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**Health Law, International Health Law, Comparative  
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**VOLUME 2 - Nº 01 – 2024**

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## Editorial – Volume 2 – n° 01- 2024

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The Journal targets a broad and diverse audience of academicians, professionals, and students in Law, Medicine, Biomedicine, as well as policy makers, law operators, and legislators in health care.

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**Profa. Dra. Verônica Scriptore Freire e Almeida**  
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## ADVANCES AND RISKS FOR ARTIFICIAL INTELLIGENCE IN HEALTHCARE <sup>1</sup>

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## Advances and risks for artificial intelligence in healthcare

**Abstract**

**Context:** Artificial Intelligence (AI) has experienced remarkable progress, becoming an indispensable tool for solving a wide range of technological and economic challenges. **Problem:** This article explores the current state of AI, with a special focus on machine learning techniques, including artificial neural networks, discusses the current state of these areas, the challenges they face and the research opportunities that present themselves; in addition, it highlights concerns related to the social impacts and ethical issues of AI. **Objectives:** to present problems and issues related to AI, assessing the impact on society and presenting possible ways to mitigate the risks of AI. **Methods:** A critical-narrative review was carried out based on scientific texts and documents. **Results:** AI is a promising technology with the potential to generate significant benefits for society. However, AI also presents risks and challenges that need to be considered. Studies into the social impacts and ethical issues of AI are important to ensure that this technology is developed and used responsibly. **Conclusions:** AI is a technology with the potential for positive impact, but it also presents risks that need to be mitigated. It is important that studies into the social impacts and ethical issues of AI are carried out on an ongoing basis and that they tackle the following aspects: (1) technical: a) prejudice and discrimination; b) lack of transparency; c) lack of control; (2) social: d) loss of jobs; e) social inequality; f) environmental impacts; (3) ethical: g) autonomy; h) responsibility; i) privacy.

**Keywords:** social discrimination, equity, personal autonomy, damage liability, social control policies.

**Introduction**

In recent years, science has witnessed a remarkable advancement in the application of artificial intelligence (AI) in healthcare, marking a revolution in medicine and healthcare across the world.

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This transformation is driven by the dizzying progress of information technologies, of which AI emerges as a driving force. Unlike the early days of AI, where machines were restricted to repetitive tasks and specific commands, modern AI encompasses an impressive range of cognitive functions, encompassing aspects of what we traditionally refer to as human intelligence.

Swaminathan (WHO, 2021, p.5) recognizes the transformative potential of AI in healthcare, stating that it represents a promising opportunity to raise standards of medical care on a global scale.

AI not only promises to improve the speed and accuracy of disease diagnosis and screening, but also supports clinical services and strengthens medical research, while also contributing to significant advances in drug development.

However, the increasing use of AI in healthcare is not without its challenges. The collection and processing of confidential patient data raises ethical and privacy concerns, requiring strict protection measures. Furthermore, enthusiasm around the potential of AI can lead to overly technological approaches to complex health problems, challenging the quest for equity in access to medical innovations. Issues of racial bias and prejudice also arise when low-quality or inadequate data is used in AI.

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This article explores the rise of AI in medicine, highlighting its positive impacts and ethical challenges. It also examines the evolution of deep neural networks and their applications in healthcare, as well as the importance of high-quality data and the careful selection of algorithms.

It also addresses the need for equitable distribution of AI-based health technologies and the importance of maintaining up-to-date and effective systems. In this context, we analyze how AI is redefining diagnoses, treatments and medical research, with a critical focus on the ethical and social issues surrounding this technological advance.

Regarding legislation, the imminent artificial intelligence (AI) revolution in healthcare is redefining paradigms, with the implementation of AI, in particular the deep learning approach, playing a prominent role. Oversight of AI in healthcare has become crucial, requiring the promotion of technological innovations and the creation of a solid regulatory framework to ensure its use for human well-being.

The Bill n. 2338/2023 in Brazil, in line with the General Data Protection Law, proposes a comprehensive principled approach, aiming to regulate AI in healthcare. These principles encompass issues of privacy, ethics, transparency and responsibility, reflecting ongoing international debates.

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The project also deals with high-risk systems, sandboxes (testing environment used by programmers and developers to safely test new programs, applications and platforms in isolation, without the risk of interfering or damaging any environment, without ramifications on the real world) and the supervision exercised by the National Data Protection Authority, representing a significant advance in the regulation of AI in the country, with an emphasis on the responsible development of this technology.

