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AI-BASED ADVERSE DRUG REACTION PREDICTION AND THERAPEUTIC SAFETY: A REVIEW

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Abstract:

Adverse drug reactions (ADRs) remain a major challenge in healthcare, contributing to patient morbidity, mortality, and increased healthcare costs. Effective therapy safety requires timely detection, assessment, and prevention of drug-related adverse events. Traditional pharmacovigilance systems rely on spontaneous reporting and manual data analysis, which are often limited by underreporting and delayed signal detection. Artificial Intelligence (AI), including Machine Learning (ML) and Deep Learning (DL), has emerged as a transformative tool in healthcare and drug safety monitoring. AI-based predictive models utilize electronic health records, clinical databases, social media, and biomedical literature to identify potential ADRs and drug-drug interactions. Natural Language Processing (NLP) and data mining techniques further enhance ADR detection and risk prediction. AI also supports personalized medicine and clinical decision support systems, improving therapeutic outcomes and patient safety. Despite challenges related to data privacy, ethics, and model reliability, recent advancements highlight the growing potential of AI-driven pharmacovigilance. This review explores the role of AI in ADR prediction, therapy safety, current developments, and future prospects in drug safety management.

Keywords: Artificial Intelligence (AI), Drug Safety, Drug-Drug Interactions, Pharmacovigilance, Personalised Medicine

1. INTRODUCTION

One of the main causes of morbidity, mortality, extended hospital stays, and higher healthcare costs globally, adverse drug reactions (ADRs) continue to be a significant problem in contemporary healthcare. Many drug-related adverse events are not discovered until drugs are widely used in a variety of patient populations, despite extensive preclinical and clinical testing.[1] Clinical observations, post-marketing surveillance programs, and databases for spontaneous reporting are examples of traditional pharmacovigilance systems. Although these methods have greatly enhanced drug safety monitoring, they are frequently constrained by underreporting, delayed reporting, a lack of clinical data, and challenges in locating intricate safety signals in big datasets.

As a result, there is a growing demand for sophisticated analytical tools that can aid in proactive therapeutic safety management and anticipate adverse drug reactions before they happen.[2]

Pharmacovigilance and drug safety evaluation have been profoundly changed by recent developments in artificial intelligence (AI), especially machine learning (ML), deep learning (DL), and natural language processing (NLP).[3] Large volumes of structured and unstructured healthcare data, such as genomic data, electronic health records, administrative claims databases, biomedical literature, social media content, and spontaneous adverse event reporting systems, can be analysed by AI technologies. By revealing hidden patterns and intricate relationships between patient characteristics, drug properties, comorbidities, and other factors, AI-based models enable the prediction of adverse drug reactions (ADRs) earlier and more accurately than traditional statistical methods [4].

2. ADVERSE DRUG REACTIONS AND PHARMACOVIGILANCE

When a medication is administered at dosages frequently used for disease prophylaxis, diagnosis, or treatment, adverse drug reactions (ADRs) can happen. ADRs are unintended, harmful, and undesirable reactions. Due to their substantial effects on patient morbidity, mortality, extended hospital stays, and increased healthcare costs, adverse drug reactions (ADRs) are a serious public health concern.[5] Many adverse drug reactions (ADRs) are only discovered after a medication is widely used in clinical settings, despite advancements in drug development and regulatory evaluation. This highlights the significance of ongoing post-marketing surveillance. Through the identification, evaluation, comprehension, and prevention of adverse drug effects, pharmacovigilance plays a crucial role in healthcare systems. Pharmacovigilance makes use of electronic health records, post-marketing surveillance programs, and clinical research to help guarantee the safe and responsible use of pharmaceuticals.[6]

2.1 Drug Adverse Reaction Types:

The Rawlins and Thompson classification system is frequently used to classify ADRs:

Enhanced reactions, or type A:
These responses are consistent, dose-dependent, and associated with a drug's established pharmacological action. They are typically avoidable and make up 70–80% of ADRs. Examples include bleeding brought on by anticoagulants and hypoglycemia brought on by insulin.

