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Review

A Retrospective Study of Robotics in Adverse Drug Reaction - Monitoring and Errors

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Abstract

Adverse Drug Reactions (ADRs) remain a major concern in healthcare, contributing significantly to patient morbidity, hospital admissions, and healthcare costs worldwide. Traditional pharmacovigilance systems, which rely on spontaneous reporting and retrospective analysis, often face limitations such as underreporting, delayed detection, and inefficiency in handling large-scale data. This review explores the integration of robotics and artificial intelligence (AI) in ADR monitoring systems, highlighting their transformative potential in enhancing drug safety surveillance. AI-driven technologies, including machine learning and natural language processing, enable real-time data analysis, improved signal detection, and predictive modeling using diverse data sources such as electronic health records, clinical trials, and social media. Robotics further enhances efficiency by automating repetitive tasks like data collection, processing, and reporting, thereby reducing human error and workload. The study evaluates various AI methodologies, including supervised and unsupervised learning models, and discusses their applications in signal detection, data processing, and adverse event prediction. Despite these advancements, challenges such as data quality dependency, lack of model transparency, integration barriers, ethical concerns, and regulatory limitations persist. The review also emphasizes future directions, including global data collaboration, personalized pharmacovigilance, integration with pharmacogenomics, and the development of standardized AI regulations. Overall, the integration of robotics and AI in ADR monitoring represents a significant advancement toward proactive, efficient, and accurate pharmacovigilance systems, with the potential to improve patient safety and healthcare outcomes.

Keywords: ADR, Pharmacovigilance, AI, Robotics, Machine Learning, NLP, Drug Safety, Signal Detection

1. Introduction

1. ADVERSE DRUG REACTION

Unintentional negative effects that arise from taking a medication are known as Adverse Drug Reaction (ADRs). They can be anything from mild adverse effect like a headache to serious, potentially fatal reaction like anaphylaxis. ADRs are crucial for patients and lead to more illness, hospital stays, and even fatalities. According to estimates from the world health organization (WHO), adverse drug reactions (ADRs) account for approximately 10% of hospital admission and 6.5% of hospital charges globally. Reducing the impact of adverse drug reaction (ADRs) on patients and the healthcare system requires early detection.

2. Pharmacovigilance

A crucial area of drug safety is pharmacovigilance (PV), which focuses on identifying,evaluating averting negative drug reactions.Spontaneous reporting systems (SRS)and retrospective data analysis, which suffer from underreporting, delays, and limited coverage, are crucial to the traditional PV process .AI presents a revolutionary chance to revitalize PV by incorporating real-time, automated and predictive safety surveillance with the emergence of digital healthcare systems.

3. ARTIFICIAL INTELLIGENCE

By improving medication safety through cutting-edge technologies like machine learning and natural language processing, artificial intelligence is transforming pharmacovigilance. Despite obstacles, these advancements allow for through data analysis, prompt intervention, and effective, accurate detection of adverse drug reactions. This science of identifying, evaluating, comprehending, and averting side effects or any other drug-related issues is known as pharmacovigilance. The limitations of conventional pharmacovigilance systems have been brought to light by the growing complexity of drug safety monitoring as well as the massive amount of data produced by healthcare systems.

DATA FOR ARTIFICAL INTELLIGENCE BASED ADVERSE DRUG REACTION DETECTION:

A variety of datasets are used by AI models, such as:

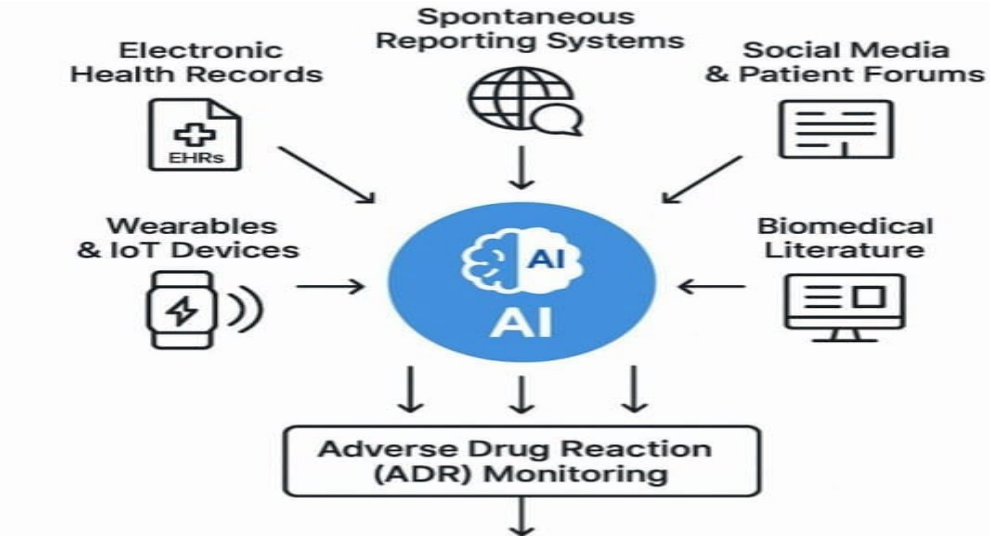
- EHRs, or electronic health records.
- Systems for spontaneous reporting (FAERS, VIGIBASE)
- Online forums and social media.
- Clinical trial data and medical literature.
- Data on insurance and claims.

