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Leveraging Machine Learning Techniques for Predicting Adverse Drug Reactions: A Comprehensive Review

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Abstract

Background: Adverse drug reactions (ADRs) pose significant risks to patient safety and healthcare outcomes. As the complexity of medications and patient conditions increases, traditional methods of predicting ADRs are often insufficient. The integration of machine learning (ML) techniques into healthcare offers a promising approach to enhance the prediction and management of ADRs.

Methods: This review systematically examines peer-reviewed literature published from 2009 to 2023, focusing on ML applications in predicting ADRs. Databases such as PubMed and Web of Science were utilized to gather relevant studies. Key criteria for inclusion involved the use of ML models to analyze clinical data, including electronic health records and patient-reported outcomes.

Results: The analysis identified 53 studies that employed a variety of ML algorithms, including support vector machines (SVM), artificial neural networks (ANN), and natural language processing (NLP) techniques. The majority of these studies reported significant improvements in the accuracy of ADR predictions compared to traditional methods. Notably, SVM and NLP were the most frequently utilized models, demonstrating strong effectiveness in extracting relevant insights from complex datasets.

Conclusion: The findings underscore the potential of machine learning to revolutionize the prediction of adverse drug reactions, ultimately enhancing patient safety. However, challenges remain regarding data standardization, algorithm interpretability, and the integration of these models into clinical practice. Future research should focus on developing standardized metrics for evaluating ML performance in ADR

prediction, as well as exploring the real-world applicability of these technologies in diverse healthcare settings.

Keywords: Adverse drug reactions, machine learning, patient safety, predictive modeling, healthcare analytics.

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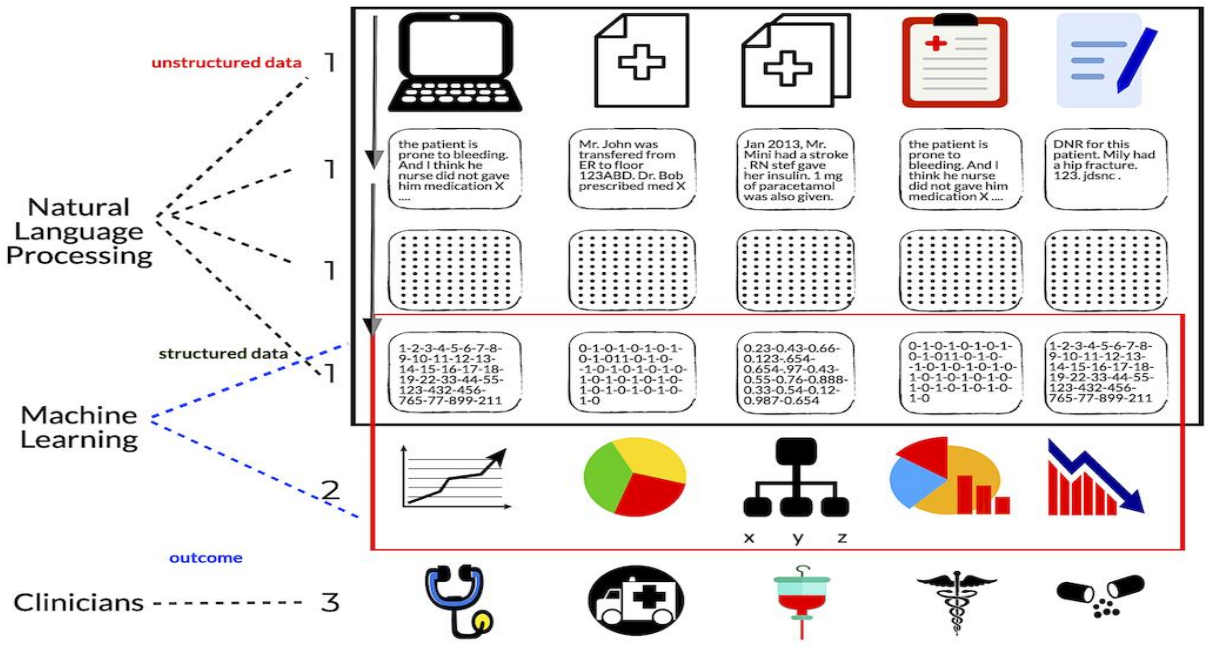
1. Introduction

Patient safety is characterized by the elimination of avoidable damage to a patient and the reduction of risk connected with the healthcare process [1,2]. Each aspect of the caregiving process has a certain level of inherent risk. Following the adoption of resolution WHA55.18 on "Quality of Care: Patient Safety" at the 55th World Health Assembly in 2002, there has been a growing focus on patient safety issues and adverse occurrences within healthcare environments. Notwithstanding the safety actions and expenditures by federal and local governments, business organizations, and concerned institutions, studies persist in reporting adverse patient safety results [3-5].

