"REVIEW ON ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING IN PHARMACOVIGILANCE"

S. ANJALA[1]*, M. AMMULU. ATCHAYA[1], L. PRAVEEN[1], **R. SUBASHINI[2]**,

S. ANJALA, M.AMMULU, L. ATCHAYA, L. PRAVEEN

Department of Pharmacy practice

[1] PG students: Department of Pharmacy practice

[2]Head of the department, pharmacy practice

Swamy Vivekanandha college of pharmacy, Namakkal, Tiruchengode

Affiliated The Tamilnadu Dr.M.G.R. Medical university Chennai.

Corresponding author:

S.Anjala

Department of Pharmacy Practice

Swamy vivekannadha college of pharmacy

ABSTRACT

Through the monitoring, detection, and prevention of adverse drug reactions (ADRs), pharmacovigilance (PV) plays a critical role in guaranteeing the safety of medications. PV has historically been a laborious, resource-intensive procedure that depends on gathering and analyzing vast amounts of diverse data from publications, clinical trials, electronic health records, and spontaneous reporting systems. PV is changing dramatically with the introduction of AI and ML. In case processing, signal detection, literature mining, and social media monitoring, artificial intelligence (AI) methods including natural language processing (NLP), deep learning, and robotic process automation (RPA) have

improved efficiency. Patient safety and regulatory compliance are enhanced by these advances, which make it possible to automate repetitive procedures, identify safety signals early, and do predictive risk assessments. Notwithstanding these benefits, there are still issues with data quality, model transparency, moral dilemmas, and regulatory approval. Resolving these problems is essential for widespread adoption to be effective. In order to integrate intelligent technologies into international drug safety frameworks, this review focuses on the foundations of AI and ML, their uses in pharmacovigilance, current obstacles, and future possibilities.

KEY WORDS

Artificial Intelligence, Machine Learning, Deep Learning, Natural Language Processing, Big Data, Adverse Drug Reactions, Signal Detection, Safety Reports for Individual Cases, Robotic Process Automation, Predictive Pharmacovigilance, Data Mining, Clinical Trials, Social Media Monitoring, and Real-world Data on Drug Safety.

INTODUCTION

The field of pharmacovigilance (PV) is essentially data-driven since it necessitates the gathering, handling, and analysis of substantial amounts of data from several, unrelated sources [1]. This position has changed over time, and humans' preoccupation with "recreating" human intelligence in robots is not new. A lot of information systems teams are currently working on learning algorithms that "mimic" human decision-making and learning. Machine learning is a subset of artificial intelligence in which machines are given new ability to "learn" without explicit programming. [2]. According to intelligent automation—which includes machine learning (ML) and artificial intelligence (AI) has begun to transform how safety and pharmacovigilance (PV) experts handle and evaluate data to aid in decision-making [3]. To reduce this stress, a system that uses methods and instruments from the pharmacovigilance research area was used. Ongoing ADR monitoring of currently available medications is carried out by this system [4]. Effective medications can be brought to market faster, and their long-term safety after being approved for sale can be regularly assessed [5]. All things

considered, AI helps businesses streamline or automate time-consuming procedures, uncover data insights faster, assist with writing documents, and eventually free up human labor for higher-value jobs and analyses. AI has been successfully used in pharmacovigilance to manage individual case safety reports (ICSRs) for tasks including processing ICSRs (i.e., case intake, evaluation, follow-up, and distribution) [6]. Although ML models are powerful, they have flaws that can limit their applicability in pharmacovigilance. For instance, their black-box nature [7,8] makes them incompatible with certain areas of causal inference in their current state [9]. To be effective, nevertheless, they require sizable (or information-rich) data sets when applicable [10].

PHARMACOVIGILANCE'S PAST

The successive advancements in pharmacovigilance [11,12,13,14,15,16]

Year	Developments
1747	The very first known clinical trials by James Lind proved the usefulness of lemon juice in preventing scurvy
1937	Death of more than 100 children due to toxicity of sulphanilamide
1950	Aplastic anaemia was reported due to Chloramphenicol toxicity
1961	Worldwide tragedy due to thalidomide toxicity
1963	16th World Health congregation recognizes significant to rapid action on Adverse Drug Reactions (ADRs)
1968	WHO research project for international drug monitoring on a pilot scale
1996	Global standards level clinical trials initiated in India
1997	India attached with WHO Adverse Drug Reaction Monitoring Program.
1998	Initiation of Pharmacovigilance in India.
2002	67th National Pharmacovigilance Centre established in India
2004-05	India launched National Pharmacovigilance Program.
2005	The accomplishment of structured clinical trials in India
2009-10	Pharmacovigilance Program (PvPI) started.