ADVANTAGES OF ARTIFICIAL INTELLIGENCE IN ADR DETECTION:

- Improved signal detection: ML reveals hidden patterns
- Quicker reactions: Lowers the time it takes to find new ADRs.
- Enhanced regulatory compliance: Encourages evidence -based safety choices.
- Scalability: Manages large, expanded datasets

Subtle relationship between medication, genetic markers, comorbidities, and adverse drug reaction can be found by deep learning models.

- Automated causality evaluated.
- AI can model causality using frameworks such as Bayesian networks or Bradford hill criteria.
- Compared to manual systems, automated systems can manage large amounts of data at lower marginal costs.



Why is it important to implement artificial intelligence in adverse drug reaction monitoring

Conventional adverse reaction monitoring (ADR) techniques are no longer adequate due to the increasing complexity and volume of greatly increase the effectiveness and precision of adverse event detection and analysis, allowing for a more proactive strategy to improve patient safety.

APPLICATIONS OF ARTIFICIAL INTELLIGENCE IN ADVERSE DRUG REACTION MONITORING:

The detection, assessment, and management of adverse drug reaction (ADRs) are being completely transformed by the incorporation of AI technologies. The current uses of AI in ADR monitoring are examined in this section, with an emphasis on hoe it can improve ADR detection.

- Substantial strain on healthcare systems, with an estimated $30.1 billion in management expenses each year. This emphasizes the urgent need for more effective techniques to track, identify, and stop adverse drug reaction (ADRs)during the pre-marketing stages of drug surveillance
- ADR monitoring procedures have changed as a result of the development of AI application for ADR detection since the late 1990s.It can be roughly divided into three stages, each of which is distinguished by unique developments in machine learning, natural language processing (NLP) and statistical method.
- When data mining algorithms for signal detection in spontaneous reporting system (SRS) were introduced in the early 2000s, the use of AI in ADR monitoring got underway. More advance AI application in ADR monitoring was made possible by groundbreaking techniques like the Multi-item

Gamma Poisson Shrinker (MGPS) and the Bayesian Confidence Propagation Neural Network (BCPNN) method. Since then, AI has been used in a number of ADR monitoring application, such as signal detection, automated case processing, and real-world evidence analysis

Application of AI in ADR Monitoring

FUTURE SCOPE OF ARTIFICIAL INTELLIGENCE IN ADVERSE DRUG REACTION MONITORING

Because it continues to improve regulatory decision -making, lower adverse drug reaction (ADRs), and increase drug safety, artificial intelligence in ADR monitoring has a promising future. However, if artificial intelligence is to realize its full potential, a number of significant advancements are expected in the upcoming years.

ENHANCE GLOBAL DATA COLLABRATION

The development of international data-sharing systems is one of the most significant future directions in adverse drug reaction monitoring. Currently among various hospitals, healthcare facilities, and regulatory agencies, which restricts in-depth analysis.

When artificial intelligence collaborates globally, it can combine data from various sources, such as:

- Electronic Health Records, or EHRs.
- Social Networks

FAERS Carolina's Global Adverse Event Database:

By combining these data sets, AI can provide global real-time adverse event detection. This would significantly reduce the time it takes for regulatory agencies to identify potential drug safety issues and enable them to respond more quickly

Predictive and Personalized Adverse Drug Reaction Monitoring

AI in ADR monitoring is also moving toward personalized and predictive medicine. With the use of machine learning algorithms, AI may assess genetic data, medical histories, and patient demographics to predict how individual would respond to particular drugs. The technique that will help with early detection of adverse drug reactions (ADRs) before they occur is called predictive ADR monitoring. Identifying the

patients who are most likely to experience severe adverse effect. Improving overall patient safety by tailoring drug regimens to the individual characteristics of each patient.

Unlike a generalized approach, personalized pharmacovigilance has the potential to significantly reduce drug-related hospitalizations and enhance treatment outcomes.