The incorporation of artificial intelligence (AI) into the healthcare system is transforming dynamics, including the roles of healthcare practitioners, while also generating new opportunities to enhance patient safety outcomes and the quality of treatment. The term AI is widely defined as a computer software capable of making intelligent judgments [6-8]. This research adopts the operational definition of AI as the capacity of a computer or healthcare device to evaluate vast healthcare data, uncover concealed insights, detect hazards, and improve communication [9]. In this context, AI includes machine learning and natural language processing. Machine learning allows computers to use labeled (supervised learning) or unlabeled (unsupervised learning) data to uncover hidden knowledge or anticipate outcomes without direct programming [9]. Machine learning and natural language processing, among several AI kinds, significantly influence the healthcare sector and are often used within this industry [10-13].

The third area of machine learning is reinforcement learning, when an algorithm endeavors to complete a task while learning from its triumphs and failures. Machine learning also includes artificial neural networks, often referred to as deep learning. Natural language processing aims to enhance a computer's capacity to comprehend human language and then convert text into machine-readable structured data for analysis using machine-learning methods [14]. The literature lacks a clear delineation between natural



language processing and machine learning. Nonetheless, as seen in Figure 1, research within the healthcare domain has included natural language processing with machine learning techniques [15].

Figure 1. Schematic depiction of the conversion of unstructured text into machine-readable structured data using natural language processing, enabling further analysis by machine-learning algorithms.

Artificial intelligence has the capacity to aid physicians in enhancing diagnostic accuracy [16-18] and has made significant contributions to medication discovery [19-21], customized medicine, and patient care monitoring [14,22-24]. Artificial intelligence has been integrated into electronic health record systems to discover, evaluate, and alleviate risks to patient safety. The implementation of AI in healthcare presents various risks and challenges at the individual level (e.g., awareness, education, trust), macro level (e.g., regulation and policies, potential injuries from AI errors), and technical level (e.g., usability, performance, data privacy, and security) [25].

The assessment of AI accuracy does not inherently reflect clinical efficacy [26]. The area under the receiver operating characteristic curve (AUROC) is another prevalent statistic, however it may not be the most suitable for clinical relevance [27]. These AI measures may be difficult for physicians to comprehend or may lack therapeutic significance [28]. Furthermore, AI models have been assessed via many criteria and provide distinct metrics such as the F1 score, accuracy, and false-positive rate, which reflect diverse facets of AI's analytical ability. Comprehending the operation of intricate AI requires technical expertise that is uncommon among doctors. Furthermore, therapists may lack the requisite knowledge to recognize inherent flaws in the AI, such data bias, overfitting, or other software problems that might lead to erroneous results. Deficiencies in AI may lead to inaccurate drug dosages and suboptimal treatment outcomes [29-33].

Moreover, a system malfunction in a prevalent AI might result in many patient casualties, in contrast to a restricted number of injuries caused by a provider's mistake [34]. Moreover, there have been instances in which conventional analytical procedures surpassed machine-learning techniques [9]. Given the extensive efficacy of AI, it is essential to comprehend both the beneficial and adverse effects of AI on patient safety outcomes [35].

Artificial intelligence in the healthcare system may aid at both the clinical and diagnostic levels [36]. AI serves as a potent instrument that may be used in the healthcare sector to uncover nuanced patterns in data, which physicians can then evaluate to detect novel clinical and health-related concerns [9]. Recent research and reviews have mostly concentrated on the efficacy of AI in diagnostics, particularly in illness detection [37-42], as well as the use of AI robots in surgical procedures and disease management [43-46]. Additional research has used AI systems to aid in healthcare settings, such as evaluating fall risks [47] and identifying prescription problems [48,49]. Nonetheless, several studies focus on AI development and performance, revealing a significant deficiency in research examining the function and influence of AI at the clinical level on patient safety outcomes.