Using the collection of scientific texts (carried out on the Scielo portals, the Virtual Health Library and the World Health Organization portal) and documents (collected on the Brazilian legislation portal), a critical-narrative review of qualitative bias (Lamy, 2020, pp. 337-340).

**1. Structuring technical concepts**

Before entering the specific scope of health, it is important to establish some structuring technical concepts that allow for a more in-depth discussion on the topic of this investigation.

**1.1 Machine Learning**

The goal of machine learning is to train programs using examples. With a substantial number of examples (input), the

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machine builds hypotheses (output), derived from these data (Mitchell, 1997).

Machine learning is the result of an area of computer science that focuses on the development of algorithms (sequence of logical and structured steps to carry out a task) that allow this learning and adapt accordingly. Machine learning algorithms are designed to find patterns in data and use them to make predictions, suggestions, or decisions.

Inductive inference is one of the main methods used in machine learning. It is a process of generalizing patterns observed in a set of data. The accuracy of inductive inference depends on the quantity and quality of the data. More data and more accurate data lead to more accurate generalizations.

There are three main categories of machine learning: supervised, unsupervised, and reinforcement (Honda et al, 2017).

In supervised learning – the most commonly employed approach (Sas, 2023) – the algorithm is provided with a training data set that includes examples of objects and their desired classifications. The purpose of the algorithm is to enable the automated process of identifying objects and their classifications from examples that have not yet been labeled.

In unsupervised learning, examples are presented to the algorithm without being labeled. The algorithm then analyzes

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the similarities between the attributes of the examples and groups them based on these similarities. From this analysis, the algorithm tries to identify whether there are natural groupings or clusters among the examples. After identifying the groupings, it is common to conduct additional analysis to understand the meaning of each group within the context of the problem at hand.

In reinforcement learning, the algorithm is not given the correct answer, but is guided by signals of reinforcement, reward or punishment. The algorithm formulates hypotheses based on the examples and evaluates whether these hypotheses were successful or not based on the reinforcing signals. Reinforcement learning finds significant application in fields such as gaming and robotics, and is widely used in these contexts (Honda et al, 2017).

Solving problems through machine learning is not always a simple task and requires certain requirements. First, it is essential to have a solid set of examples, often requiring the construction and ongoing maintenance of that set, as the data is not always ideal. It is crucial to employ techniques to improve data quality when necessary.

Furthermore, it is worth highlighting that not all machine learning algorithms are suitable for solving all types of

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problems. Therefore, it is important to carefully select the appropriate algorithms for each problem in question.

After training, it is crucial to evaluate whether the algorithm is effectively solving the problem and with what degree of accuracy. Finally, it is important to highlight that machine learning systems must be updated regularly, as changes in data can affect the performance and effectiveness of the system.

Machine learning also depends on two major challenges: (a) making machines understand human language in the same way that humans understand it (natural language processing, in English: NLP), (b) allow machines to perform tasks that normally require human vision, such as object recognition, movement detection, analysis of facial expressions (computer vision).

**1.2 Artificial neural networks**

Artificial neural networks (ANN) – mathematical models inspired by the structure of biological neural networks – allow machine learning to solve several problems simultaneously. Because of this, they allow deep learning.

The perceptron, one of the most basic learning models in neural networks, was designed by Frank Rosenblatt in 1957 to solve simple linear separation problems. This is a simple

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learning model composed of a single layer of McCulloch-Pitts - MCP neurons (Mcculloch et al, 1943).

This model uses a learning rule based on error correction, that is, on the difference between the desired response (inserted by humans) and the network response (resulting from the application of the algorithm).

The process involves two phases: training and testing. During the training phase, the network is presented with a labeled data set, that is, a data set that contains expected input and output examples. Network parameters, such as weights, are adjusted for each new example, so that the network learns to generate the expected response for each input (Rosenblatt, 1957). After tuning the parameters, the network is evaluated with a different, unlabeled dataset. The network's performance is evaluated based on its ability to generate correct answers to the test examples.

Simple perceptron neural networks, like the original perceptron, can only solve linear problems. For more complex problems, neural networks with more than one layer of neurons are needed. These networks are called multilayer neural networks (multi-layer perceptron – MLP). The most common method for training MLPs is the backpropagation algorithm, which adjusts the weights of connections between neurons in

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order to minimize the error between the network output and the desired value (Rumelhart; Hinton; Williams, 1986).

Other techniques, such as support vector machines - SVM (Cortes et al., 1995) - began to demonstrate superior results to MLPs in several applications, such as image recognition. However, the scenario changed (Bengio et al., 2015) with the emergence of deep neural networks (DNN).