AI Driven Regulatory Decision-Making

The use of AI in administrative decision- making is another exciting future application of AI in adverse drug reaction monitoring. Currently, regulatory agencies like the food and drug administration (FDA) and world health organisation (WHO) physically audit reports of antagonistic incidents that have recently issued security alerts or medical reviews. This handle takes a lot of time and is prone to delays.

this process can be greatly accelerated by AI by:

1. Real- time analysis of massive amounts of adverse reaction eventsSafety signals from pharmacovigilance databases can be naturally distinguished.
2. Providing quicker and more accurate security information to administrative experts.
3. As AI continues to advance, it is expected that administrative bodies will increasingly rely on AI-Powered to ensure faster data-driven decision- making.

Integration of AI With Pharmacogenomics

- **Pharmacogenomics**

The investigation of how your unique genetic makeup influences how you react to drugs. AI will likely be incorporated into pharmacogenomics in the future, where monitoring adverse drug reaction will resemble predicting each patient's unique response.

AI models are able to identify genetic variations that may put individuals at risk for negative drug reaction. Healthcare professionals can select the safety and most effective medication for each patient with the use of genetic data.

Major adverse drug events will be eliminated and trial-and- error prescribing will be reduced thanks to this integration.

AI and pharmacogenomics in adverse drug reaction monitoring can aid in creation of individualized treatment regimens, preventing drug- related complication. This field's future appears promising for both patient and the healthcare system.

- **Creating Standardized AI Regulations:**

For AI to reach its full potential in adverse drug reaction monitoring, uniform international laws are required. The use of AI in drug safety monitoring is currently unregulated in most countries.

- **The Future's Scope Encompasses:**

Establishing integration regulatory standards for AI- based adverse drug reaction monitoring. Guaranteeing AI systems' objectivity, fairness, and openness. Promoting the moral application of AI while protecting patient privacy.

Once uniform regulations are established, pharmaceutical companies and healthcare providers will feel more at ease using AI for medication safety monitoring. This will ultimately result in faster and more precious adverse drug reaction monitoring results.

2. STUDY GOALS

This review's main goals are to compile and evaluate the body of research on AI-enhanced adverse drug reaction monitoring.

Important areas consist of:

❖ **Assessment of the pharmacovigilance system in place:**

Research shows that a fundamental framework for ADR monitoring is provided by spontaneous reporting, regulatory databases like the FDA's FAERS and the WHO's VIGIBASE, and conventional analytical techniques. Nevertheless, these systems frequently have trouble detecting delayed signals and have trouble managing complicated, large-scale datasets.

❖ **AI technology integration:**

Research has shown that AI algorithms can enhance pharmacovigilance procedures by improving signal detection, automation data extraction, and predicting adverse drug reaction in real time.

Clinical notes, electronic health records (EHRs), and social media platforms have all benefited from the application of machine learning and deep learning models in conjunction with natural language processing, which has produced more accurate and timely insights.

❖ **Possibilities and difficulties:**

While AI offers transformative potential including personalized risk assessment and proactive safety monitoring its implementation raises issues such as algorithmic transparency, and validation requirements. In order to fully reap the benefits of AI- driven photovoltaic systems, we address these issues as part of the survey of review.

❖ **Methodological strategy:**

The methodological framework of this study is designed to ensure a rigorous, evidence- based evaluation of AI application in adverse drug reaction monitoring. The following methods were used:

➢ **Organized review of the literature:**

Using databases like PubMed, Scopus, and Web of Science, a through and methodical review of scientific literature was carried out. Pre-reviewed articles, official reports, and white papers Published between 2000 and 2005 were found using keywords such as adverse drug reaction monitoring, artificial intelligence, machine learning, signal detection, and adverse drug reaction.

➢ **Case studies:**

A number of real-world applications of AI in adverse drug reaction monitoring were examined, including automated signal detection systems used by regulatory agencies (Such as the FDA's sentinel initiative and the EMA's EVDAS) and AI-enabled ADR monitoring frameworks implemented in pharmacogenomic and hospital settings.

➢ **Comparative analysis of Artificial Intelligence tools:**

The study included a comparative analysis of current AI-driven pharmacovigilance platforms and algorithms, assessing how well they performed in terms of accuracy, scalability, interpretability, and regulatory compliance. This analysis offered a fair assessment of the state of AI in ADR monitoring today and in the future.

➢ **Comparative Analysis with Traditional Methods**

The performance of AI models was compared with traditional pharmacovigilance methods to demonstrate the added value of AI in ADR prediction. The time-to-detection, accuracy, and recall rates of the results were compared to those of existing rule-based systems and clinical trial reporting. The comparative analysis helped to understand how AI can be advantageous in proactive ADR monitoring.

When taken as a whole, these approaches address the more general ethical and policy aspects of digital transformation in drug safety surveillance while enabling an integrative assessment of how AI technologies are transforming adverse drug reaction monitoring from data collection to decision-making.

