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REVIEW ON BENEFITS AND METHODS OF USING ARTIFICIAL INTELLIGENCE IN PHARMACOVIGILANCE

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ABSTRACT

Artificial intelligence through machine learning uses algorithms and prior learnings to make predictions.Recently, there has been interest to include more artificial intelligence in pharmacovigilance of products already in the market and pharmaceuticals in development. The aim of this study was to identify and describe the uses of artificial intelligence in pharmacovigilance through a systematic literature review.Embase and MEDLINE database searches were conducted for articles published from January 1, 2015 to July 9,2021 using search terms such as 'pharmacovigilance,' 'patient safety,' 'artificial intelligence,' and 'machine learning' in the title or abstract. Scientific articles that contained information on the use of artificial intelligence in all modalities of patient safety or pharmacovigilance were reviewed and synthesized using a pre-specified data extraction template. Articles with incomplete information and letters to editor, notes, and commentaries were excluded. Sixty-six articles were identified for evaluation. Most relevant articles on artificial intelligence focused on machine describe the use of artificial intelligence in patient safety and pharmacovigilance in general.learning, and it was used in patient safety in the identification of adverse drug events (ADEs) and adverse drug reactions(ADRs) (57.6%),processing safety reports (21.2%), extraction of drug–drug interactions (7.6%), identification of populations at high risk for drug toxicity or guidance for personalized care (7.6%), prediction of side effects (3.0%), simulation of clinical trials (1.5%), and integration of prediction uncertainties into diagnostic classifiers to increase patient safety(1.5%).Artificial intelligence has been used to identify safety signals through automated processes and training with machine learning models; however, the findings may not be generalizable given that there were different types of data included in each source.Conclusion Artificial intelligence allows for the processing and analysis of large amounts of data and can be applied to various disease states. The automation and machine learning models can optimize pharmacovigilance processes and provide a more efficient way to analyze information relevant to safety, although more research is needed has an impact on the quality of safety analyses. It is expected that its use will increase in the near future, particularly with its role in the prediction of side effects and ADRs..

KEYWORDS : *Benefit, Difference between AI and Generative AI, Methods using Pharmacovigilance*

1.INTRODUCTION

fascination of humans to 'recreate' human intelligence in machines is not new and this situation has evolved overtime. Currently, many information systems groups are developing learning algorithms to 'mimic' how humans learn and make decisions. Machine learning is part of artificial intelligence where new capabilities are incorporated into machines to 'learn' without explicitly programming [1], and create algorithms to accomplish a task while learning from its successes and failures [2]. Machine learning encompasses supervised learning, unsupervised learning, reinforcement learning, and recommender systems, including artificial neural networks and deep learning [3].The integration of artificial intelligence into the healthcare system is changing the role of healthcare providers and creating new potential to improve patient safety outcomes [4] and quality of care [5]. Artificial intelligence is being used to improve patient safety in both inpatient and outpatient settings . It has also been used to minimize preventable harm by incorporating digital approaches that allow for communication between patients and their healthcare providers [6]. In pharmacovigilance, the use of artificial intelligence is increasing in various areas including safety operations, signal management, and identification of target populations. There is a need to understand the current landscape of artificial intelligence in pharmacovigilance and what opportunities there are for further advancement in this area. The objective of this systematic literature review is to describe the use of artificial intelligence in patient safety and pharmacovigilance in general.