DNNs are MLPs with multiple hidden layers, which allow them to learn more complex representations of data. DNNs have revolutionized the field of Machine Learning, achieving superior results across a wide range of tasks, including image recognition, Natural Language Processing (NLP), and machine translation.

Deep neural networks (DNNs) were inspired by the human brain's ability to detect local features and perform selection of relevant information. They are currently the most effective machine learning technique for solving problems.

**1.3 Artificial intelligence**

Starting from the concept that artificial intelligence (AI) is the ability of a non-natural entity to evaluate information received and draw inferences from this information, Boldissera (2023) states that artificial intelligence can be classified into

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three categories: specialized AI, general AI and superintelligent AI.

Expert AI, also known as narrow or weak AI, is shaped by highly specialized algorithms in specific domains. These systems store large volumes of data and apply algorithms to perform complex tasks, but limited to the scope for which they were developed. This category, which is very developed, includes expert systems and recommendation systems (Granatyr, 2017).

General AI, or strong AI, is structured by algorithms with human-like capabilities across a wide variety of tasks, such as those sought in natural language processing and computer vision. According to Boldissera (2023), this is the stage at which science focuses its current efforts.

Superintelligent AI relies on algorithms that significantly outperform humans at virtually every task. There are still no AI systems with this level of capability and it remains uncertain whether systems more intelligent than humans will be developed in the future (Trueman, 2013).

Successful solutions using AI have in common the ability to solve complex problems efficiently and effectively. These solutions are often based on machine learning techniques, which allow systems to learn from data and adapt to new situations.

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**2. Artificial intelligence in healthcare**

We are currently witnessing a new era of industrial transformation, driven by the advancement of information technologies, including artificial intelligence (AI). In this context, machines are no longer limited to repetitive tasks, but also perform cognitive functions, involving the use of what we traditionally consider as intelligence.

Swaminathan (WHO, 2021, p.5) stated in the first global report for guidance and use of AI: artificial intelligence (AI) represents a promising opportunity to improve healthcare on a global scale; it has the potential to improve the speed and accuracy of diagnoses and disease screening, provide support in clinical services and strengthen health investigations, in addition to contributing to the advancement of drug research.

AI is a technology increasingly explored in healthcare. The advancement of future medicine is the focus of research in several countries and Brazil has advanced in the implementation of public health policies that use AI (Lemes, 2020, p.166).

According to Torres (2023), AI has the potential to be a powerful tool for combating tropical diseases, as early detection of outbreaks is one of the applications of AI in public health. It can be used to analyze large sets of patient data, including clinical data, environmental data, and social media data. This

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can help identify patterns and trends that could indicate an outbreak is in progress.

In areas with limited resources and infrastructure, this technology may be a viable solution for improving disease surveillance. It can be used to automate tasks such as classifying suspected cases, contact tracing and analyzing epidemiological data. This can free up human resources for other activities, such as medical care and health education (WHO, 2021, p.6).

In addition to early detection of outbreaks, neural networks can improve the diagnosis and treatment of tropical diseases, assist in the development of new medicines and vaccines, and expand responses to public health emergencies (SBMT, 2023).

Automation has taken on a certain role in the area of diagnosis, with notable advances. Currently, there are automatic diagnostic systems that have exceptional precision and accuracy, occasionally surpassing even the diagnoses made by healthcare professionals. A notable example is the robot developed by the company iFlytek, which passed China's national medical licensing exam, demonstrating the ability of these technologies to offer reliable, high-quality diagnoses (Costa, 2019).

The evolution of AI is revolutionizing medicine, improving diagnostics and accelerating medical research. With great

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optimism, Swaminathan (WHO, 2021, p. 5) highlights its global potential in improving health. However, its use raises ethical and data security concerns.

Despite advances, the use of AI in healthcare raises transnational ethical, legal, commercial and social concerns. Many of these concerns are not unique to AI. The use of software and computing in healthcare has challenged developers, governments, and healthcare providers for half a century, and AI presents additional and new ethical challenges that go beyond the purview of traditional regulators and participants in healthcare systems.

Ethical challenges must be adequately addressed if AI is to be widely used to improve human health, notably those of preserving human autonomy and ensuring equitable access to these technologies (WHO, 2021, p.25).

Unbridled optimism regarding the potential benefits of AI must not worsen the unequal distribution of access to health technologies within and between rich and low-income countries. The digital divide could worsen unequal access to health technologies by geography, gender, age or device availability if countries do not take appropriate action. Furthermore, the inappropriate use of AI can also perpetuate or worsen prejudices (OPAS, 2021).