3. SOURCES OF DATA

Two Main Sources are.

1. Post- Marketing and Clinical Data

Patient- specific data, drug usage history, and ADRs reported were obtained from Electronic Health Records (EHRs) and adverse event reporting databases. These are important sources for training AI models on ADR incidents and possible predictors

2. Textual information for Natural Language Processing Analysis

Drug side effects were taken out of unstructured data in clinical notes, scientific publications, and patient forums via natural language process techniques. Structured data is complemented by these sources, which capture ADRs that may be underreported in formal reporting systems.

3. KEY METRICS INCLUDED:

- **Receiver Operating Characteristic (ROC) and Area Under Curve (AUC):**

The model's ability to distinguish between real ADRs and non-ADRs was assessed using these metrics.

- **Curve of Precision-Recall (PRC):**

This metric was used to assess the model's performance on minority classes (actual ADRs) because ADR data is unbalanced

- **F1- Score:**

Combining precision and recall is particularly helpful in determining the ratio of false positives to false negatives.

- **Analysis of Confusion Matrix:**

This allowed us to minimize false positives (erroneously predicting an ADR), as well as to interpret the types and frequency of errors. Using cross-validation techniques like k-fold cross-validation, the generalizability was validated across a range of patient groups and drug categories.

TOOLS AND SOFTWARE:

- **Language for programming:**

Python and its machine learning libraries, SKIKIT-Learn, TensorFlow, and PYTORCH, were used to develop the model.

- **Tools for data processing:**

Pandas, NUMPY, and NLTK were used for data handling and NLB preprocessing. Large-scale unstructured data was extracted from EHRs using frameworks like spark NLP.

- **Tools for Visualization:**

To interpret and present model results, ROC curves, confusion matrices, and other performance metrics were plotted using MATPLOTLIB and SEABORN.

4. MACHINE LEARNING

Over the past ten years, artificial intelligence (AI) has grown thanks to new developments in machine learning (ML) in a variety of scientific and medical domains. Many have conjectured that these same technologies might be used to address the fundamental issues with ADR monitoring.

Since the early 1990s, there has been a steady increase in the use of these techniques for data related to human safety.

In order to describe the current state of ML in Adverse Drug Reaction and to shed light on how recent developments in AI and ML can be applied to enhance different Adverse Drug components, this review aims to systematically identify works that use ML, broadly defined, for safety data.

Since there are certain factors that may account for the recent success of ML that may or may not be present for Adverse Drug Reaction applications, care must be taken when attempting to extrapolate the success of ML in other areas compared with Adverse Drug Reaction.

EVALUATION CRITERIA:

We evaluated each paper using the following standards in order to determine the degree to which Adverse Drug Reaction studies are enabled to current trends in the larger ML literature:

- **Type of task:**

Each study was divided into one of three groups according to the main methodology: data intake, data analysis, or signal detection.

- **Identification of signals:**

Papers that are "traditional" Adverse Drug Reaction analyses that aim to estimate a statistical quantity for signal detection, such as the information component, odds ratio, etc. Alternative machine learning techniques for signal detection may also fall under this category.

- **Data intake:**

papers that process different types of safety data using machine learning models so they can be stored in databases or used for downstream tasks like signal detection.

For Illustration:

Add named entity recognition, adverse event detection, and other preprocessing tasks.

- **Analysis of data:**

Articles that use safety data but don't fit into any of the aforementioned categories. Topic modelling and adverse event clustering are two examples.

- **Size of the dataset:**

Each study's name and the quantity of data points it used to train and/or evaluate its methodology were gathered. We reported the "most specific" number when there were several reported dataset sizes.

- **For Illustration**

We chose the smaller number if a study used millions of safety reports from the FDA Adverse Event Reporting System (FAERS) but trained and evaluated models on a subset of thousands of reports pertaining to acute kidney injury.

SUPERVISEDANDUNSUPERVISED MODELS FOR SIGNAL DETECTION:

- A key component of pharmacovigilance is signal detection, and AI provides a variety of model types for spotting possible adverse drug events (ADEs) based on trends in pharmaceutical and clinical data. **These methods generally belong to supervised and unsupervised learning paradigms**, each of which has advantages appropriate for various pharmacovigilance workflow stages.
- **Vector Machines (SVMs) are commonly used supervised learning models that perform well in high-dimensional spaces**. In pharmacovigilance, SVMs have been applied to classify patient records as

indicative or non-indicative of ADEs, based on symptom profiles, dosage, and demographic metadata. Their margin-based approach allows them to isolate boundaries between normal and adverse responses with relatively few false positives.