Odd Reactions (Type B):
These unpredictable, dose-independent reactions have nothing to do with the drug's known pharmacological effects.[7] Genetic or immunological mechanisms are frequently at play. Two examples are Stevens-Johnson syndrome linked to specific anticonvulsants and penicillin-induced anaphylaxis.

Chronic Reactions, or Type C:
These reactions are linked to cumulative dose effects and happen after extended drug exposure. Adrenal suppression after long-term corticosteroid therapy is one example.

Delayed Reactions of Type D:
It takes a long time for these adverse drug reactions (ADRs) to appear following drug exposure. Two examples are the carcinogenicity and teratogenicity of some drugs.[8]

End-of-use reactions, or type E:
When a medication is stopped, these reactions happen. Rebound hypertension following an abrupt cessation of antihypertensive medication and opioid withdrawal syndrome are two examples.

Treatment failure, or type F:
These reactions, which frequently result from drug interactions, resistance, or improper dosage, involve an unanticipated lack of therapeutic efficacy.

Adverse Drug Reaction Causes and Risk Factors

ADRs are brought on by several things, including:

Patient-related factors: ADR risk is increased by age, gender, genetic variations, pregnancy, renal impairment, hepatic dysfunction, and many comorbidities. Due to polypharmacy and altered pharmacokinetics, older patients are especially vulnerable.[9]
Drug-related factors: The risk of adverse drug reactions (ADRs) is increased by lengthy treatment periods, complicated medication schedules, high dosages, and drugs with a narrow therapeutic index.
Polypharmacy and Drug-Drug Interactions: Taking several drugs at once raises the risk of side effects and interactions, particularly for people with long-term medical conditions.
Medication errors: Preventable adverse drug reactions (ADRs) can result from improper prescription, dispensing, administration, or monitoring [10].
Genetic and Immunological Factors: People may be at risk for serious adverse drug reactions due to pharmacogenetic variations and hypersensitivity reactions.

2.2Pharmacovigilance'sfunction:

The World Health Organisation (WHO) defines pharmacovigilance as "the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems." It is essential for identifying new safety signals, assessing benefit-risk profiles, minimising medication-related harm, and assisting regulatory decision-making. Effective pharmacovigilance systems enhance patient outcomes and therapeutic safety by enabling the early detection of uncommon and harmful adverse drug reactions (ADRs) that might not be seen during clinical trials.[11]

2.3 Traditional Pharmacovigilance methods:

Post-marketing surveillance techniques are the cornerstone of traditional pharmacovigilance systems. The most popular approach is the Spontaneous Reporting System (SRS), where patients, pharmaceutical companies, and medical professionals voluntarily report suspected adverse drug reactions (ADRs) to national or international databases.[12] The WHO global database VigiBase, EudraVigilance, and the FDA Adverse Event Reporting System (FAERS).

Case reports, case series, cohort event monitoring, prescription event monitoring, and recurring safety update reports are additional traditional pharmacovigilance techniques. Cohort and prescription event monitoring allow for the systematic observation of drug safety in real-world populations, while case reports and case series frequently offer the first hint of hitherto unidentified adverse reactions [13]. Signal detection methods like the Reporting Odds Ratio (ROR) and Proportional Reporting Ratio (PRR) are frequently used in large reporting databases to find possible correlations between medications and adverse events (Kaur et al., 2015).

These conventional techniques have made it much easier to identify uncommon and dangerous adverse drug reactions (ADRs), which has prompted regulatory actions like safety warnings, label modifications, recommendations for restricted use, and drug withdrawals from the market[14].

2.4 Limitations of Conventional Pharmacovigilance Systems:

Despite their vital role in ensuring medication safety, conventional pharmacovigilance systems have a number of well-known shortcomings. Underreporting is one of the main issues since only a small portion of actual ADRs are reported. Underreporting is caused by a variety of factors, including ignorance, uncertainty about causality, time constraints, and the conviction that known reactions don't need to be reported (Sahu et al., 2014).

Another disadvantage of spontaneous reporting databases is the lack of information on the total number of exposed patients, which makes it impossible to accurately estimate the incidence or prevalence of adverse drug reactions (ADRs).[15] Additionally, reports frequently lack demographic, clinical, or medication-related data, which lowers the quality of safety assessments (Khalil & Huang, 2020).