Numerous research have shown the great accuracy of AI in healthcare. Nonetheless, its true impact (whether detrimental or beneficial) may only be discerned when it is incorporated into clinical environments or understood and used by healthcare professionals [50]. Consequently, we believe that patient safety and AI performance may not inherently align. The use of AI in healthcare relies on data sources such electronic health record systems, sensor data, and patient-reported information. EHR systems may include more critical scenarios for certain patient demographics. Specific patient groups may exhibit a greater number of illnesses or may get care at numerous hospitals. Some subsets of patients with uncommon illnesses may lack enough numbers for a predictive analytic method. Consequently, clinical data obtained from electronic health records may be susceptible to biases [9,50]. Due to these inherent biases, AI accuracy may be deceptive when trained on a limited subset or small sample size of patients with unique conditions.

Moreover, individuals with restricted access to healthcare may undergo fewer diagnostic tests and obtain inadequate drugs, resulting in insufficient health information in the EHR to prompt early intervention [51,52]. Furthermore, institutions document patient information variably; hence, if AI models developed at one institution are used to evaluate data at another, this may lead to inaccuracies [52]. For example, machine-learning algorithms created at a university hospital to forecast patient-reported outcome measures, typically recorded by patients with high education and income, may not be relevant when applied in a community hospital that predominantly caters to underrepresented low-income patient populations.

A 2017 analysis [53] indicated that just 54% of research that formulated prediction models using EHRs included missing data. Recent studies and reviews have predominantly concentrated on the efficacy and impact of AI systems in diagnostics, particularly for disease identification [37-42], and the role of AI robotics in surgical procedures and disease management [43-46]. However, there is a deficiency of research examining and documenting the effects of AI employed at the clinical level on patient safety outcomes, as well as the attributes of the AI algorithms utilized. Therefore, it is crucial to examine the impact of AI on patient safety outcomes in clinical settings, as well as the documented performance of AI in the literature.

2. Methods

We conducted a search for peer-reviewed papers in the PubMed, PubMed Central, and Web of Science databases from 2009 to 2023 to find articles that met the scope and eligibility criteria of this systematic literature review.

3. The efficacy of AI in healthcare

Numerous research studies have been undertaken to demonstrate the analytical efficacy of AI in healthcare, especially as a diagnostic and prognostic instrument. This is the first systematic review examining and illustrating research that demonstrates the impact of AI (machine learning and natural language processing methods) on clinical patient safety outcomes. We discovered 53 studies relevant to the review. This 53-research used 38 distinct AI systems/models to evaluate patient safety results, with support vector machines (n=17) and natural language processing (n=12) being the most prevalent. The majority of the analyzed studies indicated favorable improvements in patient safety outcomes.

The analysis of all experiments revealed a deficiency in a standardized benchmark among the reported AI models. Despite differing AI performance levels, the majority of research has shown a beneficial effect on safety outcomes, suggesting that safety results do not inherently align with AI performance metrics [26]. One recognized research, which achieved an accuracy of 0.63 and used Patient Assisting Net-Based Diabetes Insulin Titration (PANDIT), indicated a detrimental effect of AI on safety results. suggestions provided by PANDIT that did not align with those of nurses (1.4% of the suggestions) were classified as hazardous. The research using natural language processing to extract clinical information from patient safety reports has shown a beneficial effect on patient safety outcomes, with an accuracy of 0.53 [54]. Likewise, the FDA-sanctioned computer-aided diagnosis from the 1990s, which markedly enhanced the recall rate of diagnoses, did not provide improvements in safety or patient outcomes [54]. Our analysis indicates that AI algorithms are hardly evaluated against a standard of care, such as physicians or clinical gold standards.

Dependence on AI results that have not been assessed against a common benchmark fulfilling clinical criteria might be deceptive. 2008 research [55] developed and verified an enhanced iteration of the QRISK cardiovascular disease risk algorithm (QRISK2). The research indicated enhanced performance of QRISK2 relative to its predecessor. Nonetheless, QRISK2 was not evaluated against any clinical gold standard. In 2016, eight years later, The Medicines & Healthcare Products Regulatory Agency discovered a flaw in the QRISK 2 calculator, which inaccurately assessed the risk of cardiovascular disease. The regulatory organization said that one-third of general practitioner practices in England may have been impacted owing to the QRISK2 mistake. Numerous Standards Development Organizations worldwide are formulating information technology and AI standards to meet diverse standardization requirements in cloud computing, cybersecurity, and the Internet of Things [56]. Nevertheless, there has been less effort to standardize artificial intelligence in the healthcare sector. Health care encompasses several divisions, each

with distinct needs (clinical standards). Consequently, health care necessitates "vertical standards," which are criteria formulated for certain domains, including medication safety (pharmaceuticals), specialized surgical procedures, outpatient and inpatient treatment for distinct health issues, and emergency departments [56]. Conversely, standards that are improperly designed for a particular purpose may impede patient safety.