- Neural networks, particularly deep learning architectures, provide enhanced performance for complex and non-linear datasets**. Recurrent Neural Networks (RNNs) and Long Short-Term Memory (LSTM)models** are particularly effective for sequential data, making them well-suited to analysing patient timelines and identifying latent drug-event dependencies.
- Decision trees, on the other hand, are frequently utilized in rule-based decision support systems and provide excellent interpretability. Clinicians can better comprehend model recommendation thanks to their tree-like structure, which is easily translated into clinical logic. They might, however, perform poorly in terms of generalization, particularly in big, noisy datasets.
- When labelled data is scarce in the early phases of AD Exploration, unsupervised learning models such as DBSCAN, K-means clustering, and hierarchical clustering are especially helpful. By grouping similar clinical cases together, these algorithms enable researchers to find co-occurrence patterns or hidden ADE subtypes. Additionally, unsupervised models aid in outlier detection by highlighting uncommon or unusual reactions for additional research.
- In the end, signal detection benefits from a careful blending of these models, chosen according to the clinical questions being addressed, computational resources, and dataset characteristics.

NATURAL LANGUAGE PROCESSING

NLP Methods Early exploratory studies frequently used rule-based methods involving lexicon matching and pattern detection, but statistical machine learning classifiers—particularly **support vector machines (SVMs)** and **neural networks**—have largely replaced them.

For sequence labelling and document classification, the focus has shifted to deep learning architectures **such as convolutional and recurrent neural networks (CNNs, RNNs)** since 2017. A growing trend that aligns with usability requirements for practical adoption is multi-task models that jointly detect entities, relations, and events within text.

Transfer learning techniques that make use of clinical language models, such as Clinical BERT, which have been trained on millions of EHR notes, have great potential for multi-site ADE detection that is generalizable without sacrificing patient privacy

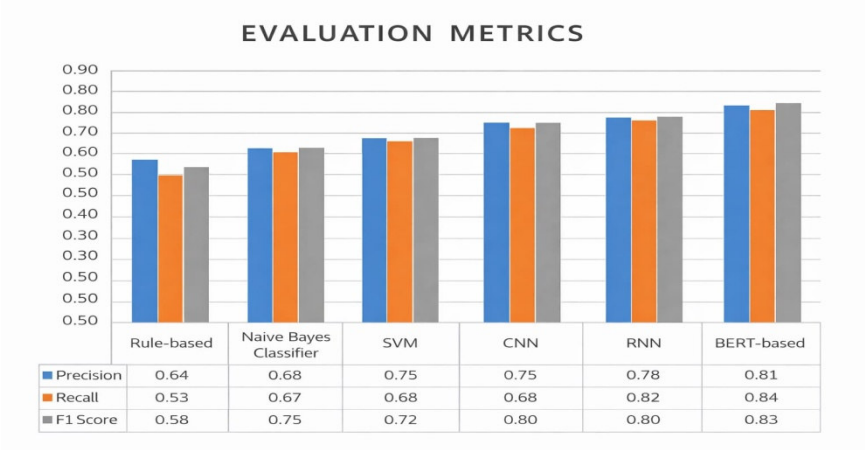
Evaluation of NLP techniques for Adverse drug reaction detection

NLP Method	Precision	Recall	F1 Score
Rule-Based	0.61-0.81	0.52-0.73	0.58-0.79
Naive Bayes classifier	0.71-0.83	0.63-0.77	0.68-0.81
SVM	0.73-0.85	0.67-0.82	0.72-0.84
CNN	0.80-0.89	0.75-0.86	0.79-0.88
RNN	0.82-0.91	0.78-0.88	0.81-0.90

The standard machine learning paradigm of training and testing on stratified splits of datasets was used for evaluation. The revolutionary potential of contemporary NLP and machine learning to transform pharmacovigilance powered by EHR-derived insights is demonstrated in this review.

A significant chance to transition from reactive to predictive, preventive safety surveillance is provided by neural networks. To better analyse model transportability, recent studies make use of datasets from various institutions. The most frequently reported metrics were precision, recall, and F1-score.

Although deep learning architectures and neural networks performed better than traditional classifiers, issues with model opacity were brought up. Statistical process control methods for automated anomaly detection show translational edge for hospital settings



	Rule-based	Naive Bayes Classifier	SVM	CNN	RNN	BERT-based
Precision	0.64	0.68	0.75	0.75	0.78	0.81
Recall	0.53	0.67	0.68	0.68	0.82	0.84
F1 Score	0.58	0.75	0.72	0.80	0.80	0.83

Graph shows the average score of each type of evaluation metric for six different models

The graph above, which is shown in Figure, displays the average score for each kind of evaluation metric for six distinct models. With precision of 0.71, recall of 0.63, and f1 score of 0.90, we find that the BERT model performs better than the other models on all three metrics.