Fundamentals of ML

Learning from Machines (ML)

Algorithms that learn from past data to generate predictions or choices without being explicitly programmed for every task are used in machine learning (ML), a branch of artificial intelligence. As ML models are exposed to more data, they get better over time, which makes them especially well-suited for tasks like safety signal identification, duplicate detection, and adverse event classification [18]

Different Machine Learning Algorithm Types

Supervised Learning

In order to predict results, supervised learning entails training a model using a labeled dataset. Based on documented adverse responses, supervised learning may categorize drug-event pairs in PV [19].

Unsupervised Learning:

These algorithms use unlabeled data to uncover hidden patterns. For instance, trends in spontaneous reporting systems that were previously unknown are found using clustering algorithms [20].

Reinforcement Learning:

Using rewards and punishments, algorithms are taught the best course of action. It is currently less prevalent in PV, although it has potential for adaptive decision-making systems [21].

NATURAL LANGUAGE PROCESSING

NLP is one of the main areas of study in computer science and artificial intelligence. The theories and techniques that facilitate efficient natural language communication between computers and people are the focus of NLP research. The main objective of natural language processing (NLP), a scientific discipline that integrates computer science, linguistics, and mathematics, is to convert human (or natural) language into commands that computers can follow. The two areas of study that make up NLP are Natural Language Generation (NLG) and Natural Language Understanding (NLU). Natural language (human language) comprehension is NLU's main goal. [22] through document decoding and information extraction for use in subsequent processes. NLG, on the other hand, is the process of producing text in human-understandable natural languages using structured data, text, images, audio, and video.[23].

PV using AI and big data

The massive amounts of data that modern PV systems handle come from patient forums, claims databases, EHRs, and spontaneous reporting systems like VigiBase and FAERS. In order to produce empirical evidence and enhance medication safety monitoring, artificial intelligence facilitates the integration and analysis of these intricate datasets [24]

Tools & Technologies for AI

Programming languages like Python and R are frequently used in AI development, as are machine learning frameworks like TensorFlow, PyTorch, and Scikit-learn. These tools facilitate model construction, data preprocessing, and performance assessment in photovoltaic applications [25].

SOURCES OF DATA FOR AI/ML IN PHARMACOVIGILANCE

Pharmacovigilance applications of artificial intelligence (AI) and machine learning (ML) significantly depend on having access to sizable, varied, and high-quality datasets. These data sources include scholarly publications, clinical trials, electronic health records, social media, and spontaneous reporting systems. AI models are able to detect safety signals, identify adverse drug reactions (ADRs), and assist prompt regulatory decisions more effectively than traditional approaches when such structured and unstructured data are integrated [24].

1. Systems for Scented Reporting (SRS)

The FDA Adverse Event Reporting System (FAERS), VigiBase, and EudraVigilance are among the platforms that provide spontaneous adverse event reports. These reports are the main sources of information for PV signal detection and case evaluation. Because these datasets are consistent and structured, they can be used for supervised machine learning and data mining[26].

2. Health Information Systems (EHRs)

EHRs hold longitudinal patient data, such as clinician notes, prescriptions, lab results, and diagnoses. When applied to EHRs, AI/ML models can identify possible medication safety signals before unprompted reports, particularly when clinical narratives are mined using natural language processing [27,28].

3. Information from clinical trials

Safety reports, case narratives, and other data from randomized controlled trials (RCTs) are excellent, carefully selected sources. The demographic and scope of this data are restricted, but it is nevertheless helpful for training machine learning algorithms to detect uncommon or unreported ADRs [29].

