Review article

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ARTIFICIAL INTELLIGENCE IN DRUG DEVELOPMENT, CLINICAL TRIALS, AND HEALTHCARE

Vangelis Karalis[1], Aleksandra Catić-Đorđević[2]

The use of artificial intelligence (AI) in drug development, clinical trials, and clinical practice represents a transformative advancement in healthcare. AI technologies offer unprecedented capabilities to analyze vast datasets, identify patterns, and generate actionable insights, thereby revolutionizing various aspects of the healthcare ecosystem. This review aims to offer a thorough overview of current research on AI applications in healthcare. In drug development, AI-driven approaches rationalize the process of identifying potential therapeutic compounds, accelerating the route from discovery to market approval. Within clinical trials, AI-powered analytics optimize trial design, reduce sample size, patient recruitment, and data analysis, increasing statistical power and efficiency. Moreover, in clinical practice AI applications empower healthcare providers with decision support systems, personalized treatment recommendations, and predictive analytics, leading to more effective and personalized patient care. While challenges such as ethical considerations and regulatory frameworks remain, the potential benefits of AI in driving medical innovation and improving patient outcomes are substantial, underlining the importance of continued research, collaboration, and responsible application of AI in healthcare.

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[1]National and Kapodistrian University of Athens, Department of Pharmacy, Athens, Greece
[2]University of Niš, Faculty of Medicine, Niš, Serbia

Contact: Aleksandra Catić-Đorđević
81 Dr. Zorana Djindjića Blvd., 18000 Niš, Serbia
E-mail: aleksandra1610@yahoo.com

Artificial intelligence

Introduction

Artificial intelligence (AI) refers to the imitation of human intelligence within computer systems. This field focuses on creating machines that can perform tasks on par with or even exceeding human capabilities (1). The methodology involves gathering data, establishing rules for its application, making either tentative or final decisions, and continuously refining the process through self-correction. The fields of AI and its subset, machine learning (ML), have produced considerable interest across diverse industries, with pharmaceutical sciences being no exception. The exponential growth in data from myriad sources, coupled with advancements in analytical tools and the continuous refinement of ML algorithms, has led to a rapid proliferation of ML applications within pharmaceutical sciences. From revolutionizing drug discovery and development processes to enabling the realization of personalized medicine, ML applications in this domain highlight the transformative potential of AI. Throughout history, the quest of AI has been characterized by four primary approaches, each supported by distinct groups using specific methodologies (2). These approaches refer to: a) Act humanly, b) Think humanly, c) Act rationally, and d) Think rationally.

In this context, the intersection of AI and healthcare has sparked a paradigm shift in how we approach drug development, clinical trials, and healthcare. In recent years, AI technologies have emerged as powerful tools capable of analyzing vast quantities of data, identifying intricate patterns, and generating actionable insights with unprecedented speed and accuracy (3). Within the fields of drug discovery and development, AI algorithms are revolutionizing the identification of potential therapeutic compounds, expediting the research process from bench to bedside. In parallel, AI-driven analytics are reshaping the landscape of clinical trials, optimizing trial design, patient recruitment, and data analysis to enhance efficiency and efficacy. Moreover, within healthcare, AI applications are empowering healthcare providers with decision support systems, personalized treatment recommendations, and predictive analytics, thereby revolutionizing patient care delivery. As we delve deeper into the field of AI in healthcare, it becomes increasingly evident that these technologies hold immense promise in accelerating medical innovation, improving patient outcomes, and ultimately transforming the way we approach healthcare delivery.

Historical background

The ancient Greeks held reasoning faculties in high regard, viewing them as the hallmark of human uniqueness that set humans apart from other creatures (1). They honored the ability to think logically and critically as a defining characteristic of humanity, shaping the foundation of Western philosophy and science. The ancient Greek philosopher Plato (5th BC century), as well as religious thinkers many centuries later, expanded upon this notion by introducing the concept of the soul (1). Beyond mere reasoning, humans were believed to possess a soul—a divine essence imparted by their creator—which granted them a unique position in the cosmic order. This synthesis of reason and soul provided a holistic framework for understanding human nature, blending philosophical inquiry with theological reflection. His student, Aristotle, codified laws governing logical thought (1). His development of syllogistic reasoning laid a solid foundation for subsequent philosophical and scientific quests, shaping scholarly discourse on the human mind for centuries. In the 16th century, the polymath Leonardo da Vinci, conceptualized a mechanical calculator; a testament to his approach to engineering and mathematics (1). Although da Vinci never constructed the device himself, modern reconstructions based on his designs have validated its feasibility, showcasing his remarkable foresight and contributions to the early development of mechanical computing.

