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Review Article

Artificial Intelligence And Machine Learning In Adverse Drug Events And Precision Oncology: Current Advances, Challenges, And Future Perspectives

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ABSTRACT

Adverse drug reactions (ADRs) are a major cause of preventable morbidity, mortality, prolonged hospitalization, and increased healthcare expenditure worldwide. Conventional pharmacovigilance systems primarily depend on spontaneous reporting, which is often limited by under-reporting, incomplete clinical information, delayed signal detection, and reporting bias. Recent advances in artificial intelligence (AI) and machine learning (ML) have transformed pharmacovigilance by enabling early prediction of ADRs, individualized drug response assessment, and treatment-related toxicity prediction using electronic health records, pharmacovigilance databases, drug–target interaction data, genomic information, and other real-world evidence. Machine learning algorithms including Random Forest, Support Vector Machine, XGBoost, LightGBM, Artificial Neural Networks, and Deep Learning have demonstrated promising predictive performance across a wide range of clinical applications, particularly in oncology. These models facilitate prediction of chemotherapy-induced neutropenia, hepatotoxicity, nephrotoxicity, hematological toxicity, and therapeutic response, thereby supporting precision medicine and personalized treatment strategies. Explainable AI techniques further improve model transparency and clinician confidence, promoting safer implementation in clinical practice. This review summarizes the current evidence regarding AI- and ML-based approaches for ADR prediction, discusses commonly used algorithms, major data sources, performance evaluation metrics, clinical applications, ethical and regulatory considerations, current limitations, and future research directions.

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The integration of AI with pharmacovigilance has the potential to improve drug safety, optimize therapeutic outcomes, reduce healthcare costs, and support evidence-based clinical decision-making.

INTRODUCTION

Adverse Drug Events (ADEs) remain one of the most common causes of preventable morbidity and mortality globally and a huge burden to the patient and health care system. According to WHO, ADEs refer to any form of a harmful and unexpected reaction to medicines, which takes place at therapeutic use of drugs for either treatment, diagnosis or prevention. Many cases that end up at the emergency room, prolonged hospital stays, higher expenses for care and reduced quality of life are caused by these negative effects of drugs. Vulnerable populations with regard to ADRs include geriatric, pediatric patients, patients with cancer and multiple medication use.

Existing pharmacovigilance has largely been based on spontaneous reporting platforms like the UK's Yellow Card Scheme, WHO's VigiBase and FDA's Adverse Event Reporting System (FAERS). These systems have clearly led to major drug safety signals, but have inherent limitations. They can be less effective in identifying rare or patient-specific ADRs due to underreporting, incomplete patient records, reporting bias, inconsistent data quality, and delays in signal detection. Seeking to understand the relationships between these various factors that influence ADR risk, traditional statistical methods have proven to be inadequate.

The new opportunities brought by machine learning (ML) and artificial intelligence (AI) in pharmacovigilance (PV) have been realized by recent advancements.Recent advancements in pharmacovigilance (PV) have seen new opportunities in the field of predictive PV, which is enabled by machine learning (ML) and artificial intelligence (AI). Using AI, computers can be trained on vast amounts of structured and unstructured data from the healthcare industry, and find patterns or trends that would not be apparent to humans. Some algorithms like Random Forest, Support Vector Machine (SVM), eXtreme Gradient Boosting (XGBoost), Light Gradient Boosting Machine (LightGBM), Artificial Neural Networks (ANN), and deep learning models can utilize laboratory data, genomics, drug-target interaction databases, imaging data, and real-world data to predict ADRs more accurately than many traditional methods. These methods can help identify relationships between variables that go beyond linear relationships and help to highlight risk factors that would not have shown up in linear models, leading to earlier interventions and more individualized treatment plans.

AI has a particularly important role to play in oncology, where patients are often treated with highly toxic drugs that have narrow therapeutic windows. By predicting chemotherapy-induced neutropenia, hepatotoxicity, nephrotoxicity, haematological toxicity and therapy response prior to therapy, the clinician has the opportunity to tailor the choice of drug, dosage, minimize serious side effects and optimize survival. Explainable AI provides another added value here: by making model predictions interpretable, it helps to develop clinician trust and increase the number of models used in clinical practice.

Despite these advances, several challenges remain before AI-powered pharmacovigilance can become a standard component of clinical practice.Nevertheless, there are several hurdles to overcome before AI-powered pharmacovigilance can become a routine part of clinical practice. Issues of data heterogeneity, missing data, class imbalance, external validation, algorithmic bias, privacy, ethics, and regulation still restrict the

ability to make these predictive models reliable and generalizable. Addressing these challenges will need continued efforts from a multidisciplinary team of clinicians, pharmacists, data scientists, regulators, and health care institutions.