Because of public concern, regulatory actions, or media attention, conventional systems are also vulnerable to reporting bias, which can increase the frequency of reporting regardless of the actual occurrence of unfavorable events. [1 Furthermore, using traditional methods to identify specific patient risk factors, delayed adverse effects, and complex drug-drug interactions is difficult. Manual review and signal detection have become more challenging and resource-intensive due to the increasing volume of pharmacovigilance data (Pendota et al., 2017).

Because of this, traditional pharmacovigilance is frequently reactive rather than predictive, detec ting safety issues only after significant patient exposure has taken place. These restrictions have sparked interest in cutting-edge computational techniques like artificial intelligence and machine learning, which present chances for better signal identification, earlier ADR detection, and enhanced therapeutic safety monitoring.[17]

3. ARTIFICIAL INTELLIGENCE IN HEALTHCARE AND PHARMACOVIGILANCE:

Unprecedented opportunities for the use of artificial intelligence (AI) in healthcare have been made possible by the quick growth of healthcare data produced by clinical trials, wearable technology, insurance claims, genomic databases,

electronic health records (EHRs), and pharmacovigilance reporting systems. Computational systems that are capable of learning, reasoning, pattern recognition, prediction, and decision-making—tasks that have historically required human intelligence—are referred to as artificial intelligence. The growing number and complexity of adverse drug reaction (ADR) reports in pharmacovigilance have put traditional surveillance methods to the test. Millions of individual case safety reports are submitted annually to databases such as WHO-VigiBase, EudraVigilance, and the FDA Adverse Event Reporting System (FAERS). Manually reviewing these reports requires a lot of time and effort, and it is often insufficient to recognize complex safety signals. Applying AI-based methods to improve signal detection, ADR prediction, causality assessment, and therapeutic safety evaluation has therefore attracted a lot of attention.

3.1 Machine Learning-Based Assessment of Drug Safety:

Computers can recognize patterns in data without explicit programming thanks to machine learning (ML), a branch of artificial intelligence. By finding correlations between variables, machine learning algorithms create predictive models that get better with more data. In the healthcare sector, machine learning approaches have demonstrated significant promise for the analysis of extensive clinical and pharmacological datasets.

The three main types of machine learning techniques used in pharmacovigilance are supervised, unsupervised, and reinforcement learning. To categorize safety signals and forecast adverse drug reactions, supervised learning algorithms like Random Forests, Support Vector Machines (SVMs), Decision Trees, Logistic Regression, and Gradient Boosting Machines are frequently employed. These models can identify patients who are at risk of adverse events after being trained on labeled datasets with known ADR outcomes.

Numerous studies have shown that ML models perform better than traditional statistical methods in identifying safety signals and forecasting the occurrence of ADRs. Machine learning systems can provide more thorough risk assessments and facilitate proactive intervention strategies by combining demographic, clinical, laboratory, genetic, and medication-related data.

3.2 Applications of Deep Learning in Pharmacovigilance:

Artificial neural networks with several hidden layers are used in deep learning (DL), a subfield of machine learning, to handle complicated and massive datasets. Because deep learning models can automatically extract important features from both structured and unstructured data, they have become increasingly popular in the healthcare industry. Deep learning algorithms like Convolutional Neural Networks (CNNs), Recurrent Neural Networks (RNNs), Long Short-Term Memory (LSTM) networks, and Transformer-based architectures are being used more and more in pharmacovigilance. These models are especially helpful for analysing data from spontaneous reporting systems, social media, biomedical literature, and electronic health records.Natural Language Processing (NLP), a subfield of artificial intelligence that is frequently combined with deep learning, enables the automated extraction of adverse event data from clinical narratives, discharge summaries, physician notes, and published scientific literature. The high accuracy of NLP systems in identifying drug names, adverse reactions, disease conditions, and temporal relationships significantly reduces the workload associated with manual case review.