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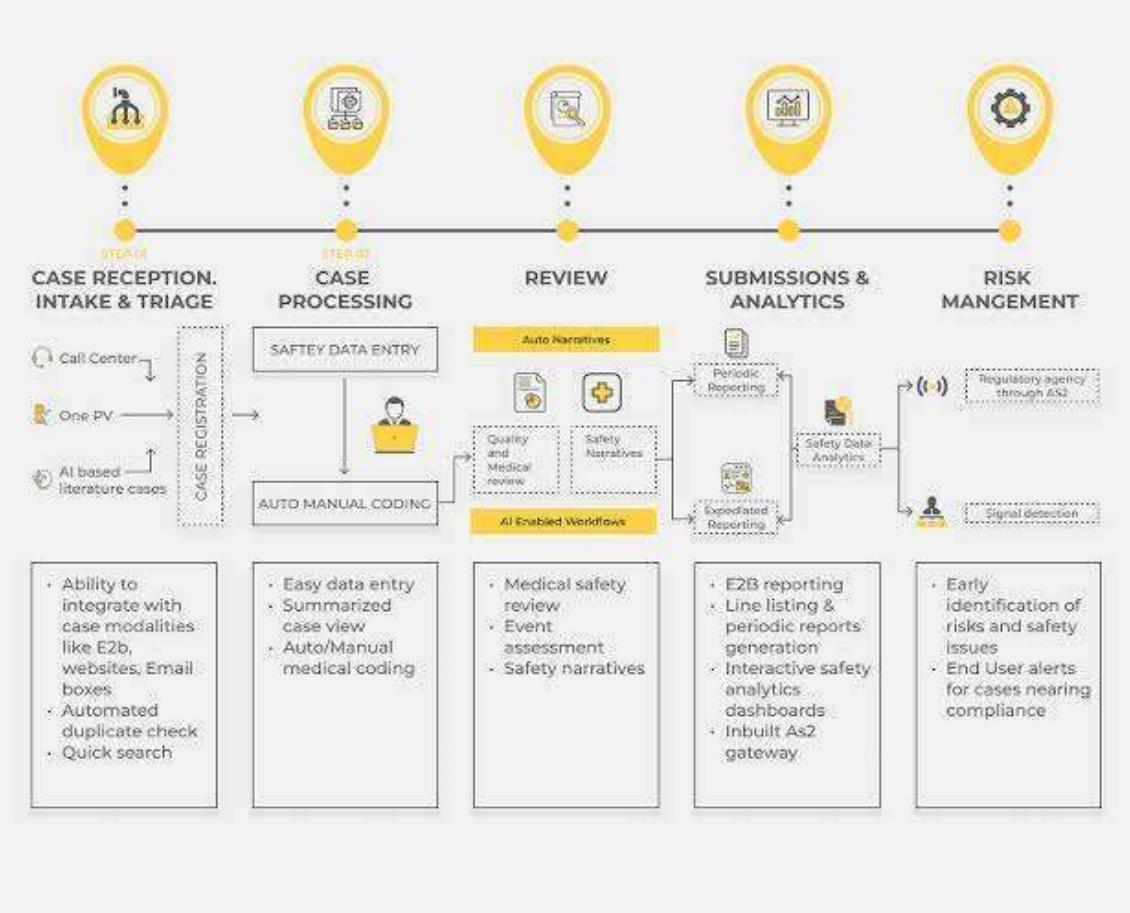


Fig. 1 Pharmacovigilance software

Benefits

Business & Economic Benefits

Automation & Efficiency: AI automates repetitive and mundane tasks, freeing up human workers for complex, creative, and strategic initiatives.

Cost Reduction: By optimizing processes and automating labor-intensive tasks, AI can lower operational costs.
Improved Decision-Making: more AI can process and analyze massive amounts of data faster than humans, identifying hidden trends and prov iding data-driven insights for better strategic planning.

Innovation: AI serves as a catalyst for innovation, enabling businesses to develop cutting-edge solutions and explore new possibilities.
Scalability: AI systems are highly scalable, allowing for continuous operation and expansion of capabilities without significant physical limitations.

Operational Benefits

24/7 Availability: Unlike humans, AI systems can operate continuously without fatigue, providing constant service and support.
Reduced Human Error: By following precise algorithms, AI systems reduce the likelihood of mistakes caused by fatigue, distraction, or emotion.

Enhanced Safety: AI can perform dangerous tasks in hazardous environments, such as rescue operations or deep-sea inspections, improving safety for humans.

Continuous Learning: Machine learning models enable AI systems to learn and improve over time, leading to better performance and accuracy.

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Customer & Societal Benefits
Personalized Experiences: AI analyzes customer data to provide customized recommendations, services, and interactions, leading to higher customer satisfaction.

Improved Customer Service: AI-powered solutions like chatbots offer quick responses and personalized support, enhancing the customer experience.