The databases they rely on, the use of such databases in drug safety, clinical trial efficiency, and their evaluation, explainable AI, and future research and challenges on their use, ethical issues, and the future of their research. In doing so, it illustrates how AI is increasingly playing a role in evidence-based clinical decision-making, precision medicine, and drug safety in general.

Conventional Pharmacovigilance

Pharmacovigilance is concerned with the detection, assessment, understanding and prevention of adverse effects and other medicine-related problems. The traditional surveillance methods are based on spontaneous reporting systems like the FAERS, WHO VigiBase and UK Yellow Card Scheme. The systems have been able to capture many significant safety signals over the years, but they suffer from underreporting, incomplete clinical data, reporting bias and delays in detecting signals. Rare or patient-specific ADRs thus can easily be overlooked through traditional methods, or only emerge long after.

Artificial Intelligence In Healthcare

Artificial intelligence enables computers to perform tasks - pattern recognition, learning from data, prediction, and clinical decision support - that would normally require human judgement. Given its ability to process vast amounts of complex clinical information from electronic health records, laboratory tests, genomics, drug-target interactions, and real-world evidence, machine learning, one of the key pillars of AI, has emerged as a valuable asset in the pharmacovigilance field. ML algorithms can detect non-linear relationships and interactions between multiple variables, making them more suitable models for predicting ADRs and individual treatment responses, unlike traditional statistical models. This is supported by recent studies in oncology where prediction models like Random Forest, SVM, Gradient Boosting, Artificial Neural Networks, and deep learning have all been found to be useful for predicting chemotherapy toxicity, neutropenia, and treatment response.

Adverse Drug Reaction Prediction Using Machine Learning Algorithms

Machine learning has emerged as a key part of contemporary pharmacovigilance due to its capability to analyse vast amounts of heterogeneous clinical data and identify connections that standard statistics cannot. Instead of depending on making assumptions, the ML algorithms are trained directly on the available data and get better to the extent they are exposed to new data. These models are used to estimate the risk of drug related toxicity based on laboratory data, drug history, comorbidities, genetic information, drug-drug interactions, and electronic health records. The approach most suitable to the prediction target, the size of the data set, the need for interpretable results, the computational resources used, and the intended clinical application will determine which method is used.

- **Logistic Regression**

Logistic regression is still the most widely used baseline model in clinical prediction studies. It models the relationship between predictor variables and a binary result, estimating the probability of the result. Its coefficients can be converted into odds ratios making it easy to

understand and interpret how each of the risk factors contributes to the prediction. The major drawback of this is that it assumes linearity between the predictors and the outcome and hence is not useful in more complex or nonlinear clinical situations.

- **Decision Tree**

Decision trees are used to classify patients into groups by different sequential rules based on clinical variables. Their utility is their simplicity of use – the pathway to the decision can be visualised and thus they can be useful for clinical decision support. The drawback is that a single tree can easily overfit the training data, which has a detrimental effect on its performance on external data.

- **Random Forest**

Random Forest is an ensemble technique which trains hundreds of trees using majority voting and sampling the data in the dataset with replacement. This will minimize overfitting and increase robustness, stability and predictiveness. It is excellent at dealing with missing values, complex interactions and high dimensional data and is consistently one of the most effective predictors of ADRs, chemotherapy-induced neutropenia, and other drug toxicities.

- **Support Vector Machine (SVM)**

Support Vector Machine's mechanism is to find the hyperplane which most optimally differentiates between groups of patients. It can also be used to model nonlinear relationships when using kernel functions and has often been used successfully on medium-sized, high dimensional datasets. It has a few drawbacks, such as its computational expense and the fact that it is relatively hard to interpret.

- **XGBoost**

Regularisation helps XGBoost avoid over-fitting and generalise its predictions, and the trees are built sequentially, minimising prediction error at each stage using gradient boosting. It has demonstrated its capacity to accurately forecast drug toxicity, treatment reaction, and clinical results based on EHR data.

- **LightGBM**

LightGBM is a fast and memory-efficient version of gradient boosting, suitable for large-scale datasets. This also makes it ideal for nationwide pharmacovigilance databases where training speed and scale is important.

- **Artificial Neural Networks**

Artificial Neural Networks are loosely based on interconnected biological neurons and are capable of learning complex nonlinear relationships. Understands how to detect underlying patterns in laboratory, imaging and genomic data, although generally requires larger sample sizes and is more difficult to interpret than simpler models.

- **Deep Learning**

Deep learning involves utilizing several layers of neural networks to automatically identify high-level features in structured and unstructured data. It has been used in predicting the responses of chemotherapy, interpreting medical images, analysing genomic data, and supporting precision oncology in general.