4. AI-BASED ADR PREDICTION:

4.1. Data sources used for prediction:

The quality and accessibility of data determine how well AI and big data work for ADR prediction. The following sources of information are essential for creating reliable prediction models:

A. Electronic Health Records (EHRs):

EHRs include comprehensive patient information, such as demographics, medical history, medications, test results, and clinical notes. Based on past patient outcomes, these records are a treasure trove for locating possible adverse drug

reactions. Particularly, trends and connections between medication administration and adverse outcomes might be found in longitudinal data gathered over time [18]. However, because EHRs have several disadvantages, using data from EHRs for ADR prediction models should be done carefully to improve data quality and conclusions' generalizability. One of these challenges is "data heterogeneity." This is due to the fact that various healthcare systems employ various EHR platforms, terminologies, and coding schemes. Medication names may not be standardized, laboratory test names or units may vary, and adverse effects may be documented using disparate terminology.

Missing data is widespread: Important exposures or results may be missing or incorrectly reported; lab tests may be ordered seldom or structured fields may be left blank. Misclassification or under coding of adverse drug reactions (ADRs) is a prevalent occurrence in both diagnosis and medication coding [19].

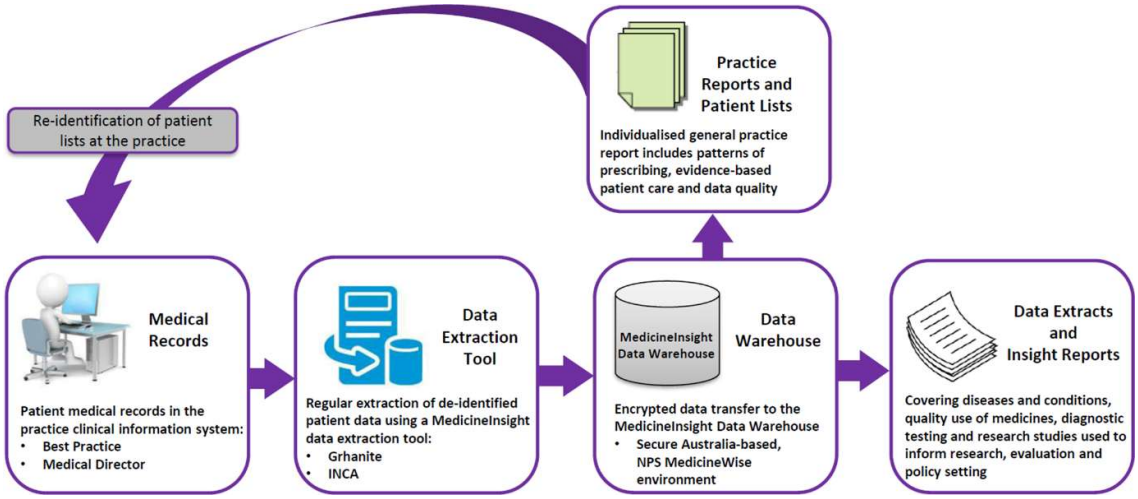

Figure 1: Medicine Insight electronic health record (EHR) data extraction, transformation, warehousing, and reporting procedures [20].

B. Pharmacovigilance Databases:

Worldwide pharmacovigilance databases, including the European Medicines Agency (EMA) database, WHO's VigiBase, and the FDA Adverse Event Reporting System (FAERS), gather spontaneous reports of adverse drug reactions (ADRs) from patients and healthcare professionals. These databases are essential for identifying adverse drug reactions (ADRs) that happen after a medicine is put on the market. They are the main source of data used to build ADR prediction algorithms, making extensive retrospective research possible [18].

The major pharmacovigilance databases include:

VigiBase®: The largest global database of ICSRs, VigiBase is run by the Uppsala Monitoring Center under the World Health Organization (WHO) and receives reports from nations taking part in the WHO Programme for International Drug Monitoring. International signal detection and trend analysis are supported [21]

FDA Adverse Event Reporting System (FAERS): The US Food and Drug Administration (FDA) maintains the FDA Adverse Event Reporting System (FAERS), which gathers voluntary reports from consumers and healthcare providers as well as required reports from manufacturers. It is widely employed in pharmacovigilance research and signal detection.

EudraVigilance: The European database for tracking and evaluating any adverse events related to medications approved in the European Economic Area is run by the European Medicines Agency (EMA). It makes it easier to continuously check the safety of pharmaceuticals across Europe[22].