Democratization of Expertise: AI can make specialized knowledge and expertise more accessible across various sectors, fostering greater understanding and capability.

Addressing Global Challenges: AI is being used to find solutions for complex global issues in areas like healthcare, education, and environmental protection.

2.METHODS

2.1 Study Design

This is a non-quantitative systematic literature review, which was carried out following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guide- lines [7] and recommendations of the Cochrane Handbook for Systematic Reviews of Interventions [8]. For this type of systematic literature review, there was no requirement to register the protocol.

2.2 Data Source

The literature search was conducted in two phases to account for new results available since the time the first phase was conducted. The search used the databases Embase (1980-March 22, 2021 for phase one, 1980-July 9, 2021 for phase two) and MEDLINE (1946-March 22, 2021 for phase or phone, 2017-July 9, 2021 for phase two) and was ultimately limited to the period of January 1, 2015-July 9, 2021. A list of relevant titles, abstracts, and references were uploaded in an Excel spreadsheet for review. The search strategy for each of the two phases is included in the tables in Online Resources 1-2 (see Electronic Supplementary Material [ESM)). 2.3 Article Selection
Any scientific article that contained information on the use of artificial intelligence in patient safety and/or pharmacovigilance was reviewed.

2.3.1 Inclusion Criteria

The inclusion criteria comprised scientific articles where artificial intelligence was used in patient safety and/or pharmacovigilance; articles regarding modeling algorithms used for safety signal identification, characterization, assessment, or management; articles in the English language only; no geographical limit; and articles published between January 1, 2015 and July 9, 2021.

2.3.2 Exclusion Criteria

The exclusion criteria comprised articles with incomplete information (e.g. abstracts or posters with no full text), ters to editor, notes, commentaries, and duplicated articales.

2.4 Literature Review

The first screening of titles and abstracts was carried out independently by three researchers (JP, TB, and MS) using pre-determined inclusion and exclusion criteria to decide whether the abstract was relevant for article procurement. In addition, two additional researchers (OA and MS) indepen- dently did a second review. A consensus meeting was held to discuss the discrepancies between the reviewers' assessments of the abstracts and a final decision was made on the articles to be procured.

The second level of screening of full articles was con- ducted independently by three researchers (OA, DK, and PY) using the same predetermined inclusion and exclusion criteria. The quality control (QC) for the selection of full articles was carried out by four researchers (PY, TJ, TB, MS).

All data were extracted using an Excel spreadsheet where researchers also recorded reasons for exclusion. The initial Excel spreadsheet included fields listed in the table in Online Resource 3 (see ESM). The Excel spread- sheet was tested using the first abstracts included in the literature search. The detailed documentation of the search and review contributed to build the PRISMA flow dia- gram (Fig. 1). Duplicated abstracts or full papers were also excluded in the final selection.

2.5 Statistical Methods

This is a descriptive study and not an analytic study, so there is no hypothesis testing.