Comparison And Clinical Selection

There is no one algorithm that fits all pharmacovigilance applications. Random Forest, XGBoost and LightGBM tend to perform better on large clinical datasets, whereas logistic regression

and decision trees are considered more interpretable when it is the most important consideration. When dealing with multimodal data, such as genetics and imaging, deep learning is the more likely approach to take. In practice, the decision of which model to choose is a balance between predictive performance, interpretability, computational efficiency and the degree of external validation of the model.

Table 1 - Comparison And Clinical Selection

Algorithm	Main Strength	Major Limitation	Best Data Type	Typical ADR Application
Logistic Regression	Highly interpretable	Linear assumptions	Clinical variables	Baseline risk prediction
Decision Tree	Simple decision rules	Overfitting	Small datasets	Risk stratification
Random Forest	Robust and accurate	Reduced interpretability	Large EHR datasets	ADR / neutropenia prediction
SVM	Excellent nonlinear classification	Complex tuning	High-dimensional data	Cancer response prediction
XGBoost	High predictive performance	Parameter optimisation	Structured EHR	Drug toxicity prediction
LightGBM	Fast training	Sensitive to parameters	Big data	Population pharmacovigilance
ANN	Learns complex relationships	Needs large datasets	Mixed clinical data	Outcome prediction
Deep Learning	Automatic feature extraction	Black-box model	Imaging / omics	Precision oncology

Electronic Health Records (EHRS) And Pharmacovigilance

The performance of a machine learning model depends to a large extent on the quality and diversity of the data used to train it. Electronic Health Records (EHRs) constitute one of the most valuable databases that contain longitudinal data from patients collected on a regular basis as they receive routine care – including age, sex, body weight, diagnoses, lab results, medication history, allergies, vital signs, imaging reports, clinical outcomes and much more. This implies that some of the ML algorithms may be able to identify some of the correlations between patient characteristics and risk of ADR that are beyond the ability of a human being. EHRs give more context of the clinical situation, and importantly, can predict ADRs before they occur, rather than after, unlike spontaneous reporting systems.

In modern times of predictive pharmacovigilance, EHRs are widely used in conjunction with certain pharmacovigilance databases and molecular databases. The more data that can be combined the better the model will be, since each data source will provide a different type of information, e.g. data from pharmacovigilance databases will provide real world safety data, while molecular databases will provide information on drug-target interactions, protein networks and biological pathways involved in toxicity.

Table 2- Electronic Health Records (EHRS) And Pharmacovigilance

Database	Main Content	Primary Purpose	Strength	Limitation
FAERS	US spontaneous ADR reports	Signal detection	Large real-world dataset	Under-reporting and reporting bias
WHO VigiBase	Global ADR reports	International safety monitoring	Worldwide coverage	Variable report quality
Yellow Card Scheme	UK ADR reports	National surveillance	Long-term monitoring	Incomplete reports
STITCH	Drug-protein interactions	Mechanistic prediction	Links drugs with biological targets	Depends on available interaction data
SIDER	Known drug side effects	ADR annotation	Curated adverse-effect resource	Limited to reported effects
DrugBank	Drug and pharmacology data	Drug discovery	Comprehensive drug information	Requires frequent updates

Artificial Intelligence In Precision Oncology

Precision oncology is designed to personalize the selection of treatment for each patient by incorporating clinical, molecular and genetic information in the right patient at the right time. AI has speeded up this with the ability to analyse high-dimensional datasets; gene-expression profile, somatic mutations, proteomics, radiological imaging, pathology slides and EHRs, to name a few, which allows identification of patients, who are more likely to respond to a specific anticancer drug or have serious treatment-related toxicity.

Prognosis Of Chemotherapy Side Effects.

The most common causes for treatment cessation and/or death during chemotherapy include hepatotoxicity, nephrotoxicity, cardiotoxicity, haematological toxicity, neutropenia and febrile neutropenia. Models created using the standard lab measurements, demographics, treatment plans, and genomic biomarkers have yielded promising results for predicting these complications and include Random Forest, SVM, XGBoost, ANN and deep learning. Early identification of the high-risk patient allows dose adjustment, the use of a granulocyte colony-stimulating factor (G-CSF) and more specific supportive care.

Drug Response Prediction

One of the other key uses of AI is to anticipate patient reactions to treatment before it even starts. The ML models integrate gene-expression profiles, mutation information, drug-target interaction networks and ex vivo drug sensitivity measurements to determine the probability of a response to an anticancer drug. In particular, methods of ensemble learning have yielded promising results in AML and other cancers, including a reduction in exposure to ineffective treatment, improved outcomes and closer of care towards true precision medicine.