The rule-based classifier and Naive Bayes classifier perform the worst, while the CNN and RNN models also do well with metrics in the range of 0.81-0.87. All things considered, the findings point to BERT-based models as the optimal option for text classification tasks. But if computational resources are available, CNNs and RNNs might also be excellent options.

DEEP LEARNING

One kind of machine learning is deep learning (Wang et al., 2020) The field of artificial intelligence (AI) has shown great promise and extremely efficient method that can integrate and examine various biological data types to produce fresh theories. Deep The field of drug discovery makes extensive use of learning. Repurposing, but its use in ADR prediction using There aren't many data on gene expression**.**

Unlike other databases, like (LINCS), which have been employed to forecast several ADRs in a single investigation, OpenTG-GATEs have been utilized to look into toxicities. To the best of ourknowledge, no efforts have been undertaken to offer a generalframework for utilizing Open to predict multiple ADRsTG-Gates.

Open TG-GATEs Database

Open TG-Gates' design offers a numberof benefits over theLINCS database, primarily the incorporation of in vivo samples withvarying administration times and dosages. Consequently, wecreated our analysis to include several samples withdistinct durations and dosages for every compound,requiring further data noise-removal proceduresprocessing. This study outlines our method for producingsystematic ADR prediction models based on deep learning. Thismethod integrates ADR occurrence information, such as frequencyinformation from the FDA Adverse Event Reporting System (FAERS)database, using Open TG's gene expression profiles Gates.

We demonstrate how to enhance the models' functionality.by utilizing hyperparameter optimization and feature selectionalgorithms. The models and techniques outlined in ourResearch provides useful instruments to evaluate the probability of ADRs.during the process of finding new drugs.

Standardized FAERS Data

Latory activities (MedDRA). terms (PT) (Wood, 1994).FAERS (FDA Adverse Event Reporting System) is "a databasethat collects adverse event reports, medication error reports, andproduct quality complaints resulting in adverse events that weresubmitted to FDA" . However,since the terms used in the FAERS database are left to the reporterto decide, inaccurate descriptions may often be incorporated,such as using general, vague terms to describe adverse events ortreatments (Wong et al., 2015). To surmount this issue, we usedthe portion of the FAERS dataset standardized by Banda et al. They had curated and standardized the entries of theFAERS database for 11 years (2004–2015) following MedicalDictionary for Regulatory Activities (MedDRA) preferredterms (PT) (Wood, 1994).

Every compound-ADR combination was extracted. from the total number of reports (4.8 million).Among the difficulties of using the FAERS database in ADRsprediction models is the presence of reports with multiple drugsused , which is expected in patients with chronicillnesses. In these situations, untrustworthy associations are added tothe data noise. In order to resolve this problem, we only utilized the associations inwhich the drug was designated as the main suspect (PS). We determined how many reports there were for eachcombination of compound-adverse drug events and computed thetotal number of reports regarding the compound in question, as well as thetotal number of reports of the adverse event.

We evaluated the compound-ADR's importance. Correlations using the one-sided Fisher test (Ghosh, 1988)The R function "fisher. Test" with the parameter (alternativeThe "greater"). A significant p-value is only returned by this option in theUnlike the "two sides" test, in the event of a positive association,which evaluates associations that are both positive and negative.

Errors Involved In Robotics Monitoring By Adverse Drug Reaction

1. Dependency on Data Quality:

The quality of artificial intelligence tools depends on the quality of the data they are fed. The system may misinterpret results if safety reports or medical records have biased information, errors, or missing details. This may lead to false safety signals or, worse, the neglect of significant risks.

2. The "black box" problem:

A lot of sophisticated AI systems, particularly deep learning models, produce results without providing an explanation. This lack of transparency makes it challenging for regulators and healthcare professionals to completely trust or validate the findings, particularly when patient safety is at risk.

3. Implementation and Integration Barriers:

It is difficult to integrate AI into current pharmacovigilance workflows because it necessitates large investments in infrastructure, training, and system compatibility, which can be prohibitive for many organizations, particularly smaller pharmaceutical companies.

4. Risk of Overreliance:

Although AI is capable of processing vast amounts of data rapidly, human judgment cannot be entirely replaced by it. Contextual awareness and clinical knowledge are still crucial. An excessive reliance on algorithms may result in the failure to detect rare occurrences or subtle safety concerns.

5. Privacy and Ethical Issues:

Sensitive patient data is involved in pharmacovigilance in ADR monitoring. Large amounts of this data are needed for AI systems, which raises questions about data security, confidentiality, and adherence to stringent privacy laws in various jurisdictions.