C. Genomic Data:

Information derived from a person's genetic composition, such as DNA sequences, gene expression profiles, and genetic polymorphisms that affect treatment response, is referred to as genomic data. Genomic information is increasingly being incorporated into artificial intelligence (AI) models in pharmacovigilance and personalized medicine to forecast adverse drug responses (ADRs) and maximize treatment choices. Individual variances in pharmacological efficacy and toxicity can be attributed to genetic variants that impact drug absorption, distribution, metabolism, excretion, and pharmacodynamics responses [23]. Pharmacogenomics data offer important insights into the mechanisms behind inter-individual heterogeneity in drug safety and efficacy, claim Amann et al. (2023). Genetic variations that encode transport proteins, drug targets, and drug-metabolizing enzymes can drastically change treatment results and put patients at risk for serious adverse drug reactions. The authors stressed that precision medicine strategies that maximize therapy benefits while limiting toxicity are supported by incorporating genomic data into clinical decision-making [24]. Besides that, Whirl-Carrillo et al. (2021) emphasized how necessary curated pharmacogenomic knowledge bases—like PharmGKB—can be to the use of genomic discoveries in healthcare settings. In order to promote safer medication usage, these resources gather data that connects genetic variations with drug responses and offer dosage recommendations created by expert groups. Despite its potential, the routine use of genetic data in pharmacovigilance is riddled with challenges. These include the need for standardized methods for data integration, the underrepresentation of different groups in genomic studies, the restricted accessibility of genomic testing in some healthcare settings, and worries about patient privacy and data security. For AI-driven precision pharmacovigilance to reach its full potential, these obstacles must be removed [25].

D.Cliical Trials Data:

One of the most crucial sources of information for assessing the efficacy and safety of pharmaceutical medicines prior to their marketing approval is clinical trial data. Patient demographics, treatment plans, test results, adverse event reports, clinical outcomes, and follow-up data gathered throughout Phase I–IV studies are all included in these datasets. Clinical trial data offer organized, high-quality evidence that may be utilized to create predictive models for spotting possible safety issues early in the drug development process when it comes to AI-based adverse drug response (ADR) prediction. Blinova et al. (2022) claim that the incorporation of artificial intelligence into clinical trial analysis has improved the capacity to detect safety signals, forecast toxicities associated with treatment, and optimize risk assessment techniques. By analysing multidimensional clinical trial records, machine learning algorithms can identify patterns linked to the occurrence of adverse drug reactions (ADRs), increasing the sensitivity of conventional pharmacovigilance techniques. AI tools, according to the authors, make it easier to move from reactive safety monitoring to proactive adverse event prediction during medication development [26].

4.2 Role of NLP and Data Mining in AI-Based ADR Prediction:

- Natural Language Processing (NLP)

A subfield of artificial intelligence called natural language processing (NLP) gives computers the ability to comprehend, analyse, and derive useful information from unstructured text input. NLP has emerged as a key tool in pharmacovigilance for detecting adverse drug reactions (ADRs) from sources such clinical notes, discharge summaries, biological literature, electronic health records (EHRs), social media posts, and spontaneous reporting systems [27].

Several crucial tasks are typically involved in NLP applications in pharmacovigilance:

a. Named Entity Recognition (NER): Identifies biomedical entities in text, including drug names, ADR words, symptoms, and diseases.
b. Relation extraction: finds connections between drugs and side effects that are reported in clinical narratives.
c. Entity normalization: The process of mapping extracted ADR terms to conventional terminologies, like the Medical Dictionary for Regulatory Activities (MedDRA), is known as entity normalization.
d. Text classification: separates texts that are important to ADR from those that are not.

e. Information Retrieval: Enables the retrieval of safety-related data from extensive literature collections and biomedical databases.

The capacity of NLP to efficiently use electronic health records (EHRs) is one of its main advantages. Important information about medication use and adverse events that might not be recorded by structured reporting systems is frequently found in clinical notes. NLP systems can enhance pharmacovigilance dataset's completeness and facilitate the early identification of ADR signals by processing these narratives [28].