In the 20th century, Alan Turing introduced the concept of "effective calculability" as a solution to this fundamental challenge (4). Turing's work laid the basis for computational models, establishing the concept of algorithms, as step-by-step procedures for calculations. The genesis of artificial neural networks (ANNs) can be traced back to 1943, with the development of an initial neural network composed of electrical circuits (5). This research aimed to replicate the intricate interactions between neurons in the human brain, laying the foundation for the burgeoning field of neural networks and their applications in AI. The formal establishment of AI as a distinct field occurred in 1956 during a historic conference held at Dartmouth College (6). This landmark event brought together prominent researchers to explore the potential of creating machines capable of simulating various aspects of human intelligence. The Dartmouth conference marked the official birth of AI, heralding decades of intensive research and development in the field.

The computer stands as one of the most monumental technological advancements since the advent of the printing press in the 15th century (1, 7). During World War II, early iterations of computers were utilized by the military forces of Germany and the western allies, although these machines exerted little resemblance to modern computers. For example, America's ENIAC, weighing 30 tons and spanning an entire basement, relied on 17,000 vacuum tubes. In the 1950s, IBM embarked on the development of business computers, which were notably smaller than their military counterparts, occupying only a fraction of a room space. Over the subsequent two decades, computers evolved into forms more akin to those familiar today, albeit still considerably large. By the late 1980s, the personal computer had become a ubiquitous presence, with approximately 20% of US households owning at least one (1). This widespread integration signified a pivotal moment, as artificial intelligence began to permeate homes and workplaces nationwide, underscoring the swift assimilation of advanced computing technologies into everyday life.

AI classification

AI can be classified into several main types based on the learning approach used (Table 1):

Supervised learning: The AI system is trained on labeled data, where the inputs and desired outputs are provided (8). The system then learns to map the inputs to the outputs, allowing it to make predictions on new, unseen data. Examples include image classification, spam detection, and predictive analytics.

Unsupervised learning: The AI system is given unlabeled data and must find patterns and structure within it on its own (8−11). The goal is to discover hidden insights and groupings in the data. Examples include customer segmentation, anomaly detection, and recommendation systems.

Reinforcement learning: The AI system learns by interacting with an environment and receiving feedback (rewards or penalties) based on its actions (12). It then adjusts its behavior to maximize the rewards, allowing it to learn complex tasks through trial and error. Examples include game-playing AIs, robotics, and autonomous vehicles.

Table 1. Popular machine learning algorithms

Linear Regression	K-Means Clustering	Reinforcement learning
Logistic Regression	Hierarchical Clustering	Q-Learning
Decision Trees	Density-Based Spatial Clustering of Applications with Noise (DBSCAN)	Deep Q-Networks (DQN)
Random Forests	Gaussian Mixture Models (GMM)	State-Action-Reward-State-Action (SARSA)
Support Vector Machines (SVM)	Principal Component Analysis (PCA)	Policy Gradient Methods
K-Nearest Neighbors (KNN)	Independent Component Analysis (ICA)	Actor-Critic Methods
Naive Bayes	t-Distributed Stochastic Neighbor Embedding (t-SNE)	Deep Deterministic Policy Gradient (DDPG)
Neural Networks	Self-Organizing Maps (SOM)	Proximal Policy Optimization (PPO)
Gradient Boosting Machines (GBM)	A priori Algorithm	Advantage Actor-Critic (A3C/A2C)
Adaptive Boosting (AdaBoost)	Association Rules	Monte Carlo Methods

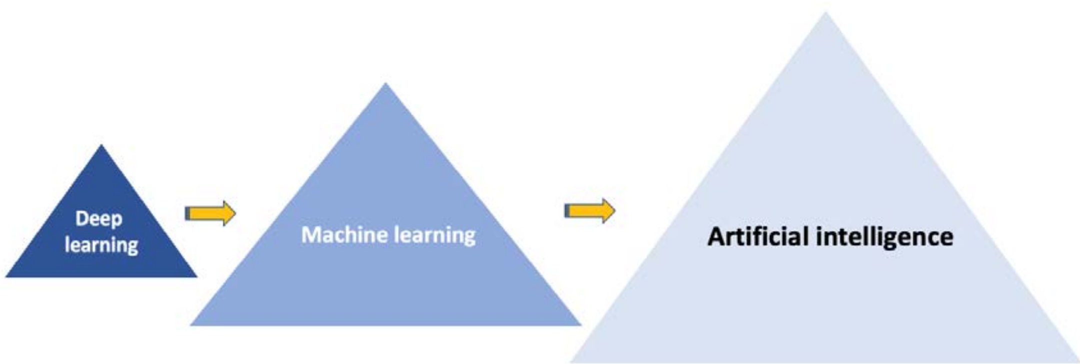

Figure 1. Association among the terms deep learning, machine learning, and artificial intelligence