Clinical Significance

Clinicians can combine EHRs, pharmacovigilance databases and biological information to shift the paradigm in drug safety monitoring from a reactive approach to a predictive and proactive approach. These AI-based solutions are bolstering patient safety, cutting down on healthcare expenses, minimizing toxicity, and streamlining

drug selection, all central tenets of precision medicine.

Explainable Artificial Intelligence (Xai)

Although very accurate, sophisticated models like deep learning, ensemble models and artificial neural networks are also termed "black boxes," as their decision-making is hard to follow. In healthcare, prediction is not sufficient, one needs to know why a model came to a certain conclusion before being able to act based on it. That's where explainable AI (XAI) steps in: It enhances the transparency, interpretability, and accountability of AI systems, making them a vital component of trustworthy AI.

There are a number of XAI algorithms that have been developed for health applications. SHAP (Shapley Additive Explanations) provides a way of measuring the contribution of each predictor to a specific prediction, while LIME (Local Interpretable Model-Agnostic Explanations) locally fits simpler, interpretable models to the more complex ones. In pharmacovigilance and precision oncology, feature importance ranking and saliency maps, attention mechanisms, and rule-based explanations are becoming more and more common, enabling clinicians to uncover the clinical, laboratory or genetic factors that increase a patient's risk for an ADR.

Evaluation Of AI Models In Terms Of Their Performance

Before any machine learning model is used in the clinic, it is necessary to rigorously evaluate the model - there is no single measurement that is enough, so a combination of measurements is typically reported. With imbalanced datasets, accuracy (or the percentage of correct predictions overall) can be a misleading metric. Sensitivity (recall) gives the ability of a model to identify patients who will have an ADR, and specificity the ability to identify patients who will not have an ADR. Precision is the ratio of the number of correctly predicted ADR cases to the number of cases predicted as ADR, and the F1-score is a trade-off between precision and recall. The overall discrimination can be summarised in the ROC-AUC, and when the ADR outcomes are rare, the Precision-Recall AUC is useful. Finally, external validation and calibration analysis is necessary to ensure the model's validity for various patients.

Tablw 3- Evaluation Of AI Models In Terms Of Their Performance

Metric	Definition	Ideal Value	Importance
Accuracy	Overall correct predictions	High	General performance
Sensitivity	True positive rate	High	Avoid missed ADRs
Specificity	True negative rate	High	Reduce false alerts
Precision	Positive predictive value	High	Reliable prediction
F1-score	Precision and recall balance	High	Imbalanced datasets
ROC-AUC	Overall discrimination	Near 1.0	Model comparison
Calibration	Agreement between predicted and observed risk	Good agreement	Clinical reliability

Challenges And Limitations

While the potential is promising, there are some challenges that hamper the impact of AI in pharmacovigilance. Numerous published studies have been based on a retrospective, single-centre data set, which makes it difficult to apply their results to other settings. Data may be incomplete, incorrectly coded, contain duplicate entries, be skewed, or have poor quality. Predictive accuracy may be reduced by missing, inconsistent coding, duplicate records, class imbalance, and uneven data quality.

Another significant challenging aspect is interpretability. Issues such as algorithmic bias, fairness in patient populations, privacy, cybersecurity, informed consent and adherence to regulations like GDPR and HIPAA must be considered.

Future Perspectives

The potential for AI in pharmacovigilance is heavily reliant on the ability to connect multimodal healthcare information, including EHRs, genomics, proteomics, metabolomics, mobile health applications, real-time monitoring, imaging, and wearable devices. Explainable AI should help build trust in the use of AI by physicians and regulatory bodies, and integrated learning could enable hospitals to work together without exposing patient information directly. New technologies like digital twins, large language modelling, causal AI, and reinforcement learning can also enhance the individualisation of treatment decisions and predict adverse drug reactions before the patient is given a medication. Standardisation of reporting and prospective, multicentre clinical studies are needed to translate this research into routine healthcare.

CONCLUSION

Predictive pharmacovigilance and precision oncology have come a long way to AI and machine learning. These methods combine clinical, laboratory, genetic, and pharmacological information to aid in the choice of the appropriate therapy, contribute to the development of personalized care and allow for the identification of patients who are at risk for ADRs earlier than previously. Random Forest, XGBoost, SVM, LightGBM, ANN and deep learning have had promising performance in various clinical scenarios. The key to successful implementation will be meticulous external validation, clear algorithms, ethical considerations, comprehensive data security measures, and ongoing clinical trial advancements—all of which will be essential to the effects of an eventual AI influence on drug safety and healthcare outcomes.

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