- Data Mining:

The process of utilizing statistical and computational methods to uncover hidden patterns, correlations, and trends within huge datasets is known as data mining. Data mining is widely utilized in pharmacovigilance to find previously unknown ADR signals from sizable safety databases [29]. Another crucial method for finding recurrent connections between drugs and side effects is association rule mining. This method can identify trends indicating that particular adverse drug reactions (ADRs) often occur with particular medications or drug combinations by analyzing huge datasets. Furthermore, clustering algorithms help identify common traits and potential risk factors linked to adverse reactions by grouping medications or patients with similar ADR profiles. Classification techniques and knowledge graph mining are examples of more sophisticated approaches. Decision trees, support vector machines, and random forests are examples of classification algorithms that use patient demographics, clinical features, and drug-related data to forecast the probability of adverse drug reactions. To discover new drug-ADR correlations, knowledge graph mining combines data from several biomedical sources, such as DrugBank, SIDER, and electronic health records. By facilitating thorough analysis of diverse healthcare data, these methods have improved the predictive capacities of AI-based pharmacovigilance systems. [30].

- Role of NLP and Data Mining in ADR Prediction:

Because they make it possible to extract and analyze information from vast and intricate healthcare datasets, natural language processing (NLP) and data mining have become crucial elements of contemporary pharmacovigilance systems. Underreporting and delayed signal detection are common problems with traditional spontaneous reporting systems. As a result, AI-based methods that make use of NLP and data mining techniques offer chances for better patient safety and early detection of adverse drug reactions (ADRs). NLP approaches can convert unstructured clinical narratives included in electronic health records (EHRs) into structured data appropriate for pharmacovigilance analyses, according to Luo et al. (2017). Important details about pharmaceutical exposure, symptoms, and adverse events that might not be documented in standardized reporting systems are often found in clinical notes. From these narratives, NLP techniques like named entity recognition, relation extraction, and text classification make it easier to automatically identify medications and the bad events that go along with them. The authors emphasized that by using actual clinical data to more effectively identify adverse medication events, NLP-based pharmacovigilance has the potential to improve current surveillance systems [31].

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systems could improve post-marketing surveillance. the speed and thoroughness of ADR detection, incorporating NLP and data mining into pharmacovigilance systems could improve post-marketing surveillance [32].

5. AI IN THERAPY SAFETY:

5.1 Drug-drug interaction prediction:

Particularly for individuals taking several drugs, drug-drug interactions (DDIs) are a significant contributor to adverse drug reactions (ADRs), treatment failure, and higher healthcare expenditures. Clinical trials, spontaneous reporting systems, and post-marketing surveillance are the mainstays of traditional DDI identification techniques. These methods, however, frequently take a long time and can miss uncommon or unknown interactions. Through the integration of extensive biomedical data and the identification of intricate drug connections, artificial intelligence (AI) has become a potential approach for DDI prediction. By using data such chemical structures, molecular characteristics, therapeutic targets, side-effect profiles, and pharmacological pathways, machine learning and deep learning approaches have greatly improved the prediction of possible DDIs. According to the authors, algorithms such as Random Forests, Support Vector Machines, Convolutional Neural Networks (CNNs), and Graph Neural Networks (GNNs) have shown excellent prediction accuracy in identifying both known and unknown medication interactions. By quickly screening thousands of medication combinations, these computational methods enable researchers to identify clinically significant DDIs earlier [33].

The review also highlighted explainable artificial intelligence's (XAI) increasing significance in DDI prediction. Despite the high predicted accuracy of many deep learning models, their "black-box" characteristics may prevent them from being widely used in therapeutic settings. Explainable models boost therapist confidence and facilitate well-informed therapy choices by offering insight into the elements influencing anticipated interactions. The authors came to the conclusion that incorporating explainable AI into DDI prediction systems is a significant step toward safer drug usage and successful clinical application. Similar to this, Marzouk et al. (2025) noted that AI-based DDI prediction systems are increasingly using a variety of data sources, such as genomic datasets, DrugBank, TWOSIDES, electronic health records, and pharmacovigilance databases. AI models can find hidden interaction patterns and enhance the identification of patients at risk for drug-related harm by merging these diverse resources. Such prediction algorithms have the potential to improve clinical decision-making, lower avoidable adverse events, and promote personalized medicine, according to the scientists. Despite these developments, there are still a number of obstacles. The dependability and application of AI-based DDI prediction systems are still influenced by the availability of high-quality datasets, class imbalance problems, model interpretability, and the requirement for prospective clinical validation. However, it is anticipated that continued advancements in machine learning techniques and growing healthcare datasets will enhance the precision and usefulness of DDI prediction models in standard clinical practice [34].