Deep learning (DP) is a powerful subdivision of machine learning (Figure 1) that utilizes ANNs with multiple hidden layers to learn complex patterns in data (13, 14). Unlike more traditional ML algorithms that rely on manual feature engineering, DP models can automatically extract relevant features from raw data, enabling them to tackle increasingly complex problems. Deep learning has been particularly successful in areas like computer vision, natural language processing, and speech recognition, where it has outperformed previous state-of-the-art methods (2). By using the hierarchical structure of neural networks, DP models are able to learn high-level abstractions from low-level inputs, allowing them to make highly accurate predictions and classifications. While DP models require large amounts of training data and significant computational resources, they have become an invaluable tool in the field of AI, powering many of the most advanced intelligent systems and applications we see today. As the field continues to evolve, DP is likely to play an even more central role in the development of increasingly capable and versatile AI systems.

AI in Drug Development

Over the past two centuries, the field of medicine has undergone a remarkable evolution, progressing from reliance on simple herbal remedies to the development of intricate pharmaceutical formulations and dosage forms (15). However, the process of bringing a new drug to market remains a lengthy and complex journey, often spanning several years and involving substantial financial investments, largely due to the high attrition rate inherent in drug development. Consequently, there is a pressing need to streamline this process by using state-of-the-art technologies, including AI.

Machine learning, plays a significant role in pharmaceutical sciences, particularly in drug research and development, where techniques like high-throughput screening and combinatorial chemistry are extensively utilized (16–18). As the volume of such research continues to escalate, the importance of ANNs in facilitating drug discovery processes has grown exponentially (19, 20). Moreover, the advent of extensive datasets pertaining to potential medicinal compounds has heralded the era of big data in medicine (21). This paradigm shift necessitates the adoption of AI technologies capable of effectively modeling dynamic, heterogeneous, and vast repositories of drug-related data.

Deep learning models in computational chemistry have transformed drug development, notably in terms of predicting drug-target interactions, creating novel compounds, and anticipating ADMET properties for translational research (22). Machine learning techniques, instrumental in target development and drug discovery, have been integrated into various research and development pipeline stages , using advancements in ML theory and pharmacological data accumulation (23, 24). Machine learning accelerates virtual screening, reducing costs and enhancing accuracy using web-based tools (25, 26).

Utilizing an established treatment for a novel condition presents a favorable scenario wherein the new medication can bypass Phase I clinical trials and proceed directly to Phase II trials (27). This approach offers the potential for expedited development timelines and reduced overall costs, rendering drug repurposing an increasingly attractive strategy. In the era of big data, the convergence of AI and network medicine leads to innovative data science applications in disease characterization, medication evaluation, treatment selection, and target identification with unprecedented precision (28). Emerging systems biology methodologies use ML algorithms to analyze medication effects, separating from traditional reliance on chemical similarity and molecular docking. Notably, such studies have been exemplified in remdesivir trials for COVID-19 treatment (28). Similarly, in the fight against the Hepatitis C virus (HCV), network-based medication repurposing efforts have led to the discovery of 16 potentially repurposable medicines (29). These innovative approaches underline the transformative potential of AI-driven strategies in drug repurposing, offering novel avenues for accelerating therapeutic discoveries and optimizing treatment outcomes.

During the pre-formulation stage of drug development, assessing the physicochemical properties of a medicinal substance is pivotal (30). These properties govern critical aspects such as solubility, stability, excipient interactions, and ultimately, bioavailability. Determining the water solubility of a new drug compound is particularly crucial as it directly impacts absorption across various administration routes (31). Techniques like surfactants, complexation, and cocrystal formation are used to enhance aqueous solubility (31). Predicting drug solubility in silico using AI is of paramount importance (31, 32). Additionally, substantial progress has been made in utilizing ML, particularly transfer learning, in pharmaceutical settings (33). Integrated techniques combining transfer learning and multitask learning have shown promise in predicting various pharmacokinetic parameters with strong generalization ability (33). ANNs have been extensively used to predict formulation and process-related characteristics such as drug dissolution and release, showcasing remarkable success and potential for rapid and efficient manufacturing optimization (34). In the same vein, early consideration of interactions among materials and conditions during drug manufacturing is vital to prevent subsequent losses in time and resources (35). AI is increasingly applied in pharmaceutical technology to streamline operations and gain insights into formulation-process interactions. Quality-by-Design is a systematic approach integrating quality into product development through a well-defined framework (36). ANNs play a crucial role in drug development, linking material related parameters to *in vivo* performance (36).