6. Temporal dynamic of drug safety profile:

The safety of a drug can change over time as more real-world data becomes available. AI models trained only on clinical trial data may not detect new side effects that appear after the drug is marketed. This change in data patterns is called concept drift in machine learning. Therefore, AI models must be updated regularly to include new adverse drug reaction (ADR) information.

AI models need continuous learning to update with new data over time. However, maintaining model stability while allowing adaptation is challenging. Data from sources like EHRs and reporting systems must be integrated carefully to avoid overfitting to short-term trends

7. Technical aspects:

Differences in the names of medications and illnesses, description technical difficulties for data processing, labelling, and integration may arise from a variety of factors, including the prevalence of negative drug effects, the diversity and challenges of local languages, ambiguities, and a lack of knowledge about self-medication.

Language ambiguity and a medical word's many meanings or implications are among its main drawbacks.

8. Regulatory issues:

Using AI technology to automate ADR Regulation of the monitoring system is necessary for quality and validation. Regulations are necessary to guarantee validation and accuracy for application in real-world settings and specific patient populations, even though Indian regulatory authorities have not yet specified the regulatory framework for the use of AI

Furthermore, regulations play a critical role in striking a balance between the commercial interests and transparency of technology companies and the safety and well-being of medical professionals.Crucially, the regulatory framework must take into account the certification and approval process for adaptive AI systems as new data becomes available and technology is update.

For sustainable AI-based PV systems, all of these will require government funding for infrastructure, research, and training. Without research and development funding, the nation will be forced to rely on AI tools created in resource-intensive nations, which could be very expensive.

9. Algorithm Prejudice:

Another significant obstacle to using AI for ADR monitoring is algorithmic bias. Biases in the training data may be inadvertently reinforced by AI systems, producing skewed and possibly dangerous results. For example, the AI may fail to identify adverse drug reactions unique to certain populations if those populations are underrepresented in the data.

10. Interpretability

Furthermore, getting regulatory approval and earning the respect of the scientific and medical communities depend on how interpretable AI models are. Nevertheless, a lot of AI models operate as "black boxes," making it challenging to comprehend how they make decisions. The adoption of AI technologies in pharmacovigilance may be hampered by this lack of transparency since stakeholders might be reluctant to depend on systems they do not fully understand.

11. Combining Current Pharmacovigilance Systems:

There are organizational and technical difficulties when integrating AI with current pharmacovigilance systems. Significant upgrades and modifications are required because many existing systems are unable to handle the volume and complexity of data that AI systems require. Furthermore, opposition from parties used to conventional pharmacovigilance techniques can be a significant obstacle. It will take careful change management, effective communication of AI's advantages, and extensive training programs to overcome this resistance. The successful application of AI in pharmacovigilance depends on a seamless transition.

12. Human-AI Cooperation:

Maximizing the advantages of AI in pharmacovigilance requires effective human-AI cooperation. AI systems ought to be created to support and improve human judgment. This entails creating AI tools that are easy to use and fit in with current workflows.

To effectively interact with and utilize AI systems, healthcare professionals must receive adequate training. Using a human- centred design approach guarantees that AI systems are user-friendly and satisfy their needs. The accuracy and effectiveness of ADR monitoring initiatives can be greatly increased by this cooperative dynamic.

13. Human-AI interaction:

Human factors and human-computer interaction have naturally been impacted by the advancement and uptake of technology, first in terms of physical ergonomics and later in terms of cognitive and organizational ergonomics. Bainbridge talked about several **"ironies of automation**"—difficulties stemming, among other things, from the presumption that switching from human operators to fully automated systems would only have immediate and long-term advantages.

However, there are a number of potential problems that could arise, such as decreased (or even eliminated) opportunities to train new employees; a loss of skill over an extended period and a loss of vigilance while monitoring a long running process.

14. Underreporting of ADRs in herbal and conventional medicines:

Herbal medications are typically thought to be safe,and their safety monitoring may be neglected, the underreporting of adverse drug reaction (ADRs) is especially problematic. Health care providers and patients are urged to report adverse drug reactions (ADRs), even if they are unsure which medication is causing the ADR, to reduce the burden of underreporting. Furthermore, the medication underreporting rate was as high as 94% (Interquartile range 82-98%), according to a study by Hazell et al.

Even in cases of severe ADRs, their finding of substantial and pervasive underreporting highlights the need for programs that will raise reporting rates. Initiatives like better health care professional education and training, online reporting, pharmacist and nurse reporting, and direct patient reporting were suggested by Hazzel et al. furthermore, the development of digital technology as a result of the need to enhance ADR reporting led to a rise in the use of electronic reporting tools. Although educational interventions seem to successfully raise ADR reporting rates, their long-term effects are largely unknown.