5.2 Personalized Medicine

Customizing medical care according to a patient's genetic profile, clinical traits, lifestyle, and surroundings is known as personalized medicine. By evaluating vast and intricate information, such as genetic, proteomic, and clinical data, artificial intelligence (AI) plays a critical role in personalized medicine by forecasting patient-specific drug reactions. Clinicians can choose the best prescription and dosage for each patient by using AI algorithms to uncover genetic variants related to drug metabolism, efficacy, and toxicity. The risk of medication-related problems can be decreased by using machine learning algorithms to forecast the possibility of adverse drug reactions (ADRs) prior to starting therapy. Furthermore, by discovering biomarkers that direct treatment choices and enhance therapeutic outcomes, AI aids in the development of precision therapies. By lowering the frequency of adverse drug reactions (ADRs), increasing treatment efficacy, and eliminating trial-and-error prescribing, the incorporation of AI into personalized medicine improves therapeutic safety. In the end, this strategy enhances medication safety and care quality by facilitating the shift from a "one-size-fits-all" model to patient-centred healthcare [35].

5.3 Clinical Decision Support Systems (CDSS)

Computerized technologies called Clinical Decision Support Systems (CDSS) are intended to help medical professionals make evidence-based clinical decisions. AI-powered CDSS provides real-time suggestions for diagnosis, treatment, and medication management by integrating patient data, clinical guidelines, laboratory data, and drug records. AI-based CDSS can detect possible drug-drug interactions, contraindications, medication errors, and patient-specific risk factors linked to adverse drug reactions (ADRs) in therapeutic safety. By continuously learning from real-world clinical data and 6forecast unfavorable outcomes more accurately and optimize treatment plans [36]. AI-driven CDSS can also support individualized treatment plans, suggest dose modifications depending on hepatic or renal function, and produce alerts for high-risk drugs. These technologies greatly reduce medication-related errors and improve patient safety by increasing the precision and effectiveness of clinical decision-making. To maximize the efficacy of AI-based CDSS in healthcare settings, obstacles such data quality problems, alert fatigue, interoperability issues, and ethical considerations must be overcome [37].

6. ADVANTAGE AND CHALLANGES

6.1 Benefits of AI in Pharmacovigilance

By facilitating the quick processing and analysis of massive, diverse healthcare datasets, such as electronic health records (EHRs), spontaneous reporting systems, biomedical literature, and social media data, artificial intelligence (AI) has revolutionized pharmacovigilance. The sensitivity and promptness of safety signal identification can be enhanced by AI-driven algorithms, especially machine learning (ML) and natural language processing (NLP), which can spot adverse drug reaction (ADR) patterns that traditional statistical techniques might overlook [38]. Our review is distinct in that it aims to close this gap by offering a better knowledge of how current AI/ML standards and practices in PV correspond with the crucial success factors found in related fields like biology and medicine [39]. Automating typical pharmacovigilance operations like case triage, literature screening, duplicate detection, and data extraction is another significant benefit of AI. Pharmacovigilance specialists can concentrate on more advanced clinical evaluation and decision-making thanks to this automation, which also minimizes manual labor and shortens reporting deadlines. Additionally, AI may combine data from several real-world sources to offer a more thorough understanding of medication safety across a range of patient demographics [40]. By predicting the probability of adverse drug reactions (ADRs) before they happen, predictive AI models enable proactive risk assessment, enhancing therapeutic safety and customized medicine. AI systems can identify patients who are more likely to experience adverse events and help clinicians optimize treatment plans by integrating patient-specific data including genetics, comorbidities, laboratory values, and drug history. Additionally, AI-enhanced pharmacovigilance leads to better post-marketing surveillance, earlier regulatory interventions, and ultimately better patient outcomes [41].