In the absence of a consistent benchmark, assessing whether a certain AI system fulfills clinical criteria (gold standard) or demonstrates superior (enhances patient safety) or inferior (endangers patients) performance compared to analogous systems within a particular healthcare environment becomes difficult. To achieve optimal performance outcomes, AI systems may include inaccurate confounders into the computational process. In a particular research, an algorithm demonstrated a higher propensity to categorize a skin lesion as malignant when the input picture included a ruler, since the presence of a ruler was associated with an elevated probability of a cancerous lesion [57]. Surgical skin marks have been shown to artificially elevate a deep-learning model's melanoma likelihood scores, hence increasing the false-positive rate [58]. Furthermore, significant emphasis has been placed on the need of AI standards by industrialized nations, like the European Union, United States, China, and Japan. On February 11, 2019, the President of the United States issued Executive Order 13859, mandating government agencies to engage in the establishment of AI standards. The Center for Data Innovation and The National Institute of Standards and Technology assert that a standardized AI benchmark may function as a tool for assessing and contrasting AI systems [56]. FDA Commissioner Scott Gottlieb recognized the need of AI standardization to ensure that continuous algorithm modifications adhere to predetermined performance criteria and use a validation method that guarantees safety [59].

A significant discovery of this research is the considerable variability in AI reporting. Artificial intelligence technologies have been created to assist physicians in assessing risks and making educated judgments. Nonetheless, the data suggests that the quality of reporting in AI model research is inconsistent. The heterogeneity in AI reporting complicates the comparison of algorithms between research and may hinder agreement when selecting the most suitable AI for a certain context. Algorithms must be compared using same data typical of the target population and the same assessment measures; hence, uniform reporting of AI research would be advantageous. The existing Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis (TRIPOD) comprises 22-item checklists designed to enhance the reporting of research that create or validate prediction models [60,61]. The studies in our evaluation did not use TRIPOD for reporting results. The potential explanation for this may lie in the architecture of TRIPOD, which emphasizes a regression-based predictive model.

The explanation and elaboration paper presents examples of effective reporting techniques centered on models developed using regression analysis. A new iteration of the TRIPOD statement tailored for AI/machine-learning systems (TRIPOD-ML) is currently in development. The emphasis will be on the use of machine-learning prediction algorithms to create methodological and reporting standards for machine-learning research in healthcare [62].

Our results also highlighted the need of establishing the significance of an AI assessment measure. It is essential to identify the appropriate assessment metric(s) to be assessed in a specific healthcare scenario. AUROC is regarded as a better measure for classification accuracy, especially in the context of imbalanced datasets, since it remains unaffected by data imbalance, a common occurrence in healthcare. Nevertheless, 36 papers in our evaluation failed to disclose AUROC. Evaluation metrics like precision-recall may properly represent model performance [63]; however, only 11 papers in our analysis assessed AI using precision-recall. Employing unsuitable metrics to assess AI performance might jeopardize patient safety. Our research showed no harm to patient safety resulting from the use of incorrect AI assessment metrics. Future research should emphasize the significance of assessment metrics and ascertain if a single measure or numerous measures more effectively reflect patient safety results. Further research is required to investigate the assessment metric(s) that must be evaluated prior to endorsing an AI model.

The results of our assessment indicate that medication safety, together with the examination of clinical reports, has emerged as the predominant focus for using AI to tackle patient safety issues at the clinical level. Administration of incorrect drug or inappropriate dose might lead to lethal patient health consequences and medical misconduct [64]. The Joint Commission on Accreditation of Healthcare Organizations is particularly concerned with problems pertaining to incorrect dosing of high-alert drugs among drug safety concerns. Medical mistakes are identified as the third main cause of mortality in the United States. The bulk of the studies in our study used AI to tackle medication safety (n=23) issues, which is a substantial contributor to total medical mistakes. These articles enhanced patient safety by recognizing adverse drug responses and averting medication errors or overdosing. Future research should investigate the use of AI systems on a broader scale to reduce pharmaceutical mistakes in hospitals and clinics, therefore save more lives.

