical contexts has demonstrated encouraging possibilities.

6.3 AI for real-time monitoring and active surveillance

AI developments are making it possible to switch to more proactive surveillance techniques. This change enables more prompt interventions and early identification of possible safety concerns. In order to identify possible ADRs as they happen, real-time monitoring in PV entails ongoing analysis of multiple data sources. Active surveillance, in contrast, entails the methodical gathering and examination of safety information over the course of a product's lifecycle. These two elements of PV have been greatly enhanced by AI techniques. An important use of AI in real-time monitoring-the examination of social media posts and patient forums for early signal detection-was covered in the preceding section. A text mining technique for detecting ADRs in free-text Dutch EHRs was created and put into use by Van de Burg et al. [8].

7. CHALLENGES OF ADOPTION OF ARTIFICIAL INTELLIGENCE IN PHARMACOVIGILANCE

Pharmacovigilance (PV) is the process of identifying, assessing, and preventing side effects or other drug-related problems in order to guarantee the safety of pharmaceuticals. As Artificial Intelligence (AI) technology advances, its use in pharmacovigilance creates significant prospects and problems [9].

7.1. Opportunities

Efficiency and Speed: AI is faster than other methods at processing vast volumes of data. Medication safety hazards can be promptly detected by machine learning algorithms in patient data, social media, academic publications, and unplanned reporting. This helps prevent extensive harm by identifying Adverse Drug Responses (ADRs) earlier.

Automation of Routine Tasks: AI may be used to automate pharmacovigilance tasks such as data entry, literature reviews, and case intake. By extracting valuable information from unstructured reports, natural language processing (NLP) technologies free up human resources to make more complex decisions].

Better Signal Detection: AI models have the potential to identify connections and patterns those statistical methods miss, which could lead to better signal detection. In multi-dimensional data sources, deep learning enhances the detection of unusual or concealed ADRs].

Global Data Integration: Artificial Intelligence enhances global dataset integration and analysis from clinical trials, patient forums, regulatory databases, and electronic health records. It is feasible to provide a more comprehensive picture of drug safety across a range of populations [10]. Cost Reduction: Pharmacovigilance expenses may be reduced by automating repetitive tasks and increasing productivity, particularly in large monitoring systems. Businesses might concentrate on important PV projects [11].

7.2. Challenges

Data Availability and Quality: For accurate analysis and prediction, AI systems rely on wellstructured, high-quality data. Data in pharmacovigilance is frequently insufficient, inconsistent, or unstructured, which could lead to inaccurate insights produced by AI. It is quite challenging to maintain consistent, clean data across global networks.

Regulatory Compliance: Strict regulatory guidelines must be followed when integrating AI in pharmacovigilance. There is still uncertainty around the validation of AI models, the protection of data privacy, and the observance of compliance across different countries due to the evolving legal environment for AI.

Process Transparency: Deep learning algorithms, in particular, can function as "black boxes," making it difficult to understand the reasoning behind their output. Lack of explain ability may result in a lack of faith in pharmacovigilance, where transparency is crucial for safety and regulatory compliance. Fairness and Bias: The quality of the data utilized for training determines how effective AI systems are. The AI system may produce biased findings as a result of biased training data, possibly ignoring safety concerns for particular populations. Accurate and fair pharmacovigilance requires ensuring justice and inclusion in AI models [12].

8. LIMITATIONS

Even though AI has the potential to improve PV, there are a few issues that need to be resolved. AI's reliance on the accuracy and completeness of the data that is currently accessible is a major drawback. Inaccurate ADR detection may result from inadequate or badly curated databases. Another barrier to integrating AI with PV is ethical considerations. According to Kumar et al. the problem is the unrestricted access to patient data without the consent of the patient. In addition to violating the patient-physician relationship, this may raise moral and ethical concerns]. Another restriction that must be addressed is the interpretation of PV data. ADR reports necessitate several decision-making procedures. According to Desai.

In order to predict events before they occur, wearable technology uses sensors to collect data and generate customized metrics. Institutions should focus on minimizing potential risks and weak points for assaults.

Systems with rules for protecting protected health information and complying with the Health Insurance Portability and Accountability Act must be put in place.

To protect patient information, data encryption and authentication should be implemented [13].

9. FUTURE DIRECTOINS FOR ARTIFICIALINTILLIGENCE IN PHARMACOVIGILANCE

Pharmacovigilance, or PV, is the science of identifying, evaluating, comprehending, and averting negative drug effects. AI has the potential to revolutionize PV. The main directions I envision for the future are as follows:

9.1 Advanced Signal Detection

- To better extract negative events from unstructured data sources like social media, electronic health records, and scientific literature, natural language processing, or NLP, will keep developing.
- Pattern recognition will be enhanced by machine learning techniques to detect drug-drug interactions and previously unidentified safety signals sooner.

9.2 Real-time Monitoring Systems

- A shift from sporadic safety reviews to ongoing, real-time safety signal monitoring
- Combining several data streams (such as patient-reported outcomes, EHRs, and claims data) for a thorough safety evaluation

9.3 Personalized Risk Assessment

- AI models that use demographics, medical history, and genetic profiles to forecast a patient's
- Likelihood of experiencing particular adverse
- Better benefit-risk analysis at the patient level as opposed to the population level
- Improved Causality Evaluation.
- Improved algorithms to establish the link between adverse outcomes and medications
- A decrease in false positives while preserving the ability to detect real safety signals Applications in Regulation
- Intelligent validation technologies and automated regulatory reporting
- Predictive models that foresee regulatory issues while developing new drugs

9.4 Challenges to Address

- Making sure AI methods are transparent and able to be explained.
- Resolving issues with data privacy
- Establishing legal foundations for the application of AI in PV
- Verifying AI models in a range of demographics
- Overseeing the incorporation of AI with human knowledge

The business is moving toward a more proactive safety surveillance paradigm where AI helps to anticipate and avoid undesirable events rather than merely detecting them after they occur. Pharmaceutical businesses, IT companies, regulators, and healthcare providers will likely need to collaborate to develop best practices and standards for this shift [14].

To improve the reliability and traceability of PV data, researchers are looking on safe, transparent ways to record and assess safety signals and ADRs. Blockchain technology enables the development of an unchanging, undetectable, safe, shared record of data. Future studies must focus on improving the consistency and quality of datasets, developing XAI models, and honing NLP methods for better clinical narrative interpretation [15]. In order to support the adoption of AI in PV, regulatory frameworks should be established that ensure the creation of large, publicly available training datasets and the formulation of best practices for AI implementation.

10.CONCLUSION

The integration of artificial intelligence into pharmacovigilance represents a paradigm change from reactive to proactive drug safety management. This shift will fundamentally transform how we protect patients from drug-related hazards while optimizing therapeutic benefits.

Modernizing PV with AI integration could significantly benefit patients and medical professionals by improving data collection and analysis. Using ML and NLP, AI can collect, process, and analyze data at a rate that is unmatched, which could increase the speed of data analysis, predictive accuracy, and overall efficacy of ADR detection. Despite these limitations, combining AI with human expertise may mitigate them. Data-intensive sciences like PV must apply AI to enhance their skills in light of the exponential increase in technology over the last ten years.

events

11. AUTHOR CONTRIBUTIONS

All authors are contributed equally.

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The authors have no conflicts of interest to declare.

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