AI in Clinical Trials

The use of AI in clinical trials represents a transformative advancement in healthcare research, since it can give unprecedented capabilities to rationalize various aspects of clinical trial management and analysis (37). From patient recruitment and selection to data monitoring and analysis, AI enhances efficiency and accuracy throughout the trial lifecycle. AI-driven predictive models aid in identifying suitable patient populations, optimizing trial protocols, and predicting patient outcomes, thereby expediting trial timelines and reducing costs. Furthermore, AI facilitates real-time data monitoring, enabling early detection of adverse events and protocol deviations.

Quite recently, generative AI algorithms were proposed as an innovative way to reduce the actual human sample size by using AI-synthesized virtual patients instead (38, 39). Thus, AI-driven algorithms have been proposed for data augmentation in clinical trials. Data augmentation techniques have primarily focused on image analysis, particularly in computer vision, with methods like random rotation, noise addition, and generative adversarial networks being explored (40–43). While some studies have applied data augmentation to generate synthetic fetal ultrasound images, the present study primarily deals with numerical data augmentation (44). Variational autoencoders (VAEs) have been recognized as effective in developing generative models to produce novel synthetic data, offering advantages over conventional autoencoders by generating data from the same distribution as input data (45).

Besides, sample size estimation is pivotal in clinical trials, ensuring safety and efficacy (46). Obtaining a representative sample is essential for understanding a population, yet collecting extensive data can be challenging and resource-intensive. Each trial requires meticulous planning, including outlining objectives, endpoints, data collection, and statistical methods (46). A recent study aimed to reduce required sample sizes in clinical trials using a VAE (47). That study explored the application of VAEs to virtually increase sample sizes in clinical trials, demonstrating the feasibility of using only 20% of the original dataset without altering study outcomes (45). Even for data with high variability, VAEs substantially reduce sample size requirements, accelerating trials, cutting costs, and minimizing human exposure (45). Moving one step ahead, a subsequent study proposed the utilization of ANN specifically VAEs, to reduce the need for recruiting large participant populations in bioequivalence investigations (39). In that study, the suitability of utilizing VAEs to virtually expand the sample size in the context of a typical 2 x 2 crossover design bioequivalence study was investigated. The aim was to generate realistic synthetic data that can supplement the original trial data, potentially reducing the burden of recruiting a large number of participants (39). Both these two studies represent an important step forward in the integration of advanced AI techniques into the clinical trial process. By demonstrating the feasibility and potential benefits of using VAEs to augment bioequivalence data, they pave the way for further exploration and adoption of generative AI algorithms in various aspects of clinical research.

Machine learning approaches have also been used in the field of pharmacokinetics, aiming to address the old problem of finding an appropriate metric for absorption rate (48, 49). In recent studies, several ML approaches have been used to solve the ongoing difficulty of establishing an adequate absorption rate measure (50−52). Using Cmax as an absorption parameter presented many problems (53−55). Alternative metrics, such as Tmax and the Cmax/AUC ratio, were proposed to better characterize absorption rate features, particularly in immediate-release formulations (55). Studies comparing these measurements discovered that the Cmax/AUC ratio provided higher statistical precision and ease of use than Tmax (55, 56). However, the choice of a parameter to describe absorption rate should be based on theoretical considerations, particularly the units (51). A good absorption rate measure should represent variations in concentration over time and indicate a concentration per time unit. Unfortunately, several proposed metrics lack proper units, such as AUC, Cmax, Tmax, and even the Cmax/AUC ratio, which is measured *in time-1*.

In this context, a unique measure known as average slope (AS) was introduced by applying several computational interdisciplinary techniques (51, 52). It was shown that the usual metric, Cmax (peak plasma concentration), is insufficient to reflect the absorption rate. In contrast, the newly suggested metric, average slope, has the requisite absorption rate features, suitable units of measurement (concentration units per time), and is simply computed directly from drug concentration-time data. All ML algorithms revealed that the average slope measure outperformed other metrics used or suggested in bioequivalence studies (50−52). Simplicity and applicability are crucial for pharmacokinetic measures. Metrics like AS can be easily estimated using simple, reproducible methods without complex modeling, making them more reproducible and straightforward compared to model-based approaches (50−52). The estimation of AS can even be done manually using tools like Excel®, enhancing its accessibility. These findings highlight the necessity of reevaluating established measurements and investigating novel solutions, with ML providing a fresh viewpoint on long-standing pharmacokinetic issues.