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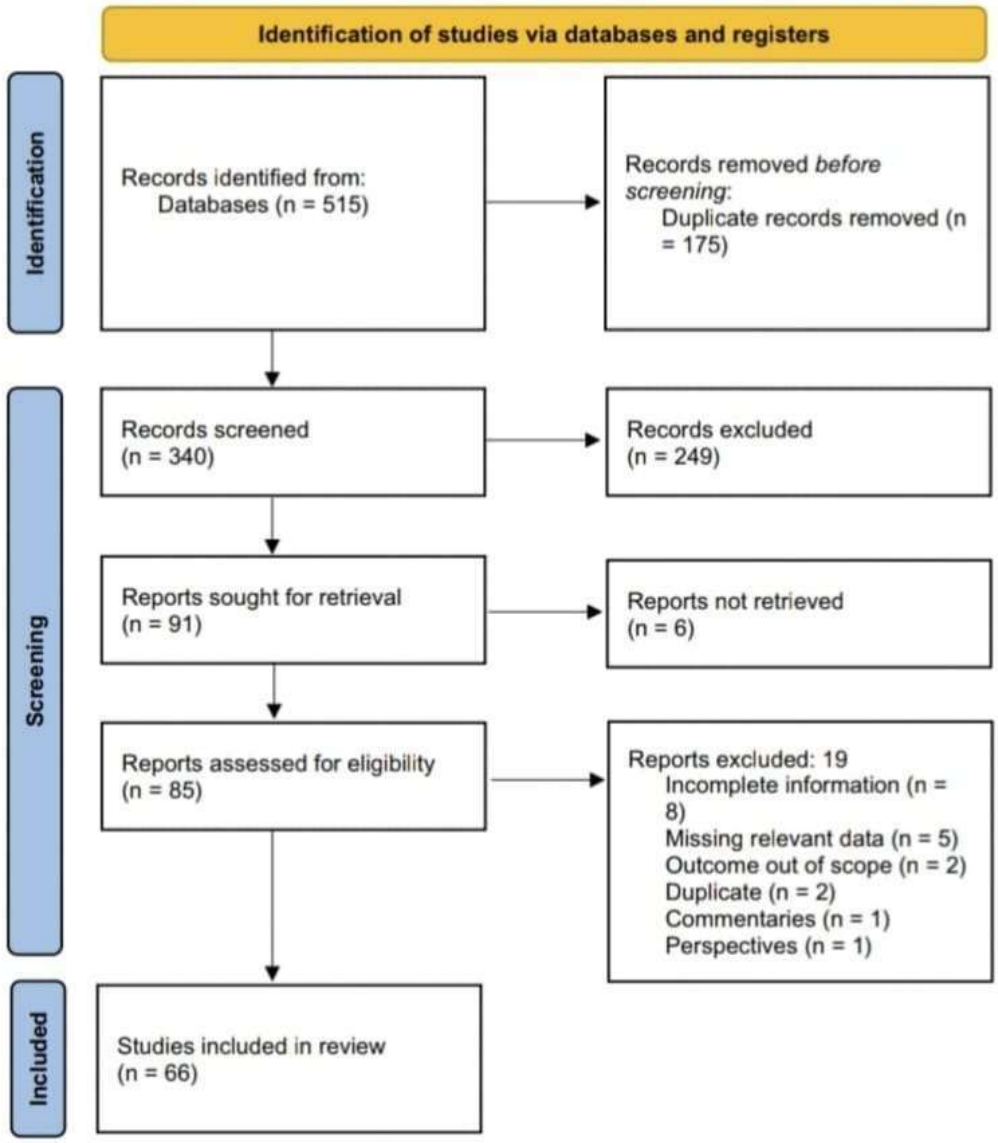


Fig. 2 Preferred Reporting Items ems for Systematic Review and Meta-Analyses (PRISMA) flow diagram showing documentation of the literature search process .

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Main differences between AI and GenAI

Aspect	Artificial Intelligence (AI)	Generative AI (GenAI)
Primary Objec ve	Analyzing data, automating processes, and making decision based on existing information.	Creating new ,original content by generating data and idea.
Key features	Decision trees ,pattern recognition , prediactive modelling.	Deep learning, neural network creative data generation.
Data usage	Relies on structured data for specific tasks.	Utilizes both structured and unstructured data.
application	Predictive analytics , fraud detection , personalized recommendations , process automation.	Automated content creation AI-generated art ,synthetic data generation, content moderation.
Technological approach	Structured analyasis and logical processes.	Dynamic,creative and adaptable for generating innovative outputs.
Cost efficiency	Generally more cost-effective for automation and specific data analyasis tasks.	Higher investement but potentially greater ROI in creative and innovative fields.
Industry impact	Broad impact across various sectors for specific,rulebased tasks.	Transformative in creative fields, content generation , and data synthesis.

3.RESULT

3.1 Article Selection

The literature search resulted in 340 articles which were evaluated for relevancy based on their titles and abstracts. Following the title and abstract review, 91 articles were sought for retrieval. After the subsequent review of full review [9-74]. The reasons for exclusion of some of the article = 8), the article was missing relevant data (n = 5), outcome out of scope (n = 2), duplicate articles (n = 2), commentaries (n = 1), and perspectives (n = 1). The details are documented in the PRISMA flow diagram (Fig. 1).