4. Research Papers and Case Studies

Peer-reviewed, high-quality data in pharmacovigilance can be found in published case reports and scientific publications. These records provide comprehensive accounts of adverse drug reactions (ADRs), interactions between drugs, and safety results that might not be recorded in spontaneous reporting systems at this time. Large quantities of biological literature databases, including PubMed, Embase, and MEDLINE, can have their drug-event correlations automatically extracted and analyzed by AI systems using text-mining techniques and Natural Language Processing (NLP). This makes it easier for pharmacovigilance specialists to prioritize safety signals, assess new information more quickly, and produce hypotheses for more research. When data from other sources is limited, case reports can be essential for signal discovery and frequently offer the first signs of uncommon or unexpected ADRs. However, because unstructured text is becoming more and more capable of being processed by AI systems, their narrative structure presents difficulties.[30]

5. Discussion boards for patients and social media

Patient forums (such as Patients Like Me, Daily Strength, and Med Help) and social media sites (such as Twitter, Facebook, and Reddit) have developed into effective additional sources of data for pharmacovigilance (PV). Patients' and caregivers' personal experiences with pharmaceuticals, such as adverse drug reactions (ADRs), drug efficacy, dosage problems, and difficulties with compliance, can be openly shared on these platforms. In contrast to official reporting systems, these channels offer uncensored, real-world accounts that can reveal new safety concerns that are missed by spontaneous reporting systems or clinical trials. They have the ability to identify adverse drug reactions (ADRs) early on, especially those that are uncommon or patient-specific. Posts and comments contain vast amounts of informal, unstructured material that are processed using AI and machine learning, particularly Natural Language Processing (NLP) and sentiment analysis. These techniques identify signals, categorize pertinent adverse event data, and derive drug-event connections.

Further improving accuracy in the mining of health-related social media content are deep learning models, like those based on transformer architectures (e.g., BERT). Although they are valuable, a number of issues still exist: Language variability and data noise (slang, typos, abbreviations), Bias in demographics: younger populations are over represented, Validation and confirmation of posts, Patient permission and anonymity raise privacy and ethical issues. [31,32,33,34,35,36,37,30,38,39].

ARTIFICIAL INTELLIGENCE TOOL APPLICATION IN PHARMACOVIGILANCE

Data entry, drug-drug interactions, subtle data patterns, and single-case reviews are repetitive, routine tasks that the AI tool has been suggested to be useful for.[40] Artificial Intelligence can also transform handwritten documents and unstructured, free-text drug safety data into machine-readable formats. [41,42] Drug safety surveillance is undergoing a dramatic transformation as a result of the incorporation of Artificial Intelligence (AI) into Pharmacovigilance (PV). Key PV processes are being automated and optimized through the use of AI technologies like machine learning (ML), natural language processing (NLP), robotic process automation (RPA), and deep learning (DL). This allows for the quicker and more precise detection and analysis of safety signals and adverse drug reactions (ADRs).[43]

1. Processing and Triage of Cases

Individual Case Safety Report (ICSR) input, classification, and triage are automated by AI programs that extract pertinent information from unstructured formats including scanned forms, clinical narratives, and PDFs. MedDRA terminology, patient data, drug-event correlations, and case seriousness are all identified with the aid of NLP. AI-based solutions speed up case processing and increase uniformity among sizable pharmacovigilance teams [43]. Automatic seriousness assessment and follow-up flagging are made easier by integration with rule-based decision engines [44].

2. Storytelling through Natural Language Processing (NLP)

The purpose of NLP algorithms is to extract valuable pharmacovigilance data by analyzing free-text narratives found in case reports, literature, and social media posts. They prepare unstructured text for further analysis by converting it into structured representations. For drug-event extraction tasks, natural language

processing (NLP) models such as BioBERT and CLAMP are trained on biomedical corpora [45,46]. Up to 60% more literature screening is effective when NLP is used [47].

3. Identifying Signals and Setting Risk Priorities

Disproportionality metrics, temporal trend analysis, and network modeling are some of the methods used by machine learning and statistical learning algorithms to identify safety warnings from massive datasets like FAERS, VigiBase, and EHRs. Based on real-time data, AI facilitates dynamic signal prioritization [48]. ML-based outlier detection techniques and Bayesian models such as BCPNN enhance early warning systems [49, 50].

4. Online monitoring and social media

AI-powered social listening technologies keep an eye on tweets, blogs, and patient forums to identify early warning signs of ADRs that conventional systems might not have yet picked up. Although the quality of the data may vary, these platforms provide quick access to patient experiences and public opinion. HealthMap, Signal Finder, and Med Watcher Social are AI systems that use sentiment analysis and natural language processing [51,30]. According to studies, social media can identify uncommon ADRs weeks before traditional publications can [32].