AI in Healthcare

AI has become increasingly important in clinical practice because of its ability to efficiently handle massive datasets, resulting in better patient care and a lower burden on healthcare staff (6). This growth prepared the path for personalized medicine, which goes beyond typical computational procedures. Predictive models, in particular, have enormous potential for diagnosing diseases, forecasting treatment outcomes, and influencing the future of preventative healthcare. AI can improve diagnostic accuracy, streamline healthcare operations, facilitate more effective disease and therapy monitoring, and modify medical procedures.

In cardiology, the integration of advanced AI algorithms, collectively known as AI, revolutionizes the analysis of cardiac data. AI systems aim to interpret data more efficiently, offering insights for diagnosing, treating, and managing cardiovascular conditions. In cardiovascular imaging, AI serves two main purposes (57). Firstly, it automates tasks like image segmentation and parameter assessment, reducing the need for human involvement. Secondly, it identifies clinically significant insights. While most applications focus on task automation, there are also advancements in algorithms for acquiring cardiac measurements. Also, the AI use in anesthesia has made tremendous progress (58, 59). Various activities are efficiently done using a variety of strategies throughout all phases of operation (60, 61). For example, while a neural network built to detect esophageal intubation is efficient, continuous capnography makes it unnecessary, disclosing previously unknown difficulties (62, 63).

In addition, the use of AI algorithms for image analysis has enormous potential in pulmonary medicine (64, 65). Lung cancer, a common and fatal illness, frequently appears as lung nodules on early imaging, making manual interpretation difficult (66). AI recognition technology can speed up picture processing, allowing for multi-parameter cluster analysis and diagnosis support (67). New results show that AI systems are effective at recognizing malignant pulmonary nodules from chest CT scans, employing deep learning technology for analysis, and assisting medical personnel in screening for lung cancer with greater accuracy (68). Another study found that a predictive approach including logistic regression analysis and particular tumor markers outperformed basic combination detection.

AI plays an important role in urology, notably in genitourinary cancers. For example, in a study on prostate cancer, AI was used to predict biopsy results (69). AI has the capacity to stage and predict disease recurrence in kidney and testicular cancer cases. Recent applications include non-oncological illnesses such as stones and functional urology. Over the last few decades, various research has looked into the use of AI in prostate cancer management, in line with the precision medicine paradigm (69). Prostate cancer diagnostics, which encompasses a variety of applications, has made substantial advances (70). In 1994, a critical study investigated the ability of ANNs to predict biopsy outcomes and treatment outcomes following radical prostatectomy (70). Another study assessed the predicted accuracy of two AI systems developed using data from a European referral database, with the goal of detecting prostate cancer early (71).

Skin disorders are often characterized by the visual characteristics of the lesions they cause. However, dermatology faces a hurdle because there are over 2,000 different dermatological disorders, some of which present identical symptoms, complicating correct diagnosis and therapy (72). This difficulty is aggravated by a dermatological scarcity, particularly in underdeveloped nations and isolated places with few medical resources (73). The convergence of big data, advancements in image recognition, and widespread smartphone usage has the potential to transform skin disease diagnosis and treatment (74). AI, in particular, holds promise for providing rapid diagnoses, expanding treatment options, and improving accessibility, especially in underserved areas and resource-constrained settings (75). The integration of AI technology and algorithms is set to become a standard approach in dermatological diagnosis and assessment, offering increased reliability in analyzing the structure and appearance of skin abnormalities, with significant progress made in facial recognition and aesthetic analysis (76).

Neuroimaging is crucial in healthcare and research, enabling the study of the brain in different conditions (77–79). Advanced analysis methods help extract meaningful insights from imaging data, aiding in understanding brain function and pathology. It has notably contributed to the rapid association of conditions in brain imaging, advancing our understanding of brain function. AI also has potential in neuro-oncology. AI algorithms are likely to advance our understanding of brain cancers and therapy. Neuro-oncology has made significant progress by integrating molecular indicators into therapy. AI systems excel at identifying these indicators from imaging data with great accuracy, especially in small patient groups. They successfully assessed the mutational status of numerous markers using distinct institutional databases (77—79).