6.2 Ethical Issues

Despite its benefits, there are a number of ethical issues with integrating AI into pharmacovigilance. Algorithmic bias, which can occur when AI models are trained on incomplete or non-representative datasets, is one of the main issues. The fairness and dependability of ADR detection may be impacted by such biases, which could result in uneven prediction performance across various demographic groups [42]. It's still unclear who is responsible for decisions made by AI. It is a complicated legal and ethical problem involving developers, healthcare organizations, regulatory bodies, and physicians to determine who is responsible when an AI system fails to identify a key safety signal or generates inaccurate recommendations. Therefore, the safe application of AI in drug safety monitoring requires strong governance mechanisms and ongoing human oversight [43].

6.3 Data Privacy and Limitations

Access to vast amounts of patient data gathered from EHRs, claims databases, registries, and digital platforms is crucial for AI-based pharmacovigilance. Thus, maintaining compliance with data protection laws and safeguarding

patient privacy are crucial problems. To prevent unauthorized access or exploitation of personal information, the use of sensitive health information requires stringent governance standards, secure data storage, and anonymization procedures [44]. A lack of common criteria for assessing AI systems, a lack of real-world validation, and challenges incorporating AI tools into current regulatory workflows are further constraints. Evidence now available indicates that while AI has significant potential to enhance drug safety and ADR prediction, its adoption necessitates high-quality data, transparent algorithms, ongoing monitoring, and cooperation between physicians, data scientists, and regulatory bodies [45].

7.RECENT ADVANCES AND FUTURE PERPECTIVES

7.1 Current Research Developments

By making it possible to analyse large-scale, diverse healthcare datasets, recent developments in artificial intelligence (AI) have drastically changed pharmacovigilance and adverse drug reaction (ADR) prediction. In order to detect possible safety signals earlier than traditional techniques, modern AI systems combine data from electronic health records (EHRs), spontaneous reporting systems (like FAERS and VigiBase), genomic databases, biomedical literature, and real-world evidence. Drug toxicity and ADR risk can be predicted with promising accuracy using machine learning (ML) methods including Random Forest, Support Vector Machine (SVM), XGBoost, and deep learning architectures like Convolutional Neural

Networks (CNNs) and Graph Neural Networks [46]. The automated extraction of ADR information from clinical notes, scholarly papers, social media, and patient reports using Natural Language Processing (NLP) and Large Language Models (LLMs) is a significant advancement in research. These methods increase the speed and sensitivity of signal detection while lessening the manual load of pharmacovigilance tasks. The increasing application of Explainable Artificial Intelligence (XAI) methods like SHAP and LIME is another significant development. By identifying the critical elements influencing ADR risk, XAI techniques enhance the interpretability and transparency of AI forecasts [47].

7.2 Future Scope of AI in Drug Safety

The shift from reactive pharmacovigilance to proactive and predictive safety management is where AI in drug safety is headed. It is anticipated that AI-driven platforms would continually monitor patient data in real time, enabling tailored treatment interventions and early detection of people at high risk for adverse drug reactions (ADRs) [48]. In order to develop dynamic models of patient health that can forecast medication safety outcomes prior to the onset of clinical symptoms, future AI systems are also anticipated to include wearable technology, digital twins, and Internet of Medical Things (IoMT) technologies. Furthermore, safe cooperation between healthcare organizations without disclosing private patient information may be made possible by developments in federated learning and privacy-preserving AI algorithms[49].

8. CONCLUSION

Artificial intelligence (AI) has become a potent tool for increasing treatment safety and predicting adverse drug reactions (ADRs). AI makes it possible to identify possible drug-related dangers early from big healthcare datasets by combining machine learning, deep learning, natural language processing, and data mining approaches. AI-based solutions provide customized treatment plans, anticipate drug-drug interactions, and enhance pharmacovigilance initiatives. Clinical decision support systems help medical practitioners make safer and more efficient treatment choices. Notwithstanding its many benefits, issues including data quality, privacy, ethics, and model openness continue to be significant factors. The precision and effectiveness of medication safety monitoring are still being enhanced by recent developments in AI. AI is anticipated to be crucial to proactive pharmacovigilance and precision medicine in the future. Overall, the integration of AI into healthcare has significant potential to reduce ADRs, improve patient outcomes, and promote safer therapeutics.

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