5. Screening of Literature and Semantic Search

Biomedical literature reviews are automated by AI using text classification and semantic analysis. By doing this, pharmacovigilance teams can lessen the strain of manual searches while still meeting regulatory literature surveillance criteria. Elsevier's Pharma Pendium, Embase, and PubMed AI filters are a few examples of platforms that offer AI-enabled literature tagging [52]. Keyword search strategies are inferior than semantic search in terms of recall and precision [53].

6. Real-World Data Analysis and EHR

To find possible adverse drug reactions (ADRs) and evaluate the safety of medications, deep learning models analyze clinical notes, EHRs, and real-world data (RWD). In order to identify complex or delayed ADRs, AI models can connect treatment history with longitudinal patient data [54]. AI is used for active surveillance in the OHDSI network and the FDA's Sentinel Initiative [55].

7. Automating processes with robotics (RPA)

Repetitive regulatory duties including creating line listings, entering data into safety databases, and submitting regular reports are handled by RPA bots. These bots provide end-to-end automation when worked with AI. RPA is used by businesses like as Bayer, Roche, and Novartis for regulatory reporting and case processing [56]. Integration of AI and RPA enables rule-based decision-making [57].

8. Document Management and Report Writing Assisted by AI

Generative AI models, such as ChatGPT and GPT-4, summarize clinical and safety data to help prepare Periodic Safety Update Reports (PSURs), Risk Management Plans (RMPs), and Benefit-Risk Assessments. Consistency is increased and human effort spent writing narrative portions is decreased by these models [58]. Regulatory correspondence and interactive Q&A for safety inquiries are examples of emerging use [59].

9. Pharmacovigilance with Predictability

Predictive models calculate the likelihood of adverse drug reactions (ADRs) based on co-medications, patient genetics, or drug characteristics even before post-marketing data is available. AI is utilized in conjunction with pharmacogenomic databases and QSAR models to forecast hazards [60]. Preventive PV aids in creating risk-reduction strategies and safer clinical trial designs [61].

Problems with ML, DL, and AI in robotics applications

Despite their obvious advantages, these technologies nevertheless present serious difficulties. Large volumes of high-quality data are required to train AI and ML algorithms, which is one of the main obstacles. However, the quality and dependability of the models may be impacted by messy or biased data, as well as the time-consuming and costly nature of data collection, labeling, and annotation [62]. This can be especially hard in robotics, where data might be hard to get and can be influenced by noise and uncertainty. Furthermore, robotics applications frequently call for real-time processing, which can be costly to compute and may call for specialized hardware. [63]. It can be difficult for AI, ML, and DL models to learn from experience and adjust to novel circumstances. The requirement that robots be able to function safely and efficiently in a variety of settings presents another difficulty [64]. Ensuring the safety of robots becomes increasingly

important as they interact with humans and grow more independent. In order to prevent accidents, identify and react to possible hazards, and steer clear of collisions with people and other objects, AI/ML/DL algorithms must be developed [65].

Challenges and Limitations

A trustworthy AI/ML implementation should have more positive impacts than bad ones and make sure that undesirable consequences can be tracked and fixed. Issues with the dearth of proven, validated applications of AI in actual safety situations may restrict the field's ability to expand.[66] published a thorough paper outlining the possible benefits and difficulties of incorporating AI into PV science. Both possibilities and difficulties are presented by AI-enhanced PV, including the need to address data privacy concerns and adjust legal frameworks. The limitations of AI applications today were examined [67], who noted that the performance of AI models depends on the quantity and quality of data, and that explainability and transparency are necessary to bridge the gap between the development and integration of AI model algorithms.

CONCLUSION

By providing scalable, effective, and predictive solutions for drug safety monitoring, artificial intelligence and machine learning are revolutionizing the field of pharmacovigilance. AI technologies greatly reduce human burden and improve decision-making, from automating the processing of individual case safety reports (ICSRs) to detecting early safety warnings from real-world data. Limitations including some models' black-box nature, reliance on high-quality data, and regulatory obstacles, however, continue to be significant difficulties. For AI to be widely used in PV, it will be essential to guarantee algorithm transparency, ethical compliance, and reliable validation. There is a lot of potential for proactive and individualized pharmacovigilance in the future when AI is combined with big data, empirical evidence, and pharmacogenomics. Ultimately, a well-rounded strategy that blends human knowledge with clever automation may guarantee safer medications and better patient results everywhere.

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