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Using limited, low-quality, and unrepresentative data in AI can deepen biases and disparities in healthcare. Biased inferences, misleading data analyses, and poorly designed health apps and tools can be harmful. Predictive algorithms based on inadequate or inappropriate data can result in significant racial or ethnic bias (LEME, 2020, p. 117).

**2.1 AI in medicine**

AI in medicine has as its main focus the creation of programs that can perform diagnoses and offer therapeutic recommendations.

Coiera (2014) explained long ago that programs or expert systems (ES), based on cognitive models of diseases, due to their connections with patient data and clinical symptoms, consider medical decision-making to be a result of controllable reasoning.

ES can be used for a variety of medical applications, including diagnosis, prognosis and therapeutic planning. They have the potential to improve the quality of medical care, making it more accurate, efficient and accessible (Widman, 1998).

The software used in the field of medicine, many of them equipped with artificial intelligence, are the result of an evolutionary trajectory that dates back to the beginnings of the

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development of expert systems (ES). An important milestone in this process was MYCIN, a system developed at Stanford University in 1970 that stood out for its ability to make diagnoses and recommend medical treatments based on even uncertain or incomplete information.

Artificial intelligence (AI) and robotics have become increasingly important tools in medicine. However, the adoption of these resources by healthcare professionals still faces reasonable obstacles, such as doctors' resistance to losing control of the decision-making process, distrust in the machines' own capabilities and the systems' difficulty in learning.

An example of a medical decision support system (sequence-aware diffusion model for longitudinal medical image generation - SADM) is DXplain, developed at the Computer Science Laboratory at Massachusetts General Hospital, which assists in diagnosis through the analysis of clinical data. It generates a list of the most likely diagnoses and justifies each of them, when necessary. Another example of SADM is the Surgical Risk MED software, which assesses the patient's cardiological and pulmonary risk before surgery (Silva, 2013).

AI and robotics are used to improve the diagnosis and treatment of diseases, as well as to reduce hospital-acquired

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infections. The use of robots in medicine began in 1985, with the PUMA 560, developed to guide needles during a brain biopsy (Claudio, 2020).

Albert Einstein Hospital, for example, adopted robotic technology in 2008. Since then, a team of doctors specializing in robotic surgeries has used the Vinci Surgical System, a robot surgeon developed by Intuitive Surgical (Claudio, 2020).

Advances in AI and robotics in medicine illustrate how these technologies have the potential to improve the quality of care and patient safety.

The emerging technology of AI is redefining paradigms and is seen as one of the most significant innovations in the field of healthcare. The implementation of AI in the medical field, particularly the deep learning approach, is especially notable (Obermeyer & Emanuel, 2016). It is expected to have a notable effect in the coming years on medical care, the administration of healthcare systems, and the interaction between patients and healthcare services, empowering patients to manage their own data and improve their health (Topol, 2019).

**3. Challenges of regulating AI in healthcare**

Unlike products that follow traditional regulation, such as medicines and medical equipment, algorithms are always

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developing and raise many new problems (Rajkomar et al., 2019).

So far, laws and regulations that understand all the new problems have not been produced, only the area of data privacy is advanced, as was done in Brazil with the General Data Protection Law (LGPD), although there are several proposals for more regulatory comprehensive, as is the Brazilian proposal outlined in bill no. 2338/2023 (Jobin; Ienca; Vayena, 2019). At the international level, the focus of discussions has led to the establishment of essential regulatory principles (Richman, 2018), such as ensuring automated decision reviews.

Bill n. 2,338/2023 presents a principle framework (articles 2 and 3) that deals with the implementation and use of artificial intelligence systems in Brazil:

“a) Valuing human dignity; b) Respect for fundamental rights and democratic principles; c) Freedom for the development of individuality; d) Protection of the environment and encouragement of sustainability; e) Equality, non-discrimination, diversity and respect for labor rights; f) Stimulating technological progress and innovation; g) Encouragement of free enterprise, fair competition and consumer protection; h) Privacy protection, data security and control of personal information; i) Encouraging research and development to promote innovation in the productive sectors and the public sector; j) Access to information and education on artificial intelligence systems and their applications; k) Inclusive growth, sustainable development and general well-being; l) Self-determination and freedom of choice; m) Active human participation in the artificial intelligence cycle and effective human

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supervision; n) Fight against discrimination; o) Justice, equity and social inclusion; p) Transparency, clarity, comprehensibility and auditability; q) Reliability and robustness of artificial intelligence and information security systems; r) Guarantee of due legal process, contestation and contradiction; s) Traceability of decisions throughout the life cycle of AI systems for accountability; t) Responsibility, accountability and full compensation for damages; u) Accountability for AI systems, responsibility for their actions and full compensation for any losses; x) Prevention, precaution and mitigation of systemic risks arising from intentional or unintentional uses, as well as unforeseen effects of artificial intelligence systems; y) Do not harm and maintain the proportion between the methods used and the legitimate purposes of AI systems.” (Federal Senate, 2023).