Imaging techniques are critical for treating pediatric neurological, neurosurgical, and neuro-oncological diseases (80). Multiparametric MRI, when paired with radiogenomic analysis, links imaging features with molecular biomarkers, which aids in illness diagnosis. However, implementing this method into everyday healthcare remains difficult. AI approaches can model large datasets linked to childhood neurological illnesses, allowing for early inclusion into prognostic modeling systems and providing a solution to this difficulty (80). ANNs have demonstrated substantial effectiveness in pediatric neuroradiology, particularly in categorizing children based on ventricular size to distinguish between normal and hydrocephalic conditions. A recent study examined hydrocephalus and controls, reaching a very high accuracy level for hydrocephalus and for controls using T2-weighted MRI scans from 399 children (81). Previous research has indicated similar effectiveness in pediatric hydrocephalus diagnosis using evolutionary adjustments to ANN techniques (82). Ultrasound has become widely adopted in clinical settings due to technological advancements and digital health infrastructure (83, 84). Breast cancer, a leading cause of cancer-related mortality, has seen significant DL utilization for diagnosing and categorizing breast masses. DL techniques applied to abdominopelvic imaging, particularly liver examination, have shown superior accuracy in evaluating liver fibrosis compared to traditional methods. In muscle illness detection and imaging segmentation, ANN-based approaches have increased diagnosis accuracy, particularly for inflammatory muscle diseases (85, 86). Digitalized image datasets, open-source algorithms, computer power increases, cloud services, and ongoing DL technique research all contribute to the rapid evolution of AI/ML tools for imaging interpretation.

Clinical decision-support systems (CDSSs) are designed to enhance the quality of clinical decision-making and, consequently, the treatment provided by healthcare organizations (87). The underlying principle is that the integration of AI-powered support systems can help address the challenges faced by clinicians in their decision-making processes (Figure 2) (88).

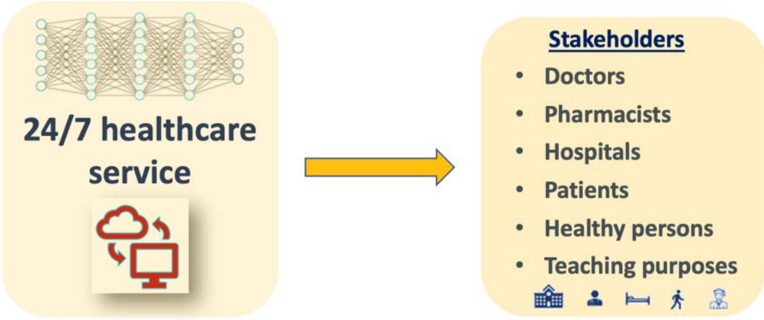

Figure 2. The benefits and stakeholders of a clinical decision support system (CDSS)

These AI-driven strategies for CDSSs can be broadly categorized into two main approaches (89):

1. *Knowledge-based approaches*: These systems rely on a comprehensive knowledge base, typically curated by domain experts, which contains clinical guidelines, rules, and best practices (89). The AI algorithms then apply this knowledge to analyze patient data and provide recommendations or alerts to clinicians.

2. *Data-driven approaches*: These systems use ML and other data-centric techniques to identify patterns and insights from large datasets of clinical information, such as electronic health records, diagnostic test results, and patient outcomes (89). The AI models can then use these data-driven insights to generate personalized recommendations and support clinical decision-making.

By incorporating these AI-powered CDSS strategies, healthcare organizations can enhance the consistency, accuracy, and timeliness of clinical decision-making, ultimately leading to improved patient outcomes and more effective treatment plans. As the field of AI in healthcare continues to evolve, the integration of these advanced decision-support systems is poised to become an essential component of modern healthcare.

Concerns and future perspectives

The incorporation of AI technologies into clinical settings represents a significant advancement in improving diagnostic precision and treatment effectiveness (90). By exploiting the power of ML and data-driven approaches, AI-powered systems can enhance various aspects of healthcare delivery, from early disease detection to personalized therapy recommendations. AI-based tools have the potential to assist clinicians in making more accurate and timely diagnoses by analyzing medical images and identifying subtle patterns that may be overlooked by human observers. This enhanced diagnostic capability can lead to earlier intervention, improved patient outcomes, and more efficient utilization of healthcare resources.

Furthermore, AI algorithms can be trained to predict disease progression, identify high-risk individuals, and recommend personalized treatment plans tailored to a patient's unique medical history and genetic profile. This personalized approach to healthcare can help healthcare providers deliver more effective and targeted therapies, minimizing the risk of adverse reactions and improving overall patient well-being. The integration of AI into healthcare also has the potential to streamline administrative tasks, automate routine workflows, and free up clinicians' time, allowing them to focus more on direct patient care. By automating tasks such as appointment scheduling, medication management, and data entry, AI can enhance the efficiency and productivity of healthcare organizations.