15. Casual inference in polypharmacy scenarios:

Polypharmacy, or using multiple medicines at the same time, makes pharmacovigilance analysis difficult for AI. AI can find links between drugs and adverse reactions, but identifying the exact cause is challenging. Traditional models mainly show associations rather than true causes. New methods like causal inference models, Infer BERT, and Bayesian networks are being used to improve this analysis. These techniques help AI better understand drug interactions and explain the causes of adverse reaction

16. Integration of multi model data sources:

Integrating multi-modal data is a major advantage of AI in pharmacovigilance because it allows more comprehensive safety monitoring. However, it also creates challenges due to differences in data quality and consistency across sources. Social media reports may be less reliable than clinical data and combining information from different systems requires effective data harmonization and normalization methods.

17. Algorithmic bias in diverse populations

AI models are frequently trained on datasets that do not accurately reflect the diversity of patient populations in the real world, particularly those used in PV. Algorithmic bias may result from this, in which the model does well for the majority group but poorly for underrepresented or minority groups, such as patients with comorbidities, older adults, or ethnic minorities

For example, models that were mainly trained on data from populations in Europe or North America might have trouble identifying adverse drug reactions (ADRs) in patients from Asia or Africa. Clinical trials, a crucial source of training data, frequently underrepresent these populations, which exacerbates the problem. Because of this underrepresentation, it may be difficult to generalize AI predictions across all demographics, which could cause some groups to miss safety signals.

To mitigate these biases, data augmentation and resampling techniques should be utilized to address imbalances in training datasets, complemented by advanced quantitative bias detection and correction methods. 41 Techniques like federated learning allow for model training on decentralized datasets from multiple regions without sharing raw data, potentially mitigating this bias.

18. Imbalanced Data in Machine Learning Models

The issue is made worse by the fact that clinical trials, a vital source of training data, frequently underrepresent these populations. It might be challenging to generalize AI predictions across all demographics as a result of this underrepresentation, which could lead to some groups missing safety signals. Although machine learning has the potential to revolutionize ADR detection, resolving issues like data heterogeneity, unbalanced datasets, and interpretability problems is crucial to guaranteeing the dependability and adoption of ML-based methods in the medical field.

Overcoming these obstacles will help incorporate machine learning into standard clinical practice, which will ultimately improve patient care and safety. Conventional methods, which use manual procedures and spontaneous reporting systems (SRS), have drawbacks like underreporting and laborious workflows.

Innovation is based on machine learning (ML) technology, which provides automation, scalability, and increased accuracy. The use of statistical techniques for ADR detection, especially those that make use of SRS and electronic medical record (EMR) data.

19. Signal Detection and Noise in ADR Surveillance

One of the main obstacles to ADR detection is signal detection and noise. The abundance of unrelated events, confounding variables, and background noise make it challenging to extract meaningful signals from massive amounts of noisy data. It becomes difficult to separate genuine ADRs from coincidental associations. In order to improve the signal-to-noise ratio and precisely identify possible ADRs, a variety of signal detection techniques are used, including statistical modelling, data mining algorithms, and disproportionality analysis.

20. AI for pharmacovigilance and signal detectionAutomation

Pharmacovigilance automation's fundamental stage is theidentification of duplicate reports. Making sure the integrity andIndividual case safety reports must be unique.prior to moving on to more general duties like signal detection and safety surveillance. Duplicate entries may cause distortion.

safety evaluations and result in false conclusions regarding the risk profile of medicine. The Uppsala Monitoring Centre (UMC) created the VIGIMatch algorithm to address this.which analyses similarities in patient demographics using machine learning techniques to find possible duplicates,drug details and descriptions of adverse events

5. CONCLUSION

The integration of robotics into adverse drug reaction (ADR) monitoring systems represents a significant advancement in pharmacovigilance. Robotics, when combined with artificial intelligence and data analytics, enhances the efficiency, accuracy, and speed of ADR detection and reporting. These systems can process large volumes of clinical data with minimal human error, improving signal detection and enabling timely identification of potential drug safety issues.

Moreover, robotics reduces the workload on healthcare professionals by automating repetitive and time-consuming tasks such as data collection, documentation, and preliminary analysis. This allows clinicians

to focus more on patient-centered care. The use of robotics also contributes to improved standardization and consistency in ADR reporting, which is critical for regulatory decision-making.

However, challenges such as high implementation costs, dependence on data quality, technical limitations, and the need for skilled personnel must be addressed for widespread adoption. Ethical concerns, data privacy, and system reliability also require careful consideration.

Overall, robotics has strong potential to transform ADR monitoring systems in hospital settings. With continued technological advancements and proper integration strategies, robotic systems can play a vital role in enhancing drug safety surveillance and improving patient outcomes.

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