Presented by the President of the Senate, Rodrigo Pacheco, on May 3, 2023, it proposes the regulation of the use of artificial intelligence in Brazil. This project is based on the work of a commission of jurists and experts who studied the topic and held more than 70 public hearings (STJ, 2023).

The Project follows the regulatory model of the AI Act, approved by the European Parliament in May 2023. This European regulation advocates the need for human supervision, security, transparency and sustainability in the development and application of AI technologies (EU, 2023).

The National Data Protection Authority (ANPD) published a preliminary analysis of Bill no. 2,338/2023. The document presents the points of convergence and conflict between the bill

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(PL) and the LGPD, reinforcing ANPD's position on promoting innovation in AI, as long as it is done responsibly (ANPD, 2023).

The PL and the LGPD share the objective of protecting the individual and collective rights of holders of personal data, especially with regard to privacy, security and transparency in data processing (ANPD, 2023).

Furthermore, both the PL and the LGPD establish that the controller is responsible for the processing of personal data and must adopt technical and administrative measures to ensure the security and protection of data. The PL's normative provisions grant the holder of personal data a series of rights, such as the right of access, rectification, deletion, portability and opposition to data processing.

Furthermore, the bill assigns to a competent authority defined by the Executive (ANPD) the competence to supervise and apply administrative sanctions in relation to the processing of personal data, and other attributes of artificial intelligence, in accordance with article 32 (Federal Senate, 2023).

The bill establishes objective civil liability for high-risk systems, which are those that present a significant risk to the fundamental rights and freedoms of personal data holders (articles 16, 17 and 18 of bill 2,338/2023). This constitutes a significant advance in relation to the LGPD, which has not been expressed on this matter (BRAZIL, 2023).

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Also worth mentioning is the bill's regulation of the use of sandboxes, of controlled environments for the development and testing of new technologies. Topic that the LGPD also did not regulate. (ANTT, 2023)

The ANPD recommends that points of conflict between the bill and the LGPD be resolved, especially those that concern the ANPD's legal responsibilities. The Authority also highlights the importance of the bill detailing issues relating to the protection of personal data in sandboxes, especially in high-risk systems (ANPD 2023).

In ANPD's preliminary analysis, this bill is an important step towards the regulation of artificial intelligence in Brazil: "Project Law No. 2338/2023, by establishing principles, guidelines and governance instruments for the development and responsible use of intelligence artificial, represents a significant advance in the regulation of this technology in Brazil" (ANPD, 2023).

**Final Considerations**

AI is a technology whose use has significant positive potential, but which also presents a series of risks that need to be mitigated.

Ethical and responsible use depends on practical and regulatory consideration of the following aspects, which we summarize:

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(1) Technical aspects:

a. Prejudice and discrimination (ensure that the use of the technologist does not generate new discrimination, for example, by restricting the usability of analyzes anchored in samples of non-diversified groups);

b. Lack of transparency and intelligibility (ensure the publication of the design of the intelligence used, and that this publication is understandable to all recipients, that is, developers, information providers, health professionals, health managers and users);

c. Lack of control (checking the quality of the inputs and analysis methods undertaken; observing whether the technology's responses are adequate and appropriate to constitutive expectations; ensuring that the machine's suggestions are only revealed if they pass the security, precision and reliability filters effectiveness for defined uses, setting points of human supervision);

(2) Social aspects:

a. Loss of jobs (verify and control the adverse effects of AI that transcend medical issues, such as those with a labor dimension);

b. Social inequality (ensure technology is made available to all audiences);

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c. Environmental impacts (verify and control the adverse effects of AI that transcend medical issues, such as those with an environmental dimension);

(3) Ethical aspects:

a. Autonomy (ensure that the decision is only suggested by the machine and always taken by the healthcare professional together with the patient; ensure that the people who will decide, in each case, receive the information that was considered in the suggestion and the method that guided the analysis and machine suggestion);

b. Responsibility (ensure that responsibility for possible damages remains human and build accountability models appropriate to the reality of AI, in which the responsibility of technology providers, care systems that use technology, professionals who use the technologies);

c. Privacy (ensure that the use of data is authorized, restricted to those authorized and anonymized, ensuring data confidentiality).

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