3.2 Sample Characteristics

Most articles had study locations from the United States of america . followed by multiple location (n = 6), France (n = 4), United Kingdom (n = 3), Sweden (n = 2), China (n = 2), Europe (n = 1), Canada (n = 1), Austria (n = 1), Morocco (n = 1), Japan (n = 1), and Tai- wan (n = 1). Some of the databases included MEDLINE (n= 8). the United Sts d and Drug Administration

Adverse Event Reporting System (FAERS) (n = 6), Side Effect Resource (SIDER) (n = 6), social media platforms (n = 6), DrugBank (n = 4), drug safety databases of indi- vidual companies (n = 2), VigiBase (n = 2), OrientDB (n = 1), Eudra Vigilance (n = 1), Japanese Adverse Drug Event Report (JADER) (n = 1), Canada Drug Adverse Reaction Online Database (MedEffect) (n = 1), EU-ADR

(n = 1), and French Spontaneous Reporting Database (n = 1). Most studies evaluated all diseases: however. some were specific to certain conditions such as cancer (n = 4), diabetes mellitus (n = 1), cardiovascular conditior dehydrogenase (DPD) deficiency (n = 1). The most identified uses of artificial intelligence in pharmacovigilance and patient safety included the identification of adverse drug events (ADEs) and adverse drug reactions (ADRs) (57.6%), pro- cessing safety reports (21.2%) drug-drug interactions (7.6%), identification of populations at high risk for drug toxicity or guidance for personalized care car (7.6%), prediction of side effects (3.0%), simulation of clinical trials (1.5%), and integration of prediction uncer- tainties into diagnostic classifiers to increase patient safety (1.5%). These percentages refer to the percentage of studies using exclusive categories that were selected based on the main aspect of each article be used to optimize processes [9].

3.3 Use of Artificial Intelligence in Pharmacovigilance

The uses of artificial intelligence in patient safety and pharmacovigilance are classified as shown in the table in Online Resource 4 (see ESM). A summary of the articles with additional information is provided in the table in Online Resource 5 (see ESM n applications artificial intelligence in this area were related to the identified characterization of ADEs and ADRs, classification of free text within safety reports, extraction of drug-drug interactions, and the identification of populations at high risk of experiencing drug toxicity.

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3.4 Using Artificial Intelligence to Detect Adverse Drug Reactions (ADRs) and Adverse Drug Events

Machine learning ADEs, perform safety surveillance, and manage signal detection. One application of machine learning being used is the automation of classifying first-person reports of social media. Alvaro et al. used Twitter to gather evidence about ADRs after identifying messages ('tweets reported individual patient experiences. They manually annotated 1548 tweets containing keywords related to selective serotonin reuptake inhibitors (SSRI) and cognitive enhancers . They used a range of supervised machine learning models to successfully recognize first-hand experiences in the tweets, thus showing the value in applying -marketing pharmacovigilance efforts in social media [10]. The application of machine learning in social media was described in several the advantages include the ability to detect ADRs that may not be captured by medical professionals, the opportunity to process and analyze large volumes of data quickly, and the abundance of personal information present in social media posts as they relate to ADRs [11, 12]. The disadvantages include excess 'noise' within the data and the informal or irregular text that is often used in social media posts. Additionally, GavrielovYusim et al. evaluated text processing in social media posts and Found that there is a tradeoff between the amount of the manual screening needed in lower levels of social media processing with its potential to miss adverse events when compared with higher levels of social media processing that use natural language processing (NLP)

Basile et al. identified polypharmacy and patient diversity as some of the opportunities to use machine learning in detecting ADRs[13]. These opportunities can be pre- sent in multiple phases of drug development ranging from pre-marketing to post-marketing safety assessments[14]. e automation present in earning techniques is becoming increasingly more useful as patients continue to present with multiple disease states, medications, and ADRs. Some institutions, such as Connecticut Children's Medical Center, have utilized machine learning to successfully streamline the use of adverse event reports by comparing rule-based queries and semi-supervised machine learning against a reference standard[15]. Aside from being used to detect ADRs, machine learning can also be used specifically to classify ADRs. Chauvet et al. determined the seriousness of patient cases through different algorithms based on their precision, recall, and accuracy[16].