As the adoption of AI in clinical settings continues to grow, it is crucial to address the ethical and regulatory considerations surrounding the use of these technologies. Ensuring data privacy, algorithmic transparency, and human oversight will be essential to maintaining patient trust and upholding the highest standards of healthcare. Overall, the integration of AI into healthcare represents a significant step forward in improving diagnostic accuracy, treatment outcomes, and the overall quality of healthcare delivery. As the field continues to evolve, the synergistic collaboration between clinicians and AI-powered systems will pave the way for a more personalized, efficient, and effective healthcare landscape.

As the integration of AI into healthcare becomes more widespread, it is crucial that healthcare professionals receive comprehensive training and education on the capabilities, limitations, and ethical considerations of these emerging technologies (91). Effective training programs should prepare clinicians, nurses, and other healthcare staff with a fundamental understanding of AI principles, including ML algorithms, data preprocessing, and model interpretability. Healthcare professionals should be trained to critically evaluate the inputs, outputs, and decision-making processes of AI-powered systems, ensuring that they can make informed judgments about the reliability and appropriateness of the recommendations provided. Additionally, training should address the ethical implications of AI in healthcare, such as data privacy, algorithmic bias, and the maintenance of human oversight and accountability. By investing in the training and upskilling of healthcare professionals, organizations can foster a culture of AI-readiness and empower their staff to effectively use these advanced tools to enhance diagnostic accuracy, treatment planning, and patient outcomes. Ongoing education and collaborative learning opportunities will be essential as the field of AI in healthcare continues to evolve rapidly. Ultimately, the successful integration of AI will depend on the ability of healthcare professionals to understand, trust, and responsibly utilize these transformative technologies.

While AI systems become more integrated into clinical decision-making processes, it is crucial that these technologies adhere to principles of transparency, traceability, and explainability (92). Healthcare professionals and patients must be able to understand how AI-powered algorithms arrive at their recommendations and predictions, in order to build trust and ensure responsible deployment. Transparency refers to the need for AI systems to be open and accountable, with clear documentation on the data sources, model architectures, and training procedures used. Traceability involves maintaining detailed logs of the AI system decision-making process, allowing for retrospective auditing and debugging. Explainability, on the other hand, focuses on the ability to interpret the reasoning behind an AI system outputs, enabling healthcare providers to validate the logic and make informed decisions. By prioritizing these key attributes, AI developers and healthcare organizations can foster greater trust and acceptance of these transformative technologies. Clinicians must be able to understand the strengths, limitations, and potential biases of AI systems, and patients should have confidence that their personal health data is being handled ethically and responsibly. Upholding principles of transparency, traceability, and explainability will be essential as AI continues to shape the future of healthcare delivery.

Regulatory bodies overseeing medical device certification and approval have been slow to address the issue of explainable AI and its implications for product development and marketing. While the FDA takes a comprehensive approach to advancing AI-based medical products, explicit mention of explainability is lacking (93, 94). Instead, there is an emphasis on ensuring transparency and clarity in the output and algorithms provided to users, with a focus on understanding the software's functionalities and its evolutionary changes. Similarly, the Medical Device Regulation (MDR) does not directly address the need for explainability in AI and ML-based medical devices (95). However, accountability and transparency remain crucial, particularly concerning the information provided about the development process of machine learning and deep learning models used in medical treatment. Future regulations will likely require manufacturers to provide detailed insights into model training and evaluation, data usage, and overall methodologies used in their creation.

The legal landscape for AI in healthcare is constantly changing, with new rules and regulations expected to address liability concerns. Healthcare practitioners must be aware of these shifts as legislative frameworks evolve to promote ethical, transparent, and responsible practices in the development and deployment of AI technologies. There are disparities between Europe and the United States in terms of international guidelines on legal difficulties resulting from the use of AI in healthcare, with each region taking its own approach. The European Union has adopted a proactive approach, recognizing the particular issues AI brings to liability regimes and enacting the Artificial Intelligence Act to ensure coherence and legal clarity for AI use, notably in healthcare (96).