This document reviews research that have examined safety concerns as outlined by the Health Insurance Portability and Accountability Act (HIPAA) and the US Department of Health & Human Services (HHS). The HIPAA laws designate risk analysis as a component of the administrative safeguard mandate to enhance patient safety. The HHS promotes the examination of clinical notes to monitor, identify, and assess any dangers to patients. Numerous research (n=21) in our evaluation used AI to evaluate patient risk from clinical notes. These investigations used artificial intelligence and clinical data to extract safety-related information, including fall hazards, Pyxis inconsistencies, patient misidentification, patient severity, and postoperative surgical problems. Our results demonstrate that AI approaches, particularly natural language processing, have used clinical notes and reports as a data source to extract patient information about various safety problems, including clinical notes, discharge summaries, and other related matters [65-67]. Our analysis reveals that AI has the capacity to provide significant insights for accurate patient treatment by detecting prospective health or safety hazards [68], enhancing healthcare quality, and minimizing clinical mistakes [69]. Although identified as a significant contributor to weariness, professional burnout, and patient damage [61,70,71], just 9 research in our study used AI to enhance clinical alarms. Despite research on clinical alarms demonstrating favorable results in reducing false alarms and detecting patient health deterioration, the scant number of studies (n= 9) on these matters indicates that the topic remains at an early stage of exploration. Consequently, more investigation is required to validate the influence of AI on patient safety results.

4. Conclusion

This comprehensive review revealed significant research deficiencies requiring the scientific community's attention. The bulk of the studies in the review have not emphasized critical features of AI, including (a) variability in AI reporting, (b) absence of a uniform benchmark, and (c) need to ascertain the significance of AI assessment metrics. The observed deficiencies in AI systems suggest that more research is necessary, along with the participation of the FDA and NIST to establish a framework that standardizes AI assessment metrics and sets a baseline to guarantee patient safety. Consequently, our assessment advocates for the health care sector and AI developers to embrace an interdisciplinary and systems approach to examine the comprehensive effects of AI on patient safety outcomes and other health care settings.

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استخدام تقنيات التعلم الآلي للتنبؤ بالتفاعلات الدوائية الضارة: مراجعة شاملة

الملخص

الخلفية :تمثل التفاعلات الدوائية الضارة (ADRs) مخاطر كبيرة على سلامة المرضى ونتائج الرعاية الصحية. ومع تزايد تعقيد الأدوية وحالات المرضى، غالبًا ما تكون الطرق التقليدية للتنبؤ بـ ADRs غير كافية. يتيح دمج تقنيات التعلم الآلي (ML) في الرعاية الصحية نهجًا واعدًا لتحسين التنبؤ وإدارة هذه التفاعلات.

الطرق :استعرضت هذه المراجعة بشكل منهجي الأدبيات المحكمة المنشورة بين عامي 2009 و2023، مع التركيز على تطبيقات التعلم الآلي في التنبؤ بـ .ADRs تم استخدام قواعد بيانات مثل PubMed و Web of Scienceلجمع الدراسات ذات الصلة. شملت معايير الإدراج استخدام نماذج التعلم الآلي لتحليل البيانات السريرية، بما في ذلك السجلات الصحية الإلكترونية ونتائج المرضى المبلغ عنها.

النتائج :حددت المراجعة 53 دراسة استخدمت مجموعة متنوعة من خوارزميات التعلم الآلي، بما في ذلك آلات المتجهات الداعمة(SVM) ، والشبكات العصبية الاصطناعية(ANN) ، وتقنيات معالجة اللغة الطبيعية .(NLP) أبلغت غالبية هذه الدراسات عن تحسينات كبيرة في دقة التنبؤ بـ ADRs مقارنة بالطرق التقليدية. كان من الجدير بالذكر أن SVM و NLPهما النموذجان الأكثر استخدامًا، حيث أظهرا فعالية قوية في استخراج رؤى ذات صلة من مجموعات البيانات المعقدة.

الاستنتاج :تؤكد النتائج على إمكانات التعلم الآلي لإحداث ثورة في التنبؤ بالتفاعلات الدوائية الضارة، مما يعزز في نهاية المطاف سلامة المرضى. ومع ذلك، لا تزال هناك تحديات تتعلق بتوحيد البيانات، وقابلية تفسير الخوارزميات، ودمج هذه النماذج في الممارسات السريرية. يجب أن تركز الأبحاث المستقبلية على تطوير مقاييس موحدة لتقييم أداء التعلم الآلي في التنبؤ بـADRs ، بالإضافة إلى استكشاف التطبيقات الواقعية لهذه التقنيات في بيئات الرعاية الصحية المتنوعة.

الكلمات المفتاحية :التفاعلات الدوائية الضارة، التعلم الآلي، سلامة المرضى، النمذجة التنبؤية، تحليلات الرعاية الصحية.