Artificial intelligence can also play an important role in specific disease states, such as diabetes. HypoDetect, a NLP system which allows users to see blood glucose measure- ments displayed in a graphical format and analyze the measurements for hypoglycemic events n algorithm, has detecting hypoglyce data inputs early so that treatment can be promptly initiated. In disease states like diabetes where early identification of symptoms is critical to patient safety, systems such as HypoDetect can improve safety efforts and patient out- comes[17]. On a similar note, the under-reporting of safety events can compromise patient safety and has been an issue in recent vears . Ménard et al. used a curated data set from 104 completed Roche/Genentech sponsored clinical studies which included patient demographics, vitals, and disease and learning model to predict the number of adverse events. The model has the potential to be useful for initiating quality assurance measures early on and promptly filing potential adverse events. This can be crucial to the safety of patients as every ADR needs to be properly assessed within a set time frame.

A common theme in many of the articles was the ability for machine learning to analyze a large amount of data to gather information about the side effects of therapies, which can subsequently be used to improve pharmacovigilance systems[18]. One innovative approach to this involves using propensity scores to present a new automated signal detection strategy for pharmacovigilance systems[19]. Understandably, one of the issues that arise from such techniques is providing a reasonable number of signals for further analysis by experts with the fewest possible false associations.

novel approach is using deep-learning no works or prediction models to model the ADR relationship between a medication and symptoms. Specifically, E-Synthesis is a Bayesian framework for safety assessments that compiles data to provide the Bayesian probability of a drug causing an ADR. This association can to pharmacovigilance efforts and analyzing the safety profile of medications.

3.5 Using Artificial Intelligence to Process Safety Reports

Another application of machine learning in pharmacovigi- lance is in assessing the skill of NLP to classify unstruc- tured free text within patient safety incident reports. Evans et al. tested the ability of autonomously onomously classifying free text within patient safety incident reports to determine severity of harm outcomes and found that NLP can act as a safety net by identifying cases that lead to severe harm or death. However, it is not a perfect method and cannot yet replace manual review altogether . Additionally, the technical nature of medical text makes this process difficult to com- plete [20].

Many studies evaluated the use of machine learning in creening patient safety reports, such as within electronic health records. Marella et al. foun learning algorithms and text mining are useful methods for screening and analyzin uctured data sets of adverse event and near-miss reports collected through passive surveillance reporting systems [21]. Yang et al. took a more specific approach by developing a deep learn- ing model that was evaluated on different data sets to iden- tify allergic reactions in the free-text narrative of hospital

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safety reports and evaluated their generalizability. The study found that the model could be used to improve allergy care, potentially enabling real-time event surveillance for medical errors and system improvement [22]. Ultimately, learning has as the the potential potential to be used in many ways for addressing pharmacovigilance needs in various settings such as identifying keywords in patient safety reports that may require attention to prevent harm at clinical sites and postmarketing surveillance of ADRs in the pharmaceuticalindustry.

3.6 Using Artificial Intelligence to Extract Drug- Drug Interactions

Artificial intelligence can be used to extract drug-drug int actions or predict the effect of a drugdrug interaction. Ben Abacha et al. incorporated machine learning techniques with both featurebased and kernel-based methods for successful drug-drug interaction extraction. Bouzillé et al. used to automatically detect drug-drug interaction to improve drug safety monitoring in a hospital setting .They created an efficient machine learning model using laboratory tests and treatment data that could detect patients that may have had an ADE that was linked to a drug drug interaction. Machine learning can be particularly useful in pharmacovigilance because models can learn from a small number of drug-drug interaction combinations to predict many potential drug-drug interactions.

3.7 Using Artificial Intelligence to Identify Patients at High Risk for ADRs

Machine learning can be used to identify populations at high risk for experiencing ADRs or to guide personalized care. Chandak tatonetti developed a machine learning algorithm called AwareDX : analysing women at risk for Experiencing Drug toxicity," that predicts sex-specific risk of adverse drug effect with high precision by using a machine learning adaptation of propensity score matching. Machine learning techniques can also be used to identify more targeted patients, such as those susceptible to fluoropyrimidine toxicity due to DPD deficiency. Investigators used machine learning models to train patterns of toxicity, which were later used to estimate the number of patients with toxicity related to DPD and found that the model has potential for a future use but could have some over fitting [23]. While there is still some progress left to be made in the application of machine learning in identifying patients at high risk of ADRs, these techniques are an excellent starting point.