The EU intends to promote safe AI use while also encouraging technological innovation. In comparison, the USA lacks a complete legal structure. However, the FDA acknowledges the regulatory implications of AI in healthcare and is aiming to maintain continued oversight of AI as a medical device through strategic planning (97). The FDA's measures include increasing transparency by mandating makers to provide extensive descriptions of the operational mechanisms of AI devices in order to promote a comprehensive understanding of device advantages and hazards. In addition, attempts are underway to eliminate potential bias in AI systems by taking into account aspects such as training data sources and demographics. The FDA has issued a discussion paper proposing a regulatory framework for changes to AI-based medical software to assure the safety of AI technology in healthcare (98).

Conclusion

In conclusion, the utilization of AI across the spectrum of drug development, clinical trials, and healthcare heralds a new era in healthcare innovation. The capacity of AI to analyze through huge volumes of data, identify patterns, and generate insights at unprecedented speeds has reshaped how we approach medical research and patient care. In drug development, AI algorithms streamline the process of identifying promising drug candidates, accelerating the journey from discovery to market availability. Likewise, in clinical trials, AI-powered analytics optimize trial design, patient recruitment, and data analysis, fostering greater efficiency and precision. Moreover, within healthcare, AI-driven tools enable healthcare providers to make more informed decisions, tailor treatments to individual patients' needs, and predict disease progression with greater accuracy. Nevertheless, the incorporation of AI in healthcare comes with its own set of challenges and considerations. Ethical concerns surrounding data privacy, algorithm bias, and transparency in decision-making must be carefully addressed to ensure the responsible and equitable deployment of AI technologies. Additionally, regulatory frameworks need to evolve to keep pace with the rapid advancements in AI-driven healthcare solutions, striking a balance between fostering innovation and safeguarding patient safety. Despite these challenges, the potential benefits of AI in transforming healthcare delivery are profound. By harnessing the power of AI to augment human expertise, we can unlock new frontiers in medical research, improve clinical outcomes, and ultimately enhance the quality of life for patients worldwide. Moving forward, sustained investment in research, interdisciplinary collaboration, and stakeholder engagement will be key to realizing the full potential of AI in revolutionizing drug development, clinical trials, and healthcare.

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VEŠTAČKA INTELIGENCIJA U RAZVOJU LEKOVA, KLINIČKIM ISTRAŽIVANJIMA I ZDRAVSTVU

Vangelis Karalis[1], Aleksandra Catić Đorđević[2]

[1]Nacionalni i Kapodistrijski univerzitet u Atini, Departman za farmaciju, Atina, Grčka
[2]Univerzitet u Nišu, Medicinski fakultet, Niš, Srbija

Kontakt: Aleksandra Catić Đorđević
Bulevar dr Zorana Đinđića 81, 18000 Niš, Srbija
E-mail: aleksandra1610@yahoo.com

Primena veštačke inteligencije (engl. *artificial intelligence* – AI) u razvoju lekova, kliničkim istraživanjima i zdravstvenoj zaštiti predstavlja transformativno napredovanje zdravstvene nege uopšte. Tehnologije bazirane na AI-ju pružaju neprocenjive mogućnosti za analizu ogromnih skupova podataka i identifikaciju primenljivih obrazaca pošto revolucionarno modifikuju različite aspekte eko-sistema zdravstvene zaštite. Cilj ovog revijalnog rada bio je da pruži pregled aktuelnih istraživanja o primeni veštačke inteligencije u zdravstvu. Pristupi bazirani na AI-ju u razvoju lekova racionalizuju proces identifikacije potencijalnih terapijski aktivnih supstanci i ubrzavaju put od otkrića do odobrenja za promet. U kliničkim istraživanjima, analitika ojačana primenom AI-ja optimizuje dizajn studija, smanjuje veličinu uzorka, regrutovanje bolesnika i vreme potrebno za analizu podataka, povećavajući pritom statističku relevantnost i validnost rezultata. Pored toga, aplikacije bazirane na upotrebi AI-ja u kliničkoj praksi osnažuju pružaoce zdravstvenih usluga sistemima za podršku u donošenju odluka, personalizovanim preporukama za lečenje i prediktivnoj analitici, što vodi do nege bolesnika koja je znatno efikasnija i personalizovana u većoj meri. Premda ostaju izazovi poput etičkih razmatranja i regulatornih zakonskih okvira, značajna je potencijalna dobrobit od upotrebe AI-ja u medicinskim inovacijama i poboljšanju ishoda lečenja bolesnika. Naglasak treba staviti na važnost kontinuiranih istraživanja, saradnje i odgovorne primene veštačke inteligencije u zdravstvu.

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***Ključne reči**: veštačka inteligencija, razvoj lekova, klinička istraživanja, mašinsko učenje, dubinsko učenje*

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