3.8 Using Artificial Intelligence to Predict Drug Side

Like its use in identifying patients at high risk for experiencing ADRS, machine predict side effects from drugs. Mower et al. focused on post-marketing drug illance knowledge extracted from literature can add to the performance of spontaneous reporting system methods using downstream machine learn . This can be particularly useful in predicting drug side effects because spontaneous reporting systems often have bias and under-reporting which can limit the availability of data [24]. Wang et al. predicted potential side effects and ADRs using a tumor-biomarker knowledge graph and determined that this method is useful for potential ADR identification based on biomarkert. The model can be valuable for future applications that may require mechanism-based research of ADRs [25].

3.9 Using Artificial Intelligence to Simulate Clinical Trials

Chen et al. used machine learning in conjunction with real-world data to simulate colorectal cancer clinical trials and ents ous adverse events measured from simulations comparing wo trea se to the risk ratios calculated from the trials, thus showing the potential utility of machine learning and real-world data in simulating clinical trials.

3.10 Using Artificial Intelligence to Integrate Prediction Uncertainties

1 intelligence used to integrate prediction uncertainties in patient safety. Laveset al. quantified the ty of deep learning-based computer-aided diagnosis for patient safety. The basis for the work relies on the concept that models that are trained for the diagnosis of c not have the capability to indicate when case is too ambiguous for an output. The study found that modeling prediction certainty with deep learning can produce more dependable results that can assist with safety efforts.

Roles of AI in pharmacovigilance

Artificial intelligence (AI) helps make pharmacovigilance faster , more accurate , and more efficient.
It can analyaze massive data from :
1.Electronic health records (EHRs).
2.Clinical trails reports.
3.Social media posts.
4.Spontaneous adverse event reporting systems.

Other different AI methods used in pharmacovigilance

1. Natural Language Processing (NLP)

Extracts useful information from unstructured text (like doctor notes, patient comments, or reports).

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Identifies adverse drug reactions (ADRs) automatically. Example: Detecting phrases like "rash after taking amoxicillin" from patient reviews.

2. Machine Learning (ML)

ML algorithms can predict the probability of adverse drug reactions based on patient history, demographics, and dosage.
They can also detect patterns and signals that humans might miss. Example: Using logistic regression
or random forest to find correlations between certain drugs and side effects.

3. Deep Learning

Neural networks (especially LSTM and Transformers) can handle complex data from images, text, and sequences.
Used for automatic classification of case reports or signal detection.
Example: BERT-based models used by the FDA for analyzing large text datasets.

4. Data Mining Techniques

Techniques like disproportionality analysis or Bayesian networks are enhanced using Al to identify safety signals earlier.
Example: Detecting unexpected patterns in the WHO's VigiBase or FDA's FAERS databases.

5. Predictive Analytics

Al models can forecast potential safety issues before they occur in real-world patients.

CONCLUSIONS

Artificial intelligence is actively being used in pharmacovigilance and patient safety to gather information on ADRs and ADEs, to perform surveillance and signal detection, to process ICSRs, to process patient safety event reports and clinical narratives, to extract drug–drug interactions and predict the effects of drug–drug interactions,to identify populations at high risk for experiencing ADRs and guide personalized care, to predict drug side effects, to simulate clinical trials, and to integrate prediction uncertainties into diagnostic classifiers to increase patient safety. There is potential for artificial intelligence to be used in pharmacovigilance and patient safety in more ways than were identified in this review in the coming years as people gain more exposure to artificial intelligence methods. The growth of this field may be limited by challenges related to the lack of validated, established uses of artificial intelligence in reallife safety settings.Supplementary Information The online version contains supplementary material available at https:// doi.org/ 10. 1007/ s40290- 022- 00441-z.

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